

REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

Product code: 102000028562

Product name: Deltamethrin + flupyradifurone

EC 85 (10+75 g/L)

Chemical active substances:

Deltamethrin, 10 g/L

Flupyradifurone, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Bayer Crop Science Division

Submission date: 01/08/2019 (intended)

MS Finalisation date: June 2021 (initial assessment)

February 2022 (final Core Assessment)

Version history

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) No additional information or assessments after the commenting period.

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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substances.

Noticed data gaps are:

- 2-years storage stability study in HDPE packaging.


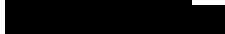
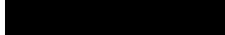
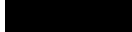
1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

This section of the draft registration report is a core document and as such will be submitted in all countries where the product will be registered. Since the legal name of the applicant may vary depending on the country this information is provided in the National document (Part A, point 1.1, Application background). The registration holder will be either Bayer or one of its' legal entities in the countries.

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Name: Bayer S.A.S.
Division Crop Science
Address: 16, rue Jean-Marie Leclair
CS 90106
69266 Lyon Cedex 09
France
Contact: 
Telephone number: 
Fax: 
E-mail: 

Location of the production site


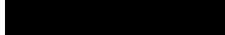

CONFIDENTIAL information - data provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Deltamethrine

Name Bayer AG
Address: Kaiser-Wilhelm-Allee 1
51373 Leverkusen
Germany

Main contact for the active substance(s) is:

Contact: 
Tel number: 
E-mail: 

Location of the production site

CONFIDENTIAL information - data provided separately (Part C).

Flupyradifurone

Name Bayer AG
Address: Kaiser-Wilhelm-Allee 1
D-51373 Leverkusen
Germany

Main contact for the active substance is:

Contact:

Tel number:

Fax number:

E-mail:

Location of the production site

CONFIDENTIAL information - data provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Deltamethrin

Deltamethrin	min. 985 g/kg (This purity is in full compliance to the FAO specification 333/TC; May 2005)
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There is no relevant impurity.

1.2.3.2 Flupyradifurone

Flupyradifurone	min. 960 g/kg
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Flupyradifurone has been approved by the EU Commission with COMMISSION IMPLEMENTING REGULATION (EU) 2015/2084 of 18 November 2015. The registered purity of the active substance in this Regulation is ≥ 960 g/kg.

Since this purity was derived from a pilot scale synthesis, one of the specific provisions in the approving Regulation was that the applicant shall submit confirmatory information as regards the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of some individual impurities.

Bayer Crop Science division has now implemented the industrial scale manufacturing process and proposes to elevate the purity of the technical grade active ingredient from ≥ 960 g/kg to ≥ 980 g/kg. The corresponding documents including a new material accountability study have been submitted to the Rapporteur Member State, The Netherlands, and, in copy, to EFSA and the Commission.

There is no relevant impurity.

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

The list below contains existing / proposed trade names/marks for the product. This list may not be exhaustive and the specific trade names for each country can be found in the relevant Part A.

Trade name:	Sivanto Energy
Company code number:	deltamethrin + flupyradifurone EC 85 (10 + 75 g / L) DLT+FPF EC 85 (10+75 g/L) DLT+FPF EC 85 81703299 (material No.) 102000028562 (specification No.)

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

The formulation DLT+FPF EC 85 (10+75 g/L) was not the representative formulation for the Approval or the Renewal of any of the active substances.

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L)	FAO Limits (min – max) (g/L or g/kg)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Deltamethrin	10	8.5 – 11.5	10.03	0.86
Flupyradifurone	75	67.5 – 82.5	76.59	6.47

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

** Based on the density of the formulation = 1.16 (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4-2: Safener and synergists

Safener / synergist	Declared content of the safener / synergist (g/L or g/kg)	FAO Limits (min – max) (g/L or g/kg)	Technical content (g/L or g/kg)	Technical content (%w/w)
None				

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
None	

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-4: Information on active substances

Type	Name/Code Number	
ISO common name	Deltamethrin	
CAS No.	52918-63-5	
EC No.	2582566	
CIPAC No.	333	

Type	Name/Code Number	
ISO common name	Flupyradifurone	
CAS No.	951659-40-8	
EC No.	Not allocated	

Type	Name/Code Number	
CIPAC No.	987	

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

Table 1.4-5: Information on safeners/ synergists / co-formulant

Type	Name/Code Number	
Safener /synergist	None	-
ISO common name	-	-
CAS No.	-	-
EC No.	-	-

Co-formulants:

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Emulsifiable concentrate	[Code: EC]
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1.6 Function (KCP 1.6)

Insecticide

2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

Deltamethrin + Flupyradifurone EC 85 (10 + 75 g/L) is an EC formulation consisting of a light yellow to brown emulsifiable concentrate with a characteristic odour. The pH of the neat product is 3.1 – 3.3. The pH of a 1% aqueous dilution is 3.7. It has no oxidising, explosive or flammable properties. Accelerated storage stability tests indicate that the product will exhibit acceptable chemical and physical stability under normal storage conditions as indicated by the product label. The physical/chemical properties of this product indicate that the product would give satisfactory handling and dilution properties in the field when it is used as recommended. High density polyethylene – COEX (HDPE) (HDPE/EVOH and HDPE/PA) containers have been found suitable for storage of this product.

The intended concentration of use is 0.083% to 0.375%.

Concentration used in studies: 0.125% - 0.5%.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

None


Notifier Proposals for Risk and Safety Phrases (KCP 12)

Reference:	KCP Section 12/01
Title:	DLT+FPF EC 10+75 G
Report:	Anon.; 2019; M-567053-03-1
Authority registration No:	--
Guideline(s):	--
Deviations:	--
GLP/GEP:	no
Acceptability:	Yes
Duplication (if vertebrate study):	No

Classification

Hazard class(es), categories:	Acute toxicity: category 4 Acute toxicity : category 4 Skin sensitisation: Category 1 Serious eye damage: category 1 Acute aquatic toxicity: category 1 Chronic aquatic toxicity: category 1
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Labelling

Signal Word :	Danger 
Hazard statement	H 302 + H 332: Harmful if swallowed or if inhaled H 317 May cause an allergic skin reaction. H 318: Causes serious eye damage H 410: Very toxic to aquatic life with long lasting effects EUH401: To avoid risks to human health and the environment, comply with the instruction for use
Precautionary statement	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

Compliance with FAO specifications:

The product DLT+FPF EC 85 complies with FAO specifications.

Formulation used for tests

The following batch has been used in the physico-chemical studies:
 102000028562; batch number: 2014-012629; 10.03 g/L deltamethrin; 76.59 g/L flupyradifurone.

Composition of all these batches are described in Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	OCSPP 830.6302 OCSPP 830.6304 OCSPP 830.6303 Or visual	102000028562 batch: 2014-012629	Physical state: Liquid Colour: yellow Odour: odourless	N	Hennig-Gizewski, S.; 2015; M-513765-01-1	Accepted.
Explosive properties (KCP 2.2.1)	EC A14	102000028562 batch: 2014-012629	Not explosive in the sense of EC guidelines A14	Y	Keldenich, H. P.; 2015; M-518123-01-1	Accepted.
Oxidizing properties (KCP 2.2.2)	EC A21 (liquids)	102000028562 batch: 2014-012629	No oxidising properties under the conditions of the test	Y	Keldenich, H. P.; 2015; M-518123-01-1	Accepted.
Flash point (KCP 2.3.1)	EC A9 DIN EN ISO 2719 OPPTS 830.6315	102000028562 batch: 2014-012629	134°C	Y	Keldenich, H. P.; 2015; M-518123-01-1	Accepted.
Flammability (KCP 2.3.2)	-	-	Not required as the formulation is an EC formulation	-	-	-
Self-heating (KCP 2.3.3)	EC A15 DIN 51794	102000028562 batch: 2014-012629	410°C	Y	Keldenich, H. P.; 2015; M-518123-01-1	Accepted.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	102000028562 batch: 2014-012629	0.54%	Y	Hennig-Gizewski, S.; 2015; M-513765-01-1	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT75.3 OCSPP 830.7000	102000028562 batch: 2014-012629	pH = 3.7 (1% dilution in deionised water) Since pH of 1% dilution was found to be 3.7, acidity test according to CIPAC MT 191 has been performed and the acidity was found to be 0.54% (0.02 N NaOH). As the acidity value of 0.54% is so low, no corrosiveness to metals is expected.	Y	Hennig-Gizewski, S.; 2015; M-513765-01-1 Zhang Y.; 2021 M-770383-01-1	Accepted. None of the co-formulas is classified as H290. The test for corrosiveness against metals is not deemed necessary.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Viscosity (KCP 2.5.1)	OECD 114 CIPAC MT 192 OCSPP 830.7100	102000028562 batch: 2014-012629	Kinematic viscosity: shear rate 20 s-1 $v = \eta / \rho = 28.2 \times 10^{-6} \text{ m}^2/\text{s}$ at 20 °C $v = \eta / \rho = 13.1 \times 10^{-6} \text{ m}^2/\text{s}$ at 40 °C shear rate 100 s-1 $v = \eta / \rho = 28.4 \times 10^{-6} \text{ m}^2/\text{s}$ at 20°C $v = \eta / \rho = 13.4 \times 10^{-6} \text{ m}^2/\text{s}$ at 40 °C Dynamic viscosity: shear rate 20 s-1 $\eta = 32.6 \times 10^{-3} \text{ Pa s}$ at 20 °C $\eta = 14.9 \times 10^{-3} \text{ Pa s}$ at 40 °C shear rate 100 s-1 $\eta = 32.9 \times 10^{-3} \text{ Pa s}$ at 20 °C $\eta = 15.3 \times 10^{-3} \text{ Pa s}$ at 40 °C	Y	Hennig-Gizewski, S.; 2015; M-513765-01-1	Accepted. The product can be considered as surface active.
Surface tension (KCP 2.5.2)	OECD115 EC A5	102000028562 batch: 2014-012629	25 mN/m undiluted (25 °C) 35 mN/m at a dilution of 1 g/L (deionised water, 20°C) According to EC guideline A.5 the preparation should be regarded as being a surface-active material (surface tension < 60 mN/m).	Y	Hennig-Gizewski, S.; 2015; M-513765-01-1	Accepted. The product can be considered as surface active.
Relative density (KCP 2.6.1)	OECD 109 EC A3 OCSPP 830.7300	102000028562 batch: 2014-012629	$D_4^{20} = 1.158 \text{ g/mL}$ $D_4^{40} = 1.139 \text{ g/mL}$	Y	Hennig-Gizewski, S.; 2015; M-513765-01-1	Accepted.
Bulk density (KCP 2.6.2)	-	-	Not required as the formulation is a liquid.	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Storage Stability after 14 days at 54° C (KCP 2.7.1/01)	CropLife International Technical Monograph No 17, 6.1 CIPAC-Handbook Volume J / 2000 MT 46.3 EPA Product Properties Test Guideline OCSPP 830.6317.SUPP US EPA Memorandum “Accelerated Storage Stability and Corrosion Characteristics Study Protocol”, 2012-11-16	102000028562 batch: 2014-012629	<p>Stable for 2 weeks at 54 °C with respect to the content of the active ingredients</p> <p>Packaging material: COEX/EVOH (1000 ml bottles)</p> <p>The packaging material was found to be stable and suitable for use with the formulation. COEX/EVOH can be recommended as packaging material</p> <p>See detailed results in Table 2-1</p>	Y	<u>Rexer, K.; 2016; M-523981-02-1</u>	<p>Study accepted.</p> <p>After storage no unacceptable decrease of the content of active substance was determined and the product complied with the FAO specifications.</p> <p>The HDPE/EVOH container showed no indications of significant weight loss or physical deterioration that would interfere with the safe handling of the product. No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage, evaluation of this parameter after storage is not necessary.</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Storage Stability after 14 days at 54° C (KCP 2.7.1/02)	CropLife International Technical Monograph No 17, 6.1 CIPAC-Handbook Volume J / 2000 MT 46.3 EPA Product Properties Test Guideline OCSPP 830.6317.SUPP US EPA Memorandum “Accelerated Storage Stability and Corrosion Characteristics Study Protocol”, 2012-11-16		Stable for 2 weeks at 54 °C with respect to the content of the active ingredients Packaging material: COEX/PA (1000 ml bottles) The packaging material was found to be stable and suitable for use with the formulation. COEX/PA can be recommended as packaging material See detailed results in Table 2-2	Y	<u>Rexer, K.; 2016; M-523979-02-1</u>	Study accepted. After storage no unacceptable decrease of the content of active substance was determined and the product complied with the FAO specifications. The HDPE/PA container showed no indications of significant weight loss or physical deterioration that would interfere with the safe handling of the product. No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage, evaluation of this parameter after storage is not necessary
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	102000028562 batch: 2014-012629	Not needed as stable for 14 days at 54 °C	-	-	-
Minimum content after heat stability testing (KCP 2.7.3)	-	-	-	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Effect of low temperatures on stability (KCP 2.7.4/01)	CropLife International Technical Monograph No 17, 6.3 CIPAC-Handbook Volume J / 2000 MT 39.3	102000028562 batch: 2014-012629	Cold stability 7 days at 0 °C No changes on the preparation were detected, thus deltamethrin + flupyradifurone EC 85 (10+75 g/L) appears to be stable throughout the test period of 7 days at 0 °C (packaging material: COEX/EVOH).	Y	<u>Rexer, K.; 2016; M-523981-02-1</u>	Accepted.
Effect of low temperatures on stability (KCP 2.7.4/02)	CropLife International Technical Monograph No 17, 6.3 CIPAC-Handbook Volume J / 2000 MT 39.3	102000028562 batch: 2014-012629	Cold stability 7 days at 0 °C No changes on the preparation were detected, thus deltamethrin + flupyradifurone EC 85 (10+75 g/L) appears to be stable throughout the test period of 7 days at 0 °C (packaging material: COEX/PA)	Y	<u>Rexer, K.; 2016; M-523979-02-1</u>	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Ambient temperature shelf life (KCP 2.7/03)	-	102000028562 batch: 2014-012629	Shelf life 2 years at ambient temperature The formulation deltamethrin + flupyradifurone EC 85 (10+75 g/L) was found to be stable throughout the test period of 2 years at ambient temperature and non-corrosive to COEX/EVOH used as packaging material. See detailed results in Table 2-5	Y	<u>Rexer, K.; 2017; M-579373-01-1</u>	Study accepted. After storage no unacceptable decrease of the content of active substance was determined and the product complied with the FAO specifications. The HDPE/EVOH container showed no indications of significant weight loss or physical deterioration that would interfere with the safe handling of the product. No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage, evaluation of this parameter after storage is not necessary. Period of validity: 2 years

