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

Toxicology, Metabolism Data & Assessment of Risks for Humans

Great Britain

March 2026

Version History

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

Contents

B.6. Toxicology and Metabolism Data and Assessment of risks for humans

The representative product, S-2399 60 g/L EC is an emulsifiable concentrate (EC) containing 60 g/L inpyrfluxam. It is used as a professional fungicide on cereal crops.

Information on the acute toxicity and other hazard properties of all components has been obtained from the SDS (Safety Data Sheets) provided by the applicant. The outcome of the calculations and weight-of-evidence approach are summarised below. For further details please see volume 4, section C.2.3.4.

S-2399 60 g/L EC meets the criteria for classification for the following human health hazards according to the GB CLP Regulation:

- Acute oral toxicity, category 4 (H302, harmful if swallowed)
- Skin irritation, category 2 (H315, causes skin irritation)
- Eye damage, category 1 (H318, causes serious eye damage)
- STOT SE, category 3 (H335, may cause respiratory irritation)
- STOT SE, category 3 (H336, may cause drowsiness or dizziness)
- Aspiration toxicity, category 1 (H304, may be fatal if swallowed and enters airways)

B.6.1. Acute toxicity of plant protection product

There are no studies addressing the acute toxicity, skin and eye irritation or skin sensitisation potential of the representative product S-2399 60 g/L EC. The toxicological data requirements for the representative product have been addressed by applying the calculation method as per the GB CLP Regulation.

B.6.1.1. Oral

The oral acute toxicity estimate (ATE) of S-2399 60 g/L EC is 1808 mg/ kg bw. This is below the cut-off for classification of 2000 mg/kg bw given in the GB CLP Regulation. Therefore, S-2399 60 g/L EC meets the criteria for classification for acute oral toxicity, category 4 (H302), according to the GB CLP Regulation.

B.6.1.2. Dermal

The product does not contain any components classified for acute dermal toxicity. Therefore, S-2399 60 g/L EC does not meet the criteria for the classification for acute dermal toxicity, in accordance with the GB CLP Regulation.

B.6.1.3. Inhalation

The ATE of the product for acute inhalation toxicity is 16.6 mg/L (dust/mist). This is above the limit for classification of 5.0 mg/L given in the GB CLP Regulation. Therefore, S-2399 60

g/L EC does not meet the criteria for classification for acute inhalation toxicity, according to the GB CLP Regulation.

B.6.1.4. Skin irritation

The sum of the relevant co-formulants classified for skin irritation in category 2 (H315) is 36.56%; this exceeds the generic concentration limit for classification of a mixture in category 2 of ≥10%, given in the GB CLP Regulation. Therefore, S-2399 60 g/L EC meets the criteria for classification for skin irritation, category 2 (H315) according to the GB CLP Regulation.

B.6.1.5. Eye irritation

The sum of the relevant co-formulants classified for serious eye damage in category 1 is 45.16%; this exceeds the generic concentration limit for classification of a mixture in category 1 of ≥3%, given in the GB CLP Regulation. Therefore, S-2399 60 g/L EC meets the criteria for classification for eye damage, category 1 (H318) according to GB CLP Regulation.

B.6.1.6. Skin sensitisation

To meet the data requirement for skin sensitisation with the calculation method, data on the skin sensitisation potential of all relevant co-formulants, present at ≥1%, is required. Information on all relevant co-formulants was available.

According to the available information, the product does not contain any co-formulants which are classified for skin sensitisation Therefore, the product does not meet the criteria for classification for skin sensitisation according to the GB CLP Regulation.

Therefore, S-2399 60 g/L EC does not meet the criteria for the classification for skin sensitisation based on the available information, in accordance with the GB CLP Regulation.

B.6.1.7. Supplementary studies on the plant protection product

None available and none required

B.6.1.8. Supplementary studies for combinations of plant protection products

Not available and not required.

B.6.2. Dermal absorption

The dermal penetration of inpyrfluxam formulated as S-2399 60 g/L EC has been investigated in an in vitro study using human skin, in accordance with OECD TG 428. The available study was interpreted in accordance with the EFSA Guidance on Dermal Absorption (2017).

Reference:	KCP 7.3/01
Report Title:	Inpyrfluxam 60g/L (V16-7) - In Vitro Absorption through Human Dermatomed Skin Using [^{14}C]-Inpyrfluxam
Author(s) & Year:	[redacted] (2020)
Document No, Authority registration No	Dermal Technology Laboratory Ltd. Med IC4, Keele University Science and Business Park, Keele, Staffordshire, ST5 5NL, UK Study number: JV2469
Substance used:	[phenyl-14C] Inpyrfluxam and blank S-2399 formulation Lot/ Batch: CFQ44108
Method of analysis:	Not required
Guideline(s):	OECD 428 (2004) EFSA Guidance on dermal absorption (2017)
Deviations:	The receptor chamber wash was not analysed, deviating from the OECD guidelines and EFSA (2017) guidance.
Impact of the deviation:	The mean recoveries for the formulation concentrate and the dilution were 101% and 100% respectively. This ensures that there was no substance missing from the analyses. Therefore, the observed deviation does not impact the integrity of the study.
GLP or GEP:	Yes
Acceptability:	Yes
Study relied upon:	Yes

Methods

The dermal penetration of inpyrfluxam formulated as S-2399 60 g/L EC was investigated in an in vitro experiment performed on human skin. Eight human dermatomed skin samples were exposed to the formulation concentrate (59.8 g/L inpyrfluxam), and a dilution (1/400, 0.139 g/L inpyrfluxam) for 6 hours and sampled up to 24 hours. Results were analysed according to the EFSA guidance on dermal absorption (2017), with use of the BfR calculator, to determine the absorbed dose.

One cell (Cell 15) from the concentrate group was excluded from the results due to an unrepresentatively high value in the remaining skin, compared with other cells. The individual mass balance values have been presented in italics for clarity.

Results

For the formulation concentrate (59.8 g/L) absorption was not considered complete at T=0.5, therefore only the values for tape strips 1 and 2 were excluded from the absorbed dose. The

mean total recovery was 101.34% of the applied dose. The calculated dermal absorption value for inpyrfluxam in the concentrated product is 8.8%.

For the dilution (0.139 g/L) absorption was considered complete at T=0.5, therefore the values for all tape strips were excluded from the absorbed dose. The mean total recovery was 100% of the applied dose. The calculated dermal absorption value for the tested dilution for inpyrfluxam in the diluted product tested is 20%.

Results are summarised in table 6.2-2. Individual cell values for the concentrate formulation and spray dilution are presented in Tables 6.2-3, and -4, respectively.

