

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: **102000025743**

Product name(s): **Foramsulfuron +Thiencarbazone-methyl**

Active substance(s) **OD 80 (50 +30 g/L)**

Central zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT: Poland

(Re-authorization)

Applicant: **Bayer CropScience Division**

Submission date: **31/08/2020**

MS Finalisation date: **10/2021 ; 12/2021 ; 01/2022**

Version history

When	What
31/08/2020	Original Bayer Crop Science document (Regulation 1107/2009 - Art. 43) Foramsulfuron
October 2021	The renewal of the authorisation of the PPP (Art 43); zRMS evaluation
December 2021	ZRMs corrected evaluation according to reviewed comments from cMS and Applicant.
January 2022	zRMS correction after additional data submission

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted to support the re-authorisation of the plant protection product **FSN+TCM OD 80 (50+30 g/L)** in Poland under Article 43 of Regulation (EC) No 1107/2009. The product is to be used as an herbicide on sugar beet.

Poland agreed to act as the zRMS for the evaluation of the Core Assessment in the Central Zone.

FSN+TCM OD 80 is a plant protection product containing 50 g/L foramsulfuron, and 30 g/L thien carbazon-methyl.

FSN+TCM OD 80 was not the representative formulation for the EU re-approval of foramsulfuron. FSN+TCM OD 80 was not the representative formulation for the EU approval of thien carbazon-methyl.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 and Part C and where appropriate, the addendum for Poland. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at MS level by the EU review. It also includes assessment of data and information relating to FSN+TCM OD 80 where that data has not been considered in the EU review. Unless otherwise stated, assessments for the safe use of FSN+TCM OD 80 have been made using endpoints agreed in the EU review of foramsulfuron and thien carbazon-methyl.

This document describes the specific conditions of use and labelling required in Poland for the re-authorisation of FSN+TCM OD 80.

The active substances foramsulfuron and thien carbazon-methyl are approved in accordance with Regulation (EC) No 1107/2009¹.

The active substance **foramsulfuron** has been evaluated on EU level according to the Commission Regulation (EU) N° 1107/2009 (Commission Implementing Regulation (EU) 2020/616, May 2020), full details are provided in the EU renewal assessment report (SANTE-2016-11214 Rev. 2, March 2020) and related documents and are summarised in the EFSA conclusion (EFSA Journal 2016;14(3):4421).

¹ Commission Implementing Regulation (EU) 2020/616 of 5th of May 2020 renewing the approval of the active substance foramsulfuron in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Commission Implementing Regulation (EU) No 145/2014 of 14 February 2014 approving the active substance thien carbazon, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

The active substance **thiencarbazone-methyl** has been evaluated on EU level according to the Commission Regulation (EU) N° 1107/2009 (Commission Implementing Regulation (EU) No 145/2014, February 2014). Full details are provided in the EU renewal assessment report (SANCO/12602/2013 rev 2, March 2018) and related documents and are summarised in the EFSA conclusion (EFSA Journal 2013;11(7):3270).

1.2 Letters of Access

Bayer is the owner of the complete set of data reviewed for the EU re-approval of the active substance foramsulfuron.

Bayer is the owner of the complete set of data reviewed for the EU approval of the active substance thiencarbazone-methyl.

No letter of access is required.

1.3 Justification for submission of tests and studies

The studies submitted are necessary for re-authorisation of FSN+TCM OD 80 and are in accordance with Reg. (EU) No. 284/2013.

Vertebrate studies

The tests and studies on vertebrate animals submitted within this dossier are necessary to complete the data package as required in the Commission Regulation (EU) No 284/2013 setting out the data requirements for Plant Protection Products. Existing data was not available from another source.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as mentioned in the list of references in Appendix 4.

The “List of data submitted by the applicant and relied on” defines the list of studies and reports, submitted to Poland. Based on Article 59 of Regulation 1107/2009 Bayer claims **2.5 years protection** for new studies and reports submitted from the date of re-authorisation of product FSN+TCM OD 80.

For studies previously relied on for a decision, please respect the data protection already given.

The “List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review” contains data for which a claim for data protection is made, as detailed below.

- Foramsulfuron: this claim for protection is made as the studies and reports were submitted and used as the basis for the renewal of the active substance under Regulation 1107/2009. Based on Article 59 of the Regulation, Bayer claims **2.5 years protection** for these studies and reports.
- Thiencarbazone-methyl: the active substance was approved under the approval criteria of Council Directive 91/414/EEC. As a new substance, all studies are protected at EU level in all EU Member States from the Entry into Force (EIF) of the 1st EU approval until **30th of June 2024**.

These studies may not be used by the authorities for the benefit of other applicants during this period without the consent of Bayer.

The part C of this dossier is confidential. No part of this document or any information contained therein

may be disclosed to any third party.

2 Details of the authorization decision

2.1 Product identity

Product code	FSN+TCM OD 80 Specification No.: 102000025743
Product name in MS	Conviso One
Authorisation number	R-40/2017 wu
Function	Herbicide
Applicant	Bayer AG
Active substance(s) (incl. content)	Foramsulfuron: 50 g/L Thiencarbazone-methyl: 30 g/L
Formulation type	Oil dispersion [Code: OD]
Packaging	Bottles: 250 mL, 500 mL, 1 L Material: COEX/EVOH Coextruded high density polyethylene (HDPE) with an internal barrier layer made of ethylene vinyl alcohol copolymer (EVOH) or Material: COEX/PA Coextruded high density polyethylene (HDPE) with an internal barrier layer made of polyamide (PA) Bottles: 3 L, 5 L, 10 L, (15 L + cardboard) Material: COEX/PA Coextruded high density polyethylene (HDPE) with an internal barrier layer made of polyamide (PA)
Co-formulants of concern for national authorisations	None
Restrictions related to identity	none
Mandatory tank mixtures	none
Recommended tank mixtures	none

2.2 Conclusion

The evaluation of the application for FSN+TCM OD 80 resulted in the decision to grant the authorization.

Toxicology section:

Classification for FSN+TCM OD 80 is: H304,H315, H317, H318, H332, H351. According to the EFSA calculation, it can be concluded that the risk for operator worker, resident/bystander is acceptable

Ecotoxicology:

The evaluation of the application for FSN+TCM OD 80 resulted in the decision to grant the authorization.

Residue section:

Uses are accepted.

Physical and chemical properties:

~~One of the co-formulants and its equivalent contains *solvent naphtha, light fraction* (CAS no. 64742-95-6) which is on the list of co-formulants, which are not accepted for inclusion in plant protection products according to the Regulation (EU) 2021/383 of 3 March 2021. It is necessary to replace mentioned component and provide confirmation of the equivalence of the new composition.~~

2.3 Substances of concern for national monitoring

Foramsulfuron and thien carbazole-methyl are not considered substances of concern. No national monitoring data is required for foramsulfuron and thien carbazole-methyl.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Aspiration hazard: Category 1 Skin irritation: Category 2 Skin sensitisation: Category 1 Serious eye damage: Category 1 Acute toxicity: Category 4 Carc.2 Acute aquatic toxicity: Cat.1 Chronic aquatic toxicity: Cat. 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	
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Signal word:	Danger
Hazard statement(s):	H304 May be fatal if swallowed and enters airways H315 Causes skin irritation H317 May cause an allergic skin reaction H318 Causes serious eye damage H332 Harmful if inhaled H351 Suspected of causing cancer H410 Very toxic to aquatic life with long lasting effects. EUH401 To avoid risks to human health and the environment, comply with the instructions for use use.
Precautionary statement(s):	P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. P331 Do NOT induce vomiting. P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor/ physician. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308+P313: IF exposed or concerned: Get medical advice/attention. P501 Dispose of contents/container in accordance with local regulation.
Additional labelling phrases:	-

Special rule for labelling of plant protection product (PPP):	
	ECHA Committee for Risk Assessment RAC Adopted 18 March 2021
Further labelling statements under Regulation (EC) No 1272/2008:	
	-

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	<p>Aquatic organisms:</p> <p>The risk for aquatic organisms is considered acceptable when following risk mitigation measures are applied to surface water bodies.</p> <ul style="list-style-type: none"> 10 m VFSmod or 5 m VFSmod + 50% drift reduction for use in group B (1 × 1.0 L prod./ha) 5 m VFSmod for use in group C (2 × 0.5 L prod./ha) <p>Non target terrestrial plants:</p> <p>The risk for non-target plants is considered acceptable with the use of a 10 m buffer zone, or alternatively 5 m buffer zone and 50% drift reducing spray nozzles, or alternatively</p>

	90% drift reducing spray nozzles for use in group B (1 × 1.0 L prod/ha) <ul style="list-style-type: none"> The risk for non-target plants is considered acceptable with the use of a 5 m buffer zone, or alternatively 75% drift reducing spray nozzles for use in group C (2 × 0.5 L prod/ha)
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2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None	
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2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
respective code if available	national PPE requirements
Worker protection:	
respective code if available	national PPE requirements
Integrated pest management (IPM)/sustainable use:	
respective code if available	e.g. The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.
Environmental protection	
respective code if available	<p>Aquatic organisms:</p> <p>The risk for aquatic organisms is considered acceptable when following risk mitigation measures are applied to surface water bodies.</p> <ul style="list-style-type: none"> 10 m VFSmod or 5 m VFSmod + 50% drift reduction for use in group B (1 × 1.0 L prod./ha) 5 m VFSmod for use in group C (2 × 0.5 L prod./ha) <p>Non target terrestrial plants:</p> <p>The risk for non-target plants is considered acceptable with the use of a 10 m buffer zone, or alternatively 5 m buffer zone and 50% drift reducing spray nozzles, or alternatively 90% drift reducing spray nozzles for use in group B (1 × 1.0 L prod/ha)</p> <p>The risk for non-target plants is considered acceptable with the use of a 5 m buffer zone, or alternatively 75% drift reducing spray nozzles for use in group C (2 × 0.5 L prod/ha)</p>
Other specific restrictions	
respective code if available	-

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:

respective code if available	-
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2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
respective code if available	e.g. The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.	use number from GAP table in 2.6
Environmental protection:		Relevant for use no.
respective code if available	e.g. The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed.	use number from GAP table in 2.6

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 2020, date: 2020- June

PPP (product name/code): **FSN+TCM OD 80**

Formulation type: OD ^(a, b)

Active substance 1: foramsulfuron

Conc. of as 1: 50 g/L ^(c)

Active substance 2: thien carbazon-methyl

Conc. of as 2: 30 g/L ^(c)

Safener: -

Conc. of safener: - ^(c)

Synergist: -

Conc. of synergist: - ^(c)

Applicant: Bayer CropScience

Professional use: ☒

Zone(s): Central ^(d)

Non professional use: ☐

Verified by MS: yes/no

Field of use: herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fn, G, Gn, Gnp or I**	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syn- ergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val between applica- tions (days)	L product / ha a) max. rate per appl. b) max. to- tal rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
22	POL	Sugar beet	F	AETCY, ECHCG, VIOAR,	spraying	10-18	a) 1	-	a) 1	a) FSN 50 + TCM 30	100-300	as per		acceptable

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destina- tion / pur- pose of crop)	F, Fn, Fn G, Gn, Gnp or I**	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syn- ergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val between applica- tions (days)	L product / ha a) max. rate per appl. b) max. to- tal rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		(BEAVA)		STEME, LAMPU, MATIN, CHEAL, GALAP, POLCO, PO- LAV, POLPE, BRSNN, VERPE, THLAR, POAAN, VERAR	(broadcast, overall)		b) 1		b) 1	b) FSN 50 + TCM 30		growth stage		
32	POL	Sugar beet (BEAVA)	F	AETCY, ECHCG, VIOAR, STEME, LAMPU, MATIN, CHEAL, GALAP, POLCO, PO- LAV, POLPE, BRSNN, VERAR, THLAR, POAAN, VERPE	spraying (broadcast, overall)	10-18 B1: 10-12 B2: 12-18	a) B1: 1 B2: 1 b) 2	B1: - B2: - 10 d after B1	a) B1: 0.5 B2: 0.5 b) 1	a) FSN 25 + TCM 15 b) FSN 50 + TCM 30	100-300	as per growth stage		acceptable
Zonal uses (certain types of protected crops)														
-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Minor uses according to Article 51 (zonal uses)														
-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Minor uses according to Article 51 (interzonal uses)														
-	-	-	-	-	-	-	-	-	-	-	-	-	-	

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l

(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPG-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPG-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a liquid suspension beige with a paint like odour. It is not explosive, has no oxidising properties. The product is not flammable/has a flash point of 83.5°C. It has a self-ignition temperature of 420 °C. In aqueous solution (1%), it has a pH value around 4.04. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C and 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE/EVOH & HDPE/PA. Its technical characteristics are acceptable for an OD type formulation. The intended concentration of use is 0.16% to 1.25%.

No tank mixture is recommended.

Implications for labelling: none.

Compliance with FAO specifications: the product complies with FAO specifications for an OD type product.

3.2 Efficacy (Part B, Section 3)

Please refer to 3.3.

3.3 Efficacy data

The submission of the product FSN+TCM OD 80 for re-registration is made under Article 43 of Regulation (EC) No 1107/2009. As the uses to be supported are the same as the currently registered ones, this does not trigger the need for new data requirements and therefore, no additional information is provided. However, the analysis of the resistance risk has been updated in accordance with the EPPO method PP 1/213: "Resistance risk analysis."

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

An analysis of the resistance risk was provided in accordance with the EPPO method PP 1/213: "*Resistance risk analysis*". EPPO Standard PP 1/213(3) EPPO Standard PP 1/213(4) 'Resistance Risk Analysis' provides a framework for resistance risk assessment and resistance risk management (Anonymous, 2015). To a great extent, the resistance risk assessment considers the inherent risk of resistance evolution and depends on various factors, some of which are associated with the product and others with the weed. A detailed analysis of the risk of resistance and its management was prepared and this document followed the framework presented within the guideline PP1/213(4).

Applicant presented an analysis of the resistance risk, in accordance with the EPPO method PP 1/213: "Resistance risk analysis".

Resistance against B/2 herbicides is known for various species. In the data-base of www.weedscience.org, ~~24~~ 25 cases of resistance against foramsulfuron and ~~2~~ 4 cases against thiencarbon-methyl are momentarily

documented.

Group B/2 herbicides bind to the substrate binding site of the acetolactate synthase (ALS) enzyme, thus preventing the production of essential amino acids, and without these amino acids, the plant eventually dies. The mechanism of resistance found against sulfonylureas is a so-called target site mechanism. Target site resistance is caused by a mutation on the enzyme at the site where the herbicide molecule binds, thus stopping the plant's normal biochemical processes.

Foramsulfuron (FSN) belongs to the sulfonyl-urea chemical family. Conducted by the xylem and the phloem, foramsulfuron acts by the inhibition of the acetolactate synthase ALS (acetoxyacid synthase AHAS). It is mainly absorbed through the foliage of weeds. Absorption by roots makes only a minor contribution to the overall efficacy. This active ingredient controls many annual broad leaved weeds and grass weeds already established when the product is applied.

Thiencarbazone-methyl belongs to the sulfonyl-amino-carbonyl-triazolinone (SACT) chemical family. and acts on the inhibition of the acetolactate synthase ALS. After an application in either pre-emergence or early post-emergence of weeds, this active substance is rapidly absorbed by leaves and roots, and then conducted by the xylem and the phloem. Translocation by phloem is very important because it allows the transport of the herbicide from mature leaves to newly-grown shoots and roots.

Table: Overview of the resistance cases for foramsulfuron

#	Year	Species	Country	MOAs	Actives	Situations
1	2017	Poa annua	Australia (New South Wales)	ALS inhibitors (B/2)	bispyribac-sodium, rimsulfuron, iodosulfuron-methyl-sodium, foramsulfuron	Golf courses
2	2017	Poa annua	Australia (New South Wales)	ALS inhibitors (B/2), EPSP synthase inhibitors (G/9), Microtubule Assembly inhibitors (K1/3), Photosystem II- Serine 264 Binders (C1/5), Unknown (Z/27)	endothall, bispyribac-sodium, rimsulfuron, simazine, glyphosate, propyzamide = pronamide, iodosulfuron-methyl-sodium, foramsulfuron	Golf courses
3	2017	Poa annua	Australia (South Australia)	ALS inhibitors (B/2)	bispyribac-sodium, rimsulfuron, iodosulfuron-methyl-sodium, foramsulfuron	Golf courses
4	2017	Poa annua	Australia (Victoria)	ALS inhibitors (B/2)	bispyribac-sodium, rimsulfuron, iodosulfuron-methyl-sodium, foramsulfuron	Golf courses
5	2019	Apera spica-venti	Belgium	ALS inhibitors (B/2)	iodosulfuron-methyl-sodium, foramsulfuron, mesosulfuron-methyl	Wheat
6	2004	Parthenium hysterophorus	Brazil	ALS inhibitors (B/2)	imazethapyr, chlorimuron-ethyl, cloransulam-methyl, iodosulfuron-methyl-sodium, foramsulfuron	Soybean
7	2006	Bidens subalternans	Brazil	ALS inhibitors (B/2), Photosystem II- Serine 264 Binders (C1/5)	atrazine, iodosulfuron-methyl-sodium, foramsulfuron	Corn (maize)
8	2011	Setaria viridis	France	ALS inhibitors (B/2)	nicosulfuron, foramsulfuron	Corn (maize)
9	2013	Echinochloa crus-galli var. crus-galli	France	ALS inhibitors (B/2)	foramsulfuron, penoxsulam	Corn (maize), Rice
10	2015	Digitaria sanguinalis	France	ALS inhibitors (B/2)	nicosulfuron, foramsulfuron	Corn (maize)
11	2009	Echinochloa phyllolopogon (=E. oryzicola)	Greece	ALS inhibitors (B/2)	bispyribac-sodium, nicosulfuron, rimsulfuron, imazamox, foramsulfuron, penoxsulam	Rice

#	Year	Species	Country	MOAs	Actives	Situations
12	2015	Sorghum halepense	Hungary	ALS inhibitors (B/2)	nicosulfuron, foramsulfuron	Corn (maize), Fallow
13	2008	Amaranthus palmeri	Israel	ALS inhibitors (B/2)	pyrithiobac-sodium, rimsulfuron, iodosulfuron-methyl-sodium, foramsulfuron, trifloxysulfuron-sodium, mesosulfuron-methyl	Corn (maize), Cotton, Watermelon
14	2019	Amaranthus tuberculatus (=A. rudis)	Israel	ALS inhibitors (B/2)	pyrithiobac-sodium, foramsulfuron, trifloxysulfuron-sodium	Corn (maize), Cotton, Sunflower
15	2009	Sorghum halepense	Mexico	ALS inhibitors (B/2)	nicosulfuron, rimsulfuron, primisulfuron-methyl, foramsulfuron	Corn (maize)
16	2012	Poa annua	United States (Alabama)	ALS inhibitors (B/2)	imazaquin, bispyribac-sodium, foramsulfuron, trifloxysulfuron-sodium	Turf
17	2006	Sorghum bicolor	United States (Indiana)	ALS inhibitors (B/2)	nicosulfuron, foramsulfuron	Corn (maize), Soybean
18	2006	Sorghum halepense	United States (Kentucky)	ALS inhibitors (B/2)	nicosulfuron, primisulfuron-methyl, foramsulfuron	Corn (maize)
19	2006	Setaria faberi	United States (Michigan)	ALS inhibitors (B/2)	imazethapyr, nicosulfuron, foramsulfuron	Corn (maize), Soybean
20	2014	Poa annua	United States (Mississippi)	ALS inhibitors (B/2)	foramsulfuron	Golf courses
21	2004	Setaria faberi	United States (Pennsylvania)	ALS inhibitors (B/2)	nicosulfuron, imazamox, foramsulfuron	Corn (maize)
22	2013	Poa annua	United States (Tennessee)	ALS inhibitors (B/2), Photosystem II- Serine 264 Binders (C1/5)	simazine, foramsulfuron, trifloxysulfuron-sodium	Golf courses, Turf
23	2004	Rottboellia cochinchinensis (=R. exaltata)	Venezuela	ALS inhibitors (B/2)	nicosulfuron, iodosulfuron-methyl-sodium, foramsulfuron	Corn (maize)
24	2010	Sorghum halepense	Venezuela	ALS inhibitors (B/2)	nicosulfuron, iodosulfuron-methyl-sodium, foramsulfuron	Corn (maize)
25	2020	Amaranthus retroflexus	Ukraine	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	imazethapyr, thifensulfuron-methyl, tribenuron-methyl, flumetsulam, imazamox, florasulam, iodosulfuron-methyl-Na, foramsulfuron, thien-carbazone-methyl	Corn (maize),

Table: Overview of the resistance cases for thien-carbon-methyl

#	Year	Species	Country	MOAs	Actives	Situations
1	2009	Senecio vulgaris	France	ALS inhibitors (B/2)	tribenuron-methyl, prosulfuron, metsulfuron-methyl, flazasulfuron, imazamox, florasulam, iodosulfuron-methyl-sodium, mesosulfuron-methyl, thien-carbazone-methyl	Grapes, Wheat
2	2011	Conyza canadensis	United States (Kansas)	ALS inhibitors (B/2)	thifensulfuron-methyl, chlor-sulfuron, tribenuron-methyl, metsulfuron-methyl, rimsulfuron, iodosulfuron-methyl-sodium, thien-carbazone-methyl	Corn (maize), Cotton, Soybean, Wheat
3	2019	Ambrosia artemisiifolia	Serbia	Inhibition of Acetolactate Synthase	tribenuron-methyl, imazamox, thien-carbazone-methyl	Corn (maize), Soybean, Sugar

#	Year	Species	Country	MOAs	Actives	Situations
				HRAC Group 2 (Legacy B)		beets, Sunflower
4	2020	<i>Amaranthus retroflexus</i>	Ukraine	Inhibition of Aceto-lactate Synthase HRAC Group 2 (Legacy B)	imazethapyr, thifensulfuron-methyl, tribenuron-methyl, flumetsulam, imazamox, florasulam, iodosulfuron-methyl-Na, foramsulfuron, thien-carbazone-methyl	Corn (maize), Sunflower

However, several dicotyledonous weeds species have been reported with resistance to ALS inhibitors worldwide and also in Europe. Most of these were found to be resistant to sulfonylureas. The inherent risk of thien-carbon-methyl and foramsulfuron has to be classified as ~~medium to~~ high:

- inherent risk related to active substance is considered to be high for the application of Conviso One in sugar beet.
- inherent risk related to target weeds is considered to be high for the application of Conviso One in sugar beet.
- agronomic risk) is considered to be high for the application of Conviso One in sugar beet.

