European Commission

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

Blood meal

Volume 1

Rapporter Member State: Austria
Co-Rapporter Member State: Lithuania

Version History

When	What
2018/02	Original dossier submission by applicant
2018/04	Revised dossier submission by applicant
2018/12	Draft RAR by RMS AT
2019/02	Draft RAR by RMS AT after commenting by Co-RMS LT

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Level 1

Blood meal

1. STATEMENT OF SUBJECT MATTER AND PURPOSE FOR WHICH THIS REPORT HAS BEEN PREPARED AND BACKGROUND INFORMATION ON THE APPLICATION

1.1. CONTEXT IN WHICH THIS DRAFT ASSESSMENT REPORT WAS PREPARED

1.1.1. Purpose for which the draft assessment report was prepared

The purpose of this application is to renew the approval of the active substance Blood meal submitted under article 14 of Regulation (EU) No. 1107/2009 and in accordance with Regulation (EU) No 844/2012.

1.1.2. Arrangements between rapporteur Member State and co-rapporteur Member State

Not relevant, no special arrangements were made.

1.1.3. EU Regulatory history for use in Plant Protection Products

Blood meal was included in the Annex I of Directive 91/414 under Inclusion Directive 2008/127/EC RMS for assessment of blood meal was Belgium. The Regulation (EU) No 1107/2009 repealed and replaced the Directive 91/414/EEC and the active substance blood meal is deemed to be approved under that Regulation and included in the Annex to Regulation (EC) No 540/2011 amended by Commission Implementing Regulation (EU) No 369/2012 and Commission Implementing Regulation (EU) 2017/195.

Blood meal was included in Annex I under provision as use in game repellent. The SANCO report for blood meal (SANCO/2604/08 - rev 1-4 dated 11th July 2014) and Peer review document EFSA 2011 (EFSA Journal 2011;9(10):2394) are considered to provide the relevant information for the re-registration of blood meal. The formulated product Certosan contains 99.8 % blood meal and is therefore identical with the active ingredient. Data obtained with the product can be used also for the active substance blood meal.

1.1.4. Evaluations carried out under other regulatory contexts

No information provided by the applicant.

1.2. APPLICANT INFORMATION

1.2.1. Name and address of applicant(s) for approval of the active substance

Plantskydd AB
Törsjö 444
264 53 Ljungbyhed
Sweden
Telephone No: [redacted]
E-mail address: [redacted]
Contact: [redacted]

1.2.2. Producer or producers of the active substance

CONFIDENTIAL information, please refer to Volume 4

1.2.3. Information relating to the collective provision of dossiers

Not relevant

1.3. IDENTITY OF THE ACTIVE SUBSTANCE

1.3.1. Common name proposed or ISO-accepted and synonyms	Blood meal
1.3.2. Chemical name (IUPAC and CA nomenclature)	
IUPAC	Not applicable
CA	Not applicable
1.3.3. Producer's development code number	[redacted] Telephone No: [redacted] Fax No: [redacted] E-mail address: [redacted]
1.3.4. CAS, EEC and CIPAC numbers	
CAS	90989-74-5
EEC	292-731-9
CIPAC	909
1.3.5. Molecular and structural formula, molecular mass	
Molecular formula	Not applicable
Structural formula	Not applicable
Molecular mass	Not applicable
1.3.6. Method of manufacture (synthesis pathway) of the active substance	
1.3.7. Specification of purity of the active substance in g/kg	≥ 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. 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.
1.3.8. Identity and content of additives (such as stabilisers) and impurities	
1.3.8.1. *Additives*	CONFIDENTIAL information - data provided separately in Volume 4
1.3.8.2. *Significant impurities*	CONFIDENTIAL information - data provided separately in Volume 4
1.3.8.3. *Relevant impurities*	None
1.3.9. Analytical profile of batches	CONFIDENTIAL information - data provided separately in Volume 4

1.4. INFORMATION ON THE PLANT PROTECTION PRODUCT

1.4.1. Applicant	Plantskydd AB Törsjö 444 264 53 Ljungbyhed Sweden Telephone No: [redacted] E-mail address: [redacted] Contact: [redacted]
1.4.2. Producer of the plant protection product	[redacted] Telephone No: [redacted] Fax No: [redacted] E-mail address: [redacted]
1.4.3. Trade name or proposed trade name and producer's development code number of the plant protection product	Blood meal
1.4.4. Detailed quantitative and qualitative information on the composition of the plant protection product	
1.4.4.1. **Composition of the plant protection product**	Haemoglobin powder 990 g/kg
1.4.4.2. **Information on the active substances**	See table below
1.4.4.3. **Information on safeners, synergists and co-formulants**	CONFIDENTIAL information - data provided separately in Volume 4.
1.4.5. Type and code of the plant protection product	Wettable powder (WP)
1.4.6. Function	Game repellent
1.4.7. Field of use envisaged	Professional and non-professional use in forestry (deciduous and conifer forest trees), and in agriculture (horticulture: ornamental crop production; fruit production.
1.4.8. Effects on harmful organisms	Blood meal has no direct effect on the target organisms. Due to its unpleasant taste and odour, blood meal prevents game damaging plants.

Type	**Name/Code Number**
ISO common name	Blood meal
CAS No	90989-74-5
EC No	292-731-9
CIPAC No	909
Salt, ester anion or cation present	No

1.5. DETAILED USES OF THE PLANT PROTECTION PRODUCT

1.5.1. Details of representative uses

Crop and/or situation (a)	Member State	Product Name	F G 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 a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	Kg a.i./hl min max (g/hl)	Water l/ha min max	Kg a.i./ha min max (*) (g/ha)		
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 coniferous	North	Certosan	F	Vole repellent	WP	99,8%	Coating with brush or dipping	all season	1	-	4.99	5-15	a) 19.96 b) 19.96	na	

trees in forestry 3FORC Agriculture and garden3FRUC, 3ORTC				MICRAR			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 classification (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) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(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 synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j)Growth stage at 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 application 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) Any remarks or details about the uses

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

1.5.2. Further information on representative uses

Please refer to 1.5.1.

1.5.3. Details of other uses applied for to support the setting of MRLs for uses beyond the representative uses

No additional MRL application submitted.

