Committee for Risk Assessment

RAC

Annex 1

Background document

to the Opinion proposing harmonised classification and labelling at Community level of

aluminium phosphide

ECHA/RAC/CLH-O-0000002201-92-01/A1

EC number: 244-088-0
CAS number: 20859-73-8

Adopted

2 December 2011

CONTENTS

TABLES

PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

Substance Name: **Aluminium phosphide**

EC Number: **244-088-0**

CAS number: **20859-73-8**

Purity: Min. > 83 % w/w

Impurities: The confidential information can be found in the "Confidential Annex" or the technical dossier.

The current Annex VI entry and the proposed harmonised classification

	CLP Regulation (EC) No 1272/2008	**Directive 67/548/EEC (Dangerous Substances Directive; DSD)**
Current entry in Annex VI, CLP Regulation	Water-react. 1 H260 EUH029 EUH032 Acute Tox. 2* H300 Aquatic Acute 1 H400 M = 100	F; R15/29 T+; R28 R32 N; R50 C ≥ 0,25 % N; R50
Current proposal for consideration by RAC	Acute Tox. 3 H311 Acute Tox. 2 H300	Xn; R21
Resulting harmonised classification (future entry in Annex VI, CLP Regulation)	Water-react. 1 H260 EUH029 EUH032 Acute Tox. 1 H330 Acute Tox. 2 H300 Acute Tox. 3 H311 Aquatic Acute 1 H400 M = 100	F; R15/29 R32 T+; R26 T+; R28 Xn; R21 N; R50 C ≥ 0,25 % N; R50

*Minimum classification

Proposed classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling[1]			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard state-ment Code(s)	Pictogram, Signal Word Code(s)	Hazard state ment Code(s)	Suppl. Hazard statement Code(s)		
015-004-00-8	Aluminium phosphide	244-088-0	20859-73-8	Water-react. 1 Acute Tox. 2 Acute Tox. 3 Acute Tox. 1 Aquatic Acute 1	H260 H300 H311 H330 H400	Dgr. GHS02 GHS06 GHS09	H260 H300 H311 H330 H400	EUH029 EUH032	M = 100	-

[1] RAC also recommends to add to the labelling, “P260 - Do not breath dust/fume/gas/mist/vapours/spray”

Proposed classification and labelling in accordance with the criteria of Directive 67/548/EEC

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
015-004-00-8	Aluminium phosphide	244-088-0	20859-73-8	F; R15/29 T+; R26/28 Xn; R21 R32 N; R50	F; T+ ; N R:15/29-26/28-21-50 S:(1/2)-3/9/14/49-8-22-30-36/37-43-45-60-61	N; R50: C ≥ 0.25 %	

JUSTIFICATION

See also Annex 1 to this BD document (summary record of the TC C&L meeting).

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

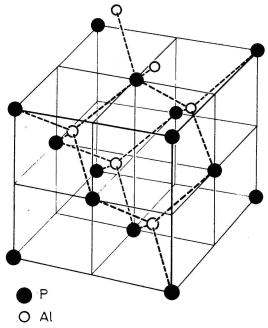
1.1 Name and other identifiers of the substance

Chemical Name: Aluminium phosphide
EC Name: Aluminium phosphide
CAS Number: 20859-73-8
IUPAC Name: Aluminium phosphide

1.2 Composition of the substance

The confidential information can be found in the "Confidential Annex" or the technical dossier.

Chemical Name: Aluminium phosphide
EC Number: 244-088-0
CAS Number: 20859-73-8
IUPAC Name: Aluminium phosphide
Molecular Formula: AlP
Structural Formula:



Molecular Weight: 57.96 g/mol
Typical concentration (% w/w): Min. > 83
Concentration range (% w/w): confidential

1.3 Physico-chemical properties

Table 1: Summary of physico- chemical properties of aluminium phosphide

REACH ref Annex, §	Property	IUCLID section	Purity/Specification	Value	[enter comment/reference or delete column]
VII, 7.1	Physical state at 20°C and 101.3 kPa	4.1	Aluminium phosphide, approx. 85 %	grayish green powder with a garlic or carbide-like odour	EC Safety Data Sheet (2008), Detia Freyberg GmbH
VII, 7.2	Melting/freezing point	4.2	Aluminium phosphide, technical 86.5 %	No melting point was observed under test conditions up to 500 °C	Smeykal, H. (2002); report no. 20020427.01
VII, 7.3	Boiling point	4.3	Aluminium phosphide, technical 86.5 %	No boiling point was observed under test conditions up to 500 °C at 1013.3 hPa	Smeykal, H. (2002); report no. 20020427.01
VII, 7.4	Relative density	4.4	Aluminium phosphide, technical 86.5 %	2.32 at 23.5 °C	Smeykal, H. (2002); report no. 20020427.02
VII, 7.5	Vapour pressure	4.6	Aluminium phosphide, technical 86.5 %	<< 10-5 Pa at 25 °C	Smeykal, H. (2002); report no. 20020427.01
VII, 7.6	Surface tension	4.10		not determined (hydrolysis)	
VII, 7.7	Water solubility	4.8		not determined (hydrolysis)	
VII, 7.8	Partition coefficient n-octanol/water (log value)	4.7		not determined (hydrolysis)	
VII, 7.9	Flash point	4.11		Testing is technically not possible, substance is a solid.	BAM, II.2 (2010)
VII, 7.10	Flammability	4.13		Flammable solids: The test substance could not be ignited with a flame. The substance is not a highly flammable solid in the sense of Guideline 92/69/EEC, A.10. Flammability in contact with water: In contact with water the test substance evolves highly flammable gases in dangerous quantities. The gas ignites spontaneously. The substance is highly flammable in the sense of Guideline	Smeykal, H. (2002); report no. 20020427.03 Smeykal, H. (2002); report no. 20020427.03

