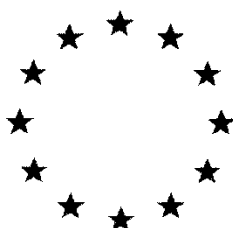


European Commission



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

BLOOD MEAL

Volume 3 – B.8 (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

Table of contents

B.8. ENVIRONMENTAL FATE AND BEHAVIOUR	4
B.8.1. FATE AND BEHAVIOUR IN SOIL.....	4
B.8.1.1. Route of degradation in soil.....	4
B.8.1.2. Rate of degradation in soil	4
B.8.1.3. Adsorption and desorption in soil.....	5
B.8.1.4. Mobility in soil	5
B.8.2. FATE AND BEHAVIOUR IN WATER AND SEDIMENT	5
B.8.2.1. Route and rate of degradation in aquatic systems (chemical and photochemical degradation)	5
B.8.2.2. Route and rate of biological degradation in aquatic systems	5
B.8.2.3. Degradation in the saturated zone.....	6
B.8.2.4. Impact on water treatment procedures.....	6
B.8.3. FATE AND BEHAVIOUR IN AIR	6
B.8.3.1. Route and rate of degradation in air	6
B.8.3.2. Transport via air	6
B.8.3.3. Local and global effects.....	6
B.8.4. DEFINITION OF THE RESIDUE.....	6
B.8.4.1. Definition of the residue for risk assessment.....	6
B.8.4.2. Definition of the residue for monitoring	6
B.8.5. MONITORING DATA CONCERNING FATE AND BEHAVIOUR OF THE ACTIVE SUBSTANCE, METABOLITES, DEGRADATION AND REACTION PRODUCTS.....	6
B.8.6. REFERENCES RELIED ON	6

B.8. ENVIRONMENTAL FATE AND BEHAVIOUR

B.8.1. FATE AND BEHAVIOUR IN SOIL

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 The Regulation (EU) No 1107/2009 repealed and replaced the Directive 91/414/EEC and the active substance Blood meal is deemed to be approved under that Regulation and included in the Annex to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 1-4 dated 11th July 2014) and Peer review document EFSA 2011 (EFSA Journal 2011;9(10):2394) are considered to provide the relevant information for the re-registration of Blood meal. The reference product Certosan contains 99.8% blood meal and can therefore be considered identical with the active ingredient. Data obtained with the product can be used also for the active substance Blood meal.

No studies for the fate and behaviour in soil will be submitted for any of the endpoints; studies to be provided are not considered necessary due to the following reasons:

- Blood meal will be used as game repellent and will be applied by brushing, spraying or dipping individual plants or plant parts. The contamination of the environment is negligible
- Blood meal is used as fertiliser in organic farming in much higher rates than as game repellent: blood meal is included as fertiliser in the Annex I of the Commission Regulation 834/2007 on organic production.

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

B.8.1.1. Route of degradation in soil

The degradation of blood meal follows the normal route of organic N-combinations in nature.

B.8.1.1.1. Aerobic degradation

Not required (EFSA Journal 2011;9(10):2394)

B.8.1.1.2. Anaerobic degradation

Not required (EFSA Journal 2011;9(10):2394)

B.8.1.1.3. Soil photolysis

Not required (EFSA Journal 2011;9(10):2394)

B.8.1.2. Rate of degradation in soil

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

The influence of an application with blood meal of 20 kg/ha to the natural N-content in soils of 900 – 9000 kg/ha in 0-20 cm depth is negligible.

B.8.1.2.1. Laboratory studies

Not required (EFSA Journal 2011;9(10):2394)

B.8.1.2.2. Field studies

Not required.

B.8.1.3. Adsorption and desorption in soil***B.8.1.3.1. Adsorption and desorption***

No data – not required

B.8.1.3.2. Aged sorption

No data – not required

B.8.1.4. Mobility in soil***B.8.1.4.1. Column leaching studies***

No data – not required

B.8.1.4.2. Lysimeter studies

No data – not required

B.8.1.4.3. Field leaching studies

No data – not required

B.8.2. FATE AND BEHAVIOUR IN WATER AND SEDIMENT

The degradation of blood meal follows the normal route of organic N-combinations in nature. The formulation is applied on trees by coating with brush, spraying or dipping of individual plants. Thus exposure of surface water is negligible. 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.

B.8.2.1. Route and rate of degradation in aquatic systems (chemical and photochemical degradation)***B.8.2.1.1. Hydrolytic degradation***

Blood meal is expected to be stable to hydrolysis for periods of days at ca. pH 7.3-7.5 (EFSA Journal 2011;9(10):2394).

B.8.2.1.2. Direct photochemical degradation

The fate and behaviour of blood meal is expected to follow the normal pathways of dissipation and degradation common to naturally occurring residues of biological origin. The degradation of organic N-combinations starts with mineralisation followed by nitrification. There is no abiotic pathway.

B.8.2.1.3. Indirect photochemical degradation

No data are provided or considered necessary.

B.8.2.2. Route and rate of biological degradation in aquatic systems***B.8.2.2.1. Ready biodegradability***

No information presented, not required.

B.8.2.2.2. Aerobic mineralisation in surface water

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

B.8.2.2.3. Water/sediment studies

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

B.8.2.2.4. Irradiated water/sediment studies

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

B.8.2.3. Degradation in the saturated zone

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

B.8.2.4. Impact on water treatment procedures

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

B.8.3. FATE AND BEHAVIOUR IN AIR

The formulation is applied on trees by coating with brush, spraying or dipping of individual plants. No exposure of air expected.

B.8.3.1. Route and rate of degradation in air

Not required.

B.8.3.2. Transport via air

Not required.

B.8.3.3. Local and global effects

Not relevant.

B.8.4. DEFINITION OF THE RESIDUE

The degradation of blood meal follows the normal route of organic N-combinations in nature. Therefore no residue definition is proposed for blood meal for all environmental compartments.

B.8.4.1. Definition of the residue for risk assessment

No residue definition for risk assessment is proposed, not applicable (EFSA Journal 2011;9(10);2394).

B.8.4.2. Definition of the residue for monitoring

No residue definition for monitoring proposed, not applicable (EFSA Journal 2011;9(10);2394).

B.8.5. MONITORING DATA CONCERNING FATE AND BEHAVIOUR OF THE ACTIVE SUBSTANCE, METABOLITES, DEGRADATION AND REACTION PRODUCTS

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

B.8.6. REFERENCES RELIED ON

In every chapter (B.1, B.2, etc.) in Volume 3 (AS) the reference relied on heading should start with a paragraph indicating how the literature search was carried out and if this is considered acceptable. It should also be indicated if the RMS can agree with the justifications given by the notifier (especially for non-relevant literature). This is not expected to be a detailed study-by-study consideration. Relevant literature would be evaluated and assessed in the normal way within each section.

For (draft) renewal assessment reports the reference lists at the end of each section/chapter (sorted by data requirement) should include the newly submitted data relied upon as well as those original submitted tests and studies that are still considered relevant to support the application for renewal. However these studies should be

clearly identified in the reference list as well as in the individual study sections. This could be done by consistent use of a statement for each study:

Previous evaluation: responded “N.A”. for NAS, “Submitted for the purpose of renewal”, or “In DAR (year)”, “In addendum to DAR (year)” or any other appropriate

For blood meal searches and reviews of the published literature are presented in the following document: Blood meal MCA section 9

Summary:

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. 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. The retrieved results were then exported to user-built databases to facilitate editing with reference management software. Specific relevance criteria have been developed for each section.

Table 8.6.1: Results of the study selection process for Blood meal

Data requirement(s) captured in the search	Environmental fate
Total number of summary records retrieved after all searches of peer-reviewed literature (excluding duplicates)	78
Number of summary records excluded from the search results after rapid assessment for relevance	77
Total number of full-text documents assessed in detail	0
Number of studies of unclear relevance excluded from further consideration after detailed assessment for relevance	--
Number of studies not excluded for relevance after detailed assessment	--
Number of studies excluded from further consideration after detailed assessment for reliability	--
Number of studies included in the dossier after detailed assessment of full text documents for reliability	0

Database selection and search strategy

Four different bibliographic databases were selected according to their subject areas as well as their accessibility: ScienceDirect, PubMed, Wiley online library and TOXLINE.

All results were exported to user-built databases. Studies corresponding to the data requirements were selected from the user-built database; all search results retrieved from the four databases have been separately checked for relevance, applying the relevance criteria presented below (table 8.6.3).

The results of the search process for scientific peer reviewed open literature in bibliographic databases are summarized in table 8.6.2.

Table 8.6.2: 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
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 update	--	--	--	--
Search strategies	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 7	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 15	1. "Blood meal" OR "90989-74-5" (advanced search, title, journals) OR 15	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) OR 18

	ceratopogonidae OR trypanosoma OR triatoma OR amblyomma OR infestans OR vector OR triatominae OR malaria (title, abstract, keywords))		ixodes[Title/Abstract] OR ricinus[Title/Abstract] OR ixodidae[Title/Abstract] OR persculatus[Title/Abstract] OR chagas[Title/Abstract] OR culicoides[Title/Abstract] OR disease[Title/Abstract] OR ceratopogonidae[Title/Abstract] OR trypanosoma[Title/Abstract] 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)	31	2. ("blood meal"[Title]) AND larvae[Title/Abstract]	2	2. ("blood meal"[Title]) AND larvae[Title/Abstract]	0	2. ("blood meal"[Title]) AND larvae[Title/Abstract]	0
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 duplicates	78							

Criteria for study relevance and study selection:

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

Table 8.6.3: Criteria for relevance for environmental fate and behavior

Data requirements (1107/2009 data point)	Criteria for relevance
CA 7.1 Fate and behavior in soil	1. Environmental studies conducted with the active substance, metabolites or product containing the active substance (defined test material) addressing any of the data requirements. 2. Studies investigating/describing/quantifying the occurrence of the respective substance in the environment 3. Subject of the publication can be clearly related to the respective data requirement and compartment 4. Field studies relevant for European conditions with regard to climate, soil conditions etc. 5. Literature reviews and analytical papers are excluded 6. No mixtures of different a.i
CA 7.2 Fate and behavior in water and sediment	
CA 7.3 Fate and behavior in air	
CA 7.5 Monitoring Data	

Criteria for study reliability

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

Results of the study selection process:

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

Table 8.6.4: Results of the study selection process

Data requirement(s) captured in the search	Blood meal [n]
Total number of summary records retrieved after all searches of peer-reviewed literature (excluding duplicates)	78
Number of summary records excluded from the search results after rapid assessment for relevance	77
Total number of full-text documents assessed in detail	0
Number of studies of unclear relevance excluded from further consideration after detailed assessment for relevance	--
Number of studies not excluded for relevance after detailed assessment	--
Number of studies excluded from further consideration after detailed assessment for reliability	--
Number of studies included in the dossier after detailed assessment of full text documents for reliability	0

Comments RMS

The literature search is acceptable. It largely followed the EFSA Guidance on “Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009”.

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation

			Published or not					
No studies have been submitted.								