Section A1 Applicant

Annex Point IIA1

1.1 Applicant

Name:	Detia Freyberg GmbH
Address:	Dr.-Werner-Freyberg-Str. 11 D-69514 Laudenbach
Telephone:	[redacted]
Fax number:	[redacted]
E-mail address:	[redacted]

1.2 Manufacturer of Active Substance (if different)

Name:	as above
Address:	
Telephone:	
Fax number:	
E-mail address:	
Location of manufacturing plant:	

1.3 Manufacturer of Product(s) (if different)

as above

1) Product 1

2) Product n

	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*

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 [redacted]

2.8.1.2 Function [redacted]

2.8.2 IUPAC name [redacted]

2.8.3 CAS-No [redacted]

2.8.4 EC-No [redacted]

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]

[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	
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 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

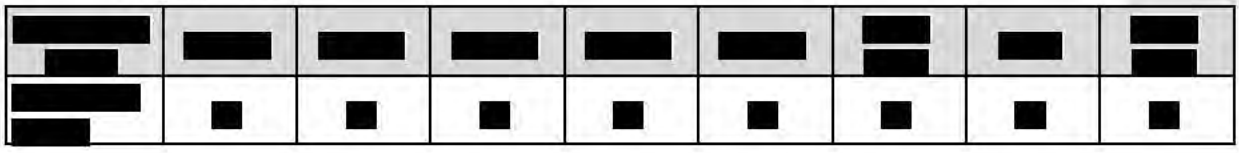
2.8.5 Other

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	
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 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

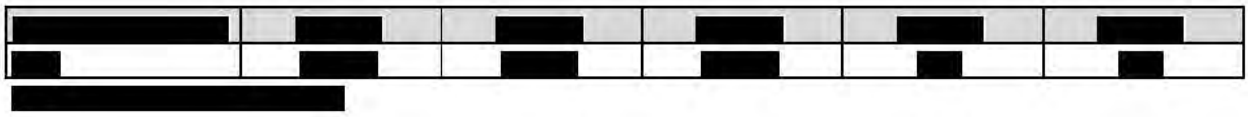
2.8.5 Other

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	
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 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 [redacted]

2.8.1.2 Function [redacted]

2.8.2 IUPAC name [redacted]

2.8.3 CAS-No [redacted]

2.8.4 EC-No [redacted]

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]

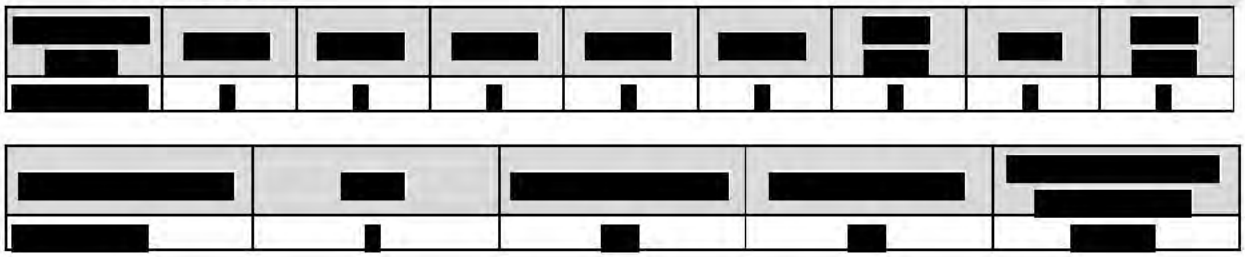
Component [g/kg]	batch 1	batch 2	batch 3	batch 4	batch 5
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

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	
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 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	
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 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	
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 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]

[redacted]

[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	
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	

Company Name	Name of A.S.	Month/Year
Detia Freyberg GmbH	Aluminium phosphide	June 2004

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

Official use only

Subsection

2.10.1 Human exposure towards active substance

The following form requests information about occupational exposure towards the active substances based on Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC.

Further information of the Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances (short title: TGD for Risk Assessment for New and Existing Substances) was taken into account.

The detailed structure supports the company to avoid further requests for the required data.

2.10.1.1 Production

2.10.1.1.1 Likely tonnage to be placed on the market per year [IIA V.5.8]

[Note: This field is taken from section IIA V.5.8 and must be filled in only in this chapter. This option will be available only in the electronic form]

Produced	☒
Imported	☐
Quantity lower	
Quantity upper	
Unit (Quantity)	
Year	
Remarks / further specifications	[redacted]

2.10.1.1.2 Description of process

Temperature of process	[redacted]
Pressure of process	[redacted]
Use pattern	[redacted]
Type of process	[redacted]
Batch size	[redacted]
Throughput	

Company Name	Name of A.S.	Month/Year

Further description of process

Remarks / further specifications

2.10.1.1.3 Workplace description

[redacted]

x

Pattern of control *In the following section describe the actual used pattern of control.*

Engineering controls [redacted]

Administrative procedures [redacted]

Personal protective equipment [redacted]

Remarks / further specifications

Company Name	Name of A.S.	Month/Year

2.10.1.1.4 Exposure

2.10.1.1.4.1 Task

[redacted]

Note: If more than one task is indicated fill in the fields of inhalation and dermal exposure for each task. Please use the field below "Further Task?" (end of 2.10.1.1.4.1.2) which support your fill in procedure.