				92/69/EEC, A.12 Pyrophoric properties: The classification procedure need not to be applied because the inorganic substance is known to be stable into contact with air at room temperature for prolonged periods of time (days).	BAM, II.2 (2010)
VII, 7.11	Explosive properties	4.14		Aluminium phosphide has no explosive properties in the sense of Guideline 92/69/EEC, A.14.	Smeykal, H. (2002); report no. 20020427.04
VII, 7.12	Relative Self-ignition temperature for solids	4.12		Guideline 92/69/EEC, A.16: No self ignition was registered until the maximum temperature of 401 °C.	Smeykal, H. (2002); report no. 20020427.04
VII, 7.13	Oxidising properties	4.15		The classification procedure need not be applied because the inorganic substance does not contain oxygen or halogen atoms.	BAM, II.2 (2010)
	Thermal stability	4.19		OECD Test No.113 (DSC): Neither an endothermic nor an exothermal effect until 500°C (No self-reactive substance	Smeykal, H. (2002); report no. 20020427.01

Table 2: Summary of physico- chemical properties of phosphine

REACH ref Annex, §	Property	IUCLID section	Purity/Specification	Value	[enter comment/reference or delete column]
VII, 7.1	Physical state at 20°C and 101.3 kPa	4.1	Phosphine, technical purity unknown	Gaseous with a fouly, fishy or garlic -like odour	Römpp, 2006: Version 2.10. Georg Thieme Verlag 2006
VII, 7.2	Melting/freezing point	4.2	Phosphine, technical purity unknown	-133°C	Römpp, 2006: Version 2.10. Georg Thieme Verlag 2006
VII, 7.3	Boiling point	4.3	Phosphine, technical purity unknown	-87°C	Römpp, 2006: Version 2.10. Georg Thieme Verlag 2006
VII, 7.4	Relative density	4.4	Phosphine, technical purity unknown	1.53 at 20 °C A density of 1.41 g/L was calculated on the basis of an ideal gas.	Römpp, 2006: Version 2.10. Georg Thieme Verlag 2006
VII, 7.5	Vapour pressure	4.6	Phosphine, technical purity unknown	3295 kPa at 22 °C	CRC Handbook of Chemistry and Physics 1991: 82nd Edition 1991-1992, page 6-91
VII, 7.6	Surface tension	4.10		The test has not be conducted as a surface tension of > 60mN/m at 20°C is expected to due the chemical structure of the substance.	
VII, 7.7	Water solubility	4.8	Phosphine, purity unknown	24 ml / 100 ml water at 24 °C	Phosphine and Selected Metal Phosphides, WHO, Geneva, 1988, p. 17–19
VII, 7.8	Partition coefficient n-octanol/water (log value)	4.7	Phosphine, technical purity unknown	Log Pow 0.9 at 21 °C	W. Schlösser, 1989: Untersuchungsbericht Octanol-Wasser-Verteilungskoeffizient von PH3, Labor für Geoanalytik, Hildesheim, Germany, Auftrags-Nr. 05011, 29.09.1989
VII, 7.9	Flash point	4.11		The submission of data or the performance of a test on the flash-point of Phosphine is not considered to be required since it is no liquid whose vapours can be ignited.	Justification, Detia, 2004

VII, 7.10	Flammability	4.13	Phosphine pure grade	auto ignition temperature of 38°C Extremely flammable and pyrophoric	Phosphine and Selected Metal Phosphides, WHO, Geneva, 1988, p. 17 – 19
VII, 7.11	Explosive properties	4.14	Phosphine, purity unknown	Phosphine forms explosive mixtures with air concentrations greater than 1.8%	Phosphine and Selected Metal Phospides, WHO, Geneva, 1988, p. 17 – 19
VII, 7.12	Relative Self-ignition temperature for solids	4.12		Test item is no solid.	
VII, 7.13	Oxidising properties	4.15		Only for solids (EC method A. 17)	
	Thermal stability	4.19		Thermal decomposition at 550°C	Application for registration of "Detia Gas-Ex-B forte", Detia Freyberg GmbH, Laudenbach, B/7, 16.12.94

2 MANUFACTURE AND USES

2.1 Manufacture

Not relevant for this type of dossier.

2.2 Identified uses

Not relevant for this type of dossier.

2.3 Uses advised against

Not relevant for this type of dossier.

3 CLASSIFICATION AND LABELLING

3.1. Classification in Annex I of Directive 67/548/EEC (up to 31st ATP)

F; R15/29
T+; R28
R32
N; R50
(Index number: 015-004-00-8)

3.2. Classification in Annex VI of Regulation (EC) No. 1272/2008

Water-react. 1 H260
EUH029
EUH032
Acute Tox. 2* H300
Aquatic Acute 1 H400
M = 100
(Index number: 015-004-00-8)

3.3. Self classification(s)

The applicant under Dir. 98/8/EC proposed classification as under section 3.1.

4. Physico-chemical properties

4.1.1. Explosivity

In a standard study (Smeykal, H. (2002); report no. 20020427.04), Aluminium phosphide was found not to exhibit any explosive properties. No classification for explosivity is proposed.

4.1.2. Flammability

In standard study (Smeykal, H. (2002); report no. 20020427.03) Aluminium phosphide was classified as highly flammable in the sense of Guideline 92/69/EEC, A.12. In contact with water the test substance evolves highly flammable gases in dangerous quantities. The gas ignites spontaneously.
In standard study (Smeykal, H. (2002); report no. 20020427.03) Aluminium phosphide could not be ignited with a flame. The substance is not a highly flammable solid in the sense of Guideline 92/69/EEC, A.10, and did not exhibit any pyrophoric properties.
In standard study (Smeykal, H. (2002); report no. 20020427.04) no self ignition according to Guideline 92/69/EEC, A.16 was registered until the maximum temperature of 401 °C.

Proposed classification and labelling based on Directive 67/548/EEC:
F Highly flammable; R15/R29 Contact with water liberates extremely flammable toxic gases.

Proposed classification and labelling based on Regulation (EC) No 1272/2008:
Water-react. 1, H260; EUH029, GHS02, Danger

4.2. Oxidising potential

No experimental data on oxidising properties:
Testing can be waived based on a consideration of the chemical structure in accordance with REACH Column 2 of Annex VII, section 7.13: The classification procedure need not be applied because the inorganic substance does not contain oxygen or halogen atoms,
No classification for oxidising properties is proposed.

5. ENVIRONMENTAL FATE PROPERTIES

No modifications of existing environmental classification as included in Annex VI of CLP regulation is proposed.

6. HUMAN HEALTH HAZARD ASSESSMENT

The assessment presented in the following subsections is based on the notion that the toxicity of metal phosphides is primarily characterised by the effects caused by liberation of hydrogen phosphide (PH_3) gas. For this reason, studies performed with other metal phosphides, or PH_3 itself were considered adequate for assessing AlP toxicity. If a different metal phosphide was used as test material, dose levels were converted based on the respective maximum amount of PH_3 liberable by the respective compounds.