Table 6.2-2: *In vitro* dermal penetration of Inpyrfluxam from S-2399 60 g/L EC through human skin - % Recovery data

Dose group	High dose (Formulation concentrate)		Low dose (Spray dilution 1:400)	
Target concentration [mg/mL]	60		0.15	
Target dose [µg/cm^2]	600		150	
Mean actual applied dose [µg/cm^2]	598		139	
Recovery [%]	Mean	SD	Mean	SD
Dislodgeable dose				
Skin wash after 6 and 24 hours	93.33	8.69	84.10	4.52
Donor chamber wash	3.29	4.42	0.15	0.13
Skin associated dose				
Tape strips 1-2	0.08	0.07	0.05	0.05
Tape strips 3-5	**0.06**	0.05	0.05	0.06
Skin preparation	**4.17**	4.61	**4.68**	4.56
Absorbed dose				
Receptor fluid	**0.41**	0.20	**11.01**	2.09
Receptor chamber wash	N/A	N/A	N/A	N/A
Total recovery	101.34	4.09	100.03	1.04
LLC of t_0.5 absorption	46.12	5.89	77.22	5.74
Absorption complete?	No		Yes	
Measured absorption if LLC of t_0.5<=75%	4.64	4.56	N/A	N/A
Measured absorption if LLC of t_0.5>75%	N/A	N/A	15.70	4.90
Measured absorption corrected	4.64	4.56	15.70	4.90
Relevant absorption estimate	8.836		19.814	
Final estimate (rounded)	**8.8**		**20**	

Figures in bold included in EFSA “absorbed” dose value.

Table 6.2-3: High dose level (concentrate commercial formulation – 60 g/L) Individual cell values.

Test compartment	Dose recovered (%)								Mean %	SD
	Cell 4 Donor 1620	*Cell 15 Donor 1621*	Cell 21 Donor 1623	Cell 31 Donor 1623	Cell 39 Donor 1617	Cell 47 Donor 1620	Cell 52 Donor 1621	Cell 68 Donor 1618		
Donor chamber	1.25	*1.10*	0.085	11.3	7.70	0.203	0.506	2.00	3.29	4.42
Skin wash at 6 hours	98.5	*37.8*	99.3	13.2	25.9	95.2	86.8	67.4	69.5	36.0
Skin wash at 24 hours	7.54	*22.7*	1.15	72.8	58.6	2.99	7.23	16.7	23.9	29.3
Stratum corneum Tape strip 1	0.023	*0.033*	0.001*	0.082	0.043	0.022	0.023	0.111	0.044	0.039
Stratum corneum Tape strip 2	0.015	*0.023*	0.0003*	0.084	0.035	0.020	0.014	0.065	0.033	0.030
Stratum corneum Tape strip 3	0.009*	*0.017*	0.001*	0.059	0.031	0.008*	0.009*	0.042	0.023	0.022
Stratum corneum Tape strip 4	0.010	*0.019*	0.0004*	0.044	0.020	0.008*	0.007*	0.036	0.018	0.016
Stratum corneum Tape strip 5	0.008*	*0.022*	0.002*	0.037	0.020	0.005*	0.005*	0.034	0.016	0.015
Remaining skin	0.866	***36.7***	0.300	6.71	4.29	0.317	3.59	13.1	4.17	4.62
Receptor fluid at 12 hours	0.438	*0.341*	0.095	0.140	0.226	0.191	0.357	0.106	0.222	0.130
Receptor fluid at 24 hours	0.721	*0.701*	0.199	0.300	0.499	0.392	0.601	0.191	0.415	0.202
Total recovered	109	*99.2*	101	105	97.2	99.1	98.8	99.7	101	4.09

* <LOQ; Values in italics (*Cell 15 Donor 1621)* were not included in the calculation due to the spurious high radioactivity in remaining skin.

Table 6.2-5: Low dose level (1:400 spray dilution – 0.15 g/L) Individual cell values

Test compartment	Dose recovered (%)								Mean %	SD
	Cell 8 Donor 1621	Cell 19 Donor 1621	Cell 24 Donor 1623	Cell 38 Donor 1617	Cell 43 Donor 1620	Cell 51 Donor 1620	Cell 84 Donor 1618	Cell 85 Donor 1623		
Donor chamber	0.039*	0.084	0.101	0.075	0.226	0.148	0.438	0.107	0.152	0.128
Skin wash at 6 hours	81.9	83.6	80.6	67.6	85.0	81.5	79.4	82.7	80.3	5.42
Skin wash at 24 hours	2.26	1.91	6.53	5.83	3.07	2.65	6.01	2.25	3.81	1.95
Stratum corneum Tape strip 1	0.002*	0.008*	<LOD*	0.064	0.015*	0.018*	0.083	0.029*	0.027*	0.031
Stratum corneum Tape strip 2	<LOD*	<LOD*	<LOD*	0.050	<LOD*	0.015*	0.047	0.004*	0.014*	0.022
Stratum corneum Tape strip 3	<LOD*	0.014*	0.002*	0.042*	<LOD*	0.001*	0.024*	0.008*	0.012*	0.015
Stratum corneum Tape strip 4	<LOD*	<LOD*	<LOD*	0.022*	<LOD*	0.017*	0.060	<LOD*	0.012*	0.021
Stratum corneum Tape strip 5	<LOD*	0.005*	<LOD*	0.035*	0.015*	<LOD*	0.076	<LOD*	0.017*	0.027
Remaining skin	1.47	2.26	4.54	15.4	2.23	2.76	5.90	2.91	4.68	4.56
Receptor fluid at 12 hours	12.5	9.16	6.38	8.68	8.08	10.2	6.64	12.0	9.21	2.27
Receptor fluid at 24 hours	13.8	10.3	8.32	11.8	9.47	12.2	8.80	13.4	11.0	2.08
Total recovered	99.5	98.2	100	101	100	99.3	101	101	100	1.03

* <LOQ

Conclusion

In conclusion, the absorption of [phenyl-14C]-inpyrfluxam formulated as S-2399 60g/L EC through human skin was low. The majority of the applied inpyrfluxam was washed off the skin after 6 hours.

The human dermal penetration estimates of inpyrfluxam in S-6399 60g/L EC to be used for risk assessment were calculated as **8.8 %** for the concentrate (59.8 g/L inpyrfluxam) and **20%** for a spray dilution (0.139 g/L inpyrfluxam).

For the representative uses of the product, the lowest concentrated in-use dilution is 0.3 g/L inpyrfluxam, according to the GAP table provided. This is higher than the concentration of

inpyrfluxam in the dilution tested in the study, therefore the pro-rata correction is not appropriate. Taking a conservative approach, the calculated dermal absorption of 20% for inpyrfluxam formulated as S-2399 60 g/L EC at 0.139 g/L will be applied to the dilution of 0.3 g/L.

B.6.3. Available toxicological data relating to co-formulants

SDSs have been submitted for all co-formulants. Information from these SDSs has been considered to address the classification of the product for other human health hazards beyond acute toxicity, skin and eye irritation and skin sensitisation.

