European Commission

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

BLOOD MEAL

Volume 3 – B.6 (PPP) – Certosan

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
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Table of contents

B.6. TOXICOLOGY AND METABOLISM DATA AND ASSESSMENT OF RISKS FOR HUMANS

This document reviews the toxicological studies for the product Certosan containing the active substance Blood meal.
This dossier is presented to support the renewal of approval of the active substance Blood meal under 1107/2009. The product Certosan is the representative formulation and has previously been evaluated according to Uniform Principles.

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 The Regulation (EU) No 1107/2009 repealed and replaced the Directive 91/414/EEC and the active substance Blood meal is deemed to be approved under that Regulation and included in the Annex to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

The product Certosan is a non-toxic game repellent. The product will be used as protection coating on deciduous and coniferous trees in forestry and fruit trees in orchards as well as on ornamentals. The product can be applied all-season. Certosan will be sprayed or painted mixed with water onto the trees using knapsack sprayer or brushes. Whole plants can be dipped in the solution.

No studies were carried out with the product. Blood meal will be prepared of pork Blood. No data regarding toxicity were submitted as the usual toxicological data requirements have been waived by EFSA, EPA and PMRA. For further details one should refer to the respective publications (KCP 7.1/01: Anonymous (1991) and KCP 7.1/02: Anonymous (2003); Registration reports of EPA and PMRA:).
Blood meal is of food - grade quality and blood is consumed as food in different forms in different cultures.

B.6.1. ACUTE TOXICITY OF PLANT PROTECTION PRODUCT

No studies on the acute toxicity of Certosan were carried out as the product does not contain an active substance or formulants classified as hazardous.
Blood meal will be prepared of pork blood. No data regarding toxicity were submitted as the usual toxicological data requirements have been waived by EPA and PMRA.
During the production process, the ingredient will be heated for 20 minutes at 200 -250 °C. No parasites, viruses, bacteria or spoors will survive these conditions. Blood meal for Certosan derives only from pork Blood from Sweden and is essentially free of Blood from bovine origin. Thus, contamination with BSE prions is impossible

B.6.1.1. Oral

Not regarded necessary. No studies were carried out and no end-points were defined.

B.6.1.2. Dermal

Not regarded necessary. No studies were carried out and no end-points were defined.

B.6.1.3. Inhalation

Not regarded necessary. No studies were carried out and no end-points were defined.

B.6.1.4. Skin irritation

Not regarded necessary. According to the nature of the product and the toxicological profile of the formulants/active substance no studies were carried out and no end-points were defined.

B.6.1.5. Eye irritation

Not regarded necessary. According to the nature of the product and the toxicological profile of the formulants/active substance no studies were carried out and no end-points were defined.

B.6.1.6. Skin sensitization

Not regarded necessary. According to the nature of the product and the toxicological profile of the formulants/active substance no studies were carried out and no end-points were defined.

B.6.1.7. Supplementary studies on the plant protection product

EFSA Journal 211;9(10): 2394 : A data gap was identified for a shelf-life study including evidence to demonstrate that, when opened, the blood meal does not become contaminated with human pathogens or support their growth.
Therefore, the following test was conducted with the product Certosan :

Authors (year)	l
Title	**Determination of the storage stability of Blood Meal (Certosan) at room temperature (duration two years)**
Owner, Date	Flügel GmbH, Plantskydd AB, 14.09.2015
Testing facility	MikroBiologie Krämer GmbH Odilienplatz 3 D-66763 Dillingen, Germany subcontracted by Laus GmbH Auf der Schafweide 20 D-67489 Kirrweiler, Germany
Dates of work	17.06.2013 – 27.08.2015
Test substance	Blood meal
Test method	DIN ISO 6887-1
GLP/GEP	yes, but determination of human pathogenic germs was performed non-GLP

An open and a closed package (approx. 1 kg ± 200g) were sent to the "MikroBiologie Krämer GmbH" on the sampling points 0, 6, 12 and 24 months ± 1 week. The test item samples were transferred at room temperature.
The absence of the following human pathogenic germs and the potential support of their growth were examined at 6, 12 and 24 months ± 1 week in an open and in a closed package:
- *Shigella,* (quantitatively, the lowest detection limit 100 CFU/g)
- *Staphylococcus aureus* (quantitatively, the lowest detection limit 100 CFU/g)
- *Pseudomonas aeruginosa,* (quantitatively, the lowest detection limit 100 CFU/g)
- *Eschericha coli,* (quantitatively, the lowest detection limit 100 CFU/g)
- *Enterobacteria,* (quantitatively, the lowest detection limit 100 CFU/g)
- *Thermo-tolerant coliforms*, (quantitatively, the lowest detection limit 100 CFU/g)
- *Listeria monocytogenes,* (quantitatively, the lowest detection limit 100 CFU/g)
- *Candida albicans,* (quantitatively, the lowest detection limit 100 CFU/g)
- *Salmonella*, (qualitatively in 100 g)
- *Vibrio,* (qualitatively in 100 g)

The following results were observed on day 0 and after 6, 12 and 24 months in an open and in a closed packages:

Human Pathogenic Germs	**Method**	**Result***
Shigella	DIN EN ISO 21567:2005	< 100 CFU/g***

Staphylococcus aureus at 37°C	DIN EN ISO 6888-1	< 100 CFU/g
Pseudomonas aeruginosa at 25 °C	DIN EN ISO 13720:2008	< 100 CFU/g
Eschericha coli (incubation on TBX agar)**	DIN ISO 16649-1:2001-4	< 100 CFU/g
Enterobacteria at 30 °C	DIN ISO 21528-2:2004	< 100 CFU/g
Thermo-tolerant coliforms	NFV08-060	< 100 CFU/g
Listeria monocytogenes	DIN EN ISO 11290-2	< 100 CFU/g
Candida albicans	L 01.00-37	< 100 CFU/g
Salmonella ssp. (2. agar: Salmonella-Brilliance-Agar)**	DIN EN ISO 6579:2003	in 100 g unverifiable
Vibrio (agar medium: thiosulfate-citrate-bile salts-sucrose agar and MacConkey agar)**	ISO/TS 21872-2:2007	in 100 g unverifiable

*correspond to a limit value
**(XX) = modification of the method
***Colony forming unit per gram

Differentiated pathogen (on day 0 only): *Enterococcus faecalis* (differentiation by growth of *Staphylococcus aureus* and *Vibrio), Leclercia adecarboxlata* (differentiation by growth of *Salmonella ssp.* and *Vibrio*)

The absence of a variety of human pathogenic germs and the potential support of their growth were examined at 6, 12 and 24 months ± 1 week in an open and in a closed package. All germs examined were found below the detection limit or were unverifiable.

B.6.1.8. Supplementary studies for combinations of plant protection products

Not required, tank mixtures are not recommended for Certosan.

B.6.2. DERMAL ABSORPTION

Dermal absorption to Certosan was not evaluated as part of the EU review of Blood meal. According to the nature of the product and the toxicological profile of the formulants/active substance no toxicological studies were carried out.

B.6.3. AVAILABLE TOXICOLOGICAL DATA RELATING TO CO-FORMULANTS

CONFIDENTIAL information - data provided separately (Document J-CP)

B.6.4. EXPOSURE DATA

B.6.4.1. Operator exposure

The following is stated in the EFSA conclusion (2011) and is still considered valid for the renewal of blood meal:

The representative uses evaluated 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)

According to the nature of the product and the toxicological profile of the formulants/active substance no toxicological studies were carried out and no AOEL was determined.

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

According to the non-toxic nature of the product/active substance no toxicological studies were carried out. Therefore, no calculation of an operator exposure was performed.

A study to measure operator exposure under practical conditions of use was not performed since the nature of the product/active substances does not raise safety concerns.

B.6.4.2. Bystander and resident exposure

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

The product consists of 998 g/kg Blood meal and does not contain impurities or micro-organisms known to be toxic. Exposure and risk to bystanders is negligible.

Exposure and risk to bystanders should be minimal, if any.

B.6.4.3. Worker exposure

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

According to the nature of the product and the toxicological profile of the formulants/active substance no toxicological studies were carried out and no AOEL was determined. Therefore, no calculation of a worker exposure can be performed.

No measurements on worker exposure were performed as the formulation is non-toxic.

B.6.5. EXPOSURE AND RISK ASSESSMENT

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

B.6.6. REFERENCES RELIED ON

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

B 6.8.2	Affolter, O.	2015	Determination of the storage stability of Blood Meal (Certosan) at room temperature (duration two years) Report No. 13022801G001 Laus GmbH GLP: yes, but determination of human pathogenic germs was performed non-GLP unpublished	N	Y	new study	Flügel GmbH, Plantskydd AB	-