EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: production and distribution chain
D3 - Chemicals, Contaminants and Pesticides

Procymidone

SANCO/4064/2001 final

5 January 2007

Review report for the active substance **procymidone**

finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 3 March 2006
in view of the inclusion of procymidone 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 procymidone, 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. Procymidone 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, Sumitomo (UK) plc on 21 July 1993 and Helm AG on 23 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance procymidone 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 procymidone on the basis of the dossiers submitted by the notifiers. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for procymidone this deadline was 30 April 1996.

Only Sumitomo Chemical Agro Europe S.A submitted in time a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore

[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.

Sumitomo Chemical Agro Europe S.A 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 15 January 2001 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 procymidone 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 procymidone from Sumitomo Chemical Agro Europe S.A, on 29 January 2001.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States on 31 January 2001 as well as to Sumitomo Chemical Agro Europe S.A being the main data submitter, on 24 January 2001.

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 February to September 2002.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 11 October 2002 for comments and further clarification.

To confirm the evaluation made by the RMS, an assistant RMS (Germany) was named. On April 21rd, 2001, a tripartite meeting with the main data submitter, Germany and the rapporteur Member State was organised to confirm the evaluation made by the rapporteur Member State, to evaluate the additional studies to be required and to evaluate if a safe use could be identified.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review were referred to the **Standing Committee on the Food Chain and Animal Health**, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from September 2002 to March 2004, and was finalised in the meeting of the **Standing Committee** on 3 March 2006.

The review did not reveal any open questions or concerns which would have required a consultation of the Scientific Committee on Plants.

The present review report contains the conclusions of the final examination; given the importance of the draft assessment report, the peer review report (i.e. full report) and the comments and

clarifications submitted after the peer review as basic information for the final examination process, these documents are considered respectively as background documents A, B and C to this review report and are part of it.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed and finalised in support of the Directive 2006/132/EC concerning the inclusion of procymidone in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing procymidone they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

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

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

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

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing procymidone 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 procymidone containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the main data submitter and mentioned in the list of uses supported by available data (attached as Appendix IV to this Review Report).

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 8,34%) 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. Provisional estimates of acute dietary exposure of adults and toddlers revealed that the Acute Reference Dose (ARfD) are 96,7% for plums and 37% for cucumber.

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 procymidone 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 main data submitter Sumitomo Chemicals Agro Europa S.A., none of the manufacturing impurities 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 were identified during the re-evaluation process. These endpoints are listed in Appendix II.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing procymidone

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

- Member States must observe the acute dietary exposure situation of consumers;

Member States must also apply risk mitigation measures and pay particular attention to the protection of:

- aquatic organisms where relevant, an appropriate distance must be kept between treated areas and surface water bodies.

- birds and mammals. Conditions of authorisation shall include risk mitigation measures, such as a judicious timing of the application and the selection of those formulations which, as a result of their physical presentation or the presence of agents that ensure an adequate avoidance, minimise the exposure of the concerned species;
- Conditions of authorisation shall include risk mitigation measures;
- operators, who must wear suitable protective clothing, in particular gloves, coveralls, rubber boots and face protection or safety glasses during mixing, loading, application and cleaning of equipment, unless the exposure to the substance is adequately precluded by the design and construction of the equipment itself or by the mounting of specific protective components on such equipment;

- workers, who must wear suitable protective clothing, in particular gloves, if they must enter a treated area before the specific re-entry period has expired.

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 procymidone in Annex I under the current inclusion conditions.

However, Member States shall request the submission of further confirmatory data and information to prove the acceptability of the active substance when applied in situations where there is a likelihood of long-term exposure of wild mammals, and on the sewage treatment applied in the case of greenhouse applications.

Further studies shall be requested to address the potential endocrine disrupting properties of procymidone within two years after the adoption of the Test Guidelines on endocrine disruption by the Organisation for Economic Cooperation and Development (OECD).

Member States must ensure that the authorisation holders report at the latest on 31 December of each year on incidences of operator health problems, may require sales data and a survey of use patterns so that a realistic picture of the use conditions and the possible toxicological impact of procymidone can be obtained.

8. Information on studies with claimed data protection

For information of any interested parties, Appendix III gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available to the Commission services at the time this review report was prepared; but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC neither does it commit the Commission.

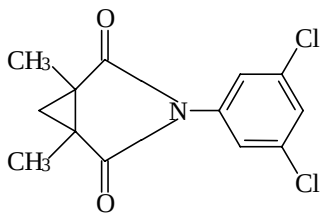
9. Updating of this review report

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

APPENDIX I

Identity, physical and chemical properties

PROCYMIDONE

Common name (ISO)	PROCYMIDONE
Chemical name (IUPAC)	N-(3,5-dichlorophenyl)-1,2-dimethylcyclopropane-1,2-dicarboximide
Chemical name (CA)	3-(3,5-dichlorophenyl)-1,5-dimethyl-3-azabicyclo [3.1.0.] hexane,-2,4-dione
CIPAC No	383
CAS No	32809-16-8
EEC No	251-233-1
FAO SPECIFICATION	Not allocated
Minimum purity	985 g/kg
Molecular formula	$C_{13}H_{11}Cl_2NO_2$
Molecular mass	284.1
Structural formula	

Melting point	164-165 °C
Boiling point	Not required
Appearance	white granular powder with a musty odour
Relative density	1.43 at 22°C
Vapour pressure	2.3×10^{-5} at 25°C
Henry's law constant	2.65×10^{-3} at 20-25 °C
Solubility in water	2.46 mg/l at 20°C 3.07 mg/l at 25°C
Solubility in organic solvents	Acetone : 180 g/l at 25°C Toluene : 66 g/l Benzene : 86 g/l Methanol : 16 g/l Ethyl acetate : 115 g/l Cyclohexanone : 148 g/l Isopropanol : 5 g/l Ethylene glycol : 0.5 g/l Chloroform : 216 g/l Acetonitrile : 101 g/l
Partition co-efficient (log P_{ow})	$LogP_{ow}$ = 3.30 at 25 °C, pH6
Hydrolytic stability (DT_{50})	pH9, DT_{50} : 28 min at 30 °C pH7, DT_{50} : 3.8 days at 30°C pH5, DT_{50} : 62days
Dissociation constant	No pKa value from pH 2-12 at 20°C
Quantum yield of direct photo-transformation in water at λ >290 nm	3.23×10^{-1} mol x $einstein^{-1}$
Flammability	not flammable
Explosive properties	not explosive
UV/VIS absorption (max.)	in acidic solution : λ max : 210 nm (ε = 37641 mol^{-1} cm^{-1}) in neutral solution : λ max : 210 nm (ε = 37390 mol^{-1} cm^{-1}) in basic solution : λ max : 220 nm (ε = 29100 mol^{-1} cm^{-1}) 251 nm (ε = 14800 mol^{-1} cm^{-1}) No absorbance > 290 nm
Photostability in water (DT_{50})	DT_{50} (days) $\approx$ 8 days under sunlight