Unless otherwise noted, studies were conducted under GLP conditions.

The metal phosphides such as aluminium phosphide, trimagnesium diphosphide, trizinc diphosphide, tricalcium diphosphide fulfil the criteria for grouping and read across as defined in the section1.5 of Annex XI of the Regulation 1907/2006/EC because they have the following common characteristics;

1) they have common functional group, which in this case is phosphorus atom which during breakdown of metal phosphide release a phosphorus radical with trivalent binding capability (Holleman, A. F., 2001; Knight, M. W. 2006)

2) All the metal phosphides have common breakdown products via physical-chemical process, particularly as a result of hydrolysis of phosphides in contact with water or biological fluids which is phosphine (PH_3). This substance is in fact responsible for most of toxic activity of metal phosphides (Dikshith T. S. S., Prakash V. Diwan 2003;
http://www.fao.org/docrep/X5042E/x5042E0a.htm)
Thus, since the two criteria for grouping and read across approach (common functional group and common breakdown product) are fulfilled it is highly probable that their physicochemical, toxicological and ecotoxicological properties are likely to be similar.

6.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

Table 3: Summary of toxicokinetic studies

Method/ Guideline	**Route**	**Species, Strain, Sex, No/group**	**Dose levels, Duration of exposure**	**Results**	**Reference**
No guideline, Non-GLP	Oral	Rats, number, bw and sex not stated	Zinc ^{32}P-phosphide, suspension in milk 40 mg/kg bw (> LD_{50}) and lower dose (not specified), single application	Mortality↑ at high dose, PH_3 detectable in liver	Curry, A.S. et al. (1959); Nature 184, 642 – 643
		Rats, sex not stated, 6 animals	Zinc ^{32}P-phosphide, suspension in milk 10 mg/rat, single application	Mortality↑, phosphide and PH_3 detectable in liver	
		Rats and guinea pigs, no further information given	No information given	Urinary excretion: main product is hypophosphite	

Method/ Guideline	**Route**	**Species, Strain, Sex, No/group**	**Dose levels, Duration of exposure**	**Results**	**Reference**
No guideline, Non-GLP	Oral, subcutan-eous, per rectum	Rattus norvegicus Berk, number, bw and sex not stated	Zinc ^{32}P-phosphide, suspended in water 40 mg/kg bw	Oral application: After 6-8 h, ^{32}P was detectable in all organs and tissues with temporarily higher levels in liver and medulla oblongata. Application per rectum: After 24 h ^{32}P was detectable in large intestine, arterial blood, liver and kidneys. Subcutaneous injection: After 24 h ^{32}P was detectable only around the point of injection	Andreev, S.B. et al. (1959): 2nd Int. Conf. Peaceful Uses Atomic Energy 1958 (27), 85 – 92
	Oral		Zinc phosphide, ^{32}P- and ^{65}Zn- labelled, pure compound Sublethal, lethal, 2-, 3- and 4-fold lethal doses	The distribution of ^{32}P was similar to that in the above experiment. ^{65}Zn was found in all organs. The ratio of ^{32}P to ^{65}Zn was different in different tissues.	
Not applicable	Inhalation			Inhaled PH_3 is considered to be readily absorbed through the lungs, excretion with urine as hypophosphite and phosphite and via lungs as PH_3	WHO (1988), Environmental Health Criteria 73, pp 48-51 (1)

(1) This refers to a section on the toxicokinetics and metabolism in mammals within a WHO monograph on phosphine and metal phosphides. Although not a study report in itself, it represents an opinion peer-reviewed by a round of international experts and should be used to complement the submitted data base in the absence of other experimental data.

The available studies for this endpoint are of low reliability. However, in light of the chemical nature of aluminium phosphide as well as for reasons of animal welfare, it was decided that further testing would not provide essential new information and that the available studies could be used for risk assessment.

Following oral administration of zinc phosphide, ^{32}P was rapidly absorbed from the gastrointestinal tract. Inhaled PH_3 is considered to be rapidly and quantitatively absorbed through the lungs. ^{32}P was detectable in all organs and tissues, with temporarily higher levels in liver and medulla oblongata. PH_3 is excreted as such with the expired air or, after metabolic oxidation, with the urine in the form of hypophosphite and phosphite.

In the absence of experimental data, for dermal absorption of both aluminium phosphide and PH_3 a default value of a maximum of 10 % was assumed based on expert judgement in consideration of the following reasoning:

- Due to the nature of the formulated product (pellets or tablets), only a minor part of the active substance, if any, is expected to come into contact with the skin.
- Contact with the (humid) skin surface would be expected to initiate liberation of PH_3 gas making systemic absorption highly unlikely.
- In previous evaluations by both the WHO (Environmental Health Criteria 73, 1988) and the German 'MAK Commission' for aluminium phosphide/PH_3 dermal absorption was stated to be ‘negligible’.
- In decades of approved use, no casualties or serious intoxications have been reported for operators dermally exposed to aluminium phosphide.

It is noticed that under special occlusive conditions of dermal exposure, aluminium phosphide, and most probably other phosphides can be absorbed through skin causing skin irritation and death of animals (Dickhaus, S. and Heisler, E. (1987)).

6.2. Acute toxicity

6.2.1. Acute toxicity: oral

In 1999, the TC C&L agreed to classify aluminium phosphide as T+; R28 according to Dir. 67/548/EEC (inc. 29th ATP). When translating this harmonised DSD classification into a harmonised CLP classification the minimum classification Acute Tox 2*, H300 was assigned. Based on this CLH proposal, the dossier submitter would like to confirm this classification.

Table 4: Summary of acute oral toxicity

Method/ Guideline	**Route**	**Species, Strain, Sex, No/group**	**Dose levels (mg/kg bw)**	**Value LD_{50}/LC_{50} (mg/kg bw)**	**Remarks**	**Reference**
Similar to OECD 401, Non-GLP	Oral	Rat, Wistar albino 5M+5F	Aluminium phosphide, 1 % in vaseline (petrolatum) 7.94-8.92-10.0-11.2	LD_{50} M+F: 8.7	**R 28**	Sterner, W. and Stiglic, A. (1977), report no. 0-0-51-77
OECD 401	Oral	Mouse, NMRI/HAN Bö 5M+5F	Aluminium phosphide, suspended in sesame oil 6.81-10.0-14.7-21.5	LD_{50} M+F: 14.8	**R 28**	Leuschner, J. (1992), report no. 7129/92

Aluminium phosphide is of high toxicity when administered orally to rats and mice.

