Food and Agriculture Organization
of the United Nations

FAO SPECIFICATIONS AND EVALUATIONS

FOR AGRICULTURAL PESTICIDES

PHOSMET

O,O-dimethyl S-phthalimidomethylphosphorodithioate

Note: Evaluation Report only

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PHOSMET

DISCLAIMER[1]

FAO specifications are developed with the basic objective of promoting, as far as practicable, the manufacture, distribution and use of pesticides that meet basic quality requirements.

Compliance with the specifications does not constitute an endorsement or warranty of the fitness of a particular pesticide for a particular purpose, including its suitability for the control of any given pest, or its suitability for use in a particular area. Owing to the complexity of the problems involved, the suitability of pesticides for a particular purpose and the content of the labelling instructions must be decided at the national or provincial level.

Furthermore, pesticides which are manufactured to comply with these specifications are not exempted from any safety regulation or other legal or administrative provision applicable to their manufacture, sale, transportation, storage, handling, preparation and/or use.

FAO disclaims any and all liability for any injury, death, loss, damage or other prejudice of any kind that may arise as a result of, or in connection with, the manufacture, sale, transportation, storage, handling, preparation and/or use of pesticides which are found, or are claimed, to have been manufactured to comply with these specifications.

Additionally, FAO wishes to alert users to the fact that improper storage, handling, preparation and/or use of pesticides can result in either a lowering or complete loss of safety and/or efficacy.

FAO is not responsible, and does not accept any liability, for the testing of pesticides for compliance with the specifications, nor for any methods recommended and/or used for testing compliance. As a result, FAO does not in any way warrant or represent that any pesticide claimed to comply with a FAO specification actually does so.

[1] This disclaimer applies to all specifications published by FAO.

INTRODUCTION

FAO establishes and publishes specifications* for technical material and related formulations of agricultural pesticides, with the objective that these specifications may be used to provide an international point of reference against which products can be judged either for regulatory purposes or in commercial dealings.

From 1999 onward, the development of FAO specifications follows the **New Procedure**, described first in the 5th edition of the "Manual on the development and use of FAO specifications for plant protection products" and later in the 1st edition of "Manual for Development and Use of FAO and WHO Specifications for Pesticides" (2002) - currently available as 3rd revision of the 1st edition (2016) - , which is available only on the internet through the FAO and WHO web sites.

This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package, the procedure and evaluation applied by FAO and the Experts of the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS). [Note: prior to 2002, the Experts were of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent, which now forms part of the JMPM, rather than the JMPS.]

FAO Specifications now only apply to products for which the technical materials have been evaluated. Consequently, from the year 1999 onwards the publication of FAO specifications under the **New Procedure** has changed. Every specification consists now of two parts namely the specifications and the evaluation report(s):

Part One: **The Specification** of the technical material and the related formulations of the pesticide in accordance with chapters 4 to 9 of the "Manual on development and use of FAO and WHO specifications for pesticides".

Part Two: The Evaluation Report(s) of the pesticide, reflecting the evaluation of the data package carried out by FAO and the JMPS. The data are provided by the manufacturer(s) according to the requirements of chapter 3 of the "FAO/WHO Manual on Pesticide Specifications" and supported by other information sources. The Evaluation Report includes the name(s) of the manufacturer(s) whose technical material has been evaluated. Evaluation reports on specifications developed subsequently to the original set of specifications are added in a chronological order to this report.

FAO specifications developed under the **New Procedure** do not necessarily apply to nominally similar products of other manufacturer(s), nor to those where the active ingredient is produced by other routes of manufacture. FAO has the possibility to extend the scope of the specifications to similar products but only when the JMPS has been satisfied that the additional products are equivalent to that which formed the basis of the reference specification.

Specifications bear the date (month and year) of publication of the current version. Evaluations bear the date (year) of the Meeting at which the recommendations were made by the JMPS.

* NOTE: PUBLICATIONS ARE AVAILABLE ON THE INTERNET AT (http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmps/ps-new/en/) OR IN HARDCOPY FROM THE PLANT PROTECTION INFORMATION OFFICER.

PHOSMET

INFORMATION

ISO common name phosmet (ISO 1750, published)

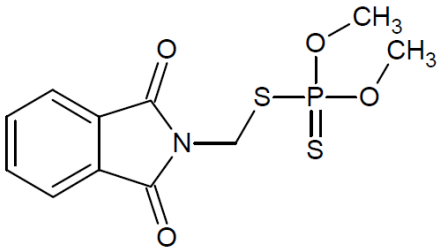
Chemical names

IUPAC *O,O*-dimethyl *S*-phthalimidomethylphosphorodithioate

CA *S*-[(1,3-dihydro-1,3-dioxo-2*H*-isoindol-2yl)methyl] *O,O*-dimethyl phosphorodithioate

