



2,4-DB

7601/VI/97-final

2 December 2002

Review report for the active substance **2,4-DB**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 3 December 2002 in view of the inclusion of 2,4-DB 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 2,4-DB, 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. 2,4-DB 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, ACI International on 30 July 1993 and AH Marks & Co Ltd on 20 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance 2,4-DB 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 2230/95⁽⁴⁾, designated Greece as rapporteur Member State to carry out the assessment of 2,4-DB on the basis of the dossiers submitted by the notifiers. 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 2,4-DB this deadline was 30 April 1995.

¹ OJ No L 366, 15.12.1992, p.10.

² OJ L 259, 13.10.2000, p. 27.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

Only AH Marks & Co Ltd submitted a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore AH Marks & Co Ltd was the main data submitter. Information has furthermore been submitted by third parties, including the European Environmental Bureau.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Greece submitted on 30 April 1996 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 2,4-DB 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 2,4-DB from AH Marks & Co Ltd, on 25 July 1997.

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 4 June 1997 as well as to AH Marks & Co Ltd being the main data submitter, on 29 May 1997.

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 September 1997 to January 1998.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 7 April 1998 for comments and further clarification.

In accordance with the provisions of Article 6(4) of Directive 91/414/EEC concerning consultation in the light of a possible unfavourable decision for the active substance the Commission organised a tripartite meeting with the main data submitter and the rapporteur Member State for this active substance on 7 May 1998. The main data submitter provided further data in order to meet the initial concerns.

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 December 1998 to June 2002 and was finalised in the meeting of the Standing Committee on 3 December 2002.

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 Directive **2003/31/EC**⁵ concerning the inclusion of 2,4-DB in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing 2,4-DB 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 2,4-DB 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 91/414/EEC, for each 2,4-DB containing plant protection product for which Member States will grant or review the authorisation.

⁵ OJ N° L101, 23.4.03, p. 3.

Furthermore, these conclusions were reached within the framework of the following uses which were proposed and supported by the main data submitter:

- grassland, spring barley (undersown)

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) for a 60 kg adult is 1.1 % of the Acceptable Daily Intake (ADI) of 0.02 mg/kg bw/day, based on the FAO/WHO European Diet (1998).

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 2,4-DB are given in Appendix I.

The active substance shall comply at least 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. However the minimum purity should be 940 g/kg.

The review has established that for the active substance notified by the main data submitter, AH Marks & Co Ltd, the manufacturing impurities dioxins and furans, which are of toxicological concern, are kept at non-detectable levels.

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 as identified during the re-evaluation process are set out under point 1 above. These endpoints are listed in Appendix II. For salts of 2,4-DB other than the evaluated Sodium-salt, it may be necessary to use other endpoints than those 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 2,4-DB

On the basis of the proposed and supported uses, 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:

- Particular attention should be given to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. 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 2,4-DB 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 bridging studies for salts or esters others than the evaluated Sodium-salt and for additional studies to investigate the dermal absorption of the active substance under different conditions of use.

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.

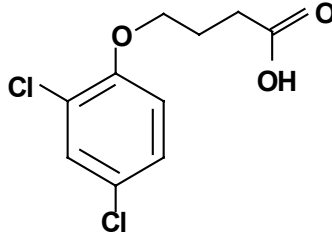
9. Updating of this review report

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 2,4-DB in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

2,4-DB

Common name (ISO)	2,4-DB
Development Code (for new actives only)	
Chemical name (IUPAC)	4-(2,4-dichlorophenoxy) butyric acid
Chemical name (CA)	4-(2,4-dichlorophenoxy) butanoic acid
CIPAC No	83
CAS No	94-82-6
EEC No	EINECS No: 2023669
FAO SPECIFICATION	890 g/kg (\pm 30 g) (FAO Provisional Specification 83/TC/(S)/-, 1983)
Minimum purity	940 g/kg
Molecular formula	$C_{10}H_{10}Cl_2O_3$
Molecular mass	249.1
Structural formula	

Melting point	113.5-117.5 °C (96.1%)
Boiling point	Not relevant
Appearance	pure a.s.: white powder with no discernible odour technical a.s. (96.1%): solid with odour similar to that of chlorinated phenols and colour 10 YR 9/2 (Munsell Colour System).
Relative density	$D_4^{22} = 1.461$ at 22 °C (96.1%)
Vapour pressure	7.08×10^{-7} mmHg or 9.44×10^{-5} Pa at 23.6 °C (technical of unknown purity)
Henry's law constant	3.14×10^{-4} Pa m ³ mol ⁻¹ (it was calculated using the value of vapour pressure at 23.6 °C and the value of water solubility at 25 °C)
Solubility in water	pH 5 : 0.062 g/l at 20 °C (100.5%) pH 7 : 4.385 g/l pH 9 : 454.8 g/l
Solubility in organic solvents	n-heptane: 0.43 g/kg at 20 °C xylene: 10.5 g/kg
	1,2-dichloroethane: 12.3 g/kg methanol: 113.8 g/kg
	acetone: 185.2 g/kg ethyl acetate: 90.7 g/kg
Partition co-efficient (log P_{ow})	pH 5 : log P _{ow} = 2.94 at 20 °C (100.5%) pH 7 : log P _{ow} = 1.35 pH 9 : log P _{ow} = -0.25
Hydrolytic stability (DT₅₀)	pH__5__ : Not hydrolyzed at 25 °C pH__7__ : Not hydrolyzed at 25 °C pH__9__ : Not hydrolyzed at 25 °C
Dissociation constant	pK _a = 4.1
Quantum yield of direct photo-transformation in water at ε >290 nm	Φ = 0.027
Flammability	Not flammable
Explosive properties	Non-explosive
UV/VIS absorption (max.)	In neutral solvent system: λ _{max} : 230 nm, 284 nm, 291 nm (shoulder) ε (dm ³ /mol/cm): ε ₂₃₀ = 9820, ε ₂₈₄ = 2260, ε ₂₉₁ = 1790
Photostability in water (DT₅₀)	pH 5: DT ₅₀ = 5.1 days under xenon lamp equivalent to 6.3 natural sunlight days pH 7: DT ₅₀ = 13.9 days under xenon lamp equivalent to 17.2 natural sunlight days pH 9: DT ₅₀ = 5.6 days under xenon lamp equivalent to 6.9 natural sunlight days

APPENDIX II

END POINTS AND RELATED INFORMATION

2,4-DB

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rapid and almost complete (> 90 %, 48 hours based on urinary and biliary excretion).
Distribution:	Widely distributed, highest residue in fat
Potential for accumulation:	Low
Rate and extent of excretion:	Mainly excreted via urine (~51%) and less via feces (~1%) and bile (~25%) over three days
Toxicologically significant compounds:	2,4-DB, 2,4-D acid, 2,4-DCP
Metabolism in animals:	2,4-DB, 2,4-D, conjugates of 2,4-dichlorophenol

Acute toxicity

Rat LD ₅₀ oral:	1470 mg/kg bw; R 22
Rat LD ₅₀ dermal:	> 2000 mg/kg bw
Rat LC ₅₀ inhalation:	> 2.3 mg/l air /4h exposure
Skin irritation:	Non-irritant
Eye irritation:	Non irritant;
Skin sensitization (test method used and result):	Sensitising (M & K); R43

Short term toxicity

Target / critical effect:	Liver, kidneys, thyroid, adrenals, testes and ovaries
Lowest relevant oral NOAEL / NOEL:	90-d dog : 8 mg/kg b.w./d 1-y dog : 1.86 mg/kg b.w./d (~2 mg/kg b.w./d)
Lowest relevant dermal NOAEL / NOEL:	21-d rabbit: 1000 mg/kg b.w./d, for systemic toxicity
Lowest relevant inhalation NOAEL / NOEL:	No data required

Genotoxicity

No genotoxic potential

Long term toxicity and carcinogenicity

Target / critical effect:

Kidneys/ Increased weight (rat and mouse)
Liver (rat) and testes (mouse)

Lowest relevant NOAEL:

2y rat: 60 ppm (2.48 and 3.23 mg/kg bw/d for males
and females, respectively)

Carcinogenicity:

No carcinogenic potential

Reproductive toxicity

Target / critical effect - Reproduction:

Toxic effects on kidneys in parents and pups

Lowest relevant reproductive NOAEL /
NOEL:

<60 ppm (< 3 mg/kg bw/d)

Target / critical effect - Developmental
toxicity:

No developmental toxicity or teratogenicity

Lowest relevant developmental
NOAEL / NOEL:

Rat: 31.25 mg/kg bw/d

Delayed neurotoxicity

No data required

Other toxicological studies

No data required

Medical dataFrom the available epidemiological studies no clear
association between cancer development and
exposure to phenoxyherbicides (including 2,4-DB)
could be established.**Summary**

	Value	Study	Safety factor
ADI:	0.02 mg/kg bw	dog, 1y study	100
AOEL systemic:	0.08 mg/kg bw/d	dog, 90d study	100
AOEL inhalation:	Not required		
AOEL dermal:	Not required		
ARfD (acute reference dose): (if ARfD is required, please provide also information on dietary intake for children, e.g. NESTI)	Not required. No risk to consumers via acute residue exposure		