APPENDIX II

END POINTS AND RELATED INFORMATION

PROCYMIDONE

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Moderately rapidly (Tmax 6-12h); >80 % based on urinary excretion at 100 mg/kg bw
Distribution:	Widely distributed; highest levels in fat (urogenital)
Potential for accumulation:	No potential for accumulation.
Rate and extent of excretion:	Rapidly excreted: >90 % within 48 hours at 100 mg/kg bw
Toxicologically significant compounds:	Parent compound, 3,5-dichloroaniline, CCA (main environmental metabolite).
Metabolism in animals:	Extensively metabolised in rats. Oxidation of the methyl group, cleavage of the imide, hydroxylation and conjugation.

Acute toxicity

Rat LD_{50} oral:	>5000 mg/kg bw
Rat LD_{50} dermal:	>5000 mg/kg bw
Rat LC_{50} inhalation:	>1.5 mg/l
Skin irritation:	Not irritant
Eye irritation:	Not irritant
Skin sensitization (test method used and result):	Not sensitising (M & K)

Short term toxicity

Target / critical effect:	Hepatotoxicity (rat and mouse), testicular atrophy (mouse)
Lowest relevant oral NOAEL / NOEL:	NOEL 26-week rat: 150 ppm (7.5 mg/kg bw/d) based on findings in the first three months
Lowest relevant dermal NOAEL / NOEL:	NOEL 28-day rat: 1000 mg/kg bw/d
Lowest relevant inhalation NOAEL / NOEL:	No data: not required

Genotoxicity

No genotoxic potential

Long term toxicity and carcinogenicity

Target / critical effect:	Liver: hepatotoxicity in rats and mice. Testes: testicular interstitial cell hyperplasia in rats.
Lowest relevant NOAEL:	2-year rat NOAEL: 100 ppm (4.6mg/kg bw/d)
Carcinogenicity:	Liver: hepatoblastoma in mice, Bibliographic data provided indicate than incidence observed in the study seems to be in the bibliographic range. Testes: testicular interstitial cell tumors in rats.

Reproductive toxicity

Target / critical effect - Reproduction:	2-generation rat study: Parents: increased liver and testes weights Offspring: hypospadia, reduced anogenital distance, increased testicular weight, decreased prostate weight
Lowest relevant reproductive NOAEL / NOEL:	2-generation rat study: NOAEL = 50 ppm (2.5 mg/kg bw/d)
Target / critical effect - Developmental toxicity:	Rat: reduced anogenital distance, hypospadia, testicular atrophy, undescended testes
Lowest relevant developmental NOAEL / NOEL:	Rat developmental study: 3.5 mg/kg bw/d

Delayed neurotoxicity

Not required

Other toxicological studies

Mechanistic studies

Antiandrogenic activity and hypersecretion of testosterone in the rat.

Procymidone inhibits androgen from binding to rodent and human receptor.

<u>Studies on metabolites</u>

3,5 dichloroaniline (rat minor metabolite):

Rat LD_{50} oral = 820 mg/kg bw

Rat LD_{50} dermal = 1250 mg/kg bw

Medical data

No adverse reports (up to 2001)

Summary

	Value	Study	Safety factor
ADI:	0.025 mg/kg bw/d	Rat 2-generation	100
AOEL systemic:	0.035 mg/kg bw/d	Rat developmental study	100
ARfD (acute reference dose):	0.035 mg/kg bw	Rat Developmental	100

Dermal absorption

2.2 % (in vitro human/rat and in vivo rat studies)

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	0.3% (122d) in acidic soil
Non-extractable residues after 100 days:	27 – 35% (122d) in neutral/alkaline soil 7.6 – 15.6% (122 d) in acidic soil
Major metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	Procymidone- NH-COOH reached 28.1% after 14 days in neutral/alkaline soils Procymidone-NH-COOH only reached 4.1% (14 d) in acidic soils The degradation pathway procedes via a further molecular cleavage and small amounts of cyclopropane- derivatives and chlorophenol derivatives may subsequently be formed

Supplemental studies

Anaerobic:	Route of degradation same as for aerobic degradation Procymidone- NH-COOH :14.9 % in neutral/alkaline soil Procymidone-NH-COOH only reached 4.0% in an acidic soil
Soil photolysis:	Parent did not degrade therefore no metabolites
Remarks:	none

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):	Rate of Procymidone degradation is pH dependent, being faster in alkaline soils than acidic soils: 48 d – 189 d (n=2, r^2 >0.992) neutral/alkaline soil 520 d – 2381 d (n=2, r^2 >0.957) acidic soil Rate of Procymidone-NH-COOH degradation is pH dependent, being faster in acidic soils than alkaline soils Procymidone- NH-COOH: 5.48 d (r^2=0.987) acidic 13.03 d (r^2=0.975) neutral 17.96 d (r^2=0.979) alkaline
DT_{90}lab (20 °C, aerobic):	Procymidone: 675 d – 1068 d (n=2, r^2 >0.992) neutral/alkaline soil n/a – 8585 d (n=2, r^2 >0.957) acidic soil Procymidone- NH-COOH: 39.36 d (r^2=0.987) acidic 32.18 d (r^2=0.975) neutral 287.80 d (r^2=0.979) alkaline
DT_{50}lab (10 °C, aerobic):	Procymidone: Q_{10} values of 2.2 (FOCUS, 1996) result in DT_{50} values of 106-5236 days for procymidone and 12.1 – 39.5 days for procymidone-NH-COOH by calculation from 20°C data
DT_{50}lab (20 °C, anaerobic):	Procymidone: DT_{50lab} (20°C, anaerobic): 4 to 5 months (at 25 °C)

Field studies (country or region)

