



EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Desmedipham  
SANCO/4061/2001- final  
13 February 2004

### Review report for the active substance **desmedipham**

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 desmedipham 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 desmedipham, 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<sup>(1)</sup> 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<sup>(2)</sup>, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Desmedipham 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, Stefes Research GmbH on 09.07.1993, Kemira Agro Benelux on 05.07.1993, Pen-Taso-Materia Medica Center GmbH on 14.07.1993, Barclay Chemicals on 27.06.1993 or on 27.07.1993 and B.V. Luxan on 21.07.1993 notified to the Commission of their wish to secure the inclusion of the active substance desmedipham 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<sup>(3)</sup>, as last amended by Regulation (EC) No 2230/95<sup>(4)</sup>, designated Finland as rapporteur Member State to carry out the assessment of desmedipham 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

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<sup>1</sup> OJ No L 366, 15.12.1992, p.10.

<sup>2</sup> OJ No L 259, 13.10.2000, p.27.

<sup>3</sup> OJ No L 107, 28.04.1994, p.8.

<sup>4</sup> OJ No L 225, 22.09.1995, p.1.

3600/92, as well as for other parties with regard to further technical and scientific information; for desmedipham this deadline was 31.10.1995.

Only AgrEvo GmbH (now Bayer CropScience) submitted in time a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore AgrEvo GmbH (now Bayer CropScience) was considered to be the main data submitter. Dossier submitted by Barclay Chemicals Ltd. was considered incomplete and contained an insufficient level of detail for regulatory purposes. Due to the lack of relevant information the Barclay Chemicals dossier was not at all evaluated. Luxan, Kemira Agro Oy and Stefes Pflanzenschutz GmbH withdrew their notification. Pen-Tsao Materia has not informed whether or not to withdraw its notification.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Finland submitted on 08.05.2000 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 desmedipham 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 desmedipham from AgrEvo GmbH (now Bayer CropScience), 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 on 27.06.2000 as well as to AgrEvo GmbH (now Bayer CropScience) being main data submitter, on 25.08.2000.

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 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 November 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<sup>5</sup> concerning the inclusion of desmedipham in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing desmedipham 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 desmedipham will fulfil the safety requirements laid down in Article 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

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<sup>5</sup> OJ No L 120, 24.4.2004, p.26.

91/414/EEC, for each desmedipham 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) for a 60 kg adult is 11,94 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Additional intake from water are not expected to give rise to intake problems.

Estimates of acute dietary exposure of adults and toddlers revealed that the Acute Reference Dose (ARfD) would not be exceeded (IESTI calculation, 9 % or 4 % for respectively adults or children).

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 desmedipham are given in Appendix I.

As there is no FAO specification, the active substance shall comply with the specification of minimum purity, which is given in Appendix I of this report.

The review has established that for the active substance notified by the main data submitter AgrEvo GmbH (now Bayer CropScience), none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

Dossier submitted by Barclay Chemicals Ltd. was consider incomplete and contained an insufficient level of detail for regulatory purposes. Due the lack of relevant information the Barclay Chemicals dossier was not at all evaluated and therefore it is not possible to consider

whether it 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 desmedipham**

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 and earthworms.

Risk mitigation measures should be applied where appropriate

## **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 desmedipham 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 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.

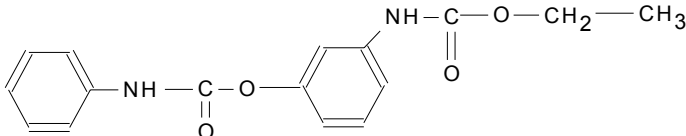
## **8. Information on studies with claimed data protection**

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 desmedipham in Annex I of the Directive.

**APPENDIX I****Identity, physical and chemical properties****DESPEMIDPHAM**

<b>Common name (ISO)</b>	Desmedipham
<b>Chemical name (IUPAC)</b>	ethyl 3'-phenylcarbamoyloxy-carbanilate ethyl 3-phenylcarbamoyloxyphenylcarbamate
<b>Chemical name (CA)</b>	ethyl[3-[[[(phenylamino)carbonyl]oxy]phenyl]carbamate
<b>CIPAC No</b>	477
<b>CAS No</b>	13684-56-5
<b>EEC No</b>	EINECS: 2371985
<b>FAO SPECIFICATION</b>	There is no FAO specification for desmedipham
<b>Minimum purity</b>	min. 970 g/kg
<b>Molecular formula</b>	C <sub>16</sub> H <sub>16</sub> N <sub>2</sub> O <sub>4</sub>
<b>Molecular mass</b>	300.3
<b>Structural formula</b>	

<b>Melting point</b>	118.5 °C (99.6 % pure)
<b>Boiling point</b>	No boiling point, decomposition begins at 234 °C. (98.1 % pure)
<b>Appearance</b>	Colourless, crystalline powder, practically odourless. (99,6% pure)
<b>Relative Density</b>	-
<b>Density</b>	1.32 g/cm <sup>3</sup> at 20 °C (99.2 % pure)
<b>Vapour pressure</b>	4·10 <sup>-8</sup> Pa at 25 °C, extrapolated (99.6 % pure)
<b>Henry's law constant</b>	4.3 · 10 <sup>-7</sup> Pa · m <sup>3</sup> · mol <sup>-1</sup>
<b>Solubility in water</b>	pH 4 : 7 mg/l at 25 °C (99.6 % pure)
<b>Solubility in organic solvents</b>	All in g/l at 20 °C: hexane: 0.02; toluene: 1.2; dichloromethane: 19.8; methanol: 187; acetone: 285; ethyl acetate: 182
<b>Partition co-efficient (log P<sub>ow</sub>)</b>	3.39 at 22 °C and pH 3.9
<b>Hydrolytic stability (DT<sub>50</sub>)</b>	pH 5: DT <sub>50</sub> = 70 days at 22 °C pH 7: DT <sub>50</sub> = 19.6 h at 22 °C pH 9: DT <sub>50</sub> = 0.17 h at 22 °C
<b>Dissociation constant</b>	Desmedipham does not dissociate.
<b>Quantum yield of direct photo-transformation in water at λ &gt;290 nm</b>	2.38 · 10 <sup>-5</sup>
<b>Flammability</b>	Not to be considered as highly flammable.
<b>Explosive properties</b>	Not to be considered as explosive.
<b>UV/VIS absorption (max.)</b>	λ <sub>max</sub> : 203 nm, ε <sub>max</sub> : 55726 l mol <sup>-1</sup> cm <sup>-1</sup> λ <sub>max</sub> : 236 nm, ε <sub>max</sub> : 43133 l mol <sup>-1</sup> cm <sup>-1</sup> λ <sub>max</sub> : 273 nm, ε <sub>max</sub> : 3363 l mol <sup>-1</sup> cm <sup>-1</sup> at pH 6.2
<b>Photostability in water (DT<sub>50</sub>)</b>	Stable.

## APPENDIX II

### END POINTS AND RELATED INFORMATION

#### DESMEDIPHAM

## 1 Toxicology and metabolism

### Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rapid. 80% , based on urinary excretion in 24 h
Distribution:	Widely distributed, highest residues in red blood cells
Potential for accumulation:	Low potential for accumulation; however, a fairly long half-life (ca. 100 h) was observed in red blood cells
Rate and extent of excretion:	Rapid. Over 90 % within 30 h
Toxicologically significant compounds:	Parent compound and metabolites. 3- and 4-aminophenol 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, conjugation

### Acute toxicity

Rat LD <sub>50</sub> oral:	>5000 mg/kg
Rat LD <sub>50</sub> dermal:	>2000 mg/kg
Rat LC <sub>50</sub> inhalation:	>7.4 mg/l
Skin irritation:	Non irritant
Eye irritation:	Non irritant
Skin sensitization (test method used and result):	Not sensitising

### 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). Thyroidal effects in rat and dog (T3+T4 decreased, hypertrophy and hyperplasia)
Lowest relevant oral NOAEL / NOEL:	100 ppm (4.3 mg/kg bw/day) (90-day, dog)
Lowest relevant dermal NOAEL / NOEL:	No data. Not required
Lowest relevant inhalation NOAEL / NOEL:	No data. Not required

**Genotoxicity**

Positive in a mouse lymphoma test and weakly positive in an *in vitro* test in CHO cells. Negative results in two limited bone marrow micronucleus tests in mice.

A new *in vivo* study for induction of micronuclei in rat bone marrow was required and was found to be negative. No classification for mutagenicity is warranted.

**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). Thyroidal effects (hypertrophy, hyperplasia and reduction of T4)

Lowest relevant NOAEL:

60 ppm (3.2 mg/kg bw/day), 2-year rat study

Carcinogenicity:

No carcinogenic potential

**Reproductive toxicity**

Target / critical effect - Reproduction:

Reduced litter size, decreased body and organ weight of pups at parentally toxic dose levels

Lowest relevant reproductive NOAEL / NOEL:

50 ppm (4 mg/kg bw/day)

Target / critical effect - Developmental toxicity:

Rat: delayed skeletal ossification, supernumerary ribs; Rabbit: reduced fetal body weights, postimplantation losses, early embryonic deaths. The effects were observed at maternally toxic dose levels in both species

Lowest relevant developmental NOAEL / NOEL:

Rat: 10 mg/kg bw/day

**Delayed neurotoxicity**

No data. Not required

**Other toxicological studies**

An Ames *Salmonella* test on the metabolite EHPC was performed and found to be negative

**Medical data**

Medical data from two production plants showed no adverse effects among workers. In a literature search one case-report was found describing allergic contact dermatitis at occupational exposure to Betamix.

## Summary

	Value	Study	Safety factor
ADI:	0.03 mg/kg bw/day	2-year, rat	100
AOEL systemic:	0.04 mg/kg bw/day	90-day, dog	100
AOEL inhalation:	Not allocated, not necessary		
AOEL dermal:	Not allocated, not necessary		
ARfD (acute reference dose):	0.1 mg/kg bw/day	80-day, dog (met-Hb formation). Developmental toxicity, rat	100

## Dermal absorption

1% based on an absorption study <i>in vivo</i> in rat, and comparative <i>in vitro</i> penetration studies with rat and human skin
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**Rate of degradation**

**Laboratory studies**

DT<sub>50</sub>lab (20 °C, aerobic):

DT<sub>90</sub>lab (20 °C, aerobic):

DT<sub>50</sub>lab (10 °C, aerobic):

DT<sub>50</sub>lab (20 °C, anaerobic):

range 3.2 – 175 days, n=12, median 17 days
18 – 714 days, n=11; average 142 days, median 73 days; r <sup>2</sup> values not given
no study
phenyl label: 0.34 days in water phase 0.57 days in water phase aniline label: 0.30 days in water phase 0.41 days in water phase

**Field studies (country or region)**

DT<sub>50f</sub> from soil dissipation studies:

DT <sub>50f</sub> : Germany, bare soil, three sites: 4.8 days at pH 6.2, 8.8 days at pH 7.1, 9.0 days at pH 6.9 mean 7.5 days (1 <sup>st</sup> order, r <sup>2</sup> = 0.94-0.98)  USA California, one site, 12.2 days, r <sup>2</sup> =0.95 (USA, N.Dakota, one site, 41.5 days, r <sup>2</sup> =0.53)  (In USA, N.Dakota: EHPC detected at max. 87 % of applied DMP at day 28) (DT <sub>50</sub> of 9 days has been used in the PEC <sub>soil</sub> calculation)
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DT<sub>90f</sub> from soil dissipation studies:

DT <sub>90f</sub> : Germany (sites described above): 18.5, 29.2 and 29.8 days, mean 25.8 days, n=3 USA, California: 40 days  (DT <sub>90</sub> of 30 days has been used in the PEC <sub>soil</sub> calculation)
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Soil accumulation studies:

no study submitted nor required
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Soil residue studies:

no study submitted nor required
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**Remarks:**

e.g. effect of soil pH on degradation rate

no clear pH dependence
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## Adsorption/desorption

$K_f / K_{oc}$ :

$K_d$ :

pH dependence:

DMP:  $K_{oc}$  values not possible to obtain due to high hydrolysis rate – no new study submitted

$R_f$  values of 0.02 - 0.07 in 4 soils, corresponding the  $K_{oc}$  values of 13898, 5927, 10389 and 11952 L/kg

EHPC:  $K_{oc}$  124-335; 4 soils

No pH dependence

## Mobility

### Laboratory studies:

Column leaching:

Guideline: BBA

Precipitation: 200 mm in 2 days

Soils: 3 German standard soils

Use rate: 1.5 kg /ha as Betanal AM 21 formulation, corresponding to 0.5 kg  $^{14}C$ -DMP/ha

Leachate: total residue <0.5 % of AR in all soils, not characterised further

Soil columns: total residue ~95 % of AR, mainly in top 5 cm, not characterised further

Aged residue leaching:

Guideline: BBA IV 4-2

Soils: German standard soil 2.1

Use rate:  $^{14}C$ -AP-labelled DMP 250 g/ha

Aged for: 5 days

Precipitation: 200 mm in 2 days

Leachate: total residue 3.3 % of AR in leachate, EHPC 0.3 % of AR, m-aminophenol 1.65 % of AR, unknown 1.4 % of AR, no DMP could be found (LOD = 0.04 % of AR)

Soil column: Over 85 % of AR in the top 10 cm of soil, mainly as EHPC, only traces of DMP could be found

Volatiles: during ageing about 3 % of AR volatilised

**Field studies:**

Lysimeter/Field leaching studies:

Location: Switzerland, Itingen  
Study type: lysimeter, 3 years  
Soil: 1 sandy soil with low content of organic C  
Number of applications: 1 X 480 g/ha (highest field use rate) in first year or in two successive years, no applications in the third year  
Crops: fodder beet 2 years + winter wheat + barley  
Average annual rainfall: 1043 mm  
Average annual leachate volume: 440 mm  
% radioactivity in leachate (max/year): totally 0.31 % of AR (1<sup>st</sup> year application) or 0.46 % of AR (1<sup>st</sup> + 2<sup>nd</sup> year applications) was found in leachates  
Yearly mean concentrations: total radioactivity 0.09 – 0.1, 0.10 – 0.32, 0.10 – 0.39 µg/l for year 1, 2, and 3 respectively. No DMP or EHPC was found in leachates (LOD for parent and parent equivalents was 0.05 µg/l), m-aminophenol was not analysed

**Remarks:**

No groundwater contamination expected

## 2.2 Fate and behaviour in water

### Abiotic degradation

Hydrolytic degradation:

pH 5, 22 °C : 70 days  
25 °C: 39 days

pH 7, 22 °C: 19.6 h  
25 °C: 12 h

pH 9, 22 °C: 0.17 h  
25 °C: 7 min

Major metabolites:

**EHPC:** stable at pH 4, 5, 7 and 9 at 50 °C

Photolytic degradation:

stable

Major metabolites:

stable

### Biological degradation

Readily biodegradable:

no

Water/sediment study:

2 systems; phenyl- and aniline labelled DMP;  
First order kinetic model  
0.1-3.1 days  
0.3-10.4 days  
2.2-4.0 days  
7.3-13.3 days

DT<sub>50</sub> water:

DT<sub>90</sub> water:

DT<sub>50</sub> whole system:

DT<sub>90</sub> whole system:

Distribution in water / sediment systems  
(active substance)

Phenyl label: Max 9 % in sediment at day 14  
Aniline label: Max 5 % in sediment at day 21

Distribution in water / sediment systems  
(metabolites)

Water (two systems):  
EHPC: max 96 % at day 1 and 22.7 % at day 100  
Aniline: max 72 % at day 0 and 14.9 % at day 100  
Sediment (two systems):  
EHPC: max 13 % at day 100  
Aniline: not found in sediment

Accumulation in water and/or sediment:

due to quite rapid dissipation no accumulation is expected

**Degradation in the saturated zone** no study submitted nor required

Remarks:

None

## 2.3 Fate and behaviour in air

### Volatility

Vapour pressure:

$4 \cdot 10^{-8}$ Pa at 25 °C, extrapolated (99.6 % pure)
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Henry's law constant:

$4.3 \cdot 10^{-7}$ Pa · m <sup>3</sup> · mol <sup>-1</sup>
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### Photolytic degradation

Direct photolysis in air:

Not studied, no data required
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Photochemical oxidative degradation in air

10.8 hours (Atkinson method)
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DT<sub>50</sub>:

Volatilisation:

from plant surfaces: after 24 h less than 3 % was volatilised
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from soil: after 24 h no volatilisation
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Remarks:

PECair considered negligible
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### 3 Ecotoxicology

#### Terrestrial Vertebrates

Acute toxicity to mammals:

rat: LD50 > 5000 mg a.i./kg bw (formulations:  
Betanal AM 11 >5000 mg/kg bw, Betanal  
Progress >2000 mg/kg bw,  
Kemifam Pro FL >2000 mg/kg bw)

Acute toxicity to birds:

bobwhite quail: LD50 > 2000 mg/kg bw, NOEL  
500 mg/kg  
mallard duck: LD50 >2000 mg/kg bw, NOEL 2000  
mg/kg

Dietary toxicity to birds:

mallard duck: LC50 > 5000 mg/kg feed; LC50  
>5200 mg/kg feed, NOEC 1300 mg/kg feed  
bobwhite quail: LC50 >5000 mg/kg feed, NOEC  
5000 mg/kg feed; LC50 >5620 mg/kg feed,  
NOEC 1000 mg/kg feed; LC50 > 5200 mg/kg  
feed, NOEC 1300 mg/kg feed

Reproductive toxicity to birds:

bobwhite quail: NOEC 450 mg/kg feed  
mallard duck: NOEC 90 mg/kg feed

Reproductive toxicity to mammals:

2-year rat study: NOAEL 50 ppm  
corresponding to 3 mg/kg bw/day

**Aquatic Organisms****DMP**

	Species	Time scale	Endpoint	Toxicity (mg/ l) for DMP if not mentioned differently
Acute toxicity fish:	Bluegill sunfish	96 hours	LC50	0.25
	Rainbow trout	96 hours	LC50	8.6 (formulation) 1.38
Long term toxicity fish:	Rainbow trout	28 days	NOEC	0.20
Bioaccumulation fish:	Rainbow trout	7 days	BCF	157
Acute toxicity invertebrate:	Daphnia magna	48 hours	EC50	0.45
	Daphnia magna	48 hours	EC50	3.7 (formulation) 0.59
Chronic toxicity invertebrate:	Daphnia magna	21 days	NOEC	0.01
Acute toxicity algae:	Selenastrum capricornutum green alga	96 hours	EbC50	0.01
	Pseudokirchneriella subcapitata green alga	72 hours	EbC50	0.95 (formulation) 0.15
Chronic toxicity sediment dwelling organism:	Chironomids	28 days	NOEC	1.0
Acute toxicity aquatic plants:	Lemna minor	7 days	EC50	> 5.2

**EHPC**

	Species	Time scale	Endpoint	Toxicity (mg/ l)
Acute toxicity fish:	Rainbow trout	96 hours	LC50	42
Acute toxicity invertebrate:	Daphnia magna	48 hours	EC50	12
Acute toxicity algae:	Selenastrum capricornutum green alga	96 hours	EbC50	23
Chronic toxicity sediment dwelling organism:	Chironomids	28 days	NOEC	0.47

**Aniline**

	Species	Time scale	Endpoint	Toxicity (mg/ l)
Acute toxicity fish:	Rainbow trout	96 hours	LC50	10.6
Chronic toxicity fish:	Fathead minnow	32 days	NOEC	0.42
Acute toxicity invertebrate:	Daphnia pulex	48 hours	EC50	0.1
Chronic toxicity invertebrate:	Ceriodaphnia dubia	7 days	NOEC	0.0081
Acute toxicity algae:	Selenastrum capricornutum green alga	96 hours	EbC50	19

**Honeybees**

Acute oral toxicity:

> 50 µg/bee (technical DMP); > 48.6 µg/bee or >7.8 µg DMP/bee (Betanal AM 11)
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Acute contact toxicity:

> 50 µg/bee (technical DMP); > 25 µg/bee (technical DMP); 339 µg/bee or 54.2 µg DMP/bee (Betanal AM 11)
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## Other arthropod species

Studies with lead formulation and intended application rates are coloured with light grey.

<i>Test species</i>	Dose (kg as/ha)	Stage	% Effect/ Endpoints
<i>Syrphus corollae</i>	2 % corresp. to DMP: 0.064	larvae	- 54 % /development
<i>Poecilus cupreus</i>	6 l/ha -> DMP: 0.096	adult	0 % /mortality
<i>Poecilus</i>	3l/ha -> DMP: 0.480	adult	0 % /mortality - 27 %feeding activity
<i>Aleochara bilineata</i>	3 l/ha-> DMP: 0.048	adult	+15 % /parasiting behaviour
<i>Coccinella septempunctata</i>	3 l/ha-> DMP: 0.480	larvae	- 1.2 %/pre-imaginal mortality; fecundity assessment
<i>Aleochara bilineata</i>	6 l/ha -> DMP: 0.090	adult	-9.8 %/hatching parasiting behaviour
<i>Pardosa spp.</i>	0.2, 2.5 and 4 l/ha -> DMP: 0.005, 0.63 and 0.1	adult	-21% /mortality feeding behaviour
<i>Chrysosperla carnea</i>	6 l/ha -> DMP: 0.096	life cycle	-15 % /reproduction
<i>Coccinella septempunctata</i>	6 l/ha -> DMP: 0.096	larvae	-5 %/development
<i>Typhlodromus pyri</i>	3 l/ha -> DMP: 0.480 (extended lab study)	proto-nymphs	- 28 %/reproduction
<i>Aphidius rhopalosiphi</i>	1.7 l/ha-> DMP: 0.044	adult	30 % /mortality fecundity
<i>Aphidius rhopalosiphi</i>	3 l/ha -> DMP: 0.480	adult	0 % /mortality

## Earthworms

Acute toxicity:

> 79 mg DMP/kg soil (technical DMP)  
> 160 mg DMP/kg soil (Betanal AM 11)

Reproductive toxicity:

NOEC 800 g DMP/ha in test with Betanal AM 11 corresponds to 1.1 mg DMP/kg soil dw → refined NOEC 2.47 mg DMP/kg soil dw (based on actual bulk density and actual application amount)

## Soil micro-organisms

Nitrogen mineralization:

Deviation < ± 25 % of control within 100 days in two studies:

Betanal AM 11: No significant effect up to 1.2 kg DMP/ha

1) Betanal Progress OF 1 x and 5 x field rate, corresponding to ca. 0.16 and 0.8 mg DMP/kg soil, 2 soils, 60 days.

2) Kemifam Pro FL 1 x and 10 x field rate, corresponding to ca. 0.12 and 1.2 mg DMP/kg soil, 2 soils, 97 days.

Carbon mineralization:

Deviation < ± 25 % of control within 100 days in two studies:

Betanal AM 11: No significant effect up to 1.2 kg DMP/ha

1) Betanal Progress OF 1 x and 5 x field rate, corresponding to ca. 0.16 and 0.8 mg DMP/kg soil, 2 soils, 60 days.

2) Kemifam Pro FL 1 x and 10 x field rate, corresponding to ca. 0.12 and 1.2 mg DMP/kg soil, 2 soils, 97 days.

**APPENDIX IIIA****DESMEDIPHAM**

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**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports<sup>6</sup> on previous use in granting national authorizations</b>
IIA 4.2.2	Anspach, Th.	2003a	Validation of DFG Method S 19 (extended revision) for the determination of residues of desmedipham and its metabolite EHPC 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-0228V Date:23.01.2003, GLP, Non Published BAY No. C 029322	
IIA 4.2.3	Anspach, Th.	2003b	Enforcement methods (including validation) for the determination of residues of desmedipham, its metabolite EHPC, and aniline in drinking and surface water. Dr. Specht & Partner Chemische Laboratorien GmbH, Hamburg, Germany, Report No. BAY-0227V Date:29.01.2003, GLP, Non Published BAY No. C 029547	

<sup>6</sup> 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 <sup>6</sup> on previous use in granting national authorizations
IIA 4.2.1	Billian, P.	2003a	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.	2003b	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 2.2.	Bittner P and Rexer K.	1999a	Determination of the density, desmedipham substance, technical. AVO, No: C003501 GLP, unpublished	
IIA 2.14.	Bittner P and Rexer K.	1999b	Determination of the surface tension, desmedipham substance, technical. AVO, No: C003500 GLP, unpublished	
IIA 4.1	Bogdoll, B. and Eichelmann, Ch.	2003a	Analytical method, Determination of desmedipham and the organic impurities in desmedipham technical grade and pure active ingredient by HPLC. Bayer CropScience GmbH, Product Technology – Analytics Frankfurt, Frankfurt am Mein, Germany, Report No. AL061/02-1 Date:03.03.2003, Non GLP, Non Published BAY No. C 030431	

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 <sup>6</sup> on previous use in granting national authorizations
IIA 4.1	Bogdoll, B. and Eichelmann, Ch.	2003b	Validation of the analytical method AL061/02-1 for the determination of desmedipham and of the organic impurities in desmedipham technical material. Bayer CropScience GmbH, Product Technology – Analytics Frankfurt, Frankfurt am Main, Germany, Report No. PA02/077 Date:26.02.2003, GLP, Non Published BAY No. C 030190	
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. C 031372	
IIA 4.2.5	Campbell J.K.	1996	Determination of desmedipham and ethyl-3-hydroxyphenyl carbamate in beef tissues, cream, skim and whole milk by HPLC-UV and GC-ECD. AVO, No: C162 not GLP, unpublished	
IIA 1.11.	Cichy M. and Klöckner C.	1997	AE B038107, Desmedipham – analytical profile of typical production batches and validation of the analytical methods. AVO, No: A63703 GLP, unpublished	
IIA 2.5.1	Cichy, M. and Poerschke, R.	1999	Spectral data (UV/VIS, IR, MS, <sup>1</sup> H-NMR, <sup>13</sup> C-NMR) and molar extinction coefficient. AVO, No: C003749 GLP, unpublished	

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports<sup>6</sup> on previous use in granting national authorizations</b>
IIA 2.6	de Vries R.	1994a	Determination of the water solubility of desmedipham at pH 9 and pH 11. AVO, No: C504 GLP, unpublished	
IIA 2.8	de Vries R.	1994b	Determination of the partition coefficient (n-octanol/water) of desmedipham by high performance liquid chromatography (HPLC). AVO, No: C503 GLP, unpublished	
IIA 4.2.1.	Fisher K.	1989	Validation of analytical method no. 3801 for the analysis of desmedipham in rodent maintenance diets. AVO, No: C507 GLP, unpublished	
II A 2.13.	Klais O.	1998	Explosive properties of Desmedipham. AVO, No: A63720 not GLP, unpublished	
IIA 2.3.1	Klais O.	1999a	Temperature dependence of the vapour pressure of desmedipham, reports no DMP/C86 and DMP/C501. AVO, No: C003493 not GLP, unpublished	
IIA 2.13. IIA 2.15.	Klais O.	1999b	Explosive and oxidizing properties of phenmedipham, desmedipham, ethofumesate and of "Betanal Progress", a composition of the active substances. AVO, No: C003494 not GLP, unpublished	
IIA 4.2.2.	Leeijen N. & Melkebeke T.	1994a	Validation of an analytical method for residues of desmedipham in soil. AVO, No: R502 GLP, unpublished	
IIA 4.2.3.	Leeijen N. & Melkebeke T.	1994b	Validation of analytical method for residues of desmedipham in water. AVO, No: R500 GLP, unpublished	
IIA 4.2.4	Leeijen N. & Melkebeke T.	1994c	Validation of an analytical method for residues of desmedipham in air. AVO, No: R501 GLP, unpublished	

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports<sup>6</sup> on previous use in granting national authorizations</b>
IIA 4.2.5.	McGuire G.M.	1992	Development and validation of analytical method no. 5092 for the determination of desmedipham in dog plasma and subsequent analysis of plasma samples from IRI project no. 650639. AVO, No: C506 GLP, unpublished	
IIA 2.3.2	Miklautz H.	1994	The Henry constant of desmedipham (DMP, ZK 14 494) at 20°C. AVO, No: C31/2 not GLP, unpublished	
IIA 2.2.	Müller Th.	1998	Desmedipham - pour and tap bulk density, attachment to report no DMP/C70. AVO, No: C003687 not GLP, unpublished	
IIA 2.1.1	Smeykal H.	1999	Desmedipham, substance, pure, melting point/melting range. AVO, No: C003554 GLP, unpublished	
IIA 4.2.1.	Straszewski A. & Wrede- Rücker A.	1993	Analytical method for the determination of residues of desmedipham and a major metabolite in sugar beet (roots and leaves) by HPLC. AVO, No: R75 not GLP, unpublished	
IIA 2.4.1	Suessmann R. and Rexer K.	1999a	Determination of the physical form. Desmedipham substance pure. AVO, No: C006312 not GLP, unpublished	
IIA 2.4.1	Suessmann R. and Rexer K.	1999b	Determination of the colour. Desmedipham substance pure. AVO, No: C006310 not GLP, unpublished	
IIA 2.4.2	Suessmann R. and Rexer K.	1999c	Determination of the odour. Desmedipham substance pure. AVO, No: C006311 not GLP, unpublished	
IIA 2.9.2	Tschampel M.	1994	The phototransformation of desmedipham (Schering code no. ZK 14 494) in synthetic natural water. AVO, No: W135 GLP, unpublished	

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports<sup>6</sup> on previous use in granting national authorizations</b>
IIA 2.11.1. IIA 2.11.2. IIA 2.15.	Weinig P.	1995	Determination of the flammability, autoflammability and oxidizing properties of desmedipham. AVO, No: C120 GLP, unpublished	
IIA 4.2.1.	Williams L.E.	1993	Validation of an analytical method for the determination of residues of desmedipham and a major metabolite in sugar beet leaves and roots by HPLC. AVO, No: R77 GLP, unpublished	
IIA 4.2.4.	Wrede - Rucker A.	1993	Analytical method for the determination of desmedipham in air. AVO, No: W117 GLP, unpublished	
IIA 4.2.1	Wrede A.	1997	Residues of desmedipham, phenmedipham and ethofumesate and their major metabolites in chickpeas treated with Betanal Progress in Southern Europe (Spain). AVO, No: A63695 GLP, unpublished	
IIA 4.2.3	Wrede A.	1999b	Enforcement method and validation of surface and drinking water by HPLC/UV. Desmedipham (AE B038107), AE F132319. AVO, No: C005112 GLP, unpublished	
IIA 4.2.1	Wrede, A.	1999a	Data generation method with validation for sugar beets by LC-MS/MS. Phenmedipham (AE B038584), Desmedipham (AE B038107), AE B038210, AE F132319 AVO, No: C004350 GLP, unpublished	
IIA 4.2.1	Wrede, A.	2001	Independent laboratory validation (ILV) of the DFG S19-method for sugar beet roots by GC-MS. BCS, No: C018043 GLP, unpublished	

**B.6 Toxicology and metabolism**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
IIA, 5.3.1	Allen, T.R. Corney, S.J. Frei, Th. Bidermann, K. Luetkemaier, H. Vogel, O. Pappritz, G.	1991	Desmedipham: Determination of the no-effect level for methemoglobin production.  Research and Consulting Company AG, Switzerland and Experimental Pathology Consulting AG, Switzerland. No:T102, Project 250288 GLP, Unpublished	
IIA, 5.1.3	Creedy, C.L.	1991	The magnitude and nature of desmedipham residues in the laying hen following daily oral administration on 1.5 mg [ <sup>14</sup> C] –desmedipham per bird.  Schering Agrochemical Ltd, Great Britain No: M14, Report TOX/91/198-26, Study TOX/90460 GLP, Unpublished	
IIA, 5.1.3	Creedy, C.L.	1992	The magnitude and nature of desmedipham residues in the milk and meat of a cow following oral administration for 4 days at 0.4 mg/kg body weight.  Schering Agrochemical Ltd, Great Britain No: M15, Report TOX/92/198-28, Study TOX/90459 GLP, Unpublished	
IIA, 5.1.1	Creedy, C.L.	1993a	Absorption, distribution, excretion and metabolism in rat after oral administration.  Schering Agrochemical Ltd, Great Britain No: M16, Report TOX/93-198-31 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	Creedy, C.L.	1993b	Clearance of a single oral dose from rat tissues. Schering Agrochemical Ltd, Great Britain No: M9, Report TOX/93-198-39, Study TOX/93071-72A GLP, Unpublished	
IIA 7.3	Davies, D.J.	2000	Desmedipham: <i>In vitro</i> absorption through human and rat epidermis. Central Toxicology Laboratory, Alderley Park, Macclesfield, Cheshire, UK. C009292, Project TOX 00027 GLP, unpublished	
IIA 5.1	Fisher, P.	2003	(Aniline-U-14C) Desmedipham: supplementary metabolite investigations following repeated oral administration to the dairy cow. Bayer CropScience Study No: SA 03096 Report No: C037207 GLP, unpublished	
IIA, 5.5.2	Husband, R.F.A Wood, C.M. McKenzie, J.	1994	Desmedipham: 80 week oral (dietary) carcinogenicity study in the mouse. Toxicol Laboratories Ltd., U.K. No: T583, Report KIR/6/94 GLP, Unpublished	
IIA, 5.1.3	Jackson, J.R.	1993	The metabolism of desmedipham in the rat. Schering Agrochemical Ltd, Great Britain No: M17, Report TOX/93-198-32, Study TOX/91174 GLP, Unpublished	
IIA, 5.5	Jackson, M. Millar, P.	2000	Desmedipham: Rat dietary 2-year combined chronic toxicity and oncogenicity study: Re-examination of histopathological findings and statistical analysis. Study Number TOX 99065 GLP, Unpublished	

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
IIA 5.5	Jackson, M. and Mallyon, B.	2000	Desmedipham. Rat dietary 2-year combined chronic toxicity and oncogenicity study: Re-examination of histopathological findings and statistical analysis. AVO C007649 GLP, unpublished	
IIA, 7.3	Jones, B.K.	2000	Desmedipham: In vivo dermal penetration study in rat. Central Toxicology Laboratory, Alderley Park, Macclesfield, Cheshire, UK C009291, Project TOX 99065 GLP, Unpublished	
IIA, 7.3	Jones, B.K.	2000	Desmedipham: In vivo dermal penetration study in rat. Central Toxicology Laboratory, Alderley Park, Macclesfield, Cheshire, UK. C009291, Project TOX 00025AVO GLP, Unpublished	
IIA 5.5	Mallyon, B. (Mallyon, 2001a)	2001	Desmedipham: Response to the request for historical control data on the combined rat chronic toxicity and oncogenicity study by RCC AVO C015969 Not GLP, Unpublished	
IIA 5.6	Mallyon, B. (Mallyon, 2001b)	2001	Desmedipham: Response to the request for additional historical control data on the rat teratogenicity study conducted by Inveresk Research International AVO C015969 Not GLP, Unpublished	
II A, 5.4	Mallyon, B.	2003	Desmedipham rat micronucleus test Bayer CropScience Report No: C031144 GLP: Yes Unpublished	
IIA 5.5	Suter, P., Horst, K. Luetkemaier, H. Western, H. Terrier, Ch. Sachsse, K.	1986	Desmedipham: 2 year chronic toxicity and oncogenicity study with desmedipham technical in rats by dietary administration. Research and Consulting Company AG, Switzerland No. T56 Project 020968 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 7.3	Wicke, H.	2001	Desmedipham, EU Review. Re-assessment of operator exposure for Betanal Progress OF (Code: AE B049913 01 EC23 A3) and Betanal AM 11 (Code: AE B038584 01 EC 31 A1) based on new dermal absorption in vivo and in vitro. AVO C011211 not GLP, Published	
IIA 5.6	Wilson, J.A. Barton, S.J.	1991	Two generation reproduction study in rats Inveresk Research International Ltd, Scotland, No. T522, Project 490175, Report 7715 not GLP, Unpublished	

**B.7 Residue data**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
IIA, 6.6 /22	Anon	1994	Kemifam Combi (125 g/l phenmedipham + 40 g/l desmedipham ,EC formulation) residue tests in sugar beet in France 1990  Generated by: Laboratory Coopagri Bretagne  Company file No: R503  No GLP, unpublished	
IIA, 6.3 /23	Anon	1994	Kemifam Combi FL (125 g/l phenmedipham + 40 g/l desmedipham, sc formulation) residue test in sugar beet in Hungary 1993.  Generated by: Plant Health ad Soil Conservation Station of Csongr�ad County, H�odmez�v�as�rhely,Hungary.  Company file No: R506  No GLP, unpublished	
IIA, 6.1 /3	Caley, C.Y., Haswell, A.,	1995	The metabolism of <sup>14</sup> C-desmedipham in sugar beet- a glasshouse study.  Generated by: Inveresk Research International Limited, Tranent EH33 2NE, Scotland  Company file No: M501  GLP, unpublished	
IIA, 6.1 /4	Celorio, J.-I..	1995	Metabolism of desmedipham in the sugar beet ( <i>Beta vulgaris l.</i> ).  Generated by: AgrEvo GmbH; Frankfurt; Germany.  Company file No: M18  No GLP, unpublished	
IIA, 6.9 /1	Downey, S.S; Meyer, B.N.	1993	Confined accumulation study of [ <sup>14</sup> C]-desmedipham in rotational crops.  Generated by: NOR-AM Chemical Company; Pikeville, NC 27863, USA  Company file No: W114  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
II A, 6.2	Hardwick, T	2002	( <sup>14</sup> C)-Desmedipham: Absorption, distribution, metabolism and excretion following repeated oral administration to the laying hen. Report No: C022599 GLP: Yes Unpublished	
IIA 6.6 /26	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). Generated: Hoechst Shering AgrEvo GmbH Study identification ER 95 ECS 440 Company file No: R 82 GLP, unpublished	
IIA 6.6 /25	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. Generated: Hoechst Shering AgrEvo GmbH Study identification ER 94 ECS 442 Company file No: R 81, A.63609 GLP, unpublished	
IIA 6.2	McCombe, W.S.	2002	[ <sup>14</sup> C]-Desmedipham: Absorption, distribution, metabolism and excretion following repeated oral administration to the lactating cow. Aventis CropScience Ltd, Study number C024502 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 6.3	Moede, J.	1990	Total residues of desmedipham in sugar- and fodderbeets following applications of a 1.6 % EC-formulation in Germany 1989 (and first addendum to the report). Generated by: Schering Company file No: R66	
IIA 6.6 /28	Welcker, H. & Wrede, A.	1999	Decline of residues in sugar beet European Union (southern zone) 1998. Desmedipham, AE B038107 (emulsifiable concentrate EC) 7.98 % w/w (=79 g/l)Code: AE B038584 01 EC16 A202 Generated: AgrEvo GmbH Study No: ER 98 ECS 542 GLP, unpublished	
IIA 6.3	Wrede, A.	2002	MRLs for desmedipham in sugar beet and fodder beet. Bayer Crop Science Report no: 02F060 Study no: C026544 Date: 25 September 2002 GLP: No Published: No	
IIA 6.3	Wrede, A.	1997	Residues of desmedipham, phenmedipham and ethofumesate and their major metabolites in chickpeas treated with Betanal Progress in Southern Europe (Spain). <i>AgrEvo GmbH</i> BAY No: A63695 GLP, unpublished	
IIA, 6.6 /24	Wrede, A.	1995	Residues in sugar beet after application of Betanal Progress of in France 1993. Generated by: AgrEvo Company file No: R78 No GLP, unpublished	
IIA, 6.6 /21	Wrede-Rücker, A.	1993	Desmedipham/phenmedipham: EC (Betanal Progress, CQ 1069) residues in sugar beets Great Britain 1992. Generated by: Schering Company file No: R76 GLP, unpublished	

**B.8 Environmental fate and behaviour**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
IIA 7.2.1.1	Andre, J.C.	2003	(14C)-Desmedipham: Aqueous hydrolysis at pH 4,5,7 and 9 at 25°C. Batelle Memorial Institute, USA AG020007 35818 /C028787 GLP Unpublished Bayer CropScience	
IIA 7.2.1.1	Andre, J.C.	2003	(14C)-Ethyl (3-hydroxyphenyl)carbamate: Aqueous hydrolysis at pH 4,5,7 and 9 at 25°C. Batelle Memorial Institute, USA AG020019 35913 /C030022 GLP Unpublished Bayer CropScience	
IIA 7.1.2	Andre, J.C.	2003	(14C)-Ethyl (3-hydroxyphenyl)carbamate: Adsorption to and desorption from four soils. Batelle Memorial Institute, USA AG020008 35821/ C030020 GLP Unpublished Bayer CropScience	
II A B.7.2.1/1	Brüehl, R.; Tarara, G.	1994	Determination of the adsorption of desmedipham and n-m-hydroxyphenylethylcarbamate to soils AVO W59/2 GLP yes Publ. No	
II B.7.2.5/1	Burgener, A.	1998	<sup>14</sup> C-Desmedipham (AE B038107 and EHPC, AE F132319): mobility and degradation in soil in outdoor lysimeters. AVO GLP Yes Publ. No	

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
II A B.7.1.4/2	Burri, R.	1994	Photodegradation study of 14c- desmedipham on soil W526 AVO GLP Yes Publ. No	
II A B.7.7/2	de Vries, R.	1994	Determination of the rate of volatilisation of desmedipham from soil and plant surface (Dwarf Runner Bean). W562 AVO GLP Yes Publ. No	
II A B.7.2.4/2	Forster, V.	1992	The mobility of (ul-14c) desmedipham following aging in Hatzenbühl soil W63/3 AVO GLP No Publ. No	
II A B.7.2.4/3	Mackie, J.A., Hall, B.E.	1992	(14C)-desmedipham aged soil leaching W502 AVO GLP No Publ. No	
II A B.7.2.5/1	Morgenroth, U., Burgener, A.	1995	14C-desmedipham: mobility and degradation in soil in outdoor lysimeters W503 AVO GLP Yes Publ. No	
IIA 7.2.1.3.2	Sabourin, P.	2003	(14C)-Desmedipham: Degradation and rentention in two water/sediment systems Batelle Memorial Institute AG020004 35822 /C029978 GLP Unpublished Bayer CropScience	

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 7.1.1.1.2	Sabourin, P.J.	2003	(14C)-Desmedipham: Anaerobic soil degradation Batelle AgriFood, USA AG020003 35820/ C029977 GLP Unpublished Bayer CropScience	
IIA 7.1.1.1.2	Sabourin, P.J.	2003	(14C)-EHPC: Rate of degradation in three soils at 20°C. Batelle AgriFood , USA AG020005 35819 /C029854 GLP Unpublished Bayer CropScience	
II A B.7.1.1/8 B.7.2.4/4	Sadowsky- Dunkman, I.	1993	The leaching of desmedipham in German standard soil 2.1 following an ageing period. W127 AVO GLP Yes Publ. No	
IIA 7.2.1.3.2	Schaefer, D.	2003	Kinetic evaluation of desmedipham water/sediment studies to determine input parameters for aquatic PEC calculations. Bayer CropScience OE3/038c C030958 Not GLP Unpublished Bayer CropScience	
IIA 7.3	Schaefer, D.	2003a	Calculation of PEC values in soil for desmedipham and its main metabolite EHPC. Bayer CropScience <i>Not GLP, un published</i> BAY no: C030957	

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 7.3	Schaefer, D	2003b	Calculations of PEC values in surface water and sediment for desmedipham and its main metabolites EHPC and aniline. Bayer CropScience Not GLP, unpublished BAY no: C030956.	
IIA 7.3	Schaefer, D.	2003c	Predicted environmental concentrations in groundwater for desmedipham and its main metabolite EHPC, using the European FOCUS groundwater scenarios. Bayer Cropscience Not GLP, unpublished BAY No : C030955	
II A B.7.4.2/3	Schanné, C.	1994	Determination of the direct phototransformation of 14C-desmedipham in a buffered medium at pH 5 W506 AVO GLP Yes Publ. No	
II A B.7.4.4/2	Seyfried B.	1994	[14C]-desmedipham: degradation and metabolism in water/sediment systems.W561, W527 AVO GLP Yes Publ. No	
II A B.7.4.2/2	Tschampel, M.	1992	The phototransformation of desmedipham (Schering code no: 14494) in water. W106 / A63459 AVO GLP Yes Publ. No	

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
II A B.7.4.3/4	Wuethrich	1993	Determination of biochemical and chemical oxygen demand of desmedipham dispersed in water W505 AVO GLP Yes Publ. No	

**B.9 Ecotoxicology**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Reports on previous use in granting national authorizations</b>
IIA 8.2.1	Barber, I.	2000	Desmedipham, substance technical, Code AE B038107. Relative toxicity of desmedipham and its hydrolysis metabolite EHCP (ethyl-3-hydroxyphenyl carbamate) to aquatic organisms. AVO B003059 not GLP, Unpublished	
IIA 8.1.3 IIIA 10.3	Barber, I.	2001	Assessment of the long-term risk to birds and wild mammals from the use of sugar beet herbicide formulations containing desmedipham. AVO B003191 not GLP, Unpublished	
Evaluation table: Point 3.1	Barber, I.	2002	Assessment of risk to aquatic organisms from the metabolite aniline. Aventis CropScience - AE B038107 / B003896 Not GLP Unpublished Aventis CropScience	

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 8.5.5	Baxter, I	1999	Phenmedipham + desmedipham + emulsifiable concentrate, 160 + 160 g/l. Toxicity of the herbicide AE B038584 01 EC29 A1 to the parasitic wasp, <i>Aphidius rhopalosiphii</i> , in laboratory and extended laboratory tests. AE B038584 01 EC29 A103 BAY No: C005083 GLP, unpublished	
II B.8.1.3/1	Beavers, J.B.; Haberlein, D.; Mitchell, L.R.; Jaber, M.	1995	Technical desmedipham : northern bobwhite quail dietary one generation reproduction study AVO, W142 GLP, unpublished	
II B.8.1.3/2	Beavers, J.B.; Haberlein, D.; Mitchell, L.R.; Jaber, M.	1995	Technical desmedipham : mallard duck dietary one generation reproduction study AVO, W143 GLP, unpublished	
II B.8.2.3/1	Blakemore, G.C.	1993	Uptake, depuration and bioconcentration of [ <sup>14</sup> C]-desmedipham by bluegill sunfish ( <i>Lepomis macrochirus</i> ) AVO, W111 GLP, unpublished	
II B.8.2.3/2	Burri, R.	1994	Accumulation and elimination of <sup>14</sup> C-desmedipham by rainbow trout in a dynamic flow trough system. AVO, W516 GLP, unpublished	
IIA 8.2.8	Christ, M.T. & Abedi J.	2002	Effect to <i>Lemna gibba</i> (Duckweed) in a growth inhibition test . Desmedipham technical 98.2 %-w/w  Bayer CropScience 02AL/37913 02AL/37913 /B004118 GLP Unpublished Bayer CropScience	

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; IIIA, 10.	Ebeling, M & Ludwig F.	2002	Desmedipham: Chronic toxicity to the sediment dwelling organism <i>Chironomus riparius</i> .  Bayer CropScience CE02/066 C027641 GLP Unpublished Bayer CropScience	
IIA 8.2	Ebeling, M & Nguyen	2003	Effects on growth and reproduction of earthworms ( <i>Eisenia fetida</i> ). Phenmedipham + desmedipham ; emulsifiable concentrate 160+160 g/L Bayer CropScience GLP, unpublished BAY No : C028007	
IIA 8.5	Halsall, N.	1999	Evaluation of the effects of pesticides on the ladybird beetle <i>Coccinella septempunctata</i> in the laboratory Phenmedipham + desmedipham. Emulsifiable concentrate, 160 + 160 g/l. AE B038584 01 EC29 A103 BAY No: C005521 GLP, unpublished	
II B.8.2.6/4	Hughes, J. S., Williams, T. L.	1993	The toxicity of desmedipham technical to <i>Anabaena flos-aquae</i> (tier 1) AVO, W123 GLP, unpublished	
II B.8.2.6/5	Hughes, J. S., Williams, T. L.	1993	The toxicity of desmedipham technical to <i>Navicula pelliculosa</i> (tier 2) AVO, W124 GLP, unpublished	
II B.8.2.6/6	Hughes, J. S., Williams, T. L.	1993	The toxicity of desmedipham technical to <i>Skeletonema costatum</i> (tier 1) AVO, W125 GLP, unpublished	
II B.8.2.8/1	Hughes, J. S., Williams, T. L.	1993	The toxicity of desmedipham technical to <i>Lemna gibba</i> (tier 1) AVO, W126 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
II B.8.2.6/3	Hughes, J. S.; Williams, T. L.	1993	The toxicity of desmedipham technical to <i>Selenastrum capricornutum</i> (tier 2) AVO, W122 GLP, unpublished	
IIA 8.2.1	Mead, C and Mullee, D. M.	2000	Ethyl-3-hydroxyphenyl carbamate (EHPC) 99 % w/w substance technical. Algal inhibition test – <i>Pseudokirchneriella subcapitata</i> . AVO C009000. GLP, Unpublished	
IIA, 8.6	Menne H		Pre- and Post emergence herbicidal screening of AE F132319 (EHPC – A metabolite of Desmedipham (AE B038107) Bayer CropScience C026434 - Not GLP Unpublished Bayer CropScience	
II B.8.3.2/5	Moreth, L.	1993	Betanal Progress (SCH 44130 H): auswirkungen von pflanzenschutzmitteln auf <i>aleochara bilineata</i> : erweiterter labor-test Betanal Progress (SCH 44130 H): effect of pesticides on <i>aleochara bilineata</i> ; extended laboratory study AVO, W115 not GLP, unpublished	
Evaluation table: Point 3.1	Neumann, P.	2003	Aquatic TER values for aniline, a metabolite of desmedipham (Addendum to document B003896). Bayer CropScience - C031061 Not GLP Unpublished Bayer CropScience	

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
Evaluation table: Point 3.1	Neumann, P.	2003	Aquatic TER values for desmedipham and EHPC  Bayer CropScience - C031062 Not GLP Unpublished Bayer CropScience	
Evaluation table: Open Point 3.10	Neumann, P.	2003	Long-term risk assessment for earthworms for the exposure to desmedipham and EHPC.  Bayer CropScience - C031167 Not GLP Unpublished Bayer CropScience	
II B.8.1.2/3	Park W.	1992	A dietary LC50 toxicity study with the bobwhite quail.  AVO, W563 GLP, unpublished	
II B.8.3.2/6	Petto, R	1995	Effects of kemifam pro fl on the reproduction of <i>aleochara bilineata</i> gyll. ( <i>coleoptera, staphylinidae</i> ) in the laboratory  AVO, W537 GLP, unpublished	
II B.8.2.6/1	Schupner, J.K.; Stachura, B.J.	1993	The toxicity of desmedipham technical to the green algae, <i>selenastrum capricornutum</i>  AVO; W116/2 GLP, unpublished	
II B.8.2.2.1/ 2	Sewell, I.G., Wetton, P.M., Barlett, A.J.	1994	Fish, juvenile growth test - 28 days: assessment of the effect of desmedipham on the growth of juvenile rainbow trout ( <i>oncorhynchus mykiss</i> )  AVO, W515 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; IIIA, 10.	Sowig, P. and Weller, O.	1999	Acute toxicity to <i>Daphnia magna</i> (Waterflea) Phenmedipham + desmedipham; Emulsifiable concentrate 160 + 160 g/L. AgrEvo CE99/029 (or C004848) - GLP Unpublished AgrEvo	
IIA, 8.2; IIIA, 10.	Sowig, P. and Weller, O.	1999	Algal growth inhibition – <i>Pseudokirchneriella subcapitata</i> . Phenmedipham + desmedipham; Emulsifiable concentrate 160 + 160 g/L.  AgrEvo CE99/032 (or C004930) - GLP Unpublished AgrEvo	
IIA, 8.2; IIIA, 10.	Sowig, P., Weller, O., and Gosch, H.	1999	Acute toxicity to <i>Oncorhynchus mykiss</i> (Rainbow trout) Phenmedipham + desmedipham; Emulsifiable concentrate 160 + 160 g/L.  AgrEvo CE99/030 (or C004972) - GLP Unpublished AgrEvo	
II B.8.2.4/3	Stachura, B.J.	1996	Desmedipham technical 96,8 % W:W daphnia acute toxicity. AVO, DMP/W149 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
II B 8.5	Waltersdorfer, A.	1999 a	Toxicity to the ground dwelling predator <i>Poecilus cupreus</i> L. (Coleoptera, Carabidae) in laboratory. Phenmedipham + Desmedipham, Emulsifiable concentrate, 160 + 160 g/l. AE B038584 01 EC29 A103 BAY No: C005153 GLP, unpublished	
II B 8.5	Waltersdorfer, A.	1999 b	Toxicity to the mite <i>Typhlodromus pyri</i> SCHEUTEN (Acari, Phytoseiidae) using an extended laboratory test. Phenmedipham + Desmedipham, Emulsifiable concentrate, 160 + 160 g/l. AE B038584 01 EC29 A103 BAY No: C005530 GLP, unpublished	
IIA 8.2.1	Wetton, P.M. and Mullee, D. M. (Wetton and Mullee, 2001a)	2000	Ethyl-3-hydroxyphenyl carbamate (EHPC) 99 % w/w substance technical. Acute toxicity to rainbow trout ( <i>Oncorhynchus mykiss</i> ). AVO C008801 GLP, Unpublished	
IIA 8.2.1	Wetton, P.M. and Mullee, D. M. (Wetton and Mullee, 2001b)	2000	Ethyl-3-hydroxyphenyl carbamate (EHPC) 99 % w/w substance technical. Acute toxicity to <i>Daphnia magna</i> . AVO C008802 GLP, Unpublished	
II A.8.2.1/6	Zok, S.	1997	The Acute toxicity of EHPC to Zepira fish AVO, C001577 GLP, unpublished	

**APPENDIX IIIB****DESMEDIPHAM**

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**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	
IIA 4.2.2	Anspach, Th.	2003 a	Validation of DFG Method S 19 (extended revision) for the determination of residues of desmedipham and its metabolite EHPC 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-0228V Date:23.01.2003, GLP, Non Published BAY No. C 029322	
IIA 4.2.3	Anspach, Th.	2003 b	Enforcement methods (including validation) for the determination of residues of desmedipham, its metabolite EHPC, and aniline in drinking and surface water. Dr. Specht & Partner Chemische Laboratorien GmbH, Hamburg, Germany, Report No. BAY-0227V Date:29.01.2003, GLP, Non Published BAY No. C 029547	

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, Ch.	2003 a	Analytical method, Determination of desmedipham and the organic impurities in desmedipham technical grade and pure active ingredient by HPLC. Bayer CropScience GmbH, Product Technology – Analytics Frankfurt, Frankfurt am Mein, Germany, Report No. AL061/02-1 Date:03.03.2003, Non GLP, Non Published BAY No. C 030431	

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	
IIA 4.1	Bogdoll, B. and Eichelmann, Ch.	2003 b	Validation of the analytical method AL061/02-1 for the determination of desmedipham and of the organic impurities in desmedipham technical material. Bayer CropScience GmbH, Product Technology – Analytics Frankfurt, Frankfurt am Main, Germany, Report No. PA02/077 Date:26.02.2003, GLP, Non Published BAY No. C 030190	
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. C 031372	
IIA 4.2.1	Wrede, A.	2001	Independent laboratory validation (ILV) of the DFG S19-method for sugar beet roots by GC-MS. BCS, No: C018043 GLP, unpublished	

**B.6 Toxicology and metabolism**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	
IIA 7.3	Davies, D.	2000	Desmedipham: In vitro absorption through human and rat epidermis. Central Toxicology Laboratory, Alderley Park, Macclesfield, Cheshire, UK. C009292, Project TOX 00027 GLP, unpublished	

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	
IIA 5.10	Jackson, M.	2000	Desmedipham, Code AE B038107. Proposal for acute reference dose. AVO B003059 not GLP, Unpublished	
IIA 5.5	Jackson, M. and Mallyon, B.	2000	Desmedipham. Rat dietary 2-year combined chronic toxicity and oncogenicity study: Re-examination of histopathological findings and statistical analysis. AVO C007649 GLP, unpublished	
IIA, 5.5	Jackson, M., Millar, P.	2000	Desmedipham: Rat dietary 2-year combined chronic toxicity and oncogenicity study: Re-examination of histopathological findings and statistical analysis. Study Number TOX 99065 GLP, Unpublished	
IIA, 7.3	Jones, B.K.	2000	Desmedipham: In vivo dermal penetration study in rat. Central Toxicology Laboratory, Alderley Park, Macclesfield, Cheshire, UK. C009291, Project TOX 00025AVO GLP, Unpublished	
IIA 5.5	Mallyon, B.	2001	Desmedipham, response to the request for historical control data on the combined rat chronic toxicity and oncogenicity study by RCC. AVO C015969. GLP, Unpublished	
IIA 5.5	Suter, P., Horst, K. Luetkemaier, H. Western, H. Terrier, Ch. Sachsse, K.	1986	Desmedipham: 2 year chronic toxicity and oncogenicity study with desmedipham technical in rats by dietary administration. Research and Consulting Company AG, Switzerland No. T56 Project 020968 GLP, Unpublished	
IIA 7.3	Wicke, H.	2001	Desmedipham, EU Review. Re- assessment of operator exposure for Betanal Progress OF (Code: AE B049913 01 EC23 A3) and Betanal AM 11 (Code: AE B038584 01 EC 31 A1) based on new dermal absorption in vivo and in vitro. AVO C011211 not GLP, Published	

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	
IIA 7.3	Wicke, H.	2001	Re-assessment of operator exposure for Betanal Progress OF (Code AE B038584 01 EC31 A1) based on new dermal absorption in vivo and in vitro. AVO C011211 not GLP, Unpublished	
IIA 5.6	Wilson, J.A. Barton, S.J.	1991	Two generation reproduction study in rats Inveresk Research International Ltd, Scotland, No. T522, Project 490175, Report 7715 not GLP, Unpublished	

**B.7 Residue data**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	
II A, 6.2	Creedy, C.L.	1991	The magnitude and nature of desmedipham residues in the laying hen following daily oral administration of 1.5 mg [ <sup>14</sup> C]-desmedipham per bird Schering Agrochemical Ltd, Great Britain No: M14, Report No: TOX/91/198-26, Study TOX/90460 GLP: Yes Unpublished	
II A, 6.2	Creedy, C.L.	1992	The magnitude and nature of desmedipham residues in the milk and meat of a cow following oral administration for 4 days at 0.4 mg/kg body weight Schering Agrochemical Ltd, Great Britain No: M15, Report No: TOX/92/198-28, Study TOX/90459 GLP: Yes 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	
II A, 6.2	Hardwick, T	2002	( <sup>14</sup> C)-Desmedipham: Absorption, distribution, metabolism and excretion following repeated oral administration to the laying hen. Report No: C022599 GLP: Yes Unpublished	
IIA 6.2	McCombe, W.S.	2002	[ <sup>14</sup> C]-Desmedipham: Absorption, distribution, metabolism and excretion following repeated oral administration to the lactating cow. Aventis CropScience Ltd, Study number C024502 GLP, unpublished	
IIA 6.3	Moede, J.	1990	Total residues of desmedipham in sugar- and fodderbeets following applications of a 1.6 % EC-formulation in Germany 1989 (and first addendum to the report). Generated by: Schering Company file No: R66	
IIA 6.3	Wrede, A.	2002	MRLs for desmedipham in sugar beet and fodder beet. Bayer Crop Science Report no: 02F060 Study no: C026544 Date: 25 September 2002 GLP: No Published: No	

**B.8 Environmental fate and behaviour**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	
IIA 7.2.1.1	Andre, J.C.	2003	(14C)-Desmedipham: Aqueous hydrolysis at pH 4,5,7 and 9 at 25°C. Batelle Memorial Institute, USA AG020007 35818 /C028787 GLP Unpublished Bayer CropScience	
IIA 7.2.1.1	Andre, J.C.	2003	(14C)-Ethyl (3-hydroxyphenyl)carbamate: Aqueous hydrolysis at pH 4,5,7 and 9 at 25°C. Batelle Memorial Institute, USA AG020019 35913 /C030022 GLP Unpublished Bayer CropScience	
IIA 7.1.2	Andre, J.C.	2003	(14C)-Ethyl (3-hydroxyphenyl)carbamate: Adsorption to and desorption from four soils. Batelle Memorial Institute, USA AG020008 35821/ C030020 GLP Unpublished Bayer CropScience	
IIA 7.1.1.1.2	Sabourin, P.J.	2003	(14C)-Desmedipham: Anaerobic soil degradation Batelle AgriFood, USA AG020003 35820/ C029977 GLP Unpublished Bayer CropScience	
IIA 7.1.1.1.2	Sabourin, P.J.	2003	(14C)-EHPC: Rate of degradation in three soils at 20°C. Batelle AgriFood , USA AG020005 35819 /C029854 GLP Unpublished Bayer CropScience	

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	
IIA 7.2.1.3.2	Sabourin, P.	2003	(14C)-Desmedipham: Degradation and retention in two water/sediment systems Batelle Memorial Institute AG020004 35822 /C029978 GLP Unpublished Bayer CropScience	
IIA 7.2.1.3.2	Schaefer, D.	2003	Kinetic evaluation of desmedipham water/sediment studies to determine input parameters for aquatic PEC calculations. Bayer CropScience OE3/038c C030958 Not GLP Unpublished Bayer CropScience	

**B.9 Ecotoxicology**

<b>Annex point/ reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	
IIA 8.2.1	Barber, I.	2000	Desmedipham, substance technical, Code AE B038107. Relative toxicity of desmedipham and its hydrolysis metabolite EHCP (ethyl-3-hydroxyphenyl carbamate) to aquatic organisms. AVO B003059 not GLP, Unpublished	
IIA 8.1.3 IIIA 10.3	Barber, I.	2001	Assessment of the long-term risk to birds and wild mammals from the use of sugar beet herbicide formulations containing desmedipham. (). AVO B003191 GLP, Unpublished	
Evaluation table: Point 3.1	Barber, I.	2002	Assessment of risk to aquatic organisms from the metabolite aniline. Aventis CropScience- AE B038107 / B003896 Not GLP Unpublished Aventis CropScience	
IIA 8.2.8	Christ, M.T. & Abedi J.	2002	Effect to <i>Lemna gibba</i> (Duckweed) in a growth inhibition test . Desmedipham technical 98.2 %-w/w Bayer CropScience 02AL/37913 02AL/37913 /B004118 GLP Unpublished Bayer CropScience	
IIA, 8.2; IIIA, 10.	Ebeling, M & Ludwig F.	2002	Desmedipham: Chronic toxicity to the sediment dwelling organism <i>Chironomus riparius</i> . Bayer CropScience CE02/066 C027641 GLP Unpublished Bayer CropScience	

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	Ethyl-3-hydroxyphenyl carbamate (EHPC) 99 % w/w substance technical. Algal inhibition test – <i>Pseudokirchneriella subcapitata</i> . AVO C009000. GLP, Unpublished	
IIA, 8.6	Menne H		Pre- and Post emergence herbicidal screening of AE F132319 (EHPC – A metabolite of Desmedipham (AE B038107) Bayer CropScience C026434- Not GLP Unpublished Bayer CropScience	
Evaluation table: Point 3.1	Neumann, P.	2003	Aquatic TER values for aniline, a metabolite of desmedipham (Addendum to document B003896). Bayer CropScience- C031061 Not GLP Unpublished Bayer CropScience	
Evaluation table: Point 3.1	Neumann, P.	2003	Aquatic TER values for desmedipham and EHPC Bayer CropScience- C031062 Not GLP Unpublished Bayer CropScience	
Evaluation table: Open Point 3.10	Neumann, P.	2003	Long-term risk assessment for earthworms for the exposure to desmedipham and EHPC. Bayer CropScience- C031167 Not GLP Unpublished Bayer CropScience	
IIA, 8.2; IIIA, 10.	Sowig, P. and Weller, O.	1999	Acute toxicity to <i>Daphnia magna</i> (Waterflea) Phenmedipham + desmedipham; Emulsifiable concentrate 160 + 160 g/L. AgrEvo CE99/029 (or C004848)- GLP Unpublished AgrEvo	

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; IIIA, 10.	Sowig, P. and Weller, O.	1999	Algal growth inhibition – <i>Pseudokirchneriella subcapitata</i> . Phenmedipham + desmedipham; Emulsifiable concentrate 160 + 160 g/L. AgrEvo CE99/032 (or C004930)- GLP Unpublished AgrEvo	
IIA, 8.2; IIIA, 10.	Sowig, P., Weller, O., and Gosch, H.	1999	Acute toxicity to <i>Oncorhynchus mykiss</i> (Rainbow trout) Phenmedipham + desmedipham; Emulsifiable concentrate 160 + 160 g/L. AgrEvo CE99/030 (or C004972)- GLP Unpublished AgrEvo	
IIA 8.2.1	Wetton, P.M. and Mullee, D. M.	2000	Ethyl-3-hydroxyphenyl carbamate (EHPC) 99 % w/w substance technical. Acute toxicity to rainbow trout ( <i>Oncorhynchus mykiss</i> ). AVO C008801 GLP, unpublished	
IIA 8.2.1	Wetton, P.M. and Mullee, D. M.	2000	Ethyl-3-hydroxyphenyl carbamate (EHPC) 99 % w/w substance technical. Acute toxicity to <i>Daphnia magna</i> . AVO C008802. GLP, unpublished	

## APPENDIX IV

## List of uses supported by available data

## DESMEDIPHAM

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/ha  min max	water l/ha  min max	kg as/ha  min max		
Sugar & fodder beet	EU	Betanal AM 11	F	Annual dicot weeds	EC	160	Overall spray	Postemergence, from cotyledons to 2-4 leaf stage	1 2	5-14		200-300	0.240 0.480	-	Sequential application

- 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) | (i) | g/kg or g/l   |
| (b) | Outdoor or field use (F), glasshouse application (G) or indoor application (I)  | (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 |
| (c) | e.g. biting and suckling insects, soil born insects, foliar fungi, weeds  |     |   |
| (d) | e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  | (k) | The minimum and maximum number of application possible under practical conditions of use must be provided   |
| (e) | GCPF Codes - GIFAP Technical Monograph No 2, 1989   | (l) | PHI - minimum pre-harvest interval  |
| (f) | All abbreviations used must be explained  | (m) | Remarks may include: Extent of use/economic importance/restrictions   |
| (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                      |     |   |