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Ambient temperature shelf life (KCP 2.7/04)	-	102000028562 batch: 2014-012629	Shelf life 2 years at ambient temperature The formulation deltamethrin + flupyradifurone EC 85 (10+75 g/L) appears to be stable throughout the test period of 2 years at ambient temperature and non-corrosive to COEX/PA used as packaging material See detailed results in Table 2-6	Y	Rexer, K.; 2017; M-579371-01-1	Study accepted. After storage no unacceptable decrease of the content of active substance was determined and the product complied with the FAO specifications. The HDPE/PA container showed no indications of significant weight loss or physical deterioration that would interfere with the safe handling of the product. No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage, evaluation of this parameter after storage is not necessary. Period of validity: 2 years
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	102000028562 batch: 2014-012629	Not required as formulation is stable at ambient temperature for at least 2 years.	-	-	-
Wettability (KCP 2.8.1)	-	-	Not applicable for EC formulations	-	-	-
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	102000028562 batch: 2014-012629	0.5 % of the preparation in CIPAC D water: after 10 sec 57 mL after 1 min 0 mL after 3 min 0 mL after 12 min 0 mL	N	Hennig-Gizewski, S.; 2015; M-513765-01-1	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Suspensibility (KCP 2.8.3.1)	-	-	Not applicable for EC formulation	-	-	-
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not applicable for EC formulation	-	-	-
Dispersion stability (KCP 2.8.3.3)	-	-	Not applicable for EC formulation	-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not applicable for EC formulation	-	-	-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not applicable for EC formulation	-	-	-
Wet sieve test (KCP 2.8.5.1.2)	-	-	Not applicable for EC formulation	-	-	-
Dust content (KCP 2.8.5.2.1)	-	-	Not applicable for EC formulation	-	-	-
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not applicable for EC formulation	-	-	-
Attrition (KCP 2.8.5.3)	-	-	Not applicable for EC formulation	-	-	-
Hardness and integrity (KCP 2.8.5.4)	-	-	Not applicable for EC formulation	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Emulsifiability (KCP 2.8.6.1)	CIPAC MT 36.3	102000028562 batch: 2014-012629	0.125% in CIPAC standard water A <u>Initial emulsifiability</u> spontaneous 0.125% in CIPAC standard water D <u>Initial emulsifiability</u> spontaneous 0.500% in CIPAC standard water A <u>Initial emulsifiability</u> spontaneous 0.500% in CIPAC standard water D <u>Initial emulsifiability</u> spontaneous	N	<u>Hennig-Gizewski, S.; 2015: M-513765-01-1</u>	Accepted. It should be noted that according to the currently proposed GAP table (please refer to all intended uses, Part B0), the lowest intended use concentration is 0.083% and is not covered by the concentrations for the product used in the studies. However, since no effects are observed at the lowest concentration tested, no negative effects are expected at the lowest proposed concentration.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Emulsion stability (KCP 2.8.6.2)	CIPAC MT 36.3	102000028562 batch: 2014-012629	0.125% in CIPAC standard water A <u>Separation after 30 min</u> no sediment, no oil, no cream <u>Separation after 120 min</u> no sediment, no oil, no cream <u>Separation after 24 h</u> no sediment, no oil, no cream 0.125% in CIPAC standard water D <u>Separation after 30 min</u> no sediment, no oil, no cream <u>Separation after 120 min</u> no sediment, no oil, no cream <u>Separation after 24 h</u> no sediment, no oil, no cream 0.500% in CIPAC standard water A <u>Separation after 30 min</u> no sediment, no oil, no cream <u>Separation after 120 min</u> no sediment, no oil, no cream <u>Separation after 24 h</u> no sediment, no oil, no cream 0.500% in CIPAC standard water D <u>Separation after 30 min</u> no sediment, no oil, no cream <u>Separation after 120 min</u> no sediment, no oil, no cream <u>Separation after 24 h</u> no sediment, no oil, no cream	N	<u>Hennig-Gizewski, S.; 2015: M-513765-01-1</u>	Accepted. It should be noted that according to the currently proposed GAP table (please refer to all intended uses, Part B0), the lowest intended use concentration is 0.083% and is not covered by the concentrations for the product used in the studies. However, since no effects are observed at the lowest concentration tested, no negative effects are expected at the lowest proposed concentration.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT 36.3	102000028562 batch: 2014-012629	0.125 % in CIPAC standard water A Re-emulsification. after 24 h: complete Separation after 24.5 h: no sediment, no oil, no cream 0.125 % in CIPAC standard water D Re-emulsification. after 24 h: complete Separation after 24.5 h: no sediment, no oil, no cream 0.500 % in CIPAC standard water A Re-emulsification. after 24 h: complete Separation after 24.5 h: no sediment, no oil, no cream 0.500 % in CIPAC standard water D Re-emulsification. after 24 h: complete Separation after 24.5 h: no sediment, no oil, no cream	N	<u>Hennig-Gizewski, S.; 2015: M-513765-01-1</u>	Accepted. It should be noted that according to the currently proposed GAP table (please refer to all intended uses, Part B0), the lowest intended use concentration is 0.083% and is not covered by the concentrations for the product used in the studies. However, since no effects are observed at the lowest concentration tested, no negative effects are expected at the lowest proposed concentration.
Flowability (KCP 2.8.7.1)	-	-	Not applicable for EC formulation	-	-	-
Pourability (KCP 2.8.7.2)	-	-	Not applicable for EC formulation	-	-	-
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not applicable for EC formulation	-	-	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Where relevant please refer to local recommendations.	-	-	-
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Where relevant please refer to local recommendations.	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Adhesion to seeds (KCP 2.10.1)	-	-	Not applicable for EC formulation	-	-	-
Distribution to seed (KCP 2.10.2)	-	-	Not applicable for EC formulation	-	-	-
Other/special studies (KCP 2.11)	-	-	There is no other / special study	-	-	-

Results referring to point KCP 2.7.1/01: storage stability after 14 days at 54°C – COEX/EVOH (Rexer, K.; 2016; M-523981-02-1)

Test / Method	Initial	14 days at 54 °C
Content of a.s. AM023614MF1		
deltamethrin	10.0 g/L	9.9 g/L
Content of a.s. AM023614MF1		
flupyradifurone	76.7 g/L	76.4 g/L
Content of water CIPAC MT 30.5	0.11 %	0.13 %
Corrosion characteristics OCSPP 830.6320	Not applicable	No deterioration of the packaging material and no adverse interaction with the formulation were observed.
Change in weight	Not applicable	Not significant (- 0.04 %)
Deformation	None	Signs of panelling on one side (1 cm).
Leakage	None	No leaking
Effect on closure	None	Leak proof
Packaging / preparation interaction	Not applicable	No seepage and no separation.
Colour OCSPP 830.6302	Yellow	Yellow
Odour OCSPP 830.6304	Odourless	Weak aromatic odour
Physical state OCSPP 830.6303	Liquid	Liquid
Acidity CIPAC MT 191	0.54 %	0.52 %
pH-value CIPAC MT 75.3 OCSPP 830.7000	1 % in deionised water	
	3.7	3.7
Relative density 92/69/EEC A.3 OECD 109 OCSPP 830.7300	D ₄ ²⁰ 1.158	D ₄ ²⁰ 1.158
Persistent foaming CIPAC MT 47.3	0.5 % w/w in CIPAC standard water D	
Foam after 10 s	57 mL	50 mL
Foam after 1 min	0 mL	0 mL
Foam after 3 min	0 mL	0 mL
Foam after 12 min	0 mL	0 mL
Emulsion characteristics CIPAC MT 36.3	0.125 % w/w in CIPAC standard water A	
Initial emulsifiability	Spontaneous	Spontaneous

Test / Method	Initial	14 days at 54 °C
Separation after 30 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Separation after 120 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Separation after 24 h	No sediment, no oil, no cream	No sediment, no oil, no cream
Re-emulsifiability after 24 h	Completely	Completely
Separation after further 30 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Emulsion characteristics CIPAC MT 36.3	0.125 % w/w in CIPAC standard water D	
Initial emulsifiability	Spontaneous	Spontaneous
Separation after 30 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Separation after 120 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Separation after 24 h	No sediment, no oil, no cream	No sediment, no oil, no cream
Re-emulsifiability after 24 h	Completely	Completely
Separation after further 30 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Emulsion characteristics CIPAC MT 36.3	0.5 % w/w in CIPAC standard water A	
Initial emulsifiability	Spontaneous	Spontaneous
Separation after 30 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Separation after 120 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Separation after 24 h	No sediment, no oil, no cream	No sediment, no oil, no cream
Re-emulsifiability after 24 h	Completely	Completely
Separation after further 30 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Emulsion characteristics CIPAC MT 36.3	0.5 % w/w in CIPAC standard water D	
Initial emulsifiability	Spontaneous	Spontaneous
Separation after 30 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Separation after 120 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Separation after 24 h	No sediment, no oil, no cream	No sediment, no oil, no cream
Re-emulsifiability after 24 h	Completely	Completely
Separation after further 30 min	No sediment, no oil, no cream	No sediment, no oil, no cream

Results referring to point KCP 2.7.1/02: storage stability after 14 days at 54°C – COEX/PA (Rexer, K.; 2016; M-523979-02-1)

Test / Method	Initial	14 days at 54 °C
Content of a.s. AM023614MF1		
deltamethrin	10.0 g/L	9.9 g/L
Content of a.s. AM023614MF1		
flupyradifurone	76.7 g/L	76.2 g/L
Content of water CIPAC MT 30.5	0.11 %	0.13 %
Corrosion characteristics OCSPP 830.6320	Not applicable	No deterioration of the packaging material and no adverse interaction with the formulation were observed.
Change in weight	Not applicable	Not significant (+ 0.05 %)
Deformation	None	Signs of panelling on one side (1 cm).
Leakage	None	No leaking
Effect on closure	None	Leak proof
Packaging / preparation interaction	Not applicable	No seepage and no separation.
Colour OCSPP 830.6302	Yellow	Yellow
Odour OCSPP 830.6304	Odourless	Weak aromatic odour
Physical state OCSPP 830.6303	Liquid	Liquid
Acidity CIPAC MT 191	0.54 %	0.52 %
pH-value CIPAC MT 75.3 OCSPP 830.7000	1 % in deionised water	
	3.7	3.7
Relative density 92/69/EEC A.3 OECD 109 OCSPP 830.7300	D ₄ ²⁰ 1.158	D ₄ ²⁰ 1.158
Persistent foaming CIPAC MT 47.3	0.5 % w/w in CIPAC standard water D	
Foam after 10 s	57 mL	48 mL
Foam after 1 min	0 mL	0 mL
Foam after 3 min	0 mL	0 mL
Foam after 12 min	0 mL	0 mL
Emulsion characteristics CIPAC MT 36.3	0.125 % w/w in CIPAC standard water A	
Initial emulsifiability	Spontaneous	Spontaneous