DT_{50f} from soil dissipation studies:	Procymidone 3 studies in Northern France (NEU) and 3 in Southern France (SEU) First order DT_{50f}: 17 d– 158d (n=3, mean = 105 d) neutral/alkaline soils 161- 497 d (n=3, mean = 343 days) acidic soils
DT_{90f} from soil dissipation studies:	Procymidone First order DT_{90f}: 56 d– 525d (n=3, mean = 349 d) neutral/alkaline soils 535 - 1651 d (n=3, mean = 1139 days) acidic soils

Soil accumulation studies:	No accumulation over 4 yr in two neutral/alkaline soils (evidence of enhanced biodegradation). No specific studies on acidic soils but sites used for accumulation had similar dissipation DT_{50} values to one of the acidic sites
Soil residue studies:	not relevant

Remarks: e.g. effect of soil pH on degradation rate	In aerobic conditions, degradation of procymidone is pH dependent (faster in alkaline soils)

Adsorption/desorption

K_f / K_{oc}:	Procymidone
K_d:	K_{oc} 199 – 513 (mean value: 378 . pH of the soils = 7)
pH dependence:	No pH dependence seen (nor expected since compound is not ionic) OC dependence

Mobility

Laboratory studies:

Column leaching:	Amount in leachate: 33.9% (parent) in worst case conditions 32.8 % (Procymidone-NH-COOH) in worst case conditions
Aged residue leaching:	Aged for 28 days in darkness at 25°C. Amount in leachate: 4.4 % (parent) in worst case conditions 8.1 % (Procymidone-NH-COOH) in worst case conditions

Field studies:

Lysimeter/Field leaching studies:	2 Lysimeter studies in Northern Germany. Application 2 x 0.75 kg a.s./ha/yr to peas. Rainfall 1132, 881 and 961 mm in each year. Re-application to one core in 2nd year. Total ^{14}C equivalents >0.1 µg/l annual average in all years Procymidone <0.1 µg/l annual average in all years (max. 0.098 µg/l in extremely wet year following initial "flush" in only one lysimeter) Procymidone-NH-COOH 0.229 µg/l annual average in only one core in extremely wet 1st year following initial "flush". All other years and results <0.1 µg/l annual average One lysimeter gave extremely high results compared to the other results
Remarks:	the results obtained in one lysimeter must be considered extremely high in comparison with other results

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	pH 4: Parent 25°C: 87.7-99 d 20°C (calculated): 127.2-143.6 d Procymidone NH-COOH 25°C: 0.7-1.0 d (ModelMaker) 20°C (calculated): 1.02-1.05 d pH 5.0: Parent 45°C : 20.4 d 30°C : 62.1 d 15°C : 334.3 d 20°C (calculated): 191.7 d pH 7: Parent 25°C: 16.9-17.2 d 20°C (calculated): 24.5-24.9 d Procymidone NH-COOH 25°C: 56-58 d (ModelMaker) 20°C (calculated): 81-84 d pH 7.1: Parent 45°C : 20.0 h 30°C : 3.8 d 15°C : 31.5 d pH 9: Parent 25°C: 0.05-0.07 d 20°C (calculated): 0.07-0.10 d Procymidone NH-COOH 25°C: stable pH 9.0: Parent 45°C : 28.4 min 30°C : 1.9 h 15°C : 12.7 h
Major metabolites:	Procymidone NH-COOH and then CCA or DCA (11 %)
Photolytic degradation:	Mainly hydrolysis Quantum efficiency/ 0.323 at 304 nm DT 50 (1meter depth) 66 days
Major metabolites:	Procymidone NH-COOH

Biological degradation

Readily biodegradable:	No
Water/sediment study:	
DT_{50} water: DT_{90} water:	Biphasic, described by sequential first order equations: 1st phase (1st 1-2 days) DT_{50} 0.5-1.1 d, DT_{90} 1.8-3.6 d 2nd phase (1-2 days onwards) DT_{50} 62-99d, DT_{90} 205-329 d
DT_{50} whole system: DT_{90} whole system:	Biphasic described by sequential first order equations:: 1st phase (1st 1-2 days) DT_{50} 0.5-2.3 d, DT_{90} 1.8-7 d 2nd phase (1-2 days onwards) DT_{50} 187d, DT_{90} 620 d
Distribution in water / sediment systems (active substance)	Max 32.7 % in sediment after 100 days
Distribution in water / sediment systems (metabolites)	Procymidone-NH-COOH Max 21.4 % in sediment after 30 d
Accumulation in water and/or sediment:	no accumulation is expected

Degradation in the saturated zone

Data are not required

Remarks: none

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	2.3×10^{-5} Pa at 25°C
Henry's law constant:	2.65×10^{-3} Pa m^3 mol^{-1} at 20-25 °C

Photolytic degradation

Direct photolysis in air:	Not relevant, due to low vapour pressure
Photochemical oxidative degradation in air DT_{50}:	DT_{50} 9.2 h (Atkinson calculation)
Volatilisation:	from plant surfaces: no data, not relevant from soil: no data, not relevant

Remarks:	none

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD50 > 5 000 mg a.s./kg b.w.
Acute toxicity to birds:	Procymidone: LD50 (quail, mallard) > 4 092 mg a.s./kg b.w. (male), > 7 895 mg a.s./kg b.w. (female). Procymidone 50 WP: LD50 (bobwhite quail) > 2 000 mg./kg b.w. > 1020 mg a.s./kg b.w.
Dietary toxicity to birds:	LC50 (quail) > 5 200 ppm
Reproductive toxicity to birds:	NOEC (quail) = 1 000 ppm
long term toxicity to mammals:	NOEL = 50 ppm (12.5 mg/kg b.w./d), multi generation study.

