

Section A4.1 Annex Point IIA, IV.4.1/01	Analytical Methods for Detection and Identification [REDACTED] CONFIDENTIAL	
	1 REFERENCE	Official use only
1.1 Reference	[REDACTED] (2012b). [REDACTED] analytical method validation. Harlan Laboratories Ltd, unpublished report No. 41105159. May 21 st , 2012.	
1.2 Data protection	[REDACTED]	
1.2.1 Data owner	[REDACTED]	
1.2.2 Companies with letter of access	[REDACTED]	
1.2.3 Criteria for data protection	[REDACTED] [REDACTED]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.2 Guideline study	Yes. SANCO/3030/99, 11 July 2000.	
2.3 GLP	Yes.	
2.4 Deviations	No.	
2.5	3 MATERIALS AND METHODS	
3.2 Preliminary treatment		
3.2.1 Extraction	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	
3.2.2 Cleanup	[REDACTED] [REDACTED]	
3.3 Detection		
3.3.1 Separation method	[REDACTED]	
3.3.2 Detector	[REDACTED]	
3.3.3 Standard(s)	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	
3.3.4 Interfering substance(s)	[REDACTED] [REDACTED] [REDACTED]	
3.4 Linearity		
3.4.1 Calibration range	[REDACTED] [REDACTED]	

Section A4.1	Analytical Methods for Detection and Identification					
Annex Point IIA, IV.4.1/01						
3.4.2	Number of measurements					
3.4.3	Linearity					
3.5	Specifity: interfering substances					
3.6	Recovery rates at different levels					
3.6.1	Relative standard deviation					
3.7	Limit of determination					
3.8	Precision					
3.8.1	Repeatability					

Section A4.1 Annex Point IIA, IV.4.1/01	Analytical Methods for Detection and Identification [REDACTED] [REDACTED]	
	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	
3.8.2 Independent laboratory validation	[REDACTED]	
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.2 Materials and methods	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	
4.3 Conclusion	The analytical method for the determination of sulphate in copper sulphate pentahydrate was successfully validated. The method meets the EU criteria with respect to specificity, linearity, accuracy and precision according to the guidance given in SANCO/3030/00. The method requires equipment and instrumentation which are commonly available in many well-equipped laboratories. The method is considered to be suitable for monitoring purposes.	
4.3.1 Reliability	I	
4.3.2 Deficiencies	[REDACTED]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPporteur MEMBER STATE	
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Reliability		
Acceptability		
Remarks		
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Date		

Section A4.1 Annex Point IIA, IV.4.1/01	Analytical Methods for Detection and Identification <div></div> CONFIDENTIAL	
Results and discussion		
Conclusion		
Reliability		
Acceptability		
Remarks		

Section A4.1	Analytical Methods for Detection and Identification	
Annex Point IIA, IV.4.1/01	Determination of copper in copper sulphate	
	1 REFERENCE	Official use only
1.1 Reference	██████████ (2003). ██████████ ██████████ Analytical method validation. SafePharm Laboratories, unpublished report No. 1513/002.	
1.2 Data protection	████	
1.2.1 Data owner	██████████	
1.2.2 Companies with letter of access	████	
1.2.3 Criteria for data protection	██ ████████████████████	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes. SANCO/3030/99, 11 July 2000.	
2.2 GLP	Yes.	
2.3 Deviations	No.	
	3 MATERIALS AND METHODS	
3.1 Preliminary treatment		
3.1.1 Extraction	██	
3.1.2 Cleanup	████	
3.2 Detection		
3.2.1 Separation method	████	
3.2.2 Detector	████████████████████████████████████	
3.2.3 Standard(s)	████████████████	
3.2.4 Interfering substance(s)	██ ██	
3.3 Linearity	██ ████████████████████	
3.3.1 Calibration range	██	
3.3.2 Number of measurements	██	
3.3.3 Linearity	██	

Section A4.1 Annex Point IIA, IV.4.1/01	Analytical Methods for Detection and Identification 	
3.4 Specificity: interfering substances		
3.5 Recovery rates at different levels		
3.5.1 Relative standard deviation		
3.6 Limit of determination		
3.7 Precision		
3.7.1 Repeatability		
3.7.2 Independent laboratory validation		
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1 Materials and methods		
4.2 Conclusion	<p>The method presented is based on the CIPAC electrolytic method (44/TC/M3.1). CIPAC methods are collaboratively tested and are, therefore, applicable for the determination of total copper in the copper containing technical materials. A second CIPAC method, based on titration, is available (44/TC/M3.2).</p> <p>The method meets the EU criteria with respect to specificity, linearity, accuracy and precision according to the guidance given in SANCO/3030/00. The method requires equipment and instrumentation which are commonly available in many well-equipped laboratories. The method is considered to be suitable for monitoring purposes.</p> <p>The method presented has been validated for copper oxychloride and Bordeaux mixture. However, the method is based on destruction of the salt by heating with nitric acid, to release the copper ion, followed by gravimetric determination of copper after electrolysis. The method will not be influenced by the form of copper salt, so is equally applicable to copper sulphate pentahydrate.</p>	
4.2.1 Reliability		
4.2.2 Deficiencies		

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	Evaluation by Competent Authorities	
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Remarks		

Section A4.1	Analytical Methods for Detection and Identification	
Annex Point IIA, IV.4.1/02	Determination of water in copper sulphate pentahydrate	
	CONFIDENTIAL	
	1 REFERENCE	Official use only
1.1 Reference	██████████ (2012a). ██████████ analytical profile of batches. Harlan Laboratories Ltd, unpublished report No. 41105158. May 21 st , 2012.	
1.2 Data protection	████	
1.2.1 Data owner	██████████	
1.2.2 Companies with letter of access	████	
1.2.3 Criteria for data protection	██ ████████████████████████████████████	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.2 Guideline study	No	
2.3 GLP	Yes.	
2.4 Deviations	No.	
2.5	3 MATERIALS AND METHODS	
3.2 Preliminary treatment		
3.2.1 Extraction	██ ██ ██ ██ ██ ████████████████████████████████████	
3.2.2 Cleanup	██████████	
3.3 Detection		
3.3.1 Separation method	████████████████████████████████████	
3.3.2 Detector	████████████████████████████████████	
3.3.3 Standard(s)	████████████████████████████████████	
3.3.4 Interfering substance(s)	████████████████████████████████████	
3.4 Linearity		
3.4.1 Calibration range	██████████	
3.4.2 Number of measurements	██████████	
3.4.3 Linearity	██████████	
3.5 Specifity: interfering	██████████	