Test / Method	Initial	14 days at 54 °C
Separation after 30 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Separation after 120 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Separation after 24 h	No sediment, no oil, no cream	No sediment, no oil, no cream
Re-emulsifiability after 24 h	Completely	Completely
Separation after further 30 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Emulsion characteristics CIPAC MT 36.3	0.125 % w/w in CIPAC standard water D	
Initial emulsifiability	Spontaneous	Spontaneous
Separation after 30 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Separation after 120 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Separation after 24 h	No sediment, no oil, no cream	No sediment, no oil, no cream
Re-emulsifiability after 24 h	Completely	Completely
Separation after further 30 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Emulsion characteristics CIPAC MT 36.3	0.5 % w/w in CIPAC standard water A	
Initial emulsifiability	Spontaneous	Spontaneous
Separation after 30 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Separation after 120 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Separation after 24 h	No sediment, no oil, no cream	No sediment, no oil, no cream
Re-emulsifiability after 24 h	Completely	Completely
Separation after further 30 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Emulsion characteristics CIPAC MT 36.3	0.5 % w/w in CIPAC standard water D	
Initial emulsifiability	Spontaneous	Spontaneous
Separation after 30 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Separation after 120 min	No sediment, no oil, no cream	No sediment, no oil, no cream
Separation after 24 h	No sediment, no oil, no cream	No sediment, no oil, no cream
Re-emulsifiability after 24 h	Completely	Completely
Separation after further 30 min	No sediment, no oil, no cream	No sediment, no oil, no cream

Results referring to the point KCP 2.7.4/02: cold stability 7 days at 0°C (Rexer, K.; 2016; M-523981-02-1)

Test / Method	
Separation visual inspection	
Initial	No visible separation
After 7 days at 0 °C	No visible separation

After 7 days at 0 °C and 24 hours warming to ambient temperature	No visible separation
--	-----------------------

Results referring to the point KCP 2.7.4/03: cold stability 7 days at 0°C (Rexer, K.; 2016; M-523979-02-1)

Test / Method	
Separation visual inspection	
Initial	No visible separation
After 7 days at 0 °C	No visible separation
After 7 days at 0 °C and 24 hours warming to ambient temperature	No visible separation

Results referring to the point KCP 2.7.4/03: 2 year ambient storage stability in COEX/EVOH (1000 ml) (Rexer, K.; 2017; M-579373-01-1)

Test Method	Initial	2 years at ambient temp
Content of a.s. AM023614MF1	10.0 g/L	10.1 g/L
deltamethrin		
Content of a.s. AM023614MF1	76.7 g/L	76.7 g/L
flupyradifurone		
Content of water CIPAC MT 30.5	0.11 %	0.16 %
Packaging stability (COEX/EVOH) OCSPP 830.6320	Not applicable	No deterioration of the packaging material and no adverse interaction with the formulation were observed
Change in weight	Not applicable	Not significant (< 0.1 %)
Change in colour	Not applicable	None
Leakage	No leaking	No leaking
Effect on closure	Leak proof	Leak proof
Deformation	None	Slight signs of panelling on one side. (10 mm).
Packaging / preparation interaction	None	No seepage. No separation. No crystallization.
Colour OCSPP 830.6302	Yellow	Yellow
Odour OCSPP 830.6304	Odourless	Weak aromatic
Physical state OCSPP 830.6303	Liquid	Liquid
Acidity CIPAC MT 191	0.54 %	0.58 %
pH-value CIPAC MT 75.3 OCSPP 830.7000	1 % in deionised water	
	3.7	3.7
Relative density (EC) 440/2008 A.3	D ₄ ²⁰ 1.158	D ₄ ²⁰ 1.158

Test Method	Initial	2 years at ambient temp
OECD 109 OCSP 830.7300		
Persistent foaming CIPAC MT 47.3	0.5 % w/w in CIPAC standard water D	
Foam after 10 s	57 mL	61 mL
Foam after 1 min	0 mL	0 mL
Foam after 3 min	0 mL	0 mL
Foam after 12 min	0 mL	0 mL
Emulsion characteristics CIPAC MT 36.3	0.125 % w/w in CIPAC standard water A	
Initial emulsifiability	Spontaneous	Spontaneous
Separation after 30 min	None	None
Separation after 120 min	None	None
Separation after 24 h	None	None
Re- emulsifiability after 24 h	Completely	Completely
Separation after further 30 min	None	None
Emulsion characteristics CIPAC MT 36.3	0.125 % w/w in CIPAC standard water D	
Initial emulsifiability	Spontaneous	Spontaneous
Separation after 30 min	None	None
Separation after 120 min	None	None
Separation after 24 h	None	None
Re- emulsifiability after 24 h	Completely	Completely
Separation after further 30 min	None	None
Emulsion characteristics CIPAC MT 36.3	0.5 % w/w in CIPAC standard water A	
Initial emulsifiability	Spontaneous	Spontaneous
Separation after 30 min	None	None
Separation after 120 min	None	None
Separation after 24 h	None	None
Re- emulsifiability after 24 h	Completely	Completely
Separation after further 30 min	None	None
Emulsion characteristics CIPAC MT 36.3	0.5 % w/w in CIPAC standard water D	
Initial emulsifiability	Spontaneous	Spontaneous
Separation after 30 min	None	None
Separation after 120 min	None	None
Separation after 24 h	None	None
Re- emulsifiability after 24 h	Completely	Completely
Separation after further 30 min	None	None

Results referring to the point KCP 2.7.4/04: 2 year ambient storage stability in COEX/PA (1000 ml) (Rexer, K.; 2017; M-579371-01-1)

Test Method	Initial	2 years at ambient temp
Content of a.s. AM023614MF1	10.0 g/L	10.1 g/L
deltamethrin		
Content of a.s. AM023614MF1	76.7 g/L	76.8 g/L
flupyradifurone		
Content of water CIPAC MT 30.5	0.11 %	0.1 %
Packaging stability (COEX/PA) OCSPP 830.6320	Not applicable	No deterioration of the packaging material and no adverse interaction with the formulation were observed
Change in weight	Not applicable	Not significant (< 0.1 %)
Change in colour	Not applicable	None
Leakage	No leaking	No leaking
Effect on closure	Leak proof	Leak proof
Deformation	None	Slight signs of panelling on one side. (14 mm).
Packaging / preparation interaction	None	No seepage. No separation. No crystallization.
Colour OCSPP 830.6302	Yellow	Yellow
Odour OCSPP 830.6304	Odourless	Weak aromatic
Physical state OCSPP 830.6303	Liquid	Liquid
Acidity CIPAC MT 191	0.54 %	0.59 %
pH-value CIPAC MT 75.3 OCSPP 830.7000	1 % in deionised water	
	3.7	3.6
Relative density (EC) 440/2008 A.3 OECD 109 OCSPP 830.7300	D ₄ ²⁰ 1.158	D ₄ ²⁰ 1.158
Persistent foaming CIPAC MT 47.3	0.5 % w/w in CIPAC standard water D	
Foam after 10 s	57 mL	59 mL
Foam after 1 min	0 mL	0 mL
Foam after 3 min	0 mL	0 mL
Foam after 12 min	0 mL	0 mL
Emulsion characteristics CIPAC MT 36.3	0.125 % w/w in CIPAC standard water A	
Initial emulsifiability	Spontaneous	Spontaneous
Separation after 30 min	None	None
Separation after 120 min	None	None

Test Method	Initial	2 years at ambient temp
Separation after 24 h	None	None
Re- emulsifiability after 24 h	Completely	Completely
Separation after further 30 min	None	None
Emulsion characteristics CIPAC MT 36.3	0.125 % w/w in CIPAC standard water D	
Initial emulsifiability	Spontaneous	Spontaneous
Separation after 30 min	None	None
Separation after 120 min	None	None
Separation after 24 h	None	None
Re- emulsifiability after 24 h	Completely	Completely
Separation after further 30 min	None	None
Emulsion characteristics CIPAC MT 36.3	0.5 % w/w in CIPAC standard water A	
Initial emulsifiability	Spontaneous	Spontaneous
Separation after 30 min	None	None
Separation after 120 min	None	None
Separation after 24 h	None	None
Re- emulsifiability after 24 h	Completely	Completely
Separation after further 30 min	None	None
Emulsion characteristics CIPAC MT 36.3	0.5 % w/w in CIPAC standard water D	
Initial emulsifiability	Spontaneous	Spontaneous
Separation after 30 min	None	None
Separation after 120 min	None	None
Separation after 24 h	None	None
Re- emulsifiability after 24 h	Completely	Completely
Separation after further 30 min	None	None

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

The nature and characteristics of the packaging: information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport and handling, resistance to and compatibility with the contents of the packaging, have been submitted, evaluated and are considered to be acceptable.

Table 4.1-1: Packaging information

Volume	50 ml	100 ml	250 ml
Material I	HDPE	HDPE	HDPE
Material II	Coex HDPE/EVOH	Coex HDPE/EVOH	Coex HDPE/EVOH
Material III			Coex HDPE/PA
Shape / size [mm]	cylindrical / 44x 82.6 mm	cylindrical / 44 x 114.5 mm	cylindrical / 62.5 x 137 mm
Opening	27.8 mm	27.8 mm	45 mm
Closure	Screw cap	Screw cap	Screw cap
Seal	HF seal, Foam Disc	HF seal, Foam Disc	HF seal, Foam Disc
Construction	Extruded, blow moulded	Extruded, blow moulded	Extruded, blow moulded
UN/ADR	compliant	compliant	compliant
Volume	500 ml	1 L	3 L
Material I	HDPE	HDPE	HDPE
Material II	Coex HDPE/EVOH	Coex HDPE/EVOH	
Material III	Coex HDPE/PA	Coex HDPE/PA	Coex HDPE/PA
Shape / size [mm]	cylindrical / 69 x 193 mm	cylindrical / 88.5 x 244.5 mm	rectangular / 190 x 140 x 236 mm
Opening	45 mm	45 mm	57.8 mm
Closure	Screw cap	Screw cap	Screw cap
Seal	HF seal, Foam Disc	HF seal, Foam Disc	HF seal, Foam Disc
Construction	Extruded, blow moulded	Extruded, blow moulded	Extruded, blow moulded
UN/ADR	compliant	compliant	compliant
Volume	5 L	10 L	15 L
Material I	HDPE	HDPE	HDPE
Material II			
Material III	Coex HDPE/PA	Coex HDPE/PA	Coex HDPE/PA
Shape / size [mm]	rectangular / 190 x 140 x 309 mm	rectangular / 226 x 186 x 370 mm	rectangular / 245 x 225 x 404 mm
Opening	57.8 mm	57.8 mm	57.8 mm
Closure	Screw cap	Screw cap	Screw cap
Seal	HF seal, Foam Disc	HF seal, Foam Disc	HF seal
Construction	Extruded, blow moulded	Extruded, blow moulded	Extruded, blow moulded
UN/ADR	compliant	compliant	compliant

Complying with CropLife International recommendation for one way agrochemical packaging design criteria for liquids and solids [Guidelines for the safe formulation and packaging of crop protection products (Guideline 6)].

Resistance of the packaging material:

The material proposed for use (High Density Poly Ethylene) are known from experience to be compatible with water based formulations and are resistant to the influences of chemicals.

~~However,~~ The resistance of the packaging material HDPE/PA and HDPE/EVOH to its contents has been tested in the accelerated storage stability and the 2 year storage stability studies in accordance with CropLife International Technical Monograph No 17 (June 2009). The results show that no detrimental effects were noted thus demonstrating the acceptability of the packaging material.

Accelerated storage stability data (54 °C for 14 days), two year ambient storage stability data and low temperature storage stability data, (0 °C for 7 days) were submitted in HDPE EVOH, HDPE PA/glass packaging. All appropriate tests were carried out and there are no outstanding areas of concern with data submitted demonstrating the stability of the formulation on storage.

Study Comments: IIIA 4.1/01	<p>Determination of the stability of the packaging material was carried out by means of a visual inspection. The result was reported in conventional terms appropriate to describe the packaging material of the test item. This includes information about deformation or leakage of the packaging, effect on closure and weight change. The final value resulting from one valid assessment was reported:</p> <ul style="list-style-type: none"> - Result of analytical data confirmed that there has been no significant reduction in the contents of the active substances in both studies. - No adverse changes in the tested physical properties were detectable. The packaging materials were found to be of suitability for use with the formulation. It is expected that COEX/EVOH and COEX/PA will safely withstand normal handling and practical use. <p>The formulation appears to be stable throughout the test period of 2 years at ambient temperature and non-corrosive to COEX/PA and COEX/PA used as packaging material.</p>
Agreed endpoint: IIIA 4.1/01	<p>The packaging materials HDPE/EVOH and HDPE/PA tested in the 2-years storage stability studies have been approved and are suitable for the storage of the plant protection product.</p> <p>For packages made of HDPE for EC formulation additional study should be provided, extrapolation from HDPE/PA and HDPE/EVOH to HDPE is not acceptable.</p>

Report:	KIIIA 4.2.1/01, H. Schaffrath/D. Krüger 2020
Title:	<p>Compatibility Testing of Hostalen GF 4750 in DLT+FPF EC 10+75 according to Laboratory Methods A, B1, and C1 Test period: July 15, 2020 – September 16, 2020. Report no.: 2020/00198 Bayer CropScience AG, Monheim, Germany GLP/GEP: No Unpublished</p>
Document No:	M-770245-01-2
Guidelines:	None
GLP	No

Report:	KIIIA 4.2.1/02, Zhang, Y. 2021
Title:	<p>Statement to the requests of the authorities of Poland on Physicochemical properties of Sivanto Energy. Bayer CropScience AG, Monheim, Germany GLP/GEP: No Unpublished</p>
Document No:	M-770383-01-1
Guidelines:	None
GLP	No

The high-molecular-weight polyethylene material Hostalen GF 4750, which has the following physical properties, was tested:

Material: Hostalen GF 4750

Density: 0.95 [g/cm³]

Melt index: 32 [g/10 min/190 °C/21.6 kg]

Testing includes the determination of swelling, residual tensile strength, and oxidative and molecular degradation according to DIN EN ISO 13274.

