Section A1 Applicant

Annex Point IIA1

1.1	**Applicant**	Name: Address: Telephone: Fax number: E-mail address:	Detia Freyberg GmbH Dr.-Werner-Freyberg-Str. 11 D-69514 Laudenbach [redacted] zulassung@detia-degesch.de
1.2	**Manufacturer of Active Substance** (if different)	Name: Address: Telephone: Fax number: E-mail address:	Detia Freyberg GmbH Dr.-Werner-Freyberg-Str. 11 D-69514 Laudenbach [redacted]
1.3	**Manufacturer of Product(s) (if different)** **1) Product 1** **2) Product n**	Name: Address: Telephone: Fax number: E-mail address:	Detia Freyberg GmbH Dr.-Werner-Freyberg-Str. 11 D-69514 Laudenbach [redacted]

[redacted]

Section A1 Applicant

Annex Point IIA1

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Give date of action
Materials and methods	State if the applicants version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.
Conclusion	Adopt applicant's version or include revised version
Reliability	Based on the assessment of the method include appropriate reliability indicator
Acceptability	acceptable / not acceptable (give reasons if necessary, e.g. if a study is acceptable despite a poor reliability indicator). Discuss the relevance of deficiencies.
Remarks	

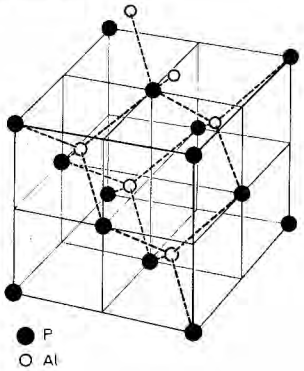
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A2 Identity of Active Substance

Official use only

Subsection (Annex Point)

2.1	**Common name (IIA2.1)**	Aluminium phosphide
2.2	**Chemical name (IIA2.2)**	IUPAC: Aluminium phosphide CAS-name: Aluminium phosphide (AlP)
2.3	**Manufacturer´s development code number(s) (IIA2.3)**	Not applicable, since manufactures's code numbers are not routinely assigned.
2.4	**CAS No and EC numbers (IIA2.4)**	
2.4.1	**CAS-No**	20859-73-8
	Isomer 1	
	Isomer n	
2.4.2	**EC-No**	244-088-0
	Isomer 1	
	Isomer n	
2.4.3	**Other**	
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**	
2.5.1	**Molecular formula**	AlP
2.5.2	**Structural formula**	AlP lattice



2.5.3	**Molecular mass**	57.96
2.6	**Method of manufacture of the active substance (IIA2.1)**	[redacted]

Section A2 Identity of Active Substance

[redacted]

2.7 Specification of the purity of the active substance, as appropriate (IIA2.7)

[redacted]

2.8 Identity of impurities and additives, as appropriate (IIA2.8)

see separate standard format in the confidential part of the dossier (reference A2.8).

2.8.1 Isomeric

[redacted]

Section A2 Identity of Active Substance

	composition	[redacted]
2.9	**The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)**	[redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and methods	*State if the applicants version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of the method include appropriate reliability indicator*
Acceptability	*acceptable / not acceptable* *(give reasons if necessary, e.g. if a study is acceptable despite a poor reliability indicator). Discuss the relevance of deficiencies.*
Remarks	
	COMMENTS FROM ...
Date	Give date of comments submitted
Results and discussion	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability	Discuss if deviating from view of rapporteur member state
Remarks	

Section A2.8
Annex Point IIA2.8

Identity of impurities and additives (active substance)
fill in one form for each impurity/additive

Subsection

Official use only

2.8.1.1 Common name
2.8.1.2 Function

2.8.2 IUPAC name

2.8.3 CAS-No

2.8.4 EC-No

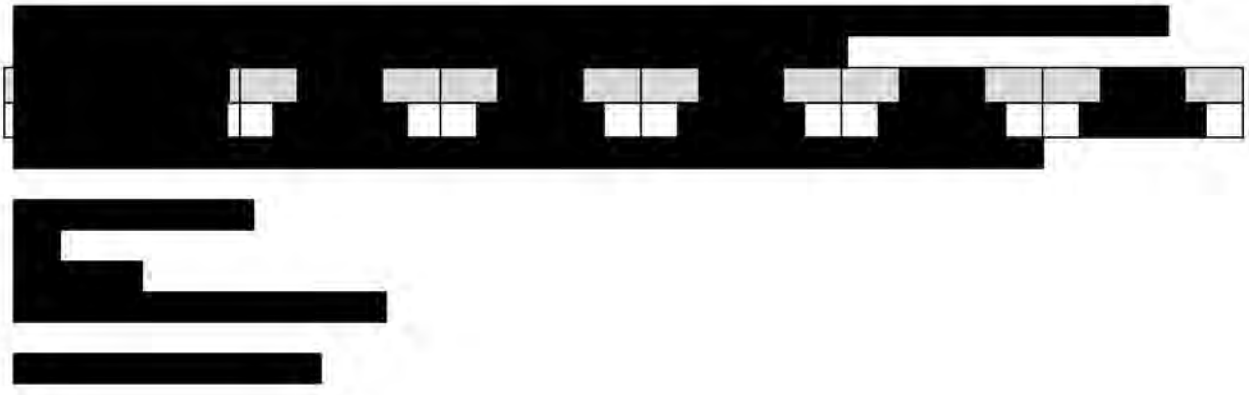
2.8.5 Other

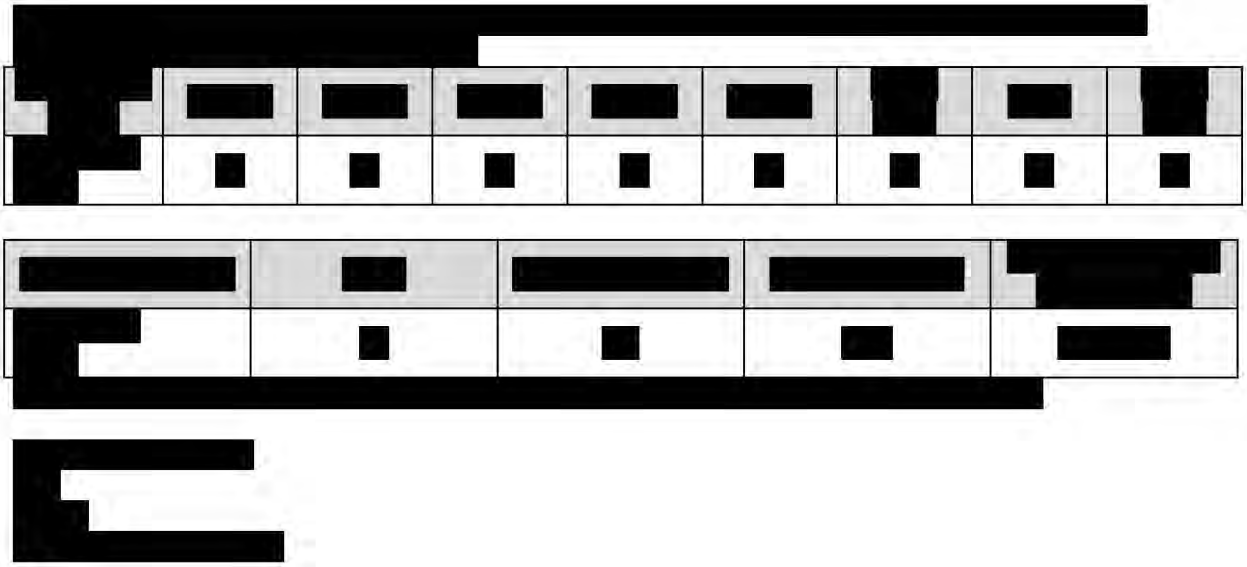
2.8.6 Molecular formula

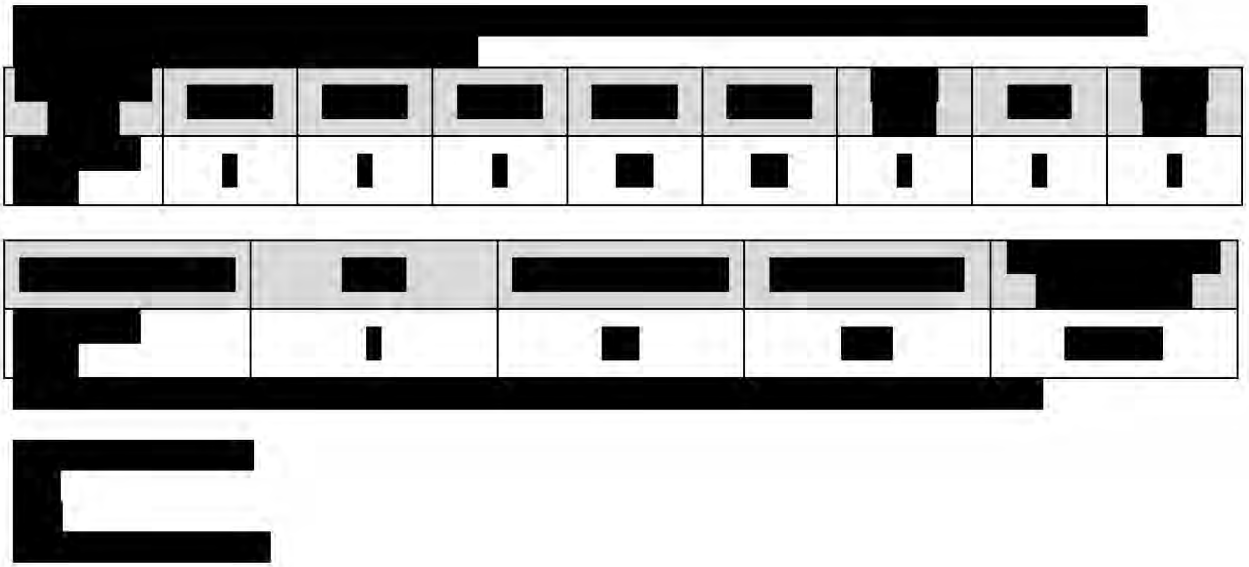
2.8.7 Structural formula

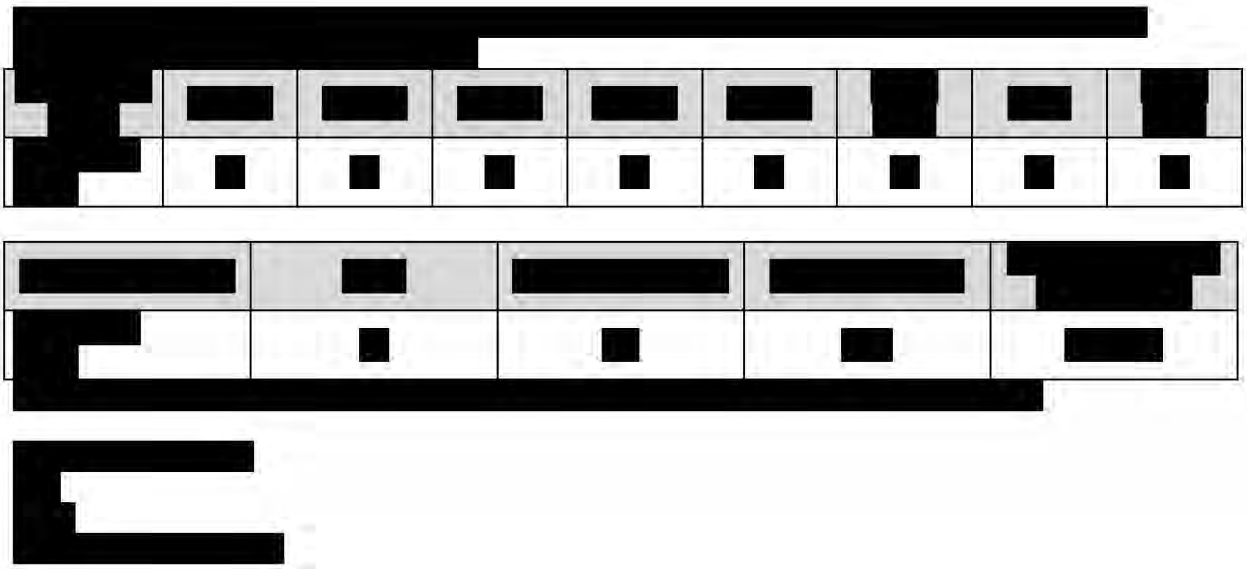
2.8.8 Molecular mass

2.8.9 Concentration of the impurity or additive
typical and range of concentrations









Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	Give date of comments submitted
Results and discussion	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion. Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability	Discuss if deviating from view of rapporteur member state
Remarks	

Section A2.8
Annex Point IIA2.8

Identity of impurities and additives (active substance)
fill in one form for each impurity/additive

Subsection

Official use only

2.8.1.1 Common name

2.8.1.2 Function

2.8.2 IUPAC name

2.8.3 CAS-No

2.8.4 EC-No

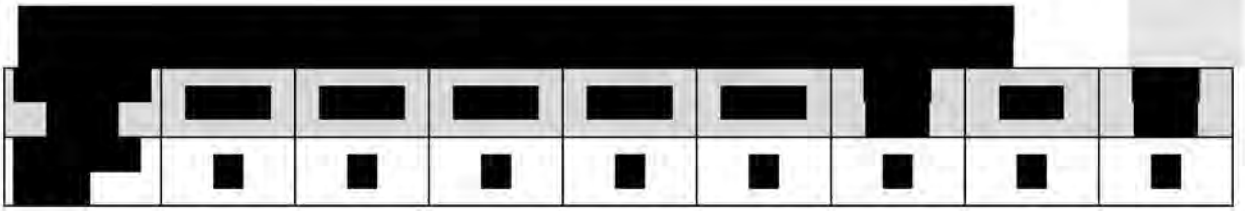
2.8.5 Other

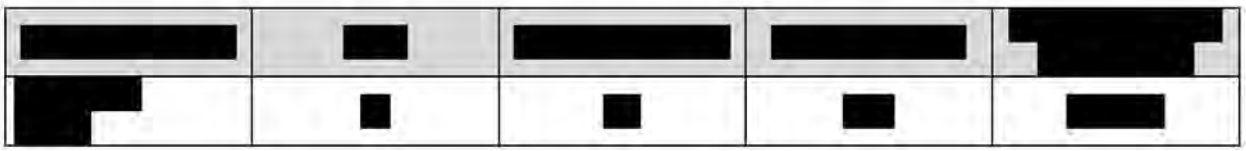
2.8.6 Molecular formula

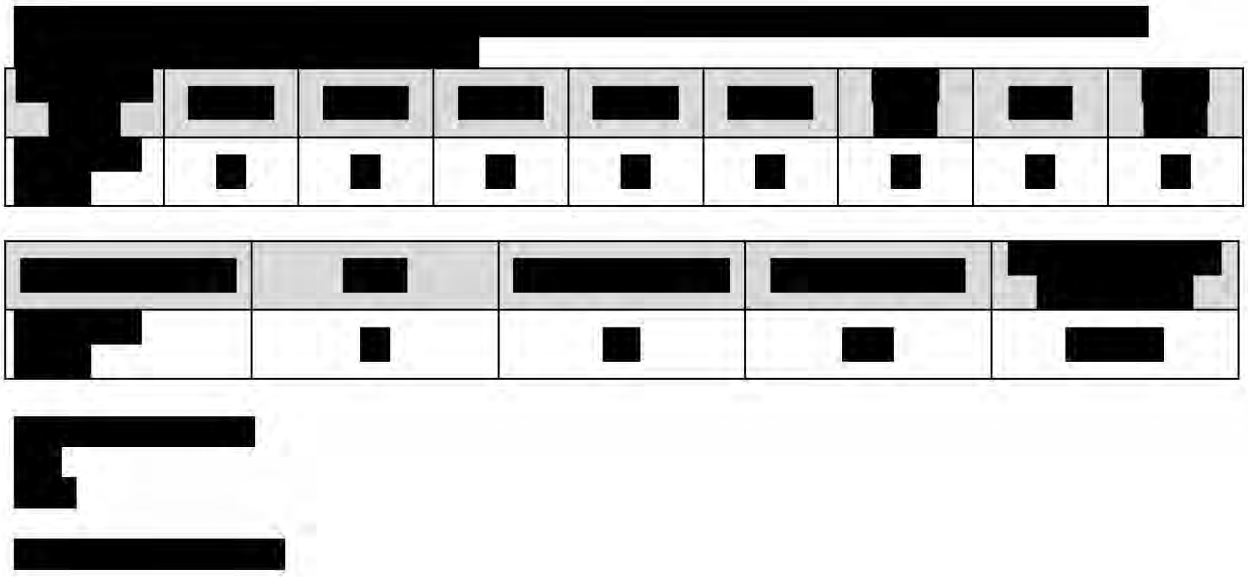
2.8.7 Structural formula

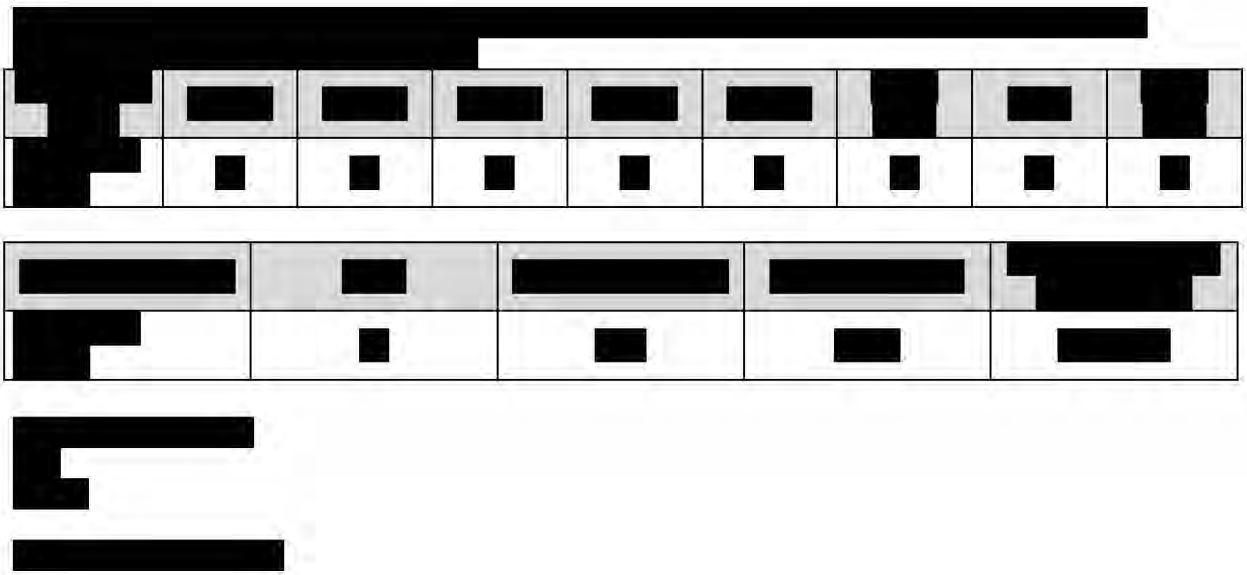
2.8.8 Molecular mass

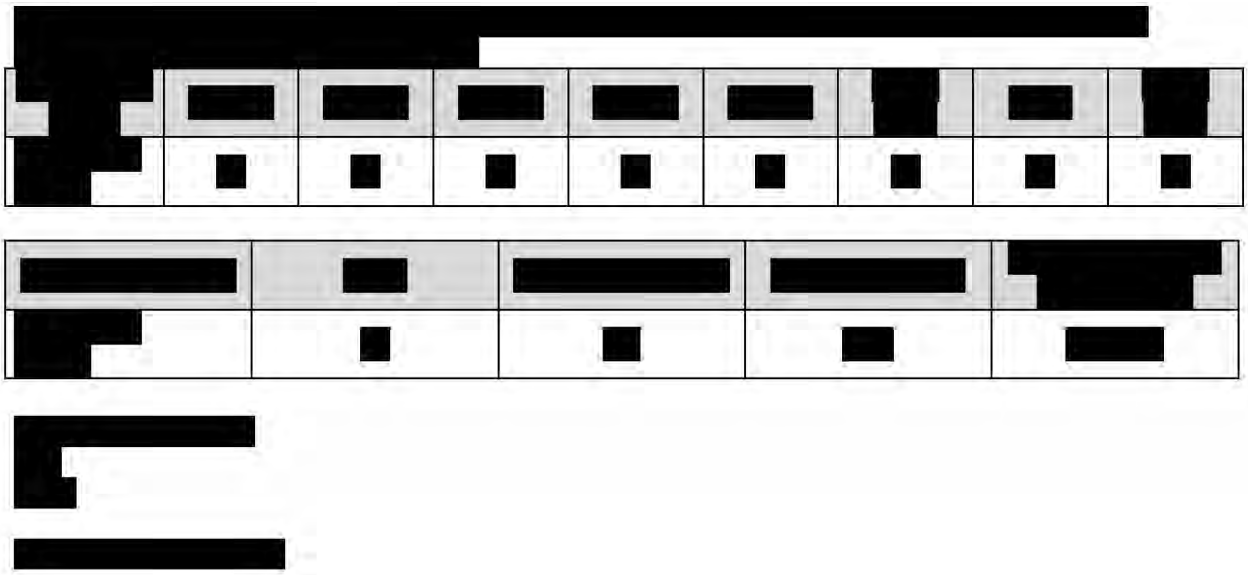
2.8.9 Concentration of the impurity or additive
typical and range of concentrations











Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	Give date of comments submitted
Results and discussion	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion. Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability	Discuss if deviating from view of rapporteur member state
Remarks	

Section A2.8
Annex Point IIA2.8

Identity of impurities and additives (active substance)
fill in one form for each impurity/additive

Subsection

Official use only

2.8.1.1 Common name
2.8.1.2 Function

2.8.2 IUPAC name

2.8.3 CAS-No

2.8.4 EC-No

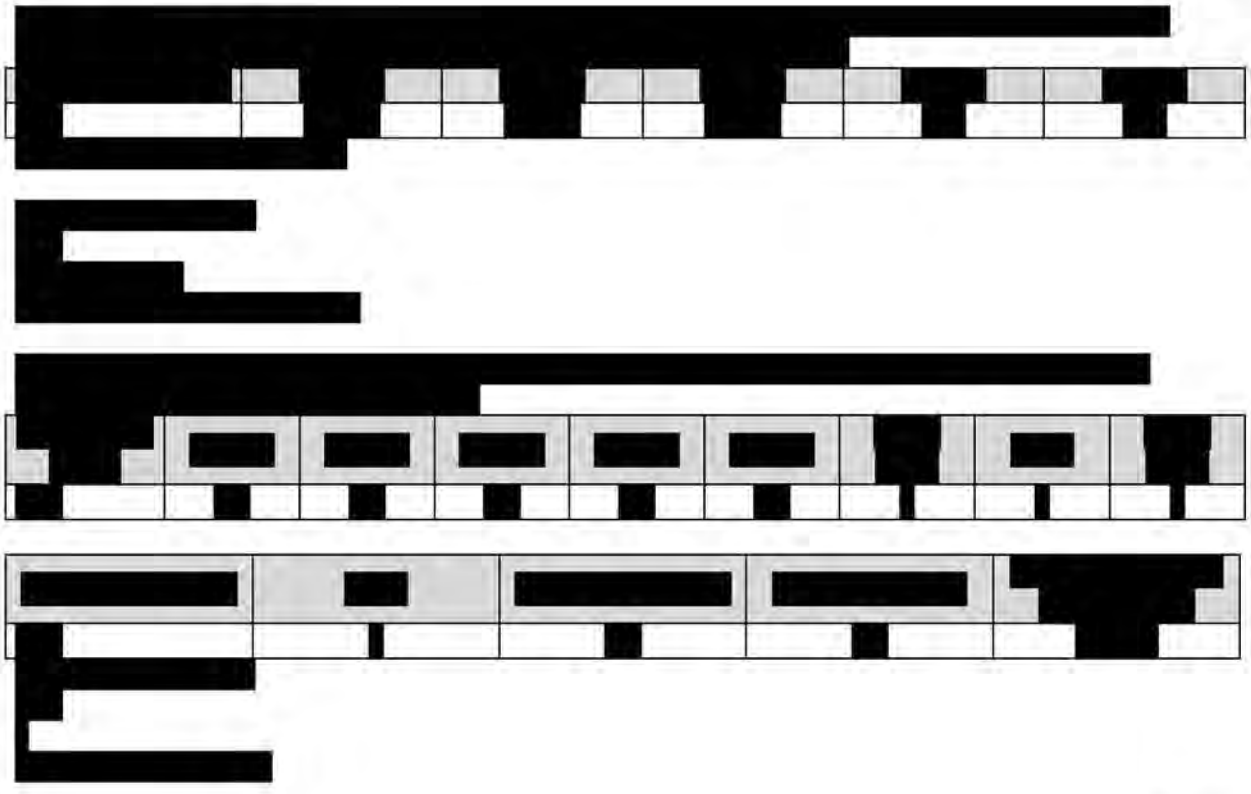
2.8.5 Other

2.8.6 Molecular formula

2.8.7 Structural formula

2.8.8 Molecular mass

2.8.9 Concentration of the impurity or additive
typical and range of concentrations



Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	Give date of comments submitted
Results and discussion	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion. Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability	Discuss if deviating from view of rapporteur member state
Remarks	

Section A2.8
Annex Point IIA2.8

Identity of impurities and additives (active substance)
fill in one form for each impurity/additive

Subsection

Official use only

2.8.1.1 Common name [redacted]

2.8.1.2 Function [redacted]

2.8.2 IUPAC name [redacted]

2.8.3 CAS-No

2.8.4 EC-No

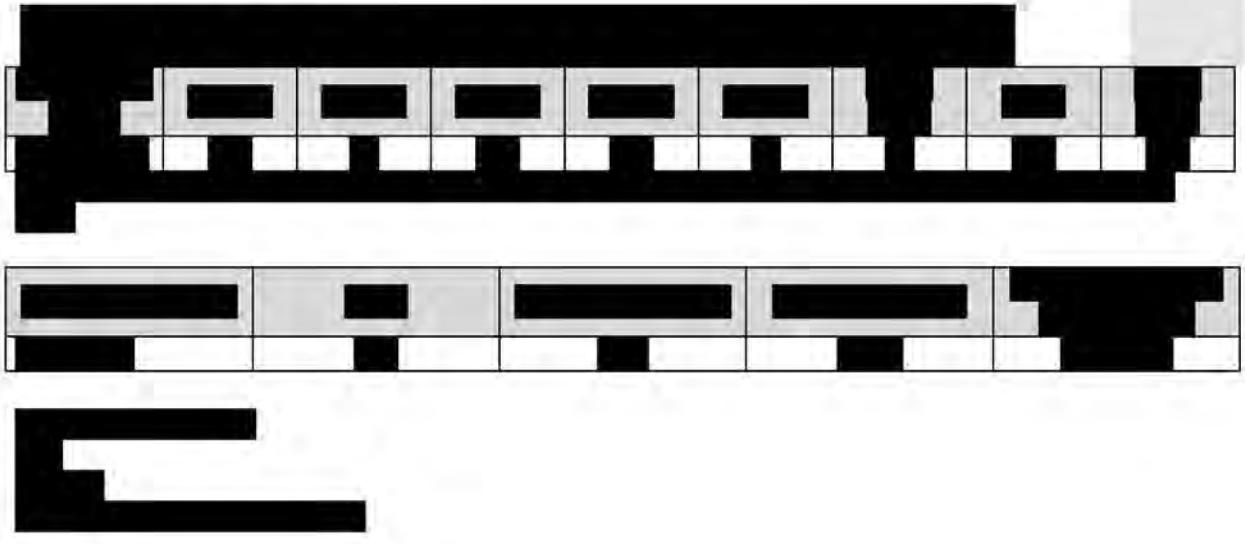
2.8.5 Other

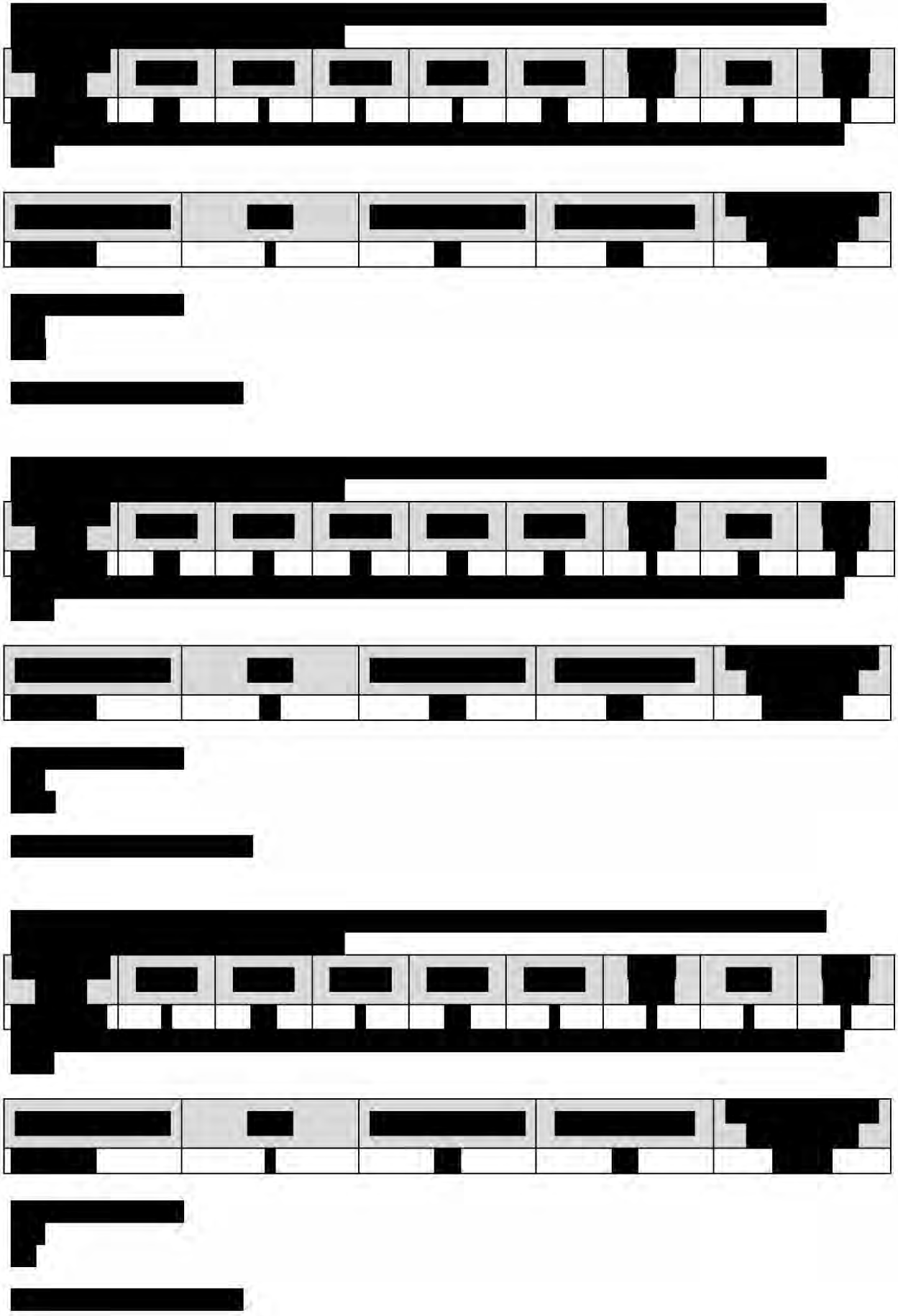
2.8.6 Molecular formula [redacted]

2.8.7 Structural formula [redacted]

2.8.8 Molecular mass [redacted]

2.8.9 Concentration of the impurity or additive
typical and range of concentrations [redacted]





Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	Give date of comments submitted
Results and discussion	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion. Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability	Discuss if deviating from view of rapporteur member state
Remarks	

Section A2.8
Annex Point IIA2.8

Identity of impurities and additives (active substance)
fill in one form for each impurity/additive

Official use only

Subsection

2.8.1.1 Common name
2.8.1.2 Function

2.8.2 IUPAC name

2.8.3 CAS-No

2.8.4 EC-No

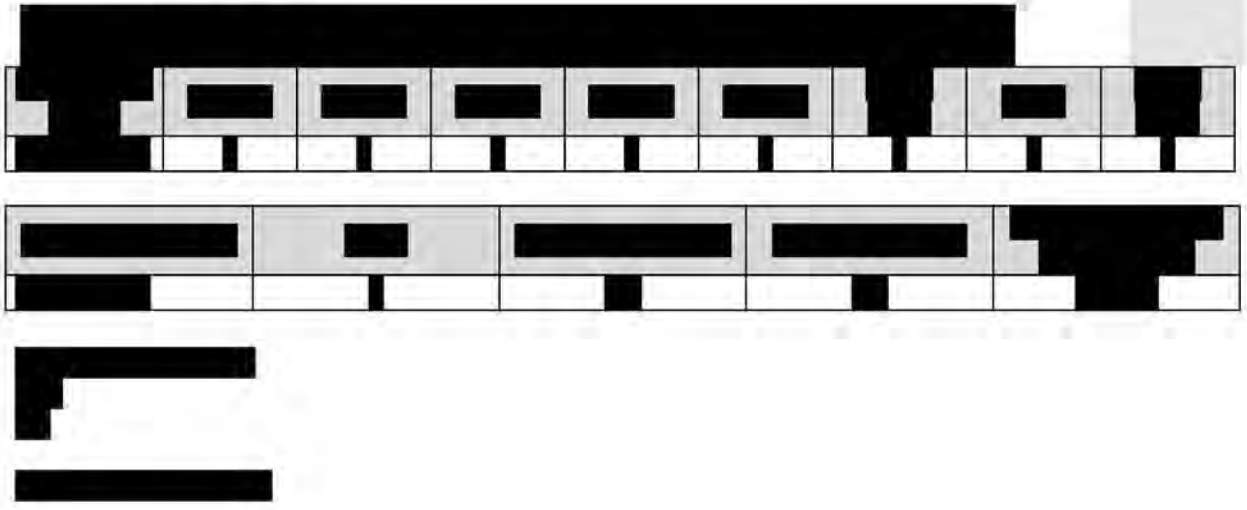
2.8.5 Other

2.8.6 Molecular formula

2.8.7 Structural formula

2.8.8 Molecular mass

2.8.9 Concentration of the impurity or additive
typical and range of concentrations



Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	Give date of comments submitted
Results and discussion	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion. Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability	Discuss if deviating from view of rapporteur member state
Remarks	

Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Subsection		Official use only
2.10.2	**Environmental exposure towards active substance**	
2.10.2.1	**Production**	
	(i) Releases into water	
	(ii) Releases into air	
	(iii) Waste disposal	
2.10.2.2	**Intended use(s)**	
	Affected compartment(s) and Predicted concentration in the affected in compartments: water	
	sediment	
	air	

Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

[redacted]

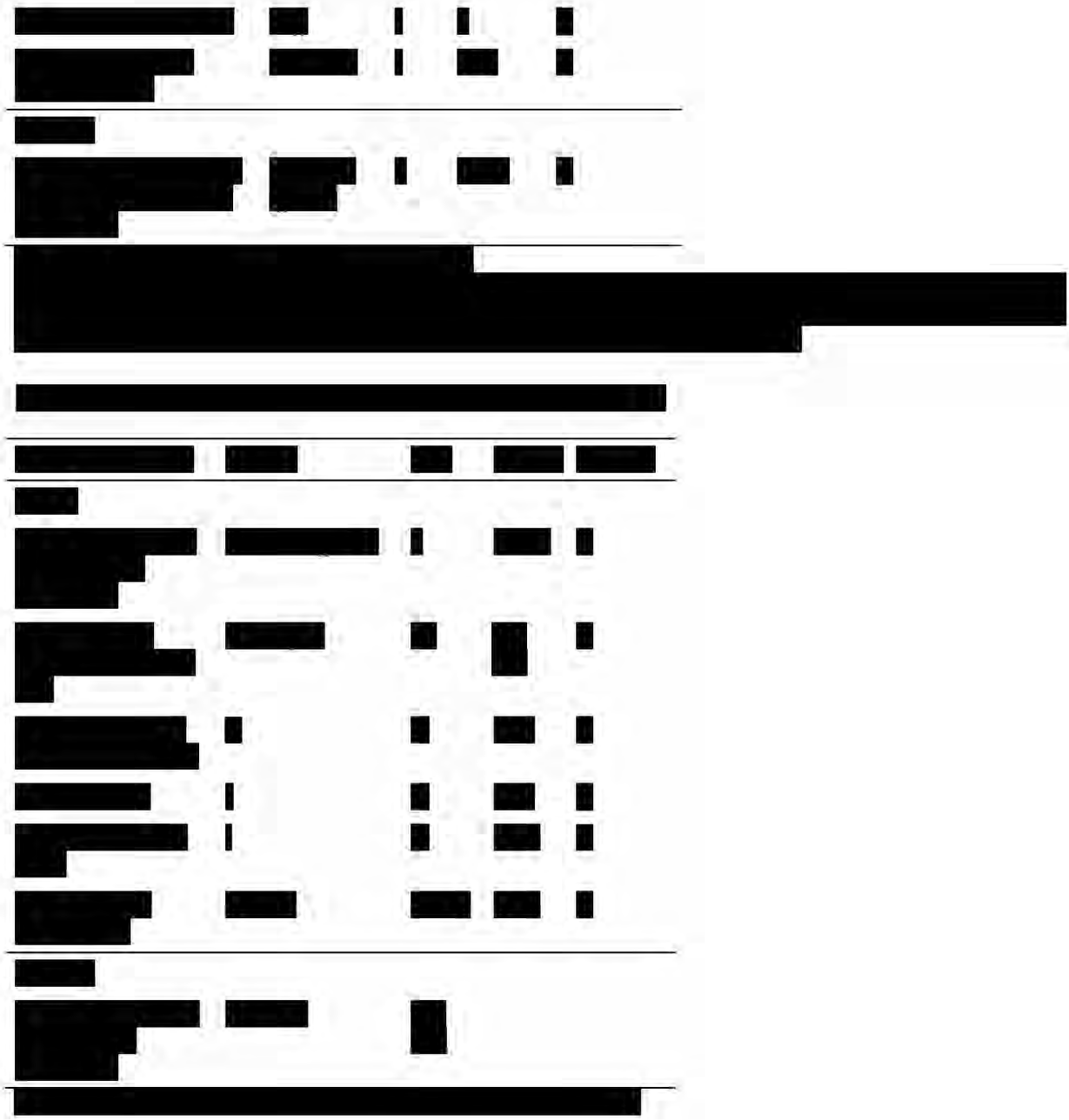
Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

soil

[redacted]

