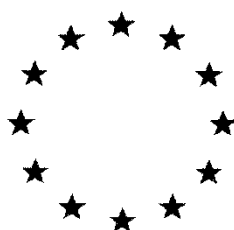


European Commission



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

BLOOD MEAL

Volume 3 – B.9 (AS)

Rapporteur Member State: Austria
Co-Rapporteur 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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B.9. ECOTOXICOLOGY DATA (CA 9)

This document supports the application for renewal of the regulatory approval of **Blood meal**. This document presents ecotoxicological studies on the active substance **Blood meal**.

This document covers data and risk assessments which were not part of the original dossier and which are necessary to reflect changes:

- In requirements under Commission Regulation (EU) No 283/2013, and the associated Annex, which repeals Commission Regulation (EU) No 544/2011 which, under Regulation (EC) 1107/2009, replaced the requirements of Annex II to Directive 91/414/EEC
- In scientific and technical knowledge since the approval or last renewal of the approval
- To representative uses

Where the conclusions of the EU review had specific areas of concern on **Blood meal**, new data and/or reviews and/or risk assessments have been provided. Where additional and/or new data on **Blood meal** are provided, a justification has been included. In addition, a justification has been given if new data are required but none were provided.

For the renewal of the active substance **Blood meal** in Annex I, data to support the application for inclusion regarding ecotoxicology is provided in the following section. Studies, where available, are summarised under the respective data points.

In the case where published literature is used to **scientifically justify or support** why a study was not deemed necessary to be conducted or as supporting information, only a superscript is referenced in the text, while full bibliographical information can be found in a respective footnote. Relevant literature from the EFSA- compliant literature search, which has to be evaluated on full-text level, is discussed under the respective data point under point B.9.10.1.

B.9.0. INTRODUCTION

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. 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 reference product Certosan contains 99.8 % blood meal, meaning that the product is interchangeable for the active substance with all characteristics. Data obtained with the product can be used also for the active substance blood meal.

Blood meal (e.g. Certosan) is a game repellent and will be used as protection coating on the outer surface of trees. The applied solution dries off to a layer and unfolds its action by its deterrent smell and taste. The product leads to a reduction of losses caused by game biting of trees during all-season.

Table 9.0-1 : Substances and metabolites of environmental relevance (structure, synonyms and codes)

| Code | IUPAC name | Compound found in | Structural formula |
|--------------------------|---|--------------------------------------|--------------------|
| Blood meal | Not applicable (CAS no.: 90989-74-5) | Environment (soil, surface water) | Not applicable |
| No relevant metabolites. | | | |

B.9.1. EFFECTS ON BIRDS AND OTHER TERRESTRIAL VERTEBRATES

B.9.1.1. Effects on birds

Effects on birds for Blood meal were not evaluated as part of the EU review of Blood meal (Draft Assessment Report Blood meal, 2008) but addressed in the DAR Addendum in March 2011.

There the following statement is provided:

All environmental toxicology studies of dried blood have been waived for the following reasons:

- *The use pattern involves spot treatments to young trees and, therefore, exposure of non-target organisms [here birds] should be negligible;*
- *The manufacturing process ensures that potential mammalian pathogens are inactivated and proteins are denaturated;*
- *Blood meal is an important ingredient in foodstuffs.*

Moreover in the Blood meal EFSA Conclusion (EFSA Journal 2011;9(10):2394) it is stated that “[w]here less targeted spray methods of application are employed, the contamination of food items for birds and mammals cannot be excluded. However, blood meal could be a food source for omnivorous birds and mammals or it acts as a repellent for herbivorous birds and mammals. Therefore, it can be concluded that the risk to birds and mammals is considered to be low for these application methods.”

Birds are not assumed to feed on the treated trees and exposure is considered rather negligible. The product is non-toxic and will dry off to a protective coat. Blood meal is an additive in food and feed, consisting to of 80 % crude protein. It is even used in the diet for poultry¹. So it is unlikely that birds will be harmed by the use of the product. No hazard is expected and therefore no toxicological studies were carried out.

Overall RMS conclusion – Effects on birds:

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.

B.9.1.1.1. Acute oral toxicity to Birds

Please refer to B.9.1.1.

B.9.1.1.2. Short-term dietary toxicity to birds

Please refer to B.9.1.1.