Aquatic Organisms

	Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Acute toxicity fish:	fish	procymidone	Acute flow through	LC50	7.22
	fish	procymidone	Acute flow through	LC50	10.25
	fish	procymidone	Acute	LC50	> 10
	fish	procymidone	Acute	LC50	> 10
	fish	Sumisclex 50WP	Acute flow through	LC50	3.6 (1.8 mg a.s./l) [1]
	fish	Sumisclex 50WP	Acute	LC50	537 (268 mg a.s./l)
	fish	Sumisclex 50WP	Acute flow through	LC50	22.88 (11.4 mg a.s./l)
	fish	Sumisclex 50WP	Acute	LC50	677 (338 mg a.s./l)
	fish	Sumisclex 50WG	Acute	LC50	25 (12.5 mg a.s./l)
	fish	Sumisclex 50WG	Acute	LC50	74 (37 mg a.s./l)
	fish	PCM-NH-COONa	Acute semi static	LC50	> 92
Long term toxicity fish:	fish	procymidone	Chronic	NOEC	0.48
Bioaccumulation fish:	130-155				

	Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Acute toxicity invertebrate:	daphnids	procymidone	Acute	EC50	> 1.8
	daphnids	procymidone	Acute	EC50	> 4.2
	daphnids	procymidone	Acute	EC50	> 10
	daphnids	Procymidone 50WP	Acute	EC50	1.3 (0.47 mg a.s./l)
	daphnids	PCM-NH-COONa	Acute	EC50	> 95
Chronic toxicity invertebrate:	daphnids	procymidone	Chronic flox through	NOEC	0.99
Acute toxicity algae:	algae	procymidone		EC50	2.6
	algae	procymidone		EC50	4.67
	algae	PCM-NH-COONa		EC50	21
Chronic toxicity sediment dwelling organism:	NOEC (28d) = 0.12 mg as/l (*chironomus riparius*) ???				

Honeybees

Acute oral toxicity:	LD50 > 100 microg a.s./bee
Acute contact toxicity:	LD50 > 100 microg a.s./bee

Other arthropod species

Test species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect
Trichogramma cacoeciae	adults	Sumisclex WG 50	1.5	parasitization	19
Aphidius matricariae	adults	Sumisclex WG 50	1.5	mortality parasitization	2.9 - 21.7
Chrysoperla carnea	larvae, adults	Bay 89200F	0.664	mortality reproduction	- 3.09 - 37.88
Chrysoperla carnea	larvae, adults	Sumisclex 0.15%	0.664	mortality reproduction	10.5 16
Syrphus corollae	larvae, adults	Sumisclex 0.15%	0.664	mortality reproduction	- 7.7 **43.7**
Amblyseius potentillae	proto-nymphs	Sumislex 0.075%	0.15	mortality fecundity	1.2 16
Typhlodromus pyri	proto-nymphs	Sumislex 0.075%	0.15	mortality fecundity	29.7 - 7
Poecilus cupreus	adults	Sumisclex WG 50	1.5	mortality food consumption	0 0

Earthworms

Acute toxicity:	LC50 (procymidone) > 1 000 mg a.s./kg soil LC50 (50% WG) > 519 mg a.s./kg soil LC50 (PCM-NH-COO-Na) > 1 000 mg/kg soil
Reproductive toxicity:	NOEC (50% SC) = 3 750 g a.s./ha

Soil micro-organisms

Nitrogen mineralization:	Effects of 2.0 and 20 mg preparation (50% WG)/kg soil < 25%
Carbon mineralization:	Effects of 2.0 and 20 mg preparation (50% WG)/kg soil < 25% PCM-NH-COO-Na : no effect at 0.5 and 2.5 mg/kg soil

APPENDIX IIIA

PROCYMIDONE

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	Reports[5] on previous use in granting national authorizations
IIA, 2.1.1, 2.3.2, 2.4.1, 2.6, 2.10, 2.11.1, 2.11.2, 2.13, 2.14	Betteley, J.M.T.	1996	Procymidone Physicochemical Properties Huntingdon Life Sciences Ltd. Owner: Sumitomo Chemical Co., Ltd. BP-0050 GLP, Unpublished	
IIA, 2.1.3	Sanders J.M.	1991	Procymidone - Determination of Stability Ricerca Inc. Owner: Sumitomo Chemical Co., Ltd. BP-11-0038 GLP, Unpublished	
IIA, 2.2	Sweetapple, G.G.	1991	Procymidone- Determination of Absolute Density Ricerca Inc. Owner: Sumitomo Chemical Co., Ltd. BP-01-0032 GLP, Unpublished	
IIA, 2.3.1	Lorence, P.J.	1991	Procymidone - Determination of Vapour Pressure Ricerca Inc. Owner: Sumitomo Chemical Co., Ltd. BP-11-0035 GLP, Unpublished	
IIA, 2.5.1	Okamoto. M.	1995	Spectral Studies of Procymidone Owner: Sumitomo Chemical Co., Ltd BP-50-0049 GLP, Unpublished	

[5] Entries are based on information received from the Notifier(s) and in certain cases Member States. Neither the Commission nor the Member States are responsible for the completeness or validity of this information received.

