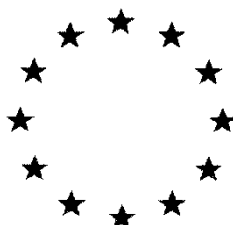


European Commission



**Draft Assessment Report prepared according to the Commission
Regulation (EU) N° 1107/2009**

ISOFLUCYPRAM

Volume 3 – B.2 (PPP) – Isoflucypram EC 50

**Rapporteur Member State : United Kingdom
Co-Rapporteur Member State : France**

Version History

When	What
March 2019	Initial DAR

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B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT BCS-CN88460 EC 50 G (500 G/L)

The maximum and minimum in-use concentrations of the product (based on the details of the intended uses presented in Volume 1, Section 1.5.1), are 1.5 %v/v and 0.375 %v/v respectively.

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results		Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1. APPEARANCE							
Physical state and colour B.2.1/01	OCSPP- 830.6302 (colour) 830.6303 (state) 830.6304 (odour) Visual Olfactory	BCS-CN88460 EC 50 G (50 g/l) Specification number: 1020000031262 Batch Number: 2016-003265	Colour: light brown Physical state: clear liquid Odour: weak paint like		Acceptable	Y	Güldner, W., 2016 FM0295 (PCF00)G01 M-573141-01-1
B.2.2. EXPLOSIVE AND OXIDIZING PROPERTIES							
Explosive properties B.2.2/01	Reg (EC) 440/2008 Method A.14 OCSPP 830.6316	BCS-CN88460 EC 50 G (50 g/l) Specification number: 1020000031262 Batch Number: 2016-003265	Mechanical sensitivity with respect to shock. (drop-weight test)	Not sensitive to shock.	Acceptable Not classified as an explosive substance.	Y	Drafz, M., 2016 2016/00544 M-563828-01-1
			Mechanical sensitivity with respect to friction.	N/A to liquid formulations			
			Thermal stability. (steel tube test)	Not explosive when heated under confinement.			
Oxidizing properties B.2.2/02	Reg (EC) 440/2008 Method A.21	BCS-CN88460 EC 50 G (50 g/l) Specification number: 1020000031262 Batch Number: 2016-003265	Mixture	Time taken for pressure rise from 690 to 2070 kPa	Acceptable. Not classified as an oxidising substance. The variation in the individual values is large with the value for run 1 being more than 30% greater from the mean value, and therefore falling outside the quality criteria of the method. That said, the sample times are all significantly longer than that for the reference material, demonstrating that the product does not possess oxidising properties. The RMS	Y	Drafz, M., 2016 2016/00544 M-563828-01-1
			Reference	2.55			
			Sample -run1	31.75			
			Sample-run 2	14.25			
			Sample-run 3	13.0			
			Sample-run 4	11.0			
			Sample-run 5	17.25			
			Sample (mean)	17.45			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results		Comments (Acceptable / Non acceptable)	GLP	Reference
					considers that no further data are required.		
B.2.3. FLAMMABILITY AND AUTO-FLAMMABILITY							
Flash point of the liquids formulations B.2.3/01	Reg (EC) 440/2008 Method A.9 OCSPP 830.6315	BCS-CN88460 EC 50 G (50 g/l) Specification number: 1020000031262 Batch Number: 2016-003265	136.0 °C Pensky-Martens closed cup method		Acceptable Not classified as flammable	Y	Drafz, M., 2016 2016/00544 M-563828-01-1
Flammability of solid formulations B.2.3/02					Not applicable to liquid formulations		
Self-heating of formulation B.2.3/03	Reg (EC) 440/2008 Method A.15 (DIN 51794)	BCS-CN88460 EC 50 G (50 g/l) Specification number: 1020000031262 Batch Number: 2016-003265	355 °C		Acceptable. Not classified as a self-heating substance.	Y	Drafz, M., 2016 2016/00544 M-563828-01-1
B.2.4. ACIDITY/ALKALINITY AND PH VALUE							
pH of the neat aqueous formulation B.2.4/01					Not required for non-aqueous PPPs		
pH of a 1 % dilution of the solid or non aqueous formulation B.2.4/02	CIPAC MT 75.3 OCSPP 830.7000	BCS-CN88460 EC 50 G (50 g/l) Specification number: 1020000031262 Batch Number: 2016-003265	pH of 1% aqueous solution: 7.3		Temperature not reported. Applicant to provide details.	Y	Güldner, W., 2016 FM0295 (PCF00)G01 M-573141-01-1
Acidity / Alkalinity B.2.4/03					Not required as the pH of a 1% aqueous dispersion is >4 and <10.		
B.2.5. VISCOSITY AND SURFACE TENSION							
	Dynamic		Shear rate s ⁻¹	Dynamic viscosity (mPa s)	Acceptable	Y	Güldner, W., 2016