2.10.1.1.4.1.1 Inhalationexposure

[redacted]

Description of method [redacted]

Frequency of task(s) [redacted]

Duration of task(s) [redacted]

Form during handling [redacted]

Year(s) of measurement [redacted]

Number of measurements [redacted]

Type of measurements [redacted]

Exposure concentration

Typical case [redacted]

Reasonable worst case [redacted] x

Remarks [redacted]

2.10.1.1.4.1.2 Dermal exposure x

Description of method [redacted]

Frequency of task

Duration of task [redacted]

Form during handling [redacted]

Exposed parts of the body [redacted]

[redacted]

Year(s) of measurement [redacted]

Company Name	Name of A.S.	Month/Year

Number of measurements	[redacted]
Type of measurements	[redacted]
	[redacted]
Exposure concentration	[redacted]
Typical case	
Reasonable worst case	
Remarks	
Further Task?	☐

Company Name	Name of A.S.	Month/Year

2.10.1.2 Intended uses

2.10.1.2.1 Use of active substance for the formulation of biocidal product

2.10.1.2.1.1 Likely tonnage to be placed on the market per year [IIA V.5.8]

[redacted]

[*Note: this information is taken from section IIA V.5.8 and must be filled in only in the actual chapter. This option will be available only in the electronic form*]

Produced	☒
Imported	☐
Quantity lower	
Quantity upper	
Unit (Quantity)	
Year	
Remarks / further specifications	

2.10.1.2.1.2 Description of process

Temperature of process	[redacted]
Pressure of process	[redacted]
Use pattern	
Type of process	[redacted]
Batch size	
Throughput	
Further description of process	
Package details	[redacted]
	[redacted]
	[redacted]
Site inventory	
Storage information	

Company Name	Name of A.S.	Month/Year

Concentration of marketed formulation	[redacted]	
Remarks / further specifications		
2.10.1.2.1.3 Workplace description	[redacted]	x
Pattern of control	[redacted]	
Engineering controls	[redacted]	
Administrative procedures	[redacted]	
Personal protective equipment	[redacted]	
Remarks / further specifications		

Company Name	Name of A.S.	Month/Year

2.10.1.2.1.4 Exposure

2.10.1.2.1.4.1 Task

[redacted]

2.10.1.2.1.4.1.1 Inhalation exposure x

Description of method	[redacted]
Frequency of task(s)	[redacted]
Duration of task(s)	[redacted]
Form during handling	[redacted]
Year(s) of measurement	[redacted]
Number of measurements	[redacted]
Type of measurements	[redacted]
Exposure concentration	[redacted]
Typical case	[redacted]
Reasonable worst case	[redacted] x
Remarks	[redacted]

2.10.1.2.1.4.1.2 Dermal exposure x

Description of method	[redacted]
Frequency of task(s)	
Duration of task(s)	[redacted]
Form during handling	[redacted]
Exposed parts of the body	[redacted]
Year(s) of measurement	[redacted]
Number of measurements	[redacted]
Type of measurements	[redacted]
Exposure concentration	[redacted]
Typical case	

Company Name	Name of A.S.	Month/Year

Reasonable worst case

Remarks

Further Task? ☐

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date [redacted]

2.10.1.1 Production [redacted]

Company Name	Name of A.S.	Month/Year

[redacted]

2.10.1.2.1
Use of active substance for the formulation of biocidal product

[redacted]

Company Name	Name of A.S.	Month/Year

[redacted]

Reliability [redacted]

[redacted]

Acceptability [redacted]

Remarks

COMMENTS FROM ...

Date *Give date of comments submitted*

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

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

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]

soil

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]

[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 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
2.10.1	**Human exposure towards active substance**	*Guidance is given in the TNsG on Human Exposure as well as the Technical Guidance Document on Risk Assessment*
2.10.1.1	**Production**	
	i) Description of process	[redacted]
	ii) Workplace description	
	iii) Inhalation exposure	
	iv) Dermal exposure	
2.10.1.2	**Intended use(s)**	
	1. Professional Users	[redacted]
	i) Description of application process	[redacted]
	ii) Workplace description	[redacted]
	iii) Inhalation exposure	[redacted]
	iv) Dermal exposure	[redacted]
	2. Non-professional Users including the general public	[redacted]
2.10.2	**Environmental exposure towards active substance**	

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

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):

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]

soil

[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

[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

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]
Date	[redacted]
Materials and methods	[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

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	

[redacted]

[redacted]

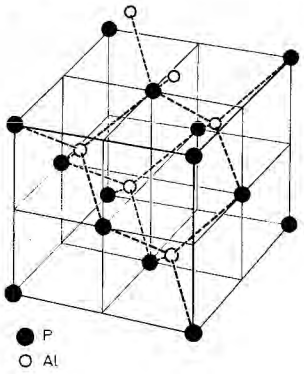
[redacted]

Section A2 Identity of Active Substance

Subsection (Annex Point)

Official use only

2.1	**Common name (IIA2.1)**	Aluminium phosphide
2.2	**Chemical name (IIA2.2)**	IUPAC: Aluminium phosphide
		CA: 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

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

Component (g/kg)	lower value	mean	upper value	theoretical value	value established by applicant
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

x

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

[redacted]