Applicant did not present any sensitivity data (neither historical baseline sensitivity data from the initial registration nor e.g. sensitivity data produced from typical field populations-even if these have been exposed to the selection pressure). So, in the opinion of ZRMs the EPPO requirements of PP 1/213(4) are not fulfilled. However, taking into account that both a.s. foramsulfuron and thien-carbazone are high risk a.s. anyway, it may be acceptable to waive the sensitivity data.

Analysis of the inherent risk:

Both active substances belong to HRAC group B/2 which exhibits a very high resistance risk. The original target organisms of CONVISO ONE are a wide range of dicotyledonous weed species, *Alopecurus myosuroides*, *Echinochloa crus-galli* and *Poa annua*. A number of resistance cases against HRAC group B/2 herbicides have been reported for grasses such as *Alopecurus myosuroides* and *Apera spica-venti* in various European countries including Germany, UK, France and Poland mainly in winter cereals. In addition, some cases of ALS resistance are reported for *Lolium species*, *Avena species* and *Echinochloa species* in cereals, maize and rice. For *Avena fatua*, resistance to ALS inhibitors has already been reported in Germany. Regarding grass weed species, particularly *Alopecurus myosuroides* and *Echinochloa species* can be considered to have a high risk to develop resistance against ALS inhibiting herbicides in general or CONVISO ONE in specific. In addition, numerous dicotyledonous biotypes have been reported with resistance to ALS inhibitors in Europe and in the Central Zone. Most of these biotypes were found to be resistant to sulfonylureas. Regarding the existing dicotyledonous biotypes with resistant to ALS inhibitors, *Matricaria spp.*, *Kochia scoparia*, *Stellaria media* and *Papaver rhoeas* are the dicotyledonous weeds most likely to develop resistance as many resistance cases have been reported for these species in the Central Zone. Regarding crop sugar beets, mainly *Chenopodium album*, *Matricaria species*, *Stellaria media*, *Mercurialis annua*, *Amaranthus retroflexus*, *Polygonum spp.* or *Aethusa cynapium* are of importance in the Central Zone. Of those species especially *Matricaria species* and *Stellaria media* exhibit a high resistance risk. The inherent risk of both two active substances therefore has to be classified as high regarding both dicotyledonous and grass species. The applicant has not provided data on the sensitivity variation of the target species.

Agronomic risk:

The herbicide CONVISO ONE is intended to be used post-emergent for the control of dicotyledonous weed species, *Alopecurus myosuroides*, *Echinochloa crus-galli* and *Poa annua* in ALS tolerant sugar beet varieties. It seems that the use of CONVISO ONE in ALS tolerant sugar beet varieties does not lead to a significantly higher risk of ALS resistance development of monocotyledonous weeds because of the very low importance and appearance of the high risk grass weeds *Alopecurus myosuroides* and *Apera spica-venti* in sugar beets. This conclusion cannot be followed. Although the two species are of higher importance in winter cereals, especially *Alopecurus myosuroides* is also frequently found in sugar beets and is therefore prone to resistance evolution. Due to the narrow efficacy spectrum these triflurosulfuron herbicides, they are

used as part of herbicides regimes comprising of a high number of additional active substances from differing MoA groups for the control of the target weeds so that the selection pressure by ALS herbicides is considerably low in conventional sugar beet varieties so far. The agronomic risk of CONVISO ONE therefore has to be assessed as being high. However, the design of the respective crop rotations and the associated frequency of application of CONVISO ONE may differ in the various Member States in the Central Zone and a national specific assessment of the agronomic risk is therefore recommended. The applicant has not provided any information on the individual resistance risk within the different Member States in the Central zone.

In order to minimize the risk of occurrence and development of herbicide weed resistance we should follow Good Agricultural Practice:

- ✓ follow strictly the directions on the plant protection product label,
- ✓ apply the product at the recommended dose and within the recommended time frame to ensure optimal weed control weeds,
- ✓ adjust the choice of the herbicide and the decision as to whether or not to carry out the treatment to the prevailing weed infestation
- ✓ adapt the choice of herbicide and the decision on treatment to the prevailing (or potential) weed infestation, taking into account the dominant species and damage thresholds and pest thresholds,
- ✓ use a rotation of herbicides (active substances) with different mechanisms of action
- ✓ use a mixture of herbicides with different mechanisms of action,
- ✓ use in rotation and/or in a mixture herbicides affecting several weed life processes with different mechanisms of action,
- ✓ use herbicides with a particular mechanism of action only once during the growing season,
- ✓ adjust tillage measures to field conditions, especially to the type and intensity of weeds,
- ✓ use various methods of weed control, including crop rotation, etc,
- ✓ use certified seed,
- ✓ clean agricultural machinery to prevent weed propagation material from being transferred to other sites,
- ✓ destroy weeds at field edges and baulks,
- ✓ inform the permit holder if weed control is not satisfactory,
- ✓ for more information, contact your advisor, the permit holder, or the permit holder's.

Resistance management strategy proposed by the applicant is acceptable. However, in the opinion of Evaluator each of cMS can change or adjust risk assessment considering the national requirements and may designate additional measures relating to resistance prevention on the national level.

Also, cMS should remember that design of the respective crop rotations and the associated frequency of application of CONVISO ONE may differ in the various Member States in the Central Zone and a national specific assessment of the agronomic risk is therefore recommended. In the opinion of Evaluator, each cMS should do this separately at national level.

To avoid the selection of herbicide resistant biotypes, pre-launch programs have been established to define different anti-resistance management strategies for the ALS-tolerant sugar beet. The strategies adopted rely on pro-active resistance management by defining main crop rotations and associated weed control measures. Thus, strategies focus on diversity in the cropping system and monitoring suspected herbicide failures. The stewardship developed to support the herbicide tolerant sugar beet variety includes diagnostic support by scrutinizing complaints and potentially resistant weeds as well as to provide tailor-made management advice based on investigations of possible herbicide resistance mechanism(s). Applying the above mentioned IWM stewardship measures will allow the sustainable use ALS tolerant sugar beet and to provide a new weed management option to farmers.

3.3.2 Adverse effects on treated crops

The submission of FSN+TCM OD 80 for re-registration is made under Article 43 of Regulation (EC) No 1107/2009. As the uses to be supported are the same as the currently registered ones, this does not trigger the need for new data requirements and therefore, no additional information is provided.

3.3.3 Observations on other undesirable or unintended side-effects

The submission of FSN+TCM OD 80 for re-registration is made under Article 43 of Regulation (EC) No 1107/2009. As the uses to be supported are the same as the currently registered ones, this does not trigger the need for new data requirements and therefore, no additional information is provided.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Analytical methods for the determination of foramsulfuron and thien carbazon-methyl and the relevant impurities in the plant protection product FSN+TCM OD 80 were not evaluated as part of the EU (re)-approval of the active substances. All relevant data were provided in this dossier and were considered adequate.

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available and validated for all analytes included in the residue definition for plant and animal commodities, soil, drinking and surface water, body fluids and air.

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

FSN+TCM OD 80 was neither the representative formulation for the EU re-approval of foramsulfuron nor the EU approval of thien carbazon-methyl.

FSN+TCM OD 80 has a low toxicity with respect to acute oral and dermal toxicity. It is a skin and eye irritant and therefore has to be labelled as H315 (Causes skin irritation) and H318 (Causes serious eye damage), respectively. It is a skin sensitizer and has to be labelled as H317 (May cause an allergic skin reaction). Its inhalation toxicity value triggers the classification as H332 (Harmful if inhaled), and according ECHA Committee for Risk Assessment RAC Adopted 18 March 2021 H351(Suspected of causing cancer)

3.5.2 Operator exposure

Risk assessments were conducted according to the following guidance document: *Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products*; EFSA Journal 2014;12(10):3874.

The critical use pattern of 1 x 1.0 L product/ha was investigated. No unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended and with the following risk mitigation measures:

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear - arms, body and legs covered. In addition gloves during mixing and loading and when handling contaminated surfaces during application.
Workers	Acceptable	None
Bystanders	Acceptable	None
Residents	Acceptable	None

Combined exposure risk assessment (the active substances and the safener) was carried out demonstrating that the use of FSN+TCM OD 80 according to the intended use pattern(s) is not expected to present a risk for operators, workers, bystanders and residents.

3.5.3 Worker exposure

Please refer to 3.5.2.

3.5.4 Bystander and resident exposure

Please refer to 3.5.2.

3.6 Residues and consumer exposure (Part B, Section 7)

Please refer to 3.5.2.

3.6.1 Residues

Foramsulfuron

Stability of Residues

Storage stability studies conducted on maize were considered as non-acceptable during the EU re-approval review of foramsulfuron (EFSA Journal 2016; 14(3)).

New studies were provided. Studies are accepted.

The results of these studies showed that Foramsulfuron and its metabolite AE F153745 are stable in Sugar beet (body, leaf with root collar), Wheat (shoot, grain, straw) samples when stored at $\leq -18^{\circ}\text{C}$ for period of up to 24 months. Metabolite AE F092944 are stable in wheat matrices (grain, green material, straw) for 24 months.

Sufficient stability has been demonstrated to support the residue data presented in this submission.

No further data are required to support the proposed uses.

Relevant information on the stability of residues in the final or any intermediate extracts can be derived from the fortification experiments performed during sample analysis.

Note concerning Metabolite AE F092944:

According to OECD 506 guideline for High water content category matrices:

If the stability of test substance in three diverse commodities in this category is confirmed, further examination with other crops that belong to this category is unnecessary.

And for High starch content category:

If the stability of test substance in two diverse commodities in this category is confirmed, further examination with other commodities that belong to this category is unnecessary.

Extrapolation is not possible. Only for wheat shoot (High water content category) and for wheat grain (High starch content category) data are available.

However, the AE F092944 metabolite is a provisional candidate for inclusion in the risk assessment definition. Metabolism studies in beet do not indicate the possibility of residues of this compound above the LOQ. The stability of parent compound has been confirmed by storage stability data. Additionally, this metabolite is common to a number of pyrimidinylsulfonylurea substances. The absence of studies on this metabolite does not constitute an inability to register the product. PL proposes that the applicant should provide the missing data after registration of the product.

Metabolism in plants

Two metabolism studies in sugar beets (primary crops) were conducted with [pyrimidine-2-¹⁴C]- and [phenyl-UL-¹⁴C]-foramsulfuron and have been submitted by the applicant to support the 1st registration of the product in the zone. Version 01 were submitted in 2015. Version 2 are the amended reports (correction of mistakes, names of person and test facilities).

A new confined rotational crop study is submitted in the framework of this application.

Sufficient data have been provided to acknowledge the metabolism of foramsulfuron in rotational crops. The metabolism of foramsulfuron in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

EU end points:

Plant residue definition for monitoring and risk assessment: Foramsulfuron

Metabolite AE F092944 is provisionally a candidate for inclusion in the risk assessment definition (EFSA Journal 2016;14(3):4421).

AE F092944 is a common metabolite to a number of pyrimidinylsulfonylurea herbicides. A final decision on the risk assessment definition is therefore pending a comprehensive consumer risk assessment, considering the different possible sources of exposure including the potential transfer to livestock matrices and the full clarification with regard to the toxicological properties of AE F092944.

The results of the new studies are consistent with the EFSA conclusions.

The above new studies should be assessed at the EU level.

Magnitude of residues in plants

Applicant provided trials which were already submitted and therefore reviewed in the zonal dossiers submitted to LIT (zRMS, North), FRA (zRMS, South), GER (zRMS, Central) in 2015 in order to support the 1st registration of the product in each zone. They are reported in this document as they are considered to be reviewed via a zonal process but not via an EU peer reviewed process. Foramsulfuron and its metabolite AE F153745 were analysed. These studies are acceptable to support the application.

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application to support the proposed cGAP. A package of field trials was performed to determine the magnitude of the Foramsulfuron and metabolite AE F092944 residues in sugar beet and to clarify the consumer risk assessment including potential transfer to livestock matrices (see EFSA 2016; 14(3):4421 and §7.1.2.1)

The results of the new trials showed that no AE F092944 residues above the LOQ were observed in any parts of the plant, whether in body or in leaves. Significant exposure of consumers to AE F092944 is not expected.

The residues arising from the proposed uses will not exceed the MRLs established for sugar beets (0.01 mg/kg, Regulation (EC) No 289/2014). Extrapolation from sugar beets to fodder beets is possible.

Uses are accepted.

Note concerning independency of the trials:

The 8 residue trials from 12-2139 and 13-2009 can be considered as replicates to trials 12-2138 and 13-2000. Nevertheless, the number of trials provided is still sufficient (13) to support the in-tended use.

Magnitude of residues in livestock

The use of foramsulfuron in sugar beet/fodder beet according to the recommended GAP is not likely to result in significant residues in any of these animal commodities. Moreover, the assessment of the guanidine metabolite for the use on sugar beet and fodder beet demonstrated that livestock are not significantly exposed to this metabolite.

Based on the previous model of the dietary burden calculation, EFSA 2016 stated that the livestock feeding studies are not triggered for foramsulfuron (dietary burden <0.004 mg/kg bw/day). By considering the new model, the results were slightly different. For the reasons exposed above, residue levels in ruminant commodities are expected to remain below the LOQ of 0.01 mg/kg in milk and other edible tissues. Therefore, it can be concluded that no livestock feeding study is needed.

Magnitude of residues in processed commodities

No further data are required to support the proposed uses. The use of FSN+TCM OD 80 in sugar beet/fodder beet according to the intended GAP does not result in significant residues (i.e. > 0.1 mg/kg) of foramsulfuron in sugar beet root/fodder beet at harvest; residues were below the limit of quantification (0.01 mg/kg).

Magnitude of residues in representative succeeding crops

As stated by EFSA 2016, field rotational crop studies are not required as no residues are expected in succeeding crops according to confined rotational studies. No new data submitted in the frame-work of this application.

Other / special studies

Not required.

Thiencarbazone-methyl

No new data submitted in the framework of this application with the exception of Hoffmann, M.; Barrière, I., 2020. *EU approval renewal of the active substance thiencarbazone-methyl—Waiver for studies investigating residues in honey*. The presented arguments were accepted.

Stability of Residues

Available storage stability data in plant matrices cover the intended uses of FSN+TCM OD 80 on sugar beet.

Thiencarbazone-methyl (BYH 18636) and its metabolite BYH18636-N-desmethyl and BYH18636-MMT-glucoside are stable in high starch content, high water content, high oil content and dry matrices for 26 months.

Metabolism in plants

Plant residue definition for monitoring—Thiencarbazone-methyl (EFSA Journal 2013;11(7):3270; EFSA Journal 2020;18(1):5957)

Plant residue definition for risk assessment—Sum of thiencarbazone-methyl, BYH18636-N-desmethyl and BYH18636-MMT-glucoside, expressed as thiencarbazone-methyl (EFSA Journal 2013;11(7):3270;

EFSA Journal 2020;18(1):5957)

Conversion factor from enforcement to RA — Not necessary (EFSA Journal 2013;11(7):3270; EFSA Journal 2020;18(1):5957)

Available data are sufficient to cover the proposed uses.

Magnitude of residues in plants

Trials: data were evaluated in the zonal dossiers submitted to LIT (zRMS, North), FRA (zRMS, South) and GER (zRMS, Central) in 2015 in order to support the 1st registration of the product in each zone. They are reported in this document as being EU data as they were submitted to RMS (FRA) to support Art. 12.1 of EU Regulation No 396/2005 (refer to Evaluation Report prepared by RMS France — 2019 and EFSA Journal 2020;18(1):5957).

According to the available data, the intended uses on sugar beet are considered acceptable, for out door uses.

Magnitude of residues in livestock

EFSA Journal 2020;18(1):5957: The dietary burdens calculated were found to be below the trigger value of 0.1 mg/kg DM for each group and further investigation of residues as well as the setting of MRLs in commodities of animal origin is not necessary.

Magnitude of residues in processed commodities

For thien carbazon-methyl processing trials are not required

Magnitude of residues in representative succeeding crops

Residues in rotational crops at the proposed application rate in the EU are unlikely to exceed 0.01 mg/kg and therefore rotational crop field trials are not required.

Other / special studies

Not required.

Use of an application together with a safener is acceptable.

3.6.2 Consumer exposure

The proposed uses of the active substances and the safener in the formulation FSN+TCM OD 80 do not lead to unacceptable acute and chronic risks for the consumer.

Foramsulfuron	
TMDI (% ADI) according to EFSA PRIMo 3.1	0.5 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo 3.1	Not required, as TMDI is below 100%
IESTI (% ARfD) according to EFSA PRIMo 3.1*	Not relevant as no ARfD proposed
NTMDI (% ADI) **	Not relevant
NEDI (% ADI)**	Not relevant
NESTI (% ARfD) **	Not relevant as no ARfD proposed

Thien carbazon-methyl	
TMDI (% ADI) according to EFSA PRIMo 3.1	0.5 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo 3.1	Not relevant

IESTI (% ARfD) according to EFSA PRIMo 3.1*	Not relevant as no ARfD proposed
NTMDI (% ADI)**	Not relevant
NEDI (% ADI)**	Not relevant
NESTI (% ARfD) **	Not relevant as no ARfD proposed

* include raw and processed commodities if both values are required for PRIMo

** if national model is available

Combined exposure and risk assessment

The product is a mixture of two active substances for which no acute reference dose has been allocated.

The uses under consideration provide only a minor contribution to the overall chronic exposure of consumers to pesticide residues.

3.7 Environmental fate and behaviour (Part B, Section 8)

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

For the active substances foramsulfuron, thien carbazon-methyl and their metabolites, PEC_{soil} calculations were based on a “risk envelope approach”, addressing the maximum registered application rate and overall worst case exposure situation (no tillage, no crop interception).

The modelling input parameters for the active substances and relevant metabolites did not deviate from EU agreed endpoints (except the max. occurrence observed value for metabolite AE F153745 – deviation fully justified).

Use No.	Risk envelope covering all uses of foramsulfuron, thien carbazon-methyl
Crop	Risk envelope approach – all crops
Application rate (g as/ha)	60 g a.s./ha foramsulfuron (risk envelope) 40 g a.s./ha thien carbazon-methyl (risk envelope)
Number of applications/interval	1 / -
Crop interception (%)	0 %
Depth of soil layer (relevant for plateau concentration) (cm)	risk envelope approach – 10 cm (no tillage)

The resulting PEC_{soil} calculations overestimate the actual exposure due to use of the product, and thus further increase the conservatism of the Tier 1 risk assessments.

These PEC_{soil} values were taken into account in the ecotoxicological risk assessments.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The predicted environmental concentrations in groundwater (PEC_{gw}) for foramsulfuron, thien carbazon-methyl and their metabolites were calculated using the simulation model FOCUS PEARL (v4.4.4), FOCUS PELMO (v5.5.3), FOCUS MACRO (v5.5.4).

The modelling input parameters for the active substances and relevant metabolites did not deviate from EU agreed endpoints.

Foramsulfuron

The active substance and its metabolites did not breach the EU threshold value of 0.1 µg/L for the intended uses of the formulation.

Thiencarbazone-methyl

In agreement with the Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (SANCO/2010/13170), for products containing two or more active substances -and when the 1st substance is renewed- there is no need to evaluate data related to the 2nd substance. Thiencarbazone-methyl (TCM) is the active ingredient not being renewed and therefore data pertaining to TCM should not be evaluated in this submission.

Nevertheless, PEC_{gw} were calculated upon ZRMS's request. The active substance and its metabolites (except metabolite BYH 18636-carboxylic acid) did not breach the EU threshold value of 0.1 µg/L for the intended uses of the formulation.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

Calculations related to PEC_{sw/sed} were done according to 2 different approaches:

- The effectiveness of vegetated filter strips for mitigating entries into surface water via runoff can be modelled using the PRZM-SWAN-VFSMOD models (SETAC MAGPIE working group, 2013). Calculations for the individual substances foramsulfuron, AE F130619 and thiencarbazone-methyl considering VFS_{mod} (Step 4, for run-off scenarios only - National dossier) were carried out.
- Calculations (Core dossier) to enable to enable a stepwise ecotoxicological risk assessment according the tiered approaches of the EFSA Aquatic Guidance Document (AGD)², a comprehensive set of exposure calculations and supportive information for exposure description were presented.

As a first step, a **spray-drift exposure calculation for the formulated product** was made (use of Ganzelmeier tabulated standard drift values).

Thereafter, exposure calculations for the individual components (active substances and metabolites) via the FOCUS_{sw} approach were made as follows:

(a) FOCUS Steps 1-2 - PEC_{sw/sed} for a generic risk envelope use pattern covering all uses: to enable a simplified screening level assessment for components and organisms characterised by a wide margin of safety even when based on highly conservative exposure assumptions.

(b) FOCUS Step 3 – PEC_{sw/sed} (maximum and TWA) for the critical GAPS: to enable Tier 1 risk assessment based on the accurate GAP and standard FOCUS Step 3 exposure description, where assessment was not resolved at the screening level. For the present product and uses, this applies for the herbicidal active components foramsulfuron, its metabolite AE F130619 and thiencarbazone-methyl on which all further risk assessments will concentrate.

(c) FOCUS Step 4 – PEC_{sw/sed} (maximum and TWA) for the critical GAPS: to enable consideration of exposure mitigating measures, where required.

(d) FOCUS Step 3-4 - Time course plots (FOCUS year) and exposure pattern analysis to selected scenarios: to enable a refined risk assessment considering time-variability of the exposure, based on AGD option Tier 2C.