¹ https://www.lw-heute.de/mediaarchiv/grab_pic.php?id=24993
<http://www.sternensteine.de/wildvogel/krumbieg/data/vovo04.htm>

B.9.1.1.3. Sub-chronic toxicity and reproduction to birds

Please refer to B.9.1.1.

B.9.1.2. Effects on terrestrial vertebrates other than birds

Effects on mammals for Blood meal were not evaluated as part of the EU review of Blood meal (Draft Assessment Report Blood meal, 2008) but addressed in the DAR Addendum in March 2011.

There the following statement is provided:

All environmental toxicology studies of dried blood have been waived for the following reasons:

- *The use pattern involves spot treatments to young trees and, therefore, exposure of non-target organisms [here mammals] should be negligible;*
- *The manufacturing process ensures that potential mammalian pathogens are inactivated and proteins are denaturated;*
- *Blood meal is an important ingredient in foodstuffs.*

Moreover in the Blood meal EFSA Conclusion (EFSA Journal 2011;9(10):2394) it is stated that “[w]here less targeted spray methods of application are employed, the contamination of food items for birds and mammals cannot be excluded. However, blood meal could be a food source for omnivorous birds and mammals or it acts as a repellent for herbivorous birds and mammals. Therefore, it can be concluded that the risk to birds and mammals is considered to be low for these application methods.”

Mammals are not assumed to feed on the treated trees and exposure is considered rather negligible. The product is non-toxic and will dry off to a protective coat. Blood meal is an additive in food and feed, consisting to of 80 % crude protein. So it is unlikely that mammals will be harmed by the use of the product. No hazard is expected and therefore no toxicological studies were carried out.

Overall RMS conclusion – Effects on mammals:

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.

B.9.1.2.1. Acute oral toxicity to mammals

Please refer to B.9.1.2.

B.9.1.2.2. Long-term and reproduction toxicity to mammals

Please refer to B.9.1.2.

B.9.1.3. Active substance bioconcentration in prey of birds and mammals

Please refer to B.9.1.2.

B.9.1.4. Other data on effects on terrestrial vertebrate wildlife (birds, mammals, reptiles and amphibians)

Please refer to B.9.1.2. The risk to terrestrial vertebrate wildlife is considered to be low.

B.9.1.5. Potential for endocrine disruption

There are no indications or evidences of endocrine disrupting properties of Blood meal. Blood meal is an additive in food and feed, consisting to of 80 % crude protein. The literature search indicates no endocrine disrupting properties of Blood meal (please refer to B.9.10).

Overall RMS conclusion – Potential for endocrine disruption:

The argumentation above is accepted, potential endocrine disrupting effects posed by Blood meal are considered unlikely and the data requirement was sufficiently addressed.

B.9.2. EFFECT ON AQUATIC ORGANISMS

No toxicity studies on aquatic organisms with the active substance Blood meal were submitted for Annex I inclusion of Blood meal, a data gap was identified by EFSA during the former evaluation (EFSA Journal 2011;9(10):2394). Therefore, conduction of acute aquatic toxicity tests with fish, invertebrate and algae is principally required in order to allow classification. These studies are available for the formulation Certosan (99.8% Blood meal) by Muckle (2013a, 2013b & 2013c), submitted for the renewal of Blood meal. The studies are presented in Vol. 3 CP B9.

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 ingredient Blood meal is accidentally got into surface water, it should be taken in account that Blood meal is commonly used as fish feed.

B.9.2.1. Acute toxicity to fish

Overall RMS conclusion:

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] submitted for the renewal of Blood meal is presented in Vol. 3 CP B9. This study is considered to address the data requirement sufficiently.

B.9.2.2. Long-term and chronic toxicity to fish

No long-term and chronic toxicity studies on fish were submitted for neither Annex I inclusion of Blood meal nor are considered necessary for the renewal.

Overall RMS conclusion:

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.

B.9.2.2.1. Fish early life stage test

Please refer to CA B9, B.9.2.2.

B.9.2.2.2. Fish full-life-cycle test

Overall RMS conclusion:

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).

B.9.2.2.3. Bioconcentration in fish

Overall RMS conclusion:

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.