[redacted]



Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A3 Annex Point 3.2.1	Henry's Law Constant	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	Technically not feasible [X] Scientifically unjustified [ ]	
Limited exposure [ ]	Other justification [ ]	
Detailed justification: [redacted]		
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification		
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A3 **Annex Point 3.4**	**Absorption spectra** Mass spectra	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [X]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A3 **Annex Point 3.5**	**Solubility in water** [redacted]	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [X]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification: [redacted]		
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A3 **Annex Point 3.6**	**Dissociation constant** [redacted]	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [X]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A3 **Annex Point 3.7**	**Solubility in organic solvents, including the effect of temperature on solubility** *Schmitt, S., Voigt M., Detia Freyberg GmbH, Laudenbach, Germany, 2003*	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [X]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
	[redacted]**FROM OTHER MEMBER STATE** *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A3 **Annex Point 3.8**	**Stability in organic solvents used in b.p. and identity of relevant breakdown products** [redacted]	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [X]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A3 **Annex Point 3.9**	**Partition coefficient n-octanol/water** [redacted]	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [X]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
	[redacted]**FROM OTHER MEMBER STATE** *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A3 Annex Point 3.12	Flash-point	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification: [redacted]		
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A3 Annex Point 3.12	Flash-point	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification: [redacted]		
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A3 **Annex Point 3.13**	**Surface tension** [redacted]	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [X]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted] occurs	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A3 **Annex Point 3.16**	**Oxidizing properties** [redacted]	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [X]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
	[redacted]**FROM OTHER MEMBER STATE** *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1 Melting point, boiling point, relative density (IIA3.1)								
3.1.1 Melting point	92/69/EEC, A.1 (DSC) (Melting point/ Melting range)	[redacted]	**result: Melting point > 500° C pressure: 1013 hPa**	[redacted]	Y	1	[redacted] Aluminium phosphide technical: MELTING POINT/MELTING RANGE, BOILING POINT/BOILING RANGE, VAPOUR PRESSURE, [redacted]	
3.1.2 Boiling point	92/69/EEC, A.2 (DSC) (Boiling point/ Boiling range)	[redacted]	**result: Boiling point > 500° C** **pressure: 1013.3 hPa**	[redacted]	Y	1	Aluminium phosphide technical: MELTING POINT/MELTING RANGE, BOILING POINT/BOILING RANGE, VAPOUR PRESSURE [redacted]	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1.3 Bulk density/ relative density	92/69/EEC, A.3 (air comparison pycnometer method) (Density of liquids and soils)	[redacted]	Density: 2.32 g/cm³ at 23.5°C Relative density : D^{R}_{4}: 2.32	-	Y	1	[redacted] Aluminium phosphide: Relative density. [redacted]	
3.2 Vapour pressure (IIA3.2)	92/69/EEC, A.4 (vapour pressure balance) (Screening test for thermal stability and stability on air)	[redacted]	**result: 1.11 E-8 at 25°C**	[redacted]	Y	1	[redacted] Aluminium phosphide technical: MELTING POINT/MELTING RANGE, BOILING POINT/BOILING RANGE, VAPOUR PRESSURE, [redacted]	
3.2.1 Henry´s Law Constant (Pt. I-A3.2)			**measured/calculated: result:**	justification for non-submission is provided	n.a.	0 (justification)		
3.3 Appearance (IIA3.3)								
3.3.1 Physical state	solid							
3.3.2 Colour	grey							
3.3.3 Odour	"foul, fishy, garlicky" (technical phosphine)							

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.4 Absorption spectra (IIA3.4) **UV/VIS** **IR** **NMR** **MS**	n.a.	[redacted]	n.a.	[redacted]	n.a.	0 (State-ment)	[redacted] Statement of the evaluation of UV/Vis, IR and NMR spectra of aluminium and magne-sium phosphide, [redacted] Statement of the per-formance of the following test: Mass Spectra, [redacted]	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.5 Solubility in water (IIA3.5) Water solubility 1 Water solubility 2	*including effects of pH (5-9)* n.a.	[redacted]	**result:** **temperature:** **pH:** n.a.	[redacted]	n.a.	0 (State-ment)	[redacted] Statement of the performance of the following tests according to EU Test Guideline 92/69/EWG: A6 Solubility in water, A8 Distribution coefficient, A17 Fire enhancing properties, C7 Hydrolysis abiotic decomposition, [redacted]	
3.6 Dissociation constant (-)	n.a.	[redacted]	n.a.	[redacted]	n.a.	0 (State-ment)	[redacted] Statement of the performance of the following tests according to EU Test Guideline 92/69/EWG: A6 Solubility in water, A8 Distribution coefficient, A17 Fire enhancing properties, C7 Hydrolysis abiotic decomposition, [redacted]	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA3.1)	n.a.	[redacted]	**result: temperature: n.a.**	[redacted]	n.a.	0 (State-ment)	[redacted] Statement of the performance of the following tests according to CIPAC Method MT 181: Solubility in organic solvents, [redacted]	
3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2)	n.a.	[redacted]	n.a.	[redacted]	n.a.	0 (State-ment)	[redacted] Statement of the performance of the following tests according to CIPAC Method MT 181: Solubility in organic solvents [redacted]	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.9 Partition coefficient n-octanol/water (IIA3.6) log Pow 1 log Pow 2	*including effects of pH (5-9)* n.a.	[redacted]	n.a. **result:** **temperature:** **pH:**	[redacted]	n.a.	0 (State-ment)	[redacted] Statement of the performance of the following tests according to EU Test Guideline 92/69/EWG: A6 Solubility in water, A8 Distribution coefficient, A17 Fire enhancing properties, C7 Hydrolysis abiotic decomposition, [redacted]	
3.10 Thermal stability, identity of relevant breakdown products (IIA3.7)	92/69/EEC A.1 (DTA) (Screening test for thermal stability and stability in air)	[redacted]	The test substance shows neither endothermic nor exothermic effects up to the highest test temperature of 500°C	-	Y	1	[redacted] Aluminium phosphide technical: MELTING POINT/MELTING RANGE, BOILING POINT/BOILING RANGE, VAPOUR PRESSURE, [redacted]	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.11 Flammability, including auto-flammability and identity of combustion products (IIA3.8)	96/69/EEC A.10 Flammability (solids) A.12 Flammability (substances and preparations which, in contact with water evolve highly flammable gases in dangerous quantities) EEC, A.16 (Auto-flammability, solids – Determination of relative self-ignition temperature) EEC, A13 (Pyrophoric properties of solids and liquids)	[redacted]	Flammability The test substance is not a readily combustible solid in the sense of Guideline 92/69/EEC, A.10 Flammability (substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities) The test substance is hazardous in the sense of Guideline 92/69/EEC, method A.12. In contact with water the test substance evolves highly flammable gases in dangerous quantities. The gas ignites spontaneously.	[redacted]	Y	1	[redacted] Aluminium phosphide technical: FLAMMABILITY (SOLIDS), FLAMMABILITY (SUBSTANCES AND PREPARATIONS WHICH, IN CONTACT WITH WATER OR DAMP AIR, EVOLVE HIGHLY FLAMMABLE GASES IN DANGEROUS QUANTITIES). Siemens Axiva GmbH [redacted] [redacted] Aluminium phosphide technical: EXPLOSIVE PROPERTIES, AUTO-FLAMMABILITY (SOLIDS – DETERMINATION OF RELATIVE SELF-IGNITION	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
				[redacted]			TEMPERATURE). [redacted]	
3.12 Flash-point (IIA3.9)	EEC, A.9 (Flash point)	[redacted]	n.a.	[redacted]	n.a.	0 (justification)		
3.13 Surface tension (IIA3.10)	n.a.	[redacted]	Determination of the surface tension is technically not feasible	[redacted]	n.a	0 (Statement)	[redacted]: Statement of the performance of the following tests according to EU Test Guideline 92/69/EWG: A6 Solubility in water, A8 Distribution coefficient, A17 Fire enhancing properties, C7 Hydrolysis abiotic decomposition [redacted]	
3.14 Viscosity (-)	n.a.	n.a.	n.a.	only required for liquids	n.a.			

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.15 Explosive properties (IIA3.11)	EEC, A14 (Explosive properties)	[redacted]	The test substance has no danger of explosion according to the explosive properties in the sense of Guideline 96/69/EEC, A. 14.	-	Y	1	[redacted] Aluminium phosphide technical: EXPLOSIVE PROPERTIES, AUTO-FLAMMABILITY (SOLIDS – DETERMINATION OF RELATIVE SELF-IGNITION TEMPERATURE). [redacted]	
3.16 Oxidizing properties (IIA3.12)	EEC, A.17 (Oxidizing properties)	[redacted]	Determination of the oxidizing properties is scientifically unjustified	[redacted]	n.a.	0 (Statement)	[redacted]: Statement of the performance of the following tests according to EU Test Guideline 92/69/EWG: A6 Solubility in water, A8 Distribution coefficient, A17 Fire enhancing properties, C7 Hydrolysis abiotic decomposition, [redacted]	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.17 Reactivity towards container material (IIA3.13)	After a two years storage stability test the containers (aluminium bottles) were checked for visible defects (deformation, change in colour).	[redacted]	Containers (aluminium bottles) are resistant and do not react with Aluminium phosphide	-	n.a.	n.a.	[redacted] Determination of the Storage Stability of Phostoxin, [redacted]	
	The subject of test is evaluation of corrosion resistance of Al-cans to AlP containing "Detia Vole Killer" at 55 °C according DIN 50905.	[redacted]	The exposed specimens did not show any relevant corrosion effects. The tested material is **corrosion resistant** in the medium tested, according to the criteria applicable for transport tanks, and therefore **suitable** for transport of AlP.		n.a..	n.a.	[redacted] Evaluation of the Corrosive Effect of Aluminum Phosphide on Al-Cans According EU-Biocide Product Approval and DIN 50905, [redacted]	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	
Materials and methods	
Conclusion	
Reliability	
Acceptability	
Remarks	
	Comments from ...
Date	Give date of comments submitted
Results and discussion	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability	Discuss if deviating from view of rapporteur member state
Remarks	

Section A3	Physical and Chemical Properties of Phosphine (CAS 7803-51-2)							
Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1 Melting point, boiling point, relative density (IIA3.1)								
3.1.1 Melting point	Not stated	[redacted]	**result: Melting point** - 133° C **pressure:**	published	n.a.	n.a.	Römpp, 2006: Version 2.10. Georg Thieme Verlag 2006	
3.1.2 Boiling point	Not stated	[redacted]	**result: Boiling point** – 87° C	published	n.a.	n.a.	Römpp, 2006: Version 2.10. Georg Thieme Verlag 2006	
3.1.3 Bulk density/ relative density	n.a	[redacted]	1.529 g/l (density at 20°C)	A.s. is gaseous. published	n.a.	n.a.	Römpp, 2006: Version 2.10. Georg Thieme Verlag 2006	
3.2 Vapour pressure (IIA3.2)	Not stated	[redacted]	3295 kPa at (22°C)	published	n.a.	n.a.	CRC, 1991: Handbook of Chemistry and Physics. 82nd Edition 1991-1992, p. 6-91	
3.2.1 Henry´s Law Constant (Pt. I-A3.2)	calculated	[redacted]	**calculated result:** 320480 Pa m^3 mol^{-1}	Calculation based on a water solubility of 24 ml/100 ml water at 24°C and a vapour pressure of 3295 kPa at 22°C (density: 1.529 g/l at 20°C).	n.a.	n.a.	Calculated: Application for registration of "Detia Gas-Ex-B forte", Detia Freyberg GmbH, Laudenbach, B/7, 16.12.94	
3.3 Appearance (IIA3.3)								
3.3.1 Physical state	gaseous							
3.3.2 Colour	colorless							

Section A3	Physical and Chemical Properties of Phosphine (CAS 7803-51-2)							
Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.3.3 Odour	"foul, fishy, garlicky" (technical phosphine)							
3.4 Absorption spectra (IIA3.4)			For the results please see the referenced spectra				Phosphine and Selected Metal Phosphides, WHO, Geneva, 1988, p. 17 –19	
UV/VIS	n.a	[redacted]		published	n.a.	n.a.		
IR	n.a.	[redacted]		published	n.a.	n.a.	Gmelins Handbuch der Anorganischen Chemie 16, Phosphor Teil C (1965), p.17 –19	
NMR	n.a.	[redacted]		published	n.a.	n.a.		
MS	n.a.	[redacted]		published	n.a.	n.a.	E. Fluck, The Chemistry of Phosphine, Fortschr. D. chem.. Forschung; Springer Verlag (1973). Reprint form Vol. 35, p.8 - 11	

Section A3	Physical and Chemical Properties of Phosphine (CAS 7803-51-2)							
Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.5 Solubility in water (IIA3.5) Water solubility 1 Water solubility 2	*including effects of pH (5-9)* n.a.	[redacted]	**result:** 24 ml / 100 ml water **temperature:** 24°C **pH:** Solubility is little affected by the pH.	[redacted]	n.a.	n.a.	Phosphine and Selected Metal Phosphides, WHO, Geneva, 1988, p. 17 –19	
3.6 Dissociation constant (-)	n.a.	[redacted]	pK (B) = 27.4 pK (S) = 28.8 (27°C)	[redacted]	n.a.	n.a.	Application for registration of "Detia Gas-Ex-B forte", Detia Freyberg GmbH, Laudenbach, B/7, 16.12.94	
3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA3.1)	Not stated	[redacted]	319 ml/100 ml acetic acid at 20°C 445 ml/100 ml acetone at 22.4°C 715 ml/100 ml toluene at 22.5°C	[redacted]	n.a.	n.a.	Phosphine and Selected Metal Phosphides, WHO, Geneva, 1988, p. 17 –19	
3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2)	n.a.	[redacted]	n.a.	[redacted]	n.a.	n.a.		

Section A3	Physical and Chemical Properties of Phosphine (CAS 7803-51-2)							
Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.9 Partition coefficient n-octanol/water (IIA3.6)	92/69/EEC, A.8 (shaking method)	[redacted]	Log Pow= 0.9 at 21°C	[redacted]	N	2	[redacted]: Untersuchungsbericht Octanol-Wasser-Verteilungskoeffizient von PH3, Labor für Geoanalytik, Hildesheim, Germany, [redacted] 29.09.1989	
3.10 Thermal stability, identity of relevant breakdown products (IIA3.7)	n.a.	[redacted]	Thermal decomposition at 550°C	[redacted]	n.a.	n.a.	Application for registration of "Detia Gas-Ex-B forte", Detia Freyberg GmbH, Laudenbach, B/7, 16.12.94	
3.11 Flammability, including auto-flammability and identity of combustion products (IIA3.8)	n.a.	[redacted]	Pure Phosphine has an autoignition temperature of 38°C.	[redacted]	n.a.	n.a.	Phosphine and Selected Metal Phosphides, WHO, Geneva, 1988, p. 17 –19	
3.12 Flash-point (IIA3.9)	n.a.	[redacted]	n.a.	[redacted]	n.a.	0 (justification)		

Section A3	Physical and Chemical Properties of Phosphine (CAS 7803-51-2)							
Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.13 Surface tension (IIA3.10)	n.a.	[redacted]	n.a.	[redacted]	n.a	n.a.		
3.14 Viscosity (-)	n.a.	[redacted]	107(10^{-7} Pa(s at 0 °C	[redacted]	n.a.	n.a.	[redacted] Tabellenbuch brennbarer und gefährlicher Stoffe. Staatsverlag der Deutschen Demokratischen Republik, Berlin 1979, page 113	
3.15 Explosive properties (IIA3.11)	n.a.	[redacted]	Phosphine forms explosive mixtures with air concentrations greater than 1.8%	[redacted]	n.a.	n.a.	Phosphine and Selected Metal Phospides, WHO, Geneva, 1988, p. 17 –19	
3.16 Oxidizing properties (IIA3.12)	n.a.	[redacted]	n.a.	[redacted]	n.a.	n.a.		