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
Viscosity of the liquid formulation B.2.5/01	CIPAC MT 192 OECD 114 OCSPP 830.7100	BCS-CN88460 EC 50 G (50 g/l) Specification number: 1020000031262 Batch Number: 2016-003265		20 °C	40 °C			FM0295 (PCF00)G01 M-573141-01-1
			20	36.68	16.45			
			100	36.57	16.64			
	Kinematic CIPAC MT 192 OECD 114 OCSPP 830.7100	BCS-CN88460 EC 50 G (50 g/l) Specification number: 1020000031262 Batch Number: 2016-003265	Shear rate s ⁻¹	Kinematic viscosity (mm ² s ⁻¹)		Acceptable. Classified as a Category 1 aspiration hazard and the product label should carry the hazard staemenmt H304	Y	Güldner, W., 2016 FM0295 (PCF00)G01 M-573141-01-1
				20 °C	40 °C			
				20	37.62			
		100	37.51	17.34				
Surface tension of the formulation B.2.5/02	Reg (EC) 440/2008 Method A.5 OECD 115	BCS-CN88460 EC 50 G (50 g/l) Specification number: 1020000031262 Batch Number: 2016-003265	σ = 27 mN/m at 25°C (undiluted) σ = 32 mN/m at 20°C (1 g/l aqueous solution)			Acceptable. BCS-CN88460 EC 50 G (50 g/l) is surface active. Note: surface tension should be determined at the highest in-use concentration. Based on the details of the intended uses (Volume 1, Section 1.5.1), the highest in-use concentration is 1.5% v/v (based on an application rate of 1.5 L/ha in a water volume of 100 L/ha). Data are available for the undiluted formulation and a 1 g/l aqueous solution (~0.1 % v/v). As these concentrations bracket the highest in-use concentration, the RMS considers that no further data are required.	Y	Güldner, W., 2016 FM0295 (PCF00)G01 M-573141-01-1
B.2.6. RELATIVE DENSITY AND BULK DENSITY								
Relative density of the liquid formulation B.2.6/01	Reg (EC) 440/2008 Method A.3 OECD 109 OCSPP 830.7300	BCS-CN88460 EC 50 G (50 g/l) Specification number: 1020000031262	D ₄ ²⁰ 0.975 D ₄ ⁴⁰ 0.960			Acceptable	Y	Güldner, W., 2016 FM0295 (PCF00)G01 M-573141-01-1

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
		Batch Number: 2016-003265				
Bulk density (pour and tap) of powder or granules B.2.6/02				Not required for liquid formulations		
B.2.7. STORAGE STABILITY AND SHELF-LIFE: EFFECTS OF TEMPERATURE ON TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT						
Stability after accelerated storage (54°C during 14 days, 8 weeks at 40°C, 12 weeks at 35°C or 18 weeks at 30°C) B.2.7/01	CIPAC MT 46.3	BCS-CN88460 EC 50 G (50 g/l) Specification number: 1020000031262 Batch Number: 2016-003265	Stable throughout the test period of 2 weeks at 54 °C with respect to active content, appearance, pH, relative density, persistent foam and emulsion characteristics. Packaging material: COEX/PA and COEX/EVOH For detailed results see Tables 1 and 2 in the Appendix.	Acceptable Analytical method AM027115MF1 was used to determine the active substance content. Method details and associated validation data have been submitted for method AM027115MF2, which is an updated version of the same method. The applicant has stated that all testing (including the accelerated and cold storage stability) have been performed according to the validated method. Refer to Volume 3CP, section B.5.1.1.1 A statement was submitted to support the non-submission of data on the content of the relevant impurity BCS-CN45153 after storage. It reports that BCS-CN45153 is formed in a side reaction during manufacture of the technical material and could not form during the formulation process or storage of the product. The RMS agrees; data are not required on the levels of the relevant impurity BCS-CN45153 in the product after storage.	N	Göldner, W., Hoppe, M., 2016 FM0295(ACF03)N01 M-574894-01-1 Adelt, I., 2018 M-617424-01-2
Effect of low temperature on stability of liquid formulation B.2.7/02	CIPAC MT 39.3	BCS-CN88460 EC 50 G (50 g/l) Specification number: 1020000031262 Batch Number: 2016-003265	No separated material after 7 days at 0 °C. Packaging material: COEX/PA and COEX/EVOH	Acceptable	N	Göldner, W., Hoppe, M., 2016 FM0295(ACF03)N01 M-574894-01-1

