Draft Assessment Report

Evaluation of Active Substances

Plant Protection Products

Prepared according to **assimilated Regulation No 1107/2009**
as it applies in Great Britain

Inpyrfluxam

Volume 3 – B.2 (S-2399 60 g/L EC)

Physical & Chemical Properties

Great Britain

March 2026

Version History

When	What
November 2025	Initial DAR
March 2026	Updates made after ECP

Contents

B.2. Physical and Chemical Properties of the Plant Protection Product Inpyrfluxam.

It is noted the product 'S-2399 60 g/L EC' is also referred to under the product code S-2399 6 EC and S-2399 60 g/L EC (V16-7). The proposed in-use concentrations of 'S-2399 60 g/L EC' are 0.5 – 2.0% v/v.

Test or Study Annex 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	Visual method	S-2399 60 g/L EC (V16-7) Batch number: V16-7L1901	*Colour:* Clear yellow *Physical state:* Homogenous liquid, free from visible suspended matter and sediment	Acceptable.	Y	Study report number: 24897 TPF-0060 [redacted] (2021)

B.2.2. Explosive and Oxidising Properties

Explosive properties B.2.2/01	DSC	S-2399 60 g/L EC (V16-7) Batch number: V16-7L1901	The total heat decomposition of Run 1 was 53.4 J/g and the onset of exothermic decomposition is <500 °C. The total heat decomposition of Run 2 was 56.0 J/g and the onset of exothermic decomposition is <500 °C.	Acceptable. Not classified as explosive.	Y	Study report number: GLP3016006183R1/ 2019 TPF-0054 [redacted] (2020)
	UN RTDG Appendix 6 (Theoretical estimation)	S-2399 60 g/L EC (V16-7) Batch number: V16-7L1901	The calculated oxygen balance is <-200 for the active substance and all relevant co-formulants. Therefore, the explosive properties of S-2399 60 g/L EC has been predicted to be negative.	Acceptable. Not classified as explosive		Study report number: GLP3016006183R1/ 2019 TPF-0054 [redacted] (2020)
Oxidising properties B.2.2/02	*UN RTDG Appendix 6* *(Theoretical estimation)*	*S-2399 60 g/L EC (V16-7)* *Batch number: V16-7L1901*	*The oxidising properties of S-2399 EC is predicted to be negative based on the composition of the active substance and relevant co-formulants.*	*Not Acceptable.* *Acceptable data is provided below.*	*Y*	*Study report number: GLP3016006183R1/ 2019* *TPF-0054* [redacted] *(2020)*
	UN Test O.2	S-2399 6 EC (V16-7)	The 1:1 mixture of the test item and cellulose was observed to have a mean pressure rise	Acceptable. Not classified as oxidising.	Y	Study report number: GLP3016017793R1/2025 TPF-0083 [redacted] (2025)

		Batch number: V16-7L2401	time greater than that of a 1:1 mixture of 65 % nitric acid and cellulose.			
B.2.3. Flammability and Auto-flammability						
Flash point of the liquids formulations B.2.3/01	EC Test A.9	S-2399 60 g/L EC (V16-7) Batch number: V16-7L1901	The test item was found to have a flash point of 65 °C (using the close cup method).	Acceptable. Not classified as a flammable liquid.	Y	Study report number: GLP3016006183R1/ 2019 TPF-0054 [redacted] (2020)
Flammability of solid formulations B.2.3/02	-	-	Not relevant to an EC formulation.	Acceptable.	-	-
Self-heating of formulation B.2.3/03	EC Test A.15	S-2399 60 g/L EC (V16-7) Batch number: V16-7L1901	The test item was found to have an auto-ignition temperature of 302 °C.	Acceptable.	Y	Study report number: GLP3016006183R1/ 2019 TPF-0054 [redacted] (2020)

B.2.4. Acidity / Alkalinity and pH value

pH of the neat aqueous formulation B.2.4/01	-	-	Not relevant to an EC formulation.	Acceptable.	-	-
pH of a 1% dilution of the solid or non-aqueous formulation B.2.4/02	CIPAC MT 75.3	S-2399 60 g/L EC (V16-7) Batch number: V16-7L1901	pH of 1% dilution at 22 °C: 5.43	Acceptable.	Y	Study report number: 24897 TPF-0060 [redacted] (2021)
Acidity / Alkalinity B.2.4/03	CIPAC MT 191	S-2399 60 g/L EC (V16-7) Batch number: V16-7L1901	Not required as the pH of the 1% dilution is > 4 and < 10.	Acceptable.	Y	Study report number: 24897 TPF-0060 [redacted] (2021)

B.2.5. Viscosity and Surface Tension

Viscosity of the liquid formulation B.2.5/01	ASTM D445 based on OECD Test Guideline 114	S-2399 60 g/L EC (V16-7)	Kinematic viscosity at 20°C: **Tube number** / **Time (s)** / **Kinematic viscosity (mm²/s)** 0 / 3058 / 7.8193	Acceptable. The formulation is a Newtonian liquid (viscosity is independent from	Y	Study report number: 24897 TPF-0060

