



PHOSPHANE

List of Annex II studies which were considered
as relied upon for the evaluation with a view to
Annex I inclusion
and for which the main submitter has claimed
data protection

Version 1

Rapporteur Member State: Germany

July 2013

PHOSPANE

List of **Annex II studies** which were considered
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Version 1 - (July 2013)

B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ¹ on previous use in granting national authorizations
KIIA 1.10.2 KIIA 1.11.1 KIIA 1.8.1 KIIA 1.8.2 (OECD)	Szolga, W.S.	2001	Preliminary analysis and methods validation of phosphane technical grade active ingredient CY-WE-2000-01 - GLP: Y, published: N 1693116 / 1693117 / 1693114 / 1693115	
KIIA 2.8.1 (OECD)	Tiemann, J.	2006	Phosphine - Estimation of the octanol water partition coefficient 203-351-A2-020801-01 - GLP: N, published: N 1693136 /	
KIIA 3.7 (OECD)	Anonymous	2006	Safety data sheet - Phosphine 100/en - GLP: N, published: N 1693143 /	
KIIA 4.2.1 KIIA 4.2.3 (OECD)	Szolga, W.S.	2001	Preliminary analysis and methods validation of phosphane technical grade active ingredient CY-WE-2000-01 - GLP: Y, published: N 1693146 / 1693147	
KIIA 4.3 (OECD)	Hamberger, R.	2007	Validation of an Analytical Method for the Determination of Phosphine in Plant Material 20071030/01-RVP - GLP: Y, published: N 1693148 /	
KIIA 4.3 (OECD)	Gazzotti, L.	2007	Independent Laboratory Validation of the Residue Analytical Method for the Determination of Phosphine in Coffee (fatty matrix) and Grains (dry matrix) 20075510/01-RVP - GLP: Y, published: N 1693149 /	

¹ Entries are based on information received from the main data submitter and in certain cases Member States. Neither the Commission nor the Member States are responsible for the completeness or validity of this information received.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports¹ on previous use in granting national authorizations
KIIA 4.5 (OECD)	Hamberger, R.	2007	Validation of an Analytical Method for the Determination of Phosphine in Drinking Water and Surface Water 20071030/01-RVW - GLP: Y, published: N 1693150 /	
KIIA 4.7 (OECD)	Hamberger, R	2007	Validation of an Analytical Method for the Determination of Phosphine in Air 20071030/01-RVA - GLP: Y, published: N 1693151 /	
KIIA 4.7 (OECD)	Mende, P.	2009	Report amendment no.1 to study 20071030/01-RVA: Validation of an Analytical Method for the Determination of Phosphine in Air 20071030/01-RVA GLP: N, published: N 1849303 /	

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
KIIA 5.2.1	Bieler, C.	2007	Statement on acute oral toxicity Rep. no. 203351-A2-050201-01 GLP: N, published: N 1693156	
KIIA 5.2.2	Bieler, C.	2007	Statement on acute percutaneous toxicity Rep. no. 20331-A2-050202-01 GLP: N, published: N 1693158	
KIIA 5.2.3 (OECD)	Newton, P.E.	1989	An acute inhalation toxicity study of phosphine (PH ₃) in the rat. PROJECT NO.: 87-8029 GLP: Y, published: N 1797359 / TOX9751198	N UPL* N CYT Y DET
KIIA 5.2.4	Bieler, C.	2007	Statement on dermal irritation Rep. no. 203351-A2-050204-01 GLP: N, published: N 1693163	
KIIA 5.2.5	Bieler, C.	2007	Statement on eye irritation Rep. no. 203351-A2-050205-01 GLP: N, published: N 1693165	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
KIIA 5.2.6 (OECD)	Bieler, C.	2007	Statement on skin sensitization, Annex IIA, Point 5.2.6 203351-A2-050206-01 GLP: N, published: N 1693167 /	
KIIA 5.2.6 (OECD)	Brunt, P.	2001	Zinc phosphide: Skin sensitisation in the guinea pig - Magnusson and Kligman maximisation method 1483/003 GLP: Y, published: N 1797372 / TOX2002-179	
KIIA 5.3.2 KIIA 5.3.3 (OECD)	Bieler, C.	2007	Statement on 90-day oral toxicity, Annex IIA, Point 5.3.2 203351-A2-050302-01 GLP: N, published: N 1693168 / 1693169	
KIIA 5.3.2 (OECD)	Newton, P.E.	1990	A thirteen week inhalation toxicity study of phosphine (Ph ₃) in the rat. PRO 87-8030 GLP: Y, published: N 1797377 / TOX9751194	N UPL* Y CAS Y DET
KIIA 5.4.1 (OECD)	Rajwani, L. S.	2000	Salmonella typhimurium reverse mutation assay of Aluminium phosphide technical 2567 GLP: Y, published: N 1797380 / TOX2006-220	
KIIA 5.4.1 (OECD)	Stankowski, L.F.	1990	Ames/salmonella plate incorporation assay on hydrogen phosphide (PH ₃). PH 301-DA-001-89 GLP: Y, published: N 1797383 / TOX2001-685	N UPL* Y CAS Y DET
KIIA 5.4.2 (OECD)	Bieler, C.	2007	Statement on clastogenicity in mammalian cells, Annex IIA, Point 5.4.2 203351-A2-050402-01 GLP: N, published: N 1693175 /	
KIIA 5.4.2 (OECD)	SanSebastian, J.R.	1990	Structural chromosome aberration in Chinese hamster ovary (CHO) cells induced by hydrogen phosphide (PH ₃). (in vitro) PH 320-DA-001-89 GLP: Y, published: N 1797385 / TOX2001-686	Y DET* N UPL