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results		Comments (Acceptable / Non acceptable)	GLP	Reference
Shelf life following storage at ambient temperature B.2.7/03					Study is now available but was not submitted in time for evaluation. Astatement was submitted to support the non-submission of data on the content of the relevant impurity BCS-CN45153 after storage. It reports that BCS-CN45153 is formed in a side reaction during manufacture of the technical material and could not form during the formulation process or storage of the product. The RMS agrees; data are not required on the levels of the relevant impurity BCS-CN45153 in the product after storage.		Adelt, I., 2018 M-617424-01-2
B.2.8. TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT							
B.2.8.1. Wettability							
Wettability of solid formulation B.2.8.1/01					Not required for liquid formulations		
B.2.8.2. Persistence foaming							
Persistence of foaming of the diluted formulation B.2.8.2/01	CIPAC MT 47.3	BCS-CN88460 EC 50 G (50 g/l) Specification number: 1020000031262 Batch Number: 2016-003265	Standing time	Volume of foam (ml)	Data have been provided att he highest in-use concentration only. Data at the lowest in-use concentration of 0.375 %v/v are required.	Y	Güldner, W., 2016 FM0295 (PCF00)G01 M-573141-01-1
			10 seconds	68			
			1 minute	14			
			3 minutes	6			
			12 minutes	4			
		Test performed using CIPAC standard water D at the highest in-use concentration (1.5 % v/v)					
B.2.8.3. Suspensibility							
Suspensibility of water dispersible formulation B.2.8.3/01					Not required for an EC formulation		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Spontaneity of dispersion of water dispersible formulation B.2.8.3/02				Not required for an EC formulation		
Dispersion stability of SE, OD or EG formulation B.2.8.3/03				Not required for an EC formulation		
B.2.8.4. Degree of dissolution and dilution stability						
Degree of dissolution of water soluble formulation B.2.8.4/01				Not required for an EC formulation		
Dilution stability of water soluble formulation B.2.8.4/02				Not required for an EC formulation		
B.2.8.5. Particle size distribution, dust content, attrition and mechanical stability						
B.2.8.5.1. Particle size distribution						
Wet sieve test of water dispersible formulation B.2.8.5.1/01				Not required for an EC formulation		
Size distribution of particles of powder or suspension concentrate formulation B.2.8.5.1/02				Not required for an EC formulation		
Nominal size range of granule B.2.8.5.1/03				Not required for an EC formulation		
B.2.8.5.2. Dust content						
Dust content of granular formulation B.2.8.5.2/01				Not required for an EC formulation		
B.2.8.5.3. Attrition						

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results		Comments (Acceptable / Non acceptable)	GLP	Reference	
Attrition characteristics of granules and tablets B.2.8.5.3/01					Not required for an EC formulation			
B.2.8.5.4. Hardness and integrity								
Hardness of tablets B.2.8.5.4/01					Not required for an EC formulation			
Integrity of tablets B.2.8.5.4/02					Not required for an EC formulation			
B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability								
Emulsifiability, emulsion stability and re-emulsifiability of formulation B.2.8.6/01			Emulsion characteristics in standard water A	Result		Acceptable	Y	Güldner, W., 2016 FM0295 (PCF00)G01 M-573141-01-1
				0.2 %v/v	1.5 %v/v			
			Initial	spontaneous	spontaneous			
			Separation after 30 mins	none	none			
			Separation after 2 hours	none	none			
			Separation after 24 hours	none	none			
			Re-emulsifiability	complete	complete			
			Separation after 30 mins	none	none			
			Emulsion characteristics in standard water D	Result				
				0.2 %v/v	1.5 %v/v			
			Initial	spontaneous	spontaneous			
			Separation after 30 mins	none	none			
			Separation after 2 hours	none	none			
			Separation after 24 hours	none	none			
			Re-emulsifiability	complete	complete			
			Separation after 30 mins	none	none			
			B.2.8.7. Flowability, pourability and dustability					

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Flowability of granular formulation B.2.8.7/01				Not required for an EC formulation		
Pourability of suspensions B.2.8.7/02				Not required for an EC formulation		
Dustability of dustable powders after accelerated storage B.2.8.7/03				Not required for an EC formulation		
B.2.9. PHYSICAL AND CHEMICAL COMPATIBILITY WITH OTHER PRODUCTS INCLUDING PLANT PROTECTION PRODUCTS WITH WHICH ITS USE IS TO BE AUTHORISED						
Physical and chemical compatibility of tank mixtures B.2.9/01				No tank mixes are proposed		
B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS						
Distribution and adhesion to seeds B.2.9.10/01				Not required for an EC formulation		
B.2.11. OTHER STUDIES						