2.8.1 Isomeric 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	[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 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	[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
3.1.3 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** **3.3.2 Colour** **3.3.3 Odour**	 solid grey "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.	n.a.	n.a.	[redacted]	n.a.	0 (State-ment)	[redacted] Statement of the evaluation of UV/Vis, IR and NMR spectra of aluminium and magnesium phosphide, [redacted]	
3.5 Solubility in water (IIA3.5) Water solubility 1 Water solubility 2	*including effects of pH (5-9)* n.a.	n.a.	**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.	n.a.	n.a.	[redacted]	n.a.	0 (State-ment)	Schmitt, S.; Voigt, M.: [redacted] Statement of the performance of the following tests according to EU Test Guideline 92/69/EWG: A6 Solubility in water,	

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
							A8 Distribution coefficient, A17 Fire enhancing properties, C7 Hydrolysis abiotic decomposition, [redacted]	
3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA3.1)	n.a.	n.a.	**result: temperature: n.a.**	[redacted]	n.a.	0 (State-ment)	Schmitt, S.; Voigt, M.: [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.	n.a.	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.	n.a.	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]	
3.11 Flammability, including auto-flammability and identity of	96/69/EEC A.10 Flammability (solids)	[redacted]	Flammability The test substance is not a readily combustible solid in the sense of Guideline	[redacted]	Y	1	[redacted] Aluminium phosphide technical: FLAMMABILITY (SOLIDS),	

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
combustion products (IIA3.8)	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]	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]			FLAMMABILITY (SUBSTANCES AND PREPARATIONS WHICH, IN CONTACT WITH WATER OR DAMP AIR, EVOLVE HIGHLY FLAMMABLE GASES IN DANGEROUS QUANTITIES). [redacted] Aluminium phosphide technical: EXPLOSIVE PROPERTIES, AUTO-FLAMMABILITY (SOLIDS – DETERMINATION OF RELATIVE SELF-IGNITION TEMPERATURE). [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
							[redacted]	
3.12 Flash-point (IIA3.9)	EEC, A.9 (Flash point)	n.a.	n.a.	[redacted]	n.a.	0 (justification)		
3.13 Surface tension (IIA3.10)	n.a.	n.a.	Determination of the surface tension is technically not feasible	n.a.	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.			
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	

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
							TEMPERATURE). [redacted]	
3.16 Oxidizing properties (IIA3.12)	EEC, A.17 (Oxidizing properties)	n.a	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]	
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]	

	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]e
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 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:**	[redacted]	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	[redacted]	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)	[redacted]	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)	p[redacted]	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}	[redacted]	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]		[redacted]	n.a.	n.a.		
IR	n.a.	[redacted]		[redacted]	n.a.	n.a.	Gmelins Handbuch der Anorganischen Chemie 16, Phosphor Teil C (1965), p.17 –19	
NMR	n.a.	[redacted]		[redacted]	n.a.	n.a.		
MS	n.a.	[redacted]		[redacted]	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, [redacted]	
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]	n.a.	[redacted]	n.a.	n.a.		x
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.		
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 [redacted]

3.14 Viscosity [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*

Official use only

1. REFERENCE

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

1.2. Data protection [redacted]

1.2.1. Data owner Detia Freyberg GmbH

2 Guideline: [redacted]

3 Materials and Methods (principle of analyses) [redacted]

Recheck of the method: [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 IIA4.1.1 *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) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1.1 (a) *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: Detia Freyberg GmbH

1.2.3 Criteria for data protection: [redacted]

2 Guideline:

[redacted]

3 Test substance

Materials and Methods (principle of analyses)

[redacted]

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

Annex Point IIA4.1.1 (a) | *Routine analysis of the technical active substance Aluminium Phosphide*

[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]

3.3 Linearity

[redacted]

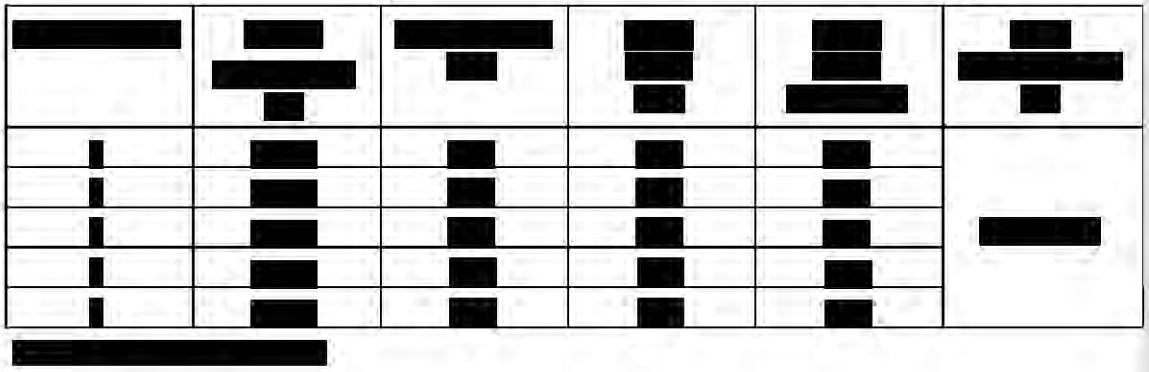
[redacted]

[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]

3.3.2 Number of measurements [redacted]

3.7 Precision

3.7.1 Repeatability [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 (a) *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 aluminium nitride 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]

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) **Analytical Methods for Detection and Identification**

Annex Point IIA4.1.2 (a) *Analytical methods for the analysis of impurities: Aluminium nitride*

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: 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]

[redacted]

[redacted]

3.3 Linearity

[redacted]

3.3.2 Number of measurements

[redacted]

3.3.3 Linearity

[redacted]

3.4 Specificity

[redacted]