RESULTS:

Swelling:

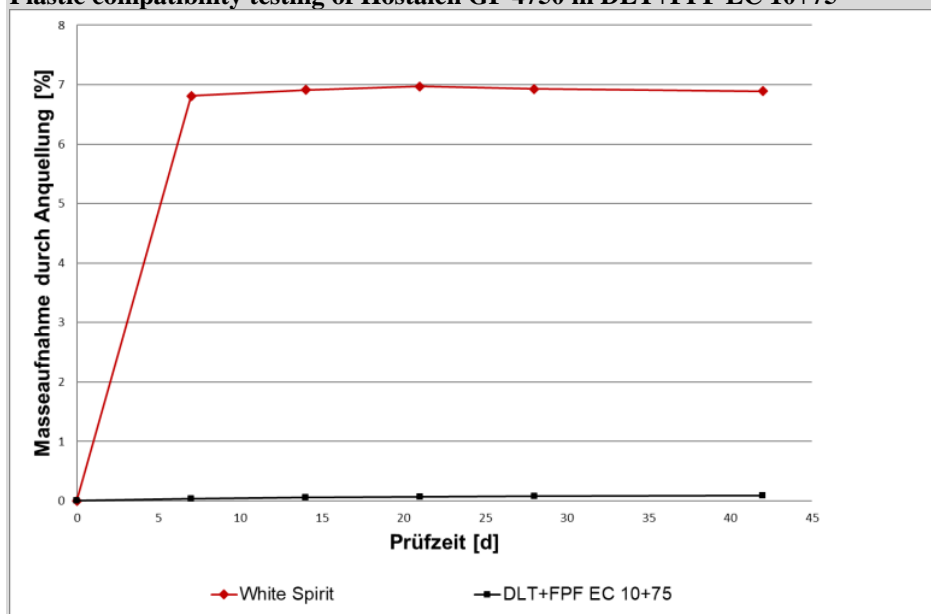
The following results were determined in the context of swell testing:

- Hostalen GF 4750 in DLT+FPF EC 10+75: 0.09%

The level of increase in mass in the standard test liquid white spirit (6.9% by mass).

The increase in mass is in line with the specification in the standard.

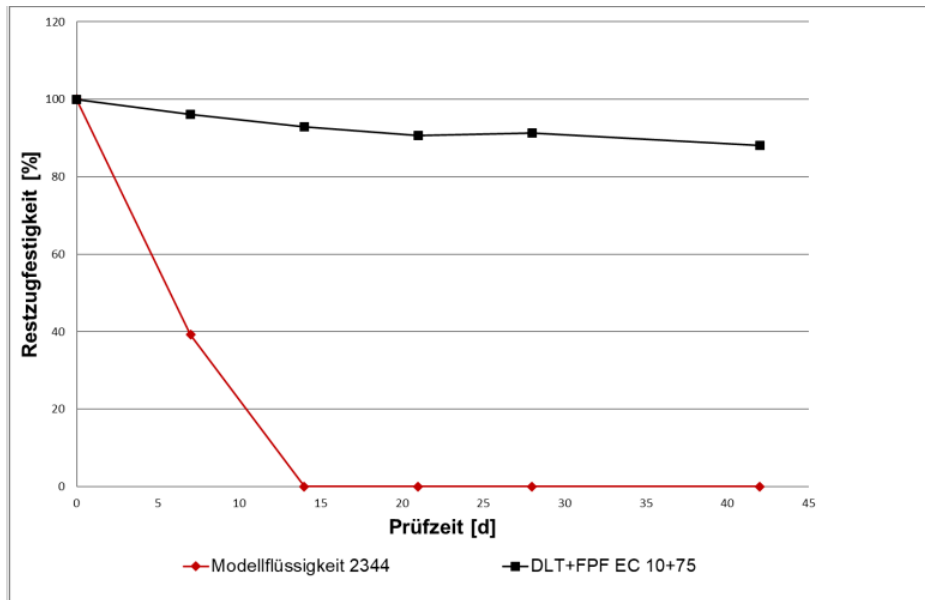
Plastic compatibility testing of Hostalen GF 4750 in DLT+FPF EC 10+75



Pin impression tests, determination of residual tensile strength:

After 42 days of immersion in DLT+FPF EC 10+75 (88.1%), the determined residual tensile strengths of Hostalen GF 4750 were well above the residual tensile strengths of the standard test liquid PFL-FR 2344. Plastic compatibility testing of Hostalen GF 4750 in DLT+FPF EC 10+75 compared with the standard test medium model liquid 2344;

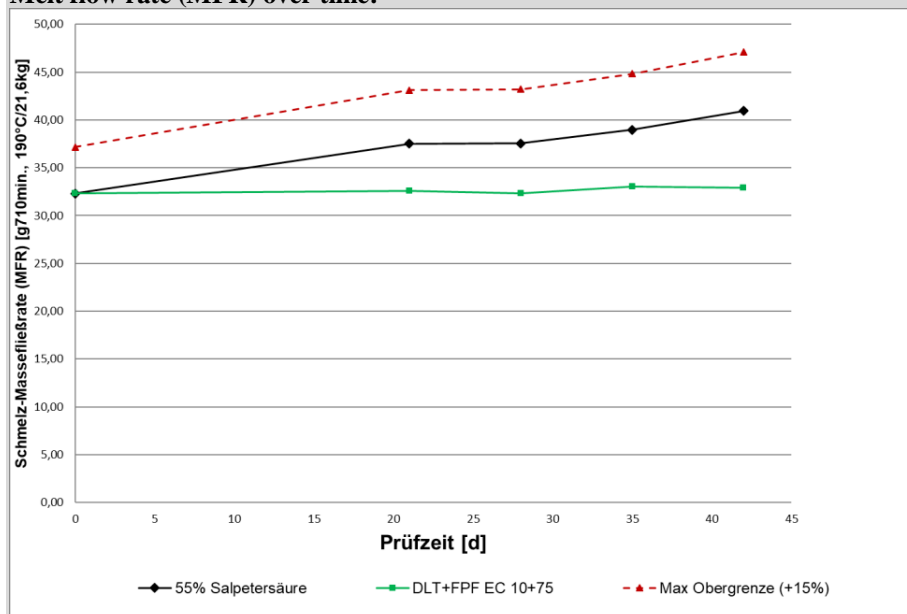
Residual tensile strength over time



Oxidative and molecular degradation:

The determined melt flow rates (MFR) of Hostalen GF 4750 in DLT+FPF EC 10+75 remained below the melt flow rates (MFR) of the standard test medium nitric acid 55% throughout the entire test period. Plastic compatibility testing of Hostalen GF 4750 in DLT+FPF EC 10+75 compared with the standard test medium nitric acid 55%;

Melt flow rate (MFR) over time:



The resistance of the test material Hostalen GF 4750 was investigated in line with DIN EN ISO 13 274. In comparison with the specified standard test liquids of the design type approval, the tested medium causes much lower sensitivity to stress cracking than the standard test liquid model liquid PFL-FR 2344, the increase in mass due to swelling in the test medium is much lower than in white spirit, and the melt flow rate (MFR) is much lower than in nitric acid 55%.

Based on the available results, an approved container made from HDPE can be used for DLT+FPF EC 10+75. The container to be used must have design type approval from BAM for white spirit and PFL-FR 2344. The maximum allowable values for density and vapor pressure of the product have to be taken into account.

Stability studies have shown that the formulated product Sivanto Energy is stable under the test conditions in HDPE / PA and HDPE / EVOH packagings. Furthermore, a compatibility study has been performed with Sivanto Energy in a container made from high-molecular-weight polyethylene material (HDPE) according to DIN EN ISO 13 274 including the determination of swelling, residual tensile strength, and oxidative and molecular degradation.

Based on the compatibility test results, it can be concluded that formulated product Sivanto Energy is compatible with HDPE container ensuring its usability being a suitable packaging for storage purpose.

As a result, a comparable stability performance of Sivato Energy in HDPE packaging to the one in HDPE / PA and HDPE / EVOH packagings could be foreseen without further results from a separate test package in HDPE.

Study Comments: IIIA 4.1/02	The applicant submitted additional data demonstrating the stability of the product in HDPE packaging. The presented documents can be considered as supporting the acceptance of packaging, however, taking into account the lack of accelerated storage study and ambient storage stability study in HDPE packaging, as well as the fact that HDPE compared to HDPE/PA and HDPE/EVOH is considered as “worse case”, in our opinion, the presented data is not sufficient to accept the HDPE packaging.
Agreed endpoint: IIIA 4.1/02	For packages made of HDPE for EC formulation storage stability study should be provided, extrapolation from HDPE/PA and HDPE/EVOH to HDPE is not acceptable.

IIIA 4.2 Procedures for Cleaning Application Equipment

IIIA 4.2.1 Procedures for cleaning application equipment and protective clothing

General statement

All application equipment and contaminated protective clothing should be washed/cleaned with water or a diluted detergent solution and thoroughly rinsed. Care should be taken not to spill the contaminated washings from application equipment into waste water channels. Contaminated cleaning liquids should be disposed of safely according to local regulations.

Application equipment:

Product left over in field spraying equipment which has not been sufficiently cleaned may cause damage during sequential treatment of sensitive crops. As a consequence, cleaning out of field spraying equipment is an essential part of the recommendations for use of plant protection product.

Procedure:

Empty the spraying equipment completely on the field just sprayed. Remove all filters and nozzles, scrub clean and rinse them with clean water. Put 10 % clean water into tank to cover the agitator. Operate a tank flushing system if fitted. Circulate water through the pump and controls for at least one minute. Drain sprayer, collect washings. Repeat procedure once more. Pump last washing water out through boom feed hoses and pipes. Collect washings. Clean off the outside of the sprayer using minimum water volumes. Collect washings. Replace cleaned nozzles and filters. Collect and put all washings back into the tank and spray out on the field headland, or otherwise safely dispose of them. Ensure the sprayer systems are completely drained before storage. Store Plant Protection Equipment in a properly designated store.

Protective clothing:

All contaminated clothing should be washed/cleaned through with a dilute detergent solution and thoroughly rinsed with clean water.

- Impermeable overalls, boots and face shields should be washed clean and dried.
- Permeable overalls should be laundered after use.
- Disposable overalls and gloves should be washed and disposed of as contaminated waste.
- Gloves and boots should be washed clean, if necessary on the insides as well.

IIIA 4.2.2 Effectiveness of the cleaning procedures

The product is dispersible in water. Therefore it can be removed from surfaces with water. Adding a dilute detergent solution will enhance the effectiveness of the cleaning process.

The SL-formulation contains considerable amounts of propylene-carbonate, due to which the formulation may adhere to the wall of the container. Consequently, the rinsed residue of the SL-formulation will be somewhat higher than for the standard SC-formulations. Therefore, in case that material has dried on surfaces, the use of heated water (25°C) will improve the cleaning effectiveness also.

Nevertheless, under practical conditions of use in the EU and given that the rinsing water is not colder than 7°C the rinsed residues will be negligible.

According to Efficacy Guideline 302, proposed by PSD and published in December 2001 by the European and Mediterranean Plant Protection Organization as document 02/9740, specific studies to prove the cleaning efficacy of application equipment is not required, if the product is not expected to cause plant damage at recommended use rates. This holds true for almost all insecticides and fungicides and specifically for the Flupyradifurone SL 200.

Therefore, further studies are not considered to be necessary.

Nevertheless, a study is presented below that had been requested for herbicides (in case of problems of residues when spraying occurs to avoid phytotoxicity in fields) and insecticides (decontamination of tanks if residues occur).