Dermal absorption

app. 1.1 % at lowest dose tested

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

at day 118 : 42.1 % of CO₂

Non-extractable residues after 100 days:

at day 118 : 33.2% of bound residues

Major metabolites above 10 % of applied active substance: name and/or code
% of applied rate (range and maximum)

2,4-D
range of 2,4-D: 1.7 - 26.1 % of applied radioactivity (A.R.)
maximum of 2,4-D at day 48 : 26.1 %

Supplemental studies

Anaerobic:

metabolite: 2,4-D, maximum value 26% at day 31

Soil photolysis:

DT₅₀ at 25±1 °C : 33.5 days

Remarks:

None

Rate of degradation

Laboratory studies

DT₅₀lab (20 °C, aerobic):

(USA site) (1 site)
24.5 days at 25±1 °C
(UK sites) (4 sites)
1 - 2 days (2, 4-DB)
2.3 – 17.1 days (2,4-D) (R²: 0.9-0.99)

DT₉₀lab (20 °C, aerobic):

(UK sites) (4 sites)
4 – 7.3 days (2, 4-DB)
5.2 – 43.3 days (2,4-D)(R²: 0.9-0.99)

DT₅₀lab (10 °C, aerobic):

(USA site) (1 site)
81.34 days (estimated by the RMS)
(UK sites) (4 sites)
2.22 – 4.45 days (estimated by the RMS)

DT₅₀lab (20 °C, anaerobic):

<u>water</u> : 15 d.. <u>soil</u> : 68 d <u>total system</u> : 57 d. Duration : 0-120 day , R ² : 0.9-0.98, (UK site)

Field studies (country or region)

DT_{50f} from soil dissipation studies:

24 days in California (warm and dry conditions) 7.2 days in N. Carolina (warm and humid conditions)
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DT_{90f} from soil dissipation studies:

no data are provided

Soil accumulation studies:

no data are provided

Soil residue studies:

Not required

Remarks:

e.g. effect of soil pH on degradation rate

None

Adsorption/desorption

K_f / K_{oc}:K_{oc} (2,4-DB):

USA sites (n = 3):

sandy: 455.8, silt loam: 37.8, sandy loam: 194.5,
clay loam: 112.5-133.8

European sites (UK, n = 3):

SCL: 321, SL/L: 361, SL: 407

K_{oc} (2,4-D):

USA sites (n = 3):

clay: 58.1, clay: 74, silt loam: 41, sandy loam: 31,
loam; 35K_d:K_d (2,4-DB):

USA sites (n = 3):

sandy: 0.795, silt loam: 0.461, sandy loam: 1.47,
clay loam: 3.27-3.89K_d (2,4-D):

USA sites (n = 3):

clay: 1.22, clay: 1.26, silt loam: 2.23, sandy loam:
0.22, loam; 3.08

pH dependence:

USA sites (n=3)

Yes, Negative

K_{oc}=1407.74 [± 612.94 , (*t-value* = 2.29)]-186.908 [± 99.36 , (*t-value* = -1.88)]*pH, (*r*² of the model
= 77.97 %).Note: 1. The K_{oc} = 37.8 is considered as an
outlier and therefore was not taken into account.
2. The above equation, which describes the
correlation between K_{oc} and pH, is estimated by
the RMS.European sites (UK) (n=3)No. (*r*² of the model = 50.83 %).

Mobility

Laboratory studies:

Column leaching:

no data are provided

Aged residue leaching:

2,4-DB (column leachate) : <0.2% of applied
radioactivity2,4-D in the leachate : 0.035 - 0.1 µg/l

Field studies:

Lysimeter/Field leaching studies:

2,4-DB was not detected at soil depth > 0.15 m.

Remarks:

None

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

No degradation for the pH values 5, 7 and 9 tested
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Major metabolites:

None

Photolytic degradation:

DT ₅₀ :	6.3 days	17.2 days	6.9 days
	pH 5	pH 7	pH 9

Major metabolites:

none

Biological degradation

Readily biodegradable:

no data are provided

Water/sediment study:

DT₅₀ water:

12.2 - 12.6 days

DT₉₀ water:

40.4-41.9 days

DT₅₀ whole system:

15.8 – 18.4 days (R ² : 0.90 – 0.95)

DT₉₀ whole system:

52.5-61.1 days

Distribution in water / sediment systems
(active substance)

2,4-DB (at day 14) : 60% in water phase , 25-28% in sediment
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Distribution in water / sediment systems
(metabolites)

2,4-D (at day 14) : not found in water, 3.5 – 4.6% in sediment
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Accumulation in water and/or sediment:

Not expected

Degradation in the saturated zone

no data are provided

Remarks:

None

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

7.08x10 ⁻⁷ mmHg or 9.44x10 ⁻⁵ Pa at 23.6 °C (technical of unknown purity)
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Henry's law constant:

3.14x10 ⁻⁴ Pa m ³ mol ⁻¹ (it was calculated using the value of vapour pressure at 23.6 °C and the value of water solubility at 25 °C)
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Photolytic degradation

Direct photolysis in air:

no data are provided

Photochemical oxidative degradation in air

DT₅₀:

0.75 days or 9 hours (based on a 12 hour day)

Volatilisation:

from plant surfaces: no data are provided from soil: no data are provided
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Remarks:

None

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:

Acute toxicity to birds:

Dietary toxicity to birds:

Reproductive toxicity to birds:

Short term oral toxicity to mammals:

877 mg as/kg bw (rats)
1545 mg as/kg bw <i>Colinus virginianus</i> (Bobwhite quail)
> 5000 mg as/kg (NOEC = 2500 mg a.s./kg) <i>Colinus virginianus</i> (Bobwhite quail)
NOEC 1000 ppm <i>Colinus virginianus</i> (Bobwhite quail) (2,4D acid as the test substance)
Mouse (28 day NOEL) 43 mg/kg/day (300 ppm)

Aquatic Organisms

Acute toxicity fish:

Long term toxicity fish:

Bioaccumulation fish:

Acute toxicity invertebrate:

Chronic toxicity invertebrate:

Species	Time scale	Toxicity (mg/ l)	Endpoint
<u>Butyrac 200</u> (2,4-DB DMA 26% w/w):			
<i>Oncorhynchus mykiss</i>	96 h		3.5
	LC ₅₀		
<u>2,4-DB Sodium 400 g/L:</u>			
<i>Oncorhynchus mykiss</i>	96 h		17.8
	LC ₅₀		
2,4-DB sodium 400 g/L			
Brachydanio rerio	96 h	43.2 mg formul./L or 14.7 mg a.s./L – NOEC 12.5 mg formul./L	
<u>2,4-D acid 96.1 %:</u>			
<i>Pimephales promelas</i>	32 d		63.4 mg /L NOEL
Not required Log P = 2.62			
<u>2,4-DB acid (99.6% a.i.):</u>			
<i>Daphnia magna</i>	48 h	25 mg /L	EC ₅₀
<u>2,4-DB DMA (25.8 gr a.i./lt):</u>			
<i>Daphnia magna</i>	48 h	25 mg /L	EC ₅₀
<u>2,4-DB Sodium 400 g/L:</u>			
<i>Daphnia magna</i>	21 d (reproduction)	4.29 mg /L - 3 mg /L NOEC	EC ₅₀

Acute toxicity algae:

Butyrac 200 (2,4-DB DMA 26%):*Selenastrum capricornutum* 120 h > 1.1
EC₅₀2,4-DB sodium 400 g/L:*Selenastrum capricornutum* 72 h > 100 mg
formul./L E_rC₅₀ or 34 mg a.s./L – NOEC_r > 100
mg formul./L*Selenastrum capricornutum* 72 h > 54.6 mg
formul./L E_bC₅₀ – NOEC_b 12.5 mg formul./L2,4-DB Sodium 400 g/L:*Scenedesmus subspicatus* 72 h 48.1 mg
formulation/L, based on average specific growth
rate (μ) E_rC₅₀*Scenedesmus subspicatus* 72 h 23.2 mg
formul./L, based on the area under the growth
curves (A) E_bC₅₀

Chronic toxicity sediment dwelling organism:

Not required

Acute toxicity aquatic plants: (for herbicides
only)2,4-DB Sodium 400 g/L:*Lemna minor* 7 d 68.8 mg/L (based
on the average specific growth rate (μ))
E_rC₅₀*Lemna minor* 7 d 29 mg/L (based on
frond number) E_rC₅₀

Honeybees

Acute oral toxicity:

> 100 μg 4-(2,4-dichlorophenoxy)butyric acid
95.4% w/w /bee

Acute contact toxicity:

> 100 μg 4-(2,4-dichlorophenoxy)butyric acid
95.4% w/w /bee

Other arthropod species

*Test species**T. pyri* (2,4-DB Sodium 400 g/L (as acid))*A. rhopalosiphi* (2,4-DB Sodium 400 g/L (as
acid))

Application (Kg a.s./ha)	Status	Effects
1.8	Proto- nymph	-13%, Eggs / fem.
1.8	Adult	3% Mortality

P. cupreus (2,4-DB Sodium 400 g/L (as acid))

C. carnea (2,4-DB Sodium 400 g/L (as acid))

1.8	Adult	26% Food cons.
1.8	Larvae	10% Mortality

Earthworms

Acute toxicity:

Eisenia foetida LC50 > 1000 mg a.s./kg (2,4-DB 95.4%)

Reproductive toxicity:

Not required

Soil micro-organisms

Nitrogen mineralization:

Effects < 25% (a treatment rate equivalent to the maximum protected field application rate, 1.8 kg a.s./ha equivalent to 2.4 mg a.s./kg oven dry equiv.)