Synonyms none

Structural formula



Molecular formula $C_{11}H_{12}NO_4PS_2$

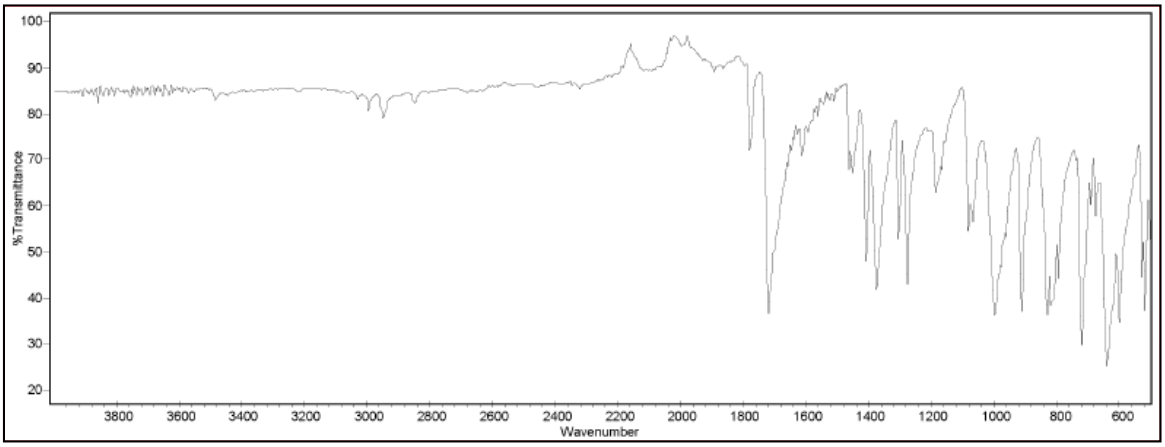
Relative molecular mass 317.3

CAS Registry number 732-11-6

CIPAC number 318

Identity tests Retention time in HPLC-UV analysis or IR spectroscopy.

Infrared spectrum of phosmet TC



PART TWO

EVALUATION REPORT

PHOSMET

2019 **FAO/WHO evaluation report** based on submission of information

PHOSMET

FAO/WHO EVALUATION REPORT 318 / 2019

Recommendations

The Meeting recommended that:

(I) The evaluation report for phosmet should be published based on the data package submitted.

(II) The FAO specifications for the TC, WP and EC can be published subject to the availability of the collaborativley tested analytical method and satisfactory clarification of some open points.

Appraisal

Phosmet is an organophosporous insecticide, acting by inhibition of acetyl cholinesterase (AChE). Phosmet is not systemic nor translaminar in plants and acts by contact, ingestion and inhalation. It is not under patent.

The Meeting considered data and supporting information submitted in 2017 by Gowan Company (Gowan), for the development of new FAO specifications for phosmet TC, EC, WP and WG.

Phosmet has been evaluated by the WHO IPCS in 2004 and by JMPR in 1994 for toxicity and in 1997 for residues. The ADI of 0-0.01 mg/kg bw was established in 1994. In a 2003 amendment on phosmet, JMPR concluded "The Meeting established an acute RfD of 0.2mg/kgbw based on the NOAEL of 2mg/kg bw (the highest dose tested) for inhibition of erythrocyte cholinesterase in men and women, and a safety factor of 10." The IPCS hazard classification of Phosmet is: moderately hazardous, class II.

The supporting data on phosmet TC, WP, WG and EC formulations were broadly in accordance with the requirements of the third revision of the first edition of the Manual on development and use of FAO and WHO specifications for pesticides [FAO/WHO Manual, 2016].

The Meeting was provided with commercially confidential information on the manufacturing process and batch analysis data on all impurities present at or above 1 g/kg and their manufacturing limits in the TC. Mass balances were high (98.9 – 100.07 % in the batch analysis data). The proposed minimum purity of phosmet in the TC was 950 g/kg, lower than the calculated limit based on the 5-batch analysis data. Gowan stated that the proposed limit was in line with the limit approved in the EU, and provided analytical data on their product of 3 years, and the results were in line with their proposed manufacturing limit.

Among the various impurities identified and quantified, the Meeting concluded that the following impurities should be considered as potentially relevant or relevant:

- *iso*-phosmet and phosmet-oxon
- water with a limit of 3 g/kg

The Meeting noted, that *iso*-phosmet and phosmet-oxon are more potent AChE -inhibitors than phosmet itself. Using the estimation of the maximum acceptable levels with the equation provided in Appendix H of the Manual would result in a tolerable content of 76 g/kg for iso-phosmet and of 16.6 g/kg for phosmet-oxon, respectively, to keep the increase in hazard expressed as AChE inhibition below 10 %.

Gowan proposed to set the maximum actual limits for these two impurities at 0.8 and 0.4 g/kg for the oxon and *iso*-phosmet in the TC, respectively. As the levels of *iso*-phosmet and phosmet-oxon may increase in storage, the limits for these two impurities in EC, WP and WG, the control limits for isophosmet was 70 g/kg of phosmet found in the formulation, which was not in accordance with the TC specification, and the proposer stated that based on available toxicity data and the manual, the upper limit for iso-phosmet should be 70 g/kg.

Furthermore, the residues of an aromatic solvent used in the manufacturing process were suggested to be relevant at 1 g/kg, yet the Meeting concluded that at these levels the residues of the solvent are deemed to be non-relevant. In addition, the Meeting, based on the manufacturing route, hypothesized on the possible occurrence of trimethyl phosphate and sulfo-TMPP (*O,O,O',O'*-tetramethyl dithiopyrophosphate) in the finished TC. Gowan explained, that that based on their manufacturing route these impurities were not possible to occur. The explanation was accepted by the Meeting.

The identity tests for phosmet rely on comparing the retention times of the sample and an authentic phosmet standard using HPLC method, and by IR spectroscopy.