Report:	KIIIA 4.2.2/01, Friessleben, R. 2008
Title:	Summary and conclusive report of studies on spray tank cleaning realized in the years 2000 - 2008
Document No:	M-357166-01-1
Guidelines:	None
GLP	No

The report summarizes the results of trials on tank cleaning realized in the years 2000 - 2008. These trials were carried out because registration of crop protection products requires specific information on the cleaning of sprayer tanks to avoid damages during subsequent treatments.

During this period, 72 studies were conducted, in which a total of 60 active substances (16 fungicides, 33 herbicides, 3 safeners, 7 insecticides and 1 growth regulator) were tested. All tests were done with the same spraying equipment and under the same test protocol, thus the differences found in the results reflect the different behaviour of active substances and formulation systems.

Within this report it has been shown that cleaning efficacy does not depend on chemical or formulation related parameters and therefore a global statement on tank cleaning efficacy is justified. The results can be summarized as follows:

1. The established cleaning procedure, including two rinsing processes and the careful cleaning of all filters, is able to remove or reduce active substances leftover down to neglectable quantities.
2. By following the tank cleaning recommendation product groups (herbicides, fungicides, insecticides, and growth regulators), formulations and concentrations differ only quantitatively. The cleaning success follows an exponential function of the general formula $y = a e^{-bx}$. From one cleaning step to the next one, the initial concentration is reduced by at least one order of magnitude.
3. After filling the tank with fresh water, the active substance concentrations in all trials are either below the Limit of Quantification or are not relevant as far as biological effects during follow-up treatments are concerned.

4. According to the extensive number of results available, the recommendations on the product label regarding tank cleaning can apply equally to all products.

As a conclusion it can be proposed that no further studies for individual formulations need to be performed.

Study Comments: IIIA 4.2.2/01	Acceptable.
Agreed endpoint: IIIA 4.2.2/01	The proposed cleaning procedure is considered sufficient.

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 2.1 / 01 ... also filed: KCP 2.4 / 01 KCP 2.5 / 01 KCP 2.6 / 01 KCP 2.8.2 / 01 KCP 2.8.6 / 01	Hennig-Gizewski, S.	2015	Physical, chemical and technical properties of deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Final report Report No.: FM0239(PCF00)G01, Edition Number: M-513765-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 2.2 / 01 ... also filed: KCP 2.3 / 01	Keldenich, H. P.	2015	Safety-relevant data of deltamethrin + flupyradifurone EC 85 (10+75 g/L) Report No.: 2014/00975, Edition Number: M-518123-01-1 Bayer Technology Services GmbH, Leverkusen, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 2.3 / 01 ... also filed: KCP 2.2 / 01	Keldenich, H. P.	2015	Safety-relevant data of deltamethrin + flupyradifurone EC 85 (10+75 g/L) Report No.: 2014/00975, Edition Number: M-518123-01-1 Bayer Technology Services GmbH, Leverkusen, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 2.4 / 01 ... also filed: KCP 2.1 / 01 KCP 2.5 / 01 KCP 2.6 / 01 KCP 2.8.2 / 01 KCP 2.8.6 / 01	Hennig-Gizewski, S.	2015	Physical, chemical and technical properties of deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Final report Report No.: FM0239(PCF00)G01, Edition Number: M-513765-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 2.5 / 01 ... also filed: KCP 2.1 / 01 KCP 2.4 / 01 KCP 2.6 / 01 KCP 2.8.2 / 01 KCP 2.8.6 / 01	Hennig-Gizewski, S.	2015	Physical, chemical and technical properties of deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Final report Report No.: FM0239(PCF00)G01, Edition Number: M-513765-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP 2.6 / 01 ... also filed: KCP 2.1 / 01 KCP 2.4 / 01 KCP 2.5 / 01 KCP 2.8.2 / 01 KCP 2.8.6 / 01	Hennig-Gizewski, S.	2015	Physical, chemical and technical properties of deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Final report Report No.: FM0239(PCF00)G01, Edition Number: M-513765-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 2.7 / 01	Rexer, K.	2016	Storage stability at elevated temperature and cold stability of deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Packaging material: COEX/EVOH - Final report (14 days) - 1. Amendment Report No.: FM0239(ACF03)N01, Edition Number: M-523981-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2016-10-07 GLP/GEP: No unpublished	No	Bayer
KCP 2.7 / 02	Rexer, K.	2016	Storage stability at elevated temperature and cold stability of deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Packaging material: COEX/PA - Final report (14 days) - 1. Amendment Report No.: FM0239(ACF02)N01, Edition Number: M-523979-02-1 Bayer CropScience AG, Monheim, Germany ... amended: 2016-10-07 GLP/GEP: No unpublished	No	Bayer
KCP 2.7 / 03	Rexer, K.	2017	Shelf life of deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Packaging material: COEX/EVOH - Final report (2 years) Report No.: FM0239(SLF03)N01, Edition Number: M-579373-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 2.7 / 04	Rexer, K.	2017	Shelf life of deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Packaging material: COEX/PA - Final report (2 years) Report No.: FM0239(SLF02)N01, Edition Number: M-579371-01-1 Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer

Data Point	Author(s)	Year	Title Company Report No. Source GLP or GEP status published or not	Vertebrate study Y/N	Owner
KCP 2.8.2 / 01 ... also filed: KCP 2.1 / 01 KCP 2.4 / 01 KCP 2.5 / 01 KCP 2.6 / 01 KCP 2.8.6 / 01	Hennig-Gizewski, S.	2015	Physical, chemical and technical properties of deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Final report Report No.: FM0239(PCF00)G01, Edition Number: M-513765-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 2.8.6 / 01 ... also filed: KCP 2.1 / 01 KCP 2.4 / 01 KCP 2.5 / 01 KCP 2.6 / 01 KCP 2.8.2 / 01	Hennig-Gizewski, S.	2015	Physical, chemical and technical properties of deltamethrin + flupyradifurone EC 85 (10+75 g/L) - Final report Report No.: FM0239(PCF00)G01, Edition Number: M-513765-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP Section 12 / 01	Anon.	2019	DLT+FPF EC 10+75 G Report No.: M-567053-03-1 Bayer AG, Leverkusen, Germany GLP/GEP: n.a. unpublished	No	Bayer
KCP 4.2.1/01	H. Schaffrath/D. Krüger	2020	Compatibility Testing of Hostalen GF 4750 in DLT+FPF EC 10+75 according to Laboratory Methods A, B1, and C1, Test period: July 15, 2020 – September 16, 2020 Report No.: M-770245-01-2 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 4.2.1/02 KCP 2.4.2/02	Zhang Y.	2021	Statement to the requests of the authorities of Poland on Physicochemical properties of Sivanto Energy. Report No.: M-770383-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 4.2.2/01	Friessleben, R.	2008	Summary and conclusive report of studies on spray tank cleaning realized in the years 2000 – 2008 Report No.: M-357166-01-1 Bayer CropScience AG, Monheim, Germany GLP/GEP: No 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.

