

# **FINAL REGISTRATION REPORT**

## **Part B**

### **Section 5**

#### **Analytical Methods**

Detailed summary of the risk assessment

Product code:

Product name(s):

Chemical active substance:

Ferric phosphate, 10.0 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

#### **CORE ASSESSMENT**

Applicant: Sharda Cropchem España S.L.

Submission date: November 2020

Updated: 03/2023, 05/2023

MS Finalisation date: 07/2021; 10/2021; 05/2023

## Version history

When	What
06.2021	RMS Assessment
10.2021	The Final Version of the RR
03.2023	Update by Applicant - Part B5 (RI determination and analytical method validation for RI) and equivalency report
05.2023	Update by Applicant - Part B5 (update of RI determination and analytical method validation for RI)
05.2023	Assessment of Applicant's update (equivalence and RI determination and analytical methods validation for RI) by zRMS

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## 5 Analytical methods

### 5.1 Conclusion and summary of assessment

### 5.2 Conclusion and summary of assessment

Sufficiently sensitive and selective analytical methods are available for the active substance.

Noticed data gaps:

no methods to show the determination of relevant impurities in the plant protection product have been provided.

Study is “on-going”

- none

Ferric phosphate is listed in Annex IV of Regulation (EC) No 396/2005. Therefore, a residue definition and MRLs were not established.

Analytical methods for determination of residues are not required.

Commodity/crop	Supported/ Not supported
Fruit crops	Not required
Vegetable crops	Not required
Field crops	Not required
Grapevine	Not required
Ornamentals	Not required
Hop	Not required

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

#### 5.3.1 Analysis of the plant protection product (KCP 5.1.1)

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

An overview on the acceptable methods and possible data gaps for analysis of Ferric phosphate in plant protection product is provided as follows:

Reference: KCP 5.1.1

Report Iron phosphate 1.0% GB: Analysis of active substances content and physicochemical properties of initial preparation and preparation after accelerated storage procedure (CIPAC MT 46.3). B. Krzysiak-Warzała, 2017, Report No. 18/2017/BA-AD

Guideline(s):	No
Deviations:	No
GLP:	Yes
Acceptability:	Yes

**Materials and methods**

The test was carried out in X-Ray Fluorescence Spectrometry Laboratory of Analytical Department of ICSO “Blachownia”. The XTF analysis were performed according to the internal test procedure BA-AH/PB-01 “General procedure for determination of elemental composition in X-Ray Fluorescence Spectrometry Laboratory”. In measurements energy dispersive X-ray fluorescence spectrometer (EDXRF) were used.

**Equipment**

Bruker Spectrometer EDXRF Ranger S2  
 Fusion Fluxana, Vulcan type  
 SCALTEC analytical balance

**Reagents**

Flux agent Lithium tetraborate, PD Instruments

**Fluxing parameters**

The sample (1 g) was mixed with the flux (approx. 8 g of lithium tetraborate) in platinum crucible. The mixture was heated in a fuser to give a borate alloy.

**XRF measurement conditions**

X-Ray tube voltage: 40 kV  
 X-Ray tube current: 250µA  
 Filter: AL 500µm  
 Time of scan: 100s  
 The measurements included the sum of the signals FeK<sub>α1</sub> and FeK<sub>β1</sub>, i.e. energy range: 6.710 ± 0.621 keV.

**Validation - Results and discussions**

The validation of the analytical method for the determination of ferric in the test item Iron Phosphate 1.0% GB was performed and provided the following parameters:

**Table 5.3-1: Methods suitable for the determination of Ferric phosphate in plant protection product Iron phosphate 2.97% GB**

	Ferric phosphate
Author(s), year	B. Krzysiak-Warzała, 2017
Principle of method	XRF
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	6 points 0.06 – 0.70% of Fe $Y = 0.0575x - 0.0299$ $R = 0.99894$

	Ferric phosphate
<b>Precision – Repeatability Mean</b> n = 3 (%RSD)	%RSD = 1.84-8.54 – 9.38%
<b>Accuracy</b> n = 5 (% Recovery)	%Recovery = 96.99-98.57%
<b>Interference/ Specificity</b>	No interference

**Conclusion**

The analytical method for determination of iron phosphate phosphate in the test item Iron Phosphate 1.0 GB was validated.