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports[5] on previous use in granting national authorizations
IIA, 2.7	Kawashima, M.	1995	Solubility of Procymidone in Organic Solvents Owner: Sumitomo Chemical Co., Ltd BP-50-0044 Not GLP, Unpublished	
IIA, 2.9.1	Lentz, N.R.	2002	A hydrolysis study of [14C]procymidone in water Ricerca, LLC Owner: Sumitomo Chemical Co., Ltd BM-0073 GLP, Unpublished	
IIA, 2.9.3	Brodsky, J.	1997	Determination of the Direct Phototransformation of Procymidone in Water C.A.U. GmbH Owner: Sumitomo Chemical Co., Ltd BP-0053 GLP, Unpublished	
IIA, 2.9.4	Thomas, E.A.	1991	Procymidone - Determination of Dissociation Constant Ricerca Inc. Owner: Sumitomo Chemical Co., Ltd BP-11-0034 GLP, Unpublished	
IIA, 4.1.1	Mukumoto, M.	2003	Analytical method for the determination of active substance in procymidone technical material. Owner: Sumitomo Chemical Co., Ltd. BA-0086 GLP, Unpublished	
IIA, 4.1.1	Mukumoto, M.	2003	Determination of procymidone content by current and new analytical methods. Owner: Sumitomo Chemical Co., Ltd. BA-0088 GLP, Unpublished	
IIA, 4.2.1	Roberts, N.L., Macdonald, I.A., Gillis, N.A.	1992	Procymidone, Method of Analysis for the Gas Chromatographic Determination of Residues in Grapes Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BA-21-0049 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[5] on previous use in granting national authorizations
IIA, 4.2.1	Roberts, N.L., Macdonald, I.A., Gillis, N.A.	1992	Procymidone, Method of Analysis for the Gas Chromatographic Determination of Residues in Wine Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BA-21-0048 GLP, Unpublished	
IIA, 4.2.1	Roberts, N.L., Macdonald, I.A., Gillis, N.A., Howie, D.	1992	Procymidone, Method of Analysis for the Gas Chromatographic Determination of Residues in Must Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BA-21-0047 GLP, Unpublished	
IIA, 4.2.1	Roberts, N.L., Macdonald, I.A., Gillis, N.A., Howie, D.	1994	Procymidone, Method of Analysis for the Gas Chromatographic Determination of Residues in Grape Juice Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BA-41-0053 GLP, Unpublished	
B.4.2.1.	Nishikawa, Y., Ohnishi, J., Kato, T., Yamada, H.	1994	Residue Analytical Method for Procymidone in Milk and Tissues of Bovine Generated by: Sumitomo Chemical Co. Ltd Submitted by: Sumitomo Chemical Co. Ltd Company file No.: BA-40-0052 Unpublished	
IIA, 4.2.1	Provot, G.	1997	Method Validation for the Quantification of Procymidone in Pears Centre International de Toxicologie (C.I.T.) Owner: Sumitomo Chemical Co., Ltd BA-0071 GLP, Unpublished	
IIA, 4.2.1	Provot, G.	1997	Method Validation for the Quantification of Procymidone in Peaches Centre International de Toxicologie (C.I.T.) Owner: Sumitomo Chemical Co., Ltd BA-0072 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[5] on previous use in granting national authorizations
IIA, 4.2.1	Provot, G.	1997	Method Validation for the Quantification of Procymidone in Plums Centre International de Toxicologie (C.I.T.) Owner: Sumitomo Chemical Co., Ltd BA-0073 GLP, Unpublished	
IIA, 4.2.1	Weeren, R.D., Pelz, S.	2000	Validation of the DFG method S19 (extended revision) for the determination of residues of procymidone in specimens of commodities with high water content (white cabbage). Specht and Partner Owner: Sumitomo Chemical Co., Ltd BA-0076 GLP, Unpublished	
IIA, 4.2.1	Weeren, R.D., Pelz, S.	2000	Validation of the DFG method S19 (extended revision) for the determination of residues of procymidone in specimens of fruits with high acid content (currant). Specht and Partner Owner: Sumitomo Chemical Co., Ltd BA-0077 GLP, Unpublished	
IIA, 4.2.1	Weeren, R.D., Pelz, S.	2000	Validation of the DFG method S19 (extended revision) for the determination of residues of procymidone in samples of commodities with high fat content (rapeseed). Specht and Partner Owner: Sumitomo Chemical Co., Ltd BA-0078 GLP, Unpublished	
IIA, 4.2.1	Weeren, R.D., Pelz, S.	2000	Validation of the DFG method S19 (extended revision) for the determination of residues of procymidone in specimens of cereals and other dry crops (barley grain and straw). Specht and Partner Owner: Sumitomo Chemical Co., Ltd BA-0081 GLP, Unpublished	
				Not seen in the analytical section

