European Commission

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

Blood meal

List of End Points

Rapporteur Member State: Austria
Co-Rapporteur Member State: Lithuania

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)	Blood meal
Function (*e.g.* fungicide)	Game repellent

Rapporteur Member State	Austria
Co-rapporteur Member State	Lithuania

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

Chemical name (IUPAC)	Not applicable.
Chemical name (CA)	Not applicable.
CIPAC No	909
CAS No	90989-74-5
EC No (EINECS or ELINCS)	292-731-9
FAO Specification (including year of publication)	No FAO specification exists.
Minimum purity of the active substance as manufactured	≥ 990 g/kg (haemoglobin) The following quality criteria are applied: - Food grade quality blood collected in authorised slaughterhouses; - Destruction of pathogens and protein denaturation occur during blood processing; - Blood of porcine origin. Blood meal is an animal by-product from category 3. It shall comply with: - Regulation (EC) No 1069/2009, - Commission Regulation (EU) No 142/2011 *- Regulation (EC) No 853/2004*

Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	The following quality criteria are applied: - Food grade quality blood collected in authorised slaughterhouses, - Destruction of pathogens and protein denaturation occur during blood processing - Blood of porcine origin. Commission Regulation 142/2011, implementing Regulation 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive, lays down provisions regarding to the quality criteria of such material for use in feed material or in organic fertilizers and soil improvers (rules for process, microbiologic requirements, …). Regulation 853/2004 lays down specific hygiene rules for food of animal origin too. None.
Molecular formula	Not applicable.
Molar mass	Not applicable.
Structural formula	Not applicable.

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

Melting point (state purity)	Not relevant Blood meal is a well-known widely traded commodity, used as food additive, organic fertilizer ect.
Boiling point (state purity)	Not relevant (see melting point).
Temperature of decomposition (state purity)	Not relevant (see melting point).
Appearance (state purity)	red brownish powder with vaguely fish like smell.
Vapour pressure (state temperature, state purity)	Not relevant (see melting point).
Henry's law constant (state temperature)	Not relevant (see melting point).
Solubility in water (state temperature, state purity and pH)	50 -1000 mg /L at 20°C (pH) (5) the concentration of the test item lay in the range 23.1 – 729.1 mg/L water p.A. resp. 12.0- 684.9 mg/L
Solubility in organic solvents (state temperature, state purity)	Not relevant (see melting point).
Surface tension (state concentration and temperature, state purity)	Not relevant (see melting point).
Partition coefficient (state temperature, pH and purity)	Not relevant (see melting point).
Dissociation constant (state purity)	Not relevant (see melting point).
UV/VIS absorption (max.) incl. ε (state purity, pH)	Not relevant (see melting point).
Flammability (state purity)	Not considered as highly flammable, not considered as auto-flammable.
Explosive properties (state purity)	Not relevant (see melting point).
Oxidising properties (state purity)	Not relevant (see melting point).

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

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)		
Deciduous and coniferous trees in forestry 3FORC	Central North	Certosan	F	Game repellent 1CERVF (CERVEL, DAMADA, CAPRCA, ALCSAL); 1LEPUF (LEPUSP, ORYTCU)	WP	99,8 %	Coating with brush, Spraying or dipping individual plants, entire plants	all season	1	-	4.99	80-400	a) 19.8 b) 19.8	na	
Trees in orchards 3FRUC	Central North	Certosan	F	Game repellent 1CERVF (CERVEL, DAMADA, CAPRCA, ALCSAL); 1LEPUF (LEPUSP, ORYTCU)	WP	99,8 %	Coating with brush, Spraying or dipping individual plants, entire plants	all season	1	-	4.99	80-400	a) 19.8 b) 19.8	na	
Ornamental plants 3ORTC	Central North	Certosan	F	Game repellent 1CERVF (CERVEL, DAMADA, CAPRCA); 1LEPUF (LEPUSP, ORYTCU)	WP	99,8 %	Coating with brush, Spraying or dipping individual plants, entire plants	all season	1	-	4.99	80-400	a) 19.8 b) 19.8	na	
Deciduous and coniferous trees in forestry 3FORC Agriculture and garden 3FRUC, 3ORTC	North	Certosan	F	Game repellent 1CERVF (CERVEL, DAMADA, CAPRCA); 1LEPUF (LEPUSP, ORYTCU)	WP	99,8 %	Coating with brush or dipping individual plants; entire plants	all season	1	-	4.99	5-15	a) 19.96 b) 19.96	na	
Deciduous and	North	Certosan	F	Vole repellent MICRAR	WP	99,8 %	Coating with brush or	all season	1	-	4.99	5-15	a) 19.96 b) 19.96	na	

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)		
coniferous trees in forestry 3FORC Agriculture and garden3FRUC, 3ORTC							dipping individual plants; entire plants								
Deciduous and coniferous trees in forestry 3FORC Agriculture and garden 3FRUC, 3ORTC	North	Certosan	F	Vole repellent MICRAR	WP	99,8 %	Spraying individual plants; entire plants	all season	1	-	4.99	5-15	a) 19.96 b) 19.96	na	

(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)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth 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
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

A GAP table in the current format is provided in part B (CP) 3.