(e) FOCUS Step 3-4 - Time course plots (multi-year simulation) and exposure pattern analysis to selected scenarios: to provide confirmative information on multi-annual representativeness of the preceding assessments.

² “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015). (Cited as “EFSA Aquatic Guidance Document” or “AGD”)

The modelling input parameters for the active substance thien carbazon-methyl and its relevant metabolites did not deviate from EU agreed endpoints.

The modelling input parameters for the active substance foramsulfuron and its metabolites (except for AE F153745, maximum occurrence observed) did not deviate from EU agreed endpoints. A full justification was provided for the endpoint used for metabolite AE F153745 (maximum occurrence observed).

The results of $PEC_{sw/sed}$ for the active substances and their metabolites were used for the ecotoxicological risk assessments.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The fate of the active substances foramsulfuron and thien carbazon-methyl have been evaluated within the EU evaluation process for the active ingredients.

No additional studies are considered for this assessment.

The vapour pressures at 20 °C of the active substances are below 10^{-5} Pa at 20°C. Hence the active substances are regarded as non-volatile.

Therefore exposure of adjacent surface waters and terrestrial ecosystems from volatilization followed by subsequent deposition is not expected

Implications for labelling resulting from environmental fate assessment: There are no specific implications for labelling resulting from environmental assessment.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Foramsulfuron, thien carbazon-methyl

The acute and long-term risks of the active substances to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies on the active substances and maximum residues occurring on food items following applications according to the proposed use pattern(s). The acute and long-term screening step TER values were above the trigger value of 10 and 5, respectively.

For the active substances, due to the $k(f)_{oc}$ and $\log P_{ow}$ values, the risk assessments for exposure via drinking water from puddles and risk of secondary poisoning were not considered necessary.

Combined toxicity

For the acute and long-term assessments, the TER_{MIX} values were above the trigger value of 10 and 5, respectively, indicating no unacceptable risk from the use of the product.

Terrestrial vertebrates (other than birds)

Foramsulfuron, thien carbazon-methyl

The acute and long-term risks of the active substance to mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies on the active substances and maximum residues occurring on food items following applications according to the proposed use pattern(s).

The acute and long-term screening step TER values were above the trigger value of 10 and 5, respectively. Furthermore, due to the $k(f)_{oc}$ and $\log P_{ow}$ values, the risk assessments for exposure via drinking water from puddles and risk of secondary poisoning were not considered necessary.

Combined toxicity

For the acute and long-term assessments, the TER_{MIX} values were above the trigger value of 10 and 5, respectively, indicating no unacceptable risk from the use of the product.

No measures for exposure mitigation need to be taken into account for the protection of birds, mammals, and other terrestrial vertebrate wildlife.

In overall conclusion, the risk for terrestrial vertebrates is acceptable for the use of FSN+TCM OD 80 according to the intended use pattern(s).

3.8.2 Effects on aquatic species

Effects on aquatic species of FSN+TCM OD 80 were not evaluated as part of the EU assessment of the active substances. Studies on the toxicity to aquatic organisms have been carried out with the active substances foramsulfuron, thienencarbazone-methyl and their relevant metabolites as well as with the formulated product.

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009 - AGD”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

A comprehensive risk assessment was established for the formulation FSN+TCM OD 80 via a stepwise procedure such as described below:

- **Spray-drift assessment (formulated product):** performed as a first step and based on the measured formulation endpoints for each organism group.
- As the **MDR calculation** indicated concentration additive toxicity behaviour of the formulation, any further risk assessment considerations and refinements were made on the level of the individual active components.
- **Screening level:** a "generic risk envelope approach" was presented for FOCUS steps 1 and 2. For the inactive metabolites, all risk assessments for aquatic organisms were passed at this stage without any refinement and even if worst case PEC_{sw} values were considered.
- **AGD Tier 1** risk assessment: based on the accurate GAP and FOCUS Step 3 and Step 4, where the risk assessment was not passed at the screening level before (e.g. aquatic macrophytes).

Based on the tiered risks assessments and taking into account the combined assessment for relevant scenarios for Poland, the following risk mitigations could be proposed:

- 10 m VFSmod or 5 m VFSmod + 50% drift reduction for use in group B (**1 × 1.0 L prod./ha**)
- 5 m VFSmod for use in group C (**2 × 0.5 L prod./ha**)

Implications for labelling: The formulation need to be classified as H410 (Very toxic to aquatic life with long lasting effects) in relation to its aquatic endpoints.

3.8.3 Effects on bees

Effects on bees of FSN+TCM OD 80 were not evaluated as part of the EU assessment of the active substances. New studies were performed with the active ingredients and the formulation.

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002). The risk to bees was demonstrated to be acceptable for all intended use(s) of the product.

No additional measures for exposure mitigation are triggered for the protection of bees.

According to Reg.284/2009 the chronic test to adult bee and chronic test for larvae should be submitted when GD for Bees will be implemented.

3.8.4 Effects on other arthropod species other than bees

Effects on non-target arthropods of FSN+TCM OD 80 were not evaluated as part of the EU assessment of the active substances. New studies performed with the formulation we carried out.

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

It can be concluded that no unacceptable risk to non-target arthropods in the in-field and the off-field is to be expected from the use of FSN+TCM OD 80 in sugar beet according to the intended use pattern(s).

No additional measures for exposure mitigation are triggered for the protection of arthropod species other than bees.

3.8.5 Effects on soil organisms

Effects on earthworms and other non-target soil organisms of FSN+TCM OD 80 were not evaluated as part of the EU assessment of the active substances. New studies were submitted with this formulation.

The evaluation of the risk for earthworms and other non-target soil organisms (meso and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The acute and/or long-term risk of the active substances and their relevant metabolites and of the formulated product were assessed, based on maximum PEC_{soil} .

It could be concluded that the use of FSN+TCM OD 80 in sugar beet according to the recommended use patterns does not lead to unacceptable risk to earthworms and other soil macro-organisms.

No additional measures for exposure mitigation are triggered for the protection of soil organisms.

3.8.6 Effects on non-target terrestrial plants

Effects on non-target terrestrial plants of FSN+TCM OD 80 were not evaluated as part of the EU assessment of the active substances. New studies were submitted with this formulation.

Based on the probabilistic risk assessment, it is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields, when considering the following mitigation measures:

- **1 × 1.0 L product/ha:** a 10 m buffer zone, or alternatively 5 m buffer zone and 50% drift reducing spray nozzles, or alternatively 90% drift reducing spray nozzles
- **2 × 0.5 L product/ha:** a 5 m buffer zone, or alternatively 75% drift reducing spray nozzle

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No further information is available or considered to be necessary.

3.9 Relevance of metabolites (Part B, Section 10)

Foramsulfuron

None of the metabolites of the active substance was predicted to reach or exceed the EU threshold value of 0.1 µg/L for any of the FOCUS groundwater scenarios. The risk for groundwater is acceptable and no relevance assessment for any of the assessed metabolites is required.

Thiencarbazone-methyl

For the metabolite BYH 18636-carboxylic acid, PEC_{gw} was above the trigger value of 0.1 µg/L. The relevance of the groundwater metabolite BYH 18636-carboxylic acid was assessed and the assessment agreed at EU level. BYH 18636-carboxylic acid is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.

Overall, there are no concerns for groundwater when the product is used according to the registered use patterns.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

A comparative assessment is not requested at the time of the submission for re-registration as none the active substances are a candidate for substitution according to Article 50(1) of Regulation (EC) No 1107/2009.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

Pozostałości: brak uwag

Posiadacz zezwolenia:

Bayer AG., Kaiser-Wilhelm-Allee 1, 51373 Leverkusen, Republika Federalna Niemiec,
tel.: +33 4 72854950, fax: +33 4 72854936

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

Bayer Sp. z o.o., Al. Jerozolimskie 158, 02-326 Warszawa, tel.: 22 572 35 00,
fax: 22 572 36 03

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

.....

Conviso One

Środek przeznaczony do stosowania przez użytkowników profesjonalnych


Herbicyd do stosowania wyłącznie w odmianach buraka cukrowego posiadających odporność na herbicydy z grupy sulfonilomoczników

Zawartość substancji czynnych:

foramsulfuron (substancja z grupy pochodnych sulfonilomocznika) – 50 g/l (4,85%)

tienkarbazon metylu (substancja z grupy triazolinonów) – 30 g/l (2,91%)

**Zezwolenie MRiRW nr R – 40/2017 wu z dnia 20.10.2017 r.
ostatnio zmienione decyzją MRiRW nr R -431/2019d z dnia 11.07.2019 r.**

	
Niebezpieczeństwo	
H304	Połknięcie i dostanie się przez drogi oddechowe może grozić śmiercią.
H315	Działa drażniąco na skórę.
H317	Może powodować reakcję alergiczną skóry.
H318	Powoduje poważne uszkodzenie oczu.
H332	Działa szkodliwie w następstwie wdychania.
H351	Podejrzewa się, że powoduje raka
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P261	Unikać wdychania mgły/par/rozpylonej cieczy.
P280	Stosować rękawice ochronne/ odzież ochronną/ ochronę oczu/ ochronę twarzy.
P301 + P310	W PRZYPADKU POŁKNIECIA: Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem.
P331	NIE wywoływać wymiotów.
P305+ P351 + P338	

308+P313 P310	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. W przypadku narażenia lub styczości: Zasięgnąć porady/ zgłosić się pod opiekę lekarza. Natychmiast skontaktować się z OŚRODKIEM ZATRUCÍ/ lekarzem
P333 + P313 P362+P364 P391	W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/ zgłosić się pod opiekę lekarza. Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem. Zebrać wyciek.

OPIS DZIAŁANIA

HERBICYD selektywny o działaniu układowym, stosowany nalistnie, w formie zawiesiny olejowej do rozcieńczania wodą, przeznaczony do stosowania wyłącznie w odmianach buraka cukrowego posiadających odporność na herbicydy z grupy inhibitorów ALS.

Zgodnie z klasyfikacją HRAC substancje czynne zaliczane są do grupy B.

DZIAŁANIE NA CHWASTY

Środek zawiera substancje czynne zaliczane do inhibitorów syntazy acetylmleczanowej (ALS), co prowadzi do blokowania biosyntezy aminokwasów rozgałęzionych, a tym samym do zaburzeń w biosyntezie białek, a w efekcie zahamowania rozwoju i wzrostu chwastów.

Środek pobierany jest poprzez liście i częściowo także przez korzenie chwastów. Najskuteczniej zwalcza chwasty we wczesnych fazach rozwojowych w okresie ich intensywnego wzrostu od fazy siewek do fazy 4 liści właściwych. Pełen efekt chwastobójczy widoczny jest po upływie 2-4 tygodni od wykonania zabiegu. Dzięki działaniu tienkarbazonu metylu poprzez glebę środek częściowo ogranicza zachwaszczenie wtórne.

Herbicyd wykazuje szerokie spektrum zwalczania chwastów w tym także gatunków jednoliściennych, co pozwala na ograniczenie konieczności dodatkowego użycia graminy cydu.

Chwasty wrażliwe:	blekot pospolity, chwastnica jednostronna, fiołek polny, gwiazdnica pospolita, jasnota purpurowa, maruna bezwonna, komosa biała, przytulia czepna, rdestówka powojowata (rdest powojowaty), rdest ptasi, rdest plamisty, samosiewy rzepaku, przetacznik polny (w fazie siewki), tobołki polne, wiechlina roczna
Chwasty średnio-odporne:	przetacznik perski (dawki dzielone)
Chwasty odporne	przetacznik perski (zabieg jednorazowy)

STOSOWANIE ŚRODKA OCHRONY ROŚLIN

Środek przeznaczony do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego.

Burak cukrowy

Zabieg jednorazowy

Termin stosowania: środek stosować od fazy widocznego pierwszego liścia właściwego do fazy 8 liści buraka cukrowego (BBCH 11-18).

Zabieg należy uzależnić od fazy rozwojowej chwastów, w tym w szczególności od fazy rozwojowej komosy białej. Zabieg należy wykonać nie później niż w fazie, gdy widoczne na polu chwasty (w tym komosa biała) osiągną fazę maksymalnie 4 liści właściwych.

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 100-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

lub

System dawek dzielonych

Pierwszy zabieg

Termin stosowania: środek stosować od fazy widocznego pierwszego liścia właściwego do fazy 2 liści (BBCH 10 - 12).

Termin zabiegu należy uzależnić od stadium rozwojowego występujących chwastów, w tym w szczególności od fazy rozwojowej komosy białej. Zabieg należy wykonać nie później niż w fazie gdy widoczne na polu chwasty (w tym komosa biała) osiągną maksymalnie 2- 4 liście właściwe.

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 0,5 l/ha.

Drugi zabieg

Termin stosowania: środek stosować od fazy 2 liści do fazy 8 liści buraka cukrowego (BBCH 12-18). Zabieg należy wykonać nie później niż w fazie gdy widoczne na polu chwasty (w tym komosa biała) osiągną maksymalnie 2- 4 liście właściwe

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,5 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

Odstęp pomiędzy zabiegami: 10-14 dni

Zalecana ilość wody: 100-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

Uwagi:

- Należy ściśle przestrzegać zalecanego odstępu czasowego pomiędzy zabiegami (maksymalnie 14 dni), aby umożliwić całkowite zniszczenie chwastów znajdujących się na plantacji.
- Okres bez opadów atmosferycznych od chwili wykonania zabiegu: 2 godziny

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Nie dotyczy

1. Strategia zarządzania odpornością

W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów na herbicydy należy zgodnie z Dobrą Praktyką Rolniczą:

- postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin – stosować środek w zalecanej dawce, w zalecanym terminie zapewniającym optymalne zwalczanie chwastów,
- dostosować dobór środka chwastobójczego oraz decyzji o wykonaniu zabiegu do panującego (ewentualnie potencjalnego) zachwaszczenia, z uwzględnieniem gatunków dominujących i progów szkodliwości,
- stosować rotację herbicydów (substancji czynnych) o różnym mechanizmie działania,
- stosować mieszankę herbicydów (substancji czynnych) o różnym mechanizmie działania,
- stosować w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów (o różnym mechanizmie działania),
- stosować herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
- dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
- używać różnych metod kontroli zachwaszczenia, w tym zmianowania upraw itp.,
- używać kwalifikowanego materiału siewnego,
- czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,
- niszczyć chwasty na skrajach pól i miedzach,
- informować posiadacza zezwolenia o nie satysfakcjonującym zwalczaniu chwastów,
- w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.

2. Środka nie stosować:
 - na plantacjach roślin chorych lub osłabionych przez przymrozki lub szkodniki,
 - na rośliny mokre,
 - w temperaturze powietrza (mierzonej przy gruncie) poniżej 10°C i powyżej 25°C,
 - w okresie południowych upałów i silnego nasłonecznienia,
 - w przypadku dużych dobowych wahań temperatury pomiędzy dniem a nocą (>20°C),
 - w okresie spodziewanych przymrozków,
 - w ilości wody większej niż 300 l/ha,
 - łącznie z roztworem saletrzano-mocznikowym (RSM), siarczanem amonowym lub innymi nawozami lub odżywkami,
 - na plantacjach z widocznymi objawami niedoborów składników pokarmowych widocznych na blaszkach liściowych buraka.
3. Podczas stosowania środka nie dopuścić do:
 - znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych (zaleca się stosowanie końcówek antyznoszeniowych),
 - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.
4. Zaleca się stosowanie środka w temperaturach 10-15°C.

NASTĘPSTWO ROŚLIN

Środek rozkłada się w glebie w ciągu okresu wegetacji nie stwarzając zagrożenia dla roślin uprawianych następczo. W przypadku, gdy przebieg wegetacji nie odbiegał od normy, po zbiorze buraków i wykonaniu tradycyjnej orki i zespołu uprawek przedsiewnych na danym polu można uprawiać jesienią pszenicę ozimą, a wiosną następnego roku: pszenicę jary, jęczmień jary, rzepak jary, buraki cukrowe – również odmiany wrażliwe na herbicydy z grupy sulfonilomoczników, fasolę, rajgras angielski, gorczycę, soję, słonecznik, groch, kukurydzę i ziemniaki.

W przypadku wcześniejszej likwidacji plantacji buraków (np. w wyniku uszkodzenia roślin przez przymrozki, choroby lub szkodniki) na tym polu po wykonaniu orki i pełnej mechanicznej uprawy przedsiewnej można powtórnie wysiewać wyłącznie odmiany buraka cukrowego posiadające odporność na herbicydy z grupy inhibitorów ALS lub wysiewać kukurydzę.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzenia cieczy użytkowej opakowanie z herbicydem wielokrotnie wstrząsnąć w celu uzyskania jednorodnej zawiesiny, a następnie dokładnie odmierzyć potrzebną jej ilość. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza.

W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.

Opryskiwać z włączonym mieszadłem, bezpośrednio po sporządzeniu cieczy użytkowej środka.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

Nie pozostawiać cieczy użytkowej środka w zbiorniku opryskiwacza bez mieszania przez dłuższy czas np. przez noc.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Zarówno przed wykonaniem zabiegu w uprawie buraka jak i po wykonaniu zabiegu należy opryskiwacz dokładnie, kilkakrotnie wymyć i opłukać stosując zalecane do tego celu środki czyszczące i neutralizujące.

Nawet niewielka ilość herbicydu osadzającego się na ściankach opryskiwacza może doprowadzić do uszkodzenia lub zniszczenia opryskiwanej wrażliwej rośliny uprawnej.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

~~W celu ochrony pszczół i innych owadów zapylających nie stosować na rośliny uprawne w czasie kwitnienia. Nie używać w miejscach gdzie pszczoły mają pożytek. Nie stosować na uprawę kiedy występują w niej kwitnące chwasty.~~

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 10 m lub 5 metrowej zadarnionej strefy ochronnej wraz z użyciem końcówek rozpylaczy redukujących znoszenie o 50% od zbiorników i cieków wodnych dla jednorazowego zastosowania w dawce **1 x 1 L/ha**

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 5 metrowej zadarnionej strefy ochronnej dla zastosowania w dawce **2 x 0.5 L/ha**

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości:

Zabieg jednorazowy 1,0 l/ha

- ~~20~~ 10 m od terenów nieużytkowanych rolniczo lub
- ~~40~~ 5 m od terenów nieużytkowanych rolniczo z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50% lub
- 5–1m od terenów nieużytkowanych rolniczo z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%.

System dawek dzielonych 2 x 0,5 l/ha

- ~~10 m od terenów nieużytkowanych rolniczo lub~~
- 5 m od terenów nieużytkowanych rolniczo z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50% lub
- 1 m od terenów nieużytkowanych rolniczo z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 75 90%.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0 °C - 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku połknięcia: Natychmiast skontaktować się z ośrodkiem zatruc/lekarzem. Nie wywoływać wymiotów.

W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. Natychmiast skontaktować się z ośrodkiem zatruc/ lekarzem.

W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/ zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

Bayer is the owner of all data related to foramsulfuron and thiencarbazone-methyl. No Letter of Access is therefore required.

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Core dossier – Central Zone – D-015225-01

The Confidential data are not reported below as no data protection is claimed for confidential data.

