

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

2,4-D

7599/VI/97-final

1 October 2001

**COMMISSION WORKING DOCUMENT - DOES NOT NECESSARILY REPRESENT THE VIEWS OF
THE COMMISSION SERVICES**

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

Finalised in the Standing Committee on Plant Health at its meeting on 2 October 2001
in view of the inclusion of 2,4-D 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-D, 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 1972/99⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. 2,4-D 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, Law Offices of Samuel Pisar (Nufarm) on 25 June 1993, Rhône-Poulenc Agrochimie on 15 July 1993, Agrolinz on 26 July 1993, ACI International on 30 July 1993, DowElanco Europe on 15 July 1993, CFPI on 28 July 1993, Sanachem International on 23 July 1993, AH Marks & Co Ltd on 20 July 1992, Thoro Nielsen Aps on 20 July 1993, Iberotam on 26 July 1993, Helm AG on 23 July 1993, Calliope SA on 21 July 1993 and B.V. Luxan on 21 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance 2,4-D 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-D 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-D this deadline was 31 October 1995.

Rhône-Poulenc Agro, DowElanco Europe (now Dow AgroSciences), AH Marks & Co Ltd, Agrolinz (now Nufarm Austria) and Nufarm UK formed a task force and jointly submitted a dossier to the rapporteur Member State which was considered as complete. This task force comprising five companies was the main data submitter. With a letter dated 4 May 1999, Rhône-Poulenc Agro has informed the Commission that it has transferred its notification to Nufarm Austria. On 2 September 1999, McKenna & Cuneo, L.L.T. acting on behalf of PBI Gordon, has submitted a

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 244, 16.09.1999, p.41.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

late notification. On 4 September 2001, McKenna & Cuneo, L.L.T. acting on behalf of BASF Aktiengesellschaft, has submitted a second late notification. On 12 October 1999, the Commission took note of these late notifications and the participation of the respective notifiers collectively with the other notifiers as co-owners of the dossier. The second dossier prepared by Sanachem International (now Dow AgroSciences) was considered incomplete. In their letter of 20 May 1998, Dow AgroSciences informed that any further proceeding with the notification for 2,4-D made on behalf of Sanachem International is not intended. Information has furthermore been submitted by the European Environmental Bureau.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Greece submitted on 17 January 1997 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-D 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-D from the 2,4-D task force Rhône-Poulenc Agro, DowElanco Europe (now Dow AgroSciences), AH Marks & Co Ltd, Agrolinz (now Nufarm Austria) and Nufarm UK on 20 October 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 Rhône-Poulenc Agrochimie being the designated representative of the 2,4-D task force, on 26 June 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 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 Plant 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 February 1999 to October 2001, and was finalised in the meeting of the Standing Committee on 2 October 2001.

The present review report contains the conclusions of this 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.

These documents were also submitted to the Scientific Committee for Plants for separate consultation on the adequate animal model to be used for the derivation of the ADI (Acceptable Daily Intake) and the AOEL (Acceptable Operator Exposure Level). In its opinion, which was formally adopted on 21 May 2001, the Committee noted that mice and rats appear to be the preferable species to be used for human risk assessment⁵.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, have been developed and finalised in support of the Directive **2001/103/EC** concerning the inclusion of 2,4-D in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing 2,4-D they have to take in

⁵ Opinion of the scientific Committee on Plants regarding the inclusion of 2,4-D in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market. SCP/2,4D/002-Final.

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-D 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-D containing plant protection product for which Member States will grant or review the authorisation.

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

- **2,4-D Acid:** winter and spring cereals, pasture, green manuring crops, grass-seeds, fallow land, borders of arable land and pastures.
- **2,4-D 2-EHE:** winter cereals.

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 1.4 % of the Acceptable Daily Intake (ADI) of 0.05 mg/kg b.w./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-D are given in Appendix I.

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

The review has established that for the active substance notified by the 2,4-D data submitters participating in the initial task force, the manufacturing impurities dioxins and furans, which are of toxicological concern, are kept at non-detectable levels.

In accordance with the provisions of Article 13(5) of Directive 91/414/EEC, the review has established, on the basis of the information currently available, that the substances notified by all the other data submitters participating in the initial task force do not, in the meaning of Article 13(2) and (5) of the Directive, differ significantly in degree of purity and nature of impurities from the composition registered in the dossier submitted by the main data submitter and they all comply with the FAO specification.

For sources other than the ones participating in the initial task force, Member States should ask for the submission of additional data concerning the identity of the active substance.

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 derivatives of 2,4-D other than the acid and the 2-ethyl hexyl ester evaluated, 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-D

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:

- Leaching to groundwater: 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.
- Operator safety: Member States should pay particular attention to dermal absorption of the active substance under different conditions of use.
- For products containing 2,4-D 2-EHE appropriate risk mitigation measures or higher tier testing may be required to ensure protection of non-target arthropods.

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-D 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

- *In vivo* dermal absorption study in the rat with 2,4-D ester.
- *In vitro* dermal absorption study on rat and human skin with 2,4-D ester.

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.

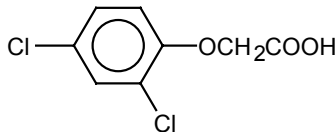
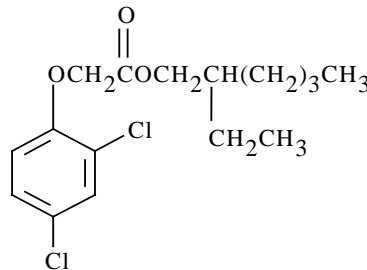
9. Updating of this review report

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 Plant Health, in connection with any amendment of the inclusion conditions for 2,4-D in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties*

2,4-D

	Acid	Ethylhexyl ester
Common name (ISO)	2,4-D	2,4-D 2-EHE
Chemical name (IUPAC)	(2,4-dichlorophenoxy) acetic acid	(2,4-dichlorophenoxy) acetic acid, 2-ethylhexyl ester
Chemical name (CA)	acetic acid, (2,4-dichlorophenoxy)	-
CIPAC No	1	1.3
CAS No	94-75-7	1928-43-4
EEC No	202-361-1	217-673-3
FAO SPECIFICATION	AGP:CP/310 (FAO 1994)	AGP:CP/310 (FAO 1994)
Minimum purity	960 ± 15 g/kg As given by FAO specification	920 g/kg minimum As given by FAO specification
Molecular formula	C ₈ H ₆ Cl ₂ O ₃	C ₁₆ H ₂₂ Cl ₂ O ₃
Molecular mass	221.0	333.26
Structural formula		
Melting point	139.25 °C	< -37°C
Boiling point	not applicable.	not determinable. Degradation occurs at t>200 C

	Acid	Ethylhexyl ester
Appearance	white or off-white crystalline powder, slight phenolic odour.	non viscous clear golden yellow liquid, characteristic odour of aromatic esters.
Relative density	bulk density: 0.66g/ml tap density: 0.81g/ml	pure a.s.: 1.1502 technical a.s.: 1.1527
Vapour pressure	1.9×10^{-5} Pa at 25°C	4.80×10^{-4} Pa at 25°C
Henry's law constant	1.3×10^{-5} Pa m ³ mol ⁻¹ at 25 C	1.82 Pa m ³ mol ⁻¹
Solubility in water	pH 1 buffered: 311 ± 4 mg/l at 25°C pH 5 buffered: 20031 ± 1149 mg/l at 25°C pH 5 unbuffered: 29934 ± 2957mg/l pH 7 buffered: 23180 ± 590 mg/l at 25°C pH 7 unbuffered: 44558 ± 674 mg/l pH 9 buffered: 34196 ± 1031 mg/l at 25°C pH 9 unbuffered: 41314 ± 335 mg/l	86.7 µg/l (pH effect not investigated as, the compound is neither acidic nor basic)
Solubility in organic solvents (at 20 °C)	n-hexane 0.03 g/l at 25°C toluene 6.4 g/l dichloromethane 13 g/l methanol ≥810 g/l isopropanol 220 g/l n-octanol 120 g/l acetone 390 g/l ethylacetate 170 g/l	> 250 g/l in n-heptane, p-xylene, dichloro-methane, 2-propanol, n-octanol, acetone, ethylacetate, acetonitrile
Partition co-efficient (log P_{ow})	pH 1: logP _{ow} = 2.70 at 25°C pH 5: logP _{ow} = 0.18 at 25°C pH 7: logP _{ow} = - 0.83 at 25°C pH 9: logP _{ow} = -1.01 at 25°C	logP _{ow} = 5.78 at 25°C (pH not stated)

	Acid	Ethylhexyl ester
Hydrolytic stability (DT₅₀)	pH 5: not hydrolyzed at 25°C DT ₅₀ = estimated to be 2 years pH 7: not hydrolyzed at 25°C DT ₅₀ = estimated to be 2 years pH 9: not hydrolyzed at 25°C DT ₅₀ = estimated to be 2 years	pH 5: DT ₅₀ = 99.7 d pH 7: DT ₅₀ = 48.3 d pH 9: DT ₅₀ = 55.2 h
Dissociation constant	K _a = 1.71×10 ⁻³ at ionic strength I=0.01 K _a = 1.86×10 ⁻³ at ionic strength I=0.05 K _a = 1.20×10 ⁻³ at ionic strength I=0 at 25°C	not applicable.
Quantum yield of direct photo-transformation in water at ε >290 nm	Q ≤ 0.014 mol Einstein ⁻¹	Q = 1.246 mol Einstein ⁻¹
Flammability	moderately flammable (ignition time = 1.1min.)	not applicable (liquid).
Explosive properties	not explosive.	not explosive.
UV/VIS absorption (max.)	λ _{max} =207, 232,287,290 nm. ε values at the corresponding wavelenghts have not been submitted except ε ₂₉₀ =164.97 l/mol cm	λ _{max} =203.6, 228.3,283.2nm. ε _{203.6} = 3.31×10 ⁴ M ⁻¹ cm ⁻¹ , ε _{228.3} = 8.38×10 ³ M ⁻¹ cm ⁻¹ , ε _{283.2} = 2.27×10 ³ M ⁻¹ cm ⁻¹
Photostability (DT₅₀)	DT ₅₀ =12.98 d in sterile aqueous buffer of pH=7 at 25°C	DT ₅₀ =128.2 d under natural sunlight in sterile aqueous buffer of pH=5

* These endpoints are based on the 2,4-D acid from the notifier Rhône-Poulenc Agrochimie and on the 2,4-D EHE from the notifier Dow Elanco Europe (Dow AgroSciences). Details on the results for test materials from other sources, which were evaluated can be found in the assessment report.

APPENDIX II**ENDPOINTS AND RELATED INFORMATION****2,4-D****1 Toxicology and metabolism****Absorption, distribution, excretion and metabolism in mammals**

	Acid	Ethylhexyl ester
Rate and extent of absorption:	rapid and almost complete (> 90 % within 48 h)	rapid and almost complete (84-95 % within 72 h)
Distribution:	higher concentration in kidney and liver. Also identified in CNS	no data available
Potential for accumulation:	low	no data available
Rate and extent of excretion:	higher than 90 % at 48 h via urine, up to 10 % via faeces	rapid excretion 64% via urine, 18% via faeces, 10% via CO ₂ (ester label)
Toxicologically significant compounds:	2,4-D acid, 2,4-DCP	immediate transformation to 2,4-D acid, 2,4-DCP
Metabolism in animals:	97% excreted unchanged, 2,4-D conjugates (minor metabolites)	2,4-D acid (50.7%), 2-ethylhexanol was metabolized to polar compounds.

Acute toxicity

	Acid	Ethylhexyl ester
Rat LD ₅₀ oral:	425-764 mg/kg bw	720-982 mg/kg bw
Rat LD ₅₀ dermal:	>2000 mg/kg bw	>2000 mg/kg bw
Rat LC ₅₀ inhalation:	>1.79 mg/l (4 hr exposure)	> 5.39 mg/l (4 hr exposure)
Skin irritation:	Non-irritant (4 hr exposure)	Non-irritant (4 hr exposure)
Eye irritation:	Severe eye irritant	Non-irritant.
Sensitization (test method used and result):	Skin sensitizer	Sensitizer (Buehler method)

Short term toxicity

	Acid	Ethylhexyl ester
Target / critical effect:	Kidney & liver / organ weight and function markers	Kidney / organ weight and function markers
Lowest relevant oral NOAEL / NOEL:	15 mg/kg b.w./day (rats)	22.6 mg/kg b.w./day (rats)
Lowest relevant dermal NOAEL / NOEL:	10 mg/kg bw/d for local effects, 100 mg/kg bw/d for systemic toxicity (21-d dermal, rabbit)	16.3 mg/kg bw/d for local effects 162.8 mg/kg bw/d for systemic toxicity (21-d dermal, rabbit)
Lowest relevant inhalation NOAEL / NOEL:	No data required.	No data required.

Genotoxicity

some positives <i>in vitro</i> , negative <i>in vivo</i> in mammals (micronucleus test). No evidence of UDS induction <i>in vivo</i>	Negative at Ames, UDS and micronucleus assays
--	---

Long term toxicity and carcinogenicity

Target / critical effect:	kidney/histopathology	No data required. See 2,4-D acid.
Lowest relevant NOAEL:	5 mg/kg b.w./day (based on submitted data both in rats and mice)	No data required. See 2,4-D acid.
Carcinogenicity:	No evidence of carcinogenicity	No data required. See 2,4-D acid.

Reproductive toxicity

Target / critical effect - Reproduction:	decreased pup survival and body weight at parentally toxic doses (rat)	See 2,4-D acid.
Lowest relevant reproductive NOAEL / NOEL:	overall repro/par NOAEL= 5 mg/kg bw/day	See 2,4-D acid.
Target / critical effect - Developmental toxicity:	fetotoxicity at maternally toxic doses (rat)	fetotoxicity at maternally toxic doses (rat)
Lowest relevant developmental NOAEL:	25 mg/kg bw/d (rat)	16 mg/kg bw/d (rat)

**Neurotoxicity/
Delayed neurotoxicity**

clear indications of neurotoxicity at high dose levels (reversible)	See 2,4-D acid.
---	-----------------

Other toxicological studies

Acid	Ethylhexyl ester
2,4-DCP: some positive genotoxicity results <i>in vivo</i> . Equivocal results on carcinogenicity in male mice	2,4-DCP: some positive genotoxicity results <i>in vivo</i> . Equivocal results on carcinogenicity in male mice

Medical data

from the available epidemiological studies no clear association between cancer development and exposure to phenoxyherbicides (including 2,4-D and 2,4-D 2-EHE) could be established	from the available epidemiological studies no clear association between cancer development and exposure to phenoxyherbicides (including 2,4-D and 2,4-D 2-EHE) could be established
---	---

Summary (Acid and ester)

	Value	Study	Safety factor
ADI:	0.05mg/kg bw/d	long term (mouse and rat)	100
AOEL systemic:	0.15 mg/kg bw/d	subacute and subchronic (dog and mice) short term: (mouse and rat)	100
AOEL inhalation:	Not required.		
AOEL dermal:	Not required.		
ARfD (acute reference dose):	Not required. No risk to consumers via acute residue exposure.		
Dermal absorption			
	Acid	Ethylhexyl ester	
	~2% based on the submitted data in man*	10 % default value in the absence of adequate experimental data.	

* indicative value, must be evaluated for each authorisation

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

Acid	Ethylhexyl ester
36 % at day 114	No data were provided for the mineralization after 100 days. However, it ranged between 60 to 80 % at day 60.
27.9 % at day 114	No data were provided.
None greater than 10 %.	2,4-D, no data were provided.

Non-extractable residues after 100 days:

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

Supplemental studies

Anaerobic:

No data were provided. A new study on anaerobic degradation is required if late autumn or winter applications are intended.	No data were provided.
---	------------------------

Soil photolysis:

2,4-D is stable to soil photodegradation.	No data were provided.
---	------------------------

Remarks:

None.	None.
-------	-------

Rate of degradation	Acid	Ethylhexyl ester
Laboratory studies:		
DT _{50lab} (20 °C, aerobic):	2 - 59 d (Average: 13.67 d)	1.5 d (25 °C)
DT _{90lab} (20 °C, aerobic):	67.7 d (calculated by the rapporteur).	4 d (25 °C)
DT _{50lab} (10°C, aerobic):	No data were provided.	No data were provided.
DT _{50lab} (20°C, anaerobic):	No data were provided. A new study on anaerobic degradation is required if late autumn or winter applications are intended.	No data were provided.
Field studies (country or region):		
DT _{50f} from soil dissipation studies:	4.6 - 17.2 d (Sweden) (Average: 9.9 d)	< 1 d (Canada)
DT _{90f} from soil dissipation studies:	Not provided. Not required.	≈ 1 d
Soil accumulation studies:	No data were provided.	No data were provided.
Soil residue studies:	No data were provided.	No data were provided.
Remarks: e.g. effect of soil pH on degradation rate:	None.	None.
Adsorption/desorption		
K _f / K _{oc} :	K _{oc} = 5-212, K _{OC (MEAN)} = 56. Wide range of soils differing in texture, pH and clay content.	No data were provided because 2,4-D 2-EHE is unstable in water with a DT ₅₀ value of 79 min.
pH dependence:	At low pH values (e.g. 4 – 6), the adsorption of 2,4-D is greater than at neutral or alkaline pH.	None.

Mobility**Laboratory studies:**

Column leaching:

Acid	Ethylhexyl ester
<p>A Loamy Sand (LS) soil with higher organic matter (1.85%), was much more effective in reducing the mobility of 2,4-D comparing to a Sandy soil with lower organic matter (0,12%).</p> <p>After 48 mm of percolating water about 70% of the initial amount of 2,4-D was recovered in the first 5 cm increment of the SL soil and 1.4 % between 10 and 15 cm, whereas in the Sandy soil most of the 2,4-D (73%) was found between 10-15 cm.</p> <p>The persistence of 2,4-D was considerable more important in LS soil. Application of 200 mm of percolating water resulted in the presence of less than 15% of the herbicide below the 25 cm soil depth.</p>	No data were provided.
<p>In a loamy sand soil, the concentration of 2,4-D in the pooled leachate was 0.035 - 0.100 µg/l.</p>	No data were provided.

Aged residue leaching:

Field studies:

Lysimeter/Field leaching studies:

Acid	Ethylhexyl ester
A lysimeter study was performed with 750 g a.s./ha applied in June to spring cereals. 2,4-D as well as its metabolites (2,4-DCP, 2-CP, 4-CP and 2,4-DCA) were not detected in any of the analysed leachate or in the soil layers of the lysimeters at the end of the incubation period (after 2 years).	No data were provided.

Remarks:

None.	None.
-------	-------

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation :

Major metabolites:

Photolytic degradation:

Major metabolites:

	Acid	Ethylhexyl ester
Hydrolytic degradation :	2,4-D is not hydrolysed at $24.9 \pm 0.1^\circ\text{C}$ and pH values 5, 7 and 9.	pH 5: $\text{DT}_{50} = 99.7$ days at 25°C . pH 7: $\text{DT}_{50} = 48.3$ days at 25°C . pH 9: $\text{DT}_{50} = 52.2$ hours at 25°C .
Major metabolites:	None.	pH5: None. pH 7 & 9: 2,4-D was the major degradation product.
Photolytic degradation:	$\text{DT}_{50} = 13$ d at $24.8 \pm 0.7^\circ\text{C}$.	2,4-D 2-EHE is not a photosensitive compound ($\text{DT}_{50} = 128.2$ days at $25.3 \pm 0.02^\circ\text{C}$).
Major metabolites:	1,2,4-benzenetriol (better = 1,2,4-trihydroxy-benzene) is the major photodegradation product (31.7 % at the end of the 30-day incubation period). No further data were provided for this product.	None.

Biological degradation

Ready biological degradability:

Water/sediment study:

DT₅₀ water:DT₉₀ water:DT₅₀ whole system:DT₉₀ whole system:Distribution in water / sediment systems
(active substance)Distribution in water / sediment systems
(metabolites)

Accumulation in water and/or sediment:

Degradation in the saturated zone**Remarks:**

	Acid	Ethylhexyl ester
Ready biological degradability:	No data were provided.	No data were provided.
Water/sediment study:		
DT ₅₀ water:	Not calculated.	No data were provided.
DT ₉₀ water:	Not calculated.	
DT ₅₀ whole system:	29 d. (This value can be used either for water or for sediment.).	
DT ₉₀ whole system:	Not calculated.	
Distribution in water / sediment systems (active substance)	Water/Sediment ratio (W/S): 4.69 at day 0 4.73 at day 4 4.10 at day 7 4.15 at day 14 4.76 at day 25 2.23 at day 46	
Distribution in water / sediment systems (metabolites)	No major metabolites were produced.	
Accumulation in water and/or sediment:	Not expected.	Not expected.
Degradation in the saturated zone	DT ₅₀ = 831 - 1907 d at 10 °C. (Average: 1369 d) DT ₅₀ = 969 - 982 d at 20 °C. (Average: 975.5 d)	No data were provided.
Remarks:	None.	None.

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

Henry's law constant:

Photolytic degradation

Direct photolysis in air:

Photochemical oxidative degradation in air (DT₅₀):

Volatilisation:

Remarks:

	Acid	Ethylhexyl ester
Vapour pressure:	1.9×10 ⁻⁵ Pa at 25 °C.	4.8 x 10 ⁻⁴ Pa at 25 °C.
Henry's law constant:	1.33×10 ⁻⁵ Pa m ³ mol ⁻¹ at 25 °C.	1.82 Pa m ³ mol ⁻¹ at 25 °C.
	Acid	Ethylhexyl ester
Direct photolysis in air:	No data were provided.	No data were provided.
Photochemical oxidative degradation in air (DT ₅₀):	6 d	No data were provided.
Volatilisation:	No data were provided. The acid is not volatile.	Relatively low. Degradation to 2,4-D acid was rapid (72.4 % during the 15-day study). The acid is not volatile.
Remarks:	None.	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:

Acid	Ethylhexyl ester
469 mg a.s./kg bw	896 mg a.s./kg bw
> 500 mg a.s./kg bw	663 mg a.s./kg bw
> 5620 mg a.s./kg	> 5620 mg a.s./kg
NOEC 1000 ppm	Rapid hydrolysis to the acid form, therefore no risk is anticipated. No further data are required
25 mg/kg bw/d (developmental toxicity rat)	16 mg/kg bw/d (developmental toxicity rat)

Aquatic Organisms

Acute toxicity fish:

Long term toxicity fish:

Bioaccumulation fish:

Acute toxicity invertebrate:

Chronic toxicity invertebrate:

LC50 = 100 mg/l (<i>Pimephales promelas</i> ; 96 h)	LC50 >1.9 mg/l (<i>Menidia beryllina</i> ; 96 h)
32-day NOEC = 63.4 mg/l (<i>Pimephales promelas</i>)	The substance has low water solubility, quickly degraded to the acid form, low persistence in natural systems is expected. However from a 32 day embryo- larval test the overall NOEC was 0.12 mg a.s./l (physical effect of the undissolved material)
BCF = 10 (3-day fish & algae test)	Not required as DT ₅₀ in natural water is 6.2 h
EC50 = 100 mg/l (<i>Daphnia magna</i> ; 48 h)	EC50 >1.91 mg/l (<i>Daphnia magna</i> ; 96 h)
21-day NOEC = 46.2 mg/l (<i>Daphnia magna</i>)	The substance has low water solubility, quickly degraded to the acid form, low persistence in natural systems is expected. However a 21 day EC50 was 1.35 mg a.s./l

	Acid	Ethylhexyl ester
Acute toxicity algae:	96-hr EC50 = 24.2 mg/l (<i>Selenastrum capricornutum</i>)	120-day EC50 = 0.23 mg/l (<i>Skeletonema costatum</i>)
Chronic toxicity sediment dwelling organism:	No further data are required due to the low toxicity of the active substances to <i>Daphnia magna</i> .	No further data are required due to the low toxicity of the active substances to <i>Daphnia magna</i> . The ester is quickly degraded to the acid so chronic exposure is not anticipated
Acute toxicity aquatic plants:	14-day EC50 = 0.58 mg/l; 14-day NOEC = 0.27 mg/l (<i>Lemna gibba</i>)	14-day EC50 = 0.50 mg/l (<i>Lemna gibba</i>)

Honeybees

Acute oral toxicity:

94 µg/bee	>100 µg/bee
>100 µg/bee	>100 µg/bee

Other arthropod species

Poecilus cupreus

Mortality: < 30 % (5-6 week old adults; 2.80 kg a.s./ha; BAS 009011H)	No data have been submitted. Hydrolysis to the acid is very rapid in soil (1.5 days and/or 79 minutes) therefore the effect can be diminished under field conditions. At the same time risk mitigation measures are recommended or higher tier testing may be required at MS level
Inhibition of parasitisation rate: 38.9 % (adults: 0.95 kg a.s./ha; U 46 Combi fluid)	No data have been submitted

Trichogramma cacoeciae

Aphidius rhopalosiphi.

Aleochara bilineata

Typhlodromus pyri

Acid	Ethylhexyl ester
<p>Mortality 7.5% - Reduction in beneficial capacity 13.2% (adults: 3.0 kg a.s./ha; 2,4-D DMA 600 g/l - Desormone liquid)</p> <p>Mortality 0% - Reduction in beneficial capacity - 29.6% (adults: 0.15 (5% drift) kg a.s./ha; 2,4-D DMA 600 g/l - Desormone liquid)</p>	<p>Mortality 100% (at 5% drift 12.5%) – Reduction in beneficial capacity 100% (at 5% drift 23.1%) (adults: 0.564 Kg a.e./ha and 0.0282 kg a.e./ha (5% drift); 2,4-D EHE 572 g/l – Esteron 60)</p>
<p>Reduction of laying performance and hatchability: No mortality observed in adults (2.80 kg a.s./ha; U 46 Combi fluid)</p>	<p>No data have been submitted. Hydrolysis to the acid is very rapid in soil (1.5 days) therefore the effect can be diminished under field conditions. At the same time risk mitigation measures are recommended or higher tier testing may be required at MS level</p>
<p>Mortality 5.3% - Reduction in beneficial capacity 6.2% (protonymphs: 3.0 kg a.s./ha; 2,4-D DMA 600 g/l - Desormone liquid)</p> <p>Mortality 8.5% - Reduction in beneficial capacity 10.3% (protonymphs: 0.15 (5% drift) kg a.s./ha; 2,4-D DMA 600 g/l - Desormone liquid)</p>	<p>Mortality 4.3% (at 5% drift 6.4%)- Reduction in beneficial capacity 20.6% (at 5% drift - 2%) (protonymphs: 0.564 Kg a.e./ha and 0.0282 Kg a.e./ha (5% drift); 2,4-D EHE 572 g/l – Esteron 60)</p>

Earthworms

	Acid	Ethylhexyl ester
Acute toxicity:	350 mg a.s./kg d. wt. soil	Not required due to rapid hydrolysis to the acid form, with DT ₅₀ in soil of 1.5 days.
Reproductive toxicity:	Not submitted. Not required	Not required due to rapid hydrolysis to the acid form, with DT ₅₀ in soil of 1.5 days and DT ₉₀ < 100 days.

Soil micro-organisms

Nitrogen mineralization:	No adverse effects for up to 10 kg a.s./ha over a period of 28 d in field soil	Not required due to rapid hydrolysis to the acid form, with DT ₅₀ in soil of 1.5 days
Carbon mineralization:	No adverse effects for up to 10 kg a.s./ha over a period of 28 d in field soil	Not required due to rapid hydrolysis to the acid form, with DT ₅₀ in soil of 1.5 days

APPENDIX IIIA**2,4-D**

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 inclusion¹.

A.1: Identity, Physicochemical properties, Analytical methods

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 authorizations
IIA 2.1, 2.2, 2.4	Hersey, R	1995	2,4-D Determination of Physical Chemical Properties. A H Marks Report N°: 94/0010 AHM GLP/GEP: yes unpublished	
IIA 2.1, 2.2 (Doc J)	Hersey, R	1995	2,4-D 2EH Determination of Physical Chemical Properties A H Marks Report N°: 94/0011 AHM GLP/GEP: yes unpublished	
IIA 1.11 (Doc J)	Hersey, R	1997	5 Batch Purity, Impurity Profile, Ash and water of 2,4-Dichlorophenoxyacetic acid (Technical grade). (OPPTS Guideline 830.1700) A H Marks Report No 97/0014 AHM GLP/GEP: yes unpublished	
IIA 1.11 (Doc J)	Landvoigt, W	1990	Analysis of DD/DF in 2,4-D Acid A H Marks Chemserv Industrie Service GmbH. Austria Report N°: Marks 0689 GLP/GEP: yes unpublished	

¹ List based on a detailed analysis from Greece (background document C).

² Reports received from Member States at the date of finalisation of the present review report (not exhaustive).

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, 1.11 (Doc J)	Kinnunen, C. A.	1995	Series 62-1: Preliminary Analysis of Product Sample of Flake 2,4-Dichlorophenoxyacetic Acid. DAS Dow AgroSciences, Report N°: GH-C 3714 GLP/GEP: yes unpublished	
IIA 1.11	Hay P.	1995	(2,4-Dichlorophenoxy)acetic acid process trace contaminant study Nufarm UK Ltd Nufarm Ltd, Report N°: LR 95/05 GLP/GEP: No unpublished	
IIA 1.11 (Doc J)	Hay P. and Kravets E.	1995	(2,4-Dichlorophenoxy)acetic acid Impurity study Nufarm UK Ltd Nufarm Ltd, Report N°: LR 95/06 GLP/GEP: No unpublished	
IIA 1.11 (Doc J)	Biedermann K.	1995	Determination of the purity and the impurities of 2,4-D acid technical Nufarm GmbH & Co KG RCC Switzerland Report No. 392938 GLP/GEP: yes unpublished	
IIA 1.11 (Doc J)	Landvoigt W.	1995	Analysis of mono to tetra-chlorinated Dioxins in 5 batches of technical 2,4-D acid Nufarm GmbH & Co KG Chemie Linz GmbH Report 0295 GLP/GEP: yes unpublished	
IIA 1.11 (Doc J)	Landvoigt W.	1993	2,4-D 2-EHE (2,4-D IOE): Final report – Assay of Dibenzo-p-dioxins and Dibenzogurans in 2,4-D IOE by GC/MS Nufarm GmbH & Co KG Chemserv Industry Service GmbH Report No. 9358042-9358048 GLP/GEP: 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 ² on previous use in granting national authorizations
IIA 1.11.1 (Doc J)	Etchepareborda, I. & Sancricca, J.	1991	"Preliminary Analysis of 2,4-Dichlorophenoxyacetic Acid 97%." GOR* Laboratorio de Estudios Analiticos, Atanor S.A. Report No. Not Assigned GLP/GEP: yes unpublished	
IIA 1.11.2 (Doc J)	Landvoigt, W.	1991	EPA Reg. No. 2217-455 - Certification of Limits for Dibenzo-p-dioxin/Dibenzofurans. GOR Chemserv Industrie Service, Ges.m.b.H., Linz Austria. Report No. Not Assigned GLP/GEP: yes unpublished	
IIA, 2.8	Bailey R.E. & Hopkins D.L.	1987	2,4-D: Determination of the octanol/water partition coefficient INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER,RPA, NUF** DowElanco Rep. Dow Es-Drl 002-2297-9 GLP/GEP: no unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/26)
IIA 2.5	Buddle G.C. and Clarke D.E.	1992	2,4-Dichlorophenoxyacetic acid 2-Ethylhexyl ester, lot PJS 282: suitability for use as an Analytical Standard NUF* Rhone-Poulenc Agriculture Ltd, Rep.No: P92/264 GLP/GEP: yes unpublished	
IIA 2.3	Chakrabarti A. & Gennirich S.M.	1987 a	Vapor pressure of the 2,4-D ethylhexyl ester INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** DowElanco, Rep. N°: ML-AL-87-400048 GLP/GEP: no unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/20)

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 authorizations
IIA 2.3	Chakrabarti A.K., and Gennrich S.M.	1987 b	Vapor pressure of 2,4D INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** DowElanco, Rep. ML-AL 87-40047 GLP/GEP: no unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/ 19)
IIA 2.7	Cicotti M.	1991	Determination of the solubility of 2,4-D in organic solvents in accordance with EPA 63-8 and BBA Guidelines NUF Batelle Europe, Rep. N°: BE-P-1-91- 01-BG GLP/GEP: yes unpublished	
IIA 2.9	Concha M., Shepler B.S. and Erhardt-Zabik S.	1993 b	Hydrolysis of [¹⁴ C] 2,4-D ethylhexyl at pH 5, 7, and 9 NUF, ROP, AGR, DOE, BAS, AHM*** Rep.No: PTRL 387W-1 PTRL-West, Inc, California, USA. GLP/GEP: yes unpublished	
IIA 2.9	Creeger S.M., Cohen S.P. and Tamma R.V.	1989 a	Hydrolysis of 2,4-D in aqueous solutions buffered at pH 5,7 and 9 BAS, ROP, AGR*, NUF, AHM, DOE Rep. CHMR, 5135A Center for Hazardous Materials Research. GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/ 41)
IIA 2.9	Creeger S.M., Cohen S.P. and Tamma R.V.	1989 b	Aqueous photodegradation of 2,4- Dichlorophenoxyacetic acid in pH 7 buffered solution BAS, ROP, AGR, NUF, AHM, DOE CHMR, Rep. N°: 5488A GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/ 42)
IIA 2.3	Downey J.R.	1987 a	Henry's Law Constant for 2,4D in water INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** DowElanco, Rep. N°: MI-AI 8740527 GLP/GEP: no 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 ² on previous use in granting national authorizations
IIA 2.3	Downey J.R.	1987 b	Henry's Law Constant for 2,4-D ethylhexyl ester in water INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** DowElanco, Rep.No: ML-AL 87-40535. GLP/GEP: no unpublished	
IIA 2.11	Ducloux and Bourrigaud M.	1981	Study on the behaviour of active ingredients in case of firegases of active ingredient NUF Rhone-Poulenc, Rep. N°:CRB/EV 31139 GLP/GEP: no unpublished	
IIA 2.6	Helmer D.C.	1987 a	Determination of the Water Solubility of 2,4-D- Dichlorophenoxy Acetic acid, 2-ethylhexyl ester The Dow Chemical Company, Rep. N°: ML-AL 87-70817 GLP/GEP: no unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/23)
IIA 2.8	Helmer D.C.	1987 b	Determination of the Octanol/water Partition Coefficient of 2,4-D- Dichlorophenoxy Acetic acid, 2-ethylhexyl ester INT BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** DowElanco, Rep.No: ML-AL 87-70819 GLP/GEP: no unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/28)
IIA 2.6	Hopkins D.L.	1987 a	2,4-D: Determination of the water solubility INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** DowElanco, Rep. Dow Es-Drl 002-2297-8 GLP/GEP: no unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/24)
IIA 2.10	Iosson I.	1992	Reactive Chemicals Hazard Data DowElanco, Rep.No: RCK-92-0065. GLP/GEP: no 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 ² on previous use in granting national authorizations
IIA 2.1	Kinunnen C.A.	1994	Series 63: determination of the Boiling point of 2,4-Dichlorophenoxyacetic acid 2-ethylhexyl ester (2,4-D EHE) TGA DowElanco, Rep.No:FOR94080. GLP/GEP: yes unpublished	
IIA 2.5, 2.9	Klöpffer W.	1991	Determination of the phototransformation in water of 2,4D BAS, ROP, AGR, NUF, AHM, DOE Batelle Europe, Rep. N°: BE-P-118-91-PHO-01 GLP/GEP: yes unpublished	
IIA 2.10	Maestracci M.	1994	2,4-D - Estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions NUF Rhone-Poulenc, Rep. N°: RD/CRLD/AN/ 9415680. GLP/GEP: yes unpublished	
IIA 2.1, 2.4, 2.5	Patel P.T., Keating S. and Buddle G.C.	1991 a	2,4D, lot 1375: Suitability as an analytical reference standard NUF Rhone-Poulenc, Rep. N°: D.Ag.1591. GLP/GEP: no unpublished	
IIA 2.5	Patel P.T., Keating S. and Buddle G.C.	1991 b	Impurity 2,4-dichlorophenol, lot 52932, suitability as an analytical standard NUF Rhone-Poulenc, Rep. N°: D.Ag. 1584. GLP/GEP: no unpublished	
IIA 2.6	Potter R.B.	1990	2,4-D ethylhexyl ester: solubility in industrial water. BAS, AGR, NUF, AHM, DAS, ROP DowElanco, Rep.No: ES-DR-0019-1208-8. GLP/GEP: 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 ² on previous use in granting national authorizations
IIA 2.1, 2.2, 2.4	Weibull A.	1994 a	2,4-D 2-Ethylhexyl ester. Series 63, Physical and chemical Properties Part One: Physical characteristics NUF Rhone-Poulenc, Rep.No: 5262-93 part I Nobel Corporate Services AB, Sweden GLP/GEP: yes unpublished	
IIA 2.7	Weibull A.	1994 b	2,4-D 2-Ethylhexyl ester. Series 63, Physical and chemical Properties Part Three: Solvent Stability NUF Rhone-Poulenc, Rep.No: 5262-93 part III Nobel Corporate Services AB, Sweden GLP/GEP: yes unpublished	
IIA 2.9	Weibull A.	1994 c	2,4-D 2-Ethylhexyl ester. Series 63, Physical and chemical Properties PartTwo: pH and dissociation Constant NUF Rhone-Poulenc, Rep.No: 5262-93 part II Nobel Corporate Services AB, Sweden GLP/GEP: yes unpublished	
IIA 2.10	Weibull A.	1994 d	2,4-D 2-Ethylhexyl ester. Series 63, Physical and chemical Properties Part Four: Stability NUF Rhone-Poulenc, Rep.No: 5262-93 part IV Nobel Corporate Services AB, Sweden GLP/GEP: yes unpublished	
IIA, 4.1	Anonymous	1983	Liquid Chromatographic Analysis of 2,4-Dichlorophenoxyacetic Acid. DAS Dow AgroSciences, ML-AM-80-4B GLP/GEP: no unpublished	
IIA 4.2	Anonymous	1989	Determination of 2,4D in feed BAS, ROP, AGR, NUF, AHM, DOE Hazleton, Rep. N°: No 2184-117- Analytical method No 218(R1) GLP/GEP: no 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 ² on previous use in granting national authorizations
IIA 4.1	Hardy I.A.J, Hojabri H., Outram J.R. and Warren T.F.	1987	2,4D-Analytical examination of batches 3376, 3377, 3378, 3379 and 3383 manufactured by RPA, Appendix I to V NUF Rhone-Poulenc, Rep. N°: Ag.255. GLP/GEP: no unpublished	
IIA 4.2	Howard J.	1996	Development and validation of Analytical Methodology for the Quantitation of Residues of 2,4-D in Beef Muscle, Liver, Kidney, Fat and Milk. ROP, NUF, DOE, AGR, BAS, AHM*** PTRL, Report N°: 1848. GLP/GEP: yes unpublished	
IIA 4.2	Howard J.	1996	Development and validation of Analytical Methodology for the Quantitation of Residues of 2,4-D in Poultry Muscle, Liver, Fat and Eggs. ROP, NUF, DOE, AGR, BAS, AHM*** PTRL, Report N°: 1874. GLP/GEP: yes unpublished	
IIA 4.2	James J.W.	1993	The Determination of 2,4-D ACID in/on Various Raw Agricultural Commodities and Their Processed Fractions. BAS, ROP, AGR, NUF, DOE, AHM*** EN-CAS Analytical Labs. Project#93-0018 GLP/GEP: yes unpublished	
IIA, 4.1	McCabe, T	1997	Validation of a Method for the Determination of Impurities in 2,4-Dichlorophenoxyacetic Acid (2,4-D) Technical Grade of Active Ingredient by Liquid Chromatography. DAS Dow AgroSciences, DECO GL-AL 96-005302 GLP/GEP: 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 ² on previous use in granting national authorizations
IIA, 4.1	McCabe, T	1997	Validation of a Method for the Assay of 2,4-Dichlorophenoxyacetic Acid (2,4-D) Technical Grade of Active Ingredient by Liquid Chromatography. DAS Dow AgroSciences, DECO GL-AL 96-004688 GLP/GEP: yes unpublished	
IIA 4.2	Ormand J.R.	1992	Automated Method for Monitoring 2,4-D in Laboratory Rodent Chow. 2,4-Dichlorophenoxyacetic acid study K-002372-064, as shown in Appendix E p.407-421 of dietary Oncogenicity study in B6C3F1 Mice-Two year interim report BAS, ROP, AGR, NUF, DOE, AHM*** DowElanco Study K-002372-064 GLP/GEP: yes unpublished	
IIA 4.1	Patel P.T. and Buddle G.C.	1991	Supplementary validation for production chemistry series 62 NUF Rhone-Poulenc, Rep. N°: D.Ag.1588 Study No: P-91-016. GLP/GEP: yes unpublished	
IIA 4.2	Reichert N.	1994	Development and validation of a method for the determination of 2,4-D, MCPA, Dichlorprop-P and Mecoprop-P in air AHM, ROP, BAS RCC Umweltchemie, Project 439705. GLP/GEP: yes unpublished	
IIA 4.1	Silvestre D.	1989	2,4D-Determination of polychlorinated dibenzo-p-dioxins and dibenzofurans by GC/MS NUF Rhone-Poulenc, Rep. RP/CID/P/ANA N° 343-098 DS/IN- Appendix 2, p.99-118. GLP/GEP: yes unpublished	

A.2: Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 5.2	Auletta C.S. and Daly I.W.	1986	An acute inhalation toxicity study of 2,4-Dichlorophenoxyacetic acid in the rat. INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** Bio/dynamics Inc., Project N° 86-7893 GLP/GEP: no unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/ 64)
IIA 5.2	Berdasco N.M.	1992	2,4-D Acid: Primary dermal irritation study in New Zealand White Rabbits. ROP, AGR, BAS, NUF, DOE, AHM*** DowElanco Study ID: K-002372-060 GLP/GEP: yes unpublished	
IIA 5.2	Cieslak F.S	1992	2,4-Dichlorophenoxyacetic acid, 2- ethylhexyl ester: Acute Aerosol Inhalation Toxicology Study with Fischer 344 Rats. ROP, AGR, NUF, DOE, BAS, AHM*** DowElanco, Rep.No: KO20054-015 GLP/GEP: yes unpublished	
IIA 5.4	Cifone A.	1990	Mutagenicity test on 2,4-D-2-ethylhexyl ester in the In Vitro Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay. ROP, AGR, NUF, DOE, BAS, AHM Hazleton Lab., Rep.No: 10980-0-447 GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/ 95)
IIA 5.4	Clifone M.A.	1990	Mutagenicity test on 2,4-D acid (2,4-D) in the in vitro rat primary hepatocyte unscheduled DNA synthesis assay ROP, AGR, NUF, DOE, BAS, AHM Hazleton Lab., Study N° : 10979-0-447 GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/ 94)
IIA 5.3	Dalgard D.W.	1992	4-week exploratory rangefinding study in dogs with the 2-ethylhexyl ester of 2,4-D. ROP, AGR, NUF, DOE, BAS, AHM*** Hazleton Lab., Rep.No: HWA 2084- 122 GLP/GEP: 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 5.3	Dalgard D.W.	1993 a	13-week dietary toxicity study with the 2-ethylhexyl ester of 2,4-D in dogs. ROP, AGR, NUF, DOE, BAS, AHM*** Hazleton Lab., Rep.No: HWA 2184-127 GLP/GEP: yes unpublished	
IIA 5.5	Dalgard D.W.	1993 b	52-Week Dietary Toxicity study with 2,4-Dichlorophenoxyacetic acid (2,4D) in Dogs ROP, AGR, NUF, DOE, BAS, AHM*** Hazi.Lab., Study N°:2184-124 GLP/GEP: yes unpublished	
IIA 5.3	Dalgard D.W.	1993 c	13-week Dietary Toxicity Study of 2,4-D in dogs. ROP, AGR, NUF, DOE, BAS, AHM*** Hazleton Lab., Study HWA 2184-125 GLP/GEP: yes unpublished	
IIA 5.2	Dange M.	1994 a	2,4-D-acute dermal LD50 in the rat. NUF Rhone-Poulenc, Rep. N°: SA 94109 GLP/GEP: yes unpublished	
IIA 5.2	Dange M.	1994 b	2,4-D-Acute dermal irritation test in the rabbit. NUF Rhone-Poulenc, Rep. N°: SA 94104 GLP/GEP: yes unpublished	
IIA 5.2	Dange M.	1994 c	2,4-D-acute eye irritation test in the rabbit. NUF Rhone Poulenc, Rep. N°: SA 94106 GLP/GEP: yes unpublished	
IIA 5.2	Dange M.	1994 d	2,4-D-Acute oral LD50 in the rat NUF Rhone-Poulenc, Rep. N°: SA 94107 GLP/GEP: 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 5.1	Dryzga M.D., Brzak K.A. and Nolan R.J.	1992	2,4-Dichlorophenoxyacetate 2-ethylhexyl ester: Metabolism in Fischer 344 rats. BAS, ROP, AGR, NUF, DOE, AHM*** DowElanco, Rep.No: K-020054-009 GLP/GEP: yes unpublished	
IIA 5.4	Durward R.	1994	2,4-D Mutation of L5178Y mouse lymphoma Cells at the Thimidine Kinase TK+/- Locus. Fluctation Assay. NUF Safeparm Lab., Study N°:238/39 GLP/GEP: yes unpublished	
IIA 5.1	Eiseman J.L.	1984	The pharmacokinetic evaluation of ¹⁴ C-2,4-Dichlorophenoxyacetic acid (2,4-D) in the mouse. INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** Hazleton Lab., Project N° 2184-104. GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/44)
IIA 5.1	Frantz S.W. and Kropscott B.E.	1984	2-ethylhexyl 2,4-Dichlorophenoxyacetate: Pharmacokinetic evaluation of the 2-Ethylhexyl (isooctyl)ester of 2,4-D orally administered to Fischer 344 rats. INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** DowElanco, Rep.No: K-020054-007B GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/45)
IIA 5.2	Gargus J.L.	1986	Dermal sensitization study in Guinea pigs; 2,4-Dichlorophenoxyacetic acid. INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** Hazleton Lab., Project N° 2184-105 GLP/GEP: no 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 5.3	Gorzinski S.J. & Wade C.E.	1981 a	Purified 2,4-Dichlorophenoxyacetic acid (2,4D): Result of a 13-week subchronic dietary toxicity in the CDF Fischer 344 rat. INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** DowElanco, Rep. N°: RR0946. GLP/GEP: yes unpublished	
IIA 5.3	Gorzinski S.J. and Wade C.E.	1981 b	Technical grade 2,4Dichlorophenoxyacetic acid (2,4D): Result of a 13-week subchronic dietary toxicity study in the CDF Fischer 344 rat. INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** DowElanco, Rep. N°: RR0695. GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/81)
IIA 5.1	Guo M. and Stewart S.	1993	Metabolism of Uniformly ¹⁴ C-Ring Labeled 2,4-Dichlorophenoxyacetic acid in Lactating Goats. ROP, AGR, NUF, DOE, BAS, AHM*** ABC Laboratories, Rep. N° 40630. GLP/GEP: yes unpublished	
IIA 5.2	Hilderbrand B. and Kirsch P.	1983 a	Report on the study of the irritation to the intact and abraded dorsal skin of the white rabbit based on 2,4-D. ROP, AGR, NUF, DOE, BAS, AHM*** BASF, Rep. N°: RZ- N° 83/190 GLP/GEP: no unpublished	
IIA 5.2	Hilderbrand B. and Kirsch P.	1983 b	Report on the study of the irritation to the eye of the white rabbit based on Draize of 2,4-D ROP, AGR, NUF, DOE, BAS, AHM*** BASF, Rep. N°: RZ- N°: 83/192 GLP/GEP: no 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 5.6	Hoberman A.M.	1990	Developmental toxicity (Embryo-fetal toxicity and teratogenic potential) study of 2,4-Dichlorophenoxyacetic acid (2,4-D Acid) administered orally via stomach tube to tube to New Zealand White rabbit ROP, AGR, NUF, AHM, DOE, BAS Argus Research Lab., Rep. N°: 320-003 GLP/GEP: yes unpublished	
IIA 5.4	Ivett J.L.	1990 a	Mutagenicity test on 2,4-D ACID. In vivo mouse micronucleus assay ROP, AGR, NUF, AHM, DOE, BAS Hazleton Lab., Study N°: 10979-0-455 GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/91)
IIA 5.4	Ivett J.L.	1990 b	Mutagenicity test on 2,4-D-2-ethylhexyl ester in Vivo Mouse Micronucleus Assay. ROP, AGR, NUF, AHM, DOE, BAS Hazleton Lab., Rep.No: 10980-0-455 GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/92)
IIA 5.2, IIIA 7.1	Jeffery M.M.	1986	ESTERON* 6E Herbicide: dermal sensitisation Potential in the Hartley Guinea Pig. DAS DAS, Rep.No: HET-M-004438-001 GLP/GEP: no unpublished	
IIA 5.5	Jeffries T.K., Yano B.L. and Ormand J.R.	1994	2,4-Dichlorophenoxyacetic acid: Chronic Toxicity/Oncogenicity study in Fischer 344 Rats. ROP, AGR, NUF, DOE, BAS, AHM*** Dow Chemical Study N°:K-002372-0641B. GLP/GEP: 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 5.2	Johnson D.E.	1981 a	2,4-Dichlorophenoxyacetic acid, isooctyl ester; Determination of Acute Oral LD ₅₀ in Fischer 344 Rats INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** International Research and Development Corporation, Rep.No: 490-002 GLP/GEP: yes unpublished	
IIA 5.2	Johnson D.E.	1981 b	2,4-Dichlorophenoxyacetic acid, isooctyl ester; determination of Acute Dermal LD ₅₀ in Rabbits INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** International Research and Development Corporation, Rep.No: 490-005 GLP/GEP: yes unpublished	
IIA 5.9	Kreiger R.I. and Lunchick C.	1993	Human exposure assessment for 2,4-D Acid. ROP, AGR, DAS, NUF, BAS, AHM*** Jellinek, Schwartz & Connoly, Inc. GLP/GEP: no unpublished	
IIA 5.4	Lawlor T.E. and Valentine D.C.	1990 a	Mutagenicity test on 2,4-Dichlorophenoxyacetic Acid (2,4-D) in the Salmonella/Mammalian-Microsome Reverse Mutation Assay (Ames test). ROP, AGR, NUF, DOE, BAS, AHM Hazleton Lab., Study N°:10979-0-401. GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/97)
IIA 5.4	Lawlor T.E. and Valentine D.C.	1990 b	Mutagenicity test on 2,4-D-2-ethylhexyl ester in the Salmonella/Mammalian-Microsome Reverse Mutation assay (Ames Test). ROP, AGR, NUF, DOE, BAS, AHM Hazleton Lab., Rep.No: 10980-0-401 GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/98)

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	Martin T.	1992 a	Developmental Toxicity (Embryo-Fetal Toxicity and Teratogenic Potential) Study of 2,4-D Ethylhexyl Ester (2,4-D Isooctyl ester) administered Orally via Gavage to CrI : CD®BR VAF/Plus® Rats. NUF, ROP, AGR, DOE, BAS, AHM*** Angus Research Lab., Rep.No: 320-005 GLP/GEP: yes unpublished	
IIA 5.6	Martin T.	1992 b	Developmental Toxicity (Embryo-Fetal Toxicity and Teratogenic Potential) Study of 2,4-D Ethylhexyl Ester (2,4-D Isooctyl ester) administered Orally via Stomach Tube to New Zealand White Rabbits. NUF, ROP, AGR, DOE, BAS, AHM*** Angus Research Lab., Rep.No: 320-006 GLP/GEP: yes unpublished	
IIA 5.6	Martin T.	1992 c	Developmental Toxicity (Embryo-Fetal Toxicity and Teratogenic Potential) Study of 2,4-D Acid administered Orally via Stomach Tube to New Zealand White Rabbits. NUF, ROP, AGR, DOE, BAS, AHM*** Angus Research Lab., Rep.No: 320-003 GLP/GEP: yes unpublished	
IIA 5.7	Mattsson J.L., Jeffries T.K. and Yano B.L.	1994 a	2,4-D: Chronic Neurotoxicity Study in Fischer 344 Rats. ROP, AGR, NUF, DOE, BAS, AHM*** DowElanco N° K-002372-064N. GLP/GEP: yes unpublished	
IIA 5.7	Mattsson J.L., McGuirk R.J. and Yano B.L.	1994 b	2,4-D: Acute Neurotoxicity Study in Fischer 344 Rats. ROP, AGR, NUF, DOE, BAS, AHM*** DowElanco N° K-002372-066 GLP/GEP: yes (Except analysis of animals' feed and drinking water) 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 5.2	Meyer J.R. and Johnson D.E.	1981 a	2,4-Dichlorophenoxyacetic acid, technical. Determination of Acute Oral LD50 in Fischer 344 Rats. INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** International Research & Development Corporation, Rep. N°: 490-001 GLP/GEP: yes unpublished	
IIA 5.2	Meyer J.R. and Johnson D.E.	1981 b	2,4-Dichlorophenoxyacetic acid, technical. Determination of Acute Dermal LD50 in Rabbits. INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** International Research & Development Corporation, Rep. N°: 490-004 GLP/GEP: yes unpublished	
IIA 5.2	Rees P.B.	1994	2,4-D-Delayed contact hypersensitivity test in the guinea pig. NUF Pharmaco LSR, Rep. N°: 94/RHA525/0516 GLP/GEP: yes unpublished	
IIA 5.6	Rodwell D.E.	1983 a	A Teratology Study in Fischer 344 Rats with 2,4-Dichlorophenoxyacetic acid. INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** WIL Research Lab., Rep. N°: WIL-81135 GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/100)
IIA 5.8	Rodwell D.E.	1983 b	A teratology study in Fischer 344 Rats with 2,4-Dichlorophenol. INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** WIL Research Lab., Rep. N° WIL-81134 GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/103)

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	Rodwell D.E.	1985	A dietary Two-Generation Reproduction Study in Fischer 344 Rats with 2,4-Dichlorophenoxyacetic acid. INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** WIL Research Lab., Rep. N° : WIL-81137 GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/101)
IIA 5.3	Schulze G.E.	1990 a	Subchronic Toxicity Study in dogs with 2,4-Dichlorophenoxyacetic Acid. ROP, AGR, NUF, DOE, BAS, AHM Hazleton Lab., Study N°: 2184-115 GLP/GEP: yes unpublished	
IIA 5.3	Schulze G.E.	1990 b	21-day dermal irritation and dermal toxicity study in rabbits with 2,4-Dichlorophenoxyacetic Acid. ROP, AGR, NUF, DOE, BAS, AHM Hazleton Lab., Study N° : 2184-109 GLP/GEP: yes unpublished	
IIA 5.3	Schulze G.E.	1990 c	21-day dermal Irritation and dermal Toxicity Study in Rabbits with 2,4-Dichlorophenoxyacetic Acid 2-Ethylhexyl Ester. ROP, AGR, NUF, DOE, BAS, AHM Hazleton Lab., Rep.No: HLA 2184-110 GLP/GEP: yes unpublished	
IIA 5.3	Schulze G.E.	1991 a	Subchronic Toxicity Study in Rats with 2,4-Dichlorophenoxyacetic acid. ROP, AGR, NUF, DOE, BAS, AHM Hazleton Lab., Study N° 2184-116 GLP/GEP: yes unpublished	
IIA 5.3	Schulze G.E.	1991 b	Subchronic Toxicity Study in Mice with 2,4-Dichlorophenoxyacetic Acid. ROP, AGR, NUF, DOE, BAS, AHM Hazleton Lab., Study N° : 2184-117 GLP/GEP: 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 5.3.	Schulze G.E.	1991 c	Subchronic Toxicity Study in Rats with 2,4-Dichlorophenoxyacetic Acid 2-Ethylhexyl Ester. ROP, AGR, NUF, DOE, BAS, AHM Hazleton Lab., Rep.No: HLA 2184-112 GLP/GEP: yes unpublished	
IIA 5.3	Serota D.G.	1983 a	Subchronic study in rats 2,4-D acid. INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** Hazleton Lab., Study Project N° 2184-102 GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/84/85)
IIA 5.3	Serota D.G.	1983 b	Subchronic Toxicity Study in Mice with 2,4-Dichlorophenoxyacetic Acid. INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** Hazleton Lab., Study N°: 2184-100 GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/83)
IIA 5.5	Serota D.G., Vargas K.J., Alasker R.D. and Matchotka S.M.	1986	Combined chronic toxicity and oncogenicity study in rats. INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** Hazleton Lab., Study N°: 2184-103 GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/89)
IIA 5.5	Serota D.G.	1987	Oncogenicity study in mice with 2,4-Dichlorophenoxyacetic acid (2,4-D). INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** Hazleton Lab., Study N°: 2184-101 GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/90)

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	Smith F.A., Nolan R.J., Hermann E.A. and Ramsey J.C.	1980	The pharmacokinetic evaluation of the 2,4-Dichlorophenoxyacetic acid (2,4-D) in Fisher rats. INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** Toxicology Research Laboratory, Rep. N° 0697 GLP/GEP: no unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/46)
IIA 5.1	Timchalk C., Dryzga M.D. and Brzak K.A.	1990	2,4-Dichlorophenoxyacetic acid, tissue distribution and metabolism of ¹⁴ C-labelled 2,4-dichlorophenoxyacetic acid in Fischer 344 . BAS, ROP, AGR, NUF, AHM, DOE DowElanco, Rep. N° K-2372-(47) GLP/GEP: yes unpublished	

A.3: Residue

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 6.14.5	Barker W.	1995	Determination of frozen storage stability for 2,4-D in/on crops. EN-CAS analytical laboratories ROP, AGR, NUF, DOE, BAS, AHM*** EN-CAS, project No 930044 GLP/GEP: yes unpublished	
IIA 6.2	Guo M. and Stewart S.	1993	Metabolism of uniformly ¹⁴ C-Ring Labeled 2,4-Dichlorophenoxyacetic acid in Lactating goats ROP, AGR, NUF, DOE, BAS, AHM*** ABC Laboratories, Rep. N° 40630 GLP/GEP: yes unpublished	
IIA 6.6	Hastings M.J. and Rawle N.	1994	Residues of 2,4-D in Soft Wheat at Harvest following Application of EF-1223 - Italy 1993 DAS DowElanco, Rep.No: GHE-P-3446 GLP/GEP: yes unpublished	
IIA 6.6	Hastings M.J. and Brett R.	1995 a	Residues of 2,4-D in Winter Wheat at Intervals following Application of EF-1223 - Italy 1993 DAS DowElanco, Rep.No: GHE-P-3923 GLP/GEP: yes unpublished	
IIA 6.6	Hastings M.J. and Brett R.	1995 b	Residues of 2,4-D in Winter Barley at Intervals following Application of EF-1223 - Italy 1993 DAS DowElanco, Rep.No: GHE-P-3922 GLP/GEP: yes unpublished	
IIA 6.6	Hastings M.J. and Rawle N.	1995 c	Residues of 2,4-D in Durum Wheat at Harvest following Application of EF-1223 - Italy 1993 DAS DowElanco, Rep.No: GHE-P-3447# GLP/GEP: 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 6.4	Krautter and Downs J.H.	1997	2,4-D: Magnitude of residues in meat and milk of lactating dairy cows. ROP, NUF, DOE, AGR, BAS, AHM*** PTRL East report no. 1889, May 24, 1996. GLP/GEP: yes unpublished	
IIA 6.6	Pfarl C.	1993 a	Residues of 2,4-D in cereals treated with 2.01 Dicopur flussig NUF Agrolinz, Rep. N° 1169 GLP/GEP: yes unpublished	
IIA 6.6	Pfarl C.	1993 b	Residues of 2,4-D in cereals treated with 1.0 l Dicopur fluid NUF Agrolinz, Rep. N° 1166 GLP/GEP: yes unpublished	
IIA 6.6	Pfarl C.	1993 c	Residues of 2,4-D in cereals treated with 1.1 l Spritz Hormin 600/ha and 1.5 l U 46 D-Fluid NUF Agrolinz, Rep. Agrolinz N° 1153 GLP/GEP: yes unpublished	
IIA 6.6	Pfarl C.	1993 d	Residues of 2,4-D in grassland treated with 2.3 l Spritz Hormin 600/ha and 2.0 l U 46 D-Fluid NUF Agrolinz, Rep. N° 1156 GLP/GEP: yes unpublished	
IIA 6.1	Puglis J.M. and Smith G.A.	1992	Metabolism of ¹⁴ C-(2,4-Dichlorophenoxy)-acetic acid, 2-ethylhexyl ester in potatoes ROP, AGR, NUF, DOE, BAS, AHM*** ABC Laboratories, Rep.N° 38075 GLP/GEP: yes unpublished	
IIA 6.1	Puvanesarajah V.	1992 a	Metabolism of ¹⁴ C-(2,4-Dichlorophenoxy)acetic acid, 2-ethylhexyl ester in Wheat ROP, AGR, NUF, DOE, BAS, AHM*** ABC Lab., Rep.N° 38076 GLP/GEP: 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 6.1	Puvanesarajah V.	1992 b	Supplemental Data for the study "Metabolism of 14C-(2,4-Dichlorophenoxy)acetic acid, 2-ethylhexyl ester in Wheat" ROP, AGR, NUF, DOE, BAS, AHM*** ABC Lab, Rep.N° 38076-01 GLP/GEP: yes unpublished	
IIA 6.2	Puvanesarajah V. and Bliss M.E.	1992 d	Metabolism of uniformly ring labeled (14C)2,4-Dichlophenoxyacetic acid in poultry ROP, AGR, NUF, DOE, BAS, AHM*** ABC Lab, Rep.N° 38077 GLP/GEP: yes unpublished	
IIA 6.1	Smith G.A.	1991	Metabolism of 14C-(2,4-Dichlorophenoxy)acetic acid-Dimethylamine Salt in apples ROP, AGR, NUF, DOE, BAS, AHM ABC Lab., Rep.N° 38072 GLP/GEP: yes unpublished	

A.4: 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	Burgener A.	1993	2,4-D (in Form of DMA Salt): Mobility and degradation in Soil in Outdoor Lysimeters ROP, AGR, NUF, DOE, BAS, AHM*** RCC, Project 272586 GLP/GEP: yes unpublished	
IIA 7.2	Cohen S.P., Tamma R.V. and Creeger S.M.	1989 a	Hydrolysis of 2,4-D in aqueous solutions buffered at pH 5,7 and 9 ROP, AGR, NUF, DOE, BAS, AHM CHMR, 5135A GLP/GEP: yes unpublished	
IIA 7.2	Cohen S.P., Tamma R.V. and Creeger S.M.	1989 b	Aqueous photodegradation of 2,4-Dichlorophenoxyacetic acid in pH 7 buffered solution ROP, AGR, NUF, DOE, BAS, AHM CHMR, 5488A GLP/GEP: yes unpublished	
IIA 7.1	Cohen S.P.	1991 a	Aerobic Soil Metabolism Study of 2,4-D ROP, AGR, NUF, DOE, BAS, AHM*** CHMR, 6503A GLP/GEP: yes unpublished	
IIA 7.1	Cohen S.P.	1991 b	Mobility of unaged 2,4-D acid using batch equilibrium technique ROP, AGR, NUF, DOE, BAS, AHM CHMR, 6224A GLP/GEP: yes unpublished	
IIA 7.2	Concha M. and Shepler K.	1993 a	Aerobic aquatic metabolism of 2,4-Dichlorophenoxyacetic acid ROP, AGR, NUF, DOE, BAS, AHM*** PTRL Rep. N°: 393W-1 PTRL West Inc. GLP/GEP: yes unpublished	
IIA 7.2	Concha M. and Shepler B.S.,	1993 b	Photodegradation of [¹⁴ C] 2,4-D ethylhexyl ester in buffered aqueous solution at pH5 by natural sunlight ROP, AGR, NUF, DOE, BAS, AHM*** PTRL-West, Rep.No: 390W-1 GLP/GEP: 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 7.2	Concha M., Shepler B.S. and Erhardt-Zabik S.	1993 c	Hydrolysis of [¹⁴ C] 2,4-D ethylhexyl in natural water ROP, AGR, NUF, DOE, BAS, AHM*** PTRL-West, Rep.No: 395W-1 GLP/GEP: yes unpublished	
IIA 7.2	Concha M., Shepler B.S. and Erhardt-Zabik S.	1993 d	Hydrolysis of [¹⁴ C] 2,4-D ethylhexyl at pH 5, 7, and 9 ROP, AGR, NUF, DOE, BAS, AHM*** PTRL-West, Rep.No: 387W-1 GLP/GEP: yes unpublished	
IIA 7.2	Doyle R.C.	1991 a	Laboratory volatility of the 2-ethylhexylester of 2,4-D acid Industry Task Force I on 2,4-D Ref. IIT Research Institute T080307T601 INT, BAS, GIL, FAR, GOR, TRA, AHM, AZC, CHL, DOE, MOB&FER, ROP, NUF** Pharmacology & Toxicology Research Lab. GLP/GEP: yes unpublished	
IIA 7.2	Klopffer W.	1991	Determination of the phototransformation in water of 2,4-D ROP, AGR, NUF, DOE, BAS, AHM Batelle Europe, Study Nr BE-P-118-91-PHO-01 GLP/GEP: yes unpublished	
IIA 7.2	Maestracci M.	1994	2,4-D-Estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions NUF Rhone-Poulenc, Rep. R&D/CRLD/AN/9415680 GLP/GEP: yes unpublished	
IIA 7.1	McCoy K.M. and Lehmann R.G.	1988	Soil adsorption properties of 2,4-D, 2-ethylhexyl ester and butyl ester of 2,4-D DAS, Dow Agricultural Chemistry R & D Labs, Rep. N°: GH-C 1993 GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/40)

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	Tamma-Vithala R.V. and Creeger S.M.	1989	Photodegradation of 2,4-Dichlorophenoxyacetic acid on soil BAS, ROP, AGR, NUF, AHM, DOE CHMR, 5485A GLP/GEP: yes unpublished	
IIA 7.2	Vithala R.V., Cohen S.P. and Creeger S.M.	1990	Anaerobic aquatic metabolism of 2,4-Dichlorophenoxyacetic acid BAS, ROP, AGR, NUF, AHM, DOE CHMR, 5847A GLP/GEP: yes unpublished	
IIA 7.1	Zohner A.	1990 a	Determination of the mobility of soil-aged residues by soil column leaching test for ¹⁴ C-2,4-D acid (EPA Guidel.) ROP, AGR, NUF, AHM, DOE, BAS Agrolinz, Rep. N°: 989 GLP/GEP: yes unpublished	
IIA 7.1	Zohner A.	1990 b	Determination of the mobility of soil-aged residues by soil column leaching test for ¹⁴ C-2,4-D acid (BBA Guidelines) ROP, AGR, NUF, AHM, DOE, BAS Agrolinz, Rep. N°: 1013 GLP/GEP: yes unpublished	

A.5: Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA 8.3	Adema M.M. and Roza P.	1989	The acute toxicity of U 46-D-Fluid (500g 2,4-D acid as dimethylamine salt) to Eisenia Fetida ROP, AGR, NUF, AHM, DOE, BAS TNO, report N° 89/153 GLP/GEP: yes unpublished	
IIA 8.2, IIIA 10.2	Alexander H.C., Gersich F.M., Mayes M.A. and Applegarth S.L.	1983	The acute toxicity of 2,4-Dichlorophenoxy acetic acid isooctyl ester to representative aquatic organisms DAS, Dow Elanco, Rep.No: ES-DR-0019-1208-3 GLP/GEP: yes unpublished	
IIA 8.3	Backus P. and Crosby K.	1992	Effect of 2,4-D DMAS on vegetative vigor of plants ROP, AGR, NUF, DOE, BAS, AHM*** Ricerca, Rep. N° 3722-90-0408-BE-001 GLP/GEP: yes unpublished	
IIA 8.1, IIIA 10.1	Beavers J.B.	1984 a	2,4-Dichlorophenoxy acetic acid isooctyl ester: An acute oral toxicity study with the mallard DAS Wildlife International , Rep.No: 103-229 GLP/GEP: yes unpublished	
IIA 8.1, IIIA 10.1	Beavers J.B.	1984 b	2,4-Dichlorophenoxy acetic acid isooctyl ester: A dietary Lc50 study with the bobwhite quail DAS Wildlife International, Rep.No: 103-227 GLP/GEP: yes unpublished	
IIA 8.1, IIIA 10.1	Beavers J.B.	1984 c	2,4-Dichlorophenoxy acetic acid isooctyl ester: A dietary Lc50 study with the mallard DAS Wildlife International, Rep.No: 103-228 GLP/GEP: 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	Bogers M. and Enninga I.C.	1990 a	2,4-D Acid (as DMA-salt). 96-Hour acute toxicity study (LC ₅₀) in the rainbow trout ROP, AGR, NUF, AHM, DOE, BAS RCC Notox B.V. Project 019620 GLP/GEP: yes unpublished	
IIA 8.2	Bogers M. and Enninga I.C.	1990 b	2,4-D Acid (as DMA-salt). 96-Hour acute toxicity study (LC ₅₀) in the carp (static) ROP, AGR, NUF, AHM, DOE, BAS RCC Notox B.V. Project 018977 GLP/GEP: yes unpublished	
IIA 8.1	Culotta J., Foster J., Grimes J., Hoxter K.A., Smith G.J. and Jaber M.	1990 a	2,4-D (2,4-Dichlorophenoxyacetic acid). A dietary LC ₅₀ study with the mallard ROP, AGR, NUF, AHM, DOE, BAS Wildlife International, Project N°: 103- 307 GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/ 105)
IIA 8.1	Culotta J., Hoxter K.A., Foster J., Smith G.J. and Jaber M.	1990 b	2,4-D (2,4-Dichlorophenoxyacetic acid). A dietary LC ₅₀ study with the Northern Bobwhite ROP, AGR, NUF, AHM, DOE, BAS Wildlife International, Project N°: 103- 306 GLP/GEP: yes unpublished	
IIA 8.3	Hoxter, K.A., Palmer, S.J. and Krueger, H.O.	1997 a	2,4-D Dimethylamine salt : An Acute Oral Toxicity Study with the Honey Bee ROP, NUF, DOE, AHM, BAS, GOR Wildlife International, Project N°: 467- 101 GLP/GEP: yes unpublished	
IIA 8.3	Hoxter, K.A., Palmer, S.J. and Krueger, H.O.	1997 b	2,4-D 2-Ethylhexyl ester : An Acute Oral Toxicity Study with the Honey Bee Wildlife International, Project N°: 467- 103A ROP, NUF, DOE, AHM, BAS, GOR GLP/GEP: 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 8.1	Hoxter K.A., Culotta J. and Jaber M.	1990	2,4-D Dimethylamine salt: An acute oral toxicity study with the Northern Bobwhite ROP, AGR, NUF, AHM, DOE, BAS Wildlife International, Project N°: 103-310 GLP/GEP: yes unpublished	
IIA 8.2	Hughes J.S.	1990 a	The toxicity of 2,4-D to <i>Senenastrum capricornutum</i> ROP, AGR, NUF, AHM, DOE, BAS Malcolm Pirnie, Project ID 0460-05-1100-1 GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/107)
IIA 8.2	Hughes J.S.	1990 b	The Toxicity of 2,4-D, Dimethylamine salt to <i>Lemna Gibba</i> ROP, AGR, NUF, AHM, DOE, BAS Malcolm Pirnie, Project ID 0460-05-1100-1 GLP/GEP: yes unpublished	UK: Submitted for national review. Authorisations maintained 1992. (UK ref: SC9184/112)
IIA 8.2	Hughes J.S.	1990 c	The toxicity of 2,4-D Ethylhexyl ester to <i>Selanastrum capricornutum</i> ROP, AGR, NUF, AHM, DOE, BAS Malcolm Pirnie, Rep.No: 0460-05-1100-2 GLP/GEP: yes unpublished	
IIA 8.2	Hughes J.S.	1990 d	The toxicity of 2,4-D Ethylhexyl ester to <i>Anabaena flos-aquae</i> ROP, AGR, NUF, AHM, DOE, BAS Malcolm Pirnie, Rep.No: B460-07-1 GLP/GEP: yes unpublished	
IIA 8.2	Hughes J.S.	1990 e	The toxicity of 2,4-D Ethylhexyl ester to <i>Skeletonema costatum</i> ROP, AGR, NUF, AHM, DOE, BAS Malcolm Pirnie, Rep.No: B460-07-3 GLP/GEP: yes unpublished	
IIA 8.2	Hughes J.S.	1990f	The toxicity of 2,4-D Ethylhexyl ester to <i>Navicula pelliculosa</i> ROP, AGR, NUF, AHM, DOE, BAS Malcolm Pirnie, Rep.No: B460-07-2 GLP/GEP: 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	Hughes J.S.	1990 g	The toxicity of 2,4-D Ethylhexyl ester to <i>Lemna gibba</i> G3 ROP, AGR, NUF, AHM, DOE, BAS Malcolm Pirnie, Rep.No: B460-07-4 GLP/GEP: yes unpublished	
IIA 8.2	Mark U. and Hantink-de Rooy E.	1989	2,4-D, Dimethylamine salt: Prolonged Toxicity study with <i>Daphnia magna</i> , under semi-static test conditions ROP, AGR, NUF, AHM, DOE, BAS AKZO, Rep. N°: F89122 GLP/GEP: yes unpublished	
IIA 8.2	Mayes M.A., Gorzinski S.J., Potter R.B. and Richardson C.H.	1990 a	2,4-Dichlorophenoxyacetic acid: (2-ethylhexyl ester): Evaluation of the Toxicity to early Life stages of the Fathead Minnow, <i>Pimephales promelas Rafinesque</i> ROP, AGR, NUF, AHM, DOE, BAS DowElanco, Rep.No: ES-DR-0019-1208-7 GLP/GEP: yes unpublished	
IIA 8.2	Mayes M.A., Gorzinski S.J., Potter R.B. and Richard-son C.H.	1990 b	2,4-Dichlorophenoxyacetic acid: Evaluation of the toxicity to early life stages of the Fathead minnow ROP, AGR, NUF, AHM, DOE, BAS DowElanco, Rep. N°:ES-DR-0002-2297-10 GLP/GEP: yes unpublished	
IIA 8.3	Palmer, S.J. and Krueger, H.O.	1997 a	2,4-D Dimethylamine salt : An Acute Contact Toxicity Study with the Honey Bee ROP, NUF, DOE, AHM, BAS, GOR Wildlife International, Project N°: 467-102, GLP/GEP: yes unpublished	
IIA 8.3	Palmer, S.J. and Krueger, H.O.	1997 b	2,4-D 2-Ethylhexyl ester : An Acute Contact Toxicity Study with the Honey Bee ROP, NUF, DOE, AHM, BAS, GOR Wildlife International, Project N°: 467-104, GLP/GEP: 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	Vaishav D.D., Yurk J.J. and Wade B.A.	1990 a	2,4-D Acid-Acute toxicity to Tidewater Silverside (<i>Menidia Beryllina</i>) under Flow-through conditions. ROP, AGR, NUF, AHM, DOE, BAS Environmental Science & Engineering, Rep. N°: 3903008000-0210-3140 GLP/GEP: yes unpublished	
IIA 8.2	Vaishnav D.D., Yurk J.J. and Wade B.A.	1990 b	2,4-Dichlorophenoxyacetic acid: Acute toxicity to pink shrimp (<i>Panaeus duorarum</i>) under flow-through conditions ROP, AGR, NUF, AHM, DOE, BAS Environmental Science & Engineering Rep. N°: ESE 3903008000-0200-3140 GLP/GEP: yes unpublished	
IIA 8.2	Ward T.J. and Boeri R.L.	1991 a	Chronic toxicity of 2,4-D to the Daphnid (<i>Daphnia magna</i>) ROP, AGR, NUF, AHM, DOE, BAS EnviroSystems, Study N°: 9040-D GLP/GEP: yes unpublished	
IIA 8.2	Ward T.J. and Boeri R.L.	1991 b	Acute flow-through Toxicity of 2,4-D 2-ethylhexyl ester to the Tidewater Silverside, <i>Menidia beryllina</i> ROP, AGR, NUF, AHM, DOE, BAS EnviroSystems Division, Rep.No: 9035-D GLP/GEP: yes unpublished	
IIA 8.2	Ward T.J. and Boeri R.L.	1991 c	Chronic toxicity of 2,4-D, 2-ethylhexyl ester, to the Daphnid, <i>Daphnia magna</i> ROP, AGR, NUF, DOE, BAS, AHM EnviroSystems Division, Rep.No: 9041-D GLP/GEP: yes unpublished	
IIA 8.3, IIIA 10.2	Ward T.J. and Boeri R.L.	1991 d	Acute Flow-through Mollusc Shell deposition Test with 2,4-D, 2-ethylhexyl ester ROP, AGR, NUF, DOE, BAS, AHM EnviroSystems Division, Rep.No: 9034-D GLP/GEP: 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	Ward T.J. and Boeri R.L.	1991 e	Acute flow-through toxicity of 2,4-D, 2-Ethylhexyl ester to the grass shrimp, <i>Palaemonetes pugio</i> ROP, AGR, NUF, DOE, BAS, AHM EnviroSystems Division, Rep.No:9036-D GLP/GEP: yes unpublished	
IIA 8.3	Zohner A.	1989 a	Effects of U 46-D-Fluid (500g/l 2,4-D acid as DMA salt) on soil respiration ROP, AGR, NUF, DOE, BAS, AHM Agrolinz, Rep. N° 978-Project M8818-1 GLP/GEP: yes unpublished	
IIA 8.3	Zohner A.	1989 b	Investigations of the Side Effects of U 46-M-Fluid (500g/l 2,4-D acid as DMA salt) on the ammonification and nitrification in two representative agricultural soils ROP, AGR, NUF, DOE, BAS, AHM Agrolinz, Rep. N° 969-Project M8823 GLP/GEP: yes unpublished	

*: (INT)=INTERAG, (BAS)=BASF, (GIL)=GILMORE INC, (FAR)= FARMLAND, (GOR)= P.B.I. GORDON, (TRA)=TRANSBASS, (AHM)= A.H. MARKS, (AZC)= AKZO, (CHL)= CHEMIE LINZ, (AGL)= AGROLINZ, (DAS, DOE)=DOW, (MOB & FER)= MOBAY BAYER & FERMENTA, (RPA, ROP)= RHONE-POULENC, (AGR)= AGROGOR (consortium Agrolinz – PBI Gordon), (NUF)= NUFARM

** = All references marked with "NUF**" are also property of Nufarm

*** = According to the agreement between the US TF and AHM, AHM has the right to cite these references but is not entitled to get any hard copy of these studies

APPENDIX IIIB**2,4-D**

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 (Doc J)	Banwell, M	1998	4 batch Impurity, Impurity profile, of 2,4-Dichlorophenoxyacetic acid, 2- ethylhexanol ester (Technical Grade) A H Marks Report N°: not assigned AHM* GLP/GEP: yes unpublished
IIA 1.11 (Doc J)	Bass R V	1999	Determination of the Chlorinated Dibenzo-p-dioxin and Dibenzofuran content of 5 batches of 2,4- Dichlorophenoxyacetic acid Technical Grade Active Ingredient A H Marks Report N°: 99/0073 AHM GLP/GEP: yes unpublished
IIA 1.11 (Doc J)	Bass R V	1999	Preliminary analysis of 5 batches of 2,4-Dichlorophenoxyacetic acid, 2- ethylhexyl ester technical grade active ingredient A H Marks Report N°: 98/0064 AHM GLP/GEP: 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 1.11 (Doc J)	Hersey, R	1998	Properties of 2,4-Dichlorophenoxyacetic acid, 2-ethylhexylester (Technical Grade Active Ingredient) A H Marks Report No 98/0041 AHM GLP/GEP: yes unpublished
IIA 1.11 (Doc J)	Hutchinson, N D	1998	<u>4 batch Impurity, Impurity profile, of 2,4-Dichlorophenoxyacetic acid, 2-ethylhexanol ester (Technical Grade)</u> A H Marks Report N°: not assigned AHM GLP/GEP: yes unpublished
IIA 1.11 (Doc J)	Hutchinson, N D	1998	Free Phenols in 2,4-Dichlorophenoxyacetic acid A H Marks Report N°: not assigned AHM GLP/GEP: yes unpublished
IIA 1.11 (Doc J)	Hutchinson, N D	1998	Triethanolamine insolubles of 2,4-Dichlorophenoxyacetic acid, Technical Grade Active Ingredient A H Marks Report No 98/0042 AHM GLP/GEP: yes unpublished
IIA 1.11 (Doc J)	Hutchinson, N D	1999	Preliminary analysis of 5 batches of 2,4-Dichlorophenoxyacetic acid technical grade active ingredient A H Marks A H Marks & Company Limited Report No. 98/0057 GLP/GEP: yes unpublished
IIA 1.11 (Doc J)	Hamilton T.D.	1999	Five Batch Analysis of 2,4-D 2-Ethyl-1-Hexyl Ester Technical DAS* Dow AgroSciences Lab Report Code DECO GL-AL 99-002231 GLP/GEP: 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 1.9 (Doc J)	Madsen, S	2000	2,4-Dichlorophenoxyacetic Acid Technical: Supplemental Manufacturing Information DAS Dow AgroSciences, Report N°: GH-C 3714 GLP/GEP: No unpublished
IIA 1.11 (Doc J)	Clarisse B.	1998	2,4-D 2-EHE technical: Determination of purity and impurities – Analytical profile of 5 batches, including method validations Nufarm GmbH & Co KG CFPI Agro Report OT09/C/2497 GLP/GEP: yes unpublished
IIA 4.1	Cousin J. and Reynaud R.	1998	Product Chemistry for 2,4-D 2-ethylhexylester Series 62 Analysis and certification of Product Ingredients. Supplemental report NUF Rhône-Poulenc Agro, Rep. N°: 97-135 GLP/GEP: yes unpublished
IIA, 4.1 Doc J	Hamilton T.D. & Kastl P.E.	1999	Ester Specific Analytical Method for Determination of Esters of 2,4-Dichlorophenoxyacetic Acid (2,4-D) and Related Impurities DAS Dow AgroSciences Rep. N°: DECO GL-AL 99-000252 GLP/GEP: yes unpublished

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 5.3	Berthe P.	1998	2,4-D Acid : Clarification regarding implied effects on white blood cell count in the two subchronic studies in mice <u>AHM, DAS, NUF, GOR, BAS</u> <u>Rhône-Poulenc Agro, Report 02.07.1998</u> GLP/GEP: no unpublished
IIA, 5.8	Fisher P.	1998	2,4-D & 2,4-DB: Comparison of the metabolic fate of 2,4-D & 2,4-DB in the rat DAS, NUF, AHM, GOR, BAS Rhône-Poulenc Agro, Report No not allocated GLP/GEP: no unpublished
IIA, 5.4	Gillam A.M. & Cameron D	1998	2,4-D : Measurement of Unscheduled DNA Synthesis in Rat Liver Using an In vivo/In vitro procedure DAS, NUF, AHM, GOR, BAS Covance, Report N°198/118-D5140 GLP/GEP: yes unpublished
IIA, 5.3	Gopinath C. and Bruner R.H.	1998	Independent Pathology Peer Review of Kidney Tissue from Rats and Mice assigned to multiple (8) studies to evaluate the subchronic toxicity of 2,4-D DAS, NUF, AHM, GOR, BAS Pathology Associates International GLP/GEP: yes unpublished
IIA, 5.3	Timchalk C.	1998	Relevance of Dog Toxicity Data for Evaluation of Human Health Risk from Exposure to 2,4- Dichloro-phenoxyacetic acid (2,4-D) and Related Organic Acids AHM, DAS, NUF, RPA, GOR, BAS Batelle Richland WA/USA Report from 23.06.1998 GLP/GEP: no 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, 5.3	Timchalk C.	1998	Allometric Theory and its Application in Pharmacology/Toxicology Inter-Species Comparisons and Risk Assessment AHM, DAS, NUF, RPA, GOR, BAS Batelle Richland WA/USA Report from 02.10.1998 GLP/GEP: no unpublished
IIA 5.5	Jeffries T.K., Yano B.L., Ormand J.R. and Battjes J.E.	1995	Chronic Toxicity/Oncogenicity study in Fischer 344 rats with 2,4-Dichlorophenoxyacetic acid (2,4-D) ROP, AGR, NUF, DOE, BAS, AHM*** Dow chemical Study N°: K-002372-064F. GLP/GEP: yes unpublished
IIA 5.5	Stott W.T., Johnson K.A., Gilbert K.S., Ormand J.R. and Battjes J.E.	1995 a	2,4-Dichlorophenoxyacetic acid: Dietary Oncogenicity study in B6C3F1 Mice - Two year final report ROP, AGR, NUF, DOE, BAS, AHM*** Dow chemical Study N°:K-002372-063F GLP/GEP: yes unpublished
IIA 5.5	Stott W.T., Johnson K.A., Gilbert K.S., Ormand J.R. and Battjes J.E.	1995 b	2,4-Dichlorophenoxyacetic acid: Dietary Oncogenicity study in male B6C3F1 Mice - Two year final report- ROP, AGR, NUF, DOE, BAS, AHM*** Dow chemical Study N°:K-002372-063M GLP/GEP: yes unpublished

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 6.6	Zietz E.	1999	Determination of the residues of 2,4-D acid in grassland following treatment with EXP (2,4-D acid as DMA salt) under field conditions in Southern Europe – Season 1998 – incl. Field phase report NUF, DAS, AHM, GOR, BAS Institut Fresenius Rep. N°: IF-98/09047-00 GLP/GEP: yes unpublished
IIA, 6.6	Zietz E.	1999	Determination of the residues of 2,4-D acid in grassland following treatment with EXP (2,4-D acid as DMA salt) under field conditions in Northern Europe – Season 1998 – incl. Field phase report NUF, DAS, AHM, GOR, BAS Institut Fresenius Rep. N°: IF-98/10147-00 GLP/GEP: yes unpublished
IIA, 6.6	Zietz E.	2000	Determination of the Residues of 2,4-D Acid in Grassland following treatment with EXP (2,4-D acid as DMA–salt) under field conditions in Northern Europe. NUF, DAS, AHM, GOR, BAS Report/file IF-99/09726-00 GLP/GEP: yes unpublished
IIA, 6.6	Zietz E.	2000	Determination of the Residues of 2,4-D Acid in Grassland following treatment with EXP (2,4-D acid as DMA–salt) under field conditions in Southern Europe. NUF, DAS, AHM, GOR, BAS Report/file IF-99/09725-00 GLP/GEP: yes unpublished

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 7.4	Jarvis T.	2000	Demonstration of safe use of 2,4-D herbicide in the European Union: a Groundwater PEC scenarios modelling approach. AHM, DAS, GOR, NUF, BAS JSC International Ltd, Report No 24D/02/01 GLP/GEP: yes unpublished

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, 8.3.2, IIIA, 10.5	Kühner C.	1998 a	Desormone liquide (2,4-D DMA salt) : Acute Toxicity to the Predatory Mite, <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) in the Laboratory AHM, DAS, NUF, GOR, BAS <u>GAB Biotechnology & IFU</u> <u>Umweltanalytik, Report No 98117/01-</u> <u>NLTp</u> GLP/GEP: yes unpublished
IIA, 8.3.2, IIIA, 10.5	Kühner C.	1998 b	Desormone liquide (2,4-D DMA salt) : Acute Toxicity to the Aphid Parasitoid, <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) in the Laboratory AHM, DAS, NUF, GOR, BAS GAB Biotechnology & IFU Umweltanalytik, Report No 98117/01- NLAp GLP/GEP: yes unpublished
IIA, 8.3.2, IIIA, 10.5	Kühner C.	1998 c	Esteron 60 (2,4-D EHE) : Acute Toxicity to the Predatory Mite, <i>Typhlodromus</i> <i>pyri</i> Scheuten (Acari, Phytoseiidae) in the Laboratory AHM, DAS, NUF, GOR, BAS GAB Biotechnology & IFU Umweltanalytik, Report No 98132/01- NLTp GLP/GEP: yes unpublished
IIA, 8.3.2, IIIA, 10.5	Kühner C.	1998 d	Esteron 60 (2,4-D EHE) : Acute Toxicity to the Aphid Parasitoid, <i>Aphidius</i> <i>rhopalosiphi</i> (Hymenoptera, Braconidae) in the Laboratory AHM, DAS, NUF, GOR, BAS <u>GAB Biotechnology & IFU</u> <u>Umweltanalytik, Report No 98132/01-</u> <u>NLAp</u> GLP/GEP: 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, 8.1.3.	Mitchell L.	2000	2,4-D acid : A pilot reproduction study with the Northern Bobwhite AHM, DAS, GOR, NUF, BAS Wildlife International, Rep. N° : 467-105 GLP/GEP: yes unpublished
IIA, 8.1.3.	Mitchell L.	2000	2,4-D acid : A reproduction study with the Northern Bobwhite Generated by Wildlife International Ltd Owned by AHM, DAS, GOR, NUF, BAS Report No 467-106 30.10.2000 GLP, not published

*: (INT)=INTERAG, (BAS)=BASF, (GIL)=GILMORE INC, (FAR)= FARMLAND, (GOR)= P.B.I. GORDON, (TRA)=TRANSBASS, (AHM)= A.H. MARKS, (AZC)= AKZO, (CHL)= CHEMIE LINZ, (AGL)= AGROLINZ, (DAS, DOE)=DOW, (MOB & FER)= MOBAY BAYER & FERMENTA, (RPA, ROP)= RHONE-POULENC, (AGR)= AGROGOR (consortium Agrolinz – PBI Gordon), (NUF)= NUFARM

** = All references marked with "NUF**" are also property of Nufarm

*** = According to the agreement between the US TF and AHM, AHM has the right to cite these references but is not entitled to get any hard copy of these studies