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

~~Study on going.~~

An overview on the acceptable methods and possible data gaps for analysis of relevant impurities in plant protection product is provided as follows:

<del>Comments of zRMS:</del>	<del>Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information</del>
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<del>Reference:</del>	<del>KCP 5.1.1.2</del>
<del>Report</del>	<del>Method validation and determination of relevant impurities Lead, Mercury and Cadmium in Iron Phosphate 1% GB, Mr. K. Vasu, 2023, Report No.: 11255/2022</del>
<del>Guideline(s):</del>	<del>Yes SANCO 3030/99 rev. 5</del>
<del>Deviations:</del>	<del>No</del>
<del>GLP:</del>	<del>Yes</del>
<del>Acceptability:</del>	<del>Yes</del>

**Materials and methods**

<del>Active substance:</del>	
<del>Test substance name:</del>	<del>Iron phosphate 1.0% GB</del>
<del>Appearance:</del>	<del>Light blue granules</del>
<del>Chemical Abstract Name:</del>	<del>Ferric Phosphate</del>
<del>IUPAC Name:</del>	<del>Ferric Phosphate</del>
<del>CAS No.:</del>	<del>10045-86-0</del>
<del>Common Name:</del>	<del>Iron Phosphate</del>
<del>Formulation Type:</del>	<del>Granular Bait</del>
<del>Batch No.:</del>	<del>SCL 9008002</del>
<del>Active Content (% w/w):</del>	<del>0.99% w/w</del>
<del>Molecular Weight:</del>	<del>150.82</del>
<del>Molecular Formula:</del>	<del>FePO<sub>4</sub></del>

Date of Manufacture: 15<sup>th</sup> May 2022  
Date of Expiry: 14<sup>th</sup> May 2024

**Reference Standard I:**

Product Name: ICP multi-element standard solution IV  
Lot No.: HC15457555  
Cadmium Purity (mg/L): 999 mg/L  
Lead Purity (mg/L): 1001 mg/L  
Date of release: 27/07/2021  
Minimum shelf life: 30/04/2024  
Supplier: Sigma Aldrich

**Reference Standard II:**

Product Name: Multielement Calibration Standard 2A – HG  
Lot No.: 13 140HGY2A  
Cadmium Purity (%): 99.99 %  
Date of release: 30/06/2022  
Minimum shelf life: 31/12/2023  
Supplier: Agilent Technologies

**Instruments / Apparatus:**

Instrument name: ICPMS  
Make: Thermo Fisher  
Model: iCAP RQ (Quadrupole)  
Detector: MS Detector  
Interface Pressure: 1.94-1.98  
Interface Temperature: 31.35°C  
Plasma cooling water flow: 0.91 lit/min  
Exhaust flow: 0.309-0.359 mbar  
Spray chamber temperature: 2.63°C  
Nebulizer flow: 1.009 lit/min  
Cool gas flow: 13 lit/min  
Auxiliary flow: 0.798 lit/min  
Measurement mode: Standard  
Sample run time: 60 sec  
Gas source: Argon  
Elements: Hg<sup>202</sup>, Cd<sup>111</sup> and Pb<sup>208</sup>

**Method validation****Specificity**

- Multi-element Stock Solution (Cadmium and Lead)

An aliquot of 5.000 mL ICP multi-element standard IV solution (Purity 999 – Cadmium and 1001 – Lead mg/L) was taken into a 50 mL volumetric flask, diluted and made up to the mark with 2% Nitric acid. The concentration was equivalent to 99.99 mg/L of Cadmium and 100.1 mg/L Lead respectively. Then five Standard Solutions were prepared (10.00 mg/L, 1.00 mg/L, 0.1 mg/L, 0.01 mg/L, 0.004 mg/L).

- Multi-element Stock Solution (Mercury)

An aliquot of 5.000 mL ICP multi-element standard 2A HG solution (Purity 99.99%, 10.00 mg/L) was taken into a 50 mL volumetric flask, diluted and made up to the mark with 2% Nitric acid. The concentration was equivalent to 1.00 mg/L. Then two Standard Solutions were prepared (0.1 mg/L, 0.0025 mg/L).

