



CALCIUM PHOSPHIDE

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 2.0

Rapporteur Member State: Germany

June 2011

Calcium phosphide

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 2 - (June 2011)

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 BVL registration number	Reports¹ on previous use in granting national authorisation
AIIA-1.11; AIIA-4.1.1; AIIA-4.1.2; AIIIA-5.1.1	Kiefer, R.	2006	Determination of calcium phosphide and six impurities in five batches of calcium phosphide technical. 20061152/01 GLP, unpublished CHE2006-1128	
AIIA-1.11; AIIA-4.1.1; AIIIA-5.1.1	Martens-Menzel, R.	2000	Validation of the Determination of Phosphine in Air by Means of IR Absorption Spectrometry. GLP, unpublished CHE2005-115	
AIIA-1.11; AIIA-2.9.1	Martens-Menzel, R.	2000	Report about the Gas Development from Soil Fumigants Containing Phosphides. GLP, unpublished CHE2005-113	
AIIA-1.11	Martens-Menzel, R.	2000	Translation of important parts from 3th draft VSG GC 81. GLP, unpublished CHE2006-1171	
AIIA-3.1; AIIIA-6.2	Anonymous	2000	Experimentální podminky. not GLP, unpublished BIO2005-97	
AIIA-3.1; AIIA-3.3; AIIA-3.4.2; AIIIA-3.1; AIIIA-3.3; AIIIA-6.2	Deriu, P.	1996	Essai Polytanol Taupicide. not GLP, unpublished BIO2005-94	
AIIA-3.1; AIIIA-6.2	Jakowlew, A.A.	2001	Gutachten über die Prüfungsunterlagen für das Zoozid Polytanol 18 %. not GLP, unpublished BIO2005-99	

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 BVL registration number	Reports¹ on previous use in granting national authorisation
AIIA-3.1; AIIIA-3.3; AIIIA-6.2	Kirillowa, M.N.	2002	Report on a study of the biological efficacy of and the setting out of regulations for the use of a Chemische Fabrik Wülfel GmbH and Co. zoozide Polytanol (18%). not GLP, unpublished BIO2005-101	
AIIA-3.1; AIIIA-6.2	Kirillowa, M.N.	2001	Bericht über die Erforschung der biologischen Wirksamkeit und Festlegung von Reglement bei Anwendung von Polytanol. not GLP, unpublished BIO2005-98	
AIIA-3.1; AIIA-3.4.2; AIIIA-3.3; AIIIA-6.2	Truchetet, D.	2000	Compte-Rendue d'Essai officiel 2000 Toute culture-Campagnol terrestre. 99100021 not GLP, unpublished BIO2005-96	
AIIA-2.3.1	Smeykal, H.	2001	Zinc phosphide: Vapour pressure. 20010674.03 GLP, unpublished CHE2006-288	
AIIA-1.11; AIIA-2.9.1	Martens-Menzel, R.	2000	Report about the Gas Development from Soil Fumigants Containing Phosphides. GLP, unpublished CHE2005-113	
AIIA-2.11.2	Möller, M.	2007	Auto-flammability A.16 (Solids - determination of relative self-ignition temperature) GLP, unpublished CHE2007-406	
AIIA-2.13; AIIA-2.15	Lüth, P.	2004	Classification of product "Polytanol" in accordance with method EC A.14 - Explosive Properties and method EC A.17 - Oxidising Properties (Solids). not GLP, unpublished CHE2005-121	
AIIA-1.11; AIIA-4.1.1; AIIA-4.1.2; AIIIA-5.1.1	Kiefer, R.	2006	Determination of calcium phosphide and six impurities in five batches of calcium phosphide technical. 20061152/01 GLP, unpublished CHE2006-1128	

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), Report No. GLP or GEP status (where relevant) Published or not BVL registration number	Reports¹ on previous use in granting national authorisation
AIIA-1.1.1; AIIA-4.1.1; AIIIA-5.1.1	Martens-Menzel, R.	2000	Validation of the Determination of Phosphine in Air by Means of IR Absorption Spectrometry. GLP, unpublished CHE2005-115	
AIIA-4.2.1; AIIA-4.2.5	Witte, A.	2001	Residue analysis of Zinc phosphide in animal tissues method validation - Method validation. 20001426/01-RVAT GLP, unpublished MET2002-60	
AIIA-4.2.3; AIIIA-5.2	Werle, H.	1999	Method Validation for the Determination of Residues of Phosphine in Surface Water and Potable Water. 995040303 GLP, unpublished MET2000-49	

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.

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 BVL registration number	Reports on previous use in granting national authorizations
AIIA-5.2.1; AIIA-5.3.1; AIIA-5.3.2; AIIIA-7.1.1	Venugopala Rao, K.	1999	Acute oral toxicity study with Polytanol in Wistar rats. 2739/99 GLP, unpublished TOX2000-105	
AIIA-5.2.2; AIIIA-7.1.2	Dickhaus, S., Heisler, E.	1987	Akute Toxizitätsprüfung von der Substanz Aluminiumphosphid nach dermalen Applikation an der Ratte (OECD-Guidelines no. 404) (Acute toxicological study on compound Aluminiumphosphid after dermal application to the rat). 1-4-142-87 GLP, unpublished TOX2000-93	
AIIA-5.2.3; AIIIA-7.1.3	Newton, P.E.	1989	An acute inhalation toxicity study of phosphine (PH ₃) in the rat. PROJECT NO.: 87-8029 not GLP, unpublished TOX97-51198	Task Force deviation Data Protection: UPL = N DET = Y
AIIA-5.2.3; AIIIA-7.1.3	Shimizu, Y., Ogawa, Y., Tokiwa, K.	1982	Acute inhalation toxicity testing of hydrogen phosphide in rats. NRI 82-7489 not GLP, unpublished TOX2005-280	
AIIA-5.2.3; AIIA-5.3.3; AIIIA-7.1.3	Venugopala Rao, K.	2001	Acute inhalation toxicity study with Polytanol in Wistar rats. 3078/00 GLP, unpublished TOX2002-822	
AIIA-5.2.4	Brunt, P.	2001	Zinc phosphide: Acute dermal irritation in the rabbit. 1483/001 GLP, unpublished TOX2005-168	
AIIA-5.2.4; AIIIA-7.1.4	Dickhaus, S., Heisler, E.	1987	Prüfung von Aluminiumphosphid auf primäre Hautreizwirkung an der intakten Haut des Kaninchens (OECD-Guidelines no. 406). (Irritant effects of Aluminiumphosphid on intact skin of Rabbits). 1-3-183-87 GLP, unpublished TOX2000-94	