Flupyradifurone

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 2.1.1 /01	Smeykal, H.	2010	BYI 02960, pure substance: Melting point, boiling point, thermal stability Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20090051.01, Edition Number: M-367370-01-1 Date: 2010-03-25 GLP/GEP: yes, unpublished ...also filed: KIIA 2.1.2 /01 ...also filed: KIIA 2.1.3 /01	N	Bayer
KIIA 2.1.1 /02	Smeykal, H.	2011	Flupyradifurone (BYI 02960), technical substance: Melting point, boiling point, thermal stability Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110197.01, Edition Number: M-414242-01-1 Date: 2011-09-16 GLP/GEP: yes, unpublished ...also filed: KIIA 2.1.2 /02 ...also filed: KIIA 2.1.3 /02	N	Bayer
KIIA 2.1.2 /01	Smeykal, H.	2010	BYI 02960, pure substance: Melting point, boiling point, thermal stability Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20090051.01, Edition Number: M-367370-01-1 Date: 2010-03-25 GLP/GEP: yes, unpublished ...also filed: KIIA 2.1.1 /01 ...also filed: KIIA 2.1.3 /01	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 2.1.2 /02	Smeykal, H.	2011	Flupyradifurone (BYI 02960), technical substance: Melting point, boiling point, thermal stability Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110197.01, Edition Number: M-414242-01-1 Date: 2011-09-16 GLP/GEP: yes, unpublished ...also filed: KIIA 2.1.1 /02 ...also filed: KIIA 2.1.3 /02	N	Bayer
KIIA 2.1.3 /01	Smeykal, H.	2010	BYI 02960, pure substance: Melting point, boiling point, thermal stability Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20090051.01, Edition Number: M-367370-01-1 Date: 2010-03-25 GLP/GEP: yes, unpublished ...also filed: KIIA 2.1.1 /01 ...also filed: KIIA 2.1.2 /01	N	Bayer
KIIA 2.1.3 /02	Smeykal, H.	2011	Flupyradifurone (BYI 02960), technical substance: Melting point, boiling point, thermal stability Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110197.01, Edition Number: M-414242-01-1 Date: 2011-09-16 GLP/GEP: yes, unpublished ...also filed: KIIA 2.1.1 /02 ...also filed: KIIA 2.1.2 /02	N	Bayer
KIIA 2.2 /01	Bogdoll, B.; Strunk, B.	2011	Flupyradifurone (BYI 02960), pure substance: Relative density Bayer CropScience, Report No.: PA09/006, Edition Number: M-412635-01-1 Date: 2011-08-18 GLP/GEP: yes, unpublished	N	Bayer
KIIA 2.2 /02	Eyrich, U.; Bogdoll, B.	2011	Flupyradifurone (BYI 02960), technical substance : Relative density Bayer CropScience, Report No.: PA11/063, Edition Number: M-414075-01-1 Date: 2011-09-16 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 2.3.1 /01	Smeykal, H.	2008	BYI 02960, pure substance: Vapour pressure - Final report Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20080615.01, Edition Number: M-309853-01-1 Date: 2008-10-10 GLP/GEP: yes, unpublished ...also filed: KIIA 7.4.9 /01	N	Bayer
KIIA 2.4.1 /01	Bogdoll, B.; Strunk, B.	2011	Flupyradifurone (BYI 02960), pure substance - Physical characteristics colour, physical state and odour Bayer CropScience, Report No.: PA09/008, Edition Number: M-412655-01-1 Date: 2011-08-18 GLP/GEP: yes, unpublished ...also filed: KIIA 2.4.2 /01	N	Bayer
KIIA 2.4.1 /02	Eyrich, U.; Bogdoll, B.	2011	Flupyradifurone (BYI 02960), technical substance: Physical characteristics colour, physical state and odour Bayer CropScience, Report No.: PA11/062, Edition Number: M-414072-01-1 Date: 2011-09-16 GLP/GEP: yes, unpublished ...also filed: KIIA 2.4.2 /02	N	Bayer
KIIA 2.4.2 /01	Bogdoll, B.; Strunk, B.	2011	Flupyradifurone (BYI 02960), pure substance - Physical characteristics colour, physical state and odour Bayer CropScience, Report No.: PA09/008, Edition Number: M-412655-01-1 Date: 2011-08-18 GLP/GEP: yes, unpublished ...also filed: KIIA 2.4.1 /01	N	Bayer
KIIA 2.4.2 /02	Eyrich, U.; Bogdoll, B.	2011	Flupyradifurone (BYI 02960), technical substance: Physical characteristics colour, physical state and odour Bayer CropScience, Report No.: PA11/062, Edition Number: M-414072-01-1 Date: 2011-09-16 GLP/GEP: yes, unpublished ...also filed: KIIA 2.4.1 /02	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 2.5.1.1 /01	Peters; S.	2009	Spectral data set of BYI 02960 a.i. - Reference material Bayer CropScience, Report No.: 15-600-2439, Edition Number: M-345761-01-1 Date: 2009-04-07 GLP/GEP: yes, unpublished ...also filed: KIIA 2.5.1.2 /01 ...also filed: KIIA 2.5.1.3 /01 ...also filed: KIIA 2.5.1.4 /01 ...also filed: KIIA 2.5.1.5 /01	N	Bayer
KIIA 2.5.1.2 /01	Peters; S.	2009	Spectral data set of BYI 02960 a.i. - Reference material Bayer CropScience, Report No.: 15-600-2439, Edition Number: M-345761-01-1 Date: 2009-04-07 GLP/GEP: yes, unpublished ...also filed: KIIA 2.5.1.1 /01 ...also filed: KIIA 2.5.1.3 /01 ...also filed: KIIA 2.5.1.4 /01 ...also filed: KIIA 2.5.1.5 /01	N	Bayer
KIIA 2.5.1.3 /01	Peters; S.	2009	Spectral data set of BYI 02960 a.i. - Reference material Bayer CropScience, Report No.: 15-600-2439, Edition Number: M-345761-01-1 Date: 2009-04-07 GLP/GEP: yes, unpublished ...also filed: KIIA 2.5.1.1 /01 ...also filed: KIIA 2.5.1.2 /01 ...also filed: KIIA 2.5.1.4 /01 ...also filed: KIIA 2.5.1.5 /01	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 2.5.1.4 /01	Peters; S.	2009	Spectral data set of BYI 02960 a.i. - Reference material Bayer CropScience, Report No.: 15-600-2439, Edition Number: M-345761-01-1 Date: 2009-04-07 GLP/GEP: yes, unpublished ...also filed: KIIA 2.5.1.1 /01 ...also filed: KIIA 2.5.1.2 /01 ...also filed: KIIA 2.5.1.3 /01 ...also filed: KIIA 2.5.1.5 /01	N	Bayer
KIIA 2.5.1.5 /01	Peters; S.	2009	Spectral data set of BYI 02960 a.i. - Reference material Bayer CropScience, Report No.: 15-600-2439, Edition Number: M-345761-01-1 Date: 2009-04-07 GLP/GEP: yes, unpublished ...also filed: KIIA 2.5.1.1 /01 ...also filed: KIIA 2.5.1.2 /01 ...also filed: KIIA 2.5.1.3 /01 ...also filed: KIIA 2.5.1.4 /01	N	Bayer
KIIA 2.6 /01	Wiche, A.; Bogdoll, B.	2011	BYI 02960, pure substance: Solubility in distilled water (pH 7), at pH 4 and pH 9 (flask method) Bayer CropScience, Report No.: PA09/003, Edition Number: M-409513-01-1 Date: 2011-06-17 GLP/GEP: yes, unpublished	N	Bayer
KIIA 2.7 /01	Eyrich, U.; Bogdoll, B.	2011	Flupyradifurone (BYI 02960): Solubility in organic solvents Bayer CropScience, Report No.: PA09/005, Edition Number: M-414064-01-1 Date: 2011-09-16 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 2.8.1 /01	Bogdoll, B.; Strunk, B.	2011	Flupyradifurone (BYI 02960), pure substance: Partition coefficient 1-octanol / water at pH 4, pH 7 and pH 9 (HPLC-method) Bayer CropScience, Report No.: PA09/004, Edition Number: M-414485-01-1 Date: 2011-09-26 GLP/GEP: yes, unpublished ...also filed: KIIA 2.8.2 /01	N	Bayer
KIIA 2.8.2 /01	Bogdoll, B.; Strunk, B.	2011	Flupyradifurone (BYI 02960), pure substance: Partition coefficient 1-octanol / water at pH 4, pH 7 and pH 9 (HPLC-method) Bayer CropScience, Report No.: PA09/004, Edition Number: M-414485-01-1 Date: 2011-09-26 GLP/GEP: yes, unpublished ...also filed: KIIA 2.8.1 /01	N	Bayer
KIIA 2.9.1 /01	Mislankar, S.; Woodard, D.	2011	BYI-02960: Hydrolytic degradation Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERVP019, Edition Number: M-398952-01-1 Date: 2011-01-07 GLP/GEP: yes, unpublished ...also filed: KIIA 7.5 /01	N	Bayer
KIIA 2.9.2 /01	Hall, L. R.	2011	Phototransformation of [14C]BYI 02960 in aqueous pH 7 buffer - amended report Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERVP042-1, Edition Number: M-418426-02-1 Date: 2011-11-28 ...Amended: 2012-03-05 GLP/GEP: yes, unpublished ...also filed: KIIA 2.9.4 /01 ...also filed: KIIA 7.6 /01	N	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KIIA 2.9.3 /01	Heinemann, O.	2011	BYI 02960: Determination of the quantum yield and assessment of the environmental half-life of the direct photo-degradation in water Bayer CropScience, Report No.: MEF-11/554, Edition Number: M-414756-01-2 EPA MRID No.: 48843668 Date: 2011-09-26 GLP/GEP: yes, unpublished ...also filed: KIIA 2.9.4 /02 ...also filed: KIIA 7.6 /02	N	Bayer
KIIA 2.9.4 /01	Hall, L. R.	2011	Phototransformation of [14C]BYI 02960 in aqueous pH 7 buffer - amended report Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: MERV042-1, Edition Number: M-418426-02-1 Date: 2011-11-28 ...Amended: 2012-03-05 GLP/GEP: yes, unpublished ...also filed: KIIA 2.9.2 /01 ...also filed: KIIA 7.6 /01	N	Bayer
KIIA 2.9.4 /02	Heinemann, O.	2011	BYI 02960: Determination of the quantum yield and assessment of the environmental half-life of the direct photo-degradation in water Bayer CropScience, Report No.: MEF-11/554, Edition Number: M-414756-01-2 EPA MRID No.: 48843668 Date: 2011-09-26 GLP/GEP: yes, unpublished ...also filed: KIIA 2.9.3 /01 ...also filed: KIIA 7.6 /02	N	Bayer
KIIA 2.9.5 /01	Wiche, A.; Bogdoll, B.	2011	Flupyradifurone (BYI 02960), pure substance : Dissociation constant in water Bayer CropScience, Report No.: PA10/048, Edition Number: M-414102-01-1 Date: 2011-09-16 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 2.11.1 /01	Smeykal, H.	2011	Flupyradifurone (BYI 02960), technical substance: flammability (solids) Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110197.03, Edition Number: M-414249-01-1 Date: 2011-09-16 GLP/GEP: yes, unpublished	N	Bayer
KIIA 2.11.2 /01	Smeykal, H.	2011	Flupyradifurone (BYI 02960), technical substance: auto-flammability Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110197.05, Edition Number: M-414252-01-1 Date: 2011-09-16 GLP/GEP: yes, unpublished	N	Bayer
KIIA 2.11.2 /02	Smeykal, H.	2011	Flupyradifurone (BYI 02960), technical substance: autoflammability (UN Bowes Cameron Cage Test) Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110197.07, Edition Number: M-414257-01-1 Date: 2011-09-16 GLP/GEP: yes, unpublished	N	Bayer
KIIA 2.13 /01	Smeykal, H.	2011	Flupyradifurone (BYI 02960), technical substance: explosive properties Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110197.04, Edition Number: M-414250-01-1 Date: 2011-09-16 GLP/GEP: yes, unpublished	N	Bayer
KIIA 2.14 /01	Eyrich, U.; Bogdoll, B.	2011	Flupyradifurone (BYI 02960), technical substance : Determination of the surface tension Bayer CropScience, Report No.: PA11/065, Edition Number: M-414086-01-1 Date: 2011-09-16 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 2.15 /01	Smeykal, H.	2011	Flupyradifurone (BYI 02960), technical substance: oxidizing properties Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110197.06, Edition Number: M-414253-01-1 Date: 2011-09-16 GLP/GEP: yes, unpublished	N	Bayer
KIIA 2.16 /01	Eyrich, U.; Bogdoll, B.	2011	Flupyradifurone (BYI 02960), pure substance: Determination of the pH-value in distilled water Bayer CropScience, Report No.: PA09/007, Edition Number: M-412128-01-1 Date: 2011-08-09 GLP/GEP: yes, unpublished	N	Bayer
KIIA 2.16 /02	Eyrich, U.; Bogdoll, B.	2011	Flupyradifurone (BYI 02960), technical substance : Determination of the pH-value in distilled water Bayer CropScience, Report No.: PA11/064, Edition Number: M-414084-01-1 Date: 2011-09-16 GLP/GEP: yes, unpublished	N	Bayer
KIIA 2.17.1 /01	Wagner, S.	2011	Chemical storage stability of BYI 02960 - Flupyradifurone (BYI 02960) Bayer CropScience, Report No.: 15-155-2438, Edition Number: M-411305-01-1 Date: 2011-07-19 GLP/GEP: yes, unpublished	N	Bayer
KIIA 2.17.2 /01	Wagner, S.	2011	Stability to normal and elevated temperature, metals, and metal ions and corrosion characteristics to plastic containers of flupyradifurone (BYI 02960) according to OPPTS 830.6313 and 830.6320 Bayer CropScience, Report No.: 15-160-2527, Edition Number: M-413798-01-1 Date: 2011-09-12 GLP/GEP: yes, unpublished	N	Bayer
KIIA 2.18 /01	Eyrich, U.; Bogdoll, B.	2011	Flupyradifurone (BYI 02960), technical substance : The oxidation or reduction properties Bayer CropScience, Report No.: PA11/066, Edition Number: M-414080-01-1 Date: 2011-09-16 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 2.18 /02	Petrovic, P.	2011	Flupyradifurone (BYI 02960), technical substance: Complex formation ability in water Allessa Chemie GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: B 015/2011, Edition Number: M-414563-01-1 Date: 2011-09-21 GLP/GEP: yes, unpublished	N	Bayer
KIIA 2.18 /03	Smeykal, H.	2011	Flupyradifurone (BYI 02960), technical substance: Particle size distribution Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110197.02, Edition Number: M-414246-01-1 Date: 2011-09-16 GLP/GEP: yes, unpublished	N	Bayer

Deltamethrin

Annex point / reference num- ber	Author(s)	Year	Title Source (<i>where different from company</i>) Company name, Report No., Date, GLP/GEP status (<i>where relevant</i>) published or not	Vertebrate study	Owner
KCA 2.1 / 01	Sweetapple, G. G.	1990	Deltamethrin active ingredient: Determination of melting point. Ricerca, Inc., USA Bayer Report No.: A70753 Edition Number: M-149247-01-1 Date: 1990-03-29 GLP/GEP: Yes, unpublished ... also filed: KCA 2.14 / 04 KCA 2.3 / 02	No	Bayer
KCA 2.1 / 02	Maier, T.; Rexer, K.	1988	Deltamethrin substance, technical. Decomposition point. Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A38362 Edition Number: M-120009-01-1 Date: 1988-06-23 GLP/GEP: No, unpublished ... also filed: KCA 2.14 / 01	No	Bayer
KCA 2.1 / 03	Smeykal, H.	2012	Deltamethrin (AE F032640): Melting point, boiling point, thermal stability Siemens AG, Frankfurt am Main, Germany Bayer Report No.: 20120214.01 Edition Number: M-440513-01-1 Date: 2012-10-23 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.1 / 04	Cichy, M.	2012	Deltamethrin (AE F032640) - AE F032640-01-11 Bayer Report No.: 09084-01 Edition Number: M-384805-02-1 Date: 2012-04-26 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.3 / 04 KCA 2.6 / 05 KCA 2.8 / 07 KCA 2.9 / 06	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.2 / 01	Yoder, S. J.	1991	Deltamethrin A.I. - Determination of vapour pressure. Ricerca, Inc., Analytical Services, Painesville, OH, USA Bayer Report No.: A47916 Edition Number: M-136657-01-1 Date: 1991-09-12 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.2 / 02	Grelet, D.	1995	Deltamethrin: Henry's law constant. Roussel Uclaf, Romainville, France Bayer Report No.: A70747 Edition Number: M-149242-01-1 Date: 1995-03-21 GLP/GEP: No, unpublished	No	Bayer
KCA 2.2 / 03	Smeykal, H.	2012	Deltamethrin (AE F032640), pure substance: Vapour pressure Siemens AG, Frankfurt am Main, Germany Bayer Report No.: 20120215.01 Edition Number: M-440512-01-1 Date: 2012-10-23 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.2 / 04	Weilbaecher, R.	2007	Deltamethrin (AE F032640) - AE F032640 00 1B99 0012 Bayer Report No.: AZ 14153 Edition Number: M-289644-01-1 Date: 2007-06-28 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.4 / 04 KCA 2.5 / 04 KCA 2.7 / 03	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.2 / 05	Weilbaecher, R.	2008	1st addendum to certificate AZ 14153 Bayer Report No.: M-298849-01-1 Date: 2008-03-12 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.4 / 05 KCA 2.5 / 05 KCA 2.7 / 04	No	Bayer
KCA 2.2 / 06	Ziemer, F.	2012	Deltamethrin (AE F032640): Calculation of the Henry's law constant Bayer Report No.: AF12/060 Edition Number: M-441192-01-1 Date: 2012-11-12 GLP/GEP: No, unpublished	No	Bayer
KCA 2.3 / 01	Thomas, E. A.; Sweetapple, G. G.	1990	Deltamethrin active ingredient: Determination of color, physical state, odor, density and pH. Ricerca, Inc., USA Bayer Report No.: A70752 Edition Number: M-149246-01-1 Date: 1990-03-29 GLP/GEP: Yes, unpublished ... also filed: KCA 2.14 / 05	No	Bayer
KCA 2.3 / 02	Sweetapple, G. G.	1990	Deltamethrin active ingredient: Determination of melting point. Ricerca, Inc., USA Bayer Report No.: A70753 Edition Number: M-149247-01-1 Date: 1990-03-29 GLP/GEP: Yes, unpublished ... also filed: KCA 2.1 / 01 KCA 2.14 / 04	No	Bayer

