

FINAL REGISTRATION REPORT

Part B

Section 5

Analytical Methods

Detailed summary of the risk assessment

Product code: XNJ25 251 g/kg

Chemical active substance:

Quartz sand, 251 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Product re-authorisation; Art. 43)

Applicant: FMC Corporation

Submission date: 24/11/2023

MS Finalisation date: 11/2025

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Version history

When	What
November 2023	Original submission
March 2024	Dossier sent for evaluation
June 2025	zRMS evaluation of dRR
November 2025	Final RR

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zRMS comments:

The text highlighted in grey was provided by the zRMS.

5 Analytical methods

Product Cervacol Extra was one of the representative formulations considered during the EU evaluation.

EU evaluated methods of analysis are available for the determination of the active substance in the technical material and in formulation Cervacol Extra.

Analytical methods for the determination of residues in food and feed of plant origin, in food of animal origin, body fluids and tissues and in environmental compartments are not required due to the fact that no residue definitions are proposed.

For Task force Avenarius Agro GmbH and Cheminova Deutschland GmbH & Co. KG EFSA lists three outstanding issues with respect to analytical methods (Section 10, EFSA (2022)):

- Applicant Task force Avenarius and Cheminova to provide data on the active substance content in the formulation ‘Cervacol Extra’ before and after accelerated storage, before and after shelf life at ambient temperature and the analytical method used for its determination (relevant for representative uses evaluated for ‘Cervacol Extra’).
- Applicant Task force Avenarius and Cheminova to provide a validated method for the determination of the quartz sand in the active substance as manufactured (relevant for the representative uses evaluated for ‘Cervacol Extra’).
- Applicant Task force Avenarius and Cheminova to provide validation data for the proposed laser granulometry method for the determination of particle size distribution of the technical active substance. It should be noted that a method that can determine particles with a diameter $\leq 10 \mu\text{m}$ is required. Alternatively, any other validated method that can determine particles with a diameter $\leq 10 \mu\text{m}$ can be provided (see Section 1)

The analytical methods as requested above have been validated and are summarized in this Part B5.

A new spectrophotometric method was validated to determine particles with a diameter $\leq 10 \mu\text{m}$. Validation data for the laser granulometry method is therefore no longer required and is not submitted.

5.1 Conclusion and summary of assessment

Analytical methods for the determination of residues in food and feed of plant origin, in food of animal origin, body fluids and tissues and in environmental compartments are not required due to the fact that no residue definitions or MRLs are proposed.

Sufficiently sensitive and selective analytical methods are **not** available for the active substance and relevant impurities in the plant protection product.

Noticed data gaps are: **none**

- ~~data gap 1~~
- ~~data gap 2~~
- ~~data gap 3~~

~~Sufficiently sensitive and selective analytical methods are not available for all analytes included in the residue definitions.~~ Analytical methods for the determination of residues in food and feed of plant origin, in food of animal origin, body fluids and tissues and in environmental compartments are not required due to the fact that no residue definitions or MRLs are proposed.

Noticed data gaps are:

- None

Commodity/crop	Supported/ Not supported
Deciduous (3FOBC) and coniferous trees (3FOCC) in forestry	Supported

5.2 Methods used for the generation of pre-authorization data (KCP 5.1)

5.2.1 Analysis of the plant protection product (KCP 5.1.1)

5.2.1.1 Determination of active substance and/or variant in the plant protection product (KCP 5.1.1)

A new analytical method to determine the content of the active substance in Cervacol Extra is provided to address an outstanding issue as raised in EFSA (2022).

Comments of zRMS:	Accepted
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Reference:	KCP 5.1.1/01
Report:	Giorgi, S., (2022); Determination of the Active Ingredient Content of the Cervacol Extra, Including Validation of the Analytical Method
Report No.:	FMC-58762
Testing Facility Report No.:	21354-01C
Guidelines	Yes, SANCO 3030/99 rev. 5
Deviations:	None
GLP:	Yes
Acceptability:	Yes

CONCLUSIONS

The active ingredient (Silicon dioxide) and its impurity (crystalline silica <10µm) in the preparation Cervacol Extra was determined by a spectrophotometric method, validated in the course of this study and coded as MA CCF 614-1.

