Appendix to:

EFSA (European Food Safety Authority), 2020. Conclusion on the peer review of the pesticide risk assessment of the active substance blood meal. EFSA Journal 2020;18(2):6006, 39 pp. doi:10.2903/j.efsa.2020.6006

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Appendix A – List of end points for the active substance and the representative formulation

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

| Active substance (ISO Common Name) | Blood meal |
|-----------------------------------|------------|
| Function (e.g. fungicide)         | Game, vole repellent |
| Rapporteur Member State           | Austria    |
| Co-rapporteur Member State        | Lithuania  |

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

| Chemical name (IUPAC) | Not applicable. |
|-----------------------|-----------------|
| Chemical name (CA)    | Not applicable. |
| CIPAC No              | 909             |
| CAS No                | 90989-74-5      |
| EC No (EINECS or ELINCS) | 292-731-9   |
| FAO Specification (including year of publication) | No FAO specification exists. |
| Minimum purity of the active substance as manufactured | 100 % blood meal haemoglobin content: min 80%. |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | None. |
| The following quality criteria are applied: | Blood meal is an animal by-product from category 3. |
| - blood of porcine origin; | It shall comply with: |
| - food grade quality blood collected in authorised slaughterhouses; | - Regulation (EC) No 1069/2009, |
| - destruction of pathogens and protein denaturation occurring during blood processing; | - Commission Regulation (EU) No 142/2011 |
| Blood meal is an animal by-product from category 3. | - Regulation (EC) No 853/2004 |
| It shall comply with: | - Council Directive 97/78/EC |
| - Regulation (EC) No 1069/2009, | |
| - Commission Regulation (EU) No 142/2011 | |
| - Regulation (EC) No 853/2004 | |
| - Council Directive 97/78/EC | |
| Property            | Value       |
|---------------------|-------------|
| Molecular formula   | Not applicable. |
| Molar mass          | Not applicable. |
| Structural formula  | Not applicable. |
### Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

| Property                                                                 | Value                                                                 |
|--------------------------------------------------------------------------|----------------------------------------------------------------------|
| Melting point (state purity)                                             | Not relevant                                                          |
| Boiling point (state purity)                                             | Not relevant                                                          |
| Temperature of decomposition (state purity)                              | Not relevant                                                          |
| Appearance (state purity)                                                | red brownish powder with vaguely fish like smell.                     |
| Vapour pressure (state temperature, state purity)                       | Not relevant                                                          |
| Henry’s law constant (state temperature)                                | Not relevant                                                          |
| Solubility in water (state temperature, state purity and pH)            | 68.1 - 556.3 mg/L at 20°C (pH 5)                                      |
|                                                                           | the concentration of the test item was in the range                    |
|                                                                           | 23.1 – 729.1 mg/L water p.A. resp. 12.0 - 684.9 mg/L                   |
| Solubility in organic solvents (state temperature, state purity)        | Not relevant                                                          |
| Surface tension (state concentration and temperature, state purity)     | Not relevant                                                          |
| Partition coefficient (state temperature, pH and purity)                | Not relevant                                                          |
| Dissociation constant (state purity)                                    | Not relevant                                                          |
| UV/VIS absorption (max.) incl. $\varepsilon$ (state purity, pH)         | Not relevant                                                          |
| Flammability (state purity)                                              | Not considered as highly flammable, not considered as auto-flammable. |
| Explosive properties (state purity)                                     | Not relevant                                                          |
| Oxidising properties (state purity)                                     | Not relevant                                                          |
| Crop and/or situation (a) | Member State or Country | Product name | FG or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | PHI (days) (m) | Remarks |
|--------------------------|--------------------------|--------------|-------------|----------------------------------------|-------------|------------|-------------------------------|----------------|---------|
| Deciduous and coniferous trees in forestry 3FORC | Central North | Certosan F | Game repellent 1CERVF, DAMADA, CAPRCA, ALCASAL; 1LEPUF (LEPUSP, ORYTCU) | WP 99.8 % | Coating with brush, Spraying or dipping individual plants, entire plants | all seasons 1 - | 4.99 - 24.95 | 80-400 | 19.96 na |
| Trees in orchards 3FRUC | Central North | Certosan F | Game repellent 1CERVF, DAMADA, CAPRCA, ALCASAL; 1LEPUF (LEPUSP, ORYTCU) | WP 99.8 % | Coating with brush, Spraying or dipping individual plants, entire plants | all seasons 1 - | 4.99 - 24.95 | 80-400 | 19.96 na |
| Ornamental plants 3ORTC | Central North | Certosan F | Game repellent 1CERVF, DAMADA, CAPRCA; 1LEPUF (LEPUSP, ORYTCU) | WP 99.8 % | Coating with brush, Spraying or dipping individual plants, entire plants | all seasons 1 - | 4.99 - 24.95 | 80-400 | 19.96 na |
| Deciduous and coniferous trees in forestry 3FORC Agriculture and garden 3FRUC, 3ORTC | North | Certosan F | Game repellent 1CERVF, DAMADA, CAPRCA; 1LEPUF (LEPUSP, ORYTCU) | WP 99.8 % | Coating with brush or dipping individual plants; entire plants | all seasons 1 - | 7.5 - 10 | 5-15 | 19.96 na | Coating/painting: 500 g/1000 plants dipping: 750 g/1000 plants |
| Crop and/or situation (a) | Member State or Country | Product name | F G or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | PHI (days) (m) | Remarks |
|--------------------------|-------------------------|--------------|--------------|--------------------------------------|-------------|------------|-------------------------------|----------------|---------|
| Deciduous and coniferous trees in forestry 3FORC Agriculture and garden 3FRUC, 3ORTC | North | Certosan | F | Vole repellent MICRAR | WP 99.8% Coating with brush or dipping individual plants; entire plants | all seasons | 1 | - | 7.5-10 | 5-15 | 19.96 | na | Coating/painting: 500 g/1000 plants dipping: 750 g/1000 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 seasons | 1 | - | 4.99 - 24.95 | 80-400 | 19.96 | na | |

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypry). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval
Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (blood meal) Regulation (EC) No 1107/2009 Article 8.1(g))

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

| Crop and/or situation (a) | Member State or Country | Product name | F G or I (b) | Pests or Group of pests controlled (c) | Preparation Type (d-f) | Conc. a.s. (i) | method kind (f-h) | range of growth stages & season (j) | number min-max (k) | Interval between application (min) | Application rate per treatment kg a.s./ha min-max (l) | Water L/ha min-max | kg a.s./ha min-max (l) | PHI (days) (m) | Remarks |
|--------------------------|-------------------------|--------------|-------------|--------------------------------------|------------------------|----------------|------------------|-----------------------------------|------------------|---------------------------------|-------------------------------|------------------|--------------------------|------------|---------|
| MRL Application for inclusion of blood meal into Annex IV of Regulation 396/2005 (according to Article 8.1(g) of Regulation (EC) No 1107/2009) | None |

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval
Further information, Efficacy

Effectiveness (Regulation (EU) Nº 284/2013, Annex Part A, point 6.2)

Representative uses are already authorized at national level and have been evaluated according to uniform principles.

Uses as game repellent in forestry: Certosan at the max. dose of 20 kg/ha achieved 78-91 % control against damage caused by game species (ICERVF, ILEPUF).

Uses as game repellent in orchards (fruit trees) and ornamentals: A limited set of data is available for uses in fruit trees and ornamentals, and no data are available for MICRAR.

Adverse effects on field crops (Regulation (EU) Nº 284/2013, Annex Part A, point 6.4)

Uses in forestry: No signs of phytotoxicity were visible on forest trees. A negative effect on the yield of forest trees is not expected, and processing is not relevant. Certosan seems to be safe to forest plants.

Uses in orchards (fruit trees) and ornamentals: A limited set of crop safety data is available for uses in fruit trees, and in ornamentals.

All uses: A negative impact on yield is unlikely. A negative impact on the quality of fruit or trees, and so on processing cannot be excluded. The quality of ornamentals may also be negatively affected.

Observations on other undesirable or unintended side-effects (Regulation (EU) Nº 284/2013, Annex Part A, point 6.5)

Due to the selectivity of Certosan, any negative impact on adjacent crops and on propagation is unlikely.

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

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

Activity against target organism

No data submitted, not required.
Methods of Analysis

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

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

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

Residue definitions for monitoring purposes

| Food of plant origin | Not required (no residue definition) |
| Food of animal origin | Not required |
| Soil | Not required |
| Sediment | Not required |
| Water | Not required |
| Surface | blood meal |
| Drinking/ground | blood meal |
| Air | Not required |
| Body fluids and tissues | Not required |

Monitoring/Enforcement methods

| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | No residue definition. |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | Not relevant. |
| Soil (analytical technique and LOQ) | Not relevant. |
| Water (analytical technique and LOQ) | ICP-OES, LOQ 1 µg/L of iron |
| Air (analytical technique and LOQ) | Not relevant. |
| Body fluids and tissues (analytical technique and LOQ) | Not relevant, not needed. |
### Classification and labelling with regard to physical and chemical data (Regulation (EU) No 283/2013, Annex Part A, point 10)

| Substance | Blood meal |
|-----------|------------|
| Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]¹: | No current harmonised classification from physical/chemical point of view. |
| Peer review considerations: | No classification. |

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

Blood meal has a non-toxic mode of action and is non-toxic by itself. 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 occurring during blood processing**
- **Blood of porcine origin**

Blood meal is produced in accordance with current feed and food EU legislations. Based upon these statements, taking into account that the substance does not in itself present a toxicological concern, and that blood is a major constituent of the human body and in general of all vertebrates, the waiver for toxicological studies was deemed acceptable.

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

| Parameter                                                                 | Result                      |
|--------------------------------------------------------------------------|-----------------------------|
| Rate and extent of oral absorption/systemic bioavailability              | No data - not required      |
| Toxicokinetics                                                           | No data - not required      |
| Distribution                                                             | No data - not required      |
| Potential for bioaccumulation                                            | No data - not required      |
| Rate and extent of excretion                                             | No data - not required      |
| Metabolism in animals                                                    | No data - not required      |
| In vitro metabolism                                                      | No data - not required      |
| Toxicologically relevant compounds (animals and plants)                  | No data - not required      |
| Toxicologically relevant compounds (environment)                         | No data - not required      |

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

| Parameter                  | Result                      |
|----------------------------|-----------------------------|
| Rat LD<sub>50</sub> oral   | No data - not required      |
| Rat LD<sub>50</sub> dermal  | No data - not required      |
| Rat LC<sub>50</sub> inhalation | No data - not required |
| Skin irritation            | No data - not required      |
| Eye irritation             | No data - not required      |
| Skin sensitisation         | No data - not required      |
| Phototoxicity              | No data - not required      |

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

| Parameter                 | Result                      |
|---------------------------|-----------------------------|
| Target organ / critical effect | No data - not required |
| Relevant oral NOAEL       | No data - not required      |
| Relevant dermal NOAEL     | No data - not required      |
Relevant inhalation NOAEL

| Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4) |
|---------------------------------------------------------------|
| In vitro studies                                          | No data - not required |
| In vivo studies                                          | No data - not required |
| Photomutagenicity                                        | No data - not required |
| Potential for genotoxicity                                | No data - not required |

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

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

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

| Reproduction toxicity                                    |
|----------------------------------------------------------|
| Reproduction target / critical effect                    | No data - not required |
| Relevant parental NOAEL                                  | No data - not required |
| Relevant reproductive NOAEL                              | No data - not required |
| Relevant offspring NOAEL                                 | No data - not required |

Developmental toxicity

| Developmental target / critical effect                   |
|----------------------------------------------------------|
| Relevant maternal NOAEL                                  | No data - not required |
| Relevant developmental NOAEL                             | No data - not required |

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

| Acute neurotoxicity                                      | No data - not required |
| Repeated neurotoxicity                                   | No data - not required |
| Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity) | No data - not required |

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

| Supplementary studies on the active substance | No data - not required |
| Endocrine disrupting properties                | According to the ECHA/EFSA guidance (2018) the ED assessment is waived (see introduction to impact on human and animal health above); blood meal is not an endocrine disruptor in humans. |
Studies performed on metabolites or impurities: No data - not required

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9): No data - not required

### Summary2 (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

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

*The setting of reference values was not deemed necessary as the substance does not present a toxicological concern. Blood meal is food-grade and exposure already exists as blood is consumed as food in various forms in many cultures. This conclusion is in line with the conclusion reached during the previous peer review (EFSA, 2011).

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

Representative formulation: Certosan: No data - not required

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

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

2 If available include also reference values for metabolites
### Classification with regard to toxicological data (Regulation (EU) No 283/2013, Annex Part A, Section 10)

| Substance: | Blood meal |
|------------|------------|
| Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]³: | No current harmonised classification. |
| Peer review considerations: | No classification required. |

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³ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.
Residues in or on treated products food and feed

Metabolism studies, methods of analysis and residue definitions in plants

Not required.

The substance is proposed to be included in Annex IV of Regulation (EC) No 396/2005.

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                       |             |         |                |                |                |
| Root crops                        |             |         |                |                |                |
| Leafy crops                       |             |         |                |                |                |
| Cereals/grass                     |             |         |                |                |                |
| Pulses/oilseeds                  |             |         |                |                |                |
| Miscellaneous                     |             |         |                |                |                |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                     |             |         |                |           |                |
| Leafy crops                          |             |         |                |           |                |
| Cereal (small grain)                 |             |         |                |           |                |
| other                                |             |         |                |           |                |

| Conditions | Stable? | Comment/Source |
|------------|---------|----------------|
|            |         |                |
| Processed commodities (hydrolysis study) | Pasteurisation (20 min, 90°C, pH 4) | Not required |
|-----------------------------------------|----------------------------------|--------------|
|                                         | Baking, brewing and boiling (60 min, 100°C, pH 5) | Not required |
|                                         | Sterilisation (20 min, 120°C, pH 6) | Not required |
| Other processing conditions              |                                   |              |

| Can a general residue definition be proposed for primary crops? | N/A |
| Rotational crop and primary crop metabolism similar? | N/A |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | N/A |

| Plant residue definition for monitoring (RD-Mo) | Not required. Proposed to be included in Annex IV of Regulation (EC) No 396/2005. |
| Plant residue definition for risk assessment (RD-RA) | Not required. Proposed to be included in Annex IV of Regulation (EC) No 396/2005. |
| Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs) | Not applicable |
Stability of residues in plants

Not required.

Blood meal is proposed to be included in Annex IV of Regulation (EC) No 396/2005.

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

Magnitude of residues in plants

Not required.

Blood meal is proposed to be included in Annex IV of Regulation (EC) No 396/2005.

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

| Commodity | Region/Indoor (a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR (b) (mg/kg) | STMR (c) (mg/kg) | CF (d) |
|-----------|------------------|-----------------------------------------------------------------|-----------------|------------------------|---------------|-----------------|-------|
|           |                  |                                                                 |                 |                        |               |                 |       |
| NEU       | Mo: -            | RA: -                                                            |                 |                        |               |                 |       |

Representative uses: game repellent – the use is not relevant
### Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1) – Not required

| Commodity | Region/Indoor (a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR (b) (mg/kg) | STMR (c) (mg/kg) | CF (d) |
|-----------|------------------|---------------------------------------------------------------|----------------|------------------------|----------------|----------------|--------|
| NEU       | Mo: - RA: -      |                                                               |                |                        |                |                |        |
| NEU       | Mo: - RA: -      |                                                               |                |                        |                |                |        |

- Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.
- (a): NEU: Outdoor trials conducted in northern Europe; SEU: Outdoor trials conducted in southern Europe; Indoor: indoor EU trials or Country code: if non-EU trials.
- (b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
- (c): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
- (d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

*Indicates that the MRL is proposed at the limit of quantification.*
Residues in rotational crops

Not required.

Blood meal is proposed to be included in Annex IV of Regulation (EC) No 396/2005.

Overall summary

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | N/A |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | N/A |

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

| Commodity | Region/Indoor (a) | PBI (days) (b) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR (c) (mg/kg) | STMR (d) (mg/kg) | CF (e) |
|-----------|------------------|----------------|---------------------------------------------------------------|----------------|------------------------|----------------|-----------------|-------|
| NEU       | 30               | 120            | Mo: - RA: -                                                  |                | Mo: - RA: -            | Mo: - RA: - |                  |       |
|           |                  | 365            |                                                               |                |                        |                |                  |       |
| SEU       | 30               | 120            |                                                               |                |                        |                |                  |       |
|           |                  | 365            |                                                               |                |                        |                |                  |       |

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

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

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

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

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

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

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

Not required.

Blood meal is proposed to be included in Annex IV of Regulation (EC) No 396/2005.

| Processed commodity | Number of valid studies\(^{(a)}\) | Processing Factor (PF) | \(\text{CF}\_p\)\(^{(b)}\) | Comment/ Source |
|---------------------|-----------------------------------|------------------------|-----------------|----------------|
|                     |                                   | Individual values      | Median PF       | Tentative\(^{(c)}\) |

PF: Processing factor (=Residue level in processed commodity expressed according to RD-Mo/ Residue level in raw commodity expressed according to RD-Mo);
\(\text{CF}\_p\): Conversion factor for risk assessment in processed commodity (=Residue level in processed commodity expressed according to RD-RA / Residue level in processed commodity expressed according to RD-Mo)

\(^{(a)}\): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur)
\(^{(b)}\): Median of the individual conversion factors for each processing residues trial.
\(^{(c)}\): A tentative PF is derived based on a limited dataset.

Residues in livestock

Not relevant. Not required.

Nature of residues and methods of analysis in livestock

Not required.

Blood meal is proposed to be included in Annex IV of Regulation (EC) No 396/2005.
Magnitude of residues in livestock

Summary of the residue data from livestock feeding studies

Not required.

Blood meal is proposed to be included in Annex IV of Regulation (EC) No 396/2005.

**Consumer risk assessment**

Toxicological reference values are not required for blood meal.

The substance is proposed to be included in Annex IV of Regulation (EC) No 396/2005.

| ADI | TMDI according to EFSA PRIMo | Not required |
|-----|------------------------------|--------------|
|     | NTMDI, according to (to be specified) |               |
|     | Highest IEDI, according to EFSA PRIMo (rev.x) |               |
|     | NEDI (% ADI), according to (to be specified) |               |
|     | Assumptions made for the calculations |               |

| ARfD | IESTI (% ARfD), according to EFSA PRIMo | Not required |
|------|------------------------------------------|--------------|
|      | NESTI (% ARfD), according to (to be specified) |               |
|      | Factors included in IESTI and NESTI |               |

Recommended MRLs

No MRLs are recommended. The substance is proposed to be included in Annex IV of Regulation (EC) No 396/2005.
### Environmental fate and behaviour

#### Route of degradation (aerobic) in soil (Regulation (EU) No 283/2013, Annex Part A, point 7.1.1.1)

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

#### Route of degradation (anaerobic) in soil (Regulation (EU) No 283/2013, Annex Part A, point 7.1.1.2)

| Parameter                                                                 | Description                                                                                                                                  |
|---------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| Mineralisation after 100 days                                            | Not required, not relevant.                                                                                                                                 |
| Non-extractable residues after 100 days                                   | Not required, not relevant.                                                                                                                                 |
| Metabolites that may require further consideration for risk assessment    | Not required, not relevant.                                                                                                                                 |

#### Route of degradation (photolysis) on soil (Regulation (EU) No 283/2013, Annex Part A, point 7.1.1.3)

| Parameter                                                                 | Description                                                                                                                                  |
|---------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| Metabolites that may require further consideration for risk assessment    | Not required, not relevant.                                                                                                                                 |
| Mineralisation at study end                                               | Not required, not relevant.                                                                                                                                 |
| Non-extractable residues at study end                                     | Not required, not relevant.                                                                                                                                 |
Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)
Not required.

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)
Not required.

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)
Not required.

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

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

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

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

| Endpoint | Not required, not relevant. |
|----------|-----------------------------|
| Soil accumulation and plateau concentration | |

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)
Not required.

Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)
Not required.
Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Not required.

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

Not required.

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

Not required.

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

| Column leaching | Not required/ not relevant. |
|-----------------|-----------------------------|

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

| Column leaching | Not required/ not relevant. |
|-----------------|-----------------------------|

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

| Lysimeter/ field leaching studies | Not required/ not relevant. |
|-----------------------------------|-----------------------------|

The formulation is applied on trees by coating with brush, spraying or dipping of individual plants. Exposure of surface water is expected to be negligible, when spray is targeted to the base of trees or the trunk. Further studies investigating the fate in water are not required when brushing, dipping or targeted spraying to the base of trees or trunks is employed as an application method. According to the GAP, the formulation can be applied by spraying the entire plant. When less targeted spraying techniques such as tractor-mounted hydraulic sprayers or air-assisted broadcast spraying are employed on the entire plant, further information on the degradation of the active substance in water/sediment is required.

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

| Hydrolytic degradation of the active substance and metabolites > 10 % | Not required/ not relevant. |
|-------------------------------------------------------------------|-----------------------------|
Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %

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

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

Readily biodegradable (yes/no)

No data submitted, substance considered not readily biodegradable.

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

No information available, not required.

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

Not required for the intended application on trees by coating with brush, spraying or dipping of individual plants.

Data gap for intended spray application on entire plant when less targeted spraying techniques such as tractor-mounted hydraulic sprayers or air-assisted broadcast spraying are employed.

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

Direct photolysis in air

Photochemical oxidative degradation in air

Volatilisation

Metabolites

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

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

Generally not applicable, considering the nature of the substance and the limited exposure from the representative uses. The degradation of blood meal follows the normal route of organic N-combinations in nature. However, for the exception where application is made by less targeted spraying techniques such as tractor-mounted hydraulic sprayers or air-assisted broadcast spraying to entire
plants, blood meal requires further consideration by ecotoxicology.

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

Not relevant.

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

| Location                      | Description                                                                 |
|-------------------------------|-----------------------------------------------------------------------------|
| Soil                          | Not relevant.                                                               |
| Surface water                 | Not relevant.                                                               |
| Ground water                  | Not relevant.                                                               |
| Air                           | Not relevant.                                                               |

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

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

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

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

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

**PEC_{gw}** From lysimeter / field studies - Not required/ not relevant.

| Parent       | 1st year | 2nd year | 3rd year |
|--------------|----------|----------|----------|
| Annual average (µg/L) |          |          |          |
### PEC surface water and PEC sediment (Regulation (EU) No 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

**Parent**

| Parameters used in FOCUSsw step 1 and 2 | Blood meal |
|----------------------------------------|------------|

| Parameters used in FOCUSsw step 3 (if performed) | Application rate |
|--------------------------------------------------|------------------|
|                                                   | 20 kg/ha         |

**Parameters used in FOCUSsw step 1 and 2**

| Version control no. of FOCUS calculator: | 3.2 |
|-----------------------------------------|-----|
| Molecular weight (g/mol):               | Not applicable |
| KOC/KOM (mL/g):                         | 10   |
| DT50 soil (d):                          | 1000 days (default) |
| DT50 water/sediment system (d):         | 1000 d(default) |
| DT50 water (d):                         | 1000 |
| DT50 sediment (d):                      | 1000 |
| Crop interception (%):                  | 0 % (no) |

**Parameters used in FOCUSsw step 3 (if performed)**

| Application rate |
|------------------|
| Not relevant.    |

**Crop and growth stage:** hand-held application (<50 cm and <50 cm)

**Number of applications:** 1

**Interval (d):** -

**Application rate(s):** 20000 g a.s./ha

**Application window:** October to February, North-EU

**Metabolite X**

| Parameters used in FOCUSsw step 1 and 2 | Application rate |
|----------------------------------------|------------------|
| Not relevant.                          |                  |

| Parameters used in FOCUSsw step 3 (if performed) |
|--------------------------------------------------|

| FOCUS STEP 1 Scenario | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|-----------------------|--------------------------|--------------------------|--------------------------|
|                       |                          | Actual | TWA | Actual | TWA |
| Hand held < 50 cm     | 0                        | 6760   |    | 675.58 |    |
| Hand held > 50 cm     | 0                        | 7110   |    | 710.22 |    |
| FOCUS STEP 2 Scenario | Day after overall maximum | PEC\textsubscript{SW} (µg/L) | PEC\textsubscript{SED} (µg/kg) |
|----------------------|---------------------------|-----------------------------|-----------------------------|
|                      |                           | Actual                      | TWA            | Actual                      | TWA            |
| Hand held < 50 cm    | 0                         | 3460                        | 345.9          |
| Hand held >50 cm     | 0                         | 3810                        | 380.44         |

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

Method of calculation

- 

**PEC**

Maximum concentration

Not required/ not relevant.
Ecotoxicology

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

| Species          | Test substance | Time scale | End point | Toxicity (mg/kg bw per day) |
|------------------|----------------|------------|-----------|-----------------------------|
| **Birds**        |                |            |           |                             |
| -                | Blood meal (a.s.) | Acute     | LD<sub>50</sub> | No data.                   |
| -                | Certosan (99.8% a.s. w/w) | Acute     | LD<sub>50</sub> | No data.                   |
| -                | Blood meal (a.s.) | Long-term | NOAEL    | No data.                   |
| **Mammals**      |                |            |           |                             |
| -                | Blood meal (a.s.) | Acute     | LD<sub>50</sub> | No data.                   |
| -                | Certosan (99.8% a.s. w/w) | Acute     | LD<sub>50</sub> | No data.                   |
| -                | Blood meal (a.s.) | Long-term | NOAEL    | No data.                   |

Endocrine disrupting properties (Annex Part A, points 8.1.5)

For blood meal, in line with the waiver applied for humans and mammals as non-target organisms, an assessment of the endocrine disruption potential for non-target organisms other than mammals in accordance with the ECHA/EFSA guidance (2018) was not considered scientifically necessary and was thus waived.

Additional higher tier studies (Annex Part A, points 10.1.1.2):
Not required.

Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):
No data.

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

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

No toxicity from the active substance blood meal and the formulated product Certosan is expected to birds and other terrestrial vertebrates. Blood meal can be considered as possible food source for omnivorous/carnivorous terrestrial vertebrates, and is intended to act as a repellent for herbivorous terrestrial vertebrates. Therefore a potential risk to birds and mammals (including the consumption of unintentional oversprayed feed items following spray applications) is considered as low and the calculation of acute and long-term TER values is not considered necessary.
Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)*

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

| Group | Test substance | Time-scale (Test type) | End point | Toxicity |
|-------|----------------|------------------------|-----------|----------|
| **Laboratory tests** | | | | |
| **Fish** | | | | |
| - | a.s. | Acute 96 hr (static, or semi-static or flow-through) | Mortality, LC$_{50}$ | No data. |
| | | | | |
| Rainbow trout *(Oncorhynchus mykiss)* | Certosan (99.8 % Blood meal) | Acute, 96 hr (semi static) | Mortality, LC$_{50}$ | > 33.5 (mm)$_{2}$ |
| - | a.s. | Chronic (static, or semi-static or flow-through) | Growth, or development, or behaviour, or reproduction NOEC | No data. |
| **Aquatic invertebrates** | | | | |
| - | a.s. | 48 h (static, or semi-static or flow-through) | Mortality, EC$_{50}$ | No data. |
| Daphnia magna | Certosan (99.8 % Blood meal) | Acute, 48 hr (semi static) | Mortality, EC$_{50}$ | > 62.4 (mm)$_{2}$ |
| - | a.s. | 21 d (static, or semi-static or flow-through) | Reproduction or development, NOEC | No data. |
| **Sediment-dwelling organisms** | | | | |
| - | a.s. | 28 d (static, or semi-static or flow-through) | NOEC | No data. |
| **Algae** | | | | |
| - | a.s. | 72 h (static, or semi-static or flow-through) | Growth rate: E$_{r}$C$_{50}$ (NOEC) [Biomass: E$_{b}$C$_{50}$ (NOEC) Yield: E$_{y}$C$_{50}$ (NOEC)] | No data. |
| Group | Test substance | Time-scale (Test type) | End point | Toxicity$^1$
|---|---|---|---|---|
| *Desmodesmus subspicatus* | Certosan (99.8 % Blood meal) | 72 hr (static) | Growth rate: Biomass Integral (AUC$^3$): Yield: | $E_{50} > 59$ (mm)$^2$ $E_{10} > 6$ (mm) $NOE < 6$ (mm)$^4$

$E_{50} > 59$ (mm)$^2$ $E_{10} = 1.4$ (mm) $NOE < 6$ (mm)$^4$

$E_{50} = 16.4$ (mm) $E_{10} = 1.1$ (mm) $NOE < 6$ (mm)$^4$

| Higher plant | No data. | Further testing on aquatic organisms | Not required. | For blood meal, in line with the waiver applied for humans and mammals as non-target organisms, an assessment of the endocrine disruption potential for non-target organisms other than mammals in accordance with the ECHA/EFSA guidance (2018) was not considered scientifically necessary and was thus waived.

$^1$ (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; a.s.: active substance

$^2$ Limit of solubility

$^3$ AUC: Area Under the Curve

$^4$ The two lowest test concentrations (nominal 4.6 & 10 mg/L) could not be analytically verified
### Bioconcentration in fish (Annex Part A, point 8.2.2.3)

|                              | Active substance | Metabolite 1 | Metabolite 2 | Metabolite 3 |
|------------------------------|------------------|--------------|--------------|--------------|
| logP<sub>O/w</sub>           |                  |              |              |              |
| Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content) | 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. |              |              |              |
| Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content) |                  |              |              |              |
| Annex VI Trigger for the bioconcentration factor |                  |              |              |              |
| Clearance time (days) (CT<sub>50</sub>) |                  |              |              |              |
| (CT<sub>90</sub>)           |                  |              |              |              |
| Level and nature of residues (%) in organisms after the 14 day depuration phase |                  |              |              |              |
| Higher tier study           |                  |              |              |              |
| Not required.                |                  |              |              |              |
Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) No 284/2013, Annex Part A, point 10.2)

FOCUS step 1-2 – PEC/RAC ratios for all proposed uses when less targeted spraying techniques such as tractor-mounted hydraulic sprayers or air-assisted broadcast spraying are employed for Certosan (1 x 19.8 kg product/ha and 1 x 20 kg product/ha), acceptability of risk: PEC/RAC < 1

| Group | Fish acute | Invertebrates. acute | Algae |
|-------|------------|----------------------|-------|
|       | *Oncorhynchus mykiss* | *Daphnia magna* | *Desmodesmus subspicatus* |
| Endpoint | LC$_{50}$ | EC$_{50}$ | E$_{rC_{50}}$ |
| (µg/L) | > 33500 | > 62400 | > 59000 |
| AF | 100 | 100 | 10 |
| RAC (µg/L) | > 335 | > 624 | 5900 |

**FOCUS Scenario**

PEC$_{gl-max}$ (µg/L)

| Step 1 | PEC$_{gl-max}$ (µg/L) | PEC/RAC | AF | PEC/RAC | AF | PEC/RAC |
|--------|----------------------|---------|----|---------|----|---------|
| spraying < 50 cm | 6760 | < 20.2 | 100 | < 10.8 | 100 | < 1.1 |
| spraying > 50 cm | 7110 | < 21.2 | 100 | < 11.4 | 100 | < 1.2 |

**Step 2**

| spraying < 50 cm | 3460 | < 10.3 | 100 | < 5.5 | 100 | < 0.6 |
| spraying > 50 cm | 3810 | < 11.4 | 100 | < 6.1 | 100 | < 0.7 |

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

For the uses as the more direct application methods to the plants / trees (by brush, hand-held spraying directed to the tree base or trunk, or dipping of individual plants at planting), negligible environmental exposure is expected (see Section 4).
Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

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

| Species        | Test substance       | Time scale/type of endpoint | End point                  | Toxicity          |
|----------------|----------------------|-----------------------------|----------------------------|-------------------|
| -              | Blood meal (a.s.)    | Acute                       | Oral toxicity (LD₅₀)       | No data.          |
| *Apis mellifera* | Certosan (99.8% Blood meal) | Acute (48 h)               | Oral toxicity (LD₅₀)       | > 198 µg product/bee |
| -              | Blood meal (a.s.)    | Acute                       | Contact toxicity (LD₅₀)    | No data.          |
| *Apis mellifera* | Certosan (99.8% Blood meal) | Acute (48 h)               | Contact toxicity (LD₅₀)    | > 200 µg product/bee |
| -              | Blood meal (a.s.)    | Chronic                     | 10 d-LC₅₀                  | No data.          |
| -              | Certosan (99.8% Blood meal) | Chronic                      | 10 d-LC₅₀                  | No data.          |
| -              | Blood meal (a.s.)    | Bee brood development       | NOEClarvae                 | No data.          |
| -              | Certosan (99.8% Blood meal) | Bee brood development       | NOEClarvae                 | No data.          |
| -              | Blood meal (a.s.)    | Sub-lethal effects (behavioural and reproductive) | NOEC hypopharyngeal glands | No data.          |
| -              | Certosan (99.8% Blood meal) | Sub-lethal effects (behavioural and reproductive) | NOEC hypopharyngeal glands | No data.          |

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

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

Risk assessment for exposure to contaminated water

| Risk assessment scenario | Water consumption (µL/bee) | ETR | Trigger |
|--------------------------|----------------------------|-----|---------|
| Guttation                | 11.4                       | 0.03| 0.2     |
| Surface water            | 11.4                       | 0.00| 0.2     |
ETR: Exposure Toxicity Ratio

The risk via consumption of contaminated water was assessed as low.

**Effects on other arthropod species (Regulation (EU) No 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) No 284/2013 Annex Part A, point 10.3.2)**

**Laboratory tests with standard sensitive species**

| Species                | Test Substance | End point       | Toxicity                  |
|------------------------|----------------|-----------------|---------------------------|
| *Typhlodromus pyri*    | a.s., preparation | Mortality, LR$_{50}$ | No data. $^1$          |
|                        |                | Reproduction, ER$_{50}$ |                           |
| *Aphidius rhopalosiphi*| a.s., preparation | Mortality, LR$_{50}$ | No data. $^1$          |
|                        |                | Reproduction, ER$_{50}$ |                           |

**Additional species**

| Species       | Test Substance                      | End point | Toxicity                  |
|---------------|-------------------------------------|-----------|---------------------------|
| *Poecilus curpeus* | Certosan (99.8% Blood meal) | LR$_{50}$ | > 40 kg product/ha         |
| *Pardosa spp.* | Certosan (99.8% Blood meal)       | LR$_{50}$ | > 40 kg product/ha         |

$^1$ Data on the two standard species were waived.

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

For targeted application methods (coating with brush, dipping) a relevant exposure is considered to be negligible. For less targeted application methods (i.e. spraying) exposure cannot 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 curpeus* and *Pardosa* spp. Therefore, further calculations regarding the risk for non-target arthropods following the exposure to Certosan were not considered necessary.

**Extended laboratory tests, aged residue tests**

No data.

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

No data.

**Semi-field tests**
No data.

Field studies
No data.

Additional specific test
No data.

**Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) No 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) No 284/2013 Annex Part A, points 10.4, 10.5)**

| Test organism           | Test substance                          | Application method of test a.s./ OM¹ | Time scale | End point                      | Toxicity          |
|-------------------------|-----------------------------------------|-------------------------------------|------------|-------------------------------|-------------------|
| Earthworms              | Blood meal / Certosan (99.8% Blood meal) | -                                   | -          | Growth, reproduction, behaviour | No data.          |
| Other soil macroorganisms |                                        |                                     |            |                               |                   |
| *Folsomia candida*     | Blood meal / Certosan (99.8% Blood meal) | -                                   | -          | Mortality, reproduction, behaviour | No data.          |
| *Hypoaspis aculeifer*  | Blood meal / Certosan (99.8% Blood meal) | -                                   | -          | Mortality, growth, reproduction, behaviour | No data.          |

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

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

| Blood meal / Certosan (99.8% Blood meal) | No data. For targeted application methods (coating with brush, dipping) a relevant exposure is considered to be negligible. For less targeted application methods (i.e. spraying) exposure cannot be excluded, however due to 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. Furthermore, it should be noted, that blood meal is a fertiliser in organic farming (refer to the EU-Regulation No. 1069/2009) and the application rate is multiple compared to the use of Certosan (up to 2500 kg fertiliser/ha).

Toxicity/exposure ratios for soil organisms

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

For targeted application methods (coating with brush, dipping) a relevant exposure is considered to be negligible. For less targeted application methods (i.e. spraying) exposure cannot be excluded, however due to 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. Furthermore, it should be noted, that blood meal is a fertiliser in organic farming (refer to the EU-Regulation No. 1069/2009) and the application rate is multiple compared to the use of Certosan (up to 2500 kg fertiliser/ha).

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

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

Screening data

No data.

For targeted application methods (coating with brush, dipping) a relevant exposure is considered to be negligible. For less targeted application methods (i.e. spraying) exposure cannot be excluded, however due to 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.
protein) in soil is considered sufficient to demonstrate a low risk to non-target plants and to address the data requirement. Therefore a further consideration of a risk assessment is not considered necessary.

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

Laboratory dose response tests

| Species | Test substance | ER<sub>50</sub> (g/ha) vegetative vigour | ER<sub>50</sub> (g/ha) emergence | Exposure (g/ha) | TER | Trigger |
|---------|----------------|-----------------------------------------|---------------------------------|----------------|-----|---------|
|         | Blood meal / Certosan (99.8% Blood meal) | No data. | No data. | - | - | - |

Extended laboratory studies: No data. Semi-field and field test: No data.

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

| Test type/organism | End point |
|--------------------|-----------|
| Activated sludge   | No data.  |
| \textit{Pseudomonas sp.} | No studies were submitted to address the effects on effects on biological methods for sewage treatment. The waiver for standard toxicity studies is considered acceptable. For the proposed application methods (coating with brush, dipping, spraying) a relevant exposure of activated sludge is considered to be negligible. Therefore a low risk to biological methods of sewage treatment is considered. |

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

| Available monitoring data concerning adverse effect of the a.s. |
| No data. |
| Available monitoring data concerning effect of the PPP. |
| No data. |

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

| Compartment | |
A residue definition is not needed\(^2\)

| Compartment | Residue Definition |
|-------------|-------------------|
| soil        | A residue definition is not needed\(^2\) |
| surface water | Blood meal |
| sediment   | A residue definition is not needed\(^2\) |
| groundwater | Blood meal |

\(^1\) Metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent compound.

\(^2\) According to the intended uses blood meal is used as a repellent which is applied onto trees or parts of trees or ornamentals.

Blood meal is used as fertiliser in organic farming in much higher amounts. Blood meal consists out of dried blood, which is a natural substance. It is not possible to distinguish between the residues arising from the use of blood meal as a plant protection product and its natural presence in the environmental compartments.

### Classification and labelling with regard to ecotoxicological data (Regulation (EU) No 283/2013, Annex Part A, Section 10)

| Substance | Blood meal |
|-----------|------------|
| Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]\(^4\): | - |
| Peer review considerations: | - |

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