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 / 01 ... also filed: KCP 2.4 / 01 KCP 2.5 / 01 KCP 2.6 / 01 KCP 2.8.2 / 01 KCP 2.8.3 / 01 KCP 2.8.5.1 / 01 KCP 2.8.7 / 01	Rexer, K.	2013	Physical, chemical and technical properties of foramsulfuron + thiencarbazon-methyl OD 80 (50+30 g/L) Final report Report No.: FM0165(PCF00)G01, Edition Number: M-461419-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked to support 1 st registration.	Bayer
KCP 2.2 / 01 ... also filed: KCP 2.3 / 01	Keldenich, H. P.	2013	Safety-relevant data of foramsulfuron + thiencarbazon-methyl OD 80 (50+30 g/L) Report No.: 2013/00169, Edition Number: M-458775-01-1 Bayer Technology Services GmbH, Leverkusen, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked to support 1 st registration.	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.3 / 01 ... also filed: KCP 2.2 / 01	Keldenich, H. P.	2013	Safety-relevant data of foramsulfuron + thien carbazole-methyl OD 80 (50+30 g/L) Report No.: 2013/00169, Edition Number: M-458775-01-1 Bayer Technology Services GmbH, Leverkusen, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1 st registration.	Bayer
KCP 2.4 / 01 ... also filed: KCP 2.1 / 01 KCP 2.5 / 01 KCP 2.6 / 01 KCP 2.8.2 / 01 KCP 2.8.3 / 01 KCP 2.8.5.1 / 01 KCP 2.8.7 / 01	Rexer, K.	2013	Physical, chemical and technical properties of foramsulfuron + thien carbazole-methyl OD 80 (50+30 g/L) Final report Report No.: FM0165(PCF00)G01, Edition Number: M-461419-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1 st registration.	Bayer
KCP 2.5 / 01 ... also filed: KCP 2.1 / 01 KCP 2.4 / 01 KCP 2.6 / 01 KCP 2.8.2 / 01 KCP 2.8.3 / 01 KCP 2.8.5.1 / 01 KCP 2.8.7 / 01	Rexer, K.	2013	Physical, chemical and technical properties of foramsulfuron + thien carbazole-methyl OD 80 (50+30 g/L) Final report Report No.: FM0165(PCF00)G01, Edition Number: M-461419-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1 st registration.	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.6 / 01 ... also filed: KCP 2.1 / 01 KCP 2.4 / 01 KCP 2.5 / 01 KCP 2.8.2 / 01 KCP 2.8.3 / 01 KCP 2.8.5.1 / 01 KCP 2.8.7 / 01	Rexer, K.	2013	Physical, chemical and technical properties of foramsulfuron + thien carbazone-methyl OD 80 (50+30 g/L) Final report Report No.: FM0165(PCF00)G01, Edition Number: M-461419-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1 st registration.	Bayer
KCP 2.7 / 01 ... also filed: KCP 2.8.2 / 02 KCP 2.8.3 / 02	Rexer, K.	2014	Storage stability at elevated temperature of foramsulfuron + thien carbazone-methyl OD 80 (50+30 g/L) - Packaging material: COEX/PA - Final report (8 weeks) / 1. amendment - Report No.: FM0165(ACF02)N01, Edition Number: M-464718-03-1 Bayer CropScience AG, Monheim, Germany ... amended: 2014-02-10 GLP/GEP: No unpublished	No	No	-	Bayer
KCP 2.7 / 02 ... also filed: KCP 2.8.2 / 03 KCP 2.8.3 / 03	Rexer, K.	2014	Storage stability at elevated temperature and cold stability of foramsulfuron + thien carbazone-methyl OD 80 (50+30 g/L) - Packaging material: COEX/EVOH - Final report (8 weeks) / 1. amendment - Report No.: FM0165(ACF03)N01, Edition Number: M-464720-03-1 Bayer CropScience AG, Monheim, Germany ... amended: 2014-02-10 GLP/GEP: No unpublished	No	No	-	Bayer
KCP 2.7 / 03	Rexer, K.	2015	Shelf life of foramsulfuron + thien carbazone-methyl OD 80 (50+30 g/L) - Packaging material: COEX/PA - Final report (2 years) Report No.: FM0165(SLF02)N01, Edition Number: M-525611-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.7 / 04	Rexer, K.	2018	Shelf life (2 years) of foramsulfuron + thien carbazone-methyl OD 80 (50+30 g/L) - Packaging material: COEX/EVOH - Final report / 1. Amendment Report No.: FM0165(SLF03)N01, Edition Number: M-525601-02-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2018-05-03 GLP/GEP: No unpublished	No	No	-	Bayer
KCP 2.8.2 / 01 ... also filed: KCP 2.1 / 01 KCP 2.4 / 01 KCP 2.5 / 01 KCP 2.6 / 01 KCP 2.8.3 / 01 KCP 2.8.5.1 / 01 KCP 2.8.7 / 01	Rexer, K.	2013	Physical, chemical and technical properties of foramsulfuron + thien carbazone-methyl OD 80 (50+30 g/L) Final report Report No.: FM0165(PCF00)G01, Edition Number: M-461419-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1 st registration.	Bayer
KCP 2.8.2 / 02 ... also filed: KCP 2.7 / 01 KCP 2.8.3 / 02	Rexer, K.	2014	Storage stability at elevated temperature of foramsulfuron + thien carbazone-methyl OD 80 (50+30 g/L) - Packaging material: COEX/PA - Final report (8 weeks) / 1. amendment - Report No.: FM0165(ACF02)N01, Edition Number: M-464718-03-1 Bayer CropScience AG, Monheim, Germany ... amended: 2014-02-10 GLP/GEP: No unpublished	No	No	-	Bayer
KCP 2.8.2 / 03 ... also filed: KCP 2.7 / 02 KCP 2.8.3 / 03	Rexer, K.	2014	Storage stability at elevated temperature and cold stability of foramsulfuron + thien carbazone-methyl OD 80 (50+30 g/L) - Packaging material: COEX/EVOH - Final report (8 weeks) / 1. amendment - Report No.: FM0165(ACF03)N01, Edition Number: M-464720-03-1 Bayer CropScience AG, Monheim, Germany ... amended: 2014-02-10 GLP/GEP: No unpublished	No	No	-	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.8.3 / 01 ... also filed: KCP 2.1 / 01 KCP 2.4 / 01 KCP 2.5 / 01 KCP 2.6 / 01 KCP 2.8.2 / 01 KCP 2.8.5.1 / 01 KCP 2.8.7 / 01	Rexer, K.	2013	Physical, chemical and technical properties of foramsulfuron + thiencarbazone-methyl OD 80 (50+30 g/L) Final report Report No.: FM0165(PCF00)G01, Edition Number: M-461419-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1 st registration.	Bayer
KCP 2.8.3 / 02 ... also filed: KCP 2.7 / 01 KCP 2.8.2 / 02	Rexer, K.	2014	Storage stability at elevated temperature of foramsulfuron + thiencarbazone-methyl OD 80 (50+30 g/L) - Packaging material: COEX/PA - Final report (8 weeks) / 1. amendment - Report No.: FM0165(ACF02)N01, Edition Number: M-464718-03-1 Bayer CropScience AG, Monheim, Germany ... amended: 2014-02-10 GLP/GEP: No unpublished	No	No	-	Bayer
KCP 2.8.3 / 03 ... also filed: KCP 2.7 / 02 KCP 2.8.2 / 03	Rexer, K.	2014	Storage stability at elevated temperature and cold stability of foramsulfuron + thiencarbazone-methyl OD 80 (50+30 g/L) - Packaging material: COEX/EVOH - Final report (8 weeks) / 1. amendment - Report No.: FM0165(ACF03)N01, Edition Number: M-464720-03-1 Bayer CropScience AG, Monheim, Germany ... amended: 2014-02-10 GLP/GEP: No unpublished	No	No	-	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.8.5.1 / 01 ... also filed: KCP 2.1 / 01 KCP 2.4 / 01 KCP 2.5 / 01 KCP 2.6 / 01 KCP 2.8.2 / 01 KCP 2.8.3 / 01 KCP 2.8.7 / 01	Rexer, K.	2013	Physical, chemical and technical properties of foramsulfuron + thienicarbazone-methyl OD 80 (50+30 g/L) Final report Report No.: FM0165(PCF00)G01, Edition Number: M-461419-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1 st registration.	Bayer
KCP 2.8.7 / 01 ... also filed: KCP 2.1 / 01 KCP 2.4 / 01 KCP 2.5 / 01 KCP 2.6 / 01 KCP 2.8.2 / 01 KCP 2.8.3 / 01 KCP 2.8.5.1 / 01	Rexer, K.	2013	Physical, chemical and technical properties of foramsulfuron + thienicarbazone-methyl OD 80 (50+30 g/L) Final report Report No.: FM0165(PCF00)G01, Edition Number: M-461419-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1 st registration.	Bayer
KCP 5.1.1 / 01	Michel, A.	2013	Determination of foramsulfuron and thienicarbazone-methyl in formulations ; Assay HPLC, external standard Report No.: AM017812MF2, Edition Number: M-426823-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2013-04-09 GLP/GEP: No unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1 st registration.	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1 / 02	Kienow, A.; Michel, A.	2013	Validation of HPLC-method AM017812MF2 - Determination of foramsulfuron and thiencarbazone-methyl in formulations - foramsulfuron + thiencarbazone-methyl OD 80 (50+30 g/L) Report No.: VB1-AM017812MF2, Edition Number: M-451436-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer
KCP 5.1.1 / 03	Michel, A.	2013	Determination of foramsulfuron byproduct AE F092944, AE F153745 and AE F130619 in formulations ; Assay HPLC, external standard Report No.: AM020213MF1, Edition Number: M-460493-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer
KCP 5.1.1 / 04	Bastian-Bertrams, V.; Michel, A.	2015	Validation of HPLC-method AM020213MF1 - Determination of foramsulfuron byproducts AE F092944, AE F153745 and AE F130619 in formulations - foramsulfuron + thiencarbazone-methyl OD 80 (50+30 g/L) Report No.: VB1.1-AM020213MF1, Edition Number: M-460499-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2015-03-04 GLP/GEP: No unpublished	No	No	-	Bayer
KCP 5.1.1 / 05	Michel, A.	2013	Determination of thiencarbazone-methyl byproduct AE 1364547 in formulations ; Assay HPLC, external standard Report No.: AM020313MF1, Edition Number: M-454650-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1 / 06	Bastian-Bertrams, V.; Michel, A.	2015	Validation of HPLC-method AM020313MF1 - Determination of thiencarbazone-methyl byproduct AE 1364547 in formulations - foramsulfuron + thien-carbazone-methyl OD 80 (50+30 g/L) Report No.: VB1.1-AM020313MF1, Edition Number: M-453185-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2015-03-03 GLP/GEP: No unpublished	No	No	-	Bayer
KCP 5.1.2.5 / 01	Lakaschus, S.; Amann, S.; Winter, O.; Gizler, A.	2013	Validation of the BCS method no. 01207 (based on modified QuEChERS method) for the determination of selected BCS analytes and their metabolites in carrot, apple, orange, oilseed rape seed and beans Report No.: S10-00279, Edition Number: M-424756-02-1 Eurofins Agroscience Services Chem GmbH (EAS Chem), Hamburg, Germany ... amended: 2013-12-11 GLP/GEP: Yes unpublished	No	Yes		Bayer
KCP 5.1.2.5 / 02	Schulte, G.; Oel, D.	2013	Analytical method 01340 for the determination of residues of foramsulfuron and its metabolite AE F153745 in/on plant matrix (sugar beet body and leaf) by HPLC-MS/MS Report No.: MR-12/046, Edition Number: M-450947-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1 st registration.	Bayer
KCP 5.1.2.5 / 03	Kaussmann, M.	2017	Modification M002 of the residue analytical method 01376 for the determination of foramsulfuron, iodosulfuron-methyl, metsulfuron-methyl and AE F153745 in/on plant material by HPLC-MS/MS Report No.: 01376/M002, Edition Number: M-587949-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Yes		Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2.5 / 04	Kaussmann, M.	2017	Analytical method 01514 for the determination of AE F092944, AE F059411 and AE 0031838 in/on plant by HPLC-MS/MS Report No.: P602166508, Edition Number: M-583894-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Yes	Study not submitted to authorities to support foramsulfuron containing product	Bayer
KCP 5.1.2.6 / 01	Braune, M. Sandau, C.	2013	Method 01350 for the determination of AE F130619 in test water by HPLC-MS/MS Report No.: MR-12/082, Edition Number: M-445044-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer
KCP 5.1.2.6 / 02	Schmeer, K.; Stuke, S.	2009	Description of the multi-residue analytical method 01163 for the simultaneous determination of pesticides by HPLC-MS/MS in plant materials and feeding stuff based on the official QuEChERS method Report No.: 01163, Edition Number: M-354028-01-1 Method Report No.: MR-09/104 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer
KCP 5.2.1 / 01	Stuke, S.	2015	Modification 001 of analytical method 01360 for the determination of amidosulfuron, metsulfuron-methyl, iodosulfuron-methyl-sodium, mesosulfuron-methyl, and foramsulfuron in samples from plant origin by HPLC-MS/MS Report No.: MR-15/090, Edition Number: M-537921-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Yes	Study not submitted to authorities to support foramsulfuron containing product	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2.2 / 01	Schoening, R.; Koester, P.	2013	Modification M001 of the analytical method 01022 for the determination of residues of BYH18636 and BYH18636-MMT in animal matrices Report No.: 01022/M001, Edition Number: M-459804-01-1 Method Report No.: MR-13/059 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Yes	Study not submitted to authorities to support foramsulfuron containing product	Bayer
KCP 5.2.2 / 02	Wilde, N.	2013	Independent laboratory validation of BCS analytical method no. 01022/M001 for the determination of residues of BYH18636 (thiencarbazone-methyl) and BYH18636-MMT in egg, using LC/MS/MS Report No.: P 3025 G, Edition Number: M-482949-01-1 PTRL Europe GmbH, Ulm, Germany GLP/GEP: Yes unpublished	No	Yes	Study not submitted to authorities to support foramsulfuron containing product	Bayer
KCP 5.2.3 / 01	Kaussmann, M.	2016	Analytical method 01478 for the determination of various pesticides and selected pesticide metabolites in plasma by HPLC-MS/MS Report No.: 01478, Edition Number: M-551992-01-1 Bayer S.A.S., Bayer CropScience, Lyon, France GLP/GEP: Yes unpublished	No	Yes	Study not submitted to authorities to support foramsulfuron containing product	Bayer
KCP 5.2.3 / 02	Kaussmann, M.	2016	Analytical method 01495 for the determination of various pesticides and selected pesticide metabolites in blood plasma by HPLC-MS/MS Report No.: 01495, Edition Number: M-570324-01-1 Method Report No.: P683166506 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Yes	Study not submitted to authorities to support foramsulfuron containing product	Bayer
KCP 5.2.4 / 01	Koch, V.	2017	Analytical method 01522 for the determination of thiencarbazone-methyl in soil by HPLC-MS/MS Report No.: 01522, Edition Number: M-583905-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Yes	Study not submitted to authorities to support foramsulfuron containing product	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2.5 / 01	Krebber, R.; Ruttmann, F.	2016	Analytical method 01503 for the determination of AE F130619 in drinking and surface water by HPLC-MS/MS Report No.: P 684 167053, Edition Number: M-563516-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Yes	Study not submitted to authorities to support foramsulfuron containing product	Bayer
KCP 5.2.5 / 02	Krebber, R.	2014	Modification M001 of the analytical method 01387 for the determination of various pesticides in drinking and surface water by HPLC-MS/MS Report No.: 01387/M001, Edition Number: M-494841-02-1 Method Report No.: MR-14/053 Bayer CropScience AG, Monheim, Germany ... amended: 2014-10-23 GLP/GEP: Yes unpublished	No	Yes	Study not submitted to authorities to support foramsulfuron containing product	Bayer
KCP 5.2.5 / 03	Stanislawski, T.	2015	Independent laboratory validation of BCS method 01387 (Modification 001) for the determination of various pesticides in surface water by DI-HPLC-MS/MS Report No.: P 3287 G, Edition Number: M-509775-01-1 PTRL Europe GmbH, Ulm, Germany GLP/GEP: Yes unpublished	No	Yes	Study not submitted to authorities to support foramsulfuron containing product	Bayer
KCP 6.3 / 01	Collavo, A.; Kaiser, J.	2020	Statement - Information on the occurrence or possible occurrence of the development of resistance of the plant protection product - FSN+TCM OD 80 (50+30 g/L) Report No.: M-685081-01-1 Bayer AG, Crop Science Division, Frankfurt am Main, Germany GLP/GEP: n.a. unpublished	No	No	-	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.1 / 01	xxx	2013	Foramsulfuron + thien carbazole-methyl OD 80 (50+30 g/L) - Acute oral toxicity study in rats Report No.: 13/014-001P, Edition Number: M-453344-01-1 xxxx GLP/GEP: Yes unpublished	Yes	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration	Bayer
KCP 7.1.2 / 01	xxx	2013	Foramsulfuron + thien carbazole-methyl OD 80 (50+30 g/L) - Acute dermal toxicity study in rats Report No.: 13/014-002P, Edition Number: M-453346-01-1 xxx GLP/GEP: Yes unpublished	Yes	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration	Bayer
KCP 7.1.3 / 01	xxx	2013	Acute inhalation toxicity study (nose-only) in the rat with FSN+TCM OD 50+30 G Report No.: 13/014-004P, Edition Number: M-461014-01-1 xxx GLP/GEP: Yes unpublished	Yes	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration	Bayer
KCP 7.1.4 / 01	xxx	2013	Foramsulfuron + thien carbazole-methyl OD 80 (50+30 g/L) - Acute skin irritation study in rabbits Report No.: 13/014-006N, Edition Number: M-456379-01-1 xxx GLP/GEP: Yes unpublished	Yes	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.5 / 01	xxx	2013	Foramsulfuron + thien carbazole-methyl OD 80 (50+30 g/L) - Acute eye irritation study in rabbits - FSN+TCM OD 50+30 G Report No.: 13/014-005N, Edition Number: M-453831-01-1 xxx GLP/GEP: Yes unpublished	Yes	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration	Bayer
KCP 7.1.6 / 01	xxx	2013	Foramsulfuron + thien carbazole-methyl OD 50+30 g/L - Local lymph node assay in the mouse Report No.: 13/014-037E, Edition Number: M-456378-01-1 xxx GLP/GEP: Yes unpublished	Yes	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration	Bayer
KCP 7.3 / 01	Bernal, J.	2015	In-vitro human skin penetration of 14C-thien carbazole-methyl and foramsulfuron OD 80 formulation (specification no 102000025743) Report No.: S15-01966, Edition Number: M-537205-01-1 Eurofins Agroscience Services, Chem SAS, Vergèze, France GLP/GEP: Yes unpublished	No	Yes		Bayer
KCP 9.1.3 / 01	Heine, S.	2017	Foramsulfuron (FSN) and metabolites: PECsoil EUR - Use in arable crops in Europe Report No.: EnSa-16-0693, Edition Number: M-570502-02-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2017-01-16 GLP/GEP: No unpublished	No	No	-	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.1.3 / 02	Bolekhan, A.	2016	Thiencarbazone-methyl (TCM) and metabolites: PECsoil EUR - Use in various crops in Europe Report No.: EnSa-16-0780, Edition Number: M-569933-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer
KCP 9.2.4.1 / 01	Heine, S.; Srinivasan, P.	2016	Foramsulfuron (FSN) and metabolites: PECgw FOCUS PEARL, PELMO, MACRO EUR - Use in sugar beets in Europe Report No.: EnSa-16-0770, Edition Number: M-576932-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer
KCP 9.2.4.1 / 02	Bolekhan, A.; Hoerold, C.	2016	Thiencarbazone-methyl (TCM) and metabolites: PECgw FOCUS PEARL, PELMO EUR - Use in sugarbeet and maize in Europe Report No.: EnSa-16-0806, Edition Number: M-577187-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer
KCP 9.2.4.1 / 03	Bolekhan, A.; Hoerold, C.	2018	Thiencarbazone-methyl (TCM) and metabolites: PECgw FOCUS MACRO EUR - Use in sugarbeet and maize in Europe Report No.: EnSa-18-0269, Edition Number: M-620310-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer
KCP 9.2.5 / 01	Heine, S.	2016	Foramsulfuron (FSN) and metabolites: PECsw,sed FOCUS EUR - Use in arable crops in Europe Report No.: EnSa-16-0746, Edition Number: M-570503-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.2.5 / 02	Heine, S.; Srinivasan, P	2016	Foramsulfuron (FSN) and metabolites: PECsw, sed FOCUS EUR - Use in sugar beets in Europe Report No.: EnSa-16-0765, Edition Number: M-582622-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer
KCP 9.2.5 / 03	Bolekhan, A.	2017	Multi-year PECsw calculations for sulfonylurea herbicides in Europe: Description of methodology Report No.: EnSa-17-0541, Edition Number: M-602115-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer
KCP 9.2.5 / 04	Heine, S.; Hammel, K.; Bolekhan, A.	2018	Foramsulfuron (FSN) and metabolite AE F130619: PECsw FOCUS EUR (multi-year) - Use in maize and sugar beets in Europe Report No.: EnSa-17-0353, Edition Number: M-592861-02-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2018-03-08 GLP/GEP: No unpublished	No	No	-	Bayer
KCP 9.2.5 / 05	Bolekhan, A.; Porschewski, R.	2017	Thiencarbazon-methyl (TCM) core PECsw EUR - Modelling core info document for surface water risk assessment in Europe Report No.: EnSa-16-0916, Edition Number: M-600279-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer
KCP 9.2.5 / 06	Bolekhan, A.	2017	Thiencarbazon-methyl (TCM) and metabolites: PECsw, sed FOCUS EUR - Use in arable crops in Europe Report No.: EnSa-17-0557, Edition Number: M-600622-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.2.5 / 07	Bolekhan, A.; Hoerold, C.	2016	Thiencarbazone-methyl (TCM): PECsw,sed FOCUS EUR - Use in sugar beet in Europe Report No.: EnSa-16-0807, Edition Number: M-582854-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer
KCP 9.2.5 / 08	Heine, S.; Hammel, K.; Bolekhan, A.	2017	Thiencarbazone-methyl (TCM): PECsw FOCUS EUR (multi-year) - Use in maize and sugar beets in Europe Report No.: EnSa-17-0354, Edition Number: M-592862-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer
KCP 10.2 / 01	Sinclair, C. J.	2009	Predicting the environmental fate and ecotoxicological and toxicological effects of pesticide transformation products Publisher: unknown Journal: unknown Year: 2009 Report No.: M-551653-01-1 GLP/GEP: n.a. published	No	No	-	published
KCP 10.2.1 / 01	xxx	2016	Re-evaluation of acute fish study with metabolite AE F092944 (M-131422-01-1) in context of mesosulfuron approval renewal (EFSA request, Point 33) Report No.: M-549001-01-1 GLP/GEP: No unpublished	Yes	No	-	Bayer
KCP 10.2.1 / 02	Kuhl, K.	2017	Amendment no. 2: Lemna gibba G3 - Growth inhibition test with foramsulfuron tech. (BCS-AH47624) under peak exposure conditions Report No.: EBFS0001, Edition Number: M-572386-03-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2017-06-08 GLP/GEP: Yes unpublished	No	Y	Study never submitted in the country to support foramsulfuron containing product registration	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2.1 / 03	Kuhl, K.	2016	Lemna gibba G3 - Growth inhibition test with AE F130619 (BCS-AU59648) under peak exposure conditions - Final Report - Report No.: EBFS0002, Edition Number: M-574191-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Yes	Study not submitted to authorities to support foramsulfuron containing product	Bayer
KCP 10.2.1 / 04	Kuhl, K.	2016	Amendment no.1 - Lemna gibba G3 - Growth inhibition test with thien carbazole-methyl tech. (BCS-AG17468) under peak exposure conditions - Final report - Report No.: EBG0002, Edition Number: M-568404-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2016-12-07 GLP/GEP: Yes unpublished	No	Yes	Study not submitted to authorities to support foramsulfuron containing product	Bayer
KCP 10.2.1 / 05	Bruns, E.	2013	Lemna gibba G3 - Growth inhibition test with BYH 18636 (thien carbazole-methyl) under peak exposure conditions Report No.: EBG0002, Edition Number: M-462568-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer
KCP 10.2.1 / 06	Banman, C. S.; Moore, S.	2013	Toxicity of thien carbazole-methyl technical to the aquatic macrophyte, myriophyllum spicatum under peak exposure conditions Report No.: EBG0048, Edition Number: M-466233-01-1 SynTech Research Laboratory Services, LLC, Stilwell, KS, USA GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2.1 / 07	Bruns, E.	2014	Lemna gibba G3 - Growth inhibition test with foramsulfuron + thiencarbazone-methyl OD 80 (50 + 30) G under static conditions Report No.: EBGSP149, Edition Number: M-477103-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer
KCP 10.2.3 / 01	Solga, A.; Heine, S.	2018	Justification for the use of time-weighted average concentrations in the chronic risk assessment for foramsulfuron and aquatic plants Report No.: M-615294-02-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: n.a. unpublished	No	No	-	Bayer
KCP 10.2.3 / 02	Schmitt, W.; Bruns, E.; Dollinger, M.; Sowig, P.	2013	Mechanistic TK/TD-model simulating the effect of growth inhibitors on Lemna populations Publisher: Elsevier B.V., Location: Amsterdam, Journal: Ecological Modelling, Volume: 255, Pages: 1-10, Year: 2013 Report No.: M-455483-01-1 GLP/GEP: n.a. published	No	No	-	published
KCP 10.2.3 / 03	Heine, S.	2017	Lemna TK/TD modelling - Compound-specific parameterization and validation for foramsulfuron and its metabolite AE F130619 Report No.: EnSa-17-0346, Edition Number: M-591817-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer
KCP 10.2.3 / 04	Heine, S.	2017	Lemna TK/TD modelling - Compound-specific parameterization and validation for thiencarbazone-methyl Report No.: EnSa-17-0347, Edition Number: M-591850-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2.3 / 05	Heine, S.	2019	Lemna TK/TD modelling: Assessing the impact of FSN+TCM OD 80 applications on Lemna in Europe (FOCUS _{sw}) Report No.: EnSa-18-0891, Edition Number: M-665818-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer
KCP 10.2.3 / 06	Heine, S.	2019	Lemna TK/TD modelling: Assessing the impact of FSN+TCM OD 80 applications on Lemna in Europe (FOCUS _{sw} multiyear) Report No.: EnSa-18-0892, Edition Number: M-665817-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	No	-	Bayer
KCP 10.3.1 / 01	Maynard, S. K.; Albuquerque, R.; Weber, C.; von Merey, G.; Geiger, M. F.; Becker, R.; Keppler, J.; Maschke, J.; Brougham, K.; Couson, M.	2015	1.8 Weeds in the treated field - a realistic scenario for pollinator risk assessment ? Publisher: Julius-Kuehn Archiv, Location: Ghent, Belgium Journal: 12th International Symposium of the ICP-PR Bee Protection Group Volume: 450, Pages: 56-62, Year: 2015 Report No.: M-542146-01-1 GLP/GEP: n.a. published	No	No	-	published
KCP 10.3.1.1.1 / 01 ... also filed: KCP 10.3.1.1.2 / 01	Sekine, T.	2013	Effects of foramsulfuron + thienencarbazone-methyl OD 80 (50+30) G (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory Report No.: 81151035, Edition Number: M-461860-01-1 IBACON GmbH, Rossdorf, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.1.1.2 / 01 ... also filed: KCP 10.3.1.1.1 / 01	Sekine, T.	2013	Effects of foramsulfuron + thien carbazone-methyl OD 80 (50+30) G (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory Report No.: 81151035, Edition Number: M-461860-01-1 IBACON GmbH, Rossdorf, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer
KCP 10.3.2.2 / 01	Waibel, J.	2013	Toxicity to the predatory mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) using an extended laboratory test on apple Thien carbazone-methyl + Foramsulfuron OD 80 (30+50 g/L) Report No.: CW13/014, Edition Number: M-457257-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer
KCP 10.3.2.2 / 02	Waibel, J.	2013	Toxicity to the parasitoid wasp <i>Aphidius rhopalosiphii</i> (Hymenoptera: Braconidae) using an extended laboratory test on barley - Thien carbazone-methyl + foramsulfuron OD 80 (30+50 g/L) Report No.: CW13/013, Edition Number: M-469970-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer
KCP 10.3.2.2 / 03	Waibel, J.	2013	Toxicity to the green lacewing <i>Chrysoperla carnea</i> (Neuroptera: Chrysopidae) using an extended laboratory test on apple Thien carbazone-methyl + Foramsulfuron OD 80 (30+50 g/L) Report No.: CW13/015, Edition Number: M-469943-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.2 / 04	Schmitzer, S.	2013	Effects of thien carbazone-methyl + foramsulfuron OD 80 (30+50 g/L) on the reproduction of rove beetles Aleochara bilineata - Extended laboratory study - Dose response test Report No.: 81291071, Edition Number: M-461869-01-1 IBACON GmbH, Rossdorf, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer
KCP 10.3.2.2 / 05	Jans, D.	2014	Toxicity to the parasitoid wasp Aphidius rhopalosiphi (Hymenoptera: Braconidae) using an extended laboratory test on barley thien carbazone-methyl + foramsulfuron OD 80 (30+50 g/L) Report No.: CW13/057, Edition Number: M-477760-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer
KCP 10.4.1.1 / 01	Kratz, M.	2013	Foramsulfuron + thien carbazone-methyl OD 80 (50+30) G: Effects on survival, growth and reproduction of the earthworm Eisenia fetida tested in artificial soil Report No.: kra/Rg-R-144/13, Edition Number: M-468316-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer
KCP 10.4.2.1 / 01	Frommholz, U.	2013	Foramsulfuron + thien carbazone-methyl OD 80 (50+30) G: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil Report No.: FRM-Coll-155/13, Edition Number: M-459537-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.4.2.1 / 02	Kratz, M. A.	2013	Foramsulfuron + thien carbazole-methyl OD 80 (50+30) G: Influence on mortality and reproduction of the soil mite species Hypoaspis aculeifer tested in artificial soil Report No.: kra-HR-86/13, Edition Number: M-462709-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer
KCP 10.5 / 01	Schulz, L.	2013	Foramsulfuron + thien carbazole-methyl OD 80 (50+30) G: Effects on the activity of soil microflora (nitrogen transformation test) Report No.: 13 10 48 045 N, Edition Number: M-460665-01-1 BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer
KCP 10.6.2 / 01	Koehler, P.	2013	Thien carbazole-methyl + Foramsulfuron OD 80 (30 + 50 g/L) - Effects on the seedling emergence and growth of ten species of non-target terrestrial plants (Tier 2) Report No.: SE13/007, Edition Number: M-467676-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer
KCP 10.6.2 / 02	Koehler, P.	2014	Thien carbazole-methyl + foramsulfuron OD 80 (30 + 50 g/L) - Effects on the vegetative vigour of ten species of non-target terrestrial plants (Tier 2) Report No.: VV13/006, Edition Number: M-491267-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.6.2 / 03	Koehler, P.	2014	Thiencarbazone-methyl + foramsulfuron OD 80 (30 + 50 g/L) - Effects on the vegetative vigour of ten species of non-target terrestrial plants (Tier 2) Report No.: VV14/012, Edition Number: M-496996-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer
KCP 10.6.4 / 01	Koehler, P.	2014	Thiencarbazone-methyl + foramsulfuron OD 80 (30 + 50 g/L) -Effects on the vegetative vigour of seven species of non-target terrestrial plants under semi-field conditions (Higher Tier) Report No.: HT14/016, Edition Number: M-502816-01-1 Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: No unpublished	No	No	-	Bayer
KCP 10.7 / 01	Gladbach, A.; Ebeling, M.; Weyers, A.	2017	Technical stand-alone combined toxicity assessment for the Central zone Report No.: M-571377-02-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: n.a. unpublished	No	No	-	Bayer
KCA 5.8.1 / 01	xxx	1995	Hoe 092944; substance technical (Code: Hoe 092944 00 ZD99 0001) Testing for acute oral toxicity in the male and female Wistar rat Report No.: A49161, Edition Number: M-138232-02-1 xxx ... amended: 1995-04-20 GLP/GEP: Yes unpublished	Yes	Y	Study never submitted in the country	Bayer
KCA 5.8.1 / 02	xxx	1995	TBS-1203: Acute oral toxicity study in male mice Report No.: A55629, Edition Number: M-139539-01-1 xxx GLP/GEP: No unpublished	Yes	No	-	

