

# 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: 102000012886

Product name: Fluopyram + trifloxystrobin SC 500

(250 + 250 g/L)

Chemical active substances:

Fluopyram, 250 g/L

Trifloxystrobin, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

(re-authorization)

Applicant: Bayer CropScience Division

Submission date: 30/06/2020

MS Finalisation date: July 2021 (initial Core Assessment)

February 2022 (final Core Assessment)

### Version history

When	What
June 2020	Original Bayer submission
July 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 <del>struck through and shaded for transparency</del> .
February 2022	Final report (Core Assessment after the commenting period)  Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow, while not agreed use pattern is <del>struck through and shaded</del> .

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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: None

The product fluopyram + trifloxystrobin SC 500 (250 + 250 g/L) (FLU + TFS SC 500 / Product Code 102000012886) has not been previously evaluated at zonal level. It was not the representative formulation during the renewal of approval of trifloxystrobin. All data and information assessed during the EU re-evaluation of trifloxystrobin is considered EU peer-reviewed data. New data relied on by the applicant but not previously evaluated at EU peer review are highlighted in yellow (new data). New risk assessments according to new guidance / endpoints are highlighted in yellow as well.

Non-renewed substance fluopyram: according to the guidance SANCO/2010/13170 rev. 14, 7 October 2016, for products containing two or more substances, there is no need to evaluate data related to the « non-renewed » substance(s). It is therefore our understanding that only data pertaining to combitox assessment will be taken into consideration.

## **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.  
Address: xxxx

xxxx

#### **Location of the production site**

CONFIDENTIAL information - data provided separately (Part C).

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

Name xxx  
Address: xxxx

xxxxx

#### **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)

Fluopyram min. purity 965 g/kg

No toxicologically or eco-toxicologically relevant impurities are expected to be formed during the formulation process.

Trifloxystrobin min. 975 g/kg

Relevant impurity: Benzene acetix acid, 2-(chloromethyl)- $\alpha$ -(methoxyimino)-, methylester, (E)- (AE 1344136) max. 4 g/kg

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

Trade name: Please refer to Registration Report Part A for the relevant country

Company code number: Fluopyram + trifloxystrobin SC 500 (250 + 250 g/L)  
FLU+TFS SC 500 (250+250)  
FLU + TFS SC 500  
102000012886  
UVP 84469882

### 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 FLU + TFS SC 500 was not the representative formulation for the Annex I Renewal of the active substance(s) Trifloxystrobin.

**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)	Technical content* (g/L)	Technical content** (%w/w)
Fluopyram	250	235-265	259.1	22.14
Trifloxystrobin	250	235-265	256.4	21.92

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

\*\* Based on the density of the formulation = 1.17 g/cm<sup>3</sup>

**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**

AE 1344136 is considered as relevant impurity. AE 1344136 is a process impurity linked to the active substance trifloxystrobin. Therefore, it cannot be formed neither during the formulation process nor during

the storage of the formulation. Method and validation are available.

Relevant impurity	Maximum content (g/L or g/kg)
AE 1344136	1.0

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

**Table 1.4-4: Information on fluopyram**

Type	Name/Code Number	
ISO common name	Fluopyram	No variant (e.g. salt, ester) is present
CAS No.	658066-35-4	not applicable
EC No.	616-219-00-5	not applicable
CIPAC No.	807	not applicable

**Table 1.4-5: Information on trifloxystrobin**

Type	Name/Code Number	
ISO common name	Trifloxystrobin	No variant (e.g. salt, ester) is present
CAS No.	141517-21-7	
EC No.	604-237-6	
CIPAC No.	617	

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

Not applicable as the formulation FLU + TFS SC 500 does not contain any safener and synergists.

**Table 1.4-6: Information on safeners/ synergists / co-formulant**

Type	Name/Code Number	
Safener /synergist	-	-
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: Suspension Concentrate

Code: SC

#### 1.6 Function (KCP 1.6)

Fungicide.



## 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. The appearance of the product is that of a light beige suspension, with a slightly pungent odour. It is not explosive and has no oxidising properties. The product has no flash point up to 102°C. It has a self-ignition temperature of 370°C. In aqueous solution it has a pH value around 6.8 at room temperature. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE (and COEX (EVOH)). Its technical characteristics are acceptable for a SC formulation.

The intended concentration of use is ~~0.05~~ 0.02% to ~~1.0~~ 0.4%.

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

No labelling necessary due to physical or chemical properties described above.

### Notifier Proposals for Risk and Safety Phrases (KCP 12)

No labelling necessary due to physical or chemical properties described above.

### Safety data sheets

#### FLU + TFS SC 500 – spec. 102000012886

Reference:	KCP Section 12/01
Title:	Luna Sensation
Report:	<a href="#">Anon.; 2020; M-661063-02-1</a>
Authority registration No:	--
Guideline(s):	--
Deviations:	--
GLP/GEP:	Not applicable
Acceptability:	Yes
Duplication (if vertebrate study):	No

#### Trifloxystrobin – spec. 102000007792

Reference:	KCP Section 12/02
Title:	Trifloxystrobin techn muster internation
Report:	<a href="#">Anon.; 2019; M-633730-03-1</a>
Authority registration No:	--
Guideline(s):	--
Deviations:	--
GLP/GEP:	Not applicable
Acceptability:	Yes
Duplication (if vertebrate study):	No

### Fluopyram – spec. 102000034703

Reference:	<b>KCP Section 12/03</b>
Title:	Fluopyram technical
Report:	<a href="#">Anon.; 2020; M-663098-02-1</a>
Authority registration No:	--
Guideline(s):	--
Deviations:	--
GLP/GEP:	Not applicable
Acceptability:	Yes
Duplication (if vertebrate study):	No

### Compliance with FAO specifications:

The product Specification 102000012886 (fluopyram + trifloxystrobin SC 500 (250 + 250 g/L)) complies with FAO specification for SC formulations.

### Formulation used for tests

The following batches have been used in the physico-chemical studies:

1. Specification 102000012886, Batch-Number: 2007-000441; containing 254 g/L fluopyram and 253 g/L trifloxystrobin.
2. Specification 102000012886, Batch-Number: 2007-000441; (safety relevant data report), containing 251.5 g/L fluopyram and 253.5 g/L trifloxystrobin.
3. Specification 102000012886, Batch-Number: LOT: 300045; containing 249.2 g/L fluopyram and 252.7 g/L trifloxystrobin.
4. Specification 102000012886, Batch-Number: 2015-009127-01; containing 247 g/L fluopyram and 254 g/L trifloxystrobin.
5. Specification 102000012886, Batch-Number: PAIS005173; containing 246.2 g/L fluopyram and 250.8 g/L trifloxystrobin