Section A4.1		Analytical Methods for Detection and Identification					
Annex Point IIA, IV.4.1/02							
substances							
3.6	Recovery rates at different levels						
3.6.1	Relative standard deviation						
3.7	Limit of determination						
3.8	Precision						
3.8.1	Repeatability						
3.8.2	Independent laboratory validation						
		4 APPLICANT'S SUMMARY AND CONCLUSION					
4.2	Materials and methods						
4.3	Conclusion	The loss of water on drying is considered a suitable method for the determination of water in copper sulphate pentahydrate.					
4.3.1	Reliability						

Section A4.1	Analytical Methods for Detection and Identification	
Annex Point IIA, IV.4.1/02	CONFIDENTIAL	
4.3.2 Deficiencies		
	Evaluation by Competent Authorities	
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Materials and methods		
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Reliability		
Acceptability		
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Conclusion		
Reliability		
Acceptability		
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Section A4.1 Annex Point IIA, IV.4.1/02	Analytical Methods for Detection and Identification [REDACTED] [REDACTED] CONFIDENTIAL	
	1 REFERENCE	Official use only
1.1 Reference	[REDACTED] (2003). [REDACTED] [REDACTED] Analytical method validation. SafePharm Laboratories, unpublished report No. 1513/002.	
1.2 Data protection	[REDACTED]	
1.2.1 Data owner	[REDACTED]	
1.2.2 Companies with letter of access	[REDACTED]	
1.2.3 Criteria for data protection	[REDACTED] [REDACTED]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.2 Guideline study	Yes. SANCO/3030/99, 11 July 2000.	
2.3 GLP	Yes.	
2.4 Deviations	No.	
2.5	3 MATERIALS AND METHODS	
3.2 Preliminary treatment		
3.2.1 Extraction	[REDACTED] [REDACTED]	
3.2.2 Cleanup	[REDACTED]	
3.3 Detection		
3.3.1 Separation method	[REDACTED]	
3.3.2 Detector	[REDACTED]	
3.3.3 Standard(s)	[REDACTED]	
3.3.4 Interfering substance(s)	[REDACTED] [REDACTED]	
3.4 Linearity		
3.4.1 Calibration range	[REDACTED]	
3.4.2 Number of measurements	[REDACTED]	
3.4.3 Linearity	[REDACTED]	
3.5 Specificity: interfering substances	[REDACTED] [REDACTED]	
3.6 Recovery rates at different levels	[REDACTED] [REDACTED] [REDACTED]	

Section A4.1		Analytical Methods for Detection and Identification				
Annex Point IIA, IV.4.1/02		<div></div> <div></div> <div></div>				
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		<div></div>	<div></div>	<div></div>	<div></div>	
		<div></div>	<div></div>	<div></div>	<div></div>	
3.6.1 Relative standard deviation		<div></div> <div></div>				
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		<div></div>	<div></div>	<div></div>	<div></div>	
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		<div></div>	<div></div>	<div></div>	<div></div>	
3.7 Limit of determination		<div></div>				
3.8 Precision						
3.8.1 Repeatability		<div></div>				
3.8.2 Independent laboratory validation		<div></div>				
		4 APPLICANT'S SUMMARY AND CONCLUSION				
4.2 Materials and methods		<div></div> <div></div>				
4.3 Conclusion		<p>These method presented is an established method which is based on specific chemistry and is broadly accepted as appropriate for determination of heavy metals.</p> <p>The method meets the EU criteria with respect to specificity, linearity, accuracy and precision according to the guidance given in SANCO/3030/00. The method requires equipment and instrumentation which are commonly available in many well-equipped laboratories. The method is considered to be suitable for monitoring purposes.</p> <p>In addition, the CIPAC methods MT 99 (arsenic) and MT 92.1 (lead) are available and these are collaboratively tested procedures.</p> <p>Validation data presented has been validated for <div></div><div></div> However, the method is based on destruction of the compounds by nitric acid digestion to free cadmium, lead and arsenic. The method will not be influenced by the form of copper salt, so is</p>				

Section A4.1	Analytical Methods for Detection and Identification	
Annex Point IIA, IV.4.1/02	<div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 150px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 80px; height: 15px;"></div>	
	equally applicable to copper sulphate pentahydrate.	
4.3.1 Reliability		
4.3.2 Deficiencies	■	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		
Materials and methods		
Conclusion		
Reliability		
Acceptability		
Remarks		
	COMMENTS FROM ...	
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Results and discussion		
Conclusion		
Reliability		
Acceptability		
Remarks		

Section A4.1	Analytical Methods for Detection and Identification	
Annex Point IIA, IV.4.1/03	Determination of impurities in copper sulphate pentahydrate - arsenic, cadmium, iron, nickel, lead, zinc, sulphate CONFIDENTIAL	
	1 REFERENCE	Official use only
1.1 Reference	(2007). Analytical method validation. SafePharm Laboratories, unpublished report No. 1513/022.	
1.2 Data protection		
1.2.1 Data owner		
1.2.2 Companies with letter of access		
1.2.3 Criteria for data protection		
	2 GUIDELINES AND QUALITY ASSURANCE	
2.2 Guideline study	Yes. SANCO/3030/99, 11 July 2000.	
2.3 GLP	Yes.	
2.4 Deviations	No.	
2.5	3 MATERIALS AND METHODS	
3.2 Preliminary treatment		
3.2.1 Extraction		
3.2.2 Cleanup		
3.3 Detection		
3.3.1 Separation method		
3.3.2 Detector		
3.3.3 Standard(s)		
3.3.4 Interfering substance(s)		
3.4 Linearity		
3.4.1 Calibration range		
3.4.2 Number of measurements		

Section A4.1		Analytical Methods for Detection and Identification						
Annex Point IIA, IV.4.1/03		<div></div> <div></div> <div></div>						
3.4.3	Linearity	<div></div>						
3.5	Specifity: interfering substances	<div></div> <div></div>						
3.6	Recovery rates at different levels							
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3.6.1	Relative standard deviation							
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3.7	Limit of determination	<div></div>						
3.8	Precision							
3.8.1	Repeatability	<div></div>						
3.8.2	Independent laboratory validation	<div></div>						
		4 APPLICANT'S SUMMARY AND CONCLUSION						
4.2	Materials and methods	<div></div> <div></div> <div></div> <div></div>						
4.3	Conclusion	The methods presented are established method which are based on specific chemistry and are broadly accepted as appropriate for						