1.5.4. Overview on authorisations in EU Member States

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ***	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	SE, LV, LT	Deciduous and coniferous trees in forestry, agriculture and garden	F	Game repellent	coating with brush or dipping individual plants; entire plants	all-season	-	-	20	19.96	5 - 15	n.a.		
2	SE, LV, LT	Deciduous and coniferous trees in forestry, agriculture and garden	F	Game repellent	spraying individual plants; entire plants	all-season	-	-	20	19.96	200-400	n.a.		
3	SE, LV, LT	Deciduous and coniferous trees in forestry, agriculture and garden	F	Mice repellent	coating with brush or dipping individual plants; entire plants	all-season	-	-	20	19.96	5 - 15	n.a.		
4	SE, LV, LT	Deciduous and coniferous trees in forestry, agriculture and garden	F	Mice repellent	spraying individual plants; entire plants	all-season	-	-	20	19.96	200-400	n.a.		
5	AU,	Deciduous	F	Game	spraying	all-	1-2	-	0.5 / 1000	0.499	5 L	n.a.	the	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ***	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
	BE; DE, FR	and coniferous trees in forestry		repellent: big game (*Cervidae*), small game (*Lepus sp.*, *Oryctolagus sp.*)	with portable equipment individual plants; entire plants	season			plants	/1000 plants	/1000 plants		application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment	
6	AU, BE; DE, FR	Deciduous and coniferous trees in forestry	F	Game repellent: big game (*Cervidae*), small game (*Lepus sp.*, *Oryctolagus sp.*)	spraying with tractor mounted equipment	all-season	1-2	-	20	19.96	400	n.a.		
7	AU, BE; DE, FR	Deciduous and coniferous trees in forestry	F	Game repellent: big game (*Cervidae*), small game (*Lepus sp.*, *Oryctolagus sp.*)	atomising with portable equipment individual plants; entire plants	all-season	1-2	-	20	19.96	200	n.a.		
8	AU, BE; DE, FR	Deciduous and coniferous trees in forestry	F	Game repellent: big game (*Cervidae*), small game (*Lepus sp.*, *Oryctolagus sp.*)	coating with brush individual plants; entire plants	all-season	1-2	-	0.5 / 1000 plants	0.499 /1000 plants	4-5 L /1000 plants	n.a.	the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment	
9	AU,	Deciduous	F	Game	dipping	all-	1-2	-	0.75	0.7485	7.5-	n.a.	the	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ***	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
	BE; DE, FR	and coniferous trees in forestry		repellent: big game (*Cervidae*), small game (*Lepus sp.*, *Oryctolagus sp.*)	individual plants; entire plants	season			/1000 plants	/1000 plants	10 L /1000 plants		application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment	
10	AU, BE; DE, FR	Fruit trees in orchard	F	Game repellent: big game (*Cervidae*), small game (*Lepus sp.*, *Oryctolagus sp.*)	spraying with portable equipment individual plants; entire plants	all-season	1-2	-	0.5 /1000 plants	0.499 /1000 plants	5 L /1000 plants	n.a.	the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment	
11	AU, BE; DE, FR	Fruit trees in orchard	F	Game repellent: big game (*Cervidae*), small game (*Lepus sp.*, *Oryctolagus sp.*)	spraying with tractor mounted equipment	all-season	1-2	-	20	19.96	400	n.a.		
12	AU, BE; DE, FR	Fruit trees in orchard	F	Game repellent: big game (*Cervidae*), small game (*Lepus sp.*, *Oryctolagus sp.*)	atomising with portable equipment individual plants; entire plants	all-season	1-2	-	20	19.96	200	n.a.		
13	AU,	Fruit trees	F	Game	coating	all-	1-2	-	0.5 /1000	0.499	4-5	n.a.	the	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ***	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
	BE; DE, FR	in orchard		repellent: big game (*Cervidae*), small game (*Lepus sp.*, *Oryctolagus sp.*)	with brush individual plants; entire plants	season			plants	/1000 plants	L /1000 plants		application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment	
14	AU, BE; DE, FR	Fruit trees in orchard	F	Game repellent: big game (*Cervidae*), small game (*Lepus sp.*, *Oryctolagus sp.*)	dipping individual plants; entire plants	all-season	1-2	-	0.75 /1000 plants	0.7485 /1000 plants	7.5-10 L /1000 plants	n.a.	the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment	
15	AU, BE; DE, FR	Ornamentals	F	Game repellent: big game (Cervidae), small game (Lepus sp., Oryctolagus sp.)	spraying with portable equipment individual plants; entire plants	all-season	1-2	-	0.5 /1000 plants	0.499 /1000 plants	5 L /1000 plants	n.a.	the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ***	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
16	AU, BE; DE, FR	Ornamentals	F	Game repellent: big game (Cervidae), small game (Lepus sp., Oryctolagus sp.)	spraying with tractor mounted equipment	all-season	1-2	-	20	19.96	400	n.a.		
17	AU, BE; DE, FR	Ornamentals	F	Game repellent: big game (Cervidae), small game (Lepus sp., Oryctolagus sp.)	atomising with portable equipment individual plants; entire plants	all-season	1-2	-	20	19.96	200	n.a.		
18	AU, BE; DE, FR	Ornamentals	F	Game repellent: big game (Cervidae), small game (Lepus sp., Oryctolagus sp.)	coating with brush individual plants; entire plants	all-season	1-2	-	0.5 /1000 plants	0.499 /1000 plants	4-5 L /1000 plants	n.a.	the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment	
19	AU, BE; DE, FR	Ornamentals	F	Game repellent: big game (Cervidae), small game (Lepus sp., Oryctolagus sp.)	dipping individual plants; entire plants	all-season	1-2	-	0.75 /1000 plants	0.7485 /1000 plants	7.5-10 L /1000 plants	n.a.	the application rate per ha depends on the number of trees which were grown per ha since the application is a single plant treatment	

*F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Level 2

Blood meal

2. SUMMARY OF ACTIVE SUBSTANCE HAZARD AND OF PRODUCT RISK ASSESSMENT

2.1. IDENTITY

Blood meal contains ≥ 990 g/kg (haemoglobin).

2.2. PHYSICAL AND CHEMICAL PROPERTIES

2.2.1. Summary of physical and chemical properties of the active substance

Blood meal is a dark red brown powder. Blood meal is non-flammable, non-explosive and is not an oxidizing agent. It solubility in water is 50-1000 mg/L, so that it is moderately water soluble.

2.2.2. Summary of physical and chemical properties of the plant protection product

Since the product contains 99.8 %, blood meal can be considered being identical to the active substance.
The plant protection product Certosan is dark red brown fine powder, almost odourless with tingle of fish. The product does not exhibit any explosive or oxidising properties, and is non-flammable and does not self-ignite. It has a pH of 7.53 (1% w/w suspension). In addition, the wet sieve test showed that the Certosan distributed differently on the surface of water. Persistent foaming is within the range. The human pathogenic germs are under the limit values before and after storage. The product is stable for 2 years at 20°C.
Its technical characteristics are acceptable for a wettable powder (WP) formulation.

2.3. DATA ON APPLICATION AND EFFICACY

2.3.1. Summary of effectiveness

A total 58 efficacy trials (thereof 30 GEP trials) was provided. All trials were carried out in the EPPO Maritime zone, except for 6 EPPO South-east zone trials, from 1994 up to 2013.

Winter and summer game browsing in forests trees: Across Maritime zone GEP trials (7 resp. 12), Certosan achieved 88.8 resp. 91.4 % control (summer resp. winter game browsing) on conifer trees (n=4), and 81.8 % resp. 78.3 % control (summer, resp. winter game browsing) on deciduous trees (n=3). Reference products achieved comparable levels of control. Performance of Certosan was comparable in South-east zone trials. Assessed pest species were CERVEL, DAMADA, CAPRCA, LEPUEU and ORYTCU.

Game browsing in orchards/vineyards: Across two Maritime zone GEP-trials (apple orchards) Certosan achieved 81 % control, and was clearly outperformed by the reference products (92 % control). In one South-east zone trial (vineyard) at low pest pressure Certosan achieved 83.5 % control.
Assessed pest species were CAPRCA, LEPUEU and ORYTCU.

Game browing in ornamentals: Across two Maritime zone GEP-trials at very low pest pressure Certosan performed well against ORYTCU with 82 % control.

The applicant claimed that the repellent effect of Certosan is based on its unpleasant smell and taste for the game, thus the results from the forest trees can be extrapolated and used for the fruit trees, and ornamentals as well. However, in forestry only economically relevant trees are protected, and others serve as feed. On the contrary, in orchards/vineyards and in ornamental production all plants have to be protected, and no alternative feed is available for the game. Therefore results of forest trials cannot be extrapolated to orchards and vineyards. Further data are needed to confirm the results gained from forest trials,

No trials are available assessing efficacy of Certosan against voles MICRAR.

2.3.2. Summary of information on the development of resistance

Certosan is a repellent which is effective by smell and taste due to the active substance blood meal.
Therefore typical resistance or cross-resistance mechanisms as known from chemical active substances will not occur. A habituation effect cannot completely be excluded.
Game repellents with the active ingredient blood meal have been used for several decades. No incidence of game species resistant against Certosan, or habituated to Certosan, was reported.

2.3.3. Summary of adverse effects on treated crops

No signs of phytotoxicity of the test product were visible on forest trees as well as on fruit trees or ornamental plants. Certosan seems to be safe to plants.

Quality of yield, processing, yield:
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. A negative effect on forest trees is not expected.
A negative impact on yield is unlikely.

2.3.4. Summary of observations on other undesirable or unintended side-effects

Adverse effects on beneficial organisms (other than bees)
Please refer to B.3 (CP) Section 10.

Adverse effects on parts of plant used for propagating purposes
Due to the selectivity of the product, any negative impact on propagation is unlikely.

Impact on succeeding crops
Negative effects on succeeding crops are not expected, since blood meal can also be used as a fertilizer.

Impact on other plants including adjacent crops
A negative impact by drift on other plants is highly unlikely, due to crop safety of the product.

2.4. FURTHER INFORMATION

2.4.1. Summary of methods and precautions concerning handling, storage, transport or fire

Storage Conditions

Blood meal should be stored in original sealed or resealed bags in a dry place

Transport

No dangerous goods. Not classified. No special precautions, other than dry conditions, are necessary.

Fire

Blood meal itself does not burn.

2.4.2. Summary of procedures for destruction or decontamination

Blood meal is a natural product. No negatives effects on the environment are reported.

Blood meal can be used as fertiliser even in organic farming. Destruction or Decontamination of spills is not necessary, only because of aesthetic reasons.

2.4.3. Summary of emergency measures in case of an accident

Blood meal is not hazardous.

Appropriate exhaust ventilation and filtering should be provided where dust can be generated.

2.5. METHODS OF ANALYSIS

2.5.1. Methods used for the generation of pre-authorisation data

Adequate method for water is available for the analysis of the technical compound and risk assessment analysis.

2.5.1.1. Methods for risk assessment

No methods are required for soil and air since blood meal is a natural non-toxic compound.

There are clear indications that it may be expected that blood meal does not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment (SANCO/2604/08 – rev 4, 11 July 2014) Technical a.s. impurities in technical a.s plant protection product.

2.5.2. Methods for post control and monitoring purposes

Not required. No residue definition. (EFSA Journal 2011;9(10):2394).

Blood meal is a food item itself. Accordingly, no analytical method for feed and food is deemed required, and since no MRLs have been set, no method is required according to SANCO/825/00 rev. 8.1 from 16.11.2010

The product will not be used on plants intended for food or feed.

Adequate method is available to monitor the respective current residue definition only in drinking water and surface water. A summary of adequate enforcement method is given in the table below:

Method (EU evaluated)	Analytes	LOQ (mg/kg)	Primary method	Confirmatory method	Independent lab validation
Monitoring (new study)	Iron	Water: - surface water (0.1 µg/L)	Affolter, O. (2013c) ICP-OES-Method	-	-

2.6. EFFECTS ON HUMAN AND ANIMAL HEALTH

Blood meal has a non-toxic mode of action and is non-toxic by itself. The used substance has food grade quality. In order to ensure that the active substance is of low risk to humans, the following quality criteria are applied:

- Food grade quality blood collected in authorized slaughterhouses
- Destruction of pathogens and protein denaturation occur during blood processing
- Blood of porcine origin

Blood meal is produced in accordance with current feed and food EU legislations.

Based upon these statements, and taking into account that the substance does not in itself present a toxicological concern, the waiver for toxicological studies was deemed acceptable.

2.6.1. Summary of absorption, distribution and excretion in mammals

No data are necessary for blood meal (EFSA Journal 211;9(10): 2394)

2.6.2. Summary of acute toxicity

No data are necessary for blood meal (EFSA Journal 211;9(10): 2394)

2.6.3. Summary of short-term toxicity

No data are necessary for blood meal (EFSA Journal 211;9(10): 2394)

2.6.4. Summary of genotoxicity

No data are necessary for blood meal (EFSA Journal 211;9(10): 2394)

2.6.5. Summary of long-term toxicity and carcinogenicity

No data are necessary for blood meal (EFSA Journal 211;9(10): 2394)

2.6.6. Summary of reproductive toxicity

No data are necessary for blood meal (EFSA Journal 211;9(10): 2394)

2.6.7. Summary of neurotoxicity

No data are necessary for blood meal (EFSA Journal 211;9(10): 2394)

2.6.8. Summary of further toxicicological studies on the active substance

The absence of the following human pathogenic germs were confirmed at 0, 6, 12 and 24 months ± 1 week in an open and in a closed package of the product Certosan (Affolter, O., 2015) :

- *Shigella,* (quantitatively, the lowest detection limit 100 CFU/g)
- *Staphylococcus aureus* (quantitatively, the lowest detection limit 100 CFU/g)
- *Pseudomonas aeruginosa,* (quantitatively, the lowest detection limit 100 CFU/g)
- *Eschericha coli,* (quantitatively, the lowest detection limit 100 CFU/g)
- *Enterobacteria,* (quantitatively, the lowest detection limit 100 CFU/g)
- *Thermo-tolerant coliforms*, (quantitatively, the lowest detection limit 100 CFU/g)
- *Listeria monocytogenes,* (quantitatively, the lowest detection limit 100 CFU/g)
- *Candida albicans,* (quantitatively, the lowest detection limit 100 CFU/g)
- *Salmonella*, (qualitatively in 100 g)
- *Vibrio,* (qualitatively in 100 g)

The product Certosan consists to 99.8 % of the active substance blood meal. Therefore, the test conducted with the product and the results are also valid for the active substance.

2.6.9. Summary of toxicological data on impurities and metabolites

No metabolites identified

2.6.10. Summary of medical data and information

2.6.11. Toxicological end point for assessment of risk following long-term dietary exposure - ADI

The setting of reference values was not deemed necessary, as the substance does not present a toxicological concern.

2.6.12. Toxicological end point for assessment of risk following acute dietary exposure - ARfD (acute reference dose)

Not required.

2.6.13. Toxicological end point for assessment of occupational, bystander and residents risks – AOEL

Not required.

2.6.14. Summary of product exposure and risk assessment

No exposure assessment was deemed necessary, as the substance does not present a toxicological concern. Blood meal is food-grade and exposure already exists, as blood is consumed traditionally as food in different forms in many cultures.

2.7. RESIDUE

Blood meal will be used as game repellent by protection coating on the outer surface of deciduous and coniferous trees in forestry, agricultural plants and ornamentals in garden.
Blood meal is produced form dried blood of food grade quality and is collected in authorised slaughterhouses. It has been heat-treated to destroy microorganism contamination and is required to be of food grade quality.
The product will be applied by brushing, spraying or dipping the target plants only and dries off to a water insoluble coat and is intended for an all-season application.
The use in orchards is the only use that is of possible relevance concerning consumer and livestock exposure to blood meal residues. To avoid potential risks to consumers, the use of blood meal of food grade quality in accordance with current EU legislation for animal by-products, as well as evidence that there will be no growth of human pathogens in the product when used.

2.7.1. Summary of storage stability of residues

Not required

2.7.2. Summary of metabolism, distribution and expression of residues in plants, poultry, lactating ruminants, pigs and fish

Not required

2.7.3. Definition of the residue

Not applicable

2.7.4. Summary of residue trials in plants and identification of critical GAP

Not required

2.7.5. Summary of feeding studies in poultry, ruminants, pigs and fish

Not required

2.7.6. Summary of effects of processing

Not required

2.7.7. Summary of residues in rotational crops

Not required

2.7.8. Summary of other studies

No additional studies were submitted.

2.7.9. Estimation of the potential and actual exposure through diet and other sources

No toxicological end points (ADI, ARfD) are set for blood meal. A quantitative risk assessment for the consumer is therefore not required.

2.7.10. Proposed MRLs and compliance with existing MRLs

Blood meal a natural occurring substance of very low toxicity (no toxicological end points proposed). With respect to the intended use as game repellent and the low toxicity consumer intake exposure to blood meal is considered as very unlikely.
Blood meal meets the criteria for inclusion in Annex IV of Regulation (EC) No 396/2005 and is therefore, proposed to be included into Annex IV of Regulation (EC) No 396/2005.

2.7.11. Proposed import tolerances and compliance with existing import tolerances

Not applicable

2.8. FATE AND BEHAVIOUR IN THE ENVIRONMENT

The fate and behaviour in the environment of blood meal residues is expected to follow the normal pathways of dissipation and degradation common to naturally occurring residues of biological origin. Considering the nature of the substance and most methods of application leading to negligible levels of environmental exposure, further consideration of its fate and behaviour in the environment was concluded to be unnecessary since only targeted application methods are intended.

