



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Iprodione

5036/VI/98-final

3 December 2002

Review report for the active substance **iprodione**

Finalised in the Standing Committee on Plant Health at its meeting on 3 December 2002
in view of the inclusion of iprodione 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 iprodione, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EEC) No 3600/92⁽¹⁾ laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 2266/2000⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Iprodione 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, Rhône-Poulenc Agro (now Bayer Crop Science) on 15 July 1993, AgriChem on 15 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 iprodione 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 France as rapporteur Member State to carry out the assessment of iprodione on the basis of the dossier submitted by the notifier. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC)

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 259, 13.10.2000, p.27.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

No 3600/92, as well as for other parties with regard to further technical and scientific information; for iprodione this deadline was 30 April 1995.

Only Rhône-Poulenc Agro (now Bayer Crop Science) submitted in time a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore Rhône-Poulenc Agro (now Bayer Crop Science) was considered to be the main data submitter. No information has furthermore been submitted by third parties.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, France submitted on 18 July 1996 to the Commission the report of its examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of iprodione 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 iprodione from the main data submitter on 17 December 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 as well as to the sole data submitter, on 18 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 Pesticide Safety Directorate (PSD) in York, United Kingdom, from March to July 1998.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the sole data submitter on 4 September 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 September 1999 to December 2002, and was finalised in the meeting of the Standing Committee on 3 December 2002.

These documents were also submitted to the Scientific Committee for Plants for separate consultation. The Scientific Committee was asked to comment on the predicted environmental concentrations in soil and groundwater, and on the acceptable operator exposure level proposed

by the rapporteur. In its opinion⁵ the Committee agreed that sufficient information was available to reliably estimate the leaching behaviour of the substance for soils with pH above 6. However, leaching in soils with pH below 6 deserves further attention, as groundwater contamination above 0.1 µg/l may occur in some realistic vulnerable situations when the substance is used at high rates. The Committee saw no need for a correction factor for oral absorption, nor for the use of an additional safety factor for the establishment of the acceptable operator exposure level. The observations of the Scientific Committee were taken into account in this Review Report.

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

2. Purposes of this review report

This review report, including the background documents and appendices thereto, have been developed and finalised in support of the Directive **2003/31/EC**⁶ concerning the inclusion of iprodione in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing iprodione they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

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

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

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

⁵ Opinion of the scientific Committee on Plants on specific questions from the Commission concerning the evaluation of iprodione in the context of Council Directive 91/414/EEC. SCP/IPRODIO/002-final adopted 31 January 2002.

⁶ OJ N° L101, 23.4.03, p. 3.

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 iprodione 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 iprodione 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:

- Fungicide to be used on vines, fruits, vegetables, arable crops, ornamentals, turf and for seed treatment⁷.

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

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is 20 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Additional intake from water and products of animal origin are not expected to give rise to intake problems. An Acute Reference Dose was not allocated.

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 iprodione 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 sole data submitter Rhône-Poulenc Agro (now Bayer CropScience), none of the manufacturing impurities

⁷ Details on the uses investigated are provided in the background documents.

considered are, on the basis of information currently available, of toxicological or environmental concern.

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.

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 iprodione

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 : Member States should pay particular attention to the potential for ground water contamination when the active substance is applied **at high use rates** (in particular use in turf) on acidic soils (pH below 6) under vulnerable climatic conditions.

Aquatic organisms : Member States must carefully consider the risk to aquatic invertebrates if the active substance is applied directly adjacent to surface waters. Risk mitigation measures should be applied, where appropriate.

7. List of studies to be generated

No further studies were identified which were at this stage considered necessary in relation to the inclusion of iprodione 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. In particular field dissipation studies on iprodione and its metabolites may be required at Member State level, which may also trigger long term studies for soil organisms.

Residues trials data are required at member state level for the following crops: cherry, strawberry, banana, kiwi fruit, tomato, onion, pepper, aubergine, cucumber, gherkins, courgette, melon, watermelon, flowering brassica, lettuce and similar crops, kohlrabi, spinach, herbs, peas (fresh), asparagus, celery and rice

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.

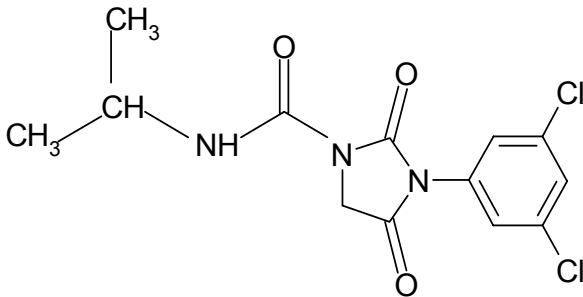
9. Updating of this review report

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 iprodione in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

IPRODIONE

Common name (ISO)	Iprodione
Chemical name (IUPAC)	3-(3,5-dichlorophenyl)-N-isopropyl-2,4-dioxoimidazolidine -1-carboxamide
Chemical name (CA)	3-(3,5-dichlorophenyl)-N-(1methyl ethyl)-2,4-dioxo-1-imidazolidine carboxamide
CIPAC No	278
CAS No	(36734-19-7)
EEC No	253 -178-9
FAO SPECIFICATION	960 g/kg - (loss on drying maximum 10 g/kg)
Minimum purity	960 g/kg
Molecular formula	C ₁₃ H ₁₃ Cl ₂ N ₃ O ₃
Molecular mass	330.17
Structural formula	

Melting point	134 °C
Boiling point	Not relevant (iprodione is a solid at room temperature)
Appearance	White crystalline powder
Relative density	996 g/l (20 °C)
Vapour pressure	5 · 10 ⁻⁷ Pa (for pure compound at 25 °C) 4 · 10 ⁻⁵ Pa (for pure compound at 51 °C)
Henry's law constant	0.7 · 10 ⁻⁵ Pa·m ³ ·mol ⁻¹
Solubility in water	96.1 % pure but acceptable pH 3: 13 mg/l at 20 °C pH 7: 12.2 mg/l at 20 °C pH 9: unstable
Solubility in organic solvents	At 20°C: hexane: 0.59 g/l toluene: 147 g/l n-octanol: 10 g/l acetonitrile: 168 g/l acetone: 342 g/l ethyl acetate: 225 g/l dichloromethane: 450 g/l
Partition co-efficient (log P_{ow})	pH 3: 2.99 pH 5: 3.0
Hydrolytic stability (DT₅₀)	pH = 5 at 25°C Iprodione: DT ₅₀ = 146 d (phenyl ¹⁴ C) pH = 7 at 25°C Iprodione: DT ₅₀ = 3 d (phenyl ¹⁴ C) pH = 8 at 25°C Iprodione: DT ₅₀ = 0.2d (phenyl ¹⁴ C)
Dissociation constant	Not relevant (no protonation; no dissociation occurs in water).
Quantum yield of direct photo-transformation in water at ε >290 nm	Not relevant (no phototransformation occurs; iprodione does not absorb between 295 & 650 nm).
Flammability	Product starts to ignite at 150°C – 200°C.
Explosive properties	Not explosive.
UV/VIS absorption (max.)	Maximum 204.5 nm, ε = 44333 l·mol ⁻¹ ·cm ⁻¹ at 295 nm in acetonitrile ε less than 10
Photostability in water (DT₅₀)	Under simulated sunlight: DT ₅₀ about 67 d at pH 5 and 25 °C DT ₅₀ : < 1 h at pH 9 Stability is pH-dependent.