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[5] on previous use in granting national authorizations
IIA, 4.2.2	Benwell, L.	1996	Procymidone: The Validation of an Analytical Method for the Determination of Residues in Soil Corning Hazleton (Europe), CHE Owner: Sumitomo Chemical Co., Ltd BA-0059 GLP, Unpublished	
IIA, 4.2.2	Weeren, R.D., Pelz, S.	2000	Validation of the Corning Hazleton (Europe) test method (CHE study number 1482/1) for the determination of residues of procymidone in soil. Specht and Partner Owner: Sumitomo Chemical Co., Ltd BA-0083 GLP, Unpublished	
IIA, 4.2.2	Wimbush, J.	2002	PCM-NH-COOH: Degradation in three soils (analytical procedures only). Covance Laboratories Ltd Owner: Sumitomo Chemical Co., Ltd. BA-0084 GLP, Unpublished	
IIA, 4.2.3	Wais, A.	2001	Development and validation of the residue analytical method for procymidone in surface water. RCC Ltd Owner: Sumitomo Chemical Co., Ltd BA-0079 GLP, Unpublished	
IIA, 4.2.3	Wolf, S.	2001	Validation of the multi-residue method F12 for procymidone in drinking water. RCC Ltd Owner: Sumitomo Chemical Co., Ltd BA-0082 GLP, Unpublished	
IIA, 4.2.3	Wimbush, J.	2002	PCM-NH-COOH: Validation of an analytical method for the determination of residues in surface water. Covance Laboratories Ltd Owner: Sumitomo Chemical Co., Ltd BA-0085 GLP, Unpublished	
IIA, 4.2.4	Takahashi, M., Tsuzuki, M.	1996	Analytical Method for Procymidone in Air Owner: Sumitomo Chemical Co., Ltd BA-0058 Not 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	Reports on previous use in granting national authorizations
IIA, 5.1	Mikami, N., Yamamoto, H.	1976	Metabolism of N-(3',5'-Dichlorophenyl)-1,2-Dimethylcyclopropane-1,2-Dicarboximide in Rats Owner: Sumitomo Chemical Co., Ltd BM-60-0002 Not GLP, Unpublished	
IIA, 5.1	Kimura, K., Shiba, K., Iba, K.	1988	Comparative Metabolism of Procymidone in Rats and Mice Owner: Sumitomo Chemical Co., Ltd BM-80-0019 Not GLP, Unpublished	
IIA, 5.1	Struble, C.B.	1992	Metabolism of ^{14}C-Procymidone in Rats (Preliminary and Definitive Phases) Volume 1 of 2 : Absorption, Distribution, Elimination and Tissue Residues Hazleton Wisconsin Inc. Owner: Sumitomo Chemical Co., Ltd BM-21-0033 GLP, Unpublished	
		1992	Metabolism of ^{14}C-Procymidone in Rats (Preliminary and Definitive Phases) Volume 2 of 2; Metabolite Identification Hazleton Wisconsin Inc. Owner: Sumitomo Chemical Co., Ltd BM-21-0034 GLP, Unpublished	
		1993	Metabolism of ^{14}C-Procymidone in Rats (Preliminary and Definitive Phases). Volume 2 of 2: Metabolite Identification Amendment No.1 to the Final Report Hazleton Wisconsin Inc. Owner: Sumitomo Chemical Co., Ltd BM-31-0040 GLP, Unpublished	
IIA, 5.1	Tarui, H.	2003	Rat *in vitro* metabolism of procymidone. Owner: Sumitomo Chemical Co., Ltd. BM-0085 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, 5.2.3	Suzuki, T., Kato, T.	1988	Acute Inhalation Toxicity of Sumilex in Rats Owner: Sumitomo Chemical Co., Ltd BT-60-0116 GLP, Unpublished	
	Tsuji, R.	1994	Acute Inhalation Toxicity of Sumilex in Rats (Addendum to report) Owner: Sumitomo Chemical Co., Ltd BT-40-0178 GLP, Unpublished	
IIA, 5.2.6	Nakanishi, T., Nakatsuka, I., Kogiso, S.	1991	Skin Sensitisation Test of Procymidone in Guinea-pigs Owner: Sumitomo Chemical Co., Ltd BT-10-0146 GLP, Unpublished	
IIA, 5.3.2	Dalgard, D.W., Machotka, S.V.	1992	Chronic Toxicity Study in Dogs with Procymidone Hazleton Washington Inc. Owner: Sumitomo Chemical Co., Ltd BT-21-0162 GLP, Unpublished	
IIA, 5.3.3	Ogata, H.	2002	28-day repeated dose dermal toxicity study of procymidone TG in rats. Panapharm Laboratories Co., Ltd Owner: Sumitomo Chemical Co., Ltd BT-0200 GLP, Unpublished	
IIA, 5.3.3	Ogata, H.	2001	7-day repeated dose dermal toxicity study of procymidone TG in rats. Panapharm Laboratories Co., Ltd Owner: Sumitomo Chemical Co., Ltd BT-0198 GLP, Unpublished	NOT IN DAR AND IN ADDENDA
IIA, 5.4.1	Kogiso, S.	1991	Reverse Mutation Test of Sumilex in Bacterial System Owner: Sumitomo Chemical Co., Ltd BT-10-0138 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, 5.4.1	Hara, M.	1991	In vitro Unscheduled DNA Synthesis (UDS) Assay of Sumilex in Rat Hepatocytes Owner: Sumitomo Chemical Co., Ltd BT-10-0142 GLP, Unpublished	
	Hara, M., Ota, M., Kogiso, S.	1992	Comments on the EPA's "Date Evaluation Report" of the report entitled "In vitro Unscheduled DNA Synthesis (UDS) Assay of Sumilex in Rat Hepatocytes" Owner: Sumitomo Chemical Co., Ltd BT-20-0149 GLP, Unpublished	
IIA, 5.4.1	Hara, M.	1991	In vitro Chromosomal Aberration Test of Sumilex in Chinese Hamster Ovary Cells (CHO-K1) Owner: Sumitomo Chemical Co., Ltd BT-10-0141 GLP, Unpublished	
IIA, 5.6.1	Milburn, G.M., Moreland, S.F.	1991	Procymidone: Multigeneration Reproduction Study in the Rat (First Supplement - Additional Histopathology) ICI Central Toxicology Laboratory Owner: Sumitomo Chemical Co., Ltd BT-11-0140 GLP, Unpublished	
IIA, 5.6.1	Zühlke, U.	1991	S-7131 Seven Day Oral (Gavage) Range-finding Study in the Cynomolgus Monkey Hazleton Deutschland GmbH Owner: Sumitomo Chemical Co., Ltd BT-11-0143 GLP, Unpublished	
IIA, 5.6.1	Hodge, M.C.E., Williams, M.C.H., Hollis, K.J., Moreland, S.F., Greenwood, M.R., McLean, L.J., Foster, P.M.D.	1991	Procymidone : One Generation Study in the Rat ICI Central Toxicology Laboratory Owner: Sumitomo Chemical Co., Ltd BT-11-0144 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, 5.6.1	Bee, W.	1992	S-7131 90 Day Oral (Gavage) Subchronic Study in the Cynomolgus Monkey Hazleton Deutschland GmbH Owner: Sumitomo Chemical Co., Ltd BT-21-0147 GLP, Unpublished	
		1993	S-7131 90 Day Oral (Gavage) Subchronic Toxicity Study in the Cynomolgus Monkey - Determinaiton of Luteinizing Hormone (LH) Hazleton Deutschland GmbH Owner: Sumitomo Chemical Co., Ltd BT-31-0163 GLP, Unpublished	
IIA, 5.6.2	Hoberman, A.M.	1992	Dosage-range Developmental Toxicity (Embryo-fetal Toxicity and Teratogenic Potential) Study of Procymidone Administered Orally to Crl: CD/BR VAF/Plus Presumed Pregnant Rats Argus Research Laboratory Inc. Owner: Sumitomo Chemical Co., Ltd BT-21-0160 GLP, Unpublished	