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)	Visual	Spec 102000012886 Batch-Number: 2007-000441	Physical state: suspension Colour: light beige Odour: slightly pungent	N	Gueldner, W.; Hoppe, M.; 2007 <a href="#">M-291446-01-2</a>	Accepted.
	Olfactory	Spec 102000012886 Batch-Number: 2015-009127-01	Physical state: suspension Colour: white Odour: paint like	N	Hoppe, M.; 2016 <a href="#">M-569298-01-1</a>	Accepted.
Explosive properties (KCP 2.2.1)	EC A.14	Spec 102000012886 Batch-Number: 2007-000441	Not explosive in the sense of EC Guideline A.14  It can be concluded from the negative result according to A14 that the formulation should not be classified as explosive according to CLP.	Y	Rexer, K.; Zindel, J.; 2008 <a href="#">M-296771-01-2</a>	Accepted.
	EC A.14 OCSPP 830.6316	Spec 102000012886 Batch-Number: PAIS005173	Not explosive in the sense of EC Guideline A.14  It can be concluded from the negative result according to A14 that the formulation should not be classified as explosive according to CLP.	Y	Drafz, M.; 2016 <a href="#">M-563665-01-1</a>	Accepted.
Oxidizing properties (KCP 2.2.2)	EC A.21	Spec 102000012886 Batch-Number: 2007-000441	No oxidizing properties in the sense of EC Guideline A.21  It can be concluded from the negative result according to A21 that active substance should not be classified as oxidising according to CLP.	Y	Rexer, K.; Zindel, J.; 2008 <a href="#">M-296771-01-2</a>	Accepted.
		Spec 102000012886 Batch-Number: PAIS005173	No oxidizing properties in the sense of EC Guideline A.21  It can be concluded from the negative result according to A21 that active substance should not be classified as oxidising according to CLP.	Y	Drafz, M.; 2016 <a href="#">M-563665-01-1</a>	Accepted.
Flash point (KCP 2.3.1)	EC A.9	Spec 102000012886 Batch-Number: 2007-000441	Higher than 100°C  It can be concluded from the result according to A9 that the formulation should not be classified as flammable liquid according to CLP.	Y	Rexer, K.; Zindel, J.; 2008 <a href="#">M-296771-01-2</a>	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	EC A.9 DIN EN ISO 2719 OCSP 830.6315	Spec 102000012886 Batch-Number: PAIS005173	No flash point up to 102°C  It can be concluded from the result according to A9 that the formulation should not be classified as flammable liquid according to CLP.	Y	Drafz, M.; 2016 <a href="#">M-563665-01-1</a>	Accepted.
Flammability (KCP 2.3.2)	-	-	Not required as the formulation is not a solid nor a gas.	-	-	-
Self-heating (KCP 2.3.3)	EC A.15	Spec 102000012886 Batch-Number: 2007-000441	Auto ignition temperature: 370°C  It can be concluded from the result according to A15 that the formulation should not be classified as auto-flammable liquid according to CLP.	Y	Rexer, K.; Zindel, J.; 2008 <a href="#">M-296771-01-2</a>	Accepted.
	EC A.15 DIN 51794	Spec 102000012886 Batch-Number: PAIS005173	Auto ignition temperature: 380°C  It can be concluded from the result according to A15 that the formulation should not be classified as auto-flammable liquid according to CLP.	Y	Drafz, M.; 2016 <a href="#">M-563665-01-1</a>	Accepted.
Acidity or alkalinity and pH (KCP 2.4.1)	-	-	Acidity/alkalinity not required as the preparation is neither strongly acidic (pH < 4) nor strongly alkaline (pH > 10).	-	-	-
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	According to CIPAC MT 75.3 (electrometric determination)	Spec 102000012886 Batch-Number: 2007-000441	6.8 (undiluted under N <sub>2</sub> -atmosphere and room temperature) 6.8 (1% in de-ionized water under N <sub>2</sub> -atmosphere and room temperature)	Y	Gueldner, W.; Hoppe, M.; 2007 <a href="#">M-291446-01-2</a>	Accepted.
	CIPAC MT 75.3 OCSP 830.7000	Spec 102000012886 Batch-Number: 2015-009127-01	6.3 (undiluted) 6.3 (1% in de-ionized water)	Y	Hoppe, M.; 2016 <a href="#">M-569298-01-1</a>	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Viscosity (KCP 2.5.1)	According to CIPAC MT 192	Spec 102000012886 Batch-Number: 2007-000441	<b>Kinematic viscosity:</b> Calculated: shear rate 20 s <sup>-1</sup> $\nu = \eta / \rho = 2.27 \cdot 10^{-4}$ m <sup>2</sup> /s at 20°C $\nu = \eta / \rho = 1.88 \cdot 10^{-4}$ m <sup>2</sup> /s at 40°C shear rate 100 s <sup>-1</sup> $\nu = \eta / \rho = 0.86 \cdot 10^{-4}$ m <sup>2</sup> /s at 20°C $\nu = \eta / \rho = 0.62 \cdot 10^{-4}$ m <sup>2</sup> /s at 40°C  <b>Dynamic viscosity:</b> shear rate 20 s <sup>-1</sup> $\eta = 0.2657$ Pa s at 20°C $\eta = 0.2189$ Pa s at 40°C shear rate 100 s <sup>-1</sup> $\eta = 0.1004$ Pa s at 20°C $\eta = 0.0725$ Pa s at 40°C	Y	Gueldner, W.; Hoppe, M.; 2007 <a href="#">M-291446-01-2</a>	Accepted.
	CIPAC MT 192 OECD 114 OCSPP 830.7100	Spec 102000012886 Batch-Number: 2015-009127-01	<b>Kinematic viscosity:</b> Calculated: shear rate 20 s <sup>-1</sup> $\nu = \eta / \rho = 229.9 \cdot 10^{-6}$ m <sup>2</sup> /s at 20°C $\nu = \eta / \rho = 182.0 \cdot 10^{-6}$ m <sup>2</sup> /s at 40°C shear rate 100 s <sup>-1</sup> $\nu = \eta / \rho = 101.4 \cdot 10^{-6}$ m <sup>2</sup> /s at 20°C $\nu = \eta / \rho = 72.50 \cdot 10^{-6}$ m <sup>2</sup> /s at 40°C  <b>Dynamic viscosity:</b> shear rate 20 s <sup>-1</sup> $\eta = 269.4 \cdot 10^{-3}$ Pa s at 20°C $\eta = 209.1 \cdot 10^{-3}$ Pa s at 40°C shear rate 100 s <sup>-1</sup> $\eta = 118.9 \cdot 10^{-3}$ Pa s at 20°C $\eta = 83.30 \cdot 10^{-3}$ Pa s at 40°C	Y	Hoppe, M.; 2016 <a href="#">M-569298-01-1</a>	Accepted.
Surface tension (KCP 2.5.2)	According to OECD 115	Spec 102000012886 Batch-Number: 2007-000441	$\sigma = 38$ mN/m at 25°C (undiluted) According to EC guideline A.5 the preparation should be classified as a surface-active material	Y	Gueldner, W.; Hoppe, M.; 2007 <a href="#">M-291446-01-2</a>	Accepted. The preparation is surface-active.
	OECD 115 EC A.5	Spec 102000012886 Batch-Number: 2015-009127-01	$\sigma = 40$ mN/m at 25°C (undiluted) $\sigma = 47$ mN/m at 20°C (1 g/L in deionised water) According to EC guideline A.5 the preparation should be regarded as a surface-active material	Y	Hoppe, M.; 2016 <a href="#">M-569298-01-1</a>	Accepted. The preparation is surface-active.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Relative density (KCP 2.6.1)	According to OECD 109	Spec 102000012886 Batch-Number: 2007-000441	D <sub>4</sub> <sup>20</sup> = 1.172 D <sub>4</sub> <sup>40</sup> = 1.163	Y	Gueldner, W.; Hoppe, M.; 2007 <a href="#">M-291446-01-2</a>	Accepted.
	OECD 109 EC A.3 OCSPP 830.7300	Spec 102000012886 Batch-Number: 2015-009127-01	D <sub>4</sub> <sup>20</sup> = 1.172 D <sub>4</sub> <sup>40</sup> = 1.149	Y	Hoppe, M.; 2016 <a href="#">M-569298-01-1</a>	Accepted.
Bulk density (KCP 2.6.2)	-	-	No study provided since this is only required for a solid formulation	-	-	-
Storage Stability after 14 days at 54° C (KCP 2.7.1)	According to CIPAC MT 46.3  The a.s. content fluopyram and trifloxystrobin were determined by GC (gas chromatography) according to the fully validated analytical method AM009707MF1, using the standard substance dipentylphthalate (DIPP) as internal standard with a content of 100 %.	Spec 102000012886 Batch-Number: 2007-000441	Stable for 2 weeks at 54 °C in HDPE with respect to content, packaging stability, appearance, pH, relative density, persistent foaming, suspensibility, spontaneity, wet sieving, particle size and pourability.  For detailed results see table below.	N	Gueldner, W.; Hoppe, M.; 2010 <a href="#">M-290919-02-1</a>	Studies accepted.  After storage no unacceptable decrease of the content of active substances was determined and the product complied with the FAO specifications.  The HDPE and 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.
		Spec 102000012886 Batch-Number: 2015-009127-01	Stable for 2 weeks at 54 °C in HDPE with respect to content, packaging stability, appearance, pH, relative density, persistent foaming, suspensibility, spontaneity, wet sieving, particle size and pourability.  For detailed results see table below.	N	Gueldner, W.; Hoppe, M.; 2016 <a href="#">M-552272-01-1</a>	
		Spec 102000012886 Batch-Number: 2015-009127-01	Report on the analytical details	N	Gueldner, W.; 2017 <a href="#">M-604894-01-1</a>	
			Stable for 2 weeks at 54 °C in COEX(EVOH) with respect to content, packaging stability, appearance, pH, relative density, persistent foaming, suspensibility, spontaneity, wet sieving, particle size and pourability.  For detailed results see table below.	N	Gueldner, W.; Hoppe, M.; 2016 <a href="#">M-552276-01-1</a>	
			Report on the analytical details	N	Gueldner, W.; 2017 <a href="#">M-604897-01-1</a>	
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not needed as stable after 14 days at 54 °C	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Minimum content after heat stability testing (KCP 2.7.3)	According to CIPAC MT 46.3	Spec 102000012886 Batch-Number: 2007-000441	The active substance content did not decline to less than 95 % of the content prior to the test	N	Gueldner, W.; Hoppe, M.; 2010 <a href="#">M-290919-02-1</a>	Accepted.
		Spec 102000012886 Batch-Number: 2015-009127-01	The active substance content did not decline to less than 95 % of the content prior to the test	N	Gueldner, W.; Hoppe, M.; 2016 <a href="#">M-552272-01-1</a>	Accepted.
		Spec 102000012886 Batch-Number: 2015-009127-01	The active substance content did not decline to less than 95 % of the content prior to the test	N	Gueldner, W.; Hoppe, M.; 2016 <a href="#">M-552276-01-1</a>	Accepted.
Effect of low temperatures on stability (KCP 2.7.4)	According to CIPAC MT 39.3	Spec 102000012886 Batch-Number: 2007-000441	Stable throughout the test period of 7 days at 0 °C with respect to wet sieving and suspensibility Packaging material: HDPE  For detailed results see table below.	N	Gueldner, W.; Hoppe, M.; 2010 <a href="#">M-290919-02-1</a>	Accepted.
		Spec 102000012886 Batch-Number: 2015-009127-01	Stable throughout the test period of 7 days at 0 °C with respect to separation, wet sieving and suspensibility Packaging material: HDPE  For detailed results see table below.	N	Gueldner, W.; Hoppe, M.; 2016 <a href="#">M-552272-01-1</a>	Accepted.
		Spec 102000012886 Batch-Number: 2015-009127-01	Stable throughout the test period of 7 days at 0 °C with respect to separation, wet sieving and suspensibility Packaging material: COEX(EVOH)  For detailed results see table below.	N	Gueldner, W.; Hoppe, M.; 2016 <a href="#">M-552276-01-1</a>	Accepted.
Ambient temperature shelf life (KCP 2.7.5)	According to GIFAP Monograph No. 17  A.S. Content: AM009707MF1, GLC/ISTD, full	Spec 102000012886 Batch-Number: 2007-000441	The formulation is stable for at least 2 years at ambient conditions in HDPE with respect to content, packaging stability, appearance, pH, relative density, persistent foaming, suspensibility, spontaneity, wet sieving, particle size and pourability.  For detailed results see table below.	N	Gueldner, W.; Hoppe, M.; 2010 <a href="#">M-290919-02-1</a>	Studies accepted.  After storage no unacceptable decrease of the content of active substance was determined and the product complied with the