		Batch number: V16-7L1901	<table><tr><td></td><td>3050</td><td>7.7989</td></tr><tr><td colspan="2">Mean</td><td>7.8091</td></tr><tr><td rowspan="2">1</td><td>839</td><td>7.7566</td></tr><tr><td>839</td><td>7.7566</td></tr><tr><td colspan="2">Mean</td><td>7.7566</td></tr></table> Kinematic viscosity at 40°C: <table><tr><th>Tube number</th><th>Time (s)</th><th>Kinematic viscosity (mm²/s)</th></tr><tr><td rowspan="2">0</td><td>1797</td><td>4.5949</td></tr><tr><td>1798</td><td>4.5975</td></tr><tr><td colspan="2">Mean</td><td>4.5962</td></tr><tr><td rowspan="2">1</td><td>499</td><td>4.6133</td></tr><tr><td>499</td><td>4.6133</td></tr><tr><td colspan="2">Mean</td><td>4.6133</td></tr></table>	the shear stress/rate). Based on the calculated kinematic viscosity and the formulation composition, S-2399 60 g/L EC must be classified as a Category 1 aspiration hazard and the product label should carry the hazard statement H304.		[redacted] (2021)
Surface tension of the formulation B.2.5/02	EC Test A.5	S-2399 60 g/L EC (V16-7) Batch number: V16-7L1901	Neat formulation: 26.4 mN/m at 25 °C 2.0% v/v formulation: 28.1 mN/m at 20 °C	Acceptable. The tested concentrations accommodate the highest in-use concentration of S-2399 60 g/L EC. Testing the neat formulation is not strictly required but has been reported for completeness. The formulation is considered to be surface active.	Y	Study report number: 24897 TPF-0060 [redacted] (2021)

B.2.6. Relative Density and Bulk Density

Relative density of the liquid formulation B.2.6/01	CIPAC MT 3.3.2 EC Test A.3	S-2399 60 g/L EC (V16-7) Batch number: V16-7L1901	Relative Density at 20°C: 0.9273	Acceptable.	Y	Study report number: 24897 TPF-0060 [redacted] (2021)
Bulk density (pour and tap) of powder or granules B.2.6/02	-	-	Not relevant to an EC formulation.	Acceptable.	-	-

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 46.3.1	S-2399 60 g/L EC (V16-7) Batch number: V16-7L1901	The test item was stored in a 250 mL HDPE/PA bottle for 14 days at 54 °C. The physical and chemical properties before and after storage are reported in Appendix 1.	Acceptable. No significant changes on storage. Refer to Appendix 1.	Y	Study report number: 24897 TPF-0060 [redacted] (2021)

Effect of low temperature on stability of liquid formulation B.2.7/02	CIPAC MT 39.3	S-2399 60 g/L EC (V16-7) Batch number: V16-7L1901	The test item was stored in two different containers for 7 days at 0 °C. A 100 mL cone shaped centrifuge tube was used for stability and a closed glass bottle was used for all other physical and chemical properties. The physical and chemical properties before and after storage are reported in Appendix 2.	Acceptable. No significant changes on storage. Refer to Appendix 2.	Y	Study report number: 24897 TPF-0060 [redacted] (2021)
Shelf life following storage at ambient temperature B.2.7/03	-	S-2399 60 g/L EC (V16-7) Batch number: V16-7L1901	The test item was stored in a 250 mL HDPE/PA bottle for 1 year at 20 °C. The physical and chemical properties before and after storage are reported in Appendix 3.	Acceptable. No significant changes on storage. Refer to Appendix 3.	Y	Study report number: 24897 TPF-0060 [redacted] (2021)
	-	S-2399 60 g/L EC (V16-7) Batch number: V16-7L1901	The test item was stored in a 250 mL HDPE/PA bottle for 2 years at 20 °C. The physical and chemical properties before and after storage are reported in Appendix 4.	Acceptable. No significant changes on storage. Refer to Appendix 4.	Y	Study report number: 24897 TPF-0060 [redacted] (2021)

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 relevant to an EC formulation.	Acceptable.	-	-

B.2.8.2. Persistence foaming

Persistence of foaming of the diluted formulation B.2.8.2/01	CIPAC MT 47.3	S-2399 60 g/L EC (V16-7) Batch number: V16-7L1901		Acceptable The persistence of foaming was tested at concentrations of 0.5 and 2.0% v/v in CIPAC water D, which covers the highest and lowest in-use concentrations of S-2399 60 g/L EC. The maximum amount of foam measured was within the acceptable limit of 60 mL after 1 minute.	Y	Study report number: 24897 TPF-0060 [redacted] (2021)

	mL of foam	
	0.5% v/v	**2.0% v/v**
10 seconds	8	25
1 minute	Ring (<0.5)	0
3 minutes	Ring (<0.5)	0
12 minutes	0	0

B.2.8.3. Suspensibility						
Suspensibility of water dispersible formulation B.2.8.3/01	-	-	Not relevant to an EC formulation.	Acceptable.	-	-
Spontaneity of dispersion of water dispersible formulation B.2.8.3/02	-	-	Not relevant to an EC formulation.	Acceptable.	-	-
Dispersion stability of SE, OD or EG formulation B.2.8.3/03	-	-	Not relevant to an EC formulation.	Acceptable.	-	-
B.2.8.4. Degree of dissolution and dilution stability						
Degree of dissolution of water soluble formulation B.2.8.4/01	-	-	Not relevant to an EC formulation.	Acceptable.	-	-
Dilution stability of water soluble formulation B.2.8.4/02	-	-	Not relevant to an EC formulation.	Acceptable.	-	-

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 relevant to an EC formulation.	Acceptable.	-	-
Size distribution of particles of powder or suspension concentrate formulation B.2.8.5.1/02	-	-	Not relevant to an EC formulation.	Acceptable.	-	-
Nominal size range of granule B.2.8.5.1/03	-	-	Not relevant to an EC formulation.	Acceptable.	-	-
B.2.8.5.2. Dust content						
Dust content of granular formulation B.2.8.5.2/01	-	-	Not relevant to an EC formulation.	Acceptable.	-	-
B.2.8.5.3. Attrition						
Attrition characteristics of granules and tablets B.2.8.5.3/01	-	-	Not relevant to an EC formulation.	Acceptable.	-	-