Final assessment:

Comparison with criteria: the LD_{50} values (range from 8.7 to 14.8 mg/kg bw) obtained from two acute oral toxicity studies performed with rats and mice (Sterner, W. and Stiglic, A. (1977) and Leuschner, J. (1992)) were within the range (5-50 mg/kg bw) for classification as Acute Tox Category 2 H300 Fatal if swallowed under the Regulation (EC) 1272/2008 criteria and are below the value of 25 mg/kg bw established for the classification as T+; R28 Very toxic if swallowed according to Directive 67/548/EEC criteria.

As supporting information (see table below), there is an oral LD_{50} of 11.2 mg/kg bw obtained from a study with trimagnesium diphosphide in rats (Sterner, W. and Chibanguza, G. (1980)) that can be read across to AlP after recalculation from Mg_3P_2 taking into account a factor of 0.86 (MW PH_3 33.998g/mol/MW AlP 57.96g/mol)/(MW PH_3 33.998g/mol /MW Mg_3P_2 134.86 g/mol). This leads to an LD_{50} value of 9.6 mg/kg and is therefore supporting the hazard classification as mentioned above.

Similar to OECD 401, Non-GLP	Oral	Rat, Wistar albino 5M+5F	Trimagnesium diphosphide, 1 % in vaseline (petrolatum) 8.97-10-11.3-12.6 (calculated as pure a.s.)	M+F: 11.2	**R 28**	Sterner, W. and Chibanguza, G. (1980), report no. 1-4-666-79

6.2.2. Acute toxicity: dermal

The Dossier Submitter has included a proposal for this hazard classification under Directive 67/548/CEE and CLP Regulation based on animal testing (Dickhaus, S. and Heisler, E. (1987)).

Table 6: Summary of acute dermal toxicity studies

Method/ Guideline	**Species, strain, Sex, No/ group**	**Dose levels (mg/kg bw)**	**Value LD_{50}**	**Remarks/deviations**	**Results**	**Reference**
OECD 402	Rat, Wistar albino 5M+5F	Aluminium phosphide, 500-1000-2000 (occlusive conditions, 24 hours)	LD_{50} M+F (d 14): 900 mg/kg bw	Purity/batch number of test material not stated Vehicle not stated – not clear whether the test substance had been applied moistened or applied as a powder. The size of the exposed skin area is not reported. The method of calculation LD_{50} is not mentioned but performed with combination with Gauss´ integral method	No death occurred at 500 mg/kg bw AlP/kg bw, while at dose of 1000 mg/kg bw 3/5 M and 3/5 F died (days 1 -7) and all animals died at 2000 mg/kg bw (days 1-4). Body weight gain was gradually reduced at increasing AlP dose levels. Animals showed sedation, apathy, coma prior to death. In all dose groups light oedema and haemorrhagic infiltration were observed at treated skin area. No information is given concerning recovery of survivors.	Dickhaus, S. and Heisler, E. (1987) report no. 1-4-142-87, 09/1987

Two additional acute dermal studies where animals were exposed to AlP (Stephen F. (2000) and Joshi M. (1998)) were added in this section as supportive information.

Table 7: Additional supportive studies on Acute Dermal Toxicity

Method/ Guideline	**Species, strain, Sex, No/ group**	**Dose levels (mg/kg bw)**	**Value LD50**	**Remarks/deviations**	**Results**	**Reference**

OPPTS 870.1200	Rat Wistar, 5M/each level + 5 F/highest level	Aluminium phosphide 0-280-420-630 Moistened with peanut oil. (occlusive conditions, 24 hours)	LD_{50} M+F : 461.2 mg/kg bw	Temperature of experimental animal room was higher during the study (27-28°C instead of recommended 20±3°C) This study should be disregarded since temperature of animal room was much higher than recommended, which most probably make animals much more sensitive to toxic action of aluminium phosphide.	No death occurred at 280 mg/kg bw. All early deaths occurred within 48 hours after dermal application. At dose of 420 mg/kg bw 2/5M died (day 1 – 5 hours 30 min) and at dose of 630 mg/kg bw 4/5 M and 4/5F died (day 1 – 5 hours 30 min – 2x, 48 hours – 2x) . Clinical signs in treated animals on the day of dosing and the day after - lethargy, tremors, abdominal breathing and piloerection. No signs were observed on the subsequent days up to the end of observation period. All surviving animals showed normal body weight gain following dosing. At necropsy no external abnormalities were detected. Vascular/inflammatory alteration in lungs, mottling of liver and haemorragic contents in stomach and small intestinal	Stephen F. (2000), JRF report study No. 2566
No guideline, Non-GLP	Rat Wistar 5M + 5F	Aluminium phosphide 0-637.7-1275-2550 Moistened with peanut oil (occlusive conditions, 24 hours)	LD_{50} M+F: 901 mg/kg bw	Temperature of experimental animal room was higher during the study (27-28°C instead of recommended 20±3°C) Observation period limited to 7 days This study should be disregarded since temperature of animal room was much higher than recommended, which most probably make animals much more sensitive to toxic action of aluminium phosphide.	At dose of 637.7 mg/kg bw 1/5M and 1/5F died (day 1 – 1-3 hours), while at dose of 1275 mg/kg bw 4/5M and 4/5 F died (day 1 -24 hour) and all animals died at 2550 mg/kg bw (F: 2x 1-3 hour (day 1), 3x24 hour (day1); M: 1x 1-3 hour (day 1), 4x24 hour (day1). Clinical signs in treated animals on the day of dosing and the day after dosing were lethargy, abdominal breathing, nasal irritation, polyurea and diarrhoea. No signs were observed on the subsequent days up to the end of observation period. All surviving animals	Joshi M. (1998), JRF report study No. 363,27.10

					showed normal body weight gain following dosing.	

Aluminium phosphide displays moderate acute dermal toxicity.

During the public consultation some comments regarding this endpoint were received. Some Member States expressed that they were in support of this classification proposal. One Member State questioned whether it could be possible that the mortalities in this study were due to phosphine being liberated since aluminium phosphide reacts with the moisture in the air and in sweat. If so, the observed mortalities could be secondary to phosphine gas toxicity.

The Rapporteurs consider that it seems unlikely that the mortalities in the dermal toxicity study were due to inhaled phosphine (liberated from AlP) due to the occlusive conditions how the substance was applied to the skin of the animals. However, based on the submitted data it is not totally clear whether occlusive dressing would have prevented phosphine gas from escaping the site of exposure (nasal irritation was observed in one study (Joshi. M. (1998)).

Besides, there is no information showing that the gas is not able to penetrate the skin. The only information available is that the dermal absorption (based on expert judgment as no experimental data are available) of the metal phosphides is at a maximum 10%.

Assuming that: (i) the study followed the OECD guidelines where the occulation was tight and limited the evaporation of the gas, and (ii) without further information excluding ability of phosphine to penetrate the skin, the results of these studies are considered relevant for classification of AlP for acute dermal toxicity.

Comparison with classification criteria

The LD_{50} value obtained from the acute dermal toxicity (LD_{50}: 900 mg/kg bw) is within the range (200-1000 mg/kg bw) for Acute Tox Category 3 H311 under the Regulation (EC) 1272/2008 criteria and within the range (400-2000 mg/kg) for classification as Xn; R21 according to Directive 67/548/EEC criteria. The LD_{50} values of 461.2 mg/kg bw and 901 mg/kg bw were obtained from two other studies performed with AlP, but non-compliant with guidelines, are in support of this hazard class classification.

6.2.3. Acute toxicity: inhalation

This endpoint was not originally covered in the CLH proposal. No classification is currently included for this hazard class in Annex VI and no modification was proposed by the submitting Member State.

However, during the public consultation one Member State proposed an additional classification as Acute Tox. 1, H330 according to Regulation (EC) 1272/2008 and as T+, R26 according to Directive 67/548/EC. According to the Member State, this classification was justified by the LC_{50} = 0.048 mg/l obtained from Roy, B.C. (1998) (phosphine liberated from aluminium phosphide dust). Moreover, two references were cited which reported that phosphine gas is released from inhaled aluminium phosphide dust in the moist air sacs of the lung. Finally, they stated that the draft EFSA Scientific Report (2008) proposed, as well, to classify aluminium phosphide with T+; R26.

PH_3, which is developed following hydrolysis of metalphosphides after contact with water or acids, is very toxic by inhalation. Phosphine itself is classified as T+; R26 Very toxic by inhalation according to Directive 67/548/EC and translated into a minimum classification as Acute Tox. 2*

(inhalation) H330: Fatal if inhaled according to CLP Regulation. However aluminium phosphide is not classified with regard to inhalation toxicity.

Taking into consideration the comments raised during public consultation, that inhalation is a major route of concern due to the intrinsic properties of AlP (EUH029) as a metalphosphide (toxicological mode of action primarily based on effects caused by hydrolysis of phosphine in contact with water or moisture) and that the exposure to AlP dust during several steps of the manufacture process may occur (as it was demonstrated by additional information provided by Schluter, Gutberlet and Holthenrich exposure assessment report (2011)), RAC considered to evaluate further the available acute inhalation toxicity studies using AlP and other metal phosphides based on the grouping of substances and read across approach (REACH, Annex XI, 1.5).

Table 5: Summary of acute inhalation toxicity studies

Method/ Guideline	**Route**	**Species, Strain, Sex, No/group**	**Dose levels (mg/kg bw)**	**PH_3 LC_{50} (ppm) (mg/L air /4h)**	**Calculated LC_{50} of AlP (assuming 100% hydrolysis reaction to PH_3)**	**Reference**
Not mentioned, Non-GLP	Inhalation, whole body, 4 hours exposure to gaseous phosphine	Rat, ChR-CD 6M+0F	PH_3 Dose levels not reported	LC_{50} M: 11 ppm equivalent to (1): 0.015 mg PH_3 /L air	0.02 mg AlP/L	1) Waritz, R.S. and Brown R.M. (1975); Amer. Ind. Hyg. Assoc. J., p 452
No guideline, non GLP	Inhalation, head only exposure chamber Exposure most probably to gaseous phosphine and aerosol of AlP	Rat Wistar, 5M+5F	PH3, generated from aluminium phosphide 0-15.4-26-47 ppm	LC50 M+F: 34.6 ppm equivalent to (1): 0.048 mg PH_3/L	0.08 mg AlP/L	2) Roy, B.C. (1998) TOX2006-215
Similar to OECD 403, Non-GLP	Inhalation, whole body, 1 h exposure to gaseous phosphine generated by reaction of magnesium phosphide and distilled water	Rat, Slc:SD 10M+10F	PH_3, generated from trimagnesium diphosphide 150-165-182-200-220-242 ppm	M+F 204/179 ppm equivalent to (1): 0.29/0.25 mg PH_3/L air (M/F) calculated for 4 hour exposure 0.072mg PH_3/L for males or 51 ppm calculated for 4 hour exposure 0.063mg PH_3/L for females or 44 ppm	0.12mg AlP/L for males 0.11mg AlP/L for females	3) Shimizu, Y. et al. (1982), report no. NRI 82-7489

(1) 1 ppm PH_3 is equivalent to 1.41 µg/L air, density of pure PH_3 (20 °C): (34 g/mol)/(24.1 L/mol) = 1.41 g/L

(2) Assuming an hourly respiratory volume (rat) of 45 L/(h kg bw)

It should be noted that in all these studies the animals were not exposed to aerosol of AlP or trimagnesium phosphide but were exclusively or mostly exposed to phosphine gas from a gas container or a gas generated in the container of metal phosphide being a part of the "dust' generating system. From the studies information, it is not possible to determine the proportion of phosphine gas and metal phosphide aerosol in the inhaled air (Roy B.C. 1998; Shimizu 1982) due to the way phosphine or phosphide aerosols were generated and measured.

