EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Food Safety: plant health, animal health and welfare, international questions
E1 - Plant health

Phenmedipham
SANCO/4060/2001 - final
13 February 2004

Review report for the active substance **phenmedipham**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 13 February 2004
in view of the inclusion of phenmedipham in Annex I of Directive 91/414/EEC

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of phenmedipham, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EEC) No 3600/92([1]) laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 2266/2000([2]), has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Phenmedipham is one of the 90 existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, AgrEvo GmbH on 27.07.1993, Feinchemie Schwebda on 11.06.1993, Stefes Research GmbH 09.07.1993, Pen-Taso-Materia Medica Center GmbH on 14.07.1993, United Phosphorus Ltd.(=MTM Agrochemicals) on 12.07.2003, Task Force Phenmedipham TOP 2 on 22.07.1993, Barclay Chemicals on 27.06.1993 or on 27.07.1993, Helm AG on 23.07.1993, Calliope SA on 21.07.1993, B.V. Luxan on 21.07.1993 and Phytorus SA on 26.07.1993, notified to the Commission of their wish to secure the inclusion of the active substance phenmedipham in Annex I to the Directive.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, Task Force on Phenmedipham (TOP 2), on behalf of the phenmedipham task force (comprising now Bayer CropScience and United Phosphorus Ltd.), notified to the Commission on 27.07.1993 of their wish to secure the inclusion of the active substance phenmedipham in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EEC) No 3600/92, the Commission, by its Regulation (EEC) No 933/94([3]), as last amended by Regulation (EC) No

[1] OJ No L 366, 15.12.1992, p.10.

[2] OJ No L 259, 13.10.2000, p.27.

[3] OJ No L 107, 28.04.1994, p.8.

2230/95([4]), designated Finland as rapporteur Member State to carry out the assessment of phenmedipham on the basis of the dossier submitted by the notifier. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for phenmedipham this deadline was 31.10.1995.

Task Force on Phenmedipham, Barclay Chemicals Ltd. and Phytorus A/S submitted each a dossier to the Rapporteur Member State. Only Task Force on Phenmedipham (TOP 2) on behalf of the phenmedipham task force (comprising now Bayer CropScience, and United Phosphorus Ltd.), submitted a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Dossiers submitted by Barclay Chemicals Ltd. and Phytorus A/S were consider incomplete. Therefore, Task Force on Phenmedipham (TOP 2) being the designated representative of the phenmedipham task force, was considered to be the main data submitter. Information has furthermore been submitted by third parties (AgriChem, 9.8.2000)

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Finland submitted on 05.01.2000 to the Commission the report of its examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of phenmedipham in Annex I to the Directive. Moreover, in accordance with the same provisions, the Commission and the Member States received also the summary dossier on phenmedipham from Task Force on Phenmedipham (TOP 2) on 13.11.2001.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States as well as to Task Force on Phenmedipham (TOP 2) being the designated representative of the phenmedipham task force, on 20.04.2000.

The Commission organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review), in particular on each of the following disciplines:

- identity and physical /chemical properties ;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from November 2001 to July 2002.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 11.09.2002 for comments and further clarification.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the peer review report (i.e. full report) and the comments and

[4] OJ No L 225, 22.09.1995, p.1.

clarifications on the remaining issues, received after the peer review were referred to the Standing Committee on the Food Chain and Animal Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from 2003 to February 2004, and was finalised in the meeting of the Standing Committee on 13 February 2004.

The review did not reveal any open questions or concerns which would have required a consultation of the Scientific Committee on Plants.

The present review report contains the conclusions of the final examination; given the importance of the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications submitted after the peer review as basic information for the final examination process, these documents are considered respectively as background documents A, B and C to this review report and are part of it.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed and finalised in support of the Directive 2004/58/EC[5] concerning the inclusion of phenmedipham in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing phenmedipham they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 7(6) of Regulation (EEC) No 3600/92, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request. Moreover the Commission will send a copy of this review report (not including the background documents) to all operators having notified for this active substance under Article 4(1) of this Regulation.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing phenmedipham will fulfil the safety requirements laid down in Article

[5] OJ No L 120, 24.4.2004, p.26.

5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each phenmedipham containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the main data submitter and mentioned in the list of uses supported by available data (attached as Appendix IV to this Review Report). No unacceptable effects on the environment is predicted in the proposed and supported conditions of use when the product is applied every third year.

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is 2.55 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Additional intake from water and products of animal origin are not expected to give rise to intake problems.

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 6 of this report.

4. Identity and Physical/chemical properties

The main identity and the physical/chemical properties of phenmedipham are given in Appendix I.

The active substance shall comply with the FAO specification and there seem not to be reasons for deviating from that specification; the FAO specification is given in Appendix I of this report.

The review has established that for the active substance notified by the main data submitter Task Force on Phenmedipham (TOP 2), none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

The information on identities submitted by Barclay Chemicals Ltd. and Phytorus S/A were incomplete and it is not possible to consider whether they differ significantly or not in degree of purity and nature of impurities from the composition registered in the dossier submitted by the main data submitter.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in Appendix II.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing phenmedipham

On the basis of the proposed and supported uses (as listed in Appendix IV), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- Member States must pay particular attention to the protection of aquatic organisms.

7. List of studies to be generated

No further studies were identified which were at this stage considered necessary in relation to the inclusion of phenmedipham in Annex I under the current inclusion conditions.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. This may particularly be the case for a fully validated method with confirmation for the impurities in the technical material at a LOQ < 0.1 % w/w, for a confirmatory method for the determination of toluene in the technical material or for information to demonstrate that there are no unacceptable effects on the environment when the substance is applied more often than every third year.

8. Information on studies with claimed data protection

For information of any interested parties, Appendix III gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available to the Commission services at the time this review report was prepared; but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC neither does it commit the Commission.

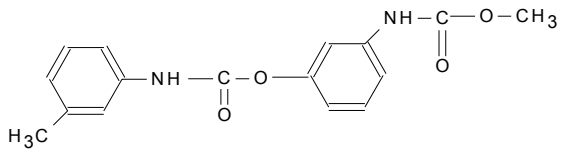
9. Updating of this review report

The technical information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Such adaptations will be examined and finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for phenmedipham in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

PHENMEDIPHAM

Common name (ISO)	Phenmedipham
Chemical name (IUPAC)	methyl 3-(3-methylcarbaniloyloxy)carbanilate; 3-methoxycarbonylaminophenyl 3´-methylcarbanilate
Chemical name (CA)	3-[(methoxycarbonyl)amino]phenyl (3-methylphenyl) carbamate
CIPAC No	77
CAS No	13684-63-4
EEC No	EINECS: 2371990
FAO SPECIFICATION	AGP: CP/90, (1980); min. 97.0 ± 1 %
Minimum purity	min. 970 g/kg
Molecular formula	$C_{16}H_{16}N_2O_4$
Molecular mass	300.3
Structural formula	

Melting point	142.7 °C (99.2 % pure)
Boiling point	No boiling point, decomposition begins at 147 °C.
Appearance	Colourless, crystalline powder, odourless. (99.6% pure)
Relative Density	-
Density	1.359 g/cm3 at 20 oC (99.3 % pure)
Vapour pressure	$7 \cdot 10^{-10}$ Pa at 25 °C (99.3 % pure)
Henry's law constant	$5 \cdot 10^{-8}$ Pa · m^3 · mol^{-1} at 20°C
Solubility in water	pH 3,4: 1,8 mg/l at 20 °C (99.0 % pure) Phenmedipham decomposes at neutral or basic pH.
Solubility in organic solvents	All in g/l at 20 °C: toluene: 0.97; dichloromethane: 16.7; methanol: 36.2; acetone: 165; ethyl acetate: 56.3; isooctane 0.16
Partition co-efficient (log P_{ow})	3.59 at 22 °C and pH 4
Hydrolytic stability (DT_{50})	pH 5: DT_{50} = 47 d at 25 °C; pH 7: DT_{50} = 12 h at 25 °C; pH 9: DT^{50} = 7 min at 25 °C;
Dissociation constant	Phenmedipham does not dissociate.
Quantum yield of direct photo-transformation in water at λ >290 nm	Photochemically stable.
Flammability	Not to be considered as highly flammable.
Explosive properties	Not to be considered as explosive.
UV/VIS absorption (max.)	λ_{max}: 205 nm, ε_{max}: 59646 l mol^{-1} cm^{-1} λ_{max}: 237 nm, ε_{max}: 37848 l mol^{-1} cm^{-1} λ_{max}: 274 nm, ε_{max}: 2761 l mol^{-1} cm^{-1} at pH 6.2
Photostability in water (DT_{50})	Photochemically stable.