Section A3	Physical and Chemical Properties of Phosphine (CAS 7803-51-2)							
Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.17 Reactivity towards container material (IIA3.13)	n.a.	[redacted]	Containers are resistant and do not react with Aluminium phosphide and the released Phosphine (see II A 3.13, Aluminium phosphide related part)	[redacted]	n.a.	n.a.	[redacted] Determination of the Storage Stability of Phostoxin, [redacted]	

	Evaluation by Competent Authorities Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	
Materials and methods	
Conclusion	
Reliability	
Acceptability	
Remarks	
	Comments from ...
Date	Give date of comments submitted
Materials and methods	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability	Discuss if deviating from view of rapporteur member state
Remarks	

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1.1 *Routine analysis of the technical active substance*

Official use only

1. REFERENCE

1.1 Reference [redacted] Determination of Hydrogen Phosphide and Aluminium Phosphide respectively, [redacted] 23.01.03

1.2. Data protection ~~No~~ Yes

1.2.1. Data owner Detia Freyberg GmbH

2 Guideline: No

(no guidelines available)

3 Materials and Methods (principle of analyses) Test substance: Aluminium phosphide

$AlP + 3H_2O \rightarrow PH_3 + Al(OH)_3$ (1)

$PH_3 + 3HgCl_2 \rightarrow P(HgCl)_3 + 3HCl$ (2)

$HCl + KOH \rightarrow H_2O + KCl$ (3)

[redacted]

Recheck of the method: [redacted]

[redacted]	[redacted]	

Section A4 (4.1-4.3)	**Analytical Methods for Detection and Identification**
Annex Point IIA4.1.1	*Routine analysis of the technical active substance*

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

[redacted]

4.2 Conclusion

[redacted]

4.2.1 Reliability

[redacted]

4.2.2 Deficiencies

[redacted]

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3)
Annex Point IIA4.1.1

Analytical Methods for Detection and Identification

Routine analysis of the technical active substance Aluminium Phosphide

Official use only

1. REFERENCE

1.1 Reference

[redacted]Determination of Aluminium Phosphide and Six Impurities in Five Batches of Aluminium Phosphide Technical, [redacted]

1.2. Data protection

[redacted]

1.2.1. Data owner

[redacted]

1.2.3 Criteria for data protection

[redacted]

2 Guideline:

[redacted]

3 Test substance

[redacted]

Materials and Methods (principle of analyses)

[redacted]

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1.1 *Routine analysis of the technical active substance Aluminium Phosphide*

[redacted]

[redacted]

[redacted]						
[redacted]						
[redacted]						

3.3 Linearity

[redacted]

[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						

3.3.2 Number of measurements [redacted]

3.7 Precision

3.7.1 Repeatability [redacted]

[redacted]

[redacted]

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

[redacted]

4.2 Conclusion

[redacted]

4.2.1 Reliability [redacted]

4.2.2 Deficiencies [redacted]

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1.1 *Routine analysis of the technical active substance Aluminium Phosphide*

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Official use only

1. REFERENCE

1.1	**Reference**	[redacted] Determination of the [redacted] concentration. [redacted]
1.2	**Data protection**	No
1.2.1	Data owner	Detia Freyberg GmbH
	Guideline	No (no guidelines available)
	Test substance	[redacted]
	Materials and Methods (principle of analyses)	[redacted]

2. APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	[redacted]
4.2	**Conclusion**	[redacted]
4.2.1	Reliability	[redacted]
4.2.2	Deficiencies	[redacted]

Section A4 (4.1-4.3)	**Analytical Methods for Detection and Identification**
Annex Point IIA4.1.2	*Analytical methods for the analysis of impurities:* [redacted]

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1.2 (a) *Analytical methods for the analysis of impurities:* [redacted]

Official use only

1. REFERENCE

1.1	**Reference**	[redacted] Determination of Aluminium Phosphide and Six Impurities in Five Batches of Aluminium Phosphide Technical. [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Detia Freyberg GmbH
1.2.3	Criteria for data protection	[redacted]
2	**Guideline**	[redacted]
3	**Test substance**	[redacted]
	Materials and Methods (principle of analyses)	[redacted]

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1.2 (a) *Analytical methods for the analysis of impurities:* [redacted]

[redacted]

[redacted]

3.3 Linearity

[redacted]

3.3.2 Number of measurements

[redacted]

3.3.3 Linearity

[redacted]

3.4 Specificity

[redacted]

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1.2 (a) *Analytical methods for the analysis of impurities:* [redacted]

[redacted]

3.5 Recovery rates at different levels

[redacted]

3.7 Precision

3.7.1 Repeatability

[redacted]

[redacted]

2. APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods [redacted]

4.2 Conclusion [redacted]

4.2.1 Reliability [redacted]

4.2.2 Deficiencies

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
[redacted]	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.3 *Analytical methods for the analysis of impurities:* [redacted]

Official use only

1. REFERENCE

1.1	**Reference**	[redacted] Determination of the [redacted] concentration. [redacted]
1.2	**Data protection**	[redacted]
1.2.1	Data owner	Detia Freyberg GmbH
	Guideline	[redacted]
	Test substance	[redacted]
	Materials and Methods (principle of analyses)	[redacted]

2. APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	[redacted]
4.2	**Conclusion**	[redacted]
4.2.1	Reliability	[redacted]
4.2.2	Deficiencies	[redacted]

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.3 *Analytical methods for the analysis of impurities: Aluminium oxide*

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.4 *Analytical methods for the analysis of impurities: Metals*

Official use only

1. REFERENCE

1.1	**Reference**	[redacted]Determination of [redacted] in technical aluminium phosphide.[redacted]
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
	Guideline	[redacted]
	Test substance	[redacted]
	Materials and Methods (principle of analyses)	[redacted]
	Equipment	[redacted]
	Performance of the Experiment	[redacted]

2. APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	[redacted]
4.2	**Conclusion**	[redacted]
4.2.1	Reliability	[redacted]
4.2.2	Deficiencies	[redacted]

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.4 *Analytical methods for the analysis of impurities: Metals*

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.4 (a) *Analytical methods for the analysis of impurities: Magnesium*

Official use only

1. REFERENCE

1.1	**Reference**	[redacted] Determination of Aluminium Phosphide and Six Impurities in Five Batches of Aluminium Phosphide Technical, [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Detia Freyberg GmbH
1.2.3	Criteria for data protection	[redacted]
2	**Guideline**	[redacted]
3	**Test substance**	Aluminium phosphide, technical; [redacted]
	Materials and Methods (principle of analyses)	[redacted]

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1.4 (a) *Analytical methods for the analysis of impurities: Magnesium*

[redacted]

[redacted]

3.2 Detection

[redacted]

3.2.1 Separation method

[redacted]

3.2.2 Detector

[redacted]

3.2.3 Standard(s)

[redacted]

3.3 Linearity

[redacted]

3.3.1 Calibration range

[redacted]

3.3.2 Number of measurements

[redacted]

3.3.3 Linearity

[redacted]

[redacted]

3.4 Specificity

[redacted]

3.7 Precision

3.7.1 Repeatability

[redacted]

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.4 (a) *Analytical methods for the analysis of impurities: Magnesium*

4.1 Materials and methods [redacted]

4.2 Conclusion [redacted]

4.2.1 Reliability [redacted]

4.2.2 Deficiencies [redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and methods	*State if the applicants version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of the method include appropriate reliability indicator*
Acceptability	acceptable / not acceptable *(give reasons if necessary, e.g. if a study is acceptable despite a poor reliability indicator). Discuss the relevance of deficiencies.*
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.4 (b) *Analytical methods for the analysis of impurities:* [redacted]

Official use only

1. REFERENCE

1.1	**Reference**	[redacted] Determination of Aluminium Phosphide and Six Impurities in Five Batches of Aluminium Phosphide Technical. [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Detia Freyberg GmbH
1.2.3	Criteria for data protection	[redacted]
2	**Guideline**	[redacted]
3	**Test substance**	[redacted]
	Materials and Methods (principle of analyses)	[redacted]

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.4 (b) *Analytical methods for the analysis of impurities:* [redacted]

[redacted]

3.2 Detection

3.2.1 Separation method

[redacted]

3.2.2 Detector

[redacted]

3.2.3 Standard(s)

[redacted]

3.3 Linearity

[redacted]

3.3.1 Calibration range

[redacted]

3.3.2 Number of measurements

[redacted]

3.3.3 Linearity

[redacted]

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1.4 (b) *Analytical methods for the analysis of impurities:* [redacted]

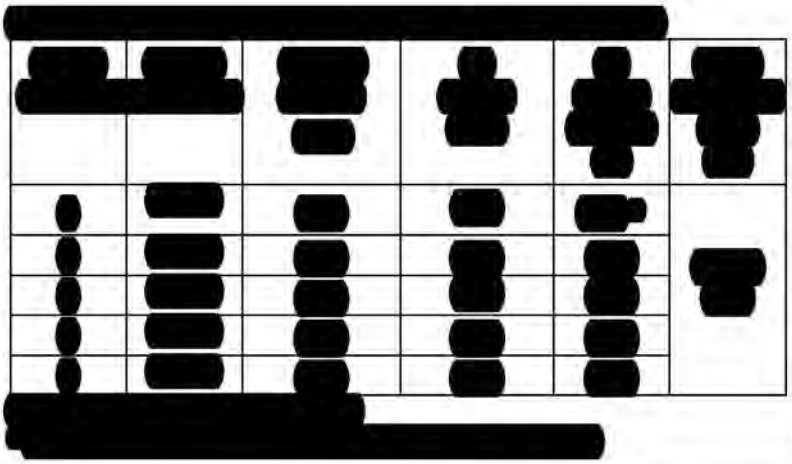
3.4 Specificity

[redacted]

3.7 Precision

3.7.1 Repeatability

[redacted]



[redacted]

2. APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

[redacted]

4.2 Conclusion

[redacted]

4.2.1 Reliability

[redacted]

4.2.2 Deficiencies

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.4 (c) *Analytical methods for the analysis of impurities:* [redacted]

Official use only

1. REFERENCE

1.1	**Reference**	[redacted] Determination of Aluminium Phosphide and Six Impurities in Five Batches of Aluminium Phosphide Technical. [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Detia Freyberg GmbH
1.2.3	Criteria for data protection	[redacted]
2	**Guideline**	[redacted]
3	**Test substance**	[redacted]
	Materials and Methods (principle of analyses)	[redacted]

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.4 (c) *Analytical methods for the analysis of impurities:* [redacted]

[redacted]

3.2 Detection

3.2.1 Separation method [redacted]

3.2.2 Detector [redacted]

3.2.3 Standard(s) [redacted]

3.3 Linearity [redacted]

3.3.1 Calibration range [redacted]

3.3.2 Number of measurements [redacted]

3.3.3 Linearity [redacted]

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.4 (c) *Analytical methods for the analysis of impurities:* [redacted]

3.4 Specificity

[redacted]

3.5 Recovery rates at different levels

[redacted]

3.5.1 Relative standard deviation

[redacted]

3.6 Limit of determination

[redacted]

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1.4 (c) *Analytical methods for the analysis of impurities:* [redacted]

3.7 Precision

3.7.1 Repeatability

[redacted]

[redacted]				

[redacted]

[redacted]

2. APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

[redacted]

4.2 Conclusion

[redacted]

4.2.1 Reliability

[redacted]

4.2.2 Deficiencies

[redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.4 (d) *Analytical methods for the analysis of impurities:* [redacted]

Official use only

1. REFERENCE

1.1	**Reference**	[redacted] Determination of Aluminium Phosphide and Six Impurities in Five Batches of Aluminium Phosphide Technical. [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Detia Freyberg GmbH
1.2.3	Criteria for data protection	[redacted]
2	**Guideline**	[redacted]
3	**Test substance**	[redacted]
	Materials and Methods (principle of analyses)	[redacted]

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.4 (d) *Analytical methods for the analysis of impurities* [redacted]

[redacted]

3.2 Detection

3.2.1 Separation method [redacted]

3.2.2 Detector [redacted]

3.2.3 Standard(s) [redacted]

3.3 Linearity [redacted]

3.3.1 Calibration range [redacted]

3.3.2 Number of measurements [redacted]

3.3.3 Linearity [redacted]

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.4 (d) *Analytical methods for the analysis of impurities:* [redacted]

3.4 Specificity

[redacted]

3.5 Recovery rates at different levels

[redacted]

3.5.1 Relative standard deviation

[redacted]

3.6 Limit of determination

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1.4 (d) *Analytical methods for the analysis of impurities:* [redacted]

2. APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods [redacted]

4.2 Conclusion [redacted]

4.2.1 Reliability [redacted]

4.2.2 Deficiencies [redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.5 *Analytical methods for the analysis of impurities:* [redacted]

Official use only

1. REFERENCE

1.1	**Reference**	[redacted] Determination of Aluminium Phosphide and Six Impurities in Five Batches of Aluminium Phosphide Technical, [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Detia Freyberg GmbH
1.2.3	Criteria for data protection	[redacted]
2	**Guideline**	The Principles of Good Laboratory Practice (Chemical Act, attachment [redacted]
3	**Test substance**	[redacted]
	Materials and Methods (principle of analyses)	[redacted]

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.5 *Analytical methods for the analysis of impurities:* [redacted]

[redacted]

3.2 Detection

3.2.1 Separation method

[redacted]

3.2.2 Detector

[redacted]

3.2.3 Standard(s)

[redacted]

3.3 Linearity

[redacted]

3.3.1 Calibration range

[redacted]

3.3.2 Number of measurements

[redacted]

3.3.3 Linearity

[redacted]

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1.5 *Analytical methods for the analysis of impurities:* [redacted]

3.4 Specificity

[redacted]

3.5 Recovery rates at different levels

[redacted]

3.5.1 Relative standard deviation

[redacted]

3.6 Limit of determination

[redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted]

[redacted]	[redacted]		[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]		[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	

[redacted]

[redacted]

[redacted]

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.5 *Analytical methods for the analysis of impurities:* [redacted]

2. APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	[redacted]
4.2	**Conclusion**	[redacted]
4.2.1	Reliability	1
4.2.2	Deficiencies	No

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.5 (a) *Analytical methods for the analysis of impurities:* [redacted]

Official use only

1. REFERENCE

1.1	**Reference**	[redacted] Determination of Aluminium Phosphide and Six Impurities in Five Batches of Aluminium Phosphide Technical. [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Detia Freyberg GmbH
1.2.3	Criteria for data protection	[redacted]
2	**Guideline**	[redacted]
3	**Test substance**	[redacted]
	Materials and Methods (principle of analyses)	[redacted]

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.1.5 (a) *Analytical methods for the analysis of impurities:* [redacted]

[redacted]

[redacted]					
[redacted]					
[redacted]					

[redacted]

3.2 Detection

3.2.1 Separation method

[redacted]

3.2.2 Detector

[redacted]

3.2.3 Standard(s)

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1.5 (a) *Analytical methods for the analysis of impurities:* [redacted]

3.3 Linearity

[redacted]

3.3.1 Calibration range

[redacted]

3.3.2 Number of measurements

[redacted]

3.3.3 Linearity

[redacted]

3.4 Specificity

[redacted]

3.5 Precision

3.5.1 Repeatability

[redacted]

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1.5 (a) *Analytical methods for the analysis of impurities:* [redacted]

2. APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods [redacted]

4.2 Conclusion [redacted]

4.2.1 Reliability [redacted]

4.2.2 Deficiencies [redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3)

Annex Point IIA4.1/4.2 & IIIA-IV.1

Analytical Methods for Detection and Identification of Phosphine which is evolvable from Human Blood

Official use only

1 REFERENCE

1.1 Reference [redacted]

1.2 Data protection Yes

(indicate if data protection is claimed)

1.2.1 Data owner Zinc phosphide pool

1.2.2

1.2.3 Criteria for data protection [redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study [redacted]

2.2 GLP [redacted]

2.3 Deviations [redacted]

3 MATERIALS AND METHODS

3.1 Preliminary treatment [redacted]

3.1.1 Enrichment No enrichment

3.1.2 Cleanup [redacted]

3.2 Detection [redacted]

3.2.1 Separation method [redacted]

Section A4 (4.1-4.3)

Annex Point IIA4.1/4.2 & IIIA-IV.1

Analytical Methods for Detection and Identification of Phosphine which is evolvable from Human Blood

3.2.2 Detector [redacted]

3.2.3 Standard(s) [redacted]

3.2.4 Interfering substance(s) [redacted]

3.3 Linearity [redacted]

3.3.1 Calibration range [redacted]

3.3.2 Number of measurements [redacted]

3.3.3 Linearity [redacted]

3.4 Specifity: interfering substances [redacted]

3.5 Recovery rates at different levels [redacted]

3.5.1 Relative standard deviation

3.6 Limit of determination [redacted]

3.7 Precision [redacted]

3.7.1 Repeatability [redacted]

3.7.2 Independent laboratory [redacted]

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification of Phosphine which is evolvable from Human Blood**

Annex Point IIA4.1/4.2 & IIIA-IV.1

validation

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

[redacted]

4.2 Conclusion

[redacted]

4.2.1 Reliability [redacted]

4.2.2 Deficiencies [redacted]

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification of Phosphine which is evolvable from Human Blood

Annex Point IIA4.1/4.2 & IIIA-IV.1

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3)

Annex Point IIA4.1/4.2 & IIIA-IV.1

Analytical Methods for Detection and Identification of Phosphine which is evolvable from Milk, Liver and Muscle

Official use only

1 REFERENCE

1.1	**Reference**	[redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Zinc phosphide Pool
1.2.2		
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	[redacted]
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

3.1	**Preliminary treatment**	[redacted]
3.1.1	Enrichment	[redacted]
3.1.2	Cleanup	[redacted]
3.2	**Detection**	[redacted]
3.2.1	Separation method	[redacted]
3.2.2	Detector	[redacted]
3.2.3	Standard(s)	[redacted]

Section A4 (4.1-4.3)

Annex Point IIA4.1/4.2 & IIIA-IV.1

Analytical Methods for Detection and Identification of Phosphine which is evolvable from Milk, Liver and Muscle

3.2.4	Interfering substance(s)	
3.3	**Linearity**	
3.3.1	Calibration range	
3.3.2	Number of measurements	
3.3.3	Linearity	
3.4	**Specifity: interfering substances**	
3.5	**Recovery rates at different levels**	
3.5.1	Relative standard deviation	

Section A4 (4.1-4.3)

Annex Point IIA4.1/4.2 & IIIA-IV.1

Analytical Methods for Detection and Identification of Phosphine which is evolvable from Milk, Liver and Muscle

3.6 Limit of determination

3.7 Precision

3.7.1 Repeatability

3.7.2 Independent laboratory validation

Section A4 (4.1-4.3)

Annex Point IIA4.1/4.2 & IIIA-IV.1

Analytical Methods for Detection and Identification of Phosphine which is evolvable from Milk, Liver and Muscle

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

[redacted]

4.2 Conclusion

[redacted]

4.2.1 Reliability

[redacted]

4.2.2 Deficiencies

[redacted]

Section A4 (4.1-4.3)

Annex Point IIA4.1/4.2 & IIIA-IV.1

Analytical Methods for Detection and Identification of Phosphine which is evolvable from Milk, Liver and Muscle

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2005/09/23
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) Annex Point IIA4.1/4.2 & IIIA-IV.1	Analytical Methods for Detection and Identification of Phosphine in Blood	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [x] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	No data submission intended	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	

Section A4 (4.1-4.3) **Annex Point IIA4.1/4.2 & IIIA-IV.1**	**Analytical Methods for Detection and Identification of Phosphine in Blood**
Conclusion	[redacted]
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.2 (a) *Residues in soil*

Official use only

1. REFERENCE

1.1	**Reference**	[redacted]EXAMINATION OF THE DECOMPOSITION BEHAVIOUR OF HYDROGEN PHOSPHIDE (PHOSPHINE) IN STANDARD SOILS,[redacted]
1.2	**Data protection**	No
1.2.1	Data owner	Detia Freyberg GmbH
	GLP	No (investigations were performed at time when GLP was not mandatory)
	Materials and Methods	Test item: phosphine, batch no.: not available, soil characteristics: standard soil SP 213 (Lufa Speyer) very humous, clay-like sand; standard soil 313 (Lufa Speyer) middle-humous, clay-like sand. Analytical determination: A certain amount of PH_3/N_2 mixture is conveyed through standard soils. After a pre-given period, the remaining PH_3 is expelled by pure N_2 and directed through Dräger-tubes for measurement.
3.3/3.4/3.6	**Linearity/ Specificity/ Limit of quantification**	[redacted]
3.3/3.7.1	**Recovery rate/ Reproduceability**	Th[redacted]

[redacted]

[redacted]

3.7.2	**Independent laboratory validation**	not stated

2. APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	Phosphine is expelled by pure N_2 and directed through Dräger-tubes for measurement.
4.2	**Conclusion**	The established method fulfils the requirement for monitoring residues of Aluminium phosphide in soil.
4.2.1	Reliability	2
4.2.2	Deficiencies	No