In the study by Roy B.C. (1998), the only study in which AlP (dust) has been used and therefore that could be assumed to be the most relevant, it was reported that aluminium phosphide technical powder was loaded into the dust reservoir of the generator system and phosphine gas liberated from

it PH_3 ; the mean concentrations were measured in the breathing zone. Less than 1% of the pre-weight of AlP in the chamber system was converted to phosphine, therefore more than 99% of the pre-weight of AlP had been recovered following the end of the exposure duration. This results indicate that efficiency of hydrolysis of powdered aluminium phosphide in the container by water present as humidity in the air passing through this container is rather low; i.e. 1% of the total mass during 4 hours.

Having in mind that in the Roy study, aluminium from the hydrolyzed AlP has remained in the container and only phosphorus in a form of phosphine was released, the way of aerosol concentration measurement was done was not very precise. Taking into account that loss of weight of AlP powder in the container after 4 hour exposure was much larger than a total mass of the phosphine produced during 4 hours (based on direct measurements) it is highly probable that in the air of the inhalation chamber were present both a phosphine, measured in air by direct monitoring device and AlP dust, not measured and not taken into account when calculating LC50 of that mixture.

The results seem to be in agreement with the hydrolysis rate of AlP formulated products i.e. pellets and tablets (Schmitt, S. 2007) where the liberation of PH_3 starts rapidly (up to 15 % PH_3 release in the first hour) and increases with the humidity (approx. 5 % release at 60 % and approx. 15 % at 90 % humidity after one hour). However, it takes some time (up to 200 hours, for AlP at 60 % humidity) to complete the liberation of PH_3 to 100 %.

However, in case of exposure to AlP dust particles in the workplace at several steps during the manufacture process, as illustrated by Schluter, Gutberlet and Holthenrich exposure assessment report (2011), the inhaled metalphosphide particles will penetrate into the airways and alveoli and will be deposited in moist mucus and respiratory epithelium causing a very quick and complete hydrolysis to phosphine.

Moreover, as referred in EHC 73 (1988), aluminium or magnesium phosphide powder, if inhaled, releases phosphine for absorption on contact with the moist respiratory epithelium. Studies by the inhalation route indicate that both the concentration and duration of exposure are important determinants of acute lethality and that different mammalian species are essentially similar in susceptibility.

Based on these considerations, the LC_{50} values for AlP dust have been calculated by applying a factor of 1.57 (MW AIP/MW PH_3) to the LC_{50} of PH_3 assuming 100% hydrolysis (table 5) Furthermore, RAC considers it to be relevant to classify aerosols of AlP for acute inhalation toxicity.

Comparison with the criteria

The LC_{50} for AlP dust were calculated to be in the range of 0.02 – 0.12 mg/L (Table 5). The classification criteria for acute inhalation toxicity for dusts for category 1 is ATE $\leq$ 0.05 mg/l, thus taking into account the lowest value of LC_{50} for AlP is 0.02mg/L, the substance is proposed to be classified to that category. The other calculated LC_{50} values 0.08 mg/l and 0.12 are only slightly above this cut-off value and are considered to give additional support for the classification. The highest value of 0.12mg/l was obtained in the study (Shimizu,1982) where exposure lasted only for 1 hour and concentration was not measured but calculated based on amount Mg_3P_2 added to a chamber with water. The LC_{50} value of 0.08 mg/L was obtained based on the study of Roy, in which the method of measurement was not very well documented. Thus it was considered that the lowest LC_{50} value of 0.02 mg/L obtained from the Waritz and Brown study (1975) is the most convenient to be used for the classification. This value is in support of classification as acute

inhalation toxic category 1 (dust) - H330 Fatal if inhaled (ATE ≤ 0.05) within CLP criteria and to category T^+ R26 Very toxic for inhalation (≤ 0.5mg/l/4h) according to DSD criteria.

Additional precautionary statement

The Rapporteurs recommend to add P260 - Do not breath dust/fume/gas/mist/vapours/spray that result from S22 – Do not breath dust proposed by Directive 67/548/EEC, as proposed by the dossier submitter but not translated to a P statement.

Recommendation regarding phosphine classification

According to the Rapporteurs, phosphine, which is currently classified Acute Tox. 2* - H330 (and T+, R26) should be reclassified as Acute Tox. 1 – H330 within CLP, having in mind that the LC_{50} of phosphine from three studies in a range 11 – 51 ppm is well below the guidance values of 100 ppm for acute inhalation toxicity hazard category 1 for toxic gases. While the classification according the DSD, T+, R26 is appropriate since all LC_{50} values are in a range of 0.015 – 0.072mg/l which is well below the DSD guidance value ≤0.5mg/l/4h for this category.

Furthermore, it is recommended to add to the labelling, "P260 - Do not breath dust/fume/gas/mist/vapours/spray that translates from S22 – Do not breath dust" according to Directive 67/548/EEC, as proposed by the dossier submitter.

6.2.4. Acute toxicity: other routes

No data are available.

6.2.5. Summary and discussion of acute toxicity

Acute oral toxicity

Aluminium phosphide was highly toxic when administered orally to rats and mice. LD_{50} values of 8.7 and 14.8 mg/kg bw were obtained from two acute oral toxicity studies, in rat and mice respectively.

The LD_{50} values (range from 8.7 to 14.8 mg/kg bw) obtained from these studies are within the range (5-50 mg/kg bw) for classification as Acute Tox 2 H300 under the Regulation (EC) 1272/2008 criteria and are below the value of 25 mg/kg bw established for the classification as T+; R28 Very toxic if swallowed according to Directive 67/548/EEC criteria.

All comments received during the public consultation were in support of this classification proposal.

In conclusion, the minimum classification as "Acute Tox. 2", H300 is confirmed.

Acute dermal toxicity

Aluminium phosphide displayed moderate acute dermal toxicity in a rat study compliant with OECD guideline 402. The LD_{50} (14d) was calculated as 900 mg/kg bw for both sexes.

The LD_{50} value obtained from the acute dermal toxicity (LD_{50}: 900 mg/kg bw) is within the range (200-1000 mg/kg bw) for Acute Tox Category 3 H311 under the Regulation (EC) 1272/2008 criteria and within the range (400-2000 mg/kg) for classification as Xn; R21 according to Directive 67/548/EEC criteria. The LD_{50} values of 461.2 mg/kg bw and 901 mg/kg bw obtained from two other studies performed with AIP, but non-compliant with guidelines are in support of this hazard class classification.

According to RAC, the additional classification/labelling for acute dermal toxicity is justified.