2.8.1. Summary of fate and behaviour in soil

Blood meal contains more than 80 % crude protein. The degradation of organic N-combinations starts with the mineralisation followed by the nitrification. The speed of this process depends on the soil temperature.

The influence of an application with blood meal of 20 kg/ha 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.

2.8.2. Summary of fate and behaviour in water and sediment

The degradation of blood meal follows the normal route of organic N-combinations in nature. The formulation is applied on trees by coating with brush, spraying or dipping of individual plants. Exposure of surface water is negligible. Further studies investigating the fate in water are not required.

2.8.3. Summary of fate and behaviour in air

The formulation is applied on trees by coating with brush, spraying or dipping of individual plants. No exposure of air expected. No study investigating the fate and behaviour in air is required.

2.8.4. Summary of monitoring data concerning fate and behaviour of the active substance, metabolites, degradation and reaction products

Blood meal is used as fertiliser in organic farming in much higher rates than as game repellent: blood meal is included as fertiliser in the Annex I of the Commission Regulation 834/2007 on organic production. Therefore monitoring data are deemed to be unnecessary.

2.8.5. Definition of the residues in the environment requiring further assessment

Not required. The degradation of blood meal follows the normal route of organic N-combinations in nature. Therefore no residue definition is proposed for blood meal for all environmental compartments.

2.8.6. Summary of exposure calculations and product assessment

Soil: No calculations of PECS are deemed necessary and a calculation has not been done upon inclusion in Annex I (see DAR Blood meal, September 2008 and Peer Review document EFSA 2011). Blood meal is included as fertilizer in the Annex I of the Commission Regulation 834/2007 on organic production.
Groundwater: This data point is not applicable as no metabolites of toxicological concern are built during degradation. Blood meal is included as fertilizer in the Annex I of the Commission Regulation 834/2007 on organic production.
Surface water and sediment. 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. The target plants will be sprayed directly and individually with backpack sprayer. Certosan can also be painted on individual target plants or whole plants can be dipped in the solution.
A PEC_{SW} calculation using the program EVA 2.1 was provided. The calculation is based on an application of 20 kg Certosan with a backpack sprayer, the maximum PEC_{SW} value is 6653 µg/L
Air: The product will be coated onto trees with brush, spraying or dipping of individual plants. The product dries off to a protective, water-insoluble film. No exposure of air is expected.
Other routes of exposure: Only targeted application to plant parts or single plants are intended. No other routes of exposure are expected.

2.9. EFFECTS ON NON-TARGET SPECIES

2.9.1. Summary of effects on birds and other terrestrial vertebrates

The waiver for standard toxicity studies on birds presented above is considered acceptable taking into account that Blood meal, consisting mainly out of protein, can serve as food item of omnivorous birds or as a repellent for herbivorous birds. Thus adverse effects posed by Blood meal are considered unlikely and the data requirement is considered sufficiently addressed.

The waiver for standard toxicity studies on mammals presented above is considered acceptable taking into account that Blood meal, consisting mainly out of protein, can serve as food item of omnivorous mammals and is intended to be a repellent for herbivorous mammals.
Thus adverse effects posed by Blood meal are considered unlikely and the data requirement is considered sufficiently addressed.

2.9.2. Summary of effects on aquatic organisms

Fish:
There are no toxicity endpoints on fish available for the pure active substance Blood meal. However an acute toxicity study with the formulation Certosan (99.8% Blood meal) by [redacted] (2013a) submitted for the renewal of Blood meal is presented in Vol. 3 CP B9. This study is considered to address the data requirement sufficiently.

A waiver for the performance of long-term and chronic toxicity studies on fish is considered acceptable. For targeted application methods (coating with brush, dipping) an exposure is considered to be negligible. For less targeted application methods (i.e. spraying) exposure can not be excluded, however the available acute toxicity

studies with the formulation Certosan (99.8% Blood meal) on fish (please refer to Vol. 3 CP B9) are considered sufficient to demonstrate a low concern and to address the data requirement. Even if the active substance Blood meal accidentally enters the surface water, it should be taken in account that Blood meal is commonly used as fish feed.
Therefore in conclusion, adverse long-term effects to fish posed by Blood meal are considered unlikely and the data requirement was sufficiently addressed.

A fish full life cycle study is not required, since Blood meal is neither considered to have a potential for bioaccumulation (see CA, B.9.2.2.3) nor it is a potential endocrine disruptor (see CA, B.9.2.3).

No studies on bioconcentration in fish were submitted for neither Annex I inclusion of Blood meal nor are considered necessary for renewal. 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.
The argumentation above is accepted, potential endocrine disrupting effects posed by Blood meal are considered unlikely and the data requirement was sufficiently addressed.

Table 9.3.1-1 summarises the results of the available acute toxicity study conducted with Certosan ([redacted], 2013a). The relevant endpoint to be used for the acute risk assessment of Certosan (99.8% Blood meal) is the 96-hours LC_{50} > 33.5 mg a.s./L.

Aquatic invertebrates:
There are no toxicity endpoints on *Daphnia* or other aquatic invertebrates available for the pure active substance Blood meal. However an acute toxicity study with the formulation Certosan (99.8% Blood meal) by Muckle (2013b) submitted for the renewal of Blood meal is presented in Vol. 3 CP B9. This study is considered to address the data requirement sufficiently.

A waiver for the performance of long-term and chronic toxicity studies on aquatic invertebrates is considered acceptable. For targeted application methods (coating with brush, dipping) an exposure is considered to be negligible. For less targeted application methods (i.e. spraying) exposure can not be excluded, however the available acute toxicity studies with the formulation Certosan (99.8% Blood meal) on *Daphnia* (please refer to Vol. 3 CP B9) are considered sufficient to demonstrate a low concern and to address the data requirement.
Therefore in conclusion, adverse long-term effects to aquatic invertebrates posed by Blood meal are considered unlikely and the data requirement was sufficiently addressed.

Table 9.3.1-2 summarises the result of the available acute invertebrate toxicity study conducted with Certosan (Muckle, 2013b). The relevant endpoint to be used for the acute risk assessment of Certosan is the 48-hours EC_{50} > 62.4 mg a.s./L, based on mean measured test concentrations.

Algae:
There are no toxicity endpoints on algae available for the pure active substance Blood meal. However an effect study on algae with the formulation Certosan (99.8% Blood meal) by Muckle (2013c) submitted for the renewal of Blood meal is presented in Vol. 3 CP B9. This study is considered to address the data requirement sufficiently.

Table 9.3.1-3 summarises the result of the available effect study on algae conducted with Certosan (Muckle, 2013c). The relevant endpoint to be used for the risk assessment of Certosan is the 72-hours E_rC_{50} > 59 mg a.s./L, based on mean measured test concentrations.

2.9.3. Summary of effects on arthropods

Bees:
Please refer to the acute contact and oral toxicity formulation study with Certosan (99.8% Blood meal) by Kleiner (1996b) from the former evaluation of Blood meal, presented in Vol. 3 CP B9. This study is considered to address the data requirement sufficiently.

No chronic toxicity studies on bees were submitted for neither Annex I inclusion of Blood meal nor are considered necessary for re-evaluation. A waiver is requested since Blood meal is not considered to be an attractive food source for bees, therefore chronic exposure to bees is considered negligible and the data requirement is considered sufficiently addressed.

Table 9.5.1-1 summarises the results of the available acute toxicity study conducted with Certosan (Kleiner, 1996b). The relevant endpoint to be used for the acute risk assessment of Certosan (99.8% Blood meal) is the 48-hours LD_{50} of > 198 µg product/bee for oral toxicity and > 200 µg product/bee for contact toxicity.

Other NTAs:
The waiver for standard toxicity studies on non-target arthropods other than bees presented above is considered acceptable. For targeted application methods (coating with brush, dipping) an exposure is considered to be negligible. For less targeted application methods (i.e. spraying) exposure can not be excluded, however the available toxicity studies with the formulation Certosan (99.8% Blood meal) on non-target arthropods (please refer to Vol. 3 CP B9) are considered sufficient to demonstrate a low concern and to address the data requirement.

Table 9.5.2-1 summarises the result of the available effect study on *Poecilus curpeus* conducted with Certosan (Kleiner, 1996a). The relevant endpoint to be used for the risk assessment of Certosan is the LR_{50} > 40 kg product/ha.

Table 9.5.2-2 summarises the result of the available effect study on *Pardosa spp.* conducted with Certosan (Kleiner, 1996c). The relevant endpoint to be used for the risk assessment of Certosan is the LR_{50} > 40 kg product/ha.

2.9.4. Summary of effects on non-target soil meso- and macrofauna

Earthworms:
The waiver for standard toxicity studies on sub-lethal effects on earthworms is considered acceptable. 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 concern to earthworms and to address the data requirement.

2.9.5. Summary of effects on soil nitrogen transformation

No studies were submitted by the notifier to address the effects on soil nitrogen transformation. The waiver for standard toxicity studies is considered acceptable. 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 fully 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 concern to soil microorganisms and to address the data requirement.

2.9.6. Summary of effects on terrestrial non-target higher plants

No studies were submitted by the notifier to address the effects on non-target plants. The waiver for standard toxicity studies is considered acceptable. 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 fully excluded, however the use of Blood meal as fertiliser, the natural mineralisation of Blood meal (consisting to >80% out of protein) in soil and the absence of phytotoxic effects in the efficacy section is considered sufficient to demonstrate a low concern to non-target plants and to address the data requirement.

2.9.7. Summary of effects on other terrestrial organisms (flora and fauna)

There are no endpoints on other terrestrial organisms available from the former evaluation on Blood meal.
The literature review did not indicate any toxic effects on other terrestrial organisms either. Blood meal is a fertiliser in organic farming. No negative effects on other non-target organisms are reported.

2.9.8. Summary of effects on biological methods for sewage treatment

No studies were submitted by the notifier to address the effects on non-target plants. 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 and the the data requirement is sufficiently addressed.

2.9.9. Summary of product exposure and risk assessment

Birds & mammals

The risk assessment for birds and mammals was conducted according to the EFSA Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009;7(12):1438).

Blood meal consists mainly out of denaturated protein, the formulated product Certosan (99.8% Blood meal) has a non-toxic mode of action and is also considered to be non-toxic by itself.
According to the applicant the following quality criteria are applied to the active substance:

- *Food grade quality Blood collected in authorized slaughterhouses*
- *Destruction of pathogens and protein denaturation occur during Blood processing*
- *Blood of porcine origin*

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 TER values is not considered necessary.

The calculation of acute and long-term toxicity/exposure ratios is not considered necessary

Aquatic organisms

The risk assessment was carried out according to EFSA Journal 2013;11(7):3290.

For targeted application methods (coating with brush, dipping) an exposure is considered to be negligible. For less targeted application methods (i.e. spraying) exposure can not be excluded, however the available acute toxicity studies with the formulation Certosan (99.8% Blood meal) on fish and *Daphnia* as well as effect data on algae are considered sufficient to demonstrate a low concern. Nevertheless a worst case risk assessment based on the PEC/RAC ratio is presented below.

Exposure

Aquatic organisms may be exposed to Blood meal as a consequence of the accidental entry of the compound into the environmental compartments by run-off or drift events. However, these events are highly unlikely, as the common application technique is applying the formulated product directly on the individual trees or parts of trees. Therefore contamination of the environment under good working practice is considered unlikely to occur. If applied under weather conditions as recommended, accidental entry into water systems should be minimal and of no safety concern. Even if the active substance Blood meal is accidentally got into surface water, it should be taken in account that Blood meal is commonly used as fish feed. Nevertheless RMS calculated PEC_{SW} values using FOCUS Step 1 and 2. The application pattern was set to “no interception”, “North Europe, October - February” and the crop type was set to “hand held application, crop <50 cm” and “hand held application, crop > 50 cm” (please refer to Vol. 3 CP B8 B.8.5). The initial worst-case PEC_{SW} values for STEPs 1-2 were used in the risk assessment.

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.

Bees

The risk assessment for honey-bees addresses both the EFSA Bee Guidance Document (EFSA Journal 2013;11(7):3295) and the Terrestrial Ecotoxicology GD (SANCO/10329/2002).

The use pattern involves treatments on deciduous and coniferous trees in forestry, trees in orchards and ornamental plants at a maximum single application rate of 19.96 kg a.s./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.

Other NTAs

The risk assessment was addressed according to the ESCORT 2 Guidance Document (2000).

The use pattern involves treatments on deciduous and coniferous trees in forestry, trees in orchards and ornamental plants at a maximum single application rate of 19.96 kg a.s./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.

Earthworms and other soil non-target organisms

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).

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 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.

Soil nitrogen transformation

The risk assessment for soil nitrogen transformation was addressed according to the Terrestrial Ecotoxicology GD (SANCO/10329/2002).

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).

Non-target terrestrial plants

The risk assessment for non-target plants was addressed according to the Terrestrial Ecotoxicology GD (SANCO/10329/2002).

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), please refer to Vol. 3 CP B3 B.3.11. 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).

2.10. CLASSIFICATION AND LABELLING

Proposed classification according to Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification [1)]	Reason for no classification [2)]
2.1.	Explosives	-	-	-	conclusive but not sufficient for classification
2.2.	Flammable gases	-	-	-	conclusive but not sufficient for classification
2.3.	Flammable aerosols	-	-	-	conclusive but not sufficient for classification
2.4.	Oxidising gases	-	-	-	conclusive but not sufficient for classification
2.5.	Gases under pressure	-	-	-	conclusive but not sufficient for classification
2.6.	Flammable liquids	-	-	-	conclusive but not sufficient for classification
2.7.	Flammable solids	-	-	-	conclusive but not sufficient for classification
2.8.	Self-reactive substances and mixtures	-	-	-	conclusive but not sufficient for classification
2.9.	Pyrophoric liquids	-	-	-	conclusive but not sufficient for classification
2.10.	Pyrophoric solids	-	-	-	conclusive but not sufficient for classification
2.11.	Self-heating substances and mixtures	-	-	-	conclusive but not sufficient for classification
2.12.	Substances and mixtures which in contact with water emit flammable gases	-	-	-	conclusive but not sufficient for classification
2.13.	Oxidising liquids	-	-	-	conclusive but not sufficient for classification
2.14.	Oxidising solids	-	-	-	conclusive but not sufficient for classification
2.15.	Organic peroxides	-	-	-	conclusive but not sufficient for classification
2.16.	Substance and mixtures corrosive to metals	-	-	-	conclusive but not sufficient for classification

3.1.	Acute toxicity - oral	-	-	-	conclusive but not sufficient for classification
	Acute toxicity - dermal	-	-	-	conclusive but not sufficient for classification
	Acute toxicity - inhalation	-	-	-	conclusive but not sufficient for classification
3.2.	Skin corrosion / irritation	-	-	-	conclusive but not sufficient for classification
3.3.	Serious eye damage / eye irritation	-	-	-	conclusive but not sufficient for classification
3.4.	Respiratory sensitisation	-	-	-	conclusive but not sufficient for classification
3.4.	Skin sensitisation	-	-	-	conclusive but not sufficient for classification
3.5.	Germ cell mutagenicity	-	-	-	conclusive but not sufficient for classification
3.6.	Carcinogenicity	-	-	-	conclusive but not sufficient for classification
3.7.	Reproductive toxicity	-	-	-	conclusive but not sufficient for classification
3.8.	Specific target organ toxicity –single exposure	-	-	-	conclusive but not sufficient for classification
3.9.	Specific target organ toxicity – repeated exposure	-	-	-	conclusive but not sufficient for classification
3.10.	Aspiration hazard	-	-	-	conclusive but not sufficient for classification
4.1.	Hazardous to the aquatic environment	-	-	-	conclusive but not sufficient for classification
5.1.	Hazardous to the ozone layer	-	-	-	conclusive but not sufficient for classification

[1)] Including specific concentration limits (SCLs) and M-factors
[2)] Data lacking, inconclusive, or conclusive but not sufficient for classification

Labelling: Signal word: -
Hazard statements: -
Precautionary statements: -

Proposed notes assigned to an entry:
Notes in accordance with CLP Regulation, Annex VI, Section 1.1.3

Proposed classification according to Dangerous Substances Directive (Directive 67/548/EEC)

Hazardous property	**Proposed classification**	**Proposed SCLs**	**Current classification [1)]**	**Reason for no classification [2)]**
Explosiveness	-	-	-	conclusive but not sufficient for classification
Oxidising properties	-	-	-	conclusive but not sufficient for classification
Flammability	-	-	-	conclusive but not sufficient for classification
Other physico-chemical properties *[Add rows when relevant]*	-	-	-	conclusive but not sufficient for classification
Thermal stability	-	-	-	conclusive but not sufficient for classification
Acute toxicity	-	-	-	conclusive but not sufficient for classification
Acute toxicity – irreversible damage after single exposure	-	-	-	conclusive but not sufficient for classification
Repeated dose toxicity	-	-	-	conclusive but not sufficient for classification
Irritation / Corrosion	-	-	-	conclusive but not sufficient for classification
Sensitisation	-	-	-	conclusive but not sufficient for classification
Carcinogenicity	-	-	-	conclusive but not sufficient for classification
Mutagenicity – Genetic toxicity	-	-	-	conclusive but not sufficient for classification
Toxicity to reproduction – fertility	-	-	-	conclusive but not sufficient for classification
Toxicity to reproduction – development	-	-	-	conclusive but not sufficient for classification
Toxicity to reproduction – breastfed babies. Effects on or via lactation	-	-	-	conclusive but not sufficient for classification
Environment	-	-	-	conclusive but not sufficient for classification

[1)] Including SCLs
[2)] Data lacking, inconclusive, or conclusive but not sufficient for classification

Labelling: Indication of danger: -
R-phrases: -
S-phrases: -

2.11. RELEVANCE OF METABOLITES IN GROUNDWATER

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.

No Metabolites were identified for Blood meal.

2.11.1. STEP 1: Exclusion of degradation products of no concern

Not required.

2.11.2. STEP 2: Quantification of potential groundwater contamination

No Metabolites were identified for Blood meal.

2.11.3. STEP 3: Hazard assessment – identification of relevant metabolites

2.11.3.1 STEP 3, Stage 1: screening for biological activity
Not required.

2.11.3.2 STEP 3, Stage 2: screening for genotoxicity
Not required.

2.11.3.3 STEP 3, Stage 3: screening for toxicity
Not required.

2.11.4. STEP 4: Exposure assessment – threshold of concern approach

Not required.

2.11.5. STEP 5: Refined risk assessment

Not required.

2.11.6. Overall conclusion

No metabolites of toxicological concern are built during degradation.

2.12. CONSIDERATION OF ISOMERIC COMPOSITION IN THE RISK ASSESSMENT

2.12.1. Identity and physical chemical properties
Not relevant.

2.12.2. Methods of analysis

Not relevant.

2.12.3. Mammalian toxicity
Not relevant.

2.12.4. Operator, Worker, Bystander and Resident exposure
Not relevant.

2.12.5. Residues and Consumer risk assessment
Not relevant.

2.12.6. Environmental fate
Not relevant.

2.12.7. Ecotoxciology
Not relevant.

2.13. RESIDUE DEFINITIONS

2.13.1. Definition of residues for exposure/risk assessment

Food of plant origin: Blood meal is proposed to be included in Annex IV of Regulation (EC) No 396/2005. Therefore, no residue definition is proposed.

Food of animal origin: Blood meal is proposed to be included in Annex IV of Regulation (EC) No 396/2005. Therefore, no residue definition is proposed.

Soil: The degradation of blood meal follows the normal route of organic N-combinations in nature. Therefore, no residue definition is proposed.

Groundwater: The degradation of blood meal follows the normal route of organic N-combinations in nature. Therefore, no residue definition is proposed.

Surface water: The degradation of blood meal follows the normal route of organic N-combinations in nature. Therefore, no residue definition is proposed.

Sediment: The degradation of blood meal follows the normal route of organic N-combinations in nature. Therefore, no residue definition is proposed.

Air: The degradation of blood meal follows the normal route of organic N-combinations in nature. Therefore, no residue definition is proposed.

2.13.2. Definition of residues for monitoring

Food of plant origin: Blood meal is proposed to be included in Annex IV of Regulation (EC) No 396/2005. Therefore, no residue definition is proposed.

Food of animal origin: Blood meal is proposed to be included in Annex IV of Regulation (EC) No 396/2005. Therefore, no residue definition is proposed.

Soil: The degradation of blood meal follows the normal route of organic N-combinations in nature. Therefore, no

residue definition is proposed.

Groundwater: The degradation of blood meal follows the normal route of organic N-combinations in nature. Therefore, no residue definition is proposed.

Surface water: The degradation of blood meal follows the normal route of organic N-combinations in nature. Therefore, no residue definition is proposed.

Sediment: The degradation of blood meal follows the normal route of organic N-combinations in nature. Therefore, no residue definition is proposed.

Air: The degradation of blood meal follows the normal route of organic N-combinations in nature. Therefore, no residue definition is proposed.

Level 3

Blood meal

3. PROPOSED DECISION WITH RESPECT TO THE APPLICATION

3.1. BACKGROUND TO THE PROPOSED DECISION

3.1.1. Proposal on acceptability against the decision making criteria – Article 4 and annex II of regulation (EC) No 1107/2009

3.1.1.1. Article 4				
		Yes	No	
i)	It is considered that Article 4 of Regulation (EC) No 1107/2009 is complied with. Specifically the RMS considers that authorisation in at least one Member State is expected to be possible for at least one plant protection product containing the active substance for at least one of the representative uses.	x		Representative uses considered to comply with Article 4
3.1.1.2. Submission of further information				
		Yes	No	
i)	It is considered that a complete dossier has been submitted	x		Dossier is considered to be complete for the evaluation.
ii)	It is considered that in the absence of a full dossier the active substance may be approved even though certain information is still to be submitted because: (a) the data requirements have been amended or refined after the submission of the dossier; or (b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision.			Not required. Dossier is considered to be complete for the evaluation.
3.1.1.3. Restrictions on approval				
		Yes	No	
	It is considered that in line with Article 6 of Regulation (EC) No 1107/2009 approval should be subject to conditions and restrictions.		x	Fate: No restrictions required.
3.1.1.4. Criteria for the approval of an active substance				
Dossier				
		Yes	No	
	It is considered that the dossier contains the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and Acute Reference Dose (ARfD).			Not applicable. The toxicological requirements for this submission were waived. On the basis that there is no toxicological concern associated with the use of this active ingredient, the setting of toxicological endpoints was not required and a risk assessment was not conducted.

	It is considered that the dossier contains the information necessary to carry out a risk assessment and for enforcement purposes (relevant for substances for which one or more representative uses includes use on feed or food crops or leads indirectly to residues in food or feed). In particular it is considered that the dossier: (a) permits any residue of concern to be defined; (b) reliably predicts the residues in food and feed, including succeeding crops (c) reliably predicts, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing; (d) permits a maximum residue level to be defined and to be determined by appropriate methods in general use for the commodity and, where appropriate, for products of animal origin where the commodity or parts of it is fed to animals; (e) permits, where relevant, concentration or dilution factors due to processing and/or mixing to be defined.	X		All relevant data were submitted to address the consumer exposure. Based on the assessment of the available data for blood meal no MRL has to be established and blood meal is proposed to be included in Annex IV of Regulation (EC) No 396/2005.
	It is considered that the dossier submitted is sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.	X		See detailed evaluation in sections 8 and 9.
Efficacy				
		Yes	No	
	It is considered that it has been established for one or more representative uses that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective.	X		Representative uses are already authorized on national level and have been evaluated according to uniform principles. Certosan at the max. dose of 20 kg/ha achieved 78-91 % control against damage caused by game species (1CERVF, 1LEPUF) on forest trees. A limited set of data is available for uses in fruit trees, and ornamentals, and no data are available for MICRAR. For further information see 2.3.
Relevance of metabolites				
		Yes	No	
	It is considered that the documentation submitted is sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.	X		The degradation of blood meal follows the normal route of organic N-combinations in nature. Metabolites were not determined, further studies are not required considering natural N-content in soil and negligible exposure.
Composition				
		Yes	No	
	It is considered that the specification defines the minimum degree of	X		Blood meal contains ≥ 990 g/kg haemoglobin as an active substance.

	purity, the identity and maximum content of impurities and, where relevant, of isomers/diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.			
	It is considered that the specification is in compliance with the relevant Food and Agriculture Organisation specification, where such specification exists.			Not relevant
	It is considered for reasons of protection of human or animal health or the environment, stricter specifications than that provided for by the FAO specification should be adopted			Not relevant
Methods of analysis				
		Yes	No	
	It is considered that the methods of analysis of the active substance, safener or synergist as manufactured and of determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities greater than 1 g/kg in the active substance, safener or synergist as manufactured, have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.	X		As the whole natural product is regarded as active substance, no specific analytical method can be proposed to analyse Blood meal. The concentration of Blood meal (Certosan) was determined through a mehod using ICP-OES via measurement of Iron the filtratered test solutions.
	It is considered that the methods of residue analysis for the active substance and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.			Not relevant, see Level 2, Section 2.13
	It is confirmed that the evaluation has been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.	X		
Impact on human health				
Impact on human health - ADI, AOEL, ARfD				
		Yes	No	
	It is confirmed that (where relevant) an ADI, AOEL and ARfD can be established with an appropriate safety margin of at least 100 taking into account the type and severity of effects and the vulnerability of specific groups of the population.			Not applicable. The toxicological requirements for this submission were waived. On the basis that there is no toxicological concern associated with the use of this active ingredient, the setting of toxicological endpoints was not required and a risk assessment was not conducted.
Impact on human health – proposed genotoxicity classification				
		Yes	No	
	It is considered that, on the basis of assessment of higher tier		X	Not applicable. Since blood meal has food grade quality, no data are

	genotoxicity testing carried out in accordance with the data requirements and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as mutagen category 1A or 1B.**			necessary.
Impact on human health – proposed carcinogenicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as carcinogen category 1A or 1B.**		X	Not applicable. Since blood meal has food grade quality, no data are necessary.
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			Not applicable.
Impact on human health – proposed reproductive toxicity classification				
		Yes	No	
i)	It is considered that, on the basis of assessment of the reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as toxic for reproduction category 1A or 1B.**		X	Not applicable. Since blood meal has food grade quality, no data are necessary.
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic			Not applicable.

	proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			
Impact on human health – proposed endocrine disrupting properties classification				
		Yes	No	
i)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **carcinogenic category 2 and toxic for reproduction category 2 and on that basis shall be considered to have endocrine disrupting properties**		X	Not relevant anymore. At the time of evaluation the interim criteria are replaced by the scientific criteria for the determination of endocrine disrupting properties outlined in Regulation (EU) 2018/605. Blood meal does not present a toxicological concern and all other toxicological data requirements were waived. An ED assessment following the new ECHA/EFSA - Guidance for the identification of endocrine disruptors is therefore not required. Since blood meal has food grade quality, no data are necessary.
ii)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **toxic for reproduction category 2 and** in addition the RMS considers the substance **has toxic effects on the endocrine organs and on that basis shall be considered to have endocrine disrupting properties**		X	Not relevant anymore. See above.
iii)	Linked to either i) or ii) immediately above. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			Not applicable.
Fate and behaviour in the environment				
Persistent organic pollutant (POP)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent organic pollutant (POP) as laid out in Regulation 1107/2009		X	The fate and behaviour in the environment of blood meal residues is expected to follow the normal pathways of dissipation and degradation common to naturally occurring residues of biological origin. Considering the nature of the

	Annex II Section 3.7.1.			substance and most methods of application leading to negligible levels of environmental exposure, further consideration of its fate and behaviour in the environment was concluded to be unnecessary since only targeted application methods are intended.
Persistent, bioaccumulative and toxic substance (PBT)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent, bioaccumulative and toxic (PBT) substance as laid out in Regulation 1107/2009 Annex II Section 3.7.2.		X	The fate and behaviour in the environment of blood meal residues is expected to follow the normal pathways of dissipation and degradation common to naturally occurring residues of biological origin. Considering the nature of the substance and most methods of application leading to negligible levels of environmental exposure, further consideration of its fate and behaviour in the environment was concluded to be unnecessary since only targeted application methods are intended.
Very persistent and very bioaccumulative substance (vPvB).				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a a very persistent and very bioaccumulative substance (vPvB) as laid out in Regulation 1107/2009 Annex II Section 3.7.3.		X	The fate and behaviour in the environment of blood meal residues is expected to follow the normal pathways of dissipation and degradation common to naturally occurring residues of biological origin. Considering the nature of the substance and most methods of application leading to negligible levels of environmental exposure, further consideration of its fate and behaviour in the environment was concluded to be unnecessary since only targeted application methods are intended.
Ecotoxicology				
		Yes	No	
	It is considered that the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) under realistic proposed conditions of use of a plant protection product containing the active substance, safener or synergist. The RMS is content that the assessment takes into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance, safener or synergist is expected to affect adversely by the intended use.	X		An acceptable risk to all organisms relevant for the ecotoxicology assessment is considered to be demonstrated. Please refer to Level 2 2.9 above for the summaries of the risk assessment.
	It is considered that, on the basis of the assessment of Community or internationally agreed test guidelines, the substance **HAS** endocrine		X	Endocrine disrupting effects are considered unlikely.

	disrupting properties that may cause adverse effects on non-target organisms.			
	Linked to the consideration of the endocrine properties immediately above. It is considered that the exposure of non-target organisms to the active substance in a plant protection product under realistic proposed conditions of use is negligible.		X	Exposure is not considered neglible due to the method of application (which also includes less targeted methods like spraying). However relevant exposure of non-target organisms is considered to be unlikely, or only to a small extent, and moreover endocrine disrupting effects are considered unlikely.
	It is considered that it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist: — will result in a negligible exposure of honeybees, or — has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.	X		Exposure to honey bees is considered unlikely and acute contact and oral toxicity are low. Please refer to Level 2 2.9 for the summary of the risk assessment.
Residue definition				
		Yes	No	
	It is considered that, where relevant, a residue definition can be established for the purposes of risk assessment and for enforcement purposes.		X	Blood meal meets the criteria for inclusion in Annex IV of Regulation (EC) No 396/2005 and is therefore, proposed to be included into Annex IV of Regulation (EC) No 396/2005. No MRL has to be established and a residue definition is not considered relevant.
Fate and behaviour concerning groundwater				
		Yes	No	
	It is considered that it has been established for one or more representative uses, that consequently after application of the plant protection product consistent with realistic conditions on use, the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater complies with the respective criteria of the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.	X		The fate and behaviour in the environment of blood meal residues is expected to follow the normal pathways of dissipation and degradation common to naturally occurring residues of biological origin. Considering the nature of the substance and most methods of application leading to negligible levels of environmental exposure, further consideration of its fate and behaviour in the environment was concluded to be unnecessary since only targeted application methods are intended.