IIA, 5.6.2	Hoberman, A.M.	1992	Developmental Toxicity (Embryo-foetal Toxicity and Teratogenic Potential Including a Postnatal Evaluation) Study of Procymidone Administered Orally via Gavage to Crl:CD BR/VAF Plus Presumed Pregnant Rats Argus Research Laboratory Inc. Owner: Sumitomo Chemical Co., Ltd BT-21-0161 GLP, Unpublished	
	Hoberman, A.M.	1992	Developmental Toxicity (Embryo-foetal Toxicity and Teratogenic Potential Including a Postnatal Evaluation) Study of Procymidone Administered Orally via Gavage to Crl:CD BR/VAF Plus Presumed Pregnant Rats (Amendment) Argus Research Laboratory Inc. Owner: Sumitomo Chemical Co., Ltd BT-21-0164 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, 5.8.1	Kogiso, S., Kasaoka, Y., Kato, H. Nakatsuka, I.	1992	Reverse Mutation Test of CCA in Bacterial Systems Owner: Sumitomo Chemical Co., Ltd BT-20-0148 GLP, Unpublished	
IIA, 5.8.1	Murli, H.	1992	Dose Range Finding Study for In vivo Murine Micronucleus Test on CCA Hazleton Washington Inc. Owner: Sumitomo Chemical Co., Ltd BT-21-0158 GLP, Unpublished	
IIA, 5.8.1	Murli, H.	1992	Mutagenicity Test on CCA: In vivo Mammalian Micronucleus Assay Hazleton Washington Inc. Owner: Sumitomo Chemical Co., Ltd BT-21-0159 GLP, Unpublished	
IIA, 5.8.1	Saito, K.	1992	Metabolism of CCA in Rats Owner: Sumitomo Chemical Co., Ltd BM-20-0032 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, 6.0	Macdonald, I.A. Gillis, N.A.	1992	Procymidone: Determination of the Storage Stability in Grapes and Wine. Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0326 GLP, Unpublished	
IIA, 6.0	Macdonald, I.A., Gillis, N.A., Howie, D.	1992	Procymidone: Determination of Storage Stability at Residue Levels in Must and Pomace Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0318 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, 6.0	Roberts, N.L., Macdonald, I.A., Gillis, N.A.	1992	Procymidone and 3,5-Dichloroaniline: Determination of Stability of Residues in Grapes and Wine Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0315 GLP, Unpublished	
IIA, 6.0	Halasz-Laky, V.	1993	Determination of Procymidone Storage Stability in Strawberry Samples Toxicological Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0283 GLP, Unpublished	
IIA, 6.0	Ambrus, A.	1994	Determination of Storage Stability of Procymidone Residues in Sunflower Seed Plant Health and Soil Conservation Station (FNTA) Owner: Sumitomo Chemical Co., Ltd BR-41-0469 GLP, Unpublished	
IIA, 6.0	Ambrus, A.	1994	Determination of Storage Stability of Procymidone Residues in Sour Cherry Plant Health and Soil Conservation Station (FNTA) Owner: Sumitomo Chemical Co., Ltd BR-41-0470 GLP, Unpublished	
IIA, 6.0	Halasz-Laky, V.	1994	Storage Stability Study of Procymidone in Eggplant Toxicological Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-41-0467 GLP, Unpublished	
IIA, 6.0	Macdonald, I.A., Gillis, N.A., Howie, D.	1995	Procymidone: Determination of Stability of Residues in Tomatoes Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-51-0461 GLP, Unpublished	
IIA, 6.0	Macdonald, I.A., Gillis, N.A., Howie, D.	1995	Procymidone: Determination of Stability of Residues in Cucumbers Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-51-0462 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, 6.0	Macdonald, I.A., Gillis, N.A., Howie, D.	1995	Procymidone: Determination of Stability of Residues in Lettuce. Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-51-0463 GLP, Unpublished	
IIA, 6.0	Macdonald, I.A., Gillis, N.A., Howie, D.	1995	Procymidone: Determination of Stability of Residues in Haricot Beans Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-51-0464 GLP, Unpublished	
IIA, 6.0	Macdonald, I.A., Gillis, N.A., Howie, D.	1995	Procymidone: Determination of Stability of Residues in Shallots Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-51-0465 GLP, Unpublished	
IIA, 6.0	Ross, M.K., Ewing, A., Kimmel, E., Ruzo, L.O.	1991	Metabolism of ^{14}C-Phenyl Procymidone in Grapes and Grape Commodities: Grape Metabolism Study PTRL-West Inc. Owner: Sumitomo Chemical Co., Ltd BM-11-0029 GLP, Unpublished	
IIA, 6.1	Ross, M.K., Ewing, A., Kimmel, E., Ruzo, L.O.	1991	Metabolism of ^{14}C-Carbonyl Procymidone on Grapes and Grape Commodities: Grape Metabolism Study PTRL -West Inc. Owner: Sumitomo Chemical Co., Ltd BM-11-0028 GLP, Unpublished	
IIA, 6.1, 6.5.1	Ross, M.K., Toia, R.F.	1992	Metabolism of ^{14}C-Phenyl- and ^{14}C-Carbonyl Procymidone in Grapes and Grape Commodities: Wine and Pomace PTRL-West Inc. Owner: Sumitomo Chemical Co., Ltd BM-21-0035 GLP, Unpublished	
IIA, 6.1	Fujisawa, T., Collins, E.H., Toia, R.F.	1994	A Metabolism study with Unlabelled ^{14}C-Phenyl and ^{14}C-Carbonyl Procymidone on Grapes PTRL -West Inc. Owner: Sumitomo Chemical Co., Ltd BM-41-0041 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, 6.1	Croucher, A., Hill, A.	1996	Procymidone: Metabolism in Lettuce Corning Hazleton (Europe) Owner: Sumitomo Chemical Co., Ltd BM-0062 GLP, Unpublished	
IIA, 6.2	Struble, C.B.	1992	Metabolism of ^{14}C-Procymidone in Lactating Goats - Definitive Study Hazleton Wisconsin Inc. Owner: Sumitomo Chemical Co., Ltd BM-21-0037 GLP, Unpublished	
IIA, 6.2	Struble, C.B.	1992	Metabolism of ^{14}C-Procymidone in Laying Hens - Definitive Study (In Life Phase) Hazleton Wisconsin Inc. Owner: Sumitomo Chemical Co., Ltd BM-21-0036 GLP, Unpublished	
		1992	Metabolism of ^{14}C-Procymidone in Laying Hens -(Definitive Study - Characterisation and Identification of Residues) Hazleton Wisconsin Inc. Owner: Sumitomo Chemical Co., Ltd BM-21-0038 GLP, Unpublished	
IIA, 6.3	Viglietta, M.	1994	The Determination of residues of procymidone in Pears treated with Sumisclex by Gas chromatography Owner: Sumitomo Chemical Co., Ltd BR-41-0444 GLP, Unpublished	
IIA, 6.3	Grolleau, G.	1997	Magnitude of the residue of procymidone in pear raw agricultural commodity European Agricultural Services Owner: Sumitomo Chemical Co., Ltd BR-0490 GLP, Unpublished	
IIA, 6.3	Grolleau, G.	1997	Magnitude of the residue of procymidone in plum raw agricultural commodity European Agricultural Services Owner: Sumitomo Chemical Co., Ltd BR-0489 GLP, Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 6.3	Benet, F., Massenot, F.	1995	Etude de residus de procymidone dans des prunes et pruneaux SOPRA Owner: Sumitomo Chemical Co., Ltd BR-0478F GLP, Unpublished	
