



# Draft Assessment Report

## Evaluation of Active Substances

Plant Protection Products

Prepared according to **Regulation (EC) 1107/2009**  
as it applies in Great Britain

### Elemental iron

### List of Endpoints

Great Britain

October 2023

## Version History

When	What
November 2021	Initial DAR
February 2022	Updated post Expert Committee on Pesticides (ECP) Independent Scientific Advice (ISA) (November 2021 meeting)
October 2023	Updated following submission of additional information on Ecotoxicology
January 2024	Updates made after comments from the applicant

**List of end points**

Evaluator	Month and year	Active Substance
HSE	October 2023	Elemental iron

**Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis****Identity, Physical and Chemical Properties, Details of Uses, Further Information  
(Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)**

Active substance (ISO Common Name)	Elemental iron
Function ( <i>e.g.</i> fungicide)	Molluscicide
Evaluator	HSE

**Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)**

Chemical name (IUPAC)	Iron
Chemical name (CA)	Fe
Producer's development code	None
CIPAC No	No CIPAC number is allocated for elemental iron
CAS No	7439-89-6
EC No (EINECS or ELINCS)	231-096-4
FAO Specification (including year of publication)	Not currently available
Minimum purity of the active substance as manufactured	989 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Arsenic: 0.03 g/kg Mercury: 0.0001 g/kg Lead: 0.003 g/kg Cadmium: 0.001 g/kg Nickel: 0.2 g/kg
Molecular formula	Fe(0)
Molar mass	55.845 g/mol
Structural formula	-

**Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)**

Melting point (state purity)	1535°C (100%)
Boiling point (state purity)	2750°C (100%)
Temperature of decomposition (state purity)	Not determined
Appearance (state purity)	Grey lustrous powder (100%)
Vapour pressure (state temperature, state purity)	Negligible
Henry's law constant (state temperature)	N/A
Solubility in water (state temperature, state purity and pH)	Insoluble
Solubility in organic solvents (state temperature, state purity)	Insoluble
Surface tension (state concentration and temperature, state purity)	N/A
Partition coefficient (state temperature, pH and purity)	N/A
Dissociation constant (state purity)	N/A
UV/VIS absorption (max.) incl. $\epsilon$ (state purity, pH)	Not relevant since iron is insoluble
Flammability (state purity)	Not flammable (98%)
Explosive properties (state purity)	Not explosive (98%)
Oxidising properties (state purity)	Not oxidising (98%)

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Evaluator	Month and year	Active Substance
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### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

#### Summary of representative uses evaluated, for which all risk assessments needed to be completed (elemental iron) (Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

Crop and/ or situation  (a)	Region	Product name	F G or I  (b)	Pests or Group of pests controlled  (c)	Formulation		Application				Application rate per treatment			PHI (days)  (l)	Remarks:  (m)
					Type  (d-f)	Conc. of as  (i)	Method Kind  (f-h)	Growth stage & season  (j)	number min max  (k)	interval between applications (days)	kg as/hl  min max	water L/ha  min max	kg as/ha  min max		
All edible and non edible crops (outdoor & protected)	GB	Iron 1% RB	F/G/I	Molluscs	RB	10 g/kg	Spreading	When infestation appears (peak mainly in spring & autumn)	1-6	Minimum 5	Not applicable because the product is intended to be applied as a ready to use granular bait	Not applicable because the product is intended to be applied as a ready to use granular bait	0.08	Not required	Maximum Seasonal application rate 0.48 kg as/ha

## List of end points

### Evaluator

### Month and year

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HSE

October 2023

Elemental iron

## Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Crop and/ or situation  (a)	Region	Product name	F G or I  (b)	Pests or Group of pests controlled  (c)	Formulation		Application				Application rate per treatment			PHI (days)  (l)	Remarks:  (m)
					Type  (d-f)	Conc. of as  (i)	Method Kind  (f-h)	Growth stage & season  (j)	number min max  (k)	interval between applications (days)	kg as/hl  min max	water L/ha  min max	kg as/ha  min max		
Amenity Vegetation	GB	Iron 1% RB	F/G/I	Molluscs	RB	10 g/kg	Spreading	When infestation appears (peak mainly in spring & autumn)	1-6	Minimum 5	Not applicable because the product is intended to be applied as a ready to use granular bait	Not applicable because the product is intended to be applied as a ready to use granular bait	0.08	Not required	Maximum Seasonal application rate 0.48 kg as/ha

<p>(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>	<p>(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). <b>In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).</b></p> <p>(j) Growth stage 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</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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Evaluator	Month and year	Active Substance
HSE	October 2023	Elemental iron

### Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

**Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (elemental iron)**  
**Regulation (EC) N° 1107/2009 Article 8.1(g)**

**Important note: efficacy, environmental risk and risk to humans by exposure other than via their diet have not been assessed for these uses**

Crop and/or situation (a)	Member State or Country	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.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															
n/a	n/a	n/a	n /a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

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|---|---|
| <p>(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p> | <p>(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. fluoroxypr). <b>In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialdicarb-isopropyl).</b></p> <p>(j) Growth stage 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</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p> |
|---|---|

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### Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

#### Further information, Efficacy

##### Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

The representative uses/ GAPs are supported.

##### Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

The representative uses/ GAPs are supported.

##### Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

The representative uses/ GAPs are supported.

##### Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

Activity against target organism

<i>Met1</i>	<i>Met2</i>	<i>Met3</i>	<i>Met4</i>	<i>Met5</i>	<i>Met6</i>
<i>yes/no</i>	<i>yes/no</i>	<i>yes/no</i>	<i>yes/no</i>	<i>yes/no</i>	<i>yes/no</i>



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## Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

### Methods of Analysis

#### Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)	ICP-OES
Impurities in technical a.s. (analytical technique)	ICP-OES(data gap), AFS(data gap), GFAAS
Plant protection product (analytical technique)	ICP-OES (data gap)

#### Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

##### Residue definitions for monitoring purposes

Food of plant origin	Not relevant
Food of animal origin	Not relevant
Soil	Not relevant
Sediment	Not relevant
Water surface	Not relevant
drinking/ground	Not relevant
Air	Not relevant
Body fluids and tissues	Not relevant

##### Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Soil (analytical technique and LOQ)	Not required
Water (analytical technique and LOQ)	Not required
Air (analytical technique and LOQ)	Not required
Body fluids and tissues (analytical technique and LOQ)	Not required

#### Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

Substance	Iron
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### Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]<sup>1</sup>:

None

Peer review proposal <sup>2</sup> for harmonised classification according to Regulation (EC) No 1272/2008:

None

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<sup>1</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

<sup>2</sup> It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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## Section 2 Mammalian Toxicology

### Impact on Human and Animal Health

#### Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability	Oral absorption 10 % – 50 %, equivalent to bioavailability. Variable and inefficient absorption, bioavailability is based on individual iron status ( <i>human data</i> ). An estimate of 50 % oral absorption considered appropriate for the AOEL
Toxicokinetics	Tissue concentrations of iron are physiologically regulated by active absorption and transport mechanisms
Distribution	Widely distributed since iron is essential for critical cellular processes. Main storage in liver, bone marrow, spleen and endocrine pancreas
Potential for bioaccumulation	No evidence for accumulation under normal physiological conditions.
Rate and extent of excretion	No specific mechanisms. Trace amounts of iron lost via desquamation of GIT and urinary tract mucosa, epidermis, menses, sweat, hair, gastric secretions (including bile)
Metabolism in animals	No metabolites. Iron is incorporated into functional or storage proteins
<i>In vitro</i> metabolism	Not required
Toxicologically relevant compounds (animals and plants)	Iron (ionic forms)
Toxicologically relevant compounds (environment)	Iron (ionic forms)

#### Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

Rat LD <sub>50</sub> oral	> 2000 mg/kg bw (read-across from ferric phosphate)	
Rat LD <sub>50</sub> dermal	Not required	
Rat LC <sub>50</sub> inhalation	> 5.15 mg/L air /4h (nose only exposure to elemental iron)	
Skin irritation	Non-irritant (read-across from ferric phosphate)	
Eye irritation	Non-irritant (read-across from ferric phosphate)	
Skin sensitisation	No test data Not sensitising (read-across from iron sulphate). Elemental iron is authorised in the	

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## Section 2 Mammalian Toxicology

	EU as a food additive and dietary supplement)	
Phototoxicity	Not required	

## Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

Target organ / critical effect	Rat: Iron deposition in liver in rats by the oral route from 35 mg/kg bw/d Human: No critical effect identified (oral)	
Relevant oral NOAEL	Rats: 3.2 mg/kg bw/d Human: 50 mg/d (0.8 mg/kg bw/d) from chronic database on human food supplements (read-across to iron sulphate and ferric phosphate)	
Relevant dermal NOAEL	No data - not required	
Relevant inhalation NOAEL	4 –week, rat: Pulmonary inflammation, cellular proliferation, impaired particle clearance, deficits in macrophage function and macrophage aggregation. Aerosol exposure 6 h to iron carbonyl dust LOAEC 50 mg elemental iron/m <sup>3</sup> NOAEC 5 mg/m <sup>3</sup> adjusted to an 8h exposure of 3.75 mg/m <sup>3</sup> Considered not relevant to elemental iron.	

## Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

<i>In vitro</i> studies	<i>In vitro</i> Comet Assay (A549 human alveolar cell immortalised cell line) -negative No further data required ( <i>read-across to iron sulphate and ferric phosphate</i> )	
<i>In vivo</i> studies	No data – not required	
Photomutagenicity	No data – not required	
Potential for genotoxicity	No genotoxicity potential	

## Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

Long-term effects (target organ/critical effect)	Iron deposition in liver in rats by the oral route	
Relevant long-term NOAEL	50 mg/day (dietary supplement dose in humans)	
Carcinogenicity (target organ, tumour type)	Elemental iron is unlikely to pose a hazard to humans	

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<b>Evaluator</b>	<b>Month and year</b>	<b>Active Substance</b>
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**Section 2 Mammalian Toxicology**

Relevant NOAEL for carcinogenicity

Not required

**Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)****Reproduction toxicity**

Reproduction target / critical effect

No adverse effects on reproduction or fertility. Iron supplementation at 30-120 mg/person/d as recommended during pregnancy, depending on individual iron status (WHO, 2016)

Relevant parental NOAEL

Not required

Relevant reproductive NOAEL

Not required

Relevant offspring NOAEL

Not required

**Developmental toxicity**

Developmental target / critical effect

No adverse effects on development of the foetus or young

Relevant maternal NOAEL

Not required

Relevant developmental NOAEL

Not required

**Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)**

Acute neurotoxicity

Study not required

Repeated neurotoxicity

Study not required

Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)

Study not required

**Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)**

Supplementary studies on the active substance

Not required

Endocrine disrupting properties

Not an endocrine disrupter

Studies performed on metabolites or impurities

Not required

**Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)**

No adverse effects on health in manufacturing personnel, no reports of poisoning from use of elemental iron as a dietary supplement

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## Section 2 Mammalian Toxicology

### Summary<sup>3</sup> (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

	Value	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	0.80 mg/kg bw/d	Human chronic dietary supplementation dose	1
Acute Reference Dose (ARfD)	Not required	-	-
Acceptable Operator Exposure Level (AOEL)	0.40	Human chronic dietary supplementation dose	1*
Acute Acceptable Operator Exposure Level (AAOEL)	Not required	-	-

\* Correction for limited oral absorption/bioavailability (50 %).

### Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

Representative formulation (‘Final Bite’ RB)

10 % (no study data) based on physico-chemistry and physiological factors.  
Elemental iron is poorly soluble in aqueous and organic solvent. The PPP (1% w/w elemental iron) is a granular, nearly dust-free and no passive migration of solid elemental iron powder is expected to reach the systemic circulation.

### Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Operators

‘Final Bite’  
Model: EFSA Calculator (version: 30 March 2015)  
Use: Application to bare soil via broadcast tractor mounted equipment, application rate 0.08 kg a.s./ha  
Exposure estimates (model): % of AOEL  
Without PPE: 1

Use: Application to bare soil via manual application, application rate, 0.08 kg a.s./ha  
Exposure estimates (model): % of AOEL  
Without PPE: 98

Workers

‘Final Bite’  
Use: Application to bare soil, application rate 6 x 0.08 kg a.s./ha, exposure (dermal) during handling of treated soil  
EFSA Guidance:  
% of AOEL  
Without PPE: <1

<sup>3</sup> If available include also reference values for metabolites (none required for elemental iron)

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## Section 2 Mammalian Toxicology

Bystanders and residents

‘Final Bite’	
<u>Use:</u> Bare soil, tractor mounted equipment, application rate 6 x 0.08 kg a.s./ha	
Model: EFSA Calculator (version: 30 March 2015)	
<u>Child Resident (and bystander)*</u>	% AOEL
Surface Deposits	<1
<u>Adult Resident (and bystander)*</u>	
Surface Deposits	<1
* Elemental iron does not have an assigned AAOEL. Therefore, the exposure risk assessment for residents also covers bystander exposure.	

## Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance :

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]<sup>4</sup> :

Peer review proposal<sup>5</sup> for harmonised classification according to Regulation (EC) No 1272/2008:

Elemental iron
No harmonised classification
None (Human Health)

<sup>4</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

<sup>5</sup> It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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## Section 3 Residues

### Residues in or on treated products food and feed

### Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

<b>Primary crops</b> (Plant groups covered) <b>OECD Guideline 501</b>	<b>Crop groups</b>	<b>Crop(s)</b>	<b>Application(s)</b>	<b>DAT (days)</b>	
	Fruit crops	-	-	-	
	Root crops	-	-	-	
	Leafy crops	-	-	-	
	Cereals/grass crops	-	-	-	
	Pulses/Oilseeds	-	-	-	
	Miscellaneous	-	-	-	
	No data – not required				
<b>Rotational crops</b> (metabolic pattern) <b>OECD Guideline 502</b>	<b>Crop groups</b>	<b>Crop(s)</b>	<b>PBI (days)</b>	<b>Comments</b>	
	Root/tuber crops	-	-	No data – not required	
	Leafy crops	-	-		
	Cereal (small grain)	-	-		
	Other	-	-		
	Rotational crop and primary crop metabolism similar?	No data – not required			
<b>Processed commodities</b> (standard hydrolysis study) <b>OECD Guideline 507</b>	<b>Conditions</b>				
	20 min, 90°C, pH 4				
	60 min, 100°C, pH 5				
	20 min, 120°C, pH 6				
Residue pattern in processed commodities similar to residue pattern in raw commodities?	No data – not required				
Plant residue definition for monitoring (RD-Mo) <b>OECD Guidance, series on pesticides No 31</b>		Not required			
Plant residue definition for risk assessment (RD-RA)		Not required			
Conversion factor (monitoring to risk assessment)		Not required			



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### Section 3 Residues

#### Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

<b>OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish)</b>	<b>Animal</b>	<b>Dose</b> (mg/kg bw/d)	<b>Duration</b> (days)	<b>N rate/comment</b>
<b>Animals covered</b>	Laying hen	-	-	-
	Goat/Cow	-	-	-
	Pig	-	-	-
	Fish	-	-	-
	Not required			
Time needed to reach a plateau concentration in milk and eggs (days)		No data – not required		
Animal residue definition for monitoring (RD-Mo) <b>OECD Guidance, series on pesticides No 31</b>		No data – not required		
Animal residue definition for risk assessment (RD-RA)		No data – not required		
Conversion factor (monitoring to risk assessment)		No data – not required		
Metabolism in rat and ruminant similar (Yes/No)		No data – not required		
Fat soluble residues (Yes/No) <b>(FAO, 2009)</b>		No data – not required		

#### Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

<b>Confined rotational crop study</b> (Quantitative aspect) <b>OECD Guideline 502</b>	No data – not required
<b>Field rotational crop study</b> <b>OECD Guideline 504</b>	No data – not required

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## Section 3 Residues

### Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)

#### OECD Guideline 506

Plant products (Category)	Commodity	T (°C)	Stability (Month/Year)			
High water content	-	-	-			
High oil content	-	-	-			
High protein content	-	-	-			
High starch content	-	-	-			
High acid content	-	-	-			
No data – not required						
Animal	Animal commodity	T (°C)	Stability (Month/Year)			
-	Muscle	-	-			
-	Liver	-	-			
-	Kidney	-	-			
-	Milk	-	-			
-	Egg	-	-			
No data – not required						

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## Section 3 Residues

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) [OECD Guideline 509](#), [OECD Guidance, series on pesticides No 66](#) and [OECD MRL calculator](#)

Crop	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
Representative uses						
			No data – not required			
Summary of the data on formulation equivalence <a href="#">OECD Guideline 509</a>						
Crop	Region	Residue data (mg/kg)	Recommendations/comments			
			No data – not required			
Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)						
Product(s)	Region	Residue data (mg/kg)	Recommendations/comments			
			No data – not required			

(a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.