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.3 / 03	Ziemer, F.; Strunk, B.	2012	Deltamethrin (AE F032640): Physical characteristics colour, physical state and odour Bayer Report No.: PA12/088 Edition Number: M-440685-01-1 Date: 2012-10-31 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.3 / 04	Cichy, M.	2012	Deltamethrin (AE F032640) - AE F032640-01-11 Bayer Report No.: 09084-01 Edition Number: M-384805-02-1 Date: 2012-04-26 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.1 / 04 KCA 2.6 / 05 KCA 2.8 / 07 KCA 2.9 / 06	No	Bayer
KCA 2.4 / 01	Devaux, P.	1993	Deltamethrin: Structural analysis. AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom Bayer Report No.: A70764 Edition Number: M-149258-01-1 Date: 1993-11-23 GLP/GEP: No, unpublished	No	Bayer
KCA 2.4 / 02	Maurer, T.; Schaefer, D.	2002	Additional information on hydrolysis of deltamethrin at pH8 and contribution of hydrolysis to the overall dissipation of deltamethrin from surface/natural water bodies Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C018813 Edition Number: M-206738-01-1 Date: 2002-01-21 GLP/GEP: No, unpublished ... also filed: KCA 7.2.1.1 / 02 KCA 7.2.1.2 / 04	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.4 / 03	Cichy, M.; Junker, H.; Doerner-Rieping, S.	2013	Amendment No 1 to spectral data (UV / VIS, IR, 1H-NMR, 13C-NMR, MS) and molar extinction coeffi- cients for deltamethrin (AE F032640) Bayer Report No.: PA11/084 Edition Number: M-420781-02-1 Date: 2011-12-19 ... amended: 2013-05-22 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.4 / 04	Weilbaecher, R.	2007	Deltamethrin (AE F032640) - AE F032640 00 1B99 0012 Bayer Report No.: AZ 14153 Edition Number: M-289644-01-1 Date: 2007-06-28 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.2 / 04 KCA 2.5 / 04 KCA 2.7 / 03	No	Bayer
KCA 2.4 / 05	Weilbaecher, R.	2008	1st addendum to certificate AZ 14153 Bayer Report No.: M-298849-01-1 Date: 2008-03-12 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.2 / 05 KCA 2.5 / 05 KCA 2.7 / 04	No	Bayer
KCA 2.4 / 06	Cichy, M.	2009	Determination of the specific optical rotation of deltamethrin (AE F032640) Bayer Report No.: AF09/008 Edition Number: M-337809-01-1 Date: 2009-03-02 GLP/GEP: No, unpublished	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.4 / 07	Bowen, T.	2008	Certificate of analysis of deltamethrin (AE F032640) - AE F032640-01-06 Bayer Report No.: AZ 15443 Edition Number: M-309552-01-1 Date: 2008-10-21 GLP/GEP: n.a., unpublished confidential	No	Bayer
KCA 2.4 / 08	Golka, I.; Patzke, D.	2018	Determination of the specific optical rotation of five batches of technical deltamethrin (AE F032640) Bayer Report No.: PA18/069 Edition Number: M-642212-01-1 Date: 2018-11-26 GLP/GEP: Yes, unpublished ... also filed: KCA 1.9 / 04	No	Bayer
KCA 2.5 / 01	Yoder, S. J.	1990	Deltamethrin A.I. - Determination of solubility in water, n-Octanol, and Xylenes. Ricerca, Inc., Analytical Services, Painesville, OH, USA Bayer Report No.: A45109 Edition Number: M-129043-01-1 Date: 1990-10-04 GLP/GEP: Yes, unpublished ... also filed: KCA 2.6 / 01	No	Bayer
KCA 2.5 / 02	Muehlberger, B.; Jordan, G.	2000	Solubility in water at 20 degrees C - Deltamethrin, substance: pure - Code: AE F032640 00 1B99 0012 Aventis Research & Technologies Deutschland GmbH & Co KG, Analytisches Laboratorium, Frankfurt am Main, Germany Bayer Report No.: C009221 Edition Number: M-198231-01-1 Date: 2000-08-02 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.5 / 03	Bogdoll, B.; Strunk, B.	2012	Solubility of deltamethrin (AE F032640) in distilled water (column elution method) Bayer Report No.: PA09/042 Edition Number: M-439336-01-1 Date: 2012-10-10 GLP/GEP: Yes, unpublished	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.5 / 04	Weilbaecher, R.	2007	Deltamethrin (AE F032640) - AE F032640 00 1B99 0012 Bayer Report No.: AZ 14153 Edition Number: M-289644-01-1 Date: 2007-06-28 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.2 / 04 KCA 2.4 / 04 KCA 2.7 / 03	No	Bayer
KCA 2.5 / 05	Weilbaecher, R.	2008	1st addendum to certificate AZ 14153 Bayer Report No.: M-298849-01-1 Date: 2008-03-12 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.2 / 05 KCA 2.4 / 05 KCA 2.7 / 04	No	Bayer
KCA 2.6 / 01	Yoder, S. J.	1990	Deltamethrin A.I. - Determination of solubility in water, n-Octanol, and Xylenes. Ricerca, Inc., Analytical Services, Painesville, OH, USA Bayer Report No.: A45109 Edition Number: M-129043-01-1 Date: 1990-10-04 GLP/GEP: Yes, unpublished ... also filed: KCA 2.5 / 01	No	Bayer
KCA 2.6 / 02	Muehlberger, B.; Jordan, G.	2000	Solubility in organic solvents at 20 degrees C Deltamethrin substance technical Code: AE F032640 00 1D99 0002 Aventis Research & Technologies Deutschland GmbH & Co KG, Analytisches Laboratorium, Frankfurt am Main, Germany Bayer Report No.: C009220 Edition Number: M-198230-01-1 Date: 2000-08-02 GLP/GEP: Yes, unpublished	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.6 / 03	Taranta, C.; Rexer, K.	2000	Determination of the storage stability (Accelerated storage test 14 days at 54 degrees C) Deltamethrin emul- sifiable concentrate 25 g/L Code: AE F032640 00 EC03 B008 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C008271 Edition Number: M-197340-01-1 Date: 2000-04-14 GLP/GEP: No, unpublished	No	Bayer
KCA 2.6 / 04	Wiche, A.; Ziemer, F.	2012	Deltamethrin (AE F032640), technical substance: Solubility in organic solvents Bayer Report No.: PA12/089 Edition Number: M-439977-01-1 Date: 2012-10-16 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.6 / 05	Cichy, M.	2012	Deltamethrin (AE F032640) - AE F032640-01-11 Bayer Report No.: 09084-01 Edition Number: M-384805-02-1 Date: 2012-04-26 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.1 / 04 KCA 2.3 / 04 KCA 2.8 / 07 KCA 2.9 / 06	No	Bayer
KCA 2.7 / 01	Yoder, S. J.	1991	Deltamethrin A.I. - Determination of Octanol/Water partition coefficient. Ricerca, Inc., Analytical Services, Painesville, OH, USA Bayer Report No.: A47915 Edition Number: M-136655-01-1 Date: 1991-09-12 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.7 / 02	Wiche, A.; Bogdoll, B.	2012	Deltamethrin (AE F032640), pure substance: Partition coefficient 1-octanol / water (HPLC method) Bayer Report No.: PA10/070 Edition Number: M-437011-01-1 Date: 2012-08-17 GLP/GEP: Yes, unpublished	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.7 / 03	Weilbaecher, R.	2007	Deltamethrin (AE F032640) - AE F032640 00 1B99 0012 Bayer Report No.: AZ 14153 Edition Number: M-289644-01-1 Date: 2007-06-28 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.2 / 04 KCA 2.4 / 04 KCA 2.5 / 04	No	Bayer
KCA 2.7 / 04	Weilbaecher, R.	2008	1st addendum to certificate AZ 14153 Bayer Report No.: M-298849-01-1 Date: 2008-03-12 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.2 / 05 KCA 2.4 / 05 KCA 2.5 / 05	No	Bayer
KCA 2.7 / 05	Eyrich, U.; Ziemer, F.	2013	BCS-BY84407 (4'OH-Deltamethrin): Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 (HPLC method) Bayer Report No.: PA13/028 Edition Number: M-454807-01-1 Date: 2013-05-29 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.7 / 06	Doerner-Rieping, S.	2012	Deltamethrin (AE F032640) - BCS-BY84407-01-01 Bayer Report No.: 09494-00 Edition Number: M-441171-01-1 Date: 2012-11-08 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.14 / 09	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.7 / 07	Zierner, F.; Kloeckner, C.	2013	BCS-CW57835 (Serinyl-BrCA): Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 (shake flask method) Bayer Report No.: PA13/015 Edition Number: M-451650-01-1 Date: 2013-04-19 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.7 / 08	Doerner-Rieping, S.	2012	Deltamethrin (AE F032640) - BCS-CW57835-01-01 Bayer Report No.: 09495-00 Edition Number: M-441562-01-1 Date: 2012-11-08 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.14 / 11	No	Bayer
KCA 2.7 / 09	Wiche, A.; Bogdoll, B.	2012	AE F108569 (alpha-R-isomer of deltamethrin): Partition coefficient 1-octanol / water (HPLC method) Bayer Report No.: PA10/067 Edition Number: M-437019-01-1 Date: 2012-08-17 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.7 / 10	Weilbaeher, R.	2009	Deltamethrin (AE F032640) - AE F108569-PU-02 Bayer Report No.: AZ 15832 Edition Number: M-346741-01-1 Date: 2009-04-28 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.14 / 13	No	Bayer
KCA 2.7 / 11	Wiche, A.; Bogdoll, B.	2012	AE 0035073 (trans-isomer of Deltamethrin): Partition coefficient 1-octanol / water (HPLC method) Bayer Report No.: PA10/068 Edition Number: M-435781-01-1 Date: 2012-07-30 GLP/GEP: Yes, unpublished	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.7 / 12	Bogdoll, B.; Eyrich, U.	2012	AE 0035073 (trans-isomer of deltamethrin): Partition coefficient 1-octanol / water (slow stirring method) Bayer Report No.: PA10/081 Edition Number: M-436125-01-1 Date: 2012-08-01 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.7 / 13	Weilbaeher, R.	2010	Deltamethrin (AE F032640) - AE 0035073 00 1B97 0001 Bayer Report No.: AZ 16455 Edition Number: M-364155-01-1 Date: 2010-02-23 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.14 / 15	No	Bayer
KCA 2.7 / 14	Eyrich, U.; Bogdoll, B.	2012	AE F108565 (Br2CA): Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 (shake flask method) Bayer Report No.: PA10/064 Edition Number: M-432956-01-1 Date: 2012-06-20 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.7 / 15	Heun, U.	2005	AE F108565 00 1B99 0001 (Project: Deltamethrin (AE F032640)) Bayer Report No.: AZ12928 Edition Number: M-259102-01-1 Date: 2005-10-17 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.14 / 19	No	Bayer
KCA 2.7 / 16	Eyrich, U.; Peschke, C.; Bogdoll, B.	2012	AE F109036 (mPBacid): Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 (shake flask meth- od) Bayer Report No.: PA10/066 Edition Number: M-435852-01-1 Date: 2012-07-26 GLP/GEP: Yes, unpublished	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.7 / 17	Weilbaecher, R.	2010	Deltamethrin (AE F032640) - AE F109036 00 1B99 0001 Bayer Report No.: AZ 16815 Edition Number: M-388654-01-1 Date: 2010-08-17 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.14 / 24	No	Bayer
KCA 2.7 / 18	Wiche, A.; Bogdoll, B.	2012	AE F114152 (mPBald): Partition coefficient 1-octanol / water (HPLC method) Bayer Report No.: PA10/065 Edition Number: M-437023-01-1 Date: 2012-08-17 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.7 / 19	Weilbaecher, R.	2008	Deltamethrin (AE F032640) - AE F114152 00 1B98 0001 Bayer Report No.: AZ 14984 Edition Number: M-301211-01-1 Date: 2008-04-22 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.14 / 27	No	Bayer
KCA 2.8 / 01	Lasselin, C.	1995	Compatibilites du Decis. Procida Roussel Uclaf, France Bayer Report No.: A71241 Edition Number: M-149708-01-1 Date: 1995-04-18 GLP/GEP: n.a., unpublished	No	Bayer
KCA 2.8 / 02	Smith, A. M.	1990	Determination of aqueous hydrolysis rate constant and half-life of deltamethrin. Bionomics Laboratories, USA Bayer Report No.: A45079 Edition Number: M-129026-01-1 Date: 1990-07-02 GLP/GEP: Yes, unpublished ... also filed: KCA 7.2.1.1 / 03	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.8 / 03	Wang, W. W.; Reyn- olds, J. L.	1991	Aqueous photolysis of 14C-deltamethrin XenoBiotics Laboratories, Inc., Plainsboro, NJ, USA Bayer Report No.: A47960 Edition Number: M-136754-01-1 Date: 1991-07-18 GLP/GEP: Yes, unpublished ... also filed: KCA 7.2.1.2 / 01	No	Bayer
KCA 2.8 / 04	Maurer, T.	2000	Determination of the quantum yield of direct photolysis in aqueous solution Deltamethrin Code: AE F032640 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer Report No.: C008524 Edition Number: M-197547-01-1 Date: 2000-05-26 GLP/GEP: No, unpublished	No	Bayer
KCA 2.8 / 05	Ziemer, F.	2013	Deltamethrin (AE F032640): Statement on the dissociation constant / pH-independency of the water solu- bility and partition coefficient Bayer Report No.: AF12/053 Edition Number: M-461537-01-1 Date: 2013-08-09 GLP/GEP: No, unpublished	No	Bayer
KCA 2.8 / 06	Eyrich, U.; Ziemer, F.	2012	Deltamethrin (AE F032640): Determination of the pH-value in distilled water Bayer Report No.: PA12/090 Edition Number: M-441961-01-1 Date: 2012-11-21 GLP/GEP: Yes, unpublished	No	Bayer