APPENDIX II

END POINTS AND RELATED INFORMATION

PHENMEDIPHAM

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rapid. 85%, based on urinary excretion in 24 - 30 h
Distribution:	Widely distributed, highest residues in blood (methylphenyl ring label)
Potential for accumulation:	Low potential for accumulation
Rate and extent of excretion:	Rapid. Over 90% within 24 - 30 h
Toxicologically significant compounds:	Parent compound and metabolites. 3-aminophenol and 3-aminotoluene may be of special toxicological concern
Metabolism in animals:	Extensively metabolised. Oxidative/hydrolytic cleavage of parent molecule, hydroxylation of aromatic ring structures, acetylation of amine groups and further oxidation of methyl groups

Acute toxicity

Rat LD_{50} oral:	>8000 mg/kg
Rat LD_{50} dermal:	>2000 mg/kg
Rat LC_{50} inhalation:	>7.0 mg/l (nose only)
Skin irritation:	Non irritant
Eye irritation:	Non irritant
Skin sensitization (test method used and result):	Not sensitising (M & K)

Short term toxicity

Target / critical effect:	Effects on red blood cells (methemoglobinemia and hemolytic anemia) and related effects (hemosiderin deposition in spleen, liver and kidneys)
Lowest relevant oral NOAEL / NOEL:	150 ppm (13 mg/kg bw/day) (90-day, rat)
Lowest relevant dermal NOAEL / NOEL:	No data. Not required
Lowest relevant inhalation NOAEL / NOEL:	No data. Not required

Genotoxicity	Clastogenic *in vitro*. Non-genotoxic *in vivo* (mouse bone marrow: negative for chromosome aberrations and micronuclei induction; mouse spermatogonial cells: negative for induction of chromosomal aberrations)

Long term toxicity and carcinogenicity

Target / critical effect:	Effects on red blood cells (methemoglobinemia and hemolytic anemia) and related histopathological effects in spleen, liver and kidneys (increased weight, hemosiderosis, extramedullar hematopoiesis).
Lowest relevant NOAEL:	60 ppm (3 mg/kg bw/day) (2-year, rat)
Carcinogenicity:	No carcinogenic potential

Reproductive toxicity

Target / critical effect - Reproduction:	Reduced pup weight at parentally toxic dose levels
Lowest relevant reproductive NOAEL / NOEL:	25 mg/kg bw/day (two-generation, rat)
Target / critical effect - Developmental toxicity:	Retarded ossification in rats and rabbits at maternally toxic dose levels
Lowest relevant developmental NOAEL / NOEL:	Rabbit: 225 mg/kg bw/day

Delayed neurotoxicity	No data. Not required
Other toxicological studies	No data. Not required
Medical data	Four different studies were supplied which reported cases of allergic dermatitis, photoallergic dermatosis, allergic rhinitis and toxic hepatitis in pesticide operators and field workers who had applied Betanal or Betamix formulations of phenmedipham

Summary

	Value	Study	Safety factor
ADI:	0.03 mg/kg bw/day	2-year, rat	100
AOEL systemic:	0.13 mg/kg bw/day	90-day, rat	100
AOEL inhalation:	Not allocated, not necessary		
AOEL dermal:	Not allocated, not necessary		
ARfD (acute reference dose):	Not allocated, not necessary		

Dermal absorption

1% (based on an absorption study *in vivo* in rat, and comparative *in vitro* penetration studies with rat and human skin)

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	CO_2 evolved: 13.3 – 16.5 % of AR within 120 days, AP ^{14}C-labelled, low temperature/low moisture (n=1) 9.7 – 11.3 % of AR within 120 days, phenoxy ring –U-^{14}C labelled (n=3)
Non-extractable residues after 100 days:	63.6 – 64.1 % of AR within 120 days, AP ^{14}C-labelled, low temperature/low moisture (n=1) 71.3 – 73.8 % of AR within 120 days phenoxy ring –U-^{14}C labeled (n=3)
Major metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	MHPC max 14 % of AR at day 14 (n=1) APMP max 4 % of AR after 56 days (n=1) (label position AP) MHPC max 54 % at day 5 (n=1, ring-U-labelled)

Supplemental studies

Anaerobic:	CO_2 evolved 6.6 % of AR, NER 74.3 % of AR after 97 days, MHPC max 19 % of AR after 32 days (label position AP, n=1)
Soil photolysis:	DT_{50} 79 hours on irradiated soil photochemical products: 3-aminophenol and 3-methoxycarbonylaminophenol max 17.8 % of AR (sum of all polar products) after 105 hours of irradiation (n=1)
Remarks:	None

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):	26, 42, 43 d, mean=37 days (n=3, r^2 = 0.932 - 0.953)
DT_{90}lab (20 °C, aerobic):	85, 138, 143 days (n=3, r^2 = 0.932 – 0.953)
DT_{50}lab (10 °C, aerobic):	27 days
DT_{50}lab (20 °C, anaerobic):	15 days (n=1, r^2 = 0.934)

Field studies (country or region)

DT_{50f} from soil dissipation studies:	first order kinetics, DT_{50f}: Germany, bare soil, four sites: 5.8 days at pH 5.0, 9.0 days at pH 6.9, 15.7 days at pH 7.1, 39.9 days at pH 6.0, mean 17.6 days (n=4, r^2 not available, 1st order) USA, California, one site: sandy loam, on red beet stage 4-6 leaf: 13.3 days at pH 7.0 (n=1, r^2 not available, 1st order) metabolites: no DT_{50} values calculated in the field studies
DT_{90f} from soil dissipation studies:	DT_{90f}: Germany, sites described above: range 30 - 133 days, mean 82 days (n=4 , r^2 not available, 1st order)
Soil accumulation studies:	no data submitted nor required
Soil residue studies:	no data submitted nor required

Remarks: e.g. effect of soil pH on degradation rate	no clear pH dependence

Adsorption/desorption

K_f / K_{oc}: PMP	K_{oc}: PMP: 657, 934, 1072, mean = 888, 1/n = 0.821, 0.865, 0.854 (soil samples, n = 3, equilibrium time 2.5 hours) 469, 728, mean = 599, 1/n = 0.82, 0.84 (sediments, n=2, equilibrium time 3 hours)
MHPC	K_{oc}: MHPC: 212, 138, 58, 470, mean = 220, 1/n = 0.515, 0.699, 0.949, 0.805 (n = 4, one outlier excluded) K_d: MHPC: 0.57 - 4.8
pH dependence:	Yes, due to the hydrolysis processes which indirect affect the adsorption of parent. No dependence for the metabolites. For FOCUS gw modelling with FOCUS_PEARL v. 1.1.1 following median K_{om} values were used: PMP: 422, 1/n = 0.84 MHPC: 101, 1/n = 0.752

Mobility

Laboratory studies:

Column leaching:	1) Guideline: US EPA subdiv. N, para 163.1 Precipitation: 920 ml corresponding to 50.8 cm rainfall in 10 days (92 ml/d) Soils: 2 soils, label positions AP and T Use rate: 0.825 kg/ha (AP) and 1.1 kg/ha (T) Leachate: total residue 0.33 - 0.45 % of AR in leachates, not characterized further Soil columns: total residue 88.1 – 92.6 % of AR in soil columns (mainly in the top 5 cm), NER 43.1 – 53.1 % and 34.9 – 60.4 % extractable of it Volatiles 3.72 – 7.27 % of AR during the leaching period.

	2) Guideline: US EPA subdiv. N, para 163.1 Precipitation: 560 mm in 5 days Soil: 2 soils, label positions AP and T Use rate 1.65 kg/ha Leachate: total residue 0.6 - 2.3 % of AR in leachates, not characterized further Soil columns: total residue 89.5 – 95.4 % of AR in soil columns (mainly in the top 10 cm), extractable 26 – 64 % of it, mainly unchanged parent Volatiles not trapped. 3) Guideline: BBA Precipitation: 200 ml/day for 2 days Soils: 3 soils, label position AP Use rate: 1.5 kg/ha Leachate: total residue <0.5 % of AR in leachates, not characterized further
Aged residue leaching:	1) Guideline: BBA Soils: 1 soil, German standard soil 2.1 Use rate: 960 g/ha, label position T Aged at 20 degrees C, 40 % MWHC, for 33 days Precipitation: 2 days irrigation of 200 mm Leachate: 0.48 % of AR was found in the leachate, not characterized further Soil column: 96.2 % of AR remained in soil, mainly in the top 10 cm Volatiles: 5.7 % of AR. 2) Guideline: EPA Vol 40, No 123, Part II, 1975 Soils: 2 soils, German standard soils 2.2 and 2.3 Use rate: 1.25 kg/ha, label position AP Aged at 25-30 degrees C, 70 % MWHC, for 30 days Precipitation: 45 days irrigation of 125 mm/day Leachate: 0.58 and 1.66 % of AR was found in the leachates, not characterized further Soil column: 99.1 – 112.9 % of AR remained in the soil, mainly in the top 6 cm. The aged soil was not analysed further for the metabolites.