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.8.1 / 03	Stammberger, I.	1992	Hoe 092944 - substance, technical (Code: Hoe 092944 00 ZD99 0001) Study of the mutagenic potential in strains of Salmonella typhimurium (Ames Test) and Escherichia coli Report No.: A48871, Edition Number: M-137963-01-1 Hoechst AG, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Yes	Study never submitted in the country	Bayer
KCA 5.8.1 / 04	Spruth, B.	2017	Mutagenicity study of AE F092944 in the Salmonella typhimurium reverse mutation assay (in vitro) Report No.: 35401, Edition Number: M-644749-01-1 LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG, Hamburg, Germany GLP/GEP: Yes unpublished	No	Yes	Study never submitted in the country	Bayer
KCA 5.8.1 / 05	Anon.	2015	AE F092944 - Derek Nexus report Report No.: M-685932-01-1 xxx GLP/GEP: No unpublished	Yes	No	-	Bayer
KCA 5.8.1 / 06	xxx	2019	Amidosulfuron - In silico assessment of the metabolite AE F092944 Report No.: M-654051-01-1 xxx GLP/GEP: n.a. unpublished	Yes	No	-	Bayer
KCA 5.8.1 / 07	Naumann, S.	2018	BYH18636-carboxylic acid (BCS-AT36039, AE 1394083): Micronucleus test in human lymphocytes In vitro Report No.: 1889000, Edition Number: M-630020-01-1 Envigo CRS GmbH, Rossdorf, Germany GLP/GEP: Yes unpublished	No	Yes	Study never submitted in the country	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.1 / 01	Lakaschus, S.; Gizler, A.	2017	Amendment no. 3 to final report - 7 days freezer storage stability study with different combinations of a total of 61 analytes (parent and metabolite molecules) and five matrix types (high water / acidic / starch / protein / oil) Report No.: S13-03307, Edition Number: M-480441-06-1 Eurofins Agroscience Services Chem GmbH (EAS Chem), Hamburg, Germany ... amended: 2017-08-16 GLP/GEP: Yes unpublished	No	Y	Study never submitted in the country	Bayer
KCA 6.1 / 02	Thies, S.	2015	Storage stability testing of foramsulfuron and AE F153745 on sugar beet, leaf and sugar beet, body (final report after 24 months at <= 20 degree centigrade) Report No.: 2013/0037/01, Edition Number: M-503516-02-1 Currenta GmbH & Co. OHG, Leverkusen, Germany ... amended: 2015-06-02 GLP/GEP: Yes unpublished	No	Y	Study never submitted in the country	Bayer
KCA 6.1 / 03	Kaussmann, M.	2019	Storage stability of foramsulfuron, iodosulfuron-methyl and their metabolites AE F153745, AE F092944, AE F059411 and AE 0031838 in wheat (grain, green material, straw) for 24 months - Final report Report No.: P642176501, Edition Number: M-635482-02-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2019-04-23 GLP/GEP: Yes unpublished	No	Y	Study never submitted in the country	Bayer
KCA 6.2.1 / 01	Klempner, A.	2019	Amendment no. 1: Metabolism of [phenyl-UL-14C] foramsulfuron in sugar beets Report No.: EnSa-12-0375, Edition Number: M-454861-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2019-09-25 GLP/GEP: Yes unpublished	No	Y	Study never submitted in the country	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.1 / 02	Klempner, A.	2018	Amendment no. 1: Metabolism of [pyrimidine-2-14C]foramsulfuron in sugar beets Report No.: EnSa-12-0511, Edition Number: M-454046-02-1 Bayer AG, Crop Science Division, Monheim, Germany ... amended: 2018-07-02 GLP/GEP: Yes unpublished	No	Y	Study never submitted in the country	Bayer
KCA 6.3 / 01	Stuke, S.; Diehl, P.	2014	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spray application of foramsulfuron & BYH 18636 OD 80 in the field in United Kingdom, Germany, France (North) and the Netherlands Report No.: 12-2138, Edition Number: M-480852-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer
KCA 6.3 / 02	Stuke, S.; Diehl, P.	2014	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spray application of foramsulfuron & BYH 18636 OD 80 in the field in United Kingdom, Germany, France (North) and the Netherlands Report No.: 12-2139, Edition Number: M-480864-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer
KCA 6.3 / 03	Stuke, S.	2014	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spraying of foramsulfuron & BYH 18636 OD 80 in the field in Germany, the Netherlands and United Kingdom Report No.: 13-2000, Edition Number: M-494921-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2014-11-10 GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3 / 04	Stuke, S.; Diehl, P.	2014	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spraying of foramsulfuron & BYH 18636 OD 80 in the field in Germany and The Netherlands Report No.: 13-2009, Edition Number: M-496362-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1st registration.	Bayer
KCA 6.3 / 05	Kaussmann, M.; Houtermans, M.	2018	Determination of the residues of foramsulfuron in/on sugar beet after spray application of foramsulfuron & BYH 18636 OD 80 in the field in Germany, the United Kingdom and northern France Report No.: 17-2033, Edition Number: M-642771-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: Yes unpublished	No	Y	Study never submitted to the country	Bayer
KCA 6.3 / 06	Pourcelot, A.; Bomann, W.	2018	Conviso One - Use of fodder and sugar beet leaves for animal feeding Report No.: M-636830-01-1 Bayer S.A.S., Crop Science Division, Lyon, France GLP/GEP: n.a. unpublished	No	No	-	Bayer
KCA 6.6.1 / 01	Rieder, B.	2019	Report amendment no.1 to final report - Metabolism of [pyrimidine-2-14C] foramsulfuron in rotational crops Report No.: S16-01039, Edition Number: M-625836-02-1 Eurofins Agrosience Services EcoChem GmbH / Eurofins Agrosience Services Ecotox GmbH, Niefern-Oeschelbronn, Germany ... amended: 2019-01-28 GLP/GEP: Yes unpublished	No	Y	Study never submitted to the country	Bayer
KCA 6.10.1 / 01	Wegener, M.; Pourcelot, A.; Hoffmann, M.	2020	Overview on the potential occurrence of residues in honey following application of Conviso One (FSN + TCM OD 80) in herbicide tolerant sugar beets Report No.: M-683705-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: n.a. unpublished	No	No	-	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.10.1 / 02	Hoffmann, M.; Barrière, I.	2020	EU approval renewal of the active substance thiencarbazon-methyl - Waiver for studies investigating residues in honey Report No.: M-679156-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: n.a. unpublished	No	No	—	Bayer

National dossier – D-016517-01

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protect. claimed Y/N	Justification if data pro- tection is claimed	Owner
KCP 9.2.5 / 01	Chapple, A. C.; Srinivasan, P.	2019	Foramsulfuron (FSN) and metabolite: PECsw Step4 VFSSMOD EUR - Use in maize, cereals and sugar beet in Europe Report No.: EnSa-19-0507, Edition Number: M-684841-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	N	N	-	Bayer
KCP 9.2.5 / 02	Zolfaghari, R.; Srinivasan, P.	2020	Thiencarbazone-methyl (TCM): PECsw Step4 VFSSMOD EUR - Use in maize, cereals and sugarbeets in Europe Report No.: EnSa-20-0171, Edition Number: M-684842-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	N	N	-	Bayer

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 upon.

Bayer is the owner of the data package peer-reviewed for the EU re-approval of the active substance **foramsulfuron**.

Bayer is the owner of the data package peer-reviewed for the EU approval of the active substance **thiencarbazone-methyl**.

Data protection will be requested when relevant at MS level in the Part A.

Foramsulfuron

The following studies are considered as already evaluated at EU peer review.

They are either referenced in the document entitled ("Renewal under Regulation (EC) 1107/2009. Foramsulfuron - List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to approval of the active substance and for which the main data submitter has claimed data protection RMS: Finland Co-RMS: Slovakia. April 2016) or are referenced in the Draft Renewal Assessment Report under Regulation (EC) 1107/2009 (Rapporteur Member State: Finland Co- Rapporteur Member State: Slovakia. 2015/2016).

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Verte- brate study Y/N	Data pro- tection claimed Y/N	Justification if data protection is claimed	Owner
B.5.1.2.1 KCA 4.1.2 /02	Stuke, S.	2013	Modification M001 of the residue analytical method DGM F03/98-0 for the determination of metsulfuron-methyl (AE F075736), iodosulfuron -methyl-sodium (AE F115008), foramsulfuron (AE F130360), AE F153745 in corn (green material) by HPLC-MS/MS at a LOQ of 0.01 mg/kg Bayer CropScience, Report No.: MR-13/047, Edition Number: M-461902-01-1 , Method Report No.: MR-13/047 GLP/GEP: Yes unpublished	N	Y		Bayer

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.5.2.1 KCA 4.2 /20	Stuke, S.; Ballmann, C.	2013	Analytical method 01360 for the determination of amidosulfuron, metsulfuron-methyl, iodosulfuron-methyl-sodium, mesosulfuron-methyl, and foramsulfuron in samples from plant origin by HPLC-MS/MS Bayer CropScience, Report No.: MR-13/007, Edition Number: M-455564-01-1 , MethodReport No.: MR-13/007 GLP/GEP: Yes unpublished	N	Y		Bayer
B.5.2.1 KCA 4.2 /21	Konrad, S.	2013	Independent lab validation of BCS method 01360 for the determination of residues of amidosulfuron, metsulfuron-methyl, iodosulfuron-methyl-sodium, mesosulfuron-methyl and foramsulfuron in samples from plant origin by HPLC-MS/MS Currenta GmbH & Co. OHG, Leverkusen, Germany BCS, Report No.: 2013/0060/01, Edition Number: M-470160-01-1 GLP/GEP: Yes unpublished	N	Y		Bayer
B.5.2.2. KCA 4.2 /23	Wrede, A.	2001	Validation of the Enforcement Method EM F07/00-0 for Animal tissue, Milk and Egg by LC-MS/MS- Amidosulfuron (AE F075032) - Metsulfuron-methyl (AE F075736) - Iodosulfuron-methyl-sodium (AE F115008) -Mesosulfuron-methyl (AE F130060) -Foramsulfuron (AE F130360) Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C011226, Edition Number: M-200439-01-1 , EPA MRID No.: 46229001 GLP/GEP: Yes unpublished	N	Y		Bayer

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.5.2.2. KCA 4.2 /24	Randolph, R.	2004	Independent Laboratory Validation for Aventis CropScience GmbH Analytical method No. EM/F07/00-0, Enforcement method for animal Tissue, Milk and Egg by LC-MS/MS Pyxant Labs, Inc., Colorado Springs, CO, USA Bayer CropScience, Report No.: B004802, Report includes Trial Nos.: RAMMY004, Edition Number: M-240268-01-1 EPA MRID No.: 48080501 GLP/GEP: Yes unpublished	N	Y		Bayer
B.5.2.2. KCA 4.2 /26	Moore, S.	2010	Independent laboratory validation of an analytical method 01208/M001 for the determination of amidosulfuron (AE F075032), metsulfuron-methyl (AE F075736), iodosulfuron-methyl-sodium (AE F115008), mesosulfuron-methyl (AE F130060), foramsulfuron (AE F130360) in animal tissues (meat, fat, liver, kidney), egg, and milk by HPLC-MS/MS Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: RAMML014, Edition Number: M-398300-01-1 GLP/GEP: Yes unpublished	N	Y		Bayer
B.5.2.3. KCA 4.2 /27	Freitag, T.	2008	Amendment no. 0001 to report no.: MR-08/138-Analytical Method 01115 for the determination of residues of amidosulfuron, iodosulfuron-methyl-sodium, metsulfuron-methyl, mesosulfuron-methyl and foramsulfuron in soil by HPLC-MS/MS Bayer CropScience, Report No.: M-310074-03-1 , Edition Number: M-310074-03-1 , Method Report No.: MR-08/138 GLP/GEP: Yes unpublished	N	Y		Bayer

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.5.2.4. KCA 4.2 /28	Krebber, R.; Braune, M.	2007	Analytical method 01058 for the determination of amidosulfuron, foramsulfuron, iodosulfuron-methyl-sodium, mesosulfuron-methyl and the metabolite metsulfuron-methyl (AE F075736) in drinking and surface water by HPLC-MS/MS Bayer CropScience, Report No.: 01058, Edition Number: M-291466-01-1 , Method Report No.: MR-07/292 GLP/GEP: Yes unpublished	N	Y		Bayer
B.5.2.4. KCA 4.2 /29	Krebber, R.; Braune, M.	2013	Analytical method 01387 for the determination of various pesticides in drinking and surface water by HPLC-MS/MS Bayer CropScience, Report No.: MR-13/085, Edition Number: M-466732-01-1 , Method Report No.: MR-13/085 GLP/GEP: Yes unpublished	N	Y		Bayer
B.5.2.4. KCA 4.2 /30	Stanislawski, T.	2013	Independant laboratory validation of BCS analytical methods 01333 and 01387 for determination of various pesticides in surface water by Di-HPLC-MS/MS PTRI Europe, Ulm, Germany Bayer CropScience, Report No.: P3117 G., Edition Number: M-470714-02-1 GLP/GEP: No unpublished	N	Y		Bayer
KCA 6.1 /02	Cole, M. G.	2001	Stability of AE F130360 and AE F153745 Residues in Corn (forage, stover and grain) During Frozen Storage, USA, 1998 (Minimum Storage Interval of 616 Days) Aventis CropScience USA LP, Residue Chemistry, USA Report No.: B003134, Report includes Trial Nos.: CF98R004, Edition Number: M-238787-01-1 GLP/GEP: yes unpublished	N	Y		Bayer