APPENDIX II

END POINTS AND RELATED INFORMATION

IPRODIONE

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rapidly absorbed, at least 60 %: conservative estimate based on urine : 53 % (male) - 67 % (female)
Distribution:	Widely distributed.
Potential for accumulation:	None.
Rate and extent of excretion:	Rapid: 98 % in urine and faeces over 96 h after single oral dose: predominantly in urine
Toxicologically significant compounds:	Parent compound, RP36115 (10 %), RP36112. Plant residues similar to animal metabolites.
Metabolism in animals:	Extensive (approximately 95 % of absorbed dose \approx 20 metabolites)

Acute toxicity

Rat LD ₅₀ oral:	> 2000 mg/kg bw
Rat LD ₅₀ dermal:	> 2500 mg/kg bw
Rat LC ₅₀ inhalation:	> 5.16 mg/l air
Skin irritation:	Non irritant.
Eye irritation:	Non irritant.
Skin sensitization (test method used and result):	Non-sensitiser (Buehler).

Short term toxicity

Target / critical effect:

Liver, adrenal, testes, ovary, prostate, kidney, haematology, seminal vesicles (weight changes, hyperplasia, atrophy)

Lowest relevant oral NOAEL / NOEL:

31 mg/kg bw/d (90-d rat study)

Lowest relevant dermal NOAEL / NOEL:

Rabbit / 21-d : 100 mg/kg bw/d

Lowest relevant inhalation NOAEL / NOEL:

None. No study required.

Genotoxicity

No genotoxic potential.

Long term toxicity and carcinogenicity

Target / critical effect:

Rat/mouse: liver, adrenals, kidney, testes, ovary, accessory genital organs, extramedullary hematopoiesis, spleen hemosiderosis

Lowest relevant NOAEL:

6.1 mg/kg bw/d (2 y rat study)

Carcinogenicity:

Rat : Intestinal Leydig cell tumours
Mouse : benign & malignant liver cell tumours in 2 sexes; luteomas of ovary**Reproductive toxicity**

Target / critical effect - Reproduction:

Pup viability and weight at parentally toxic dose levels.

Lowest relevant reproductive NOAEL / NOEL:

17 mg/kg bw/d

Target / critical effect - Developmental toxicity:

Rat: body weight; delayed development, ano-genital distance at maternal toxic dose levels
Rabbit: abortions, post implantation loss at maternal toxic dose levels.

Lowest relevant developmental NOAEL / NOEL:

20 mg/kg bw/day (rat and rabbit)

Delayed neurotoxicity

None expected. No study required.

Other toxicological studies

Inhibition of testosterone secretion *in vivo* and *in vitro*.
Weak competitive androgen receptor binding.
No effect of iprodione on plasma and testicular levels of testosterone *in vivo*.
Inhibition of cholesterol transport into mitochondria.
Inhibition of enzyme activities.
Induction of cytp450 and hepatocyte proliferation

Medical data

No reported adverse effects in workers, or poisoning incidents.

Summary

	Value	Study	Safety factor
ADI:	0.06 mg/kg bw/day	2 year rat oral study	100
AOEL systemic:	0.3 mg/kg bw/day	90 d oral rat study	100
AOEL inhalation:	Not allocated (not necessary)		
AOEL dermal:	Not allocated		
ARfD (acute reference dose):	Not allocated (not necessary)		

Dermal absorption

1 % (based on rat *in vivo*, and rat and human *in vitro*)

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

Phenyl moiety : 5 %

Non-extractable residues after 100 days:

Soil pH < 5.8: max. 75 % radioactivity
Soil pH = 7.6: 40 to 60 % radioactivity

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

RP 30228: max. 31 %
RP 36221: max. 17 %

Note:

- RP 30228 is a transposition product (possibility of reformation of iprodione from RP 30228 : not relevant in aerobic soil conditions) ;
- formation of RP 36221 is transient

Supplemental studies

Anaerobic:

RP 30228 : max. 53 % (81 d)

Soil photolysis:

RP 25040 + LS70942 (mixture): 14 % (7 d)

Remarks:

None.

Rate of degradation

Laboratory studies

Method of calculation: estimation of first half-life

Iprodione:

DT₅₀lab (20 °C, aerobic):

pH : 6.8 = 26 d (at 25 °C)

DT₉₀lab (20 °C, aerobic):

pH : 6.8 = 85 d

DT₅₀lab (10 °C, aerobic):

pH : 6.8 = 160 d (at 15 °C)

DT₅₀lab (20 °C, anaerobic):

pH 7.3, loamy soil = 31-65 d

RP 30 228

DT₅₀lab and DT₉₀lab (20 °C, aerobic):

No calculation (degradation very limited)

DT₅₀lab (20 °C, anaerobic) :

pH 6.3 = 24.35 d (first order) in the aqueous phase and stable in the solid phase

DT₉₀lab (20 °C, anaerobic):

pH 6.3 = 80.87 d (first order) in the aqueous phase and stable in the solid phase

Field studies (country or region)DT_{50f} from soil dissipation studies:DT_{90f} from soil dissipation studies:

Soil accumulation studies:

Soil residue studies:

Remarks:

e.g. effect of soil pH on degradation rate

Adsorption/desorptionK_f / K_{oc}:K_d

pH dependence:

K_f / K_{oc} (metabolites):**Mobility****Laboratory studies:**

Column leaching:

Aged residue leaching:

Field studies:

Lysimeter/Field leaching studies:

Remarks:

Method of calculation : estimation of first half-life

US sites	Organic loam soil (North Carolina) pH = 4.8-6.3	Sandy low organic soil (California) 7.9-8.5
Iprodione :	42 d	126 d
RP 30 228	319 d	215 d

Iprodione : DT_{90f} : not calculated
RP 30228 : DT_{90f} : not calculated

no accumulation

Repeated treatments

pH 5.7 DT₅₀ = 60 d - 25 d - 5 dpH 6.5 DT₅₀ = 30 d - 12 d - 4 d

see above

very limited degradation under pH 6.

Iprodione

K_f: 0.2 - 6.52K_{oc}: 202 - 543 (4 soils)

1/n: 1 - 0.89

no evidence

RP 30228

K_{oc}: 6608 - 58120 (3 soils)

1/n: 1.2 - 2.6

4 soils

Leachate : 0.2 - 1.9 % of total

4 soils	leachate %	a.s.	RP30228	RP35606
Sand (96 %)	52.2	6.3	13.1	27.1

Other <1
soilsUS data submitted not sufficient, no further data
required at this time.

None.

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

pH = 5 Iprodione:	DT ₅₀ = 146 d (phenyl ¹⁴ C)
pH = 7 Iprodione:	DT ₅₀ = 3 d (phenyl ¹⁴ C)
pH = 8 Iprodione:	DT ₅₀ = 0.2d (phenyl ¹⁴ C)

Relevant metabolites:

pH = 5 Metabolites: mainly RP 35606 (11.4 % after 30 d)
pH = 7 Metabolites: mainly RP 35606 (15 % max after 125 h) - DT ₅₀ = 1.1 d (25°C) and RP30228 (46 % after 125 h, DT ₅₀ not calculated as RP 30228 is stable)
pH = 8 Metabolites: mainly RP 30228 (max 92 % after 2 h, DT ₅₀ : 1.8 d) RP 356 06 : DT ₅₀ = 2.1 d (25°C)

Photolytic degradation:

DT ₅₀ = 67 d (simulated sunlight - phenyl ¹⁴ C)

Relevant metabolites:

Metabolites < 10%

Biological degradation

Readily biodegradable:

Not readily biodegradable.