3) Guideline: EPA Vol 40, No 123, Part II, 1975 Soils: 2 soils, German standard soils 2.2 and 2.3 Use rate: 1.65 kg/ha on soil 2.2 and 1.25 kg/ha on soil 2.3, label position T Aged at 25-30 degrees C, 75 % MWHC, for 30 days Precipitation: 45 days irrigation of 125 mm/day Leachate: 1.37 - 1.83 % of AR was found in the leachates, not characterized further Soil column: 72.9 – 88.7 % of AR remained in the soil, mainly in the top 5 cm. The aged soil was not characterized further for the metabolites.

Field studies:

Lysimeter/Field leaching studies:

1) Location: UK Study type: lysimeter Soils: loamy sand, low content of organic matter Number of applications: one single application of 0.942 kg/ha in the first year, study continued over 2 years Crops: sugar beet + wheat Average annual rainfall: 757 mm (1st year), 948 mm (2nd year) Average annual leachate volume: 200 mm/ first year (25 % of the precipitation), 445 mm/ second year (47 % of the precipitation) % radioactivity in the leachate (max/year): after 2 years totally 0.8 - 1.1 % of AR was leached Peak annual average concentrations: total radioactive residues 1.28 – 1.9 μg/l in the first year, 1.1 – 1.33 μg/l in the second year (40 % of AR in leachate attributed to humic acid type fragments and up to 27 % incorporated with naturally occurring compounds), MHPC 0.006 μg/l, PMP could not be detected in any of the samples (LOD = 0.03 μg/l Phenmedipham a.s.equivalents).

2) Location: Germany Study type: lysimeter Soils: loamy sand with low organic matter content Number of applications: 1.0 kg/ha either once or in two successive years, study continued for up to 3 years Crops: sugar beet (1 or 2 successive years) + wheat Average annual rainfall: 860 mm/year (cumulative sum of 2582 mm within 3 years) Average annual leachate volume: 428 mm % radioactivity in the leachate (max/year): after 2 years totally 0.22 - 0.32 % of AR was leached Peak annual average concentrations: total radioactive residues 0.314 – 0.805 μg/l (water soluble humic acid-type components, due to the low radioactivity the further characterization was not possible). MHPC was calculated as <0.01 μg as equivalents/l. (LOQ = 0.017 μg/l for PMP and 0.010 μg/l for MHPC).

Remarks:	No groundwater contamination expected

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	DT_{50} / DT_{90} / r^2 pH 4: 259 d / 861 d / -0.9726 pH 5: 47 d / 156 d / -0.9958 pH 7: 12 h / 39 h / -0.9922 pH 9: 7 min / 24 min / -0.9860 (25 °C, 1st order kinetics)
Major metabolites:	MHPC
Photolytic degradation:	no degradation (artificial light source, λ > 290 nm)
Major metabolites:	None

Biological degradation

Readily biodegradable:	no
Water/sediment study:	
DT_{50} water:	0.1 – 0.3 days (√t/1st order, r^2 = 0.989, 0.544, n=2)
DT_{90} water:	0.6 – 3.4 days (√t/1st order, r^2 = 0.989, 0.544, n=2)
DT_{50} whole system:	0.11, 0.12, 0.18 days (1st order kinetics, r^2 = 0.942 – 0.978, n=3)
DT_{90} whole system:	0.38, 0.40, 0.60 days (1st order kinetics, r^2 = 0.942 – 0.978, n=3)
Distribution in water / sediment systems (active substance)	1 - 2 % of AR in water phase and 51 - 55 % in sediment after 126 days (non-sterilised samples, 2 label positions, 2 systems),
Distribution in water / sediment systems (metabolites)	44 - 51 % of AR in water and 39 - 44 % in sediment after 126 days (sterilised samples, 1 label position, 2 systems). MHPC: 60 - 70 % of AR within 1 - 2 days 1 % of AR after 126 days
Accumulation in water and/or sediment:	Due to quite rapid degradation of PMP and MHPC no accumulation is expected

Degradation in the saturated zone

no data submitted nor required

Remarks:

Rapid hydrolysis of PMP in neutral and alkanline pH to MHPC

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	7×10^{-10} Pa at 25 °C
Henry's law constant:	5×10^{-8} Pa x m^3 x mol^{-1}

Photolytic degradation

Direct photolysis in air:	not studied, no data required
Photochemical oxidative degradation in air DT_{50}:	6.7 hours derived by the Atkinson method of calculation
Volatilisation:	from plant surfaces: no data from soil surface: no data

Remarks:	PECair considered negligible

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	rat: LD50 >8000 mg a.i./kg body weight (formulation >2000 mg/kg)
Acute toxicity to birds:	mallard duck: LD50 and NOEL >2100 mg/kg body weight mallard duck & japanese quail: LD50 >2500 mg/kg body weight, NOEL 2500 mg/kg as in the first study with mallard no effects were found, the higher NOEL value from the last study could be used in the risk assessment
Dietary toxicity to birds:	mallard duck : NOEC 2000 mg/kg feed bobwhite quail: NOEC 5000 mg/kg feed
Reproductive toxicity to birds:	bobwhite quail: NOEC 1200 mg/kg feed
Reproductive toxicity to mammals:	2-generation rat study: NOAEL 100 mg/kg corresponding to 6.8 mg PMP/kg b.w./day

Aquatic Organisms

PMP

	Species	Time scale	Endpoints	Toxicity (mg/l) (active substance if not mentioned differently)
Acute toxicity fish:	Rainbow trout	96 hours	LC50	1.71
	Rainbow trout	96 hours	LC50	6.9 (formulation) 1.1
Long term toxicity fish:	Rainbow trout	21 days	NOEC	0.32
Bioaccumulation fish:	Rainbow trout	64 hours	BCF	165
Acute toxicity invertebrate:	Daphnia magna	48 hours	EC50	0.41
	Daphnia magna	48 hours	EC50	5.7 (formulation) 0.9
Chronic toxicity invertebrate:	Daphnia magna	21 days	NOEC	0.061
	Daphnia magna	21 days	NOEC	0.025
Acute toxicity algae:	Selenastrum capricornutum green alga	72 hours	EbC50 (based on nominal values due to the unclear reporting in the original study, however used in the risk assessment as being the lowest value)	0.086
Chronic toxicity sediment dwelling organism:	Chironomus riparius	28 days	NOEC	0.37
Acute toxicity aquatic plants:	Lemna minor	14 days	EbC50 NOEC	0.23 0.028

MHPC

	Species	Time scale	Endpoint	Toxicity (mg/ l)
Acute toxicity fish:	Rainbow trout	96 hours	LC50	75
Acute toxicity invertebrate:	Daphnia magna	48 hours	EC50	14
Acute toxicity algae:	Pseudokirchneriella subcapitata green alga	96 hours	EbC50	30

Honeybees

Acute oral toxicity:	>100 µg/bee (product containing 160 g PMP/l) >16 µg/bee (a.i., calculated based on the PMP-content of the product)
Acute contact toxicity:	50 µg/bee

