# *European Commission*

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

# BLOOD MEAL

## Volume 3 – B.5 (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.5. METHODS OF ANALYSIS

This document reviews the analytical methods 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.

## B.5.1. METHODS USED FOR THE GENERATION OF PRE-AUTHORISATION DATA

### B.5.1.1. Analysis of the Plant Protection Product (CP 5.1.1)

Analytical methods for the determination of Blood meal and their impurities and relevance of CIPAC methods were evaluated as part in the EU review. The respective data are considered adequate and are not included in this submission. Additional studies to support the registration of Certosan not previously assessed are presented within this dossier. All relevant data are provided and are considered adequate.

#### B.5.1.1.1. Method for the determination of Active substance in the preparation

In the formulation the content of Iron can be determined by ICP-OES or AAS.

The report is considered confidential, here only the method is roughly described.

| **Ref. Point:** | **KCP 5.1.1/01** |
|---|---|
| Authors: | Affolter, O. (2013a) |
| Title: | Determination of iron in the test item Blood Meal (Certosan) according to SANCO 3030/99, rev. 4 (5 batch analysis) |
| Company/Source: | Laus GmbH, Kirrweiler, Germany |
| Report No. | 13013101G404 |
| Report date: | 19.02.2013 |
| Guideline: | SANCO 3030/99 rev. 4 |
| GLP | Yes |

Method description

The iron content in the active ingredient was determined by AAS using an air/acetylene flame and detection at 248.327 nm.

Method validation

The validation data of method 13013101G404 (SOP 114 00 520) were determined for the formulation Certosan. It was with respect to precision, accuracy, linearity and specificity proved that the method is suitable for the determination of iron in the WP-formulation.

Table containing the methods and validation of the methods (formulation Certosan)

| **Analyte** | **Linearity n= 5** | **Accuracy Mean [%]** | **Repeatability n=5 [% RSD]** | **Specificity/Interferences** |
|---|---|---|---|---|
| Iron | 0.1 – 2.0 mg/L (0.02-0.4 % w/w) r = 0.9997 | No information on recovery. For consecutive addition steps only linearity was determined. | For 5 batches RSD between 1.59 and 3.37 % were determined RSDr = 3.25 % | AAS can be regarded as highly specific. |

Summary

The iron content in Certosan can be quantified by AAS. The method was developed for quantifying iron content in Certosan.

ICP-OES method for determination of Fe in Certosan

| **Ref. Point:** | **KCP 5.1.1/01** |
|---|---|
| Authors: | Affolter, O. (2015) |
| Title: | Determination of the storage stability of Blood Meal (Certosan) at room temperature |
| Company/Source: | Laus GmbH, Kirrweiler, Germany |
| Report No. | 13022801G001 |
| Guideline: | SANCO 3030/99 rev. 4 |
| GLP | Yes |

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Specificity & Confirmation of identification: ICP-OES is a highly specific method for chemical elements.

• Calibration (Linearity): The linearity was checked using 5 to 8 different concentrations (1 – 40 µg/L). Detailed results can be found in table below.

• Accuracy (Recovery): Samples of all batches were spiked with 0.5 and 1 mg/kg of the reference substance. Recovery rates of the spiked samples were determined and the mean was found to be between 75 and 125 %.

• Precision (Repeatability): As no sample spiked with reference material was analyzed 5 times no precision could be determined.

Table containing the methods and validation of the methods (formulation Certosan)

| **References** | **Method** | **Analyte** | **Specificity / interferences** | **Calibration** | **Accuracy** | **Precision** |
|---|---|---|---|---|---|---|
| Affolter O. (2015); | ICP-OES | Fe | No interferences | n = 7<br>0.1 – 2.5 mg/L (0.02 – 0.5 %w/w)<br>R > 0.999 | - | n = 5<br>RSD 2.26 %<br>RSDr 3.30 % |

### B.5.1.1.2. Methods for the determination of degradation products in the preparation

There is no decrease of the content in the active substance in the preparation after storage therefore an analytical method and validation is not needed.

### B.5.1.1.3. Methods for the determination of relevant impurities identified in the technical material or which may be formed during manufacture of the preparation or from degradation of the preparation during storage

Blood meal does not contain any impurity of toxicological or ecotoxicological concern.

### B.5.1.1.4. Methods for the determination of relevant co-formulants or components of co-formulants, where required by the national competent authorities.

With respect to toxicological, eco-toxicological or environmental aspects the product does not contain any relevant formulants. Therefore, a special analytical method and validation is not needed.

### B.5.1.1.5. Applicability of existing CIPAC methods

No CIPAC method is available for the determination of Blood meal in WP formulations.

### B.5.1.2. Methods for the Determination of Residues

The active ingredient will be used in a game repellent formulation. No residues of toxicological concern will occur on animals or plants. No analytical methods for the determination of residues for products of plant and animal origin are required. The residue definition and MRL's setting are not applicable for the active substance and formulation.

### (a) Methods in soil, water, sediment, air and any additional matrices used in support of environmental fate studies

No studies on the environmental fate of Certosan are submitted, and consequently no analytical methods for environmental fate studies are included in this dossier.

### (b) Methods in soil, water and any additional matrices used in support of efficacy studies

No efficacy studies are submitted, and consequently no analytical methods for efficacy studies are included in this dossier.

### (c) Methods in feed, body fluids and tissues, air and any additional matrices used in support of toxicological studies

No toxicological studies are submitted, and consequently no analytical methods for toxicological studies are included in this dossier.

### (d) Methods in body fluids, air, and any additional matrices used in support of operator, worker, resident and bystander exposure studies

No human exposure studies are submitted, and consequently no analytical methods for human exposure studies are included in this dossier.

### (e) Methods in or on plants, plant products, processed food commodities, food of plant and animal origin, feed and any additional matrices used in support of residues studies

No residue studies are submitted, and consequently no analytical methods for residue studies are included in this dossier.

### (f) Methods in soil, water, sediment, feed and any additional matrices used in support of ecotoxicology studies

New studies testing the effect of Certosan on aquatic organisms are submitted within this dossier.
Within these studies submitted, under KCP 10.2.1/01-10.2.1/03 the content of the Blood Meal (Certosan) in the test solution was determined by calculation from the carbon content of the test item and DOC measurement following SOP 118 009 02. No further details on the analytic method are provided within this dossier.

### (g) Methods in water, buffer solutions, organic solvents and any additional matrices resulting from the physical and chemical properties tests

No analytical methods are included in new physico-chemical studies.

## B.5.2. METHODS FOR POST-AUTHORISATION CONTROL AND MONITORING PURPOSES (CP 5.2)

### (a) Methods for the determination of residues in or on plants, plant products, processed food commodities, food and feed of plant and animal origin

As no residue definitions/MRLs are set, no methods are required.

### (b) Methods for the determination of residues in body fluids and tissues

Methods for body fluids and tissues are not required, because blood meal is not considered to be toxic or very toxic (T / T+) nor is it classified according to GHS as follows: Acute toxicity (cat. 1-3), CMR (cat. 1) or STOT (cat. 1)

### (c) Methods for the determination of residues in soil

As no residue definitions/MRLs are set, no methods are required.

### (d) Methods for the determination of residues in water

As no residue definitions/MRLs are set, no methods are required.

### (e) Methods for the determination of residues in air, unless the applicant shows that exposure of operators, workers, residents or bystanders is negligible

As no residue definitions/MRLs are set, no methods are required.

## B.5.3. REFERENCES RELIED ON

| Data Point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|---|---|---|---|---|---|---|---|
| KCP 5.1.1/01 | Affolter, O | 2013 | Determination of Iron in the test item<br>Blood Meal (Certosan) according to SANCO 3030/99, rev. 4<br>(5 batch analysis)<br>LAUS GmbH<br>Report No. 13013101G404<br>GLP: yes<br>unpublished | N | Y | - | Plantskydd AB | N |