The method for Silicon dioxide determination was validated for specificity, linearity, repeatability and accuracy, in compliance with SANCO/3030/99 rev.5 (22/03/19). The reagent blank solution showed no interference. The spectrum of active ingredient(s) in the sample solution matched the spectrum in the reference item(s) solution. Specificity was also confirmed by XRPD at Redox's facility. The detector response was linear ($r^2 > 0.98$) for the active ingredient in the concentration range considered. Active ingredient concentrations in sample solutions were within the linear range of the detector response. Horrat was within limits (≤ 1), and the active ingredient content was in compliance with Regulation (EU) No. 528/2012. Accuracy was within the limits determined by the active ingredient's concentration. The data presented in this report demonstrate that the analytical method provides a specific, reliable, accurate and precise procedure for the determination of active ingredient in the Cervacol Extra product. The analytical method developed for the determination of Crystalline silica <10µm in Cervacol Extra was validated with respect to specificity, linearity of detector response, precision and accuracy. Square correlation coefficient (r^2) and modified Horwitz values (%RSD) fulfilled the requirements of SANCO/3030/99 rev. 5. The data presented in this report demonstrate that the analytical method provides a specific, reliable, accurate and precise procedure for the determination of impurity Crystalline silica <10µm in the Quartz sand technical.

For the detailed evaluation of new/additional studies it is referred to Appendix 2.

5.2.1.2 Description of analytical methods for the determination of relevant impurities (KCP 5.1.1)

Respirable crystalline silica (SiO₂) with a diameter $\leq 10 \mu\text{m}$ was considered as a relevant impurity with a maximum amount of 1 g/kg.

The study summarized under Section 5.2.1.1 includes a validated method to determine crystalline silica in the formulation Cervacol Extra. Please refer to 5.2.1.1 and Appendix 2 respectively.

5.2.1.3 Description of analytical methods for the determination of formulants (KCP 5.1.1)

Not required. Since the formulants or other constituents in Cervacol Extra are not considered to be of particular toxicological, ecotoxicological or environmental concern, corresponding analytical methods are not considered to be required.

5.2.1.4 Applicability of existing CIPAC methods (KCP 5.1.1)

No CIPAC methods exist.

5.2.2 Methods for the determination of residues (KCP 5.1.2)

Analytical methods for the determination of residues in food and feed of plant origin, in food of animal origin, body fluids and tissues and in environmental compartments are not required due to the fact that no residue definitions are proposed.

5.3 Methods for post-authorization control and monitoring purposes (KCP 5.2)

5.3.1 Analysis of the plant protection product (KCP 5.2)

The methods already submitted in accordance with the requirements set out in Section 5.2.1 can be applied.

5.3.2 Description of analytical methods for the determination of residues of quartz sand (KCP 5.2)

5.3.2.1 Overview of residue definitions and levels for which compliance is required

Compared to the residue definition proposed in the Renewal Assessment Report (incl. its addenda) the current legal residue definition is identical.

No residue definitions have been set and thus no analytical methods are required or submitted respectively.

5.3.2.2 Other studies/information

A study was conducted to determine silica and impurities, in five batches of quartz sand technical. While

the results are summarized in confidential Part C, the validation of the method used for the determination is summarized below.

Comments of zRMS:	Accepted
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Reference:	5.2/01
Report:	Giorgi, S., (2022); Determination of silica and impurities, including validation of the analytical method, in five batches of Quartz sand technical
Report No.:	FMC-58761
Testing Facility Report No.:	21355-01C
Guidelines	SANCO 3030/99 rev. 5
Deviations:	None
GLP:	Yes
Acceptability:	Yes

5.3.3 Active ingredient (Silicon dioxide) method validation summary

Method principle: Silicon dioxide was determined spectrophotometrically.

Specificity: The spectrum of the Molybdenum blue complex obtained from test item was compared with spectrum of the Molybdenum blue complex obtained from reference item. Specificity was also confirmed by XRPD at Redox's facility.