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	validation details please refer to the Section 5.	-	(E)-(2-chloromethyl-phenyl)-methoxyimino acetic acid methyl ester (CGA 344605, AE 1344136) in technical trifloxystrobin is generated by the production process of the technical active substance and cannot be formed during manufacturing or storage of formulations containing trifloxystrobin. Determination of AE 1344136 before and after storage stability in formulations containing technical trifloxystrobin is not necessary.	N	Schneider, K., 2019 <a href="#">M-625082-02-1</a> Statement	FAO specifications.  The HDPE and HDPE/EVOH container showed no indications of significant weight loss or physical deterioration that would interfere with the safe handling of the product.
		Spec 102000012886 Batch-Number: 2015-009127-01	The formulation is stable for at least 2 years at ambient conditions in HDPE with respect to content, packaging stability, appearance, pH, relative density, persistent foaming, suspensibility, spontaneity, wet sieving, particle size and pourability.  For detailed results see table below.	N	Gueldner, W.; 2018 <a href="#">M-628022-01-1</a>	No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage, evaluation of this parameter after storage is not necessary.
		Spec 102000012886 Batch-Number: 2015-009127-01	The formulation is stable for at least 2 years at ambient conditions in COEX(EVOH) with respect to content, packaging stability, appearance, pH, relative density, persistent foaming, suspensibility, spontaneity, wet sieving, particle size and pourability.  For detailed results see table below.	N	Gueldner, W.; 2018 <a href="#">M-628023-01-1</a>	Period of validity: 2 years
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not required as shelf life at ambient temperature is expected to be stable at least 24 months.	-	-	-
Wettability (KCP 2.8.1)	-	-	No study provided since this is only required for a solid formulation	-	-	-
Persistence of foaming (KCP 2.8.2)	According to CIPAC MT 47.2	Spec 102000012886 Batch-Number: 2007-000441	0.08% in CIPAC D water: after 10 sec 24 mL after 1 min 22 mL after 3 min 22 mL after 12 min 19 mL	N	Gueldner, W.; Hoppe, M.; 2007 <a href="#">M-291446-01-2</a>	Accepted.



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Spec 102000012886 Batch-Number: LOT: 300045	0.30% in CIPAC D water: after 10 sec 30 mL after 1 min 25 mL after 3 min 21 mL after 12 min 20 mL  0.50% in CIPAC D water: after 10 sec 32 mL after 1 min 25 mL after 3 min 23 mL after 12 min 22 mL	N	Gueldner, W.; Hoppe, M.; 2011 <a href="#">M-413898-01-1</a>	
	CIPAC MT 47.3	Spec 102000012886 Batch-Number: 2015-009127-01	0.30% in CIPAC D water: after 10 sec 33 mL after 1 min 30 mL after 3 min 28 mL after 12 min 28 mL	N	Hoppe, M.; 2016 <a href="#">M-569298-01-1</a>	Accepted.
Suspensibility (KCP 2.8.3.1)	According to CIPAC MT 184  A.S. Content: AM009707MF1, GLC/ISTD, full validation details please refer to the Section 5.	Spec 102000012886 Batch-Number: 2007-000441	0.02% of the preparation in CIPAC D water: Fluopyram assay: 83% Trifloxystrobin assay: 82% 0.08% of the preparation in CIPAC D water: Fluopyram assay: 100% Trifloxystrobin assay: 100%	N	Gueldner, W.; Hoppe, M.; 2007 <a href="#">M-291446-01-2</a>	Accepted.
		Spec 102000012886 Batch-Number: LOT: 300045	0.30% of the preparation in CIPAC D water: Fluopyram assay: 99% Trifloxystrobin assay: 100% 0.50 % of the preparation in CIPAC D water: Fluopyram assay: 98% Trifloxystrobin assay: 100%	N	Gueldner, W.; Hoppe, M.; 2011 <a href="#">M-413898-01-1</a>	Accepted.
	CIPAC MT 184  A.S. Content: AM009707MF1, GLC/ISTD, full validation details please refer to the Section 5.	Spec 102000012886 Batch-Number: 2015-009127-01	0.01% of the preparation in CIPAC D water: Fluopyram assay: 100% Trifloxystrobin assay: 102% 0.30% of the preparation in CIPAC D water: Fluopyram assay: 97% Trifloxystrobin assay: 99%	N	Hoppe, M.; 2016 <a href="#">M-569298-01-1</a>	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Spontaneity of dispersion (KCP 2.8.3.2)	According to CIPAC MT 160	Spec 102000012886 Batch-Number: 2007-000441	Preparation in CIPAC D water: Fluopyram assay: 100% Trifloxystrobin assay: 100%	N	Gueldner, W.; Hoppe, M.; 2007 <a href="#">M-291446-01-2</a>	Accepted.
	CIPAC MT 160	Spec 102000012886 Batch-Number: 2015-009127-01	Preparation in CIPAC D water: Fluopyram assay: 97% Trifloxystrobin assay: 97%	N	Hoppe, M.; 2016 <a href="#">M-569298-01-1</a>	Accepted.
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for an SC formulation	-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	No study provided since this is only required for water soluble formulations	-	-	-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	According to CIPAC MT 187	Spec 102000012886 Batch-Number: 2007-000441	90% ≤ x µm      x = 3.25 µm 50% ≤ x µm      x = 1.27 µm 10% ≤ x µm      x = 0.57 µm	Y	Gueldner, W.; Hoppe, M.; 2007 <a href="#">M-291446-01-2</a>	Accepted.
	CIPAC MT 187	Spec 102000012886 Batch-Number: 2015-009127-01	90% ≤ x µm      x = 5.61 µm 50% ≤ x µm      x = 2.00 µm 10% ≤ x µm      x = 0.80 µm	Y	Hoppe, M.; 2016 <a href="#">M-569298-01-1</a>	Accepted.
Wet sieve test (KCP 2.8.5.1.2)	According to CIPAC MT 185	Spec 102000012886 Batch-Number: 2007-000441	Residue on a 75 µm sieve: 0.02%	N	Gueldner, W.; Hoppe, M.; 2007 <a href="#">M-291446-01-2</a>	Accepted.
	CIPAC MT 185	Spec 102000012886 Batch-Number: 2015-009127-01	Residue on a 75 µm sieve: 0.01%	N	Hoppe, M.; 2016 <a href="#">M-569298-01-1</a>	Accepted.
Dust content (KCP 2.8.5.2.1)	-	-	No study provided since this is only required for granular formulations	-	-	-
Particle size of dust (KCP 2.8.5.2.2)	-	-	No study provided since this is only required for granular formulations	-	-	-
Attrition (KCP 2.8.5.3)	-	-	No study provided since this is only required for granular formulations	-	-	-
Hardness and integrity (KCP 2.8.5.4)	-	-	No study provided since this is only required for tablet formulations	-	-	-
Emulsifiability (KCP 2.8.6.1)	-	-	No study provided since this is only required for formulations forming emulsions	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Emulsion stability (KCP 2.8.6.2)	-	-	No study provided since this is only required for formulations forming emulsions	-	-	-
Re-emulsifiability (KCP 2.8.6.3)	-	-	No study provided since this is only required for formulations forming emulsions	-	-	-
Flowability (KCP 2.8.7.1)	-	-	No study provided since this is only required for granular formulations	-	-	-
Pourability (KCP 2.8.7.2)	According to CIPAC MT 148	Spec 102000012886 Batch-Number: 2007-000441	Residue: 2.32% Rinsed residue: 0.12%	N	Guedner, W.; Hoppe, M.; 2007 <a href="#">M-291446-01-2</a>	Accepted.
	CIPAC MT 148	Spec 102000012886 Batch-Number: 2015-009127-01	Residue: 3.03% Rinsed residue: 0.14%	N	Hoppe, M.; 2016 <a href="#">M-569298-01-1</a>	Accepted.
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	No study provided since this is only required for dustable powders	-	-	-
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.	-	-	-
Adhesion to seeds (KCP 2.10.1)	-	-	No study provided since this is only required for seed treatment formulations	-	-	-
Distribution to seed (KCP 2.10.2)	-	-	No study provided since this is only required for seed treatment formulations	-	-	-
Other/special studies (KCP 2.11)	-	-	There is no other / special study	-	-	-

**Results referring to points KCP 2.7.1, 2.7.4 and 2.7.5: Storage stability after 7 days at 0°C, 14 days at 54°C and 2 years at ambient temperature (M-290919-02-1)**