[redacted]

3.5 Recovery rates at different levels

[redacted]

[redacted]

[redacted]

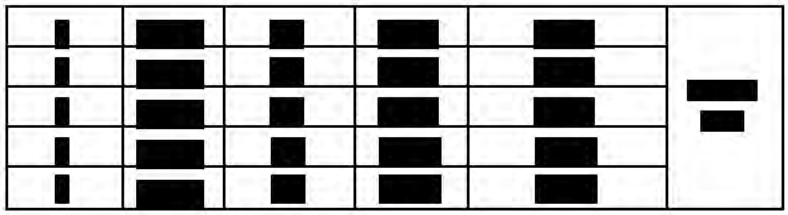
[redacted]

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

Official use only

1. REFERENCE

1.1	**Reference**	[redacted] Determination of the aluminium oxide 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)	The aluminium oxide content is given by the total aluminium content [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 metals in technical aluminium phosphide [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]
	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 [redacted]

1.2.1 Data owner: Detia Freyberg GmbH

1.2.3 Criteria for data protection: [redacted]

2 Guideline [redacted]

[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 (a) *Analytical methods for the analysis of impurities: Magnesium*

[redacted]

[redacted] x

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]

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*

3.4 Specificity

[redacted]

3.7 Precision

3.7.1 Repeatability

[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]

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*

	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 IIA4.1.4 (b) *Analytical methods for the analysis of impurities: Total Aluminium*

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	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: Total Aluminium*

[redacted]

Compound	Batch 40270	Batch 40272	Batch 40277	Batch 40279	Batch 40285
GAB Code	20051467	20051468	20051469	20051470	20051471
total aluminium [weight-%]1	40.4	41.2	40.9	40.5	40.4

[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]

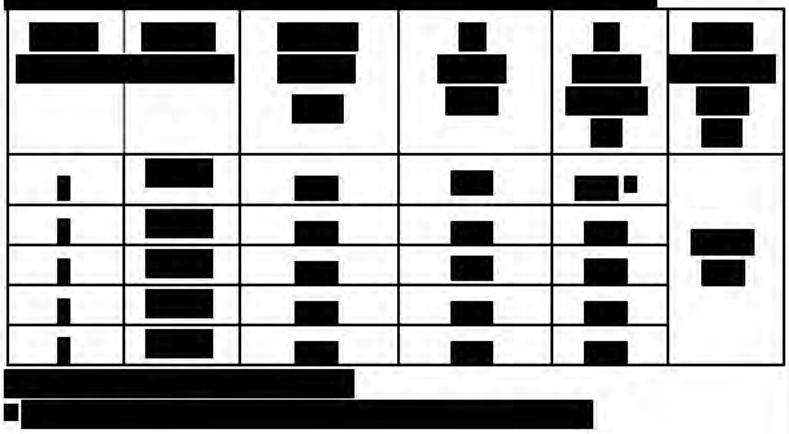
3.4 Specificity

[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

[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: Total Aluminium*

	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: Silicon*

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: 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: Silicon*

[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: Silicon*

3.4 Specificity

[redacted]

3.5 Recovery rates at different levels

[redacted]

3.5.1 Relative standard deviation

[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]

3.6 Limit of determination

[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[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: Silicon*

3.7 Precision

3.7.1 Repeatability

[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]

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 (c) *Analytical methods for the analysis of impurities: Silicon*

	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: Iron*

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: 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: Iron*

[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: Iron*

3.4 Specificity

[redacted]

3.5 Recovery rates at different levels

[redacted]

3.5.1 Relative standard deviation

[redacted]

[redacted]

3.6 Limit of determination

[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: Iron*

3.7 Precision

3.7.1 Repeatability

[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] t a mean analyte content of 1.0 % were regarded as to be acceptable.

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: Iron*

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: Arsenic*

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: 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 *Analytical methods for the analysis of impurities: Arsenic*

[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: Arsenic*

3.4 Specificity

[redacted]

3.5 Recovery rates at different levels

[redacted]

3.5.1 Relative standard deviation

[redacted]

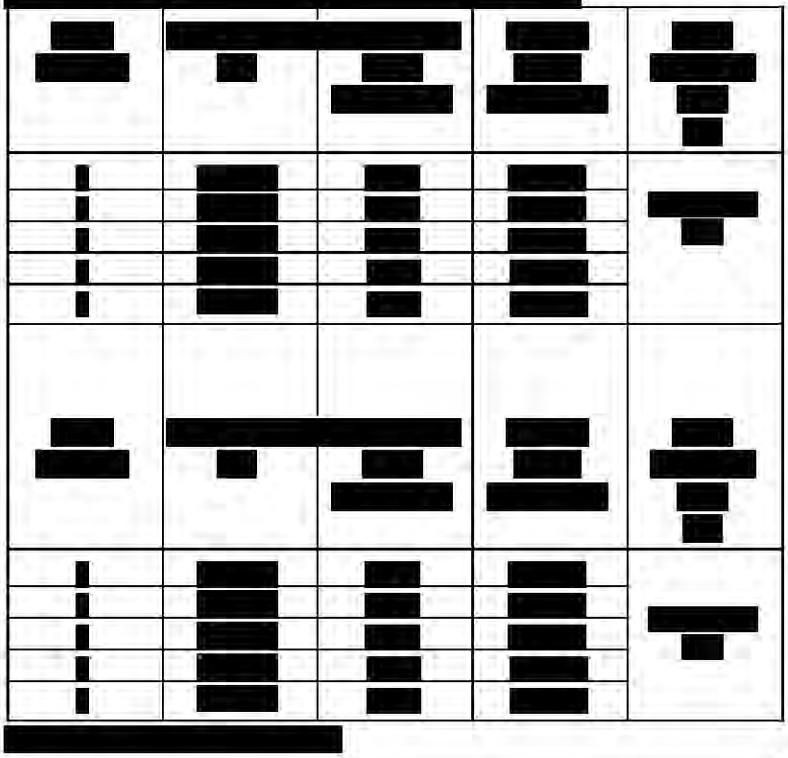
3.6 Limit of determination

[redacted]

3.7 Precision

3.7.1 Repeatability

[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: Arsenic*

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 (a) *Analytical methods for the analysis of impurities: Total Phosphorus*

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: 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: Total Phosphorus*

[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: Total Phosphorus*

[redacted]

3.3 Linearity

[redacted]

3.3.1 Calibration range

[redacted]

3.3.2 Number of measurements

[redacted]

3.3.3 Linearity

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: Total Phosphorus*

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 IIA4.2 (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 [redacted]

1.2.1 Data owner Detia Freyberg GmbH

GLP [redacted]

Materials and Methods [redacted]

3.3/3.4/3.6 Linearity/ Specificity/ Limit of quantification [redacted]

3.3/3.7.1 Recovery rate/ Reproduceability [redacted]

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

[redacted]

3.7.2 Independent laboratory validation

[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 IIA4.2 (a) *Residues in soil*

	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 IIA4.2 (b)

Analytical Methods for Detection and Identification
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 (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

[redacted]

1.2.1 Data owner

Scotts Celafor GmbH & Co KG, Ingelheim, Germany

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

[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	[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] Residue analysis of Zinc Phosphide in human blood, [redacted]

1.2 Data protection

[redacted]

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]

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

[redacted]

3.2.2 Detector

3.2.3 Standard(s)

3.2.4 Interfering substance(s)

3.3 Linearity

3.3.1 Calibration range

3.3.2 Number of measurements

3.3.3 Linearity

3.4 Specifity: interfering substances

3.5 Recovery rates at different levels

3.5.1 Relative standard deviation

3.6 Limit of determination

3.7 Precision

3.7.1 Repeatability

3.7.2 Independent laboratory

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

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)

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

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

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)

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] Residue analasis of Zinc Phosphide in Animal Tissues, [redacted]
1.2	**Data protection**	[redacted]
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

[redacted]

3.6 Limit of determination

[redacted]

3.7 Precision

3.7.1 Repeatability

[redacted]

3.7.2 Independent laboratory validation

[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

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	[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 (d) *Residues in animal and human body fluids and tissues*

Official use only

1. REFERENCE

1.1	**Reference**	L.T.F. Chan, R.J. Crowley, D. Delliou, R.Geyer (1983): Phosphine Analysis in Post Mortem Specimens Following Ingestion of Aluminium Phosphide; Journal of Analytical Toxicology, Vol. 7, July/August 1983
1.2	**Data protection**	No
1.2.1	Data owner	published
2.1	**Guideline**	not stated
2.2	**GLP**	not stated
3	**Materials and Methods**	In this study post mortem specimens from the body of a 27-year-old man who had ingested an unknown quantity of Phostoxin tablets (Degesch) were analysed. A simple and rapid headspace procedure is outlined for the analysis of phosphine in post mortem specimens using GC/NPD procedures.
	Method description:	*Reagents*: A primary gravimetric standard gas mixture of 5.1 ± 0.1 ppm of phosphine in nitrogen (certified) was obtained from Commonwealth Industrial Gases Ltd.. A 10% sulphuric acid solution was prepared using analytical grade concentrated sulphuric acid and deionised water. *Glassware*: Glass headspace vials (75.5 mm x 23 mm) were obtained from Perkin Elmer. The sealed vials had a capacity of 24 ml. Two graduated glass gas-tight syringes, one 1 ml and one 5 ml were used for transferring and injecting the standard gas mixture and headspace gases. *Instrumentation*: Analysis was carried out on a Hewlett-Packard Model 5730A GC/NPD, Model 18789A. Porapak Q, 100/120 mesh column packing was used in a 1.4 m x 4 mm i.d. glass column. The flow rate of the nitrogen carrier gas was 30ml/min. The hydrogen and air flow rates to the detector were 4 ml/min and 50 ml/min, respectively. The temperature settings of the chromatograph were: injector 150°C, detector 200°C and column 80°C. *Sample Preparation for Tissues and Blood*: The homogenized sample, either 1 g or 1 ml, was placed in a headspace vial that had been flushed with nitrogen. Two millilitres of 10% sulphuric acid was added. The vial was immediately sealed and shaken on a vortex mixer for 30 seconds. A 1 ml aliquot of the headspace was then injected into the gas chromatograph. *Phosphine standards*: Standards of 500 pg/ml and 1000 pg/ml concentration were prepared by adding 1 ml of deionised water and 2 ml of 10% sulphuric acid to two headspace vials that had been flushed with nitrogen and sealed. Using a 5 ml syringe, 1.5 ml and 3.0 ml aliquots of the standard gas mixture were transferred to the prepared vials. The vials were shaken on a vortex mixer for 30 seconds and 2 ml aliquots of the headspace were injected into the gas chromatograph. Quantitation of the post mortem specimens for phosphine was performed by peak height measurements relative to those of the standards. Under the conditions described, the retention time of phosphine was 2.9 min.