Water/sediment study:

DT₅₀ water:

For iprodione < 6 h (pH 7.5 - 7.9) Metabolites: RP 35606 and RP 30228
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DT₉₀ water:

For iprodione according to DT ₅₀ (pH 7.5 - 7.9)
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DT₅₀ whole system:

< 30 d

DT₉₀ whole system:

< 30 d

Distribution in water / sediment systems
(active substance)

Immediate: > 76 % radioactivity in water after 100 d: 77 to 81 % in the sediment and ≈ 6 % in water. Iprodione rapidly degraded with rapid transfer of degradation products to sediment. Slow decrease of bound degradation products in sediment.

Distribution in water / sediment systems
(metabolites)

RP 35606 in surface water decreases from 71.3% until < 5% after 60 d with less of 5% in sediment
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Accumulation in water and/or sediment:

RP30228 does not exceed significantly 10% (24 h) in surface water reaching 70% in sediment.

no accumulation of iprodione in water RP 30228 : very limited degradation in the entire system

Degradation in the saturated zone

No data provided. Not required

Remarks:

None.

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

$5 \cdot 10^{-7}$ Pa (for pure compound at 25 °C)

$4 \cdot 10^{-5}$ Pa (for pure compound at 51 °C)

Henry's law constant:

$0.7 \cdot 10^{-5}$ Pa·m ³ ·mol ⁻¹
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Photolytic degradation

Direct photolysis in air:

Not required

Photochemical oxidative degradation in air

DT ₅₀ : 85 min

DT₅₀:

Volatilisation:

From plant surfaces:	not required
From soil:	< 0.1 %

Remarks:

None.

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD ₅₀ (rat) > 2000 mg/kg
Acute toxicity to birds:	LD ₅₀ (bobwhite quail/mallard duck) > 2000 mg/kg bw
Dietary toxicity to birds:	LC ₅₀ (bobwhite quail/mallard duck) > 5620 ppm
Reproductive toxicity to birds:	NOEC = 300 ppm (quail) NOEC = 300 ppm (mallard duck)
Short term oral toxicity to mammals:	NOEL (90 d-rat): 300 ppm

Aquatic Organisms

Acute toxicity fish:	LC ₅₀ (trout): 4.1 mg a.s./l LC ₅₀ (bluegill): 3.7 mg a.s./l LC ₅₀ (different species) 3.1-7.7 mg a.s./l
Long term toxicity fish:	NOEC (34 days): 0.26 mg a.s./l
Bioaccumulation fish:	BCF: 34.8 (edible); 46.8 (non edible); 70 (whole fish)
Acute toxicity invertebrate:	EC ₅₀ (daphnids) 48h : 0.66 mg a.s./l
Chronic toxicity invertebrate:	NOEC (21 days): 0.17 mg a.s./ha
Acute toxicity algae:	EC ₅₀ : 1.8 mg a.s./l
Chronic toxicity sediment dwelling organism:	not relevant
Metabolite RP 30228 :	
Acute toxicity fish:	LC ₅₀ (bluegill): 0.55 mg /l
Acute toxicity algae:	EC ₅₀ : (<i>S. subspicatus</i>) 0.5 mg /l
Chronic toxicity sediment dwelling organism:	NOEC 28 d (<i>Chironomus riparius</i> : 100µg/l)

Honeybees

Acute oral toxicity:	LD ₅₀ > 25 µg/bee
Acute contact toxicity:	LD ₅₀ > 200 µg/bee

Other arthropod species

<i>Aphidius matricariae</i> (adults)	Effect (beneficial capacity ¹) = - 13.9 % (0.75 kg a.s./ha; test substance : WP 50%)
<i>Aphidius rhopalosiphi</i> (adults)	Effect (beneficial capacity ¹) = - 9 % (15 kg a.s./ha; test substance : WP 50%)
<i>Trichogramma cacoeciae</i> (adults)	Effect (beneficial capacity) = + 91 % (0.78 kg a.s./ha; test substance : WP50%)
<i>Trichogramma cacoeciae</i> (pupae in host eggs)	Effect (beneficial capacity) = 0 % (0.78 kg a.s./ha; test substance : WP50%)
<i>T. pyri</i> (protonymphs)	Effect (beneficial capacity) = + 84.3 % (0.75 kg a.s./ha; test substance : WP50%)
<i>T. pyri</i> (protonymphs)	Effect (beneficial capacity) = + 11.9 % (15 kg a.s./ha; test substance : WP 50%)
<i>Poecilus cupreus</i> (adults)	Effect (mortality) = 0 % Effect (food consumption) = 0% (15 kg a.s./ha; test substance : WP 50%)
<i>C. carnea</i> (larvae)	Effect (beneficial capacity) = + 20.6 % (0.78 kg a.s./ha; test substance : WP 50%)
<i>C. carnea</i> (larvae)	Effect (mortality) = 0 % Effect (fecundity) = 1.15 ² (15 kg a.s./ha; test substance : WP 50%)
<i>C. 7-punctata</i> (larvae)	Effect (beneficial capacity) = - 7.2 % (0.78 kg a.s./ha; test substance : WP50%)
<i>E. balteatus</i> (larvae, adults)	Effect (beneficial capacity) = + 6.3 % (0.78 kg a.s./ha; test substance : WP50%)

¹ reduction (+) or increase (-) of beneficial capacity² ratio untreated/treated**Earthworms**

Acute toxicity:

> 1000 mg a.s./kg soil

Reproductive toxicity

iprodione : NOEC = 1000 mg/kg soil
RP 30228 : NOEC = 1000 mg/kg soil

RP 32596 : NOEC = 100 mg/kg soil

Soil micro-organisms

Nitrogen mineralization:

At 2 and 10 mg/kg soil: no effect

Carbon mineralization:

At 2 and 10 mg/kg soil: no effect

APPENDIX III A

IPRODIONE

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

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

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports² on previous use in granting national authorizations
IIA,1 Doc. J	Chabert, M. & Chabassol, Y.	1991	Iprodione Technical Grade. Analysis and certification of product ingredients. Rhône-Poulenc Report R&D/CRLD/AN/9115023 (April 1991) GLP, unpublished	
IIA,1 Doc. J	Cousin J. & Valcarce M.H.	1995	Technical iprodione. Analysis and certification of product ingredients. Rhône-Poulenc Report R&D/CRLD/AN/9416886 (January 1995) GLP, unpublished	
IIA,2.3	Cousin, J.	1994	Iprodione active ingredient. Henry's law constant Rhône Poulenc Report No 9416666 (November 1994) GLP, unpublished	
IIA, 2.6	Bascou, J.P.	1991	Iprodione technical grade. Solubility in water at 20°C GLP = yes Published : No Owner : Rhône Poulenc	
IIA,2.9	Cousin, J.	1994	Iprodione. dissociation constant (Assessment) Rhône Poulenc Report No 9416667 (November 1994) GLP : not applicable, unpublished	
IIA,2.10	Maestracci, M.	1994	Iprodione. Estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions Rhône-Poulenc Report No 9416338 (September 1994) GLP, unpublished	
IIA,2.11	Fillion, J.	1995	Determination of the flammability and the relative self-ignition temperature of "iprodione technique" Rhône Poulenc Report No 95-037-SEC (March 1995) GLP, unpublished	
IIA,2.11	Fillion, J.	1995	Determination of the flammability and the relative self-ignition temperature of "iprodione micronisé" Rhône Poulenc Report No 95-042-SEC (March 1995) GLP, unpublished	