Other human health hazards

Specific Target Organ Toxicity – Single exposure (STOT-SE)

Respiratory tract irritation

The sum of the relevant ingredients classified for STOT-SE in category 3 (H335 – respiratory tract irritation) is 34.4% which exceeds the generic concentration limit (GCL) for classification of a mixture in category 3 of ≥ 20% given in the GB CLP Regulation.

Therefore, S-2399 60 g/L EC meets the criteria for classification for STOT-SE, category 3 (H335) according to the GB CLP Regulation.

Narcotic effects

The sum of the relevant ingredients classified for STOT-SE in category 3 (H336 – narcotic effects) is 42.6 %, which exceeds the GCL for classification of a mixture in category 3 of ≥ 20% given in the GB CLP Regulation.

Therefore, S-2399 60 g/L EC meets the criteria for classification for STOT-SE, category 3 (H336) according to the GB CLP Regulation.

Aspiration toxicity

The product contains >10% of a co-formulant that is classified for aspiration toxicity category 1 (H304) and the product has a kinematic viscosity of ≤ 20.5 mm^2 /s at 40^oC.

Therefore, S-2399 60 g/L EC meets the criteria for the classification for aspiration toxicity in category 1 (H304) according to the GB CLP Regulation.

Consideration of classification of in-use dilutions

The product is intended to be diluted for use. Therefore, a consideration of the classification of the in-use dilutions is required.

None of the co-formulants are present above the respective GCLs in the highest concentrated in-use dilution of the representative product. Therefore, the in-use dilutions of the representative product do not meet the criteria for classification for any human health hazards category according to the GB CLP Regulation.

B.6.4. Exposure data

'S-2399 60 g/L EC' is the representative formulation for the approval of the active substance inpyrfluxam. A summary of the application parameters pertinent to the operator, bystander, resident and worker exposure assessment for 'S-2399 60 g/L EC' are presented below.

Table B.6.4-1: Summary of 'S-2399 60 g/L EC' application parameters pertinent to the operator, bystander, resident and worker exposure assessment.

'S-2399 60 g/L EC'	
Formulation type	Emulsifiable concentrate (EC)
Use	For use as a professional fungicide on cereal crops (winter and spring wheat, winter and spring barley, and durum wheat)
Classification	**From DAR 18, Volume 3CP, Section B.6.1:** H302: Harmful if swallowed H304: May be fatal if swallowed and enters airways H315: Causes skin irritation H318: Causes serious eye damage H335: May cause respiratory irritation H336: May cause drowsiness or dizziness
Packaging	**From DAR 16, Volume 3CP, Section B.4.4:** 1, 5, 10, 20 L HDPE/PA containers
Active substance	
Active substance concentration	60 g/L inpyrfluxam
Systemic AOEL	**From DAR 01, Volume 1, Section 2.6.13:** **Inpyrfluxam:** 0.04 mg/kg bw/day
Systemic AAOEL	**From DAR 01, Volume 1, Section 2.6.14:** **Inpyrfluxam:** 0.2 mg/kg bw
Dermal absorption	**From DAR 18, Volume 3CP, Section B.6.2:**

	Inpyrfluxam: • Concentrate (59.8 g/L): 8.8 % • Dilution (0.139 g a.s./L): 20 % *In-vitro dermal absorption study (Johnson, IR., 2020)* To be used in this evaluation: • Dilution (0.3 g a.s./L): 20 %
Oral absorption	**Inpyrfluxam:** 100 %
Vapour pressure	**From DAR 04, Volume 3CA, Section B.2.2:** **Inpyrfluxam (purity 99.9%):** 3.8 x 10^{-8} Pa at 20ºC 1.2 x 10^{-7} Pa at 25ºC
Molecular weight of active substance	**From DAR 03, Volume 3CA, Section B.1.1:** **Inpyrfluxam:** 333.38 g/mol
Application Scenarios	
Maximum individual dose	1.5 L product/ha equivalent to 0.09 kg inpyrfluxam/ha
Maximum number of applications per year	1 per year
Interval between applications	365 days
Application volume	75 – 300 L/ha
Spray concentration range	Considering all proposed uses: **Inpyrfluxam:** 0.3 g a.s./L (300 L) – 1.2 g a.s./L (75 L)
Maximum total dose	See maximum individual dose
Application method	Vehicle mounted boom sprayer
Re-entry activity	Inspection/irrigation
Latest time of application	BBCH 71 PHI 35 days

Estimates of operator, worker, bystander and resident exposure have been conducted in line with the 2014 EFSA exposure guidance[1] and the respective calculator (hereafter referred to as the EFSA Calculator).

At the time of the active substance evaluation, the 2022 EFSA exposure guidance[2] and corresponding online model (hereafter referred to as the online EFSA OPEX Model) have since been implemented in GB. Therefore, to ensure consistency in future product assessments and authorisations, estimates of operator, worker, bystander and resident exposure have also been conducted in line with the 2022 EFSA exposure guidance.

The two versions of the EFSA exposure guidance use different terminology for the non-dietary exposure assessment. Both versions of the guidance require an acute exposure assessment for substances that have the potential to induce an adverse health effect after a single exposure event (on one day). The estimates of acute exposure are then compared to the acute acceptable operator exposure level (AAOEL). An exposure assessment is also required where adverse effects may be caused by longer periods of contact, ranging from weeks to months. The 2014 EFSA exposure guidance refers to this as ‘longer term’ exposure, whilst the 2022 EFSA exposure guidance refers to this as ‘short term exposure’. These estimates are then compared to the acceptable operator exposure level (AOEL). For consistency, the 2022 EFSA guidance terminology (‘short term exposure’) has been used throughout for the non-dietary exposure assessment of inpyrfluxam.

B.6.4.1. Operator exposure

Considering the proposed uses of the representative product ‘S-2399 60 g/L EC’, the maximum application rate of 1.5 L product/ha for use on spring and winter cereals represents the critical GAP for operator exposure.

A first tier evaluation of operator exposure has been conducted based on the maximum application rate and highest dermal absorption values (worst case scenario). A summary of the predicted short term and acute operator exposure to inpyrfluxam for the proposed uses of ‘S-2399 60 g/L EC’ is presented in the following tables. Outputs from the EFSA Calculator (version 30 March 2015) and the online EFSA OPEX Model (version 1.1.2) are presented in Appendix 1 (Estimates 1 and 2).

[1] European Food Safety Authority (2014). Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, EFSA Journal 2014;12(10):3874.

[2] European Food Safety Authority (2022). Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products, EFSA Journal 2022;20(1):7032.