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 BVL registration number	Reports on previous use in granting national authorizations
AIIA-5.2.5	Brunt, P.	2001	Zinc phosphide: Acute eye irritation in the rabbit. 1483/002 GLP, unpublished TOX2005-171	
AIIA-5.2.5; AIIIA-7.1.5	Dickhaus, S., Heisler, E.	1987	Augenreiztest am Kaninchen mit Aluminiumphosphid nach OECD no. 405. (Irritant effects of Aluminiumphosphid on rabbit eye). 1-3-184-87 not GLP, unpublished TOX2000-95	
AIIA-5.2.6; AIIIA-7.1.6	Brunt, P.	2001	Zinc phosphide: Skin sensitisation in the guinea pig – Magnusson and Kligman maximisation method. 1483/003 GLP, unpublished TOX2002-179	
AIIA-5.3.2	Schnellhardt, M., Gebhardt, M., Bräter, M., et al.;	1985	Study on the subchronical toxicity of Aluminium phosphide – 90-day-test on growing wistar rats. Not GLP, unpublished TOX2005-282	
AIIA-5.3.3	Newton, P.E.	1990	An thirteen week inhalation toxicity study of phosphine (PH ₃) in the rat. 87-8030 GLP, unpublished TOX2001-684	Task Force deviation Data Protection: UPL = N DET = Y
AIIA-5.4.1	Leuschner, F.	1992	Phosphine: Mutagenicity study in mammalian cells (V79) in vitro – HGPRT Test. 6990/91 GLP, unpublished TOX2005-284	
AIIA-5.4.1	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, unpublished TOX2001-686	Task Force deviation Data Protection: UPL = N DET = Y
AIIA-5.4.1	Stankowski, L.F.	1990	Ames/salmonella plate incorporation assay on hydrogen phosphide (PH ₃). PH 301-DA-001-89 GLP, unpublished TOX2001-685	Task Force deviation Data Protection: UPL = N DET = Y

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 BVL registration number	Reports on previous use in granting national authorizations
AIIA-5.4.1	Sutou, S., Yamamoto, K., Shirakawa, H.	1982	In vitro microbial mutagenicity testing of hydrogen phosphide. 82-7492 not GLP, unpublished TOX2005-283	
AIIA-5.4.2	McKeon, M.E.	1993	Genotoxicity test on Phosphine in the in vivo/in vitro assay for unscheduled DNA synthesis in rat primary hepatocyte cultures at two timepoints. A0040-0-494 GLP, unpublished TOX2005-285	Task Force deviation Data Protection: UPL = N DET = Y
AIIA-5.5	Newton, P.E.	1998	2-year combined inhalation chronic toxicity and oncogenicity study of phosphine in rats. 750-001 ! 182-007 GLP, unpublished TOX2000-98	Task Force deviation Data Protection: UPL = N DET = Y
AIIA-5.6.2	Schroeder, R.E.	1989	An inhalation developmental toxicity study of phosphine (PH ₃) in rats. 89-3413 GLP, unpublished TOX2001-687	Task Force deviation Data Protection: UPL = N DET = Y
AIIA-5.7; AIIA-5.8.2	Schaefer, G.J.	1998	90-day inhalation neurotoxicity study of phosphine in rats Vol. 1 to 5. 750-003 GLP, unpublished TOX2006-176	Task Force deviation Data Protection: UPL = N DET = Y
AIIA-5.7	Schaefer, G.J.	1998	Acute neurotoxicity study of phosphide in rats. (delayed neurotoxicity following acute exposure). 750-002 GLP, unpublished TOX2000-97	Task Force deviation Data Protection: UPL = N DET = Y
AIIA-5.9.1	Asher, P.P.	2005	Report on health status of factory workers exposed during manufacturing of Aluminium phosphide. Not GLP, unpublished TOX2006-225	
AIIA-5.9.1	Guth, E.	2003	Occupational Health Care for Employees under Hydrogen Phosphide (PH ₃) Exposition. not GLP, unpublished TOX2004-2205	

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.

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company, Report No. GLP or GEP status (where relevant) Published or not BVL registration number	Reports on previous use in granting national authorizations
AIIA-6.0; AIIIA-8.0	Martens-Menzel, R.	2000	Report of Examination 98/2 (Storage Stability of Polytanol Pellets). GLP, unpublished RIP2005-112	
AIIA-6.0; AIIIA-8.0	Martens-Menzel, R.	1998	Report of Examination 98/1 (Storage Stability of Polytanol Pellets). GLP, unpublished RIP2005-111	

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.

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 BVL registration number	Reports on previous use in granting national authorizations
AIIA-7.2.1.1	Martens-Menzel, R.	2000	Report about the gas development from soil fumigants containing phosphides. GLP, unpublished WAS2005-48	

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.

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 BVL registration number	Reports on previous use in granting national authorizations
--	------------------	-------------	--	--

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.