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, 2.13	Colbalchini, C	1994	Determination of the explosion properties of iprodione Rhône Poulenc Report No 94-020-SEC (November 1994) GLP, unpublished	
IIA,2.14	Cousin, J.	1995	Iprodione active ingredient surface tension Rhône Poulenc Report No 9515121 (January 1995) GLP, unpublished	
IIA,2.15	Cousin, J.	1994	Iprodione active ingredient oxidizing properties (Assessment) Rhône Poulenc Report No 9415744 (May 1994) GLP : not applicable, unpublished	
IIA,4.1 Doc. J	Chabert, M & Chabassol, Y.	1990	Method I-465-09-90-E Technical iprodione. GC determination of RP32870. Rhône-Poulenc Report AG/CRLD/AN/9016517 (October 1990) GLP , unpublished	
IIA,4.1 Doc. J	Chabert, M & Chabassol, Y.	1991	Method I-618-12-90-E Technical iprodione. HPLC Determination of Impurities RP32872, RP37540 and RP41608 Rhône-Poulenc Report AG/CRLD/AN/9115039 (January 1991) GLP, unpublished	
IIA,4.1 Doc. J	Chabert, M. & Chabassol, Y.	1991	Method I-619-12-90-E HPLC determination of RP25039, RP25040, RP25331, RP25710, RP26018, RP26020, RP30228, RP32596, RP32871, RP36221, RP37176, RP37177, RP37364, RP37506, RP40837, RP42196, RP70061, RP404017. Rhône-Poulenc Report AG/CRLD/AN/9115048 (January 1991) 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	Reports² on previous use in granting national authorizations
IIA,4.2.1	Guillet, M. & Yslan, F.	1998	Iprodione and its metabolites : replacement of benzene by toluene In the analytical methods for their determination in products of animal origin, exemplified with milk Rhône-Poulenc Report N 9816725 (October 1998) GLP, unpublished	
IIA,4.2.1	Simonin, B.	1997	Method AR 144-97 Iprodione: analytical method for the determination of residues in plant products Rhône-Poulenc Report R&D/CRLD/AN/9716244 (September 1997) GLP, unpublished	

B.6. Toxicology & 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,5.1	Souza, G.A.D	1993	(¹⁴ -C) -iprodione: absorption, metabolism and excretion in the rat. Hazleton Europe Report No 198/61- 1011 (October 1993) GLP, unpublished	
IIA,5.2	Nachreiner, D.J.	1993	Iprodione: Acute dust inhalation toxicity study in rats. Union Carbide Report No BRRC 93N1216 (August 1993) GLP, unpublished	
IIA,5.3	Bigot, D.	1997	Iprodione. 90-day toxicity study in the rat by dietary administration Rhône-Poulenc Report SA 96277 (July 1997) GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA,5.3	Gopinath, C. Ames, S.A.	1993	Iprodione Retrospective subacute toxicity to rats by dietary administration for 13 weeks HRC Report No RNP 322/93/320 (September 1993) (Supplement to RNP 322/90767) GLP, unpublished	
IIA,5.3	Kangas, L.	1995	A 52 week dietary toxicity study of iprodione in the Beagle dog. Final report amendment no 1. BIO report No 84296 (April 1995) GLP : not applicable, unpublished	
IIA,5.3	Siglin, J.C.	1991	21-day dermal toxicity study in rabbits with iprodione technical SLS Report No 3147.107 (August 1991) GLP, unpublished	
IIA,5.4	Proudlock R.J. Elnore, E.A.	1994	Iprodione. Mouse micronucleus test. Huntingdon Research Report No RNP 442/941483 (August 1994) GLP, unpublished	
IIA, 5.5	Bars, R.	1995	Iprodione. Mechanism of testicular toxicity/ carcinogenicity in rat. Rhône-Poulenc Position paper (January 1995) GLP: not applicable, unpublished	
IIA,5.5 IIA,5.8	Bars, R.	1997	Iprodione. Mechanism of toxicity and carcinogenicity in rodents. Rhône-Poulenc Position Paper (January 1997) GLP: not applicable, unpublished	
IIA,5.5	James, R.W.	1993	Iprodione. Evaluation of observations related to the testes and ovaries in rat and mouse long term dietary studies. Huntingdon Evaluation (June 93) GLP: not applicable, unpublished	
IIA,5.5	Urtizberrea, M.	1993	Iprodione. Carcinogenicity in rodents. Rhône-Poulenc Position Paper (July 93) GLP: not applicable, unpublished	
IIA,5.5	Chambers, P.R <i>et al.</i>	1992	Iprodione. Potential tumorigenic and toxic effects in prolonged dietary administration to rats (10 volumes). HRC Report No RNP 346/920808 (December 1992) GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA,5.5	Chambers, P.R <i>et al.</i>	1993	Iprodione. Potential tumorigenic effects in prolonged dietary administration to mice (10 volumes). HRC Report No RNP 359/921240 (May 1993) GLP, unpublished	
IIA,5.6	Repetto-Larsay, M.	1997	Iprodione: Toxicology study in pregnant rat by gavage to examine sex differentiation. Rhône-Poulenc Report no SA96448 (June 1997) GLP, unpublished	
IIA,5.6	Bars, R.	1997	Iprodione. Discussion on the effects of iprodione on pregnancy and on parameters of sex differentiation in the rat Rhône-Poulenc Position Paper (March 1997) GLP: not applicable, unpublished	
IIA,5.6	Bars, R.	1998	Iprodione. Discussion on the effects of iprodione on pregnancy and on parameters of sex differentiation in the rat. Rhône-Poulenc Position Paper (June 1998) GLP: not applicable, unpublished	
IIA,5.8	Eldridge, S	1996	Cell proliferation in rat testes SAI report (August 1996) GLP, unpublished	
IIA,5.8	Groene, E.M..	1999	Human androgen receptor binding assay with the fungicide iprodione and 7 mammalian metabolites TNO Report No V99.616 (June 1999) GLP, unpublished	
IIA,5.8	Bigot, D.	1996	Iprodione.Exploratory 14-day toxicity study in the mouse by dietary administration Rhône-Poulenc Report SA95131 (October 1996) GLP, unpublished	
IIA,5.8	Benahmed, M.	1995	Update on the effects of iprodione and its metabolites on testosterone secretion in cultured Leydig cells. INSERM Report (January 95) (replaced by report INSERM No U407/95001, audited (July 1995) 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	Reports on previous use in granting national authorizations
IIA,5.8	Benahmed, M.	1996	Effects of iprodione and its metabolites RP36112 and RP36115 on testosterone secretion in cultured Leydig cells: sites of action. INSERM Report U407/96001 Lyon (October 1996) Non GLP, unpublished	
IIA,5.8	Fail P.A., <i>et al.</i>	1996	Toxicity Testing of a Fungicide, Iprodione: Endocrine toxicology studies of testes from Adult Male CD Sprague Dawley Rats exposed to iprodione <i>in vitro</i> , RTI Report no 532 (November 1996) GLP, unpublished	
IIA,5.8	Fail P.A., <i>et al.</i>	1994	Toxicity Testing of a Fungicide, Iprodione, in Adult Male CD Sprague Dawley Rats. RTI Report No -65C-5703 (October 1994) GLP, unpublished	
IIA,5.8	Fail P.A., <i>et al.</i>	1996	Toxicity Testing of a Fungicide, Iprodione: Endocrine toxicology studies of testes from Adult Male CD Sprague Dawley Rats exposed to iprodione <i>in vivo</i> . RTI Report no 527 (November 1996) GLP, unpublished	
IIA,5.9	Urtizbera, M.	1993	Iprodione. Medical survey observations. Rhone-Poulenc Memo No MU/NC-93/136-T0X (May 1993) GLP: not applicable, unpublished	
IIA,5.12	Ward, R.J.	1997	Iprodione: <i>In vitro</i> absorption from a 500 g/l SC formulation through human and rat epidermis CTL Report no P/ 5295 (August 1997) GLP, unpublished	
IIA,5.12	Cheng, T.	1994	Dermal absorption of ¹⁴ C-Iprodione (ROVRAL [®] 4F) in male rats Hazleton Wisconsin Inc Report no HWI 6224-208 (October 1994) GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA,5.12	Ward, R.J.	1997	Iprodione : <i>In vitro</i> absorption from a 500 g/l SC formulation through human and rat epidermis CTL Report no P/5295 (August 1997) GLP, unpublished	
IIA,5.5	Gopinath, G & Offer, J.M.	1998	Review of interstitial cell adenomas in historical control data HLS Document (June 1998) GLP, unpublished	