Linearity: The calibration curve was calculated from reference item solutions in the tabled concentration range. The correlation coefficient was found to be:

Analyte	Conc. Range	Square Correlation Coefficient r^2	Acceptability according to SANCO 3030/99 rev. 5
Silicon dioxide	0.0029-0.0072 mg/mL (57.65-144.11 %w/w) ¹	0.9983	$r^2 > 0.98$

¹ Referred to the test item solution concentration at 0.01 mg/mL

Precision: The Horrat for the whole procedure of sample preparation and measurement of five independent samples of batch 000008233-1 (21355) was found to be:

Active ingredient	RSD %	RSDr %	Hr ⁽¹⁾	Acceptability according to SANCO 3030/99 rev. 5
Silicon dioxide	0.34	1.34	0.26	$Hr \leq 1$

⁽¹⁾Horowitz ratio = RSD %/RSDr %

Representative spectra are presented in the appendices.

5.3.4 Impurity (Crystalline silica <10µm) method validation summary

Method principle: Crystalline silica <10µm was determined spectrophotometrically.

Specificity: The spectrum of the Molybdenum blue complex obtained from test item was compared with spectrum of the Molybdenum blue complex obtained from reference item. X-ray analysis of the collected fraction <10µm was performed. In absence of said fraction the analysis of the whole samples (not fractioned) was considered valid also for the fraction below 10 µm. The analytical technique adopted for qualitative analysis on quartz sand is valid for powder of different particles size, also for samples with very thin size below 10 µm, as micronized powders.

Linearity: A calibration curve of 1st degree was found. The calibration curve was calculated from standards solutions in the tabled concentration range. The correlation coefficient was found to be:

Analyte	Conc. Range	Square Correlation Coefficient r^2	Acceptability according to SANCO 3030/99 rev. 5
Crystalline silica <10µm	0.0018-0.0069 mg/mL (0.33-1.23 %w/w) ¹	0.9989	$r^2 > 0.98$

¹: %w/w based on nominal test item solution concentration of 0.56 mg/mL.

Precision: Since the content of Crystalline silica <10µm in the formulation is below LOD (0.33%), precision was determined by analysing 5 recovery samples at LOQ (0.50%):

Analyte	RSD %	RSD r%	Horrat	Acceptability according to SANCO 3030/99 rev. 5
Crystalline silica <10µm	2.06	2.97	0.69	Horrat < 1

Accuracy: The test was performed by standard addition. Suitable volumes of standard reference were added to the test item. The solutions were properly treated according to the method set-up and were performed by fortification of test item at two levels, LOQ and an appropriate second level set between the highest concentration found in test item and the concentration of the last point in the calibration curve. The mean recoveries were found to be:

Analyte	Level	Mean recovery %	Acceptability according to SANCO 3030/99 rev. 5
Crystalline silica <10µm	LOQ 0.50 %	101.8	80-120 %
	HIGH 2.0 %	89.9	90-110 %

LOD and LOQ: LOD corresponds to the lowest reference item concentration tested; LOQ corresponds to the lowest concentration at which an acceptable recovery is obtained.

Analyte	LOD	LOQ
Crystalline silica <10µm	0.33 %	0.50 %

Representative spectra are presented in the study report.

5.3.5 Metallic impurities method validation

- Method principle:** Metallic impurities were determined by an ICP-OES (Inductively Coupled Plasma-Optical Emission Spectrometry) method.
- Specificity:** Two specific wavelengths were used for each metal; furthermore, the blank solution (HNO₃ 2%) showed no interferences).
- Linearity:** A calibration curve of 1st degree was found for each analyte. The calibration curve was calculated from standards solutions in the tabled concentration range. The correlation coefficient was found to be:

Analyte	Conc. Range	Square Correlation Coefficient [r ²]	Acceptability according to SANCO 3030/99 rev. 5
Al	3.0-20.0 mg/L 0.043-0.286 % w/w ¹	0.9940	r ² >0.9801
As	3.0-20.0 mg/L 0.043-0.286 % w/w ¹	0.9965	r ² >0.9801
Cr	2.4-16.0 mg/L 0.034-0.229 % w/w ¹	0.9995	r ² >0.9801
Fe	3.0-20.0 mg/L 0.043-0.286 % w/w ¹	0.9940	r ² >0.9801
Hg	3.0-20.0 mg/L 0.043-0.286 % w/w ¹	0.9971	r ² >0.9801
Ni	0.30-2.0 mg/L 0.004-0.043% w/w ¹	0.9928	r ² >0.9801
Pb	0.30-2.0 mg/L 0.004-0.043% w/w ¹	0.9936	r ² >0.9801
Ti	3.0-20.0 mg/L 0.043-0.286 % w/w ¹	0.9977	r ² >0.9801

¹Based on test item concentration of 7 g/L.