Carbon mineralization:

Effects < 25% (a treatment rate equivalent to the maximum protected field application rate, 1.8 kg a.s./ha equivalent to 2.4 mg a.s./kg oven dry equiv.)

APPENDIX IIIA**2,4-DB**

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	Reports² on previous use in granting national authorization s
IIA 1.11	Bass R V	1999	Preliminary analysis of 5 batches of 4-(2,4-dichlorophenoxy)butyric acid A H Marks & Company Limited Report No 98/0055 GLP: Yes Published: No	
IIA 2.6, 2.7, 2.8	Hutchinson N D	1998	Solubility and Partition Coefficient of 4-(2,4-Dichlorophenoxybutyric Acid A H Marks and Company Limited Report No 98/0056 GLP: Yes Published: No	
IIA 2.9.3	Brodsky J	1999	Determination of the Direct phototransformation of 2,4-DB in water CAU GmbH, Germany A H Marks & Company Limited Report No: 785/68 GLP: Yes Published: No	

². 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 ² on previous use in granting national authorizations
IIA 2.9.4	Ruzo L O & Ewing A D	2001	Determination of the pK _a value for 2,4-DB (Amended Report) Pharmacology and Toxicology Research Laboratory USA AHM, RPA, ACE & CED Report No: P167W GLP: No Published: No	
IIA 2.10	Russell S	1998	2,4-DB: Estimation of atmospheric oxidation potential by computer modelling A H Marks & Company Limited Report No: 785/67 Covance Laboratories Ltd GLP: No Published: No	
IIA 2.11	Edwards D	1998	<i>2,4-DB: Determination of the physico-chemical properties of the substance as manufactured Covance Laboratories Ltd A H Marks & Company Limited Report No: 785/64-D2141 GLP: Yes Published: No</i>	
IIA 2.13 & IIIA 2.2	Hale M	2002	Explosive Properties of DB and DB Na Solutions A H Marks & Company Limited GLP: No Published: No	
IIA 2.15 & IIIA 2.2	Hale M	2002	Oxidising Properties of DB and DB Na Solutions A H Marks & Company Limited GLP: No Published: No	
IIA 4.1.1 & 4.1.2	Bass R V	1999	Preliminary analysis of 5 batches of 4-(2,4-dichlorophenoxy)butyric acid A H Marks & Company Ltd Report No 98/0055 GLP: Yes Published: 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 ² on previous use in granting national authorizations
IIA 4.2.1 & IIIA 5.2.1	Baxby M	2001	Independent Laboratory Validation of a Method for the Analysis of 2,4-DB, 2,4-D, 2,4-DP-p and 2,4 DCP in cereals and grass A H Marks & Company Ltd AHM ILV 01/002 GLP: Yes Published: No	
IIA 4.2.1 & IIIA 5.2.1	Baxby M	2002	Development of a Confirmatory Method for the Determination of 2,4-DB in Milk A H Marks & Company Ltd Report No AHM ILV 01/0002 GLP: No Published: No	
IIA 4.2.1 & IIIA 5.2.1	Cumberbatch D J	1999	Analytical method for the determination of 2,4-DB, 2,4-D, 2,4-DP and 2,4-DCP in cereals and grass A H Marks & Company Ltd Method No 591(issue No1) GLP: No Published: No	
IIA 4.2.1 & IIIA 5.2.1	Howard J B S	1997	Development and validation of analytical methodology for the analysis of 2,4-Dichlorophenoxybutyric acid (2,4-DB) in beef tissues and milk PTRL East Inc USA AHM, RPA, ACE & CED Report No 1000 GLP: Yes Published: 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 ² on previous use in granting national authorizations
IIA 4.2.1 & IIIA 5.2.1	Howard J B S	1998	Development and Validation of Analytical Methodology for the Analysis of 2,4-Dichlorophenoxybutyric acid (2,4-DB) in Poultry Tissues and Eggs AHM, RPA, ACE & CED Report No 1001 PTRL East Inc USA GLP: Yes Published: No	
IIA 4.2.1 & IIIA 5.2.1	Rawle N W	2000	Validation of a method for the analysis of residues of 2,4-DCP, 2,4-D, 2,4-DP-p and 2,4-DB in grass CEM Analytical Services Ltd, UK A H Marks & Company Ltd Report No CEM-1177 GLP: Yes Published: No	
IIA 4.2.1 & IIIA 5.2.1	Rawle N W	2000	Validation of a method for the analysis of residues of 2,4-DCP, 2,4-D, 2,4-DP-p and 2,4-DB in cereals CEM Analytical Services Ltd, UK A H Marks & Company Ltd Report No CEM-1178 GLP: Yes Published: No	
IIA 4.2.1 & IIIA 5.2.1	Turnbull G	2001	Validation of analytical methodology for the determination of 2,4-dichlorophenoxybutyric acid in beef tissues Central Science Laboratory, UK A H Marks & Company Ltd Report No PGD-67 GLP: Yes Published: 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 ² on previous use in granting national authorizations
IIA 4.2.1 & IIIA 5.2.1	Turnbull G	2001	Validation of analytical methodology for the determination of 2,4-dichlorophenoxybutyric acid in milk A H Marks & Company Ltd Report No PGD-75 Central Science Laboratory, UK GLP: Yes Published: No	
IIA 4.2.1 & IIIA 5.2.1	Perny A	2002	Validation of Analysis for 2,4-DCP, 2,4-D, 2,4-DP and 2,4-DB residues in cereals ANADIAG SA, France A H Marks & Company Limited Report No AHM R 00132 (R A0114) GLP: Yes Published: No	
IIA 4.2.1 & IIIA 5.2.1	Turnbull G	2001	Validation of Analytical Methodology for the Determination of 2,4-Dichlorophenoxybutyric Acid in Chicken Tissues A H Marks & Company Limited Central Science Laboratory, UK Study No PGD-68 GLP: Yes Published: No	
IIA 4.2.2 & IIIA 5.2.2	Howard J B S	1998	Development and validation of analytical methodology for the analysis of 2,4-Dichlorophenoxybutyric acid (2,4-DB), 2,4-Dichlorophenoxyacetic acid (2,4-D) and 2,4-Dichlorophenol in soil PTRL East AHM, RPA, ACE & CED Report No 2008 GLP: Yes Published: 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 ² on previous use in granting national authorizations
IIA 4.2.3 & IIIA 5.2.3	Westwood D	1997	The determination of Acidic Herbicides in waters by GC-MS From Environment Agency Publication "The determination of acidic herbicides, Bromoxynil, loxynil and Pentachlorophenol in waters, 1997", Method D GLP: No Published: Yes	
IIA 4.2.4 & IIIA 5.2.4	Bass R V	2000	Validation of the analytical method for the determination of 4-(2,4-Dichlorophenoxy)butyric acid (DB) in air A H Marks & Company Ltd Report No 00/0118 GLP: Yes Published: No	