Test / Method	Initial	Effect of low temp.**	2 weeks 54°C	2 years at ambient temp.
<b>A.S. Content</b>				
Fluopyram	21.7%	— ***	22.2%	21.6%
AM009707MF1, GLC/ISTD	254 g/L		260 g/L	253 g/L
Trifloxystrobin	21.6%	— ***	21.9%	21.5%
AM009707MF1, GLC/ISTD	253 g/L		256 g/L	252 g/L
<b>Appearance,</b> method: visual	light beige suspension	— ***	light beige suspension	light beige suspension
<b>Odour</b> method: olfactory	slightly pungent	— ***	slightly pungent	slightly pungent
<b>Packaging stability</b> HDPE	no negative effects observed	— ***	no negative effects observed	no negative effects observed
weight change	not determinate	— ***	< 0.1% no signif. change	< 0.1% no signif. change
deformation of packaging	no panelling no ballooning	— ***	no panelling no ballooning	no panelling no ballooning
leakage	no leakage	— ***	no leakage	no leakage
effect on closure	leakproof	— ***	leakproof	leakproof
packaging/preparation interaction	no claying, no sedimentation	— ***	no claying, no sedimentation	no claying, no sedimentation, 5% clear yellow liquid on the top, can be easily re-homogenized
<b>Acidity / Alkalinity *,</b> method: CIPAC MT 191	no determination	— ***	no determination	no determination
<b>pH-Value,</b> method: CIPAC MT 75.3 (undiluted sample)	6.8	— ***	6.4	6.6
(1% in CIPAC D water)	6.8	— ***	6.2	6.7
<b>Relative density,</b> method: OECD 109 D <sub>4</sub> <sup>20</sup>	1.172		1.172	1.172
<b>Persistent foaming</b> method: CIPAC MT 47.2 0.08% in CIPAC D water				
after 10 sec	24 mL	— ***	23 mL	25 mL
after 1 min	22 mL	— ***	19 mL	20 mL
after 3 min	22 mL	— ***	17 mL	18 mL
after 3 min	19 mL	— ***	10 mL	16 mL
<b>Suspensibility, (chemical assay)</b> method: CIPAC MT 184 0.02% prep. in CIPAC D water	Fluopyram 83% Trifloxystrobin 82%	Fluopyram 89% Trifloxystrobin 90%	Fluopyram 98% Trifloxystrobin 97%	Fluopyram 102% Trifloxystrobin 102%
<b>Suspensibility, (chemical assay)</b> method: CIPAC MT 184 0.08% prep. in CIPAC D water	Fluopyram 100% Trifloxystrobin 100%	Fluopyram 100% Trifloxystrobin 100%	Fluopyram 100% Trifloxystrobin 99%	Fluopyram 100% Trifloxystrobin 100%
<b>Spontaneity, (chemical assay)</b> method: CIPAC MT 160 in CIPAC D water	Fluopyram 100% Trifloxystrobin 100%	— ***	Fluopyram 100% Trifloxystrobin 100%	Fluopyram 99% Trifloxystrobin 99%
<b>Wet sieving</b> method: CIPAC MT 185 residue on a 75 µm sieve	0.02%	0.02%	< 0.01%	0.02%

Test / Method	Initial	Effect of low temp.**	2 weeks 54°C	2 years at ambient temp.
<b>Particle size distribution</b> method: CIPAC MT 187				
90% ≤ x µm	3.25 µm	— ***	6.93 µm	3.27 µm
50% ≤ x µm	1.27 µm		2.39 µm	1.29 µm
10% ≤ x µm	0.57 µm		0.89 µm	0.59 µm
<b>Pourability</b> method: CIPAC MT 148				
residue	2.32%	— ***	2.05%	1.96%
rinsed residue	0.12%	— ***	0.10%	0.11%

\* only if pH < 4 or pH >10 (pH of the undiluted sample and / or 1% in CIPAC D water)

\*\* Effect of low temperature, method: CIPAC MT 39.3, after 7 days at 0 °C

\*\*\* not required

**Results referring to the point Storage stability after 14 days at 54°C (KCP 2.7.1) in HDPE 1 L bottles ([M-552272-01-1](#))**

Test / Method	Initial	14 days at 54°C
<b>content a.s.</b> AM009707MF1, GLC/ISTD	21.2% (= 247 g/L) fluopyram	21.3% (= 249 g/L) fluopyram
	21.8% (= 254 g/L) trifloxystrobin	21.8% (= 254 g/L) trifloxystrobin
<b>packaging stability</b> OCSPP 830.6320 HDPE	no negative effects observed	no negative effects observed
weight change	not necessary	< 0.1% no significant change
deformation of packaging	no panelling no ballooning	Immediately after removal from storage of the sample (1 L bottle) stored for 14 days at 54°C ballooning was observed on the bottom of the bottle. After cooling to ambient temperature for 2 hours the effect was largely reversible and stable standing of the bottle was given.
leakage	no leakage	no leakage
effect on closure	leak proof	leak proof
packaging/preparation interaction	no claying, no sedimentation	no claying, no sedimentation
<b>colour</b> OCSPP 830.6302	white	white
<b>odour</b> OCSPP 830.6304	paint like	paint like
<b>physical state</b> OCSPP 830.6303	suspension	suspension
<b>acidity / alkalinity</b> CIPAC MT 191	The determination was not required as the pH-value was between 4.0 and 10.0.	
<b>pH-value</b> CIPAC MT 75.3 OCSPP 830.7000	undiluted	
	6.4	6.2
	1% in de-ionised water	
	6.4	6.1
<b>relative density</b> 92/69/EEC A.3 OECD 109 OCSPP 830.7300	D <sub>4</sub> <sup>20</sup> 1.165	D <sub>4</sub> <sup>20</sup> 1.167
<b>persistent foaming</b> CIPAC MT 47.3	0.30% in CIPAC standard water D	
foam after 10 s	33 mL	36 mL
foam after 1 min	30 mL	31 mL
foam after 3 min	28 mL	27 mL

Test / Method	Initial	14 days at 54°C
foam after 12 min	28 mL	24 mL
<b>suspensibility</b> CIPAC MT 184	0.01% in CIPAC standard water D	
fluopyram	100%	99%
trifloxystrobin	102%	101%
	0.30% in CIPAC standard water D	
fluopyram	97%	98%
trifloxystrobin	99%	99%
<b>spontaneity</b> CIPAC MT 160	preparation in CIPAC standard water D	
fluopyram	97%	98%
trifloxystrobin	97%	98%
<b>wet sieve test</b> CIPAC MT 185	residue on sieve	
75 µm	0.01%	0.01%
<b>particle size distribution</b> CIPAC MT 187	measurement in water, 15 s ultrasonified	
d (0.9)	5.49 µm	7.86 µm
d (0.5)	1.95 µm	2.63 µm
d (0.1)	0.79 µm	0.97 µm
<b>pourability</b> CIPAC MT 148		
residue	3.03%	2.53%
rinsed residue	0.14%	0.12%

**Results referring to the point Storage stability after 7 days at 0°C (KCP 2.7.4) in HDPE 1 L bottle (M-552272-01-1)**

Test / Method		
<b>separation</b> visual inspection	no visible separation	
Test / Method	Initial	7 days at 0°C
<b>suspensibility</b> CIPAC MT 184	0.01% w/w in CIPAC standard water D	
fluopyram	100%	99%
trifloxystrobin	102%	102%
	0.30% w/w in CIPAC standard water D	
fluopyram	97%	97%
trifloxystrobin	99%	100%
<b>wet sieving</b> CIPAC MT 185	residue on sieve	
75 µm	0.01%	< 0.01%

Due to the above described behaviour of the packaging material after storage for 14 days at 54°C a reassessment after storage for 8 weeks at 40°C of the packaging material was performed.

Test / Method	8 weeks at 40°C
<b>packaging stability</b> OCSPP 830.6320 HDPE	no negative effects observed
weight change	< 0.1% no significant change
deformation of packaging	no panelling, no ballooning
leakage	no leakage
effect on closure	leak proof
packaging / preparation interaction	no claying, no sedimentation

Recapitulating all the results from the accelerated storage test, fluopyram + trifloxystrobin SC 500 (250+250 g/L) is expected to be stable in HDPE for at least 2 years at ambient conditions.

**Results referring to the point Storage stability after 14 days at 54°C (KCP 2.7.1) in COEX (EVOH) 1 L bottles (M-552276-01-1)**

Test / Method	Initial	14 days at 54°C
<b>content a.s.</b> AM009707MF1, GLC/ISTD	21.2% (= 247 g/L) fluopyram	21.1% (= 246 g/L) fluopyram
	21.8% (= 254 g/L) trifloxystrobin	21.7% (= 253 g/L) trifloxystrobin
<b>packaging stability</b> OCSPP 830.6320 COEX(EVOH)	no negative effects observed	no negative effects observed
weight change	not necessary	< 0.1% no significant change
deformation of packaging	no panelling no ballooning	Immediately after removal from storage of the sample (1 L bottle) stored for 14 days at 54°C ballooning was observed on the bottom of the bottle. After cooling to ambient temperature for 2 hours the effect was largely reversible and stable standing of the bottle was given.
leakage	no leakage	no leakage
effect on closure	leak proof	leak proof
packaging/preparation interaction	no claying, no sedimentation	no claying, no sedimentation
<b>colour</b>	white	white

Test / Method	Initial	14 days at 54°C
OCSPP 830.6302		
<b>odour</b> OCSPP 830.6304	paint like	paint like
<b>physical state</b> OCSPP 830.6303	suspension	suspension
<b>acidity / alkalinity</b> CIPAC MT 191	The determination was not required as the pH-value was between 4.0 and 10.0.	
<b>pH-value</b> CIPAC MT 75.3 OCSPP 830.7000	undiluted	
	6.4	6.2
	1% in de-ionised water	
	6.4	6.0
<b>relative density</b> 92/69/EEC A.3 OECD 109 OCSPP 830.7300	D <sub>4</sub> <sup>20</sup> 1.165	D <sub>4</sub> <sup>20</sup> 1.166
<b>persistent foaming</b> CIPAC MT 47.3	0.30% in CIPAC standard water D	
foam after 10 s	33 mL	38 mL
foam after 1 min	30 mL	34 mL
foam after 3 min	28 mL	29 mL
foam after 12 min	28 mL	27 mL
<b>suspensibility</b> CIPAC MT 184	0.01% in CIPAC standard water D	
fluopyram	100%	96%
trifloxystrobin	102%	102%
	0.30% in CIPAC standard water D	
fluopyram	97%	97%
trifloxystrobin	99%	99%
<b>spontaneity</b> CIPAC MT 160	preparation in CIPAC standard water D	
fluopyram	97%	96%
trifloxystrobin	97%	97%
<b>wet sieve test</b> CIPAC MT 185	residue on sieve	
75 µm	0.01%	0.01%
<b>particle size distribution</b> CIPAC MT 187	measurement in water, 15 s ultrasonified	
d (0.9)	5.49 µm	7.96 µm
d (0.5)	1.95 µm	2.68 µm
d (0.1)	0.79 µm	0.98 µm
<b>pourability</b> CIPAC MT 148		
residue	3.03%	2.51%
rinsed residue	0.14%	0.13%



**Results referring to the point Storage stability after 7 days at 0°C (KCP 2.7.4) in COEX (EVOH) 1 L bottles (M-552276-01-1)**

Test / Method		
<b>separation</b> visual inspection	no visible separation	
Test / Method	Initial	7 days at 0°C
<b>suspensibility</b> CIPAC MT 184	0.01% w/w in CIPAC standard water D	
fluopyram	100%	99%
trifloxystrobin	102%	102%
	0.30% w/w in CIPAC standard water D	
fluopyram	97%	97%
trifloxystrobin	99%	100%
<b>wet sieving</b> CIPAC MT 185	residue on sieve	
75 µm	0.01%	< 0.01%

Due to the above described behaviour of the packaging material after storage for 14 days at 54°C a reassessment after storage for 8 weeks at 40°C of the packaging material was performed.

Test / Method	8 weeks at 40°C
<b>packaging stability</b> OCSP 830.6320 COEX(EVOH)	no negative effects observed
weight change	< 0.1% no significant change
deformation of packaging	no panelling, no ballooning
leakage	no leakage
effect on closure	leak proof
packaging / preparation interaction	no claying, no sedimentation

Recapitulating all the results from the accelerated storage test, fluopyram + trifloxystrobin SC 500 (250+250 g/L) is expected to be stable in COEX (EVOH) for at least 2 years at ambient conditions.

**Results referring to the point Storage stability after 2 years at ambient temperature (KCP 2.7.5) in HDPE 1 L bottles (M-628022-01-1)**

Test / Method	Initial “transfer from study <a href="#">M-552272-01-1</a> ”	2 years at ambient temperature
<b>content a.s.</b> AM009707MF1, GLC/ISTD	21.2% (= 247 g/L) fluopyram	21.2% (= 247 g/L) fluopyram
	21.8% (= 254 g/L) trifloxystrobin	21.4% (= 250 g/L) trifloxystrobin
<b>packaging stability</b> OCSPP 830.6320 HDPE	no negative effects observed	no negative effects observed
weight change	not necessary	< 0.1% no significant change
deformation of packaging	no panelling, no ballooning	no panelling, no ballooning
leakage	no leakage	no leakage
effect on closure	leak proof	leak proof
packaging/preparation interaction	no claying, no sedimentation	no claying, no sedimentation, 3% of a light brown phase on the top, can be easily re-homogenized
<b>colour</b> OCSPP 830.6302	white	white
<b>odour</b> OCSPP 830.6304	paint-like	paint-like
<b>physical state</b> OCSPP 830.6303	suspension	suspension
<b>acidity / alkalinity</b> CIPAC MT 191	The determination was not required as the pH-value was between 4.0 and 10.0.	
<b>pH-value</b> CIPAC MT 75.3 OCSPP 830.7000	undiluted	
	6.4	6.2
	1% in de-ionised water	
	6.4	6.1
<b>relative density</b> (EC) 440/2008 A.3 OECD 109 OCSPP 830.7300	D <sub>4</sub> <sup>20</sup> 1.165	D <sub>4</sub> <sup>20</sup> 1.166
<b>persistent foaming</b> CIPAC MT 47.3	0.01% in CIPAC standard water D	
foam after 10 s	17 mL	19 mL
foam after 1 min	15 mL	11 mL
foam after 3 min	13 mL	10 mL
foam after 12 min	12 mL	10 mL
	0.30% in CIPAC standard water D	
foam after 10 s	33 mL	40 mL
foam after 1 min	30 mL	37 mL
foam after 3 min	28 mL	33 mL
foam after 12 min	28 mL	32 mL
<b>suspensibility</b>	0.01% in CIPAC standard water D	

Test / Method	Initial “transfer from study <a href="#">M-552272-01-1</a> ”	2 years at ambient temperature
CIPAC MT 184		
fluopyram	100%	99%
trifloxystrobin	102%	100%
	0.30% in CIPAC standard water D	
fluopyram	97%	98%
trifloxystrobin	99%	98%
<b>spontaneity</b> CIPAC MT 160	preparation in CIPAC standard water D	
fluopyram	97%	99%
trifloxystrobin	97%	99%
<b>wet sieve test</b> CIPAC MT 185	residue on 75 µm sieve	
	0.01%	0.01%
<b>particle size distribution</b> CIPAC MT 187	measurement in water, 15 s ultrasonified	
d (0.9)	5.49 µm	5.98 µm
d (0.5)	1.95 µm	1.99 µm
d (0.1)	0.79 µm	0.81 µm
<b>pourability</b> CIPAC MT 148		
residue	3.03%	3.00%
rinsed residue	0.14%	0.17%

**Results referring to the point Storage stability after 2 years at ambient temperature (KCP 2.7.5) in COEX (EVOH) 1 L bottles ([M-628023-01-1](#))**

Test / Method	Initial “transfer from study <a href="#">M-552276-01-1</a> ”	2 years at ambient temperature
<b>content a.s.</b> AM009707MF1, GLC/ISTD	21.2% (= 247 g/L) fluopyram	21.1% (= 246 g/L) fluopyram
	21.8% (= 254 g/L) trifloxystrobin	21.4% (= 250 g/L) trifloxystrobin
<b>packaging stability</b> OCSPP 830.6320 COEX/EVOH	no negative effects observed	no negative effects observed
weight change	not necessary	< 0.1% no significant change
deformation of packaging	no panelling, no ballooning	no panelling, no ballooning
leakage	no leakage	no leakage
effect on closure	leak proof	leak proof
packaging/preparation interaction	no claying, no sedimentation	no claying, no sedimentation, 3% of a light brown phase on the top, can be easily re-homogenized
<b>colour</b>	white	white

Test / Method	Initial “transfer from study <a href="#">M-552276-01-1</a> ”	2 years at ambient temperature
OCSPP 830.6302		
<b>odour</b> OCSPP 830.6304	paint-like	paint-like
<b>physical state</b> OCSPP 830.6303	suspension	suspension
<b>acidity / alkalinity</b> CIPAC MT 191	The determination was not required as the pH-value was between 4.0 and 10.0.	
<b>pH-value</b> CIPAC MT 75.3 OCSPP 830.7000	undiluted	
	6.4	6.2
	1% in de-ionised water	
	6.4	6.1
<b>relative density</b> (EC) 440/2008 A.3 OECD 109 OCSPP 830.7300	D <sub>4</sub> <sup>20</sup> 1.165	D <sub>4</sub> <sup>20</sup> 1.167
<b>persistent foaming</b> CIPAC MT 47.3	0.01% in CIPAC standard water D	
foam after 10 s	17 mL	17 mL
foam after 1 min	15 mL	11 mL
foam after 3 min	13 mL	11 mL
foam after 12 min	12 mL	10 mL
	0.30% in CIPAC standard water D	
foam after 10 s	33 mL	40 mL
foam after 1 min	30 mL	32 mL
foam after 3 min	28 mL	30 mL
foam after 12 min	28 mL	29 mL
<b>suspensibility</b> CIPAC MT 184	0.01% in CIPAC standard water D	
fluopyram	100%	100%
trifloxystrobin	102%	100%
	0.30% in CIPAC standard water D	
fluopyram	97%	98%
trifloxystrobin	99%	98%
<b>spontaneity</b> CIPAC MT 160	preparation in CIPAC standard water D	
fluopyram	97%	98%
trifloxystrobin	97%	99%
<b>wet sieve test</b> CIPAC MT 185	residue on 75 µm sieve	
	0.01%	0.03%
<b>particle size distribution</b> CIPAC MT 187	measurement in water, 15 s ultrasonified	
d (0.9)	5.49 µm	5.85 µm
d (0.5)	1.95 µm	2.03 µm
d (0.1)	0.79 µm	0.84 µm
<b>pourability</b> CIPAC MT 148		
residue	3.03%	2.98%
rinsed residue	0.14%	0.17%

### 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 for bottles/canisters**

Type	Description
Material:	HDPE - High density polyethylene COEX/EVOH Coextruded high density polyethylene (HDPE) with an internal barrier layer made of ethylene vinyl alcohol copolymer (EVOH)
Shape/size:	cylindrical / rectangular – see below for sizes
Opening:	screw cap 32mm, 50 mm and 63 mm
Closure:	polyethylene screw cap
Seal:	HF seal, Foam Disc
Manner of construction	extruded (HDPE) co-extruded (HDPE/EV)
UN/ADR	compliant

Volume	50 ml	100 ml	250 ml
Material I	HDPE	HDPE	HDPE
Material II	-	-	-
Material III	COEX/EVOH	COEX/EVOH	COEX/EVOH
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 32 mm	Screw cap 32 mm	Screw cap 50 mm
Seal	HF seal, foam disc	HF seal, foam disc	HF seal, foam disc
Manner of 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	-	-	-
Material III	COEX/EVOH	COEX/EVOH	-
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 50 mm	Screw cap	Screw cap
Seal	HF seal, foam disc	HF seal, foam disc	HF seal, foam disc
Manner of Construction	extruded, blow moulded	extruded, blow moulded	extruded, blow moulded
UN/ADR	compliant	compliant	compliant

Volume	5 L	10 L	15 L + cardboard
Material I	HDPE	HDPE	HDPE
Material II	-	-	-
Material III	-	-	-
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, foam disc
Manner of 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 – HDPE or High-Density Polyethylene Coextruded) 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 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.

