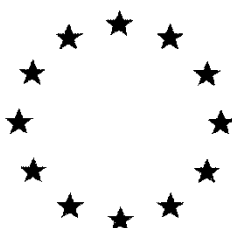


European Commission



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

Blood meal

Volume 3 – B.8 (PPP) – Certosan

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

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B.8. ENVIRONMENTAL FATE AND BEHAVIOUR

This document summarizes considerations on fate and behaviour in the environment for the product Certosan containing the active ingredient Blood meal.

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 The Regulation (EU) No 1107/2009 repealed and replaced the Directive 91/414/EEC and the active substance Blood meal is deemed to be approved under that Regulation and included in the Annex to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

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

The product is a game repellent and will be used as protection coating on the outer surface of young trees. Certosan dries off to a water insoluble coat and unfolds its action by its deterrent taste and smell. The product leads to a reduction of losses caused by game feeding on the trees during all-season.

Certosan will be applied mixed with water onto trees using backpack sprayer or brushes. Whole trees can be dipped into the solution with Certosan.

Certosan dries off to a water insoluble coat within 1-3 hours, depending of the air humidity and unfolds its action by its taste and smell. The game repellent is non-toxic and does not harm animal, men, or the environment.

Blood meal will be prepared of pork Blood. Blood is currently regulated as food additive under the Food and Drug Regulations in Canada and is deemed non-toxic. In Sweden, the same active ingredient is added to Blood-based foodstuffs in place of fresh Blood. Bakery products contain Blood for iron enrichment and colouring. Also, meat products contain Blood for colouring.

Furthermore, in organic farming Blood meal will be used as fertiliser in much higher dose rates than for the intended uses. Blood meal is included as fertiliser in the Annex I of the Commission Regulation 834/2007 on organic production.

B.8.1. FATE AND BEHAVIOUR IN SOIL

B.8.1.1. Route and rate of degradation in soil

No studies were made regarding degradation of the product in soil since Blood meal is included as fertiliser in the Annex I of the Commission Regulation 834/2007 on organic production.

The representative product contains 99.8 % blood meal and can be considered being identical with the active substance. Therefore, the results of the EFSA Journal 2011 are stated here.

B.8.1.1.1. Laboratory studies

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

B.8.1.1.2. Field studies

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

B.8.1.2. Mobility in soil

No studies on the mobility of Certosan in soil were made as the formulation is non-toxic and of no ecotoxicological concern. Blood meal is included as fertiliser in the Annex I of the Commission Regulation 834/2007 on organic production

B.8.1.2.1. Laboratory studies

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

B.8.1.2.2. Lysimeter studies

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

B.8.1.2.3. Field leaching studies

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

B.8.2. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SOIL (PEC_s)

No calculations of PEC_s are deemed necessary and a calculation has not been done upon inclusion in Annex I (see DAR Blood meal, September 2008 and Peer Review document EFSA 2011). Blood meal is included as fertiliser in the Annex I of the Commission Regulation 834/2007 on organic production.

B.8.3. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUND WATER (PEC_{GW})

This data point is not applicable as no metabolites of toxicological concern are built during degradation. Blood meal is included as fertiliser in the Annex I of the Commission Regulation 834/2007 on organic production.

B.8.4. FATE AND BEHAVIOUR IN WATER AND SEDIMENT

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

The formulation is applied on trees by coating with brush, spraying or dipping of individual plants. Exposure of surface water is 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 (EFSA Journal 2011;9(10):2394).

B.8.4.1. Aerobic mineralisation in surface water

Not applicable.

B.8.4.2. Water/sediment study

Not applicable.

B.8.4.3. Irradiated water/sediment study

Not applicable.

B.8.5. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER AND SEDIMENT (PEC_{sw}, PEC_{sd})

Certosan is a non-toxic preparation consisting of Blood meal, an active ingredient listed in Annex I of Directive 91/414/EEC. The active substance Blood meal does not pose environmental harm. Blood meal is registered as additive to foodstuffs and is used as a fertilizer in organic farming.

Certosan is produced from Blood meal of porcine origin only. The water solubility of Certosan is not to determine exactly since it depends on the shaking/stirring technique: the concentration of the test item was given with 68.1-526.2 mg/L (KCA 2.5: Affolter, O. (2013))

Certosan is used as game repellent based, on its unpleasant smell and taste, in forestry, in orchards and public green areas or parks. The target plants will be sprayed directly and individually with backpack sprayer. This is the standard practice. Certosan can also be painted on individual target plants or whole plants can be dipped in the solution. The application rate is 500 -750 g /1000 plants.

Initial PEC_{sw} value for static water bodies

The PEC_{sw} value was calculated with the programme EVA 2.1. The basis for the application with a backpack sprayer using 20 kg Certosan in 400 L water/ha.

Table 9.2 1: PEC_{sw} values following an application with a backpack sprayer

Distance [m]	PEC _{sw} [µg/L water]			
	Application technique			
	conventional	90 % reduction	75 % reduction	50 % reduction
0	6653.33	665.33	1663.33	3326.67
1	4.258	0.43	1.06	2.13

3	0.732	0.07	0.18	0.37
5	0.466	0.05	0.12	0.23

Comments RMS

None.

Additionally, the RMS calculated PEC_{SW} and PEC_{SED} values using FOCUS Step 1 and 2.

The application pattern was set to “no interception”, “North Europe, October - February” and the crop type was set to “hand held application, crop <50 cm” and “hand held application, crop > 50 cm”. The initial worst-case PEC_{SW} and PEC_{SED} values for STEPS 1-2 are given in the following table.

Crop	Step 1		Step 2	
	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]	PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]
Hand held application, crop < 50 cm	6760	675.58	3460	345.9
Hand held application, crop > 50 cm	7110	710.22	3810	380.44

B.8.6. FATE AND BEHAVIOUR IN AIR

Certosan is a non-toxic preparation. The product will be coated onto trees. The product dries off to a protective, water-insoluble film.

B.8.6.1. Route and rate of degradation in air and transport via air

Not applicable.

B.8.6.2. Predicted environmental concentrations from airborne transport

Not applicable.

B.8.7. PREDICTED ENVIRONMENTAL CONCENTRATIONS FROM OTHER ROUTES OF EXPOSURE

Not required.

B.8.8. REFERENCES RELIED ON

In every chapter (B.1, B.2, etc) in Volume 3 (PPP) the reference relied on heading should start with a cross reference to the corresponding heading in Volume 3 (AS) where it is indicated how the literature search was carried out and if this is considered acceptable. It is not considered necessary to duplicate that information in this volume. However if there are specific remarks related to the way PPPs were handled in the literature search these should be made in this volume. 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

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
No studies have been submitted								