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 (*name of active substance or the respective variant*)
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)															

(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)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth 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
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Further information, Efficacy

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

	Representative uses are already authorized on national level and have been evaluated according to uniform principles. Uses as game repellent in forestry: Certosan at the max. dose of 20 kg/ha achieved 78-91 % control against damage caused by game species (1CERVF, 1LEPUF). Uses as game repellent in orchards (fruit trees) and ornamentals: A limited set of data is available for uses in fruit trees, and ornamentals, and no data are available for MICRAR.

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

	Uses in forestry: No signs of phytotoxicity were visible on forest trees. A negative effect on the yield of forest trees is not expected, and processing is not relevant. Certosan seems to be safe to forest plants. Uses in orchards (fruit trees) and ornamentals: A limited set of crop safety data is available for uses in fruit trees, and in ornamentals. A negative impact on the quality of yield of fruit trees, and so on processing cannot be excluded. Also quality of ornamentals may be negatively affected. All uses: A negative impact on yield is unlikely.

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

	Due to the selectivity of Certosan, any negative impact on adjacent crops and on propagation is unlikely. Negative effects on succeeding crops are not expected, since blood meal can also be used as a fertilizer.

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

Activity against target organism	no data submitted, not required.

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)	The active substance will be analysed as iron content (ICP-OES).
Impurities in technical a.s. (analytical technique)	Not applicable
Plant protection product (analytical technique)	The active ingredient and the formulated product is identical.

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 required (no residue definition) According to the intended uses Blood meal is used as a repellent which is applied onto trees or part of trees. Since coating of trees is the only use of Blood meal no crops are treated directly and therefore no residues on food and/or feed may occur. Blood meal is used as fertiliser in organic farming in much higher amounts.
Food of animal origin		Not required (no residue definition, see above).
Soil		Not required (blood meal is a natural non-toxic compound, no residue definition, see above).
Sediment		Not required (blood meal is a natural non-toxic compound, no residue definition, see above).
Water	surface	ICP-OES-Method
	drinking/ground	ICP-OES-Method
Air		Not required (blood meal is a natural non-toxic compound, no residue definition, see above).
Body fluids and tissues		Not required (blood meal is a natural non-toxic compound, no residue definition, see above).

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	No residue definition. According to the intended uses Blood meal is used as a repellent which is applied onto trees or part of trees. Since coating of trees is the only use of Blood meal no crops are treated directly and therefore no residues on food and/or feed may occur. Blood meal is used as fertiliser in organic farming in much higher amounts.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not relevant. See statement above.
Soil (analytical technique and LOQ)	Not relevant. See statement above.
Water (analytical technique and LOQ)	1 µg/L is the LOQ of Iron
Air (analytical technique and LOQ)	Not relevant. See statement above.
Body fluids and tissues (analytical technique and LOQ)	Not relevant. See statement above.

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

Substance	Blood meal
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][1]:	Blood meal will not be classified from physical/chemical point of view.
Peer review proposal [2] for harmonised classification according to Regulation (EC) No 1272/2008:	No classification

[1] 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.

[2] 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.

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	No data - not required
Toxicokinetics	No data - not required
Distribution	No data - not required
Potential for bioaccumulation	No data - not required
Rate and extent of excretion	No data - not required
Metabolism in animals	No data - not required
In vitro metabolism	No data - not required
Toxicologically relevant compounds (animals and plants)	No data - not required
Toxicologically relevant compounds (environment)	No data - not required

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

Rat LD_{50} oral	No data - not required	
Rat LD_{50} dermal	No data - not required	
Rat LC_{50} inhalation	No data - not required	
Skin irritation	No data - not required	
Eye irritation	No data - not required	
Skin sensitisation	No data - not required	
Phototoxicity	No data - not required	

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

Target organ / critical effect	No data - not required	(*mention proposed classif*)
Relevant oral NOAEL	No data - not required	
Relevant dermal NOAEL	No data - not required	
Relevant inhalation NOAEL	No data - not required	

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

In vitro studies	No data - not required	
In vivo studies	No data - not required	

Photomutagenicity	No data - not required	
Potential for genotoxicity	No data - not required	(*mention proposed classif*)

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

Long-term effects (target organ/critical effect)	No data - not required	
Relevant long-term NOAEL	No data - not required	
Carcinogenicity (target organ, tumour type)	No data - not required	
Relevant NOAEL for carcinogenicity	No data - not required	

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

Reproduction toxicity

Reproduction target / critical effect	No data - not required	(*mention proposed classif*)
Relevant parental NOAEL	No data - not required	
Relevant reproductive NOAEL	No data - not required	
Relevant offspring NOAEL	No data - not required	

Developmental toxicity

Developmental target / critical effect	No data - not required	(*mention proposed classif*)
Relevant maternal NOAEL	No data - not required	
Relevant developmental NOAEL	No data - not required	

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

Acute neurotoxicity	No data - not required	(*mention proposed classif*)
Repeated neurotoxicity	No data - not required	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	No data - not required	

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

Supplementary studies on the active substance	Determination of the storage stability of Blood Meal (Certosan) at room temperature (duration two years); determination of human pathogenic germs (all below LOQ);

Endocrine disrupting properties	No data - not required
Studies performed on metabolites or impurities	No data - not required

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

No data - not required

Summary[3] (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	Not required*	-	-
Acute Reference Dose (ARfD)	Not required*	-	-
Acceptable Operator Exposure Level (AOEL)	Not required*	-	-
Acute Acceptable Operator Exposure Level (AAOEL)	Not required*	-	-

* The setting of reference values was not deemed necessary, as the substance does not present a toxicological concern. Blood meal is food-grade and exposure already exists, as blood is consumed as food in different forms in many cultures.