Acute inhalation toxicity

PH_3, which is developed following hydrolysis of metal phosphides after contact with water or acids, is very toxic by inhalation. It is classified according to Annex 1 of Directive 67/548/EEC as T+; R 26, very toxic by inhalation and translated according to Regulation (EC) 1272/2008 into the minimum classification Acute Tox. 2*, H330 Fatal if inhaled. However aluminium phosphide itself is not classified with regard to inhalation toxicity.

From the three acute inhalation studies presented in this Background Document, it appeared that the actual exposure was measured in relation to phosphine gas (PH_3).

The LC_{50} for AlP dust was calculated by applying a factor of 1.57 (MW AIP/MW PH_3) to the LC_{50} of PH_3 assuming 100% hydrolysis and found to be in the range of 0.02 – 0.12 mg/L. Due to deficiencies reported in Roy, B.C. (1998) and Shimizu, Y. et al. (1982) studies, the Rapporteurs considered that the LC_{50} value of 0.02 mg/L obtained from the Waritz and Brown study (1975) is the most convenient to be used for classification. This value is in support of classification as acute inhalation toxic category 1 (dust) - H330 Fatal if inhaled (ATE $\leq$ 0.05) within CLP criteria and to category T^+ R26 Very toxic for inhalation according to DSD criteria. The other calculated LC_{50} values 0.08 mg/l and 0.12 mg/l are only slightly above this cut-off value and are considered to give additional support for the classification.

6.3. Irritation

6.3.1. Skin

This endpoint is not covered in this proposal. No classification is included for this hazard class in Annex VI and no modification is currently proposed.

6.3.2. Eye

This endpoint is not covered in this proposal. No classification is included for this hazard class in Annex VI and no modification is currently proposed.

Respiratory tract

No experimental data are available. No classification is included for this hazard class in Annex VI and no modification is currently proposed.

6.3.3. Summary and discussion of irritation

No modification of the existing classification is proposed.

6.4. Corrosivity

No modification of the existing classification is proposed.

6.5. Sensitisation

This endpoint is not covered in this proposal. No classification is included for this hazard class in Annex VI and no modification is currently proposed.

6.6. Repeated dose toxicity

6.6.1. Repeated dose toxicity: oral

This endpoint is not covered in this proposal. No classification is included for this hazard class in Annex VI and no modification is currently proposed.

6.6.2. Repeated dose toxicity: inhalation

This endpoint is not covered in this proposal. No classification is included for this hazard class in Annex VI and no modification is currently proposed.

6.6.3. Repeated dose toxicity: dermal

No experimental animal data are available. No classification is included for this hazard class in Annex VI and no modification is currently proposed.

6.6.4. Other relevant information

There is no relevant information. No classification is included for this hazard class in Annex VI and no modification is currently proposed.

6.7. Mutagenicity

This endpoint is not covered in this proposal. No classification is included for this hazard class in Annex VI and no modification is currently proposed.

6.8. Carcinogenicity

This endpoint is not covered in this proposal. No classification is included for this hazard class in Annex VI and no modification is currently proposed.

6.9. Toxicity for reproduction

This endpoint is not covered in this proposal. No classification is included for this hazard class in Annex VI and no modification is currently proposed.

6.10. Other effects

6.10.1. Neurotoxicity

This endpoint is not covered in this proposal. No classification is included for this hazard class in Annex VI and no modification is currently proposed.

6.11. Derivation of DNEL(s) or other quantitative or qualitative measure for dose response

Not relevant for this type of dossier.

Environmental hazard assessment
No modifications of existing environmental classification and labelling is proposed.

JUSTIFICATION THAT ACTION IS REQUIRED ON A COMMUNITY-WIDE BASIS

There was agreement on Community Level that for active ingredients in biocidal and plant protection products harmonised C & L should be sought for all phys.-chemical., toxicological, and ecotoxicological endpoints addressed by the corresponding legislations.

OTHER INFORMATION

The data and conclusions presented here have already undergone a peer review by experts from the company applying for annex I inclusion, the European Member States, and the European Commission (ECB/EFSA) in the context of the inclusion procedure for aluminium phosphide into annex I of Dir. 98/8/EC and annex I of Dir. 91/414/EEC, respectively.

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7. ANNEX 1

Summary record of the TC C&L meeting

EUROPEAN COMMISSION
DIRECTORATE GENERAL JRC
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
Unit: Toxicology and Chemical Substances
European Chemicals Bureau

ECBI/07/00 Rev. 3
29 August 2000

SUMMARY RECORD

Meeting of the Commission Working Group on the Classification and Labelling of Dangerous Substances

Pesticides

ECB Ispra, 17-19 November 1999

The meeting was divided into three sessions:

Environmental Effects (Agenda Points 2-11)	17 November, 9.30 – 15.30
Joint Session (Agenda Points 12-16)	17 November, 16.00 – 17.30
Health Effects (Agenda Points 17-21)	18 November, 9.00 – 19 November, 15.30

Dr. Berggren and **Dr. Fassold** chaired the meeting.
A copy of the participants' list is attached.

ENVIRONMENTAL EFFECTS

1. Adoption of the Draft Agenda (Environmental Effects)
ECBI/44/99 - Rev. 4 Revised Draft Agenda of the meeting in Ispra 17-19 November 1999

The Draft Agenda was adopted. A copy of the agenda is attached.

2. Report from the meeting on the classification criteria for the terrestrial environment in Ispra, 16 November

A meeting on classification criteria for the terrestrial environment took place the day prior to this meeting. Dr Berggren briefly reported back from that meeting. Both experts from the Environment and the Pesticides Group had been invited to participate. The document ECBI/19/99 Add. 8, a draft proposal for classification criteria prepared by a small working group during the inter-session period since the September meeting, had been the basis for the discussions. The Group has agreed that it would be useful to define a general R-phrase to address toxicity to terrestrial organisms. Furthermore, a majority of the Group preferred to define 3 toxicity levels for acute toxicity for terrestrial organisms, as is the case for aquatic organisms. No objections were raised to use earth-dwelling organisms to identify the different toxicity levels but it was left to further discussion, which other species above soil would

Dalapon-sodium is currently not in Annex I. Current classification of dalapon acid, 607-162-00-7, in Annex I (15./25.ATP): Xn; R22 : Xi; R38-41 : R52-53.