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

Annex Point IIA4.2 (d) *Residues in animal and human body fluids and tissues*

Findings

The results are shown in the following table:

Phosphine Levels in Post Mortem Specimens Liberated after Acidification:

Sample	**Concentration**
Blood	0.5 ng/ml
Liver	3 ng/g
Stomach and contents	3000 ng/g
Urine	Insufficient sample

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

Headspace GC/NPD procedure.

4.2 Conclusion

A rapid and sensitive headspace method has been described for the analysis of post mortem samples from a death involving aluminium phosphide.

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 (d) *Residues in animal and human body fluids and tissues*

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 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 [ ]	[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]	
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	
	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 (e) *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

[redacted]

1.2.1 Data owner

Detia Freyberg GmbH, Germany

1.2.3 Criteria for data protection

[redacted]

2. GLP

[redacted]

3. Materials and Methods

[redacted]

3.3 Linearity

[redacted]

3.4 Specificity

[redacted]

3.5 Recovery

[redacted]

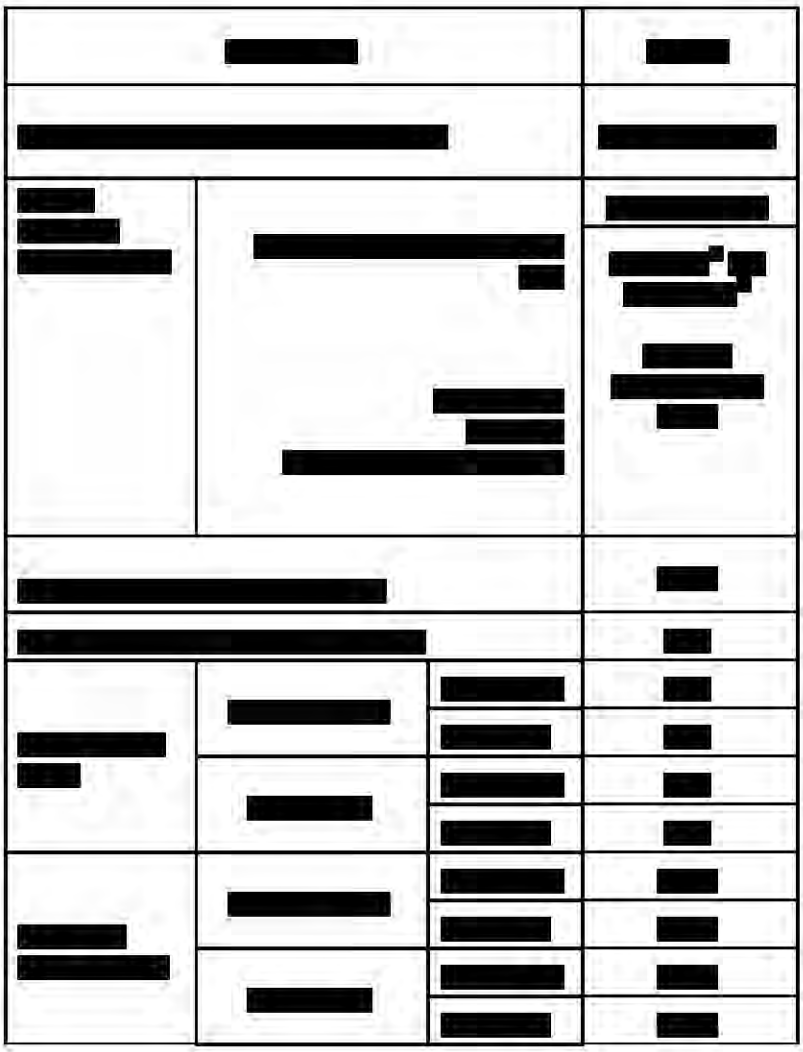
3.6 Limits of quantification and detection

[redacted]

3.7.1 Precision (repeatability of the analytical system):

[redacted]

[redacted]



3.7.2 Independent laboratory validation

[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]

	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

[redacted]

1.2.1 Data owner

[redacted]

1.2.3 Criteria for data protection

[redacted]

GLP

[redacted]

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]

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]

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	[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(a) *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

[redacted]

1.2.1 Data owner

Detia Freyberg GmbH

1.2.3 Criteria for data protection

[redacted]

2. GLP

[redacted]

3. Materials and Methods

[redacted]

Analytical determination

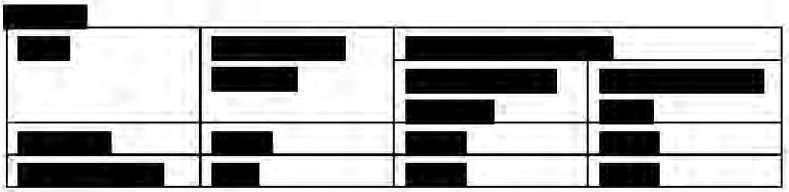
[redacted]

3.3 Linearity

[redacted]

3.5 Recovery

[redacted]



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

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

[redacted]

[redacted]

[redacted]			
[redacted]			
[redacted]			

[redacted]

[redacted]

[redacted]			
[redacted]			
[redacted]			

[redacted]

3.6 Limits of quantification and detection

[redacted]

3.7.1 Precision (repeatability of the analytical system):

[redacted]

[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]

	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)			Official use only
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)		
	PT 23 (Control of other vertebrates)	[redacted]	

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

5.4 Mode of action (including time delay) (IIA5.4)

[redacted]

5.4.1 Mode of action

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

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

	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]
Conclusion	[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 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

[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. [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

The LD_{50} (14d) for mice was calculated as 14.77 mg/kg b.w. for males and females by oral administration.