B.9.2.3. Potential for endocrine disruption

There are no indications or evidences of endocrine disrupting properties of Blood meal. Blood meal is an additive in food and feed, consisting to of 80 % crude protein. The literature search indicates no endocrine disrupting properties of Blood meal (please refer to B.9.10).

Overall RMS conclusion – Potential for endocrine disruption:

The argumentation above is accepted, potential endocrine disrupting effects posed by Blood meal are considered unlikely and the data requirement was sufficiently addressed.

B.9.2.4. Acute toxicity to aquatic invertebrates

B.9.2.4.1. Acute toxicity to *Daphnia magna*

Overall RMS conclusion:

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.

B.9.2.4.2. Acute toxicity to an additional aquatic invertebrate species

No acute toxicity studies on additional aquatic invertebrates were submitted for neither Annex I inclusion of Blood meal nor are considered necessary for the renewal.

B.9.2.5. Long-term and chronic toxicity to aquatic invertebrates

No long-term and chronic toxicity studies on aquatic invertebrates were submitted for neither Annex I inclusion of Blood meal nor are considered necessary for the renewal.

Overall RMS conclusion:

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.

B.9.2.5.1. Reproductive and development toxicity to *Daphnia magna*

Please refer to B.9.2.5.

B.9.2.5.2. Reproductive and development toxicity to an additional aquatic invertebrate species

Please refer to B.9.2.5.

B.9.2.5.3. Development and emergence in *Chironomus riparius*

Please refer to B.9.2.5.

B.9.2.5.4. Sediment dwelling organisms

Please refer to B.9.2.5.

B.9.2.6. Effects on algal growth

Overall RMS conclusion:

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.

B.9.2.6.1. Effects on growth of an additional algal species

Further testing is not considered necessary, Blood meal has no herbicidal mode of action.

B.9.2.7. Effects on aquatic macrophytes

Further testing is not considered necessary, Blood meal has no herbicidal mode of action.

B.9.2.8. Further testing on aquatic organisms

Not required.

B.9.3. EFFECTS ON ARTHROPODS

B.9.3.1. Effects on bees

There are no endpoints on bees available for the pure active substance Blood meal. However an acute contact and oral toxicity study is available for Certosan (99.8% Blood meal) by Kleiner (1996b) from the former evaluation of Blood meal. This study is presented in Vol. 3 CP B9.

B.9.3.1.1. Acute toxicity to 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.

B.9.3.1.1.1. Acute oral toxicity

Please refer to B.9.3.1.1.

B.9.3.1.1.2. Acute contact toxicity

Please refer to B.9.3.1.1.

B.9.3.1.2. Chronic toxicity to bees

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.

B.9.3.1.3. Effects on honeybee development and other honeybee life stages

Please refer to B.9.3.1.2.

B.9.3.1.4. Sublethal effects

Please refer to B.9.3.1.2.

B.9.3.2. Effects on non-target arthropods other than bees

There are no endpoints for non-target arthropods other than bees available for the pure active substance Blood meal. However studies on *Poecilus curpeus* and *Pardosa spp.* are available for Certosan (99.8% Blood meal) by Kleiner (1996a & 1996c) from the former evaluation of Blood meal. Those studies are presented in Vol. 3 CP B9.

Additionally the applicant submitted the following statement:

“Aphidius rhopalosiphi and Typhlodromus pyri are the two standard indicator species. No tests are available here for these species. However, supportive tests with the additional species Poecilus cupreus and Pardosa spp. are presented which are indicating that there would be no harmful effects on non-target arthropods. Blood meal (Certosan) will be applied directly to plant parts or individual plants. No broadcast use is intended. The supportive tests show that direct contact with blood meal is not harmful to single arthropods. Blood meal was evaluated already and RMS Belgium in 2008 and the EFSA in 2011 do not insist on tests with Aphidius and Typhlodromus and concluded on the available data that the risk from blood meal and the formulation Certosan to non-target arthropods is low.”

Overall RMS conclusion – Effects on non-target arthropods other than bees:

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.

B.9.3.2.1. Effects on *Aphidius rhopalosiphi*

Please refer to B.9.3.2.

B.9.3.2.2. Effects on *Typhlodromus pyri*

Please refer to B.9.3.2.

B.9.4. EFFECTS ON NON-TARGET SOIL MESO- AND MACROFAUNA**B.9.4.1. Earthworm – sub-lethal effects**

There are no toxicity endpoints for earthworms available for Blood meal. A waiver for the standard study is requested by the applicant. Blood meal acts as a mechanical repellent to prevent game from biting. The formulated product will be painted using a brush or sprayed directly onto tree or parts of trees, whole plants could be dipped and no broadcast application of the formulation will be done. Thus the significant contamination of soil is very unlikely.

Blood meal contains more than 80 % crude protein. The degradation of organic N-combinations starts with the mineralisation followed by the nitrification. 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.

Blood meal is unlikely to have adverse effects on earthworms, the substance is even used in organic farming as fertiliser², in vermiculture³ and vermicomposting⁴. Blood meal is commonly recommended as composting agent⁵.

Overall RMS conclusion – Effects on 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.

B.9.4.2. Effects on non-target soil meso- and macrofauna (other than earthworms)

No data, please refer to B.9.4.1.

B.9.5. EFFECTS ON SOIL NITROGEN TRANSFORMATION

There are no toxicity endpoints for soil nitrogen transformation available for Blood meal. A waiver for the standard study is requested by the applicant. Blood meal acts as a mechanical repellent to prevent game from biting. The formulated product will be painted using a brush or sprayed directly onto tree or parts of trees, whole

² Please refer to general information. There are numerous websites

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0889&from=EN>
<https://www.gardeningknowhow.com/garden-how-to/soil-fertilizers/blood-meal-fertilizer.htm>
<https://plantcaretoday.com/blood-meal-fertilizer.html>
<https://jobescompany.com/product/jobes-organics-blood-meal-granular/>
<https://www.hausgarten.net/gartenpflege/duengung/knochenmehl.html>
<https://www.syringa-pflanzen.de/blutmehl.html>

³ <https://cityofarcata.org/DocumentCenter/View/1064>

⁴ https://fa.oregonstate.edu/sites/fa.oregonstate.edu/files/recycling/resources/MR_Class/chapter_2_composting.pdf

⁵ http://www.abfall-landkreis-waldshut.de/eip/media/downloads/downloads_3_1.pdf
<http://www.steinburg.de/kreisverwaltung/informationen-der-fachaemter/amt-fuer-umweltschutz/abfallwirtschaft/abfallarten/bioabfall/kompostierung/grundregeln-kompostierung.html>
<http://www.biozac.de/biozac/biogart/kompost.htm>

plants could be dipped and no broadcast application of the formulation will be done. Thus the significant contamination of soil is very unlikely.

Blood meal contains more than 80 % crude protein. The degradation of organic N-combinations starts with the mineralisation followed by the nitrification. 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.

Blood meal is unlikely to have adverse effects on soil nitrogen transformation, it should be noted that Blood meal is a fertiliser in organic farming (refer to the EU-Regulation No. 1069/2009), in vermiculture and vermicomposting and the application rate as fertiliser is multiple compared to the use of Certosan (up to 2500 kg fertiliser/ha⁶). Blood meal is also commonly recommended as composting agent.

Overall RMS conclusion – 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.

B.9.6. EFFECTS ON TERRESTRIAL NON-TARGET HIGHER PLANTS

There are no toxicity endpoints for terrestrial non-target plants available for Blood meal. A waiver for the standard study is requested by the applicant. Blood meal acts as a mechanical repellent to prevent game from biting. The formulated product will be painted using a brush or sprayed directly onto tree or parts of trees, whole plants could be dipped and no broadcast application of the formulation will be done. It will be used on trees of forestal significance and on fruit trees in orchards as well as on ornamentals. However, in regards to nature conservation, selected trees will be left untreated to allow game to feed since trees are part of the normal feed of game. In all efficacy trials no negative impact was observed on a range of different mono- and dicotyledonous plant species.

Blood meal contains more than 80 % crude protein. The degradation of organic N-combinations starts with the mineralisation followed by the nitrification. 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.

Blood meal is unlikely to have adverse effects on non-target plants, 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/ha⁷).

Overall RMS conclusion – Effects on terrestrial non-target 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.

B.9.6.1. Summary of screening data

Please refer to B.9.6.

⁶ <https://styriafert.at/downloads/StyriaFert-Datenblatt-NPK-screen.pdf>

⁷ <https://styriafert.at/downloads/StyriaFert-Datenblatt-NPK-screen.pdf>

B.9.6.2. Testing on non-target plants

Please refer to B.9.6.

B.9.7. 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.

B.9.8. EFFECTS ON BIOLOGICAL METHODS FOR SEWAGE TREATMENT

There are no endpoints on effects on biological methods for sewage treatment available from the former evaluation on Blood meal. A waiver for the standard study is requested by the applicant. The formulated product will be painted using a brush or sprayed directly onto tree or parts of trees, whole plants could be dipped and no broadcast application of the formulation will be done. It will be used on deciduous and coniferous trees in forestry, trees in orchards and ornamental plants, therefore exposure of activated sludge is considered negligible. This is in-line with the argumentation in the Blood meal EFSA Conclusion of 2011 (EFSA Journal 2011;9(10):2394).

Overall RMS conclusion – Effects on biological methods for sewage treatment:

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

B.9.9. MONITORING DATA

Monitoring data concerning effects of the active substance to non-target organisms are not available and are not a mandatory requirement.

B.9.10. REFERENCES RELIED ON**B.9.10.1. Literature search**

A literature search (KCA 9/0001; Document ID: Blood meal 2018 M-CA sec 9-1.0, 26.03.2018) for the active substance Blood meal was performed in accordance to the provisions of the EFSA Guidance “Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) 1107/2009”.

The report (KCA 9/0001) summarises the search and selection process of the literature search performed.

| | |
|--|--|
| Data point addressed: | CA B.9.10.1 |
| Reference: | KCA 9/0001 |
| Author(s) (year): | Unknown (2018) |
| Title: | Literature data, Blood meal, Document M-CA, Section 9 |
| Laboratory report / project Number (Doc No.): | Document ID: Blood meal 2018 M-CA sec 9-1.0, 26.03.2018 (DHD-Consulting GmbH) |
| Testing facility: | Not applicable |
| Published: | No |
| Test guideline used: | EFSA Guidance “Submission of scientific peer-reviewed open literature for the |

| | |
|-----------------------|---|
| | approval of pesticide active substances under Regulation (EC) No 1107/2009; EFSA Journal 2011, 9(2):2092” |
| Deviations: | No |
| GLP: | Not applicable |
| Acceptability: | Yes |

Summary

The purpose of this report is the detailed documentation of the search process on scientific peer reviewed open literature on the active substance Blood meal and potential metabolites as required by Regulation (EC) No 1107/2009. This search process is subdivided into several subsequent selection steps, finally leading to a number of studies that are relevant and scientifically reliable and will thus be considered in the dossier. The search for scientific peer reviewed open literature was done by using the online search engines of selected databases providing articles that cover the scientific scopes that may possibly be relevant for plant protection products (e.g. biological, agricultural, chemical or medical sciences). After the selection of appropriate databases, a search strategy was developed for targeting studies on the active substance by determining significant search terms and combinations thereof to be used with the search engines (see under 0 for details). The retrieved results were then exported to user-built databases to facilitate editing with reference management software (Citavi 5.2.0.8.). In order to minimize search results by excluding obviously irrelevant studies, specific relevance criteria have been developed for each section (physical and chemical properties, analytical results, toxicology, residue behaviour, fate and behaviour in the environment, and ecotoxicology) and applied to the search results by rapid assessment of title and abstract of the studies (0). To limit the results for the physical and chemical properties section, a pre-selection of studies was performed by application of section specific search terms. Only to those pre-selected studies the relevance criteria were applied. The same was done for the analytical methods section. Relevant studies or studies of unclear relevance after rapid assessment would then be subjected to a full text assessment on relevance and also on reliability, for which also reliability criteria have been conceived corresponding to the target of the respective studies and the data requirements of the 1107/2009 data point they will be assigned to. Abstracts including a reliability check (except for toxicology) would be provided in the corresponding dossier section for studies considered to be reliable with limitations, while detailed summaries would be prepared for those studies considered to be relevant and reliable. For the toxicology section, studies considered to be reliable or reliable with limitations would be provided in an identical detailed summary format. If a study, after a relevance and/or reliability check, could only be used as supportive information, it would be provided in a short summary format.

Overall, the search for scientific peer reviewed open literature yielded the following results:

Table 9.1010-1: Results of the study selection process for Blood meal

| Data requirement(s) captured in the search | Ecotoxicology |
|---|----------------------|
| Total number of <i>summary records</i> retrieved after <i>all</i> searches of peer-reviewed literature (excluding duplicates) | 78 |
| Number of <i>summary records</i> excluded from the search results after rapid assessment for relevance | 78 |
| Total number of <i>full-text documents</i> assessed in detail | 0 |
| Number of <i>studies</i> of unclear relevance excluded from further consideration after detailed assessment for relevance | -- |
| Number of <i>studies</i> not excluded for relevance after detailed assessment | -- |

| | |
|---|----|
| Number of <i>studies</i> excluded from further consideration after detailed assessment for reliability | -- |
| Number of <i>studies</i> included in the dossier after detailed assessment of full text documents for reliability | 0 |

Identity of the active substance and metabolite(s)**Active substance**

| | |
|-----------------------|--|
| ISO name | Blood meal |
| Chemical name (IUPAC) | None |
| Chemical name (CA) | None |
| | No chemical denomination can be assigned to Blood meal because it is a dried and pulverized body tissue (blood) of porcine origin. |
| Synonym | None |
| CAS no. | 90989-74-5 |
| EEC no. | 292-731-9 |

Search methods and results

On the basis of the EFSA Guidance and along the lines of the examples provided in its Annexes, a single concept search targeting the active substances was conducted for each section. All data requirements were captured in one section-specific search analogous to the example described in the EFSA Guidance on the active ingredient Chlorpyrifos (Appendix A.4).

Active substance

The representative uses evaluated of Blood meal are as a game repellent on deciduous and coniferous trees in forestry, orchard trees and ornamental plants by direct application on the plants (brush, spray, or dipping of individual plants at plantation).

Bibliographic database selection

The EFSA Guidance neither recommends the use of a specific bibliographic database nor specifically mentions minimum prerequisites for a bibliographic database (e.g. subject areas covered, updating frequency). In fact, it is left open to the applicant to choose a bibliographic database as long as the applicant demonstrates that ‘reasonable efforts [have been made] to locate all sources’.

For this literature review, four different bibliographic databases were selected according to their subject areas as well as their accessibility: *ScienceDirect*, *PubMed*, *Wiley online library* and *TOXLINE*. These databases were chosen because they are multidisciplinary collections of online resources covering a vast majority of articles, journals, and books in the fields of life, medical and physical sciences. Moreover, they are comfortable to handle and provide efficient tools to flawlessly export search results to user-built databases to be processed by reference management software.

Search strategy

Afterwards, all results were exported to user-built databases to facilitate editing with reference management software (i.e. excluding duplicates, internal searching, tagging, sorting etc.). Studies corresponding to the data requirements of either section were selected from the user-built database comprising the overall results of the search on the active substance and potential metabolites, respectively. In order to include all information that could be contained in potentially relevant studies, all search results retrieved from the four databases have been separately checked for relevance, applying the relevance criteria as given below. Specific search terms were applied within the user-built database for the physical and chemical properties and the analytical sections to limit the results. The terms were listed below.

A preliminary unconfined search revealed that a very high proportion of the available literature would yield results addressing blood as food ('meal') for biting midges and the lot, together with diseases these organisms pass on as vectors. Hence, in order to *exclude* those irrelevant studies and at the same time (in accordance with EFSA) reduce the otherwise disproportionately huge amount of results, the search has been conducted for the active substance occurring in the study title only, together with reasonable exclusions in title, abstract and keywords (see table 9.4-1).

However, in order to *include* studies that potentially address effects on aquatic larvae of the organisms mentioned above, a second search has been performed looking for studies with "blood meal" in the title and additionally the term "larvae" in title, abstract or keywords.

In the following, the results of the search process for scientific peer reviewed open literature in bibliographic databases are summarized. A list of the bibliographic references, in a format importable to the reference management software Endnote, for any relevant studies and for studies whose relevance remains unclear as well as for studies excluded after detailed assessment will be provided separately.

Search results

Active substance – Blood meal

Table 10-2: Reporting of the search process for scientific peer-reviewed open literature on Blood meal in bibliographic databases

| Database | ScienceDirect | PubMed | Wiley online library | TOXLINE |
|------------------------------------|--|---|---|--|
| Justification of the choice | ScienceDirect scientific database contains more than 10 million journal articles and book chapters | PubMed comprises more than 21 million citations for biomedical literature from MEDLINE, life science journals, and online books | Multidisciplinary collection of online resources covering e.g. life, health and physical sciences. access to over 4 million articles from 1500 journals | TOXLINE provides bibliographic information (1840s to present) covering the biochemical, pharmacological, physiological, and toxicological effects of drugs and other chemicals. It contains over 5 million references, most with abstracts, indexing terms, and CAS Registry Numbers TOXLINE also contains references from specialized journals, government reports, meeting abstracts, and other relevant collections of toxicology literature. |
| Date of search | 20.03.2018 | 20.03.2018 | 20.03.2018 | 20.03.2018 |
| Date span of search | 2008-present | 2008-present | 2008-present | 2008-present |
| Latest database | -- | -- | -- | -- |

| Database | ScienceDirect | PubMed | Wiley online library | TOXLINE |
|-------------------|---|---|---|--|
| update | | | | |
| Search strategies | <p>1. “Blood meal” OR “90989-74-5”(advanced search, journals, article, title) NOT aedes OR culex OR anopheles OR midge OR midges OR mosquito OR mosquito OR mosquitoes OR culicidae OR pipiens OR aegypti OR gambiae OR albopictus OR leishmania OR leishmaniasis OR phlebotomus OR tick OR ixodes OR ricinus OR ixodidae OR persulatus OR chagas OR culicoides OR disease OR ceratopogonidae OR trypanosoma OR triatoma OR amblyomma OR infestans OR vector OR triatominae</p> | <p>1. ("Blood meal" OR “90989-74-5” [Title]) NOT (aedes[Title/Abstract] OR culex[Title/Abstract] OR anopheles[Title/Abstract] OR midge[Title/Abstract] OR midges[Title/Abstract] OR mosquito[Title/Abstract] OR mosquitoes[Title/Abstract] OR culicidae[Title/Abstract] OR pipiens[Title/Abstract] OR aegypti[Title/Abstract] OR gambiae[Title/Abstract] OR albopictus[Title/Abstract] OR leishmania[Title/Abstract] OR leishmaniasis[Title/Abstract] OR phlebotomus[Title/Abstract] OR tick[Title/Abstract] OR ixodes[Title/Abstract] OR ricinus[Title/Abstract] OR ixodidae[Title/Abstract] OR persulatus[Title/Abstract] OR chagas[Title/Abstract] OR culicoides[Title/Abstract] OR disease[Title/Abstract] OR ceratopogonidae[Title/Abstract] OR trypanosoma[Title/Abstract])</p> | <p>1. “Blood meal” OR “90989-74-5” (advanced search, title, journals)</p> | <p>1. Blood meal OR “90989-74-5” (advanced search, singular/plural, records with all of the words, title, including chemical synonyms and CAS numbers, excluding PubMed records)</p> |

| Database | ScienceDirect | PubMed | Wiley online library | TOXLINE |
|---|---|---|--|--|
| | OR malaria (title, abstract, keywords)) | ct] OR triatoma[Title/Abstract] OR amblyomma[Title/Abstract] OR infestans[Title/Abstract] OR vector[Title/Abstract] OR triatominae[Title/Abstract]) | | |
| | 2. "Blood meal" AND larvae (advanced search, journals, title-abstract- keywords, article) | 2. ("blood meal"[Title]) AND larvae[Title/Abstract] | 2. ("blood meal"[Title]) AND larvae[Title/Abstract] | 2. ("blood meal"[Title]) AND larvae[Title/Abstract] |
| Number of summary records retrieved | 29 (without duplicates) | 17 (without duplicates) | 14 (without duplicates) | 18 (without duplicates) |
| Total number of summary records retrieved after removing duplicate s | 78 | | | |

Criteria for study relevance and study selection

Examples of a relevance assessment are given in the EFSA Guidance; however, to receive a good overview over the available literature, the relevance criteria for selection of studies were set broader than the example given in the EFSA Guidance. If the relevance criteria were set too narrowly, many studies that might be of relevance would slip through the literature search and potential important information could not be included in the assessment. For the relevance assessment the criteria as given in the tables below were considered. All further information like e.g. purity, number of test animals per group sufficient to establish a statistical significance, was considered rather to be reliability criteria and was addressed in the reliability assessment.

In the following, the criteria for study relevance as applied during the study selection process are given for each section. Since no results regarding the formulated product relevant for submission have been found, only the data requirements for the active substance are considered.

Ecotoxicology

Table 10–3: Criteria for relevance (active substance) for ecotoxicology

| Data requirements (1107/2009 data point) | Criteria for relevance |
|---|--|
| <u>CA 8.1</u> Effects on birds and other terrestrial vertebrates | <ol style="list-style-type: none"> Reference should be made to relevant invertebrate or vertebrate species/taxa. Papers which are dealing with the effects on mammals were not included in the relevance assessment because this was considered to be covered in the section toxicology. However, studies on other non-target vertebrate species (e.g. fish, amphibians, reptiles, birds, other mammals than the relevant species for toxicological testing) or studies which are not covered by the data requirements of the section toxicology, e.g. field studies, avoidance studies, were considered in the relevance and reliability check. Ecotoxicological studies conducted with the active substance, metabolites or product containing the active substance (defined test material) addressing any of the data requirements. Subject of the publication can be clearly related to the respective data requirement Field studies relevant for European conditions with regard to species, climate, soil conditions etc. Literature reviews are excluded No mixtures of different a.i. |
| <u>CA 8.2</u> Effects on aquatic organisms | |
| <u>CA 8.3</u> Effects on arthropods | |
| <u>CA 8.4</u> Effects on non-target soil meso and macrofauna | |
| <u>CA 8.7</u> Effects on other terrestrial organisms (flora and fauna) | |

Criteria for study reliability**Ecotoxicology**

No criteria for study reliability were established for ecotoxicology since no study has been considered relevant after detailed assessment of full text documents for relevance.

Results of the study selection process

In the following, the results of the study selection process after detailed assessment of full text documents are presented for the active substance and for the metabolite(s). The results are presented separately for each section. The documentation includes:

- An overview on the results of the study selection process, for each data requirement or group of data requirements searched
- A report of all relevant studies and studies of unclear relevance that are included in a dossier after detailed assessment of full-text documents for relevance: ordered by data requirement(s)
- A report of all relevant studies and studies of unclear relevance that are included in a dossier after detailed assessment of full-text documents for relevance: ordered by author(s)
- A report of the studies excluded from the risk assessment after detailed assessment of full-text documents

Ecotoxicology

Table 10-4: Results of the study selection process, for each data requirement or group of data requirements searched

| Data requirement(s) captured in the search | Blood meal [n] |
|---|----------------|
| Total number of <i>summary records</i> retrieved after <i>all</i> searches of peer-reviewed literature (excluding duplicates) | 78 |

| | |
|---|----|
| Number of <i>summary records</i> excluded from the search results after rapid assessment for relevance | 78 |
| Total number of <i>full-text documents</i> assessed in detail | 0 |
| Number of <i>studies</i> of unclear relevance excluded from further consideration after detailed assessment for relevance | -- |
| Number of <i>studies</i> not excluded for relevance after detailed assessment | -- |
| Number of <i>studies</i> excluded from further consideration after detailed assessment for reliability | -- |
| Number of <i>studies</i> included in the dossier after detailed assessment of full text documents for reliability | 0 |

Active substance – Blood meal

No studies relevant for ecotoxicology and involving the active substance were found within the search results of the user-built database.

| | |
|------------|---|
| KCA 9/0001 | <p>Comment RMS: The literature search is compliant with the EFSA GD on open literature search (EFSA Journal 2011;9(2):2092) and is overall considered acceptable by RMS.</p> <p>Notes:</p> <ul style="list-style-type: none"> No list of studies which were excluded after a rapid relevance assessment was submitted, however for these literature data hits the provision of titles/abstracts would have been useful for a quick check. The selection of the databases is considered acceptable. |
|------------|---|

B.9.10.2. List of data and references submitted by the applicant and relied on:

| Data point | Author(s) | Year | Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
|----------------|-----------|------|---|-------------------------|--------------------------------|---|-------|
| CA B.9.10.1 | Unknown | 2018 | Literature data, Blood meal, Document M-CA, Section 9 Document ID: Blood meal 2018 M-CA sec 9-1.0, 26.03.2018 (DHD-Consulting GmbH) Not published | N | | | |

na = not applicable / ni = not indicated / nr = not relevant