On suggestion by **F** dalapon-sodium was introduced on the agenda. However both **F** and **A** stated that no data was found on the substance. It was then agreed that it would be possible to classify on the basis of the data available on the acid. There was support from toxicity studies to classify with R52 and no data on biodegrability was available, why it was agreed to classify dalapon-sodium with R52-53.

Conclusion:
The **Group** agreed to classify **dalapon-sodium** with **R52-53** for environmental effects (**R-phrases: 52/53** and **S-phrases: 61**). The health effects were still to be discussed, but as soon as concluded the proposal will be sent to DG ENV for inclusion in a future TPC.

5. Review of classification pesticides listed in Annex I with respect to the Environment.

5.1. Continued discussion of Pesticides from the 015 group (Phosphorus compounds)

Calcium phosphide (015-003-00-2).
Proposal: F; R15/29 : T+; R28 : [environment: n. c. due to lack of data ?].

ECBI/27/99	D, Classification proposals for the phosphides on the agenda of the May 99 meeting
ECBI/53/99 – Add. 20	A, proposals concerning environmental effects for the Pesticides meeting in Nov. 1999

Current classification in Annex I (12.ATP): F; R15/29 : T+; R28. The substance had not been included in the re-visits for the environment update. – For the May 1999 meeting, the **D** search for information on environmental effects of calcium phosphide had been unsuccessful, but classification proposals and information were available from **D** for two phosphides with P-code numbers (aluminium and zinc). On the question whether calcium phosphide was used at all, **A** and **Industry** related that it was registered as a pesticide in Austria, in Germany and in Luxembourg. **A** wanted to search for data until the next meeting. The **Group** confirmed the current classification for physico-chemical and health effects with F; R15/29 : T+; R28.

A did not find any additional data, and it was agreed to classify the calcium phosphide on the basis of the phosphine that would be the main metabolite. Phosphine is very toxic but not stable in water. The classification was then agreed to be N; R50 for environmental concerns.

Conclusion:
The **Group** agreed to classify **calcium phosphide** with **F; R15/29 - T+; R28 – N; R50** (**Symbols: F, T+, N; R-phrases: 15/29-28-50** and **S-phrases: (1/2-)22-43-45-61**). This proposal will be sent to **DG ENV** for inclusion in a future TPC.

Aluminium phosphide (P008), (015-004-00-8).
Proposal: F; R15/29 : T+; R28 : R32 : N; R50[/53].

ECBI/27/99	D, Classification proposals for the phosphides on the agenda of the May 99 meeting
ECBI/27/99 – Add. 1	AgrEvo, Information on Aluminium, Magnesium and Zink phosphide
ECBI/53/99 - Add. 20	A, proposals concerning environmental effects for the Pesticides meeting in Nov. 1999
ECBI/53/99 - Add. 39	EL, Classification proposals for the environment, aluminium and magnesium phosphide

Current classification in Annex I (12.ATP): F; R15/29 : T+; R28 : R32. The substance had not been included in the re-visits for the environment update. - In May 99, the **Group** agreed to classify aluminium phosphide with

Pesticides WG meeting, 17 - 19 November 1999

F; R15/29 : T+; R28 : R32 : N; R50. Discussion of the requirement to classify with R53 was to be continued after the **Environment Group** had reached a conclusion on aluminium salts.

On basis of phosphine data it was agreed not to classify with R53, as phosphine is not persistent.

Conclusion:
The **Group** agreed to classify **aluminium phosphide** with **F; R15/29 - T+; R28 - R32 - N; R50** (**Symbols: F, T+, N; R-phrases: 15/29-28-32-50** and **S-phrases: (1/2-)3/9/14-30-36/37-45-61**). This proposal will be sent to **DG ENV** for inclusion in a future TPC.

Magnesium phosphide (015-005-00-3).
Proposal: F; R15/29 : T+; R28 : [environment: n. c. due to lack of data ?].

ECBI/27/99	D, Classification proposals for the phosphides on the agenda of the May 99 meeting
ECBI/27/99 – Add. 1	AgrEvo, Information on Aluminium, Magnesium and Zink phosphide
ECBI/53/99 - Add. 20	A, proposals concerning environmental effects for the Pesticides meeting in Nov. 1999
ECBI/53/99 - Add. 39	EL, Classification proposals for the environment, aluminium and magnesium phosphide

Current classification in Annex I (12.ATP): F; R15/29 : T+; R28. – The **D** data search for the May 99 meeting had not been successful for magnesium phosphide. **Industry** stressed that it was used as a rodenticide and registered in nearly all Member States. The **Group** confirmed F; R15/29 : T+; R28. Classification for the environment was postponed to the next meeting when, hopefully, data would be available from the voluntary **P** search.

In analogy with calcium and aluminium phosphide, magnesium phosphide was classified on the basis of the main metabolite phosphine, with N; R50.

Conclusion:
The **Group** agreed to classify **magnesium phosphide** with **F; R15/29 - T+; R28 - N; R50** (**Symbols: F, T+, N; R-phrases: 15/29-28-50** and **S-phrases: (1/2-)22-43-45-61**). This proposal will be sent to **DG ENV** for inclusion in a future TPC.

Zinc phosphide (P197), (015-006-00-9).
Proposal: F; R15/29 : T+; R28 : R32 : [R52-53].

ECBI/27/99	D, Classification proposals for the phosphides on the agenda of the May 99 meeting
ECBI/27/99 – Add. 1	AgrEvo, Information on Aluminium, Magnesium and Zink phosphide
ECBI/53/99 - Add. 20	A, proposals concerning environmental effects for the Pesticides meeting in Nov. 1999

Current classification in Annex I (12.ATP): F; R15/29 : T+; R28 : R32. – In May 1999, the **Group** agreed to classify zinc phosphide with F; R15/29 : T+; R28 : R32, and *provisionally* agreed R52-53. Discussion of classification for environmental effects was to be continued after the **Environment Group** had considered zinc phosphide in parallel to other zinc compounds.

In accordance with the **A** proposal and the classification of the other phosphides, zinc phosphide was classified with N; R50 based on the toxicity of phosphine to fish. As suggested by **FIN** supported by **NL**, the **Group** agreed to classify with R53 as well, which corresponds to the classification of other zinc compounds in Annex I.
It was requested to classify phosphine for inclusion in Annex I. Phosphine will be listed at the next Pesticides agenda to be discussed both for health and environment effects.