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

Oral (Mice)

Annex Point IIA6.1.1

	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	

ANNEX

[redacted]

[redacted]

[redacted]			

Section A6.1.1/02

Annex Point IIA6.1.1

Acute Toxicity

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}

LD_{50} for albino rats (24 h) = 8.70 (8.17 –9.27) mg/kg b.w. for 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 A6.1.1/02 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

Oral (Rats)

Annex Point IIA6.1.1

	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	

ANNEX

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

Summary of Acute Toxicity

Annex Point IIA6.1

Table A6_1-1. Table for Acute Toxicity

[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**	[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}**	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	

ANNEX

[redacted]

[redacted]

Section A6.1.3 Acute Toxicity

Inhalation (Rats)

Annex Point IIA6.1.3

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

[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

Inhalation (Rats)

Annex Point IIA6.1.3

	[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]

CA-Table A6.1.3-2 [redacted]

[redacted]			
[redacted]			

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

Annex Point IIA6.1.4

3 REFERENCE

3.5 Reference

[redacted] IRRITANT EFFECTS OF ALUMINIUMPHOSPHID ON INTACT SKIN OF RABBITS, [redacted]

3.6 Data protection

[redacted]

3.6.2 Data owner: Detia Freyberg GmbH

3.6.3

4 GUIDELINES AND QUALITY ASSURANCE

4.5 Guideline study

[redacted]

4.6 GLP

[redacted]

4.7 Deviations

[redacted]

5 MATERIALS AND METHODS

5.5

[redacted]

6 RESULTS AND DISCUSSION

6.5

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.

7 APPLICANT'S SUMMARY AND CONCLUSION

7.5 Materials and methods

[redacted]

7.6 Conclusion

[redacted]

7.6.2 Reliability: [redacted]

7.6.3 Deficiencies: [redacted]

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

Annex Point IIA6.1.4

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

Annex Point IIA6.1.4

ANNEX

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

1.0	**Reference**	[redacted] IRRITANT EFFECTS OF ALUMINIUMPHOSPHID ON RABBIT EYE, [redacted]
2.0	**Data protection**	[redacted]
1.0.0	Data owner	Detia Freyberg GmbH

2 GUIDELINES AND QUALITY ASSURANCE

1.0	**Guideline study**	[redacted]
2.0	**GLP**	[redacted]
3.0	**Deviations**	[redacted]

3 MATERIALS AND METHODS

[redacted]

1 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.

1 APPLICANT'S SUMMARY AND CONCLUSION

1.0	**Materials and methods**	[redacted]
2.0	**Results and discussion**	[redacted]
3.0	**Conclusion**	
1.0.0	Reliability	[redacted]
2.0.0	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	[redacted]
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	

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[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]	[redacted]
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[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

[redacted]

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 detectable 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.

Section A6.2 Metabolism studies in mammals

Annex Point IIA6.2/01

	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	
	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]
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[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	[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 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 / 6.4 / 6.5 Repeated dose toxicity

Annex Point IIA VI.6.3.3 (Inhalation)

Official use only

		1 REFERENCE
1.1	**Reference**	Omae, K. et al. (1996): Acute and sub-acute inhalation toxicity of highly purified phosphine (PH_3) in male ICR mice; J. Occup. Health 38, 36 - 42
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**	not stated (It is not stated in this publication, if the original study was conducted according GLP, but since the investigations were carried out in 1996, it can be presumed that the study was conducted in compliance with the GLP regulations.)
2.3	**Deviations**	n. a.
		3 MATERIALS AND METHODS
3.1	**Test material**	Phosphine
3.1.1	Lot/Batch number	not stated
3.1.2	Specification	Purity: 99.995 %
3.1.2.1	Description	stable, colourless gas
3.1.2.2	Purity	99.995 %
3.1.2.3	Stability	stable
3.2	**Test Animals**	
3.2.1	Species	mouse
3.2.2	Strain	ICR
3.2.3	Source	Charles River
3.2.4	Sex	Male
3.2.5	Age/weight at study initiation	4 weeks old
3.2.6	Number of animals per group	10
3.2.7	Control animals	Yes
3.3	**Administration/ Exposure**	Inhalation

Section A6.3 / 6.4 / 6.5 Repeated dose toxicity

Annex Point IIA VI.6.3.3 (Inhalation)