<table>
<tr><td colspan="7">B.2.8.5.4. Hardness and Integrity</td></tr>
<tr><td>Hardness of tablets
B.2.8.5.4/01</td><td>-</td><td>-</td><td>Not relevant to an EC formulation.</td><td>Acceptable.</td><td>-</td><td>-</td></tr>
<tr><td>Integrity of tablets
B.2.8.5.4/02</td><td>-</td><td>-</td><td>Not relevant to an EC formulation.</td><td>Acceptable.</td><td>-</td><td>-</td></tr>
<tr><td colspan="7">B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability</td></tr>
<tr><td>Emulsifiability, emulsion stability and re-emulsifiability of formulation
B.2.8.6/01</td><td>CIPAC MT 36.3

(Visual method)</td><td>S-2399 60 g/L EC (V16-7)

Batch number: V16-7L1901</td><td>Emulsion characteristics in CIPAC water A:

<table><tr><th></th><th colspan="2">Result</th></tr><tr><th></th><th>0.5% v/v</th><th>2.0% v/v</th></tr><tr><td>Initial emulsification</td><td>Homogenous</td><td>Homogenous</td></tr><tr><td>Separation after 30 minutes</td><td>Homogenous</td><td>Homogenous</td></tr><tr><td>Separation after 2 hours</td><td>Homogenous</td><td>Cream on top (<0.5 mL)</td></tr><tr><td>Separation after 24 hours</td><td>Cream on top (<0.5 mL)</td><td>Cream on top (<0.5 mL)</td></tr><tr><td>Re-emulsification</td><td>Homogenous</td><td>Homogenous</td></tr><tr><td>Separation after 30 minutes</td><td>Homogenous</td><td>Homogenous</td></tr></table>
Emulsion characteristics in CIPAC water D:

<table><tr><th></th><th>Result</th></tr></table></td><td>Acceptable.

The emulsifiability, emulsion stability and re-emulsifiability were tested in CIPAC water A and D at the highest and lowest in-use concentrations of S-2399 60 g/L EC. A small amount of cream was observed after 2 and/or 24 hours after initial emulsification in all samples, except for 2.0% v/v in CIPAC water D (this was homogenous throughout the experiment). A homogenous emulsion was</td><td>Y</td><td>Study report number: 24897

TPF-0060

[redacted] (2021)</td></tr>
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<tr>
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<tr><td>Re-emulsification</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 30 minutes</td><td>Cream on top (<0.5 mL)</td><td>Homogenous</td></tr>
</table>
</td>
<td>formed after re-emulsification. It is noted that the 0.5% v/v in CIPAC water D separated again after 30 minutes of re-emulsification.

A label instruction recommending contiguous agitation during spraying should be included on the product label. It is noted that this is already included on the draft label.</td>
<td></td>
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</tr>
<tr><td colspan="7">B.2.8.7. Flowability, pourability and dustability</td></tr>
<tr><td>Flowability of granular formulation B.2.8.7/01</td><td>-</td><td>-</td><td>Not relevant to an EC formulation.</td><td>Acceptable.</td><td>-</td><td>-</td></tr>
<tr><td>Pourability of suspensions B.2.8.7/02</td><td>-</td><td>-</td><td>Not relevant to an EC formulation.</td><td>Acceptable.</td><td>-</td><td>-</td></tr>
<tr><td>Dustability of dustable powders after accelerated storage B.2.8.7/03</td><td>-</td><td>-</td><td>Not relevant to an EC formulation.</td><td>Acceptable.</td><td>-</td><td>-</td></tr>
</table>

B.2.9. Physical and Chemical Compatibility with other products including plant protection products with which its uses is to be authorised

Physical and chemical compatibility of tank mixtures B.2.9/01	ASTM E 1518 – 05 (Dynamic shaker method)	S-2399 60 g/L EC (V16-7) Batch number: V16-7L2402	S-2399 60 g/L EC was demonstrated to be compatible with a range of different products, containing different active substances and covering a range of different formulation types. The mixture was well dispersed with no non-rinsible residue present in any of the tests.	According to the applicant tank mixing is recommended on the label. ~~A study is ongoing and will be submitted in November 2025.~~ Data was submitted to show the compatibility of S-2399 60 g/L EC with a range of different products. The compatibility has been sufficiently demonstrated. *GLP not required, study was conducted to GEP.	N*	Study report number: 2025-013 [redacted] (2025)

B.2.10. Adherence and distribution to seeds

Distribution and adhesion to seeds B.2.10/01	-	-	Not relevant to an EC formulation.	Acceptable.	-	-

B.2.11. Other studies

-	-	-	-	-	-	-

The formulation ‘S-2399 60 g/L EC’ is an emulsifiable concentrate (EC) formulation containing 60 g/L inpyrfluxam with proposed in-use concentrations of 0.5 – 2.0 %v/v.

The appearance of the product is that of a clear yellow liquid. It is considered not to have explosive and oxidising properties and is not classified as flammable. It has an auto-ignition temperature of 302 °C, which indicates the formulation is not self-heating. When diluted with 1 % deionised water the pH value is 5.43. The kinematic viscosity is <20.5 mm^2/s and when considered together with the composition of the formulation, a Category 1 aspiration hazard classification is required and the product label should carry the hazard statement H304. The surface tension at the highest in-use concentration of the product is 28.1 mN/m indicating that the product is surface active. It’s technical characteristics are acceptable for an EC formulation.

Following both 7 days at 0 °C and 14 days at 54 °C, neither the active substance content nor the physical, chemical, and technical properties were significantly changed, indicating acceptable stability at low and high temperatures. Due to separation of the preparation being observed after low temperature storage, label instructions recommending ‘protect from frost’ and ‘shake well before use’ should be included on the product label. Data to support a shelf life of 2 years at ambient temperature when stored in HDPE/PA bottles was also submitted demonstrating acceptable stability of both the active substance content and the physical, chemical, and technical properties. Due to a layer of cream observed on the surface of the product that

readily homogenised upon mixing, a label instruction recommending contiguous agitation during spraying should be included on the product label. Tank mixing is proposed and sufficient data has been submitted to demonstrate the compatibility of S2399 60 g/L EC with other products. ~~but a tank mixing study has not been provided. A tank mixing study is to be submitted in November 2025 to address tank mixing compatibility.~~

Appendix 1 – Summary of accelerated storage stability data (14 days at 54 °C) in 250 mL HDPE/PA bottle ([redacted] 2021)

Test		Method	Initial result (T_0)	Result after 14 days at 54 °C	Comments/Acceptability
Active substance content	**Total isomer (S-2399 and S-2940)**	MET/24896-A (HPLC method)	6.613% w/w	6.583% w/w (-0.45%)	Acceptable. No significant change. The method (MET/24896-A) is fully validated in accordance with SANCO/3030/99 rev. 5. Refer to CP B5.
	***R*-isomer ratio**	MET/24896-B (HPLC method)	98.96% area	98.96% area	Acceptable. No change. The method (MET/24896-B) is fully validated in accordance with SANCO/3030/99 rev. 5. Refer to CP B5.
	S-2399 content	Calculation	6.544% w/w	6.515% w/w (-0.44%)	Acceptable. No significant change in the active substance.
Appearance		Visual	*Colour:* Clear yellow *Physical state:* Homogenous liquid, free from visible suspended matter and sediment	*Colour:* Clear yellow *Physical state:* Homogenous liquid, free from visible suspended matter and sediment	Acceptable. No change.
pH		CIPAC MT 75.3	pH of 1% dilution at 22 °C: 5.43	pH of 1% dilution at 22 °C: 5.42	Acceptable. No significant change.

<table>
<tr><td>Acidity/alkalinity</td><td>CIPAC MT 191</td><td>Not required as the pH of the 1% dilution is > 4 and < 10.</td><td>Not required as the pH of the 1% dilution is > 4 and < 10.</td><td>Acceptable.</td></tr>
<tr><td>Persistence of foaming</td><td>CIPAC MT 47.3</td><td>Persistent foaming test was conducted at 25°C in CIPAC water D.
<table><tr><th></th><th colspan="2">mL of foam</th></tr><tr><th></th><th>0.5% v/v</th><th>2.0% v/v</th></tr><tr><td>10 seconds</td><td>8</td><td>25</td></tr><tr><td>1 minute</td><td>Ring (<0.5)</td><td>0</td></tr><tr><td>3 minutes</td><td>Ring (<0.5)</td><td>0</td></tr><tr><td>12 minutes</td><td>0</td><td>0</td></tr></table></td><td>Persistent foaming test was conducted at 25°C in CIPAC water D.
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<tr><td>Emulsifiability, emulsion stability and re-emulsifiability of formulation</td><td>CIPAC MT 36.3

(Visual method)</td><td>Emulsion characteristics in CIPAC water A:
<table><tr><th></th><th colspan="2">Result</th></tr><tr><th></th><th>0.5% v/v</th><th>2.0% v/v</th></tr><tr><td>Initial emulsification</td><td>Homogenous</td><td>Homogenous</td></tr><tr><td>Separation after 30 minutes</td><td>Homogenous</td><td>Homogenous</td></tr><tr><td>Separation after 2 hours</td><td>Homogenous</td><td>Cream on top (<0.5 mL)</td></tr></table></td><td>Emulsion characteristics in CIPAC water A:
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No significant change.

A small amount of cream was observed on the top of the test item however, it readily homogenised upon mixing. Therefore, a label instruction recommending contiguous agitation during spraying should be included on the product label.</td></tr>
</table>

		Separation after 24 hours	Cream on top (<0.5 mL)	Cream on top (<0.5 mL)	Separation after 24 hours	Cream on top (<0.5 mL)	Cream on top (<0.5 mL)
		Re-emulsification	Homogenous	Homogenous	**Re-emulsification**	Homogenous	Homogenous
		Separation after 30 minutes	Homogenous	Homogenous	Separation after 30 minutes	Homogenous	Homogenous
		Emulsion characteristics in CIPAC water D:			Emulsion characteristics in CIPAC water D:		
			Result			**Result**	
			0.5% v/v	**2.0% v/v**		**0.5% v/v**	**2.0% v/v**
		Initial emulsification	Homogenous	Homogenous	Initial emulsification	Homogenous	Homogenous
		Separation after 30 minutes	Homogenous	Homogenous	Separation after 30 minutes	Homogenous	Homogenous
		Separation after 2 hours	Cream on top (<0.5 mL)	Homogenous	Separation after 2 hours	Cream on top (<0.5 mL)	Homogenous
		Separation after 24 hours	Cream on top (<0.5 mL)	Homogenous	Separation after 24 hours	Cream on top (<0.5 mL)	Homogenous
		Re-emulsification	Homogenous	Homogenous	**Re-emulsification**	Homogenous	Homogenous

		Separation after 30 minutes	Cream on top (<0.5 mL)	Homogenous	Separation after 30 minutes	Homogenous	Homogenous	
Stability of packaging	Visual	Weight (bottle 5): 278.6 g Weight (bottle 6): 276.9 g No ballooning, panelling or leaking. No observable alteration of package material by test item.			Weight (bottle 5): 278.4 g (-0.07% change) Weight (bottle 6): 276.8 g (-0.04% change) No ballooning, panelling or leaking. No observable alteration of package material by test item.			Acceptable. No changes in appearance or significant weight change.

