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.3 (S-2399 60 g/L EC)

Data on Application & Efficacy

Great Britain

March 2026

Version History

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

Contents

B.3. Data on Application and Efficacy

This Draft Assessment Report has been drafted by the Health and Safety Executive (HSE) based on the information submitted by the applicant, specifically their documents 'M-CP Section 3 DATA ON APPLICATION' and 'REPORT TO SUPPORT THE ACTIVE SUBSTANCE APPROVAL, Part B, Section 3, Efficacy Data and Information'. HSE considers that the applicant has satisfactorily addressed the Efficacy related requirements for approval of new active substances.

B.3.1. Field of use envisaged

'S-2399 60 g/L EC' is fungicide intended for the control of foliar diseases in winter and spring wheat, winter and spring barley, and durum wheat.

B.3.2. Effects on harmful organisms

The harmful organisms controlled are *Puccinia recondita* (PUCCRE) and *Puccinia striiformis* (PUCCSI) in wheat and *Puccinia hordei* (PUCCHD) in barley.

Inpyrfluxam is a carboxamide fungicide belonging to the chemical group of pyrazole-4-carboxamides. It is a succinate dehydrogenase inhibitor (SDHI) acting at the respiration complex II target site.

B.3.3. Details of intended use

Crop and/or situation (a)	GB or country For IT	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.i. (i)	method kind (f-h)	Timing/ Growth Stages & season (j)	number min-max (k)	Interval between application (min)	L product/ ha min-max (l)	Water Volume L/ha min-max	g a.s./ha min-max (l) a) max rate per appl b) max total rate per crop/season		
Winter wheat (TRZAW), Spring wheat (TRZAS), Durum wheat (TRZDU)	GB	S-2399 60 g/L EC	F	*Puccinia recondita* (PUCCRE) *Puccinia striiformis* (PUCCSI)	EC	60 g/L	Foliar spray	GS 30-71 Spring	1	N/A	1.5	75-300	90	35	
Winter barley (HORVW), Spring barley (HORVS)	GB	S-2399 60 g/L EC	F	*Puccinia hordei* (PUCCHD)	EC	60 g/L	Foliar spray	GS 30-71 Spring	1	N/A	1.5	75-300	90	35	

(a) For crops, the GB and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) State if the use is outdoor, field use (F) or glass house (G) or indoor use (I).

(c) *e.g.* biting and sucking insects, soil borne insects, foliar fungi, weeds

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).

(j) Growth stages range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide (f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	(k) Indicate the minimum and maximum number of applications possible under practical conditions of use (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha (m) PHI - minimum pre-harvest interval

B.3.4. Application rate and concentration of the active substance

S-2399 60 g/L EC contains 60 g a.s./L of the active substance inpyrfluxam. The application rates and timings are shown in the table above (section B.3.3.).

B.3.5. Method of application

Application will be via hydraulic boom sprayer with a recommended water volume of 75-300 L/ha.

B.3.6. Number and timing of applications and duration of the protection

See section B.3.3. above.

B.3.7. Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops

There are no restrictions proposed on the draft product label for S-2399 60 g/L EC. A seedling emergence study was conducted to support the ecotoxicology assessment of inpyrfluxam. The study methodology was based on OECD Guideline for the Testing of Chemicals No. 208. No effects >50% were observed in this study and therefore the non-target plant ER_{50} endpoint for inpyrfluxam was set at >91 g a.s./ha, which corresponds to >1.5 L/ha of the product S-2399 60 g/L EC, which is the highest proposed rate.

S-2399 60 g/L EC is applied to cereal crops at BBCH 30-71; therefore, a minimum of 80% interception can be expected, resulting in a maximum of 300 mL/ha S-2399 60 g/L EC being applied to the soil. Inpyrfluxam is persistent, with a DT_{50} value in soil of 383 days; however, some degradation in the soil can be expected prior to sowing any succeeding crops. Based on the lack of herbicidal effects at the maximum proposed application rate, a low risk of phytotoxicity is expected in succeeding crops from the proposed uses of S-2399 60 g/L EC. A full risk assessment on succeeding crops will be conducted at the product authorisation stage, which should include appropriate EC_{10} and PEC_{soil} values.

B.3.8. Proposed instructions for use

See section B.3.3. above. The proposed instructions for use of S-2399 60 g/L EC from the draft label are as follows:

'To protect against foliar diseases, it is recommended to apply S-2399 60 g/L EC at the onset of disease infection.

Crop Specific Information and Timing
S-2399 60 g/L EC can be used on all varieties of cereals, applied from the beginning of stem elongation to grain watery ripe (GS 30 to 71).

Rate of Use
To protect against the listed foliar diseases, S-2399 60 g/L EC is applied at 1.5 L/ha in 75-300 L of water per hectare. A maximum of only one application per crop. S-2399 60 g/L EC can be readily integrated into disease control spray programmes using other products, preferably with alternative modes of action.'

B.3.9. Effectiveness

Wheat

***Puccinia recondita* (PUCCRE)**
14 effectiveness trials were conducted in the Maritime EPPO climatic zone between 2018-2020 in wheat (10 in winter wheat and 4 in spring wheat) to assess control of *Puccinia recondita* provided by S-2399 60 g/L EC. Trials were conducted in accordance with relevant EPPO standards and Good Experimental Practice (GEP). Applications of S-2399 60 g/L EC were made between GS 31-61 with water volumes of 200-300 L/ha. 2 applications were made in all trials, which is greater than the number proposed in the GAP; however, for the purpose of demonstrating satisfactory efficacy and supporting the approval of inpyrfluxam, this is acceptable. Assessments of disease severity were focused on the upper 3 leaves. The results are presented in Table 3.9-1 below.

Table 3.9-1 – Efficacy of S-2399 60 g/L EC against *Puccinia recondita* in wheat

Assessment timing	Number of trials	% disease severity on leaves in untreated control		% control S-2399 60 g/L EC 1.5 L/Ha	
		Mean	Min-Max	Mean	Min-Max
2-3 weeks after 2 applications	4	19.91	11.38-30.16	99.99	99.94-100.00
4-6 weeks after 2 applications	10	32.84	13.04-64.22	96.39	84.85-100.00
>6 weeks after 2 applications	6	44.7	12.69-79.49	88.89	68.97-99.03

The data provided demonstrate that the proposed application rate of S-2399 60 g/L EC provides acceptable protection against *Puccinia recondita* in wheat. In most trials, S-2399 60 g/L EC provided comparable control to other solo SDHIs (fluxapyroxad or benzovindiflupyr) and higher control than solo prothioconazole.

***Puccinia striiformis* (PUCCST)**

19 effectiveness trials were conducted in the Maritime EPPO climatic zone between 2018-2020 in wheat (16 in winter wheat and 3 in spring wheat) to assess control of *Puccinia striiformis* provided by S-2399 60 g/L EC. Trials were conducted in accordance with relevant EPPO standards and Good Experimental Practice (GEP). Applications of S-2399 60 g/L EC were made between GS 31-61 with water volumes of 200-300 L/ha. 2 applications were made in all trials, which is greater than the number proposed in the GAP; however, for the purpose of demonstrating satisfactory efficacy and supporting the approval of inpyrfluxam, this is acceptable. Assessments of disease severity were focused on the upper 3 leaves. The results are presented in Table 3.9-2 below.

Table 3.9-2 – Efficacy of S-2399 60 g/L EC against *Puccinia striiformis* in wheat

Assessment timing	Number of trials	% disease severity on leaves in the untreated control		% control provided by S-2399 60 g/L EC at 1.5 L/Ha	
		Mean	Min-Max	Mean	Min-Max
2-3 weeks after 2 applications	15	37.10	10.31-98.13	92.17	70.24 - 100.00
4-6 weeks after 2 applications	16	59.05	12.49-100.00	85.97	57.34-100.00
>6 weeks after 2 applications	6	44.58	16.75-91.15	93.41	89.41-99.44

The data provided demonstrate that the proposed application rate of S-2399 60 g/L EC provides acceptable protection against *Puccinia striiformis* in wheat. In most trials, S-2399 60 g/L EC provided higher control than other solo SDHIs (fluxapyroxad or benzovindiflupyr) and solo prothioconazole.

Yield in the presence of disease

The yield of wheat was assessed in the presence of disease in 18 of the effectiveness trials. Across the 18 trials, the mean yield relative to the untreated control was 142.10% (104.40-284.20%) following an application of S-2399 60 g/L EC at 1.5 L/ha. This was slightly higher than the yield following treatment with other solo SDHIs (fluxapyroxad or benzovindiflupyr) and solo prothioconazole.

Barley

***Puccinia hordei* (PUCCHD)**

22 effectiveness trials were conducted in the Maritime EPPO climatic zone between 2018-2020 in barley (21 in winter barley and 1 in spring barley) to assess control of *Puccinia hordei* provided by S-2399 60 g/L EC. Trials were conducted in accordance with relevant EPPO standards and Good Experimental Practice (GEP). Applications of S-2399 60 g/L EC were made between GS 31-59 with water volumes of 200-300 L/ha. 2 applications were made in all trials, which is greater than the number proposed in the GAP; however, for the purpose of demonstrating satisfactory efficacy and supporting the approval of inpyrfluxam, this is acceptable. Assessments of disease severity were focused on the upper 3 leaves. The results are presented in Table 3.9-3 below.

Table 3.9-3 – Efficacy of S-2399 60 g/L EC against *Puccinia hordei* in barley

Assessment timing	Number of trials	% disease severity on leaves in the untreated control		% control provided by S-2399 60 g/L EC at 1.5 L/Ha	
		Mean	Min-Max	Mean	Min-Max
2-3 weeks after 2 applications	15	19.12	5.00- 53.62	98.07	80.43-100.00
4-6 weeks after 2 applications	16	32.96	5.69-90.80	96.03	83.70-100.00
>6 weeks after 2 applications	6	23.29	5.65-95.10	95.74	93.13-100.00

The data provided demonstrate that the proposed application rate of S-2399 60 g/L EC provides acceptable protection against *Puccinia hordei* in barley. In most trials, S-2399 60 g/L EC provided comparable control to both solo fluxapyroxad (another SDHI) and solo prothioconazole.

Yield in the presence of disease

The yield of barley was assessed in the presence of disease in 20 of the effectiveness trials. Across the 20 trials, the mean yield relative to the untreated control was 107.55% (97.95-139.40%) following an application of S-2399 60 g/L EC at 1.5 L/ha. This was slightly lower than the yield following treatment with solo fluxapyroxad (another) and solo prothioconazole.

Conclusion

The submitted data demonstrate that inpyrfluxam is sufficiently effective against some major target diseases in wheat and barley in GB. A yield benefit in the presence of disease has been demonstrated in wheat and barley following 2 applications of S-2399 60 g/L EC. Overall, the data provided suggest that the proposed application rates are realistic.

A full consideration of the effectiveness and the minimum effective dose of S-2399 60 g/L EC will be made at the product authorisation stage.

B.3.10. Information on the development of resistance

See point B.3.4. of Volume 3 – B.3 (AS) of the inpyrfluxam Draft Assessment Report for information on resistance development.

A detailed consideration of the resistance risk of S-2399 60 g/L EC, along with a resistance management strategy, will be made at the product authorisation stage.

B.3.11. Adverse effects on treated crops

Crop safety of S-2399 60 g/L EC was assessed in all of the effectiveness trials and in 12 specific disease-free trials in winter wheat (3), winter barley (5) and spring barley (4).

In multiple effectiveness trials, disease failed to develop to assessable levels and can therefore be used to assess crop safety in the absence of disease. The effectiveness and selectivity trials, which were all conducted in accordance with GEP and EPPO, and included assessments of phytotoxicity, yield, and quality.

Wheat

Phytotoxicity was assessed in a total of 53 Maritime efficacy trials (47 in winter wheat, 6 in spring wheat) and 3 crop safety trials in winter wheat (2 Maritime, 1 Mediterranean). No phytotoxic symptoms were observed during any of the 56 trials following application of S-2399 60 g/L EC at 1.5 L/ha.

Effects on yield following application of S-2399 60 g/L EC at 1.5 L/ha was assessed in 2 crop safety trials on winter wheat (1 Maritime, 1 Mediterranean). In both trials, S-2399 60 g/L EC had no negative impact on yield and was comparable to the reference product (solo prothioconazole).

Adverse effects on plant parts for propagation were assessed in all 3 crop safety trials conducted in winter wheat. S-2399 60 g/L EC had no negative impact on germination capacity and was statistically similar to both the untreated control and the prothioconazole reference product.