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA,6.6	Muller, M.A.	1994	Iprodione. Formulation EXP01671H(WP). Israel 1993 Residue in citrus (minneola tangelo). Rhône-Poulenc Report No 9415471 (April 1994) GLP, unpublished	
IIA,6.6	Viljoen, A.J.	1994	Determination of iprodione residues in a citrus sample SABS Report No 311/88739/L106 (September 1994) Non GLP, unpublished	
IIA,6.6	Viljoen, A.J.	1994	Determination of iprodione residues in a citrus sample SABS Report No 311/88740/L107 (September 1994) Non GLP, unpublished	
IIA,6.6	Viljoen, A.J.	1994	Determination of iprodione residues in a citrus sample SABS Report No 311/88745/L115 (September 1994) 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	Reports on previous use in granting national authorizations
IIA,6.6	Muller, M.A.	1994	Iprodione. Formulation EXP01861I ou Kidan (SC) - Iprodione Formulation EXP01862F (SC). Essais France 1994 - Résidus dans la cerise Rhône-Poulenc Report No 9416720 (December 1994) GLP, unpublished	
IIA,6.6	Richard, M & Muller, M.A.	1994	Iprodione. Formulation EXP01861I ou KIDAN (SC) - Essai France 1993. Résidus dans la cerise. Etude de décroissance Rhône-Poulenc Report No 9416572 (November 1994) GLP, unpublished	
IIA,6.6	Muller, M.A.	1995	Iprodione. Formulation EXP01862F (SC). Essais France 1994 - Résidus dans le raisin de table (study n°94-541) Rhône-Poulenc Report No 9515253 (March 1995) GLP, unpublished	
IIA,6.6	Mestres, R.	1994	Expérimentations résidus légumes 1992. ROVRAL FLO sur céleri rave en traitement de post récolte Service de la Protection des Végétaux Report No R. CELE 92 04/01(June 1994) GLP: not specified, unpublished	
IIA,6.6	Richard, M. & Muller, M.A.	1994	Iprodione. Formulation EXP01862F (SC) Essais France 1992-1993. Résidus dans le céleri-rave Rhône-Poulenc Report No 9415356 (March 1994) GLP, unpublished	
IIA,6.6	Mestres, R.	1994	Expérimentations résidus légumes 1992 ROVRAL FLO sur radis Service de la Protection des Végétaux Report No R. RADI 92 01/05 (June 1994) GLP : not specified, unpublished	
IIA,6.6	Muller, M.A.	1994	Iprodione. Formulation EXP01862F (SC). Essais France 1992-Résidus dans le radis Rhône-Poulenc Report No 9415355 (March 1994) GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA,6.6	Mestres, R.	1994	Expérimentations résidus légumes 1992. ROVRAL FLO sur concombre Service de la Protection des Végétaux Report No R.CONC 92 01/07(June 1994) GLP : not specified, unpublished	
IIA,6.6	Mestres, R.	1994	Expérimentations résidus légumes 1992. ROVRAL FLO sur cornichons en application foliaire Service de la Protection des Végétaux Report No R.CORN 92 01/08 (June 1994) GLP : not specified, unpublished	
IIA,6.6	Richard, M. & Muller M.A.	1994	Iprodione Formulation EXP01862F ou ROVRAL AQUA FLO (SC) Essais France 1993. Résidus dans le poireau Rhône-Poulenc Report No 9416505 (October 1994) GLP, unpublished	
IIA,6.6	Muller, M.A.	1994	Iprodione-carbendazime. Formulation EXP01926C(SC) Essais France 1993. Résidus dans la lentille Rhône-Poulenc Report No 9416339 (October 1994) GLP, unpublished	
IIA,6.6	Muller, M.A.	1994	Iprodione-carbendazime. Formulation EXP01862FC(SC) - Essais France 1993. Résidus dans lentilles Rhône-Poulenc Report No 9416343 (October 1994) GLP, unpublished	
IIA,6.6	Richard, M. & Muller, M.A.	1994	Iprodione-carbendazime. Formulation EXP.01926C(SC) - Essais France 1992. Résidus dans la lentille Rhône-Poulenc Report No 9415289 (March 1994) GLP, unpublished	
IIA,6.6	Richard, M. & Muller, M.A.	1994	Iprodione. Formulation EXP.01862F(SC). Essais France 1992 Rhône-Poulenc Report No 9415409 (March 1994) GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA,6.6	Richard M., Muller M.A.	1994	Iprodione- Chlorothalonil - Formulation EXP02348C (SC). Essais France 1992- Résidus dans le pois proteagineux. Étude 92-150 Rhône-Poulenc Report No 9415030 (January 1994) GLP, unpublished	
IIA,6.6	Richard, M. & Muller, M.A.	1994	Iprodione - carbendazime - diniconazole. Formulation - EXP02189A ou SUMISTAR (SC) Essai France 1991. Résidus dans le colza (Etude de décroissance). Rhône-Poulenc Report No 9415452 (March 1994) GLP, unpublished	
IIA,6.6	Muller, M.A.	1993	Iprodione - carbendazime - diniconazole. Formulation - EXP02189A ou SUMISTAR (SC) Essai France 19921. Résidus dans le tournesol (étude N° 92-149) Rhône-Poulenc Report No 9316979 (November 1993) GLP, unpublished	
IIA,6.6	Bird, S.J.	1994	Seed treatment - Iprodione: Residue study of linseed after treatment with EXP80038C or ROVRAL WP Rhône-Poulenc Report No 200688 (September 1994) GLP, unpublished	
IIA,6.6	Gillings, O.	1993	ROVRAL canola (rape seed) 1990 residue program Rhône-Poulenc Report No 41188 (June 1993) GLP, unpublished	
IIA,6.6	Richard, M.& Muller, M.A.	1994	Iprodione - carbendazime - diniconazole. Formulation EXP02189A ou SUMISTAR(SC) Essai France 1991. Résidus dans le colza (Etude de décroissance) Rhône-Poulenc Report No 9415452 (March 1994) GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA,6.6	Richard, M.& Muller, M.A.	1994	Iprodione - carbendazime - diniconazole. Formulation EXP02189A ou SUMISTAR (SC). Essai France 1991- Résidus dans le colza (Huile et tourteau) Rhône-Poulenc Report No 9415458 (March 1994) GLP, unpublished	

B.8 Environmental fate & 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	Burr, C.M. Newby, S.E.	1994	Iprodione: Adsorption/ desorption to and from four soils and an aquatic sediment. Rhône-Poulenc Report No P94/014 (June 1994) GLP, unpublished	
IIA,7.1	Cooper, J.L.D. <i>et al.</i>	1998	[14C]-RP030228 - Rate of degradation in three soil types under aerobic conditions Rhône-Poulenc Report No 12113 (June 1998) GLP, unpublished	
IIA,7.1	Leake, C.	1998	Iprodione: Degradation of soil metabo RP30228 under anaerobic conditions Rhône-Poulenc Position Paper (October 1998) GLP : not applicable, unpublished	
IIA,7.1	Mamouni, A.	1999	[14C]-RP30228 (metabolite of iprodione) Hydrolysis at four different pH values ; investigation as possible reformation of iprodione RCC Report No 732824 (December 1999) GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA,7.1	Unsworth, R.H.& Clarke, D.E.	1999	[14C]-RP30228: anaerobic soil metabolism Rhône-Poulenc Report no 16828 (December 1999) GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA,7.1	Mamouni, A.	1999	[14C]-RP35606 (intermediate hydrolysis product of iprodione) Hydrolysis at four different pH values RCC Report No 7328246 (December 1999) GLP, unpublished	
IIA,7.2	Newby, S.E. <i>et al.</i>	1994	Iprodione: Aged leaching study in four soils Rhône-Poulenc Report No P94/013 (July 1994) GLP, unpublished	
IIA, 7.3 IIIA,9	Wicks, J.& Leake, C.	1998	Predicted environmental concentration of iprodione and RP 30228 in sediment and RP 30228 in soil following application to turf Rhône-Poulenc Agricultural Document No 200922 (July 2, 1998) GLP : not applicable, unpublished	
IIA, 7.3 IIIA,9	Wicks, J.& Leake, C.	1998	Predicted environmental concentration of iprodione and RP 30228 in sediment and RP 30228 in soil following application to peaches Rhône-Poulenc Agricultural Document No 200922 (July 2, 1998) GLP : not applicable, unpublished	
IIA, 7.3 IIIA,9	Wicks, R.J.	1995	Predicted Environmental Concentration of iprodione in soil and surface water Rhône-Poulenc Report No 200922 (March 1995) GLP : not applicable, unpublished	
IIA,7.4	Leake, C.	1998	Iprodione: estimation of PEC _{sediment} of metabolite RP35606 Rhône-Poulenc Position Paper (October 1998) GLP : not applicable, unpublished	
IIA, 7.6 IIIA,9	Reinken, G.	2000	Iprodione: Computer simulation of the potential mobility in soil after repeated application to turf using the PELMO 3.0 model Aventis Report (March 2000) GLP, not applicable, 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,7.7	Maestracci, M.	1994	Iprodione - Estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions Rhône-Poulenc Report 9416338 (September 1994) GLP, 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	Reports on previous use in granting national authorizations
IIA,8.2.1	Bettencourt, M.	1993	RPA30228. Acute toxicity to bluegill sunfish (<i>Lepomis macrochirus</i>) under flow-through conditions SLI Report no 93-3-4684 (April 1993) GLP, unpublished	
IIA,8.2.1	Bogers, M. <i>et al</i>	1993	Acute toxicity study in the rainbow trout with RP30228 (flow-through system) RCC NOTOX Report No 077895 (April 1993) GLP, unpublished	
IIA, 8.2.1 IIIA,10.2.1	Bogers, M.	1994	96-hour Acute toxicity study in the rainbow trout with EXP.1861 suspension concentrate at 255 g/l iprodione Notox Report No 094005 (March 1994) GLP, unpublished	
IIA,8.2.3	Pottinger, T.G.	1994	A fish bioaccumulation and depuration study on iprodione. IFE Report No FH-OECD-34FT/BR (January 94) GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA,8.2.4	Bogers, M. <i>et al</i>	1993	Acute toxicity study in <i>Daphnia magna</i> with RP30228 RCC NOTOX Report No 044873 (March 1993) GLP, unpublished	
IIA, 8.2.4 IIIA,10.2.1	Bogers, M.	1993	Acute toxicity study in <i>Daphnia magna</i> with EXP1861 suspension concentrate at 255 g/l iprodione Notox Report No 093994 (September 1993) GLP, unpublished	
IIA,8.2.4	Mc Elligott, A.	1997	Iprodione. Acute toxicity (48 hours) to daphnids (<i>Daphnia magna</i>) under static conditions Rhône-Poulenc Report No SA97340 (December 1997) GLP, unpublished	
IIA, 8.2.6 IIIA,10.2.1	Bogers, M.	1993	<i>Scenedesmus subspicatus</i> . Fresh water algal growth inhibition test with EXP.1861, suspension concentrate at 255 g/l (EXP01861). Notox Report No 093961 (September 1993) GLP, unpublished	
IIA, 8.2.6 IIIA,10.2.1	Memmert, U.& Andlauer, W.	1994	Toxicity of EXP 01671 (ROVRAL) to <i>Scenedesmus subspicatus</i> (Algal growth inhibition test) RCC Umweltchemie project Report No 48 2601 (December 1994) GLP, unpublished	
IIA,8.2.7	Odin-Feurtet, M	1999	RP30228. Toxicity to the sediment dwelling chironomid larvae (<i>Chironomus riparius</i>) - 28 days Rhône-Poulenc Report No SA97341 (January 1998) GLP, unpublished	