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.1 / 01	Huang, M. N.	2000	Metabolism of (U-14C-phenyl)-AE F130360 and (2-14C-pyrimidyl)-AE F130360 in corn grown under field conditions Code: AE F130360 Report No.: C003293, Edition Number: M-185906-01-1 Aventis CropScience USA LP, Pikeville, NC, USA GLP/GEP: Yes, unpublished	N	Y		Bayer
KCA 6.2.2 / 01	xxx	1999	AE F130360: Poultry - Metabolism and nature of the residues in the eggs and edible tissues in the laying hen Report No.: C005081, Edition Number: M-191323-01-1, MRID#: 45109624 xxx GLP/GEP: Yes, unpublished	Y	Y		Bayer
KCA 6.2.3 / 01	xxx	1999	Cow - metabolism, distribution and nature of the residues in milk and edible tissues AE F130360 Code: AE F130360 00 ZE Report No.: C005046, Edition Number: M-191251-01-1, MRID#: 45109625 xxx GLP/GEP: Yes, unpublished		Y		Bayer
KCA 6.6.1 / 01	Huang, M. N.; Faulkner, T. D.	1999	Uptake of residues of (U-phenyl-14C)-AE F130360 and (2-pyrimidyl-14C)-AE F130360 in soil by rotational crops under confined conditions Report No.: C003287, Edition Number: M-185898-01-1, MRID#: 45109708 AgrEvo USA Company, Pikeville, NC, USA GLP/GEP: Yes, unpublished	N	Y		Bayer
KCA 7.1.1.3 /02	Hall, L. R.	2012	[Phenyl-UL-14C]foramsulfuron: Phototransformation on soil Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MEFSL009, Edition Number: M-422619-01-1 Date: 2012-01-17 GLP/GEP: yes, unpublished	N	Y		Bayer

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 7.1.2.1.2 /06	Shepherd, J. J.; Ripperger, R. J.	2012	[Phenyl-UL-14C]foramsulfuron sulfonamide: Aerobic soil metabolism in four US soils Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MEFSL008, Edition Number: M-425904-01-1 Date: 2012-02-23 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 7.1.4.2 /02	Burr, C. M.; Mackenzie, E.	2001	(2-14C-pyrimidyl)-AE F130360 leaching in outdoor lysimeter Aventis CropScience UK Ltd., United Kingdom Report No.: C014861, Edition Number: M-207434-01-1 Date: 2001-09-20 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 7.2.1.2 /02	Hall, L. R.	2012	Phototransformation of [14C]foramsulfuron in aqueous pH 7 buffer Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MEFSL011, Edition Number: M-425561-01-1 Date: 2012-02-22 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 7.2.1.2 /03	Heinemann, O.	2013	Foramsulfuron: Determination of the quantum yield and assessment of the environmental half-life of the direct photo-degradation in water Bayer CropScience, Report No.: EnSa-13-0305, Edition Number: M-460124-01-1 Date: 2013-07-16 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 7.2.1.3 /01	Meyer, B. N.	2009	[Phenyl-UL-14C]foramsulfuron: Phototransformation in natural water Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MEFSU004, Edition Number: M-346695-01-1 Date: 2009-05-04 GLP/GEP: yes, unpublished	N	Y		Bayer

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 7.2.1.3 /02	Meyer, B. N.	2008	[Pyrimidine-2-14C] foramsulfuron: Phototransformation in natural water Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MEFSU001, Edition Number: M-327230-01-1 Date: 2008-12-23 GLP/GEP: yes, unpublished	N	Y		Bayer Crop Science
KCA 7.2.2.2 /01	Fahrbach, M.	2013	[phenyl-UL-14C]Foramsulfuron: Aerobic Mineralization in surface water Harlan Laboratories Ltd., Itingen, Switzerland Bayer CropScience, Report No.: D62860, Edition Number: M-453421-01-1 Date: 2013-04-22 GLP/GEP: yes, unpublished	N	Y		Bayer Crop Science
KCA 8.2.1 /04	xxx	1993	Hoe 092944 - substance, technical (Hoe 092944 00 ZD99 0001) Effect to Oncorhynchus mykiss (Rainbow trout) in a Static-Acute Toxicity Test (method OECD) xxx Report No.: A50396, Edition Number: M-131422-01-1 Date: 1993-04-13 GLP/GEP: yes, unpublished	Y	Y		Bayer Crop-Science
KCA 8.2.2.1 /02	xxx	2004	Early Life Stage Toxicity of Foramsulfuron (AE F130360) Technical to the Fathead Minnow (Pimephales promelas) Under Flow-Through Conditions ;xxx Report No.: B004606, Report includes Trial Nos.: EBFSX001 (A3841201) Edition Number: M-241508-01-1 Date: 2004-03-17 GLP/GEP: yes, unpublished	Y	Y		Bayer Crop-Science

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.2.4.1 /02	Heusel, R.	1993	Hoe 092944 - substance, technical (Hoe 092944 00 ZD99 0001) Effect to Daphnia magna (waterflea) in a Static -Acute Toxicity Test (method OECD) Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: A50353, Edition Number: M-131382-01-1 Date: 1993-04-13 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.2.6.1 /02	Heusel, R.	1993	Hoe 092944 - substance, technical (Hoe 092944 00 ZD99 0001) Effect to Scenedesmus subspicatus (Green alga) in a Growth Inhibition Test (method OECD) Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: A50395, Edition Number: M-131421-01-1 Date: 1993-04-13 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.2.6.1 /03	Dorgerloh, M.	2005	Pseudokirchneriella subcapitata - growth inhibition test with AE F099095 00 1B99 0001 Bayer CropScience, Report No.: EBMMX092, Edition Number: M-254084-01-1 Date: 2005-07-08 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.2.7 /05	Dorgerloh, M.	2005	Lemna gibba G3 Exposure and recovery test with Foramsulfuron (tech.) (code: AE F130360 00 1D97 0001) BCS, Report No.: EBFSX010, Edition Number: M-250268-01-1 Date: 2005-04-26 GLP/GEP: yes, unpublished	N	Y		Bayer

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.2.7 /06	Bruns, E.	2013	Lemna gibba G3 - Growth inhibition test with foramsulfuron (tech) (AE F 130360) under peak exposure conditions Bayer CropScience, Report No.: EBFSN003, Edition Number: M-462569-01-1 Date: 2013-08-13 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.2.7 /07	Kirkwood, A.	2012	Outdoor growth inhibition and recovery of aquatic plants exposed to foramsulfuron WG 50 percent Smithers Viscient, Wareham, MA, USA Bayer CropScience, Report No.: EBFSL012, Edition Number: M-429538-01-1 EPA MRID No.: 48869701 Date: 2012-04-13 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.2.7 /08	Bruns, E.	2013	Lemna gibba G3 - Prolonged growth inhibition test with foramsulfuron (AE F130360) with stepwise decreasing concentrations over an 6 week test duration Bayer CropScience, Report No.: EBFSL014, Edition Number: M-464150-01-1 Date: 2013-09-10 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.2.7 /09	xxx	2012	Toxicity of foramsulfuron technical to the aquatic macrophyte, Myriophyllum spicatum xxx Report No.: EBFSL004, Edition Number: M-431270-01-1 Date: 2012-05-17 GLP/GEP: yes, unpublished	Y	Y		Bayer

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.2.7 /10	Sowig, P.; Weller, O.	2000	Duckweed (Lemna gibba G3) growth inhibition test AE F092944 (metabolite of ethoxysulfuron and amidosulfuron) substance technical Code: AE F092944 00 1C99 0001 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C003865, Edition Number: M-186916-01-1 Date: 2000-11-03 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.2.7 /11	Dorgerloh, M.	2005	Lemna gibba G3 - growth inhibition test with AE F099095 under static conditions (Code: AE F099095 00 1B99 0001) BCS, Report No.: EBMMX091, Edition Number: M-254496-01-1 Date: 2005-07-14 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.2.7 /12	Bruns, E.	2013	Lemna gibba G3 - Growth inhibition test with with AE F130619 (metabolite of foramsulfuron) under static conditions Bayer CropScience, Report No.: EBFSL011, Edition Number: M-452669-01-1 Date: 2013-04-15 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.2.7 /13	Bruns, E.	2013	Lemna gibba G3 - Growth inhibition test with BCS-CV29520 (metabolite of foramsulfuron) under static conditions Bayer CropScience, Report No.: EBFSN010, Edition Number: M-464163-01-1 Date: 2013-08-29 GLP/GEP: yes, unpublished	N	Y		Bayer

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.2.7 /14	Bruns, E.	2013	Lemna gibba G3 - Growth inhibition test with BCS-CW90756 (metabolite of foramsulfuron) under static conditions Bayer CropScience, Report No.: EBFSN011, Edition Number: M-464321-01-1 Date: 2013-08-29 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.2.7 /15	Hoffmann, K.	2013	Lemna gibba G3 - Growth inhibition test with BCS-AW41401 under static conditions Bayer CropScience, Report No.: EBFSN012, Edition Number: M-464386-01-1 Date: 2013-08-29 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.3.1.1.2 /02	Schmitzer S.; Sekine T.	2012	Effects of foramsulfuron tech. (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany Report No. EBFSN009 GLP, unpublished Bayer File No: M-444765-01-1	N	Y		Bayer
KCA 8.3.1.2 /01	Kling A.	2013	Foramsulfuron WG 50 W - Assessment of chronic effects to the honeybee, Apis mellifera L., in a 10 days continuous laboratory feeding limit test EurofinsAgroscience Services, EcoChem GmbH, Eutinger Straße 24, 75223 Niefern-Öschelbronn, Germany Report No. EBFSN022 GLP, unpublished Bayer File No: M-470639-01-1	N	Y		Bayer
KCA 8.3.1.3 /01	Przygoda D.; Nikolakis A.	2013	Foramsulfuron WG 50 W: Effects of a single exposure to spiked diet on honey bee larvae (Apis mellifera carnica) in an in vitro laboratory testing design Bayer CropScience AG, BCS-AG-D-EnSa-Testing, 40789 Monheim, Germany Report No. EBFSN044 GLP, unpublished Bayer File No: M-470485-01-1	N	Y		Bayer

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.3.1.3/02	Jeker L.	2013	Foramsulfuron WG 50 W - honeybee brood feeding study to evaluate potential effects on brood development and mortality of the honeybee, Apis mellifera L. (Hymenoptera: Apidae) Innovative Environmental Services (IES) Ltd, Benkenstrasse 260, 4108 Witterswil, Switzerland Report No. EBFSL013 GLP, unpublished Bayer File No: M-465326-01-1	N	Y		Bayer
KCA 8.3.1.3 /03	Schmitzer S.	2013	Foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L): Effects on honey bee brood (Apis mellifera L.) under semi-field conditions - Tunnel test – IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany Report No. EBFSN034 GLP, unpublished Bayer File No: M-468794-01-1	N	Y		Bayer
KCA 8.3.2.2 /03	Roehlig U.	2013	Effects of foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) on the predatory mite Typhlodromus pyri SCHEUTEN in a laboratory test BioChem agrar, Labor für biologische und chemische Analytik GmbH Kupferstraße 604827 Gerichshain, Germany Report No. 13 10 48 031 A GLP, unpublished Bayer file No.: M-457360-01-1	N	Y		Bayer
KCA 8.3.2.1./03	Roehlig U.	2013	Effects of foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) on the parasitic wasp Aphidius rhopalosiphi (DESTEFANI-PEREZ) in a laboratory BioChem agrar, Labor für biologische und chemische Analytik GmbH Kupferstraße 604827 Gerichshain, Germany Report No. 131048030A GLP, unpublished Bayer file No.: M-461455-01- 1	N	Y		Bayer
KCA 8.4.1 /02	Kratz, M. A.	2013	AE F092944 (BCS-AA25052): Effects on survival, growth and reproduction of the earthworm Eisenia fetida tested in artificial soil Bayer CropScience, Report No.: kra/Rg-R-147/13, Edition Number: M-461051-01-1 Date: 2013-07-31 GLP/GEP: yes, unpublished	N	Y		Bayer

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.4.1 /03	Kratz, M. A.	2013	AE F130619 (BCS-AU59648): Effects on survival, growth and reproduction of the earthworm Eisenia fetida tested in artificial soil Bayer CropScience, Report No.: kra/Rg-R-138/13, Edition Number: M-461453-01-1 Date: 2013-08-14 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.4.1 /04	Kratz, M. A.	2013	Foramsulfuron-AE F153745 (BCS-AU80017): Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil Bayer CropScience, Report No.: kra/Rg-R-140/13, Edition Number: M-459518-01-1 Date: 2013-07-17 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.4.2.1 /01	Kratz, M. A.	2012	Foramsulfuron (AE F130360) a.s.: Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil Bayer CropScience, Report No.: KRA-HR-78/12, Edition Number: M-443308-01-1 Date: 2012-12-10 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.4.2.1 /02	Frommholz, U.	2012	Foramsulfuron (AE F130360) a.s.: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil Bayer CropScience, Report No.: FRM-Coll-147/12, Edition Number: M-443369-01-1 Date: 2012-12-12 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.4.2.1 /03	Schulz, L.	2013	AE F092944 (BCS-AA25052): Effects on the reproduction of the predatory mite Hypoaspis aculeifer BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 044 S, Edition Number: M-454043-01-1 Date: 2013-05-02 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.4.2.1 /04	Friedrich, S.	2013	AE F092944 (BCS-AA25052): Effects on the reproduction of the collembolan Folsomia candida BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 045 S, Edition Number: M-451142-01-1 Date: 2013-03-28 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.4.2.1 /05	Schulz, L.	2013	Foramsulfuron-AE F130619 (BCS-AU59648): Effects on the reproduction of the predatory mite Hypoaspis aculeifer BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 046 S, Edition Number: M-454051-01-1 Date: 2013-05-02 GLP/GEP: yes, unpublished	N	Y		Bayer

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.4.2.1 /06	Friedrich, S.	2013	Foramsulfuron-AE F130619 (BCS-AU59648): Effects on the reproduction of the col- lembolan Folsomia candida BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 047 S, Edition Number: M-450824-01-1 Date: 2013-03-28 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.4.2.1 /07	Schulz, L.	2013	Foramsulfuron-AE F153745 (BCS-AU80017): Effects on the reproduction of the predatory mite Hypoaspis aculeifer BioChem agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 048 S, Edition Number: M-447606-01-1 Date: 2013-02-22 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.4.2.1 /08	Friedrich, S.	2013	Foramsulfuron-AE F153745 (BCS-AU80017): Effects on the reproduction of the col- lembolan Folsomia candida BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 049 S, Edition Number: M-450830-01-1 Date: 2013-03-28 GLP/GEP: yes, unpublished	N	Y		Bayer
KCA 8.5 /05	Schulz, L.	2013	AE F092944 (BCS-AA25052): Effects on the activity of soil microflora (Nitrogen transformation test) BioChem Agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 018 N, GLP/GEP: yes, unpublished Bayer file No.: M-453511-01-1	N	Y		Bayer
KCA 8.5 /06	Schulz, L.	2013	Foramsulfuron-AE F130619 (BCS-AU59648): Effects on the activity of soil micro- flora (nitrogen transformation test) BioChem Agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 019 N GLP/GEP: yes, unpublished Bayer file No.: M-453568-01-1	N	Y		Bayer

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 8.5 /07	Schulz, L.	2013	Foramsulfuron-AE F153745 (BCS-AU80017): Effects on the activity of soil micro-flora (Nitrogen transformation test) BioChem Agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 1321048020N GLP/GEP: yes, unpublished Bayer file No.: M-453508-01-1	N	Y		Bayer

Thiencarbazone-methyl

The following studies are considered as already evaluated at EU peer review as they are referenced in the document entitled (“Council Directive 91/414/EEC. Thiencarbazone-methyl (BYH 18636). Volume 2. Annex A to the Draft Report and Proposed Decision. List of tests and studies submitted and information available (by Annex point). 2012).