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.2 (a) *Residues in soil*

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2004-09-21
Materials and methods	Applicant's version is adopted with exception of points 4.2.2 Deficiencies and 3.3/3.4/3.6 Linearity/Specificity/Limit of quantification. The reference to the Linearity/Specificity/Limit of quantification of Dräger tubes is not sufficient. It provides only information about linearity and limits of determination of the detection technique. But no information about linearity, specificity and limit of quantification of the complete method for analysis of phosphine and aluminium phosphide respectively in soil is available. The concentration dependent release/extraction of phosphine and the occurrence of blanks are not reported.
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.2 (b) *Detection in air*

Official use only

		1. REFERENCE
1.1	**Reference**	Kettrup, A. ; Angerer, J. (1994): Luftanalysen, Sonderdruck aus DFG – Deutsche Forschungsgemeinschaft. Band 1, Ed. Greim, H., published
1.2	**Data protection**	No
1.2.1	Data owner	published
2.1	**Guideline**	Modified method of NIOSH, Manual of analytical methods, No. S332 "Phosphine", vol. 5, 1980
2.2	**GLP**	not applicable
3	**Materials and Methods**	Test item and reference substance: phosphine gas, purity 99.999 %, Messer Griesheim, Germany Analytical determination: Phosphine containing air samples were conducted through silica gel adsorption tubes impregnated with mercury cyanide. Desorption was carried out with a potassium permanganate solution by oxidation of the formed mercury phosphine complex to phosphate. Following various steps of preparation involving incubation at 65-70°C, addition of $FE(NH_4)_2(SO_4)_2$, water and molybdate, isobutyl alcohol/toluene (1/1) was added and the organic phase separated. Following further addition of sulphuric acid in methanol and $SnCl_2$, the resulting blue hetero-polymolybdate complex was quantified by photometric determination at 625 nm. Remark: As an alternative to the standard calibration with phosphine gas, a standard curve was prepared with K_2HPO_4 as reference substance. The results of this calibration were in good agreement with the phosphine standard, but are not reported specifically in this summary.
3.3	**Linearity**	For calibration purposes, phosphine gas with sample volumes of 10, 30, 50, 80 and 100 µl was adsorbed and further processed as described above. The calibration curve was found to be linear between 0.5 µg and 20 µg PH_3 (equivalent to approximately 0.0125 mg/m^3 sample air and 0.5 mg/m^3 sample air) with a correlation coefficient of 0.9958.
3.4	**Specificity**	Existing orthophosphates in air, and compounds forming molybdate complexes and being soluble in isobutene/toluene may interfere.
3.5	**Recovery**	The recovery was not explicitly stated. However, due to the results of the precision determination above, the recovery was calculated to be in the range of 100% ± 5-7% (RSD).
3.6	**Limit of quantification**	The limit of quantification was stated as 0.025 mg/m³.
3.7.1	**Precision (repeatability of the method):**	Air samples with a debit content of 0.025 – 0.25 µg/m^3 phosphine were prepared form phosphine gas and air. The phosphine content at each fortification level was determined in 10 replicates. The relative standard deviations (RSD) are summarised in the following table:

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.2 (b) *Detection in air*

Concentration µg/m³	RSD (%)
0.025	6.7
0.15	5.1
0.25	6.2

3.7.2 Independent laboratory validation

not stated

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

Test item and reference substance: phosphine gas, purity 99.999 %, Messer Griesheim, Germany

Analytical determination: Phosphine containing air samples were conducted through silica gel adsorption tubes impregnated with mercury cyanide. Desorption was carried out with a potassium permanganate solution by oxidation of the formed mercury phosphine complex to phosphate. Following various steps of preparation involving incubation at 65-70°C, addition of $FE(NH_4)_2(SO_4)_2$, water and molybdate, isobutyl alcohol/toluene (1/1) was added and the organic phase separated. Following further addition of sulphuric acid in methanol and $SnCl_2$, the resulting blue hetero-polymolybdate complex was quantified by photometric determination at 625 nm.

4.2 Conclusion

According to the data presented above, the established method was found feasible for the monitoring of phosphine residues in air.

4.2.1 Reliability

3

4.2.2 Deficiencies

Commercially available detection tubes instead of silica gel adsorption tubes impregnated with mercury cyanide should be used for determination of phosphine in air, with exception of the workplace monitoring.

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.2 (b) *Detection in air*

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.2 (b) *Detection in air*

Official use only

1. REFERENCE

1.1	**Reference**	Roels, J.; Van Langenhove, H.; Verstraete, W. (2002): Determination of phosphine in biogas and sludge at ppt-levels with gas chromatography-thermionic specific detection, Journal of Chromatography A, 952 p. 229-237, Elsevier Science B.V., published
1.2	**Data protection**	No
1.2.1	Data owner	published
2.1	**Guideline**	A commercially available, automatic, one-stage preconcentration trap combined with gas chromatography-thermionic specific detection (GC-TSD) was tested and is described in detail.
2.2	**GLP**	not stated
3	**Materials and Methods**	Equipment, analysis of samples and experimental conditions: Varian 3800 GC equipped with a Varian sample preconcentration trap (SPT). Silcosteel was used for the transfer line tubing to minimize the adsorption of phosphine. A phosphine containing glass bottle with a general purpose blue septum or a Tedlar gas sampling bag was connected to the inlet. During the first 0.25 min of the analysis, the six-port switching valve was left in the desorption position to allow the mass flow controller to equilibrate. After equilibration, the value was switched and by means of a vacuum pump gas was pulled through the SPT. The coiled tube was held at -155°C using liquid nitrogen. For the analysis of free phosphine, a typical trapping time of 5 min and a flow-rate of approx. 20 ml/min was used. The exact sample volume was measured with a gas burette. After 5.25 min, the six-port valve was switched to the desorption position and the SPT was heated at the heating rate of up to 40 °C/s. A helium gas flow of 10 ml/min, corresponding with a column head pressure of 72 kPa, was used to sweep the desorbed phosphine from the SPT to the column. The separation was performed onto a PoraPLOT Q column. The oven temperature program was 30 °C (10 min) to 100 °C at 40°C/min. The temperature of the six-port switching valve was maintained at 175°C with a valve oven. A thermionic specific detector (TSD) was used. The flow rates of the detector gases were 4.3 ml/min for hydrogen (99.9% purity), 175 ml/min for air (99.9% purity) and 25 ml/min for helium (99.9999% purity), as the make-up gas. The detector temperature was set at 250°C and the bead current was 3.0 A. Data acquisition and processing was done with STAR 4.51 software (Varian). Samplimg and sample pre-treatment: Free phosphine Pressure resistant Duran glass bottles (1 L) with open top screw cap and silicone rubber sealing with PTFE washer and a specially designed glass adapter with SVL 15 screw thread, were used for the sampling of the free phosphine. The bottles were sealed with two layers of general purpose blue septum. Sorption of phosphine onto the septa was negligible since the time between sampling and analysis was kept to a

minimum (at max. 2 h). Prior to sampling, the bottles were flushed with helium and pressurized at approx. 15 kPa relative to atmospheric pressure. At the sampling point, the bottles were evacuated to a pressure of approx. – 75kPa. After sampling, 10 ml of an oxygen-free 10 M KOH (techn. grade) solution was injected into the bottle to remove H_2S and CO_2. Afterwards the bottle was pressurized with helium to a pressure of 15 kPa and analysed as reported above. A portable tensimeter was used to measure, at each step, the pressure inside the bottles, to allow for accurate calculation of the dilutions made.

Matrix bound phosphine:

This method of analysis will not be described in this summary, because only detection of phosphine in air (= free phosphine) is relevant for this annex point!

Preparation of phosphine standards:

A certified gas standard cylinder containing 68.4 mg/m³ (∀ 3%) phosphine in nitrogen was purchased from Messer-Griesheim (Frankfurt, Germany). All other gases were also purchased from Messer. The gas cylinder was equipped with a syringe adapter. Gas standard mixtures with different concentrations were made in the following manner. Of the 68.4 mg/m³ phosphine standard, 10 ml was withdrawn from the gas cylinder with a plastic, gas-tight syringe and transferred to a 500 ml gas-sampling bulb filled with helium under standard conditions. After 10 min., an appropriate amount was transferred in a 6.35-l glass flask filled with helium under ambient temperature and pressure conditions.

3.3 Linearity

The configuration of the system was changed to construct the calibration graph and to check the linearity of response. The column was connected with a second six-port switching valve equipped with a sample loop. The column flow was 7 ml/min and the column temperature was 40 °C. Two sample loops were used and for each sample loop the calibration curve was measured two times. Slopes were within a 10 % relative error boundary. Phosphine concentrations ranging from 0.28 µg/m³ to 4.9 mg/m³ were injected. All the data points obtained were used to construct the calibration graph ($y = 674.34x$, $r^2 = 0.9946$).
The limit of detection (LOD), calculated as the amount of phosphine corresponding to a signal-to-noise ratio of 3, was 0.17pg of phosphine for the 0.12-ml sample loop. When the 0.5-ml sample loop was used, LOD rose to 0.2 pg of phosphine because of the larger dead volume resulting in increased injection band width. Injection of amounts of phosphine higher than 150 pg resulted in excessive tailing and loss of linearity.

3.4 Specificity

N_2O, NO_x, H_2S and NH_3 do not interfere with the phosphine determination under the mentioned conditions. Ethane was the most critical compound towards interference. Ethane impurities in methane did not interfere with phosphine when a trapping time of 1 min, a sampling flow of 10 ml/min and a trapping temperature below -150°C was used. Higher flows and longer trapping times lead to interference.

3.5 Recovery

The recovery was not explicitly stated.

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.2 (b) *Detection in air*

3.6	**Limit of detection**	When the SPT configuration was used, a relatively high column flow of 10 ml/min was set, to produce narrow peaks. The LOD with the SPT system was 0.3 pg of phosphine. This result is for a typical sampling volume of 100 ml, in a LOD of 3 ng/m³. Taking into account the fact, that the sample was diluted during sample pretreatment, **the LOD was 4 ng/m³ in practise.** The phosphine concentration in the atmosphere (= free phosphine) in industrialized regions is in the low ng/m³ concentration range. Therefore it did not seem appropriate to try to lower the LOD of the system.
3.7.1	**Precision (repeatability of the method):**	For the assessment of precision and accuracy (observed number of counts/expected number of counts), standards of phosphine (69.5 ng/m³) in helium and air were analysed several times during a period of 3 weeks. The accuracy for phosphine standards in helium was 89 % (N=8). In air, accuracy was significantly lower: 65 % (N=5). Precision, measured as the relative standard deviation was 7.7 % in helium and 5.2 % in air. Therefore, it was decided that when the matrix gas was air, lower sampling flows were to be used (10 ml/min).
3.7.2	**Independent laboratory validation**	not stated

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	A GC-system to measure free phosphine in biogas and matrix bound phosphine in manure and sludge was presented. The system consists of a sample preconcentration trap filled with glass bleads, connected with a capillary GC equipped with a thermionic specific detector. (further details listed above under point 3)
4.2	**Conclusion**	With a trap temperature as low as -155°C, a sampling flow of 20 ml/min and a typical total sample volume of 100 ml, free phosphine concentrations in the low ng/m³range and matrix bound phosphine in the low ng/kg dry matter range, can be accurately and reproducibly determined.
4.2.1	Reliability	2
4.2.2	Deficiencies	no

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.2 (b) *Detection in air*

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2012-05-14
Materials and methods	It should be noted that a reliable evaluation of specificity would require chromatograms of air samples. Such chromatograms are missing. It may be added that figure 3 summarizes the trapping efficiency (= recovery) of phosphine in air at different temperatures. In the range -170 °C to -130 °C this recovery was about 100 % with RSD <10 % (numerical values not reported). It should be further noted that the method allows a calibration of the entire procedure (presented with methane, but not with air). In that case the recovery becomes meaningless.
Conclusion	Applicants conclusion is adopted. The method is sufficiently validated for quantification of phosphine in air at a limit of quantification of 0.0695 µg/m^3.
Reliability	2
Acceptability	acceptable
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3)
Annex Point IIA4.2 (b)

Analytical Methods for Detection and Identification
Detection in air

Official use only

1. REFERENCE

1.1	**Reference**	Roels, J.; Van Langenhove, H.; Verstraete, W. (2002): Determination of phosphine in biogas and sludge at ppt-levels with gas chromatography-thermionic specific detection, Journal of Chromatography A, 952 p. 229-237, Elsevier Science B.V., published
1.2	**Data protection**	No
1.2.1	Data owner	published
2.1	**Guideline**	A commercially available, automatic, one-stage preconcentration trap combined with gas chromatography-thermionic specific detection (GC-TSD) was tested and is described in detail.
2.2	**GLP**	not stated
3	**Materials and Methods**	Equipment, analysis of samples and experimental conditions: Varian 3800 GC equipped with a Varian sample preconcentration trap (SPT). Silcosteel was used for the transfer line tubing to minimize the adsorption of phosphine. A phosphine containing glass bottle with a general purpose blue septum or a Tedlar gas sampling bag was connected to the inlet. During the first 0.25 min of the analysis, the six-port switching valve was left in the desorption position to allow the mass flow controller to equilibrate. After equilibration, the value was switched and by means of a vacuum pump gas was pulled through the SPT. The coiled tube was held at -155°C using liquid nitrogen. For the analysis of free phosphine, a typical trapping time of 5 min and a flow-rate of approx. 20 ml/min was used. The exact sample volume was measured with a gas burette. After 5.25 min, the six-port valve was switched to the desorption position and the SPT was heated at the heating rate of up to 40 °C/s. A helium gas flow of 10 ml/min, corresponding with a column head pressure of 72 kPa, was used to sweep the desorbed phosphine from the SPT to the column. The separation was performed onto a PoraPLOT Q column. The oven temperature program was 30 °C (10 min) to 100 °C at 40°C/min. The temperature of the six-port switching valve was maintained at 175°C with a valve oven. A thermionic specific detector (TSD) was used. The flow rates of the detector gases were 4.3 ml/min for hydrogen (99.9% purity), 175 ml/min for air (99.9% purity) and 25 ml/min for helium (99.9999% purity), as the make-up gas. The detector temperature was set at 250°C and the bead current was 3.0 A. Data acquisition and processing was done with STAR 4.51 software (Varian). Samplimg and sample pre-treatment: Free phosphine Pressure resistant Duran glass bottles (1 L) with open top screw cap and silicone rubber sealing with PTFE washer and a specially designed glass adapter with SVL 15 screw thread, were used for the sampling of the free phosphine. The bottles were sealed with two layers of general purpose blue septum. Sorption of phosphine onto the septa was negligible since the time between sampling and analysis was kept to a

minimum (at max. 2 h). Prior to sampling, the bottles were flushed with helium and pressurized at approx. 15 kPa relative to atmospheric pressure. At the sampling point, the bottles were evacuated to a pressure of approx. – 75kPa. After sampling, 10 ml of an oxygen-free 10 M KOH (techn. grade) solution was injected into the bottle to remove H_2S and CO_2. Afterwards the bottle was pressurized with helium to a pressure of 15 kPa and analysed as reported above. A portable tensimeter was used to measure, at each step, the pressure inside the bottles, to allow for accurate calculation of the dilutions made.
Matrix bound phosphine:
This method of analysis will not be described in this summary, because only detection of phosphine in air (= free phosphine) is relevant for this annex point!

Preparation of phosphine standards:
A certified gas standard cylinder containing 68.4 mg/m³ (∀ 3%) phosphine in nitrogen was purchased from Messer-Griesheim (Frankfurt, Germany). All other gases were also purchased from Messer. The gas cylinder was equipped with a syringe adapter. Gas standard mixtures with different concentrations were made in the following manner. Of the 68.4 mg/m³ phosphine standard, 10 ml was withdrawn from the gas cylinder with a plastic, gas-tight syringe and transferred to a 500 ml gas-sampling bulb filled with helium under standard conditions. After 10 min., an appropriate amount was transferred in a 6.35-l glass flask filled with helium under ambient temperature and pressure conditions.

3.3 Linearity

The configuration of the system was changed to construct the calibration graph and to check the linearity of response. The column was connected with a second six-port switching valve equipped with a sample loop. The column flow was 7 ml/min and the column temperature was 40 °C. Two sample loops were used and for each sample loop the calibration curve was measured two times. Slopes were within a 10 % relative error boundary. Phosphine concentrations ranging from 0.28 µg/m³ to 4.9 mg/m³ were injected. All the data points obtained were used to construct the calibration graph ($y = 674.34x$, $r^2 = 0.9946$).
The limit of detection (LOD), calculated as the amount of phosphine corresponding to a signal-to-noise ratio of 3, was 0.17pg of phosphine for the 0.12-ml sample loop. When the 0.5-ml sample loop was used, LOD rose to 0.2 pg of phosphine because of the larger dead volume resulting in increased injection band width. Injection of amounts of phosphine higher than 150 pg resulted in excessive tailing and loss of linearity.

3.4 Specificity

N_2O, NO_x, H_2S and NH_3 do not interfere with the phosphine determination under the mentioned conditions. Ethane was the most critical compound towards interference. Ethane impurities in methane did not interfere with phosphine when a trapping time of 1 min, a sampling flow of 10 ml/min and a trapping temperature below -150°C was used. Higher flows and longer trapping times lead to interference.

3.5 Recovery

The recovery was not explicitly stated.