Table B.6.4.1-2: EFSA Calculator estimate of short term operator exposure to inpyrfluxam for application of 'S-2399 60 g/L EC' to cereal crops

Active Substance: Inpyrfluxam				
Model data	**Level of PPE**		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL (0.04 mg/kg bw/day)**
	Mix/Load	**Application**		
Scenario: Cereals / Outdoor / Downward spraying / Vehicle mounted boom sprayer Formulation type: Emulsifiable concentrate (EC) Work rate: 50 ha Season: Not relevant				
Application rate:			0.09 kg a.s./ha	
Spray application AOEM; 75th percentile Body weight: 60 kg	Workwear (No PPE)	Workwear (No PPE)	**0.0256**	**64.0**

Based on the EFSA Calculator, the predicted short term operator exposure for application to cereal crops via vehicle mounted boom sprayer is calculated to be equivalent to 64% of the AOEL of inpyrfluxam for an operator without PPE. The predicted operator exposure is within acceptable limits.

Table B.6.4.1-3: EFSA OPEX Model estimate of short term operator exposure to inpyrfluxam for application of 'S-2399 60 g/L EC' to cereal crops

Active Substance: Inpyrfluxam				
Model data	**Level of PPE**		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL (0.04 mg/kg bw/day)**
	Mix/Load	**Application**		
Scenario: Cereals / Outdoor / Downward spraying / Vehicle mounted boom sprayer Formulation type: Emulsifiable concentrate (EC) Work rate: 50 ha Season: Not relevant				
Application rate:			0.09 kg a.s./ha	
Spray application AOEM; 75th percentile Body weight: 60 kg	Workwear (No PPE)	Workwear (No PPE)	**0.03**	**85.7**

Based on the online EFSA OPEX Model, the predicted short term systemic operator exposure for application to cereal crops via vehicle mounted boom sprayer is calculated to be equivalent to 85.7% of the AOEL of inpyrfluxam for an operator without PPE. The predicted operator exposure is within acceptable levels.

Table B.6.4.1-4: EFSA Calculator estimate of acute operator exposure to inpyrfluxam for application of 'S-2399 60 g/L EC' to cereal crops

Active Substance: Inpyrfluxam				
Model data	**Level of PPE**		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AAOEL (0.2 mg/kg bw)**
	Mix/Load	**Application**		
Scenario: Cereals / Outdoor / Downward spraying / Vehicle mounted boom sprayer Formulation type: Emulsifiable concentrate (EC) Work rate: 50 ha Season: Not relevant				
Application rate:			0.09 kg a.s./ha	
Spray application AOEM; 95th percentile Body weight: 60 kg	Workwear (No PPE)	Workwear (No PPE)	**0.1109**	**55.5**

Based on the EFSA Calculator, the predicted acute systemic operator exposure for application to cereal crops via vehicle mounted boom sprayer is calculated to be equivalent to 55.5% of the AAOEL of inpyrfluxam for an operator without PPE. The predicted operator exposure is within acceptable levels.

Table B.6.4.1-5: EFSA OPEX Model estimate of acute operator exposure to inpyrfluxam for application of 'S-2399 60 g/L EC' to cereal crops

Active Substance: Inpyrfluxam				
Model data	**Level of PPE**		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AAOEL (0.2 mg/kg bw)**
	Mix/Load	**Application**		
Scenario: Cereals / Outdoor / Downward spraying / Vehicle mounted boom sprayer Formulation type: Emulsifiable concentrate (EC) Work rate: 50 ha Season: Not relevant				
Application rate:			0.09 kg a.s./ha	
Spray application AOEM; 95th percentile	Workwear (No PPE)	Workwear (No PPE)	**0.1**	**72.2**

Body weight: 60 kg				

Based on the online EFSA OPEX Model, the predicted acute systemic operator exposure for application to cereal crops via vehicle mounted boom sprayer is calculated to be equivalent to 72.2% of the AAOEL of inpyrfluxam for an operator without PPE. The predicted operator exposure is within acceptable levels.

Classification of 'S-2399 60 g/L EC'

There are no PPE requirements for operators based on the systemic exposure estimates from the EFSA Calculator and the EFSA OPEX Model. However, 'S-2399 60 g/L EC' is classified with respect to human health.

- H302: Harmful if swallowed
- H304: May be fatal if swallowed and enters airways
- H315: Causes skin irritation
- H318: Causes serious eye damage
- H335: May cause respiratory irritation
- H336: May cause drowsiness or dizziness

Based on the classification of the product the use of suitable protective clothing (coveralls), suitable protective gloves and face protection (faceshield) is required for operators when handling the concentrate.

'S-2399 60 g/L EC' is classified for 'H335: May cause respiratory irritation' and 'H336: May cause drowsiness or dizziness'. As the representative uses are proposed on outdoor crops only, it is assumed that mixing and loading tasks will also be conducted outdoors or where there is sufficient ventilation.

On this basis, it is considered that no RPE is required for the representative use and the representative product formulation. For products classified for inhalation toxicity, requirements for respiratory protection equipment (RPE) may need to be considered for future product authorisations.

B.6.4.2. Bystander and resident exposure

Considering the proposed uses of the representative product 'S-2399 60 g/L EC', the maximum application rate of 1.5 L product/ha and minimum water volume of 75 L/ha for use on spring and winter cereals represents the critical GAP for bystander and resident exposure.

For exposure of bystanders and residents to vapour, the EFSA exposure guidance specifies default values for the average concentration of active substance in the air 24 hours after application of the product. These values are based on the volatility of the active substance (at 20°C or 25°C):

- Substances with low volatility having a vapour pressure of <5 x 10^{-3} Pa (the default average concentration in air in the 24 hours after application is 1 µg/m³).

- Moderately volatile substances with a vapour pressure between 5 × 10^{-3} Pa and 10^{-2} Pa (the default average concentration in air in the 24 hours after application is 15 µg/m³).

The vapour pressure of inpyrfluxam is stated to be 3.8 x 10^{-8} Pa at 20ºC and 1.2 x 10^{-7} Pa at 25ºC (see DAR 04 Volume 3CA, Section B2.2). Thus, for the purposes of the bystander and resident exposure assessments, the active substance inpyrfluxam is considered to have low volatility.

Resident (short term) exposure

A first tier evaluation of resident exposure has been conducted based on the maximum application rate, minimum water volume, and highest dermal absorption values (worst case scenario). A summary of the predicted short term resident exposure to inpyrfluxam for the proposed uses of 'S-2399 60 g/L EC' is presented in the following tables. Outputs from the EFSA Calculator (version 30 March 2015) and the online EFSA OPEX Model (version 1.1.2) are presented in Appendix 1 (Estimates 3 and 4).