Thiencarbazone-methyl was approved under the approval criteria of Council Directive 91/414/EEC. As a new substance, all studies referenced below are protected at EU level in all EU Member States from the EIF of the 1st EU approval until **30th of June 2024**. Only the studies, already EU peer reviewed, and which may be required to perform the combined risk assessment are listed below.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KIIA 4.3 /06	Zimmer, D.; Philipowski, C.	2006	Analytical method 00962 for the determination of residues of BYH18636 and its metabolites BYH18636-N-desmethyl and BYH18636-MMT-glucoside, and of AE 0001789 in/on plant matrices by HPLC-MS/MS Bayer CropScience AG, Report No.: 00962, Edition Number: M-278064-02-1 , Method Report No.: MR-147/05 GLP/GEP: Yes unpublished	N	Y	EU data protected	Bayer
KIIA 4.3 /09	Brumhard, B.	2006	Analytical method 00990 for the determination of residues of BYH 18636 and its metabolites in animal matrices Bayer CropScience AG, Report No.: 00990, Edition Number: M-281559-02-2 GLP Unpublished	N	Y	EU data protected	Bayer
KIIA 4.5 /01	Krebber, R.; Leppelt, L.	2007	Analytical method 01025 for the determination of thiencarbazone-methyl (BYH18636) in drinking and surface water by HPLC-MS/MS Bayer CropScience AG, Report No.: 01025, Edition Number: M-282614-01-1 , Method Report No.: MR-	N	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			96/173 GLP/GEP: Yes unpublished				
KIIA 4.3 /01	Zimmer, D.; Philipowski, C.	2006	Analytical method 00963 for the determination of residues of BYH18636 and its metabolites BYH18636-N-desmethyl and BYH18636-MMT-glucoside in/on plant matrices by HPLC-MS/MS Bayer CropScience AG, Report No.: 00963, Edition Number: M-278045-02-2 , Method Report No.: MR-148/05 GLP/GEP: Yes unpublished	N	Y	EU data protected	Bayer
KIIA 4.3 /03	Class, T.	2006	Independent laboratory validation of Bayer CropScience method No. 00963 for the determination of residues of BYH 18636 and its metabolites BYH 18636-N-desmethyl and BYH 18636-MMT-glucoside in/on plant materials by LC/MS/MS PTRL Europe, Ulm, Germany Bayer CropScience AG, Report No.: P/B 1125 G, Edition Number: M-280706-01-2 , Method Report No.: MR-148/05, Method Report No.: P/B 1125 G GLP/GEP: Yes unpublished	N	Y	EU data protected	Bayer
KIIA 4.3 /02	Bongartz, R.	2006	[Dihydrotriazole-3-14C]BYH18636: Extraction efficiency of the residue analytical method for the determination of BYH18636 residues in plant matrices using aged radioactive residues Bayer CropScience AG, Report No.: MEF-05/504, Edition Number: M-274486-01-2 GLP/GEP: Yes unpublished	N	Y	EU data protected	Bayer
KIIA 4.3 /07	Zimmer, D.; Kuppels, U.	2007	Analytical method 01022 for the determination of residues of BYH18636 and	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			BYH18636-MMT in animal matrices Bayer CropScience AG, Report No.: 01022, Edition Number: M-284284-01-2 , Method Report No.: MR-06/175 GLP/GEP: Yes unpublished				
KIIA 4.3 /08	Class, T.	2007	Independent laboratory validation of Bayer CropScience method no. 01022 for the determination of residues of BYH 18636 and its metabolite BYH 18636-MMT in animal matrices by LC/MS/MS PTRL Europe, Ulm, Germany Bayer CropScience AG, Report No.: P/B 1138 G, Edition Number: M-284346-02-2 , Method Report No.: P613065528 GLP/GEP: Yes unpublished	N	Y	EU data protected	Bayer
KIIA 4.3 /10	Schmeer, K.	2007	[Dihydrotriazole-3-14C]BYH18636 and [thiophene-4-14C]BYH18636: Extrac- tion efficiency of the residue analytical method for the determination of BYH18636 residues in animal matrices using aged radioactive residues Bayer CropScience AG, Report No.: MEF-06/292, Edition Number: M-282899-01-2 GLP/GEP: Yes unpublished	N	Y	EU data protected	Bayer
KIIA 4.4 /01	Brumhard, B.; Koch, V.	2006	Analytical method 01028 for the determination of residues of BYH18636 in soil by HPLC-MS/MS Bayer CropScience AG, Report No.: 01028, Edition Number: M-281589-01-1 GLP/GEP: Yes unpublished	N	Y	EU data protected	Bayer
KIIA 4.5 /01	Krebber, R.; Leppelt, L.	2007	Analytical method 01025 for the determination of thien carbazon-methyl	N	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			(BYH18636) in drinking and surface water by HPLC-MS/MS Bayer CropScience AG, Report No.: 01025, Edition Number: M-282614-01-, Method Report No.: MR-96/173 GLP/GEP: Yes unpublished				
KIIA 4.7 /01	Ripperger, R. J.	2007	BYH 18636: Analytical method for the determination of BYH 18636 in air Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: RAGSM003-1, Edition Number: M-284848-02-1 GLP/GEP: Yes unpublished	N	Y	EU data protected	Bayer
KIIA 5.8 /01	Wirnitzer, U.	2006	BYH 18636-carboxylic acid (project: BYH 18636) - Salmonella/microsome test - Plate incorporation and preincubation method - 1st amendment to toxicology re- port AT01522 of September 22, 2004 Report No.: AT01522A, Edition Number: M-092854-02-2 Bayer HealthCare AG, Wuppertal, Germany GLP/GEP: Yes, unpublished	No	Y	EU data protected	Bayer
KIIA 5.8 /02	Herbold, B.	2006	BYH 18636-carboxylic acid (Project: BYH 18636) - In vitro chromosome aberration test with chinese hamster V79 cells Report No.: M-250256-02-2 Bayer HealthCare AG, Wuppertal, Germany GLP/GEP: Yes, unpublished	No	Y	EU data protected	Bayer
KIIA 5.8 /03	Herbold, B.	2006	BYH 18636-carboxylic acid (Project: BYH 18636) - V79/HPRT-test in vitro for the detection of induced forward mutations Report No.: AT02038, Edition Number: M-251094-01-2 Bayer AG, Wuppertal, Germany GLP/GEP: Yes,	No	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			unpublished				
KIIA 5.8 /04	xxxx	2006	BYH 18636-carboxylic acid (AE 1394083) - Acute toxicity in the rat after oral ad- ministration Report No.: AT02902, Edition Number: M-269981-01-2 xxx GLP/GEP: Yes, unpublished	Yes	Y	EU data protected	Bayer
KIIA 5.8 /05	xxx	2007	BYH 18636-carboxylic acid - 90-day toxicity study in the rat by dietary admin- istration Report No.: SA 06035, Edition Number: M-282943-01-2 xxx GLP/GEP: Yes, unpublished	Yes	Y	EU data protected	Bayer
KIIA 6.1.1 /01	Brumhard, B.; Wolters, A.	2007	Storage stability of BYH18636 and its metabolites BYH18636-N-desmethyl and BYH18636-MMT-glucoside in plant matrices for 18 months - results for an inter- val of 0 to 12 months Report No.: MR-186/05, Edition Number: M-284222-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Y	EU data protected	Bayer
KIIA 6.1.1 /02 also filed: KIIA 6.4.2 /01	xxxx	2007	BYH 18636: Dairy cattle feeding study Report No.: MR-06/095, Edition Number: M-286140-01-2 xxx GLP/GEP: Yes unpublished	Yes	Y	EU data protected	Bayer
KIIA 6.1.1 /03 Study referenced in DAR Addendum	Brumhard, B., Wolters, A	2008	Storage stability of BYH18636 and its metabolites BYH18636-N-desmethyl and	No	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
(March 2013) also filed: KIIA 6.4.2 /01)			BYH18636-MMT-glucoside in plant matrices for 24 months Report No.: MR-07/229, Document No.: M-304143-01-1 Bayer CropScience AG GLP/GEP: Yes unpublished				
KIIA 6.2.1 /01	Bongartz, R.	2005	Metabolism of [dihydrotriazole-3-14C]BYH18636 in corn in combination with the safener AE 0001789 as a pre-emergence application Report No.: MEF-05/004, Edition Number: M-263042-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Y	EU data protected	Bayer
KIIA 6.2.1 /02	Bongartz, R.	2005	Metabolism of [thiophene-4-14C]BYH18636 in corn in combination with the safener AE 0001789 as a pre-emergence application Report No.: MEF-05/003, Edition Number: M-263405-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Y	EU data protected	Bayer
KIIA 6.2.1 /03	Bongartz, R.	2005	Metabolism of [dihydrotriazole-3-14C]BYH18636 in corn Report No.: MEF-04/182, Edition Number: M-266796-02-2 Bayer CropScience AG Amended: 15.02.2007 GLP/GEP: Yes unpublished	No	Y	EU data protected	Bayer
KIIA 6.2.1 /04	Bongartz, R.	2005	Metabolism of [thiophene-4-14C]BYH18636 in corn Report No.: MEF-04/181, Edition Number: M-256647-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
KIIA 6.2.1 /05	Bongartz, R.	2005	Metabolism of [dihydrotriazole-3-14C]BYH18636 in corn in combination with the safener isoxadifen-ethyl following two post-emergence applications at growth stages V6 and V12 Report No.: MEF-05/006, Edition Number: M-267247-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Y	EU data protected	Bayer
KIIA 6.2.1 /06	Bongartz, R.	2006	Metabolism of [thiophene-4-14C]BYH18636 in corn in combination with the safener isoxadifen-ethyl following two post-emergence applications at growth stages V6 and V12 Report No.: MEF-05/005, Edition Number: M-268530-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Y	EU data protected	Bayer
KIIA 6.2.1 /07	Sur, R.	2005	Metabolism of [dihydrotriazole-3-14C]BYH18636 in wheat Report No.: MEF-05/041, Edition Number: M-267443-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Y	EU data protected	Bayer
KIIA 6.2.1 /08	Sur, R.	2005	Metabolism of [thiophene-4-14C]BYH18636 in wheat Report No.: MEF-05/042, Edition Number: M-268145-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Y	EU data protected	Bayer
KIIA 6.2.2 /01	xxx	2006	Metabolism of [thiophene-4-14C]BYH18636 in the laying hen Report No.: MEF-05/260, Edition Number: M-279414-03-2 xxx Amended: 27.12.2006 GLP/GEP: Yes unpublished	Yes	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
KIIA 6.2.2 /02	xxx	2006	Metabolism of [dihydrotriazole-3-14C]BYH18636 in the laying hen Report No.: MEF-05/259, Edition Number: M-279676-03-2 xxx Amended: 27.12.2006 GLP/GEP: Yes unpublished	Yes	Y	EU data protected	Bayer
KIIA 6.2.3 /01	xxx	2006	[Thiophene-4-14C]BYH 18636: Absorption, distribution, excretion, and metabo- lism in the lactating goat Report No.: MEF-05/261, Edition Number: M-278516-01-2 xxx GLP/GEP: Yes unpublished	Yes	Y	EU data protected	Bayer
KIIA 6.2.3 /02	xxx	2006	[Dihydrotriazole-3-14C]BYH 18636 - Absorption, distribution, excretion, and metabolism in the lactating goat Report No.: MEF-05/307, Edition Number: M-276289-01-2 xxx GLP/GEP: Yes unpublished	Yes	Y	EU data protected	Bayer
KIIA 6.6.2 /01	Justus, K.	2006	Metabolism of [dihydrotriazole-3-14C]BYH18636 in confined rotational crops following co-application with safener AE 0001789 Report No.: MEF-06/215, Edition Number: M-277504-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Y	EU data protected	Bayer
KIIA 6.6.2 /02	Justus, K.	2006	Metabolism of [thiophene-4-14C]BYH18636 in confined rotational crops follow- ing co-application with safener AE 0001789 Report No.: MEF-05/297, Edition Number: M-275070-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
KIIA 6.6.2 /03	Justus, K.	2006	Metabolism of [dihydrotriazole-3-14C]BYH 18636 in confined rotational crops after an application rate of 30 g/ha in the presence of safener AE 0001789 Report No.: MEF-06/258, Edition Number: M-278990-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Y	EU data protected	Bayer
KIIA 6.6.2 /04	Justus, K.	2006	Metabolism of [thiophene-4-14C]BYH18636 in confined rotational crops after an application rate of 30 g/ha in the presence of safener AE0001789 Report No.: MEF-05/539, Edition Number: M-277462-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Y	EU data protected	Bayer
KIIA 6.6.2 /05	Reiner, H.	2005	Metabolism of [dihydrotriazole-3-14C]BYH18636 in confined rotational crops Report No.: MEF-05/023, Edition Number: M-261209-02-2 Amended: 16.02.2007 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Y	EU data protected	Bayer
KIIA 6.6.2 /06	Reiner, H.	2005	Metabolism of [thiophene-4-14C]BYH18636 in confined rotational crops Report No.: MEF-05/024, Edition Number: M-260471-01-2 Bayer CropScience AG GLP/GEP: Yes unpublished	No	Y	EU data protected	Bayer
KIIA 7.1.1 /01	Fliege, R.	2006	[Dihydrotriazole-3-14C] and [thiophene-4-14C] BYH 18636: Aerobic soil metabolism in four soils Bayer CropScience AG, Report No.: MEF-05/532, Edition Number: M-276687-01-2 Date: 04.07.2006 GLP, unpublished	N	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			also filed: KIIA 7.2.1 /01				
KIIA 7.1.1 /02	Fliege, R.	2005	[Dihydrotriazole-3-14C] and [thiophene-4-14C]BYH 18636: Aerobic soil metabo- lism in one US soil Bayer CropScience AG, Report No.: MEF-05/224, Edition Number: M-263213-01-2 Date: 31.08.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.1.2 /01	Fliege, R.	2006	[Dihydrotriazole-3-14C] and [thiophene-4-14C] BYH 18636: Anaerobic soil me- tabolism Bayer CropScience AG, Report No.: MEF-05/490, Edition Number: M-274584-01-2 Date: 27.04.2006 GLP, unpublished also filed: KIIA 7.2.4 /01	N	Y	EU data protected	Bayer
KIIA 7.1.3 /01	Stupp, H. P.	2005	BYH 18636: Phototransformation on soil Bayer CropScience AG, Report No.: MEF-04/561, Edition Number: M-259443-01-2 Date: 11.08.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.2.1 /01	Fliege, R.	2006	[Dihydrotriazole-3-14C] and [thiophene-4-14C] BYH 18636: Aerobic soil metab- olism in four soils Bayer CropScience AG, Report No.: MEF-05/532, Edition Number: M-276687-01-2 Date: 04.07.2006 GLP, unpublished also filed: KIIA 7.1.1 /01	N	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
KIIA 7.2.1 /02	Hammel, K.	2007	Kinetic evaluation of the aerobic metabolism of BYH 18636, BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide-carboxylic acid and BYH 18636 MMT in soil for comparison with triggers Bayer CropScience AG, Report No.: MEF-07/109, Edition Number: M-284746-01-1 Date: 28.02.2007 Non GLP, unpublished also filed: KIIA 7.2.3 /01	N	N	-	Bayer
KIIA 7.2.1 /03	Hammel, K.	2007	Kinetic evaluation of the aerobic metabolism of BYH 18636, BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide-carboxylic acid and BYH 18636 MMT in soil for modelling purposes Bayer CropScience AG, Report No.: MEF-07/024, Edition Number: M-284770-01-1 Date: 28.02.2007 Non GLP, unpublished also filed: KIIA 7.2.3 /02	N	N	-	Bayer
KIIA 7.2.3 /01	Hammel, K.	2007	Kinetic evaluation of the aerobic metabolism of BYH 18636, BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide-carboxylic acid and BYH 18636 MMT in soil for comparison with triggers Bayer CropScience AG, Report No.: MEF-07/109, Edition Number: M-284746-01-1 Date: 28.02.2007 Non GLP, unpublished also filed: KIIA 7.2.1 /02	N	N	-	Bayer
KIIA 7.2.3 /02	Hammel, K.	2007	Kinetic evaluation of the aerobic metabolism of BYH 18636, BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide-carboxylic acid and BYH 18636 MMT in soil for modelling purposes Bayer CropScience AG,	N	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			Report No.: MEF-07/024, Edition Number: M-284770-01-1 Date: 28.02.2007 Non GLP, unpublished also filed: KIIA 7.2.1 /03				
KIIA 7.2.3 /03	Heinemann, O.	2006	BYH18636-triazolinone carboxamide: Aerobic soil degradation in 3 EU soils Bayer CropScience AG, Report No.: MEF-05/519, Edition Number: M-276814-01-2 Date: 02.08.2006 GLP, unpublished	N			Bayer
KIIA 7.2.4 /01	Fliege, R.	2006	[Dihydrotriazole-3-14C] and [thiophene-4-14C] BYH 18636: Anaerobic soil me- tabolism Bayer CropScience AG, Report No.: MEF-05/490, Edition Number: M-274584-01-2 Date: 27.04.2006 GLP, unpublished also filed: KIIA 7.1.2 /01	N	Y	EU data protected	Bayer
KIIA 7.3.1 /01	Wyatt, D. R.	2007	Terrestrial field dissipation of BYH18636 in Nebraska soil, 2005 Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: MEGSP002, Edition Number: M-285681-01-1 Date: 15.03.2007 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.3.1 /02	Wyatt, D. R.	2007	Terrestrial field dissipation of BYH18636 in Illinois soil, 2005 Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: MEGSP004,	N	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			Edition Number: M-285673-01-1 Date: 15.03.2007 GLP, unpublished				
KIIA 7.3.1 /03	Wyatt, D. R.	2007	Terrestrial field dissipation of BYH18636 in California soil, 2005 Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: MEGSM013, Edition Number: M-285682-01-1 Date: 15.03.2007 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.3.1 /04	Wyatt, D. R.	2007	Terrestrial field dissipation of BYH18636 in Ontario, Canada soil, 2005 Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: MEGSP003, Edition Number: M-285678-01-1 Date: 15.03.2007 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.3.1 /05	Coukell, G.	2007	Field dissipation of BYH18636 in three Canadian soils Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: MEGSP019, Edition Number: M-285968-01-2 Date: 26.03.2007 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.3.1 /06	Heinemann, O.	2006	Determination of the residues of AE 1394083 in/on soil after spraying of AE 1394083 00 WP10 A1 (10 WP) in the field in France, Germany and Spain Bayer CropScience AG, Report No.: RA-2146/04, Report includes Trial Nos.: R 2004 0920/6	N	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			R 2004 0921/4 R 2004 0922/2 Edition Number: M-279196-01-1 Date: 19.10.2006 GLP, unpublished				
KIIA 7.3.1 /07	Heinemann, O.	2006	Determination of the residues of AE 1394083 in/on soil after spraying of AE 1394083 00 WP10 A1 (10 WP) in the field in France Bayer CropScience AG, Report No.: RA-2048/05, Report includes Trial Nos.: 0286-9 R 2005 0286/9 Edition Number: M-278040-01-1 Date: 26.09.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.3.1 /08	Hammel, K.	2007	KineticEvaluation of the dissipation of BYH 18636-carboxylic acid in soil based on field studies Bayer CropScience AG, Report No.: MEF-07/067, Edition Number: M-284723-01-1 Date: 28.02.2007 Non GLP, unpublished	N	N	-	Bayer
KIIA 7.3.3 /01	Hammel, K.	2007	Predicted environmental concentrations of BYH 18636, BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide carboxylic acid, BYH 18636-MMT and BYH 18636-triazolinone-carboxamide in soil Use in maize in the EU Bayer CropScience AG, Report No.: MEF-07/072, Edition Number: M-284827-01-1 Date: 28.02.2007 Non GLP, unpublished	N	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
KIIA 7.4.1 /01	Fliege, R.	2003	Adsorption/desorption of BYH 18636 on five soils Bayer CropScience AG, Report No.: MEF-191/03, Edition Number: M-110732-01-2 Date: 24.09.2003 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.4.2 /01	Stupp, H. P.	2004	GSE28226: Adsorption/desorption in five soils Bayer CropScience AG, Report No.: MEF-191/04, Edition Number: M-086868-01-2 Date: 26.08.2004 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.4.2 /02	Fliege, R.	2004	GSE 18448: Adsorption/desorption on five soils Bayer CropScience AG, Report No.: MEF-085/04, Edition Number: M-082278-01-2 Date: 27.05.2004 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.4.2 /03	Simmonds, M.; Early, E.	2005	[14C]-BYH18636-sulfonamide-carboxylic acid: Adsorption to and desorption from five soils Battelle UK Ltd., Ongar, United Kingdom Bayer CropScience AG, Report No.: CX/04/069, Edition Number: M-263558-01-2 Date: 07.09.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.4.2 /04	Henk, F.; Haas, M.	2004	GSE12201: Adsorption/desorption on five soils Bayer CropScience AG, Report No.: MEF-027/04, Edition Number: M-081509-01-2	N	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			Date: 08.06.2004 GLP, unpublished				
KIIA 7.4.2 /05	Koenig, H.; Fliege, R.	2006	BYH 18636-triazolinone-carboxamide (AE 1430601): Estimation of the adsorption coefficient (Koc) on soil using high performance liquid chromatography Bayer CropScience AG, Report No.: MEF-05/417, Edition Number: M-268082-01-2 Date: 23.01.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.5 /01	Haas, M.	2005	BYH18636: Hydrolytic degradation Bayer CropScience AG, Report No.: MEF-04/183, Edition Number: M-259661-01-2 Date: 10.08.2005 GLP, unpublished also filed: KIIA 2.9.1 /01	N	Y	EU data protected	Bayer
KIIA 7.5 /02	Hammel, K.	2007	Kinetic evaluation of the hydrolytic degradation of BYH 18636 (25 °C, pH 9) Bayer CropScience AG, Report No.: MEF-07/137, Edition Number: M-286045-01-1 Date: 26.03.2007 Non GLP, unpublished	N	N	-	Bayer
KIIA 7.6 /01	Sneikus, J.	2005	BYH18636: Phototransformation in water Bayer CropScience AG, Report No.: MEF-04/381, Edition Number: M-244065-02-2 Date: 06.01.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.6 /02	Heinemann, O.	2004	BYH18636: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water	N	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			Bayer CropScience AG, Report No.: MEF-04/200, Edition Number: M-093045-02-1 Date: 01.10.2004, Amended: 30.03.2007 GLP, unpublished				
KIIA 7.6 /03	Heinemann, O.	2006	BYH18636-carboxylic acid: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water Bayer CropScience AG, Report No.: MEF-06/101, Edition Number: M-274264-01-1 Date: 27.02.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.6 /04	xxx	2006	BYH18636-sulfonamide: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water xxx Report No.: MEF-06/138, Edition Number: M-274454-01-1 Date: 20.04.2006 GLP, unpublished	Yes	Y	EU data protected	BCS
KIIA 7.6 /05	Heinemann, O.	2006	BYH18636-sulfonamide-carboxylic acid: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water Bayer CropScience AG, Report No.: MEF-06/177, Edition Number: M-274499-01-1 Date: 04.05.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.6 /06	Heinemann, O.	2006	BYH18636-dicarboxy-sulfonamide: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water Bayer CropScience AG, Report No.: MEF-06/167,	N	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			Edition Number: M-274439-01-1 Date: 11.04.2006 GLP, unpublished				
KIIA 7.6 /07	Heinemann, O.	2006	BYH18636-MMT: Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation in water Bayer CropScience AG, Report No.: MEF-06/140, Edition Number: M-274491-01-1 Date: 04.05.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.7 /01	Weyers, A.	2006	BYH 18636 - Biodegradation Bayer Industry Services GmbH, Leverkusen, Germany Bayer CropScience AG, Report No.: 2005/0059/02, Edition Number: M-266049-01-1 Date: 10.02.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.7 /02	Weyers, A.	2006	BYH 18636-Sulfonamide - Biodegradation Bayer Industry Services GmbH, Leverkusen, Germany Bayer CropScience AG, Report No.: 2005/0123/01, Edition Number: M-266051-01-1 Date: 13.02.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.8.2 /01	Arthur, E. L.; Sheperd, J.; Ripperger, R. J.; Dominic, A. R.	2007	[Dihydrotriazole-3-14C and thiophene-4-14C]BYH18636: Anaerobic aquatic metabolism Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: MEGSM012, Edition Number: M-285668-01-1	N	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			Date: 15.03.2007 GLP, unpublished				
KIIA 7.8.3 /01	Henk, F.; Haas, M.	2005	BYH18636: Aerobic aquatic metabolism Bayer CropScience AG, Report No.: MEF-05/008, Edition Number: M-262178-01-2 Date: 19.08.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.8.3 /02	Sneikus, J.	2006	BYH18636-MMT: Aerobic aquatic degradation Bayer CropScience AG, Report No.: MEF-06/500, Edition Number: M-281546-01-2 Date: 23.11.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 7.8.3 /03	Hammel, K.	2007	Kinetic evaluation of the aerobic aquatic metabolism of BYH 18636, BYH 18636-carboxylic acid, BYH 18636-sulfonamide, BYH 18636-sulfonamide-carboxylic acid, BYH 18636-MMT and BYH 18636-dicarboxy-sulfonamide Bayer CropScience AG, Report No.: MEF-06/489, Edition Number: M-284750-01-1 Date: 28.02.2007 Non GLP, unpublished	N	N	-	Bayer
KIIA 7.10 /01	Fliege, R.	2005	BYH 18636 (AE 1162464): Calculation of the chemical lifetime in the tropo- sphere Bayer CropScience AG, Report No.: MEF-05/299, Edition Number: M-267793-01-2 Date: 17.10.2005 Non GLP, unpublished	N	N	-	Bayer

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KIIA 7.13 /01	Iyengar; S.; Schumacher, G.; Kaune, A.; Lasserre-Bigot, D.; Ecker, U.	2007	The non relevance of the BYH 18636 carboxylic acid (thiencarbazon-methyl-carboxylic acid) Bayer CropScience AG, Report No.: M-285847-01-2 , Edition Number: M-285847-01-2 Date: 30.03.2007 Non GLP, unpublished also filed: KIIA 5.10 /01	N	N	-	Bayer
KIIA 8.1.1 /01	xxx	2005	Acute oral toxicity for bobwhite quail (Colinus virginianus) with BYH 18636 a.s. xxx Report No.: BAR/LD075, Edition Number: M-261212-01-2 Date: 21.11.2005 GLP, unpublished	Y	Y	EU data protected	Bayer
KIIA 8.1.2 /01	xxx	2006	Technical BYH 18636: A subacute dietary LC50 with northern bobwhite xxx Report No.: EBGSM006, Edition Number: M-278496-01-1 Date: 06.08.2006 GLP, unpublished	Y	Y	EU data protected	Bayer
KIIA 8.1.3 /01	xxx	2006	Technical BYH 18636: A subacute dietary LC50 with mallards xxx Report No.: EBGSP009, Edition Number: M-278504-01-1 Date: 28.07.2006 GLP, unpublished	Y	Y	EU data protected	Bayer
KIIA 8.1.4 /01	xxx	2007	Effect of technical BYH 18636 on northern bobwhite reproduction xxx, Report No.: EBGSP008, Edition Number: M-285465-01-1 Date: 15.03.2007 GLP, unpublished	Y	Y	EU data protected	Bayer
KIIA 8.1.4 /02	xxx	2007	Effect of technical BYH 18636 on mallard reproduction	Y	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			xxx, Report No.: EBGSP007, Edition Number: M-285456-01-1 Date: 15.03.2007 GLP, unpublished				
KIIA 8.2.1.1 /01	xxx	2005	Acute toxicity of BYH 18636 technical to the rainbow trout (Oncorhynchus mykiss) under static conditions xxx, Report No.: EBGSM014, Edition Number: M-252506-01-1 Date: 03.06.2005 GLP, unpublished	Y	Y	EU data protected	Bayer
KIIA 8.2.1.2 /01	xxx	2005	Acute toxicity of BYH 18636 technical to the bluegill (Lepomis macrochirus) under static conditions xxx, Report No.: EBGSM013, Edition Number: M-257680-01-1 Date: 28.07.2005 GLP, unpublished	Y	Y	EU data protected	Bayer
KIIA 8.2.1.3 /01	xxx	2005	Acute toxicity of BYH 18636 sulfonamide to the rainbow trout (Oncorhynchus mykiss) under static conditions xxx Report No.: EBGSP001-1, Edition Number: M-262252-02-1 Date: 01.12.2005, Amended: 04.01.2007 GLP, unpublished	Y	Y	EU data protected	Bayer
KIIA 8.2.4 /01	xxx	2006	Early life stage toxicity of BYH 18636 technical to the fathead minnow (Pimephales promelas) under flow-through conditions xxx Report No.: EBGSP013, Edition Number: M-264063-01-1 Date: 12.01.2006 GLP, unpublished	Y	Y	EU data protected	Bayer
KIIA 8.3.1.1 /01	Banman, C. S.; Lam, C. V.	2005	Acute toxicity of BYH 18636 technical to the Daphnia magna under static conditions	N	Y	EU data protected	Bayer

