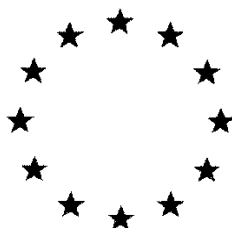


European Commission



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

BLOOD MEAL

Volume 3 – B.2 (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.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE

Throughout this document the original DAR, written by Belgium, is referred to as the DAR and this evaluation, written by Austria, is referred to as the RAR (Renewal assessment report). Studies that were evaluated in the DAR have not been re-evaluated and the results are presented in this report in **grey**. New information or new interpretation of the data has been taken into account or changes compared to the original DAR are written in black.

Tests with the reference product Certosan are cited here. Since the product contains 99.8 %, blood meal can be considered being identical to the active substance.

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1. MELTING POINT AND BOILING POINT						
Melting, freezing or solidification point B.2.1/01	-	-	Not relevant. Blood meal is a well-known widely traded commodity, used as food additive, organic fertilizer etc.	Acceptable		EFSA Journal 2011;9(10):2394
Boiling point B.2.1/02	-	-	Not relevant (see melting point)	Acceptable	-	EFSA Journal 2011;9(10):2394
Decomposition / Sublimation temperature B.2.1/03	-	-	Not relevant (see melting point)	Acceptable	-	EFSA Journal 2011;9(10):2394
B.2.2. VAPOUR PRESSURE, VOLATILITY						
Vapour pressure B.2.2/01	-	-	Not relevant (see melting point)	Acceptable	-	EFSA Journal 2011;9(10):2394
Volatility (Henry's Law constant) B.2.2/02	-	-	Not relevant (see melting point)	Acceptable	-	EFSA Journal 2011;9(10):2394

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.3. APPEARANCE (PHYSICAL STATE, COLOUR)						
Physical state and colour B.2.3/01	-	Certosan, batch # AA 153, Internal No. UCL FL/06/001	Dark red brown flour-like powder without notifiable smell	Acceptable	Y	Bockholt, K., (2006) (KCA 2.3/01)
	OPPTS 830-6302, -6302, -6304	Blood Meal (Certosan), batch no. 94015FO/1, WP 99.8% blood meal, [REDACTED]	Dark red brown powder	Acceptable	Y	Affolter, O. (2015) (KCA 2.3/02)
B.2.4. SPECTRA (UV/VIS, IR, NMR, MS), MOLAR EXTINCTION AT RELEVANT WAVELENGTHS, OPTICAL PURITY						
Ultraviolet/visible (UV/VIS) B.2.4/01	-	-	Not relevant (see melting point)	Acceptable	-	EFSA Journal 2011;9(10):2394

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.5. SOLUBILITY IN WATER						
Solubility in water B.2.5/01	OECD 105 resp. EU A.6 Shake flask method	Blood Meal (Certosan), batch no. 94015FO/1, WP 99.8% blood meal, [REDACTED]	50 - 1000 mg/L, at 20°C*, pH (5) the concentration of the test item lay in the range 23.1 – 729.1 mg/L water p.A. resp. 12.0- 684.9 mg/L * The solubility range and the solubility dependence is due to used techniques: flask method with slow-stirring techniques (<100 rpm).	Acceptable	-	Affolter, O. (2013) (KCA 2.5/01)
B.2.6. SOLUBILITY IN ORGANIC SOLVENTS						
Solubility in organic solvents B.2.6/01	-		Not relevant (see melting point)	Acceptable	-	EFSA Journal 2011;9(10):2394
B.2.7. PARTITION COEFFICIENT N-OCTANOL/WATER						
Partition coefficient n-octanol/water B.2.7/01	-	-	Not relevant (see melting point)	Acceptable	-	EFSA Journal 2011;9(10):2394
B.2.8. DISSOCIATION IN WATER						
Dissociation constant B.2.8/01	-	-	Not relevant (see melting point)	Acceptable	-	EFSA Journal 2011;9(10):2394
B.2.9. FLAMMABILITY AND SHELF-HEATING						
Flammability B.2.9/01	Ignition A10	Certosan 99.8 % blood meal	Ignition: No ignition (1050 °C, 2 min) Self-ignition: No self-ignition up to 400°C Certosan (blood meal) is not flammable	Acceptable	-	Thureson, P. 1995 KCA-2.9/01
Self-heating B.2.9/02	Self-ignition A16	Certosan 99.8 % blood meal	Not auto-flammable.	Acceptable	-	Thureson, P. 1995 KCA-2.9/01
B.2.10. FLASH POINT						

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Flash point B.2.10/01	-	-	Not relevant		-	-
B.2.11. EXPLOSIVE PROPERTIES						
Explosive properties B.2.11/01	-	Statement	Not relevant (see melting point)	Acceptable	-	EFSA Journal 2011;9(10):2394
B.2.12. SURFACE TENSION						
Surface tension B.2.12/01	-	-	Not relevant.		-	-
B.2.13. OXIDISING PROPERTIES						
Oxidizing properties B.2.13/01	-	Statement	Not relevant (see melting point)	Acceptable	-	EFSA Journal 2011;9(10):2394
B.2.14. OTHER STUDIES						
		Certosan 99.8 % blood meal Batch no. AA 153	Storage stability test 14 days 54 °C The product (=active substance) is stable at 54°C for 14 days	Acceptable	Y	Bockholt 2006 KCA-2.14-01
		Certosan 99.8 % blood meal Batch No. 94015FO/1	2 years ambient storage test The product (= active substance) is stable at room temperature for 2 years	Acceptable	Y	Affolter, O. KCA-2.14/02

Blood meal (Certosan) is a dark red brown powder. Blood meal (Certosan) is non-flammable, non-explosive and is not an oxidizing agent. Its solubility in water is 50-1000 mg/L, so that it is moderately water-soluble. It is stable at room temperature for 2 years.

B.2.15. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verteb rate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owne r	Previous evaluation
KCA 2.1	Anonym	2011	Conclusion on the peer review of the pesticide risk assessment of the active substance blood meal EFSA Journal 2011;9(10):2394 GLP/GEP: no published	N	N	-	public	Y
KCA 2.2	Anonym	2011	Conclusion on the peer review of the pesticide risk assessment of the active substance blood meal EFSA Journal 2011;9(10):2394 GLP/GEP: no published	N	N	-	public	Y
KCA 2.3	Bockholt, K.	2006	Certosan. Storage Stability Test: 14 days 54°C UCL Umwelt Control Labor GmbH Study No. PR06/005 GLP: yes unpublished	N	N	-	Plants kydd AB	Y
	Affolter, O.	2015	Determination of the storage stability of Blood Meal (Certosan) at room temperature (duration two years). LAUS GmbH 13022801G001 GLP: Y unpublished	N	Y	-	Flügel GmbH Plants kydd AB	N
KCA 2.4	Anonym	2011	Conclusion on the peer review of the pesticide risk assessment of the active substance blood meal EFSA Journal 2011;9(10):2394 GLP/GEP: no published	N	N		public	Y
KCA 2.5	Affolter, O.	2013	Determination of the solubility in water of Blood Meal (Certosan) according to OECD 105 resp. EU A.6 LAUS GmbH Study No. 13022801GH910 GLP: yes unpublished	N	Y	-	Flügel GmbH	N
KCA 2.6	Anonym	2011	Conclusion on the peer review of the pesticide risk assessment of the active substance blood meal EFSA Journal 2011;9(10):2394 GLP/GEP: no published	N	N	-	public	Y
KCA 2.7	Anonym	2011	Conclusion on the peer review of the pesticide risk assessment of the active substance blood meal EFSA Journal 2011;9(10):2394 GLP/GEP: no published	N	N	-	public	Y
KCA 2.8	Anonym	2011	Conclusion on the peer review of the pesticide risk assessment of the active substance blood meal EFSA Journal 2011;9(10):2394 GLP/GEP: no published	N	N	-	public	Y
KCA 2.9	Thureson, P.	1995	Ignition and self-ignition of solid substances to EU-directive 84/449/EEG, enclosure 384L0449/S, clause 10 and 16 GLP: no unpublished	N	N	-	Plants kydd AB	Y
KCA 2.11	Anonym	2011	Conclusion on the peer review of the pesticide risk assessment of the active substance blood meal EFSA Journal 2011;9(10):2394 GLP/GEP: no published	N	N	-	public	Y

Data Point	Author(s)	Year	Title Company 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
KCA 2.13	Anonym	2011	Conclusion on the peer review of the pesticide risk assessment of the active substance blood meal EFSA Journal 2011;9(10):2394 GLP/GEP: no published	N	N	-	public	Y
KCA 2.14	Bockholt, K.	2006	Certosan. Storage Stability Test: 14 days 54°C UCL Umwelt Control Labor GmbH Study No. PR06/005 GLP: yes unpublished	N	N	-	Plantskydd AB	N
	Affolter, O.	2015	Determination of the storage stability of Blood Meal (Certosan) at room temperature (duration two years). LAUS GmbH 13022801G001 GLP: Y unpublished	N	Y	-	Flügel GmbH Plantskydd AB	N