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 authorization s
IIA 5.1	Gibson N W et al	1991	Absorption, Distribution and Elimination of [¹⁴ C]2,4-DB in the rat PTRL, East Inc., USA AHM, RPA, ACE & CED Report No 1243 GLP: Yes Published: No	
IIA 5.1	Gibson N W et al	1999	Absorption, Distribution and Elimination of [¹⁴ C]2,4-DB in the Rat (Addendum 1 : Structural Confirmation of a 2,4-DB Rat Metabolite) A H Marks & Company Limited Report No : 2014 PTRL Laboratories GLP: Yes Published: No	
IIA 5.2.1	Holsing G C	1969	Acute Oral Administration-Rats 2,4- DB Acid AHM, RPA, ACE & CED Report No: 656-105 Hazleton Laboratories Inc., USA GLP: No Published: No	
IIA 5.2.1, 5.2.2, 5.2.4, 5.2.5	Myers R C; Geary D L	1982	Acute Toxicity and Irritancy Studies (Rat Oral LD ₅₀) AHM, RPA, ACE & CED Report No: 45-188 Bushy Run Research Center, USA GLP: Yes Published: No	
IIA 5.2.3	Nachreiner D J & Burleigh- Flayer H D	1990	2,4-DB Acid, Acute Dust Inhalation Toxicity Test in Rats AHM, RPA, ACE & CED Report No: 53-378 Bushy Run Research Center, USA GLP: Yes Published: 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
IIA 5.2.5	Holsing G C	1969	Acute Eye Irritation, Rabbits AHM, RPA, ACE & CED Report No: 656-108 Hazleton Laboratories Inc., USA GLP: No Published: No	
IIA 5.2.6	Johnson I R	2001	Technical 2,4-Dichlorophenoxybutyric acid: Local Lymph Node Assay A H Marks & Company Limited Report No: GM7533 Central Toxicology Laboratory Alderley Park Macclesfield Cheshire UK GLP: Yes Published: No	
IIA 5.3	Tisdell M	1985	Four week range-finding study in mice with 2,4-DB technical Hazleton Laboratories Inc. AHM, RPA, ACE & CED Report No. 6158-102 GLP: Yes Published: No	
IIA 5.3.2	Holsing G C	1969 a	Three month dietary administration- albino rats AHM, RPA, ACE & CED Report No: 24B-TP-69-1001 Hazleton Laboratories Inc., USA GLP: No Published: No	
IIA 5.3.2	Holsing G C	1969 b	13-Week Oral Administration - Dogs AHM, RPA, ACE & CED Report No 656-110 Hazleton Laboratories Inc USA GLP: No Published: 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
IIA 5.3.2	Holsing G C	1969 c	13-Week Oral Administration - Dogs AHM, RPA, ACE & CED Report No 656-110 Hazleton Laboratories Inc. USA GLP: No Published: No	
IIA 5.4.1	Cifone M A	1987	Mutagenicity Test on 2,4-DB tech. 98.03% in the Rat Primary Hepatocyte Unscheduled DNA synthesis. AHM, RPA, ACE & CED Report No: 9360-0-447 Hazleton Laboratories America, USA GLP: Yes Published: No	
IIA 5.4.1	Young R R	1987	Mutagenicity test on 2,4-DB Technical Lot number RTC# in the CHO/HGPRT Forward Mutation Assay AHM, RPA, ACE & CED Report No 9360-0-435 Hazleton Laboratories America, USA GLP: Yes Published: No	
IIA 5.4.1	Ivett J L	1987	Mutagenicity test on 2,4-DB tech in an in vitro cytogenetic assay measuring chromosomal aberration frequencies in Chinese Hamster Ovary (CHO) cells. AHM, RPA, ACE & CED Report No: 9360-0-437 Hazleton Laboratories America, USA GLP: Yes Published: 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
IIA 5.4.1	Jagannath D R.	1987	Mutagenicity test on 2,4-DB Technical 98.03% Lot#RTC 5838AA in the Ames Salmonella/microsome reverse mutation assay. AHM, RPA, ACE & CED Report No: 9360-0-401-TR Hazleton Laboratories America, USA GLP: Yes Published: No	
IIA 5.4.2	Burman M	1999	Induction of Micronuclei in the Bone Marrow of Treated Mice A H Marks & Company Limited Report No 785/52-D5140 Covance Laboratories Ltd GLP: Yes Published: No	
IIA 5.5	MacKenzie K M	1987 a	Lifetime dietary oncogenicity study in albino mice with 2,4-DB. AHM, RPA, ACE & CED Report No: HLA 6158-104 Hazleton Laboratories America, USA GLP: Yes Published: No	
IIA 5.5	MacKenzie K M	1987 b	Lifetime dietary combined chronic toxicity and oncogenicity study in albino rats with 2,4-DB. Hazleton Laboratories America Inc AHM, RPA, ACE & CED Report No. HLA 6158-103 GLP: Yes Published: No	
IIA 5.6	Charles J et al	1999	Developmental Toxicity Studies in Rats and Rabbits and Two-Generation Reproduction Study in Rats on 4-(2,4-Dichlorophenoxy)butyric Acid International Journal of Toxicology 18 pages 177-189 GLP: No Published: Yes	

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 5.6.1	Bottomley A M et al	1986	2,4-DB - Effect on two generations of the rat. Huntingdon Research Centre Ltd AHM, RPA, ACE & CED Report No. UNC/138-R GLP: Yes Published: No	
IIA 5.6.2	Henwood S M	1990 a	Teratology study with 2,4-DB acid in rats. AHM, RPA, ACE & CED Report No: 6224-143 Hazleton Laboratories America, USA GLP: Yes Published: No	
IIA 5.6.2	Henwood S M	1990 b	Teratology study with 2,4-DB acid in rabbits. AHM, RPA, ACE & CED Report No: 6224-145 Hazleton Laboratories America, USA GLP: Yes Published: No	
IIA 5.9.1	Coggon D; Pannett B & Winter P	1991	Mortality and incidence of cancer at four factories making phenoxy herbicides Medical Research Centre UK British Journal of Industrial Medicine 48: 173-178; 1991 GLP: No Published: Yes	
IIA 5.9.1	Kauppinen T et al	1993	Chemical Exposure in Manufacture of Phenoxy Herbicides and Chlorophenols and in Spraying Phenoxy Herbicides American Journal of Industrial Medicine 23: 903-920; 1993 GLP: No Published: Yes	

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 5.9.1	Kogevinas M et al,	1995	Soft Tissue Sarcoma and Non Hodgkin's Lymphoma in Workers Exposed to Phenoxy Herbicides, Chlorophenols and Dioxins: Two Nested Case-Control Studies Epidemiology vol6 No 4: 396-402; 1995 GLP: No Published: Yes	
IIA 5.9.1	Kogevinas M et al,	1997	Cancer Mortality in Workers Exposed to Phenoxy Herbicides, Chlorophenols and Dioxins American Journal of Epidemiology 145, No 12: 1061-1075, 1997 GLP: No Published: Yes	
IIA 5.9.1	Saracci R et al	1991	Cancer Mortality in Workers Exposed to Phenoxy Herbicides, Chlorophenols The Lancet 338, No 8774: 1027-1032; 1991 GLP: No Published: Yes	
IIA 5.9.1	Vena J et al	1998	Exposure to Dioxin and Nonneoplastic Mortality in the Expanded IARC International Cohort Study of Phenoxy Herbicide and Chlorophenol Production Workers and Sprayers Environmental Health Perspectives vol 106, supplement 2; 1998 GLP: No Published: Yes	

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 authorization s
IIA 6.1	O'Neal S	1993	Metabolic Fate and Distribution of 14C-2,4-DB Acid in Alfalfa PTRL East, USA AHM, RPA, ACE & CED Report No. 1529 GLP: Yes Published: No	
IIA 6.1	O'Neal S	1993	Metabolic Fate and Distribution of 14C-2,4-DB Acid in Peanuts PTRL East, USA AHM, RPA, ACE & CED Report No 1547 GLP: Yes Published: No	
IIA 6.3	Krautter G R	1997	Magnitude of the Residue in Meat and Milk from Dairy Cows Treated with 2,4-Dichlorophenoxybutyric Acid (2,4-DB) PTRL East Inc. AHM, RPA, ACE & CED Report No 993 GLP: Yes Published: No	
IIA 6.3	Perny A	2001	Residues of 2,4-DB Sodium Salt in Cereals in Northern Europe (analytical phase) Anadiag, France A H Marks & Company Limited AHM R 00 121 (R A 0111) GLP: Yes Published: No	
IIA 6.3	Perny A	2002 a	Validation of Analysis for 2,4-DCP, 2,4-D, 2,4-DP and 2,4-DB residues in cereals Anadiag, France, A H Marks & Company Limited AHM R 00 132 (R A0114) GLP: Yes Published: 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
IIA 6.3	Perny A	2002 b	Residue decline of 2,4-DB Sodium salt in Grassland in Northern Europe Anadiag, France, A H Marks & Company Limited AHM R 00 221 (R A 0113) GLP: Yes Published: No	
IIA 6.6	Johnson T	1995 a	Field Crop Residue Study with 2,4-DB applied to Soybeans PTRL Inc., USA AHM, RPA, ACE & CED Report No. 1641 GLP: Yes Published: No	
IIA 6.6	Johnson T	1995 b	Field Crop Residue Study with 2,4-DB applied to Peanuts PTRL Inc., USA AHM, RPA, ACE & CED AHM, RPA, ACE & CED Report No. 1706 GLP: Yes Published: No	
IIA 6.6	Krautter G R	1997	Magnitude of the Residues in Meat and Milk from Dairy Cows Treated with 2,4-Dichlorophenoxybutyric Acid (2,4-DB) PTRL East, USA AHM, RPA, ACE & CED Report No 1930 GLP: Yes Published: No	
IIA 6.6	Wardman J P	2000 a	Determination of the residue decline of 2,4-DB 2,4-D and 2,4-DCP in cereals following treatment with Marks 2,4-DB (400 g/l 2,4-DB formulated as the sodium salt under field conditions in the UK. Report No AHM R 99 151 GLP: Yes Published: 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
IIA 6.6	Wardman J P	2000 b	Determination of the residue decline of 2,4-DB and 2,4-D in grassland following treatment with Marks 2,4-DB (400 g/l 2,4-DB formulated as the sodium salt under field conditions in Northern Europe. Report No AHM R 99 158 GLP: Yes Published: No	
IIA 6.6	Old J; Venuti J	2000	2,4-DB Sodium Salt Residue Decline in Cereals in Northern Europe: Field Phase Inveresk Research International Ltd, UK A H Marks & Company Limited Report No. 18194 (Appendix 1 to Report AHM R 99 151) GLP: Yes Published: No	
IIA 6.6	Rawle N W	2000	Determination of Residues of 2,4-D, 2,4-DB and 2,4-DCP in Wheat and Barley Samples CEM Analytical Services Ltd, UK A H Marks & Company Limited Report No. CEMR-1170 (AHM R 99 122) Appendix 2 to Report AHM R 99 151 GLP: Yes Published: No	
IIA 6.6	Wardman J P	2000	Determination of the residue decline of 2,4-DB and 2,4-D in grassland following treatment with Marks 2,4-DB (400 g/l 2,4-DB formulated as the sodium salt under field conditions in the UK. Report No AHM R 98 150 GLP: Yes Published: 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
IIA 6.6	Benwell L	1999	2,4-DB: The Determination of Residues in Grassland UK, 1998 Covance Laboratories Ltd, UK A H Marks & Company Limited Report No. 785/20-D2143 (AHM R 98 100) As appendix 1 to AHM R 98 150 GLP: Yes Published: No	
IIA 6.6	Rawle N W	2000	Determination of Residues of 2,4-D, 2,4-DB and 2,4-DCP in Grass Samples CEM Analytical Services Ltd, UK A H Marks & Company Limited Report No. CEMR-1168 (AHM R 99 221) Appendix 2 to AHM R 98 150 GLP: Yes Published: No	
IIA 6.8	Gibson N A	1999	Magnitude of the Residue in Meat and Eggs from Laying Hens Treated with 4-(2,4-Dichlorophenoxybutyric) Acid (2,4-DB). PTRL East, USA AHM, RPA, ACE & CED Report No 2060 Project 994 GLP: Yes Published: No	

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 7.1.1	Ridge M A	2000	(¹⁴ C)-2,4-DB: Soil Metabolism and Degradation Covance Laboratories Ltd A H Marks & Company Limited Report No. 785/53-2142 GLP: Yes Published: No	
IIA 7.1.1.1.2	Goodyear A	2000	(¹⁴ C)-2,4-DB: Anaerobic Soil Metabolism Covance Laboratories Ltd A H Marks & Company Limited Report No. 785/54-D2142 GLP: Yes Published: No	
IIA 7.1.2	Rustum A M	1987	The adsorption and desorption of ¹⁴ C-2,4-DB on representative agricultural soils. Hazleton Laboratories America Inc AHM, RPA, ACE & CED Report No. HLA 6015-394 GLP: Yes Published: No	
IIA 7.1.3 IIIA 9.1.3	Burden A N	1999	The Predicted Environmental Concentrations of 2,4-DB and its Metabolite 2,4-D in Groundwater Covance Laboratories Ltd A H Marks & Company Limited Report No. 785/74 GLP: No Published: 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
IIA 7.1.3	de Vette H Q M	1999	A study on the adsorption/desorption of 2,4-DB to soil particles in four soil types using [¹⁴ C] 4-(2,4-Dichlorophenoxy)butyric acid (OECD draft, SETAC-Europe and EU Council 95/36/EC TNO Nutrition and Food Research Institute, Delft, The Netherlands A H Marks & Company Limited Report No IMW-99-9052-01 GLP: Yes Published: No	
IIA 7.1.3 & IIIA 9.1.3	Moyle J & Burden A N	1999	The Predicted Environmental Concentrations of 2,4-DB and its Metabolite 2,4-D in Groundwater Covance Laboratories Ltd A H Marks & Company Limited Report No. 785/66 GLP: No Published: No	
IIA 7.1.3	Ridge M A	1999	(¹⁴ C)-2,4-DB Aged Soil Leaching Covance Laboratories Ltd A H Marks & Company Limited Report No. 785/55-2142 GLP: Yes Published: No	
IIA 7.4	de Vette HQM	2001	A water/sediment degradation study of 2,4-DB using [¹⁴ C]2,4-DB TNO Netherlands A H Marks & Company Limited Report No V2419/01 GLP: Yes Published: No	
IIA 7.7 & IIIA 9.3	Russell S	1998	2,4-DB: Estimation of Atmospheric Oxidation Potential by computer modelling Covance Laboratories Ltd A H Marks & Company Limited Report No 785/67 GLP: Yes Published: No	

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 authorization s
IIA 8.1.1	Pendersen C A	1989 a	2,4-DB acid: 21 days acute oral LD ₅₀ study in bobwhite quail. AHM, RPA, ACE & CED Report No: BLAL 89 QD 132 Bio-Life Associates, USA GLP: Yes Published: No	
IIA 8.1.2	Pendersen C A	1989	Butyrac 200: 8 day dietary LC ₅₀ study in bobwhite quail. AHM, RPA, ACE & CED Report No: BLAL # 89 QC 130 Bio-Life Associates, USA GLP: Yes Published: No	
IIA 8.2	Mayes M A et al	1990	2,4-Dichlorophenoxyacetic acid: Evaluation of the toxicity to early life stages of the Fathead Minnow, <i>Pimephales promelas</i> RAFINESQUE. Generated by: Environmental toxicology & Chemistry Research Laboratory Health & Environmental Sciences, The Dow Chemical Company, Midland, Michigan, 48674. 2,4-D Task Force Report No: ES-DR-0002-2297-10 Date: 12-July-1990 GLP: Yes Published: No	
IIA 8.2.1 IIIA 10.2.1	Mattock S D	1999	2,4-DB Sodium 400 g/l: Acute Toxicity to the Rainbow Trout (<i>Oncorhynchus mykiss</i>). Covance Laboratories Ltd A H Marks & Company Limited CLE: 785/58-D2145 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	Reports on previous use in granting national authorizations
IIA 8.2.1 IIIA 10.2.1	Mattock S D	1999	2,4-DB Sodium 400 g/l: Acute Toxicity to the Zebra Fish (<i>Brachydanio rerio</i>). Covance Laboratories Ltd CLE: 785/59-D2145 A H Marks & Company Limited GLP: Yes Unpublished	
IIA 8.2.4	McNamara, P. C.	1990	2,4-DB acid - acute toxicity to daphnids (<i>Daphnia magna</i>) during a 48 hour flow-through acute exposure. AHM, RPA, ACE & CED Report No: 89-7-3031 Springborn Laboratories Inc., USA GLP: Yes Published: No	
IIA 8.2.5	Mattock S D	1999	2,4-DB Sodium 400 g/l: Reproduction Test with <i>Daphnia magna</i> . Covance Laboratories Ltd A H Marks & Company Limited CLE: 785/62-D2145 GLP: Yes Unpublished	
IIA 8.2.6 IIIA 10.2.1	Mattock, S.D.	1999	2,4-DB Sodium 400 g/L: Inhibition of Growth to the Alga <i>Scenedesmus subspicatus</i> Covance Laboratories Ltd A H Marks & Company Limited CLE: 785/60-D145 GLP: Yes Unpublished	
IIA 8.2.6 IIIA 10.2.1	Mattock, S.D.	1999	2,4-DB Sodium 400 g/L: Inhibition of Growth to the Alga <i>Selenastrum capricornutum</i> Covance Laboratories Ltd. A H Marks & Company Limited CLE: 785/70-D2145 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	Reports on previous use in granting national authorizations
IIA 8.2.8	Mattock, S.D.	1999	2,4-DB Sodium 400 g/l: Toxicity to <i>Lemna minor</i> Covance Laboratories Ltd A H Marks & Company Limited CLE: 785/61-D2145 GLP: Yes Unpublished	
IIA 8.3.1 IIIA 10.4.1	Weyman, G.S.	1999	2,4-DB: Acute Contact and Oral Toxicity to Honeybees Covance Laboratories Ltd A H Marks & Company Limited CLE: 785/41-D2145 Unpublished GLP: Yes	
IIA 8.3.2 IIIA 10.5	Mattock, S.D.	1999	2,4-DB Sodium 400 g/L: Tier I Standard Laboratory Bioassay of the Effects on <i>Poecilus cupreus</i> (Coleoptera, Carabidae) Covance Laboratories Ltd A H Marks & Company Limited CLE: 785/46-D2145 GLP: Yes Unpublished	
IIA 8.3.2 IIIA 10.5	Farrelly, E.	1999	2,4-DB Sodium 400 g/L: Tier I Standard Laboratory Bioassay of the Effects of Fresh Residues on <i>Chrysoperla carnea</i> (Neuroptera, Chrysopidae) Covance Laboratories Ltd. A H Marks & Company Limited CLE: 785/45-D2145 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	Reports on previous use in granting national authorizations
IIA 8.3.2 IIIA 10.5	Baxter, I:	1999	2,4-DB Sodium 400 g/L: Tier I Standard Laboratory Bioassay of the Effects of Fresh Residues on <i>Aphidius Rhopalosiphi</i> (Hymenoptera, Braconidae) Covance Laboratories Ltd. A H Marks & Company Limited COV-99-1 (Ref. No 785/71) GLP: Yes Unpublished	
IIA 8.3.2 IIIA 10.5	Farrelly, E.	1999	2,4-DB Sodium 400 g/L: Tier I Standard Laboratory Bioassay of the Effects of Fresh Residues on <i>Typhlodromus pyri</i> (Acari, Phytoseiidae) Covance Laboratories Ltd A H Marks & Company Limited CLE: 785/44-D2145 GLP: Yes Unpublished	
IIA 8.4.1 IIIA 6.1.1	Weyman G S	1999	2,4-DB: Acute toxicity to the earthworm <i>Eisenia foetida</i> Covance Laboratories Ltd A H Marks & Company Limited CLE: 785/42-D2145 GLP: Yes Unpublished	
IIA 8.5 IIIA 10.7.1	Keirs D.C & Briggs C R	1999	The Effect of 2,4-DB on Soil Microflora (SETAC/EPPO Guidelines) Inveresk Research A H Marks & Company Limited Report No 16977 GLP: Yes Unpublished	
IIA 8.6	Wardman J	1999	The effects of 2,4-DB on non target plant species A H Marks & Company Limited AHM S 99 012 GLP: No Published: Yes	

APPENDIX IIIB**2,4-DB**

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 1.11	Bass R V	1999	Preliminary analysis of 5 batches of 4-(2,4-dichlorophenoxy)butyric acid A H Marks & Company Limited Report No 98/0055 GLP: Yes Published: No
IIA 2.6, 2.7, 2.8	Hutchinson N D	1998	Solubility and Partition Coefficient of 4-(2,4-Dichlorophenoxy)butyric Acid A H Marks and Company Limited Report No 98/0056 GLP: Yes Published: No
IIA 2.9.3	Brodsky J	1999	Determination of the Direct phototransformation of 2,4-DB in water CAU GmbH, Germany A H Marks & Company Limited Report No: 785/68 GLP: Yes Published: No
IIA 2.9.4	Ruzo L O & Ewing A D	2001	Determination of the pK _a value for 2,4-DB (Amended Report) Pharmacology and Toxicology Research Laboratory USA AHM, RPA, ACE & CED Report No: P167W GLP: No Published: 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
IIA 2.10	Russell S	1998	2,4-DB: Estimation of atmospheric oxidation potential by computer modelling A H Marks & Company Limited Report No: 785/67 Covance Laboratories Ltd GLP: No Published: No
IIA 2.11	Edwards D	1998	<i>2,4-DB: Determination of the physico-chemical properties of the substance as manufactured</i> <i>Covance Laboratories Ltd</i> <i>A H Marks & Company Limited</i> <i>Report No: 785/64-D2141</i> <i>GLP: Yes</i> <i>Published: No</i>
IIA 2.13 & IIIA 2.2	Hale M	2002	Explosive Properties of DB and DB Na Solutions A H Marks & Company Limited GLP: No Published: No
IIA 2.15 & IIIA 2.2	Hale M	2002	Oxidising Properties of DB and DB Na Solutions A H Marks & Company Limited GLP: No Published: No
IIIA 2.1, 2.4,2.5, 2.6, 2.8	Bass R V	1998	The chemical and physical properties of DB Na salt solution at 400 g/l DB acid concentration A H Marks & Company Limited Report No: 98/0053 GLP: Yes Published: No
IIIA 2.3	Edwards D	1998	2,4-DB Sodium 400 g/l: Determination of the auto-ignition temperature Covance Laboratories Ltd A H Marks & Company Limited Report No: 785/64-D2141 GLP: Yes Published: No
IIIA 2.7	Bass R V	1998	Thermal and low temperature stability of DB Na salt solution at 400 g/l DB acid concentration A H Marks & Company Limited Report No 98/0054 GLP: Yes Published: 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
IIIA 2.7.3	Bass R V	2000	Two year storage stability of DB Na salt solution at 400 g/l DB acid concentration A H Marks & Company Limited Report No 98/0059 GLP: Yes Published: No
IIIA 2.1, 2.4,2.5, 2.6, 2.8	Bass R V	1998	The chemical and physical properties of DB Na salt solution at 400 g/l DB acid concentration A H Marks & Company Limited Report No: 98/0053 GLP: Yes Published: No
IIA 4.1.1 & 4.1.2	Bass R V	1999	Preliminary analysis of 5 batches of 4-(2,4-dichlorophenoxy)butyric acid A H Marks & Company Ltd Report No 98/0055 GLP: Yes Published: No
IIA 4.2.1 & IIIA 5.2.1	Baxby M	2001	Independent Laboratory Validation of a Method for the Analysis of 2,4-DB, 2,4-D, 2,4-DP-p and 2,4 DCP in cereals and grass A H Marks & Company Ltd AHM ILV 01/002 GLP: Yes Published: No
IIA 4.2.1 & IIIA 5.2.1	Baxby M	2002	Development of a Confirmatory Method for the Determination of 2,4-DB in Milk A H Marks & Company Ltd Report No AHM ILV 01/0002 GLP: No Published: No
IIA 4.2.1 & IIIA 5.2.1	Cumberbatch D J	1999	Analytical method for the determination of 2,4-DB, 2,4-D, 2,4-DP and 2,4-DCP in cereals and grass A H Marks & Company Ltd Method No 591(issue No1) GLP: No Published: 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
IIA 4.2.1 & IIIA 5.2.1	Howard J B S	1997	Development and validation of analytical methodology for the analysis of 2,4-Dichlorophenoxybutyric acid (2,4-DB) in beef tissues and milk PTRL East Inc USA AHM, RPA, ACE & CED Report No 1000 GLP: Yes Published: No
IIA 4.2.1 & IIIA 5.2.1	Howard J B S	1998	Development and Validation of Analytical Methodology for the Analysis of 2,4-Dichlorophenoxybutyric acid (2,4-DB) in Poultry Tissues and Eggs AHM, RPA, ACE & CED Report No 1001 PTRL East Inc USA GLP: Yes Published: No
IIA 4.2.1 & IIIA 5.2.1	Rawle N W	2000	Validation of a method for the analysis of residues of 2,4-DCP, 2,4-D, 2,4-DP-p and 2,4-DB in grass CEM Analytical Services Ltd, UK A H Marks & Company Ltd Report No CEM-1177 GLP: Yes Published: No
IIA 4.2.1 & IIIA 5.2.1	Rawle N W	2000	Validation of a method for the analysis of residues of 2,4-DCP, 2,4-D, 2,4-DP-p and 2,4-DB in cereals CEM Analytical Services Ltd, UK A H Marks & Company Ltd Report No CEM-1178 GLP: Yes Published: No
IIA 4.2.1 & IIIA 5.2.1	Turnbull G	2001	Validation of analytical methodology for the determination of 2,4-dichlorophenoxybutyric acid in beef tissues Central Science Laboratory, UK A H Marks & Company Ltd Report No PGD-67 GLP: Yes Published: 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
IIA 4.2.1 & IIIA 5.2.1	Turnbull G	2001	Validation of analytical methodology for the determination of 2,4-dichlorophenoxybutyric acid in milk A H Marks & Company Ltd Report No PGD-75 Central Science Laboratory, UK GLP: Yes Published: No
IIA 4.2.1 & IIIA 5.2.1	Perny A	2002	Validation of Analysis for 2,4-DCP, 2,4-D, 2,4-DP and 2,4-DB residues in cereals ANADIAG SA, France A H Marks & Company Limited Report No AHM R 00132 (R A0114) GLP: Yes Published: No
IIA 4.2.1 & IIIA 5.2.1	Turnbull G	2001	Validation of Analytical Methodology for the Determination of 2,4-Dichlorophenoxybutyric Acid in Chicken Tissues A H Marks & Company Limited Central Science Laboratory, UK Study No PGD-68 GLP: Yes Published: No
IIA 4.2.2 & IIIA 5.2.2	Howard J B S	1998	Development and validation of analytical methodology for the analysis of 2,4-Dichlorophenoxybutyric acid (2,4-DB), 2,4-Dichlorophenoxyacetic acid (2,4-D) and 2,4-Dichlorophenol in soil PTRL East AHM, RPA, ACE & CED Report No 2008 GLP: Yes Published: No
IIA 4.2.3 & IIIA 5.2.3	Westwood D	1997	The determination of Acidic Herbicides in waters by GC-MS From Environment Agency Publication "The determination of acidic herbicides, Bromoxynil, Ioxynil and Pentachlorophenol in waters, 1997", Method D GLP: No Published: Yes

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 4.2.4 & IIIA 5.2.4	Bass R V	2000	Validation of the analytical method for the determination of 4-(2,4-Dichlorophenoxy)butyric acid (DB) in air A H Marks & Company Ltd Report No 00/0118 GLP: Yes Published: No
IIIA 5.1.1	Bass R V	1998	Thermal and low temperature stability of DB Na salt solution at 400 g/l DB acid concentration A H Marks & Company Ltd Report No 98/0054 GLP: Yes Published: No
IIIA 5.1.1	Baxby M	2002	Validation of Accuracy of HPLC method for DB in DB Na 400 g/l A H Marks & Company Ltd Report No: R/02/01 GLP: No Published: No

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
IIA 5.1	Gibson N A; Marsh J D; Johnson T L; Lawrence L J	1999	Absorption, Distribution and Elimination of [¹⁴ C]2,4-DB in the Rat (Addendum 1 : Structural Confirmation of a 2,4-DB Rat Metabolite) A H Marks & Company Limited Report/file No : 2014 PTRL Laboratories GLP: Yes Published: No
IIA 5.2.6	Denton S M	1999	Skin sensitisation Study in the Guinea Pig (Maximisation Test according to Magnusson and Klingman) A H Marks & Company Limited Report No 785/65-D6144 Covance Laboratories Ltd GLP: Yes Published: 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
IIA 5.2.6	Johnson I R	2001	Technical 2,4-Dichlorophenoxybutyric acid: Local Lymph Node Assay A. H. Marks & Company Limited Report/file No: GM7533 Central Toxicology Laboratory Alderley Park Macclesfield Cheshire UK GLP: Yes Published: No
IIA 5.3.2	Holsing G	1969	13-Week Oral Administration - Dogs AHM, RPA, ACE & CED Report No 656-110 Hazleton Laboratories Inc USA GLP: No Published: No
IIA 5.4.2	Burman M	1999	Induction of Micronuclei in the Bone Marrow of Treated Mice A H Marks & Company Limited Report/file No 785/52-D5140 Covance Laboratories Ltd GLP: Yes Published: No
IIA 5.5	Charles J et al	1998	Chronic Dietary Toxicity/Oncogenicity Studies on 2,4-Dichlorophenoxybutyric Acid in Rodents Toxicological Sciences 46: 21-30; 1998 GLP: No Published: Yes
IIA 5.5	Charles J et al	1998	Chronic Dietary Toxicity Study on 2,4-Dichlorophenoxybutyric Acid in the Dog Toxicological Sciences 46: 134-142; 1998 GLP: No Published: Yes
IIA 5.6	Charles J et al	1999	Developmental Toxicity Studies in Rats and Rabbits and Two-Generation Reproduction Study in Rats on 4-(2,4-Dichlorophenoxy)butyric Acid International Journal of Toxicology 18 pages 177-189 GLP: No Published: Yes
IIA 5.9.1	Burgess J S	1998	Survey of employees handling phenoxy acid herbicides and relevant compounds A H Marks & Company Limited Cavell & Lind GLP: No Published: 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
IIA 5.9.1	Coggon D; Pannett B and Winter P	1991	Mortality and incidence of cancer at four factories making phenoxy herbicides Medical Research Centre UK British Journal of Industrial Medicine 48: 173-178; 1991 GLP: No Published: Yes
IIA 5.9.1	Kauppinen T et al	1993	Chemical Exposure in Manufacture of Phenoxy Herbicides and Chlorophenols and in Spraying Phenoxy Herbicides American Journal of Industrial Medicine 23: 903-920; 1993 GLP: No Published: Yes
IIA 5.9.1	Kogevinas M et al,	1995	Soft Tissue Sarcoma and Non Hodgkin's Lymphoma in Workers Exposed to Phenoxy Herbicides, Chlorophenols and Dioxins: Two Nested Case-Control Studies Epidemiology vol6 No 4: 396-402; 1995 GLP: No Published: Yes
IIA 5.9.1	Kogevinas M et al	1997	Cancer Mortality in Workers Exposed to Phenoxy Herbicides, Chlorophenols and Dioxins American Journal of Epidemiology 145, No 12: 1061-1075, 1997 GLP: No Published: Yes
IIA 5.9.1	Saracci R et al	1991	Cancer Mortality in Workers Exposed to Phenoxy Herbicides, Chlorophenols The Lancet 338, No 8774: 1027-1032; 1991 GLP: No Published: Yes
IIA 5.9.1	Vena J et al	1998	Exposure to Dioxin and Nonneoplastic Mortality in the Expanded IARC International Cohort Study of Phenoxy Herbicide and Chlorophenol Production Workers and Sprayers Environmental Health Perspectives vol 106, supplement 2; 1998 GLP: No Published: Yes
IIIA 5.11.1	Ruddock W D	1998	2,4-DB-Sodium 400 g/l: Acute Oral Toxicity Study in the Rat (Fixed Dose Procedure) A. H. Marks & Company Limited Report No 785/47-D6144 Covance Laboratories Ltd GLP: Yes Published: 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
IIIA 5.11.2	Ruddock W D	1998	2,4-DB-Sodium 400 g/l: Acute Dermal Toxicity Study in the Rat A. H. Marks & Company Limited Report No 785/48-D6144 Covance Laboratories Ltd GLP: Yes Published: No
IIIA 5.11.5	Ruddock W D	1998	2,4-DB-Sodium 400 g/l: Eye Irritation Study in the Rabbit A. H. Marks & Company Limited Report No 785/50-D6144 Covance Laboratories Ltd GLP: Yes Published: No
IIIA 5.11.6	Denton S M	1999	2,4-DB-Sodium 400 g/l: Skin Sensitisation Study in the Guinea Pig (after Magnusson and Kligman) A H Marks & Company Limited Report No 785/51-D6144 Covance Laboratories Ltd GLP: Yes Published: No
IIIA 5.12.1	Johnson I R	2001	Formulation of 2,4- Dichlorophenoxybutyric acid: Local Lymph Node Assay A. H. Marks & Company Limited Report No GM7534 Central Toxicology Laboratory Alderley Park Macclesfield Cheshire UK GLP: Yes Published: No
IIIA 5.12.2	Prinzen M K	2001	Sensitization Study with 2,4-DB Na 400g/l in Guinea P (Maximisation Test) A. H. Marks & Company Limited Report No 41013/01.11 TNO Nutrition and Food Research Utrechtseweg 48, P Box 360,3700 AJ Zeist, The Netherlands GLP: Yes Published: No
IIIA 5.14.4	Thornley K	1998	(¹⁴ C)-2,4-DB-2EHE and (¹⁴ C)-2,4-DB-Na: Dermal absorption in the rat A H Marks & Company Limited Report No 785/16-D1141 Covance Laboratories Ltd GLP: Yes Published: 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
IIIA 5.14.4	Whomsley R; Ridd I	1999	(¹⁴ C)-2,4-DB-Na : Rates of penetration through rat and human skin using an <i>in vitro</i> system A H Marks & Company Limited Report No :785/40-D1140 Covance Laboratories Ltd GLP: Yes Published: No
IIIA 5.14.4	Wilson R D	2000	Summary of the Transferable Turf Residues from the Applications of Various Forms of Phenoxy Herbicides John Wise & Associates Ltd, USA Broadleaf Turf Herbicide TFR Task Force Report No. RDW99-1028 GLP: No Published: No
IIIA 5.14.4	Wilson R D	1998	Comparison of the Transferable Turf Residues from the Application of Various Forms of Phenoxy Herbicides and the Effects from the Application of Various Spray Volumes Per Acre John Wise & Associates Ltd, USA Broadleaf Turf Herbicide TFR Task Force Report No. RDW98-0903 GLP: No Published: No

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 6.1	O'Neal S	1993	Metabolic Fate and Distribution of ¹⁴ C-2,4-DB Acid in Alfalfa PTRL East, USA AHM, RPA, ACE & CED Report No. 1529 GLP: Yes Published: No
IIA 6.1	O'Neal S	1993	Metabolic Fate and Distribution of ¹⁴ C-2,4-DB Acid in Peanuts PTRL East, USA AHM, RPA, ACE & CED Report No 1547 GLP: Yes Published: 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
IIA 6.3	Krautter G R	1997	Magnitude of the Residue in Meat and Milk from Dairy Cows Treated with 2,4-Dichlorophenoxybutyric Acid (2,4-DB) PTRL East Inc. AHM, RPA, ACE & CED Report No 993 GLP: Yes Published: No
IIA 6.3	Perny A	2001	Residues of 2,4-DB Sodium Salt in Cereals in Northern Europe (analytical phase) Anadiag, France A H Marks & Company Limited AHM R 00 121 (R A 0111) GLP: Yes Published: No
IIA 6.3	Perny A	2002 a	Validation of Analysis for 2,4-DCP, 2,4-D, 2,4-DP and 2,4-DB residues in cereals Anadiag, France A H Marks & Company Limited AHM R 00 132 (R A0114) GLP: Yes Published: No
IIA 6.3	Perny A	2002 b	Residue decline of 2,4-DB Sodium salt in Grassland in Northern Europe Anadiag, France A H Marks & Company Limited AHM R 00 221 (R A 0113) GLP: Yes Published: No
IIA 6.6	Johnson T	1995 a	Field Crop Residue Study with 2,4-DB applied to Soybeans PTRL Inc., USA AHM, RPA, ACE & CED Report No. 1641 GLP: Yes Published: No
IIA 6.6	Johnson T	1995 b	Field Crop Residue Study with 2,4-DB applied to Peanuts PTRL Inc., USA AHM, RPA, ACE & CED Report No. 1706 GLP: Yes Published: 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
IIA 6.6	Krautter G R	1997	Magnitude of the Residues in Meat and Milk from Dairy Cows Treated with 2,4-Dichlorophenoxybutyric Acid (2,4-DB) PTRL East, USA AHM, RPA, ACE & CED Report No 1930 GLP: Yes Published: No
IIA 6.6	Wardman J P	2000	Determination of the residue decline of 2,4-DB 2,4-D and 2,4-DCP in cereals following treatment with Marks 2,4-DB (400 g/l 2,4-DB formulated as the sodium salt under field conditions in the UK. Report/file No AHM R 99 151 GLP: Yes Published: No
IIA 6.6	Wardman J P	2000	Determination of the residue decline of 2,4-DB and 2,4-D in grassland following treatment with Marks 2,4-DB (400 g/l 2,4-DB formulated as the sodium salt under field conditions in Northern Europe. Report/file No AHM R 99 158 GLP: Yes Published: No
IIA 6.6	Wardman J P	2000	Determination of the residue decline of 2,4-DB and 2,4-D in grassland following treatment with Marks 2,4-DB (400 g/l 2,4-DB formulated as the sodium salt under field conditions in the UK. Report/file No AHM R 98 150 GLP: Yes Published: No
IIA 6.8	Gibson N A	1999	Magnitude of the Residue in Meat and Eggs from Laying Hens Treated with 4-(2,4-Dichlorophenoxybutyric) Acid (2,4-DB). PTRL East, USA AHM, RPA, ACE & CED Report No 2060 Project 994 GLP: Yes Published: No
IIA 6.13	FAO/WHO	1997	Guidelines for predicting dietary intake of pesticides (revised) World Health Organisation ISBN 0119518023 GLP: No Published: Yes
IIA 6.13	FAO/WHO	1998	GEMS/Food Regional Diets WHO/FSF/FOS/98.3 GLP: No Published: Yes

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 7.1.1	Ridge M A	2000	(¹⁴ C)-2,4-DB: Soil Metabolism and Degradation Covance Laboratories Ltd A H Marks & Company Limited Report No. 785/53-2142 GLP: Yes Published: No
IIA 7.1.1.1.2	Goodyear A	2000	(¹⁴ C)-2,4-DB: Anaerobic Soil Metabolism Covance Laboratories Ltd A H Marks & Company Limited Report No. 785/54-D2142 GLP: Yes Published: No
IIA 7.1.3 IIIA 9.1.3	Burden A N	1999	The Predicted Environmental Concentrations of 2,4-DB and its Metabolite 2,4-D in Groundwater Covance Laboratories Ltd A H Marks & Company Limited Report No. 785/74 GLP: No Published: No
IIA 7.1.3	de Vette H Q M	1999	A study on the adsorption/desorption of 2,4-DB to soil particles in four soil types using [¹⁴ C] 4-(2,4-Dichlorophenoxy)butyric acid (OECD draft, SETAC-Europe and EU Council 95/36/EC TNO Netherlands A H Marks & Company Limited Report No IMW-99-9052-01 GLP: Yes Published: No
IIA 7.1.3 & IIIA 9.1.3	Moyle J & Burden A N	1999	The Predicted Environmental Concentrations of 2,4-DB and its Metabolite 2,4-D in Groundwater Covance Laboratories Ltd A H Marks & Company Limited Report No. 785/66 GLP: No Published: No
IIA 7.1.3	Ridge M A	1999	(¹⁴ C)-2,4-DB Aged Soil Leaching Covance Laboratories Ltd A H Marks & Company Limited Report No. 785/55-2142 GLP: Yes Published: 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
IIA 7.4	de Vette HQM	2001	A water/sediment degradation study of 2,4-DB using [¹⁴ C]2,4-DB TNO Netherlands A H Marks & Company Limited Report No V2419/01 GLP: Yes Published: No
IIA 7.7 & IIIA 9.3	Russell S	1998	2,4-DB: Estimation of Atmospheric Oxidation Potential by computer modelling Covance Laboratories Ltd A H Marks & Company Limited Report No 785/67 GLP: Yes Published: No
IIIA 9.1.3	Garratt J	2002	The predicted environmental concentrations of 2,4-DB and its metabolite 2,4-D in groundwater using PELMO 2.01 Enviresearch A H Marks & Company Limited Report No E2002/01 GLP: No Published: No
IIIA 9.1.3	Mackay N	1996	The Predicted Environmental Concentrations of 2,4-DB in Soil, Air, Surface Water and Sediment Corning Hazleton, UK A H Marks & Company Limited Report No 1149-020-PEC-1 GLP: No Published: No
IIIA 9.1.3	Pigott G	1999	The Predicted Environmental Concentrations of 2,4-D in soil, surface water and ground water as main metabolite of 2,4-DB A H Marks & Company Limited GLP: No Published: No

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	Mayes M A et al	1990	2,4-Dichlorophenoxyacetic acid: Evaluation of the toxicity to early life stages of the Fathead Minnow, <i>Pimephales promelas</i> RAFINESQUE. Dow Chemical Company USA 2,4-D Task Force Report No: ES-DR-0002-2297-10 Date: 12-July-1990 GLP: Yes Published: No
IIA 8.2.1 IIIA 10.2.1	Mattock S D	1999	2,4-DB Sodium 400 g/l: Acute Toxicity to the Rainbow Trout (<i>Oncorhynchus mykiss</i>). Covance Laboratories Ltd A H Marks & Company Limited CLE: 785/58-D2145 GLP: Yes Unpublished
IIA 8.2.1 IIIA 10.2.1	Mattock S D	1999	2,4-DB Sodium 400 g/l: Acute Toxicity to the Zebra Fish (<i>Brachydanio rerio</i>). Covance Laboratories Ltd CLE: 785/59-D2145 A H Marks & Company Limited GLP: Yes Unpublished
IIA 8.2.5	Mattock S D	1999	2,4-DB Sodium 400 g/l: Reproduction Test with <i>Daphnia magna</i> . Covance Laboratories Ltd A H Marks & Company Limited CLE: 785/62-D2145 GLP: Yes Unpublished
IIA 8.2.6 IIIA 10.2.1	Mattock S.D.	1999	2,4-DB Sodium 400 g/L: Inhibition of Growth to the Alga <i>Scenedesmus subspicatus</i> Covance Laboratories Ltd A H Marks & Company Limited CLE: 785/60-D145 GLP: Yes Unpublished
IIA 8.2.6 IIIA 10.2.1	Mattock S D	1999	2,4-DB Sodium 400 g/L: Inhibition of Growth to the Alga <i>Selenastrum capricornutum</i> Covance Laboratories Ltd. A H Marks & Company Limited CLE: 785/70-D2145 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
IIA 8.2.8	Mattock S D	1999	2,4-DB Sodium 400 g/l: Toxicity to <i>Lemna minor</i> Covance Laboratories Ltd A H Marks & Company Limited CLE: 785/61-D2145 GLP: Yes Unpublished
IIA 8.3.1 IIIA 10.4.1	Weyman G S	1999	2,4-DB: Acute Contact and Oral Toxicity to Honeybees Covance Laboratories Ltd A H Marks & Company Limited CLE: 785/41-D2145 Unpublished GLP: Yes
IIA 8.3.2 IIIA 10.5	Mattock S D	1999	2,4-DB Sodium 400 g/L: Tier I Standard Laboratory Bioassay of the Effects on <i>Poecilus cupreus</i> (Coleoptera, Carabidae) Covance Laboratories Ltd A H Marks & Company Limited CLE: 785/46-D2145 GLP: Yes Unpublished
IIA 8.3.2 IIIA 10.5	Farrelly E	1999	2,4-DB Sodium 400 g/L: Tier I Standard Laboratory Bioassay of the Effects of Fresh Residues on <i>Chrysoperla carnea</i> (Neuroptera, Chrysopidae) Covance Laboratories Ltd. A H Marks & Company Limited CLE: 785/45-D2145 GLP: Yes Unpublished
IIA 8.3.2 IIIA 10.5	Baxter I	1999	2,4-DB Sodium 400 g/L: Tier I Standard Laboratory Bioassay of the Effects of Fresh Residues on <i>Aphidius Rhopalosiphi</i> (Hymenoptera, Braconidae) Covance Laboratories Ltd. A H Marks & Company Limited COV-99-1 (Ref. No 785/71) GLP: Yes Unpublished
IIA 8.3.2 IIIA 10.5	Farrelly, E.	1999	2,4-DB Sodium 400 g/L: Tier I Standard Laboratory Bioassay of the Effects of Fresh Residues on <i>Typhlodromus pyri</i> (Acari, Phytoseiidae) Covance Laboratories Ltd A H Marks & Company Limited CLE: 785/44-D2145 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
IIA 8.4.1 IIIA 6.1.1	Weyman G S	1999	2,4-DB: Acute toxicity to the earthworm <i>Eisenia foetida</i> Covance Laboratories Ltd A H Marks & Company Limited CLE: 785/42-D2145 GLP: Yes Unpublished
IIA 8.5 IIIA 10.7.1	Keirs D C & Briggs C R	1999	The Effect of 2,4-DB on Soil Microflora (SETAC/EPPO Guidelines) Inveresk Research A H Marks & Company Limited Report No 16977 GLP: Yes Unpublished
IIA 8.6	Wardman J	1999	The effects of 2,4-DB on non target plant species A H Marks & Company Limited AHM S 99 012 GLP: No Published: Yes