- Accuracy:** The test was performed by standard addition. Suitable volumes of standard reference solution were added to the test item solution. The solutions were properly treated according to the method set-up and were performed by fortification of test item at two levels, LOQ and an appropriate second level set between the higher concentration found in test item and the concentration of the last point in the calibration curve. The mean recoveries were found to be:

Analyte	LOQ level	Mean recovery %	Acceptability according to SANCO 3030/99 rev.5
Al	0.071 %	113.8	75-125 %
As	0.071 %	97.5	75-125 %
Cr	0.057 %	99.1	75-125 %
Fe	0.071 %	94.6	75-125 %
Hg	0.071 %	108.8	75-125 %
Ni	0.007 %	99.4	75-125 %
Pb	0.007 %	122.8	75-125 %
Ti	0.071 %	118.2	75-125 %

Analyte	High level	Mean recovery %	Acceptability according to SANCO 3030/99 rev. 5
Al	0.126 %	85.3	80-120 %
As	0.114 %	89.3	80-120 %
Cr	0.091 %	83.0	75-125 %
Fe	0.126 %	118.4	80-120 %
Hg	0.114 %	100.3	80-120 %
Ni	0.011 %	92.3	75-125 %
Pb	0.011 %	120.1	75-125 %
Ti	0.126 %	94.2	80-120 %

The accuracy was within the limits given in SANCO/3030/99 rev.5.

Precision:

The method precision (overall precision) was assessed as Horrat for the whole procedure of sample preparation and measurement of five independent samples (for Fe) or recoveries at LOQ (for all other impurities), since the analyte in the samples was below LOD.

Analyte	Horrat	Acceptability according to SANCO 3030/99 rev. 5
Al	0.45	Horrat<1
As	0.20	Horrat<1
Cr	0.66	Horrat<1
Fe	0.53	Horrat<1
Hg	0.09	Horrat<1
Ni	0.06	Horrat<1
Pb	0.13	Horrat<1
Ti	0.39	Horrat<1

Therefore, the determined precision fell within the limits given in SANCO/3030/99 rev.5 by the modified Horowitz equation.

LOD and LOQ: LOD corresponds to the lowest reference item concentration tested; LOQ corresponds to the lowest concentration at which an acceptable recovery is obtained.

Analyte	LOD	LOQ
Al	0.043 %	0.071 %
As	0.043 %	0.071 %
Cr	0.034 %	0.057 %
Fe	0.043 %	0.071 %
Hg	0.043 %	0.071 %
Ni	0.004 %	0.007 %
Pb	0.004 %	0.007 %
Ti	0.043 %	0.071 %

Representative spectra are presented in the appendices.

All the data reported in the tables of this report are rounded values taken from Excel spreadsheets, which will be archived with the raw data. The use of Excel spreadsheets to make the calculations produces more accurate endpoints. These endpoints may occasionally slightly differ from the values derived by substituting the rounded values in calculations.

5.4 Conclusion

The method for Silicon dioxide determination was validated for specificity, linearity and precision, in compliance with SANCO/3030/99 rev.5 (22/03/19).

The analytical method developed for the determination of Crystalline silica <10µm in Quartz sand technical was validated with respect to specificity, linearity of detector response, precision and accuracy. Square correlation coefficient (r^2) and modified Horwitz values (%RSD) fulfilled the requirements of SANCO/3030/99 rev. 5.

The analytical method developed for the determination of Al, As, Cr, Fe, Hg, Ni, Pb and Ti in Quartz sand technical was validated with respect to specificity, linearity of detector response, precision and accuracy. Square correlation coefficient (r^2) and modified Horwitz values (%RSD) fulfilled the requirements of SANCO/3030/99 rev. 5.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on – all documents

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	Owner
KCP 5.1.1/01	Giorgi, S.	2022	Determination of the Active Ingredient Content of the Cervacol Extra, Including Validation of the Analytical Method FMC-58762 RenoLab S.R.L. GLP: Yes Published: No	N	FMC
KCP 5.2./01	Giorgi, S.	2022	Determination of silica and impurities, including validation of the analytical method, in five batches of quartz sand technical FMC-58761 RenoLab S.R.L. GLP: Yes Published: No	N	FMC

List of data submitted by the applicant and relied on – vertebrate studies

No vertebrate studies submitted.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

No studies previously evaluated and relied upon.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review – vertebrate studies

No vertebrate studies previously submitted.

List of data submitted by the applicant and not relied on

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	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on not submitted by the applicant but necessary for evaluation

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	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of submitted analytical methods

A 2.1 Analytical methods for Quartz sand

A 2.1.1 Methods used for the generation of pre-authorization data (KCP 5.1)

A 2.1.1.1 Analytical method 1

Comments of zRMS:	Accepted
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Reference:	KCP 5.1.1/01
Report:	Giorgi, S., (2022); Determination of the Active Ingredient Content of the Cervacol Extra, Including Validation of the Analytical Method
Report No.:	FMC-58762
Testing Facility Report No.:	21354-01C
Guidelines	Yes, SANCO 3030/99 rev. 5
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Summary:

The study purpose is the determination of the active ingredient and relevant impurity content of Cervacol Extra product, and validation of the analytical method.

Material and Methods:

The active ingredient (Silicon dioxide) and its impurity (crystalline silica <10µm) in the preparation Cervacol Extra was determined by a spectrophotometric method, validated in the course of this study and coded as MA CCF 614-1.

1. Active ingredient (Silicon dioxide) method validation summary:

Results and discussions

Method principle: Silicon dioxide was determined spectrophotometrically.

Specificity: The spectrum of the Molybdenum blue complex obtained from test item was compared with spectrum of the Molybdenum blue complex obtained from reference item. Specificity was also confirmed by XRPD at Redox's facility.

Linearity: The calibration curve was calculated from 5 reference item solutions in the tabled concentration range. The correlation coefficient was found to be:

Analyte	Conc. Range	Square Correlation Coefficient r^2	Acceptability according to SANCO 3030/99 rev. 5
Silicon dioxide	0.0029-0.0072 mg/mL (14.41-36.03 %w/w) ¹	0.9997	$r^2 > 0.98$

¹ Referred to the test item solution concentration at 0.02 mg/mL

Precision: The Horrat for the whole procedure of sample preparation and measurement of five independent samples was found to be:

Active ingredient	RSD %	RSDr %	Hr ⁽¹⁾	Acceptability according to SANCO 3030/99 rev. 5
Silicon dioxide	0.63	1.65	0.38	$Hr \leq 1$

⁽¹⁾Horowitz ratio = RSD %/RSDr %

Accuracy: The test was performed by standard addition. Suitable amounts of standard reference were added to test item in order to give a lower and higher level of the nominal content. The solutions were properly treated according to the method set-up. The accuracy of the analytical method was reported as mean recovery and was found to be:

Active ingredient	Mean recovery, %	Acceptability according to SANCO 3030/99 rev. 5
Silicon dioxide	98.2	97-103 %

Content:

Active ingredient	Content	Acceptability according to Regulation (EU) No. 528/2012
Silicon dioxide	25.02±0.16 % w/w	23.85-26.36 % w/w

Impurity (Crystalline silica <10µm) method validation summary

Results and discussions

Method principle: Crystalline silica <10µm was determined spectrophotometrically.

Specificity: The spectrum of the Molybdenum blue complex obtained from test item was compared with spectrum of the Molybdenum blue complex obtained from reference item. X-ray analysis of the collected fraction <10µm was performed. In absence of said fraction the analysis of the whole samples (not fractioned) was considered valid also for the fraction below 10 µm. The analytical technique adopted for qualitative analysis on quartz sand is valid for powder of different particles size, also for samples with very thin size below 10 µm, as micronized powders.