A letter of access has been issued by Gowan to allow the Spanish regulatory authority to confirm that the confidential data on the manufacturing process and declaration of composition submitted to the FAO were the same as those submitted to the national regulatory authority. The Spanish authority has been contacted, but the confirmation is yet outstanding.

Phosmet is a white crystalline solid with a melting point of 72°C (TC). Phosmet is moderately volatile with a vapour pressure of 6.5 x 10^{-5} Pa at 25 °C. It has a water solubility of 15.2 g/l at 20 °C (pH 4.4), does not dissociate and has an octanol/water partition coefficient of 2.8. The pH dependency of the water solubility could not be tested at higher pH-values as phosmet rapidly hydrolyses at higher pH values. It is readily soluble in most organic solvents. Phosmet is hydrolysed at pH 5 and 7 and 25°C , and rapidly at pH 9 and 25°C. Photolytic half life was determined to be 4.5 days at 25°C at pH 5 in aqueous media.

The analytical methods for the determination of the active ingredient in phosmet technical, WG and WP were reversed-phase HPLC with UV detection, an in-house method validated in

accordance with EU SANCO/3030/99. This method has not yet been collaboratively validated by CIPAC. The proposer published an info sheet for CIPAC collaborative trial, in which methods for TC, WG and EC were included, but not WP. The proposer later stated that the CIPAC collaborative trial was postponed.

The impurities in the TC were determined by HPLC-UV for TC, WG and WP, and by LC-MS/MS for EC. Methods for the impurities were properly in-house validated but not peer validated. Water was determined using Karl-Fischer methods separately. The proposer has published an info sheet for a peer validation for the relevant impurity method. The proposer later stated that the CIPAC collaborative trial was suspended with no definite date.

Test methods for determination of physico-chemical properties of the TC, EC, WG and WP were OECD and CIPAC.

The hazard data included acute, sub-acute and chronic toxicity, including carcinogenicity and teratogenicity, genotoxicity and ecotoxicology, derived from the technical material manufactured by the proposer.

The Ames tests, the sister chromatid exchange (SCE) test in mammalian cells and in vitro mammalian cell gene mutation - Thymidine kinase (TK) locus (without metabolic activation, -S9) gave positive results, but in vitro mammalian cell gene mutation - Thymidine kinase (TK) locus (+S9), in vitro mammalian chromosome aberration, in vivo micronucleus test and in vivo unschedulted DNA synthesis tests (UDS) test gave negative results.

The draft specification for TC, EC, WP and WG were essentially in accordance with the requirements of the FAO/WHO Manual and were supported by appropriate studies.

TC: The Meeting questioned the relevance of water and pH, and the proposer set a limit for water at 3 g/kg. The meeting further questioned whether a pH clause should be added to maintain the stability of the active ingredient, but no response was received from the proposer.

EC, WP and WG: The method for persistent foam was CIPAC MT 47.2, which has been replaced by MT 47.3. The proposer submitted a comparison between MT 47.2 and 47.3 and argued that results obtained using MT 47.2 remain valid even when using MT 47.3. The proposer revised the specification to change the method to MT 47.3.

EC: The Meeting questioned the applicability of the clauses of water content and pH value (instead of pH range). The specification for emulsion stability and re-emulsification was not proposed, and the proposer revised the EC specification to include the clause. The content of iso-phosmet was not controlled after accelerated storage. The proposer has submitted revised specification, which is in line with the Manual. The accelerated storage test is at 54 ℃ for 14 days, however supporting data was obtained at 40℃ for 8 weeks.

WP: The Meeting questioned the applicability of the clauses of water content and pH value (instead of pH range). The content of iso-phosmet was not controlled after accelerated storage. The proposer has submitted revised specification, which is in line with the Manual.

SUPPORTING INFORMATION
FOR
EVALUATION REPORT 318/2019

USES

Phosmet is an organophosporous insecticide acting by inhibition of acetyl cholinesterase (AChE). Phosmet controls a wide variety of pests in agriculture such as *Lepidoptera*, *Coleoptera*, *Thysanoptera* and *Hemiptera*. Phosmet is not systemic nor translaminar in plants and acts by predominantly by contact, but also through ingestion and inhalation.

IDENTITY OF THE ACTIVE INGREDIENT

ISO common name phosmet (ISO 1750, published)

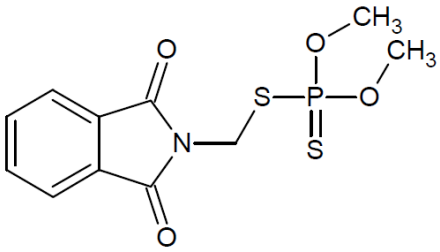
Chemical names

IUPAC *O,O*-dimethyl *S*-phthalimidomethylphosphorodithioate; *N*-(dimethoxyphosphinothioylthiomethyl)phthalimide

CA S-[(1,3-dihydro-1,3-dioxo-2H-isoindol-2yl)methyl] O,O-dimethyl phosphorodithioate

Synonyms none

Structural formula



Molecular formula	$C_{11}H_{12}NO_4PS_2$
Relative molecular mass	317.3
CAS Registry number	732-11-6
CIPAC number	318
Identity tests	Retention time in HPLC-UV analysis or IR spectroscopy.