Other arthropod species

Test species	stage	dose	Endpoint	% Effect
Typhlo-dromus pyri	proto-nymphs	480 g PMP/ha 960 g PMP/ha	mortality mortality	0 % 0 %
Aphidius rhopalo-siphi	adults on glass plate	480 g PMP/ha 960 g PMP/ha 480 g PMP/ha 960 g PMP/ha	mortality mortality mortality fecundity	63 % 43 % 7 % + 2 %
	extended, adults on barley seedlings		mortality fecundity	0 % - 35 %
Poecilus cupreus	adults	480 g PMP/ha 960 g PMP/ha	mortality feeding activity mortality feeding activity	0 % + 15 % 0 % - 15 %
Chrysoperla carnea	larvae	480 g PMP/ha 960 g PMP/ha	mortality + fecundity mortality + fecundity	- 12.96 % - 6.18 %
Syrphus corollae	larvae – develop-ment	4.375 % corresp. to 2800 g PMP/ha	mortality develop-ment	- 38 %
Coccinella septem-punctata	larvae	4.3 % corresp. to ca. 2800 g PMP/ha	predatory behaviour	- 33 %
Erigone atra spiders	adults	1440 g PMP/ha	mortality behaviour feeding	0 % 0 % + 5 %
Chrysopa carnea	larvae - development	2.25 % corresp. to ca. 1400 g PMP/ha	mortality development	0 % 0 %
Tricho-gramma cacoeciae	adults	2.25 % corresp. to ca. 1400 g PMP/ha	parasiting behaviour	- 29 %
Poecilus cupreus	adults	1430 g/ha	mortality	0 %
Bembidion lampros	adults	1440 g/ha	mortality	0 %
4 species of ground dwelling spiders	adults	0.5 % corresp. to ca. 314 g PMP/ha	mortality	0 %
Aleochara bilineata	adults	1400 g/ha	parasiting behaviour	+ 10 %

Earthworms

Acute toxicity:	LC_{50} = 244 mg/kg (TOP 2 frame formulation), corresponding to 36 mg/kg PMP
Reproductive toxicity:	NOEC = 5 kg PMP/ha, corrected by the factor of 2 for the organic carbon content of the substrate -> 2.5 kg PMP/ha, corresponding to 3.33 mg a.i./kg soil (standard soil bulk density)→ refined NOEC 10.35 mg a.i./kg soil (actual application amount and actual soil bulk density)

Soil micro-organisms

Nitrogen mineralization:	In a lab study no effects with the normal and 10 x maximum field use rate (corresponding to soil concentration of ca. 1.3 and 13 mg PMP/kg soil) compared to control in two soils. In a field study the nitrification rate was in one soil 43 to 30 % lower in the treated soil compared to the unsprayed soil after 2 weeks and at harvesting, when PMP formulation (1 kg PMP/ha) was sprayed as a tank mixture with ethofumesate (0.75 kg/ha). In the other soil the nitrification rate was 58 % higher in the treated soil compared to control. The use rate in this study corresponds to soil concentration of ca. 1.3 mg PMP/kg soil.
Carbon mineralization:	In the previous study slight reversible effects (ca 20 %) on soil respiration was observed with a normal field use rate (1 kg pmp/ha) when sprayed as a tank mixture with ethofumesate. Soil biomass was 28 - 38 % lower in the treated samples at harvesting.

APPENDIX IIIA

PHENMEDIPHAM

List of studies for which the main submitter has claimed data protection and which during the re-evaluation process were considered as essential for the evaluation with a view to Annex I inclusion.

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

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[6] on previous use in granting national authorizations
IIA 4.2.3	Anspach, T	2003 b	Enforcement method (including validation) for the determination of residues of phenmedipham and its metabolite MHPC in drinking and surface water. Dr. Specht & Partner Chemische Laboratorien GmbH, Hamburg, Germany, Report No. BAY-0225V Date:23.01.2003, GLP, Non Published BAY No. C 029326	
IIA 4.2.2	Anspach, T.	2003 a	Validation of DFG Method S 19 (extended revision) for the determination of residues of phenmedipham and its metabolite MHPC in/on soil by means of liquid chromatography with tandem mass spectrometric detection (LC-MS/MS). Dr. Specht & Partner Chemische Laboratorien GmbH, Hamburg, Germany, Report No. BAY-0223V Date:29.01.2003, GLP, Non Published BAY No. C 029546	

[6] Entries are based on information received from the Notifier(s) 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	Reports[6] on previous use in granting national authorizations
IIA 4.2.1	Billian, P.	2003 a	Analytical method 00802 for the determination of residues of phenmedipham, desmedipham and their metabolites MHPC and EHPC in/on fat, liver and kidney by HPLC-MS/MS. Bayer CropScience AG, Development – Residues, Operator and Consumer Safety, Monheim am Rhein, Germany, Report No. MR-538/03 Date:03.02.2003, GLP, Non Published BAY No. C 029972	
IIA 4.2.1	Billian, P.	2003 b	Supplement E001 of the analytical method 00802 for the determination of residues of phenmedipham, desmedipham and their metabolites MHPC and EHPC in/on milk, meat and egg by HPLC-MS/MS. Bayer CropScience AG, Development – Residues, Operator and Consumer Safety, Monheim am Rhein, Germany, Report No. MR-004/03 Date:06.03.2003, GLP, Non Published BAY No. C 030876	
IIA 2.14.	Bittner, P. and Rexer, K.	1999	Determination of the surface tension , phenmedipham substance, technical. No: C003499 GLP, unpublished	
IIA 4.1	Bogdoll, B. and Eichelmann, C.	2003 a	Analytical method, determination of phenmedipham (AE B038584) in technical material by HPLC. Bayer CropScience GmbH, Product Technology – Analytics Frankfurt, Frankfurt am Main, Germany, Report No. AL045/96-1 Date:16.01.2003, GLP, Non Published BAY No. C029011	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[6] on previous use in granting national authorizations
IIA 4.1	Bogdoll, B. and Eichelmann, C.	2003 b	Validation of the analytical method AL045/96-1 for the determination of phenmedipham AE B038584 in technical material. Bayer CropScience GmbH, Product Technology – Analytics Frankfurt, Frankfurt am Main, Germany, Report No. PA02/080 Date:13.01.2003, GLP, Non Published BAY No. C028717	
IIA 4.1	Bogdoll, B. and Eichelmann, C.	2003 c	Analytical method, determination of the organic impurities in phenmedipham technical grade and pure active ingredient by HPLC. Bayer CropScience GmbH, Product Technology – Analytics Frankfurt, Frankfurt am Main, Germany, Report No. AL046/96-1 Date:15.01.2003, GLP, Non Published BAY No. C029012	
IIA 4.1	Bogdoll, B. and Eichelmann, C.	2003 d	Validation of the analytical method AL046/96-1 for the determination of the organic impurities in phenmedipham technical material. Bayer CropScience GmbH, Product Technology – Analytics Frankfurt, Frankfurt am Main, Germany, Report No. PA02/067 Date:13.01.2003, GLP, Non Published BAY No. C028575	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[6] on previous use in granting national authorizations
IIA 4.2.1	Brumhard, B.	2003	Independent laboratory validation of enforcement method 00802/E001 for the determination of residues of phenmedipham, desmedipham and their metabolites MHPC and EHPC in/on sample materials of animal origin by HPLC-MS/MS. Bayer CropScience AG, Development – Residues, Operator and Consumer Safety, Monheim am Rhein, Germany, Report No. MR-041/03 Date:27.03.2003, GLP, Non Published BAY No. C031372	
IIA 4.2.4	Chambers J. and Everitt S.	1998	Validation of the analytical method for the determination of phenmedipham in air, 1998. No: A64017 GLP, unpublished	
IIA 4.1.	Cichy M.	1996 b	Analytical method: Determination of phenmedipham (AE B038584) in technical substance by HPLC. TFP, No: C70/3 Not GLP. unpublished	
IIA 4.1.	Cichy M.	1996 c	Analytical method phenmedipham (AE B038584): Determination of the organic impurities in technical grade and pure active ingredient by HPLC. TFP, No. C70/4 Not GLP. unpublished	
IIA 4.1.	Cichy M. and Klöckner C.	1996 b	AE B038584, Phenmedipham: Validation of the analytical methods AL045/96-0 and AL046/96-0 for the determination of a.i. and impurities in technical and pure material. No: C70/5 GLP, unpublished	
IIA 2.5.	Cichy, M. and Poerschke, R.	1999	Spectral data (UV/VIS, IR, MS, ^{1}H-NMR, ^{13}C-NMR) and molar extinction coefficient. No: C003750 GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[6] on previous use in granting national authorizations
IIA 4.1	Feucht, G. and Ruppmann, G.	2003	Validation of the analytical method AL059/02-0 for the determination of toluene (AE F125577) in phenmedipham technical material. Bayer CropScience GmbH, Product Technology – Analytics Frankfurt, Frankfurt am Main, Germany, Report No. PA02/081 Date:07.01.2003, GLP, Non Published BAY No. C028624	
IIA 4.1	Feucht, G., Riegelbeck, S. and Ruppmann, G.	2003	Analytical method, determination of toluene (AE F 125577) in pure and technical grade phenmedipham AE B038584 by gas chromatography (GC). Bayer CropScience GmbH, Product Technology – Analytics Frankfurt, Frankfurt am Main, Germany, Report No. AL059/02-0 Date:14.01.2003, GLP, Non Published BAY No. C028623	
IIA 2.3.	Harteveld, J.	1992	The vapour pressure of Top2 pure phenmedipham. No: C511 GLP, unpublished	
IIA 2.13	Klais O.	1998	Explosive properties of Phenmedipham. TFP, No: A64020 Not GLP, unpublished	
IIA 2.13. IIA 2.15.	Klais, O.	1999	Explosive and oxidizing properties of phenmedipham and of "Betanal" (AE B038584 00 EC16 A1), a composition with phenmedipham as active substance. TFP, No: C003495 Not GLP, unpublished	
IIA 2.3.	Miklautz, H.	1994	The Henry constant of phenmedipham (PMP, ZK 15320) at 20 ^{o}C. TFP, No: C65/2 Not GLP, unpublished	
IIA 2.4.1	Suessmann R. and Rexer K.	1999 e	Determination of the colour. Phenmedipham substance technical. TFP, No: C006316 not GLP, Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[6] on previous use in granting national authorizations
IIA 2.4.1	Suessmann R. and Rexer K.	1999 a	Determination of the physical form. Phenmedipham substance pure. TFP, No: C006313 not GLP, Unpublished	
IIA 2.4.1	Suessmann R. and Rexer K.	1999 b	Determination of the colour. Phenmedipham substance pure. TFP, No: C006315 not GLP, Unpublished	
IIA 2.4.2	Suessmann R. and Rexer K.	1999 c	Determination of the odour. Phenmedipham substance pure. TFP, No: C006314 not GLP, Unpublished	
IIA 2.4.1	Suessmann R. and Rexer K.	1999 d	Determination of the physical form. Phenmedipham substance technical. TFP, No: C006318 not GLP, Unpublished	
IIA 2.4.2	Suessmann R. and Rexer K.	1999f	TFP, Determination of the odour. Phenmedipham substance technical. TFP,No: C006317 not GLP, Unpublished	
IIA 2.11.	Weinig, P.	1995	Determination of the flammability, autoflammability and oxidizing properties of phenmedipham. TFP, No: C358 GLP, unpublished	
IIA 4.2.1	Williamson, P.	1995	Kemifam: Determination of phenmedipham residues in sugar beet at harvest and to prepare decline curves. Generated by: Safepharm Laboratories Limited, UK No: R506 GLP, unpublished	
IIA 4.2.4	Wrede - Rücker, A.	1993 b	Analytical method for the determination of phenmedipham in air. TFP, No: W265/2 GLP, unpublished	
IIA 4.2.5	Wrede A.	1998	Analytical method and validation for the determination of residues of phenmedipham and its metabolite MHPC in tissue, milk and egg by HPLC. TFP, No: A64037 GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[6] on previous use in granting national authorizations
IIA 4.2.1	Wrede- Rücker, A.	1993 a	Phenmedipham: Method validation study in sugar beets with ^{14}C-radiolabelled phenmedipham. TFP, No: R172 GLP, unpublished	
IIA 4.2.1	Wrede, A.	1999	Data generation method with validation for sugar beets by LC-MS/MS. TFP Phenmedipham (AE B038584), Desmedipham (AE B038107), AE B038210, AE F132319 GLP, unpublished	
IIA 4.2.1	Wrede, A.	2000	Enforcement method and validation of surface and drinking water by HPLC/UV. TFP, No: C007532 GLP, Unpublished	
IIA 4.2.1	Wrede, A.	2002	Independent laboratory validation (ILV) of the DFG S19-method for sugar beet roots by GC-MS. TFP, No: C020746 GLP, Unpublished	

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 5.4.1.2.1	Akhurst, L.C.	1994	Phenmedipham: Metaphase chromosome analysis of human lymphocytes cultured in vitro. TFP, Company file No: T227 GLP, Unpublished	
II A 5.12.2	Davies, D.J.	2000	Phenmedipham: *In vitro* absorption through human and rat epidermis Code: AE B049913 01 EC23 A3 TFP, No: C010697 GLP, Unpublished	
II A 5.12.2	Davies, D.J.	2000	Phenmedipham: In vitro absorption through human and rat epidermis TFP, Report No. C009290 GLP, Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 5.1.1/1	Elsom, L.F.	1994	Phenmedipham: Rat metabolism study. Company file No: M28 GLP, Unpublished	
II A 5.12.1	Jones, B.K.	2000	Phenmedipham: *In vivo* dermal penetration study in the rat Code: AE B049913 01 EC23 A3 TFP, No: C009289 GLP, Unpublished	
IIA, 5.5.3	Perry, C.J. Snodgrass, E.	2000	Phenmedipham: Histological evaluation extension from the 52 week chronic toxicity and 104 week carcinogenicity study in rat. TFP, Inveresk Project No. 431261 GLP, Unpublished	
II A 5.5.3	Jackson, M.C., Mallyon, B.	2000	Phenmedipham: Histological evaluation extension from the 52 week chronic toxicity and 104 week carcinogenicity study in rat TFP, Report No. C009565 GLP, Unpublished	

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.6. /2 and IIA 6.6 /44	Baker, T.	1995	Field report on the determination of phenmedipham residues in sugar beet; following a 1994 application. Generated by: Soil Survey and Land Research Centre, Cranfield University, United Kingdom TFP, Company file No: R505 GLP, Unpublished	
IIA 6.6.1 /1	Dacus, S.C.	1993	Stability of phenmedipham residues in or on sugarbeets stored at 4 °C for 5 months and processed commodities stored at -10 °C for 5 months USA, 1992. Hoechst Shering AgrEvo GmbH Company file No: R167, A.62033 No GLP, Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.9 /2 and IIA 6.9/4	Downey, S.S.	1993	Uptake of 14C-phenmedipham residues in soil by rotational crops under confined conditions. Generated by: NOR-AM Chemical Company, Pikeville, North Carolina, USA Company file No: W267 GLP, Unpublished	
IIA 6.6 /98	Helgers, A.	1996	Residues of desmedipham and phenmedipham and their major metabolites in sugar beet treated with the formulation Betanal Progress (CQ 1525) in Southern Europe (Italy). Hoechst Shering AgrEvo GmbH Study idenfication ER 95 ECS 440 Company file No: R 181 GLP, Unpublished	
IIA 6.6 /97	Klein, E.H.-J. & Wrede, A.	1996	Residues of desmedipham and phenmedipham and its major metabolites in sugar beet to establish a Maximum Residue Level following 3 applications in Southern Europe (Spain), 1994. Hoechst Shering AgrEvo GmbH Study idenfication ER 94 ECS 442 Company file No: R 180, A.63609 GLP, Unpublished	
IIA 6.6 /100	Moede	1996	Phenmedipham (Betanal), emulsifiable concentrate 157 g/l. Code: CQ 532 , residue of phenmedipham in spinach. Hoechst Shering AgrEvo GmbH Study idenfication ER 95 ECS 440 Company file No: R 82 GLP, Unpublished	
IIA 6.6 /102	Old J., Doran A., Foster A.C. & Smith A.	1999	Phenmedipham/ ethofumesate residues in peas following two applications to peas in northern/ central Europe. Inveresk Research Study no: 391905. Report no: 17080 GLP, Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.6 /101	Welcker, H. & Wrede, A.	1999	Decline of residues in sugar beet European Union (southern zone) 1998. Phenmedipham, AE B038584 (suspo-emulsion SE) 16 % w/w (=160 g/l). AE B038584 00 SE16 1602. AgrEvo GmbH Study idenfication ER 98 ECS 540 GLP, Unpublished	
IIA 6.6 /103	Welcker, H. & Wrede, A.	1999	Decline of residues in spinach European Union (southern zone) 1998. Phenmedipham, AE B038584 (suspo-emulsion SE) 16 % w/w (=160 g/l). AE B038584 00 SE16 1602. AgrEvo GmbH Study idenfication ER 98 ECS 541 GLP, Unpublished	
IIA 6.6 /3 and IIA 6.6 /45	Williamson, P.F.	1995	Kemifam: determination of phenmedipham residues in sugar beet at harvest and to prepare decline curves. Generated by: Safepharm Laboratories Limited, UK, Company file No: R506 GLP, Unpublished	
IIA 6.6.1 /2	Williamson, P.F. & Bartlett, A.J..	1995	Kemifam: Freezer storage stability data on phenmedipham residues in sugar beet. Hoechst Shering AgrEvo GmbH Project No: 689/002 Company file No: R512, A.62788 GLP, Unpublished	
IIA 6.6./99	Wrede, A.	1997	Residues of desmedipham, phenmedipham and ethofumesate and their major metabolites in chickpeas treated with Betanal Progress in Southern Europe (Spain). Hoechst Shering AgrEvo GmbH Study idenfication CR 96/011 Company file No: R182 GLP, Unpublished	
IIA 6.6 /43	Wrede-Rücker, A.	1993	Desmedipham/phenmedipham: EC (Betanal Progress, CQ 1069) residues in sugar beets great Britain 1992. Generated by: Schering AG Company file No: R168 No GLP, Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 6.6 /1 and IIA 6.6 /46	Wrede-Ruecker. A.	1995	Residues in sugar beet after application of Betanal Progress of in France 1993. Report.. Generated by: AgrEvo GmbH Company file No: R175 GLP, Unpublished	
IIA 6.6 /89	Wrede-Ruecker. A.	1995	Residues in strawberry fruit and jam after application of Betanal in Germany 1993. Generated by: AgrEvo GmbH Company file No: R176 GLP, Unpublished	
IIA 6.7 /6	Wrede-Ruecker. A.	1995	Residues in strawberry fruit and jam after application of Betanal in Germany 1993. Generated by: AgrEvo GmbH Company file No: R176 GLP, Unpublished	

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 7.2.5. /3	Allen, R., Terry, A.S., Lander, G. & Jonas W.	1998	Phenmedipham (AE B038584) Two investigations of the degradation and leaching of phenmedipham in outdoor lysimeters. No. A63800 PMP/W328 TFP not GLP, Unpublished	
IIA 7.2.5. /1	Allen, R.,Terry, A. S. and Lander, G.	1995	Phenmedipham Betanal EC 157 g/l Code : CQ532 Leaching in soil lysimeters maintained under outdoor conditions W294 TFP GLP, Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 7.2.1.1	Andre, J.C.	2003 a	(14C)-Phenmedipham. Aqueous hydrolysis at pH 4, 5, 7 and 9 at 25°C. Batelle Memorial Institute, USA TOP2 Task Force on Phenmedipham AG020006 35817 C028786 GLP, unpublished	
IIA 7.2.1.1	Andre, J.C.	2003 b	(14C)-Methyl (3-hydroxyphenyl) carbamate. Aqueous hydrolysis at pH 4, 5, 7 and 9 at 25°C. Batelle Memorial Institute, USA AG020020 35848 C030025 TOP2 Task Force on Phenmedipham GLP, unpublished	
IIA 7.4.4. /3	Bieber, W.-D.	1996	Degradation of the test substance Phenmedipham in Aerobic Sediment/Water PMP/W315, A63618 TFP GLP, Unpublished	
IIA 7.1.3.1/4.	Brady, S. S.; Moede J.; Wrede-Ruecker A.	1993	Dissipation of Phenmedipham and its major metabolite in soil following the application of SPIN-AID EC at the highest label rate in red beet trials in the USA 1989 (and addendum) W232/2 TFP not GLP, Unpublished	
IIA 7.7. /1	Brehm, M.	1992	Estimation of the photochemical-oxidative degradation of phenmedipham (Schering Code No. ZK 15 320) in the atmosphere. W251 TFP not GLP, Unpublished	
IIA 7.2.5. /2	Jonas, W.	1997	Investigation of the degradation and percolation behaviour in an agriculturally utilized soil - outdoor lysimeter study- A63800, W328 TFP not GLP, Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 7.2.3. /1	Judge, D.N.; Feyerabend, M.	1994	Unaged leaching of phenmedipham [UL-14C]-aminophenoxy- and aminomethyl-[UL-14C]-phenyl-labeled) in a US sandy loam and a US silt loam. W285 TFP not GLP, Unpublished	
IIA 7.1.11	Melkebeke, T.	1998	Determination of the degradation rate of phenmedipham in three soils NOTOX Project 185783 AgriChem bv GLP, unpublished	No Task Force study
IIA 7.1.1	Schäfer, D.	2000 a	Kinetic evaluation of the soil degradation of phenmedipham and its main metabolite MHPC under anaerobic conditions. Hoechst Schering AgrEvo GmbH, Environmental Sciences, D-65926 Frankfurt am Main, Germany. AgrEvo Report No OE00/019, Code AE B038584, February 14, 2000. TFP not GLP, Unpublished	
II A 7.4.4 /7.6	Schäfer, D.	2000 b	Calculation of sediment concentrations (PECsed) of phenmedipham and its main metabolite MHPC. Hoechst Schering AgrEvo GmbH, Environmental Sciences, D-65926 Frankfurt am Main, Germany. AgrEvo Report No OE00/020, Code AE B038584, February 14, 2000. TFP not GLP, Unpublished	
IIA 7.2.1	Schäfer, D.	2002 a	Kinetic evaluation of phenmedipham water/sediment studies to determine input parameters for aquatic PEC calculations Bayer Crop Science C025984 Not GLP, unpublished	
IIA 7.1.11	Willems, T.	1997	Determination of the degradation rate of methyl-3-hydroxy-phenylcarbamate in three soils NOTOX Project 185805 AgriChem bv GLP, unpublished	No Task Force study

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 8.4 IIIA 10.6.1	Barber, I	2002	Calculation of earthworm TER values for phenmedipham B004067 TFP not GLP, Unpublished	
IIA 8.2.1	Barber, I.	2000 b	Phenmedipham, substance technical, Code: AE B038584. Relative toxicity of phenmedipham and its hydrolysis metabolite MHPC (methyl-3-hydroxyphenyl carbamate) to aquatic organisms. Aventis CropScience USA, Report No. ENVIR/00/51. Aventis Code B003058 not GLP, Unpublished	
IIA 8.2 IIIA 10.2	Barber, I.	2002	Aquatic TER values for phenmedipham and MHPC B004066 TFP not GLP, Unpublished	
IIA 8.4 IIIA 10.6.1	Ebeling, M. & Nguyen, D.	2002	Effects on growth and reproduction of earthworms (Eisenia fetida). Phenmedipham; Suspo-emulsion 160 g/L. Bayer CropScience CE02/068 C028008 GLP, Unpublished	
IIA 8.2.7./1	Mattock, S.D.	1998	Phenmedipham Substance, technical 98 % w/w Code: AE B038584 00ID98 0001 Chronic toxicity to the sediment dwelling organism Chironomus riparius (BBA method) No: A63969 GLP, unpublished	
IIA 8.2.1	Mead, C. and Mullee D.M	2000	Methyl-3-hydroxyphenyl carbamate (MHPC) 93 % w/w substance technical. Algal growth inhibition - Pseudokirchneriella subcapitata. Safepharm Laboratories Ltd. Report No. ENVIR/00/037, Study No. ENVIR/63/AH. 11 July 2000. Aventis Code C008968. GLP, Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 8.3.2 IIIA 10.5	Mead-Briggs, M & Longley, M	1996	Phenmedipham suspoemulsion 160g/l. Toxicity of kenifam Flow to the parisitoid Aphidus rhopalosiphi in a laboratory study The University of Southampton PMP/W620 39AH A63665 GLP, Unpublished	
IIA 8.5./9	Moreth, L.	1993	BETANAL OF (SCH 44030 H): Auswirkungen von Pflanzenschutzmitteln auf ALEOCHARA BILINEATA: Erweiterter Labor-Test. (BETANAL OF (SCH 44030 H): Effect of pesticides on Aleochara bilineata: extended laboratory study) No: W270 Not GLP, unpublished	
IIA 8.4 IIIA 10.6.1	Neumann, P.	2003	Long-term risk assessment for earthworms for the exposure to phenmedipham. Bayer CropScience C029197 Not GLP, Unpublished	
IIA 8.1.3.	Rodgers, M.	1996	Phenmedipham bobwhite quail dietary reproduction and range finding studies No: W300 GLP, unpublished	
IIA 8.2.6./4	Scheerbaum, D.	1998	Phenmedipham Substance technical 98.5 % w/w Code: AE B038584 00 1D98 00, Alga, Growth Inhibition Test (Nitzschia palea, 96 h) No: A64036 GLP, unpublished	
IIA 8.2.8./1	Scheerbaum, D.	1998	Phenmedipham Substance technical 98,5% w/w Code: AE B038584 00 1D98 00 Lemna minor: Semi-static Phytotoxicity Test No: A64035 GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 8.6; III. 10.8	Thuerwaechter, F.	1999	Effect of three Betanal Formulations on Non Target Terrestrial Plants. Hoechst Schering AgrEvo GmbH, Research Biology, Hoechst Works, Frankfurt,Germany. AgrEvo Report C008966. not GLP, Unpublished	
IIA 8.3.2 IIIA 10.5	Vinall, S. P.	1996	Phenmedipham Suspoemulsion 160 g/l Toxicity of Kemifam flow to the predatory mite Typhlodromus pyri in the laboratory The University of Southampton ENVIR/96/11 38AH TOP2 GLP, Unpublished	
IIA 8.3.2 IIIA 10.5	Waltersdorfer, A	1996	Toxicity of Kemifam flow to the ground dwelling predator Poecilus cupreus L. (Coleoptera, Carabindae) in the laboratory Hoechst Schering AgrEvo GmbH A63619 GLP, Unpublished	
IIA 8.3.2 IIIA 10.5	Waltersdorfer, A	1996	Phenmedipham fluid heterogenous 160 g/l Toxicity of Kemifam flow to the filage dwelling predator Chrysoperla carnea Steph. (Neuroptera, Chrysopidae) in the laboratory Hoechst Schering AgrEvo GmbH CW96/015 A63620 GLP, Unpublished	
IIA 8.2.1	Wetton, P.M and Mullee, D.M.	2000 a	Methyl-3-hydroxyphenyl carbamate (MHPC) 93 % w/w substance technical. Acute toxicity to rainbow trout (Onchorhynchus mykiss). Safepharm Laboratories Ltd. Report No. ENVIR/00/035, Study No. ENVIR/64AH. 11 July 2000. Aventis Code C008966 GLP, Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 8.2.1	Wetton, P.M. and Mullee, D.M.	2000 b.	Methyl-3-hydroxyphenyl carbamate (MHPC) 93 % w/w substance technical. Acute toxicity to Daphnia magna. Safepharm Laboratories Ltd. Report No. ENVIR/00/036, Study No. ENVIR/62AH. 11 July 2000. Aventis Code C008967. GLP, Unpublished	

APPENDIX IIIB

PHENMEDIPHAM

List of studies which were submitted during the evaluation process and were not cited in the draft assessment report:

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**	
IIA 4.2.2	Anspach, T.	2003 a	Validation of DFG Method S 19 (extended revision) for the determination of residues of phenmedipham and its metabolite MHPC in/on soil by means of liquid chromatography with tandem mass spectrometric detection (LC-MS/MS). Dr. Specht & Partner Chemische Laboratorien GmbH, Hamburg, Germany, Report No. BAY-0223V Date:29.01.2003, GLP, Non Published BAY No. C 029546	
IIA 4.2.3	Anspach, T	2003 b	Enforcement method (including validation) for the determination of residues of phenmedipham and its metabolite MHPC in drinking and surface water. Dr. Specht & Partner Chemische Laboratorien GmbH, Hamburg, Germany, Report No. BAY-0225V Date:23.01.2003, GLP, Non Published BAY No. C 029326	

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	
IIA 4.2.1	Billian, P.	2003 a	Analytical method 00802 for the determination of residues of phenmedipham, desmedipham and their metabolites MHPC and EHPC in/on fat, liver and kidney by HPLC-MS/MS. Bayer CropScience AG, Development – Residues, Operator and Consumer Safety, Monheim am Rhein, Germany, Report No. MR-538/03 Date:03.02.2003, GLP, Non Published BAY No. C 029972	
IIA 4.2.1	Billian, P.	2003 b	Supplement E001 of the analytical method 00802 for the determination of residues of phenmedipham, desmedipham and their metabolites MHPC and EHPC in/on milk, meat and egg by HPLC-MS/MS. Bayer CropScience AG, Development – Residues, Operator and Consumer Safety, Monheim am Rhein, Germany, Report No. MR-004/03 Date:06.03.2003, GLP, Non Published BAY No. C 030876	
IIA 4.1	Bogdoll, B. and Eichelmann, C.	2003 a	Analytical method, determination of phenmedipham (AE B038584) in technical material by HPLC. Bayer CropScience GmbH, Product Technology – Analytics Frankfurt, Frankfurt am Main, Germany, Report No. AL045/96-1 Date:16.01.2003, GLP, Non Published BAY No. C029011	

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	
IIA 4.1	Bogdoll, B. and Eichelmann, C.	2003 b	Validation of the analytical method AL045/96-1 for the determination of phenmedipham AE B038584 in technical material. Bayer CropScience GmbH, Product Technology – Analytics Frankfurt, Frankfurt am Main, Germany, Report No. PA02/080 Date:13.01.2003, GLP, Non Published BAY No. C028717	
IIA 4.1	Bogdoll, B. and Eichelmann, C.	2003 c	Analytical method, determination of the organic impurities in phenmedipham technical grade and pure active ingredient by HPLC. Bayer CropScience GmbH, Product Technology – Analytics Frankfurt, Frankfurt am Main, Germany, Report No. AL046/96-1 Date:15.01.2003, GLP, Non Published BAY No. C029012	
IIA 4.1	Bogdoll, B. and Eichelmann, C.	2003 d	Validation of the analytical method AL046/96-1 for the determination of the organic impurities in phenmedipham technical material. Bayer CropScience GmbH, Product Technology – Analytics Frankfurt, Frankfurt am Main, Germany, Report No. PA02/067 Date:13.01.2003, GLP, Non Published BAY No. C028575	

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	
IIA 4.2.1	Brumhard, B.	2003	Independent laboratory validation of enforcement method 00802/E001 for the determination of residues of phenmedipham, desmedipham and their metabolites MHPC and EHPC in/on sample materials of animal origin by HPLC-MS/MS. Bayer CropScience AG, Development – Residues, Operator and Consumer Safety, Monheim am Rhein, Germany, Report No. MR-041/03 Date:27.03.2003, GLP, Non Published BAY No. C031372	
IIA 4.1	Feucht, G. and Ruppmann, G.	2003	Validation of the analytical method AL059/02-0 for the determination of toluene (AE F125577) in phenmedipham technical material. Bayer CropScience GmbH, Product Technology – Analytics Frankfurt, Frankfurt am Main, Germany, Report No. PA02/081 Date:07.01.2003, GLP, Non Published BAY No. C028624	
IIA 4.1	Feucht, G., Riegelbeck, S. and Ruppmann, G.	2003	Analytical method, determination of toluene (AE F 125577) in pure and technical grade phenmedipham AE B038584 by gas chromatography (GC). Bayer CropScience GmbH, Product Technology – Analytics Frankfurt, Frankfurt am Main, Germany, Report No. AL059/02-0 Date:14.01.2003, GLP, Non Published BAY No. C028623	
IIA 2.4.1	Suessmann R. and Rexer K.	1999 a	Determination of the physical form. Phenmedipham substance pure. TFP, No: C006313 not GLP, Unpublished	
IIA 2.4.1	Suessmann R. and Rexer K.	1999 b	Determination of the colour. Phenmedipham substance pure. TFP, No: C006315 not GLP, Unpublished	

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	
IIA 2.4.2	Suessmann R. and Rexer K.	1999 c	Determination of the odour. Phenmedipham substance pure. TFP, No: C006314 not GLP, Unpublished	
IIA 2.4.1	Suessmann R. and Rexer K.	1999 d	Determination of the physical form. Phenmedipham substance technical. TFP, No: C006318 not GLP, Unpublished	
IIA 2.4.1	Suessmann R. and Rexer K.	1999 e	Determination of the colour. Phenmedipham substance technical. TFP, No: C006316 not GLP, Unpublished	
IIA 2.4.2	Suessmann R. and Rexer K.	1999f	TFP, Determination of the odour. Phenmedipham substance technical. No: C006317 not GLP, Unpublished	
IIA 4.2.1	Wrede, A.	2002	Independent laboratory validation (ILV) of the DFG S19-method for sugar beet roots by GC-MS. TFP, No: C020746 GLP, Unpublished	
IIA 4.2.1	Wrede, A.	2000	Enforcement method and validation of surface and drinking water by HPLC/UV. TFP, No: C007532 GLP, Unpublished	

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	
II A 5.12.2	Davies, D.J.	2000	Phenmedipham: *In vitro* absorption through human and rat epidermis TFP, Report No. C009290 GLP, Unpublished	
II A 5.12.1	Jones, B.K.	2000	Phenmedipham: *In vivo* dermal penetration study in the rat TFP, Report No. C009289 GLP, Unpublished	
II A 5.5.3	Jackson, M.C., Mallyon, B.	2000	Phenmedipham: Histological evaluation extension from the 52 week chronic toxicity and 104 week carcinogenicity study in rat TFP, Report No. C009565 GLP, Unpublished	
I A 5.5.3	Perry, C.J., Snodgrass, E.	2000	Phenmedipham: Histological evaluation extension from the 52 week chronic toxicity and 104 week carcinogenicity study in rat TFP, Report No. C009565 GLP, Unpublished	

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	
IIA 6.9/3	Jenny, N.A.	1973	Plant uptake of phenmedipham soil residues. Completion of two year study. Generated by: NOR-AM Agricultural Products Inc.; Woodstock; Illinois; USA. TFP, Company file No: W33 Correction, evaluated study in monograph Not GLP., unpublished	

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	
IIA 6.9/4	Downey, S.S.	1993	Uptake of [^{14}C]-phenmedipham residues in soil by rotational crops under confined conditions. Generated by: NOR-AM chemical Company, Pikeville, North Carolina, USA TFP, Company file No: W267 GLP., unpublished	

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	
IIA 7.2.1.1	Andre, J.C.	2003 a	(14C)-Phenmedipham. Aqueous hydrolysis at pH 4, 5, 7 and 9 at 25°C. Batelle Memorial Institute, USA TOP2 Task Force on Phenmedipham AG020006 35817 C028786 GLP, unpublished	
IIA 7.2.1.1	Andre, J.C.	2003 b	(14C)-Methyl (3-hydroxyphenyl) carbamate. Aqueous hydrolysis at pH 4, 5, 7 and 9 at 25°C. Batelle Memorial Institute, USA AG020020 35848 C030025 TOP2 Task Force on Phenmedipham GLP, unpublished	
IIA, 7.1.2	Burr, C.	2002 b	PH Dependence of adsorption of phenmedipham Bayer CropScience C0025452 Not GLP, unpublished	
IIA 7.1.11	Melkebeke, T.	1998	Determination of the degradation rate of phenmedipham in three soils NOTOX Project 185783 AgriChem bv GLP, unpublished	No Task Force study

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	
IIA 7.1.1	Schäfer, D.	2000 a	Kinetic evaluation of the soil degradation of phenmedipham and its main metabolite MHPC under anaerobic conditions. Hoechst Schering AgrEvo GmbH, Environmental Sciences, D-65926 Frankfurt am Main, Germany. AgrEvo Report No OE00/019, Code AE B038584, February 14, 2000. not GLP, Unpublished	
II A 7.4.4 /7.6	Schäfer, D.	2000 b	Calculation of sediment concentrations (PECsed) of phenmedipham and its main metabolite MHPC. Hoechst Schering AgrEvo GmbH, Environmental Sciences, D-65926 Frankfurt am Main, Germany. AgrEvo Report No OE00/020, Code AE B038584, February 14, 2000. not GLP, Unpublished	
IIA 7.2.1	Schäfer, D.	2002 a	Kinetic evaluation of phenmedipham water/sediment studies to determine input parameters for aquatic PEC calculations Bayer Crop Science C025984 Not GLP, unpublished	
IIA 7.1.11	Willems, T.	1997	Determination of the degradation rate of methyl-3-hydroxy-phenylcarbamate in three soils NOTOX Project 185805 AgriChem bv GLP, unpublished	No Task Force Study

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	
IIA 8.2	Barber, I.	2000 a	Aventis CropScience, in the Expert statement point 4.1.8. included in the letter of TOP2 by Martyn Griffiths to Jouni Rokkanen, PPIC Finland, 04.08.2000 not GLP, Unpublished	
IIA 8.2.1	Barber, I.	2000 b	Phenmedipham, substance technical, Code: AE B038584. Relative toxicity of phenmedipham and its hydrolysis metabolite MHPC (methyl-3-hydroxyphenyl carbamate) to aquatic organisms. Aventis CropScience USA, Report No. ENVIR/00/51. Aventis Code B003058 not GLP, Unpublished	
IIA 8.4 IIIA 10.6.1	Barber, I	2002	Calculation of earthworm TER values for phenmedipham B004067 TFP not GLP, Unpublished	
IIA 8.2 IIIA 10.2	Barber, I.	2002	Aquatic TER values for phenmedipham and MHPC B004066 TFP not GLP, Unpublished	
IIA 8.4 IIIA 10.6.1	Ebeling, M. & Nguyen, D.	2002	Effects on growth and reproduction of earthworms (Eisenia fetida). Phenmedipham; Suspo-emulsion 160 g/L. Bayer CropScience CE02/068 C028008 GLP, Unpublished	
IIA 8.3.2 IIIA 10.5	Mead-Briggs, M & Longley, M	1996	Phenmedipham suspoemulsion 160g/l. Toxicity of kenifam Flow to the parisitoid Aphidus rhopalosiphi in a laboratory stu The University of Southampton PMP/W620 39AH A63665 GLP, Unpublished	

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	
IIA 8.2.1	Mead, C. and Mullee D.M	2000	Methyl-3-hydroxyphenyl carbamate (MHPC) 93 % w/w substance technical. Algal growth inhibition - Pseudokirchneriella subcapitata. Safepharm Laboratories Ltd. Report No. ENVIR/00/037, Study No. ENVIR/63/AH. 11 July 2000. Aventis Code C008968. GLP, Unpublished	
IIA 8.4 IIIA 10.6.1	Neumann, P.	2003	Long-term risk assessment for earthworms for the exposure to phenmedipham. Bayer CropScience C029197 Not GLP, Unpublished	
IIA 8.6; III. 10.8	Thuerwaechter, F.	1999	Effect of three Betanal Formulations on Non Target Terrestrial Plants. Hoechst Schering AgrEvo GmbH, Research Biology, Hoechst Works, Frankfurt,Germany. AgrEvo Report C008966. not GLP, Unpublished	
IIA 8.3.2 IIIA 10.5	Vinall, S. P.	1996	Phenmedipham Suspoemulsion 160 g/l Toxicity of Kemifam flow to the predatory mite Typhlodromus pyri in the laboratory The University of Southampton ENVIR/96/11 38AH TOP2 GLP, Unpublished	
IIA 8.3.2 IIIA 10.5	Waltersdorfer, A	1996	Toxicity of Kemifam flow to the ground dwelling predator Poecilus cupreus L. (Coleoptera, Carabindae) in the laboratory Hoechst Schering AgrEvo GmbH A63619 GLP, Unpublished	

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	
IIA 8.3.2 IIIA 10.5	Waltersdorfer, A	1996	Phenmedipham fluid heterogenous 160 g/l Toxicity of Kemifam flow to the filage dwelling predator Chrysoperla carnea Steph. (Neuroptera, Chrysopidae) in the laboratory Hoechst Schering AgrEvo GmbH CW96/015 A63620 GLP, Unpublished	
IIA 8.2.1	Wetton, P.M and Mullee, D.M.	2000 a	Methyl-3-hydroxyphenyl carbamate (MHPC) 93 % w/w substance technical. Acute toxicity to rainbow trout (Onchorhynchus mykiss). Safepharm Laboratories Ltd. Report No. ENVIR/00/035, Study No. ENVIR/64AH. 11 July 2000. Aventis Code C008966 GLP, Unpublished	
IIA 8.2.1	Wetton, P.M. and Mullee, D.M.	2000 b	Methyl-3-hydroxyphenyl carbamate (MHPC) 93 % w/w substance technical. Acute toxicity to Daphnia magna. Safepharm Laboratories Ltd. Report No. ENVIR/00/036, Study No. ENVIR/62AH. 11 July 2000. Aventis Code C008967. GLP, Unpublished	

APPENDIX IV
List of uses supported by available data
PHENMEDIPHAM

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Sugar & fodder beet	EU	Kemifam Flow	F	Annual dicot weeds	SE	160	Overall spray	Postemer-gence, from cotyledon to 8 leaf stage of beets	1 4	5-14		80-400	0.160-0.320 0.960	90 days	Sequential applications
Red beet (Beetroot)	EU	Kemifam Flow	F	Annual dicot weeds	SE	160	Overall spray	Postemer-gence, from cotyledon to 8 leaf stage of crop	1 3	5-14		150-400 ditto	0.160-0.320 0.960	90 days	Sequential applications

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions