EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Cyhalofop-butyl

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

Review report for the active substance **cyhalofop-butyl**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 19 April 2002 in view of the inclusion of cyhalofop-butyl in Annex I of Directive 91/414/EEC.

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of the new active substance cyhalofop-butyl, made in the context of the work provided for in Articles 5 and 6 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.

In accordance with the provisions of Article 6(2) of Directive 91/414/EEC, the Italian authorities received on 30 April 1997 an application from Dow AgroSciences Europe, hereafter referred to as the applicant, for the inclusion of the active substance cyhalofop-butyl in Annex I to the Directive. Italian authorities indicated to the Commission on 5 November 1997 the results of a first examination of the completeness of the dossier, with regard to the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive. Subsequently, and in accordance with the requirements of Article 6(2), a dossier on cyhalofop-butyl was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on Plant Health in the meeting of the working group 'legislation' thereof on 16 December 1997, during which the Member States confirmed the receipt of the dossier.

In accordance with the provisions of Article 6(3), which requires the confirmation at Community level that the dossier is to be considered as satisfying, in principle, the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive and in accordance with

the procedure laid down in Article 20 of the Directive, the Commission confirmed in its Decision 98/242[1] of 20 March 1998 that these requirements were satisfied.

Within the framework of that decision and with a view to the further organisation of the works related to the detailed examination of the dossier provided for in Article 6(2) and (4) of Directive 91/414/EEC, it was agreed between the Member States and the Commission that Italy would, as rapporteur Member State, carry out the detailed examination of the dossier and report the conclusions of its examination accompanied by any recommendations on the inclusion or non-inclusion and any conditions relating thereto, to the Commission as soon as possible and at the latest within a period of one year.

Italy submitted to the Commission on 30 November 1998 the report of its detailed scientific examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of cyhalofop-butyl in Annex I to the Directive.

On receipt of the draft assessment report, the Commission forwarded it for consultation to all the Member States as well as to Dow AgroSciences Europe being the sole applicant on 6 January 1999.

The Commission organised further an intensive consultation of specialised scientific experts from a representative 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 March to October 1999.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the sole applicant on 14 March 2000.

The dossier, draft assessment report and the peer review report (i.e. full report) including in particular an outline resumé of the remaining technical questions, 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 January 2000 to February 2002, and was finalised in the meeting of the Standing Committee on the Food Chain and Animal Health on 19 April 2002.

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

[1] OJ No L96, 28.03.1998, p.45.

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. The Committee was asked to comment on the risk to aquatic organisms and non-target arthropods and on operator exposure. In its opinion[2] the Committee noted that – on the basis of available information - aerial application of the active substance may pose an unacceptable risk to aquatic organisms within flooded paddy fields and in adjacent drainage canals, if they are of low depth. Terrestrial applications to flooded paddies may pose an unacceptable risk to aquatic organisms within the paddy fields. The Committee considered the use unlikely to be harmful to bees but highlighted remaining uncertainty with regard to other non-target arthropods, which should be addressed by an extended test. This information was subsequently provided by the notifier and evaluated. The notifier also submitted further information to refine the assessment of risks associated with aerial applications, which was done. The Scientific Committee was further of the opinion that the operator exposure to cyhalofop-butyl has been adequately addressed.

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 2002/64/EC of 18 July 2002 concerning the inclusion of cyhalofop-butyl in Annex I to Directive 91/414/EEC[3], and to assist the Member States in decisions on individual plant protection products containing cyhalofop-butyl they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

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

In parallel with the provisions of Article 7(6) of Regulation 3600/92 for existing active substances, the Commission and the 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 the applicant.

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

[2] Opinion of the scientific Committee on Plants on the evaluation of cyhalofop-butyl [DE-537] in the context of Council Directive 91/414/EEC concerning the placing of plant protection products on the market. SCP/CYHALO/002-Final of 26 March 2001

[3] OJ L 189 18.07.2002 p45

demonstrated possession of 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 cyhalofop-butyl 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 cyhalofop-butyl 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 sole submitter:

- Post-emergence herbicide in rice with a maximum application rate of 0.3 kg a.s./ha

Extension of the use pattern beyond that 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.