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.2 (b) *Detection in air*

3.6	**Limit of detection**	When the SPT configuration was used, a relatively high column flow of 10 ml/min was set, to produce narrow peaks. The LOD with the SPT system was 0.3 pg of phosphine. This result is for a typical sampling volume of 100 ml, in a LOD of 3 ng/m³. Taking into account the fact, that the sample was diluted during sample pretreatment, **the LOD was 4 ng/m³ in practise.** The phosphine concentration in the atmosphere (= free phosphine) in industrialized regions is in the low ng/m³ concentration range. Therefore it did not seem appropriate to try to lower the LOD of the system.
3.7.1	**Precision (repeatability of the method):**	For the assessment of precision and accuracy (observed number of counts/expected number of counts), standards of phosphine (69.5 ng/m³) in helium and air were analysed several times during a period of 3 weeks. The accuracy for phosphine standards in helium was 89 % (N=8). In air, accuracy was significantly lower: 65 % (N=5). Precision, measured as the relative standard deviation was 7.7 % in helium and 5.2 % in air. Therefore, it was decided that when the matrix gas was air, lower sampling flows were to be used (10 ml/min).
3.7.2	**Independent laboratory validation**	not stated

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	A GC-system to measure free phosphine in biogas and matrix bound phosphine in manure and sludge was presented. The system consists of a sample preconcentration trap filled with glass bleads, connected with a capillary GC equipped with a thermionic specific detector. (further details listed above under point 3)
4.2	**Conclusion**	With a trap temperature as low as -155°C, a sampling flow of 20 ml/min and a typical total sample volume of 100 ml, free phosphine concentrations in the low ng/m³range and matrix bound phosphine in the low ng/kg dry matter range, can be accurately and reproducibly determined.
4.2.1	Reliability	2
4.2.2	Deficiencies	no

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.2 (b) *Detection in air*

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	
Materials and methods	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.2 (c) *Residues in water*

Official use only

1. REFERENCE

1.1 Reference

[redacted]Method validation for the determination of residues of phosphine in surface water and potable water.[redacted]

1.2 Data protection

Yes

1.2.1 Data owner

[redacted]

1.2.3 Criteria for data protection

[redacted]

GLP

[redacted]

Materials and Methods

[redacted]

3.3 Linearity

[redacted]

3.4 Specificity

[redacted]

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.2 (c) *Residues in water*

[redacted]

3.5 Recovery

[redacted]

3.6 Limits of quantification and detection

[redacted]

3.7.1 Precision (repeatability of the analytical system):

[redacted]

Section A4 (4.1-4.3)	**Analytical Methods for Detection and Identification**
Annex Point IIA4.2 (c)	*Residues in water*

3.7.2	**Independent laboratory validation**	[redacted]

2. APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	Samples were analysed on phosphine using headspace gas chromatography with phosphorus/nitrogen sensitive detection (PND)
4.2	**Conclusion**	The overall average recovery value was 79.5 % with a relative standard deviation of 4 %. The limit of quantification was found to be 0.1 µg/l water. Thus, the established method fulfils the requirements for monitoring phosphine residues in water.
4.2.1	Reliability	1
4.2.2	Deficiencies	No

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.2 (c) *Residues in water*

Official use only

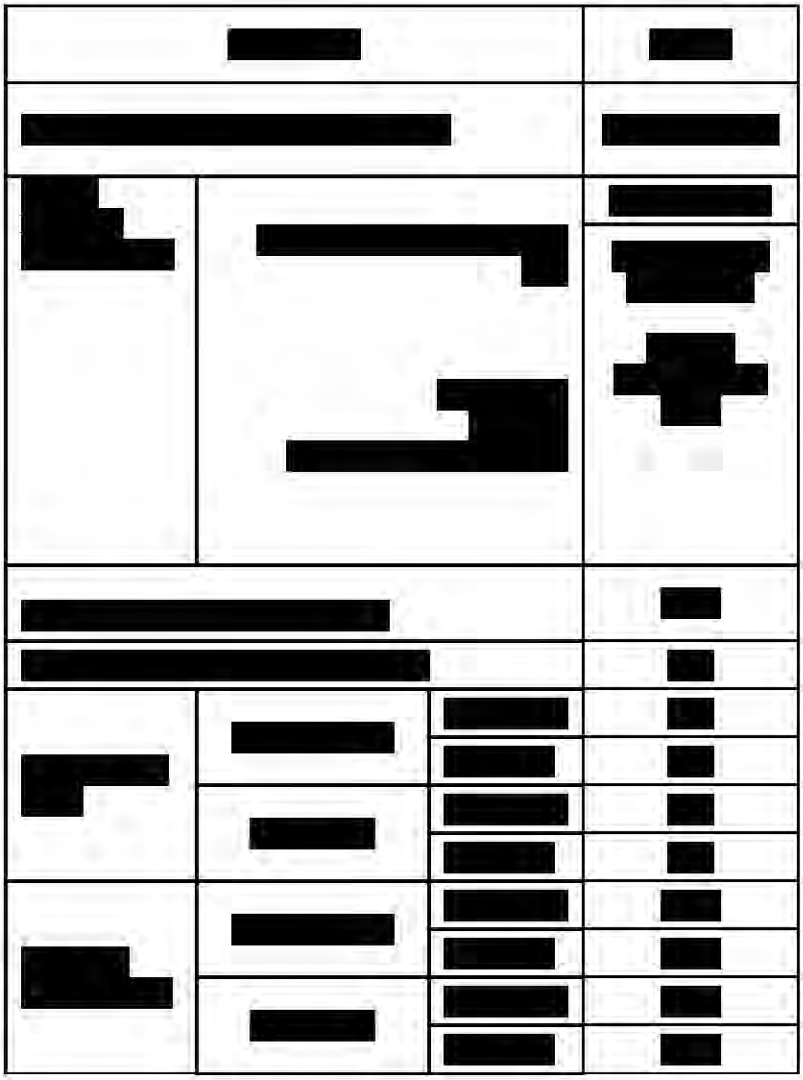
	1. REFERENCE	
1.1	**Reference**	[redacted] VALIDATION OF A CONFIRMATORY METHOD FOR DETERMINATION OF ALUMINIUM PHOSPHIDE (RELEASING PHOSPHINE) IN WATER, [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Detia Freyberg GmbH, Germany
1.2.3	Criteria for data protection	[redacted]
2.	**GLP**	yes (certified laboratroy)
3.	**Materials and Methods**	[redacted]
3.3	**Linearity**	[redacted]
3.4	**Specificity**	[redacted]
3.5	**Recovery**	[redacted]

3.6 Limits of quantification and detection

[redacted]

3.7.1 Precision (repeatability of the analytical system):

[redacted]



3.7.2	**Independent laboratory validation**	yes

4. APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	[redacted]
4.2	**Conclusion**	[redacted]
4.2.1	Reliability	[redacted]
4.2.2	Deficiencies	[redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.3 *Residues of the active substance in food or feed stuffs*

Official use only

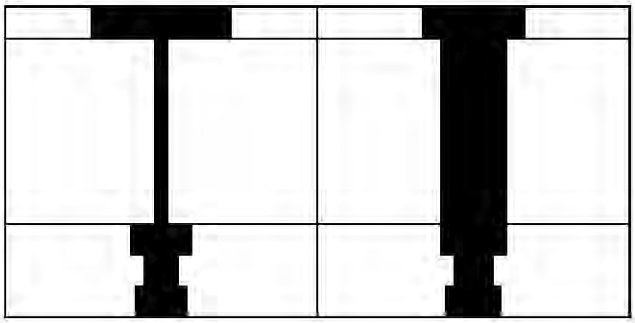
1. REFERENCE

1.1 Reference	[redacted]Determination of Residues of Detia Gas-EX-B, MAGTOXIN and PHOSTOXIN Tablets after Fumigation of Different Storage Goods, [redacted]
1.2 Data protection	Yes
1.2.1 Data owner	Detia Freyberg GmbH
1.2.3 Criteria for data protection	[redacted]
GLP	yes
Materials and Methods	[redacted]
Analytical determination	[redacted]
Detector response, injection precision and recovery	[redacted]

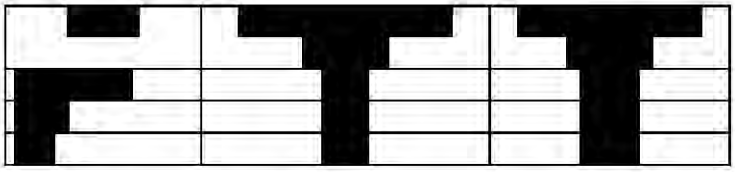
Section A4 (4.1-4.3) **Analytical Methods for Detection and Identification**

Annex Point IIA4.3 *Residues of the active substance in food or feed stuffs*

[redacted]



Quantitation Limit and Detection Limit (LOQ) [redacted]



2. APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods [redacted]

4.2 Conclusion [redacted]

4.2.1 Reliability [redacted]

4.2.2 Deficiencies [redacted]

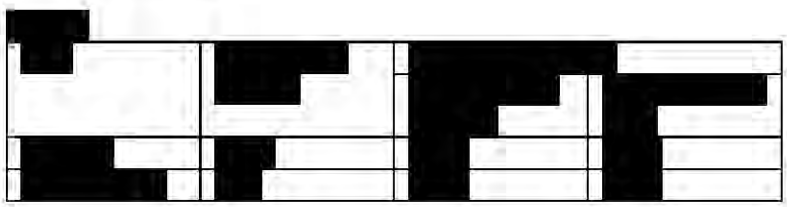
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.3 *Residues of the active substance in food or feed stuffs*

Official use only

	1. REFERENCE	
1.1	**Reference**	[redacted] Independent Laboratory Validation (ILV) of the Residue Analytical Method for the Determination of Phosphine in two Storage Goods (Maize Grain and Sunflower Seeds), [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Detia Freyberg GmbH
1.2.3	Criteria for data protection	[redacted]
2.	**GLP**	yes
3.	**Materials and Methods**	[redacted]
	Analytical determination	[redacted]
3.3	**Linearity**	[redacted]
3.5	**Recovery**	[redacted]



Section A4 (4.1-4.3) Analytical Methods for Detection and Identification

Annex Point IIA4.3 *Residues of the active substance in food or feed stuffs*

[redacted]

3.6 Limits of quantification and detection

[redacted]

3.7.1 Precision (repeatability of the analytical system):

[redacted]

[redacted]

4.1 Materials and methods

[redacted]

4.2 Conclusion

[redacted]

4.2.1 Reliability

[redacted]

4.2.2 Deficiencies

[redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A5 Effectiveness against target organisms and intended uses

Subsection (Annex Point)		
5.1	Function (IIA5.1)	[redacted]
5.2	Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)	
5.2.1	Organism(s) to be controlled (IIA5.2)	[redacted]
5.2.2	Products, organisms or objects to be protected (IIA5.2)	[redacted]
5.3	Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)	
5.3.1	Effects on target organisms (IIA5.3)	[redacted]
5.3.2	Likely concentrations at which the A.S. will be used (IIA5.3)	[redacted]
	PT14 (Rodenticide)	[redacted]
5.4	Mode of action (including time delay) (IIA5.4)	[redacted]

Section A5 **Effectiveness against target organisms and intended uses**

[redacted]

5.4.1	Mode of action	[redacted]
5.4.2	Time delay	[redacted]
5.5	Field of use envisaged (IIA5.5)	[redacted]
5.6	User (IIA5.6)	[redacted]

Section A5 Effectiveness against target organisms and intended uses

	Industrial	[redacted]
	Professional	[redacted]
	General public	[redacted]
5.7	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)	
5.7.1	Development of resistance	[redacted]
5.7.2	Management strategies	[redacted]
5.8	Likely tonnage to be placed on the market per year (IIA5.8)	[redacted]

Section A5 **Effectiveness against target organisms and intended uses**

	[redacted]
	[redacted]
	[redacted]
Date	
Materials and methods	
Conclusion	
Reliability	
Acceptability	
Remarks	
	[redacted]
Date	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

Section 5.3: Summary table of experimental data on the effectiveness of the active substance against target organisms at different fields of use envisaged, where applicable

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Section A6.1.1/01 Acute Toxicity

Annex Point IIA6.1.1 Oral (Mice)

Official use only

1. REFERENCE

1.1	**Reference**	[redacted] ACUTE TOXICITY STUDY OF ALUMINIUM PHOSPHIDE BY ORAL ADMINISTRATION TO NMRI MICE. LPT. [redacted]
1.2	**Data protection**	[redacted]
1.2.1	Data owner	Detia Freyberg GmbH

2. GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline**	[redacted]
2.2	**GLP**	Yes

3. MATERIALS AND METHODS

[redacted]

4. RESULTS AND DISCUSSION

[redacted]

4.4	**LD_{50}**	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	[redacted]
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Section A6.1.1/01 Acute Toxicity

Annex Point IIA6.1.1

Oral (Mice)

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A6.1.1/01 Acute Toxicity

Annex Point IIA6.1.1 Oral (Mice)

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

[redacted]

Section A6.1.1/02 Acute Toxicity

Annex Point IIA6.1.1 Oral (Rats)

Official use only

1. REFERENCE

1.1	**Reference**	[redacted] Acute Oral Toxicity of "Aluminiumphosphid" in Rats. [redacted]
1.2	**Data protection**	[redacted]
1.2.1	Data owner	Detia Freyberg GmbH

2. GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline**	[redacted]
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3. MATERIALS AND METHODS

[redacted]

4. RESULTS AND DISCUSSION

[redacted]

4.4	**LD_{50}**	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	[redacted]
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Section A6.1.1/02 Acute Toxicity

Oral (Rats)

Annex Point IIA6.1.1

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A6.1.1/02 Acute Toxicity

Annex Point IIA6.1.1 Oral (Rats)

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

[redacted]

Section A6.1.1/6.1.2/ 6.1.3/6.11 **Acute Toxicity**

Summary of Acute Toxicity

Annex Point IIA6.1

Table A6_1-1. Table for Acute Toxicity

Type of study	Animal species	Dose range tested	Result	Reference
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Section A6.1.2 Acute Toxicity

Annex Point IIA6.1.2 Percutaneous (Rats)

Official use only

1. REFERENCE

1.1	**Reference**	[redacted] ACUTE TOXICOLOGICAL STUDY ON COMPOUND ALUMINIUMPHOSPHID AFTER DERMAL APPLICATION TO THE RAT. [redacted]
1.2	**Data protection**	No
1.2.1	Data owner	Detia Freyberg GmbH

2. GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline**	[redacted]
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3. MATERIALS AND METHODS

[redacted]

4. RESULTS AND DISCUSSION

[redacted]

4.4	**LD_{50}**	LD_{50} (24 h) = 1520 (1350 –1700) mg/kg b.w. (males and females) LD_{50} (14 d) = 900 (800-1000) mg/kg b.w. (males and females)

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	[redacted]
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Section A6.1.2 Acute Toxicity

Percutaneous (Rats)

Annex Point IIA6.1.2

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A6.1.2 Acute Toxicity

Percutaneous (Rats)

Annex Point IIA6.1.2

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

[redacted]

Section A6.1.3 Acute Toxicity

Annex Point IIA6.1.3 Inhalation (Rats)

Official use only

1. REFERENCE

1.1 Reference [redacted] Acute Inhalation Toxicity Testing of Hydrogen Phosphide in Rats. [redacted]

1.2 Data protection [redacted]

1.2.1 Data owner: Detia Freyberg GmbH

2. GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline [redacted]

2.2 GLP [redacted]

2.3 Deviations [redacted]

3. MATERIALS AND METHODS

[redacted]

4. RESULTS AND DISCUSSION

The general symptoms in male and female rats were almost the same. [redacted]

4.4 LC_{50} 204 ppm (confidence limits 195 – 213 ppm) for male rats and 179 ppm (confidence limits 170 – 188 ppm) for female rats

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods [redacted]

5.2 Results and discussion [redacted]

5.3 Conclusion

5.3.1 Reliability [redacted]

5.3.2 Deficiencies [redacted]

Section A6.1.3 Acute Toxicity

Inhalation (Rats)

Annex Point IIA6.1.3

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]

Section A6.1.3 Acute Toxicity

Annex Point IIA6.1.3 Inhalation (Rats)

	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.1.3 **Acute Toxicity**

Annex Point IIA6.1.3 Inhalation (Rats)

ANNEX

[redacted]

[redacted]						
[redacted]						

[redacted]

[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			
[redacted]			

Section A6.1.4 Acute Dermal Irritation

Annex Point IIA6.1.4 *Specify section no., heading and species as appropriate*

Official use only

1 REFERENCE

1.1 Reference [redacted] IRRITANT EFFECTS OF ALUMINIUMPHOSPHID ON INTACT SKIN OF RABBITS. [redacted]

1.2 Data protection [redacted]

1.2.1 Data owner: Detia Freyberg GmbH

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study [redacted]

2.2 GLP [redacted]

2.3 Deviations [redacted]

3 MATERIALS AND METHODS

[redacted]

4 RESULTS AND DISCUSSION

After 24 hours of contact all localizations at intact skin did show slight oedema, further 48 hours later there were no deviations at intact skin compared to normal skin.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods [redacted]

5.2 Conclusion [redacted]

5.2.1 Reliability [redacted]

5.2.2 Deficiencies [redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.1.4/01 **Acute Dermal Irritation**

Annex Point IIA6.1.4

[redacted]

[redacted]		[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]
[redacted]			

Section 6.1.4/02 Acute Eye Irritation

Annex Point IIA6.1.4

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] IRRITANT EFFECTS OF ALUMINIUMPHOSPHID ON RABBIT EYE [redacted]
1.2	**Data protection**	[redacted]
1.2.1	Data owner	Detia Freyberg GmbH

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	[redacted]
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

[redacted]

4 RESULTS AND DISCUSSION

Post application and after washed out method slight conjunctival irritations occurred. Slightly increased reddening till 8 hours, chemosis for 1 hour only, and slightly increased secretion till 4 hours p.a.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	[redacted]
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Section 6.1.4/02 Acute Eye Irritation

Annex Point IIA6.1.4

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2006-05-24
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section 6.1.4/02 Acute Eye Irritation

Annex Point IIA6.1.4

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

[redacted]

	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]				

Section A6.1.5 Skin sensitisation

Annex Point IIA6.1.5

Specify type of study:
Buehler Test

Official use only

1 REFERENCE

1.1	**Reference**	[redacted]Evaluation of Skin sensitization of test substance Detia Gas-Ex-T Pastilhas de 3 g.[redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Detia Freyberg GmbH
1.2.2	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	[redacted]
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

3.1	**Test material**	[redacted]

Section A6.1.5 Skin sensitisation

Annex Point IIA6.1.5

Specify type of study:
Buehler Test

4 RESULTS AND DISCUSSION

At 24 and 48 hours after the challenge phase it was not observed any skin reaction in the animals receiving the test substance or physiological solution. The Skin sensitisation was considered negative.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods [redacted]

5.2 Results and discussion [redacted]

5.3 Conclusion

5.3.1 Reliability [redacted]

5.3.2 Deficiencies [redacted]

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

COMMENTS FROM ...

Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.2 Metabolism studies in mammals

Annex Point IIA6.2/01

Official use only

1 REFERENCE

1.1	**Reference**	Curry, A.S.; et al. (1959): Absorption of Zinc phosphide particles; Nature 184, 642 – 643
1.2	**Data protection**	No
1.2.1	Data owner	published
1.2.2		
1.2.3	Criteria for data protection	No data protection claimed

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	not stated
2.2	**GLP**	No
2.3	**Deviations**	not stated

There are no studies available concerning adsorption, distribution, metabolism and excretion of ingested Aluminium phosphide. However, there exist respective studies with Zinc phosphide. Although these studies do not meet current standards, they nevertheless allow for a reasonable assessment. Following oral administration, the process initiating toxic action is the same in the above metal phosphides: they are hydrolysed rapidly in the stomach, forming the toxic agent phosphine and the respective inert metal cations. Therefore the results obtained with Zinc phosphide are transferable to Aluminium phosphide.

3 MATERIALS AND METHODS

3.1	**Test material**	Zinc phosphide
3.1.1	Lot/Batch number	not stated
3.1.2	Specification	Deviating from specification given in section 2 as follows:
3.1.2.1	Description	Zinc phosphide (^{32}P-labelled)
3.1.2.2	Purity	n. a.
3.1.2.3	Stability	n. a.
3.1.2.4	Radiolabelling	^{32}P
3.2	**Test Animals**	
3.2.1	Species	Rat
3.2.2	Strain	Not stated
3.2.3	Source	Not stated
3.2.4	Sex	Not stated

Section A6.2 Metabolism studies in mammals

Annex Point IIA6.2/01

3.2.5	Age/weight at study initiation	Age not stated, weight approximately 250 g
3.2.6	Number of animals per group	6
3.2.7	Control animals	No
3.3	**Administration/ Exposure**	Oral (Suspension of Zinc phosphide (^{32}P-labelled) in commercially available evaporated milk was fed to adult rats)
3.3.1	Preparation of test site	n.a.
3.3.2	Concentration of test substance	Doses considered to be in excess of LD_{50} (40 mg/kg bw)
3.3.3	Specific activity of test substance	Phosphorus activity of 0.8mc
3.3.4	Volume applied	10 mgm.
3.3.5	Size of test site	n.a.
3.3.6	Exposure period	n.a.
3.3.7	Sampling time	n.a.
3.3.8	Samples	The livers from rats RA/2 and RA/1 were analysed separately; those from rats RA/3, 4, 5 and 6 were combined before analysis. Carbon dioxide was passed in the cold through suspensions of the cut-up livers in water and the resulting gases were passed through a filter paper soaked in silver nitrate, which was changed at half-hourly intervals. When the ß counts from the silver phosphide were low, or absent, dilute mineral acid was added and the procedure was repeated.
		4 RESULTS AND DISCUSSION
		.
4.1	**Toxic effects, clinical signs**	Table 6_2-1 shows the results that were obtained.
4.2	**Dermal irritation**	n.a
4.3	**Recovery of labelled compound**	Not stated
4.4	**Percutaneous absorption**	n.a.

Section A6.2 Metabolism studies in mammals

Annex Point IIA6.2/01

4.5	**Results of further experiments**	The authors of the article have conducted further experiments, which are barely reported in this publication: They used the same suspension as mentioned above to feed it to rats and guinea pigs. In dilute acid, zinc phosphide rapidly liberates phosphine and they showed by experiments on rats that when these animals were fed a dose of zinc phosphide in excess of the LD_{50} then, if death resulted, it occurred rapidly and moreover radioactivity was detected in the liver. In lower doses, when animals were killed more than 24 hours after ingestion, no phosphine was detectable in the liver, but on adding acid to this tissue, however, a very faint brown stain was obtained when the gases were passed through a filter paper soaked in methanolic silver nitrate. Such small quantities were present that it was not possible to obtain confirmatory reduced phosphomolybdate blue colour. Further experiments showed that the main urinary excretion product in these poisoned rats and guinea pigs was hypophosphite and that on histological examination their gastric and intestinal mucosae were intact.
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	No guideline story, for material and methods see point 3 above.
5.2	**Results and discussion**	The increase in counts following acidification in rats RA/1 and RA/3, 4, 5 and 6 shows that radioactivity is found in liver following oral administration of zinc phosphide. Rat RA/2 obviously died from phosphine poisoning, rat RA/1 had radioactivity present in its liver while the four other rats had recovered from the effects of phosphine and had no detectable amount of radioactivity left in their livers but they had absorbed significant quantities of phosphide.
5.3	**Conclusion**	
5.3.1	Reliability	2
5.3.2	Deficiencies	n.a.

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and Methods	*State if the applicants version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Results and discussion	*Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers*
Conclusion	*Adopt applicant's version or include revised version*

Section A6.2 Metabolism studies in mammals

Annex Point IIA6.2/01

Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator*
Acceptability	acceptable / not acceptable *(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)*
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

[redacted]

[redacted]

	[redacted]					
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	

[redacted]

Section A6.2 Metabolism studies in mammals

Annex Point IIA6.2/02

Official use only

1 REFERENCE

1.1	**Reference**	Andreev, S.B. et al. (1959): Some results of the use of tracer techniques in the study of plant protection; 2nd Int. Conf. Peaceful Uses Atomic Energy 1958 (27), 85 – 92
1.2	**Data protection**	No
1.2.1	Data owner	published
1.2.2		
1.2.3	Criteria for data protection	No data protection claimed

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	not stated
2.2	**GLP**	No
2.3	**Deviations**	n. a.

3 MATERIALS AND METHODS

3.1	**Test material**	Zinc phosphide
3.1.1	Lot/Batch number	not stated
3.1.2	Specification	Deviating from specification given in section 2 as follows:
3.1.2.1	Description	Zinc phosphide (^{32}P-labelled)
3.1.2.2	Purity	no data
3.1.2.3	Stability	no data.
3.1.2.4	Radiolabelling	^{32}P The experiments were carried out on the grey rat, *Rattus norvegicus* Berk, to which were administered lethal doses (8 mg per 200 g live weight) of zinc phosphide (1) orally (pure substance), (2) subcutaneously (suspended in water) or (3) per rectum (suspended in water). In the subsequent dissection, ^{32}P content was analysed in samples of blood, liver, spleen, kidneys, lungs, muscles, bones, cortex and the medulla oblongata, plus stomach and intestine.

4 RESULTS AND DISCUSSION

Section A6.2 Metabolism studies in mammals

Annex Point IIA6.2/02

(1) Already 15 minutes after the oral administration of a lethal dose of Zinc phosphide to rats, radioactivity is detectable in blood, liver and the anterior section of the intestinal tract. 30 minutes post dosing, radioactivity was also found in the posterior part of the intestine, as well as in spleen, kidneys and lungs, whereas the level in blood and livers had already considerably decreased. One hour p.a., radioactivity was widely distributed within the body, lacking only in brain, bone and muscle. At the same time, some radioactivity could already be recovered from urine. Upon death (usually within 6 – 8 hours p.a.), the radioactivity was present in all organs and tissues with a predominant accumulation in liver. Levels in stomach and intestine had considerably decreased, though still higher than in any other organ. Swelling of the stomach and the small intestine was observed in poisoned animals, which was attribute to the presence of large amounts of PH_3 by analysis (silver phosphide precipitation). Radioactivity had also accumulated at the time of death in the medulla oblongata, correlating with disturbance of breathing and supporting the assumption that the toxicity of Zinc phosphide is related to a disruption of respiratory function.
(2) For the elucidation whether phosphine is formed from Zinc phosphide only in the stomach, Zinc phosphide was also administered per rectum at the same dose level as above. 24 hours p.a., radioactivity was detectable in blood, liver and kidney, apart from the material present in the large intestine. It was not verified whether this radioactivity was in the form of phosphine or Zinc phosphide.
(3) 24 hours after the subcutaneous administration, the radioactivity was detectable only at the site of injection, indicating that decomposition of the formation of mobile toxic compounds would not occur under these circumstances.

Following oral administration of (^{32}P)-Zinc phosphide to rats, radioactivity is rapidly absorbed and distributed. The limited absorption and diminished toxicity after administration per rectum demonstrates that hydrolysis in the acidic milieu of the stomach is the key process that mediates toxicity.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	see 3
5.2	**Results and discussion**	see 4
5.3	**Conclusion**	
5.3.1	Reliability	0
5.3.2	Deficiencies	No

Section A6.2 Metabolism studies in mammals

Annex Point IIA6.2/02

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2004-11-05
Materials and Methods	Applicant's version is accepted with the remark that information about distribution of zinc given in the publication is not mentioned here. In an additional study zinc phosphide was labelled with ^{32}P and ^{65}Zn.
Results and discussion	In addition to the applicant's version, the CA remarks that ^{65}Zn was found in all organs, but the ^{32}P to ^{65}Zn ratio was different in different tissues, which leads to the conclusion that phosphorus and zinc enter into the animal's metabolic system in different ways.
Conclusion	The RMS criticises the lack of information on phosphine absorption via the lung, since humans are exposed rather to phosphine gas via inhalation than to solid AlP.
Reliability	2
Acceptability	Acceptable (see conclusion)
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.2 Metabolism studies in mammals

Annex Point IIA6.2/03

Official use only

		1 REFERENCE
1.1	**Reference**	WHO (1988), Environmental Health Criteria 73, pp. 48-51
1.2	**Data protection**	No
1.2.1	Data owner	published
1.2.2		
1.2.3	Criteria for data protection	No data protection claimed
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	not stated
2.2	**GLP**	No
2.3	**Deviations**	not stated
		3 MATERIALS AND METHODS
3.1	**Test material**	Aluminium phosphide, Magnesium phosphide, Phosphine
3.1.1	Lot/Batch number	not stated
3.1.2	Specification	Deviating from specification given in section 2 as follows:
3.1.2.1	Description	not stated
3.1.2.2	Purity	not stated
3.1.2.3	Stability	not stated
3.1.2.4	Radiolabelling	no
3.2	**Test Animals**	
3.2.1	Species	Different species, see 5.2
3.2.2	Strain	Not stated
3.2.3	Source	Not stated
3.2.4	Sex	Not stated
3.2.5	Age/weight at study initiation	not stated
3.2.6	Number of animals per group	n. a.
3.2.7	Control animals	not stated
3.3	**Administration/ Exposure**	Oral, inhalation, dermal, see 5.2

Section A6.2 Metabolism studies in mammals

Annex Point IIA6.2/03

3.3.1	Preparation of test site	n.a.
3.3.2	Concentration of test substance	Different concentrations, see 5.2
3.3.3	Specific activity of test substance	n. a.
3.3.4	Volume applied	Different volumes, see 5.2
3.3.5	Size of test site	n.a.
3.3.6	Exposure period	n.a.
3.3.7	Sampling time	n.a.
3.3.8	Samples	See 5.2

4 RESULTS AND DISCUSSION

4.1	**Toxic effects, clinical signs**	See 5.2
4.2	**Dermal irritation**	n.a.
4.3	**Recovery of labelled compound**	Not stated
4.4	**Percutaneous absorption**	n.a.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

No guideline study, for material and methods see point 3 above.

5.2 Results and discussion

Absorption

Inhalation:
Because systemic toxic effects are detectable after short exposures to very low atmospheric concentrations of phosphine, inhaled phosphine is generally considered to be readily absorbed through the lungs. Hydrolysis suggests that aluminium or magnesium phosphides deposited on the moist surfaces of the respiratory tract would release absorbable phosphine.

Dermal:
Hydrolysis of aluminium and magnesium phosphides on the skin would lead to the evolution of gaseous phosphine, which could the be absorbed by inhalation. In general, dermal absorption of phosphine and metal phosphides is insignificant.

Oral:
The oral route is not relevant to the absorption of gaseous phosphine. Human ingestion of tablets containing aluminium phosphide yielded evidence of acidhydrolysable phosphide in blood and liver (Chan et al. 1983). These results indicate that metal phosphides can be absorbed directly.

Section A6.2 Metabolism studies in mammals

Annex Point IIA6.2/03

Distribution

Inhaled phosphine produces neurological and hepatic symptoms suggesting that it reaches the nervous system and liver (Childs & Coates, 1971). Ingested phosphides have been shown to reach the liver and blood in rats and human beings (Curry et al., 1959; Meredith, 1981; Chan et al.; 1983).

Metabolic Transformation

Metal phosphides are hydrolysed to phosphine and the corresponding metal cation (Van Wazer, 1982). In rats, phosphine that is not excreted in the expired air is oxidized and appears in the urine, chiefly as hypophosphite and phosphite (Curry et al., 1959; Meredith, 1981). Meredith (1981) also reported an unidentified metabolite, detectable by paper chromatography and distinct from pyrophosphate and metaphosphate. The fact that (a) phosphine is incompletely oxidized; and (b) the proportion of an administered dose that is eliminated as expired phosphine increases with the dose suggests that the oxidative pathway is slow.

Elimination and Excretion

Hypophosphite is the principal urinary excretion product (Curry et al., 1959).

Reaction with Body Components

Phosphine reacts with some haem- and copper-containing proteins in vitro. Insect cytochrome c oxidase is reduced and not reoxidizable in air (Rajak, 1971). Mammalian haemoglobin does not react with phosphine in the absence of oxygen, but oxyhaemoglobin is converted through Fe^{3+}-containing compounds to a verdichromogen-like material (Trimborn & Klimmer, 1962). The nature of the reaction between phosphine and these proteins is uncertain, but oxyhaemoglobin is denatured and a variety of enzymes are inhibited by reaction of phosphine.

5.3 Conclusion

5.3.1 Reliability 0

5.3.2 Deficiencies n.a.

Section A6.2 Metabolism studies in mammals

Annex Point IIA6.2/03

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2006-12-07
Materials and Methods	Accepted.
Results and discussion	Accepted.
Conclusion	Accepted.
Reliability	2
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A 6.3.1 Annex Point IIA 6.3.1	Repeated dose toxicity (oral)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X]	**Technically not feasible [ ]** **Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A6.3.2 Annex Point IIA6.3.2	Repeated dose toxicity (dermal)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X]	**Technically not feasible [ ]** **Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:		
[redacted]		
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A6.4.1 Annex Point IIA VI 6.4	Subchronic oral toxicity test, non-rodent	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X]	Technically not feasible [ ]	Scientifically unjustified [X]
Limited exposure [ ]	Other justification [ ]	

Detailed justification:

[redacted]

Section A6.4.1 Annex Point IIA VI 6.4	Subchronic oral toxicity test, non-rodent
Undertaking of intended data submission [ ]	
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	Insufficient scientific proof was provided to support the applicant's justification. [redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.4.2 Annex Point IIA6.4	Subchronic toxicity (dermal)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X]	**Technically not feasible [ ]** **Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A6.3 / 6.4 / 6.5 Repeated dose toxicity

Annex Point IIA6.4.3 *(Subchronic inhalation toxicity test)*

Official use only

1 REFERENCE

1.1 Reference

[redacted]A THIRTEEN WEEK INHALATION TOXICITY STUDY OF PHOSPHINE (PH_3) IN THE RAT. [redacted]

1.2 Data protection

[redacted]

1.2.1 Data owner: Detia Freyberg GmbH

1.2.3 Criteria for data protection: [redacted]

2. GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

[redacted]

2.2 GLP

[redacted]

2.3 Deviations

[redacted]

3. MATERIALS AND METHODS

3.1 Test material

[redacted]

3.1.1 Lot/Batch number: [redacted]

3.1.2 Specification: [redacted]

3.1.2.2 Purity: [redacted]

3.2 – 3.5 Test Animals/Administration/Exposure/Examinations/Sacrifice and pathology

[redacted]

Section A6.3 / 6.4 / 6.5 Repeated dose toxicity

Annex Point IIA6.4.3 *(Subchronic inhalation toxicity test)*

[redacted]

4 RESULTS AND DISCUSSION

Three 6-hour exposures to 10 ppm phosphine were fatal to female rats. All other haematology, clinical chemistry, body weight and food consumption effects seen at this and lower exposure levels were completely reversible either during the exposure period or after a four week recovery period.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	[redacted]
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	
5.3.1	LO(A)EL	[redacted]
5.3.2	NO(A)EL	[redacted]
5.3.3	Reliability	[redacted]
5.3.4	Deficiencies	[redacted]

Section A6.3 / 6.4 / 6.5 Repeated dose toxicity

Annex Point IIA6.4.3 *(Subchronic inhalation toxicity test)*

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.4.3 Annex Point IIA VI 6.4	Subchronic inhalation toxicity test, non-rodent	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X]	Technically not feasible [ ]	Scientifically unjustified [X]
Limited exposure [ ]	Other justification [ ]	

Detailed justification:

A waiving of the subchronic study in the non-rodent species is possible, if the

[redacted]

Undertaking of intended data submission [ ]	

Section A6.4.3 Annex Point IIA VI 6.4	Subchronic inhalation toxicity test, non-rodent

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date

Evaluation of applicant's justification

Section A6.4.3 Annex Point IIA VI 6.4	Subchronic inhalation toxicity test, non-rodent
	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.3 / 6.4 / 6.5 Repeated dose toxicity

Annex Point IIA6.5/01 *Chronic toxicity (inhalation)*

Official use only

	1 REFERENCE	
1.1	**Reference**	[redacted]2-YEAR COMBINED INHALATION CHRONIC TOXICITY AND ONCOGENICITY STUDY OF PHOSPHINE IN RATS. [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Detia Freyberg GmbH
1.2.2		
1.2.3	Criteria for data protection	[redacted]
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	[redacted]
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]
	3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]
3.1.2.1	Description	[redacted]
3.1.2.2	Purity	[redacted]
3.1.2.3	Stability	[redacted]
3.2	**Test Animals**	
3.2.1	Species	[redacted]
3.2.2	Strain	[redacted]
3.2.3	Source	[redacted]
3.2.4	Sex	[redacted]
3.2.5	Age/weight at study initiation	[redacted]
3.2.6	Number of animals per group	[redacted]
3.2.7	Control animals	[redacted]

Section A6.3 / 6.4 / 6.5 Repeated dose toxicity

Annex Point IIA6.5/01 *Chronic toxicity (inhalation)*

3.3	**Administration/ Exposure**	[redacted]
3.3.1	Duration of treatment	[redacted]
3.3.2	Frequency of exposure	[redacted]
3.3.3	Postexposure period	[redacted]
3.3.4	**Oral**	
3.3.4.1	Type	[redacted]
3.3.4.2	Concentration	[redacted]
3.3.4.3	Vehicle	[redacted]
3.3.4.4	Concentration in vehicle	[redacted]
3.3.4.5	Total volume applied	[redacted]
3.3.4.6	Controls	[redacted]
3.3.5	**Inhalation**	
3.3.5.1	Concentrations	[redacted]
3.3.5.2	Particle size	[redacted]
3.3.5.3	Type or preparation of particles	[redacted]
3.3.5.4	Type of exposure	[redacted]
3.3.5.5	Vehicle	[redacted]
3.3.5.6	Concentration in vehicle	[redacted]
3.3.5.7	Duration of exposure	[redacted]
3.3.5.8	Controls	[redacted]

3.3.6 Dermal

3.3.6.1 Area covered

3.3.6.2 Occlusion

3.3.6.3 Vehicle

3.3.6.4 Concentration in vehicle

3.3.6.5 Total volume applied

3.3.6.6 Duration of exposure

3.3.6.7 Removal of test substance

3.3.6.8 Controls

3.3.7 Intraperitoneal/ Intravenous/ Intratracheal instillation

3.3.7.1 Vehicle

3.3.7.2 Concentration in vehicle

3.3.7.3 Total volume applied

3.3.7.4 Controls

3.4 Examinations

3.4.1 Observations

3.4.1.1 Clinical signs

3.4.1.2 Mortality

3.4.2 Body weight

3.4.3 Food consumption

3.4.4 Water consumption

3.4.5 Ophthalmoscopic examination

3.4.6 Haematology

[redacted]

3.4.7 Clinical Chemisty

[redacted]

3.4.8 Urinalysis

[redacted]

3.5 Sacrifice and pathology

3.5.1 Organ Weights

[redacted]

3.5.2 Gross and histopathology

[redacted]

[redacted]

3.5.3 Other examinations

3.5.4 Statistics

[redacted]

3.6 Further remarks

4 RESULTS AND DISCUSSION

4.1 Observations

4.1.1 Clinical signs

Individual clinical signs and masses are presented in the original study report.

There was no apparent test article-related effect seen in the detailed clinical observations. The findings recorded occurred with a low incidence and were sporadic.

4.1.2 Mortality

A summary of mortality is presented in a table. A record of animal fate and disposition is presented in the original study report.

[redacted]

4.2 Body weight gain

[redacted]

4.3 Food consumption and compound intake

[redacted]

4.4 Ophtalmoscopic examination

[redacted]

4.5 Blood analysis

4.5.1 Haematology

[redacted]

4.5.2 Clinical chemistry

[redacted]

[redacted]

4.5.3 Urinalysis

[redacted]

4.6 Sacrifice and pathology

4.6.1 Organ weights

[redacted]

4.6.2 Gross and histopathology

[redacted]

[redacted]

[redacted]

4.7 Other

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[redacted]

5.2 Results and discussion

[redacted]

5.3 Conclusion

5.3.1 LO(A)EL

[redacted]

5.3.2 NO(A)EL

[redacted]

5.3.3 Other

5.3.4 Reliability

[redacted]

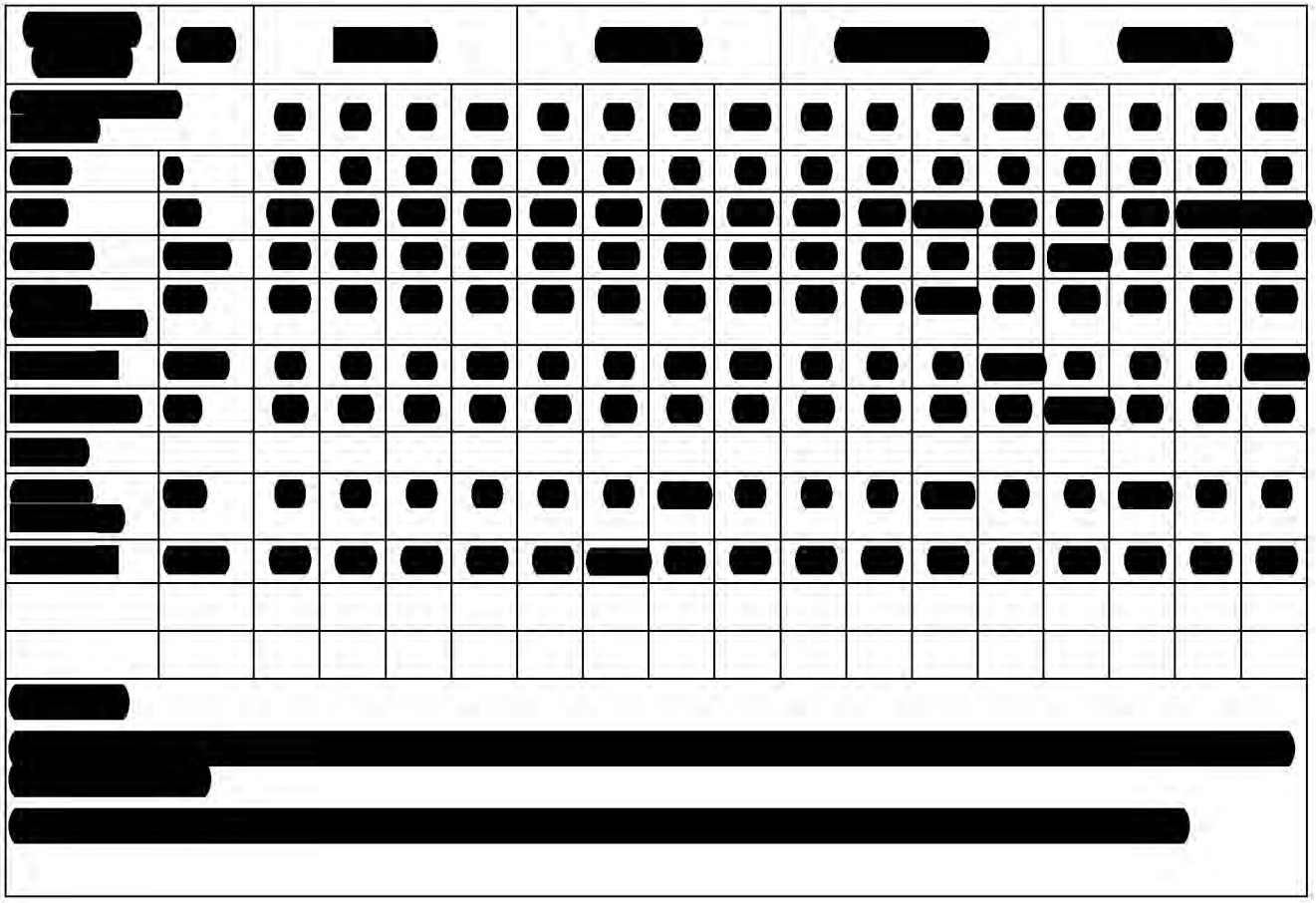
5.3.5 Deficiencies

[redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*

Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

[redacted]



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	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]											
	[redacted]		[redacted]		[redacted]		[redacted]		[redacted]		[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]			[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]											

Section A6.5/6.7 Annex Point IIA VI 6.5/6.7	Chronic toxicity/Carcinogenicity study, other mammalian	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [X]	**Technically not feasible [ ]** **Scientifically unjustified [X]**	
Limited exposure [X]	**Other justification [ ]**	

Detailed justification:

[redacted]

Section A6.5/6.7 Annex Point IIA VI 6.5/6.7	Chronic toxicity/Carcinogenicity study, other mammalian
[redacted]	
Undertaking of intended data submission [ ]	
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]

Section A6.5/6.7 Annex Point IIA VI 6.5/6.7	Chronic toxicity/Carcinogenicity study, other mammalian
	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.6.1 Genotoxicity in vitro

Annex Pt IIA VI.6.6.1/01 *In-vitro gene mutation study in bacteria*

Official use only

1 REFERENCE

1.1 Reference [redacted] IN VITRO MICROBIAL MUTAGENICITY TESTING OF HYDROGEN PHOSHIDE, [redacted]

1.2 Data protection [redacted]

1.2.1 Data owner: Detia Freyberg GmbH

1.2.2

1.2.3 Criteria for data protection: [redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study [redacted]

2.2 GLP [redacted]

2.3 Deviations [redacted]

3 MATERIALS AND METHODS

3.1 Test material [redacted]

3.1.1 Lot/Batch number: [redacted]

3.1.2 Specification: [redacted]

3.1.2.1 Description: [redacted]

3.1.2.2 Purity: [redacted]

3.1.2.3 Stability: [redacted]

3.2 Study Type [redacted]

3.2.1 Organism/cell type: [redacted]

3.2.2 Deficiencies / Proficiencies: [redacted]

3.2.3 Metabolic activation system: [redacted]

Section A6.6.1 Genotoxicity in vitro

Annex Pt IIA VI.6.6.1/01 *In-vitro gene mutation study in bacteria*

3.2.4	Positive control	[redacted]
3.3	**Administration / Exposure; Application of test substance**	
3.3.1	Concentrations	[redacted]
3.3.2	Way of application	[redacted]
3.3.3	Pre-incubation time	[redacted]
3.3.4	Other modifications	[redacted]
3.4	**Examinations**	[redacted]
3.4.1	Number of cells evaluated	[redacted]

4 RESULTS AND DISCUSSION

4.1	**Genotoxicity**	
4.1.1	without metabolic activation	No
4.1.2	with metabolic activation	No
4.2	**Cytotoxicity**	n. a.
4.3	**Further examinations**	In the toxicity test of hydrogen phosphide with Salmonella typhimurium TA 98, approximately 20% growth inhibition was observed at the highest concentration, but no toxic effect was observed at lower concentrations.

Section A6.6.1 Genotoxicity in vitro

Annex Pt IIA VI.6.6.1/01 *In-vitro gene mutation study in bacteria*

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	[redacted]
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

COMMENTS FROM ...

Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.6.1 Genotoxicity in vitro

Annex Pt IIA VI.6.6.1/01 *In-vitro gene mutation study in bacteria*

[redacted]

[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]
[redacted]		
[redacted]		
[redacted]		

[redacted]

	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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[redacted]				
[redacted]				
[redacted]				

Section A6.6.1/6.6.2/ 6.6.3 Genotoxicity in vitro

Bacterial reverse mutation test

Annex Pt IIA VI.6.6.1/02

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] Ames/Salmonella Plate Incorporation Assay on Hydrogen Phosphide (PH_3). [redacted]
1.1	**Data protection**	[redacted]
1.1.1	Data owner	Detia Freyberg GmbH
1.1.2		
1.1.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	[redacted]
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]
3.1.2.1	Description	[redacted]
3.1.2.2	Purity	[redacted]
3.1.2.3	Stability	[redacted]
3.2	**Study Type**	[redacted]
3.2.1	Organism/cell type	[redacted]

Section A6.6.1/6.6.2/ 6.6.3 — Genotoxicity in vitro

Bacterial reverse mutation test

Annex Pt IIA VI.6.6.1/02

3.2.2	Deficiencies / Proficiencies	[redacted]
3.2.3	Metabolic activation system	[redacted]
3.2.4	Positive control	[redacted]
3.3	**Administration / Exposure; Application of test substance**	[redacted]
3.3.1	Concentrations	[redacted]

Section A6.6.1/6.6.2/ 6.6.3 **Genotoxicity in vitro**

Bacterial reverse mutation test

Annex Pt IIA VI.6.6.1/02

3.3.2 Way of application

[redacted]

3.3.3 Pre-incubation time

3.3.4 Other modifications

3.4 Examinations

3.4.1 Number of cells evaluated

4 RESULTS AND DISCUSSION

4.1 Genotoxicity

Section A6.6.1/6.6.2/ 6.6.3 — Genotoxicity in vitro

Bacterial reverse mutation test

Annex Pt IIA VI.6.6.1/02

4.1.1	without metabolic activation	Yes In the Ames/Salmonella Plate Incorporation Assay inhibited growth was observed in all tester strains at doses ≥ 488 ppm with and without S9. Revertant frequencies for all doses of PH3 in all strains with S9, and in strains TA1537, TA 1538, TA98, TA100 and TA102 without S9, approximated or were less than those observed in the concurrent negative control cultures. In contrast, a statistically significant increase in revertant frequency, to approximately 2.5-fold control values, was observed in strain TA1535 at a dose of 190 ppm without S9. In addition, the increase was apparently dose dependent over the range of 0 – 190 ppm. PH3 was re-evaluated in the confirmatory assay in all six stains at doses of 73.3, 147, 228, 360, 378 and 399 ppm with and/or without S9. Inhibited growth was again observed in all tester strains at doses of 146.5, 228, 360, 378 and/or 399 ppm with and without S9. Revertant frequencies for all doses of PH3 in strains TA1535, TA1538, TA100 and TA102 with S9, and all strains without S9, approximated or were less than control values. Increased revertant frequencies, to approximately 3.2- to 4.5 fold control values, were observed in strains TA1537 and TA98 at a dose of 360 ppm with S9. However, these increase were neither statistically significant nor dose dependent (revertant frequencies at doses of 228, 378 and 399 ppm were below control values). PH3 was re-evaluated in a third assay in all six strains at doses of 99.0, 111, 152, 172, 183 and 262 ppm with and without S9. Normal growth was observed in all strains at all doses with and without S9. Revertant frequencies for all doses of PH3 in strains TA1535, TA1537, TA98, TA100 and TA102 with S9, and all strains without S9, approximated or were less than control values. In contrast, statistically significant increases in revertant frequencies, to approximately 2.1-fold control values, were observed in strain TA1538 with S9. Although these increases were apparently dose dependent, revertant frequencies at all dose levels were elevated as compared to control values. PH3 was subsequently re-evaluated in all six strains with and without S9 in two additional assays. Revertant frequencies for all doses of PH3 in all six strains in the fourth assay approximated or were less than control values at doses of 37.0 – 203 ppm with and without S9 (although no toxicity was apparent). Similar results were observed in the fifth assay at doses of 41.0, 139, 277, 518, 670 and 962 ppm (however, significant toxicity was observed in this last assay at doses of 277, 518, 670 and/or 962 ppm with and/or without S9). All positive and negative control values in all assays were within acceptable limits.
4.1.2	with metabolic activation	see 4.1.1
4.2	**Cytotoxicity**	[redacted]

Section A6.6.1/6.6.2/ 6.6.3 **Genotoxicity in vitro**

Bacterial reverse mutation test

Annex Pt IIA VI.6.6.1/02

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[redacted]

5.2 Results and discussion

[redacted]

5.3 Conclusion

5.3.1 Reliability [redacted]

5.3.2 Deficiencies [redacted]

Section A6.6.1/6.6.2/ 6.6.3 Genotoxicity in vitro

Bacterial reverse mutation test

Annex Pt IIA VI.6.6.1/02

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A6_6_1-1. Table for Gene Mutation Assay (modify if necessary)

[redacted]

[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]
[redacted]		
[redacted]		
[redacted]		

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]				
[redacted]	[redacted]				
[redacted]	[redacted]				
[redacted]	[redacted]				
[redacted]	[redacted]				
[redacted]	[redacted]				
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[redacted]	[redacted]				
[redacted]	[redacted]				
[redacted]	[redacted]				
[redacted]	[redacted]				
[redacted]	[redacted]				
[redacted]	[redacted]				
[redacted]	[redacted]				

Section A6.6.1/6.6.2/ 6.6.3 — Genotoxicity in vitro

In-vitro cytogenicity study in mammalian cells

Annex Pt IIA VI.6.6.1/03

Official use only

1 REFERENCE

1.1	**Reference**	[redacted]Structural Chromosome Abberation Chinese Hamster Ovary (CHO) Cell induced by Hydrogen Phsophide (PH_3). [redacted]
1.2	**Data protection**	[redacted]
1.2.1	Data owner	Detia Freyberg GmbH
1.2.2		
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	[redacted]
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]

Section A6.6.1/6.6.2/ 6.6.3 Genotoxicity in vitro

In-vitro cytogenicity study in mammalian cells

Annex Pt IIA VI.6.6.1/03

3.1.2.1	Description	[redacted]
3.1.2.2	Purity	[redacted]
3.1.2.3	Stability	[redacted]
3.2	**Study Type**	[redacted]
3.2.1	Organism/cell type	[redacted]
3.2.2	Deficiencies / Proficiencies	[redacted]
3.2.3	Metabolic activation system	[redacted]
3.2.4	Positive control	[redacted]
3.3	**Administration / Exposure; Application of test substance**	
3.3.1	Concentrations	[redacted]
3.3.2	Way of application	[redacted]
3.3.3	Pre-incubation time	[redacted]
3.3.4	Other modifications	[redacted]
3.4	**Examinations**	[redacted]
3.4.1	Number of cells evaluated	[redacted]

Section A6.6.1/6.6.2/ 6.6.3 **Genotoxicity in vitro**

In-vitro cytogenicity study in mammalian cells

Annex Pt IIA VI.6.6.1/03

4 RESULTS AND DISCUSSION

4.1 Genotoxicity

4.1.1 without metabolic activation [redacted]

4.1.2 with metabolic activation [redacted]

4.2 Cytotoxicity [redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

In Vitro mammalian chromosome aberration test as described in 3

5.2 Results and discussion

In conclusion, PH_3 did not produce any statistical significance at the 18 and 26-hour time intervals with and without S-9 mix. However, PH_3 induced statistically significant increase in aberrations per cell at 2500 (2733) and 5000 (4957) ppm without S-9 mix at the 8 hour time interval. Since BD produced a weak statistical increase at 8-hour time interval and none at the 18-hour time interval, it appears the S-9 mix is either detoxifying the BD or it was not tested at the appropriate dose to induce structural chromosomal aberrations. Also, it is possible that PH_3 at the highest dose tested, inactivated the S-9 mix.

5.3 Conclusion

5.3.1 Reliability [redacted]

5.3.2 Deficiencies [redacted]

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date [redacted]

Materials and Methods [redacted]

Section A6.6.1/6.6.2/ 6.6.3 Genotoxicity in vitro

In-vitro cytogenicity study in mammalian cells

Annex Pt IIA VI.6.6.1/03

Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

[redacted]

[redacted]	[redacted]		[redacted]
	[redacted]	[redacted]	
[redacted]			
[redacted]			
[redacted]			

[redacted]

	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Section A6.6.1/6.6.2/ 6.6.3 Genotoxicity in vitro

In-vitro cytogenicity study in mammalian cells

Annex Pt IIA VI.6.6.1/03

[redacted]					
[redacted]	[redacted]				
	[redacted]				
	[redacted]				
[redacted]	[redacted]				
	[redacted]				
	[redacted]				
[redacted]					
[redacted]					
[redacted]					

Section A6.6.1/6.6.2/ 6.6.3 — Genotoxicity in vitro

In-vitro gene mutation assay in mammalian cells

Annex Pt IIA VI.6.6.1/04

Official use only

1 REFERENCE

1.1	**Reference**	[redacted]PHOSPHINE. MUTAGENICITY STUDY IN MAMMALIAN CELLS (V79) IN VITRO – HGPRT-Test. [redacted]
1.2	**Data protection**	[redacted]
1.2.1	Data owner	Detia Freyberg GmbH
1.2.2		
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	[redacted]
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]
3.1.2.1	Description	[redacted]
3.1.2.2	Purity	[redacted]
3.1.2.3	Stability	[redacted]
3.2	**Study Type**	[redacted]
3.2.1	Organism/cell type	[redacted]
3.2.2	Deficiencies / Proficiencies	[redacted]
3.2.3	Metabolic activation system	[redacted]
3.2.4	Positive control	[redacted]

Section A6.6.1/6.6.2/ 6.6.3 — Genotoxicity in vitro

In-vitro gene mutation assay in mammalian cells

Annex Pt IIA VI.6.6.1/04

3.3	**Administration / Exposure; Application of test substance**	
3.3.1	Concentrations	ranged from 500 to 6580 ppm (□ 0.57 – 9.3 mg/l air) Phosphine
3.3.2	Way of application	Cell cultures were incubated in desiccators (volume approx. 5.0 l) during the exposure period. The appropriate gas concentration was fed into the desiccators. The appropriate concentration was achieved by mixing the delivered Phosphine (0.658% (v/v)) with air.
3.3.3	Pre-incubation time	one day
3.3.4	Other modifications	no
3.4	**Examinations**	Mutation frequency
3.4.1	Number of cells evaluated	1,500,000 cells are placed in 30 ml DMEM-FCS per 150 mm diameter dish.

4 RESULTS AND DISCUSSION

4.1	**Genotoxicity**	
4.1.1	without metabolic activation	No Under the present test conditions Phosphine tested up to an exposure concentration of 6580 ppm in the air in the absence and presence of metabolic activation in two independent experiments was negative in the V79 mammalian HGPRT cell mutagenicity test under conditions where the positive controls exerted potent mutagenic effects.
4.1.2	with metabolic activation	[redacted]
4.2	**Cytotoxicity**	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	[redacted]
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Section A6.6.1/6.6.2/ 6.6.3 Genotoxicity in vitro

In-vitro gene mutation assay in mammalian cells

Annex Pt IIA VI.6.6.1/04

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A6_6_1-1. Table for Gene Mutation Assay (modify if necessary)

Section A6.6.1/6.6.2/ 6.6.3 Genotoxicity in vitro

In-vitro gene mutation assay in mammalian cells

Annex Pt IIA VI.6.6.1/04

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