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

Representative formulation : Certosan	No data, not necessary

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

Operators	No exposure assessment was deemed necessary, as the substance does not present a toxicological concern.
Workers	No exposure assessment was deemed necessary, as the substance does not present a toxicological concern.
Bystanders and residents	No exposure assessment was deemed necessary, as the substance does not present a toxicological concern.

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

Substance :	Blood meal
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][4] :	No current harmonised classification.

[3] If available include also reference values for metabolites

[4] 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.

Peer review proposal [5] for harmonised classification according to Regulation (EC) No 1272/2008:	No classification required.

[5] 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.

Residues in or on treated products food and feed

Metabolism studies, methods of analysis and residue definitions in plants

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling** (DAT)	**Comment/Source**
	Fruit crops				Radiolabelled active substance: phenyl-UL-^{14}C-a.s.:
	Root crops				
	Leafy crops				
	Cereals/grass				
	Pulses/oilseeds				
	Miscellaneous				
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI** (DAT)	**Comment/Source**
	Root/tuber crops				
	Leafy crops				
	Cereal (small grain)				
	other				
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		yes/no/inconclusive/not triggered		
	Baking, brewing and boiling (60 min, 100°C, pH 5)		yes/no/inconclusive/not triggered		

	Sterilisation (20 min, 120°C, pH 6)	yes/no/inconclusive/not triggered	
	Other processing conditions		

Can a general residue definition be proposed for primary crops?	yes/no/inconclusive	comment
Rotational crop and primary crop metabolism similar?	yes/no/inconclusive/not applicable	comment
Residue pattern in processed commodities similar to residue pattern in raw commodities?	yes/no/inconclusive/not applicable	comment
Plant residue definition for monitoring (RD-Mo)	<RD> (tentative) [metabolism group]: <RD> [metabolism group 1]: <RD> [metabolism group 2]: <RD> [processed commodities]: <RD> [honey and bee products]: <RD>	
Plant residue definition for risk assessment (RD-RA)	<RD> (tentative) [metabolism group]: <RD> [metabolism group 1]: <RD> [metabolism group 2]: <RD> [rotational crops]: <RD> [processed commodities]: <RD> [honey and bee products]: <RD>	
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	Matrices with high water content, high oil content, high acid content and dry matrices: GC-ECD, LOQ 0.02 mg/kg Confirmatory method available/missing for xxxx. ILV available/missing for xxx. (Reference)	

Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T** (°C)	**Stability period**		**Compounds covered**	**Comment/Source**
				Value	**Unit**		
	High water content						
	High oil content						
	High protein content						
	High starch content						
	High acid content						
	Processed products						
	Others						

Magnitude of residues in plants

Summary of residues data from the supervised residue trials – Primary crops

Commodity	**Region/ Indoor** [(a)]	**Residue levels observed in the supervised residue trials** (mg/kg)	**Comments/Source**	**Calculated MRL** (mg/kg)	**HR** [(b)] (mg/kg)	**STMR** [(c)] (mg/kg)	**CF** [(d)]
Representative uses							
	NEU	**Mo: -** **RA:** -	Residue trials on <crop> compliant with GAP. Extrapolation to <crop> possible.		**Mo: -** **RA:** -	**Mo: -** **RA:** -	

Commodity	**Region/ Indoor** (a)	**Residue levels observed in the supervised residue trials** (mg/kg)	**Comments/Source**	**Calculated MRL** (mg/kg)	**HR** (b) (mg/kg)	**STMR** (c) (mg/kg)	**CF** (d)
Intended uses in MRL application							
	NEU	**Mo: -** **RA:** -	Residue trials on <crop> compliant with GAP. Reduced number of trials is sufficient since, also considering metabolism studie(s), a zero residue situation is expected.				
	NEU	**Mo: -** **RA:** -					
Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)							
	NEU	**Mo: -** **RA:** -					

* Indicates that the MRL is proposed at the limit of quantification.

Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

Residues in rotational crops

Overall summary

Residues in rotational and succeeding crops expected based on confined rotational crop study?	yes/no/inconclusive/not triggered	comment
Residues in rotational and succeeding crops expected based on field rotational crop study?	yes/no/inconclusive/not triggered	Comment/source

Summary of residues data from the rotational crops residue trials (if relevant, e.g. MRL, STMR, HR derived from rotational crops)

Commodity	**Region/ Indoor** (a)	**PBI (days)** (b)	**Residue levels observed in the supervised residue trials** (mg/kg)	**Comments/Source**	**Calculated MRL** (mg/kg)	**HR** (c) (mg/kg)	**STMR**(d) (mg/kg)	**CF** (e)
	NEU	30	**Mo: -** **RA:** -	Rotational crops field trials conducted at a dose rate of application covering the max PECsoil for parent (or metabolite).		**Mo: -** **RA:** -	**Mo: -** **RA:** -	
		120						
		365						
	SEU	30						
		120						
		365						

* Indicates that the MRL is proposed at the limit of quantification.

Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Country code: if non-EU trials.

(b): Plant-back interval: The interval (days, months, years) between the final application of a pesticide product to a primary crop and the planting of a rotational crop.

(c): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(d): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(e): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

Processing factors

Processed commodity	**Number of valid studies**[(a)]	**Processing Factor** (PF)		**CF_P**[(b)]	**Comment/ Source**
		Individual values	Median PF		
Apples, juice					Tentative[(c)]

PF: Processing factor (=Residue level in processed commodity expressed according to RD-Mo/ Residue level in raw commodity expressed according to RD-Mo);
CF_p: Conversion factor for risk assessment in processed commodity (=Residue level in processed commodity expressed according to RD-RA / Residue level in processed commodity expressed according to RD-Mo)
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur)
(b): Median of the individual conversion factors for each processing residues trial.
(c): A tentative PF is derived based on a limited dataset.

Residues in livestock

Not relevant or

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup (a)	Most critical commodity (b)	Trigger exceeded (Y/N)	Comments
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Cattle (all)								
Cattle (dairy only)								
Sheep (all)								
Sheep (ewe only)								
Swine (all)								
Poultry (all)								
Poultry (layer only)								
Fish			N/A					

(a): When one group of livestock includes several subgroups (e.g. poultry "all" including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as "mg/kg bw per day".
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

Nature of residues and methods of analysis in livestock

Metabolism studies, methods of analysis and residue definitions in livestock

Livestock (available studies)	**Animal**	**Dose** (mg/kg bw/d)	**Duration** (days)	**Comment/Source**
	Laying hen			
	Lactating ruminants			e.g. Goat, cow, sheep
	Pig			
	Fish			

Time needed to reach a plateau concentration in milk and eggs (days)	Milk:	Comment
	Eggs:	Comment
Metabolism in rat and ruminant similar	yes/no/inconclusive/not triggered	Comment
Can a general residue definition be proposed for animals?	yes/no/inconclusive/not triggered	Comment
Animal residue definition for monitoring (RD-Mo)	<RD> (tentative) [metabolism group 1/tissue]: <RD> [metabolism group 2/tissue]: <RD>	
Animal residue definition for risk assessment (RD-RA)	<RD> (tentative) [metabolism group 1/tissue]: <RD> [metabolism group 2/tissue]: <RD>	
Fat soluble residues	Yes/No	Comment
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	Milk, Eggs,	

Muscle, Fat, Liver Kidney: HPLC-MS/MS , LOQ 0.02 mg/kg. Confirmatory method available/missing for xxxx. ILV available/missing for xxx (Reference)

Stability of residues in livestock

Animal products (available studies)	**Animal**	**Commodity**	**T** (°C)	**Stability period**		**Compounds covered**	**Comment/ Source**
				Value	**Unit**		
		Muscle				Parent	
		Muscle				Metabolite XX	
		Fat					
		Liver				Sum of parent and metabolite X	
		Kidney					
		Milk					
		Eggs					

Magnitude of residues in livestock

Summary of the residue data from livestock feeding studies

Animal commodity	Residues at the closest feeding level (mg/kg)		Estimated value at 1N		MRL proposal (mg/kg)	CF [c]
	Mean	Highest	$STMR_{Mo}$ [a] (mg/kg)	HR_{Mo} [b] (mg/kg)		
Cattle (all) - Closest feeding level (x mg/kg bw; x N rate) [d]						
Muscle						
Fat						
Liver						
Kidney						
Cattle (dairy only) - Closest feeding level (x mg/kg bw; x N rate) [d]						
Milk [e]		n.a.				
Sheep (all) [f] - Closest feeding level (x mg/kg bw; x N rate) [d]						
Muscle						
Fat						
Liver						
Kidney						
Sheep (ewe only) [f] - Closest feeding level (x mg/kg bw; x N rate) [d]						
Milk [e]		n.a.				
Swine (all) [f] - Closest feeding level (x mg/kg bw; x N rate) [d]						
Muscle						
Fat						
Liver						
kidney						
Poultry (all) - Closest feeding level (x mg/kg bw; x N rate) [d]						
Muscle						
Fat						
Liver						
Poultry (layer only) - Closest feeding level (x mg/kg bw; x N rate) [d]						
Eggs [g]						

* Indicates that the MRL is proposed at the limit of quantification.

n.a.: not applicable

n.r. : not reported

(a): Median residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.

(b): Highest residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.

(c): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

(d): Closest feeding level and N dose rate related to the maximum dietary burden.

(e): For milk, mean was derived from samplings performed from day D1 to day D2 (daily mean of X cows).

(f): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.
(g): For eggs, mean and highest residues were derived from samplings performed from day D1 to day D2 (daily mean or daily highest of Y laying hens).

Consumer risk assessment

ARfD	X mg/kg bw (source)
Highest IESTI, according to EFSA PRIMo (rev.x)	**Scenario 1 without risk mitigation measures:** Crop1: x% of ARfD Crop2: x% of ARfD Crop3: x% of ARfD **Scenario 2 with risk mitigation measures:**
NESTI (% ARfD), according to (to be specified)	Highest NESTI: XX% ARfD (commodity)
Assumptions made for the calculations	**Scenario 1 without risk mitigation measures:** The calculation is based on the highest residue levels expected in raw agricultural commodities, except for XXXX were the derived processing factor was applied. The following CF for risk assessment were also applied: XXXX **Scenario 2 with risk mitigation measures:**

Or

Not relevant since no ARfD has been considered necessary.

ADI	X mg/kg bw per day (source)
TMDI according to EFSA PRIMo	Highest TMDI: XX% ADI (MS, diet)
NTMDI, according to (to be specified)	Highest NTMDI: XX% ADI (MS, diet)
Highest IEDI, according to EFSA PRIMo (rev.x)	**Scenario 1 without risk mitigation measures:** xx% ADI (diet) Contribution of crops assessed: Crop1: x% of ADI Crop2: x% of ADI Crop3: x% of ADI **Scenario 2 with risk mitigation measures:** 36% ADI (diet) Contribution of crops assessed: Crop1: x% of ADI Crop2: x% of ADI Crop3: x% of ADI
NEDI (% ADI), according to (to be specified)	Highest NEDI: XX% ADI (MS, diet)

Assumptions made for the calculations	**Scenario 1 without risk mitigation measures:** The calculation is based on the median residue levels derived for raw agricultural commodities, multiplied by the conversion factor for risk assessment, except for XXX where the processing factor for XXXX was also applied. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation. **Scenario 2 with risk mitigation measures:**

Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/02/2003)

Metabolite(s)	
ADI (mg/kg bw per day)	
Intake of groundwater metabolites (% ADI)	

Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: <RD-Mo>[(F)]				
Representative uses				
				The submitted data are sufficient to derive a MRL proposal for the NEU/SEU use. Risk for consumers unlikely.
				The MRL proposal reflects the more critical residue situation of the NEU use. Risk for consumers unlikely.
				The submitted data are sufficient to derive an import tolerance (US GAP). Risk for consumers unlikely.
				The MRL proposal reflects the NEU use. For the SEU use the data were not sufficient to derive a MRL proposal. Risk for consumers unlikely.
			No change	The submitted data do not provide evidence that the existing MRL has to be modified.
			Further risk management considerations required	For the NEU use a MRL proposal of 1 mg/kg was calculated.
			No MRL proposal	
MRL application				
Enforcement residue definition: 2 (if relevant, e.g. animal RD-Mo ≠ Plant RD-Mo)				

* Indicates that the MRL is set at the limit of analytical quantification (LOQ)

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005

(F): Fat soluble

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	The degradation of organic N-combinations starts with mineralisation followed by nitrification. The speed of this process depends on the soil temperature. The influence of an application of blood meal of ca.20 kg/ha compared to the natural N-content in soils of 900 – 9000 kg/ha in 0-20 cm depth is negligible. Further studies investigating the fate and behaviour in soil are not required. Blood meal is used as fertilizer in organic farming.
Non-extractable residues after 100 days	Not required, not relevant.
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	Not required, not relevant.

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

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

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 required, not relevant.
Mineralisation at study end	Not required, not relevant.
Non-extractable residues at study end	Not required, not relevant.

Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Not required.

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Not required.

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

Not required.

Combined laboratory and field kinetic endpoints for modelling (when not from different populations)*

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)	Not required, not relevant.	
Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)	Not required, not relevant.	
Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean	Not required, not relevant.	

* Only relevant after implementation of the published EFSA guidance describing how to amalgamate laboratory and field endpoints.

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration	Not required, not relevant.

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Not required.

Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Not required.

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Not required.

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 required.

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Not required.

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 required/ not relevant.

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 required/ not relevant.

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 required/ not relevant.

The formulation is applied on trees by coating with brush, spraying or dipping of individual plants. Exposure of surface water is expected to be negligible, when spray is targeted to the base of trees or the trunk. Further studies investigating the fate in water are not required when brushing, dipping or targeted spraying to the base of trees or trunks is employed as an application method.

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 required/ not relevant.

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 required/ not relevant.
Quantum yield of direct phototransformation in water at Σ > 290 nm	

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

Readily biodegradable (yes/no)	No data submitted, substance considered not readily biodegradable.

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)

Not required. Only targeted application to plant parts or single plants are intended. Exposure to surface water is negligible.

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)

Not required.

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	When the formulation is applied on trees by coating with brush, or dipping of individual plants, no exposure of air is expected. No study investigating the fate and behaviour in air is required in relation to these application methods.

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	Generally not applicable, considering the nature of the substance and the limited exposure from the representative uses. The degradation of blood meal follows the normal route of organic N-combinations in nature.

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

	Not relevant.

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

Soil (indicate location and type of study)	Not relevant.
Surface water (indicate location and type of study)	Not relevant.
Ground water (indicate location and type of study)	Not relevant.
Air (indicate location and type of study)	Not relevant.

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

Parent Method of calculation Application data	Not required/ not relevant.

Metabolite I Method of calculation Application data	Not required/ not relevant.

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter) Application rate	Not required/ not relevant.

PEC$_{(gw)}$ From lysimeter / field studies - Not required/ not relevant.

Parent	1st year	2nd year	3rd year
Annual average (µg/L)			

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 FOCUSsw step 1 and 2	Blood meal Calculation performed with EVA 2.1
Parameters used in FOCUSsw step 3 (if performed)	
Application rate	20 kg/ha

EVA 2.1				
Distance [m]	PEC_{SW} [µg/L water]			
	Application technique			
	conventional	90 % reduction	75 % reduction	50 % reduction
0	6653.33	665.33	1663.33	3326.67
1	4.258	0.43	1.06	2.13
3	0.732	0.07	0.18	0.37
5	0.466	0.05	0.12	0.23

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 3.2 Molecular weight (g/mol): Not applicable KOC/KOM (mL/g): 10 DT50 soil (d): 1000 days (default) DT50 water/sediment system (d): 1000 d(default) DT50 water (d): 1000 DT50 sediment (d): 1000 Crop interception (%): 0 % (no)
Parameters used in FOCUSsw step 3 (if performed)	Not relevant.
Application rate	Crop and growth stage: hand held application (< 50 cm and < 50 cm) Number of applications: 1 Interval (d): - Application rate(s): 20000 g a.s./ha Application window: October to February, North-EU
Metabolite *X* Parameters used in FOCUSsw step 1 and 2	Not relevant.
Parameters used in FOCUSsw step 3 (if performed)	
Application rate	
Main routes of entry	

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Hand held < 50 cm	0	6760		675.58	
Hand held >50 cm	0	7110		710.22	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Hand held < 50 cm	0	3460		345.9	
Hand held >50 cm	0	3810		380.44	

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

Method of calculation	-

PEC

Maximum concentration	Not required/ not relevant.

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				
	Blood meal (a.s.)	Acute	LD_{50}	No data.
	Certosan (99.8% a.s. w/w)	Acute	LD_{50}	No data.
	Blood meal (a.s.)	Long-term	NOAEL	No data.
Mammals				
Indicate species	Blood meal (a.s.)	Acute	LD_{50}	No data.
	Certosan (99.8% a.s. w/w)	Acute	LD_{50}	No data.
	Blood meal (a.s.)	Long-term	NOAEL	No data.
Endocrine disrupting properties (Annex Part A, points 8.1.5) The available information in the ecotoxicology section indicates that Blood meal can be considered unlikely to exhibit endocrine disrupting properties.				
Additional higher tier studies (Annex Part A, points 10.1.1.2): Not required.				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): No data.				

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

All proposed uses of Certosan (1 x 19.8 kg product/ha and 1 x 20 kg product/ha)

No toxicity from the active substance Blood meal and the formulated product Certosan is expected to birds and other terrestrial vertebrates. Blood meal can be considered as possible food source for omnivorous/carnivorous terrestrial vertebrates, and is intended to act as a repellent for herbivorous terrestrial vertebrates. Therefore a potential risk to birds and mammals (including the consumption of unintentional oversprayed feed items following spray applications) is considered as low and the calculation of acute and long-term TER values is not considered necessary.

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[1]

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Laboratory tests				
Fish				
	a.s.	Acute 96 hr (static, or semi-static or flow-through)	Mortality, LC_{50}	No data.
Rainbow trout *(Oncorhynchus mykiss)*	Certosan (99.8 % Blood meal)	Acute, 96 hr (semi static)	Mortality, LC_{50}	> 33.5 $_{(mm)}$[2]
	a.s.	Chronic (static, or semi-static or flow-through)	Growth, or development, or behaviour, or reproduction NOEC	No data.
Aquatic invertebrates				
	a.s.	48 h (static, or semi-static or flow-through)	Mortality, EC_{50}	No data.
Daphnia magna	Certosan (99.8 % Blood meal)	Acute, 48 hr (semi static)	Mortality, EC_{50}	> 62.4 $_{(mm)}$ [2]
	a.s.	21 d (static, or semi-static or flow-through)	Reproduction or development, NOEC	No data.
Sediment-dwelling organisms				
	a.s.	28 d (static, or semi-static or flow-through)	NOEC	No data.
Algae				
	a.s.	72 h (static, or semi-static or flow-through)	Growth rate: E_rC_{50} (NOEC) [Biomass: E_bC_{50} (NOEC) Yield: E_yC_{50} (NOEC)]	No data.

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Desmodesmus subspicatus	Certosan (99.8 % Blood meal)	72 hr (static)	Growth rate: Biomass Integral (AUC^3): Yield:	E_rC_{50} > 59 (mm)[2] E_rC_{10} > 6 (mm) NOE_rC < 6 (mm) * E_bC_{50} > 59 (mm)[2] E_bC_{10} = 1.4 (mm) NOE_bC < 6 (mm) * E_yC_{50} = 16.4 (mm) E_yC_{10} = 1.1 (mm) NOE_yC < 6 (mm)*
Higher plant				
No data.				
Further testing on aquatic organisms Not required.				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3) The available information in the ecotoxicology section indicates that Kieselgur can be considered unlikely to exhibit endocrine disrupting properties.				

[1] (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; a.s.: active substance
[2] Limit of solibility
[3] AUC…Area Under the Curve

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Active substance	Metabolite 1	Metabolite 2	Metabolite 3
$logP_{O/W}$	A bioconcentration study of Blood meal is not considered relevant, since Blood meal is a well-known widely traded commodity, used as food- and feed additive and organic fertilizer.			
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)				
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)				
Annex VI Trigger for the bioconcentration factor				
Clearance time (days) (CT_{50})				
(CT_{90})				
Level and nature of residues (%) in organisms after the 14 day depuration phase				
Higher tier study				
Not required.				

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

$FOCUS_{sw}$ step 1-2 – PEC/RAC ratios for all proposed uses of Certosan (1 x 19.8 kg product/ha and 1 x 20 kg product/ha), acceptability of risk: PEC/RAC < 1

Group		**Fish acute**	**Inverteb. acute**	**Algae**
Test species		***Oncorhynchus mykiss***	***Daphnia magna***	***Desmodesmus subspicatus***
Endpoint		LC_{50}	EC_{50}	E_rC_{50}
(µg/L)		> 33500	> 62400	> 59000
AF		100	100	10
RAC (µg/L)		> 335	> 624	5900
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			
Step 1				
Hand held application, crop < 50 cm	6760	**< 20.2**	**< 10.8**	**< 1.1**
Hand held application, crop > 50 cm	7110	**< 21.2**	**< 11.4**	**< 1.2**
Step 2				
Hand held application, crop < 50 cm	3460	**< 10.3**	**< 5.5**	< 0.6
Hand held application, crop > 50 cm	3810	**< 11.4**	**< 6.1**	< 0.7

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

The risk assessment indicates an acceptable risk for algae at FOCUS Step 2. However, a potential acute risk for fish and *Daphnia* is indicated at FOCUS Step 1 & 2 (i.e. PEC/RAC ratio > 1). This potential risk is considered to be acceptable since worst case assumptions are reflected in this risk assessment. No mortality/immobility of the test organisms occurred at the highest tested concentrations (which is the limit of solubility in the respective study) and no interception was taken into account for the PEC calculation. Moreover it should be taken in account that Blood meal is commonly used as fish feed. Therefore overall the risk to aquatic organisms is considered to be low.

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
	Blood meal (a.s.)	Acute	Oral toxicity (LD_{50})	No data.
Apis mellifera	Certosan (99.8% Blood meal)	Acute (48 h)	Oral toxicity (LD_{50})	> 198 µg product/bee
	Blood meal (a.s.)	Acute	Contact toxicity (LD_{50})	No data.
Apis mellifera	Certosan (99.8% Blood meal)	Acute (48 h)	Contact toxicity (LD_{50})	> 200 µg product/bee
	Blood meal (a.s.)	Chronic	10 d-LC50	No data.
	Certosan (99.8% Blood meal)			No data.
	Blood meal (a.s.)	Bee brood development	NOEClarvae	No data.
	Certosan (99.8% Blood meal)			No data.
	Blood meal (a.s.)	Sub-lethal effects (behavioural and reproductive)	NOEC hypopharyngeal glands	No data.
	Certosan (99.8% Blood meal)			No data.

Potential for accumulative toxicity: No data.
Semi-field test (Cage and tunnel test) No data.
Field tests No data.

Risk assessment for all proposed uses of Certosan (1 x 19.8 kg product/ha and 1 x 20 kg product/ha)

For targeted application methods (coating with brush, dipping) a relevant exposure is considered to be negligible. For less targeted application methods (i.e. spraying by e.g. knapsack sprayer) exposure can not be excluded, however the use of Certosan (99.8% Blood meal) is considered to pose a low risk to bees based on the available acute toxicity data. Therefore, further calculations regarding the risk of bees following the exposure to Certosan were not considered necessary.

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
Typhlodromus pyri	a.s., preparation	Mortality, LR_{50} Reproduction, ER_{50}	No data.
Aphidius rhopalosiphi	a.s., preparation	Mortality, LR_{50} Reproduction, ER_{50}	No data.
Additional species			
Poecilus curpeus	Certosan (99.8% Blood meal)	LR_{50}	> 40 kg product/ha
Pardosa spp.	Certosan (99.8% Blood meal)	LR_{50}	> 40 kg product/ha

First tier risk assessment for all proposed uses of Certosan (1 x 19.8 kg product/ha and 1 x 20 kg product/ha)

For targeted application methods (coating with brush, dipping) a relevant exposure is considered to be negligible. For less targeted application methods (i.e. spraying by e.g. knapsack sprayer) exposure can not be excluded, however the use of Certosan (99.8% Blood meal) is considered to pose a low risk to non-target arthropods based on the available toxicity data. No effects > 50% were observed up to a dose of 40 kg product/ha (equivalent to 39.96 kg a.s./ha) for the soil-dwelling arthropods *Poecilus cupreus* and *Pardosa* spp. Therefore, further calculations regarding the risk of non-target arthropods following the exposure to Certosan were not considered necessary.

Extended laboratory tests, aged residue tests

No data.

Risk assessment for all proposed uses of Certosan (1 x 19.8 kg product/ha and 1 x 20 kg product/ha) based on extended lab test or aged residue tests

No data.

Semi-field tests
No data.
Field studies
No data.
Additional specific test
No data.