Table B.6.4.2-1: EFSA Calculator estimate of resident (short term) exposure to inpyrfluxam for application of 'S-2399 60 g/L EC' to cereal crops

Active Substance: Inpyrfluxam			
Model data	**Exposure Pathway**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL (0.04 mg/kg bw/day)**
Scenario: Cereals / Outdoor / Downward spraying / Vehicle mounted boom sprayer Buffer Zone: 2-3 m Drift Reduction Technology: No DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 365 days Water volume: 75 L/ha			
Application rate:		1 x 0.09 kg a.s./ha	
Resident Child Body weight: 10 kg	Drift (75th Perc.)	**0.0065**	**16.2**
	Vapour (75th Perc.)	**0.0011**	**2.7**
	Deposits (75th Perc.)	**0.0003**	**0.8**
	Re-entry (75th Perc.)	**0.0030**	**7.6**
	Sum (Mean)	**0.0073**	**18.3**
Resident Adult Body	Drift (75th Perc.)	**0.0015**	**3.9**

weight: 60 kg	Vapour (75th Perc.)	**0.0002**	**0.6**
	Deposits (75th Perc.)	**0.0001**	**0.3**
	Re-entry (75th Perc.)	**0.0017**	**4.2**
	Sum (Mean)	**0.0024**	**6.0**

Based on the EFSA Calculator, the predicted short term systemic exposure to a child and resident are within acceptable limits for all exposure pathways, with the (mean) sum of all pathways equivalent to 18.3% of the AOEL of inpyrfluxam for a child resident, and 6% of the AOEL of inpyrfluxam for an adult resident. The estimated short term exposure to residents is also considered to cover short term exposure to bystanders.

Table B.6.4.2-2: EFSA OPEX Model estimate of resident (short term) exposure to inpyrfluxam for application of 'S-2399 60 g/L EC' to cereal crops

Active Substance: Inpyrfluxam			
Model data	**Exposure Pathway**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL (0.04 mg/kg bw/day)**
Scenario: Cereals / Outdoor / Downward spraying / Vehicle mounted boom sprayer Buffer Zone: 2-3 m Drift Reduction Technology: No DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 365 days Water volume: 75 L/ha			
Application rate:		1 x 0.09 kg a.s./ha	
Resident Child Body weight: 10 kg	Drift (75th Perc.)	**0.007**	**16.3**
	Vapour (75th Perc.)	**1e-05**	**0.03**
	Deposits (75th Perc.)	**0.0003**	**0.8**
	Re-entry (75th Perc.)	**0.003**	**7.6**
	Sum (Mean)	**0.006**	**15.6**
Resident Adult Body weight: 60 kg	Drift (75th Perc.)	**0.002**	**3.9**
	Vapour (75th Perc.)	**4e-06**	**0.01**
	Deposits (75th Perc.)	**0.0001**	**0.3**
	Re-entry (75th Perc.)	**0.002**	**4.2**
	Sum (Mean)	**0.002**	**5.4**

Based on the online EFSA OPEX Model, the predicted short term systemic exposure to a child and resident are within acceptable limits for all exposure pathways, with the (mean) sum of all pathways equivalent to 15.6% of the AOEL of inpyrfluxam for a child resident, and 5.4% of the AOEL of inpyrfluxam for an adult resident. The estimated short term exposure to residents is also considered to cover short term exposure to bystanders.

Bystander (acute) exposure

A first tier evaluation of bystander exposure has been conducted based on the maximum application rate, minimum water volume, and highest dermal absorption values (worst case scenario). A summary of the predicted acute bystander exposure to inpyrfluxam for the proposed uses of 'S-2399 60 g/L EC' is presented in the following tables. Outputs from the EFSA Calculator (version 30 March 2015) and the online EFSA OPEX Model (version 1.1.2) are presented in Appendix 1 (Estimates 5 and 6).

Table B.6.4.2-3: EFSA Calculator estimate of bystander (acute) exposure to inpyrfluxam for application of 'S-2399 60 g/L EC' to cereal crops

Active Substance: Inpyrfluxam			
Model data	**Exposure Pathway**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AAOEL (0.2 mg/kg bw)**
Scenario: Cereals / Outdoor / Downward spraying / Vehicle mounted boom sprayer Buffer Zone: 2-3 m Drift Reduction Technology: No DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 365 days Water volume: 75 L/ha			
Application rate:		1 x 0.09 kg a.s./ha	
Resident Child Body weight: 10 kg	Drift (95th Perc.)	**0.0147**	**7.4**
	Vapour (95th Perc.)	**0.0011**	**0.5**
	Deposits (95th Perc.)	**0.0010**	**0.5**
	Re-entry (95th Perc.)	**0.0030**	**1.5**
Resident Adult Body weight: 60 kg	Drift (95th Perc.)	**0.0040**	**2.0**
	Vapour (95th Perc.)	**0.0002**	**0.1**
	Deposits (95th Perc.)	**0.0004**	**0.2**
	Re-entry (95th Perc.)	**0.0017**	**0.8**

Based on the EFSA Calculator, the predicted acute systemic exposure to a child and adult bystander from the spray drift, vapour, surface deposits, and re-entry into treated crops

pathways are calculated to be within acceptable limits. The estimated acute exposure to bystanders is also considered to cover acute exposure to residents.

Table B.6.4.2-4: EFSA OPEX Model estimate of bystander (acute) exposure to inpyrfluxam for application of 'S-2399 60 g/L EC' to cereal crops

Active Substance: Inpyrfluxam			
Model data	**Exposure Pathway**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AAOEL (0.2 mg/kg bw)**
Scenario: Cereals / Outdoor / Downward spraying / Vehicle mounted boom sprayer Buffer Zone: 2-3 m Drift Reduction Technology: No DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 365 days Water volume: 75 L/ha			
Application rate:		1 x 0.09 kg a.s./ha	
Resident Child Body weight: 10 kg	Drift (95th Perc.)	**0.01**	**7.4**
	Vapour (95th Perc.)	**1e-05**	**0.007**
	Deposits (95th Perc.)	**0.001**	**0.5**
	Re-entry (95th Perc.)	**0.003**	**1.5**
Resident Adult Body weight: 60 kg	Drift (95th Perc.)	**0.004**	**2.0**
	Vapour (95th Perc.)	**4e-06**	**0.002**
	Deposits (95th Perc.)	**0.0004**	**0.2**
	Re-entry (95th Perc.)	**0.002**	**0.8**

Based on the online EFSA OPEX Model, the predicted acute systemic exposure to a child and adult bystander from the spray drift, vapour, surface deposits, and re-entry into treated crops pathways are calculated to be within acceptable limits. The estimated acute exposure to bystanders is also considered to cover acute exposure to residents.

B.6.4.3. Worker exposure

Considering the proposed uses of the representative product 'S-2399 60 g/L EC', the maximum application rate of 1.5 L product/ha for use on spring and winter cereals represents the critical GAP for worker exposure.

For active substances that have an AAOEL, an acute worker exposure assessment in principle is needed, but available data are not reliable enough to conduct the assessment (in particular with regard to Transfer Coefficient and Dislodgeable Foliar Residue values),

therefore no acute worker exposure assessment is required according to the EFSA Exposure Guidance.