4. Specific conclusions which are highlighted in this evaluation

4.1 Residues of cyhalofop-butyl in foodstuffs

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 0.74 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). This low intake value reflects the current limited use pattern for this active substance.

4.2 Exposure of operators, workers and bystanders

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

4.3 Environmental fate and behaviour and ecotoxicology

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 7 of this report.

5. Identity and Physical/chemical properties

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

The active substance shall have a minimum purity of 950 g/kg technical product.

The review has established that for the active substance notified by the applicant (Dow AgroSciences Europe), none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

6. 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 evaluation process are listed in Appendix II.

7. 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 cyhalofop-butyl

On the basis of the proposed and supported uses, the following particular issues have been identified as requiring particular and short term (within 12 months at the latest) attention from the Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- Member States must carefully consider the potential impact of aerial applications on non-target organisms and in particular to aquatic species. Conditions of authorisation must include restrictions or risk mitigation measures, where appropriate.

- Member States must carefully consider the potential impact of terrestrial applications on aquatic organisms within paddy fields. Conditions of authorisation must include risk mitigation measures, where appropriate.

8. List of studies to be generated

No further studies were identified which were considered at this stage, and under the current inclusion conditions necessary in relation to the inclusion of cyhalofop-butyl in Annex I.

However the generation/submission of additional studies, in order to support authorisations for use under certain conditions may be required at Member State level.

9. Information on studies with claimed data protection

For information of any interested parties, Appendix III gives information about the studies for which the applicant has claimed data protection and which are not present in the original dossier

neither mentioned in the draft assessment report. 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.

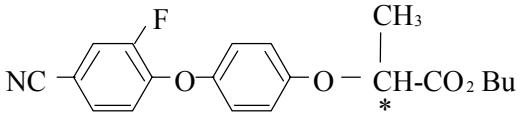
10. Updating of this review report

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

APPENDIX I

Identity, physical and chemical properties

CYHALOFOP-BUTYL

Common name (ISO)	Cyhalofop-butyl
Developmental code	DE-537
Chemical name (IUPAC)	Butyl-(R)-2-[4(4-cyano-2-fluorophenoxy) phenoxy]propionate
Chemical name (CA)	Not available.
CIPAC No	596
CAS No	122008-85-9
EEC No	Not available.
FAO SPECIFICATION	Not available.
Minimum purity	950 g/kg
Molecular formula	$C_{20}H_{20}FNO_4$
Molecular mass	357.39
Structural formula	

	Ester
Melting point	45.5 - 49.5°C (purity: 99.5%)
Boiling point	Decomposition at 270°C (purity: 99.5%)
Appearance	Off-white/buff fine granular solid (99.8% purified a.s.) Off-white/buff fine granular solid (96.3% a.s. as manufactured)
Relative density	1.17 (purity: 99.5%)
Surface tension	at 20°C, 29.5 mN/n and at 40°C, 26.5 mN/m
Vapour pressure	5.3 x 10^{-5} Pa (25°C, purity: 99.5%)
Henry's law constant	9.51 x 10^{-4} Pa m^3 mol^{-1}
Solubility in water	At 20°C (purity: 99.5%): purified water: 0.44 mg/l pH 5: 0.46 mg/l pH 7: 0.44 mg/l pH 9: rapid hydrolysis, therefore not measured
Solubility in organic solvents	At 20°C (purity: 97.4%): n-Heptane: 6.06 g/l Xylene: >250 g/l Methanol: >250 g/l Dichloroethane: >250 g/l Acetone: >250 g/l Ethyl acetate: >250 g/l Acetonitrile: >250 g/l n-Octanol: 16.0 g/l
Partition co-efficient (log P_{ow})	log K_{ow} = 3.3158 (purity: 99.5%) Test performed with distilled water; pH not declared.
Hydrolytic stability (DT_{50})	25°C / 37°C pH 1.2: not done / 41.6 h pH 4.0: > 1 y / > 1 y pH 7.0: 96.7 d / 30.6 d pH 9.0: 43.0 h / 11.5 h
Dissociation constant	Cyhalofop-butyl is an ester. Therefore pKa determined for the acid whose value is 3.80 (OECD Test Guideline 112)
Quantum yield of direct photo-transformation in water at ε >290 nm	0.157