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[1]	Time scale	End point	Toxicity
Earthworms					
	Blood meal / Certosan (99.8% Blood meal)		Chronic	Growth, reproduction, behaviour	No data.
Other soil macroorganisms					
Folsomia candida	Blood meal / Certosan (99.8% Blood meal)			Mortality, reproduction, behaviour	No data.
Hypoaspis aculeifer	Blood meal / Certosan (99.8% Blood meal)			Mortality, growth, reproduction, behaviour	No data.

[1]To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).

Higher tier testing (e.g. modelling or field studies) No data.

Nitrogen transformation	Blood meal / Certosan (99.8% Blood meal)	No data. For targeted application methods (coating with brush, dipping) a relevant exposure is considered to be negligible. For less targeted application methods (i.e. spraying) exposure can not be excluded, however the use of Blood meal as fertiliser and the natural mineralisation of Blood meal (consisting to >80% out of protein) in soil is considered sufficient to demonstrate a low risk to soil nitrogen transformation and to address the data requirement. Therefore a further consideration of a risk assessment is not considered necessary. No negative effects of the active substance Blood meal and the product Certosan on soil microbial activity are expected. Further it should be noted, that Blood meal is a fertiliser in organic farming (refer to the EU-Regulation No. 1069/2009) and the application rate is multiple compared to the use of Certosan (up to 2500 kg fertiliser/ha).

Toxicity/exposure ratios for soil organisms

All proposed uses of Certosan (1 x 19.8 kg product/ha and 1 x 20 kg product/ha)

For targeted application methods (coating with brush, dipping) a relevant exposure is considered to be negligible. For less targeted application methods (i.e. spraying) exposure can not be excluded, however the use of Blood meal as fertiliser and the natural mineralisation of Blood meal (consisting to >80% out of protein) in soil is considered sufficient to demonstrate a low risk to earthworms and to address the data requirement. The calculation of Toxicity/Exposure Ratios (TERs) is therefore not considered necessary. No negative effects of the active substance Blood meal and the product Certosan on earthworms are expected. Further it should be noted, that Blood meal is a fertiliser in organic farming (refer to the EU-Regulation No. 1069/2009) and the application rate is multiple compared to the use of Certosan (up to 2500 kg fertiliser/ha).

The low toxicity demonstrated in bees and other non-target arthropods, the use of Blood meal as fertiliser and the natural mineralisation of Blood meal (consisting to >80% out of protein) in soil is considered sufficient to demonstrate a low risk to non-target soil organisms other than earthworms and to address the data requirement. The calculation of Toxicity/Exposure Ratios (TERs) is therefore not considered necessary.

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

No data.

For targeted application methods (coating with brush, dipping) a relevant exposure is considered to be negligible. For less targeted application methods (i.e. spraying) exposure can not be excluded, however the use of Blood meal as fertiliser and the natural mineralisation of Blood meal (consisting to >80% out of protein) in soil is considered sufficient to demonstrate a low risk to non-target plants and to address the data requirement. Therefore a further consideration of a risk assessment is not considered necessary.

Further no signs of phytotoxicity of the test product were visible on coniferous and deciduous trees as well as on fruit trees or ornamental plants with the intended dose rate as well as with 2-3 times higher dose rates (assessed on forests tree species only). Hence, no negative effects of the active substance Blood meal and the formulation Certosan on non-target plants are expected. Further it should be noted, that Blood meal is a fertiliser in organic farming (refer to the EU-Regulation No. 1069/2009) and the application rate is multiple compared to the use of Certosan (up to 2500 kg fertiliser/ha).

Laboratory dose response tests

Species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
	Blood meal / Certosan (99.8% Blood meal)	No data.	No data.			
Extended laboratory studies : No data. Semi-field and field test: No data.						

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)

[2] 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	No data.
Pseudomonas sp.	No studies were submitted to address the effects on effects on biological methods for sewage treatment. The waiver for standard toxicity studies is considered acceptable. For the proposed application methods (coating with brush, dipping, spraying) a relevant exposure of activated sludge is considered to be negligible. Therefore a low concern to biological methods of sewage treatment is considered

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)

Available monitoring data concerning adverse effect of the a.s.

No data.

Available monitoring data concerning effect of the PPP.

No data.

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds[1]

Compartment	
soil	A residue definition is not needed[2]
water	A residue definition is not needed[2]
sediment	A residue definition is not needed[2]
groundwater	A residue definition is not needed[2]

[1] metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

[2] According to the intended uses Blood meal is used as a repellent which is applied onto trees or parts of trees.

Since coating of trees is the only use of Blood meal no crops are treated directly and therefore no residues on food and/or feed may occur. Blood meal is used as fertiliser in organic farming in much higher amounts. Blood meal consists out of dried blood, which is a natural substance. It is not possible to distinguish between the residues arising from the use of Blood meal as a plant protection product and its natural presence in environmental compartments.

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

Substance	Blood meal
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][6]:	-
Peer review proposal[7] for harmonised classification according to Regulation (EC) No 1272/2008:	-

[6] 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.

[7] 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.

Used compounds code(s)

Code/Trivial name*	IUPAC name/SMILES notation	Structural formula

* The compound code / trivial name in bold is the name used in the list of endpoints.