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	determination of heavy metals and sulphate. The methods meet the EU criteria with respect to specificity, linearity, accuracy and precision according to the guidance given in SANCO/3030/00. The methods require equipment and instrumentation which are commonly available in many well-equipped laboratories. The methods are considered to be suitable for monitoring purposes.	
4.3.1 Reliability	I	
4.3.2 Deficiencies		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		
Materials and methods		
Conclusion		
Reliability		
Acceptability		
Remarks		
	COMMENTS FROM ...	
Date		
Results and discussion		
Conclusion		
Reliability		
Acceptability		
Remarks		

Section A4.2(a) Annex Point IIA, IV.4.2(a)/01	Analytical Methods for Detection and Identification Copper residues in soil	
	1 REFERENCE	Official use only
1.1 Reference	██████ (2003). Validation of an analytical method for the determination of bioavailable copper in soil samples. GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, unpublished report No. 20031084/02-UVX.	
1.2 Data protection	████	
1.2.1 Data owner	████████	
1.2.2 Companies with letter of access	████	
1.2.3 Criteria for data protection	██ ████████████████████	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes. SANCO/825/00, 20 June 2000.	
2.2 GLP	Yes.	
2.3 Deviations	No.	
	3 MATERIALS AND METHODS	
3.1 Preliminary treatment		
3.1.1 Extraction	██ ██ ████████████████████████████	
3.1.2 Cleanup	████	
3.2 Detection		
3.2.1 Separation method	████	
3.2.2 Detector	██ ████████████████████████████	
3.2.3 Standard(s)	██████████	
3.2.4 Interfering substance(s)	██ ██	
3.3 Linearity		
3.3.1 Calibration range	██████████	
3.3.2 Number of measurements	████	
3.3.3 Linearity	████████████████████	

Section A4.2(a) Annex Point IIA, IV.4.2(a)/01	Analytical Methods for Detection and Identification [REDACTED]	
3.4 Specificity: interfering substances	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	
3.5 Recovery rates at different levels	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	
3.5.1 Relative standard deviation	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	
3.6 Limit of determination	[REDACTED] [REDACTED]	
3.7 Precision		
3.7.1 Repeatability	[REDACTED]	
3.7.2 Independent laboratory validation	[REDACTED] [REDACTED]	

Section A4.2(a) Annex Point IIA, IV.4.2(a)/01	Analytical Methods for Detection and Identification Copper residues in soil	
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1 Materials and methods	<div style="background-color: black; height: 1.2em; width: 100%;"></div> <div style="background-color: black; height: 1.2em; width: 100%;"></div> <div style="background-color: black; height: 1.2em; width: 100%;"></div> <div style="background-color: black; height: 1.2em; width: 100%;"></div> <div style="background-color: black; height: 1.2em; width: 100%;"></div>	
4.2 Conclusion	<p>The vast majority of copper in soil is present as an immobile non-bio-available residue. Therefore, the definition of the residue in soil is bio-available copper (i.e. dissolved copper in the soil solution and weakly adsorbed copper which can easily be released into the soil solution). Methods are presented for the determination of both bio-available copper and total copper residues in soil. The method for bio-available copper is presented above.</p> <p>The method for determination of residues of bio-available total copper in soil has been adequately validated. The method was successfully evaluated and meets the EU criteria with respect to specificity, linearity, accuracy and precision according to the guidance given in SANCO/825/00. The procedures described in the method are not consistent with standard multi-residue methods because copper is not an organic analyte. However, the method requires equipment and instrumentation which are commonly available in many well-equipped laboratories. In addition, the procedures of acid digestion and determination by ICP-AAS are recognised standard methods of analysis for inorganic elements such as copper.</p> <p>The method is considered to be suitable for both generation of registration data and for post-registration control and monitoring purposes.</p>	
4.2.1 Reliability	<div style="background-color: black; height: 1.2em; width: 100%;"></div>	
4.2.2 Deficiencies	<div style="background-color: black; height: 1.2em; width: 100%;"></div>	

Section A4.2(a) Annex Point IIA, IV.4.2(a)/01	Analytical Methods for Detection and Identification [REDACTED]	
	Evaluation by Competent Authorities	
	[REDACTED] [REDACTED]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
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Reliability		
Acceptability		
Remarks		
	COMMENTS FROM ...	
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Conclusion		
Reliability		
Acceptability		
Remarks		

Section A4.2(a) Annex Point IIA, IV.4.2(a)/02	Analytical Methods for Detection and Identification Copper residues in soil	
	1 REFERENCE	Official use only
1.1 Reference	██████████ (1989). Method validation report for terrestrial outdoor field dissipation study with copper-containing pesticides. Biospherics Inc., unpublished report No. 88-003.	
1.2 Data protection	██████████	
1.2.1 Data owner	██████████	
1.2.2 Companies with letter of access	██████████	
1.2.3 Criteria for data protection	██ ██	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Not stated. However, the method validation is considered to broadly meet the requirements of SANCO/825/00, 20 June 2000.	
2.2 GLP	Yes.	
2.3 Deviations	No.	
	3 MATERIALS AND METHODS	
3.1 Preliminary treatment		
3.1.1 Extraction	██ ██	
3.1.2 Cleanup	██████████	
3.2 Detection		
3.2.1 Separation method	██████████	
3.2.2 Detector	██	
3.2.3 Standard(s)	████████████████	
3.2.4 Interfering substance(s)	██ ██	
3.3 Linearity	██ ██ ██	
3.3.1 Calibration range	█	
3.3.2 Number of measurements	█	
3.3.3 Linearity	█	

Section A4.2(a) Annex Point IIA, IV.4.2(a)/02	Analytical Methods for Detection and Identification [REDACTED]	
3.4 Specificity: interfering substances	[REDACTED] [REDACTED] [REDACTED] [REDACTED]	
3.5 Recovery rates at different levels	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	
3.5.1 Relative standard deviation	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	
3.6 Limit of determination	[REDACTED] [REDACTED]	
3.7 Precision		
3.7.1 Repeatability	[REDACTED]	
3.7.2 Independent laboratory validation	[REDACTED] [REDACTED]	

Section A4.2(a) Annex Point IIA, IV.4.2(a)/02	Analytical Methods for Detection and Identification <div style="background-color: black; width: 150px; height: 15px;"></div>	
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1 Materials and methods	<div style="background-color: black; width: 650px; height: 20px;"></div> <div style="background-color: black; width: 650px; height: 20px;"></div> <div style="background-color: black; width: 250px; height: 20px;"></div>	
4.2 Conclusion	<p>The vast majority of copper in soil is present as an immobile non-bio-available residue. Therefore, the definition of the residue in soil is bio-available copper (i.e. dissolved copper in the soil solution and weakly adsorbed copper which can easily be released into the soil solution). Methods are presented for the determination of both bio-available copper and total copper residues in soil. The method for total copper is presented above.</p> <p>The method for determination of residues of total copper in soil has been adequately validated. The method was successfully evaluated and meets the EU criteria with respect to specificity, linearity, accuracy and precision according to the guidance given in SANCO/825/00. The procedures described in the method are not consistent with standard multi-residue methods because copper is not an organic analyte. However, the method requires equipment and instrumentation which are commonly available in many well-equipped laboratories. In addition, the procedures of acid digestion and determination by AAS are recognised standard methods of analysis for inorganic elements such as copper.</p> <p>The method is considered to be suitable for both generation of registration data and for post-registration control and monitoring purposes.</p>	
4.2.1 Reliability	<div style="background-color: black; width: 10px; height: 10px;"></div>	
4.2.2 Deficiencies	<div style="background-color: black; width: 20px; height: 10px;"></div>	

Section A4.2(a) Annex Point IIA, IV.4.2(a)/02	Analytical Methods for Detection and Identification [REDACTED]	
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Reliability		
Acceptability		
Remarks		

Section A4.2(a) Annex Point IIA, IV.4.2(a)/03, 04	Analytical Methods for Detection and Identification Copper residues in soil	
	1 REFERENCE	Official use only
1.1 Reference	<p>Method 3050B. Acid digestion of sediments, sludges and soil. USEPA Revision 2, December 1996.</p> <p>Method 220.1. Methods of chemical analysis of water and wastes. USEPA March 1983.</p>	
1.2 Data protection		
1.2.1 Data owner		
1.2.2 Companies with letter of access		
1.2.3 Criteria for data protection		
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Not applicable.	
2.2 GLP	No.	
2.3 Deviations	Not applicable.	
	3 MATERIALS AND METHODS	
3.1 Preliminary treatment		
3.1.1 Extraction		
3.1.2 Clean up		
3.2 Detection		
3.2.1 Separation method		
3.2.2 Detector		
3.2.3 Standard(s)		
3.2.4 Interfering substance(s)		
3.3 Linearity		

Section A4.2(a) Annex Point IIA, IV.4.2(a)/03, 04	Analytical Methods for Detection and Identification [REDACTED]	
3.4 Specificity: interfering substances	[REDACTED] [REDACTED]	
3.5 Recovery rates at different levels	[REDACTED] [REDACTED] [REDACTED]	
3.5.1 Relative standard deviation	[REDACTED] [REDACTED] [REDACTED]	
3.6 Limit of determination	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	
3.7 Precision		
3.7.1 Repeatability	[REDACTED] [REDACTED]	
3.7.2 Independent laboratory validation	[REDACTED] [REDACTED]	

Section A4.2(a) Annex Point IIA, IV.4.2(a)/03, 04	Analytical Methods for Detection and Identification Copper residues in soil	
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1 Materials and methods	<div style="background-color: black; width: 100%; height: 1.2em; margin-bottom: 2px;"></div> <div style="background-color: black; width: 100%; height: 1.2em; margin-bottom: 2px;"></div> <div style="background-color: black; width: 100%; height: 1.2em; margin-bottom: 2px;"></div> <div style="background-color: black; width: 100%; height: 1.2em; margin-bottom: 2px;"></div>	
4.2 Conclusion	<p>The method for determination of residues copper in soil has been collaboratively validated and is reported by the USEPA. Therefore is can be considered to be adequate in terms of the EU criteria for specificity, linearity, accuracy and precision according to the guidance given in SANCO/825/00. The procedures described in the method are not consistent with standard multi-residue methods because copper is not an organic analyte, but they are standard procedures for determination of metals. The method requires equipment and instrumentation which are commonly available in many well-equipped laboratories. The procedures of acid digestion and determination by FLAA or ICP-AES are recognised standard methods of analysis for inorganic elements such as copper.</p> <p>The method is considered to be suitable for both generation of registration data and for post-registration control and monitoring purposes.</p>	
4.2.1 Reliability	I	
4.2.2 Deficiencies	■	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		
Materials and methods		
Conclusion		
Reliability		
Acceptability		
Remarks		
	COMMENTS FROM ...	
Date		
Results and discussion		
Conclusion		
Reliability		
Acceptability		
Remarks		

Section A4.2(b) Annex Point IIA, IV.4.2(b)/01	Analytical Methods for Detection and Identification Copper residues in air	
	1 REFERENCE	Official use only
1.1 Reference	<p>██████████ (1999). Determination of suspended matter in ambient air. Measurement of the concentration by mass of As, Be, Cd, Co, Cr, Cu, Mn, Ni, Pb, Sb, Tl, Zn by atomic absorption spectrometry (AAS) after sampling on filters and digestion in an oxidising acid mixture. Published report No. VDI 2267, Part 1, VDI/DIN Manual Reinhaltung der Luft (Air Pollution Prevention).</p>	
1.2 Data protection	████	
1.2.1 Data owner	██████████	
1.2.2 Companies with letter of access	████	
1.2.3 Criteria for data protection	██ ██	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes. VDI 2267 is itself a guidance document.	
2.2 GLP	No.	
2.3 Deviations	No.	
	3 MATERIALS AND METHODS	
3.1 Preliminary treatment		
3.1.1 Extraction	██ ██ ██	
3.1.2 Cleanup	████	
3.2 Detection		
3.2.1 Separation method	████	
3.2.2 Detector	██ ██	
3.2.3 Standard(s)	██████████	
3.2.4 Interfering substance(s)	██ ██ ██ ██	
3.3 Linearity	██ ██	
3.3.1 Calibration range	█	
3.3.2 Number of measurements	█	

Section A4.2(b) Annex Point IIA, IV.4.2(b)/01	Analytical Methods for Detection and Identification [REDACTED]	
3.3.3 Linearity	[REDACTED]	
3.4 Specificity: interfering substances	[REDACTED]	
3.5 Recovery rates at different levels	[REDACTED]	
3.5.1 Relative standard deviation	[REDACTED]	
3.6 Limit of determination	[REDACTED]	
3.7 Precision		
3.7.1 Repeatability	[REDACTED]	

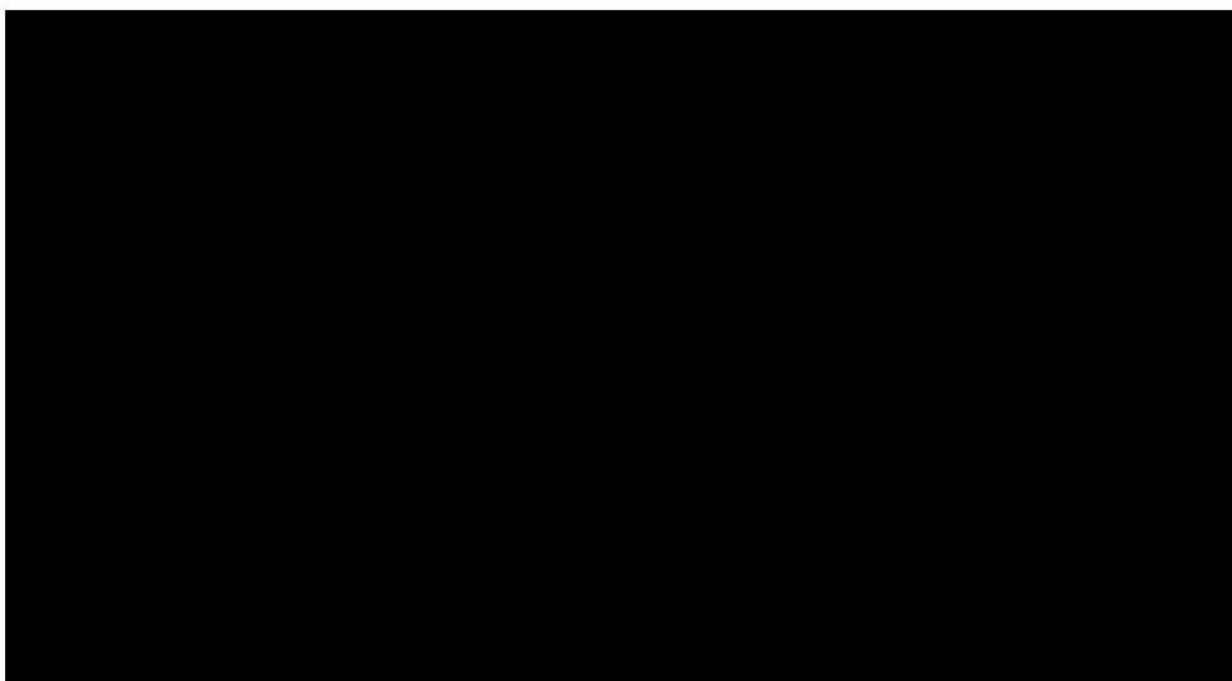
Section A4.2(b) Annex Point IIA, IV.4.2(b)/01	Analytical Methods for Detection and Identification Copper residues in air	
3.7.2 Independent laboratory validation		
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1 Materials and methods		
4.2 Conclusion	<p>A standard VDI method has been presented for the determination of copper in air. The procedures described in the method are not consistent with standard pesticide multi-residue methods because copper is not a typical organic analyte. However, the method does require equipment and instrumentation which are commonly available in many well-equipped laboratories.</p> <p>The method predates and does not completely meet the current requirements on validation as described in the EU guidance documents SANCO/825/00 and SANCO/3029/99. However, sufficient validation has been undertaken to demonstrate that method does meet the EU criteria with respect to specificity, accuracy and precision. The procedures of acid digestion and determination by AAS are generally recognised standard methods of analysis for inorganic elements such as copper.</p> <p>Therefore, the method is considered suitable for post-registration control and monitoring purposes.</p>	
4.2.1 Reliability	I	
4.2.2 Deficiencies		

	Evaluation by Competent Authorities	
	<div></div> <div></div>	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		
Materials and methods		
Conclusion		
Reliability		
Acceptability		
Remarks		
	COMMENTS FROM ...	
Date		
Results and discussion		
Conclusion		
Reliability		
Acceptability		
Remarks		

Section A4.2(b) Annex Point IIA, IV.4.2(b)/02	Analytical Methods for Detection and Identification [REDACTED]	
	1 REFERENCE	Official use only
1.1 Reference	[REDACTED] (1997). Determination of suspended matter in ambient air. Determination of the mass concentration of Be, Cd, Co, Cr, Cu, Fe, Mn, Ni, Pb, Sb, V, Zn by optical emission spectrometry (ICP-OES) after sampling on filters and digestion in an oxidising agent. Published report No. VDI 2267, Part 5, VDI/DIN Manual Reinhaltung der Luft (Air Pollution Prevention).	
1.2 Data protection	[REDACTED]	
1.2.1 Data owner	[REDACTED]	
1.2.2 Companies with letter of access	[REDACTED]	
1.2.3 Criteria for data protection	[REDACTED] [REDACTED]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes. VDI 2267 is itself a guidance document.	
2.2 GLP	No.	
2.3 Deviations	No.	
	3 MATERIALS AND METHODS	
3.1 Preliminary treatment		
3.1.1 Extraction	[REDACTED] [REDACTED] [REDACTED]	
3.1.2 Cleanup	[REDACTED]	
3.2 Detection		
3.2.1 Separation method	[REDACTED]	
3.2.2 Detector	[REDACTED]	
3.2.3 Standard(s)	[REDACTED]	
3.2.4 Interfering substance(s)	[REDACTED] [REDACTED] [REDACTED] [REDACTED]	
3.3 Linearity	[REDACTED] [REDACTED]	
3.3.1 Calibration range	[REDACTED]	
3.3.2 Number of measurements	[REDACTED]	
3.3.3 Linearity	[REDACTED]	

Section A4.2(b)	Analytical Methods for Detection and Identification	
Annex Point IIA, IV.4.2(b)/02		
3.4 Specificity: interfering substances		
3.5 Recovery rates at different levels		
3.5.1 Relative standard deviation		
3.6 Limit of determination		
3.7 Precision		
3.7.1 Repeatability		
3.7.2 Independent laboratory validation		

Section A4.2(b) Annex Point IIA, IV.4.2(b)/02	Analytical Methods for Detection and Identification [REDACTED]	
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1 Materials and methods	[REDACTED] [REDACTED] [REDACTED]	
4.2 Conclusion	<p>A standard VDI method has been presented for the determination of copper in air. The procedures described in the method are not consistent with standard pesticide multi-residue methods because copper is not a typical organic analyte. However, the method does require equipment and instrumentation which are commonly available in many well-equipped laboratories.</p> <p>The method predates and does not completely meet the current requirements on validation as described in the EU guidance documents SANCO/825/00 and SANCO/3029/99. However, sufficient validation has been undertaken to demonstrate that method does meet the EU criteria with respect to specificity, accuracy and precision. The procedures of acid digestion and determination by ICP-OES are generally recognised standard methods of analysis for inorganic elements such as copper.</p> <p>Therefore, the method is considered suitable for post-registration control and monitoring purposes.</p>	
4.2.1 Reliability	I	
4.2.2 Deficiencies	[REDACTED]	



	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		
Materials and methods		
Conclusion		
Reliability		
Acceptability		
Remarks		
	COMMENTS FROM ...	
Date		
Results and discussion		
Conclusion		
Reliability		
Acceptability		
Remarks		

Section A4.2(c) Annex Point IIA, IV.4.2(c)/01 Annex Point IIA, IV.4.2(c)/02	Analytical Methods for Detection and Identification Copper residues in water	
	1 REFERENCE	Official use only
1.1 Reference	<p><u>4.2(c)/01</u> (2001). Assessment of side effects of URA-13900-F-0-WP on the larvae of the midge, <i>Chironomous riparius</i> with the laboratory test method. GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, unpublished report No. 99520/01-ASCr (Appendix 5).</p> <p><u>4.2(c)/02</u> (2000). Assessment of side effects of URA-08740-F-0-WP on the larvae of the midge, <i>Chironomous riparius</i> with the laboratory test method. GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, unpublished report No. 99507/01-ASCr (See Appendix 9).</p>	
1.2 Data protection		
1.2.1 Data owner		
1.2.2 Companies with letter of access		
1.2.3 Criteria for data protection		
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	The guidelines for the method validation are not stated. However, the validation is considered to broadly meet the requirements of SANCO/825/00, 20 June 2000.	
2.2 GLP	Yes.	
2.3 Deviations	No.	
	3 MATERIALS AND METHODS	
3.1 Preliminary treatment		
3.1.1 Extraction		
3.1.2 Cleanup		
3.2 Detection		
3.2.1 Separation method		
3.2.2 Detector		
3.2.3 Standard(s)		
3.2.4 Interfering substance(s)		
3.3 Linearity		
3.3.1 Calibration range		
3.3.2 Number of		

Section A4.2(c)	Analytical Methods for Detection and Identification					
Annex Point IIA, IV.4.2(c)/01 Annex Point IIA, IV.4.2(c)/02						
measurements						
3.3.3 Linearity						
3.4 Specificity: interfering substances						
3.5 Recovery rates at different levels						
3.5.1 Relative standard deviation						
3.6 Limit of determination						
3.7 Precision						
3.7.1 Repeatability						
3.7.2 Independent laboratory validation						

Section A4.2(c) Annex Point IIA, IV.4.2(c)/01 Annex Point IIA, IV.4.2(c)/02	Analytical Methods for Detection and Identification <div style="background-color: black; width: 150px; height: 15px;"></div>	
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1 Materials and methods	<div style="background-color: black; width: 400px; height: 15px;"></div> <div style="background-color: black; width: 300px; height: 15px;"></div>	
4.2 Conclusion	<p>The definition of the residue in water is dissolved copper only. The method presented is for the determination of total copper in water. Use of this method as described would provide total copper residues including those bound to particulate matter in the water. Therefore, for the determination of dissolved copper only, it is necessary to carry out an initial filtration of the water prior to analysis. Water is passed through a disposable 0.45 µm membrane filter to remove particulate matter. In aquatic chemistry, water filtered through 0.45 µm membrane filters is generally considered to contain the dissolved copper fraction (e.g. in the German standard method DIN 38409 / DEV H3 for analysis of dissolved organic carbon or the international standard method ISO 11885 / DEV E22 for the analysis of metals in water).</p> <p>The method for determination of residues of total copper in water has been adequately validated and can be easily applied for analysis of dissolved copper. The method was successfully evaluated and meets the EU criteria with respect to specificity, linearity, accuracy and precision according to the guidance given in SANCO/825/00. The procedures described in the method are not consistent with standard multi-residue methods because copper is not an organic analyte. However, the method requires equipment and instrumentation which are commonly available in many well-equipped laboratories. In addition, the procedures of acid digestion and determination by ICP-EAS are recognised standard methods of analysis for inorganic elements such as copper.</p> <p>The method is considered to be suitable for both generation of registration data and for post-registration control and monitoring purposes.</p>	
4.2.1 Reliability	<div style="background-color: black; width: 10px; height: 15px;"></div>	
4.2.2 Deficiencies	<div style="background-color: black; width: 20px; height: 15px;"></div>	

Section A4.2(c) Annex Point IIA, IV.4.2(c)/01 Annex Point IIA, IV.4.2(c)/02	Analytical Methods for Detection and Identification <div style="background-color: black; width: 150px; height: 15px; margin-bottom: 10px;"></div>	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		
Materials and methods		
Conclusion		
Reliability		
Acceptability		
Remarks		
	COMMENTS FROM ...	
Date		
Results and discussion		
Conclusion		
Reliability		
Acceptability		
Remarks		

Section A4.2(c) Annex Point IIA, IV.4.2(c)/03	Analytical Methods for Detection and Identification Copper residues in water	
	1 REFERENCE	Official use only
1.1 Reference	██████████ (1989). Method validation report for terrestrial outdoor field dissipation study with copper-containing pesticides. Biospherics Inc., unpublished report No. 88-003.	
1.2 Data protection	██████████	
1.2.1 Data owner	██████████	
1.2.2 Companies with letter of access	██████████	
1.2.3 Criteria for data protection	██ ██	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Not stated. However, the method validation is considered to broadly meet the requirements of SANCO/825/00, 20 June 2000.	
2.2 GLP	Yes.	
2.3 Deviations	No.	
	3 MATERIALS AND METHODS	
3.1 Preliminary treatment		
3.1.1 Extraction	██ ██	
3.1.2 Cleanup	██████████	
3.2 Detection		
3.2.1 Separation method	██████████	
3.2.2 Detector	██	
3.2.3 Standard(s)	████████████████	
3.2.4 Interfering substance(s)	██ ██	
3.3 Linearity	██ ██ ██	
3.3.1 Calibration range	█	
3.3.2 Number of measurements	█	
3.3.3 Linearity	█	

Section A4.2(c)	Analytical Methods for Detection and Identification						
Annex Point IIA, IV.4.2(c)/03							
3.4	Specificity: interfering substances						
3.5	Recovery rates at different levels						
3.5.1	Relative standard deviation						
3.6	Limit of determination						
3.7	Precision						
3.7.1	Repeatability						
3.7.2	Independent laboratory validation						

Section A4.2(c) Annex Point IIA, IV.4.2(c)/03	Analytical Methods for Detection and Identification <div style="background-color: black; width: 150px; height: 15px;"></div>	
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1 Materials and methods	<div style="background-color: black; width: 450px; height: 15px;"></div> <div style="background-color: black; width: 450px; height: 15px;"></div> <div style="background-color: black; width: 150px; height: 15px;"></div>	
4.2 Conclusion	<p>The definition of the residue in water is dissolved copper only. The method presented is for the determination of total copper in water. Use of this method as described would provide total copper residues including those bound to particulate matter in the water. Therefore, for the determination of dissolved copper only, it is necessary to carry out an initial filtration of the water prior to analysis. Water is passed through a disposable 0.45 µm membrane filter to remove particulate matter. In aquatic chemistry, water filtered through 0.45 µm membrane filters is generally considered to contain the dissolved copper fraction (e.g. in the German standard method DIN 38409 / DEV H3 for analysis of dissolved organic carbon or the international standard method ISO 11885 / DEV E22 for the analysis of metals in water).</p> <p>The method for determination of residues of total copper in water has been adequately validated and can be easily applied for analysis of dissolved copper. The method was successfully evaluated and meets the EU criteria with respect to specificity, linearity, accuracy and precision according to the guidance given in SANCO/825/00. The procedures described in the method are not consistent with standard multi-residue methods because copper is not an organic analyte. However, the method requires equipment and instrumentation which are commonly available in many well-equipped laboratories. In addition, the procedures of acid digestion and determination by AAS are recognised standard methods of analysis for inorganic elements such as copper.</p> <p>The method is considered to be suitable for both generation of registration data and for post-registration control and monitoring purposes.</p>	
4.2.1 Reliability	<div style="background-color: black; width: 10px; height: 15px;"></div>	
4.2.2 Deficiencies	<div style="background-color: black; width: 20px; height: 15px;"></div>	

Section A4.2(c) Annex Point IIA, IV.4.2(c)/03	Analytical Methods for Detection and Identification [REDACTED]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		
Materials and methods		
Conclusion		
Reliability		
Acceptability		
Remarks		
	COMMENTS FROM ...	
Date		
Results and discussion		
Conclusion		
Reliability		
Acceptability		
Remarks		

Section A4.2(c) Annex Point IIA, IV.4.2(c)/04	Analytical Methods for Detection and Identification Copper residues in water	
	1 REFERENCE	Official use only
1.1 Reference	4.2(c)/04 [REDACTED] (1989). Community level study with [REDACTED] [REDACTED] in aquatic microcosms. Fraunhofer-Institut für Umweltchemie und Ökotoxikologie-IUCT, unpublished report No. URA-001/4-50.	
1.2 Data protection	[REDACTED]	
1.2.1 Data owner	[REDACTED]	
1.2.2 Companies with letter of access	[REDACTED]	
1.2.3 Criteria for data protection	[REDACTED] [REDACTED]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	The guidelines for the method validation are not stated. However, the validation is considered to broadly meet the requirements of SANCO/825/00.	
2.2 GLP	Yes.	
2.3 Deviations	No.	
	3 MATERIALS AND METHODS	
3.1 Preliminary treatment		
3.1.1 Extraction	[REDACTED] [REDACTED]	
3.1.2 Cleanup	[REDACTED]	
3.2 Detection		
3.2.1 Separation method	[REDACTED]	
3.2.2 Detector	[REDACTED] [REDACTED] [REDACTED] [REDACTED]	
3.2.3 Standard(s)	[REDACTED]	
3.2.4 Interfering substance(s)	[REDACTED] [REDACTED] [REDACTED] [REDACTED]	
3.3 Linearity		
3.3.1 Calibration range	[REDACTED]	
3.3.2 Number of measurements	[REDACTED]	
3.3.3 Linearity	[REDACTED]	

Section A4.2(c) Annex Point IIA, IV.4.2(c)/04	Analytical Methods for Detection and Identification [REDACTED]				
	[REDACTED]				
3.4 Specificity: interfering substances	[REDACTED] [REDACTED] [REDACTED] [REDACTED]				
3.5 Recovery rates at different levels	[REDACTED]				
	[REDACTED]		[REDACTED]		
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	
	[REDACTED]		[REDACTED]	[REDACTED]	
3.5.1 Relative standard deviation	[REDACTED] [REDACTED] [REDACTED]				
3.6 Limit of determination	[REDACTED] [REDACTED]				
3.7 Precision					
3.7.1 Repeatability	[REDACTED]				
3.7.2 Independent laboratory validation	[REDACTED] [REDACTED]				

Section A4.2(c) Annex Point IIA, IV.4.2(c)/04	Analytical Methods for Detection and Identification <div style="background-color: black; width: 150px; height: 15px;"></div>	
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1 Materials and methods	<div style="background-color: black; width: 450px; height: 15px;"></div> <div style="background-color: black; width: 450px; height: 15px;"></div> <div style="background-color: black; width: 450px; height: 15px;"></div> <div style="background-color: black; width: 450px; height: 15px;"></div> <div style="background-color: black; width: 450px; height: 15px;"></div>	
4.2 Conclusion	<p>The definition of the residue in water is dissolved copper only. The method presented is for the determination of total copper in water. Use of this method as described would provide total copper residues including those bound to particulate matter in the water. Therefore, for the determination of dissolved copper only, it is necessary to carry out an initial filtration of the water prior to analysis. Water is passed through a disposable 0.45 µm membrane filter to remove particulate matter. In aquatic chemistry, water filtered through 0.45 µm membrane filters is generally considered to contain the dissolved copper fraction (e.g. in the German standard method DIN 38409 / DEV H3 for analysis of dissolved organic carbon or the international standard method ISO 11885 / DEV E22 for the analysis of metals in water).</p> <p>The method for determination of residues of copper in water has been adequately validated and can be easily applied for analysis of dissolved copper. The method was successfully evaluated and meets the EU criteria with respect to specificity, linearity, accuracy and precision according to the guidance given in SANCO/825/00. The procedures described in the method are not consistent with standard multi-residue methods because copper is not an organic analyte. However, the method requires equipment and instrumentation which are commonly available in many well-equipped laboratories. In addition, the procedures of acid digestion and determination by AAS or ICP-OES are recognised standard methods of analysis for inorganic elements such as copper.</p> <p>The method is considered to be suitable for both generation of registration data and for post-registration control and monitoring purposes.</p>	
4.2.1 Reliability	<div style="background-color: black; width: 10px; height: 15px;"></div>	
4.2.2 Deficiencies	<div style="background-color: black; width: 20px; height: 15px;"></div>	
Evaluation by Competent Authorities		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date		
Materials and methods		
Conclusion		
Reliability		
Acceptability		
Remarks		