Study Comments: KCP 4.1/01	<p>The resistance of the packaging material 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).</p> <p>The formulation appears to be stable throughout the test period of 2 years at ambient temperature and non-corrosive to HDPE and HDPE/EVOH used as packaging material.</p>
Agreed endpoint: KCP 4.1/01	The packaging material HDPE and HDPE EVOH tested in the 2-years storage stability study has been approved and are suitable for the storage of the plant protection product.

## **4.2 Procedures for Cleaning Application Equipment**

### **4.2.1 Effectiveness of the cleaning procedures**

#### **Procedures for cleaning application equipment and protective clothing (KCP 4.2)**

##### **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.

##### **Effectiveness of the cleaning procedures**

This study is 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). Since the product is a fungicide, no phytotoxicity is expected in the field due to residues of the formulation used previously. Therefore, further studies are not considered to be necessary.

Reference:	<b>KCP 4.2/01</b>
Title:	Summary and conclusive report of studies on spray tank cleaning realized in the years 2000 - 2008
Report:	<a href="#">Friessleben, R.: 2008; M-357166-01-1</a>
Authority registration No:	--
Guideline(s):	not specified
Deviations:	--
GLP/GEP:	Not applicable
Acceptability:	Yes
Duplication (if vertebrate study):	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 behavior 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: KCP 4.2/01	Acceptable.
Agreed endpoint: KCP 4.2/01	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 (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1 / 01 KCP 2.4 / 01 KCP 2.5 / 01 KCP 2.6 / 01 KCP 2.8.2 / 01 KCP 2.8.3 / 01 KCP 2.8.5.1 / 01 KCP 2.8.7 / 01	Gueldner, W.; Hoppe, M.	2008	Physical, chemical and technical properties of fluopyram + trifloxystrobin SC 500 (250+250) G Report No.: 14 1050 5451, Edition Number: <a href="#">M-291446-01-2</a> Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 2.1 / 02 KCP 2.4 / 02 KCP 2.5 / 02 KCP 2.6 / 02 KCP 2.8.2 / 03 KCP 2.8.3 / 03 KCP 2.8.5.1 / 02 KCP 2.8.7 / 02	Hoppe, M.	2016	Physical, chemical and technical properties of fluopyram + trifloxystrobin SC 500 (250+250 g/L) Report No.: FM0111(PCF00)G01, Edition Number: <a href="#">M-569298-01-1</a> Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 2.2 / 01 KCP 2.3 / 01	Rexer, K.; Zindel, J.	2008	Safety relevant technical properties of fluopyram + trifloxystrobin SC 500 (250 + 250) g/L - Final report - Report No.: FOR0909(PC)01, Edition Number: <a href="#">M-296771-01-2</a> Bayer CropScience AG, Frankfurt am Main, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 2.2 / 02 KCP 2.3 / 02	Drafz, M.	2016	Safety-relevant data of fluopyram + trifloxystrobin SC 500 (250+250 g/L) Report No.: 2016/00598, Edition Number: <a href="#">M-563665-01-1</a> Bayer Technology Services GmbH, Leverkusen, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 2.7 / 01	Gueldner, W.; Hoppe, M.	2010	Storage stability and shelf life of fluopyram + trifloxystrobin SC 500 (250+250 g/L) - [Packaging material: HDPE] - Final report Report No.: 2007-000441-01, Edition Number: <a href="#">M-290919-02-1</a> Bayer CropScience AG, Monheim, Germany <b>... amended: 2010-01-26</b> GLP/GEP: No	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			unpublished		
KCP 2.7 / 02	Gueldner, W.; Hoppe, M.	2016	Storage stability at elevated temperature and cold stability of fluopyram + trifloxystrobin SC 500 (250+250 g/L) - Packaging material: HDPE - Final report (14 days) Report No.: FM0111(ACF01)N01, Edition Number: <a href="#">M-552272-01-1</a> Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 2.7 / 03	Gueldner, W.	2017	Storage stability at elevated temperature and cold stability of fluopyram + trifloxystrobin SC 500 (250+250 g/L) - Packaging material: HDPE - Analytical details report Report No.: FM0111(ADR00)N01, Edition Number: <a href="#">M-604894-01-1</a> Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 2.7 / 04	Gueldner, W.; Hoppe, M.	2016	Storage stability at elevated temperature and cold stability of fluopyram + trifloxystrobin SC 500 (250+250 g/L) - Packaging material: COEX(EVOH) - Final report (14 days) Report No.: FM0111(ACF03)N01, Edition Number: <a href="#">M-552276-01-1</a> Bayer CropScience AG, Monheim, Germany GLP/GEP: Yes unpublished	No	Bayer
KCP 2.7 / 05	Gueldner, W.	2017	Storage stability at elevated temperature and cold stability of fluopyram + trifloxystrobin SC 500 (250+250 g/L) - Packaging material: COEX(EVOH) - Analytical details report Report No.: FM0111(ADR00)N02, Edition Number: <a href="#">M-604897-01-1</a> Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 2.7 / 06	Schneider, K.	2019	Statement concerning storage stability data for CGA 344605, AE 1344136 in formulations of trifloxystrobin Report No.: <a href="#">M-625082-02-1</a> Bayer AG, Crop Science Division, Monheim, Germany <b>... amended: 2019-08-08</b> GLP/GEP: No unpublished	No	Bayer
KCP 2.7 / 07	Gueldner, W.	2018	Shelf life of fluopyram + trifloxystrobin SC 500 (250+250 g/L) - Packaging material: HDPE - Final report (2 years) Report No.: FM0111(SLF01)N01, Edition Number: <a href="#">M-628022-01-1</a> Bayer AG, Crop Science Division, Monheim, Germany	No	Bayer

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP/GEP: No unpublished		
KCP 2.7 / 08	Guedner, W.	2018	Shelf life of fluopyram + trifloxystrobin SC 500 (250+250 g/L) - Packaging material: COEX(EVOH) - Final report (2 years) Report No.: FM0111(SLF03)N01, Edition Number: <a href="#">M-628023-01-1</a> Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 2.8.2 / 02 KCP 2.8.3 / 02	Guedner, W.; Hoppe, M.	2011	Persistent foaming and suspensibility of fluopyram + trifloxystrobin SC 500 (250+250 g/L) - Final report - Report No.: FM0111(RP00)N01, Edition Number: <a href="#">M-413898-01-1</a> Bayer CropScience AG, Monheim, Germany GLP/GEP: No unpublished	No	Bayer
KCP 4.2 / 01	Friessleben, R.	2008	Summary and conclusive report of studies on spray tank cleaning realized in the years 2000 - 2008 Report No.: <a href="#">M-357166-01-1</a> Bayer CropScience AG, Monheim, Germany GLP/GEP: n.a. unpublished	No	Bayer
KCP Section 12 / 01	Anon.	2020	Luna Sensation Report No.: <a href="#">M-661063-02-1</a> Bayer AG, Leverkusen, Germany GLP/GEP: n.a. unpublished	No	-public data-
KCP Section 12 / 02	Anon.	2019	Trifloxystrobin techn muster internation Report No.: <a href="#">M-633730-03-1</a> Bayer AG, Leverkusen, Germany GLP/GEP: n.a. unpublished	No	Bayer
KCP Section 12 / 03	Anon.	2020	Fluopyram technical Report No.: <a href="#">M-663098-02-1</a> Bayer AG, Leverkusen, Germany GLP/GEP: n.a. unpublished	No	-public data-

# **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.

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 2.1 /01	Das, R.	1996	Report on melting point / melting range - CGA 279202 Ciba-Geigy Limited, Muenchwilen, Switzerland Bayer CropScience, Report No.: 46880, Edition Number: <a href="#">M-041431-01-1</a> Date: 1996-11-27 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.1 /02	Das, R.	1996	Report on boiling point / boiling range - CGA 279202 Ciba-Geigy Limited, Muenchwilen, Switzerland Bayer CropScience, Report No.: 46881, Edition Number: <a href="#">M-041467-01-1</a> Date: 1996-12-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.1 /03	Angly, H.	1997	Report on screening test for thermal stability and stability in air Institute of Safety and Security, Basel, Switzerland Bayer CropScience, Report No.: 97.4029.TSA, Edition Number: <a href="#">M-041479-01-1</a> Date: 1997-08-26 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.2 /01	Widmer, H.	1996	Vapour pressure of CGA 279202 Ciba-Geigy Limited, Basel, Switzerland Bayer CropScience, Report No.: 96WI29, Edition Number: <a href="#">M-041511-01-1</a> Date: 1996-11-27 GLP/GEP: yes, unpublished	N	Bayer

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 2.2 /02	Widmer, H.	1997	Vapour pressure of CGA 321113 Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 97WI30, Edition Number: <a href="#">M-078405-01-1</a> Date: 1997-09-18 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.2 /03	Widmer, H.	1997	Vapour pressure of CGA 373466 Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 97WI26, Edition Number: <a href="#">M-078554-01-1</a> Date: 1997-09-18 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.2 /04	Widmer, H.	1998	Vapour pressure of NOA 413161 Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 98WI21, Edition Number: <a href="#">M-078579-01-1</a> Date: 1998-09-29 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.2 /05	Widmer, H.	1998	Vapour pressure of NOA413163 Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 98WI23, Edition Number: <a href="#">M-078599-01-1</a> Date: 1998-10-15 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.2 /06	Widmer, H.	1997	Vapour pressure of CGA 357261 Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 97WI25, Edition Number: <a href="#">M-078492-01-1</a> Date: 1997-09-04 GLP/GEP: yes, unpublished	N	Bayer

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 2.2 /07	Widmer, H.	1997	Vapour pressure of CGA 357262 Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 97WI29, Edition Number: <a href="#">M-078532-01-1</a> Date: 1997-10-09 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.2 /08	Widmer, H.	1997	Vapour pressure of CGA 331409 Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: 97WI24, Edition Number: <a href="#">M-078459-01-1</a> Date: 1997-09-04 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.2 /09	Smeykal, H.	2012	BCS-AB39835 (Trifloxystrobin-CGA 357276): Vapour pressure Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110465.01, Edition Number: <a href="#">M-425949-01-1</a> Date: 2012-02-21 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.2 /10	Smeykal, H.	2012	BCS-CR74871 (Trifloxystrobin-NOA 409480): Vapour pressure Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110466.01, Edition Number: <a href="#">M-425954-01-1</a> Date: 2012-02-21 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.2 /11	Widmer, H.	1996	Vapour pressure of CGA 107170 Ciba-Geigy Limited, Basel, Switzerland Bayer CropScience, Report No.: 96WI34, Edition Number: <a href="#">M-078364-01-1</a> Date: 1996-12-03 GLP/GEP: yes, unpublished	N	Bayer

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 2.2 /12	Smeykal, H.	2012	BCS-AR14212 (Trifloxystrobin-2- hydroxymethyl-benzonitrile): Vapour pressure Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20120041.01, Edition Number: <a href="#">M-438195-01-1</a> Date: 2012-08-16 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.2 /13	Burkhard, N.	1997	Henry's law constant - CGA 279202 Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: MO-01-003756, Edition Number: <a href="#">M-041515-01-1</a> Date: 1997-09-01 GLP/GEP: no, unpublished	N	Bayer
KCA 2.2 /14	Burkhard, N.	1997	CGA 321113 - Henry's law constant Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: MO-01-019297, Edition Number: <a href="#">M-078427-01-1</a> Date: 1997-11-05 GLP/GEP: no, unpublished	N	Bayer
KCA 2.2 /15	Burkhard, N.	1997	CGA 373466 - Henry's law constant Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: MO-01-019355, Edition Number: <a href="#">M-078567-01-1</a> Date: 1997-12-01 GLP/GEP: no, unpublished	N	Bayer
KCA 2.2 /16	Burkhard, N.	1998	NOA 413161 - Henry's law constant Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: MO-01-019367, Edition Number: <a href="#">M-078598-01-1</a> Date: 1998-11-16 GLP/GEP: no, unpublished	N	Bayer

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 2.2 /17	Burkhard, N.	1999	NOA 413163 - Henry's law constant Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: MO-01-019381, Edition Number: <a href="#">M-078637-01-1</a> Date: 1999-04-21 GLP/GEP: no, unpublished	N	Bayer
KCA 2.2 /18	Burkhard, N.	1997	CGA 357261 - Henry's law constant Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: MO-01-019326, Edition Number: <a href="#">M-078502-01-1</a> Date: 1997-09-11 GLP/GEP: no, unpublished	N	Bayer
KCA 2.2 /19	Burkhard, N.	1997	CGA 357262 - Henry's law constant Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: MO-01-019344, Edition Number: <a href="#">M-078535-01-1</a> Date: 1997-11-04 GLP/GEP: no, unpublished	N	Bayer
KCA 2.2 /20	Burkhard, N.	1997	CGA 331409 - Henry's Law Constant Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: MO-01-019317, Edition Number: <a href="#">M-078475-01-1</a> Date: 1997-09-11 GLP/GEP: no, unpublished	N	Bayer
KCA 2.2 /21	Ziemer, F.	2012	BCS-AB39835 (Trifloxystrobin-CGA 357276): Calculation of the Henry's law constant Bayer CropScience, Report No.: AF12/013, Edition Number: <a href="#">M-431267-01-1</a> Date: 2012-05-15 GLP/GEP: no, unpublished	N	Bayer



<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 2.2 /22	Ziemer, F.	2012	BCS-CR74871 (Trifloxystrobin-NOA409480): Calculation of the Henry's law constant Bayer CropScience, Report No.: AF12/007, Edition Number: <a href="#">M-431273-01-1</a> Date: 2012-05-15 GLP/GEP: no, unpublished	N	Bayer
KCA 2.2 /23	Burkhard, N.	1996	CGA 107170 - Henry's Law Constant Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: MO-01-019270, Edition Number: <a href="#">M-078341-01-1</a> Date: 1996-12-06 GLP/GEP: no, unpublished	N	Bayer
KCA 2.2 /24	Ziemer, F.	2012	BCS-AR14212 (Trifloxystrobin-2- hydroxymethyl-benzonitrile): Calculation of the Henry's law constants Bayer CropScience, Report No.: AF12/040, Edition Number: <a href="#">M-438535-01-1</a> Date: 2012-09-13 GLP/GEP: no, unpublished	N	Bayer
KCA 2.3 /01	Das, R.	1996	Report on general physico-chemical properties, pure a.i. (aspect, colour, odour) - CGA 279202 Ciba-Geigy Limited, Muenchwilen, Switzerland Bayer CropScience, Report No.: 46887, Edition Number: <a href="#">M-041523-01-1</a> Date: 1996-11-27 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.3 /02	Das, R.	1997	Report on general physico-chemical properties, technical grade a.i. (aspect, colour, odour) - CGA 279202 Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 53274, Edition Number: <a href="#">M-041530-01-1</a> Date: 1997-08-25 GLP/GEP: yes, unpublished	N	Bayer

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 2.4 /01 KCA 2.4 /02 KCA 2.4 /03 KCA 2.4 /04	Bowen, T.; Charter, G.	2013	Spectral data (UV/VIS, IR, 1H-NMR, 13C- NMR, MS) and molar extinction coefficients of trifloxystrobin (AE C642802), pure substance Bayer CropScience, Report No.: PA12/150, Edition Number: <a href="#">M-465455-01-1</a> Date: 2013-09-11 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.4 /05	Oggenfuss, P.	1999	Spectra of CGA 321113 Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 78597, Edition Number: <a href="#">M-078430-01-1</a> Date: 1999-11-02 GLP/GEP: yes, unpublished confidential	N	Bayer
KCA 2.5 /01	Stulz, J.	1997	Report on water solubility - CGA 279202 Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 46885, Edition Number: <a href="#">M-041593-01-1</a> Date: 1997-02-12 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.5 /02	Stulz, J.	1997	CGA 321113 - Report on water solubility Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 53237, Edition Number: <a href="#">M-078424-01-1</a> Date: 1997-09-30 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.5 /03	Stulz, J.	1997	CGA 373466 - Report on water solubility Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 52618, Edition Number: <a href="#">M-078564-01-1</a> Date: 1997-10-20 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.5 /04	Stulz, J.	1998	NOA 413161 - Report on water solubility Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 64135, Edition Number: <a href="#">M-078587-01-1</a> Date: 1998-10-08 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.5 /05	Stulz, J.	1998	NOA 413163 - Report on water solubility Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 65680,	N	Bayer

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			Edition Number: <a href="#">M-078622-01-1</a> Date: 1998-10-08 GLP/GEP: yes, unpublished		
KCA 2.5 /06	Stulz, J.	1997	CGA 357261 - Report on water solubility Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 52614, Edition Number: <a href="#">M-078488-01-1</a> Date: 1997-07-04 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.5 /07	Stulz, J.	1997	CGA 357262 - Report on water solubility Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 52931, Edition Number: <a href="#">M-078528-01-1</a> Date: 1997-08-21 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.5 /08	Stulz, J.	1997	CGA 331409 - Report on water solubility Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 52429, Edition Number: <a href="#">M-078447-01-1</a> Date: 1997-07-18 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.5 /09	Ziemer, F.; Strunk, B.	2009	BCS-AB39835 (Trifloxystrobin-CGA 357276): Solubility in distilled water (column elution method) BCS, Report No.: PA11/091, Edition Number: <a href="#">M-429640-01-1</a> Date: 2009-08-19 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.5 /10	Ziemer, F.; Strunk, B.	2012	BCS-CR74871 (Trifloxystrobin-NOA409480): Solubility in distilled water (column elution method) Bayer CropScience, Report No.: PA11/095, Edition Number: <a href="#">M-430485-01-1</a> Date: 2012-05-03 GLP/GEP: yes, unpublished	N	Bayer