IIA,8.3.1.	Mead-Briggs, M	1995	A laboratory determination of the topical and oral LD50s for honey bees exposed to technical-grade iprodione. Agrochemical Evaluation unit Report No RP-95-5 (October 1995) GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 8.3.1. IIIA,10.5.1	Thompson, B.	1999	A laboratory test to determine the effect of EXP1671 (a 500 g/kg WP formulation of iprodione) on the ground beetle <i>Poecilus cupreus</i> Agrochemical evaluation Unit Report no RP-99-3 (March 1999) GLP, unpublished	
IIA, 8.3.1. IIIA,10.5.1	Thompson, B.	1999	A laboratory test to determine the effect of EXP1671 (a 500 g/kg WP formulation of iprodione) on the green lacewing <i>Chrysoperla carnea</i> Agrochemical evaluation Unit Report no RP-99-4 (March 1999) GLP, unpublished	
IIA, 8.3.2 IIIA,10.5	Baxter, I.	1999	A laboratory test to determine the effect of EXP1671(a 500 g/kg WP formulation of iprodione) on the parasitic wasp <i>Aphidius rhopalosiphii</i> Agrochemical evaluation Unit Report N° RP-99-2 (March 1999) GLP, unpublished	
IIA, 8.3.2 IIIA,10.5	Candolfi, M.P.	1994	EXP 1671 (Rovral): Laboratory acute toxicity test with the parasitic wasp (<i>Aphidius matricariae</i>) following the method of Polgar (1988), IOBC guideline (1988). Springborn Laboratories Europe Report No Ag. # 94-005-1013 (December 1994) GLP, unpublished	
IIA, 8.3.2 IIIA,10.5	Candolfi, M.P.	1994	EXP 1671 (Rovral) Laboratory contact toxicity test with the predacious mite <i>Typhlodromus pyri</i> following the method of Overmeer and van Zon (1982). Springborn Laboratories Europe Report No Ag. # 94-007-1013 (December 1994) GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 8.3.2 IIIA,10.5	Mead-Briggs, M.	1993	An evaluation of the side-effects of EXP1861 (RPA18610F) on larvae of the lacewing <i>Chrysoperla carnea</i> Steph. and the fecundity of adults arising from treated larvae AEU Southampton Report N° RP-92-2 (February 1993) GLP, unpublished	
IIA, 8.3.2 IIIA,10.5	Mead-Briggs, M.	1993	An evaluation of the side-effects of EXP.01861 (RPA18610F) on larvae of the ladybird <i>Coccinella septempunctata</i> and on the fecundity of adults arising from treated larvae AEU Southampton Report N° 92-1 (June 1993) GLP, unpublished	
IIA, 8.3.2 IIIA,10.5	Petto, R.	1993	Effects of EXP1861 (VERISAN) on <i>Trichogramma cacoeciae</i> Marchal (Hymenoptera, Trichogrammatidae) in laboratory RCC Report No 314616 (March 1993) GLP, unpublished	
IIA, 8.3.2 IIIA,10.5	Petto, R.	1993	Effects of blank formulation of EXP1861 on <i>Trichogramma cacoeciae</i> Marchal (Hymenoptera, Trichogrammatidae) in laboratory RCC Report No 422302 (August 1993) GLP, unpublished	
IIA, 8.3.2 IIIA,10.5	Petto, R.	1993	Effects of EXP.1861 (RPA18610F) on <i>Episyrphus balteatus</i> Deg (Diptera, Syrphidae) in laboratory RCC Report No 314627 (August 1993) GLP, unpublished	
IIA, 8.3.2 IIIA,10	Vinall, S.	1999	A laboratory test to determine the effect of EXP1671 (a 500 g/kg WP formulation of iprodione) on the predatory mite <i>Typhlodromus pyri</i> Agrochemical Evaluation Unit Report N° RP-99-1 (April 1999) GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 8.4.1 IIIA,10.6.1	Handley, W. & Wetton, P.M.	1992	The acute toxicity of VERISAN (RPA18610F) to earthworms (<i>Eisenia foetida</i>) Safepfarm Laboratories Report No 282/213 (March 1992) GLP, unpublished	
IIA,8.4.2.	Odin-Feurtet, M	1999	RP30228. Effects on reproduction and growth of earthworms(<i>Eisenia andrei</i>) in artificial soil Rhône-Poulenc Report No SA99156 (September 1999) GLP, unpublished	
IIA,8.4.2.	Lührs, U.	2000	Effects of RP32596 on reproduction and growth of earthworms <i>Eisenia fetida</i> (Savigny 1826) in artificial soil Ibacon Report 6480022 (January 2000) GLP, unpublished	
IIA, 8.4.2. IIIA,10	Mc Elligott, A.	1994	EXP 1671 (ROVRAL): Acute toxicity (14-day) to earthworms (<i>Eisenia foetida</i>) Rhône-Poulenc Report No 94 269 (October 1994) GLP, unpublished	
IIA,8.4.2	Mc Elligott, A.	1999	Iprodione. Effects on reproduction and growth of earthworms(<i>Eisenia andrei</i>) in artificial soil Rhône-Poulenc Report No SA99157 (October 1999) GLP, unpublished	
IIA,8.4.2 IIA.10.6	Romijn, K.	2000	Iprodione. Toxicity and risk assessment to earthworm Aventis CropScience Report (March 2000) GLP : non applicable, unpublished	
IIA, 8.5 IIIA,10.7.1	Forster, J. & Seal, K.J.	1993	Iprodione: A laboratory assessment of the effects of EXP01861(German reference RPA1861F, trade name Verisan) on soil microflora respiration and nitrogen turnover Euro Laboratories Limited Report N° ELL/726/4 (July 1993) GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 8.5 IIIA,10,7.1	Forster, J.& Seal, K.J.	1993	Iprodione: A laboratory assessment of the effects of EXP01671 on soil microflora respiration and nitrogen turnover Euro Laboratories Limited Report No ELL/752 (July 1993) Non GLP, unpublished	
IIA,8.5.2.6	Bogers, M. <i>et al</i>	1993	<i>Scenedesmus subspicatus</i> , fresh water algal growth inhibition test with RP30228 RCC NOTOX Report No 077884 (March 1993) GLP, unpublished	