Flammability	Not performed, sample would melt /decompose on the burn test.
Flash point	Closed cup: 122°C Open cup: 255°C Fire point: 265°C
Explosive properties	Non-explosive.
UV/VIS absorption (max.)	MeOH: ε ($lmol^{-1}$ cm^{-1}) at 247.8 nm = 1.61x 10^4 MeOH: ε ($lmol^{-1}$ cm^{-1}) at 233.4 nm = 1.59x 10^4 MeOH: ε ($lmol^{-1}$ cm^{-1}) at 202.6 nm = 3.27x 10^4 1M HCl in MeOH: ε ($lmol^{-1}$ cm^{-1}) at 247.6 nm = 1.64x 10^4 1M HCl in MeOH: ε ($lmol^{-1}$ cm^{-1}) at 233.4 nm = 1.64x 10^4 1M HCl in MeOH: ε ($lmol^{-1}$ cm^{-1}) at 202.2 nm = 3.70x 10^4 1M NaOH in MeOH: ε ($lmol^{-1}$ cm^{-1}) at 236.0 nm = 1.71x 10^4 1M NaOH in MeOH: ε ($lmol^{-1}$ cm^{-1}) at 211.6 nm = 1.23x 10^4 (purity 99.8%)
Photostability in water (DT_{50})	Direct phototransformation $T_{1/2}$ = 26.6 d based on first order kinetics (25°C, pH = 5)
Stability in the air	**Atmospheric half-life = estimated 5.88 hours (Atkinson calculation)** rate constant = 21.8 x 10^{-12} cm^3/molecule/s

APPENDIX II

END POINTS AND RELATED INFORMATION

CYHALOFOP-BUTYL

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rapid and virtually complete: >90%
Distribution:	Uniformly distributed.
Potential for accumulation:	No potential for bioaccumulation
Rate and extent of excretion:	Rapid, T1/2 = 3h. >90% of the repeated orally administered dose excreted in 24h. Urine >90% (major route of elimination)
Toxicologically significant compounds:	Major metabolite is DE-537 acid (66 to 79% of radioactivity)
Metabolism in animals:	Once absorbed, the active substance (DE-537) is rapidly hydrolysed to DE-537 acid and then conjugated to the acid-glucuronide. A small amount of the acid is oxidised to the DE-537 DP, which also forms a glucuronide conjugate.

Acute toxicity

Rat LD_{50} oral:	>5000 mg/kg bw
Rat LD_{50} dermal:	>2000 mg/kg bw
Rat LC_{50} inhalation:	>5.63 mg/l/4hr (dust; whole body exposure)
Skin irritation:	Non-irritant.
Eye irritation:	Non-irritant.
Skin sensitization (test method used and result):	Non-sensitiser (Buehler; M&K).

Short term toxicity

Target / critical effect:	Liver and kidney (rodents); gall bladder (dog)
Lowest relevant oral NOAEL / NOEL:	3.0 mg/kg bw/d (90-day; mouse, rat, dog)
Lowest relevant dermal NOAEL / NOEL:	Not required.
Lowest relevant inhalation NOAEL / NOEL:	Not required.

Genotoxicity	No genotoxic potential.

Long term toxicity and carcinogenicity

Target / critical effect:	Liver.
Lowest relevant NOAEL:	3 ppm, equal to 0.3 mg/kg bw/d (78 weeks: mouse)
Carcinogenicity:	No carcinogenic potential.

Reproductive toxicity

Target / critical effect - Reproduction:	No evidence of adverse effect on reproduction.
Lowest relevant reproductive NOAEL / NOEL:	NOEL Maternal toxicity = 7.9 mg/kg bw/day NOEL developmental toxicity = 80 mg/kg bw/day NOEL reproductive toxicity = 80 mg/kg bw/day
Target / critical effect - Developmental toxicity:	No evidence of a teratogenic effect.
Lowest relevant developmental NOAEL / NOEL:	Rat NOEL Maternal toxicity = 250 mg/kg bw/day NOEL foetal toxicity = 1000 mg/kg bw/day Rabbit NOEL Maternal and foetal toxicity = 40 mg/kg bw/day

Delayed neurotoxicity	No concern from other studies.

Other toxicological studies	NOEL for transient liver hyperplasia at high doses in rats = 3 mg/kg.

Medical data	Limited data available as cyhalofop-butyl is a new active substance.