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			Bayer CropScience, Stilwell, Kansas, USA Bayer CropScience AG, Report No.: EBGSM007, Edition Number: M-251028-01-2 Date: 13.05.2005 GLP, unpublished				
KIIA 8.3.1.1 /02	Banman, C. S.; Lam, C. V.	2005	Acute toxicity of BYH 18636 sulfonamide to the Daphnia magna under static con- ditions Bayer Corporation, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSP002-1, Edition Number: M-261931-02-1 Date: 05.12.2005, Amended: 04.01.2007 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.3.1.1 /03	Bruns, E.	2006	BYH 18636-sulfonamide (tech.): Comparative toxicity of two different batches of the test-item to the waterflea Daphnia magna in a static laboratory test system Bayer CropScience AG, Report No.: EBGSP081, Edition Number: M-271240-01-2 Date: 16.05.2006 Non GLP, unpublished	N	N	-	Bayer
KIIA 8.3.1.1 /04	xxx	2007	Acute toxicity of BYH 18636-sulfonamide to the waterflea Daphnia magna in a static laboratory test system - limit-test xxx Report No.: EBGSP087, Edition Number: M-282608-01-2 Date: 25.01.2007 GLP, unpublished	Y	Y	EU data protected	Bayer
KIIA 8.3.2.1 /01	xxx	2006	Chronic toxicity of BYH 18636 technical to the Daphnia magna under static re- newal conditions xxx Report No.: EBGSM008-1, Edition Number: M-264057-02-1 Date: 12.01.2006, Amended: 09.02.2007	Y	Y	EU data protected	Bayer

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			GLP, unpublished				
KIIA 8.4 /01	Dorgerloh, M.	2004	How to express growth effects on algae under 91/414/EEC? Bayer CropScience AG, Report No.: MO-04-005000, Edition Number: M-069427-01-1 Date: 18.04.2004 Non GLP, unpublished	N	N	-	Bayer
KIIA 8.4 /02	Kern, M. E.; Banman, C. S.; Lam, C. V.	2005	Toxicity of BYH 18636 technical to the green alga - Pseudokirchneriella subcapitata Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSM001, Edition Number: M-256477-01-1 Date: 26.08.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.4 /03	Banman, C. S.; Lam, C. V.	2005	Toxicity of BYH 18636 sulfonamide to the green alga Pseudokirchneriella subcapitata Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSP003, Edition Number: M-262576-01-1 Date: 15.12.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.4 /04	Kern, M. E.; Roberts, J. A.; Lam, C. K.	2005	Toxicity of BYH 18636 technical to the freshwater diatom Navicula pelliculosa Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSM015, Edition Number: M-257683-01-1 Date: 19.08.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.4 /05	Kern, M. E.; Lam, C. V.	2006	Toxicity of BYH 18636 technical to the blue-green alga Anabaena flos-aquae Bayer CropScience, Kansas City, MO, USA Bayer CropScience AG, Report No.: EBGSP012-1, Edition Number: M-264060-02-2	N	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			Date: 12.01.2006, Amended: 09.02.2007 GLP, unpublished				
KIIA 8.5.1 /01	Bruns, E.	2006	Acute toxicity of BYH 18636 (tech.) to larvae of Chironomus riparius in a 48 h static laboratory test system (Limit-Test) Bayer CropScience AG, Report No.: EBGSP037, Edition Number: M-279507-01-2 Date: 30.10.2006 GLP, unpublished	N			Bayer
KIIA 8.5.1 /02	Bruns, E.	2006	Acute toxicity of BYH 18636-carboxylic acid to larvae of Chironomus riparius in a 48 h static laboratory test system (Limit-Test) Bayer CropScience AG, Report No.: EBGSP079, Edition Number: M-281173-01-2 Date: 06.12.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.5.1 /03	Bruns, E.	2006	Acute toxicity of BYH 18636-sulfonamide-carboxylic acid to larvae of Chironomus riparius in a 48 h static laboratory test system (limit-test) Bayer CropScience AG, Report No.: EBGSP078, Edition Number: M-281523-01-2 Date: 13.12.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.6 /01	Kern, M. E.; Lam, C. V.	2006	Toxicity of BYH 18636 technical to duckweed (Lemna gibba G3) under static-renewal conditions Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSM016, Edition Number: M-269681-01-1 Date: 24.03.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.6 /02	Christ, M. T.; Lam, C. V.	2007	Exposure and recovery with BYH 18636 technical to duckweed (Lemna gibba G3) Bayer CropScience, Stilwell, KS, USA	N	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			Bayer CropScience AG, Report No.: EBGSP070, Edition Number: M-285458-01-1 Date: 15.03.2007 GLP, unpublished				
KIIA 8.6 /03	Christ, M. T.; Lam, C. V.	2007	Toxicity of BYH 18636 technical to the aquatic macrophyte Myriophyllum spi- catum, during a 14-day exposure and 14-day recovery period Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSP077, Edition Number: M-285462-01-1 Date: 15.03.2007 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.6 /04	Hoberg, J. R.	2007	BYH 18636 - comparative toxicity to three aquatic macrophytes during a 14-day exposure followed by a 14-day recovery period Springborn Laboratories, Inc., Wareham, MA, USA Bayer CropScience AG, Report No.: EBGSP086, Edition Number: M-284928-01-2 Date: 08.03.2007 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.6 /05	Banman, C. S.; Lam, C. V.	2005	Toxicity of BYH 18636 carboxylic acid to duckweed (Lemna gibba G3) under static-renewal conditions Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSP019, Edition Number: M-258496-01-1 Date: 22.09.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.6 /06	Dorgerloh, M.	2006	Lemna gibba G3 growth inhibition test with BYH 18636 -sulfonamide-carboxylic acid under static conditions Bayer CropScience AG, Report No.: EBGSP042, Edition Number: M-273657-02-2 Date: 27.06.2006, Amended: 17.11.2006	N	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			GLP, unpublished				
KIIA 8.6 /07	Christ, M. T; Lam, C. V.	2006	Toxicity of BYH 18636 sulfonamide (a metabolite of BYH 18636) to duckweed (Lemna gibba G3) under static-renewal conditions Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSP029, Edition Number: M-284166-01-1 Date: 13.12.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.6 /08	Christ, M. T; Lam, C. V.	2007	Toxicity of BYH 18636 MMT (a metabolite of BYH 18636) to duckweed (Lemna gibba G3) under static-renewal conditions Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSP040, Edition Number: M-283972-01-1 Date: 17.01.2007 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.6 /09	Christ, M. T; Hoffmann, J. M.; Lam, C. V.	2007	Toxicity of BYH 18636-dicarboxy-sulfonamide (a metabolite of BYH 18636) to duckweed (Lemna gibba G3) under static-renewal conditions Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSP045, Edition Number: M-283800-01-1 Date: 08.01.2007 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.7.1 /01	Barth, M.	2005	Acute toxicity of BYH 18636 a.i. tech. to the honeybee Apis mellifera L. under laboratory conditions BioChem agrar, Gerichshain, Germany Bayer CropScience AG, Report No.: 05 10 48 030, Edition Number: M-253914-01-2 Date: 27.06.2005 GLP, unpublished	N	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
KIIA 8.8.1.1 /01	Waltersdorfer, A.	2006	Toxicity to the parasitoid wasp <i>Aphidius rhopalosiphi</i> (DeStephani-Perez) (Hymenoptera: Braconidae) in the laboratory - BYH 18636 & AE 0001789 SC 225 + 225 g/l Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: CW06/004, Edition Number: M-269942-01-2 Date: 27.04.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.8.1.2 /01	Waltersdorfer, A.	2006	Toxicity to the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) in the laboratory BYH 18636 & AE 0001789 SC 225 + 225 g/l Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: CW06/006, Edition Number: M-270231-01-3 Date: 05.05.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.9.1 /01	Heimbach, F.	2005	BYH 18636 (tech.): Acute toxicity to earthworms (<i>Eisenia fetida</i>) tested in artificial soil Bayer CropScience AG, Report No.: LKC/RG-A-59/05, Edition Number: M-262506-01-2 Date: 13.12.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.9.1 /02	Friedrich, S.	2005	BYH 18636 carboxylic acid: Acute toxicity to the earthworm <i>Eisenia fetida</i> in artificial soil BioChem agrar, Gerichshain, Germany Bayer CropScience AG, Report No.: 05 10 48 058, Edition Number: M-259511-01-2 Date: 27.10.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.9.2 /01	Friedrich, S.	2006	BYH 18636 & AE 0001789 SC 450: Sublethal toxicity to the earthworm <i>Eisenia fetida</i> in artificial soil	N	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			BioChem agrar, Gerichshain, Germany Bayer CropScience AG, Report No.: 06 10 48 099, Edition Number: M-277481-01-2 Date: 13.09.2006 GLP, unpublished				
KIIA 8.9.2 /02	Lechelt-Kunze, C.	2005	BYH 18636-carboxylic acid (technical): Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil Bayer CropScience AG, Report No.: LKC-RG-R-17/05, Edition Number: M-260378-01-2 Date: 11.11.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.9.2 /03	Friedrich, S.	2006	BYH 18636-sulfonamide: Sublethal toxicity to the earthworm Eisenia fetida in artificial soil BioChem agrar, Gerichshain, Germany Bayer CropScience AG, Report No.: 06 10 48 063, Edition Number: M-275605-01-2 Date: 01.08.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.9.2 /04	Luehrs, U.	2006	BYH 18636-sulfonamide-carboxylic acid: effects on reproduction and growth of earthworms Eisenia fetida in artificial soil Ibacon GmbH, Rossdorf, Germany Bayer CropScience AG, Report No.: 28471022, Edition Number: M-269975-01-2 Date: 24.04.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.9.2 /05	Luehrs, U.	2006	BYH 18636-MMT: Effects on reproduction and growth of earthworms Eisenia fetida in artificial soil Ibacon GmbH, Rossdorf, Germany Bayer CropScience AG, Report No.: 28461022, Edition Number: M-269458-01-2	N	Y	EU data protected	Bayer

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			Date: 10.04.2006 GLP, unpublished				
KIIA 8.10.1 /01	Lechelt-Kunze, C.	2005	BYH 18636 tech.: determination of effects on nitrogen transformation in soil Bayer CropScience AG, Report No.: LKC-N-55/05, Edition Number: M-259518-01-2 Date: 27.10.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.10.1 /02	Lechelt-Kunze, C.	2005	Metabolite BYH 18636-carboxylic acid: Determination of effects on nitrogen transformation in soil Bayer CropScience AG, Report No.: LKC-N-56/05, Edition Number: M-259751-01-2 Date: 03.11.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.10.1 /03	Heimbach, F.	2006	Metabolite BYH 18636-sulfonamide: Determination of effects on nitrogen transformation in soil Bayer CropScience AG, Report No.: LKC-N-66/06, Edition Number: M-269346-01-2 Date: 10.04.2006 GLP, unpublished	N	Y	EU data protected	BAYER
KIIA 8.10.1 /04	Heimbach, F.	2006	Metabolite BYH 18636-sulfonamide-carboxylic acid: Determination of effects on nitrogen transformation in soil Bayer CropScience AG, Report No.: LKC-N-67/06, Edition Number: M-268712-01-2 Date: 31.03.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.10.1 /05	Heimbach, F.	2006	Metabolite BYH 18636-MMT: Determination of effects on nitrogen transformation in soil Bayer CropScience AG, Report No.: LKC-N-65/06, Edition Number: M-268710-01-2 Date: 31.03.2006	N	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			GLP, unpublished				
KIIA 8.10.2 /01	Lechelt-Kunze, C.	2005	BYH 18636 tech: Determination of effects on carbon transformation in soil Bayer CropScience AG, Report No.: LKC-C-47/05, Edition Number: M-260127-01-2 Date: 08.11.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.10.2 /02	Lechelt.Kunze, C.	2005	Metabolite BYH 18636-carboxylic acid: Determination of effects on carbon transformation in soil Bayer CropScience AG, Report No.: LKC-C-48/05, Edition Number: M-260363-01-2 Date: 14.11.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.11.1 /01	Banman, C. S.; Lam, C. V.	2005	Acute toxicity of BYH 18636 technical to the sheepshead minnow (Cyprinodon variegatus) under static conditions Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSM011, Edition Number: M-252017-01-1 Date: 27.05.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.11.1 /02	Cafarella, M. A.	2006	BYI 08330 technical - Acute toxicity to eastern oysters (Crassostrea virginica) under flow-through conditions Springborn Smithers Laboratories, Wareham, MA, USA Bayer CropScience AG, Report No.: EBGSP010, Edition Number: M-281935-01-1 Date: 20.11.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.11.1 /03	Putt, A. E.	2006	BYH 18636 technical - Acute toxicity to mysids (Americamysis bahia) under flow-through conditions Springborn Smithers Laboratories, Wareham, MA, USA Bayer CropScience AG,	N	Y	EU data protected	Bayer

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			Report No.: EBGSP011, Edition Number: M-281936-01-1 Date: 01.09.2006 GLP, unpublished				
KIIA 8.11.1 /04	Putt, A. E.	2006	BYH 18636 technical - Life-cycle toxicity test with mysids (Americamysis bahia) Springborn Smithers Laboratories, Wareham, MA, USA Bayer CropScience AG, Report No.: EBGSP004, Edition Number: M-281198-01-2 Date: 22.11.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.11.1 /05	Christ, M. T.; Lam, C. V.	2006	Toxicity of BYH 18636 technical to the saltwater diatom Skeletonema costatum Bayer CropScience, Stilwell, KS, USA Bayer CropScience AG, Report No.: EBGSM017, Edition Number: M-281203-01-1 Date: 12.07.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.12 /01	Pallett, K.; Nguyen, D. H.; Gosch, H.; Bach, F.	2006	BYH 18636 + AE 0001789 SC 450 Effects on eleven species of non-target terrestrial plants: seedling emergence and seedling growth test (Tier 2) Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: SE 06/001, Edition Number: M-281379-01-2 Date: 12.12.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.12 /02	Bach, F.; Pallett, K.	2007	Higher tier non target terrestrial plant study on the seedling emergence and growth of 4 plant species under semi-field conditions. The phytotoxic effects of TCM + CSA SC 225 + 225 G (thiencazabone-methyl + cyprosulfamide SC 225 + 225 G/L) Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: HT06/041-A1, Edition Number: M-282887-02-2 Date: 26.01.2007, Amended: 26.02.2007	N	Y	EU data protected	Bayer

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			GLP, unpublished				
KIIA 8.12 /03	Pallett, K.; Nguyen, D. H.; Gosch, H.	2006	BYH 18636 + AE 0001789 SC 450 effects on eleven species of non-target terres- trial plants: vegetative vigour test (tier 2) Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: VV 06/002, Edition Number: M-281425-01-2 Date: 13.12.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.12 /04	Bach, F.; Pallett, K.	2006	Higher tier non target terrestrial plant study on the vegetative vigour test of 3 plant species determined under semi-field conditions. The phytotoxic effects of BYH 18636 + AE 0001789 SC 225 + 225 (thiencarbazone-methyl + cyprosulfamide) Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: HT06/040-A1, Edition Number: M-281484-02-2 Date: 14.12.2006, Amended: 23.02.2007 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.12 /05	Hess, M.	2006	Evaluation of the pre-emergence biological activity of AE 1394083, the carbox- ylic acid of thiencarbazone.methyl Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: PP03067, Edition Number: M-274414-02-1 Date: 22.06.2006 Non GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.12 /06	Hess, M.	2006	Evaluation of the post-emergence biological activity of AE 1394083, the carbox- ylic acid of thiencarbazone-methyl Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: PP04013, Edition Number: M-274413-02-1 Date: 22.06.2006 Non GLP, unpublished	N	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
KIIA 8.13 /01	Barfknecht, R.	2007	Comment on the extrapolation of LD50 values from acute oral toxicity tests in rodents Bayer CropScience AG, Report No.: M-284766-01-1 , Edition Number: M-284766-01-1 Date: 07.03.2007 Non GLP, unpublished	N	N	-	Bayer
KIIA 8.15 /01	Weyers, A.	2005	BYH 18636 - Toxicity to bacteria Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, Report No.: 2005/0059/01, Edition Number: M-256617-01-2 Date: 23.08.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.15 /02	Weyers, A.	2005	BYH 18636 carboxylic acid - Toxicity to bacteria Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, Report No.: 2005/0067/01, Edition Number: M-256620-01-2 Date: 22.08.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.15 /03	Weyers, A.	2005	BYH 18636-Sulfonamide - Toxicity to bacteria Bayer Industry Services GmbH, Leverkusen, Germany Bayer CropScience AG, Report No.: 1354 N/05 B, Edition Number: M-253800-01-2 Date: 31.05.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.16.1 /01	Frommholz, U.	2006	BYH 18636 tech.: Influence on the reproduction of the collembola species Folsonia candida tested in artificial soil Bayer CropScience AG, Report No.: FRM-COLL-46/06, Edition Number: M-275211-01-2 Date: 31.07.2006 GLP, unpublished	N	Y	EU data protected	Bayer

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KIIA 8.16.1 /02	Frommholz, U.	2005	BYH 18636-carboxylic acid: Influence on the reproduction of the collembola species Folsomia candida tested in artificial soil Bayer CropScience AG, Report No.: LKC-COLL-44/05, Edition Number: M-262498-01-2 Date: 13.12.2005 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.16.1 /03	Friedrich, S.	2006	BYH 18636-sulfonamide-carboxylic acid: Effects on the reproduction of the collembolans Folsomia candida BioChem agrar, Gerichshain, Germany Bayer CropScience AG, Report No.: 06 10 48 168, Edition Number: M-280689-01-2 Date: 28.11.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.16.1 /04	Friedrich, S.	2006	BYH 18636-MMT: Effects on the reproduction of the collembolans Folsomia candida BioChem agrar, Gerichshain, Germany Bayer CropScience AG, Report No.: 06 10 48 167, Edition Number: M-280552-01-2 Date: 24.11.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.16.1 /05	Friedrich, S.	2006	BYH 18636-triazolinone-carboxamide: Effects on the reproduction of the collembolans Folsomia candida BioChem agrar, Gerichshain, Germany Bayer CropScience AG, Report No.: 06 10 48 169, Edition Number: M-280750-01-2 Date: 29.11.2006 GLP, unpublished	N	Y	EU data protected	Bayer
KIIA 8.16.2 /01	Leicher, T.	2006	BYH 18636-carboxylic acid: Effects on soil litter degradation Bayer CropScience AG, Report No.: LRT-SLD 30/06, Edition Number: M-280506-02-2	N	Y	EU data protected	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	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
			Date: 23.11.2006, Amended: 13.02.2007 GLP, unpublished				
KIIA 8.16.2 /02	McMillan-Staff, S.; Thomas, J.	2006	Residues of thien carbazone-methyl on corn - Proposal for a DT50 calculation Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-280632-02-1 , Edition Number: M-280632-02-1 Date: 11.12.2006 Non GLP, unpublished	N	N	-	Bayer

The studies referenced in the table below were submitted to RMS (FRA) and EFSA to support Art. 12 of EU Regulation No 396/2005 (refer to Review of the existing maximum residue levels for thien carbazone-methyl according to Article 12 of Regulation (EC) No 396/2005; EFSA Journal 2020;18(1):5957). These data are considered as being EU peer reviewed data.

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
Refer to 2019 Evaluation Report, FRA (RMS)	Justus, K.	2014	Amendment no 1 to metabolism of [thiophene-4-14C]thiencarbazone-methyl in sugar beets Report No.: MEF-11/905, Edition Number: M-442848-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2014-02-25 GLP/GEP: Yes unpublished	N	N	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1 st registration.	Bayer
Refer to 2019 Evaluation Report, FRA (RMS)	Justus, K.	2014	Amendment No 1 to metabolism of [dihydrotriazole-3-14C]thiencarbazone-methyl in sugar beets Report No.: MEF-11/872, Edition Number: M-442854-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2014-02-25 GLP/GEP: Yes unpublished	N	N	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1 st registration.	Bayer
Refer to 2019 Evaluation Report, FRA (RMS)	Stuke, S.	2014	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spraying of foramsulfuron & BYH 18636 OD 80 in the field in Germany, the Netherlands and United Kingdom Report No.: 13-2000, Edition Number: M-494921-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2014-11-10 GLP/GEP: Yes unpublished	N	N	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1 st registration.	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
Refer to 2019 Evaluation Report, FRA (RMS)	Stuke, S.; Diehl, P.	2014	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spraying of foramsulfuron & BYH 18636 OD 80 in the field in Germany and The Netherlands Report No.: 13-2009, Edition Number: M-496362-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	N	N	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1 st registration.	Bayer
Refer to 2019 Evaluation Report, FRA (RMS)	Stuke, S.; Diehl, P.	2014	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spray application of foramsulfuron & BYH 18636 OD 80 in the field in United Kingdom, Germany, France (North) and the Netherlands Report No.: 12-2138, Edition Number: M-480852-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	N	N	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1 st registration.	Bayer
Refer to 2019 Evaluation Report, FRA (RMS)	Stuke, S.; Diehl, P.	2014	Determination of the residues of BYH 18636 and foramsulfuron in/on sugar beet after spray application of foramsulfuron & BYH 18636 OD 80 in the field in United Kingdom, Germany, France (North) and the Netherlands Report No.: 12-2138, Edition Number: M-480852-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	N	N	Study already submitted to the country to support the initial registration of the product. Data protection asked for to support 1 st registration.	Bayer

The following tables are to be completed by MS

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner

List of data relied on and 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner