

REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: 102000028562

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

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorisation)

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When	What
August 2019	Original Bayer Crop Science Division submission
June 2021	Initial zRMS assessment. The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency .
February 2022	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded .

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Reviewer comments:

This dossier has been prepared to support the zonal registration of the product DLT+FPF EC 85. The product contains deltamethrin (10 g/L) and flupyradifurone (75 g/L) to be used as insecticide EC (Emulsifiable concentrate for spray application outdoors to low crops). Mentioned above document summarizes the data related to the toxicological studies and exposure data for the plant protection product DLT+FPF EC 85.

For the purposes of the current product registration, APPL provided an assessment of the toxicological potential based on *in vitro*, *in vivo* tests and calculation method (ATEmix). ZRMS PL, in accordance with the EC recommendations to avoid tests on animals, for the purposes of hazard classification tried to use the data obtained using the calculation method. However, due to the fact that the some of results of ATEmix calculation gave clearly different results than the *in vivo* test, for this reason ZRMS PL took into account the results of *in vivo* tests as higher tier precautionary approach for the purpose of hazard assessment.

ZRMS PL points out that since there are *in vivo* tests already exist the information gained on animal studies are more than just a classification. By accepting the already existing animal studies, the identification of effects following a single exposure to the plant protection product can be established. The data is sufficient to indicate the time course and characteristics of the effect with full details of behavioral changes and possible gross pathological findings at post-mortem. ZRMS PL is aware of some EU-countries are known for no longer accepting *in vivo* studies. On the other hand ZRMS believes that other EU-countries might be willing to see the reports that are available (if the classification based on them is different from the one obtained by calculation).

DLT+FPF EC 85 contains deltamethrin (10 g/L) and flupyradifurone (75 g/L) has a moderate toxicity in respect to acute oral, inhalation and dermal toxicity. The product is no irritant to the skin. Irritant for eye of rabbits and skin sensitizer (based on relevant ingredients and LLNA test OECD 429 mouse). Taking into account all submitted data, DLT+FPF EC 85 meet the criteria for classification and labeling for acute toxicity according to the CLP Regulation 1172/2008. (H302, H332, H318, H317)

Harmonized deltamethrin classification (ATP01 ECHA) and RAC opinion for flupyradifurone classification done by the ECHA/RAC (CLH-O-0000001412-86-228/F Adopted 14 September 2018) both classifications were taken into account when labeling the product.

Additional studies has been submitted by the APPL regarding toxicity studies for ground water metabolite difluoroacetic acid (DFA).

For detail information considering evaluation of the studies relied upon (toxicity properties) refer our comments in Appendix 2 to this dRR.

All exposure calculations used for estimation of operator, workers and B&R exposure to the active substances during application of DLT+FPF EC 85 according to the critical use(s) identify safe use of the product.

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on Deltamethrin + flupyradifurone EC 85 (10+75 g/L) *


Product name and code	DLT+FPF EC 85 (102000028562)
Formulation type	Emulsifiable concentrate [Code: EC]
Active substance(s) (incl. content)	Deltamethrin: 10 g/L Flupyradifurone: 75 g/L
Function	Insecticide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of DLT+FPF EC 85 can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for DLT+FPF EC 85 according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	Acute toxicity: category 4 H302: Harmful if swallowed Acute toxicity : category 4 H332: Harmful if inhaled Skin sensitisation: Category 1 H317: May cause an allergic skin reaction. Serious eye damage: category 1 H318: Causes serious eye damage Acute aquatic toxicity: category 1
Signal word:	Danger 
Hazard statement(s):	H 302 + H 332: Harmful if swallowed or if inhaled H317 May cause an allergic skin reaction. H 318: Causes serious eye damage
Precautionary statement(s):	P280: Wear protective gloves/ protective clothing /eye protection/face protection 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 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor/ physician. P310: Immediately call a Poison center/doctor/physician P391 Collect spillage. P501 Dispose of contents/container in accordance with local regulation.

Additional labelling phrases:	EUH401: To avoid risks to human health and the environment, comply with the instruction for use
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Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for DLT+FPF EC 85

	Result	PPE / Risk mitigation measures
Operators	Acceptable	None
Workers	Acceptable	None
Bystanders	Acceptable	None
Residents	Acceptable	None

No unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended. No specific PPE is necessary

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents is presented in the following table.

Table 6.1-4 Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8	9	10			
Use- No.*	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safener/syn- ergist (L/ha)) critical gap for operator, worker, bystander or resi- dent exposure based on [Expo- sure model]	Acceptability of exposure assess- ment			
			Method / Kind (incl. applica- tion technique ***	Max. number (min. interval between ap- plications) a) per use b) per crop/ season	Max. applica- tion rate kg as/ha a) a.s. 1 b) a.s. 2	Water L/ha min / max			Operator	Worker	Bystander	Residents
1, 2 5, 6 7, 8 11, 12 17, 18 23, 24 27, 28	Rape, Winter (BBCH 30- 49)	F	Spraying, LCTM	a) 2 b) 2 (14 days)	a) FPF 0.05625 b) DLT 0.0075	200-600	as per growth stage	EFSA guidance on the assessment of exposure of op- erators, workers, residents and by- standers in risk as- sessment for plant protection prod- ucts (2014)				

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** 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

*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 "Acceptability of exposure assessment"

A	Exposure acceptable without PPE / risk mitigation measures
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible



Data gaps

Noticed data gaps are: none.

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

Table 6.2-1: Information on active substance(s)

	Deltamethrin	Flupyradifurone
Common Name	Deltamethrin	Flupyradifurone
CAS-No.	52918-63-5	951659-40-8
Classification and proposed labelling		
With regard to toxicological endpoints (according to the criteria in Reg. 67/548/EEC or 1999/45/EC or Reg. 1272/2008, as amended)	<p>Hazard classes (s), categories: Flammable liquids: category 3 Acute toxicity: Category 4 Aspiration hazard: Category 1 Skin irritation: Category 2 Serious eye damage: Category 1 Acute toxicity: Category 4 Specific target organ toxicity - single exposure: Category 3</p> <p>Signal word: Danger</p>  <p>Hazard statement(s): H302 Harmful if swallowed. H304 May be fatal if swallowed and enters airways. H315 Causes skin irritation. H318 Causes serious eye damage. H331 Harmful if inhaled. H335 May cause respiratory irritation. H336 May cause drowsiness or dizziness. EUH401 To avoid risks to human health and the environment, comply with the instructions for use.</p> <p>Precautionary statement(s): P240 Ground/bond container and receiving equipment. P280 Wear protective gloves/protective clothing/eye protection. 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 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor/ physician. P501 Dispose of contents/container in accordance with local regulation.</p>	<p>Hazard classes (s), categories: Acute toxicity: Category 4 Specific target organ toxicity - repeated exposure: Category 2</p> <p>Code(s) for hazard pictogram(s): Xn Harmful</p>  <p>Hazard statement(s): H302 Harmful if swallowed. H373 May cause damage to organs (muscle) through prolonged or repeated exposure.</p> <p>Precautionary statement(s): P280 Wear protective gloves/ protective clothing/ eye protection. P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor/ physician. P391 Collect spillage. P501 Dispose of contents/container in accordance with local regulation.</p>
Additional C&L proposal	None	None
Agreed EU endpoints		
AOEL systemic	0.0075 mg/kg bw/d (corrected for 75 % oral absorption)	0.064 mg/kg bw/d (no adjustment according to the bioavailability had to be taken into account)
Reference	Final Review report for the active substance deltamethrin, SANCO 6504/VI/99-final	Final Review report for the active substance flupyradifurone, SANTE/11649/2015/ rev 1
Conditions to take into account/critical areas of concern with regard to toxicology		
Review Report/EFSA Conclusion for active substance	<ul style="list-style-type: none"> - Member States must pay particular attention to the operator safety and must ensure that the conditions of authorisation include appropriate protective measures. - Member states should observe the acute 	Member States shall pay particular attention to: <ul style="list-style-type: none"> - the protection of workers and operators

	dietary exposure situation of consumers in view of future revisions of Maximum Residue Levels. - Member States must pay particular attention to the protection of aquatic organisms, bees and non-target arthropods and must ensure that the conditions of authorisation include risk mitigation measures.	
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6.3 Toxicological Evaluation of Plant Protection Product

For a registration in a country outside of Europe toxicity studies were conducted. A summary of the toxicological evaluation for DLT+FPF EC 85 is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3-1: Summary of the classification with a calculation method and evaluation of the studies on acute toxicity including irritancy and skin sensitisation for DLT+FPF EC 85

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
Calculation method ATEmix* LD ₅₀ oral, rat (OECD 425)	4242.7 mg/kg bw* 550 < LD ₅₀ < 2000 mg/kg bw	Yes	Acute Tox. Cat. 4, H302	[REDACTED]: 2015; M-516318-01-1
Calculation method ATEmix* LD ₅₀ dermal, rat (OECD 402)	No relevant ingredients for calculation* LD ₅₀ > 2000 mg/kg bw	Yes	None	[REDACTED]: 2015; M-515269-01-1
Calculation method ATEmix* LC ₅₀ inhalation, rat (OECD 403)	5 mg/L air* 4-h LC ₅₀ , males: 1.31 mg/L air 4-h LC ₅₀ , females: > 4.62 mg/L air	Yes	Acute Tox. Cat. 4, H332	[REDACTED]: 2015; M-534789-01-1
Skin irritation, evaluation based on ingredients Skin irritation, rabbit (OECD 404)*	Non-irritant Non-irritant*	Yes	None	[REDACTED]: 2015; M-511430-01-1
In vitro eye irritation, ICET (OECD 438)**	Not classified as severe irritant and not classified as non-irritant.**	Supplementary	None	Váliczkó, É.; 2015; M-511433-01-1
Eye irritation, evaluation based on ingredients Eye irritation, rabbit (OECD 405)*#	Irritant Irritant*#	Yes	Eye Corr. Cat. 1, H318	[REDACTED]: 2015; M-528983-01-1
Skin sensitisation, evaluation based on ingredients* Skin sensitisation, mouse (OECD 429, LLNA)	Non-sensitiser* Sensitising	Yes	Skin Sens. Cat. 1B, H317	[REDACTED]: 2017; M-601871-01-1
Supplementary studies for combinations of plant protection products	No data – not required			

Reviewer comment:

* test system marked with grey fonts has not been considered for hazard assessment, however in case of *in vivo* test they are still scientifically valid without deviation from OECD protocols; see our comments Appendix 2

** results achieved from *in vitro* study (Valiczko, E., 2015) does not allow conclude on hazard classification of the product, thus *in vivo* studies required.

to reflect comments made during the commenting procedure, ZRMS decided to take into account the above-mentioned *in vivo* study (skin irritation) for the sake of consistency of the assessment. When discuss the results of the *in vitro* study for the endpoint of eye irritation, where the *in vitro* study does not allow to conclude on hazard classification of the product, thus in this case *in vivo* study is required and considered as next tier approach for hazard assessment.

Table 6.3-2: Additional toxicological information relevant for classification/labelling of product code/name

	Substance (Concentration in product, % w/w)*	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Deltamethrin (0.86 %)	Acute Tox. 3, H301 Acute Tox. 3, H331	Reg. 1272/2008 MSDS** CLP00/ATP01, Harmonised classification - Annex VI of Regulation (EC) No 1272/2008	See table 6.1-2 p.7
	Flupyradifurone (6.47 %)	Acute Tox. 4, H302 STOT-RE 2 (muscle), H373	RAC Opinion -CLH O-0000001412- 86-228/F Adopted 14 September 2018 Harmonised classification of the relevant substance is now available. Refer EC Reg. 2020/1182 of 19 May 2020 Article 2 Entry into force and application: It shall apply from 1 March 2022.	
Toxicological properties of non-active substance(s) (relevant for classification of product)	Alkylaryl polyglycol ether Arylethylphenylpolyglykol ether.			
	CAS 104376-75-2 (> 1 % – < 25 %)			
	2-Ethylhexanol propylene ethyleneglycol ether CAS 64366-70-7 (> 1 % – < 25 %)	Acute Tox. 4, H332		
	Propylene carbonate CAS 108-32-7 or 203-572- 1 (> 20 %)	Eye Irrit. 2, H319		
Further toxicological information	No data – not required			

* Please use concentration range or concentration limit (e.g. 1-10 % or > 1 %) as provided in MSDS.

** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

Deltamethrin

All metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required.

Flupyradifurone

Concentrations of the groundwater metabolite, 6-CNA are predicted to stay below 0.1 µg/L. Thus, no groundwater assessment is required.

The following data on metabolites with the potential to reach the groundwater in concentrations above 0.1 µg/L and requiring relevance assessment were submitted. Note that the relevance assessment of the metabolites is reported in Part B.10; the submitted toxicological studies are summarized in this document.

6.4.1 Metabolite DFA (Difluoroacetic acid)

An overview of the results of the accepted toxicological studies for groundwater metabolite DFA is given in the following table. All the studies on the metabolite have been previously considered within an EU peer review process.

DFA is unlikely to have genotoxicity potential and reference values to the parent are applicable to DFA (EFSA Journal 2015;13(2):4020).

Table 6.4-1: Summary of the results of toxicity studies for difluoroacetic acid (DFA)

Type of test, species (Guideline)	Result	Acceptability	Reference*
Bacterial reverse mutation assay in <i>S. typhimurium</i> (OECD 471)	Non-mutagenic without and with S9 mix	Yes	Sokolowski, A., 2013 M-409724-02-1*
In vitro mammalian cells gene mutation (OECD 476)	Non-mutagenic without and with S9 mix	Yes	Wollny, H. E., 2013 M-409727-02-1*
In vitro chromosome aberration tests (OECD 473)	Non clastogenic for mammalian cells <i>in vitro</i>	Yes	Bohnenberger, S., 2013 M-409726-02-1*
Acute oral, rat (OECD 423)	LD ₅₀ : 300-2000 mg/kg	Yes	██████████, 2010 M-393372-01-2*
14-day dietary toxicity study, rat (no guideline specified, no GLP)	NOAEL: 500 ppm (51 mg/kg bw/day)	Yes	██████████, 2011 M-414152-01-2*
90-day dietary toxicity study, rat (OECD 408)	NOAEL: 200 ppm (12.7-15.6 mg/kg bw/day for female and male rats, respectively)	Yes	██████████, 2012 M-424611-01-2*

* indicates that a study was reviewed at EU level

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in DLT+FPF EC 85 are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in DLT+FPF EC 85

	Deltamethrin		Flupyradifurone	
	Value	Reference	Value	Reference
Concentrate	5.3 %	New study reported in Appendix 2	3.4 %	New study reported in Appendix 2
Dilution (dilution factor)	3.2 % (0.05 g a.s./L)		1.1 % (0.375 g a.s./L)	
Dilution (dilution factor)	1.7 % (0.0064 g a.s./L)		4.9 % (0.048 g a.s./L)	

6.5.1 Justification for proposed values - Deltamethrin

Proposed dermal absorption rates for deltamethrin are based on dermal absorption studies on the formulation DLT+FPF EC 85 (10+75) G. The study results are summarized in the following table. Full summaries of studies on the dermal absorption of deltamethrin/HLT+FPF EC 85 (10+75) G are described in detail in Appendix 2.

Table 6.5-2: Summary of the results of submitted dermal absorption studies for deltamethrin

Test	Concen- trate	Spray di- lution (0.05 g a.s./L)	Spray di- lution (0.0064 g a.s./L)	Formu- lation in study	Acceptability of study	Justification provided on representa- tivity of study formulation for current product	Acceptability of justification	Reference*
In vitro (human)	5.3 %	3.2 %	1.7 %	DLT+FPF EC 85 (10+75) G	Yes, ZRMS PL agrees that proposed dermal absorption value can be used for risk assessment	Not required	No applicable	Odin, 2016

* indicates that a study was reviewed at EU level

6.5.2 Justification for proposed values - Flupyradifurone

Proposed dermal absorption rates for flupyradifurone are based on dermal absorption studies on the formulation DLT+FPF EC 85 (10+75) G. The study results are summarized in the following table. Full summaries of studies on the dermal absorption of flupyradifurone/HLT+FPF EC 85 (10+75) G are described in detail in Appendix 2.

Table 6.5-3: Summary of the results of submitted dermal absorption studies for flupyradifurone

Test	Concen- trate	Spray di- lution (0.375 g a.s./L)	Spray di- lution (0.048 g a.s./L)	Formu- lation in study	Acceptability of study	Justification provided on representativity of study formu- lation for cur- rent product	Acceptability of justifica- tion	Reference*
In vitro (human)	3.4 %	1.1 %	4.9 %	DLT+FPF EC 85 (10+75) G	Yes ZRMS PL agrees that proposed dermal absorption value can be used for risk assessment	Not required	No applicable	Blanck, 2016

* indicates that a study was reviewed at EU level

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

As no Acute Acceptable Operator Level (AAOEL) has been set for flupyradifurone during the last EU evaluation (Final Review report for the active substance flupyradifurone, SANTE/11649/2015/ rev 1) and for deltamethrin (Final Review report for the active substance deltamethrin, SANCO 3504/VI/99-final) no acute risk assessment is presented in this document. Bystander exposure to flupyradifurone and deltamethrin is then covered by the Resident exposure assessment.

Table 6.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	DLT+FPF EC 85 (10+75) G	
Formulation type	EC	
Category	Insecticide	
Container size(s), short description	Type of package: bottle Materials: High density polyethylene or High Density Polyethylene Coextruded Capacity: 100 ml Closure: screw cap, HF seal 32 mm with carton hologram seal foil PMR 80 447 574 - CAPHF or with carton hologram seal foil with shake well sticker PMR 80 448 198- CAPHF Transport and unit for sale: 20 x 100 mL (2 L in shipping case (cardboard) with transport label) Pallet: 156 unit sales (312 L) (26 units/layer; 6 layers/pallet)	
Active substance(s) (incl. content)	Deltamethrin 10 g/L	Flupyradifurone 75 g/L
AOEL systemic	0.0075 mg/kg bw/d	0.064 mg/kg bw/d
Inhalation absorption	100 %	100 %
Oral absorption	75 %	> 80 %
Dermal absorption	Concentrate: 5.3 % Dilution: 3.2 % (0.05 g a.s/L) 1.7 % (0.0064 g a.s./L) (Based on product (formulation))	Concentrate: 3.4 % Dilution: 1.1 % (0.375 g a.s./L) 4.9 % (0.048 g a.s./L) (Based on product (formulation))

6.6.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 6.1-4. A list of all intended uses within the zone is given in Part B, Section 0.

Justification

The selected GAPs cover the highest intended use rates and the representative crops.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of DLT+FPF EC 85 according to the critical use(s) is presented in Table 6.6-2. Outcome of the estimation is presented in Table 6.6-3. Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Rape, winter (max. 0.75 L product/ha)
Model(s)	All exposure calculations are in accordance with the <i>EFSA guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products.(2014)</i> ¹

¹ EFSA (European Food Safety Authority), 2014. 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, 55 pp., doi:10.2903/j.efsa.2014.3874

Table 6.6-3: Estimated operator exposure

		Deltamethrin	
		Long term exposure	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL¹
Tractor mounted boom spray application outdoors to low crops Application rate: 0.0075 kg a.s./ha			
EFSA Operator Model (75 th quantile regression) Body weight: 60 kg	Potential	0.0037	50
	no PPE ²	0.0021	28
	with PPE ³	0.0001	2

¹ AOEL (RVNAS) of deltamethrin: 0.0075 mg/kg bw/day

² no PPE: Work wear - arms, body and legs covered

³ with PPE: Work wear - arms, body and legs covered. In addition gloves during mixing and loading

		Flupyradifurone	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL¹
Tractor mounted boom spray application outdoors to low crops Application rate: 0.05625 kg a.s./ha			
EFSA Operator Model (75 th quantile regression) Body weight: 60 kg	Potential	0.0110	17
	no PPE ²	0.0067	10
	with PPE ³	0.0006	1

¹ AOEL (RVNAS) of flupyradifurone: 0.064 mg/kg bw/day

² no PPE: Work wear - arms, body and legs covered

³ with PPE: Work wear - arms, body and legs covered. In addition gloves during mixing and loading.

6.6.3 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.4 Worker exposure (KCP 7.2.3)

6.6.4.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with DLT+FPF EC 85 according to the critical use(s). Outcome of the estimation is presented in

Table 6.6-5. Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical use(s)	Rape, winter (max. 0.75 L product/ha)
Model	All exposure calculations are in accordance with the <i>EFSA guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products.(2014)</i> ²

Table 6.6-5: Estimated worker exposure

Deltamethrin			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Application in Rape, winter Number of applications: 2 application rate: 0.0075 kg a.s./ha			
2 hours/day ⁽¹⁾ , TC: 1400 cm ² /person/h ⁽²⁾ Body weight: 60 kg	Potential	0.0009	11
	no PPE ⁽³⁾	0.0013	7 1.28

Flupyradifurone			
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Application in Rape, winter Number of applications: 2 application rate: 0.05625 kg a.s./ha			
2 hours/day ⁽¹⁾ , TC: 1400 cm ² /person/h ⁽²⁾ Body weight: 60 kg	Potential	0.0059	9
	no PPE ⁽³⁾	0.0007	1

⁽¹⁾ e.g. 8 h/day for professional applications for harvesting, pruning, tying, thinning or weeding activities etc. or 2 h/day for professional applications for maintenance, inspection or irrigation activities etc.

⁽²⁾ e.g. EUROPOEM II, 2002, Post-Application Exposure of Workers to Pesticides in Agriculture or US-EPA policy paper [EPA, Science Advisory Council for Exposure; Agricultural Transfer Coefficients, Policy # 3.]. TC: Transfer coefficient

⁽³⁾ no PPE: Worker wearing long sleeved shirt, long trousers (“permeable”) but no gloves

6.6.4.2 Refinement of generic DFR value (KCP 7.2)

Not relevant.

6.6.4.3 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

² EFSA (European Food Safety Authority), 2014. 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, 55 pp., doi:10.2903/j.efsa.2014.3874

6.6.5 Bystander and resident exposure (KCP 7.2.2)

6.6.5.1 Estimation of bystander and resident exposure

Table 6.6-6 shows the exposure model(s) used for estimation of bystander and resident exposure to Deltamethrin , Flupyradifurone and . Outcome of the estimation is presented in

Table 6.6-7 and 6.6-8. Detailed calculations are in Appendix 3.

No acute acceptable operator exposure level (AAOEL) has been set during the last EU review of flupyradifurone (Final Review report for the active substance flupyradifurone, SANTE/11649/2015/ rev 1) and the last review of deltamethrin (Final Review report for the active substance deltamethrin, SANCO 3504/VI/99-final) therefore bystander exposure is covered by resident exposure.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	Rape, winter (max. 0.75 L product/ha)
Model	All exposure calculations are in accordance with the <i>EFSA guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products.(2014)</i> ³

Table 6.6-7: Estimated resident exposure to deltamethrin

		Adult ²		Child ²	
Outdoor, Downward spraying, Vehicle-mounted Application rate: 2 x 0,0075 kg a.s./ha, 14 days interval, Minimum water volume: 200 L/ha					
Routes of exposure	75 th centile (mg/kg bw/day)	in % of AOEL ¹ (RVNAS)		75 th centile (mg/kg bw/day)	in % of AOEL ¹ (RVNAS)
Spray drift ³	0.00001	0.1		0.00003	0.4
Vapour	0,00023	3.1		0,00107	14
Surface deposits	0.000005	0.1		0.00002	0.2
Entry into treated crops	0.00006	0.9		0.00012	1.5
	Sum of all pathways (mean): in % of AOEL (RVNAS)		3.8	Sum of all pathways (mean): in % of AOEL (RVNAS)	
				16	

¹ AOEL (RVNAS) of DLT: 0,0075 mg/kg bw/day

² Considered bodyweight: adult = 60 kg, child = 10 kg

³ Exposure at 2-3 m distance

³ EFSA (European Food Safety Authority), 2014. 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, 55 pp., doi:10.2903/j.efsa.2014.3874

Table 6.6-8: Estimated resident exposure to flupyradifurone

		Adult ²		Child ²	
Outdoor, Downward spraying, Vehicle-mounted Application rate: 2 x 0,05625 kg a.s./ha, 14 days interval, Minimum water volume: 200 L/ha					
Routes of exposure	75 th centile (mg/kg bw/day)	in % of AOEL ¹ (RVNAS)		75 th centile (mg/kg bw/day)	in % of AOEL ¹ (RVNAS)
Spray drift ³	0.00009	0.1		0.00038	0.6
Vapour	0,00023	0.4		0,00107	1.7
Surface deposits	0.00003	0.05		0.00015	0.2
Entry into treated crops	0.00045	0.7		0.00080	1.3
	Sum of all pathways (mean): in % of AOEL (RVNAS)		1.0	Sum of all pathways (mean): in % of AOEL (RVNAS)	
				3.2	

¹ AOEL (RVNAS) of FPF: 0,064 mg/kg bw/day

² Considered bodyweight: adult = 60 kg, child = 10 kg

³ Exposure at 2-3 m distance

6.6.5.2 Measurement of bystander and/or resident exposure

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for deltamethrin and flupyradifurone will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

6.6.6 Combined exposure

The product is a mixture of two active substances, deltamethrin and flupyradifurone.

6.6.6.1 Exposure Assessment of Deltamethrin and Flupyradifurone in DLT+FPF EC 85

Note: The combined toxicological effect of these active substances has not been investigated with regard to repeated dose toxicity.

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL/RVNAS. This is equivalent to the predicted exposure as % of systemic AOEL/RVNAS from Table 6.6-3 converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6-8: Acute risk assessment from combined exposure

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Operators – vehicle mounted downward spraying	Deltamethrin	0.28
	Flupyradifurone	0.10
	Cumulative risk Operators (HI)	0.38
Workers – inspection	Deltamethrin	0.07
	Flupyradifurone	0.01
	Cumulative risk Workers (HI)	0.08
Bystander	Deltamethrin	Not relevant

Application scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
	Flupyradifurone	Not relevant
	Cumulative risk Bystander – Adult (HI)	Not relevant
Resident - Adult	Deltamethrin	0.04
	Flupyradifurone	0.01
	Cumulative risk Resident – Adult (HI)	0.05
Resident - Child	Deltamethrin	0.16
	Flupyradifurone	0.03
	Cumulative risk Resident – Child (HI)	0.19

The Hazard Index is < 1. Thus combined exposure to all active substances in DLT+FPF EC 85 is not expected to present a risk for operators, workers, bystanders and residents. No further refinement of the assessment is required.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP 7.1.1 / 01	[REDACTED]	2015	Deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Acute oral toxicity study in the rat (Up and down procedure) Report No.: 14/384-001P, Edition Number: M-516318-01-1 [REDACTED] GLP/GEP: Yes unpublished	Yes	Bayer
KCP 7.1.2 / 01	[REDACTED]	2015	Deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Acute dermal toxicity study in the rat Report No.: 14/384-002P, Edition Number: M-515269-01-1 [REDACTED] GLP/GEP: Yes unpublished	Yes	Bayer
KCP 7.1.3 / 01	[REDACTED]	2015	Acute inhalation toxicity study (nose-only) in the rat with deltamethrin + flupyradifurone EC 85 (10+75 g/L) Report No.: 14/384-004P, Edition Number: M-534789-01-1 [REDACTED] GLP/GEP: Yes unpublished	Yes	Bayer
KCP 7.1.4 / 01	[REDACTED]	2015	Deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Acute skin irritation study in rabbits Report No.: 14/384-006N, Edition Number: M-511430-01-1 [REDACTED] GLP/GEP: Yes unpublished	Yes	Bayer
KCP 7.1.5 / 01	Váliczkó, É.	2015	Deltamethrin + flupyradifurone EC 85 (10+75 g/L) - In vitro eye irritation test in isolated chicken eyes Report No.: 14/384-038CS, Edition Number: M-511433-01-1 CiToxLAB Hungary Ltd., Veszprém, Szabadságpusztá, Hungary GLP/GEP: Yes unpublished	No	Bayer
KCP 7.1.5 / 02	[REDACTED]	2015	Deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Acute eye irritation study in rabbits Report No.: 14/384-005N, Edition Number: M-528983-01-1 [REDACTED] GLP/GEP: Yes unpublished	Yes	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP 7.1.6 / 01	[REDACTED]	2017	Deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Local lymph node assay in the mouse Report No.: 14/384-037E, Edition Number: M-601871-01-1 [REDACTED] GLP/GEP: Yes unpublished	Yes	Bayer
KCP 7.3 / 01	Odin, M.	2016	Deltamethrin + flupyradifurone EC 85 (10+75) formulation: [14C]-deltamethrin in vitro dermal absorption study using human skin Report No.: SA 15251, Edition Number: M-559234-01-1 Bayer S.A.S., Bayer CropScience, Sophia Antipolis, France GLP/GEP: Yes unpublished	No	Bayer
KCP 7.3 / 02	Blanck, M.	2016	DLT+FPF EC 85 (10+75): [14C]-flupyradifurone - In vitro dermal absorption study using human skin Report No.: SA 15253, Edition Number: M-556571-01-1 Bayer S.A.S., Bayer CropScience, Sophia Antipolis, France GLP/GEP: Yes unpublished	No	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 on.

Deltamethrin

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.1 / 01		1982	Pyrethroid metabolism: comparative fate in rats of tralomethrin, traloccythrin, deltamethrin and (1R,α S)-cis- cypermethrin. Journal: Journal of Agricultural and Food Chemistry Volume: 30 Pages: 631-636 Year: 1982 Report No.: A71114 Edition Number: M-149585-01-1 GLP/GEP: n.a., published ... also filed: KCA 6.2 / 10	Yes	published
KCA 5.1 / 02	Christian, I.; Lauck-Birkel, S.	2015	Deltamethrin AIR3: Additional data on kinetic studies and metabolism Bayer Report No.: M-533554-02-1 Date: 2015-12-01 GLP/GEP: n.a., unpublished	No	Bayer
KCA 5.1 / 03	Christian, I.; Hell-pointner, E.	2015	Deltamethrin - Additional information on the comparison of metabol Bayer Report No.: M-539732-01-1 Date: 2015-11-20 GLP/GEP: n.a., unpublished	No	Bayer
KCA 5.1 / 04	Mousquès, A.	2016	Residue data of alpha-R and trans isomers of deltamethrin Bayer Report No.: M-479846-02-1 Date: 2016-09-06 GLP/GEP: n.a., unpublished	No	Bayer
KCA 5.1 / 05	Anon.	2010	Revision of deltamethrin - Re-evaluation of MRLs and proposal for amendments KEMI, Rapporteur member state, Sweden RMS: Sweden Report No.: M-328058-02-1 Date: 2010-12-31 GLP/GEP: n.a., unpublished	No	RMS: Sweden

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.1.1 / 01	[REDACTED]	1990	Metabolism of 14C-tralomethrin in rats. [REDACTED] Bayer Report No.: A73039 Edition Number: M-151332-01-1 Date: 1990-04-05 GLP/GEP: Yes, unpublished ... also filed: KCA 6.2 / 11	Yes	Bayer
KCA 5.1.1 / 02	[REDACTED]	1978	Decamethrin Metabolism in Rats Journal: Journal of Agricultural and Food Chemistry Volume: 26 Issue: 4 Pages: 918-925 Year: 1978 Report No.: A12526 Edition Number: M-063782-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.1.1 / 03	[REDACTED]	1994	Equivalent mixture of (14C-phenyl)-cypermethrin, (14C-benzyl)-deltamethrin and (14C-phenoxyphenyl)-fenvaterate: Distribution - kinetics and excretion after single oral administration to laying hens [REDACTED] Bayer Report No.: A52315 Edition Number: M-133155-01-1 Date: 1994-03-30 GLP/GEP: Yes, unpublished ... also filed: KCA 6.2.2 / 02	Yes	Bayer
KCA 5.1.1 / 04	[REDACTED]	1979	RU22974 - Acute toxicity study in rats by the oral route. [REDACTED] Bayer Report No.: A98084 Edition Number: M-175868-01-1 Date: 1979-06-01 GLP/GEP: No, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.1.1 / 05	[REDACTED]	1992	Deltamethrin I.V. laying hens. [REDACTED] Bayer Report No.: A70791 Edition Number: M-149282-01-1 Date: 1992-10-19 GLP/GEP: No, unpublished ... also filed: KCA 5.1.2 / 05	Yes	Bayer
KCA 5.1.1 / 06	[REDACTED]	1985	Metabolism, distribution, and excretion of deltamethrin by leghorn hens. Journal: Journal of Agricultural and Food Chemistry Volume: 33 Issue: 4 Pages: 610-617 Year: 1985 Report No.: A35015 Edition Number: M-116708-01-1 GLP/GEP: n.a., published ... also filed: KCA 5.1.2 / 06 KCA 6.2.2 / 01	Yes	published
KCA 5.1.1 / 07	[REDACTED]	1986	Fate of 14C-Deltamethrin in lactating dairy cows. Journal: Journal of Agricultural and Food Chemistry Volume: 34 Issue: 4 Pages: 753-758 Year: 1986 Report No.: A34280 Edition Number: M-115057-01-1 GLP/GEP: n.a., published ... also filed: KCA 5.1.2 / 07 KCA 6.2.3 / 01	Yes	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.1.1 / 08	Solà, J.	2014	[Benzyl-14C]deltamethrin: Metabolic stability and profiling in liver microsomes from rats, mice and humans for inter-species comparison Harlan Laboratories S.A., Barcelona, Spain Bayer Report No.: EnSa-13-0820 Edition Number: M-475952-01-1 Date: 2014-02-05 GLP/GEP: Yes, unpublished	No	Bayer
KCA 5.1.1 / 09	Godin, S. J.; Scollon, E. J.; Hughes, M. F.; Potter, P. M.; DeVito, M. J.; Ross, M. K.	2006	Species differences in the in vitro metabolism of deltamethrin and esfenvalerate: differential oxidative and hydrolytic metabolism by humans and rats. Journal: Drug Metab. Dispos., Volume 34, Issue 10, Page 1764-1771, Publication Year 2006 Year: 2006 Report No.: M-476902-01-1 GLP/GEP: n.a., published	No	published
KCA 5.1.1 / 10	Godin, S. J.; Crow, J. A.; Scollon, E. J.; Hughes, M. F.; DeVito, M. J.; Ross, M. K.	2007	Identification of rat and human cytochrome P450 isoforms and a rat serum esterase that metabolize the pyrethroid insecticides deltamethrin and esfenvalerate. Journal: Drug Metab. Dispos., Volume 35, Issue 9, Page 1664-1671, Publication Year 2007 Year: 2007 Report No.: M-458601-01-1 GLP/GEP: n.a., published	No	published
KCA 5.1.1 / 11		2007	Expert statement on the gastrointestinal absorption after oral dosing of deltamethrin Bayer Report No.: MEF-07/361 Edition Number: M-291817-01-1 Date: 2007-08-17 GLP/GEP: n.a., unpublished	Yes	Bayer
KCA 5.1.2 / 01		1993	(14C-Benzyl)-deltamethrin: Distribution - Kinetics and excretion after single intravenous administration to female rats. Bayer Report No.: A51513 Edition Number: M-132447-01-1 Date: 1993-08-05 GLP/GEP: Yes, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.1.2 / 02	[REDACTED]	1993	(14C-benzyl)-deltamethrin: distribution - kinetics and excretion after single intravenous administration to female rats [REDACTED] Bayer Report No.: A98189 Edition Number: M-176064-01-1 Date: 1993-08-05 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.1.2 / 03	[REDACTED]	1990	Metabolism of (14)C-Deltamethrin in rats [REDACTED] Bayer Report No.: A97637 Edition Number: M-175044-01-1 Date: 1990-07-09 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.1.2 / 04	[REDACTED]	1990	Metabolism of 14C-deltamethrin in rats [REDACTED] Bayer Report No.: A70824 Edition Number: M-149312-01-1 Date: 1990-07-09 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.1.2 / 05	[REDACTED]	1992	Deltamethrin I.V. laying hens. [REDACTED] Bayer Report No.: A70791 Edition Number: M-149282-01-1 Date: 1992-10-19 GLP/GEP: No, unpublished ... also filed: KCA 5.1.1 / 05	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.1.2 / 06	[REDACTED]	1985	Metabolism, distribution, and excretion of deltamethrin by leghorn hens. Journal: Journal of Agricultural and Food Chemistry Volume: 33 Issue: 4 Pages: 610-617 Year: 1985 Report No.: A35015 Edition Number: M-116708-01-1 GLP/GEP: n.a., published ... also filed: KCA 5.1.1 / 06 KCA 6.2.2 / 01	Yes	published
KCA 5.1.2 / 07	[REDACTED]	1986	Fate of 14C-Deltamethrin in lactating dairy cows. Journal: Journal of Agricultural and Food Chemistry Volume: 34 Issue: 4 Pages: 753-758 Year: 1986 Report No.: A34280 Edition Number: M-115057-01-1 GLP/GEP: n.a., published ... also filed: KCA 5.1.1 / 07 KCA 6.2.3 / 01	Yes	published
KCA 5.2 / 01	[REDACTED]	1979	Toxicity studies with decamethrin, a synthetic pyrethroid insecticide. Journal: Journal of Environmental Pathology and Toxicology Issue: 2 Pages: 751-765 Year: 1979 Report No.: A20968 Edition Number: M-094154-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.2.1 / 01	[REDACTED]	1989	Acute oral toxicity study of deltamethrin in rats [REDACTED] Bayer Report No.: A70785 Edition Number: M-149276-01-1 Date: 1989-05-04 GLP/GEP: Yes, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.2.1 / 02	[REDACTED]	1989	Acute oral toxicity study of deltamethrin in rats [REDACTED] Bayer Report No.: A98128 Edition Number: M-175949-01-1 Date: 1989-05-04 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.2.1 / 03	Gaines, T. B.; Linder, R. E.	1986	Acute toxicity of pesticides in adult and weanling rats Publisher: Society of Toxicology Journal: Fundamental and Applied Toxicology Volume: 7 Pages: 299 - 308 Year: 1986 Report No.: MO-02-014393 Edition Number: M-058562-01-1 GLP/GEP: n.a., published	No	published
KCA 5.2.1 / 04	[REDACTED]	1996	Acute oral toxicity study of Deltamethrin in albino rats [REDACTED] Bayer Report No.: A55812 Report includes Trial Nos.: 53013A WIL-274001 Edition Number: M-139700-01-1 Date: 1996-08-06 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.2.1 / 05	[REDACTED]	2005	Deltamethrin technical - Acute toxicity in the rat after oral administration Bayer Report No.: AT02671 Edition Number: M-263224-01-1 Date: 2005-12-07 GLP/GEP: Yes, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.2.1 / 06		2008	AE F108569 / Deltamethrin alpha-R-isomer acute toxicity in the rat after oral administration Bayer Report No.: AT04700 Edition Number: M-304957-01-1 Date: 2008-07-11 GLP/GEP: Yes, unpublished ... also filed: KCA 5.8.1 / 11	Yes	Bayer
KCA 5.2.2 / 01		1979	Acute percutaneous toxicity to rats of decamethrin. Bayer Report No.: A28974 Edition Number: M-101629-01-1 Date: 1979-02-21 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.2.2 / 02		2000	Acute dermal toxicity in rats deltamethrin Bayer Report No.: C009679 Edition Number: M-199039-02-1 Date: 2000-07-19 ... amended: 2000-09-11 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.2.2 / 03		1992	Acute intravenous toxicity study with Deltamethrin (preparation with PEG 300) in rats Bayer Report No.: A49669 Edition Number: M-138700-01-1 Date: 1992-06-15 GLP/GEP: Yes, unpublished ... also filed: KCA 5.8 / 42	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.2.2 / 04	[REDACTED]	1992	Acute intravenous toxicity study with Deltamethrin (preparation with PEG 300) in laying hens [REDACTED] Bayer Report No.: A49666 Edition Number: M-138697-01-1 Date: 1992-06-16 GLP/GEP: Yes, unpublished ... also filed: KCA 5.8 / 44	Yes	Bayer
KCA 5.2.2 / 05	[REDACTED]	2005	Deltamethrin technical - Acute toxicity in the rat after dermal application Bayer Report No.: AT02461 Edition Number: M-258954-01-1 Date: 2005-10-06 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.2.3 / 01	[REDACTED]	1990	Acute inhalation toxicity evaluation of deltamethrin in rats [REDACTED] Bayer Report No.: A70770 Edition Number: M-149264-01-1 Date: 1990-06-09 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.2.3 / 02	[REDACTED]	1978	RU 22974 - Acute inhalation toxicity in rats. 6 hour LC 50. [REDACTED] Bayer Report No.: A28960 Edition Number: M-101619-01-1 Date: 1978-05-15 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.2.4 / 01	[REDACTED]	1979	RU22974 - Test to determine primary cutaneous irritation in the rabbit [REDACTED] Bayer Report No.: A95068 Edition Number: M-227752-01-1 Date: 1979-06-01 GLP/GEP: No, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.2.4 / 02	[REDACTED]	1989	Primary dermal irritation test of deltamethrin in rabbits [REDACTED] Bayer Report No.: A98131 Edition Number: M-175955-01-1 Date: 1989-04-17 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.2.4 / 03	[REDACTED]	2005	Deltamethrin technical - Acute skin irritation/corrosion on rabbits Bayer Report No.: AT02547 Edition Number: M-260123-01-1 Date: 2005-10-27 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.2.5 / 01	[REDACTED]	1979	RU22974. Test to evaluate ocular irritation in the rabbit. [REDACTED] Bayer Report No.: A95069 Edition Number: M-227753-01-1 Date: 1979-07-31 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.2.5 / 02	[REDACTED]	1989	Eye irritation study of deltamethrin in rabbits. [REDACTED] Bayer Report No.: A70799 Edition Number: M-149290-01-1 Date: 1989-04-17 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.2.5 / 03	[REDACTED]	2005	Deltamethrin technical - Acute eye irritation on rabbits Bayer Report No.: AT02612 Edition Number: M-260858-01-1 Date: 2005-11-18 GLP/GEP: Yes, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.2.6 / 01	[REDACTED]	1977	RU22974 - decamethrine; Decis technical - Roussel Uclaf. Sensitization test in the guinea pig. [REDACTED] Bayer Report No.: A28978 Edition Number: M-227645-01-1 Date: 1977-09-26 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.2.6 / 02	[REDACTED]	1989	Dermal sensitization study of deltamethrin in the Albino guinea pig (Buehler) [REDACTED] Bayer Report No.: A98129 Edition Number: M-175951-01-1 Date: 1989-09-07 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.2.6 / 03	[REDACTED]	2005	Deltamethrin technical (Project: Deltamethrin technical) - Study for the skin sensitization effect in guinea pigs (Buehler patch test) Bayer Report No.: AT02618 Edition Number: M-261562-01-1 Date: 2005-11-18 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.2.7 / 01	Heppenheimer, A.	2013	Deltamethrin TC: Cytotoxicity assay in vitro with BALB/c 3T3 cells: Neutral red (NR) test during simultaneous irradiation with artificial sunlight Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer Report No.: 1558000 Edition Number: M-466174-01-1 Date: 2013-09-16 GLP/GEP: Yes, unpublished	No	Bayer
KCA 5.2.7 / 02	Lynch, A. M.; Guzzie, P. J.; Bauer, D.; Gocke, E.; Itoh, S.; Jacobs, A.; Krul, C. A. M.; Schepky, A.; Tanaka, N.; Kasper, P.	2011	Considerations on photochemical genotoxicity. II: Report of the 2009 International Workshop on Genotoxicity Testing Working Group Publisher: Elsevier B.V. Journal: Mutation Research Volume: 723 Pages: 91-100 Year: 2011 Report No.: M-465377-01-1 GLP/GEP: n.a., published	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.3 / 01	[REDACTED]	1993	Deltamethrin (technical): Toxicity to dogs by repeated oral administration for 52 weeks. [REDACTED] Report No.: A70808 Edition Number: M-149298-01-1 Date: 1993-10-21 GLP/GEP: Yes, unpublished ... also filed: KCA 5.3.2 / 03	Yes	Bayer
KCA 5.3 / 02	Rehman, H.; Ali, M.; Atif, F.; Kaur, M.; Bhatia, K.; Raisuddin, S.	2006	The modulatory effect of deltamethrin on antioxidants in mice Journal: Clin. Chim. Acta, Volume 369, Issue 1, Page 61-65, Publication Year 2006 Year: 2006 Report No.: M-462613-01-1 GLP/GEP: n.a., published	No	published
KCA 5.3 / 03	Zaki, S.; Shona, S.; El-Aasar, H.; Sayed, W.	2010	Morphological and morphometric renal changes in the adult albino rat following oral administration of deltamethrin and the possible protective role of vitamin E/ Publisher: INSInet Publication Location: http://www.aensiweb.com/old/jasr/jasr/2010/280-290.pdf Journal: Journal of Applied Sciences Research (2010) , Volume 6, Issue 4, 2010 Pages: 280-290 Year: 2010 Report No.: M-476790-01-1 GLP/GEP: n.a., published	No	published
KCA 5.3.1 / 01	[REDACTED]	1977	A study of the effects of RU 22974 on food consumption in the mouse. [REDACTED] Bayer Report No.: A70877 Edition Number: M-149361-01-1 Date: 1977-10-05 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.3.1 / 02	[REDACTED]	1977	RU 22974: Study of the effects of RU 22974 on food consumption in the rat. [REDACTED] Bayer Report No.: A70878 Edition Number: M-149362-01-1 Date: 1977-03-22 GLP/GEP: No, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.3.1 / 03	[REDACTED]	1977	RU 22974: Assessment of toxicity to rats by oral administration for 13 weeks (followed by a 4-week withdrawal period). [REDACTED] Bayer Report No.: A70872 Edition Number: M-149356-01-1 Date: 1977-03-21 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.3.2 / 01	[REDACTED]	1979	RU22974. Oral toxicity study in beagle dogs [REDACTED] Report No.: A98072 Edition Number: M-175845-02-1 Date: 1979-06-01 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.3.2 / 02	[REDACTED]	1991	Deltamethrin: Oral toxicity study in beagle dogs (repeated dosage for 13 weeks with a 4-week recovery period). [REDACTED] Bayer Report No.: A70874 Edition Number: M-149358-01-1 Date: 1991-07-08 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.3.2 / 03	[REDACTED]	1993	Deltamethrin (technical): Toxicity to dogs by repeated oral administration for 52 weeks. [REDACTED] Bayer Report No.: A70808 Edition Number: M-149298-01-1 Date: 1993-10-21 GLP/GEP: Yes, unpublished ... also filed: KCA 5.3 / 01	Yes	Bayer
KCA 5.3.2 / 04	[REDACTED]	1980	2-Year Chronic Dog Feeding Study [REDACTED] Bayer Report No.: A21228 Edition Number: M-094407-01-1 Date: 1980-09-16 GLP/GEP: Yes, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.3.2 / 05	[REDACTED]	1991	Deltamethrin toxicity studies in rat by dietary administration for 13 weeks with a 4-week recovery period (3 volumes). [REDACTED] Bayer Report No.: A70875 Edition Number: M-149359-01-1 Date: 1991-07-03 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.3.2 / 06	[REDACTED]	1991	Toxicity study for 12 weeks by oral administration to mice. [REDACTED] Bayer Report No.: A70876 Edition Number: M-149360-01-1 Date: 1991-12-03 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.3.3 / 01	[REDACTED]	1993	21-day dermal toxicity study in rats with deltamethrin technical. [REDACTED] Bayer Report No.: A50968 Edition Number: M-131952-01-1 Date: 1993-04-09 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.3.3 / 02	[REDACTED]	1979	RU22974 (Decis) 3 week inhalation toxicity study in rats [REDACTED] Bayer Report No.: A95071 Edition Number: M-227755-01-1 Date: 1979-06-01 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.4.1 / 01	Peyre, M.; Chantot, J. F.; Glomot, R.; Penasse, L.; Stephenson, J. K.	1980	Detection of a mutagenic potency of Decamethrin (RU 22974). Bacterial tests Bayer Report No.: A98112 Edition Number: M-175920-01-1 Date: 1980-01-21 GLP/GEP: No, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.4.1 / 02	Hommel, K.	1989	Addendum to document A40741 Hoe 099730 00 ZC83 0001 Certificates of Analysis 04068 and 04069 Hoechst AG, Frankfurt am Main, Germany BASF Report No.: A41849 Edition Number: M-124912-01-1 Date: 1989-05-08 GLP/GEP: n.a., unpublished confidential	No	BASF
KCA 5.4.1 / 03	Pluijmen, M.; Drevon, C.; Montesano, R.; Malaveille, C.; Hautefeuille, A.; Bartsch, H.	1984	Lack of mutagenicity of synthetic pyrethroids in Salmonella typhimurium strains and in V79 Chinese hamster cells Journal: Mutation Research Volume: 137 Issue: 1 Pages: 7;16 Year: 1984 Report No.: A41894 Edition Number: M-124957-01-1 GLP/GEP: n.a., published	No	published
KCA 5.4.1 / 04	Putman, D. L.; Morris, M. J.	1989	Chromosome aberration assay of deltamethrin in Chinese hamster ovary Microbiological Associates, Inc., Bethesda, MD, USA Bayer Report No.: A98126 Edition Number: M-175946-01-1 Date: 1989-02-23 GLP/GEP: No, unpublished	No	Bayer
KCA 5.4.1 / 05	Watanabe, M.	2005	Deltamethrin: reverse mutation test in bacterial system Bayer Report No.: NR05215 Edition Number: M-253266-01-2 Date: 2005-04-20 GLP/GEP: Yes, unpublished	No	Bayer
KCA 5.4.1 / 06	Naumann, S.	2017	Deltamethrin (AE F032640): Micronucleus test in human lymphocytes in vitro Envigo CRS GmbH, Rossdorf, Germany Bayer Report No.: 1805902 Edition Number: M-577648-01-1 Date: 2017-01-12 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.4.1 / 07	Wollny, H. E.	2017	Deltamethrin (AE F032640): Gene mutation assay in Chinese hamster V79 cells in vitro (V79/HPRT) Envigo CRS GmbH, Rossdorf, Germany Bayer Report No.: 1805901 Edition Number: M-577646-01-1 Date: 2017-01-09 GLP/GEP: Yes, unpublished	No	Bayer
KCA 5.4.2 / 01	[REDACTED]	1983	Deltamethrin - Detection of a mutagenic potency. Micronucleus test in the mouse [REDACTED] Bayer Report No.: A41868 Edition Number: M-124931-01-1 Date: 1983-07-27 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.4.2 / 02	Curren, R. D.	1989	Unscheduled DNA synthesis of deltamethrin in rat primary hepatocytes. Microbiological Associates, Inc., Bethesda, MD, USA Bayer Report No.: A70853 Edition Number: M-149338-01-1 Date: 1989-03-13 GLP/GEP: Yes, unpublished	No	Bayer
KCA 5.4.2 / 03	Polakova, H.; Vargova, M.	1983	Evaluation of the mutagenic effects of decamethrin: cytogenetic analysis of bone marrow Journal: Mutation Research Volume: 120 Pages: 167;171 Year: 1983 Report No.: A41895 Edition Number: M-124958-01-1 GLP/GEP: n.a., published	No	published
KCA 5.4.3 / 01	Vannier, B.; Glomot, R.	1977	RU 22974: Mutagenic study - Dominant lethal assay in the male mouse. Roussel Uclaf, Romainville, France Bayer Report No.: A20259 Edition Number: M-149340-01-2 Date: 1977-05-17 GLP/GEP: No, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.4.3 / 02	[REDACTED]	1995	Deltamethrin technical: 97-week carcinogenicity study by oral route (dietary admixture) in mice. [REDACTED] Bayer Report No.: A70820 Edition Number: M-149308-01-1 Date: 1995-12-26 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.5 / 01	[REDACTED]	1995	Deltamethrin (technical) Potential tumorigenic and toxic effects in prolonged dietary administration to rats [REDACTED] Bayer Report No.: A56161 Edition Number: M-139996-01-1 Date: 1995-12-11 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.5 / 02	[REDACTED]	1980	RU 22974: Two year oral toxicity and carcinogenicity study in rats. [REDACTED] Bayer Report No.: A20243 Edition Number: M-093417-01-1 Date: 1980-05-06 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.5 / 03	[REDACTED]	1980	RU 22974. Two Year Oral Toxicity and Carcinogenicity Study in Mice [REDACTED] Bayer Report No.: A20242 Edition Number: M-093412-01-1 Date: 1980-05-05 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.5 / 04	[REDACTED]	1995	Deltamethrin (technical) 97-week carcinogenicity study by oral route (dietary admixture) in mice [REDACTED] Bayer Report No.: A56270 Edition Number: M-140100-01-1 Date: 1995-12-26 GLP/GEP: Yes, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.6 / 01	[REDACTED]	2001	Prenatal developmental toxicity study by oral route (gavage) in rabbits Deltamethrin [REDACTED] Bayer Report No.: C017345 Edition Number: M-204103-01-1 Date: 2001-11-14 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.6 / 02	[REDACTED]	1977	RU 22974. Teratological Study in Mouse - Rat - Rabbit [REDACTED] Bayer Report No.: A20256 Edition Number: M-093444-01-1 Date: 1977-12-20 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.6 / 03	Sargent, D. E.; Heusel, R.	2001	Aventis CropScience Response to RMS Review of the Acute Neurotoxicity Study Bayer Report No.: B003436 Edition Number: M-240464-01-1 Date: 2001-08-30 GLP/GEP: n.a., unpublished ... also filed: KCA 5.7 / 03 KCA 5.8 / 04	No	Bayer
KCA 5.6 / 04	Singer, S. S.; Hurst, K.	2001	Survey of Reports on Analysis for Deltamethrin in Milk from Cows and Humans Bayer Report No.: B003480 Edition Number: M-240501-01-1 Date: 2001-09-24 GLP/GEP: n.a., unpublished ... also filed: KCA 6.4.2 / 04 KCA 6.9 / 01	No	Bayer

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KCA 5.6.1 / 01	[REDACTED]	1992	Reproductive effects of deltamethrin administered orally in diet to Crl: CD BR VAF/Plus rats for two generations. (Vol.1/4). [REDACTED] Bayer Report No.: A70863 Edition Number: M-149348-01-1 Date: 1992-01-17 GLP/GEP: Yes, unpublished ... also filed: KCA 5.7.1 / 05	Yes	Bayer
KCA 5.6.2 / 01	[REDACTED]	1990	Developmental toxicity study of deltamethrin in rats. [REDACTED] Bayer Report No.: A70869 Edition Number: M-149353-01-1 Date: 1990-07-06 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.6.2 / 02	[REDACTED]	1990	Developmental toxicity study of deltamethrin in New Zealand white rabbits. [REDACTED] Bayer Report No.: A70865 Edition Number: M-149350-01-1 Date: 1990-05-07 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.6.2 / 03	Muhammad, B. Y.; Ray, D. E.	1997	Report on the potential developmental neurotoxicity of pyrethroids in mice : Attempts to replicate the results of Eriksson's group on the developmental neurotoxicity of pyrethroids Report No.: A74192 Edition Number: M-152443-01-1 GLP/GEP: n.a., published ... also filed: KCA 5.8 / 07	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.6.2 / 04	Leist, K. H.; Strutt, A. V.	2001	Aventis CorpScience response to RMS review on developmental neurotoxicity Deltamethrin Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C014150 Edition Number: M-206060-01-1 Date: 2001-05-31 GLP/GEP: n.a., unpublished ... also filed: KCA 5.8 / 45	No	Bayer
KCA 5.6.2 / 05	Gergs, A.; Sheets, L.; Marmugi, A.; Preuss, T. G.	2018	Simulating effect of deltamethrine on rat male pup growth and maturation using dynamic energy budget model Bayer Report No.: EnSa-18-0507 Edition Number: M-631095-01-1 Date: 2018-09-03 GLP/GEP: No, unpublished	No	Bayer
KCA 5.6.2 / 06	Kooijman, S.; Bedaux, J.	1996	Analysis of toxicity tests on Daphnia survival and reproduction Publisher: Elsevier Location: United Kingdom Journal: Water Research Volume: 30 Issue: 7 Pages: 1711-1723 Year: 1996 Report No.: M-631806-01-1 GLP/GEP: n.a., published	No	published
KCA 5.6.2 / 07	Jager, T.; Zimmer, E.	2011	Simplified dynamic energy budget model for analysing ecotoxicity data Publisher: Elsevier Journal: Ecological Modelling Volume: 225 Pages: 74-81 Year: 2012 Report No.: M-632125-01-1 GLP/GEP: n.a., published	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.6.2 / 08	Nisbet, R.; Muller, E.; Lika, K.; Kooijman, S.	2000	From molecules to ecosystems through dynamic energy budget models Journal: Journal of Animal Ecology Year: 2000 Report No.: M-634465-01-1 Date: 2000-12-31 GLP/GEP: No, published	No	published
KCA 5.6.2 / 09	Lika, K.; Kearney, M.; Freitas, V.; Van Der Veer, H.; Van Der Meer, J.; Wijsman, J.; Pecquerie, L.; Kooijman, S.	2011	The /covariation method/ for estimating the parameters of the standard Dynamic Energy Budget model I: Philosophy and approach Journal: Journal of Sea Research Year: 2011 Report No.: M-634477-01-1 Date: 2011-12-31 GLP/GEP: No, published	No	published
KCA 5.6.2 / 10	Villamor, E.; Jansen, E.	2016	Nutritional determinants of the timing of puberty Publisher: Annual Reviews Journal: Annual Review of Public Health Volume: 37 Pages: 33-46 Year: 2016 Report No.: M-634485-01-1 GLP/GEP: n.a., published	No	published
KCA 5.6.2 / 11	Soliman, A.; De Sanctis, V.; Elalaily, R.	2014	Nutrition and pubertal development Journal: Indian Journal of Endocrinology and Metabolism Volume: 18 Year: 2014 Report No.: M-634486-01-1 GLP/GEP: n.a., published	No	published
KCA 5.6.2 / 12	Marques, G.; Augustine, S.; Lika, K.; Pecquerie, L.; Domingos, T.; Kooijman, S.	2018	The AmP project: Comparing species on the basis of dynamic energy budget parameters Journal: PLoS Computational Biology Year: 2018 Report No.: M-634488-01-1 Date: 2018-08-20 GLP/GEP: No, published	No	published
KCA 5.6.2 / 13	Anon.	2008	Guidance document on mammalian reproductive toxicity and assessment - OECD 43 OECD - Organisation for Economic Co-operation and Development, Paris, France Bayer Report No.: M-645150-01-1 Date: 2008-07-24 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.7 / 01	[REDACTED]	1978	Ru 22974 (decamethrine) LD 50 determination and assessment of neurotoxicity in the domestic hen. [REDACTED] Bayer Report No.: A20307 Edition Number: M-093518-01-1 Date: 1978-01-19 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.7 / 02	[REDACTED]	1998	An acute neurotoxicity study of deltamethrin in rats. [REDACTED] Bayer Report No.: A74318 Edition Number: M-152563-01-1 Date: 1998-03-18 GLP/GEP: Yes, unpublished ... also filed: KCA 5.8 / 03	Yes	Bayer
KCA 5.7 / 03	Sargent, D. E.; Heusel, R.	2001	Aventis CropScience Response to RMS Review of the Acute Neurotoxicity Study Bayer Report No.: B003436 Edition Number: M-240464-01-1 Date: 2001-08-30 GLP/GEP: n.a., unpublished ... also filed: KCA 5.6 / 03 KCA 5.8 / 04	No	Bayer
KCA 5.7 / 04	[REDACTED]	1998	A subchronic (13-week) neurotoxicity study of deltamethrin in rats. [REDACTED] Bayer Report No.: A74317 Edition Number: M-152562-01-1 Date: 1998-03-19 GLP/GEP: Yes, unpublished ... also filed: KCA 5.8 / 02	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.7 / 05	[REDACTED]	1995	An acute neurotoxicity study of deltamethrin in rats. [REDACTED] Bayer Report No.: A74162 Edition Number: M-152413-01-1 Date: 1995-08-24 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.7 / 06	[REDACTED]	1996	A sub-chronic (13 weeks) neurotoxicity study of deltamethrin in rats. [REDACTED] Bayer Report No.: A74163 Edition Number: M-152414-01-1 Date: 1996-06-16 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.7 / 07	[REDACTED]	2006	An acute functional observational battery comparison study in rats [REDACTED] TF- Pyrethroid Report No.: 02-PWG-001 Edition Number: M-459034-01-1 Date: 2006-04-28 GLP/GEP: Yes, unpublished	Yes	TF- Pyrethroid
KCA 5.7.1 / 01	[REDACTED]	2006	A pilot study to verify the exposure of offspring during lactation to technical grade Deltamethrin administered via the diet to Wistar rats Bayer Report No.: 04-P72-VX Edition Number: M-276949-01-1 Date: 2006-04-03 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.7.1 / 02	[REDACTED]	2011	A developmental neurotoxicity screening study with technical grade deltamethrin in Wistar rats Bayer Report No.: 201469-2 Edition Number: M-270180-03-1 Date: 2006-04-03 ... amended: 2011-12-12 GLP/GEP: Yes, unpublished ... also filed: KCA 8.1.2.2 / 01	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.7.1 / 03	[REDACTED]	2009	Comparative functional observational battery study of twelve commercial pyrethroid insecticides in male rats following acute oral exposure Publisher: Elsevier Inc. Journal: Neurotoxicology : (Park Forest South), (2009) , 30(SUP), S1-S16, refs. 1/2 p. ISSN: 0161-813X Year: 2009 Report No.: M-463081-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.7.1 / 04	[REDACTED]	2018	Deltamethrin: Report on timing of preputial separation in the developmental neurotoxicity study Bayer Report No.: US0733 Edition Number: M-620177-01-1 Date: 2018-04-11 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.7.1 / 05	[REDACTED]	1992	Reproductive effects of deltamethrin administered orally in diet to CrI: CD BR VAF/Plus rats for two generations. (Vol.1/4). [REDACTED] Bayer Report No.: A70863 Edition Number: M-149348-01-1 Date: 1992-01-17 GLP/GEP: Yes, unpublished ... also filed: KCA 5.6.1 / 01	Yes	Bayer
KCA 5.7.1 / 06	[REDACTED]	2001	Evaluation of the male pubertal onset assay to detect testosterone and steroid biosynthesis inhibitors in CD rats Volume: 60 Pages: 285-295 Year: 2001 Report No.: M-292910-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.7.1 / 07	[REDACTED]	1977	Preputial separation as an external sign of pubertal development in the male rat Journal: Biology of Reproduction Volume: 17 Pages: 298-303 Year: 1977 Report No.: M-431115-01-1 GLP/GEP: n.a., published	Yes	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.7.1 / 08	Lazarini, C.; Lemonica, I.; Bernardi, M.; Habr, S.	2011	Prenatal deltamethrin low dose effects on physical development of rats. Journal: Pesticidas, Volume 17, Page 47-58, Publication Year 2007 Year: 2007 Report No.: M-462625-01-1 GLP/GEP: n.a., published	No	published
KCA 5.7.1 / 09	Ramirez, V.; Sawyer, C.	1965	Advancement of puberty in the female rat by estrogen Journal: Endocrinology Volume: 76 Pages: 1158-1168 Year: 1965 Report No.: M-645903-01-1 GLP/GEP: n.a., published	No	published
KCA 5.7.1 / 10	Saillenfait, A.; Ndiaye, D.; Sabate, J.; Denis, F.; Antoine, G.; Robert, A.; Rouiller-Fabre, V.; Moison, D.	2016	Evaluation of the effects of deltamethrin on the fetal rat testis Publisher: Wiley Online Library Journal: Journal of Applied Toxicology Volume: 36 Issue: 11 Pages: 1505-1515 Year: 2016 Report No.: M-646094-01-1 GLP/GEP: n.a., published	No	published
KCA 5.7.1 / 11	Marty, M.; Johnson, K.; Carney, E.	2003	Effect of feed restriction on Hershberger and pubertal male assay endpoints Publisher: Wiley-Liss, Inc. Journal: Birth Defects Research Part B - Developmental and Reproductive Toxicology Volume: 68 Issue: 4 Pages: 363-374 Year: 2003 Report No.: M-646095-01-1 GLP/GEP: n.a., published	No	published
KCA 5.7.1 / 12	Oconnor, J.; Cook, J.; Marty, M.; Davis, L.; Kaplan, A.; Carney, E.	2002	Evaluation of Tier I screening approaches for detecting endocrine-active compounds (EACs) Publisher: Taylor & Francis Journal: Critical Reviews in Toxicology Volume: 32 Issue: 6 Pages: 521-549 Year: 2002 Report No.: M-646096-01-1 GLP/GEP: n.a., published	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.7.1 / 13	Marty, M.; Crissman, J.; Carney, E.	2001	Evaluation of the male pubertal assays ability to detect thyroid inhibitors and dopaminergic agents Publisher: The Dow Chemical Company Journal: Toxicological Sciences Volume: 60 Issue: 1 Pages: 63-76 Year: 2001 Report No.: M-646098-01-1 GLP/GEP: n.a., published	No	published
KCA 5.7.1 / 14	Daston, G. P.; Kimmel, C. A.	1999	Endpoints of reproductive system development Publisher: International Life Sciences Institute Journal: Evaluation and Interpretation of Reproductive Endpoints for Human Health Risk Assessment Year: 1999 Report No.: M-646119-01-1 GLP/GEP: n.a., published	No	published
KCA 5.8 / 01	Leist, K. H.	1995	Pyrethroids, Toxicology: Structure-Activity Relationship Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Bayer Report No.: A74102 Edition Number: M-152355-01-1 Date: 1995-03-20 GLP/GEP: n.a., unpublished	No	Bayer
KCA 5.8 / 02		1998	A subchronic (13-week) neurotoxicity study of deltamethrin in rats. Bayer Report No.: A74317 Edition Number: M-152562-01-1 Date: 1998-03-19 GLP/GEP: Yes, unpublished ... also filed: KCA 5.7 / 04	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8 / 03		1998	An acute neurotoxicity study of deltamethrin in rats. Bayer Report No.: A74318 Edition Number: M-152563-01-1 Date: 1998-03-18 GLP/GEP: Yes, unpublished ... also filed: KCA 5.7 / 02	Yes	Bayer
KCA 5.8 / 04	Sargent, D. E.; Heusel, R.	2001	Aventis CropScience Response to RMS Review of the Acute Neurotoxicity Study Bayer Report No.: B003436 Edition Number: M-240464-01-1 Date: 2001-08-30 GLP/GEP: n.a., unpublished ... also filed: KCA 5.6 / 03 KCA 5.7 / 03	No	Bayer
KCA 5.8 / 05	Leist, K. H.	1994	Neurotoxicity of pyrethroids on developing animals Industrieverband Agrar e.V, Frankfurt am Main, Germany Report No.: MO-01-005485 Edition Number: M-047082-01-1 Date: 1994-06-14 GLP/GEP: No, unpublished	No	
KCA 5.8 / 06		1997	Neonatal neurotoxicity of pyrethroids (Review on data generated in different laboratories. Year: 1997 Report No.: A73552 Edition Number: M-151835-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 07	Muhammad, B. Y.; Ray, D. E.	1997	Report on the potential developmental neurotoxicity of pyrethroids in mice : Attempts to replicate the results of Eriksson's group on the developmental neurotoxicity of pyrethroids Report No.: A74192 Edition Number: M-152443-01-1 GLP/GEP: n.a., published ... also filed: KCA 5.6.2 / 03	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8 / 08	[REDACTED]	1998	Neurotoxic effects in adult mice neonatally exposed to 3,3',4,4'-pentachlorobiphenyl or 2,3,3',4,4'-penta-chlorobiphenyl. Changes in brain nicotinic receptors and behaviour Publisher: 1998 Elsevier Science B.V. Journal: Environmental Toxicology and Pharmacology Volume: 5 Pages: 17-27 Year: 1998 Report No.: M-450120-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 09	[REDACTED]	2000	Exposure to nicotine during a defined period in neonatal life induces permanent changes in brain nicotinic receptors and in behaviour of adult mice Publisher: Elsevier Journal: Brain Research Volume: 853 Pages: 41-48 Year: 2000 Report No.: M-449682-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 10	[REDACTED]	1998	Developmental neurotoxicity of brominated flame-retardants, polybrominated dephenyl ethers and tetra-bromo-bis-phenol A Publisher: Anon. Journal: Organohalogen Compounds Volume: 35 Issue: 9 Pages: 375-377 Year: 1998 Report No.: M-449808-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 11	[REDACTED]	2001	Brominated flame retardants: A novel class of developmental neurotoxicants in our environment? Journal: Environmental Health Perspectives Volume: 109 Issue: 9 Pages: 903-908 Year: 2001 Report No.: M-449787-01-1 GLP/GEP: n.a., published	Yes	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8 / 12	[REDACTED]	1999	PBDE, 2,2',4,4'-pentabromodiphenyl ether, causes permanent neurotoxic effects during a defined period of neonatal brain development Publisher: Anon. Journal: Organohalogen Compounds Volume: 40 Issue: 9 Pages: 333-336 Year: 1999 Report No.: M-449806-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 13	Anon.	2001	European Union risk assessment report - diphenyl ether, pentabromo derivative European Union, EU -public data- Report No.: M-449793-01-1 Date: 2001-12-31 GLP/GEP: n.a., unpublished	No	-public data-
KCA 5.8 / 14	[REDACTED]	1991	Neonatal nicotine exposure induces permanent changes in brain nicotinic receptors and behaviour in adult mice Publisher: Elsevier Journal: Developmental Brain Research Volume: 63 Pages: 201-207 Year: 1991 Report No.: A94728 Edition Number: M-169917-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 15	[REDACTED]	1983	Effects of DDT on muscarine- and nicotine-like binding sites in CNS of immature and adult mice Publisher: Elsevier Location: Amsterdam Journal: Toxicology Letters Volume: 22 Pages: 329-334 Year: 1984 Report No.: M-449730-01-1 GLP/GEP: n.a., published	Yes	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8 / 16	[REDACTED]	1986	The effects of DDT, DDOH-palmitic acid, and a chlorinated paraffin on muscarinic receptors and the sodium-dependent choline uptake in the central nervous system of immature mice Publisher: Academic Press Location: San Diego Journal: Toxicology and Applied Pharmacology Volume: 85 Pages: 121-127 Year: 1986 Report No.: M-449728-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 17	[REDACTED]	1989	Altered behaviour in adult mice exposed to a single low dose of DDT and its fatty acid conjugate as neonates Publisher: Elsevier Location: Amsterdam Journal: Brain Research Volume: 514 Pages: 141-142 Year: 1990 Report No.: M-449725-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 18	[REDACTED]	1990	Neonatal exposure to DDT and its fatty acid conjugate: Effects on cholinergic and behavioural variables in the adult mouse Publisher: Intox Press, Inc. Journal: NeuroToxicology Volume: 11 Pages: 345-354 Year: 1990 Report No.: M-449741-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 19	[REDACTED]	1992	Neuroreceptor and behavioral effects of DDT and pyrethroids in immature and adult mammals Publisher: Plenum Press Journal: The Vulnerable Brain and Environmental Risks Volume: 2 Pages: 235-251 Year: 1992 Report No.: M-449744-01-1 GLP/GEP: n.a., published	Yes	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8 / 20		1993	Neonatal exposure to DDT induces increased susceptibility to pyrethroid (bioallethrin) exposure at adult age - Changes in cholinergic muscarinic receptor and behavioural variables Publisher: Elsevier Scientific Publishers Ireland Ltd. Location: Amsterdam Journal: Toxicology Volume: 77 Pages: 21-30 Year: 1993 Report No.: A93798 Edition Number: M-168990-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 21		1996	Developmental neurotoxicity of four ortho-substituted polychlorinated biphenyls in the neonatal mouse Publisher: Elsevier Location: Amsterdam Journal: Environmental Toxicology and Pharmacology Volume: 1 Pages: 155-165 Year: 1996 Report No.: M-449692-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 22		1995	Neonatal exposure to 2,2',5,5'-tetrachlorobiphenyl causes increased susceptibility in the cholinergic transmitter system at adult age Publisher: Elsevier Location: Amsterdam Journal: Environmental Toxicology and Pharmacology Volume: 1 Pages: 217-220 Year: 1996 Report No.: M-449695-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 23		1997	Developmental neurotoxicity of environmental agents in the neonate Publisher: Intox Press, Inc. Location: USA Journal: NeuroToxicology Volume: 18 Pages: 719-726 Year: 1997 Report No.: M-449739-01-1 GLP/GEP: n.a., published	Yes	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8 / 24	[REDACTED]	2000	Neonatal exposure to neurotoxic pesticides increases adult susceptibility: A review of current findings Publisher: Intox Press, Inc. Location: USA Journal: NeuroToxicology Volume: 21 Issue: 1-2 Pages: 37-48 Year: 2000 Report No.: M-449742-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 25	[REDACTED]	1996	Low-dose effects of paraoxon in adult mice exposed neonatally to DDT: changes in behavioural and cholinergic receptor variables Publisher: Elsevier Location: Amsterdam Journal: Environmental Toxicology and Pharmacology Volume: 2 Pages: 307-314 Year: 1996 Report No.: M-449700-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 26	[REDACTED]	1994	Bioallethrin causes permanent changes in behavioural and muscarinic acetylcholine receptor variables in adult mice exposed neonatally to DDT Publisher: Elsevier Location: Amsterdam Journal: European Journal of Pharmacology Volume: 293 Pages: 159-166 Year: 1995 Report No.: M-449701-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 27	[REDACTED]	1997	Changes in behavior and muscarinic receptor density after neonatal and adult exposure to bioallethrin Publisher: Elsevier Location: New York Journal: Neurobiology of Aging Volume: 6 Pages: 545-552 Year: 1998 Report No.: M-449737-01-1 GLP/GEP: n.a., published	Yes	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8 / 28	[REDACTED]	1998	Differential expression of muscarinic subtype mRNAs after exposure to neurotoxic pesticides Publisher: Elsevier Location: New York Journal: Neurobiology of Aging Volume: 6 Pages: 553-559 Year: 1998 Report No.: M-449732-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 29	Lingk; Appel	1998	Protocol - Meeting on postnatal neurotoxicity of pyrethroids Federal Institute for Consumers Health Protection and Veterinary Medicine (BgVV), Berlin, Germany -public data- Report No.: M-449721-01-1 Date: 1998-03-17 GLP/GEP: n.a., unpublished	No	-public data-
KCA 5.8 / 30	Leist, K. H.	1997	Answers to the questions posed at the symposium entitled Neonatal toxicity of pyrethroids (11 November 1997) in Berlin AgrEvo, Hattersheim, Germany -public data- Report No.: M-449724-01-1 Date: 1997-12-23 GLP/GEP: n.a., unpublished	No	-public data-
KCA 5.8 / 31	[REDACTED]	1997	Evaluation of studies on the effects of neonatal exposure to allethrins Publisher: Anon. Journal: Anon. Pages: 1-12 Year: 1997 Report No.: M-449714-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 32	[REDACTED]	1997	Evaluation of studies on the effects of neonatal exposure to allethrins (including cyfluthrin and transfluthrin) Publisher: Anon. Journal: Anon. Pages: 1-18 Year: 1997 Report No.: M-449707-01-1 GLP/GEP: n.a., published	Yes	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8 / 33		1997	Evaluation of studies on the effects of neonatal exposure to allethrins Publisher: Anon. Journal: Anon. Pages: 1-18 Year: 1997 Report No.: M-449713-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 34	van den Berg, K. J.	1999	Pyrethroid neurotoxicity - Assessment of literature studies LivAdviescentrum Chamische Arbeidsomstanigheden -public data- Report No.: 99-090-H-251 Edition Number: M-449717-01-1 Date: 1999-12-06 GLP/GEP: n.a., unpublished	No	-public data-
KCA 5.8 / 35	Leist, K. H.	1998	IVA comments on the minutes of the meeting on postnatal toxicity of pyrethroids, 11 November 1997, BgVV, Berlin AgrEvo, Hattersheim, Germany Bayer Report No.: M-449719-01-1 Date: 1998-05-14 GLP/GEP: n.a., unpublished	No	Bayer
KCA 5.8 / 36	Gerhards, H.	1994	Neurotoxicity of pyrethroids Hoechst, Frankfurt am Main, Germany -public data- Report No.: M-449710-01-1 Date: 1994-02-14 GLP/GEP: n.a., unpublished	No	-public data-
KCA 5.8 / 37		1999	Expert panel report into possible neurotoxicity of allethrin vaporiser insecticides on neuronal development in mice: Implications for human health Publisher: Anon. Journal: Anon. Pages: 1-24 Year: 1999 Report No.: M-449703-01-1 GLP/GEP: n.a., published	Yes	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8 / 38	[REDACTED]	1995	Exposure to an organophosphate (DFP) during a defined period in neonatal life induces permanent changes in brain muscarinic receptors and behaviour in adult mice Publisher: Elsevier Science B.V. Journal: Brain Research Volume: 677 Pages: 13-19 Year: 1995 Report No.: M-450573-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 39	[REDACTED]	1983	RU 22974 - Investigation of possible neurological effects using the tilting plane test. [REDACTED] Bayer Report No.: A41890 Edition Number: M-124953-01-1 Date: 1983-05-05 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.8 / 40	[REDACTED]	1991	Neurotoxic effects of two different pyrethroids, bioallethrin and deltamethrin, on immature and adult mice: Changes in behavioral and muscarinic receptor variables Journal: Toxicology and Applied Pharmacology Volume: 108 Pages: 78-85 Year: 1991 Report No.: A71381 Edition Number: M-149821-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 41	[REDACTED]	1990	Effects of two pyrethroids, bioallethrin and deltamethrin, on subpopulations of muscarinic and nicotinic receptors in the neonatal mouse brain Journal: Toxicology and Applied Pharmacology Volume: 102 Pages: 456-463 Year: 1990 Report No.: A70738 Edition Number: M-149233-01-1 GLP/GEP: n.a., published	Yes	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8 / 42	[REDACTED]	1992	Acute intravenous toxicity study with Deltamethrin (preparation with PEG 300) in rats [REDACTED] Bayer Report No.: A49669 Edition Number: M-138700-01-1 Date: 1992-06-15 GLP/GEP: Yes, unpublished ... also filed: KCA 5.2.2 / 03	Yes	Bayer
KCA 5.8 / 43	[REDACTED]	1994	Age-dependent differences in the susceptibility of rats to deltamethrin Journal: Toxicology and Applied Pharmacology Volume: 126 Pages: 186-190 Year: 1994 Report No.: A72865 Edition Number: M-151164-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 44	[REDACTED]	1992	Acute intravenous toxicity study with Deltamethrin (preparation with PEG 300) in laying hens [REDACTED] Bayer Report No.: A49666 Edition Number: M-138697-01-1 Date: 1992-06-16 GLP/GEP: Yes, unpublished ... also filed: KCA 5.2.2 / 04	Yes	Bayer
KCA 5.8 / 45	Leist, K. H.; Strutt, A. V.	2001	Aventis CorpScience response to RMS review on developmental neurotoxicity Deltamethrin Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C014150 Edition Number: M-206060-01-1 Date: 2001-05-31 GLP/GEP: n.a., unpublished ... also filed: KCA 5.6.2 / 04	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8 / 46	[REDACTED]	1985	Changes in cerebral blood flow and glucose metabolism associated with symptoms of pyrethroid toxicity. Journal: Neurotoxicology Volume: 6 Issue: 3 Pages: 1;12 Year: 1985 Report No.: A71269 Edition Number: M-149732-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 47	[REDACTED]	1998	Perinatal developmental neurotoxicity of PCBs Publisher: Swedish Environmental Protection Agency Location: Sweden Year: 1998 Report No.: M-450684-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 48	[REDACTED]	1996	EIH report on perinatal developmental neurotoxicity Publisher: Institute for Environmental Health Report No.: M-451754-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 49	[REDACTED]	2001	Klinisch-neurologische und neurophysiologische Untersuchungen an professionellen Schädlingen- bekaempfern mit beruflicher Exposition gegenueber Pyrethroiden und anderen Pestiziden im Vergleich zu einer nicht exponierten Kontrollgruppe Publisher: BGVV Location: Germany Journal: BGVV-Hefte Pages: 1-46 Year: 2000 Report No.: M-453228-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 50	[REDACTED]	1994	Neonatal exposure to a Type-I pyrethroid (bioallethrin) induces dose-response changes in brain muscarinic receptors and behaviour in neonatal and adult mice Journal: Brain Research Volume: 645 Pages: 318;324 Year: 1994 Report No.: M-168988-02-1 GLP/GEP: n.a., published	Yes	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8 / 51	[REDACTED]	1992	Exposure to DDT during a defined period in neonatal life induces permanent changes in brain muscarinic receptors and behaviour in adult mice Journal: Brain Research Volume: 582 Pages: 277:281 Year: 1992 Report No.: M-169915-02-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 52	[REDACTED]	2005	Relative potencies for acute effects of pyrethroids on motor function in rats Publisher: Oxford University Press Journal: Toxicol. Sci., Volume 89, Issue 1, Page 271-277, Publication Year 2006 Year: 2006 Report No.: M-476568-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8 / 53	[REDACTED]	2005	Guidance on setting of acute reference dose (ARfD) for pesticides Publisher: Elsevier Ltd. Journal: Food and Chemical Toxicology Volume: 43 Pages: 1569-1593 Year: 2005 Report No.: M-476565-01-1 GLP/GEP: n.a., published	Yes	published
KCA 5.8.1 / 01	Durward, R.	1997	Bacterial reverse mutation assay (Ames Test) Becisthemic acid Code: RU23441 Safepharm Lab. Ltd., Derby, United Kingdom Bayer Report No.: A74229 Report includes Trial Nos.: TOX97103 Edition Number: M-152479-01-1 Date: 1997-10-22 GLP/GEP: Yes, unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8.1 / 02	[REDACTED]	1997	Mouse micronucleus test Becisthemic acid Code: RU23441 [REDACTED] Bayer Report No.: A74231 Report includes Trial Nos.: TOX97105 Edition Number: M-152481-01-1 Date: 1997-10-23 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.8.1 / 03	[REDACTED]	1997	Rat acute oral toxicity study Becisthemic acid Code: RU 23441 [REDACTED] Bayer Report No.: A74230 Report includes Trial Nos.: TOX97102 Edition Number: M-152480-01-1 Date: 1997-10-17 GLP/GEP: Yes, unpublished ... also filed: KCA 5.8.2 / 01	Yes	Bayer
KCA 5.8.1 / 04	Mousquès, A.	2013	Estimation of trans-isomer of deltamethrin exposure - Applicability of the TTC concept Bayer Report No.: M-448284-01-1 Date: 2013-02-04 GLP/GEP: n.a., unpublished	No	Bayer
KCA 5.8.1 / 05	[REDACTED]	2013	Trans isomer of deltamethrin - Acute oral toxicity study in rats [REDACTED] Bayer Report No.: 13/055-001P Edition Number: M-461316-01-1 Date: 2013-08-01 GLP/GEP: Yes, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8.1 / 06	Herbold, B.	2004	AE 0035073 00 1B97 0001 - Salmonella/microsome test - Plate incorporation and preincubation method Bayer Report No.: C040291 Report includes Trial Nos.: AT01051 Edition Number: M-228638-01-1 Date: 2004-03-02 GLP/GEP: Yes, unpublished	No	Bayer
KCA 5.8.1 / 07	Wollny, H. E.	2013	Gene mutation assay in Chinese hamster V79 cells in vitro (V79/HPRT) - Trans isomer of deltamethrin AE 0035073 Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer Report No.: 1549101 Edition Number: M-461312-01-1 Date: 2013-07-29 GLP/GEP: Yes, unpublished	No	Bayer
KCA 5.8.1 / 08	Bohnenberger, S.	2013	Trans isomer of deltamethrin AE 0035073: In vitro chromosome aberration test in Chinese hamster V79 cells Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer Report No.: 1549102 Edition Number: M-469011-01-1 Date: 2013-10-28 GLP/GEP: Yes, unpublished	No	Bayer
KCA 5.8.1 / 09	Mousques, A.	2016	Compilation of dRR tables for deltamethrin residue studies from 2009 onwards - Results displayed for cis-deltamethrin, trans isomer and alpha-R isomer Bayer Report No.: M-559648-01-1 Date: 2016-07-13 GLP/GEP: n.a., unpublished ... also filed: KCA 6.4 / 02	No	Bayer
KCA 5.8.1 / 10	Lasserre, D.; Christian, L.	2016	Deltamethrin - Additional information on metabolism and toxicology Bayer Report No.: M-559823-01-1 Date: 2016-07-06 GLP/GEP: n.a., unpublished	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8.1 / 11		2008	AE F108569 / Deltamethrin alpha-R-isomer acute toxicity in the rat after oral administration Bayer Report No.: AT04700 Edition Number: M-304957-01-1 Date: 2008-07-11 GLP/GEP: Yes, unpublished ... also filed: KCA 5.2.1 / 06	Yes	Bayer
KCA 5.8.1 / 12	Shipp, E.	2019	Deltamethrin - In silico assessment of the plant metabolite 3-phenoxybenzaldehyde Bayer Report No.: M-646818-01-1 Date: 2019-01-18 GLP/GEP: n.a., unpublished ... also filed: KCA 6.9 / 08	No	Bayer
KCA 5.8.1 / 13	Shipp, E.	2019	Regulatory toxicology - Position paper - Deltamethrin - In silico comparison of BrCA and Br2CA Bayer Report No.: M-646813-01-1 Date: 2019-01-18 GLP/GEP: n.a., unpublished	No	Bayer
KCA 5.8.2 / 01		1997	Rat acute oral toxicity study Becisthemic acid Code: RU 23441 Bayer Report No.: A74230 Report includes Trial Nos.: TOX97102 Edition Number: M-152480-01-1 Date: 1997-10-17 GLP/GEP: Yes, unpublished ... also filed: KCA 5.8.1 / 03	Yes	Bayer
KCA 5.8.2 / 02		2012	Deltamethrin - 28-day immunotoxicity study in the female Sprague-Dawley rat by dietary administration Bayer Report No.: SA 10360 Edition Number: M-428263-01-1 Date: 2012-03-12 GLP/GEP: Yes, unpublished	Yes	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8.2 / 03	[REDACTED]	2009	Deltamethrin: Plasma kinetic study in the male rat by gavage Bayer Report No.: SA 08235 Edition Number: M-356672-01-2 Date: 2009-09-25 GLP/GEP: Yes, unpublished	Yes	Bayer
KCA 5.8.2 / 04	[REDACTED]	2019	Deltamethrin - Toxicokinetic data Bayer Report No.: M-646790-01-1 Date: 2019-01-18 GLP/GEP: n.a., unpublished	Yes	Bayer
KCA 5.8.2 / 05	Osimitz, T.; Sheets, L.; Creek, M.; Hinderliter, P.; Brooks, M.; Moreau, M.; Song, G.; Philips, M.	2018	CAPHRA program overview: Evaluation of age-dependent sensitivity to pyrethroid insecticides TF- Pyrethroid Report No.: M-637253-01-1 Date: 2018-06-15 GLP/GEP: No, unpublished	No	TF- Pyrethroid
KCA 5.8.2 / 06	[REDACTED]	2015	Toxicokinetic assessment of blood and tissue deltamethrin concentrations following the administration of a single oral dose to mature rats [REDACTED] Report No.: UGA-TK-1 Edition Number: M-639283-01-1 Date: 2015-02-08 GLP/GEP: No, unpublished	Yes	TF- Pyrethroid
KCA 5.8.2 / 07	[REDACTED]	2016	Deltamethrin: Assessment of age differences in rat plasma protein binding [REDACTED] Report No.: UGA-PB-2 Edition Number: M-639584-01-1 Date: 2016-01-12 GLP/GEP: Yes, unpublished	Yes	TF- Pyrethroid

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8.2 / 08	██████	2016	Investigation of blood brain barrier transport of deltamethrin ██ ██ Report No.: 49817603 Edition Number: M-639585-01-1 Date: 2016-01-13 GLP/GEP: No, unpublished	Yes	TF- Pyrethroid
KCA 5.8.2 / 09	██████	2016	Investigation of the potential role of gastrointestinal membrane transporters in deltamethrin absorption ██ ██ Report No.: 49817604 Edition Number: M-639586-01-1 Date: 2016-01-13 GLP/GEP: No, unpublished	Yes	TF- Pyrethroid
KCA 5.8.2 / 10	██████	2015	Deltamethrin: Assessment of age differences in human plasma protein binding ██ ██ Report No.: 49817605 Edition Number: M-639587-01-1 Date: 2015-01-12 GLP/GEP: No, unpublished	Yes	TF- Pyrethroid
KCA 5.8.2 / 11	██████████	2016	Deltamethrin: Assessment of partition coefficients ██ ██ Report No.: 4984076 Edition Number: M-639591-01-1 Date: 2016-01-20 GLP/GEP: Yes, unpublished	Yes	TF- Pyrethroid

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8.2 / 12	[REDACTED]	2016	Deltamethrin and cis- and trans-permethrin: Studies on the kinetics of deltamethrin and cis- and trans-permethrin metabolism by rat and human liver microsomes [REDACTED] Report No.: LFR-5503/2 Edition Number: M-639647-01-1 Date: 2016-04-12 GLP/GEP: Yes, unpublished	Yes	TF- Pyrethroid
KCA 5.8.2 / 13	[REDACTED]	2016	Toxicokinetic assessment of blood and tissue deltamethrin concentrations following the administration of a single oral dose to 15-day-old pups [REDACTED] Report No.: UGA-TK-3 Edition Number: M-639649-01-1 Date: 2016-02-08 GLP/GEP: Yes, unpublished	Yes	TF- Pyrethroid
KCA 5.8.2 / 14	[REDACTED]	2016	Toxicokinetic assessment of blood and tissue deltamethrin concentrations following the administration of a single oral dose to 21-day-old pups [REDACTED] Report No.: UGA-TK-2 Edition Number: M-639650-01-1 Date: 2016-02-08 GLP/GEP: Yes, unpublished	Yes	TF- Pyrethroid
KCA 5.8.2 / 15	[REDACTED]	2017	Investigation into the in vivo association of 14-C-deltamethrin with rat plasma lipoproteins [REDACTED] Report No.: CXR1698 Edition Number: M-639757-01-1 Date: 2017-04-20 GLP/GEP: No, unpublished	Yes	TF- Pyrethroid

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8.2 / 16	[REDACTED]	2017	Association of 14-C-deltamethrin to rat lipoproteins in vitro [REDACTED] Report No.: CXR1668 Edition Number: M-639758-01-1 Date: 2017-04-14 GLP/GEP: No, unpublished	Yes	TF- Pyrethroid
KCA 5.8.2 / 17	[REDACTED]	2016	Determination of human hepatic ces1 and ces2 age-dependent developmental expression patterns in postnatal ages birth to 18 years [REDACTED] Report No.: MCS-120601-1 Edition Number: M-639762-01-1 Date: 2016-04-12 GLP/GEP: No, unpublished	Yes	TF- Pyrethroid
KCA 5.8.2 / 18	[REDACTED]	2016	Deltamethrin: Determination of rates of metabolism of deltamethrin by tissue preparations from 15, 21 and 90 day old rats [REDACTED] Report No.: LFR-5503/6 Edition Number: M-639763-01-1 Date: 2016-04-12 GLP/GEP: No, unpublished	Yes	TF- Pyrethroid
KCA 5.8.2 / 19	[REDACTED]	2016	Deltamethrin: comparison of rates of metabolism of deltamethrin by rat hepatocytes and liver subcellular fraction [REDACTED] Report No.: LFR-5503-5 Edition Number: M-639764-01-1 Date: 2016-05-02 GLP/GEP: No, unpublished	Yes	TF- Pyrethroid
KCA 5.8.2 / 20	[REDACTED]	2018	Deltamethrin: A study to determine the kinetics of metabolism of deltamethrin in rat and human plasma, rat and human liver microsomes and rat and human liver Cytosol - Final report amendment 1 CXR1574-I [REDACTED] Report No.: 50600304 Edition Number: M-639929-01-1 Date: 2018-05-31 GLP/GEP: Yes, unpublished	Yes	TF- Pyrethroid

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.8.2 / 21	Golka, I.	2019	Epimerization of deltamethrin (AE F032640) and the alpha-r-isomer (AE F108569) Bayer Report No.: AF19/002 Edition Number: M-646758-01-1 Date: 2019-01-17 GLP/GEP: n.a., unpublished ... also filed: KCA 1.9 / 05	No	Bayer
KCA 5.8.2 / 22	Shipp, E.	2019	Regulatory toxicology - Position paper - Deltamethrin - In silico assessment of specific impurities Bayer Report No.: M-646814-01-1 Date: 2019-01-18 GLP/GEP: n.a., unpublished confidential	No	Bayer
KCA 5.8.3 / 01	[REDACTED]	2006	Assessment of deltamethrin (pyrethroid insecticide) in relation to endocrine disruption Bayer Report No.: M-263733-01-1 Date: 2006-01-16 GLP/GEP: n.a., unpublished	Yes	Bayer
KCA 5.9 / 01	[REDACTED]	1985	Etude de l'efficacite d'une creme a l'alphatocopherol sur l'irritation provoquee par l'application cutanee de deltamethrine. [REDACTED] Bayer Report No.: A70888 Edition Number: M-149372-01-1 Date: 1985-08-01 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.9 / 02	Anon.	1989	Deltamethrin health and safety guide Journal: IPCS International Programme on Chemical Safety Volume: 30 Pages: 1-33 Year: 1989 Report No.: A46424 Edition Number: M-130468-01-1 GLP/GEP: n.a., published	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.9.1 / 01	[REDACTED]	1994	Donnees medicales concernant la deltamethrine. [REDACTED] Bayer Report No.: A70883 Edition Number: M-149367-01-1 Date: 1994-11-18 GLP/GEP: n.a., unpublished	Yes	Bayer
KCA 5.9.1 / 02	[REDACTED]	1994	Cutaneous subjective sensations: Pyrethroids handling in the Roussel Uclaf plants in France for 10 years. Report from occupational medical survey. [REDACTED] Bayer Report No.: A70823 Edition Number: M-149311-01-1 Date: 1994-08-09 GLP/GEP: n.a., unpublished	Yes	Bayer
KCA 5.9.2 / 01	[REDACTED]	1979	Report on the case of Decis poisoning. [REDACTED] Bayer Report No.: A71234 Edition Number: M-149701-01-1 Date: 1979-01-25 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.9.2 / 02	[REDACTED]	1987	Bilan du Decis dans l'activite du Centre anti-poison de Marseille [REDACTED] Bayer Report No.: A71237 Edition Number: M-149704-01-1 Date: 1987-01-01 GLP/GEP: n.a., unpublished	Yes	Bayer
KCA 5.9.2 / 03	He, F.; Wang, S.; Liu, L.; Chen, S.; Zhang, Z.; Sun, J.	1989	Clinical manifestations and diagnosis of acute pyrethroid poisoning Journal: Archives of Toxicology Volume: 63 Pages: 54-58 Year: 1989 Report No.: A71235 Edition Number: M-149702-01-1 GLP/GEP: n.a., published	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.9.2 / 04	Hermouet, C.	1992	Traitement de l'intoxication aigue a la deltamethrine par l'atropine et/ou le diazepam. Roussel Uclaf, Romainville, France Bayer Report No.: A70988 Edition Number: M-149469-01-1 Date: 1992-12-09 GLP/GEP: No, unpublished ... also filed: KCA 5.9.5 / 01	No	Bayer
KCA 5.9.2 / 05	[REDACTED]	1992	Intoxications par la deltamethrine: 84 cas notifies au Centre Anti Poisons de Paris de 1988 a 1992. [REDACTED] Report No.: A72704 Edition Number: M-151005-01-1 Date: 1992-01-01 GLP/GEP: No, unpublished	Yes	
KCA 5.9.3 / 01	[REDACTED]	1981	An operator study with deltamethrin including measurements of nerve conduction times. [REDACTED] Bayer Report No.: A41943 Edition Number: M-125000-01-1 Date: 1981-11-01 GLP/GEP: No, unpublished	Yes	Bayer
KCA 5.9.3 / 02	Delemotte, B.; Foulhoux, P.; Nguyen, S. N.; Fages, J.; Portos, J. L.	1987	Le risque pesticide en agriculture. Journal: Archives Maladies Professionnelles Medecine Travail et Securite Sociale (Paris) Volume: 48 Issue: 6 Pages: 467-475 Year: 1987 Report No.: A70766 Edition Number: M-149260-01-1 GLP/GEP: n.a., published	No	published
KCA 5.9.3 / 03	He, F.; Sun, J.; Han, K.; Wu, Y.; Yao, P.; Wang, S.; Liu, L.	1988	Effects of pyrethroid insecticides on subjects engaged in packaging pyrethroids Journal: British Journal of Industrial Medicine Volume: 45 Pages: 548-551 Year: 1988 Report No.: A70850 Edition Number: M-149335-01-1 GLP/GEP: n.a., published	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.9.3 / 04	Shujie, W.; Qinglang, Z.; Lan, Y.; Bohong, X.; Yurui, L.	1988	Health survey among farmers exposed to deltamethrin in the cotton fields Journal: Ecotoxicology and Environmental Safety Issue: 15 Pages: 1-6 Year: 1988 Report No.: A41945 Edition Number: M-125002-01-1 GLP/GEP: n.a., published	No	published
KCA 5.9.3 / 05	Lisi, P.	1992	Sensitization risk of pyrethroid insecticides. Journal: Contact Dermatitis Volume: 26 Pages: 349-350 Year: 1992 Report No.: A70889 Edition Number: M-149373-01-1 GLP/GEP: n.a., published	No	published
KCA 5.9.3 / 06	Zou, J. F.; Bai, J.; Sun, S. Q.	2007	One case of acute athetosis induced by benzene and deltamethrin poisoning Journal: Chin J. Ind Hyg Occup Dis Volume: 25 Issue: 10 Pages: 615-616 Year: 2007 Report No.: M-476525-01-2 GLP/GEP: n.a., published	No	published
KCA 5.9.3 / 07	Martínez-Navarrete, J.; Loria-Castellanos, J.; Nava-Ocampo, A. A.	2008	Accidental poisoning with Chinese chalk Publisher: Mattioli 1885 Journal: Acta Bio Med. Atenei Parmensis, Volume 79, Issue 1, Page 36-38, Publication Year 2008 Year: 2008 Report No.: M-476804-01-1 GLP/GEP: n.a., published	No	published
KCA 5.9.3 / 08	Diddee, S.; Aggarwal, R.	2009	Organophosphate or organochlorines or something else....? Publisher: Medknow Publications Location: http://www.ijccm.org/backissues.asp Journal: Indian Journal of Critical Care Medicine, Volume 13, Number 1, 2009 Pages: 31-33 Year: 2009 Report No.: M-476294-01-1 GLP/GEP: n.a., published	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.9.3 / 09	Rai, K.; Arora, A.; Ghosh, S.; Ahlawat, A.	2009	An unusual cause of status epilepticus. Publisher: Medknow Publications Location: http://www.ijccm.org/backissues.asp Journal: Indian Journal of Critical Care Medicine, Volume 13, Number 2, 2009 Pages: 106-107 Year: 2009 Report No.: M-476295-01-1 GLP/GEP: n.a., published	No	published
KCA 5.9.3 / 10	Magdalan, J.; Zawadzki, M.; Merwid-Lad, A.	2009	Fatal intoxication with hydrocarbons in deltamethrin preparation Publisher: SAGE Location: http://het.sagepub.com/content/28/12.toc Journal: Human and Experimental Toxicology, Volume 28, Issue 12, 2009 Pages: 791 -793 Year: 2009 Report No.: M-476302-01-1 GLP/GEP: n.a., published	No	published
KCA 5.9.3 / 11	Eken, C.; Kecec, Z.; Cete, Y.; Demiryurek, A.; Gunay, N.	2010	Oral deltamethrin ingestion due in a suicide attempt. Publisher: AEPress, s.r.o. Location: http://bmj.fmed.uniba.sk/2010/11105-13.pdf Journal: Bratislavské lekárske listy, Volume 111, Issue 5, 2010 Pages: 303-305 Year: 2010 Report No.: M-476303-01-1 GLP/GEP: n.a., published	No	published
KCA 5.9.3 / 12	Sams, C.; Jones, K.	2011	Biological monitoring for exposure to deltamethrin: A human oral dosing study and background levels in the UK general population. Publisher: Elsevier Location: http://www.sciencedirect.com/science/journal/03784274/213/1 Journal: Toxicology Letters, Volume 213, Issue 1, August 2012 Pages: 35-38 Year: 2011 Report No.: M-476774-01-1 GLP/GEP: n.a., published	No	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.9.4 / 01	Yao, P.; Li, Y.; Ding, Y.; He, F.	1992	Biological monitoring of deltamethrin in sprayers by HPLC method Journal: Journal of Hygiene, Epidemiology, Microbiology and Immunology Volume: 36 Issue: 1 Pages: 31-36 Year: 1992 Report No.: A71232 Edition Number: M-149699-01-1 GLP/GEP: n.a., published	No	published
KCA 5.9.4 / 02	Ding, B. M.; Gong, J. X.; Bao, Z. F.	2008	Analysis of the status of pesticide poisoning in Jiangsu province in 2006 Journal: Xiandai Yufang Yixue, Volume 35, Issue 11, Page 2118-2120, Publication Year 2008 Year: 2008 Report No.: M-462640-01-1 GLP/GEP: n.a., published	No	published
KCA 5.9.4 / 03	Bradberry, S. M.; Cage, S. A.; Proudfoot, A. T.; Vale, J. A.	2005	Poisoning due to pyrethroids Publisher: Adis Data Information BV. Journal: Toxicological Reviews (2005) Volume 24, Number 2, pp. 93-106 ISSN: 1172-2551 Published by: Adis International Ltd, Auckland URL: http://pt.wkhealth.com/pt/re/tox/abstract.00139709-200524020-00003.htm sessionid equals FIQX0tm0sh010s3JNCKQxnckWsKffMN9Tc5GWB Year: 2005 Report No.: M-462619-01-1 GLP/GEP: n.a., published	No	published
KCA 5.9.4 / 04	Burns, C. J.; Pastoor, T. P.	2017	Literature review and interpretation of epidemiology and exposure studies specific to pyrethroid insecticides: Pyrethroid working group phase II report Burns Epidemiology Consulting, LLC, USA TF- Pyrethroid Report No.: M-594914-01-1 Date: 2016-11-01 GLP/GEP: No, unpublished	No	TF- Pyrethroid
KCA 5.9.4 / 05	[REDACTED]	2018	Pyrethroid epidemiology: a quality-based review Publisher: https://www.bordeaux.inra.fr/cherry/docs/dossiers/Activities Journal: none Issue: 2 Year: 2016 Report No.: M-613446-01-1 GLP/GEP: n.a., published	Yes	published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 5.9.5 / 01	Hermouet, C.	1992	Traitement de l'intoxication aigue a la deltamethrine par l'atropine et/ou le diazepam. Roussel Uclaf, Romainville, France Bayer Report No.: A70988 Edition Number: M-149469-01-1 Date: 1992-12-09 GLP/GEP: No, unpublished ... also filed: KCA 5.9.2 / 04	No	Bayer
KCA 5.9.5 / 02	██████████	1992	Lettre interne sur l'efficacité des médicaments et crèmes différentes chez des gens avec des paresthesia.t ████████████████████ Bayer Report No.: A70989 Edition Number: M-149470-01-1 Date: 1992-09-21 GLP/GEP: n.a., unpublished	Yes	Bayer
KCA 5.9.5 / 03	██████	2009	Fourth national report on human exposure to environmental chemicals Publisher: Department of Health and Human Services Centers for Disease Year: 2009 Report No.: M-475775-01-1 GLP/GEP: n.a., published	Yes	published

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.1.1 /01	████████	2012	[Pyridinylmethyl-14C]BYI 02960 - Absorption, distribution, excretion, and metabolism in the rat Bayer CropScience, Report No.: MEF-11/747, Edition Number: M-422210-01-1 EPA MRID No.: 48844141 Date: 2012-01-12 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.1.1 /02	████████	2011	Quantitative whole body autoradiography of [pyridinylmethyl-14C]BYI 02960 in male and female rats: Distribution of total radioactivity and elimination from blood, organs and tissues after single oral administration including determination of radioactivity in the excreta and exhaled 14CO2 Bayer CropScience, Report No.: MEF-11/276, Edition Number: M-409993-01-2 EPA MRID No.: 48844142 Date: 2011-05-30 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.1.2 /01	████████	2011	[Furanone-4-14C]BYI 02960 - Absorption, distribution, excretion, and metabolism in the rat Bayer CropScience, Report No.: MEF-11/556, Edition Number: M-421499-01-1 EPA MRID No.: 48844143 Date: 2011-12-22 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.1.2 /02	████████	2011	Quantitative whole body autoradiography of [furanone-4-14C]BYI 02960 in male and female rats: Distribution of total radioactivity and elimination from blood, organs and tissues after single oral administration including determination of radioactivity in the excreta and exhaled 14CO2 Bayer CropScience, Report No.: MEF-11/275, Edition Number: M-409859-01-2 EPA MRID No.: 48844144 Date: 2011-05-30 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.1.2 /03	██████	2011	[Furanone-4-14C]BYI 02960 - Metabolism in organs and tissues of male and female rats Bayer CropScience, Report No.: MEF-11/271, Edition Number: M-414034-02-2 EPA MRID No.: 48844145 Date: 2011-09-12 ...Amended: 2012-02-02 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.1.3 /01	██████	2011	[Ethyl-1-14C]BYI 02960 - Absorption, distribution, excretion, and metabolism in male rats Bayer CropScience, Report No.: MEF-11/555, Edition Number: M-415647-01-1 EPA MRID No.: 48844146 Date: 2011-10-10 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.1.3 /02	██████	2011	[Ethyl-1-14C]BYI 02960 - Metabolism in organs and tissues of male and female rats (3 time-points) Bayer CropScience, Report No.: MEF-11/270, Edition Number: M-415416-02-1 EPA MRID No.: 48844147 Date: 2011-09-29 ...Amended: 2012-02-02 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.2.1 /01	██████	2009	BYI 02960 - Acute toxicity in the rat after oral administration ████████████████████ Bayer CropScience, Report No.: AT05287, Edition Number: M-349992-01-2 EPA MRID No.: 48844101 Date: 2009-06-08 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.2.2 /01	██████	2009	BYI 02960 - Acute toxicity in the rat after dermal administration ████████████████████ Bayer CropScience, Report No.: AT05288, Edition Number: M-349995-01-2 EPA MRID No.: 48844104 Date: 2009-06-08 GLP/GEP: yes, unpublished	Y	Bayer

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KIIA 5.2.3 /01	████████	2010	BYI 02960 - Activity ID TXRVP033 - Acute inhalation toxicity in rats ████████████████████ Bayer CropScience, Report No.: AT05727, Edition Number: M-362791-01-2 EPA MRID No.: 48844105 Date: 2010-01-07 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.2.4 /01	████████	2009	BYI 02960 - Acute skin irritation/corrosion on rabbits ████████████████████ Bayer CropScience, Report No.: AT05342, Edition Number: M-353761-01-2 EPA MRID No.: 48844107 Date: 2009-07-08 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.2.5 /01	████████	2009	BYI 02960 - Acute eye irritation on rabbits ████████████████████ Bayer CropScience, Report No.: AT05341 A, Edition Number: M-361319-02-2 EPA MRID No.: 48844106 Date: 2009-07-08 ...Amended: 2009-10-29 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.2.6 /01	████████	2009	BYI 02960 - Local lymph node assay in mice (LLNA/IMDS) ████████████████████ Bayer CropScience, Report No.: AT05334, Edition Number: M-353715-01-2 EPA MRID No.: 48844108 Date: 2009-06-29 GLP/GEP: yes, unpublished	Y	Bayer

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

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.3.7 /01		2012	A subacute dermal toxicity study in rats with BYI 02960 Bayer CropScience, Report No.: 11-S22-US, Edition Number: M-432336-01-1 EPA MRID No.: 48844115 Date: 2012-06-05 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.4.1 /01	Herbold, B.	2009	BYI 02960 (tested as BYI 02960 technical) (project: BYI 02960) - Salmonella/microsome test plate incorporation and preincubation method Bayer Schering Pharma AG, Wuppertal, Germany Bayer CropScience, Report No.: AT05387, Edition Number: M-354173-01-2 EPA MRID No.: 48844124 Date: 2009-07-24 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.4.1 /02	Sokolowski, A.	2011	1st amendment to report Salmonella typhimurium reverse mutation assay with BYI 02960 Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1425802, Edition Number: M-420539-02-2 EPA MRID No.: 48844125 Date: 2011-09-23 ...Amended: 2011-10-17 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.4.2 /01	Thum, M.	2009	BYI 02960 (tested as BYI 02960 technical) - In vitro chromosome aberration test with chinese hamster V79 cells Bayer Schering Pharma AG, Wuppertal, Germany Bayer CropScience, Report No.: AT05626, Edition Number: M-359746-01-2 EPA MRID No.: 48844131 Date: 2009-11-11 GLP/GEP: yes, unpublished	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.4.3 /01	Entian, G.	2009	BYI 02960 (tested as BYI 02960 technical) (project: BYI 02960) - V79/HPRT test in vitro for the detection of induced forward mutations Bayer Schering Pharma AG, Wuppertal, Germany Bayer CropScience, Report No.: AT05625, Edition Number: M-359743-01-2 EPA MRID No.: 48844128 Date: 2009-10-29 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.4.4 /01	██████████	2009	BYI 02960 - Micronucleus-test on the male mouse ██ Bayer CropScience, Report No.: AT05350, Edition Number: M-353785-01-2 EPA MRID No.: 48844134 Date: 2009-07-09 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.4.4 /02	██████████	2011	Micronucleus assay in bone marrow cells of the mouse with BYI 02960-a.i. ██ Bayer CropScience, Report No.: 1425801, Edition Number: M-420536-01-2 EPA MRID No.: 48844135 Date: 2011-11-10 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.5.2 /01	██████████	2012	BYI 02960 - Chronic toxicity and carcinogenicity study in the Wistar rat by dietary administration ██ Bayer CropScience, Report No.: SA 08337, Edition Number: M-428257-01-1 EPA MRID No.: 48844123 Date: 2012-03-05 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.5.3 /01	[REDACTED]	2012	BYI 02960 - Carcinogenicity study in the C57BL/6J mouse by dietary administration [REDACTED] Bayer CropScience, Report No.: SA 08338, Edition Number: M-425975-01-1 EPA MRID No.: 48844122 Date: 2012-02-24 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.6.1 /01	[REDACTED]	2010	Technical grade BYI 02960: A dose range-finding reproductive toxicity study in the Wistar rat [REDACTED] Bayer CropScience, Report No.: 09-P72-RB, Edition Number: M-394208-01-2 EPA MRID No.: 48844120 Date: 2010-11-01 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.6.1 /02	[REDACTED]	2011	Technical grade BYF 02960: A two-generation reproductive toxicity study in the Wistar rat [REDACTED] Bayer CropScience, Report No.: 09-R72-SA, Edition Number: M-417665-01-2 EPA MRID No.: 48844119 Date: 2011-10-17 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.6.10 /01	[REDACTED]	2010	BYI 02960: Developmental toxicity study in the rat by gavage [REDACTED] Bayer CropScience, Report No.: SA 08347, Edition Number: M-363938-01-2 EPA MRID No.: 48844116 Date: 2010-02-22 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.6.10 /02	[REDACTED]	2012	BYI 02960 - Complementary maternal tolerability study in the pregnant Sprague-Dawley rat by gavage [REDACTED] Bayer CropScience, Report No.: SA 11140, Edition Number: M-425810-01-2 EPA MRID No.: 48844118 Date: 2012-02-21 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.6.11 /01	[REDACTED]	2012	BYI 02960 - Developmental toxicity study in the rabbit by gavage [REDACTED] Bayer CropScience, Report No.: SA 10314, Edition Number: M-423559-01-1 EPA MRID No.: 48844117 Date: 2012-01-26 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.7.1 /01	[REDACTED]	2011	BYI 02960 - An acute neurotoxicity study in the rat by oral administration [REDACTED] Bayer CropScience, Report No.: SA 10096, Edition Number: M-415408-01-4 Date: 2011-09-30 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.7.4 /01	[REDACTED]	2011	BYI 02960 - A 90-day neurotoxicity study in the rat by dietary administration [REDACTED] Bayer CropScience, Report No.: SA 09283, Edition Number: M-410022-01-2 EPA MRID No.: 48844139 Date: 2011-06-28 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.7.5 /01	[REDACTED]	2012	A developmental neurotoxicity study with technical grade BYI 02960 in Wistar rats [REDACTED] Bayer CropScience, Report No.: 11-D72-UW, Edition Number: M-434203-01-1 EPA MRID No.: 48844140 Date: 2012-07-09 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.8 /01	Sokolowski, A.	2010	First amendment to report - Salmonella typhimurium reverse mutation assay with BCS-AA56716 (metabolite of BYI 02960) Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1351101, Edition Number: M-409724-02-1 Date: 2010-09-30 ...Amended: 2013-03-27 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.8 /02	Hall, C.	2010	BCS-AA56716 (metabolite of BYI 02960) - In vitro chromosome aberration test in Chinese hamster V79 cells Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1351103, Edition Number: M-409726-01-2 EPA MRID No.: 48844132 Date: 2010-12-15 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.8 /03	Wollny, H. E.	2010	First amendment to report - BCS-AA56716 (metabolite of BYI 02960) - Gene mutation assay in Chinese hamster V79 cells in vitro (V79 / HPRT) Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1351102, Edition Number: M-409727-02-1 Date: 2010-12-20 ...Amended: 2013-03-27 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.8 /04		2010	BCS-AA56716 - Acute oral toxicity in rats - Acute toxic class method Bayer CropScience, Report No.: 37066 TAR, Edition Number: M-393372-01-2 EPA MRID No.: 48844102 Date: 2010-10-22 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.8 /05	[REDACTED]	2011	BCS-AA56716 (difluoroacetic acid): Preliminary 14-day toxicity study in the rat by dietary administration [REDACTED] Bayer CropScience, Report No.: SA 10323, Edition Number: M-414152-01-2 EPA MRID No.: 48844153 Date: 2011-09-19 GLP/GEP: no, unpublished	Y	Bayer
KIIA 5.8 /06	[REDACTED]	2012	BCS-AA56716 (Difluoroacetic acid) - 90-day toxicity study in the rat by dietary administration [REDACTED] Bayer CropScience, Report No.: SA 10324, Edition Number: M-424611-01-2 EPA MRID No.: 48844113 Date: 2012-02-02 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /07	Sokolowski, A.	2011	Salmonella typhimurium reverse mutation assay with BYI 02960-difluoroethyl-amino-furanone (metabolite of byi-02960) Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1399701, Edition Number: M-409728-01-2 EPA MRID No.: 48844127 Date: 2011-05-24 GLP/GEP: no, unpublished	N	Bayer
KIIA 5.8 /08	Hall, C.	2010	BYI 02960-difluoroethyl-amino-furanone (metabolite of BYI 02960) - In vitro chromosome aberration test in Chinese hamster V79 cells Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1399703, Edition Number: M-420108-01-2 EPA MRID No.: 48844133 Date: 2010-10-07 GLP/GEP: no, unpublished	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.8 /09	Hall, C.	2010	BYI 0960-difluoroethyl-amino-furanone (metabolite of BYI 02960) - Gene mutation assay in Chinese hamster V79 cells in vitro (V79 / HPRT) Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience, Report No.: 1399702, Edition Number: M-420095-01-2 EPA MRID No.: 48844130 Date: 2010-12-20 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.8 /10	██████	2011	Micronucleus assay in bone marrow cells of the mouse with BYI 02960-difluoroethyl-aminofuranone (metabolite of BYI 02960) ██ Bayer CropScience, Report No.: M-420540-01-2 , Edition Number: M-420540-01-2 EPA MRID No.: 48844136 Date: 2011-11-28 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /11	██████	2011	In vivo unscheduled DNA synthesis in rat hepatocytes with BYI 02960-difluoroethyl-amino-furanone (metabolite of BYI 02960) ██ Bayer CropScience, Report No.: 1421402, Edition Number: M-420111-01-2 EPA MRID No.: 48844137 Date: 2011-10-26 GLP/GEP: no, unpublished	Y	Bayer
KIIA 5.8 /12	██████	2011	BYI-02960-difluoroethyl-amino-furanone acute oral toxicity in rats acute toxic class method ██ Bayer CropScience, Report No.: 37503 TAR, Edition Number: M-409674-01-2 EPA MRID No.: 48844103 Date: 2011-05-19 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.8 /13	[REDACTED]	2012	BYI 02960-difluoroethyl aminofuranone: A 14-day dose range finding toxicity/palatability study in rats [REDACTED] Bayer CropScience, Report No.: 11/116-100PE, Edition Number: M-426158-01-2 EPA MRID No.: 48844109 Date: 2012-02-24 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /14	[REDACTED]	2012	BYI 02960-difluoroethyl aminofuranone: A 28-day dietary toxicity study in wistar rats [REDACTED] Bayer CropScience, Report No.: 11/116-100P, Edition Number: M-426136-01-2 EPA MRID No.: 48844110 Date: 2012-02-29 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /15	Nobuo, M.; Yukihiro, K.	1997	Reverse mutation study on bacteria IM-0 Nippon Soda Co., Ltd., Odawara Reseach Center, Japan Nippon Soda, Report No.: G-949, Report includes Trial Nos.: 9862 Edition Number: M-195904-01-2 EPA MRID No.: 44988432 Date: 1997-09-30 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.8 /16	[REDACTED]	1997	Acute oral toxicity study in rats IM-0 [REDACTED] Nippon Soda, Report No.: G-0887, Report includes Trial Nos.: 3662 Edition Number: M-195899-01-2 EPA MRID No.: 44988421 Date: 1997-09-30 GLP/GEP: yes, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.8 /17	[REDACTED]	1997	Thirteen-week dietary subchronic toxicity study in rats IM-0 [REDACTED] Report No.: G-0889, Report includes Trial Nos.: 0259 Edition Number: M-195901-01-2 EPA MRID No.: 44988427 Date: 1997-11-28 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.8 /18	Nobuo, M.; Yukihiro, K.	1997	Reverse mutation study on bacteria IC-0 Nippon Soda Co., Ltd., Odawara Reseach Center, Japan Nippon Soda, Report No.: G-942, Report includes Trial Nos.: 9854 Edition Number: M-195932-01-2 EPA MRID No.: 44988502 Date: 1997-09-30 GLP/GEP: yes, unpublished	N	Bayer
KIIA 5.8 /19	[REDACTED]	1997	Acute oral toxicity study in rats IC-0 [REDACTED] Report No.: G-0941, Report includes Trial Nos.: 3686 Edition Number: M-195930-01-2 EPA MRID No.: 44988420 Date: 1997-09-30 GLP/GEP: yes, unpublished	Y	Bayer
KIIA 5.10 /01	[REDACTED]	2010	BYI 02960 - Biokinetic in the plasma of rats following 7 days exposure through the diet [REDACTED] Bayer CropScience, Report No.: SA 09334, Edition Number: M-385777-01-2 EPA MRID No.: 48844154 Date: 2010-07-08 GLP/GEP: no, unpublished	Y	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 5.10 /02	[REDACTED]	2011	BYI 02960: 28-day immunotoxicity study in the female wistar rat by dietary administration [REDACTED] Report No.: SA 10353, Edition Number: M-414754-01-2 EPA MRID No.: 48844148 Date: 2011-09-22 GLP/GEP: yes, unpublished	Y	Bayer

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

The toxicity study package was performed with Deltamethrin + Flupyradifurone EC 85 (10+75 g/L) batch 2014-012629 which is equivalent to Specification number: 102000028562-03. Therefore, a bridging statement is not mandatory.

Comments of zRMS:	Information sufficient. No remarks.
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A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	<p>Due to the fact that the result of ATE_{mix} calculation gave clearly different results than the <i>in vivo</i> test, for this reason ZRMS PL took into account the results of <i>in vivo</i> tests as precautionary approach.</p> <p>This study follows the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.</p> <p>The study was performed according to the OECD Test Guideline 425. These study meets the current data requirements Regulation (EU) No 284/2013. Identified deviation: none. Study is acceptable.</p> <p>Classification required according to CLP Regulation (EC) No 1272/2008.</p> <p>Acute Tox. Cat 4 H302</p>
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Calculation of acute oral toxicity

According to the Regulation (EC) No. 1272/2008 Annex 3.1.3.6.2.1 the classification of the mixture may be estimated with a calculation method:

The formulation Deltamethrin + Flupyradifurone EC 85 (10+75 g/L) contains ingredients relevant for calculation of an oral ATE_{mix} of 4242.7 mg/kg. For details please refer to Part C.

Acute oral toxicity study:

In addition, for a country outside of Europe an acute oral toxicity study was conducted with the formulation itself. In order to provide a harmonized MSDS under CLP/GHS for the current formulation the result of the acute oral toxicity study needs to be taken into account.

Reference:	KCP 7.1.1/01
Title:	Deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Acute oral toxicity study in the rat (Up and down procedure)
Report:	: 2015; 14/384-001P; M-516318-01-1
Authority registration No:	
Guideline(s):	OECD 425 (2008); Commission Regulation (EC) 440/2008 B.1.TRIS (2008); US-EPA 712-C-02-190, OPPTS 870.1100 (2002)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Materials and methods

Test material (Lot/Batch No.)	DLT+FPF EC 85 (10+75) G Specification number: 102000028562 Lot/Batch number: 2014-012629
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Species	Rat, Crl:WI (SPF-bred)
No. of animals (group size)	6 females (3 females/group)
Dose(s)	550, 2000 mg/kg bw
Exposure	Once by gavage
Vehicle/Dilution	Vehicle used was distilled water
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 1: Results of acute oral toxicity study in rats of DLT+FPF EC 85 (10+75) G

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	Mortality (%)
Female rats				
550	0/3/3	Day 0-2	-	0
2000	3/3/3	30' - time of death	Day 0-1	100

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 2: Summary of findings of acute oral toxicity study in rats of DLT+FPF EC 85 (10+75) G

Mortality:	Yes.
Clinical signs:	<p>Yes.</p> <p>At 2000 mg/kg bw, the test item caused decreased activity (slight to severe), hunched back, and prone position rate in 3/3 animals. In addition, continuous tremors (2/3 animals) and incoordination (2/3 animals) were noted. Furthermore clonic convulsion in 1/3 rats were observed on Day 0.</p> <p>At the dose level of 550 mg/kg bw, the following clinical signs were noted: decreased activity (slight to moderate) in 2/3 animals from Day 0 up to Day 2, hunched back in 3/3 animals on Day 0-1, furthermore vocalisation, continuous tremors and incoordination in 1/3 rats on Day 0. Each rat was symptom-free from Day 3 at the latest.</p>
Body weight:	Body weight gain was considered to be normal in all surviving animals.
Macroscopic examination:	<p>Apparent abnormalities in animals found dead:</p> <p>Yellowish mucoid material in the digestive content of the stomach, duodenum and jejunum and red liquid material in the perinasal area found in 1/3 found dead rats at necropsy, was considered to be related to the administration of test item. Dark/red discoloration of the collapsed/non-collapsed lungs was regarded as agonal or post mortem.</p> <p>At 550 mg/kg bw, the necropsies performed at the end of the study revealed no apparent findings.</p>

Conclusion

Under the experimental conditions, the oral LD₅₀ of DLT+FPF EC 85 (10+75) G is > 550 < 2000 mg/kg bw in rats. Thus, classification is required according to Regulation (EC) No. 1272/2008.

A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	<p>Since there is <i>in vivo</i> test already exist the information gained on animal studies are more reliable.</p> <p>This study follows the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.</p> <p>The study was performed according to the OECD Test Guideline 402. These data meets the current data requirements Regulation (EU) No 284/2013. There is no deviations from the study protocol. Study is acceptable.</p> <p>Classification is not required according to CLP Regulation (EC) No 1272/2008</p>
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Calculation of acute dermal toxicity

According to the Regulation (EC) No. 1272/2008 Annex 3.1.3.6.2.1 the classification of the mixture may be estimated with a calculation method.

The formulation Deltamethrin + Flupyradifurone EC 85 (10+75 g/L) contains no ingredients relevant for calculation of a dermal ATE_{mix}.

Therefore, the current formulation is not to be classified for dermal toxicity. For details please refer to Part C.

Acute dermal toxicity study:

In addition, for a country outside of Europe an acute dermal toxicity study was conducted with the formulation itself. In order to provide a harmonized MSDS under CLP/GHS for the current formulation the result of the acute dermal toxicity study needs to be taken into account.

Reference:	KCP 7.1.2/01
Title:	Deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Acute dermal toxicity study in the rat
Report:	2015; 14/384-002P; M-515269-01-1
Authority registration No:	
Guideline(s):	OECD 402 (1987); US-EPA 712-C-98-192, OPPTS 870.1200 (1998); Commission Regulation (EC) 440/2008 (2008)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Materials and methods

Test material (Lot/Batch No.)	DLT+FPF EC 85 (10+75) G Specification number: 102000028562 Lot/Batch number: 2014-012629
Species	Rat, Crl:WI (SPF-bred)
No. of animals (group size)	5 rats/sex
Dose(s)	2000 mg/kg bw
Exposure	24 hours (dermal, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 3: Results of acute dermal toxicity study in rats of DLT+FPF EC 85 (10+75) G

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD50 (mg/kg bw) (14 days)
Male rats				
2000	0/0/5	-	-	> 2000
Female rats				
2000	0/0/5	-	-	> 2000

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 4: Summary of findings of acute dermal toxicity study in rats of DLT+FPF EC 85 (10+75) G

Mortality:	No mortality occurred.
Clinical signs:	No clinical signs of toxicity were observed.
Body weight:	Slightly suppressed body weight gain was noted in two female rats at the dose level of 2000 mg/kg bw between Day 0 and Day 7.
Macroscopic examination:	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the dermal LD₅₀ of DLT+FPF EC 85 (10+75) G is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	<p>Due to the fact that the result of calculation gave clearly different results than the <i>in vivo</i> test, for this reason ZRMS PL took into account the results of <i>in vivo</i> tests as precautionary approach.</p> <p>This study follows the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.</p> <p>The study was performed according to the OECD Test Guideline 403. These data meets the current data requirements Regulation (EU) No 284/2013. There is no deviations from the study protocol. Study is acceptable.</p> <p>Classification is required according to CLP Regulation (EC) No 1272/2008.</p> <p>Acute Tox. Cat. 4 H332</p>
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Calculation of acute inhalation toxicity

According to the Regulation (EC) No. 1272/2008 Annex 3.1.3.6.2.1 the classification of the mixture may be estimated with a calculation method:

The formulation Deltamethrin + Flupyradifurone EC 85 (10+75 g/L) contains ingredients relevant for calculation of an inhalation ATE_{mix} of 5 mg/L air.

Therefore, the current formulation is to be classified for dermal [REDACTED] toxicity. For details please refer to Part C.

Acute inhalation toxicity study:

In addition, for a registration in a country outside of Europe an acute inhalation toxicity study was conducted with the formulation itself. In order to provide a harmonized MSDS under CLP/GHS for the current formulation the result of the acute inhalation toxicity study needs to be taken into account.

Reference:	KCP 7.1.3/01
Title:	Acute inhalation toxicity study (nose-only) in the rat with deltamethrin + flupyradi-furone EC 85 (10+75 g/L)
Report:	[REDACTED]; 2015; 14/384-004P; M-534789-01-1
Authority registration No:	
Guideline(s):	OECD 403 (2009); US-EPA OPPTS 870.1300 (1998); Council Regulation (EC) 440/2008, B.2 (2008)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Materials and methods

Test material (Lot/Batch No.)	DLT+FPF EC 85 (10+75) G Specification number: 102000028562 Lot/Batch number: 2014-012629
Species	Rat, CrI:WI (SPF-bred)
No. of animals (group size)	5.0 mg/L: 1 rat/sex (sighting study) 5.0 mg/L: 5 rats/sex 2.0 mg/L: 5 males 1.0 mg/L: 5 males 0.5 mg/L: 5 males
Concentration(s)	0.5, 1.0, 2.0, 5.0 mg/L air
Exposure	4 hours (nose-only)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 5: Concentration(s) and exposure conditions

Target conc. (mg/L air)	Nominal conc. (mg/L air)	Actual conc. (mg/L air)	MMAD * (µm)	GSD ** (µm)
0.5	1.58	0.49	1.44	2.13
1.0	3.10	1.09	1.48	2.01
2.0	5.70	2.11	1.57	2.10
5.0	12.36	4.62	1.75	2.09
5.0	17.06	6.01	1.82	2.02

* MMAD = Mass Median Aerodynamic Diameter

** GSD = Geometric Standard Deviation

Table A 6: Results of acute inhalation toxicity study in rats of DLT+FPF EC 85 (10+75) G

Concentration (mg/L air)	Toxicological results *	Duration of signs	Time of death	LC ₅₀ (mg/L air) (14 days)
Male rats				
6.01 (sighting study)	0/1/1	14 days	-	Calculated value: 1.31 mg/L
4.62	3/5/5	14 days (or until death)	Day 1 (1/3), Day 12-13 (2/3)	
2.11	5/5/5	3 h - time of death	Day 1	

Concentration (mg/L air)	Toxicological results *	Duration of signs	Time of death	LC ₅₀ (mg/L air) (14 days)
1.09	3/5/5	1/5 animals: 4 h – Day 3 1/5 animals: 3 h – Day 8 3/5 animals: 4 h – time of death	Day 1 (2/3), Day 11 (1/3)	
0.49	0/5/5	1/5 animals: 1 h – 5 h 4/5 animals: 1 h / 2 h – Day 3	-	
Female rats				
6.01 (sighting study)	0/1/1	14 days	-	> 4.62
4.62	1/5/5	1/5 animals: 1 h – Day 2 4/5 animals: 14 days (or until death)	Day 13	

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 7: Summary of findings of acute inhalation toxicity study in rats of DLT+FPF EC 85 (10+75) G

Mortality:	Yes
Clinical signs:	<p>Yes.</p> <p>Wet fur, ruffled fur and fur staining were commonly recorded mostly on the day of exposure and day following exposure. These observations were considered to be related to the restraint and exposure procedures and, in isolation, were considered not to be biologically significant.</p> <p><u>Sighting study (6.01 mg/L air):</u> Slight to severe laboured respiration and noisy respiration, decreased activity were noted for the animals on day of exposure. In addition, gasping respiration, sneezing, distended abdomen and hunched posture were observed in the exposed animals during whole observation period.</p> <p><u>Main study:</u> 4.62 mg/L air: Clinical signs similar to sighting study. 2.11 mg/L air: Slight to moderate laboured and noisy respiration, sneezing decreased activity were noted for the exposed animals on day of the exposure. 1.09 mg/L air: Slight to severe laboured, gasping and noisy respiration, sneezing, decreased activity and prone position were noted for the exposed animals on day of the exposure and/or few days after exposure. 0.49 mg/L air: Slight to moderate laboured and noisy respiration, sneezing were noted for the exposed animals on day of the exposure and/or few days after exposure.</p>
Body weight:	<p>Moderate bodyweight loss was noted in both animals from the sighting group especially during the second week of the observation period.</p> <p>Slight to moderate bodyweight loss was noted in 2/5 males and 2/5 females at 5 mg/L air, 2/5 males at 1 mg/L air.</p> <p>Normal bodyweight gain was noted for males at 0.5 mg/L air.</p>
Macroscopic examination:	<p>Apparent abnormalities in animals found dead: Test item-related dark/red discoloration of the non-collapsed/collapsed lungs and gas dilatation of the stomach (occasionally with yellow focal discoloration of the glandular mucosa), small intestines, cecum, colon or rectum found, were observed at necropsy.</p> <p>In surviving animals exposed to the concentration of 4.62 mg/L, test item-related gas dilatation of the stomach (with/without yellow/pale discoloration of the glandular mucosa), small intestines, cecum, colon or rectum and dark/red discoloration of the lungs, were recorded.</p> <p>No gross changes were seen at a concentration level of 0.49 mg/L at study termination (day 14).</p>

Conclusion

Under the experimental conditions, the inhalation LC₅₀ of DLT+FPF EC 85 (10+75) G were calculated to be 1.31 mg/L air in male and greater than 4.62 mg/L in female Wistar rats. Thus, classification is required according to Regulation (EC) No. 1272/2008.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	Summary of the <i>in vivo</i> study has been intentionally left (marked with grey fonts) for the experts who might be willing to see the reports that are available (e.g. if the classification based on them is different from the one obtained by calculation). The skin and eye irritating properties evaluated based on the additivity approach has been accepted. Classification is not required according to CLP Regulation (EC) No 1272/2008.
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Evaluation of skin irritation/ corrosion

The skin irritating properties were evaluated according to Commission Regulation (EC) No 1272/2008, Annex I table 3.2.3, for classification of mixtures.

In the current formulation the overall content of skin corrosive category 1 ingredients is 0 % which is below the generic concentration limit of ≥ 1 % for classification. The overall content of skin irritant category 2 ingredients is 0.7 % which is below the generic concentration limit of ≥ 10 % for classification.

Therefore, the current formulation is not to be classified for skin irritation. For details please refer to Part C.

Reviewer comment:

reflecting comments made by the cMS and applicant, ZRMS decided to take into account for hazard classification *in vivo* studies (refer to our detailed information p.11).

Skin irritation/corrosion study

In addition, for a registration in a country outside of Europe a skin irritation study was conducted with the formulation itself. In order to provide a harmonized MSDS under CLP/GHS for the current formulation the result of the skin irritation study needs to be taken into account.

Reference:	KCP 7.1.4/01
Title:	Deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Acute skin irritation study in rabbits
Report:	2015; 14/384-006N; M-511430-01-1
Authority registration No:	
Guideline(s):	OECD 404 ((2002); Commission Regulation (EC) 440/2008, B.4 (2008); US-EPA 712-C-98-196, OPPTS 870.2500 (1998)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Materials and methods

Test material (Lot/Batch No.)	DLT+FPF EC 85 (10+75) G Specification number: 102000028562 Lot/Batch number: 2014-012629
Species	Rabbit, New Zealand White
No. of animals (group size)	3 (males)
Initial test using one animal	Yes

	Initially, a single animal was treated. As no significant irritant effect was observed after the 1-hour exposure, the test was completed using the 2 remaining animals with an exposure period of 4 hours.
Exposure	0.5 mL (4 hours, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	72 hours
Remarks	None

Results and discussions

Table A 8: Skin irritation of DLT+FPF EC 85 (10+75) G

Animal No.		Scores after treatment *				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
1	Erythema	0	0	0	0	0.00	Not applicable
	Oedema	0	0	0	0	0.00	Not applicable
2	Erythema	0	0	0	0	0.00	Not applicable
	Oedema	0	0	0	0	0.00	Not applicable
3	Erythema	0	0	0	0	0.00	Not applicable
	Oedema	0	0	0	0	0.00	Not applicable

* scores in the range of 0 to 0

Clinical signs:	No clinical signs of toxicity were observed.
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Conclusion

Under the experimental conditions, DLT+FPF EC 85 (10+75) G is not a skin irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	Summary of the <i>in vitro</i> and <i>in vivo</i> study has been intentionally left (marked with grey fonts) for the experts who might be willing to see the reports that are available (e.g. if the classification based on them is different from the one obtained by calculation). The skin and eye irritating properties evaluated based on the additivity approach has been accepted. Classification is required according to CLP Regulation (EC) No 1272/2008. Eye Corr. Cat 1 H318
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Evaluation of eye irritation/ corrosion

The eye irritating properties were evaluated according to Commission Regulation (EC) No 1272/2008, Annex I table 3.3.3, for classification of mixtures.

In the current formulation the sum of ingredients classified as eye effects category 1 or skin corrosive category 1 is 0 % and thereby below the generic concentration limits of $\geq 3\%$ for classification as eye effects category 1, as well as below the generic concentration limits of $\geq 1\%$ for classification as eye effects category 2.

In the current formulation the sum of ingredients classified as eye effects category 2 is 52.34 % and thereby above the trigger of $\geq 10\%$ for classification of the mixture as eye irritant category 2¹.

Therefore, the current formulation is to be classified for skin eye irritation. For details please refer to Part C.

Eye irritation/corrosion study

In addition, for a registration in a country outside of Europe an eye irritation study was conducted with the formulation itself. In order to provide a harmonized MSDS under CLP/GHS for the current formulation the result of the eye irritation study needs to be taken into account.

A 2.6.1 In vitro eye irritation test in isolated chicken eyes

Reference:	KCP 7.1.5/01
Title:	Deltamethrin + flupyradifurone EC 85 (10+75 g/L) - In vitro eye irritation test in isolated chicken eyes
Report:	[REDACTED]; 2015; 14/384-038CS; M-511433-01-1
Authority registration No:	
Guideline(s):	OECD 438 (2013); Commission Regulation (EC) 1272/2008 (2008); Commission Regulation (EC) 1152/2010 (2010); amending Regulation (EC) No 440/2008 Method B 48; US-EPA 712-C-98-195, OPPTS 870.2400 (1998)
Deviations:	none
GLP/GEP:	yes
Acceptability:	
Duplication (if vertebrate study):	

Materials and methods

Test material (Lot/Batch No.)	DLT+FPF EC 85 (10+75) G Specification number: 102000028562 Lot/Batch number: 2014-012629
Species	Chicken, ROSS 308
No. of animals (group size)	3 eyes/group: Undiluted Positive control: Benzalkonium chloride, 5 % (w/v) 1 eye/group: Negative control: Physiological saline, 0.9 % (w/v)
Initial test using one animal	No
Exposure	The test item was applied in a volume of 30 µL onto the entire surface of the cornea attempting to cover the cornea surface uniformly with the test substance.
Irrigation (time point)	Yes (after an exposure period of 10 seconds from the end of the application the cornea surface was rinsed thoroughly with 20 mL physiological saline solution)
Vehicle/Dilution	None
Post exposure observation period	The control and test eyes were evaluated pre-treatment and at approximately 30, 75, 120, 180 and 240 minutes after the post treatment rinse. Minor variations within approximately ± 5 minutes were considered acceptable.
Remarks	None

Results and discussions

The mean values of the treated eyes for maximum corneal thickness change, corneal opacity change and fluorescein retention change are given below.

Changes in corneal swelling and corneal opacity change (severity 1, 1.5 or 2) was observed during the four hour observation period on all test item treated eyes. Fluorescein retention change (severity 2.5 or 3) was noted on all eyes and loosening of epithelium was also observed on one eye. These results are well above the maximum threshold for a negative but do not reach the criteria of severe irritant.

Study Code:	14/384-038CS										Strain:	ROSS 308											
Date of Exposure:	21 November 2014										Test Item:	DLT+FPF EC 85 (10+75) G											
Chamber number ↓	Corneal thickness (instrument units)										Corneal opacity score						Fluorescein retention						
Relative observation time (min) →	-45	0	Ch a n g e	30	75	Max change up to 75	120	180	240	Max change up to 240	0	30	75	120	180	240	Max Δ Opac	0	30	Δ Flu ret			
11	62	62	0.0%	62	60	0.0%	59	58	58	-6.5%	0	1	2	2	2	2	2.0	0	3	3.0			
12	61	61	0.0%	60	59	0.0%	58	57	57	-6.6%	0	0.5	1	1	1	1	1.0	0	3	3.0			
13	61	62	1.6%	66	67	8.1%	69	71	72	16.1%	0.5	1	2	2	2	2	1.5	0.5	3	2.5			
Mean values:						2.7%					1.0%							1.50					2.83

Clinical signs:	No clinical signs of toxicity were observed.
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Under the experimental conditions, DLT+FPF EC 85 (10+75) G is not classified as severe irritant and not classified as non-irritant. It is concluded that an *in vivo* study is required for proper classification.

reflecting comments made by the cMS and applicant, ZRMS decided to take into account for hazard classification *in vivo* studies. (refer to our detailed information p.11)

Reference:	KCP 7.1.5/02
Title:	Deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Acute eye irritation study in rabbits
Report:	: 2015; 14/384-005N; M-528983-01-I
Authority registration No:	
Guideline(s):	OECD 405 (2012); Commission Regulation (EC) 440/2008, B.5 (2008); US-EPA 712-C-98-195, OPPTS 870.2400 (1998)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Test material (Lot/Batch No.)	DLT+FPF EC 85 (10+75) G Specification number: 102000028562 Lot/Batch number: 2014-012629
Species	Rabbit, New Zealand White
No. of animals (group size)	1 male
Initial test using one animal	No
Exposure	0.1 mL (single instillation in conjunctival sac)
Irrigation (time point)	Yes (after the 1 hour observation as the irritation scores reached the threshold value of 2)

Vehicle/Dilution	None
Post exposure observation period	3 weeks
Remarks	None

Results and discussions

Table A 10: Eye irritation of DLT+FPF EC 85 (10+75) G

Animal No.		Scores after treatment *				Mean scores (24-72 h)	Reversible (day)
		1 h	24 h	48 h	72 h		
1	Corneal opacity	1	1	1	1	1.00	Not reversible
	Iritis	0	0	0	0	0.00	Not applicable
	Redness conjunctivae	2	2	2	2	2.00	Not reversible
	Chemosis conjunctivae	3	2	2	2	2.00	21

* scores in the range of 0 to 2 for cornea opacity and chemosis, 0 to 2 for redness of conjunctivae and 0 to 0 for iritis

Clinical signs:	No clinical signs of toxicity were observed.
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Conclusion

Under the experimental conditions, DLT+FPF EC 85 (10+75) G is an eye irritant. Thus, classification is required according to Regulation (EC) No. 1272/2008.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	<p>Due to the fact that the result of calculation/evaluation of skin sensitisation gave clearly different results than the <i>in vivo</i> test, for this reason ZRMS PL took into account the results of <i>in vivo</i> tests as precautionary approach.</p> <p>The study was performed according to the OECD Test Guideline 429. This study follows the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013. Identified deviation: none. Study is acceptable.</p> <p>Classification required according to CLP Regulation (EC) No 1272/2008.</p> <p>Skin Sens. Cat 1B H317</p>
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Evaluation of skin sensitisation

The skin sensitising properties were evaluated according to Commission Regulation (EC) No 1272/2008, Annex I table 3.4.5, for classification of mixtures.

The current formulation contains no ingredients triggering classification of the mixture for skin sensitisation. For details please refer to Part C.

Skin sensitisation study

In addition, for a registration in a country outside of Europe a skin sensitising study was conducted with the formulation itself. In order to provide a harmonized MSDS under CLP/GHS for the current formulation the result of the skin sensitisation study needs to be taken into account.

Reference:	KCP 7.1.6/01
Title:	Deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Local lymph node assay in the mouse
Report:	2017; 14/384-037E; M-601871-01-1
Authority registration No:	
Guideline(s):	OECD 429 (2010); Commission Regulation (EC) 440/2008 (2008); Commission Regulation (EC) 640/2012 (2012); US-EPA 712-C-03-197, OPPTS 870.2600 (2003)
Deviations:	none
GLP/GEP:	yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Materials and methods

Test material (Lot/Batch No.)	DLT+FPF EC 85 (10+75) G Specification number: 102000028562 Lot/Batch number: 2014-012629
Species	Mouse, CBA/J strain
No. of animals (group size)	5 female mice/group
Range finding:	Yes. The preliminary test I was started according to the Study Plan on CBA/J Rj mice using two doses (2 animals/dose) at test item concentrations of 100 % (undiluted) and 50 % (w/v) in 1% Pluronic. Based on the observed equivocal body weight data, an additional test was performed using three doses (2 animals/dose) at test item concentrations of 100 % (undiluted), 50 and 25 % (w/v) in 1% Pluronic.
Exposure (concentration(s), no. of applications)	Topical induction: The formulations of the test item were applied on the dorsal surface of both ears of experimental animals (25 µL/ear). Each animal was dosed once a day for three consecutive days (Days 1, 2 and 3).
Vehicle	1 % Pluronic
Pretreatment prior to topical application	No
Reliability check	Positive control (25 % α-Hexylcinnamaldehyde (HCA) in 1 % Pluronic) Negative control (vehicle alone, 1 % Pluronic)
Remarks	In the preliminary experiment I mice of 10 weeks of age (19.7-20.3 g) were used. In preliminary experiment II mice of 11 weeks of age (23.4-23.8 g) were used.

Results and discussions

The observed stimulation index values were 8.9, 2.0, 1.6 and 2.0 at concentrations of 25, 10, 5 and 2.5 % (w/v), respectively.

Table A 11: Results of skin sensitisation study of DLT+FPF EC 85 (10+75) G

	No. of animals	Concentration (%)	DPM / group	Stimulation index (SI)
DLT+FPF EC 85 (10+75) G	5	25	1499.7	8.9**
	5	10	345.0	2.0**
	5	5	268.5	1.6**
	5	2.5	333.1	2.0
Test Vehicle Control Group	5	(1% Pluronic)	168.5	1.0

Positive control	5	(25 % HCA in 1% Pluronic)	3834.0	22.8**
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Notes:

** = Significant (p<0.01, Mann-Whitney U-test versus negative control)

Clinical signs:	No mortality or systemic toxicity was observed during the main test. There were no indications of any irritancy at the site of application.
Body weight:	No treatment related effects were observed on the mean body weight of the groups. However, marked body weight loss (> 5 %) was detected for one animal in each of the Negative Control, and in the 25 % (w/v) dose groups. These differences are considered to be individual variability, and not related to the test item.

Conclusion

Under the experimental conditions, DLT+FPF EC 85 (10+75) G is a skin sensitiser. Thus, classification is required according to Regulation (EC) No. 1272/2008.

A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

None.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co- formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

Dermal *in vitro* absorption of Deltamethrin

Comments of zRMS:	This study follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013. The study was performed according to the OECD Test Guideline 428. These data meets the current data requirements Regulation (EU) No 284/2013. There is no deviations from the study protocol. Study is acceptable.
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Reference:	KCP 7.3/01
Title:	Deltamethrin + flupyradifurone EC 85 (10+75) formulation: [14C]-deltamethrin in vitro dermal absorption study using human skin
Report:	Odin, M.; 2016; SA 15251; M-559234-01-1
Authority registration No:	
Guideline(s):	OECD 428 (2004); OECD SeriesNo 28 (2004); EFSA Journal 2012; 10(4): 2665
Deviations:	none
GLP/GEP:	yes
Acceptability:	Yes
Duplication (if vertebrate study):	

Material and methods

Human skin:

Source: Xenometrics, Hegenheim, France.
Number and sex: minimum of 6 donors per dose level, female.
Anatomical region: Abdomen.
Thickness: 400 to 496 µm.

Test Material:

Non-radiolabelled:

Batch: PMDN001249.
Purity = 99.6% (w/w).

Radiolabelled:

[benzyl-¹⁴C]-deltamethrin
Batch: KATH6320.
Specific activity: 4.24 MBq/mg.
Radiopurity of the formulation: >99%.

Formulation:

The formulation used in this experiment was the deltamethrin+flupyradifurone EC 85 formulation (specification N° 102000028562) containing deltamethrin (10 g/L) and flupyradifurone (75 g/L). It was used at three nominal concentrations of deltamethrin: neat, 10 g/L with 2 spray dilutions of 0.05 g/L and 0.0064 g/L.

Test system:

A flow-through diffusion cell system (Franz's cell modified, Gallas, France) was used to study the absorption of the test substance (exposure area of 1 cm² skin). A diffusion cell consisted of a donor chamber and a receptor chamber between which the skin was positioned. The receptor fluid was Eagle's medium supplemented with 5% bovine serum albumin and gentamycin (50 mg/L) at a pH of 7.4. The receptor chamber was warmed by a constant circulation of warm water which maintained the receptor fluid at 32 ± 2°C (close to the normal skin temperature). The receptor fluid was pumped through the receptor chamber at a rate of 1.5 mL/h and stirred continuously whilst in the receptor chamber by means of a magnetic bar.

Skin integrity:

Before dose application, the integrity of the skin samples was assessed by measuring the trans-epidermal water loss (TEWL) from the stratum corneum. An evaporimeter probe (Tewameter TM300® System, Courage & Khazaka) was placed securely on the top of the donor chamber and the amount of water diffusing through the skin was measured. Skin samples with a TEWL of greater than 15 g/hm² were considered potentially damaged and were not used. These samples were replaced by new skin fragments which were also tested for integrity before use in the study.

Treatment: The dose preparation was applied to the split-thickness skin sample with a pipette at the rate of approximately 10 µL/cm² exposed skin. The dose preparations were assayed for radioactivity content (by LSC) by using dose checks (surrogate dose) taken before, during and after the dosing process.

Sampling: The receptor fluid passing through the receptor chamber was collected in glass vials held in a fraction collector. The fraction collector was started after dose application. Samples were then collected hourly for the duration of the experiment (24 hours). At 8 hours post-application, the skin was swabbed with freshly prepared 1% v/v Tween 80 in PBS (phosphate buffer saline) using a minimum of 15 precision wipes (Kimtech Sciences from Kimberly-Clark professional), in order to remove and retain the non-absorbed dose, until no radioactivity was detected with a Geiger-Müller monitor. At the end of the study (24 hours after application), the treated skin and the skin adjacent to the treatment site (surrounding swabs) were swabbed. Each skin sample was tape-stripped to remove the stratum corneum. This involved the application of Monaderm adhesive tape (Monaderm, Monaco) for 5 seconds before the tape was carefully removed against the direction of hair growth. This procedure was continued until a 'shiny' appearance of the epidermis was evident, which indicated that the stratum corneum had been removed. The tape-strips were collected into scintillation vials for analysis. The skin surrounding the application site (surrounding skin) was separated from the treated skin. Both surrounding skin and tape-stripped treated skin were retained for analysis.

Radioassay: The amounts of radioactivity in the various samples were determined by liquid scintillation counting (LSC). Samples were counted for 10 minutes or for 2 sigma % in an appropriate scintillation cocktail using a Packard 1900 TR counter with on-line computing facilities. Quenching effects were determined using an external standard and spectral quench parameter (tSIE) method. Efficiency correlation curves were prepared for each scintillation cocktail and were regularly checked by the use of [¹⁴C-n-hexadecane standards. The scintillation counter was recalibrated when a deviation of greater than 2% was observed when counting quality control standards. The limit of detection was taken to be twice the background values for blank samples in appropriate scintillation cocktails.

Findings:

Deltamethrin was demonstrated to be sufficiently soluble in the receptor fluid to avoid any risk of back diffusion.

Measurements of the homogeneity of the three concentrations of formulation applied indicated that it was acceptable.

The study results are presented in the following Table.

Table A 12: Mean distribution of radioactivity at 24 hours after dose application of [¹⁴C]- Deltamethrin in an EC 85 formulation at the rates of 10 g/L, 0.05 g/L and 0.0064 g/L to human skin samples.

Results expressed in terms of percentage of applied radioactivity.

Dose Levels	Distribution of radioactivity (% dose)		
	Neat formulation: High dose (10 g/L)	Dilution: Intermediate dose	Dilution: Low dose (0.0064 g/L)

Species	(0.05 g/L)		(0.05 g/L)		(0.05 g/L)	
	Human (n=4) K N° = 1.6		Human (n=6) K N° = 1		Human (n=12) K N° = 0.64	
	Mean	SD	Mean	SD	Mean	SD
SURFACE COMPARTMENT						
Skin swabs (8h)	92.31	8.12	92.94	4.66	88.36	7.78
Skin swabs (24h) ^a	1.50	1.78	1.42	0.74	2.32	1.59
Total skin swabs	93.81	6.37	94.36	4.29	90.67	7.23
Surface Dose (1 st two tape-strips)	2.38	2.52	2.92	2.51	2.93	2.83
Donor chamber	0.35	0.31	0.68	0.38	n.d.	n.a.
Total % non-absorbed	96.54	3.83	97.96	3.15	93.60	5.71
SKIN COMPARTMENT						
Skin ^b	0.76	1.00	0.38	0.32	1.27	0.68
Stratum corneum ^c	1.34	1.07	1.83	1.48	2.73	3.25
Total % at dose site	2.10	2.02	2.21	1.75	4.00	3.78
RECEPTOR COMPARTMENT						
Receptor fluid (0-24h)	0.01	0.01	0.10	0.05	n.d.	n.a.
Receptor fluid terminal	0.002	0.003	n.d.	n.a.	n.d.	n.a.
Receptor chamber	n.d.	n.a.	1.03	4.60	n.d.	n.a.
Total % directly absorbed ^d	0.01	0.02	1.13	1.61	n.d.	n.a.
STUDY:						
Total % Potentially Absorbable ^e	2.11	2.01	3.35	3.00	1.27	0.68
TOTAL % RECOVERY	98.65	2.30	101.31	4.60	97.60	4.02
Evaluation according to EFSA Guidance						
absorption >75% within half of study duration	No (include SC values)		Yes (92%) (exclude SC values)		No absorption (exclude SC values)	
standard deviation >25%	Yes		Yes		Yes	
recovery <95%	No correction needed		No correction needed		No correction needed	
Total % Potentially Absorbable adjusted according to EFSA (2017)	Mean %dose site+%directly absorbed + SD*1.6		Mean %skin+%directly absorbed + SD*1		Mean %skin+%directly absorbed + SD*0.64	
	5.3		3.2		1.7	

^a: sum of radioactivity found in swabs at termination and in surrounding swabs.

^b: sum of radioactivity found in skin after tape-stripping procedure and in surrounding skin.

^c: tape-strips excluding numbers 1 & 2 which are considered to be non-absorbed dose.

^d: sum of radioactivity found in receptor fluid (0-24h), receptor fluid terminal and receptor chamber.

^e: total % directly absorbed + total % at dose site

SD: standard deviation

n: number of skin cells used for calculation

In the above table, the presented means do not always calculate exactly from the presented individual data. This is due to rounding-up differences resulting from the use of the spreadsheet program.

Conclusion:

The dermal penetration through human dermatomed skin of [¹⁴C]-Deltamethrin in the Deltamethrin + Flupyradifurone EC 10 + 75 (DLT+FPF EC 85) formulation was investigated at three concentrations corresponding to the neat product (10 g /L) and two representative dilutions of 0.05 g/L and 0.0064 g/L.

Concentrate

The mean percentage of deltamethrin in the EC 85 formulation that was considered to be potentially absorbable (*directly absorbed plus total remaining at dose site*) over a period of 24 hours for the neat formulation was 2.11% for the human skin. Applying the EFSA guidance (2017) this value adjusts to 5.3%.

Intermediate Dose level (Spray dilution)

The mean percentage of deltamethrin in the EC 85 formulation that was considered to be potentially absorbable (*directly absorbed plus total remaining at dose site*) over a period of 24 hours for the intermediate dose rate was 3.35% for human skin. Applying the new EFSA guidance (2017) this value adjusts to 3.2%.

Low Dose level (Spray dilution)

The mean percentage of deltamethrin in the EC 85 formulation that was considered to be potentially absorbable (*directly absorbed plus total remaining at dose site*) over a period of 24 hours for the low dose rate was 1.27% for human skin. Applying the new EFSA guidance (2017) this value adjusts to 1.7%.

Therefore the following dermal absorption value can be proposed for use in the non-dietary risk assessments for [¹⁴C]-Deltamethrin in the DLT+FPF EC 85 formulation:

- 5.3% for the neat formulation (10 g/L)
- 3.2% for the intermediate dose (0.05 g/L)
- 1.7% for the low dose (0.0064 g/L).

Dermal *in vitro* absorption of Flupyradifurone

Comments of zRMS:	This study follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013. The study was performed according to the OECD Test Guideline 428. These data meets the current data requirements Regulation (EU) No 284/2013. There is no deviations from the study protocol. Study is acceptable.
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Reference:	KCP 7.3/02
Title:	DLT+FPF EC 85 (10+75): [¹⁴ C]-flupyradifurone - In vitro dermal absorption study using human skin
Report:	Blanck, M.; 2016; SA 15253; M-556571-01-1
Authority registration No:	
Guideline(s):	OECD 428 (2004); OECD Series No 28, (2004); EFSA Journal 2012: 10(4): 2665.
Deviations:	none
GLP/GEP:	yes
Acceptability:	Yes
Duplication (if vertebrate study):	

Material and methods

Human skin:

Source: Xenometrics, Hegenheim, France.
Number and sex: minimum of 4 donors per dose level, female.
Anatomical region: Abdomen.
Thickness: 381 to 498 µm.

Test Material:

Non-radiolabelled:

Batch: NLL 7780-47-4.
Purity = 99.4% (w/w).

Radiolabelled:

[pyridinylmethyl -¹⁴C]-flupyradifurone
Batch: KML 10125.
Specific activity: 3.92 MBq/mg.
Radiopurity of the formulation: >99%.

Formulation:

The formulation used in this experiment was the deltamethrin + flupyradifurone EC 85 formulation (specification N° 102000028562) containing deltamethrin (10 g/L) and flupyradifurone (75 g/L). It was used at three nominal concentrations of flupyradifurone: neat, 75 g/L with 2 spray dilutions of 0.375 g/L and 0.048 g/L.

Test system:

A flow-through diffusion cell system (Franz's cell modified, Gallas, France) was used to study the absorption of the test substance (exposure area of 1 cm² skin). A diffusion cell consisted of a donor chamber and a receptor chamber between which the skin was positioned. The receptor fluid was Eagle's medium supplemented with 5% bovine serum albumin and gentamycin (50 mg/L) at a pH of 7.4. The receptor chamber was warmed by a constant circulation of warm water which maintained the receptor fluid at 32 ± 2°C (close to the normal skin temperature). The receptor fluid was pumped through the receptor chamber at a rate of 1.5 mL/h and stirred continuously whilst in the receptor chamber by means of a magnetic bar.

- Skin integrity:** Before dose application, the integrity of the skin samples was assessed by measuring the trans-epidermal water loss (TEWL) from the stratum corneum. An evaporimeter probe (Tewameter TM300® System, Courage & Khazaka) was placed securely on the top of the donor chamber and the amount of water diffusing through the skin was measured. Skin samples with a TEWL of greater than 15 g/hm² were considered potentially damaged and were not used. These samples were replaced by new skin fragments which were also tested for integrity before use in the study.
- Treatment:** The dose preparation was applied to the split-thickness skin sample with a pipette at the rate of approximately 10 µL/cm² exposed skin. The dose preparations were assayed for radioactivity content (by LSC) by using dose checks (surrogate dose) taken before, during and after the dosing process.
- Sampling:** The receptor fluid passing through the receptor chamber was collected in glass vials held in a fraction collector. The fraction collector was started after dose application. Samples were then collected hourly for the duration of the experiment (24 hours). At 8 hours post-application, the skin was swabbed with freshly prepared 1% v/v Tween 80 in PBS (phosphate buffer saline) using a minimum of 15 precision wipes (Kimtech Sciences from Kimberly-Clark professional), in order to remove and retain the non-absorbed dose, until no radioactivity was detected with a Geiger-Müller monitor. At the end of the study (24 hours after application), the treated skin and the skin adjacent to the treatment site (surrounding swabs) were swabbed. Each skin sample was tape-stripped to remove the stratum corneum. This involved the application of Monaderm adhesive tape (Monaderm, Monaco) for 5 seconds before the tape was carefully removed against the direction of hair growth. This procedure was continued until a 'shiny' appearance of the epidermis was evident, which indicated that the stratum corneum had been removed. The tape-strips were collected into scintillation vials for analysis. The skin surrounding the application site (surrounding skin) was separated from the treated skin. Both surrounding skin and tape-stripped treated skin were retained for analysis.
- Radioassay:** The amounts of radioactivity in the various samples were determined by liquid scintillation counting (LSC). Samples were counted for 10 minutes or for 2 sigma % in an appropriate scintillation cocktail using a Packard 1900 TR counter with on-line computing facilities. Quenching effects were determined using an external standard and spectral quench parameter (tSIE) method. Efficiency correlation curves were prepared for each scintillation cocktail and were regularly checked by the use of [¹⁴C-n-hexadecane standards. The scintillation counter was recalibrated when a deviation of greater than 2% was observed when counting quality control standards. The limit of detection was taken to be twice the background values for blank samples in appropriate scintillation cocktails.

Findings:

Flupyradifurone was demonstrated to be sufficiently soluble in the receptor fluid to avoid any risk of back diffusion.

Measurements of the homogeneity of the three concentrations of formulation applied indicated that it was acceptable.

The study results are presented in the following Table.

Table A 13: Mean distribution of radioactivity at 24 hours after dose application of [¹⁴C]- Flupyradifurone in an EC 85 formulation at the rates of 75 g/L, 0.375 g/L and 0.048 g/L to human skin samples.

Results expressed in terms of percentage of applied radioactivity.

Dose Levels	Distribution of radioactivity (% dose)					
	Neat formulation: High dose (75 g/L)		Dilution: Intermediate dose (0.375 g/L)		Dilution: Low dose (0.048 g/L)	
Species	Human (n=4) K N° = 1.6		Human (n=5) K N° = 1.2		Human (n=6) K N° = 1	
	Mean	SD	Mean	SD	Mean	SD
SURFACE COMPARTMENT						
Skin swabs (8h)	100.99	2.09	95.50	4.01	93.07	4.95
Skin swabs (24h) ^a	1.22	1.88	0.50	0.40	0.47	0.24
Total skin swabs	102.21	1.78	96.01	3.76	93.54	4.75
Surface Dose (1 st two tape-strips)	0.74	1.04	0.12	0.10	1.12	1.58
Donor chamber	1.15	1.87	0.08	0.08	0.17	0.42
Total % non-absorbed	104.1	3.79	96.21	3.64	94.83	4.33
SKIN COMPARTMENT						
Skin ^b	0.667	0.48	0.09	0.10	0.39	0.38
Stratum corneum ^c	0.51	0.52	0.60	0.45	0.86	1.30
Total % at dose site	1.18	0.97	0.69	0.54	1.24	1.56
RECEPTOR COMPARTMENT						
Receptor fluid (0-24h)	0.23	0.18	0.43	0.21	1.82	1.17
Receptor fluid terminal	0.05	0.05	0.11	0.10	0.04	0.06
Receptor chamber	n.d.	n.a.	0.07	0.15	n.d.	n.a.
Total % directly absorbed ^d	0.28	0.23	0.61	0.30	1.86	1.18
STUDY: Total % Potentially Absorbable ^e	1.45	1.19	1.30	0.77	3.11	1.80
TOTAL % RECOVERY	105.6	4.89	97.50	3.27	97.93	3.27
Evaluation according to EFSA Guidance						
absorption >75% within half of study duration	No (include SC values except SC1 & SC2)		Yes (93%) (exclude SC values)		No (include SC values except SC1 & SC2)	
standard deviation >25%	Yes		Yes		Yes	
recovery <95%	No correction needed		No correction needed		No correction needed	
Total % Potentially Absorbable adjusted according to EFSA (2017)	Mean %dose site+%directly absorbed + SD*1.6		Mean %skin+%directly absorbed + SD*1.2		Mean %dose site+%directly absorbed + SD*1	
	3.4		1.1		4.9	

^a: sum of radioactivity found in swabs at termination and in surrounding swabs.

^b: sum of radioactivity found in skin after tape-stripping procedure and in surrounding skin.

^c: tape-strips excluding numbers 1 & 2 which are considered to be non-absorbed dose.

^d: sum of radioactivity found in receptor fluid (0-24h), receptor fluid terminal and receptor chamber.

^e: total % directly absorbed + total % at dose site

SD: standard deviation

n: number of skin cells used for calculation

In the above table, the presented means do not always calculate exactly from the presented individual data. This is due to rounding-up differences resulting from the use of the spreadsheet program.

Conclusion:

The dermal penetration through human dermatomed skin of [¹⁴C]-Flupyradifurone in the EC 85 formulation was investigated at three concentrations corresponding to the neat product (75 g/L) and two representative dilutions of 0.375 g/L and 0.048 g/L.

Concentrate

The mean percentage of flupyradifurone in the EC 85 formulation that was considered to be potentially absorbable (*directly absorbed plus total remaining at dose site*) over a period of 24 hours for the neat formulation was 1.45% for the human skin. Applying the EFSA guidance (2017) this value adjusts to 3.4%.

Intermediate Dose level (Spray dilution)

The mean percentage of flupyradifurone in the EC 85 formulation that was considered to be potentially absorbable (*directly absorbed plus total remaining at dose site*) over a period of 24 hours for the intermediate dose rate was 1.30% for human skin. Applying the new EFSA guidance (2017) this value adjusts to 1.1%.

Low Dose level (Spray dilution)

The mean percentage of flupyradifurone in the EC 85 formulation that was considered to be potentially absorbable (*directly absorbed plus total remaining at dose site*) over a period of 24 hours for the low dose rate was 3.11% for human skin. Applying the new EFSA guidance (2017) this value adjusts to 4.9%.

Therefore the following dermal absorption value can be proposed for use in the non-dietary risk assessments for [¹⁴C]-Flupyradifurone in the DLT+FPF EC 85 formulation:

- 3.4% for the neat formulation (75 g/L)
- 1.1% for the intermediate dose (0.375 g/L)

4.9% for the low dose (0.048 g/L).

A 2.11 Other/Special Studies

Not relevant.

Appendix 3 calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Deltamethrin

Table A 14: Operator exposure, deltamethrin, Rape, no PPE / with PPE

Substance	Deltamethrin	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0,0075 kg a.s. /ha	Spray dilution = 0,0375 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Cereals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 2, Application interval = 14 days
Percentage Absorption	Dermal for product = 5,3	Dermal for in use diluation = 3,2	Oral = 75	Inhalation = 100	
RVNAS	0,0075 mg/kg bw/day		RVAAS	Not relevant	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	
Operator Model	Mixing, loading and application AOEM				
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0037	% of RVNAS	49,58%
	Acute systemic exposure mg/kg bw/day		Not relevant	% of RVAAS	Not relevant
Mixing and Loading	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day		0,0021	% of RVNAS	28,40%
	Acute systemic exposure mg/kg bw/day		0,0086	% of RVAAS	45,06%
Mixing and Loading	Gloves = Yes		Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day		0,0001	% of RVNAS	1,73%
	Acute systemic exposure mg/kg bw/day		Not relevant	% of RVAAS	Not relevant

RVNAS = Reference Value Non Acutely toxic active Substance = AOEL

RVAAS = Reference Value Acutely toxic active Substance

A 3.1.2 Calculations for Flupyradifurone

Table A 152: Operator exposure, flupyradifurone, Rape, no PPE / with PPE

Substance	Flupyradifurone	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0,05625 kg a.s. /ha	Spray dilution = 0,28125 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Cereals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 2, Application interval = 14 days
Percentage Absorption	Dermal for product = 3,4	Dermal for in use diluation = 4,9	Oral = 100	Inhalation = 100	
RVNAS	0,064 mg/kg bw/day		RVAAS	Not relevant	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	
Operator Model	Mixing, loading and application AOEM				
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0110	% of RVNAS	17,22%
	Acute systemic exposure mg/kg bw/day		Not relevant	% of RVAAS	Not relevant
Mixing and Loading	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day		0,0067	% of RVNAS	10,45%
	Acute systemic exposure mg/kg bw/day		Not relevant	% of RVAAS	Not relevant
Mixing and Loading	Gloves = Yes		Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day		0,0006	% of RVNAS	0,97%
	Acute systemic exposure mg/kg bw/day		Not relevant	% of RVAAS	Not relevant

RVNAS = Reference Value Non Acutely toxic active Substance = AOEL

RVAAS = Reference Value Acutely toxic active Substance

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Deltamethrin

Table A 163: Estimation of worker exposure, deltamethrin, winter Rape

Substance	Deltamethrin	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0,0075 kg a.s. /ha	Spray dilution = 0,0375 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Cereals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 2, Application interval = 14 days
Percentage Absorption	Dermal for product = 5,3	Dermal for in use dilution = 3,2	Oral = 75	Inhalation = 100	
RVNAS	0,0075 mg/kg bw/day		RVAAS	0,019 mg/kg bw/day Not relevant	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	
Worker – Searching, reaching, picking	Potential exposure mg/kg bw/day		0,0009	% of RVNAS	11,42%
	Working clothing mg/kg bw/day		0,0001	% of RVNAS	1,28%
	Working clothing and gloves mg/kg bw/day		-	% of RVNAS	-

RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
RVAAS = Reference Value Acutely toxic active Substance

A 3.2.2 Calculations for Flupyradifurone

Table A 174: Estimation of worker exposure, flupyradifurone, winter Rape

Substance	Flupyradifurone	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0,05625 kg a.s. /ha	Spray dilution = 0,28125 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Cereals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 2, Application interval = 14 days
Percentage Absorption	Dermal for product = 3,4	Dermal for in use dilution = 4,9	Oral = 100	Inhalation = 100	
RVNAS	0,064 mg/kg bw/day		RVAAS	Not relevant	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	
Worker – Searching, reaching, picking	Potential exposure mg/kg bw/day		0,0059	% of RVNAS	9,28%
	Working clothing mg/kg bw/day		0,0007	% of RVNAS	1,04%
	Working clothing and gloves mg/kg bw/day		-	% of RVNAS	-

RVNAS = Reference Value Non Acutely toxic active Substance = AOEL
RVAAS = Reference Value Acutely toxic active Substance

A 3.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Deltamethrin

Table A 185: Resident exposure, deltamethrin, winter Rape

Substance	Deltamethrin	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0,0075 kg a.s. /ha	Spray dilution = 0,0375 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Cereals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	
Percentage Absorption	Dermal for product = 5,3	Dermal for in use dilution = 3,2	Oral = 75	Inhalation = 100	
RVNAS	0,0075 mg/kg bw/day		RVAAS	0,019 mg/kg bw/day Not relevant	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	
Resident - child	Spray drift (75th percentile) mg/kg bw/day		0,0000	% of RVNAS	0,44%
	Vapour (75th percentile) mg/kg bw/day		0,0011	% of RVNAS	14,27%
	Surface deposits (75th percentile) mg/kg bw/day		0,0000	% of RVNAS	0,24%
	Entry into treated crops (75th percentile) mg/kg bw/day		0,0001	% of RVNAS	1,54%
	All pathways (mean) mg/kg bw/day		0,0012	% of RVNAS	15,91%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day		0,0000	% of RVNAS	0,10%
	Vapour (75th percentile) mg/kg bw/day		0,0002	% of RVNAS	3,07%
	Surface deposits (75th percentile) mg/kg bw/day		0,0000	% of RVNAS	0,06%
	Entry into treated crops (75th percentile) mg/kg bw/day		0,0001	% of RVNAS	0,86%
	All pathways (mean) mg/kg bw/day		0,0003	% of RVNAS	3,84%

RVNAS = Reference Value Non Acutely toxic active Substance = AOEL

RVAAS = Reference Value Acutely toxic active Substance

A 3.3.2 Calculations for Flupyradifurone

Table A 196: Resident exposure, flupyradifurone, winter Rape

Substance	Flupyradifurone	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0,05625 kg a.s. /ha	Spray dilution = 0,28125 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10 ⁻³ Pa
Scenario	Cereals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 2, Application interval = 14 days
Percentage Absorption	Dermal for product = 3,4	Dermal for in use dilution = 4,9	Oral = 100	Inhalation = 100	
RVNAS	0,064 mg/kg bw/day		RVAAS	Not relevant	
DFR	3 µg a.s./cm ² per kg a.s./ha		DT50	30 days	
Resident - child	Spray drift (75th percentile) mg/kg bw/day		0,0004	% of RVNAS	0,59%
	Vapour (75th percentile) mg/kg bw/day		0,0011	% of RVNAS	1,67%
	Surface deposits (75th percentile) mg/kg bw/day		0,0001	% of RVNAS	0,23%
	Entry into treated crops (75th percentile) mg/kg bw/day		0,0008	% of RVNAS	1,25%
	All pathways (mean) mg/kg bw/day		0,0020	% of RVNAS	3,17%
Resident - adult	Spray drift (75th percentile) mg/kg bw/day		0,0001	% of RVNAS	0,14%
	Vapour (75th percentile) mg/kg bw/day		0,0002	% of RVNAS	0,36%
	Surface deposits (75th percentile) mg/kg bw/day		0,0000	% of RVNAS	0,05%
	Entry into treated crops (75th percentile) mg/kg bw/day		0,0004	% of RVNAS	0,70%
	All pathways (mean) mg/kg bw/day		0,0007	% of RVNAS	1,02%

RVNAS = Reference Value Non Acutely toxic active Substance = AOEL

RVAAS = Reference Value Acutely toxic active Substance

A 3.4 Combined exposure calculations for Deltamethrin and Flupyradifurone

Please refer to paragraph 6.6.6.

Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)

Not relevant.