Summary

	Value	Study	Safety factor
ADI:	0.003 mg/kg bw/d	78 weeks, mouse; 3 ppm, equal to 0.3 mg/kg bw/d	100
AOEL systemic:	0.03 mg/kg bw/d	90-d, mouse, rat, dog; 3.0 mg/kg bw/d	100
AOEL inhalation:	Not required.		
AOEL dermal:	Not required.		
ARfD (acute reference dose):	Not allocated, not necessary.		

Dermal absorption

On the base of the studies conducted, the mean predicted human dermal absorption values for the concentrate and spray are 1.3% and 11%, while the maximum predicted dermal absorption values for the concentrate and spray are 1.5% and 14%, respectively.

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	36.1 - 46.3% AR (after 120 days)
Non-extractable residues after 100 days:	33.7 - 44.2 % AR (after 120 days)
Relevant metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	Cyhalofop-ACID: 13 - 38% AR after 1-4 hours Cyhalofop-AMIDE: 16 - 36% AR after 8 hours Cyhalofop-DIACID: 22 - 40% AR after 8-24 hours

Supplemental studies

Anaerobic:	Route similar to aerobic degradation. Cyhalofop-ACID: 69% AR after 3 days Cyhalofop-AMIDE: 26% AR after 7 days Cyhalofop-DIACID: 83% AR after 14 days Non-extractable residues: 20% AR after 120 days
Soil photolysis:	Photolysis is not a significant route of degradation in soil, since degradation was more rapid in dark controls. Cyhalofop-ACID: 10.4% AR after 7 days (light) 46% AR after 14 days (dark)
Remarks:	None.

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):

DT_{90}lab (20 °C, aerobic):

Cyhalofop-butyl (four European soils):

DT50	DT90	R^2
3.4 h*	1.1 d*	0.9782*
3.5 h	1.1 d	0.9255
9.8 h	3.1 d	0.8750
3.7 h	1.2 d	0.8977

mean DT_{50} = 5.1 hours

* mean of two radiolabels

Metabolites (four European soils): DT_{50lab}

Cyhalofop-ACID:

DT50	R^2
10 h*	0. 9702*
08 h	0. 9988
10 h	0. 9710
21 h	0. 9877

mean = 12 h

Cyhalofop-AMIDE:

DT50	R^2
23 h*	0. 9843*
24 h	0. 9976
05 h **	-
22 h	0. 9990

mean = 19 h

Cyhalofop-DIACID:

DT50	R^2
3.3 d*	0. 9543*
3.9 d	0. 9798
0.8 d	0.9965
1.5 d	0.9999

mean = 2.4 d

* mean of two radiolabels
** only 2 time points used

DT_{50}lab (10 °C, aerobic):

4 h
(predicted value based on a two-fold decrease in degradation rate for each 10 °C decrease)

DT_{50}lab (20 °C, anaerobic):

Cyhalofop-butyl: << 1 d (four European soils)
Metabolites (one European soil):

Cyhalofop-ACID: 3.2 d (R^2 = 0.9784)

Cyhalofop-AMIDE: 4.8 d (R^2 = 0.9371)

Cyhalofop-DIACID: 21 d (R^2 = 0.9532)

Field studies (country or region)

DT_{50f} from soil dissipation studies:	Field data not required ($DT_{50(lab)}$ < 60 days).
DT_{90f} from soil dissipation studies:	Field data not required ($DT_{50(lab)}$ < 60 days).
Soil accumulation studies:	Field data not required ($DT_{50(lab)}$ < 60 days).
Soil residue studies:	Data not required ($DT_{50(lab)}$ < one third of the period between application and harvest).

Remarks: e.g. effect of soil pH on degradation rate	None.

Adsorption/desorption

K_f / K_{oc}:	<u>Cyhalofop-butyl (ml/g)</u> K_{oc}: 9637, 5775, 2066, 3509; mean = 5247 (n=4) K_d: 77.1, 57.8, 47.5, 45.6; mean = 57.0 (n=4) (determined in sterile soil due to instability in non-sterile soil) <u>Cyhalofop-ACID (ml/g)</u> K_{oc}: 176, 195; mean = 186 (n=2) K_d: 1.41, 1.95; mean = 1.68 (n=2) (estimated from studies with the active substance - metabolite too unstable in soil to test separately) <u>Cyhalofop-AMIDE (ml/g)</u> K_{oc}: 50 (n=1) K_d: 0.40 (n=1) (estimated from studies with the active substance - metabolite too unstable in soil to test separately) <u>Cyhalofop-DIACID (ml/g)</u> K_{oc}: 122, 401, 47, 27; mean = 149 (n=4) K_d: 0.97, 4.01, 1.08, 0.34; mean = 1.60 (n=4) (determined by testing metabolite separately)
pH dependence:	No pH dependence observed for parent ester. Increase in Kd/Koc with decreasing pH for diacid. Not enough data to determine pH dependence for a and amide.

Mobility

Laboratory studies:

Column leaching:	Less than 2% AR in leachate. Extensive degradation observed. Metabolites more mobile than parent, but present in extremely small quantities (< 3% AR).
Aged residue leaching:	Data not required. Adsorption data supplied for metabolites.

Field studies:

Lysimeter/Field leaching studies:	Data not required. Low leaching potential due to very rapid degradation.

Remarks:	None.

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	pH 4, 25 °C: > 1 y pH 7, 25 °C: 97 d pH 9, 25 °C: 2 d pH 1.2, 37 °C: 2 d pH 4, 37 °C: > 1 y pH 7, 37 °C: 31 d pH 9, 37 °C: 0.5 d
Relevant metabolites:	Cyhalofop acid is the only relevant hydrolysis product and is hydrolytically stable.
Photolytic degradation:	First order DT_{50} = 25 - 28 days.
Relevant metabolites:	No phototransformation products > 10% AR.

Biological degradation

Readily biodegradable:	Not readily biodegradable.
Water/sediment study:	
DT_{50} water:	1.7 - 4.5 h (mean = 3.4 h)
DT_{90} water:	5.6 -15 h (mean = 11 h)
DT_{50} whole system:	1.4 - 5.3 h (mean = 3.2 h)
DT_{90} whole system:	4.7 - 18 h (mean = 11 h)
Distribution in water / sediment systems (active substance)	32-56% AR in water and 24-36% AR in sediment immediately after application. Extensive mineralization (53-60% after 98 days).
Distribution in water / sediment systems (metabolites)	Cyhalofop-ACID: max in water 63-77% AR after 6-12 hours, max in sediment 6-10% after 3-14 days, first order DT_{50} = 4.5-8.5 days. Cyhalofop-AMIDE: max in water 10-21% AR after 1-7 days, max in sediment 2-12% after 1-7 days, first order DT_{50} = 3.9-17 days. Cyhalofop-DIACID: max in water 23-56% AR after 7-30 days, max in sediment 8-22% after 14-98 days, first order DT_{50} = 8-43 days.

Accumulation in water and/or sediment:	No accumulation of residues in water or sediment.
Degradation in the saturated zone	Not applicable.
Remarks:	None.

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	5.3 x 10^{-5} Pa at 25°C (purity: 99.5%)
Henry's law constant:	9.51 x 10^{-4} Pa m^3 mol^{-1}

Photolytic degradation

Direct photolysis in air:	Not required.
Photochemical oxidative degradation in air DT_{50}:	6 h
Volatilisation:	From soil and plant surfaces: not required.

Remarks:	None.

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	a.s.: LD_{50} > 5000 mg /kg bw (rat) 200 EC formulation: LD_{50} > 2000 mg /kg bw (>414 mg as/kg) (rat)
Acute toxicity to birds:	a.s.: LD_{50} > 2250 mg /kg bw (bobwhite quail and mallard duck) 200 EC formulation: LD_{50} >2000 mg /kg bw (>414 mg a.s./kg bw) (mallard duck)
Dietary toxicity to birds:	a.s.: LC_{50}>5620 mg /kg (8 d; mallard duck, bobwhite quail)
Reproductive toxicity to birds:	a.s.: NOEC ≥800 ppm (20 w, northern bobwhite)
Short term oral toxicity to mammals:	a.s.: NOEL: 3.0 mg/kg bw/d (90 d; mouse, rat, dog)

Aquatic Organisms

Acute toxicity fish:	Active substance: LC50 = 0.789 mg/l [ab] NOEC = 0.308 mg/l [b] (96 h; *Lepomis macrochirus*) 200 EC formulation EF-1218 LC50 > 1.41 mg/l [abd] NOEC = 0.0289 mg/l [b] (96 h; *Oncorhynchus mykiss*): Active substance DE-537 DIACID: LC50 > 100 mg/l * (96 h; *L. macrochirus*) Active substance DE-537 ACID: LC50 > 100 mg/l (96 h; *L. macrochirus*) LC50 > 100 mg/l (96 h; *O. mykiss*) Active substance DE-537 AMIDE: LC50 > 100 mg/l (96 h; *L. macrochirus*)
Long term toxicity fish:	Active substance DE-537: NOEC = 0.134 mg/l [b] DE-537 DIACID: NOEC = 10 mg/l (28 d; *Pimephales promelas*)
Bioaccumulation fish:	BCF: < 7-8

Acute toxicity invertebrate:	Active substance DE-537: EC50 > 2.7 mg/l [b] (48 h; *Daphnia magna*): 200 EC formulation EF-1218: EC50 = 3.62 mg/l [c] (48 h; *D. magna*): LC50 = 1.74 mg/l (96 h; *Procambarus clarkii*): Active substance DE-537 DIACID: EC50 > 100 mg/l (48 h; *D. magna*): Active substance DE-537 ACID: EC50 > 100 mg/l (48 h; *D. magna*): Active substance DE-537 AMIDE: EC50 > 100 mg/l (48 h; *D. magna*):
Chronic toxicity invertebrate:	Active substance DE-537 DIACID: NOEC = 100 mg/l (21 d; *D. magna*)
Acute toxicity algae:	Active substance DE-537: EC50 > 0.96 mg/l [c] (72 h; *Selenastrum capricornutum*) EC50 > 8.44 mg/l [b] (72 h; *Anabaena flos aquae*) EC50 = 1.33 mg/l [b] (120 h; *Navicula pelliculosa*) 200 EC formulation EF-1218: EC50 =9.71 mg/l [c] (72 h; *S. capricornutum*): Active substance DE-537 DIACID: EC50 > 100 mg/l (72 h; *S. capricornutum*): Active substance DE-537 ACID: EC50 > 100 mg/l (72 h; *S. capricornutum*) Active substance DE-537 AMIDE: EC50 > 50 mg/l(72 h; *S. capricornutum*)
Chronic toxicity sediment dwelling organism:	Active substance DE-537: NOEC = 10 mg/l (28 d; *Chironomus riparius*)
Acute toxicity aquatic plants:	Active substance DE-537: EC50 > 5.3 mg/l [b] (14 d; *Lemna minor*)

[a] LC50 (24h), since effects occurred within 24 hours
[b] measured concentration given as ester equivalents (DE-537 plus acid)
[c] measured concentration
[d] the corresponding measured LC50 (24h) for rainbow trout of DE-537 is >2.23 mg/l (measured NOEC 0.633 mg/l)
* confirmed by a further study submitted

Honeybees

Acute oral toxicity:	LD_{50} >40 µg a.s./bee (200 EC formulation EF-1218) LD_{50} >100 µg a.s./bee (active substance DE-537)
Acute contact toxicity:	LD_{50} >100 µg a.s./bee (200 EC formulation EF-1218) LD_{50} >100 µg a.s./bee (active substance DE-537)

Other arthropod species

	% Effect
Aphidius rhopalosiphi	Mortality: 100 % (adults; 200 EC formulation EF-1218, 0.3 kg a.s./ha)
Aphidius rhopalosiphi (extended laboratory study)	Mortality: 7.7 % (adults; 200 EC formulation EF-1218, 0.3 kg a.s./ha)
Typhlodromus pyri	Mortality: 82 % (protonymphs; 200 EC formulation EF-1218, 0.3 kg a.s./ha)
Lepthyphantes tenuis	Mortality: 30 % (adults; 200 EC formulation EF-1218, 0.3 kg a.s./ha)
Orius laevigatus	Mortality: 10 % (2^{nd} instars; 200 EC formulation EF-1218, 0.3 kg a.s./ha)
Pardosa spp.	Mortality: 10 % (adults; 200 EC formulation EF-1218, 0.3 kg a.s./ha)
Poecilus cupreus	Mortality: 3 % (adults; 200 EC formulation EF-1218, 0.3 kg a.s./ha)

Earthworms

Acute toxicity:	14 day test on *Eisenia foetida:* <u>200 EC formulation EF-1218:</u> LC_{50} = 200 mg/kg (41 mg a.s./kg), NOEC = 104 mg/kg (22 mg a.s./kg) <u>active substance DE-537:</u> LC_{50} >1000 mg/kg, NOEC = 1000 mg/kg <u>active substance DE-537 DIACID:</u> LC_{50} >1000 mg/kg, NOEC = 556 mg/kg
Reproductive toxicity:	Not required.

Soil micro-organisms

Nitrogen mineralization:	<15% deviation from control (up to 1500 g a.s./ha, day 28)
Carbon mineralization:	<10% deviation from control (up to 1500 g a.s./ha, day 28)

N.B. The Company adopted the following codes: XRD-537 (discovery research code) or DE-537 (Development code) to identify different stages of development of the molecule, but in both cases the codes identify Cyhalofop-butyl. EF-1218 is an internal code to identify a specific formulated product containing cyhalofop-butyl whose trademark is Clincher 200 EC.

APPENDIX III

CYHALOFOP-BUTYL

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 1.1	Smith, A.J.	2000	Cyhalpfop-Butyl manufacturing information: impurities. The Dow Chemical Co., Midland (A48) non-GLP, unpublished
IIA 1.11.4	Black, C.K., Healy, J.M. & Putzig, C.L.	1993	Assay of XDE-537 n-Butyl ester (AGR 295713) for use as a technical grade active ingredient. The Dow Chemical Co., Midland, ML-AL 93-030077 (A36) non-GLP, unpublished
IIA 1.11.5	Barr, S.W. & Toner, D.D.	1991	Characterization of R(+) XDE-537nbu sample AGR-295713 for toxicology studies. The Dow Chemical Co., Midland, ML-AL 91-030355 (A37) non-GLP, unpublished
IIIA 2.2	Mc Grath, G.	1998	Determination of surface tension of Cyhalofop butyl EC Herbicide,EF-1218. Huntington Life Sciences, DWC936/972555 DowElanco: GHE-P- 6981 (AM04) GLP Y unpublished
IIA 4.1	Ohdake, J.	1996	Clincher technical herbicide. DowElanco Gotemba Japan, PA-AM-95-7 (O15) non-GLP, unpublished
IIA 4.1	Ohdake, J.	1996	Impurities in Clincher technical herbicide. DowElanco Gotemba Japan; PA-AM-95-8 (O16) non-GLP, unpublished
IIA 4.1	Ohdake, J.	1996	Cyhalofop in Clincher technical herbicide. DowElanco Gotemba Japan, PA-AM-95-9 (O17) non-GLP, unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 4.1	Ohdake, J.	1996	Water in Clincher technical herbicide. DowElanco Gotemba Japanm, PA-AM-95-10 (O18) non-GLP, unpublished
IIA 4.2.1	Nicholson, A.	1998	Independent validation of DowElanco method ERC96.13 for the determination of residues of Cyhalofop in rice. DowElanco Letcombe, REV97-002, GHE-P-6845 (O19) GLP Y, unpublished
IIA 4.2.5	Nicholson, A.	1998	Determination of DE-537 and DE-537 ACID residue in human plasma and urine. DowElanco Letcombe, RV97-019, ERC 97.16 (O20) GLP Y unpublished
IIA 4.2	West, S.D.	1999	Multiresidue Method Testing for Cyhalofop-butyl. Dow AgroSciences Indy, 45308, GH-C 4994 (O21) GLP, unpublished
IIIA 5.1	Knowles, S.J.	1996	Cyhalofop butyl 200 EC herbicide. DowElanco Letcombe, EU-AM-95-7 (O07) GLP, unpublished

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not

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 6.3	Nicholson, A.	1998	The stability of DE-537 Butyl Ester and its Acid metabolite in rice fractions: immature plant, grain and straw under frozen storage conditions. DowElanco Letcombe, ST96-014, GHE-P-7126 (N09) GLP, Y, 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

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 8.1.3	Mitchell, L.R., Beavers, J.B. & Jaber, M.	1999	DE-537 nBE: A reproduction study with the northern bobwhite. Wildlife International,Ltd. 103-428, (J62) GLP, unpublished
IIA 8.2.1	Marino, T.A. & Hogan, C.K.	1999	DE-537 Acid (Cyhalofop): An Acute Toxicity Study With the Rainbow Trout, *Oncorhynchus mykiss* Walbaum. Dow Chemical Company, Midland 991148, DECO HET –DR-0357-2325-003 (J51) GLP, unpublished

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 8.2.1	Marino, T.A., Hogan, C.K., Gilles, M.M. & Rick, D.L.	1999	(R) –2-[4-[4-(Aminocarbonyl)-2-Fluorophenoxy]Phenoxy] Propanoic Acid (DE-537 Amide): An Acute Toxicity Study with the Bluegill Sunfish, Rafinesque. Dow Chemical Company, Midland, 991169, DECO HET DR– 0301–0922 - 002 (J53) GLP, unpublished
IIA 8.2.1	Marino, T.A., Hogan, C.K. & Shabrang, S.N.	1999	(R)-2-(4-(4-Carboxy-2-Fluorophenoxy)Phenoxy) Propanoic Acid (DE-537 Diacid): An Acute Toxicity Study with the Bluegill Sunfish, Rafinesque. Dow Chemical Company, Midland, 991180, DECO HET DR-0342-5705-006 (J53) GLP, unpublished
IIA 8.2.1.	Marino, T.A. Shabrang, S.N & Hogan, C.K.	1999	(R)-2-(4-(2-Fluoro-4-Cyanophenoxy)Phenoxy)Propanoic Acid (DE-537 Acid): An Acute Toxicity Study with the Bluegill Sunfish, *Lepomis macrochirus* Rafinesque. Dow Chemical Company, Midland, 991168, DECO HET DR-0287-1467-010 (J54) GLP, unpublished
IIA 8.2.2.2.	Weinberg, J.T., Kirk, H.D., McFadden, L.G. & Shebrang, S.N.	1999	De-537 n-Butyl Ester: Toxicity to the Early Life Stages of the Fathead Minnow, Pimephales promelas Rafinesque. Dow Chemical Company, Midland, 981120, DEC0 HET-DR-0298-8876-062 (J49) GLP, unpublished
IIA 8.2.4	Marino, T.A.	1999	DE-537 Amide Metabolite: An Acute Toxicity Study with the Daphnia, *Daphnia magna* Straus. Dow Chemical Company, Midland, 991150 DECO HET DR-0301-0922-001 (J55) GLP, unpublished
IIA 8.2.4	Marino, T.A.	1999	DE-537 Acid (Cyhalofop): An Acute Toxicity Study with the Daphnia, *Daphnia magna* Straus. Dow Chemical Company, Midland, 991149, DECO HET DR-0287-1467-009 (J60) GLP, unpublished
IIA 8.2.6	Jenkins, C.A.	1997	De-537 Acid Metabolite Determination of 72-hour EC_{50} to *Selenastrum capricornutum.* Huntingdon Life Sciences, 96/DES409/1168, GHE-T-757 (J22), GLP, unpublished

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or not**
IIA 8.2.6	Jenkins, C.A.	1997	DE-537 Amide Metabolite Determination of 72 hour EC_{50} to *Selenastrum capricornutum.* Huntingdon Life Sciences DES410/970237, GHE-T-762 (J23), GLP, unpublished
IIA 8.2.6	Kirk, H.D., Gilles, M.M., Hugo, J.M. & McFadden, L.G.	1999	Phytotoxicological evaluation of DE-537 N-Butyl Ester Exposed Freshwater Diatom, *Navicula pelliculosa.* Dow Chemical Company, Midland DECO-HET-DR-0298-8876-070 (J44), GLP, unpublished
III A 10.2.1	Carbonell, G	1998	Study of acute toxicity in American red crab (*Procambarus clarkii*) produced by the commercial formulation Clincher 200 g/L EC (EF-1218). InterLab University of Valencia GHE-T-951 (MJ14) GLP, unpublished
8.3.2 10.5.1	Vinall, S.	2001	An Extended-Laboratory Test to Determine the Effects of EF-1218 (200 g/L cyhalofop-butyl) on the predatory mite, *Typhlodromus pyri*