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 2.5 /11	Stulz, J.	1996	CGA 107170 - Report on water solubility Ciba-Geigy Limited, Muenchwilen, Switzerland Bayer CropScience, Report No.: 46291, Edition Number: <a href="#">M-462043-01-1</a> Date: 1996-11-05 GLP/GEP: no, unpublished	N	Bayer
KCA 2.5 /12	Wiche, A.; Ziemer, F.	2012	BCS-AR14212 (Trifloxystrobin-2- hydroxymethyl-benzonitrile): Water solubility at pH 5, pH 7 and pH 9 Bayer CropScience, Report No.: PA11/097, Edition Number: <a href="#">M-437969-01-1</a> Date: 2012-09-07 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.6 /01	Stulz, J.	1996	Solubility in organic solvents Ciba-Geigy Limited, Muenchwilen, Switzerland Bayer CropScience, Report No.: MO-01-003795, Edition Number: <a href="#">M-041643-01-1</a> Date: 1996-12-11 GLP/GEP: no, unpublished	N	Bayer
KCA 2.6 /02	Stulz, J.	1997	Report on solubility in organic solvents - CGA 279202 Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 53276, Edition Number: <a href="#">M-041631-01-1</a> Date: 1997-09-03 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.7 /01	Stulz, J.	1997	Report on octanol / water partition coefficient - CGA 279202 Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 46884, Edition Number: <a href="#">M-041647-01-1</a> Date: 1997-02-28 GLP/GEP: yes, unpublished	N	Bayer

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 2.7 /02	Stulz, J.	1997	CGA 321113 - Report on octanol / water partition coefficient Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 53236, Edition Number: <a href="#">M-078422-01-1</a> Date: 1997-09-17 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.7 /04	Stulz, J.	1998	NOA 413161 - Report on octanol/water partition coefficient Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 64134, Edition Number: <a href="#">M-078584-01-1</a> Date: 1998-10-08 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.7 /05	Stulz, J.	1998	NOA 413163 - Report on octanol/water partition coefficient Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 65679, Edition Number: <a href="#">M-078602-01-1</a> Date: 1998-10-08 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.7 /06	Stulz, J.	1997	CGA 357261 - Report on octanol/water partition coefficient Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 52613, Edition Number: <a href="#">M-078479-01-1</a> Date: 1997-06-30 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.7 /07	Stulz, J.	1997	CGA 357262 - Report on octanol/water partition coefficient Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 52930, Edition Number: <a href="#">M-078525-01-1</a> Date: 1997-07-15 GLP/GEP: yes, unpublished	N	Bayer

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 2.7 /08	Stulz, J.	1997	CGA 331409 - Report on octanol/water partition coefficient Novartis Crop Protection Muenchwilten AG, Muenchwilten, Switzerland Bayer CropScience, Report No.: 52428, Edition Number: <a href="#">M-078437-01-1</a> Date: 1997-06-24 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.7 /09	Bogdoll, B.; Peschke, C.	2012	BCS-AB39835 (Trifloxystrobin-CGA 357276): Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 (HPLC method) Bayer CropScience, Report No.: PA11/092, Edition Number: <a href="#">M-428439-01-1</a> Date: 2012-04-03 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.7 /10	Bogdoll, B.; Peschke, C.	2012	BCS-CR74871 (Trifloxystrobin-NOA409480): Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 (HPLC method) Bayer CropScience, Report No.: PA11/096, Edition Number: <a href="#">M-427343-01-1</a> Date: 2012-02-29 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.7 /11	Stulz, J.	1996	CGA 107170 - Report on octanol/water partition coefficient Ciba-Geigy Limited, Muenchwilten, Switzerland Bayer CropScience, Report No.: 46290, Edition Number: <a href="#">M-078382-01-1</a> Date: 1996-11-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.7 /12	Ziemer, F.; Peschke, C.	2013	BCS-CU98569: Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 (HPLC method) Bayer CropScience, Report No.: PA13/117, Edition Number: <a href="#">M-468182-01-1</a> Date: 2013-10-29 GLP/GEP: yes, unpublished	N	Bayer

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 2.7 /13	Wiche, A.; Ziemer, F.	2012	BCS-AR14212 (Trifloxystrobin-2- hydroxymethyl-benzonitrile): Partition coefficients 1-octanol / water at pH 5, pH 7 and pH 9 Bayer CropScience, Report No.: PA12/029, Edition Number: <a href="#">M-437970-01-1</a> Date: 2012-09-07 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.8 /01	Stulz, J.	1997	Report on dissociation constant in water - CGA 279202 Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 46883, Edition Number: <a href="#">M-041749-01-1</a> Date: 1997-04-02 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.8 /02	Jaekel, K.	1997	CGA 321113 - Report on dissociation constant in water Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: PP-97/22P.DCW, Edition Number: <a href="#">M-078398-01-1</a> Date: 1997-08-25 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.8 /03	Jaekel, K.	1997	CGA 373466 - Report on dissociation constant in water Novartis Services AG,Basel, Switzerland Bayer CropScience, Report No.: PP-97/17P.DCW, Edition Number: <a href="#">M-078541-01-1</a> Date: 1997-08-25 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.8 /04	Jaekel, K.	1998	NOA 413161 - Report on dissociation constant in water Novartis Services AG, Basel Switzerland Bayer CropScience, Report No.: PP-98/74P.DCW, Edition Number: <a href="#">M-078577-01-1</a> Date: 1998-09-07 GLP/GEP: yes, unpublished	N	Bayer

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 2.8 /05	Jaekel, K.	1998	NOA 413163 - Report on dissociation constant in water Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: PP-98/79P.DCW, Edition Number: <a href="#">M-078630-01-1</a> Date: 1998-11-11 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.8 /06	Stulz, J.	1997	CGA 357261 - Report on dissociation constant in water Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 52612, Edition Number: <a href="#">M-078482-01-1</a> Date: 1997-07-01 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.8 /07	Stulz, J.	1997	CGA 357262 - Report on dissociation constant in water Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 52929, Edition Number: <a href="#">M-078522-01-1</a> Date: 1997-07-16 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.8 /08	Stulz, J.	1997	CGA 331409 - Report on dissociation constant in water Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland Bayer CropScience, Report No.: 52427, Edition Number: <a href="#">M-078440-01-1</a> Date: 1997-09-24 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.8 /09	Winkler, S.	2012	BCS-AB39835 (trifloxystrobin-CGA 357276): Dissociation constant in water Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110465.02, Edition Number: <a href="#">M-432433-01-1</a> Date: 2012-06-04 GLP/GEP: yes, unpublished	N	Bayer



<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 2.8 /10	Winkler, S.	2012	BCS-CR74871 (trifloxystrobin-NOA 409480): Dissociation constant in water Siemens AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: 20110466.02, Edition Number: <a href="#">M-432440-01-1</a> Date: 2012-06-04 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.8 /11	Stulz, J.	1996	CGA 107170 - Report on dissociation constant in water Ciba-Geigy Limited, Muenchwil, Switzerland Bayer CropScience, Report No.: 46289, Edition Number: <a href="#">M-078371-01-1</a> Date: 1996-11-05 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.8 /12	Schmidt, M.	2012	BCS-AR14212 (Trifloxystrobin-2- hydroxymethyl-benzonitrile): Dissociation constant in water BCS, Report No.: 15-630-2570, Edition Number: <a href="#">M-437038-01-1</a> Date: 2012-08-23 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.9 /01	Angly, H.	1997	Report on flammability of solids Institute of Safety and Security, Basel, Switzerland Bayer CropScience, Report No.: 97.4029.FLS, Edition Number: <a href="#">M-041812-01-1</a> Date: 1997-08-26 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.9 /02	Angly, H.	1997	Report on relative self-ignition temperature for solids Institute of Safety and Security, Basel, Switzerland Bayer CropScience, Report No.: 97.4029.AFS, Edition Number: <a href="#">M-041821-01-1</a> Date: 1997-08-26 GLP/GEP: yes, unpublished	N	Bayer

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 2.11 /01	Angly, H.	1997	Report on explosive properties Institute of Safety and Security,Basel, Switzerland Bayer CropScience, Report No.: 97.4029.EXP, Edition Number: <a href="#">M-041830-01-1</a> Date: 1997-08-26 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.12 /01	Ryser, M.	1997	Report on surface tension of aqueous solutions - CGA 279202 Novartis Crop Protection AG, Basel, Switzerland Bayer CropScience, Report No.: PP-97/23T.SUR, Edition Number: <a href="#">M-043058-01-1</a> Date: 1997-08-25 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.13 /01	Angly, H.	1997	Report on oxidizing properties of solids Institute of Safety and Security, Basel, Switzerland Bayer CropScience, Report No.: 97.4029.OXP, Edition Number: <a href="#">M-043079-01-1</a> Date: 1997-08-26 GLP/GEP: yes, unpublished	N	Bayer
KCA 2.14 /01	Fueldner, H.	1997	Report on density of solids - CGA 279202 Ciba-Geigy Limited, Basel, Switzerland Bayer CropScience, Report No.: PP-96/63P.DES, Edition Number: <a href="#">M-041496-01-1</a> Date: 1997-02-07 GLP/GEP: yes, unpublished	N	Bayer

**List of data submitted by the applicant and not relied on**

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

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

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

### **A 2.1              Fluopyram**

No new physical and chemical data on the active substance which have not been evaluated in the EU peer review.

### **A 2.2              Trifloxystrobin**

No new physical and chemical data on the active substance and metabolites which have been not evaluated in the EU peer review.