(b): Residue levels in trials conducted according to GAP reported in ascending order (*e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Monitoring** and **Risk Assessment**.

(c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR<sub>Mo</sub>).

(d): **STMR**: Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets (STMR<sub>Mo</sub>).

## List of end points

Evaluator	Month and year	Active Substance
HSE	October 2023	Elemental iron

## Section 3 Residues

### Inputs for animal burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Representative uses				
		Not calculated Not required		

## List of end points

Evaluator	Month and year	Active Substance
HSE	October 2023	Elemental iron

### Section 3 Residues

#### Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

##### OECD Guideline 505 and OECD Guidance, series on pesticides No 73

Calculations were not required

#### MRL calculations

**Highest expected intake**  
(mg/kg bw/d)  
(mg/kg DM for fish)

Intake >0.004 mg/kg bw  
Feeding study submitted

**Representative feeding level** (mg/kg bw/d, mg/kg DM for fish) and **N rates**

Muscle

Fat

Meat<sup>(b)</sup>

Liver

Kidney

Milk<sup>(a)</sup>

Eggs

Method of calculation<sup>(c)</sup>

Ruminant				Pig/Swine		Poultry		Fish	
Beef cattle		Ram/Ewe		Breeding		Broiler		Carp	
Dairy cattle		Lamb		Finishing		Layer		Trout	
						Turkey		Fish intake >0.1 mg/kg DM	
Yes/No		Yes/No		Yes/No		Yes/No		Yes/No	
Level	Beef: N Dairy: N	Level	Lamb: N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
Estimated HR <sup>(a)</sup> at 1N	MRL proposals	Estimated HR <sup>(a)</sup> at 1N	MRL proposals	Estimated HR <sup>(a)</sup> at 1N	MRL proposals	Estimated HR <sup>(a)</sup> at 1N	MRL proposals	Estimated HR <sup>(a)</sup> at 1N	MRL proposals

<sup>(a)</sup>: Estimated HR calculated at 1N level (**estimated mean level for milk**).

<sup>(b)</sup>: HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

<sup>(c)</sup>: The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

## List of end points

Evaluator	Month and year	Active Substance
HSE	October 2023	Elemental iron

## Section 3 Residues

STMR calculations were not required.

STMR calculations	Ruminant				Pig/Swine		Poultry		Fish	
Median expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle		Ram/Ewe		Breeding		Broiler		Carp	
	Dairy cattle		Lamb		Finishing		Layer		Trout	
							Turkey			
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates	Level	Beef: N Dairy: N	Level	Lamb : N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Mean level in feeding level	Estimated STMR <sup>(b)</sup> at 1N	Mean level in feeding level	Estimated STMR <sup>(b)</sup> at 1N	Mean level in feeding level	Estimated STMR <sup>(b)</sup> at 1N	Mean level in feeding level	Estimated STMR <sup>(b)</sup> at 1N	Mean level in feeding level	Estimated STMR <sup>(b)</sup> at 1N
Muscle										
Fat										
Meat <sup>(a)</sup>										
Liver										
Kidney										
Milk										
Eggs										
Method of calculation <sup>(c)</sup>										

<sup>(a)</sup>: STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

<sup>(b)</sup>: When the mean level is set at the LOQ, the STMR is set at the LOQ.

<sup>(c)</sup>: The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by interpolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

## List of end points

Evaluator	Month and year	Active Substance
HSE	October 2023	Elemental iron

## Section 3 Residues

### Conversion Factors (CF) for monitoring to risk assessment

Conversion factors are not required.

### Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

Processing factors are not required.

### Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)

**Including all uses** (representative uses and uses related to an MRL application).

#### ADI

TMDI according to EFSA PRIMo

NTMDI, according to (to be specified)

IEDI (% ADI), according to EFSA PRIMo

NEDI (% ADI), according to (to be specified)

Factors included in the calculations

#### ARfD

IESTI (% ARfD), according to EFSA PRIMo

NESTI (% ARfD), according to (to be specified)

Factors included in IESTI and NESTI

-
Not calculated – not required
Not calculated – not required
Not calculated – not required
Not calculated – not required
-
-
Not calculated – not required
Not calculated – not required
-

### Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

Not required

## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

### Section 4 Environmental fate and behaviour

#### Environmental fate and behaviour

##### Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

Mineralisation after 100 days	Not applicable, studies were not performed.
Non-extractable residues after 100 days	Not applicable, studies were not performed.
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	Not applicable, studies were not performed.

##### Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation after 100 days	Not applicable, studies were not performed.
Non-extractable residues after 100 days	Not applicable, studies were not performed.
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not applicable, studies were not performed.

##### Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not applicable, studies were not performed.
Mineralisation at study end	Not applicable, studies were not performed.
Non-extractable residues at study end	Not applicable, studies were not performed.

#### Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Not applicable, studies were not performed.							
Soil Type	OC %	Soil pH <sup>a)</sup>	K <sub>d</sub> (mL/g)	K <sub>doc</sub> (mL/g)	K <sub>F</sub> (mL/g)	K <sub>Foc</sub> (mL/g)	1/n
Geometric mean (if not pH dependent)*							
Arithmetic mean (if not pH dependent)							
pH dependence							

<sup>a)</sup> Measured in [medium to be stated, usually calcium chloride solution or water]

\* Only relevant after implementation of the published EFSA guidance.



## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

### Section 4 Environmental fate and behaviour

#### Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching

Not applicable, studies were not performed.

#### Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching

Not applicable, studies were not performed.

#### Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

Lysimeter/ field leaching studies

Not applicable, studies were not performed.

#### Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1)

Hydrolytic degradation of the active substance and metabolites > 10 %

Not applicable, studies were not performed.

Not applicable, studies were not performed.

Not applicable, studies were not performed.

#### Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %

Not applicable, studies were not performed.

Quantum yield of direct phototransformation in water at  $\Sigma > 290$  nm

Not applicable, studies were not performed.

#### 'Ready biodegradability' (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable  
(yes/no)

Not applicable, studies were not performed.

#### Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Parent	Not applicable, studies were not performed.							
System identifier (indicate fresh, estuarine or	pH water phase	pH sed <sup>a)</sup>	t. °C <sup>b)</sup>	DT <sub>50</sub> /DT <sub>90</sub> whole sys. (suspended sediment test)	St. ( $\chi^2$ )	DT <sub>50</sub> /DT <sub>90</sub> Water (pelagic test)	St. ( $\chi^2$ )	Method of calculation

## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

## Section 4 Environmental fate and behaviour

marine)				At study temp	Normalised to x °C <sup>c)</sup>		At study temp	Normalised to x °C <sup>c)</sup>		

<sup>a)</sup> Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>b)</sup> Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C

<sup>c)</sup> Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

## Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

Parent	Not applicable, studies were not performed.									
Water / sediment system	pH water phase	pH sed <sup>a)</sup>	t. °C	DT <sub>50</sub> /DT <sub>90</sub> whole sys.	St. (χ <sup>2</sup> )	DT <sub>50</sub> /DT <sub>90</sub> water	St. (χ <sup>2</sup> )	DT <sub>50</sub> /DT <sub>90</sub> sed	St. (χ <sup>2</sup> )	Method of calculation
Geometric mean at 20°C <sup>b)</sup>										

<sup>a)</sup> Measured in [medium to be stated, usually calcium chloride solution or water]

<sup>b)</sup> Normalised using a Q10 of 2.58

## Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air

Photochemical oxidative degradation in air

Volatilisation

Metabolites

Not applicable, studies were not performed.

Not applicable, studies were not performed.

No volatilisation under ambient environmental conditions from plant or soil surfaces.

## Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure

Soil: Elemental iron (Fe), ferrous iron (Fe<sup>2+</sup>), ferric iron (Fe<sup>3+</sup>)  
 Surface water: Elemental iron (Fe), ferrous iron (Fe<sup>2+</sup>), ferric iron (Fe<sup>3+</sup>)  
 Sediment: Elemental iron (Fe), ferrous iron (Fe<sup>2+</sup>), ferric iron (Fe<sup>3+</sup>)  
 Groundwater: Elemental iron (Fe), ferrous iron (Fe<sup>2+</sup>), ferric iron (Fe<sup>3+</sup>)  
 Air: N/A

## Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

## Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5)

Soil (indicate location and type of study)

N/A Elemental iron and its two oxidation states are naturally occurring compounds

Surface water (indicate location and type of study)

N/A Elemental iron and its two oxidation states are naturally occurring compounds

Groundwater (indicate location and type of study)

N/A Elemental iron and its two oxidation states are naturally occurring compounds

## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

## Section 4 Environmental fate and behaviour

Air (indicate location and type of study)

N/A Elemental iron and its two oxidation states are naturally occurring compounds

## PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent

DT<sub>50</sub> (d): No degradation considered

Method of calculation

Kinetics: N/A

Field or Lab: No studies submitted, worst case assumption for elemental metal compound

Application data

Crop: all edible and non-edible crops  
 Depth of soil layer: 5 cm (no tillage)  
 Soil bulk density: 1.5 g/cm<sup>3</sup> (default)  
 % plant interception: Pre-emergence therefore no crop interception  
 Number of applications: 1  
 Interval (d): N/A  
 Application rate(s): 80 g a.s./ha (single dose)  
 480 g a.s./ha (maximum total dose)

PEC <sub>(s)</sub> (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.107		0.640	
Short term 24h	0.107	0.107	0.640	0.640
2d	0.107	0.107	0.640	0.640
4d	0.107	0.107	0.640	0.640
Long term 7d	0.107	0.107	0.640	0.640
28d	0.107	0.107	0.640	0.640
50d	0.107	0.107	0.640	0.640
100d	0.107	0.107	0.640	0.640
Accumulation concentration	2.140 mg/kg after 20 yr	-	12.800 mg/kg after 20 yr	-
	5.350 mg/kg after 50 yr	-	32.000 mg/kg after 50 yr	-

## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

## Section 4 Environmental fate and behaviour

### PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation	<p><b>Modelling for parent in both oxidation states Fe<sup>2+</sup> and Fe<sup>3+</sup> ions.</b></p> <p>Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.</p> <p>Model(s) used: FOCUS PELMO v5.5.3, FOCUS PEARL v4.4.4 and MACRO v5.5.4</p> <p>Crop: winter cereals (surrogate)</p> <p>Crop uptake factor: 0</p> <p>Water solubility (mg/L): 10,000 at pH 7 and 20°C (Fe<sup>2+</sup>) 1x10<sup>-9</sup> (PEARL, PELMO) or 0.001 (MACRO) at pH 7 and 20°C (Fe<sup>3+</sup>)</p> <p>Vapour pressure: 0 Pa at 20°C</p> <p>Soil DT<sub>50</sub> 100,000 d (normalisation to pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).</p> <p>K<sub>oc</sub>: 10 mL/g (Fe<sup>2+</sup> -FOCUS default for weakly adsorbing compounds) 10,000 mL/g (Fe<sup>3+</sup> -FOCUS default for strongly adsorbing compounds)</p> <p><sup>1</sup>/<sub>n</sub> = 1 (Conservative default)</p>
Application rate	<p>Gross application rate: 480 g/ha.</p> <p>Crop growth stage: BBCH 0</p> <p>Crop interception: 0%</p> <p>Application rate net of interception: 480 g/ha.</p> <p>No. of applications: 1</p> <p>Time of application: Spring: 15<sup>th</sup> March Summer: 15<sup>th</sup> June Autumn: 15<sup>th</sup> October Winter: 15<sup>th</sup> January</p>

### PEC(gw) - FOCUS modelling results (80<sup>th</sup> percentile annual average concentration at 1m)

PELMO /winter cereals	Scenario	Parent Fe <sup>2+</sup> (µg/L)			
		Spring	Summer	Autumn	Winter
	Châteaudun	520.326	508.366	512.635	536.115
	Hamburg	245.317	239.114	231.502	237.861
	Kremsmünster	204.759	195.661	195.199	203.839
	Okehampton	148.328	132.794	138.887	143.030

PEC<sub>GW</sub> values should not be relied upon in the risk assessment and are for reference only.

## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

### Section 4 Environmental fate and behaviour

PEARL /winter cereals	Scenario	Parent Fe <sup>2+</sup> (µg/L)			
		Spring	Summer	Autumn	Winter
	Châteaudun	497.831	504.756	475.996	496.735
	Hamburg	283.139	283.906	276.153	266.004
	Kremsmünster	162.317	155.820	165.222	165.577
	Okehampton	148.235	136.011	133.512	141.808

PEC<sub>GW</sub> values should not be relied upon in the risk assessment and are for reference only.

PELMO /winter cereals	Scenario	Parent Fe <sup>3+</sup> (µg/L)			
		Spring	Summer	Autumn	Winter
	Châteaudun	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001

PEC<sub>GW</sub> values should not be relied upon in the risk assessment and are for reference only.

PEARL /winter cereals	Scenario	Parent Fe <sup>3+</sup> (µg/L)			
		Spring	Summer	Autumn	Winter
	Châteaudun	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001

PEC<sub>GW</sub> values should not be relied upon in the risk assessment and are for reference only.

MACRO /winter cereals	Scenario	Parent Fe <sup>2+</sup> (µg/L)			
		Spring	Summer	Autumn	Winter
	Châteaudun	567.000	536.000	541.000	557.000

PEC<sub>GW</sub> values should not be relied upon in the risk assessment and are for reference only.

MACRO /winter cereals	Scenario	Parent Fe <sup>3+</sup> (µg/L)			
		Spring	Summer	Autumn	Winter
	Châteaudun	<0.001	<0.001	<0.001	<0.001

PEC<sub>GW</sub> values should not be relied upon in the risk assessment and are for reference only.

### PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

Parent

Parameters used in EXCEL calculator

Application rate

UK First tier PEC sw-sed (drainflow) EXCEL calculator v.1

K<sub>OC</sub>: 10 mL/g (Fe<sup>2+</sup> -FOCUS default for weakly adsorbing compounds)

10,000 mL/g (Fe<sup>3+</sup> -FOCUS default for strongly adsorbing compounds)

Fraction in sediment: 1 (conservative default)

Number of applications: 1

Interval (d): N/A

Application rate(s): 480 g a.s./ha (Maximum total dose)

Crop interception (%): 0

## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

## Section 4 Environmental fate and behaviour

### PEC surface water and PEC sediment results (UK first tier- drainflow)

Compartment	Fe <sup>2+</sup>	Fe <sup>3+</sup>
PEC <sub>SW</sub> (µg/L)	70.154	0.295
PEC <sub>SED</sub> (µg/Kg)	323.787	1.363

PEC<sub>SW</sub> and PEC<sub>SED</sub> values should not be relied upon in the risk assessment and are for reference only.

### Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation

Other routes of exposure not investigated. Not considered necessary.

#### PEC

Maximum concentration

N/A

## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

## Section 5 Ecotoxicology

### Ecotoxicology

**Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)**

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
<i>Coturnix japonica</i> (Japanese Quail)	Slug and Snail Killer (1 % Iron)	Acute	LD <sub>50</sub>	<b>3776 mg/kg bw (37 mg a.s./kg bw)*</b>
Broiler Chicken	Iron (derived from lowest concentration in commercial diet)	Long-term	NOAEL	<b>5 mg a.s./kg bw/d</b>
Mammals				
Rat	Carbonyl Iron	Acute	LD <sub>50</sub>	<b>&gt;50000 mg a.s./kg bw</b>
Rat	Carbonyl Iron	Long-term [for screening step]	NOAEL	<b>3.2 mg a.s./kg bw/d</b>
Rat	Carbonyl Iron	Long-term [for screening step]	NOAEL	200 mg a.s./kg bw/d
Endocrine disrupting properties (Annex Part A, points 8.1.5): <i>No data submitted</i>				
Additional higher tier studies (Annex Part A, points 10.1.1.2): <i>No data submitted (risk assessment based on weight of evidence using literature data)</i>				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): <i>No data submitted</i>				

\*Extrapolated endpoint (originally >2000 mg product/kg bw)

**Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)**

**[Representative use] at [application rate] g a.s./ha [x number of applications]**

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All		Acute			10
All		Long term			5
Tier 1 (Birds)					
Higher tier (birds): [in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)]					

## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

## Section 5 Ecotoxicology

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
<b>Screening Step (Mammals)</b>					
All		Acute			10
All		Long term			5
<b>Tier 1 (Mammals)</b>					
<b>Higher tier (Mammals): [in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)]</b>					
<b>Risk from bioaccumulation and food chain behaviour</b> [indicate when not relevant i.e. if Log K <sub>ow</sub> ≤ 3]					
Indicator or focal species		Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm eating birds		Long term			5
Earthworm eating mammals		Long term			5
Fish eating birds		Long term			5
Fish eating mammals		Long term			5
<b>Higher tier : [in higher tier refinement provide brief details of any refinements used]</b>					
<b>Risk from consumption of contaminated water</b>					
<b>Scenarios</b>	<b>Indicator or focal species</b>	<b>Time scale</b>	<b>PEC<sub>dw</sub> × DWR</b>	<b>TER</b>	<b>Trigger</b>
Leaf scenario	Birds	acute			5
<b>Puddle scenario, Screening step</b>					
1) Application rate (g a.s./ha)/relevant endpoint <50 (K <sub>oc</sub> <500 L/kg), TER calculation not needed					
2) Application rate (g a.s./ha)/relevant endpoint <3000 (K <sub>oc</sub> ≥500 L/kg), TER calculation not needed					
Puddle scenario	Birds	acute			10
Puddle scenario	Mammals	acute			10
Puddle scenario	Birds	Long term			5
Puddle scenario	Mammals	Long term			5

## Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)\*

\* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup>
Laboratory tests				
Fish				
No data submitted				



## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

## Section 5 Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity <sup>1</sup>
Aquatic invertebrates				
<i>D. magna</i>	Final Bite (1 % iron)	48 h (static)	Mortality, EC <sub>50</sub>	>0.5345 mg a.s./L (mm)
Sediment-dwelling organisms				
<i>No data submitted</i>				
Algae				
<i>D. subspicatus</i>	Final Bite (1 % iron)	72 h (static, or semi-static or flow-through)	Growth rate: E <sub>r</sub> C <sub>50</sub> (NOEC)	>0.529 mg a.s./L (mm) (0.529 mg a.s./L (mm))
Higher plant				
<i>No data submitted</i>				
Further testing on aquatic organisms				
<i>No data submitted</i>				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3)				
<i>No data submitted</i>				

<sup>1</sup> (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; a.s.: active substance

## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

## Section 5 Ecotoxicology

### Bioconcentration in fish (Annex Part A, point 8.2.2.3)

*No data submitted.*

## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

## Section 5 Ecotoxicology

**Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)**

**FOCUS<sub>sw</sub> step 1-3 – TERs for [active substance] – [representative use] at [application rate] g a.s./ha [x number of applications]**

Scenario	PEC global max (µg/L)	fish-acute	fish-chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged	Microcosm/ Mesocosm
		<i>Indicate species</i>	<i>Indicate species</i>	<i>Indicate species</i>	<i>Indicate species</i>	<i>Indicate species</i>	<i>Indicate species</i>	<i>Indicate species</i>	
		LC <sub>50</sub>	NOEC	EC <sub>50</sub>	NOEC	EC <sub>50</sub>	EC <sub>50</sub>	NOEC	NOEC
		x.xx µg/L	x.xx µg/L	x.xx µg/L	x.xx µg/L	x.xx µg/L	x.xx µg/L	x.xx µg/L	x.xx µg/L
<b>FOCUS Step 1</b>									
<b>FOCUS Step 2</b>									
North Europe									
South Europe									
<b>FOCUS Step 3*</b>									
D3 / ditch									
D4 / pond									
D4 / stream									
D5 / pond									
D5 / stream									
R1 / pond									
R1 / stream									
R2 / stream									
R3 / stream									
R4 / stream									
Trigger**		100	10	100	10	10	10	10	

\*[Only scenarios where the trigger is not met at FOCUS<sub>sw</sub> step 1-2 should be included in step 3.]

\*\*[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

## Section 5 Ecotoxicology

### FOCUS<sub>sw</sub> step 4 – TERs [active substance] – [representative use] at [application rate] g a.s./ha [x number of applications]

[Fate experts should also be asked to review this table to check if it is in line with their assessments]

**Organisms** *Indicate species:*

**Toxicity endpoint:** x.xx µg/L

Mitigation options	[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)	[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)	PEC <sub>sw</sub> (x.xx µg/L)	TER	Trigger
<b>FOCUS Step 4*</b>					
D3 / ditch					
D4 / pond					
D4 / stream					
D5 / pond					
D5 / stream					
R1 / pond					
R1 / stream					
R2 / stream					
R3 / stream					
R4 / stream					

\*[Only scenarios where the trigger is not met at FOCUS<sub>sw</sub> step 3 should be included in step 4].

## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

## Appendix

### Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)\*

\* This section does reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

Species	Test substance	Time scale/type of endpoint	End point	toxicity
<i>No data submitted</i>				

Potential for accumulative toxicity: <i>No</i>
Semi-field test (Cage and tunnel test) <i>No data submitted</i>
Field tests <i>No data submitted</i>

### Risk assessment for – Final Bite ( 1% iron) at 8 kg product/ha [x 6]

Risk to bees considered acceptable due to negligible exposure.

### Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

#### Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity
<i>No data submitted</i>			
Additional species			
<i>A. bilineata</i>	Final Bite (1 % iron); intact pellet	Reproduction, ER <sub>50</sub>	>737 pellets/m <sup>2</sup>
<i>P. cupreus</i>	Final Bite (1 % iron); intact pellet	Mortality, LR <sub>50</sub>	>743 pellets/m <sup>2</sup>
		Reproduction, ER <sub>50</sub>	>743 pellets/m <sup>2</sup>
<i>Pardosa</i> sp.	Final Bite (1 % iron); intact pellet	Mortality, LR <sub>50</sub>	>722 pellets/m <sup>2</sup>
		Reproduction, ER <sub>50</sub>	>722 pellets/m <sup>2</sup>

### First tier risk assessment for – Final Bite ( 1% iron) at 8 kg product/ha [x 6]

Test substance	Species	Effect (LR <sub>50</sub> g/ha)	HQ in field	HQ off field <sup>†</sup>	Trigger
	<i>Typhlodromus pyri</i>				2
	<i>Aphidius rhopalosiphii</i>				2

## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

## Appendix

<sup>†</sup>indicate distance assumed to calculate the drift rate

## Extended laboratory tests, aged residue tests

Species	Toxicity Endpoint	Exposure (pellets/m <sup>2</sup> )	Risk acceptable?
<i>Aleochara bilineata</i>	ER <sub>50</sub> > 737 pellets/m <sup>2</sup>	60*	Yes
		360**	Yes
<i>Poecilus cupreus</i>	L/ER <sub>50</sub> > 743 pellets m <sup>2</sup>	60	Yes
		360*	Yes
<i>Pardosa</i> sp.	L/ER <sub>50</sub> > 722 pellets m <sup>2</sup>	60	Yes
		360*	Yes

\*Single application rate expressed in terms of pellets/m<sup>2</sup> (equivalent to 8 kg product/ha)

\*\*Worst case accumulated pellets/m<sup>2</sup> following 6 applications as per requested GAP

Semi-field tests
<i>No data submitted</i>
Field studies
<i>No data submitted</i>
Additional specific test
<i>No data submitted</i>

## Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance	Application method of test a.s./ OM <sup>1</sup>	Time scale	End point	Toxicity
Earthworms					
<i>E. fetida</i>	Final Bite (1 % iron)	Granules ground up and mixed homogenously into soil	Chronic (56 d)	Reproduction	NOEC = 100 mg product/kg d.w.soil
<i>E. andrei</i>	Final Bite (1 % iron)	Granules applied on to soil surface	Chronic (56 d)	Reproduction	EC <sub>20</sub> = 460 pellets/m <sup>2</sup>
Other soil macroorganisms					
<i>Folsomia candida</i>	Final Bite (1 % iron)	Granules ground up mixed homogenously into soil	Chronic (28 d)	Reproduction	EC <sub>10</sub> = 1154.8 mg product/kg d.w. soil

## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

## Appendix

Test organism	Test substance	Application method of test a.s./ OM <sup>1</sup>	Time scale	End point	Toxicity
<i>Hypoaspis aculeifer</i>	Final Bite (1 % iron)	Granules ground up and mixed homogenously into soil	Chronic (14 d)	Reproduction	NOEC = 3103 mg product/kg d.w. soil

Higher tier testing (e.g. modelling or field studies):

Earthworm Field Study submitted (Axmann, 2019): No effects detected at 6 x 8 kg Final Bite/ha

(study not considered representative of wet conditions in colder season, number of earthworms too low to detect effects of test item at certain sampling points, reference item used was a spray so uncertain if it can show sensitivity of system to granular products).

Nitrogen transformation	Slug and Snail Killer (1 % iron)	28 days	-6.5 % effect at day 28 at 333.5 mg product/kg d.w.soil
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## Toxicity/exposure ratios for soil organisms

Final Bite ( 1% iron) at 8 kg product/ha [x 6]

Organism	Species	Toxicity endpoint	Exposure estimate	Endpoint	TER <sub>LT</sub>	Trigger value
Earthworm	<i>Eisenia fetida</i>	NOEC <sub>repro</sub> <sup>1)</sup>	64 mg product/kg	100 mg product/kg	<b>1.56</b>	5
Earthworm	<i>Eisenia fetida</i>	Reproduction EC <sub>20</sub> <sup>2)</sup>	156* pellets/m <sup>2</sup>	460 pellets/m <sup>2</sup>	<b>2.94</b>	5
Collembola	<i>Folsomia candida</i>	EC <sub>10 repro</sub>	64 mg product/kg	1154.8 mg product/kg dw soil	18.04	5
Predatory mites	<i>Hypoaspis aculeifer</i>	NOEC <sub>reproduction</sub>	64 mg product/kg	3103 mg product/kg dw soil	48.48	5

<sup>1)</sup> NOEC<sub>repro</sub> derived from Pavić B. 2018a

<sup>2)</sup> Reproduction EC<sub>20</sub> derived from Pavić B. 2018b

\*156 pellets m<sup>2</sup> worst case accumulated number of pellets in Axmann (2019).

## Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

### Screening data

Not required for herbicides or plant growth regulators as ER<sub>50</sub> tests should be provided

Laboratory dose response tests

## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

## Appendix

Species	Test substance	ER <sub>50</sub> (g/ha) <sup>2</sup> vegetative vigour	ER <sub>50</sub> (g/ha) <sup>2</sup> emergence	Exposure <sup>1</sup> (g/ha) <sup>2</sup>	TER	Trigger
<i>No data submitted</i>						
Extended laboratory studies : <i>No data submitted</i> Semi-field and field test: <i>No data submitted</i>						

<sup>1</sup> explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)

<sup>2</sup> for preparations indicate whether dose is expressed in units of a.s. or preparation

## Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	end point
Activated sludge	<i>No data submitted</i>

## Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

<i>No data submitted</i>
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## Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds<sup>1</sup>

Compartment	
soil	Parent (iron)
water	
sediment	
groundwater	

<sup>1</sup> metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent



## List of end points

Evaluator	Month and year	Active substance
HSE	October 2023	Elemental iron

## Appendix

### Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance	Elemental iron
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] <sup>6</sup> :	-
Peer review proposal <sup>7</sup> for harmonised classification according to Regulation (EC) No 1272/2008:	-

<sup>6</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

<sup>7</sup> It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