Appendix 2 – Summary of low temperature storage stability data (7 days at 0 °C) in a 100 mL cone shaped centrifuge tube (stability) and a closed glass bottle (all other properties) ([redacted] 2021)

Test	Method	Initial result (T_0)	Result after 7 days at 0 °C	Comments/Acceptability
Appearance	Visual	*Colour:* Clear yellow *Physical state:* Homogenous liquid, free from visible suspended matter and sediment	*Colour:* Clear yellow *Physical state:* After 7 days at 0 °C a 2 mL blank layer is observed at the bottom of the test item. After homogenisation the test item was a homogenous liquid, free from visible suspended matter and sediment	There is separation of 2 mL after 7 days storage at 0 °C. The liquid separation is greater than the acceptable limit of 0.3 mL. However, re-homogenisation occurs following mixing. Therefore, a label instruction recommending to shake well before use and protect from frost should be included on the label.
pH	CIPAC MT 75.3	pH of 1% dilution at 22 °C: 5.43	pH of 1% dilution at 22 °C: 5.41	Acceptable. No significant change.
Acidity/alkalinity	CIPAC MT 191	Not required as the pH of the 1% dilution is > 4 and < 10.	Not required as the pH of the 1% dilution is > 4 and < 10.	Acceptable.

<table>
<tr>
<td>Emulsifiability, emulsion stability and re-emulsifiability of formulation</td>
<td>CIPAC MT 36.3

(Visual method)</td>
<td>Emulsion characteristics in CIPAC water A:

<table>
<tr><th></th><th>Result</th><th></th></tr>
<tr><th></th><th>0.5% v/v</th><th>2.0% v/v</th></tr>
<tr><td>Initial emulsification</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 30 minutes</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 2 hours</td><td>Homogenous</td><td>Cream on top (<0.5 mL)</td></tr>
<tr><td>Separation after 24 hours</td><td>Cream on top (<0.5 mL)</td><td>Cream on top (<0.5 mL)</td></tr>
<tr><td>Re-emulsification</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 30 minutes</td><td>Homogenous</td><td>Homogenous</td></tr>
</table>
Emulsion characteristics in CIPAC water D:

<table>
<tr><th></th><th>Result</th><th></th></tr>
<tr><th></th><th>0.5% v/v</th><th>2.0% v/v</th></tr>
<tr><td>Initial emulsification</td><td>Homogenous</td><td>Homogenous</td></tr>
</table>
</td>
<td>Emulsion characteristics in CIPAC water A:

<table>
<tr><th></th><th>Result</th><th></th></tr>
<tr><th></th><th>0.5% v/v</th><th>2.0% v/v</th></tr>
<tr><td>Initial emulsification</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 30 minutes</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 2 hours</td><td>Homogenous</td><td>Cream on top (<0.5 mL)</td></tr>
<tr><td>Separation after 24 hours</td><td>Cream on top (<0.5 mL)</td><td>Cream on top (<0.5 mL)</td></tr>
<tr><td>Re-emulsification</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 30 minutes</td><td>Homogenous</td><td>Homogenous</td></tr>
</table>
Emulsion characteristics in CIPAC water D:

<table>
<tr><th></th><th>Result</th><th></th></tr>
<tr><th></th><th>0.5% v/v</th><th>2.0% v/v</th></tr>
<tr><td>Initial emulsification</td><td>Homogenous</td><td>Homogenous</td></tr>
</table>
</td>
<td>Acceptable.

No change.

A small amount of cream was observed on the top of the test item however, it readily homogenised upon mixing. Therefore, a label instruction recommending protect from frost and contiguous agitation during spraying should be included on the product label.</td>
</tr>
</table>

		Separation after 30 minutes	Homogenous	Homogenous	Separation after 30 minutes	Homogenous	Homogenous	
		Separation after 2 hours	Cream on top (<0.5 mL)	Homogenous	Separation after 2 hours	Cream on top (<0.5 mL)	Homogenous	
		Separation after 24 hours	Cream on top (<0.5 mL)	Homogenous	Separation after 24 hours	Cream on top (<0.5 mL)	Homogenous	
		Re-emulsification	Homogenous	Homogenous	**Re-emulsification**	Homogenous	Homogenous	
		Separation after 30 minutes	Cream on top (<0.5 mL)	Homogenous	Separation after 30 minutes	Cream on top (<0.5 mL)	Homogenous	

Appendix 3 – Summary of ambient storage stability data (1 year at 20 °C) in 250 mL HDPE/PA bottle ([redacted] 2021)

Test		Method	Initial result (T_0)	Result after 1 year at 20 °C	Comments/Acceptability
Active substance content	**Total isomer (S-2399 and S-2940)**	MET/24896-A (HPLC method)	6.613% w/w	6.629% w/w (+0.24%)	Acceptable. No significant change. The method (MET/24896-A) is fully validated in accordance with SANCO/3030/99 rev. 5. Refer to CP B5.
	***R*-isomer ratio**	MET/24896-B (HPLC method)	98.96% area	98.96% area	Acceptable. No change. The method (MET/24896-B) is fully validated in accordance with SANCO/3030/99 rev. 5. Refer to CP B5.

<table>
<tr><td></td><td>S-2399 content</td><td>Calculation</td><td>6.544% w/w</td><td>6.560% w/w

(+0.24%)</td><td>Acceptable.

No significant change in the active substance.</td></tr>
<tr><td colspan="2">Appearance</td><td>Visual</td><td>Colour: Clear yellow

Physical state: Homogenous liquid, free from visible suspended matter and sediment</td><td>Colour: Clear yellow

Physical state: Homogenous liquid, free from visible suspended matter and sediment</td><td>Acceptable.

No change.</td></tr>
<tr><td colspan="2">pH</td><td>CIPAC MT 75.3</td><td>pH of 1% dilution at 22 °C: 5.43</td><td>pH of 1% dilution at 21 °C: 5.46</td><td>Acceptable.

No significant change.</td></tr>
<tr><td colspan="2">Acidity/alkalinity</td><td>CIPAC MT 191</td><td>Not required as the pH of the 1% dilution is > 4 and < 10.</td><td>Not required as the pH of the 1% dilution is > 4 and < 10.</td><td>Acceptable.</td></tr>
<tr><td colspan="2">Persistence of foaming</td><td>CIPAC MT 47.3</td><td>Persistent foaming test was conducted at 25°C in CIPAC water D.
<table><tr><th></th><th colspan="2">mL of foam</th></tr><tr><th></th><th>0.5% v/v</th><th>2.0% v/v</th></tr><tr><td>10 seconds</td><td>8</td><td>25</td></tr><tr><td>1 minute</td><td>Ring (<0.5)</td><td>0</td></tr><tr><td>3 minutes</td><td>Ring (<0.5)</td><td>0</td></tr><tr><td>12 minutes</td><td>0</td><td>0</td></tr></table></td><td>Persistent foaming test was conducted at 25°C in CIPAC water D.
<table><tr><th></th><th colspan="2">mL of foam</th></tr><tr><th></th><th>0.5% v/v</th><th>2.0% v/v</th></tr><tr><td>10 seconds</td><td>23</td><td>30</td></tr><tr><td>1 minute</td><td>Ring (<0.5)</td><td>Ring (<0.5)</td></tr><tr><td>3 minutes</td><td>Ring (<0.5)</td><td>0</td></tr><tr><td>12 minutes</td><td>0</td><td>0</td></tr></table></td><td>Persistence of foaming is not required after storage however, the results have been assessed and are acceptable.</td></tr>
<tr><td colspan="2">Emulsifiability, emulsion stability and re-</td><td>CIPAC MT 36.3</td><td>Emulsion characteristics in CIPAC water A:</td><td>Emulsion characteristics in CIPAC water A:</td><td>Acceptable.

No significant change.</td></tr>
</table>

<table>
<tr>
<td>emulsifiability of formulation</td>
<td>(Visual method)</td>
<td>
<table>
<tr><th></th><th colspan="2">Result</th></tr>
<tr><th></th><th>0.5% v/v</th><th>2.0% v/v</th></tr>
<tr><td>Initial emulsification</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 30 minutes</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 2 hours</td><td>Homogenous</td><td>Cream on top (<0.5 mL)</td></tr>
<tr><td>Separation after 24 hours</td><td>Cream on top (<0.5 mL)</td><td>Cream on top (<0.5 mL)</td></tr>
<tr><td>Re-emulsification</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 30 minutes</td><td>Homogenous</td><td>Homogenous</td></tr>
</table>
Emulsion characteristics in CIPAC water D:
<table>
<tr><th></th><th colspan="2">Result</th></tr>
<tr><th></th><th>0.5% v/v</th><th>2.0% v/v</th></tr>
<tr><td>Initial emulsification</td><td>Homogenous</td><td>Homogenous</td></tr>
</table>
</td>
<td>
<table>
<tr><th></th><th colspan="2">Result</th></tr>
<tr><th></th><th>0.5% v/v</th><th>2.0% v/v</th></tr>
<tr><td>Initial emulsification</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 30 minutes</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 2 hours</td><td>Homogenous</td><td>Cream on top (<0.5 mL)</td></tr>
<tr><td>Separation after 24 hours</td><td>Homogenous</td><td>Cream on top (<0.5 mL)</td></tr>
<tr><td>Re-emulsification</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 30 minutes</td><td>Homogenous</td><td>Homogenous</td></tr>
</table>
Emulsion characteristics in CIPAC water D:
<table>
<tr><th></th><th colspan="2">Result</th></tr>
<tr><th></th><th>0.5% v/v</th><th>2.0% v/v</th></tr>
<tr><td>Initial emulsification</td><td>Homogenous</td><td>Homogenous</td></tr>
</table>
</td>
<td>A small amount of cream was observed on the top of the CIPAC water A 2.0% v/v sample however, it readily homogenised upon mixing. Therefore, a label instruction recommending contiguous agitation during spraying should be included on the product label.</td>
</tr>
</table>

		Separation after 30 minutes	Homogenous	Homogenous	Separation after 30 minutes	Homogenous	Homogenous	
		Separation after 2 hours	Cream on top (<0.5 mL)	Homogenous	Separation after 2 hours	Homogenous	Homogenous	
		Separation after 24 hours	Cream on top (<0.5 mL)	Homogenous	Separation after 24 hours	Homogenous	Homogenous	
		Re-emulsification	Homogenous	Homogenous	**Re-emulsification**	Homogenous	Homogenous	
		Separation after 30 minutes	Cream on top (<0.5 mL)	Homogenous	Separation after 30 minutes	Homogenous	Homogenous	
Stability of packaging	Visual	Weight: 274.3 g No ballooning, panelling or leaking. No observable alteration of package material by test item.			Weight: 274.5 g (+0.07% change) No ballooning, panelling or leaking. No observable alteration of package material by test item.			Acceptable. No changes in appearance or significant weight change.

Appendix 4 – Summary of ambient storage stability data (2 years at 20 °C) in 250 mL HDPE/PA bottle ([redacted] 2021)

Test		Method	Initial result (T_0)	Result after 2 years at 20 °C	Comments/Acceptability
Active substance content	**Total isomer (S-2399 and S-2940)**	MET/24896-A (HPLC method)	6.613% w/w	6.462% w/w (-2.28%)	Acceptable. No significant change. The method (MET/24896-A) is fully validated in accordance with SANCO/3030/99 rev. 5. Refer to CP B5.

	***R*-isomer ratio**	MET/24896-B (HPLC method)	98.96% area	99.0% area	Acceptable. No significant change. The method (MET/24896-B) is fully validated in accordance with SANCO/3030/99 rev. 5. Refer to CP B5.
	S-2399 content	Calculation	6.544% w/w	6.397% w/w (-2.25%)	Acceptable. There is a decrease in the active substance content however, it is within the acceptable limit of up to a 5% loss.
Appearance		Visual	*Colour:* Clear yellow *Physical state:* Homogenous liquid, free from visible suspended matter and sediment	*Colour:* Clear yellow *Physical state:* Homogenous liquid, free from visible suspended matter and sediment	Acceptable. No change.
pH		CIPAC MT 75.3	pH of 1% dilution at 22 °C: 5.43	pH of 1% dilution at 21 °C: 5.51	Acceptable. No significant change.
Acidity/alkalinity		CIPAC MT 191	Not required as the pH of the 1% dilution is > 4 and < 10.	Not required as the pH of the 1% dilution is > 4 and < 10.	Acceptable.
Persistence of foaming		CIPAC MT 47.3	Persistent foaming test was conducted at 25°C in CIPAC water D. **mL of foam** **0.5% v/v** **2.0% v/v**	Persistent foaming test was conducted at 25°C in CIPAC water D. **mL of foam** **0.5% v/v** **2.0% v/v**	Persistence of foaming is not required after storage however, the results have been assessed and are acceptable.

<table>
<tr>
<td></td>
<td></td>
<td>
<table>
<tr><td>10 seconds</td><td>8</td><td>25</td></tr>
<tr><td>1 minute</td><td>Ring (<0.5)</td><td>0</td></tr>
<tr><td>3 minutes</td><td>Ring (<0.5)</td><td>0</td></tr>
<tr><td>12 minutes</td><td>0</td><td>0</td></tr>
</table>
</td>
<td>
<table>
<tr><td>10 seconds</td><td>25</td><td>33</td></tr>
<tr><td>1 minute</td><td>Ring (<0.5)</td><td>0</td></tr>
<tr><td>3 minutes</td><td>Ring (<0.5)</td><td>0</td></tr>
<tr><td>12 minutes</td><td>0</td><td>0</td></tr>
</table>
</td>
<td></td>
</tr>
<tr>
<td>Emulsifiability, emulsion stability and re-emulsifiability of formulation</td>
<td>CIPAC MT 36.3

(Visual method)</td>
<td>Emulsion characteristics in CIPAC water A:
<table>
<tr><th></th><th colspan="2">Result</th></tr>
<tr><th></th><th>0.5% v/v</th><th>2.0% v/v</th></tr>
<tr><td>Initial emulsification</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 30 minutes</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 2 hours</td><td>Homogenous</td><td>Cream on top (<0.5 mL)</td></tr>
<tr><td>Separation after 24 hours</td><td>Cream on top (<0.5 mL)</td><td>Cream on top (<0.5 mL)</td></tr>
<tr><td>Re-emulsification</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 30 minutes</td><td>Homogenous</td><td>Homogenous</td></tr>
</table>
</td>
<td>Emulsion characteristics in CIPAC water A:
<table>
<tr><th></th><th colspan="2">Result</th></tr>
<tr><th></th><th>0.5% v/v</th><th>2.0% v/v</th></tr>
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<tr><td>Separation after 2 hours</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 24 hours</td><td>Cream on top (<0.5 mL)</td><td>Cream on top (<0.5 mL)</td></tr>
<tr><td>Re-emulsification</td><td>Homogenous</td><td>Homogenous</td></tr>
<tr><td>Separation after 30 minutes</td><td>Homogenous</td><td>Homogenous</td></tr>
</table>
Emulsion characteristics in CIPAC water D:</td>
<td>Acceptable.

No significant change.