APPENDIX III B**IPRODIONE**

List of studies which were submitted during the evaluation process and were not cited in the draft assessment report⁸ :

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

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA,4.2.1	Guillet, M. & Yslan, F.	1998	Iprodione and its metabolites : replacement of benzene by toluene In the analytical methods for their determination in products of animal origin, exemplified with milk Rhône-Poulenc Report N 9816725 (October 1998) GLP, unpublished
IIA,4.2.1	Simonin, B.	1997	Method AR 144-97 Iprodione: analytical method for the determination of residues in plant products Rhône-Poulenc Report R&D/CRLD/AN/9716244 (September 1997) GLP, unpublished

B.6. Toxicology & 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,5.3	Bigot, D.	1997	Iprodione. 90-day toxicity study in the rat by dietary administration Rhône-Poulenc Report SA 96277 (July 1997) GLP, unpublished	

⁸ Submitted after the 18th July 1996

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	Kangas, L.	1995	A 52 week dietary toxicity study of iprodione in the Beagle dog. Final report amendment no 1. BIO report No 84296 (April 1995) GLP : not applicable, unpublished	
IIA, 5.5	Bars, R.	1995	Iprodione. Mechanism of testicular toxicity/ carcinogenicity in rat. Rhône-Poulenc Position paper (January 1995) GLP: not applicable, unpublished	
IIA,5.5 IIA,5.8	Bars, R.	1997	Iprodione. Mechanism of toxicity and carcinogenicity in rodents. Rhône-Poulenc Position Paper (January 1997) GLP: not applicable, unpublished	
IIA,5.6	Repetto-Larsay, M.	1997	Iprodione: Toxicology study in pregnant rat by gavage to examine sex differentiation. Rhône-Poulenc Report no SA96448 (June 1997) GLP, unpublished	
IIA,5.6	Bars, R.	1997	Iprodione. Discussion on the effects of iprodione on pregnancy and on parameters of sex differentiation in the rat Rhône-Poulenc Position Paper (March 1997) GLP: not applicable, unpublished	
IIA,5.6	Bars, R.	1998	Iprodione. Discussion on the effects of iprodione on pregnancy and on parameters of sex differentiation in the rat. Rhône-Poulenc Position Paper (June 1998) GLP: not applicable, unpublished	
IIA,5.8	Eldridge, S	1996	Cell proliferation in rat testes SAI report (August 1996) GLP, unpublished	
IIA,5.8	Groene, E.M..	1999	Human androgen receptor binding assay with the fungicide iprodione and 7 mammalian metabolites TNO Report No V99.616 (June 1999) GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA,5.8	Bigot, D.	1996	Iprodione.Exploratory 14-day toxicity study in the mouse by dietary administration Rhône-Poulenc Report SA95131 (October 1996) GLP, unpublished	
IIA,5.8	Benahmed, M.	1995	Update on the effects of iprodione and its metabolites on testosterone secretion in cultured Leydig cells. INSERM Report (January 95) (replaced by report INSERM No U407/95001, audited (July 1995) Non GLP, unpublished	
IIA,5.8	Benahmed, M.	1996	Effects of iprodione and its metabolites RP36112 and RP36115 on testosterone secretion in cultured Leydig cells: sites of action. INSERM Report U407/96001 Lyon (October 1996) Non GLP, unpublished	
IIA,5.8	Fail P.A., <i>et al.</i>	1996	Toxicity Testing of a Fungicide, Iprodione: Endocrine toxicology studies of testes from Adult Male CD Sprague Dawley Rats exposed to iprodione <i>in vitro</i> , RTI Report no 532 (November 1996) GLP, unpublished	
IIA,5.8	Fail P.A., <i>et al.</i>	1996	Toxicity Testing of a Fungicide, Iprodione: Endocrine toxicology studies of testes from Adult Male CD Sprague Dawley Rats exposed to iprodione <i>in vivo</i> . RTI Report no 527 (November 1996) GLP, unpublished	
IIA,5.12	Ward, R.J.	1997	Iprodione: <i>In vitro</i> absorption from a 500 g/l SC formulation through human and rat epidermis CTL Report no P/ 5295 (August 1997) GLP, unpublished	
IIA,5.12	Ward, R.J.	1997	Iprodione : <i>In vitro</i> absorption from a 500 g/l SC formulation through human and rat epidermis CTL Report no P/5295 (August 1997) GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA,5.5	Gopinath, G & Offer, J.M.	1998	Review of interstitial cell adenomas in historical control data HLS Document (June 1998) GLP, unpublished	

B.7 Residue data

B.8 Environmental fate & 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	Cooper, J.L.D. <i>et al.</i>	1998	[14C]-RP030228 - Rate of degradation in three soil types under aerobic conditions Rhône-Poulenc Report No 12113 (June 1998) GLP, unpublished	
IIA,7.1	Leake, C.	1998	Iprodione: Degradation of soil metabo RP30228 under anaerobic conditions Rhône-Poulenc Position Paper (October 1998) GLP : not applicable, unpublished	
IIA,7.1	Mamouni, A.	1999	[14C]-RP30228 (metabolite of iprodio Hydrolysis at four different pH values investigation as possible reformation o iprodione RCC Report No 732824 (December 1 GLP, unpublished	
IIA,7.1	Unsworth, R.H.& Clarke, D.E.	1999	[14C]-RP30228: anaerobic soil metabolism Rhône-Poulenc Report no 16828 (December 1999) GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA,7.1	Mamouni, A.	1999	[14C]-RP35606 (intermediate hydrolysis product of iprodione) Hydrolysis at four different pH values RCC Report No 7328246 (December 1999) GLP, unpublished	
IIA, 7.3 IIIA,9	Wicks, J.& Leake, C.	1998	Predicted environmental concentration of iprodione and RP 30228 in sediment and RP 30228 in soil following application to turf Rhône-Poulenc Agricultural Document (July 2, 1998) GLP : not applicable, unpublished	
IIA, 7.3 IIIA,9	Wicks, J.& Leake, C.	1998	Predicted environmental concentration of iprodione and RP 30228 in sediment and RP 30228 in soil following application to peaches Rhône-Poulenc Agricultural Document (July 2, 1998) GLP : not applicable, unpublished	
IIA,7.4	Leake, C.	1998	Iprodione: estimation of PEC _{sediment} of metabolite RP35606 Rhône-Poulenc Position Paper (October 1998) GLP : not applicable, unpublished	
IIA, 7.6 IIIA,9	Reinken, G.	2000	Iprodione: Computer simulation of the potential mobility in soil after repeated application to turf using the PELMO 3.0 model Aventis Report (March 2000) GLP, not applicable, 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	Reports on previous use in granting national authorizations
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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,8.2.4	Mc Elligott, A.	1997	Iprodione. Acute toxicity (48 hours) to daphnids (<i>Daphnia magna</i>) under static conditions Rhône-Poulenc Report No SA97340 (December 1997) GLP, unpublished	
IIA,8.2.7	Odin-Feurtet, M	1999	RP30228. Toxicity to the sediment dwelling chironomid larvae (<i>Chironomus riparius</i>) - 28 days Rhône-Poulenc Report No SA97341 (January 1998) GLP, unpublished	
IIA,8.3.1.	Mead-Briggs, M	1995	A laboratory determination of the topical and oral LD50s for honey bees exposed to technical-grade iprodione. Agrochemical Evaluation unit Report No RP-95-5 (October 1995) GLP, unpublished	
IIA, 8.3.1. IIIA,10.5.1	Thompson, B.	1999	A laboratory test to determine the effect of EXP1671 (a 500 g/kg WP formulation of iprodione) on the ground beetle <i>Poecilus cupreus</i> Agrochemical evaluation Unit Report no RP-99-3 (March 1999) GLP, unpublished	
IIA, 8.3.1. IIIA,10.5.1	Thompson, B.	1999	A laboratory test to determine the effect of EXP1671 (a 500 g/kg WP formulation of iprodione) on the green lacewing <i>Chrysoperla carnea</i> Agrochemical evaluation Unit Report no RP-99-4 (March 1999) GLP, unpublished	
IIIA,10 IIA, 8.3.2	Baxter, I.	1999	A laboratory test to determine the effect of EXP1671(a 500 g/kg WP formulation of iprodione) on the parasitic wasp <i>Aphidius rhopalosiphii</i> Agrochemical evaluation Unit Report N° RP-99-2 (March 1999) GLP, unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIIA,10 IIA, 8.3.2	Vinall, S.	1999	A laboratory test to determine the effect of EXP1671 (a 500 g/kg WP formulation of iprodione) on the predatory mite <i>Typhlodromus pyri</i> Agrochemical Evaluation Unit Report N° RP-99-1 (April 1999) GLP, unpublished	
IIA,8.4.2	Mc Elligott, A.	1999	Iprodione. Effects on reproduction and growth of earthworms(<i>Eisenia andrei</i>) in artificial soil Rhône-Poulenc Report No SA99157 (October 1999) GLP, unpublished	
IIA,8.4.2.	Odin-Feurtet, M	1999	RP30228. Effects on reproduction and growth of earthworms(<i>Eisenia andrei</i>) in artificial soil Rhône-Poulenc Report No SA99156 (September 1999) GLP, unpublished	
IIA,8.4.2.	Lührs, U.	2000	Effects of RP32596 on reproduction and growth of earthworms <i>Eisenia fetida</i> (Savigny 1826) in artificial soil Ibacon Report 6480022 (January 2000) GLP, unpublished	
IIA,8.4.2 IIA.10.6	Romijn, K.	2000	Iprodione. Toxicity and risk assessment to earthworm Aventis CropScience Report (March 2000) GLP : non applicable, unpublished	