B.2.12. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCP 2.1 / 01	Gueldner, W.	2016	Physical, chemical and technical properties of BCS-CN88460 EC 50 (50 g/L) Bayer Report No.: FM0295(PCF00)G01 Edition Number: M-573141-01-1 Date: 2016-11-30 GLP/GEP: Yes, unpublished ... also filed: KCP 2.4 / 01 KCP 2.5 / 01 KCP 2.6 / 01 KCP 2.8.2 / 01 KCP 2.8.6 / 01	No	Yes	New data for a new active substance	Bayer	N/A
KCP 2.2 / 01	Drafz, M.	2016	Safety-relevant data of BCS-CN88460 EC 50 (50 g/L) Bayer Technology Services GmbH, Leverkusen, Germany Bayer Report No.: 2016/00544 Edition Number: M-563828-01-1 Date: 2016-08-25 GLP/GEP: Yes, unpublished ... also filed: KCP 2.3 / 01	No	Yes	New data for a new active substance	Bayer	N/A
KCP 2.3 / 01	Drafz, M.	2016	Safety-relevant data of BCS-CN88460 EC 50 (50 g/L) Bayer Technology Services GmbH, Leverkusen, Germany Bayer Report No.: 2016/00544 Edition Number: M-563828-01-1 Date: 2016-08-25	No	Yes	New data for a new active substance	Bayer	N/A

			GLP/GEP: Yes, unpublished ... also filed: KCP 2.2 / 01					
KCP 2.4 / 01	Gueldner, W.	2016	Physical, chemical and technical properties of BCS-CN88460 EC 50 (50 g/L) Bayer Report No.: FM0295(PCF00)G01 Edition Number: M-573141-01-1 Date: 2016-11-30 GLP/GEP: Yes, unpublished ... also filed: KCP 2.1 / 01 KCP 2.5 / 01 KCP 2.6 / 01 KCP 2.8.2 / 01 KCP 2.8.6 / 01	No	Yes	New data for a new active substance	Bayer	N/A
KCP 2.5 / 01	Gueldner, W.	2016	Physical, chemical and technical properties of BCS-CN88460 EC 50 (50 g/L) Bayer Report No.: FM0295(PCF00)G01 Edition Number: M-573141-01-1 Date: 2016-11-30 GLP/GEP: Yes, unpublished ... also filed: KCP 2.1 / 01 KCP 2.4 / 01 KCP 2.6 / 01 KCP 2.8.2 / 01 KCP 2.8.6 / 01	No	Yes	New data for a new active substance	Bayer	N/A
KCP 2.6 / 01	Gueldner, W.	2016	Physical, chemical and technical properties of BCS-CN88460 EC 50 (50 g/L) Bayer Report No.: FM0295(PCF00)G01 Edition Number: M-573141-01-1 Date: 2016-11-30 GLP/GEP: Yes, unpublished ... also filed: KCP 2.1 / 01 KCP 2.4 / 01	No	Yes	New data for a new active substance	Bayer	N/A

			KCP 2.5 / 01 KCP 2.8.2 / 01 KCP 2.8.6 / 01					
KCP 2.7 / 01	Gueldner, W.; Hoppe, M.	2016	Storage stability at elevated temperature and cold stability of BCS-CN88460 EC 50 (50 g/L) - Packaging material: COEX/PA - Final report (14 days) Bayer Report No.: FM0295(ACF02)N01 Edition Number: M-574893-01-1 Date: 2016-12-14 GLP/GEP: No, unpublished	No	No		Bayer	N/A
KCP 2.7 / 02	Gueldner, W.; Hoppe, M.	2016	Storage stability at elevated temperature and cold stability of BCS-CN88460 EC 50 (50 g/L) - Packaging material: COEX/EVOH - Final report (14 days) Bayer Report No.: FM0295(ACF03)N01 Edition Number: M-574894-01-1 Date: 2016-12-15 GLP/GEP: No, unpublished	No	No		Bayer	N/A
KCP 2.8.2 / 01	Gueldner, W.	2016	Physical, chemical and technical properties of BCS-CN88460 EC 50 (50 g/L) Bayer Report No.: FM0295(PCF00)G01 Edition Number: M-573141-01-1 Date: 2016-11-30 GLP/GEP: Yes, unpublished ... also filed: KCP 2.1 / 01 KCP 2.4 / 01 KCP 2.5 / 01 KCP 2.6 / 01 KCP 2.8.6 / 01	No	Yes	New data for a new active substance	Bayer	N/A
KCP 2.8.6 / 01	Gueldner, W.	2016	Physical, chemical and technical properties of BCS-CN88460 EC 50 (50 g/L) Bayer Report No.: FM0295(PCF00)G01 Edition Number: M-573141-01-1	No	Yes	New data for a new active substance	Bayer	N/A