Barley

Phytotoxicity was assessed in a total of 55 Maritime efficacy trials (45 winter barley, 10 spring barley) and 9 Maritime crop safety trials (5 in winter barley, 4 in spring barley). No phytotoxic symptoms were observed during any of the 64 trials following application of S-2399 60 g/L EC at 1.5 L/ha.

Effects on yield following application of S-2399 60 g/L EC at 1.5 L/ha was assessed in all 9 selectivity trials. In all 5 winter barley trials, S-2399 60 g/L EC had no negative impact on yield and was numerically comparable to the reference product (solo prothioconazole). In 1 of those trials, treatment with the reference product resulted in statistically higher yield than after treatment with S-2399 60 g/L EC, but this was only 0.34 t/ha and both products increased yield compared to the untreated control. The 4 spring barley trials are less useful as there was no untreated control, but in all cases the yield was numerically similar between barley treated with S-2399 60 g/L EC and the prothioconazole reference product.

Grain quality was also assessed in 8 of the selectivity trials, including assessments of hectolitre weight and protein content. No negative effects on quality were observed across the trials.

Adverse effects on plant parts for propagation were assessed in a single crop safety trial conducted in winter barley. S-2399 60 g/L EC had no negative impact on germination capacity and was statistically similar to both the untreated control and the prothioconazole reference product.

Effects on the transformation processes

The results from 2 transformation studies in wheat, which included milling and baking tests demonstrated that wheat treated with S-2399 60 g/L EC was comparable to the untreated control and no negative effects were observed.

The results from 4 trials in barley demonstrated no adverse effects on malting and brewing following treatment with S-2399 60 g/L EC.

Conclusion

Overall, the data indicate that the proposed use of S-2399 60 g/L EC is realistic and unlikely to have any adverse effects on wheat and barley. A full consideration of the crop safety of S-2399 60 g/L EC will be made at the product authorisation stage.

B.3.12. Observations on other undesirable or unintended side-effects

This point will be considered in full at the product authorisation stage. Effects on succeeding crops are considered in section B.3.7.

Impact on adjacent crops

A vegetative vigour test and a seedling emergence test were conducted in accordance with the OECD 227 and OECD 208 Guidelines respectively. These studies are discussed in the ecotoxicology assessment. No effects >50% observed in the vegetative vigour or seedling emergence tests at the maximum application rate of 1.5 L/ha. Therefore, the amount of S-2399 60 g/L EC that may drift onto adjacent crops at any distance, is unlikely to have a negative effect on the plants. The risk to adjacent crops is likely to be acceptable without the need for a buffer zone or drift reducing technology.

Tank cleaning

No effects >50% observed in the vegetative vigour or seedling emergence tests at the maximum application rate of 1.5 L/ha. Therefore, it is unlikely that any remaining residues of S-2399 60 g/L EC will have a negative effect on crops subsequently treated with the same application equipment. The effectiveness of any proposed tank cleaning method will be evaluated at the product authorisation stage.

Effects on beneficial and other non-target organisms

In section B.9.6.2 of the ecotoxicology section of the DAR, Volume 3CP B9, the following conclusion is made on non-target arthropods:

'The in-field and off-field risk for other non-target arthropods from the intended uses of the product S-2399 60EC in cereals is acceptable as the HQ does not exceed the trigger value for T. pyri or A. rhopalosiphi for in-field or off-field assessments at tier 1. There is no need to consider extended laboratory testing, semi-field, field or alternate route of exposure studies as acceptable risk was shown in the laboratory studies.'

B.3.13. 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
Volume 3CP point B.3	Unknown	2023	Inpyrfluxam 6EC (S-2399 60G/L EC) Emulsifiable Concentrate DOCUMENT M-CP, Section 3 DATA ON APPLICATION	N	N	N.A.	Sumitomo Chemical	N.A.
Volume 3CP point B.3	Unknown	2021	REPORT TO SUPPORT THE ACTIVE SUBSTANCE APPROVAL Part B Section 3	N	N	N.A.	Sumitomo Chemical	N.A.

			Efficacy Data and Information Product code: S-2399 6EC					
Volume 3CP point B.3	Unknown	2023	Doc C DRAFT LABEL for S-2399 60 g/L EC	N	N	N.A.	Sumitomo Chemical	N.A.

Further information

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