A first tier evaluation of worker exposure has been conducted based on the maximum application rate and highest dermal absorption values (worst case scenario). A summary of the predicted short term exposure to inpyrfluxam for re-entry workers undertaking inspection/irrigation activities in treated crops for the proposed uses of 'S-2399 60 g/L EC' is presented in the following tables. Outputs from the EFSA Calculator (version 30 March 2015) and the online EFSA OPEX Model (version 1.1.2) are presented in Appendix 1 (Estimates 7 and 8).

Table B.6.4.3-1: EFSA Calculator estimate of short term exposure to inpyrfluxam for workers undertaking inspection/irrigation activities in cereal crops that have previously been treated with 'S-2399 60 g/L EC'

Active Substance: Inpyrfluxam			
Model data	**Level of PPE**	**Total absorbed dose at day 0 (mg/kg bw/day)**	**% of systemic AOEL (0.04 mg/kg bw/day)**
Re-entry task: Inspection/irrigation Situation: Outdoor Work rate: 2 hours/day DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 365 days			
Application rate:		1 x 0.09 kg a.s./ha	
Body weight: 60 kg	Workwear (covering the arms, body and legs) TC: 1400 cm^2/person/h	**0.0025**	**6.3**

Based on the EFSA Calculator, the predicted short term exposure for a worker undertaking inspection/irrigation activities in treated cereal crops is calculated to be equivalent to 6.3% of the AOEL of inpyrfluxam for a worker wearing workwear (arms, body and legs covered). The predicted worker exposure is within acceptable limits.

Table B.6.4.3-2: EFSA OPEX Model estimate of short term exposure to inpyrfluxam for workers undertaking inspection/irrigation activities in cereal crops that have previously been treated with 'S-2399 60 g/L EC'

Active Substance: Inpyrfluxam				
Model data	**Level of PPE**	**Total absorbed dose at day 0 (mg/kg bw/day)**	**% of systemic AOEL (0.04 mg/kg bw/day)**	**Safe re-entry interval (days)**
Re-entry task: Inspection/irrigation Situation: Outdoor Work rate: 2 hours/day DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 365 days				
Application rate:		1 x 0.09 kg a.s./ha		
Body weight: 60 kg	Workwear (covering the arms, body and legs) TC: 1400 cm^2/person/h	**0.003**	**6.3**	**0**

Based on the EFSA Calculator, the predicted short term exposure for a worker undertaking inspection/irrigation activities in treated cereal crops is calculated to be equivalent to 6.3% of the AOEL of inpyrfluxam for a worker wearing workwear (arms, body and legs covered). The predicted worker exposure is within acceptable limits.

B.6.5. Exposure and risk assessment

B.6.5.1. Operator exposure

Estimates of operator exposure according to the EFSA 2014 and the EFSA 2022 exposure guidance predict that the proposed uses of 'S-2399 60 g/L EC' on cereals will result in acceptable short term and acute systemic exposure to inpyrfluxam for operators without PPE.

The estimated short term exposure for application via vehicle mounted boom sprayer according to the EFSA Calculator (version 30 March 2015) is calculated to be equivalent to 64% of the AOEL of inpyrfluxam and according to the EFSA OPEX Model (version 1.1.2) is calculated to be equivalent to 85.7% of AOEL of inpyrfluxam.

The estimated acute exposure for application via vehicle mounted boom sprayer according to the EFSA Calculator (Version: 30th March 2015) is calculated to be equivalent to 55.5% of the AAOEL of inpyrfluxam and according to EFSA OPEX Model (version 1.1.2) is calculated to be equivalent to 72.2% of the AAOEL of inpyrfluxam.

There are no PPE requirements for operators based on the systemic exposure estimates from the EFSA Calculator and the EFSA OPEX Model. However, the product 'S-2399 60 g/L EC' is classified for human health effects:

- H302: Harmful if swallowed
- H304: May be fatal if swallowed and enters airways
- H315: Causes skin irritation
- H318: Causes serious eye damage
- H335: May cause respiratory irritation
- H336: May cause drowsiness or dizziness

Based on the classification of the product the use of suitable protective clothing (coveralls), suitable protective gloves and face protection (faceshield) is required for operators when handling the concentrate.

B.6.5.2. Bystander and resident exposure

Resident exposure

Estimates of child and adult resident exposure according to the EFSA 2014 and the EFSA 2022 exposure guidance predict the proposed uses of 'S-2399 60 g/L EC' on cereal crops will result in acceptable short term systemic exposure to inpyrfluxam for all exposure pathways.

The estimated exposure according to the EFSA Calculator (version 30 March 2015) for the (mean) sum of all pathways is calculated to be equivalent to 18.3% of the AOEL of inpyrfluxam for a child resident, and 6% of the AOEL of inpyrfluxam for an adult resident.

The estimated exposure according to the EFSA OPEX Model (version 1.1.2) for the (mean) sum of all pathways is calculated to be equivalent to 15.6% of the AOEL of inpyrfluxam for a child resident, and 5.4% of the AOEL of inpyrfluxam for an adult resident.

The estimated short term exposure to residents is also considered to cover the short term exposure to bystanders.

Bystander exposure

Estimates of child and adult bystander exposure according to the EFSA 2014 and the EFSA 2022 exposure guidance predict that the proposed uses of 'S-2399 60 g/L EC' on cereal crops will result in acceptable acute systemic exposure to inpyrfluxam for the spray drift, vapour, surface deposits, and re-entry in treated crops pathways. The estimated acute exposure to bystanders is also considered to cover acute exposure to residents.

B.5.3. Worker exposure

Estimates of worker exposure according to the EFSA 2014 and the EFSA 2022 exposure guidance predict that the proposed uses of 'S-2399 60 g/L EC' on cereal crops will result in acceptable short term systemic exposure to inpyrfluxam for workers undertaking

inspection/irrigation activities wearing workwear (arms, body and legs covered). The estimated exposure according to the EFSA Calculator (version 30 March 2015) and also the EFSA OPEX Model (version 1.1.2) is calculated to be equivalent to 6.3% of the AOEL of inpyrfluxam.

B.6.6. Appendix 1: Exposure calculations

Inputs into the EFSA Calculator (version 30 March 2015):

Substance name	Inpyrfluxam	
Product name	S-2399 60 g/L EC	
Reference value non acutely toxic active substance (RVNAS)	0.04	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	0.2	mg/kg bw/day
Crop type	Cereals	
Substance properties		
Formulation type	ble concentrates, emulsifiable concentrate, etc.	
Miniumum volume water for application (liquids)	75	L/ha
Maximum application rate of active substance	0.09	kg a.s. /ha
50% Dissipation Time DT50	30	days
Initial Dislodgeable Foliar Residue	3	µg/cm2 of foliage/kg a.s. applied/ha
Dermal absorption of product	8.80%	
Dermal absorption of in-use dilution	20.00%	
Oral absorption of active substance	100.00%	
Inhalation absorption of active substance	100.00%	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <5*10-3Pa	
Scenario		
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Buffer strip	2-3	m
Number of applications	1	
Interval between multiple applications	365	days
Season (upward spraying orchards only)	not relevant	

Inputs into the online EFSA OPEX Model (version 1.1.2):

Information on product and active substance(s)

Product name	S-2399 60 g/L EC
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Product category	Other
Name of active substance	Inpyrfluxam
Concentration of active substance in product [g a.s./l or kg]	60
AOEL [mg/kg bw per day]	0.04
AAOEL [mg/kg bw]	0.2
Inhalation absorption [%]	100
Oral absorption [%]	100
Dermal absorption [%] (concentrate)	8.8
Dermal absorption [%] (dilution) 0.3 [g a.s./l or kg]	20

2. Assessed uses

Use	Crops	Max. application rate of the product [l or kg/ha]	Unit	Max. no. of applications	Interval between multiple applications [days]	Min. volume water [l/ha]	Max. volume water [l/ha]	Indoor/ outdoor	Application method	Type of cultivation	Application technique	Buffer strip [m]	Drift reduction [%]
Use 1	Field crops	1.5	l/ha	1	NA	75	300	Outdoor	Downward spraying	normal	Vehicle-mounted	2-3	0

Estimate 1: EFSA Calculator - Estimated operator exposure to inpyrfluxam for application of 'S-2399 60 g/L EC' to cereal crops via vehicle mounted boom sprayer

PPE: None

Application rate of active substance	0.09	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	4.5	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	8.80%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	20.00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	15460	57406	AOEM	
	Body	10268	111494	AOEM	
	Head	233	1281	AOEM	
	Protected hands (gloves)	92	891	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	90	658	AOEM	
	Protected head (hood and face shield)	4	72	AOEM	
	Inhalation	6	30	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	667	6896	AOEM	
	Body	373	1924	AOEM	
	Head	18	53	AOEM	
	Protected hands (gloves)	96	3972	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	10	25	AOEM	
	Inhalation	2	7	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	2.5043150	1.5360583
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0417386	0.0256010
% of RVNAS	104.35%	64.00%
Acute		
Total systemic exposure from mixing, loading and application (mg a.s./day)	16.7871078	6.6537744
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.2797851	0.1108962
% of RVAAS	139.89%	55.45%

Estimate 2: EFSA OPEX Model - Estimated operator exposure to inpyrfluxam for application of 'S-2399 60 g/L EC' to cereal crops via vehicle mounted boom sprayer

PPE: None

3.1.1. Scenario 1 : Normal, downward spraying, vehicle-mounted

3.1.1.1. Summary data - Short term exposure

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0% Crop density: Normal			
Inpyrfluxam	Application rate: 1 x 0.09 kg a.s./ha Dermal absorption (concentrate): 8.8 % Dermal absorption (in-use dilution): 20 %		
	M/L: Workwear App: Workwear	0.03	85.7

3.1.1.2. Summary data - Acute exposure

Model data	Level of PPE	Total absorbed dose [mg/kg bw]	% of systemic AAOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0% Crop density: Normal			
Inpyrfluxam	Application rate: 1 x 0.09 kg a.s./ha Dermal absorption (concentrate): 8.8 % Dermal absorption (in-use dilution): 20 %		
	M/L: Workwear App: Workwear	0.1	72.2

Estimate 3: EFSA Calculator - Estimated resident (short term) exposure to inpyrfluxam for application of 'S-2399 60 g/L EC' to cereal crops via vehicle mounted boom sprayer

Croptype	Cereals		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		*i_FormVal*
Buffer strip	2-3	m	*i_Buffer*
Application rate of the product	0.09	kg a.s./ha	*i_AppRate*
Concentration of active substance (in-use dilution for liquid applications)	1.2	g a.s./l	*d_ConcAS*
Dermal absorption of product	8.80%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	20.00%		*i_AbsorpInuse*
Oral absorption	100.00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.27	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0.001	mg/m^3	*d_AirCon*
Resident dermal spray drift exposure 75th percentile - adult	0.47	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	0.327	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0.00010	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0.00022	ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	0.22318	ml spray dilution/person	
Resident dermal spray drift exposure mean - child	0.18	ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0.00009	ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0.00017	ml spray dilution/person	
Exposure duration dermal	2	hours	*d_ReExpDur*
Exposure duration inhalation	24	hours	*d_ReExpDurInhal*
Exposure duration entry into treated crops	0.25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18.0%		*d_ClothAF*
Breathing rate adult	0.23	m^3/day/kg	*d_BreathRAd*
Breathing rate child (1-3 year old)	1.07	m^3/day/kg	*d_BreathRCh*
Drift percentage on surface (75th percentile)	5.60%		
Drift percentage on surface (mean)	4.10%		
Turf transferable residues percentage	5.00%		*d_Turf*
Transfer coeff. of surface deposits-adult	7300	cm^2/hour	*d_ReTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour	*d_ReTCCh*
Saliva extraction percentage	50.00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	9.5	events/hour	*d_ReFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20.00%		*d_DRP*
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250	cm^2/h	*d_TcEntryCh*
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h	*d_TcEntryCh*

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0646176	0.0107000	0.0033516	0.0303750	0.0730009
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0064618	0.0010700	0.0003352	0.0030375	0.0073001
% of RVNAS	16.15%	2.68%	0.84%	7.59%	18.25%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0926160	0.0138000	0.0073584	0.1012500	0.1439472
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0015436	0.0002300	0.0001226	0.0016875	0.0023991
% of RVNAS	3.86%	0.58%	0.31%	4.22%	6.00%

Estimate 4: EFSA OPEX Model - Estimated resident (short term) exposure to inpyrfluxam for application of 'S-2399 60 g/L EC' to cereal crops via vehicle mounted boom sprayer

5. Resident

5.1. Use 1 : Field crops (Outdoor)

5.1.1. Scenario 1 : Season not relevant, drift reduction 0 [%] buffer strip 2-3 [m]

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Outdoor; Season:Not relevant; Buffer zone:2-3m; Drift reduction:0%; Interval between treatments:NA; Minimum volume of water: 75 l			
Inpyrfluxam		Application rate: 1 x 0.09 kg a.s./ha Dermal absorption: 20 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.007	16.3
	Vapour (75th perc.)	1e-05	0.03
	Deposits (75th perc.)	0.0003	0.8
	Re-entry (75th perc.)	0.003	7.6
	Sum (mean)	0.006	15.6
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.002	3.9
	Vapour (75th perc.)	4e-06	0.01
	Deposits (75th perc.)	0.0001	0.3
	Re-entry (75th perc.)	0.002	4.2
	Sum (mean)	0.002	5.4

Estimate 5: EFSA Calculator - Estimated bystander (acute) exposure to inpyrfluxam for application of 'S-2399 60 g/L EC' to cereal crops via vehicle mounted boom sprayer

Croptype	Cereals		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		*i_AppEquip*
Formulation type	luble concentrates, emulsifiable concentrate, etc.		
Application rate of the product	0.09	kg a.s./ha	*i_AppRate*
Buffer strip	2-3	m	*i_Buffer*
Concentration of active substance (in-use dilution for liquid applications)	1.2	g a.s./l	*d_ConcAS*
Dermal absorption of product	8.80%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	20.00%		*i_AbsorpInuse*
Oral absorption	100.00%		*i_AbsorpOralInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.27	µg a.s./cm^2	*d_DFR*
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	*i_Volat*
Concentration in air	0.001	mg/m^3	*d_AirCon*
Bystander dermal spray drift exposure - adult	1.21	ml spray dilution/person	
Bystander dermal spray drift exposure - child	0.74	ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0.00050	ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0.00112	ml spray dilution/person	
Exposure duration	2	hours	*d_ByExpDur*
Exposure duration entry into treated crops	0.25	hours	*d_ExpDurTreatCrop*
Light clothing adjustment factor	18.0%		*d_ClothAF*
Breathing rate adult	0.23	m^3/kg bw/day	*d_BreathRAd*
Breathing rate child (1-3 year old)	1.07	m^3/kg bw/day	*d_BreathRCh*
Drift percentage on surface (90th percentile)	8.50%		
Turf transferable residues percentage	5.00%		*d_Turf*
Transfer coeff. of surface deposits-adult	14500	cm^2/hour	*d_ByTCAd*
Transfer coeff. of surface deposits-child (1-3 year old)	5200	cm^2/hour	*d_ByTCCh*
Saliva extraction percentage	50.00%		*d_SalExt*
Surface area of hands mouthed	20	cm^2	*d_AreaHM*
Frequency of hand to mouth activity	20	events/hour	*d_ByFreqHM*
Ingestion rate for mouthing of grass per day	25	cm^2	*d_MouthGrass*
Dislodgeable residues percentage transferability for object to mouth	20.00%		*d_DRP*
Transfer coefficient for entry into treated crops - a	7500	cm^2/h	*d_TcEntryAd*
Transfer coefficient for entry into treated crops - cl	2250	cm^2/h	*d_TcEntryCh*

1. Total

1.1 1-3 year old child

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.1469760	0.0107000	0.0098685	0.0303750
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0146976	0.0010700	0.0009869	0.0030375
% of RVAAS	7.35%	0.54%	0.49%	1.52%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.2387280	0.0138000	0.0221850	0.1012500
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0039788	0.0002300	0.0003698	0.0016875
% of RVAAS	1.99%	0.12%	0.18%	0.84%

Estimate 6: EFSA OPEX Model - Estimated bystander (acute) exposure to inpyrfluxam for application of 'S-2399 60 g/L EC' to cereal crops via vehicle mounted boom sprayer

6. Bystander

6.1. Use 1 : Field crops (Outdoor)

6.1.1. Scenario 1 : Outdoor, season not relevant, drift reduction 0 [%] buffer strip 2-3 [m]

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Outdoor; Season:Not relevant; Buffer zone:2-3m; Drift reduction:0%; Interval between treatments:NA; Minimum volume of water: 75 l			
Inpyrfluxam		Application rate: 1 x 0.09 kg a.s./ha Dermal absorption: 20 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days	
Bystander child Body weight: 10 kg	Drift (95th perc.)	0.01	7.4
	Vapour (95th perc.)	1e-05	0.007
	Deposits (95th perc.)	0.001	0.5
	Re-entry (95th perc.)	0.003	1.5
Bystander adult Body weight: 60 kg	Drift (95th perc.)	0.004	2
	Vapour (95th perc.)	4e-06	0.002
	Deposits (95th perc.)	0.0004	0.2
	Re-entry (95th perc.)	0.002	0.8

Estimate 7: EFSA Calculator - Estimated worker (short term) exposure to inpyrfluxam for workers undertaking inspection/irrigation activities in cereal crops that have previously been treated with 'S-2399 60 g/L EC'

PPE: Workwear (arms, body and legs covered)

Crop type	Cereals		
Indoor or outdoor	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Worker's task	Inspection, irrigation		
Main body parts in contact with foliage	Hand and body		
Application rate of active substance	0.09	kg a.s./ha	*i_AppRate*
Number of applications	1		*i_AppNo*
Interval between multiple applications	365	days	*i_AppInt*
Half-life of active substance	30	days	*d_HalflifeAS*
Multiple application factor	1.0		*d_MAF*
Dermal absorption of the product	8.80%		*i_AbsorpProduct*
Dermal absorption of the in-use dilution	20.00%		*i_AbsorpInuse*
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.27	µg a.s./cm^2	*d_DFR*
Working hours	2	hr	*d_WorkHr*
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr	*d_DermTcUCV*
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr	*d_DermTcCV1*
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr	*d_DermTcCV2*
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)	*d_InhalTcAut*
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcCut*
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)	*d_InhalTcSort*

1. Total

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	1.3500000	0.1512000	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0225000	0.0025200		
% of RVNAS	56.25%	6.30%		

Estimate 8: EFSA OPEX Model - Estimated worker (short term) exposure to inpyrfluxam for workers undertaking inspection/irrigation activities in cereal crops that have previously been treated with 'S-2399 60 g/L EC'

PPE: Workwear (arms, body and legs covered)

4. Worker

4.1. Use 1 : Field crops (Outdoor)

4.1.1. Scenario 1 : Inspection, irrigation

Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
			Inspection, irrigation; Outdoor Work rate: 2 hours/day ; Interval: NA ; Body weight: 60 kg TC (potential): 12500 cm²/h TC (workwear (arms, body and legs covered)): 1400 cm²/h TC (workwear (arms, body and legs covered) and gloves): 1250 cm²/h TC (gloves): NA cm²/h
Inpyrfluxam			Application rate: 1 x 0.09 kg a.s./ha Dermal absorption: 20 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days
Potential	0.02	56.3	0
Workwear	0.003	6.3	0
Workwear and gloves	0.002	5.6	0

B.6.7. 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 7.3/01	[redacted]	2020	Inpyrfluxam 60 g/L (V16-7) - In Vitro Absorption through Human Dermatomed Skin using [14C]-Inpyrfluxam Study number: JV2469 Dermal Technology Laboratory Ltd. Med IC4, Keele University Science and Business Park, Keele, Staffordshire, ST5 5NL, UK	N	Y	New data for a new active substance	Sumitomo Chemical Agro Europe S.A.S	No

			GLP or GEP status: GLP Unpublished					

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