3.1.2. Proposal – Candidate for substitution

Candidate for substitution				
		Yes	No	
	It is considered that the active substance shall be approved as a candidate for substitution		X	

3.1.3. Proposal – Low risk active substance

Low-risk active substances				
		Yes	No	
	It is considered that the active substance **shall be considered of low risk.** In particular it is considered that the substance **should NOT be classified or proposed for classification** in accordance with Regulation (EC) No 1272/2008 as at least one of the following: — carcinogenic, — mutagenic, — toxic to reproduction, — sensitising chemicals, — very toxic or toxic, — explosive, — corrosive. In addition it is considered that **the substance is NOT**: — persistent (half-life in soil more than 60 days), — has a bioconcentration factor higher than 100, — is deemed to be an endocrine disrupter, or — has neurotoxic or immunotoxic effects.	X		Half-life in soil was not determined and is not required.

3.1.4. List of studies to be generated, still ongoing or available but not peer reviewed

Data gap	**Relevance in relation to representative use(s)**	**Study status**		
		No confirmation that study available or on-going.	**Study on-going and anticipated date of completion**	**Study available but not peer-reviewed**
3.1.4.1. Identity of the active substance or formulation				
None				
3.1.4.2. Physical and chemical properties of the active substance and physical, chemical and technical properties of the formulation				
None				
3.1.4.3. Data on uses and efficacy				
None				
3.1.4.4. Data on handling, storage, transport, packaging and labelling				
None				
3.1.4.5. Methods of analysis				
None				
3.1.4.6. Toxicology and metabolism				
None				
3.1.4.7. Residue data				
None				
3.1.4.8. Environmental fate and behaviour				
None				

3.1.4.9. Ecotoxicology				
None				

3.1.5. Issues that could not be finalized

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) No 546/2011, and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

Area of the risk assessment that could not be finalised on the basis of the available data	**Relevance in relation to representative use(s)**
None	*[specify if measure relates to a specific representative use/use scenario/product or to all uses/products]*

3.1.6. Critical areas of concern

An issue is listed as a critical area of concern:
(a) where the substance does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II of Regulation (EC) No 1107/2009 and the applicant has not provided detailed evidence that the active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, taking into account risk mitigation measures to ensure that exposure of humans and the environment is minimised, or
(b) where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

Critical area of concern identified	**Relevance in relation to representative use(s)**
None	*[specify if concern relates to all or specific representative use/use scenario/product or to all uses/products]*

3.1.7. Overview table of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in 3.3.1, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)
All columns are grey as the material tested in the toxicological studies has not been demonstrated to be representative of the technical specification.

Representative use		Deciduous and coniferous trees in forestry Game repellent, Coating with brush, Spraying or dipping individual plants, entire plants (CEU+NEU)	Trees in orchards Game repellent, Coating with brush, Spraying or dipping individual plants, entire plants (CEU+NEU)	Ornamental plants Game repellent, Coating with brush, Spraying or dipping individual plants, entire plants (CEU+NEU)	Deciduous and coniferous trees in forestry agriculture and garden Game repellent, Coating with brush or dipping individual plants; entire plants (NEU)	Deciduous and coniferous trees in forestry agriculture and garden Vole repellent, Coating with brush or dipping individual plants; entire plants (NEU)	Deciduous and coniferous trees in forestry agriculture and garden Vole repellent, Spraying individual plants; entire plants (NEU)
Operator risk	Risk identified	-	-	-	-	-	-
	Assessment not finalised	-	-	-	-	-	-
Worker risk	Risk identified	-	-	-	-	-	-
	Assessment not finalised	-	-	-	-	-	-
Bystander risk	Risk identified	-	-	-	-	-	-
	Assessment not finalised	-	-	-	-	-	-
Consumer risk	Risk identified	-	-	-	-	-	-
	Assessment not finalised	-	-	-	-	-	-
Risk to wild non target terrestrial vertebrates	Risk identified	-	-	-	-	-	-
	Assessment not finalised	-	-	-	-	-	-
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	-	-	-	-	-	-
	Assessment not finalised	-	-	-	-	-	-
Risk to aquatic organisms	Risk identified	-	-	-	-	-	-
	Assessment not finalised	-	-	-	-	-	-
Groundwater exposure active substance	Legal parametric value breached	-	-	-	-	-	-
	Assessment not finalised	-	-	-	-	-	-

Groundwater exposure metabolites	Legal parametric value breached	-	-	-	-	-	-
	Parametric value of 10µg/L[(a)] breached	-	-	-	-	-	-
	Assessment not finalised	-	-	-	-	-	-
Comments/Remarks		-	-	-	-	-	-

The superscript numbers in this table relate to the numbered points indicated within chapter 3.1.5 and 3.1.6. Where there is no superscript number, see level 2 for more explanation.
CEU: Central Zone of European Union
NEU: Northern Zone of European Union
(a): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

3.1.8. Area(s) where expert consultation is considered necessary

It is recommended to organise a consultation of experts on the following parts of the assessment report:

Area(s) where expert consultation is considered necessary	**Justification**
None	*[specify the reasons why expert consultation is considered necessary]*

3.1.9. Critical issues on which the Co RMS did not agree with the assessment by the RMS

Points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur member state. Only the points relevant for the decision making process should be listed.

Issue on which Co-RMS disagrees with RMS	**Opinion of Co-RMS**	**Opinion of RMS**
None		

3.2. PROPOSED DECISION

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

3.3. RATIONAL FOR THE CONDITIONS AND RESTRICTIONS TO BE ASSOCIATED WITH THE APPORVAL OR AUTHORISATION(S), AS APPROPRIATE

3.3.1. Particular conditions proposed to be taken into account to manage the risks identified

Proposed condition/risk mitigation measure	Relevance in relation to representative use(s)
[redacted]	[redacted]

3.4. APPENDICES

GUIDANCE DOCUMENTS USED IN THIS ASSESSEMENT

Section (Volume 3 – B1): Identity
None

Section (Volume 3 - B2): Physicochemical properties
None

Section Data on application and efficacy
Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) 283/2013 and Regulation (EU) No 284/2013 (SANCO/10181/2013– rev. 3, December 2014).

Guidance document on data requirements on efficacy for the dossier to be submitted for the approval of new active substances contained in plant protection products (SANCO/10054/2013-rev.3 of 11. July 2013).

Section (Volume 3 - B5): Analytical methods
Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414 (SANCO/3030/99 rev. 4)

Section Toxicology

EFSA (2011). Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092

Section Residue and consumer risk assessment

EC (European Commission), 2011. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs; 7525/VI/95-rev.10.3

EFSA (2011). Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092

Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) 283/2013 and Regulation (EU) No 284/2013 (SANCO/10181/2013– rev. 2, May 2013)

Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) N° 396/2005, SANCO/11188/2013, Rev. 2, 14 September 2015

Section fate and behavior in environment

EFSA (2011). Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092.

EC (2015) Generic guidance for FOCUS surface water Scenarios. Version: 1.4, May 2015

Section ecotoxicology

EFSA (European Food Safety Authority), 2009. Guidance Document on Risk Assessment for Birds and Mammals on request of EFSA. EFSA Journal 2009; 7(12):1438.

EFSA (European Food Safety Authority), 2013. EFSA Scientific Opinion. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013; 11(7): 3290.

EFSA (European Food Safety Authority), 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2013;11(7):3295.

SANCO/10329/2002 rev.2. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev.2 final, 17 October 2002.

ESCORT 2: Candolfi, M.P.; Barrett, K.L.; Campbell P.J.; Forster, R.; Grandy, N.; Huet, M.C.; Lewis, G.; Oomen, P.A.; Schmuck, R. & Vogt, H. (2000): Guidance Document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. From the ESCORT 2 workshop, Wageningen, NL.

3.5. REFERENCE LIST

Section identity, physical chemical and analytical methods
Not relevant.

Section data on application and efficacy
Not relevant.

Section toxicology
Not relevant.

Section residue and consumer risk assessment
Not relevant.

Section fate and behavior in environment
Not relevant.

Section ecotoxicology
Not relevant.