Linearity: A calibration curve of 1st degree was found. The calibration curve was calculated from standards solutions in the tabled concentration range. The correlation coefficient was found to be:

Analyte	Conc. Range	Square Correlation Coefficient r^2	Acceptability according to SANCO 3030/99 rev. 5
Crystalline silica <10µm	0.0014-0.0068 mg/mL (0.24-1.20 %w/w) ¹	0.9992	$r^2 > 0.98$

¹: %w/w based on nominal test item solution concentration of 0.56 mg/mL.

Precision: Since the content of Crystalline silica <10µm in the formulation is below LOD (0.24%), precision was determined by analysing 5 recovery samples at LOQ (0.50%):

Analyte	RSD %	RSD r%	Horrat	Acceptability according to SANCO 3030/99 rev. 5
Crystalline silica <10µm	1.39	2.97	0.47	Horrat < 1

Accuracy: The test was performed by standard addition. Suitable volumes of standard reference were added to the test item. The solutions were properly treated according to the method set-up and were performed by fortification of test item at two levels, LOQ and an appropriate second level set between the highest concentration found in test item and the concentration of the last point in the calibration curve. The mean recoveries were found to be:

Analyte	Level	Mean recovery %	Acceptability according to SANCO 3030/99 rev. 5
Crystalline silica <10µm	LOQ 0.50 %	87.8	80-120 %
	HIGH 2.00 % w/w	91.5	90-110 %

LOD and LOQ: LOD corresponds to the lowest reference item concentration tested; LOQ corresponds to the lowest concentration at which an acceptable recovery is obtained.

Analyte	LOD	LOQ
Crystalline silica <10µm	0.24 % w/w	0.50 % w/w

Conclusion

The method for Silicon dioxide determination was validated for specificity, linearity, repeatability and accuracy, in compliance with SANCO/3030/99 rev.5 (22/03/19).

The analytical method developed for the determination of Crystalline silica <10µm in Cervacol Extra was validated with respect to specificity, linearity of detector response, precision and accuracy. Square correlation coefficient (r^2) and modified Horwitz values (%RSD) fulfilled the requirements of SANCO/3030/99 rev. 5.

A 2.1.1.1.1 Analytical method 2

Comments of zRMS:	Accepted
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Validated analytical method for the determination of the relevant impurity:

Reference:	KCP 5.1.1/01
Report:	Giorgi, S., (2022); Determination of the Active Ingredient Content of the Cervacol Extra, Including Validation of the Analytical Method
Report No.:	FMC-58762
Testing Facility Report No.:	21354-01C
Guidelines	Yes, SANCO 3030/99 rev. 5
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Please refer to A 2.1.1.1 Analytical method 1.

A 2.1.2 Methods for post-authorization control and monitoring purposes (KCP 5.2)

A 2.1.2.1 Description of analytical methods for the determination of residues in plant matrices (KCP 5.2)

No new or additional studies have been submitted.

A 2.1.2.2 Description of analytical methods for the determination of residues in animal matrices (KCP 5.2)

No new or additional studies have been submitted.

A 2.1.2.3 Description of Methods for the Analysis of Soil (KCP 5.2)

No new or additional studies have been submitted.

A 2.1.2.4 Description of Methods for the Analysis of Water (KCP 5.2)

No new or additional studies have been submitted.

A 2.1.2.5 Description of Methods for the Analysis of Air (KCP 5.2)

No new or additional studies have been submitted.

A 2.1.2.6 Description of Methods for the Analysis of Body Fluids and Tissues (KCP 5.2)

No new or additional studies have been submitted

A 2.1.2.7 Other Studies/Information

Comments of zRMS:	Accepted
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Reference:	5.2/01
Report:	Giorgi, S., (2022); Determination of silica and impurities, including validation of the analytical method, in five batches of Quartz sand technical
Report No.:	FMC-58761
Testing Facility Report No.:	21355-01C
Guidelines	SANCO 3030/99 rev. 5
Deviations:	None
GLP:	Yes
Acceptability:	Yes

Summarized in this document in Section 5.3.2.2.