Infrared spectrum of phosmet TC

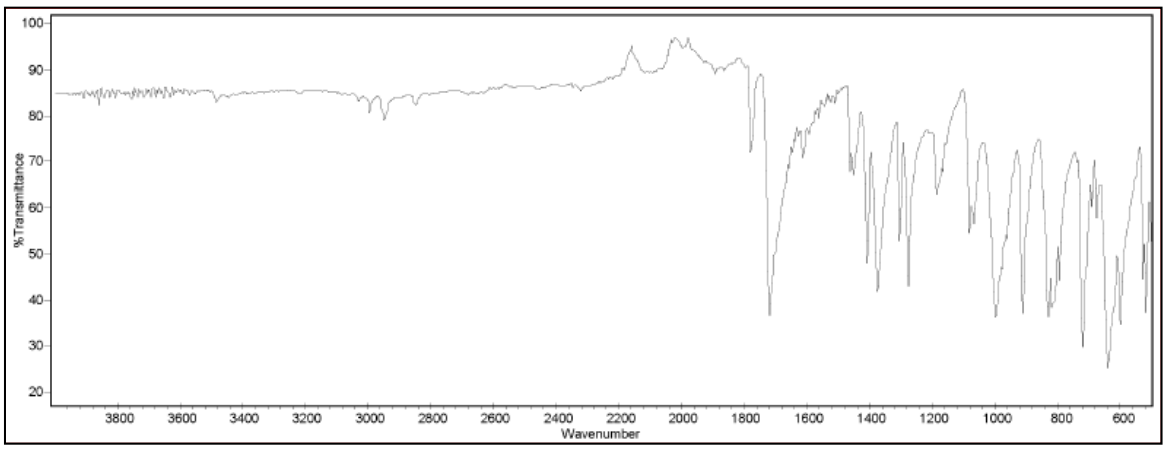


Table 1. Physico-chemical properties of pure phosmet

Parameter	Value(s) and conditions	Purity %	Method reference (and technique if the reference gives more than one)	Study number (Doc. No.)
Vapour pressure	$6.5*10^{-5}$ Pa at 25 °C	99.8	OECD 104	181-004
Melting point.	72 °C	100	EEC A.2 OECD 103	112-001
Temperature of decomposition	208.5 °C	100	EEC A.2 OECD 103	112-001
Solubility in water	15.2 g/l at 20 °C at pH 4.4	100	EEC A.6	114-003
Octanol/water partition coefficient	log P_{OW} = 2.8 at 20 °C at pH 7.5	99.7	EEC A.8 OECD 107	114-004
Hydrolysis characteristics (half lifes)	7.5 days at 25 °C at pH 5 50 hours at 40 °C at pH 5 7.8 hours at 25 °C at pH 7 140.7 min at 40 °C at pH 7 4.5 min at 25 °C at pH 9 1.5 min at 40 °C at pH 9	98	US EPA Pesticide Assessment Guideline	711-001
Photolysis characteristics	Test solutions were exposed in a photolysis chamber equipped with a xenon arc lamp (radiation intensity 158 W/m^2) for up to 14 days on an alternating 12-hour light and dark cycle. Half-life: 4.5 days at 25°C at pH 5	97.9	US EPA Pesticide Assessment Guideline	711-001
Dissociation characteristics	Does not dissociate	nr	nr	-
Solubility in organic solvents	50 - 57 g/l xylene at 20 °C 57 - 67 g/l ethyl acetate at 20 °C 143 - 167 g/l acetone at 20 °C 400 - 500 g/l xylene 1,2-dichloroethane at 20 °C 29.2 g/l methanol at 20 °C 1.04 g/l heptane at 20 °C	97	CIPAC MT 181 CIPAC MT 157	119-001

Table 2. Chemical composition and properties of phosmet technical material (TC)

Manufacturing process, maximum limits for impurities ≥ 1 g/kg, 5 batch analysis data	Confidential information supplied and held on file by FAO. Mass balances were 98.9 – 100.7 % and percentages of unknowns were 0.5 – 0.6 %.
Declared minimum phosmet content	950 g/kg
Relevant impurities ≥ 1 g/kg and maximum limits for them	None
Relevant impurities **<** 1 g/kg and maximum limits for them:	phosmet-oxon: 0.8 g/kg *iso*-phosmet: 0.4 g/kg
Stabilisers or other additives and maximum limits for them:	None

Parameter	Value and conditions	Purity %	Method reference	Study number (Doc. No.)
Melting temperature range of the TC and/or TK	66 - 69 °C	94.3	EPA (1982), section 63-5 OECD 102	181-004
Solubility in organic solvents	50 – 57 g/l xylene at 20 °C 57 – 67 g/l ethyl acetate at 20 °C 143 – 167 g/l acetone at 20 °C 400 – 500 g/l 1,2-dichloroethane at 20 °C 29.2 g/l methanol at 20 °C 1.04 g/l heptane at 20 °C	97	CIPAC MT 181 CIPAC MT 157	119-001

HAZARD SUMMARY

Phosmet has been evaluated by the WHO IPCS in 2004.

The IPCS hazard classification of Phosmet is: moderately hazardous, class II.

FORMULATIONS AND CO-FORMULATED ACTIVE INGREDIENTS

The main formulation types available are WP, WG and EC formulations.

Phosmet is not co-formulated with other pesticides in these formulations. These formulations are registered and sold in many countries in Europe, Middle East, Africa and Americas, including e.g.:

Greece, Spain, Egypt, Israel, Turkey, Tunisia, Morocco, South Africa, Argentina, Brazil, Chile, Uruguay, Mexico, Canada and USA, .

METHODS OF ANALYSIS AND TESTING

At present, no collaboratively validated analytical method for determination of phosmet in TC and formulated products is available. An in-house method for the active ingredient (including identity tests) was submitted.

The active substance Phosmet is determined by reversed phase HPLC, using UV detection at 254 nm. The method has been submitted in support of the supplementary dossier of Phosmet for the renewal of approval in EU.

The methods for determination of impurities are based on HPLC-MS/MS.

Test methods for determination of physic-chemical properties of the technical active ingredient were OECD and EEC methods, while those for the formulations were CIPAC methods, as indicated in the specifications.

PHYSICAL PROPERTIES

The physical properties, the methods for testing them and the limits proposed for the WP, WG and EC formulations, comply with the requirements of the FAO/WHO Manual (2016 edition, 3rd revision, 2016).

CONTAINERS AND PACKAGING

No special requirements for containers and packaging have been identified.

EXPRESSION OF THE ACTIVE INGREDIENT

The content of phosmet is expressed as phosmet.

ANNEX 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER

Toxicological summaries

Notes.

(i) The proposer confirmed that the toxicological and ecotoxicological data included in the summary below were derived from phosmet having impurity profiles similar to those referred to in the table 2 above.

(ii) The conclusions expressed in the summary below are those of the proposer, unless otherwise specified.

Table 3. Toxicology profile of phosmet technical material, based on acute toxicity, irritation and sensitization.

Species	**Test**	**Purity %** Note[2]	**Guideline, duration, doses and conditions**	**Result**	**Study number (Doc. No.)**
Rat –males	oral	95.4	EEC Directive, similar to OECD 401, single oral dose, 70, 100, 140, 200, 280, 400 and 560 mg/kg bw; Phosmet in 1% aqueous carboxymethylcellulose [GLP study, 1998]	LD_{50} = 230 mg/kg bw (151 – 347 mg/kg bw)	521-047
Rat – females	oral	95.4	EEC Directive, similar to OECD 401, single oral dose, 230 mg/kg bw; Phosmet in 1% aqueous carboxymethylcellulose, dose induced a mortality of 50 % [GLP study, 1998]	LD_{50} = 230 mg/kg bw.	
Rat – males	oral	96.1	EPA guidelines for Registering Pesticides, similar to OECD 401, single oral dose, 60, 75, 100, 115, 130, 150, and 170 mg/kg bw; Phosmet in polyethylene glycol 5% (v/v) in corn oil [non-GLP study, 1978]	LD_{50} = 113 mg/kg bw (101 – 127 mg/kg bw)	521-046
Rat – females	oral	96.1	EPA guidelines for Registering Pesticides, similar to OECD 4011, single oral dose, 75, 100, 115, 130, 150, 170 and 175 mg/kg bw; Phosmet in polyethylene glycol 5% (v/v) in corn oil [non-GLP study, 1978]	LD_{50} = 113 mg/kg bw (98 – 130 mg/kg bw)	

[2] Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

Species	**Test**	**Purity %** Note[2]	**Guideline, duration, doses and conditions**	**Result**	**Study number (Doc. No.)**
Rat – males/females	dermal	92.7	Similar to OECD 402, single topical dose, 1000 mg/kg bw; Phosmet in corn oil [non-GLP study, 1998]	LD_{50} > 1000 mg/kg bw	522-004
Rabbit – males/females	dermal	96.1	EPA guidelines for Registering Pesticides, similar to OECD 402, single topical dose, 5000 mg/kg bw; Phosmet in corn oil [non-GLP study, 1978]	LD_{50} > 5000 mg/kg bw	523-001
Rat – males/females	inhalation	92.5	Performed prior to OECD GL, similar to OECD 403, exposure to a saturated vapour atmosphere Phosmet for 4 hours, calculated concentration of 0.152 mg/L [non-GLP study 1977]	LC_{50} (4h) > 0.152 mg/L	523-001
Rat – males/females	inhalation	70.2	US EPA 81-3 GL, 0, 0.61, 0.66 and 3.69 mg/L for 4 hours, Formulation IMIDAN 70 WP (wettable powder).	LC_{50} (4h) = 1.6 mg/L	528-016
Rabbit – sex not indicated	skin irritation	96.1	EPA guidelines for Registering Pesticides, similar to OECD 404, single dermal treatment with 0.5 g Phosmet for 24 hours [non-GLP study 1978]	Not skin irritating	521-046
Rabbit – sex not indicated	eye irritation	96.1	EPA guidelines for Registering Pesticides, similar to OECD 405, single treatment of eye with 0.1 g Phosmet with/without washing [non-GLP study 1978]	Not eye irritating	521-046