			Date: 2016-11-30 GLP/GEP: Yes, unpublished ... also filed: KCP 2.1 / 01 KCP 2.4 / 01 KCP 2.5 / 01 KCP 2.6 / 01 KCP 2.8.2 / 01					
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Appendix 1: Summary of Accelerated Storage Stability data in COEX/PA Packaging

Test/method	Initial	After 14 days at 54°C
Active substance content	5.25 % w/w (51.2 g/L)	5.24 % w/w (51.1 g/L)
Packaging stability		
Weight change	-	<0.1%
Deformation of packaging	No panelling No ballooning	Panelling (10 mm retracted one sided)
Leakage	No leakage	No leakage
Effect on closure	Leak proof	Leak proof
Packaging/preparation interaction	No seepage No crystallisation No sedimentation	No seepage No crystallisation No sedimentation
Appearance		
colour	Light brown	Light brown
Physical state	Clear liquid	Clear liquid
odour	Weak paint like	Paint like
pH (1% aqueous solution)	7.3	7.2
Relative density (20°C)	0.975	0.976
Persistent foam		
1.5% in CIPAC standard water D		
Foam volume after 10 secs	68 ml	71 ml
Foam volume after 1 min	14 ml	9 ml
Foam volume after 3 mins	6 ml	7 ml
Foam volume after 12 mins	4 ml	5 ml
Emulsion characteristics		
0.2 % w/w in standard water A		
initial emulsifiability	spontaneous	spontaneous
separation after 30 minutes	none	none
separation after 120 minutes	none	none
separation after 24 hours	none	none
re-emulsifiability after 24 hours	complete	complete
separation after further 30 minutes	none	none

1.5 % w/w in standard water A initial emulsifiability separation after 30 minutes separation after 120 minutes separation after 24 hours re-emulsifiability after 24 hours separation after further 30 minutes	spontaneous none none none complete none	spontaneous none none none complete none
0.2 % w/w in standard water D initial emulsifiability separation after 30 minutes separation after 120 minutes separation after 24 hours re-emulsifiability after 24 hours separation after further 30 minutes	spontaneous none none none complete none	spontaneous none none none complete none
1.5 % w/w in standard water D initial emulsifiability separation after 30 minutes separation after 120 minutes separation after 24 hours re-emulsifiability after 24 hours separation after further 30 minutes	spontaneous none none none complete none	spontaneous none none none complete none

Appendix 2: Summary of Accelerated Storage Stability data in COEX/EVOH Packaging

Test/method	Initial	After 14 days at 54°C
Active substance content	5.25 % w/w (51.2 g/L)	5.23 % w/w (51.0 g/L)
Packaging stability		
Weight change	-	<0.1%
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 seepage No crystallisation No sedimentation	No seepage No crystallisation No sedimentation
Appearance		
colour	Light brown	Light brown
Physical state	Clear liquid	Clear liquid
odour	Weak paint like	Paint like
pH (1% aqueous solution)	7.3	7.2
Relative density (20°C)	0.975	0.976
Persistent foam		
1.5% in CIPAC standard water D		
Foam volume after 10 secs	68 ml	73 ml
Foam volume after 1 min	14 ml	12 ml
Foam volume after 3 mins	6 ml	8 ml
Foam volume after 12 mins	4 ml	7 ml
Emulsion characteristics		
0.2 % w/w in standard water A		
initial emulsifiability	spontaneous	spontaneous
separation after 30 minutes	none	none
separation after 120 minutes	none	none
separation after 24 hours	none	none
re-emulsifiability after 24 hours	complete	complete
separation after further 30 minutes	none	none

1.5 % w/w in standard water A initial emulsifiability separation after 30 minutes separation after 120 minutes separation after 24 hours re-emulsifiability after 24 hours separation after further 30 minutes	spontaneous none none none complete none	spontaneous none none none complete none
0.2 % w/w in standard water D initial emulsifiability separation after 30 minutes separation after 120 minutes separation after 24 hours re-emulsifiability after 24 hours separation after further 30 minutes	spontaneous none none none complete none	spontaneous none none none complete none
1.5 % w/w in standard water D initial emulsifiability separation after 30 minutes separation after 120 minutes separation after 24 hours re-emulsifiability after 24 hours separation after further 30 minutes	spontaneous none none none complete none	spontaneous none none none complete none