Section A4.2(c) Annex Point IIA, IV.4.2(c)/04	Analytical Methods for Detection and Identification [REDACTED]	
	COMMENTS FROM ...	
Date		
Results and discussion		
Conclusion		
Reliability		
Acceptability		
Remarks		

Section A4.2(c) Annex Point IIA, IV.4.2(c)/05, 06, 07	Analytical Methods for Detection and Identification Copper residues in water	
	1 REFERENCE	Official use only
1.1 Reference	<p>Method 220.2. Methods of chemical analysis of water and wastes. USEPA March 1983</p> <p>Method 7211. Copper (atomic absorption, furnace technique). USEPA July 1992</p> <p>Method 200.7. Inductively coupled plasma - Atomic emission spectrometric method for trace element analysis of water and wastes. USEPA, 1983</p>	
1.2 Data protection		
1.2.1 Data owner		
1.2.2 Companies with letter of access		
1.2.3 Criteria for data protection		
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Not applicable.	
2.2 GLP	No.	
2.3 Deviations	Not applicable.	
	3 MATERIALS AND METHODS	
3.1 Preliminary treatment		
3.1.1 Extraction		
3.1.2 Clean up		
3.2 Detection		
3.2.1 Separation method		
3.2.2 Detector		
3.2.3 Standard(s)		
3.2.4 Interfering substance(s)		
3.3 Linearity		

Section A4.2(c) Annex Point IIA, IV.4.2(c)/05, 06, 07	Analytical Methods for Detection and Identification [REDACTED]	
3.4 Specificity: interfering substances	[REDACTED] [REDACTED]	
3.5 Recovery rates at different levels	[REDACTED] [REDACTED] [REDACTED]	
3.5.1 Relative standard deviation	[REDACTED] [REDACTED] [REDACTED]	
3.6 Limit of determination		
3.7 Precision		
3.7.1 Repeatability	[REDACTED] [REDACTED]	
3.7.2 Independent laboratory validation	[REDACTED] [REDACTED]	

Section A4.2(c) Annex Point IIA, IV.4.2(c)/05, 06, 07	Analytical Methods for Detection and Identification [REDACTED]	
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1 Materials and methods	[REDACTED] [REDACTED] [REDACTED] [REDACTED]	
4.2 Conclusion	<p>The methods for determination of residues copper in water have been collaboratively validated and are reported by the USEPA. Therefore, the methods can be considered to be adequate in terms of the EU criteria for specificity, linearity, accuracy and precision according to the guidance given in SANCO/825/00. The procedures described in the methods are not consistent with standard multi-residue methods because copper is not an organic analyte, but they are standard procedures for determination of metals. The methods require equipment and instrumentation which are commonly available in many well-equipped laboratories. The procedures of acid digestion and determination by AA or ICP-AES are recognised standard methods of analysis for inorganic elements such as copper.</p> <p>The method is considered to be suitable for both generation of registration data and for post-registration control and monitoring purposes.</p>	
4.2.1 Reliability	[REDACTED]	
4.2.2 Deficiencies	[REDACTED]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		
Materials and methods		
Conclusion		
Reliability		
Acceptability		
Remarks		
	COMMENTS FROM ...	
Date		
Results and discussion		
Conclusion		
Reliability		
Acceptability		
Remarks		

Manica S.p.A.		Copper sulphate pentahydrate	January 2008
Section A4.2(d) Annex Point IIA, IV.4.2(d)/01	Analytical Methods for Detection and Identification Copper residues in animal and human body fluids and tissues		
	1 REFERENCE		Official use only
1.1 Reference	██████████ (2003). Five copper substances: Absorption, distribution, and excretion in male rats. E.I du Pont de Nemours and Company, unpublished draft report No. 11784 (Appendix C).		
1.2 Data protection	████		
1.2.1 Data owner	██████████		
1.2.2 Companies with letter of access	████		
1.2.3 Criteria for data protection	██ ██		
	2 GUIDELINES AND QUALITY ASSURANCE		
2.1 Guideline study	Yes. Guidelines not stated for the analytical method validation phase of the study, but it meets the requirements of SANCO/825/00, 20 June 2000.		
2.2 GLP	Yes.		
2.3 Deviations	No.		
	3 MATERIALS AND METHODS		
3.1 Preliminary treatment			
3.1.1 Extraction	██ ██ ██ ██		
3.1.2 Cleanup	████		
3.2 Detection			
3.2.1 Separation method	████		
3.2.2 Detector	██		
3.2.3 Standard(s)	████████████████		
3.2.4 Interfering substance(s)	██ ██		
3.3 Linearity	██ ██ ██		
3.3.1 Calibration range	█		
3.3.2 Number of measurements	█		
3.3.3 Linearity	█		

Section A4.2(d)	Analytical Methods for Detection and Identification					
Annex Point IIA, IV.4.2(d)/01						
3.4	Specificity: interfering substances					
3.5	Recovery rates at different levels					

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Section A4.2(d) Annex Point IIA, IV.4.2(d)/01	Analytical Methods for Detection and Identification [REDACTED]	
	4 APPLICANT'S SUMMARY AND CONCLUSION	
4.1 Materials and methods	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	
4.2 Conclusion	<p>The method for determination of residues in body fluids and tissues has been adequately validated. The method was successfully evaluated and meets the EU criteria with respect to specificity, linearity, accuracy and precision according to the guidance given in SANCO/825/00. The procedures described in the method are not consistent with standard multi-residue methods because copper is not an organic analyte. However, the method requires equipment and instrumentation which are commonly available in many well-equipped laboratories. In addition, the procedures of acid digestion and determination by ICP-EAS are recognised standard methods of analysis for inorganic elements such as copper.</p> <p>The method is considered to be suitable for both generation of registration data and for post-registration control and monitoring purposes.</p>	
4.2.1 Reliability	I	
4.2.2 Deficiencies	■	

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Section A4.2(d) Annex Point IIA, IV.4.2(d)/01	Analytical Methods for Detection and Identification [REDACTED]	
	Evaluation by Competent Authorities	
	[REDACTED] [REDACTED]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		
Materials and methods		
Conclusion		
Reliability		
Acceptability		
Remarks		
	COMMENTS FROM ...	
Date		
Results and discussion		
Conclusion		
Reliability		
Acceptability		
Remarks		

Section A4.3	Analytical Methods for Detection and Identification	
Annex Point IIA IV.4.3	Residues in treated food and feedingstuffs	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Detailed justification:		
Undertaking of intended data submission []		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		