European Commission

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

Blood meal

Volume 3 – B.6 (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
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B.6. TOXICOLOGY AND METABOLISM DATA

B.6.1. ABSORPTION, DISTRIBUTION, METABOLISM AND EXCRETION IN MAMMALS

B.6.1.1. Absorption, distribution, metabolism and excretion by oral route

No data are necessary for blood meal (EFSA Journal 211;9(10): 2394)

B.6.1.2. Absorption, distribution, metabolism and excretion by other routes

No data are necessary for blood meal (EFSA Journal 211;9(10): 2394)

B.6.2. ACUTE TOXICITY

Blood meal has a non-toxic mode of action and is non-toxic by itself. The used substance has food grade quality. 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 occur during blood processing
- Blood of porcine origin

Based upon these statements, and taking into account that the substance does not in itself present a toxicological concern, the waiver for toxicological studies was deemed acceptable.

B.6.2.1. Oral

No data, not required (EFSA Journal 211;9(10): 2394)

B.6.2.2. Dermal

No data, not required (EFSA Journal 211;9(10): 2394)

B.6.2.3. Inhalation

No data, not required (EFSA Journal 211;9(10): 2394)

B.6.2.4. Skin irritation

No data, not required (EFSA Journal 211;9(10): 2394)

B.6.2.5. Eye irritation

No data, not required (EFSA Journal 211;9(10): 2394)

B.6.2.6. Skin sensitization

No data, not required (EFSA Journal 211;9(10): 2394)

B.6.2.7. Phototoxicity

No studies were carried out to evaluate the phytotoxicity since the product is used since decades without any complaint. Furthermore blood meal is used in organic farming in much higher dose rates. Thus it is very unlikely that Blood meal harms plants.

B.6.3. SHORT-TERM TOXICITY

Since blood meal has food grade quality, no data are necessary

B.6.3.1. Oral 28-day study

No data, not required (EFSA Journal 211;9(10): 2394)

B.6.3.2. Oral 90- day study

No data, not required (EFSA Journal 211;9(10): 2394)

B.6.3.3. Other routes

No data available

B.6.4. GENOTOXICITY

Since blood meal has food grade quality, no data are necessary.

B.6.4.1. In vitro studies

No data, not required (EFSA Journal 211;9(10): 2394)

B.6.4.2. In vivo studies in somatic cells

No data, not required (EFSA Journal 211;9(10): 2394)

B.6.4.3. In vivo studies in germ cells

No data, not required (EFSA Journal 211;9(10): 2394)

B.6.5. LONG-TERM TOXICITY AND CARCINOGENESIS

Since blood meal has food grade quality, no data are necessary.

B.6.6. REPRODUCTIVE TOXICITY

Since blood meal has food grade quality, no data are necessary.

B.6.6.1. Generational studies

No data, not required (EFSA Journal 211;9(10): 2394)

B.6.6.2. Developmental toxicity studies

No data, not required (EFSA Journal 211;9(10): 2394)

B.6.7. NEUROTIXICTY

Since blood meal has food grade quality, no data are necessary.

B.6.7.1. Neurotoxicity studies in rodents

No data, not required (EFSA Journal 211;9(10): 2394)

B.6.7.2. Delayed polyneuropathy studies

No data, not required (EFSA Journal 211;9(10): 2394)

B.6.8. OTHER TOXICOLOGICAL STUDIES

No data available. Since blood meal has food grade quality, no data are necessary.

B.6.8.1. Toxicity studies on metabolites and relevant impurities

No metabolites identified

B.6.8.2. Supplementary studies on the active substance

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.
The product Certosan consists to 99.8 % of the active substance blood meal. Therefore, the test conducted with the product and the results are also valid for the active substance.

Authors (year)	Affolter, O. (2015)
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.6.8.3. Studies on endocrine disruption

An ED assessment following the ECHA/EFSA "Guidance for the identification of endocrine disruptors" does not appear scientifically necessary for blood meal.

B.6.9. MEDICAL DATA AND INFORMATION

Since blood meal has food grade quality, no data are necessary.

B.6.9.1. Medical surveillance on manufacturing plant personnel and monitoring studies

Since blood meal has food grade quality, no data are necessary.

B.6.9.2. Data collected on humans

Since blood meal has food grade quality, no data are necessary.

B.6.9.3. Direct observation

Since blood meal has food grade quality, no data are necessary.

B.6.9.4. Epidemiological studies

No studies available, not necessary.

B.6.9.5. Diagnosis of poisoning (determination of active substance, metabolites), specific signs of poisoning, clinical test

Since blood meal has food grade quality, no data are necessary.

B.6.9.6. Proposed treatment: first aid measures, antidotes, medical treatment

First aid measures
Inhalation: move victim to fresh air
Eye contact: rinse thoroughly with plenty of water, also under the eyelids
Skin contact: wash off with soap and plenty of water
Ingestion: no special measures necessary

B.6.10. 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	N	Y	new study	Flügel GmbH, Plantskydd AB	-

			(duration two years) Report No. 13022801G001 Laus GmbH GLP: yes, but determination of human pathogenic germs was performed non-GLP unpublished					