European Commission

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

BLOOD MEAL

Volume 3 – B.2 (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
2019/02	Draft RAR by RMS AT after commenting by Co-RMS LT

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B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT CERTOSAN

Certosan was previously evaluated as the representative formulation for the inclusion of the active substance Blood meal in Annex I of Directive 91/414/EEC. Certosan is currently registered in different European countries in a national approach. All studies have been performed with Certosan and in accordance with the current requirements and the results are deemed acceptable. The product contains 99.8 % blood meal, so statements made by EFSA for blood meal (EFSA Journal 2011;9(10):2394) are also valid for Certosan. 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.

Some studies are performed with Certosan old (first approval 2006) and other with Certosan new. Both products are regarded as non-significant change in terms of SANCO/12638/2011. For more information see dRAR 20_Volume 4 point C.1.3.4

The appearance of the product is that of a fine, flour-like powder. Exothermic decomposition of the product was found to be very unlikely and further tests for explosive or oxidising properties were considered not necessary. The product is wettable powder and will be mixed with water. The technical characteristics are acceptable for a wettable powder and its application technique (painting, spraying in a small scale, dipping trees). Stability data after 2 years of storage was observed.

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1. APPEARANCE						
Physical state and colour **B.2.1/01**	OPPTS 830-6303 OPPTS 830-6304 OPPTS 830-6302	Certosan Blood meal 99.8 % Batch No.: AA 153	Physical state: flour-like powder Colour: dark red to brown Odour: without notifiable odour	**Acceptable**	Y	Bockholt, K. (2006) Report No.: PR06/005 DAR Blood meal (2008)*
		Blood meal (Certosan) Batch No.: 94015FO/1 Purity: 99.8% (w/w)	The tested item Blood meal (Certosan) has black red colour. It is a fine powder, almost odourless with a tingle of fish. After 24 months: Blood meal (Certosan) has black red colour. It is fine powder, less homogeneous and almost odourless.	**Acceptable**		Affolter, O. (2013) (KCA 2.1/01)Affolter, O. (2015) (KCA 2.1/02)

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.2. EXPLOSIVE AND OXIDIZING PROPERTIES						
Explosive properties B.2.2/01	-		Certosan is not explosive. Not relevant. Blood meal is a well-known widely traded commodity, used as food additive, organic fertilizer	**Acceptable**		EU-evaluated: DAR 2008, Volume 3, Annex B.2
Oxidizing properties B.2.2/02	-		Certosan has no oxidising properties. Not relevant. Blood meal is a well-known widely traded commodity, used as food additive, organic fertilizer	**Acceptable**	-	EU-evaluated: DAR 2008, Volume 3, Annex B.2
B.2.3. FLAMMABILITY AND AUTO-FLAMMABILITY						
Flash point of the liquid formulation **B.2.3/01**	-				-	-
Flammability of solid formulations **B.2.3/02**	A10	Certosan Blood meal 99.8 %	No ignition (1050 °C, 2 min) Certosan is not flammable	**Acceptable**	-	EU-evaluated: DAR 2008, Volume 3, Annex B.2
Self-heating of formulation **B.2.3/03**	A16		No self-ignition up to 400°C Certosan has no self-ignition behaviour	**Acceptable**	-	EU-evaluated: DAR 2008, Volume 3, Annex B.2
B.2.4. ACIDITY/ALKALINITY AND pH VALUE						
pH of the neat aqueous formulation **B.2.4/01**	CIPAC MT 75	-	pH 7.7 pH 7.7 pH 7.6	**Acceptable**	-	EU-evaluated: DAR 2008, Volume 3, Annex B.2

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
pH of a 1 % dilution of the solid or non-aqueous formulation **B.2.4/02**	CIPAC MT 75.3	Blood meal (Certosan) Batch No.: 94015FO/1 Purity: 99.8% (w/w)	pH 1% (w/w) suspension in deionized water at 25°C pH = 7.56 pH = 7.53 (after 24 months)	**Acceptable**	Y	Affolter, O. (2015) (KCA 2.1/02)
Acidity / Alkalinity **B.2.4/03**	-	-			-	-
B.2.5. VISCOSITY AND SURFACE TENSION						
Viscosity of the liquid formulation **B.2.5/01**	-	-			-	-
Surface tension of the formulation **B.2.5/02**	-	-			-	-
B.2.6. RELATIVE DENSITY AND BULK DENSITY						
Relative density of the liquid formulation **B.2.6/01**	-	-				
Bulk density (pour and tap) of powder or granules **B.2.6/02**	CIPAC MT 33		Bulk density: 500 g/L After compaction: 625 g/K Bulk density: 500 g/L	**Acceptable**	Y	EU-evaluated: DAR 2008, Volume 3, Annex B.2

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.7. STORAGE STABILITY AND SHELF-LIFE: EFFECTS OF TEMPERATURE ON TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT						
Stability after accelerated storage (54°C during 14 days, 8 weeks at 40°C, 12 weeks at 35°C or 18 weeks at 30°C) **B.2.7/01**	CIPAC MT 75.3 CIPAC MT 53.3.1 CIPAC MT 184 CIPAC MT 185 CIPAC MT 47.2 CIPAC MT 35	Certosan, batch AA 153, int.No UCL FL/06/001	Test — Initial — At 54°C, after 14 days pH (1% (w/v)) — 7.7 — 7.5 Wettability (5g/100ml) — no sample of the test item could be wetted within 10' in standard water D. Suspensibility (25g/50mL) — 94% — 95% Wet sieve test — 1.8% residue — 3.4% residue Persistent foaming (10g/100mL) — 72 mL — 72 mL Tap density (40g/250mL) — 0.56 g/ml Change in weight: Bottle I total weight (start) = 342.09 g total weight (end) = 342.14 g sample weight = 100.93 g difference:= +0.05 g difference [% w/w]:= +0.049% Bottle II total weight (start) = 343.37 g total weight (end) = 342.82 g sample weight = 98.53 g difference:= -0.55 g difference[% w/w]:= -0.56 % Bottle III total weight (start) = 341.17 g total weight (end) = 340.74 g sample weight = 96.10 g difference:= -0.43 g difference [% w/w]:= -0.45 % Bottle IV total weight (start) = 342.60 g total weight (end) = 342.40 g sample weight = 102.63 g difference:= -0.20 g difference[% w/w]:= -0.19 % Weight difference was -0.56% . It is considered not significant	**Acceptable**	Y	EU-evaluated: DAR 2008, Volume 3, Annex B.2
Effect of low temperature on stability of liquid formulation **B.2.7/02**	-	-			-	-

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
Shelf life following storage at ambient temperature **B.2.7/03**		Blood meal (Certosan) Batch No.: 94015FO/1 Purity: 99.8% (w/w)	Stable throughout the test period of 2 years at ambient temperature in 1 kg plastic bags (PE). No changes were observed. There was no evidence of leaks or panelling after storage. Recovery rate of iron was 96.2%.			**Acceptable**	Y	Affolter, O. (2015) (KCA 2.1/02))
			Test	Initial	After 2 years			
	OPPTS 830-6303		Physical state	Fine powder	Fine powder, less homogeneous			
	OPPTS 830-6304		Odour	Almost odourless with a tingle of fish	Almost odourless			
	OPPTS 830-6302		Colour	Black red (RAL 3007)	Black red (RAL 3007)			
	CIPAC MT 75		pH (1% suspension)	7.56	7.53			
	CIPAC MT 47.1		Persistent foaming	28-33 mL	28-34 mL			
	CIPAC MT 167		Wet sieve test	2.9% residue	3.2% residue			
	CIPAC MT 53.3		Wettability	5.5 h/ 8.4 h (two determinations)	10.6 h (two determinations)			
	ICP-OES		Fe content	0.266%	0.256%			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8. TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT						
B.2.8.1. Wettability						
Wettability of solid formulation **B.2.8.1/01**	CIPAC MT 53.3	Blood meal (Certosan) Batch No.: 94015FO/1 Purity: 99.8% (w/w)	Initial After 2 years 5.5h/8.4h 10.6h (two determinations) General comment Blood meal and so the product Certosan have a low wettability in water. Therefore, the user has to follow strict the label recommendations: the spray solution must be stirred in continuously during rinsing the powder into the water. The swirling is necessary to wet the product. It is mentioned on the product label that the product should be diluted in water under continuous swirling to avoid clumping.	**Non acceptable** Acceptable limits: a preparation is considered acceptable if there is complete wetting in 1 minute without swirling. If the criterion is met without swirling then performance of the test with swirling is not required. Where a preparation is outside this limit then evidence must be submitted demonstrating acceptable wetting in the spray tank or other application equipment.	-	Affolter, O. (2015) (KCA 2.1/02)
B.2.8.2. Persistence foaming						
Persistence of foaming of the diluted formulation **B.2.8.2/01**	CIPAC MT 47.1 CIPAC MT 47.2	Blood meal (Certosan) Batch No.: 94015FO/1 Purity: 99.8% (w/w)	Initial After 2 years 28-33 mL 28-34 mL (concentration of Certosan10 g/100 ml, 10% preparation is the highest use rate as recommended by the GAP)	**Acceptable**	-	Affolter, O. (2015) (KCA 2.1/02)
B.2.8.3. Suspensibility						
Suspensibility of water dispersible formulation **B.2.8.3/01**	CIPAC MT 161 CIPAC MT 184	Certosan Blood meal 99.8 % Batch No.: 95006D96 Certosan Blood meal 99.8 % Batch No.: AA 153	98 % in a 5 % preparation 103 % in a 10 % preparation at 20 °C 94 % in standard water D at 30 °C ± 1 °C	**Acceptable**	Y	EU-evaluated: DAR 2008, Volume 3, Annex B.2

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Spontaneity of dispersion of water dispersible formulation **B.2.8.3/02**						
Dispersion stability of SE, OD or EG formulation **B.2.8.3/03**						
B.2.8.4. Degree of dissolution and dilution stability						
Degree of dissolution of water soluble formulation **B.2.8.4/01**						
Dilution stability of water soluble formulation **B.2.8.4/02**						
B.2.8.5. Particle size distribution, dust content, attrition and mechanical stability						
B.2.8.5.1. Particle size distribution						
Wet sieve test of water dispersible formulation **B.2.8.5.1/01**	CIPAC MT 167	Blood meal (Certosan) Batch No.: 94015FO/1 Purity: 99.8% (w/w)	Initial 2.9% residue After 2 years 3.2% residue	**Non acceptable** The wet sieve has to be performed according to CIPAC MT 179.1. Where max 2% on 75µm sieve is the limit. If it is outside this limit then evidence must be submitted showing the material separated will not block application equipment or present an unacceptable risk to the operator or lead to unacceptable residues or crop safety concerns.		Affolter, O. (2015) (KCA 2.1/02)

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Size distribution of particles of powder or granules **B.2.8.5.1/02**	OECD 110 CIPAC MT 187 ISO 13320-1	Certosan Blood meal > 99 % Batch No.: AA 153	Median particle size L50: 36.7 µm L10: 11.6 µm L90: 103.6 µm	**Acceptable**		EU-evaluated: DAR 2008, Volume 3, Annex B.2
Nominal size range of granule **B.2.8.5.1/03**						
B.2.8.5.2. Dust content						
Dust content of granular formulation **B.2.8.5.2/01**						
B.2.8.5.3. Attrition						
Attrition characteristics of granules and tablets **B.2.8.5.3/01**						
B.2.8.5.4. Hardness and integrity						
Hardness of tablets **B.2.8.5.4/01**						
Integrity of tablets **B.2.8.5.4/02**						
B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability						
Emulsifiability, emulsion stability and re-emulsifiability of formulation **B.2.8.6/01**						

B.2.8.7. Flowability, pourability and dustability						
Flowability of granular formulation **B.2.8.7/01**						
Pourability of suspensions **B.2.8.7/02**						
Dustability of dustable powders after accelerated storage **B.2.8.7/03**						
B.2.9. PHYSICAL AND CHEMICAL COMPATIBILITY WITH OTHER PRODUCTS INCLUDING PLANT PROTECTION PRODUCTS WITH WHICH ITS USE IS TO BE AUTHORISED						
Physical and chemical compatibility of tank mixtures **B.2.9/01**						
B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS						
Distribution and adhesion to seeds **B.2.9.10/01**						

<table>
<tr><th>Test or Study & Data point</th><th>Guideline and method</th><th>Test material purity and specification</th><th>Used methods / Results</th><th>Comments (Acceptable / Non acceptable)</th><th>GLP</th><th>Reference</th></tr>
<tr><td colspan="7">B.2.11. OTHER STUDIES</td></tr>
<tr><td>Determination of Human Pathogenic Germs
B.2.11/01</td><td>DIN ISO 6887-1</td><td>Blood meal (Certosan)
Batch No.: 94015FO/1
Purity: 99.8% (w/w)</td><td>The absence of the following human pathogenic germs and potential support of their growth were examined at initial, 6, 12 and 24 months in an open and in a closed package. 1 kg plastic bags (PE) were used:
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)
Initial After 2 years
< limit value <limit value
<table><tr><th>Human Pathogenic Germs</th><th>Method</th><th>Result*</th></tr><tr><td>Shigella</td><td>DIN EN ISO 21567:2005</td><td>< 100 CFU/g***</td></tr><tr><td>Staphylococcus aureus at 37 °C</td><td>DIN EN ISO 6888-1</td><td>< 100 CFU/g</td></tr><tr><td>Pseudomonas aeruginosa at 25 °C</td><td>DIN EN ISO 13720:2008</td><td>< 100 CFU/g</td></tr><tr><td>Eschericha coli (incubation on TBX agar)**</td><td>DIN ISO 16649-1:2001-4</td><td>< 100 CFU/g</td></tr><tr><td>Enterobacteria at 30 °C</td><td>DIN ISO 21528-2:2004</td><td>< 100 CFU/g</td></tr><tr><td>Thermo-tolerant coliforms</td><td>NFV08-060</td><td>< 100 CFU/g</td></tr><tr><td>Listeria monocytogenes</td><td>DIN EN ISO 11290-2</td><td>< 100 CFU/g</td></tr><tr><td>Candida albicans</td><td>L 01.00-37</td><td>< 100 CFU/g</td></tr><tr><td>Salmonella ssp.
(2. agar: Salmonella-Brilliance-Agar)**</td><td>DIN EN ISO 6579:2003</td><td>in 100 g
unverifiable</td></tr><tr><td>Vibrio
(agar medium: thiosulfate-citrate-bile salts-sucrose agar and MacConkey agar)**</td><td>ISO/TS 21872-2:2007</td><td>in 100 g
unverifiable</td></tr></table>*correspond to a limit value
**(XX) = modification of the method
***Colony forming unit per gram</td><td>Acceptable</td><td>N</td><td>Affolter, O. (2015) (KCA 2.1/02)</td></tr>
</table>

The plant protection product Certosan is dark red brown fine powder, almost odourless with tingle of fish. The product does not exhibit any explosive or oxidising properties, and is non-flammable and does not self-ignite. It has a pH of 7.53 (1% w/w suspension). In addition, the wet sieve test showed that the Certosan distributed differently on the surface of water. Persistent foaming is within the range. The human pathogenic germs are under the limit values before and after storage. The product is stable for 2 years at 20°C.

The swirling is necessary to wet the product. This has to be declared on the product label. The product should be diluted in water under continuous swirling to avoid clumping.

Its technical characteristics are acceptable for a wettable powder (WP) formulation.

B.2.12. REFERENCES RELIED ON

DataPoint	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
KCP 2.1/01	Affolter, O.	2013	Determination of the storage stability of Blood Meal (Certosan) at room temperatureReport-No.: 13022801G910 facility: LAUS GmbH, Germany GLP, unpublished	N	Y	-	FLU	N
KCP 2.1/01 KCP 2.1/02 KCP 2.4/02 KCP 2.7/03 KCP 2.8.1/01 KCP 2.8.1/02 KCP 2.8.5.1/01 KCP 2.11/01	Affolter, O.	2015	Determination of the storage stability of Blood Meal (Certosan) at room temperatureReport-No.: 13022801G001 facility: LAUS GmbH, Germany GLP, unpublished	N	Y	-	FLU	N

FLU- Flügel GmbH, Germany