Species	**Test**	**Purity %** Note[2]	**Guideline, duration, doses and conditions**	**Result**	**Study number (Doc. No.)**
Guinea pig - males	skin sensitisation	94.3	US EPA FIFRA Guideline § 81-6, equivalent to OECD 406, topical exposure to the pure test item at the limit dose (0.5 g for solids) moistened with saline; (modified Buehler test, 10 induction applications) [GLP study 1987]	Non-sensitising	567-006
Hen	Acute delayed neurotoxicity study	97.4	US-EPA FIFRA 81-7, study followed in principle OECD 418; An acute oral toxicity pre-test was conducted Acute delayed neurotoxicity: Oral administration (gavage) in comparison with a negative (corn oil) and a positive control group (tri-o-cresyl phosphate, TOCP). Phosmet at 600 mg/kg bw was administered orally as a 6.2 % solution in corn oil. All birds were given a s.c. injection of atropine sulfate prior to dosing. Birds with severe clinical symptoms following dosing were given a further atropine sulfate injection. After treatment, animals were observed daily for a period of up to 21/22 days for mortality, clinical signs and delayed locomotor ataxia	ChE inhibition: NOAEL < 600 mg/kg bw Neurotoxicity: NOAEL ≥ 600 mg/kg bw (LD50: 577 mg/kg bw) No potential to induce delayed neurotoxicity	541-007

Table 4. Toxicology profile of phosmet technical material based on repeated administration (subacute to chronic)

Species	**Test**	**Purity %** Note[3]	**Guideline, duration, doses and conditions**	**Result**	**Study number (Doc. No.)**
Rat - males/females	Feeding toxicity study, 90 days	98	Study performed prior to OECD GL, 0, 20, 100 and 500 ppm Phosmet (0, 2, 10, 50 mg /kg bw/d) for 90 d	NOAEL = 2 mg/kg bw/d (20 ppm)	533-002
Dog - males/females	Feeding toxicity study, 90 days	98	Study performed prior to OECD GL, 0, 10, 75 and 563 ppm Phosmet (0, 0.3, 1.9, 14.1 mg Phosmet/kg bw/d) for 90 d	NOAEL = 1.9 mg/kg bw/d (75 ppm)	533-002
Rat - males/females	Dermal toxicity study, 21 days	71.2	US EPA FIFRA 82-2; study followed in principle OECD 410, 0, 15, 22.5 and 60 mg/kg bw/d for 6 h/d by topical application to the dorsal skin, 5 d/w, for at least 3 weeks; Imidan 70-WSB in deionised water	NOAEL = 22.5 mg/kg bw/d	532-006
Rabbit - males/females	Dermal toxicity study, 21 days	Not indicated	US EPA 82-2; OECD 410, 10, 100 and 1000 mg/kg bw/d for 6 h/day by topical application to the dorsal skin, (semi-occlusive dressing), 5 d/w, for at least 3 weeks, Imidan Technical in mineral oil	NOAEL = 100 mg/kg bw/d	532-005
Rat - males/females	2-year chronic toxicity and carcinogenicity study	94.3	US-EPA FIFRA 83-5, 0, 20, 40 or 200 ppm Phosmet (males: 0, 1.1, 1.8, 9.4 mg/kg bw/d; females: 0, 1.1, 2.1, 10.9 mg/kg bw/d) for up to 24 months	NOAEL = 1.1 mg/kg bw/d (40 ppm), males/females Not carcinogenic	537-002 537-003 537-004 537-005

[3] Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

Species	**Test**	**Purity %** Note[3]	**Guideline, duration, doses and conditions**	**Result**	**Study number (Doc. No.)**
Mouse - males/females	2-year chronic toxicity and carcinogenicity study	94.7	US-EPA FIFRA 83-2; OECD 451; 0, 5, 25, 100 ppm; 0, 1, 4, 14 mg/kg bw/d (males); 0, 1.2, 5, 18 mg/kg bw/d (females)	Male mice: NOAEL = 4 mg/kg bw/d (25 ppm) Female mice: NOAEL = 5 mg/kg bw/d (25 ppm) Not carcinogenic	555-001 555-002 555-003 555-004
Dog - males/females	Supporting 2-year oral toxicity study	Not indicated	Study performed prior to OECD GL, 0, 20, 40 and 400 ppm (0, 0.5, 1, 10 mg/kg bw/d) for 2 years, Imidan	NOAEL = 1 mg/kg bw/d (40 ppm)	537-001
Rat - males/females	Generational toxicity study	95.2	US-EPA FIFRA 83-4, OECD 416; F_0 animals received 0, 20, 80 and 300 ppm for 56 days and were then mated (ratio 1:1). The administration continued through 2 generations (F_0, F_1) with two litters (F_{1a}, F_{1b}; F_{2a}, F_{2b}) per generation, Phosmet technical	Parental toxicity NOAEL ca. 1.5 mg/kg bw/d (20 ppm) Reproductive (fertility) toxicity NOAEL ca. 1.5 mg/kg bw/d (20 ppm) Developmental toxicity (foetotoxicity) NOAEL ca. 5.0 mg/kg bw/d (80 ppm)	553-002 553-003 553-004 553-005
Rat - males/females	Developmental toxicity study	96.4	US-EPA FIFRA 83-3; 5, 10 and 15 mg/kg bw/d from gestational days (GD) 7 to 19; Phosmet in corn oil	Maternal toxicity NOAEL = 5 mg/kg bw/d Developmental toxicity NOAEL ≥ 15 mg/kg bw/d	551-008

Species	**Test**	**Purity %** Note[3]	**Guideline, duration, doses and conditions**	**Result**	**Study number (Doc. No.)**
Rabbit - males/females	Developmental toxicity study	96.4	US-EPA FIFRA 83-3, OECD 414; 2, 5 and 15 mg/kg bw/d from gestational days (GD) 7 to 19 *per os* (gavage)	Maternal toxicity NOAEL = 5 mg/kg bw/d Developmental toxicity(foetotoxicity) NOAEL = 5 mg/kg bw/d Developmental toxicity (malformations) NOAEL ≥ 15 mg/kg bw/d	551-007