**Linearity**

From the specificity standard solution, the serial dilutions were made to prepare further concentrations diluted with 2% Nitric Acid. The details of the dilutions:

• Dilutions (Cadmium and Lead reference standard)

Code	Cadmium and Lead Stock Concentration (mg/L)	Aliquot taken (mL)	Final volume (mL)	Cadmium and Lead Final Concentration (mg/L)
STD 1	0.100	0.250	25	0.001
STD 2	0.100	0.500	25	0.002
STD 3	0.100	0.750	25	0.003
STD 4	0.100	1.000	25	0.004
STD 5	0.100	1.250	25	0.005
STD 6	0.100	1.500	25	0.006

• Dilutions (Mercury Reference Standard)

Code	Cadmium and Lead Stock Concentration (mg/L)	Aliquot taken (mL)	Final volume (mL)	Cadmium and Lead Final Concentration (mg/L)
STD 1	0.100	0.213	25	0.00085
STD 2	0.100	0.325	25	0.0013
STD 3	0.100	0.475	25	0.0019
STD 4	0.100	0.625	25	0.0025
STD 5	0.100	0.800	25	0.0032
STD 6	0.100	0.950	25	0.0038

The linearity of method was established by injecting six different concentrations of Multi element reference standard by ICP MS and plotting their respective concentration (w/w) against the respective peak intensity.

**Precision**

The linearity Standard Solution STD 4 (0.004 mg/L of Cadmium), (0.004 mg/L of Lead) and (0.0025 mg/L of Mercury) was used for precision determination. The prepared concentrations of sample solutions were equivalent to 1000.00 mg/L. The bracketing injection of the standard and single injection of five sample preparations were analyzed under ICP-MS to determine the relative standard deviation as per Horwitz equation.

**Limit of Detection and Limit of Quantification**

The linearity Standard Solution STD 4 (0.004 mg/L of Cadmium), (0.004 mg/L of Lead) and (0.0025 mg/L of Mercury), the expected lowest concentration of Cadmium, Lead and Mercury standard solution was prepared using 2% Nitric Acid as the diluent. Solutions were analyzed under ICP MS to determine LOD and LOQ.

**Accuracy (Recovery)**

The analytical method was validated in terms of recovery of the standard at three fortification levels. The linearity Standard Solution STD 4 (0.004 mg/L of Cadmium), (0.004 mg/L of Lead) and (0.0025 mg/L of Mercury) was used for determination of Recovery, three fortification levels were:

- T1: 0.0010 mg/L of Cadmium and Lead, 0.00085 mg/L of Mercury
- T2: 0.0020 mg/L of Cadmium and Lead, 0.0014 mg/L of Mercury
- T1: 0.0040 mg/L of Cadmium and Lead, 0.0028 mg/L of Mercury

**Validation – Results and discussions**

**Table 5.3-2: Methods suitable for the determination of the relevant impurities in plant protection product (PPP) Name/code**

	<b>Cadmium</b>	<b>Lead</b>	<b>Mercury</b>
<b>Author(s), year</b>	Mr. K. Vasu, 2023		
<b>Principle of method</b>	ICP-MS	ICP-MS	ICP-MS
<b>Linearity (linear between mg/L) (correlation coefficient, expressed as r)</b>	6 points 0.001 – 0.006 mg/L (0.0001 – 0.0006 w/w) Y = 310424000x – 2748.067 r <sup>2</sup> = 0.9995	6 points 0.001 – 0.006 mg/L (0.0001 – 0.0006 w/w) Y = 1979401714.3x – 3538.067 r <sup>2</sup> = 0.9966	6 points 0.00085 – 0.0038 mg/L (0.00009 – 0.00038 w/w) Y = 18910029.5x – 454.682 r <sup>2</sup> = 0.9924
<b>Precision – Repeatability Mean n = 5 (%RSD)</b>	Concentration (% w/w): 0.000020%  %RSD = 1.8028 %RSD <sub>R</sub> = 20.3856 %RSD <sub>r</sub> = 13.6584 Hr = 0.1320 ≤ 1	Concentration (% w/w): 0.000020%  %RSD = 3.1265 %RSD <sub>R</sub> = 20.3519 %RSD <sub>r</sub> = 13.6357 Hr = 0.2293 ≤ 1	Concentration (% w/w): 0.000014%  %RSD = 6.2917 %RSD <sub>R</sub> = 21.6039 %RSD <sub>r</sub> = 14.4746 Hr = 0.4347 ≤ 1
<b>Accuracy n = 3 at each level (% Recovery)</b>	T1 – 0.001 mg/L of Cadmium: Mean recovery: 106.09%  T2 – 0.0020 mg/L of Cadmium: Mean recovery: 106.76%  T3 – 0.0040 mg/L of Cadmium: Mean recovery: 103.74%  Total mean recovery: 103.53%	T1 – 0.001 mg/L of Lead: Mean recovery: 97.25%  T2 – 0.0020 mg/L of Lead: Mean recovery: 100.83%  T3 – 0.0040 mg/L of Lead: Mean recovery: 98.12%  Total mean recovery: 98.73%	T1 – 0.00085 mg/L of Mercury: Mean recovery: 100.54%  T2 – 0.0014 mg/L of Mercury: Mean recovery: 98.64%  T3 – 0.0028 mg/L of Mercury: Mean recovery: 101.67%  Total mean recovery: 100.28%
<b>Interference/ Specificity</b>	No interference, the method is specific		
<b>LOQ</b>	0.000118 w/w	0.000144 w/w	0.000130 w/w
<b>Comment</b>	No comments		

**Conclusion**

According to SANCO/3030/99 rev. 5 the method was successfully validated and is suitable for determination of relevant impurities Cadmium, Lead and Mercury in the test item Ferric Phosphate 1% GB.

An overview on the acceptable methods and possible data gaps for analysis of relevant impurities in plant protection product is provided as follows:

<b>Comments of zRMS:</b>	The analytical method for determination of relevant impurities (Cd, Pb, Hg) is suitable for the determination of the content of each of the relevant impurity in the plant protection product Hierro in the presence of each other, active substances
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	and other components. The proposed analytical method has been fully validated in terms of interference, specificity, linearity, accuracy (recovery and repeatability) and LOQ values. The proposed method fulfils the requirements of SANCO/3030/99 rev. 5 guidance.
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<b>Reference:</b>	<b>KCP 5.1.1-3</b>
<b>Report</b>	<b>Method validation and determination of relevant impurities Lead, Mercury and Cadmium in Iron Phosphate 1% GB, Mr. K. Vasu, 2023, Report No.: 13033/2023</b>
<b>Guideline(s):</b>	<b>Yes</b> <b>SANCO 3030/99 rev. 5</b>
<b>Deviations:</b>	<b>No</b>
<b>GLP:</b>	<b>Yes</b>
<b>Acceptability:</b>	<b>Yes</b>

**Materials and methods****Active substance:**

Test substance name:	Iron phosphate 1.0% GB
Appearance:	Light blue granules
Chemical Abstract Name:	Ferric Phosphate
IUPAC Name:	Ferric Phosphate
CAS No.:	10045-86-0
Common Name:	Iron Phosphate
Formulation Type:	Granular Bait
Batch No.:	SCL-52331
Active Content (% w/w):	0.99% w/w
Molecular Weight:	150.82
Molecular Formula:	FePO <sub>4</sub>
Date of Manufacture:	7 <sup>th</sup> March 2023
Date of Expiry:	6 <sup>th</sup> March 2025

**Reference Standard I:**

Product Name:	ICP multi-element standard solution IV
Lot No.:	HC15457555
Cadmium Purity (mg/L):	999 mg/L
Lead Purity (mg/L):	1001 mg/L
Date of release:	27/07/2021
Minimum shelf life:	30/04/2024
Supplier:	Sigma-Aldrich

**Reference Standard II:**

Product Name:	Multielement Calibration Standard 2A - HG
Lot No.:	13-140HGY2A
Cadmium Purity (µg/ml):	9.99 µg/ml
Date of release:	30/06/2022
Minimum shelf life:	31/12/2023
Supplier:	Agilent Technologies

**Instruments / Apparatus:**

Instrument name:	ICPMS
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Make:	Thermo Fisher
Model:	iCAP RQ (Quadrupole)
Detector:	MS-Detector
Interface Pressure:	1.94-1.98
Interface Temperature:	31.35°C
Plasma cooling water flow:	0.91 lit/min
Exhaust flow:	0.309-0.359 mbar
Spray chamber temperature:	2.63°C
Nebulizer flow:	1.009 lit/min
Cool gas flow:	13 lit/min
Auxiliary flow:	0.798 lit/min
Measurement mode:	Standard
Sample run time:	60 sec
Gas source:	Argon
Elements:	Hg <sup>202</sup> , Cd <sup>111</sup> and Pb <sup>208</sup>

**Method validation**

**Specificity**

- Multi element Stock Solution (Cadmium and Lead)

An aliquot of 5.000 mL ICP multi-element standard IV solution (Purity 999 – Cadmium and 1001 – Lead mg/L) was taken into a 50 mL volumetric flask, diluted and made upto the mark with 2% Nitric acid. The concentration was equivalent to 99.99 mg/L of Cadmium and 100.1 mg/L Lead respectively. Then five Standard Solutions were prepared.

- Multi element Stock Solution (Mercury)

An aliquot of 5.000 mL ICP multi-element standard 2A-HG solution (Purity 9.99 µg/ml, 10.00 mg/L) was taken into a 50 mL volumetric flask, diluted and made upto the mark with 2% Nitric acid. The concentration was equivalent to 1.00 mg/L. Then three Standard Solutions were prepared.

**Linearity**

From the specificity standard solution, the serial dilutions were made to prepare further concentrations diluted with 2% Nitric Acid. The details of the dilutions:

- Dilutions (Cadmium and Lead reference standard)

Code	Cadmium and Lead Stock Concentration (mg/L)	Aliquot taken (mL)	Final volume (mL)	Cadmium and Lead Final Concentration (mg/L)
STD-1	0.100	0.075	25	0.0003
STD-2	0.100	0.375	25	0.0015
STD-3	0.100	0.750	25	0.0030
STD-4	0.100	1.000	25	0.0040
STD-5	0.100	1.375	25	0.0055
STD-6	0.100	1.500	25	0.0060

- Dilutions (Mercury Reference Standard)

Code	Cadmium and Lead Stock Concentration (mg/L)	Aliquot taken (mL)	Final volume (mL)	Cadmium and Lead Final Concentration (mg/L)
STD-1	0.100	0.300	50	0.00006
STD-2	0.100	0.500	50	0.00010
STD-3	0.100	0.750	50	0.00015
STD-4	0.100	1.000	50	0.00020

STD-5	0.100	1.250	50	0.00025
STD-6	0.100	1.500	50	0.00030

The linearity of method was established by injecting six different concentrations of Multi element reference standard by ICP-MS and plotting their respective concentration (w/w) against the respective peak intensity.

**Precision**

The linearity Standard Solution STD-4 (0.004 mg/L of Cadmium), (0.004 mg/L of Lead) and (0.00020 mg/L of Mercury) was used for precision determination. The prepared concentrations of sample solutions were equivalent to 1000.00 mg/L. The bracketing injection of the standard and single injection of five sample preparations were analyzed under ICP-MS to determine the relative standard deviation as per Horwitz equation.

**Limit of Detection and Limit of Quantification**

The linearity Standard Solution STD-4 (0.004 mg/L of Cadmium), (0.004 mg/L of Lead) and (0.00020 mg/L of Mercury), was used for the determination of Limit of Detection and Limit of Quantification. Solutions were analyzed under ICP-MS to determine LOD and LOQ.

**Accuracy (Recovery)**

The analytical method was validated in terms of recovery of the standard at three fortification levels. The linearity Standard Solution STD-4 (0.004 mg/L of Cadmium), (0.004 mg/L of Lead) and (0.00020 mg/L of Mercury) was used for determination of Recovery, three fortification levels were:

- T1: 0.0010 mg/L of Cadmium and Lead, 0.00004 mg/L of Mercury
- T2: 0.0020 mg/L of Cadmium and Lead, 0.00007 mg/L of Mercury
- T3: 0.0045 mg/L of Cadmium and Lead, 0.0002 mg/L of Mercury

**Validation - Results and discussions**

**Table 5.3-3: Methods suitable for the determination of the relevant impurities in plant protection product (PPP) Name/code**