3.3.1	Duration of treatment	14 days or 28 days	
3.3.2	Frequency of exposure	5 days per week	
3.3.3	Postexposure period	Duration of the observation period for the subacute experiment is not reported.	
3.3.4	**Oral**	**n. a.**	
3.3.5	**Inhalation**		
3.3.5.1	Concentrations	Nominal concentration	5 ppm
		Analytical concentration	4.9 ± 0.3 ppm
3.3.5.2	Particle size	no aerosol	
3.3.5.3	Type or preparation of particles	no study with particles	
3.3.5.4	Type of exposure	Whole body	
3.3.5.5	Vehicle	highly purified nitrogen	
3.3.5.6	Concentration in vehicle	not indicated	
3.3.5.7	Duration of exposure	6 h	
3.3.5.8	Controls	Exposed to filtered room air	
3.3.6	**Dermal**	**n. a.**	
3.3.7	**Intraperitoneal/ Intravenous/ Intratracheal instillation**	**n. a.**	
3.4	**Examinations**		
3.4.1	Observations		
3.4.1.1	Clinical signs	yes, time period not indicated	
3.4.1.2	Mortality	yes, time period not indicated	
3.4.2	Body weight	yes, time period not indicated	
3.4.3	Food consumption	not indicated	
3.4.4	Water consumption	not indicated	
3.4.5	Ophthalmoscopic examination	not indicated	
3.4.6	Haematology	yes, number of animals: all animals time points: end of study Parameters: Total count of red blood cells and white blood cells (WBC) and the differential count of WBC.	
3.4.7	Clinical Chemisty	yes, number of animals: all animals time points: end of study Parameters: blood urea nitrogen, alanine aminotransferase, aspartate	

		aminotransferase, alkaline phosphatase, cholinesterase inhibition.
3.4.8	Urinalysis	no
3.5	**Sacrifice and pathology**	
3.5.1	Organ Weights	yes organs: liver, kidneys, testes, epididymides, spleen, brain, lung, pancreas
3.5.2	Gross and histopathology	yes all dose groups organs: Organs mentioned in 3.5.1 and additionally: The sciatic nerve, the skull for nasal cavity examination and the femoral bone for bone marrow analysis.
3.5.3	Other examinations	no
3.5.4	Statistics	Student's t-test of Welch's t-test was used for statistical testing of the differences in the mean effect variable for exposed and control mice.
3.6	**Further remarks**	

4 RESULTS AND DISCUSSION

4.1	**Observations**	
4.1.1	Clinical signs	In both the two- and four-week exposure groups, the animals exhibited a face washing movement and were extremely active in their cages in the initial period after the start of exposure. Approximately on hour after start of exposure, their spontaneous motor activity diminished and they gathered in the corners of the exposure cage. Except for mild piloerection, there were no other particularly noteworthy findings.
4.1.2	Mortality	One of the animals in the four-week exposure group died on day 12 after the start of exposure, and right ventricular dilation and pulmonary congestion were observed. All of the other animals survived until the day of necropsy.
4.2	**Body weight gain**	not reported
4.3	**Food consumption and compound intake**	not determined
4.4	**Ophtalmoscopic examination**	not determined
4.5	**Blood analysis**	
4.5.1	Haematology	see table A6_3_3_1
4.5.2	Clinical chemistry	see table A6_3_3_1
4.5.3	Urinalysis	not determined
4.6	**Sacrifice and pathology**	
4.6.1	Organ weights	see table A6_3_3_2

Section A6.3 / 6.4 / 6.5 Repeated dose toxicity

Annex Point IIA VI.6.3.3 (Inhalation)

4.6.2	Gross and histopathology	see table A6_3_3_3
4.7	**Other**	no other significant effects

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	
5.2	**Results and discussion**	Exposure concentrations were 4.9 ± 0.3 ppm. Animals showed face-washing and were extremely active after the start of exposure, but approximately one hour after start of exposure, their spontaneous motor activity diminished. Expect for mild piloerection, there were no other particular findings. One animal of the 4-week exposure period died on day 12, and ventricular dilatation and pulmonary congestion were observed upon necropsy. Body weight gains were significantly different from control after 2 weeks of exposure, but in the 4-week exposure group only the absolute weight of kidneys was significantly decreased. The organ weights of liver, spleen, thymus and kidneys showed statistically significant effects, whereas weights of lungs, testes, heart and brain that did not show statistically significant difference to control. Histopathologic examinations revealed pulmonary congestion in one animal of the 4-week exposure group. Inflammatory changes in the mucosa of the nasal cavity were seen only in animals of the 4-week exposure group. Haematological investigations showed a significant decrease ($p \leq 0.05$) of monocytes after 2 weeks of exposure, and a significant increase ($p \leq 0.05$) of eosinophiles after 4 weeks. ALT and BUN were significantly increased ($p \leq 0.05$) in the 4-week exposure group. There were no differences in the mature sperm counts. Inhalation exposure for up to 4 weeks resulted in a mortality of only a single animal.
5.3	**Conclusion**	
5.3.1	LO(A)EL	not determined.
5.3.2	NO(A)EL	not determined
5.3.3	Other	
5.3.4	Reliability	2
5.3.5	Deficiencies	No

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date [redacted]

Section A6.3 / 6.4 / 6.5 Repeated dose toxicity

Annex Point IIA VI.6.3.3 (Inhalation)

Materials and Methods	[redacted]
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	

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Section A6.3 / 6.4 / 6.5 Repeated dose toxicity

Annex Point
IIA VI.6.4

(Subchronic oral toxicity test)

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] Untersuchungen zur subchronischen Toxizität von Aluminiumphosphid, 90-Tage-Test an wachsenden Wistarratten, [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]

Section A6.3 / 6.4 / 6.5 Repeated dose toxicity

Annex Point IIA VI.6.4

(Subchronic oral toxicity test)

[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]

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

3.3.4.2 Concentration

3.3.4.3 Vehicle

3.3.4.4 Concentration in vehicle

3.3.4.5 Total volume applied

3.3.4.6 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

3.4.7 Clinical Chemisty

3.4.8 Urinalysis

3,5 Sacrifice and pathology

3.5.1 Organ Weights