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KIIA 5.4.4 (OECD)	McKeon, M. E.	1993	Genotoxicity test on Phosphine in the <i>in vivo/in vitro</i> assay for unscheduled DNA synthesis in rat primary hepatocyte cultures at two timepoints A0040-0-494 GLP: Y, published: N 1797390 / TOX2005-285	Y DET* N UPL
KIIA 5.5.2 (OECD)	Newton, P.E.	1998	2-year combined inhalation chronic toxicity and oncogenicity study of phosphine in rats. 750-001 ! 182-007 GLP: Y, published: N 1797401 / TOX2000-98	Y DET* N UPL
KIIA 5.5.3 (OECD)	Bieler, C.	2007	Statement on carcinogenicity in the mouse, Annex IIA, Point 5.5.3 GLP: N, published: N 1693181 /	
KIIA 5.6.1 (OECD)	Bieler, C.	2007	Statement on two-generation reproductive toxicity, Annex IIA, Point 5.6.1 203351-A2-050601-01 GLP: N, published: N 1693182 /	
KIIA 5.6.11 (OECD)	Bieler, C.	2007	Statement on teratogenicity in the rabbit, Annex IIA, Point 5.6.11 203351-A2-050611-01 GLP: N, published: N 1693184 /	
KIIA 5.6.2 (OECD)	Schroeder, R.E.	1989	An inhalation developmental toxicity study of phosphine (PH ₃) in rats. 89-3413 GLP: Y, published: N 1797404 / TOX2001-687	Y DET* N UPL
KIIA 5.7.1 (OECD)	Schaefer, G.J.	1998	Acute neurotoxicity study of phosphide in rats. (delayed neurotoxicity following acute exposure) 750-002 GLP: Y, published: N 1797405 / TOX2000-97	Y DET* N UPL
KIIA 5.7.1 (OECD)	Schaefer, G.J.	1998	90-day inhalation neurotoxicity study of phosphine in rats Vol. 1 to 5 750-003 GLP: Y, published: N 1797406 / TOX2006-176	Y CAS* Y DET N UPL
KIIA 5.9.1 (OECD)	Hartmann, H.	2006	No effects of the fumigant Frisin on health [German original] GLP: N, published: N 1693186 /	

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KIIA 5.9.1 (OECD)	Hartmann, H.	2006	Employees health statement. GLP: N, published: N 1797414 / ASB2007-5814	

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
KIIA 6.3.1 (OECD)	Knoch, E.	1998	Residues of the fumigant Frisin (active ingredient: phosphine) in barley IF-98/34196-00 GLP: Y, published: N 1693193 / RIP1999-141	
KIIA 6.3.1 (OECD)	Knoch, E.	1998	Residues of the fumigant Frisin (active ingredient: phosphine) in rye IF-98/34194-0 GLP: Y, published: N 1693194 / RIP1999-142	
KIIA 6.3.1 (OECD)	Knoch, E.	1998	Residues of the fumigant Frisin (active ingredient: phosphine) in barley IF-98/34197-00 GLP: Y, published: N 1693195 / RIP1999-143	
KIIA 6.3.1 KIIA 6.3.4 (OECD)	Knoch, E.	1998	Residues of the fumigant Frisin (active ingredient: Phosphine) in dried fruit (peach) and grain (rye) IF-98/17295-00 GLP: Y, published: N 1693196 / RIP9800986 / 1693201	
KIIA 6.3.2 KIIA 6.3.3 (OECD)	Knoch, E.	1998	Residues of the fumigant Frisin (active ingredient: Phosphine) in green coffee beans and unprocessed pistachios IF-98/15497-00 GLP: Y, published: N 1693197 / RIP9800985 / 1693199	
KIIA 6.3.2 KIIA 6.3.3 (OECD)	Knoch, E.	1998	Rückstände des Begasungsmittels FrisinR (Wirkstoff Phosphin) in Kakao-Bohnen und Haselnuss-Kernen (Residues of the fumigant FRISIN (active ingredient: phosphine) in cocoa beans and hazelnut kernels) IF-98/08821-00 GLP: Y, published: N 1693198 / RIP9800673 / 1693200	

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
none				

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
none				

* study of task forces; data protection not clear, some companies asked for data protection, some not; Y = data protection claimed, N = data protection not claimed