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.8 / 07	Cichy, M.	2012	Deltamethrin (AE F032640) - AE F032640-01-11 Bayer Report No.: 09084-01 Edition Number: M-384805-02-1 Date: 2012-04-26 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.1 / 04 KCA 2.3 / 04 KCA 2.6 / 05 KCA 2.9 / 06	No	Bayer
KCA 2.9 / 01	Hoffmann, H.	1996	Deltamethrin substance, technical 5 N 0501 B Flammability (solids) Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A56167 Edition Number: M-140002-01-1 Date: 1996-01-19 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.9 / 02	Hoffmann, H.	1996	Deltamethrin substance, technical: Flammability (solids). Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A70970 Edition Number: M-149452-01-1 Date: 1996-01-19 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.9 / 03	Le Tacon, Y.	1988	Test d'inflammabilité d'une poudre au repos. Roussel Uclaf, Romainville, France Bayer Report No.: A70750 Edition Number: M-149244-01-1 Date: 1988-04-17 GLP/GEP: n.a., unpublished	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.9 / 04	Hoffmann, H.	1996	Deltamethrin substance, technical: Auto-flammability (solids - determination of relative self-ignition tem- perature). Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A70971 Edition Number: M-149453-01-1 Date: 1996-01-19 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.9 / 05	Smeykal, H.	2012	Deltamethrin (AE F032640), technical substance: Auto - flammability (UN Bowes - Cameron - Cage - Test) Siemens AG, Frankfurt am Main, Germany Bayer Report No.: 20120214.02 Edition Number: M-440485-01-1 Date: 2012-10-23 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.9 / 06	Cichy, M.	2012	Deltamethrin (AE F032640) - AE F032640-01-11 Bayer Report No.: 09084-01 Edition Number: M-384805-02-1 Date: 2012-04-26 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.1 / 04 KCA 2.3 / 04 KCA 2.6 / 05 KCA 2.8 / 07	No	Bayer
KCA 2.11 / 01	Pedelaborde, J.; Rave- lojaona, J. L.	1985	Resultats obtenus sur l'etude de la severite et de la sensibilite des poudres a l'explosion. Roussel Uclaf, Romainville, France Bayer Report No.: A70749 Edition Number: M-149243-01-1 Date: 1985-01-01 GLP/GEP: n.a., unpublished	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.11 / 02	Smeykal, H.	2000	Explosive properties Deltamethrin substance, technical Code: AE F032640 00 1D98 0002 Axiva GmbH, Frankfurt am Main, Germany Bayer Report No.: C010909 Edition Number: M-199829-01-1 Date: 2000-12-15 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.12 / 01	Ziemer, F.	2013	Deltamethrin (AE F032640): Statement on the surface tension Bayer Report No.: AF12/054 Edition Number: M-461541-01-1 Date: 2013-08-09 GLP/GEP: No, unpublished	No	Bayer
KCA 2.13 / 01	Smeykal, H.	2005	Oxidizing properties Deltamethrin (AE F032640); substance, technical Code: AE F032640 00 1D98 0002 Siemens AG, Frankfurt am Main, Germany Bayer Report No.: C047050 Edition Number: M-247780-01-1 Date: 2005-02-24 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.13 / 02	Cichy, M.; Andrieux, M.	2003	Certificate of Analysis No. AZ 10689 Bayer Report No.: C033589 Edition Number: M-233444-01-1 Date: 2003-06-04 GLP/GEP: n.a., unpublished confidential	No	Bayer
KCA 2.14 / 01	Maier, T.; Rexer, K.	1988	Deltamethrin substance, technical. Decomposition point. Hoechst AG, Frankfurt am Main, Germany Bayer Report No.: A38362 Edition Number: M-120009-01-1 Date: 1988-06-23 GLP/GEP: No, unpublished ... also filed: KCA 2.1 / 02	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.14 / 02	Sanders, J. M.	1991	Deltamethrin A.I.: Determination of stability. Ricerca, Inc., USA Bayer Report No.: A70762 Edition Number: M-149256-01-1 Date: 1991-10-01 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.14 / 03	Meichsner, C.	1999	Calculation of the indirect photolysis reaction using the incremental method of Atkinson and the Program AOPWIN, Version 1.80 Deltamethrin InfraServ GmbH & Co Hoechst KG, Frankfurt am Main, Germany Bayer Report No.: C002214 Edition Number: M-184105-01-1 Date: 1999-01-19 GLP/GEP: No, unpublished ... also filed: KCA 7.3 / 01	No	Bayer
KCA 2.14 / 04	Sweetapple, G. G.	1990	Deltamethrin active ingredient: Determination of melting point. Ricerca, Inc., USA Bayer Report No.: A70753 Edition Number: M-149247-01-1 Date: 1990-03-29 GLP/GEP: Yes, unpublished ... also filed: KCA 2.1 / 01 KCA 2.3 / 02	No	Bayer
KCA 2.14 / 05	Thomas, E. A.; Sweetapple, G. G.	1990	Deltamethrin active ingredient: Determination of color, physical state, odor, density and pH. Ricerca, Inc., USA Bayer Report No.: A70752 Edition Number: M-149246-01-1 Date: 1990-03-29 GLP/GEP: Yes, unpublished ... also filed: KCA 2.3 / 01	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.14 / 06	Bogdoll, B.; Strunk, B.	2007	Relative density of deltamethrin (AE F032640) Bayer Report No.: PA07/040 Edition Number: M-287997-01-1 Date: 2007-05-21 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.14 / 07	Cichy, M.	2007	Certificate of analysis of deltamethrin (AE F032640) - AE F032640-01-01 Bayer Report No.: AZ 14195 Edition Number: M-287922-01-1 Date: 2007-05-14 GLP/GEP: n.a., unpublished confidential	No	Bayer
KCA 2.14 / 08	Ziemer, F.; Strunk, B.	2013	BCS-BY84407 (4'OH-deltamethrin): Water solubility at pH 5, pH 7 and pH 9 (column elution method) Bayer Report No.: PA12/128 Edition Number: M-458305-01-1 Date: 2013-06-25 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.14 / 09	Doerner-Rieping, S.	2012	Deltamethrin (AE F032640) - BCS-BY84407-01-01 Bayer Report No.: 09494-00 Edition Number: M-441171-01-1 Date: 2012-11-08 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.7 / 06	No	Bayer
KCA 2.14 / 10	Wiche, A.; Ziemer, F.	2013	Amendment no 1 to study report PA12/127 - BCS-CW57835 (Serinyl-BrCA): Water solubility at pH 5, pH 7 and pH 9 (flask method) Bayer Report No.: M-448165-02-1 Date: 2013-02-14 ... amended: 2013-02-26 GLP/GEP: Yes, unpublished	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.14 / 11	Doerner-Rieping, S.	2012	Deltamethrin (AE F032640) - BCS-CW57835-01-01 Bayer Report No.: 09495-00 Edition Number: M-441562-01-1 Date: 2012-11-08 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.7 / 08	No	Bayer
KCA 2.14 / 12	Bogdoll, B.; Strunk, B.; Zoellner, P.	2012	AE F108569 (alpha-R-isomer of deltamethrin): Solubility in distilled water (column elution method) Bayer Report No.: PA10/087 Edition Number: M-438538-01-1 Date: 2012-09-12 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.14 / 13	Weilbaecher, R.	2009	Deltamethrin (AE F032640) - AE F108569-PU-02 Bayer Report No.: AZ 15832 Edition Number: M-346741-01-1 Date: 2009-04-28 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.7 / 10	No	Bayer
KCA 2.14 / 14	Bogdoll, B.; Strunk, B.	2012	AE 0035073 (trans-isomer of deltamethrin): Solubility in distilled water (column elution method) Bayer Report No.: PA10/080 Edition Number: M-436161-01-1 Date: 2012-08-01 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.14 / 15	Weilbaecher, R.	2010	Deltamethrin (AE F032640) - AE 0035073 00 1B97 0001 Bayer Report No.: AZ 16455 Edition Number: M-364155-01-1 Date: 2010-02-23 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.7 / 13	No	Bayer

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.14 / 16	Wiche, A.; Bogdoll, B.	2012	AE F108565 (Br2CA): Solubility in water at pH 5, pH 7 and pH 9 Bayer Report No.: PA10/073 Edition Number: M-435779-01-1 Date: 2012-07-30 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.14 / 17	Wiche, A.; Bogdoll, B.	2012	AE F108565 (Br2CA): Determination of the dissociation constant in water Bayer Report No.: PA11/020 Edition Number: M-435776-01-1 Date: 2012-07-30 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.14 / 18	Dornhagen, J.	2012	AE F108565 (Br2CA): Vapour pressure Siemens AG, Frankfurt am Main, Germany Bayer Report No.: 20110093.01 Edition Number: M-438493-01-1 Date: 2012-08-02 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.14 / 19	Heun, U.	2005	AE F108565 00 1B99 0001 (Project: Deltamethrin (AE F032640)) Bayer Report No.: AZ12928 Edition Number: M-259102-01-1 Date: 2005-10-17 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.7 / 15	No	Bayer
KCA 2.14 / 20	Bogdoll, B.	2012	AE F108565 (Br2CA): Calculation of the Henry's law constants Bayer Report No.: AF12/008 Edition Number: M-438768-01-1 Date: 2012-09-25 GLP/GEP: No, unpublished	No	Bayer
KCA 2.14 / 21	Eyrich, U.; Strunk, B.; Bogdoll, B.	2012	AE F109036 (mPBacid): Water solubility at pH 5, pH 7 and pH 9 (flask method) Bayer Report No.: PA10/072 Edition Number: M-435849-01-1 Date: 2012-07-26 GLP/GEP: Yes, unpublished	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.14 / 22	Wiche, A.; Bogdoll, B.	2012	AE F109036 (mPBacid): Determination of the dissociation constant in water Bayer Report No.: PA10/086 Edition Number: M-436010-01-1 Date: 2012-08-01 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.14 / 23	Dornhagen, J.	2012	AE F109036 (mPBacid): Vapour pressure Siemens AG, Frankfurt am Main, Germany Bayer Report No.: 20110094.01 Edition Number: M-438491-01-1 Date: 2012-08-15 GLP/GEP: Yes, unpublished	No	Bayer
KCA 2.14 / 24	Weilbaeher, R.	2010	Deltamethrin (AE F032640) - AE F109036 00 1B99 0001 Bayer Report No.: AZ 16815 Edition Number: M-388654-01-1 Date: 2010-08-17 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.7 / 17	No	Bayer
KCA 2.14 / 25	Bogdoll, B.	2012	AE F109036 (mPBacid): Calculation of the Henry's law constants Bayer Report No.: AF12/009 Edition Number: M-438764-01-1 Date: 2012-09-25 GLP/GEP: No, unpublished	No	Bayer
KCA 2.14 / 26	Eyrich, U.; Bogdoll, B.	2012	AE F114152 (mPBald): Solubility in distilled water (flask method) Bayer Report No.: PA10/049 Edition Number: M-436138-01-1 Date: 2012-08-08 GLP/GEP: Yes, unpublished	No	Bayer

Annex point / reference num- ber	Author(s)	Year	Title Source (where different from company) Company name, Report No., Date, GLP/GEP status (where relevant) published or not	Vertebrate study	Owner
KCA 2.14 / 27	Weilbaeher, R.	2008	Deltamethrin (AE F032640) - AE F114152 00 1B98 0001 Bayer Report No.: AZ 14984 Edition Number: M-301211-01-1 Date: 2008-04-22 GLP/GEP: n.a., unpublished confidential ... also filed: KCA 2.7 / 19	No	Bayer
KCA 2.14 / 28	Bogdoll, B.	2012	Statement on the oxidizability of AE F114152 (3-phenoxybenzaldehyde, mPBald) Bayer Report No.: AF12/061 Edition Number: M-439613-01-1 Date: 2012-10-15 GLP/GEP: No, unpublished	No	Bayer

List of data submitted by the applicant and not relied on

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

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

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Deltamethrin

No additional data is submitted.

A 2.2 Flupyradifurone

No additional data is submitted.