A small amount of cream was observed on the top of the CIPAC water A samples however, it readily homogenised upon mixing. Therefore, a label instruction recommending contiguous agitation during spraying should be included on the product label.</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td>Emulsion characteristics in CIPAC water D:
<table><tr><th></th><th>Result</th><th></th></tr><tr><th></th><th>0.5% v/v</th><th>2.0% v/v</th></tr><tr><td>Initial emulsification</td><td>Homogenous</td><td>Homogenous</td></tr><tr><td>Separation after 30 minutes</td><td>Homogenous</td><td>Homogenous</td></tr><tr><td>Separation after 2 hours</td><td>Cream on top (<0.5 mL)</td><td>Homogenous</td></tr><tr><td>Separation after 24 hours</td><td>Cream on top (<0.5 mL)</td><td>Homogenous</td></tr><tr><td>Re-emulsification</td><td>Homogenous</td><td>Homogenous</td></tr><tr><td>Separation after 30 minutes</td><td>Cream on top (<0.5 mL)</td><td>Homogenous</td></tr></table></td>
<td><table><tr><th></th><th>Result</th><th></th></tr><tr><th></th><th>0.5% v/v</th><th>2.0% v/v</th></tr><tr><td>Initial emulsification</td><td>Homogenous</td><td>Homogenous</td></tr><tr><td>Separation after 30 minutes</td><td>Homogenous</td><td>Homogenous</td></tr><tr><td>Separation after 2 hours</td><td>Homogenous</td><td>Homogenous</td></tr><tr><td>Separation after 24 hours</td><td>Homogenous</td><td>Homogenous</td></tr><tr><td>Re-emulsification</td><td>Homogenous</td><td>Homogenous</td></tr><tr><td>Separation after 30 minutes</td><td>Homogenous</td><td>Homogenous</td></tr></table></td>
<td></td>
</tr>
<tr>
<td>Stability of packaging</td>
<td>Visual</td>
<td>Weight (bottle 9): 267.8 g

Weight (bottle 10): 263.1 g

No ballooning, panelling or leaking. No observable alteration of package material by test item.</td>
<td>Weight (bottle 9): 267.8 g (no change)

Weight (bottle 10): 263.1 g (no change)

No ballooning, panelling or leaking. No observable alteration of package material by test item.</td>
<td>Acceptable.

No changes in appearance or weight.</td>
</tr>
</table>

B.2.12. References Relied On

Literature search

A literature review has been carried out for the active substance inpyrfluxam. One literature search was submitted to address all areas of the risk assessment. HSE has assessed the suitability of the mechanics of the literature search in line with EFSA guidance on conducting literature searches (EFSA Journal 2011). The literature review was conducted in accordance with Article 8(5) of Regulation No. 1107/2009 at the time of completion, and was conducted to comply with the EFSA guidance document as published in EFSA Journal 2011; 9(2):2092.

The process of selection of relevant scientific peer-reviewed open literature was based on a single-concept search in the CAS and Dialog platform databases. The time period was limited to studies published July 2013 up to July 2023 using the search criteria of inpyrfluxam, metabolites and mixtures and related CAS numbers, common names, trade names and lab codes.

A stepwise process for selection of relevant scientific peer-reviewed open literature was undertaken:

- A rapid assessment of the summary records references (e.g., titles, abstracts, index terms, keywords) was conducted.
- Summary records which appeared to be relevant went to the next level of evaluation.
- These were further evaluated and categorized into “reliable without restriction”, “reliable with restriction”, “not reliable” and “not assignable”.

The results of the literature review are as follows:

Summary of the review	n	Justification
Total number of summary records retrieved from search	352	Appendix 1
Number of summary records excluded after rapid assessment for relevance (by title/abstract)	349	Appendix 6

Number of summary records of potential/unclear relevance assessed in further detail (by abstract/full-text)	3	Appendices 4 and 5
Number of studies excluded from the risk assessment after detailed assessment of full-text documents (i.e. not relevant)	2	
Number of studies not excluded for relevance after detailed assessment (i.e. relevant studies and studies of unclear relevance)	1	
Number of studies included in the dossier as supporting information (reliability criteria 1-2)	1	

In the area of physical and chemical data no records were considered relevant for the assessment of physical chemical properties of the active substance inpyrfluxam.

Conclusion

Regarding the literature search undertaken by the applicant, it is considered that the search is acceptable in terms of databases searched and the search criteria applied. No references of relevance to this assessment were identified.

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, KCP 2.4/01, KCP 2.4/02, KCP 2.5/01, KCP 2.5/02, KCP 2.6, KCP 2.7/01, KCP 2.7/02, KCP 2.7/03, KCP 2.8.2 and KCP 2.8.6	[redacted]	2021	Physical and chemical properties and storage stability tests of an emulsifiable concentrate (EC) containing S-2399 Wallonie recherche CRA-W, Belgium Study No. 24343 Sumitomo Chemical Co., Ltd. Report No. TPF-0060 GLP: Yes Published: No	N	Y	The study is necessary for this regulatory decision and is eligible for data protection	SUM	N.A.

KCP 2.2/01, KCP 2.2/02, KCP 2.2/03, KCP 2.3/01 and KCP 2.3/02	[redacted]	2020	Testing on Sample S-2399 60g/l EC (V16-7) DEKRA Insight (Chilworth Technology), UK Study No. GLP/3016006183 Sumitomo Chemical Co., Ltd. Report No. TPF-0054 GLP: Yes Published: No	N	Y	The study is necessary for this regulatory decision and is eligible for data protection	SUM	N.A.
KCP 2.2/04	[redacted]	2025	Oxidising Properties Testing on a Sample of S-2399 6 EC. DEKRA UK Ltd, UK Study No. GLP3016017793R1/2025 Sumitomo Chemical Co., Ltd. Report No. TPF-0083 GLP: Yes Published: No	N	Y	The study is necessary for this regulatory decision and is eligible for data protection	SUM	N.A.
KCP 2.9/01	[redacted]	2025	Physical chemical compatibility tests Physical compatibility of pesticides in aqueous	N	Y	The study is necessary for this regulatory decision and is	SUM	N.A.

			tank mixtures by dynamic shaker method S-2399 60G/L EC V16-7 tank mixed with other products PHILAGRO France Study No. 2025-013 GLP: No Published: No			eligible for data protection		

Further information

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This publication is available on the HSE website at www.hse.gov.uk/xxx

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First published 0X/26. Published by the Health and Safety Executive 0X/26.