	Cadmium	Lead	Mercury
<b>Author(s), year</b>	Mr. K. Vasu, 2023		
<b>Principle of method</b>	ICP-MS	ICP-MS	ICP-MS
<b>Linearity (linear between mg/L) (correlation coefficient, expressed as r)</b>	6 points 0.0003 – 0.0060 mg/L Y = 941 610.6x – 33.282 r <sup>2</sup> = 0.9933	6 points 0.0003 – 0.0060 mg/L Y = 13 719 973.24x – 2294.576 r <sup>2</sup> = 0.9913	6 points 0.00006 - 00030 mg/L Y = 11 211 371x – 34.01 r <sup>2</sup> = 0.9924 0.9916
<b>Precision – Repeatability Mean n = 5 (%RSD)</b>	%RSD = 3.0367 %RSD <sub>R</sub> = 10.2800 41.12 %RSD <sub>r</sub> = 6.8876 27.55 Hr = 0.4409 0.11 ≤ 1	%RSD = 3.4468 %RSD <sub>R</sub> = 10.2397 40.96 %RSD <sub>r</sub> = 6.8606 27.44 Hr = 0.5024 0.13 ≤ 1	%RSD = 4.0167 %RSD <sub>R</sub> = 18.4362 73.74 %RSD <sub>r</sub> = 12.3522 49.41 Hr = 0.3252 0.08 ≤ 1
<b>Accuracy n = 3 at each level (% Recovery)</b>	T1 - 0.001 mg/L of Cadmium: Mean marginal recovery: 100.72%  T2 - 0.0020 mg/L of Cadmium: Mean marginal recovery: 109.84%	T1 - 0.001 mg/L of Lead: Mean marginal recovery: 94.42%  T2 - 0.0020 mg/L of Lead: Mean marginal recovery: 113.13%  T3 - 0.0045 mg/L of Lead:	T1 - 0.00004 mg/L of Mercury: Mean marginal recovery: 102.14%  T2 - 0.00007 mg/L of Mercury: Mean marginal recovery: 95.33%

	<b>Cadmium</b>	<b>Lead</b>	<b>Mercury</b>
	T3 - 0.0045 mg/L of Cadmium: Mean <b>total</b> recovery: 113.57%  Total mean recovery: 108.04%	Mean <b>total</b> recovery: 114.53%  Total mean recovery: 107.36%	T3 - 0.0002 mg/L of Mercury: Mean <b>marginal</b> recovery: 111.28%  Total mean recovery: 102.92%
<b>Interference/ Specificity</b>	No interference, the method is specific		
<b>LOQ</b> <b>LOD</b>	LOD=0.000014 mg/kg LOQ=0.00018 mg/kg	LOD=0.000023 mg/kg LOQ=0.00022 mg/kg	LOD=0.000005 mg/kg LOQ=0.000037 mg/kg
<b>Comment</b>	No comments		

### Conclusion

According to SANCO/3030/99 rev. 5 the method was successfully validated and is suitable for determination of relevant impurities Cadmium, Lead and Mercury in the test item Ferric Phosphate 1% GB.

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

#### 5.3.1.4 Applicability of existing CIPAC methods (KCP 5.1.1)

A CIPAC method No. 629 is available for Ferric phosphate.

#### 5.3.2 Methods for the determination of residues (KCP 5.1.2)

Please refer to post-registration methods.

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

#### 5.4.1 Analysis of the plant protection product (KCP 5.2)

Analytical methods for the determination of the active substance and relevant impurities in the plant protection product shall be submitted, unless the applicant shows that these methods already submitted in accordance with the requirements set out in point 5.3.1 can be applied.

#### 5.4.2 Description of analytical methods for the determination of residues of Ferric phosphate (KCP 5.2)

##### 5.4.2.1 Overview of residue definitions and levels for which compliance is required

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

**Table 5.4-1: Relevant residue definitions for monitoring/enforcement and levels for which compliance is required**

Matrix	Residue definition	MRL / limit	Reference for MRL/level Remarks
Plant, high water content	According to Commission Regulation (EC) No 2015/1166 amending Reg. (EC) 540/2011, The Commission further considers that ferric phosphate is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Ferric phosphate is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. Ferric phosphate consists of compounds that are ubiquitous in the environment and that are essential for animal and plant functions. Additionally, ferric phosphate is a natural constituent of the human diet.		COMMISSION IMPLEMENTING REGULATION (EU) 2015/1166
Plant, high acid content			
Plant, high protein/high starch content (dry commodities)			
Plant, high oil content			
Plant, difficult matrices (hops, spices, tea)			
Muscle			
Milk			
Eggs			
Fat			
Liver, kidney			
Soil (Ecotoxicology)			
Drinking water (Human toxicology)			
Surface water (Ecotoxicology)			
Air			
Tissue (meat or liver)			
Body fluids			