Table 5. Mutagenicity profile of phosmet technical material based on *in vitro* and *in vivo* tests

Species	**Test**	**Purity % Note[4]**	**Guideline, duration, doses and conditions**	**Result [Classification acc. to RAC (2016)]#**	**Study number (Doc. No.)**
S typhimurium TA98, TA100, TA1535, TA1537	Ames - *in vitro*	95.7	OECD 471; plate incorporation assay +S9: 156 - 2500 µg/plate -S9: 156 - 2500 µg/plate	+S9: Positive in TA100 -S9: Positive in TA100	557-008
S. typhimurium TA98, TA100, TA1535, TA1537, TA1538, *E. coli*: WP2 hcr	Ames - *in vitro*	99	OECD 471; plate incorporation assay +S9: 10 - 5000 µg/plate -S9: 10 - 5000 µg/plate	+S9: Positive in TA100 -S9: Positive in TA100	557-010
S. typhimurium TA97, TA98 TA100, TA1535, TA1538	Ames - *in vitro*	99.63	[OECD 471]; plate incorporation assay +S9: 10 - 1000 µg/plate -S9: 10 – 1000 µg/plate	+S9: Positive in TA100, TA97 -S9: Positive in TA100, TA97	592-025
Mouse lymphoma L5178Y cells	Mammalian cell gene mutation, Thymidine kinase (TK) locus - *in vitro*	99.63	OECD 476; +S9: 4 - 40 µg/mL -S9: 20 – 100 µg/mL	+S9: Negative -S9: Positive	557-001
Mouse lymphoma L5178Y cells	Mammalian chromosome aberration	95.7	+S9: 8 – 40 µg/mL -S9: 40 – 100 µg/mL	+S9: Negative -S9: Negative	557-009

[4] Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

Species	**Test**	**Purity % Note[4]**	**Guideline, duration, doses and conditions**	**Result [Classification acc. to RAC (2016)][#]**	**Study number (Doc. No.)**
Mouse lymphoma L5178Y cells	Sister chromatid exchange test in mammalian cells	95.7	+S9: 8 – 40 µg/mL -S9: 40 – 100 µg/mL	+S9: Positive -S9: Positive	557-009
Mouse bone marrow cells	Micronucleus test – *in vivo*	95.5	OECD 474; Single oral dose 17 mg/kg bw	Negative	557-004
Mouse bone marrow cells	Micronucleus test – *in vivo*	49.9	OECD 474	Negative Supplementary information	557-007
Rat hepatocytes	Unscheduled DNA synthesis test – *in vivo*	99.4	Prior to OECD 486; 32 and 50 mg/kg bw	Negative	557-005
Rat hepatocytes	Unscheduled DNA synthesis – *in vivo*	96.1	OECD 486; 54, 180/108 mg/kg bw	Negative	557-006

Table 6. Ecotoxicology profile of phosmet technical material

Species	**Test**	**Purity % Note**	**Guideline, duration, doses and conditions**	**Result**	**Study number (Doc. No.)**
Oncorhynchus mykiss (Rainbow trout)	Acute toxicity to fish	Phosmet technical, purity 97%	OECD 203, 96 h exposure at 14.8 – 15.2°C 12.6, 27.6, 75.3, 175 and 286 µg a.s./$L_{(mm)}$ were tested in a flow-through system	96 h LC_{50} = 241 µg a.s./$L_{(mm)}$	821-008
Lepomis macrochirus (Bluegill sunfish)	Acute toxicity to fish	Phosmet technical, purity 97%	OECD 203, 96 h exposure at 21.6 – 22.5°C 4.3, 9.4, 20.7, 45.5 and 100 µg a.s./$L_{(nom)}$ were tested in a flow-through system	96 h LC_{50} = 19.7 µg a.s./$L_{(nom)}$	821-006
Oncorhynchus mykiss (Rainbow trout)	Chronic toxicity to fish - Fish early life stage	^{14}C Phosmet	OECD 210, 60 days exposure at 9.2 – 10.6°C 3.0, 6.0, 12, 25 and 50 µg a.s./$L_{(nom)}$ were tested in a flow-through system	60 day NOEC = 3.0 µg a.s./$L_{(nom)}$ 60 day EC_{10} = 4.65 µg a.s./$L_{(nom)}$	826-001 and 881-044
Daphnia magna (Water flea)	Acute toxicity to daphnids	Phosmet technical, purity 97%	OECD 202, 48 h exposure at 20.4 – 20.9°C 0.37, 0.79, 2.55, 3.32 and 8.45 µg a.s./$L_{(mm)}$ were tested in a flow-through system	48 h EC_{50} = 2.11 µg a.s./$L_{(mm)}$	822-004
Daphnia magna (Water flea)	Chronic toxicity to daphnids	^{14}C Phosmet	OECD 211, 21 days exposure at 20 – 21°C 0.17, 0.43, 0.78, 1.61 and 3.58 µg a.s./$L_{(mm)}$ were tested in a flow-through system	21 day NOEC = 0.78 µg a.s./$L_{(mm)}$ 21 day EC_{10} = 1.26 µg a.s./$L_{(mm)}$	827-001, 827-002 and 881-045
Pseudokirchneriella subcapitata (Green algae)	Toxicity to green algae	Phosmet technical, purity 97%	OECD 201, 72 h exposure at 23 – 24°C 0.14, 0.36, 0.99, 2.31, 5.43 and 15.5 mg a.s./$L_{(im)}$ were tested in a static system	24 h E_rC_{50} = 1.35 mg a.s./$L_{(im)}$*	823-002 and 881-046
Eisenia fetida (Earthworm)	Chronic toxicity to earthworms	Phosmet technical, purity 96.5%	OECD 222, 56 days exposure at 18.1 – 21.5°C 0.2, 0.36, 0.65, 1.17, 2.10, 3.78, 6.80 and 12.24 mg a.s./kg soil dw were tested in artificial soil	56 day NOEC = 6.8 mg a.s./kg soil dw 56 day EC_{10} = 5.91 mg a.s./kg soil dw	833-004

Species	Test	Purity % Note	Guideline, duration, doses and conditions	Result	Study number (Doc. No.)
Folsomia candida (Collembola)	Chronic toxicity to collembolans	Phosmet technical, purity 96.5%	OECD 232, 28 days exposure at 18.0 – 20.3°C 0.5, 0.9, 1.62, 2.92, 5.25, 9.45, 17.01 and 30.61 mg a.s./kg soil dw were tested in artificial soil	28 day NOEC = 1.62 mg a.s./kg soil dw 28 day EC_{10} = 2.34 mg a.s./kg soil dw	835-001
Hypoaspis aculeifer (Soil mite)	Chronic toxicity to soil mites	Phosmet technical, purity 96.5%	OECD 226, 14 days exposure at 19.7 – 21.4°C 1.63, 2.94, 5.29, 9.53, 17.1, 30.9, 55.6 and 100 mg a.s./kg soil dw were tested in artificial soil	14 day NOEC = 30.9 mg a.s./kg soil dw 14 day EC_{10} = 28.2 mg a.s./kg soil dw	835-002
Apis mellifera (Honey bee)	Acute toxicity to honey bees	Phosmet technical, purity 97%	OECD 213 and 214, 48 h exposure at 24°C Single doses of 0.046, 0.1, 0.22, 0.46 and 1 µg a.s./bee were tested at the contact exposure study. Single doses of 0.043, 0.092, 0.201, 0.425 and 0.852 µg a.s./bee were tested at the oral exposure study.	48 h acute contact LD_{50} = 0.22 µg a.s./bee 48 h acute oral LD_{50} = 0.37 µg a.s./bee	832-003
Apis mellifera (Honey bee)	Chronic toxicity to adult honey bees	Phosmet technical, purity 96.5%	Study in line with OECD draft TG for chronic honey bee testing. Doses of 0.010, 0.025, 0.062, 0.156 and 0.379 µg a.s./bee d were tested	10 day NOED = 0.025 µg a.s./bee d	832-010
Apis mellifera (Honey bee)	Honey bee larval toxicity, repeated exposure	Phosmet technical, purity 96.5%	OECD 237 (2013), OECD draft guidance document: Honey bee (*Apis mellifera*) larval toxicity test, repeated exposure (February 2014). Doses of 0.068, 0.123, 0.222, 0.400 and 0.720 µg a.s./larva were tested	22 day NOED = 0.222 µg a.s./larva	832-011
Anas platyrhynchos (Mallard duck)	Acute oral toxicity to birds	Phosmet technical, purity 95.4%	Study comparable to EPA 71-1, 8 days exposure Single doses of 215, 464, 1000, 2150 and 4640 mg a.s./kg bw were tested.	LD_{50} = 2065 mg a.s./kg bw	811-001 and 881-041
Anas platyrhynchos (Mallard duck)	Acute oral toxicity to birds	Phosmet technical, purity 96.2%	OPPTS 850.2100, 14 days exposure Single doses of 175, 292, 486, 810, 1350 and 2250 mg a.s./kg bw were tested. Study duration: 14 days.	LD_{50} = 1068 mg a.s./kg bw	811-004 and 881-043

Species	**Test**	**Purity % Note**	**Guideline, duration, doses and conditions**	**Result**	**Study number (Doc. No.)**
Colinus virginianus (Bobwhite quail)	Acute oral toxicity to birds	Phosmet technical, purity 97%	OPPTS 850.2100, 14 days exposure Single doses of 6, 11, 20, 36, 66 and 120 mg a.s./kg bw were tested.	LD_{50} = 56.2 mg a.s./kg bw	811-003 and 881-042
Colinus virginianus (Bobwhite quail)	Chronic toxicity to birds	Phosmet technical, purity n.a.	In line with OECD 206, bird reproduction study Dietary concentrations: 25, 60 and 150 ppm	NOED = 7.5 mg a.s./kg bw d (= 60 ppm)	813-001

mm – mean measured test concentrations, nom – nominal test concentrations, im – initial measured test concentrations, n.a. – data not available

* In line with the Phosmet Monograph v.3, B.9 Ecotoxicology (July 2005) and the Phosmet EFSA Conclusion (2011), the endpoints for algae are based on initial measured test concentrations and the worst case ErC_{50} (after 24, 48 or 72 h) is used in the risk assessment. The lowest E_rC_{50} was calculated after 24 h.

ANNEX 2

REFERENCES

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