**5.4.2.2 Description of analytical methods for the determination of residues in plant matrices (KCP 5.2)**

According to Commission Regulation (EC) No 2015/1166 amending Reg. (EC) 540/2011, The Commission further considers that ferric phosphate is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Ferric phosphate is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. Ferric phosphate consists of compounds that are ubiquitous in the environment and that are essential for animal and plant functions. Additionally, ferric phosphate is a natural constituent of the human diet.

**5.4.2.3 Description of analytical methods for the determination of residues in animal matrices (KCP 5.2)****5.4.2.4 Description of methods for the analysis of soil (KCP 5.2)**

According to Commission Regulation (EC) No 2015/1166 amending Reg. (EC) 540/2011, The Commission further considers that ferric phosphate is a low-risk active substance pursuant to Article 22 of Regu-

lation (EC) No 1107/2009. Ferric phosphate is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. Ferric phosphate consists of compounds that are ubiquitous in the environment and that are essential for animal and plant functions. Additionally, ferric phosphate is a natural constituent of the human diet.

#### **5.4.2.5 Description of methods for the analysis of water (KCP 5.2)**

According to Commission Regulation (EC) No 2015/1166 amending Reg. (EC) 540/2011, The Commission further considers that ferric phosphate is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Ferric phosphate is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. Ferric phosphate consists of compounds that are ubiquitous in the environment and that are essential for animal and plant functions. Additionally, ferric phosphate is a natural constituent of the human diet.

#### **5.4.2.6 Description of methods for the analysis of air (KCP 5.2)**

According to Commission Regulation (EC) No 2015/1166 amending Reg. (EC) 540/2011, The Commission further considers that ferric phosphate is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Ferric phosphate is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. Ferric phosphate consists of compounds that are ubiquitous in the environment and that are essential for animal and plant functions. Additionally, ferric phosphate is a natural constituent of the human diet.

#### **5.4.2.7 Description of methods for the analysis of body fluids and tissues (KCP 5.2)**

According to Commission Regulation (EC) No 2015/1166 amending Reg. (EC) 540/2011, The Commission further considers that ferric phosphate is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Ferric phosphate is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. Ferric phosphate consists of compounds that are ubiquitous in the environment and that are essential for animal and plant functions. Additionally, ferric phosphate is a natural constituent of the human diet.

#### **5.4.2.8 Other studies/ information**

Not required

**Appendix 1 Lists of data considered in support of the evaluation**

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

**List of data submitted by the applicant and 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 5.1.1	B. Krzysiak-Warzała	2017	Iron phosphate 1.0% GB: Analysis of active substances content and physicochemical properties of initial preparation and preparation after accelerated storage procedure (CIPAC MT 46.3). Report No. 18/2017/BA-AD GLP Unpublished	N	Sharda Cropchem Limited
KCP 5.1.1-2	Mr. K. Vasu	2023	Method validation and determination of relevant impurities Leas, Mercury and Cadmium in Iron Phosphate 1% GB Report No.: 11255/2022 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Limited
KCP 5.1.1-3	Mr. K. Vasu	2023	Method validation and determination of relevant impurities Leas, Mercury and Cadmium in Iron Phosphate 1% GB, Report No.: 13033/2023 Bioscience Research Foundation GLP Unpublished	N	Sharda Cropchem Limited

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
-	-	-	-	-	-

The following tables are to be completed by MS

**List of data submitted by the applicant and not relied on**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
-	-	-	-	-	-

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
-	-	-	-	-	-

## **Appendix 2 Detailed evaluation of submitted analytical methods**

### **A 2.1 Analytical methods for Ferric phosphate**

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

No new or additional studies have been submitted

#### **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 2.1.3 Other Studies/ Information**

No new or additional studies have been submitted