IIA, 6.3	Massenot, F.	1996	Procymidone: Residues in plums SOPRA Owner: Sumitomo Chemical Co., Ltd BR-0482 GLP, Unpublished	
IIA, 6.3	Massenot, F.	1997	Procymidone: Residues in plums SOPRA Owner: Sumitomo Chemical Co., Ltd BR-0492 GLP, Unpublished	
IIA, 6.3	Benet, F., Massenot, F.	1994	Residue Trials with SUMISCLEX 500 SC formulation on Peaches in France ICI SOPRA Owner: Sumitomo Chemical Co., Ltd BR-31-0445F GLP, Unpublished	
IIA, 6.3	Grolleau, G.	1997	Magnitude of the residue of procymidone in peach raw agricultural commodity European Agricultural Services Owner: Sumitomo Chemical Co., Ltd BR-0488 GLP, Unpublished	
IIA, 6.3	Benet, F.	1995	Recherche de residus de procymidone dans des peches ICI Protection de l'Agriculture Owner: Sumitomo Chemical Co., Ltd BR-0477F GLP, Unpublished	
IIA, 6.3, 6.5.2	Roberts, N.L., Macdonald, I.A., Gillis, N.A.	1992	Procymidone: Determination of Residual Concentrations in Grapes and Wine from Field Trials in Cordoba Spain (1991 trials) Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0311 GLP, Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 6.3, 6.5.2	Roberts, N.L., Macdonald, I.A., Gillis, N.A.	1992	Procymidone: Determination of Residual Concentrations in Grapes and Wine Following Field Trials in Avignon, France (1991 trials) Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0309 GLP, Unpublished	
IIA, 6.3, 6.5.2	Roberts, N.L., Macdonald, I.A., Gillis, N.A.	1992	Procymidone: Determination of Residual Concentrations in Grapes and Wine Following Field Trials in Toledo, Spain (1991 trials) Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0310 GLP, Unpublished	
IIA, 6.3, 6.5.2	Roberts, N.L., Macdonald, I.A., Gillis, N.A.	1992	Procymidone: Determination of Residual Concentrations in Grapes and Wine Following Field Trials in Asti, Italy (1991 trials) Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0312 GLP, Unpublished	
IIA, 6.3, 6.5.2	Roberts, N.L., Macdonald, I.A., Gillis, N.A.	1992	Procymidone: Determination of Residual Concentrations in Grapes and Wine Following Field Trials in Bologna, Italy (1991 trials) Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0313 GLP, Unpublished	
IIA, 6.3, 6.5.2	Roberts, N.L., Macdonald, I.A., Gillis, N.A.	1992	Procymidone: Determination of Residual Concentrations in Grapes and Wine Following Field Trials in Tours, France (1991 trials) Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0308 GLP, Unpublished	
IIA, 6.3	Brookman, D.J., Curry, K.K., Jovanovich, A.P., Kreis, P.B.	1993	Procymidone - Magnitude of residues in grapes. 1992 European trials. Huntingdon Research Centre Owner: Sumitomo Chemical Co., Ltd BR-31-0292 GLP, Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 6.3	Macdonald, I.A., Gillis, N.A., Howie, D.	1992	Determination of Residual Concentrations in Tomatoes from Field Trials in France Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0260 GLP, Unpublished	
IIA, 6.3	Macdonald, I.A., Gillis, N.A., Howie, D.	1992	Determination of Residual Concentrations in Tomatoes from Field Trials in Italy Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0261 GLP, Unpublished	
IIA, 6.3	Macdonald, I.A., Gillis, N.A., Howie, D.	1992	Determination of Residual Concentrations in Tomatoes from a Field Trial in Spain Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-11-0274 GLP, Unpublished	
IIA, 6.3	Macdonald, I.A., Gillis, N.A., Howie, D.	1992	Determination of Residual Concentrations in Tomatoes from a Field Trial in Spain Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-11-0271 GLP, Unpublished	
IIA, 6.3	Macdonald, I.A., Gillis, N.A., Howie, D.	1992	Determination of Residual Concentrations in Tomatoes from a Field Trial in Spain Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-11-0272 Not GLP, Unpublished	
IIA, 6.3	Macdonald, I.A., Gillis, N.A., Howie, D.	1992	Determination of Residual Concentrations in Tomatoes from a Field Trial in Spain Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-11-0273 Not GLP, Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 6.3	Grolleau, G.	2002	Magnitude of the residue of procymidone in protected tomato raw agricultural commodity – Northern and Southern Europe 2001. European Agricultural Service Owner: Sumitomo Chemical Co., Ltd BR-0517 GLP, Unpublished	
IIA, 6.3	Grolleau, G.	2002	Magnitude of the residue of procymidone in protected pepper raw agricultural commodity – Northern and Southern Europe 2001. European Agricultural Services Owner: Sumitomo Chemical Co., Ltd BR-0516 GLP, Unpublished	
IIA, 6.3	Macdonald, I.A., Gillis, N.A., Howie, D.	1992	Determination of Residual Concentrations in Cucumbers from Field Trials in France Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0262 GLP, Unpublished	
IIA, 6.3	Macdonald, I.A., Gillis, N.A., Howie, D.	1992	Determination of Residual Concentrations in Cucumbers from Field Trials in Italy Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0263 GLP, Unpublished	
IIA, 6.3	Grolleau, G.	2002	Magnitude of the residue of procymidone in protected cucumber raw agricultural commodity – Northern and Southern Europe 2001. European Agricultural Services Owner: Sumitomo Chemical Co., Ltd BR-0515 GLP, Unpublished	
B.6.3	Grolleau, G.	1997	Magnitude of the residue of procymidone in peach raw agricultural commodity Generated by: European Agricultural Services Submitted by: Sumitomo Chemical Co., Ltd Company file No.: BR-0488	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 6.3	Macdonald, I.A., Gillis, N.A., Howie, D.	1992	Determination of Residual Concentrations in Cucumbers from Field Trials in Spain Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0264 GLP, Unpublished	
IIA, 6.3	Benet, F., Massenot, F.	1994	Residue Trials with SUMISCLEX 500 SC formulation on Cabbage and Cauliflower in France Bernay Laboratory Owner: Sumitomo Chemical Co., Ltd BR-31-0344F GLP, Unpublished	
IIA, 6.3	Benet, F.	1994	Recherche de residus de procymidone dans des choux pommes et choux-fleurs ICI Protection de l'Agriculture Owner: Sumitomo Chemical Co., Ltd BR-41-0452F GLP, Unpublished	
IIA, 6.3	Benet, F.	1995	Procymidone: Residues in head cabbage and cauliflower SOPRA Owner: Sumitomo Chemical Co., Ltd BR-0480 GLP, Unpublished	
IIA, 6.3	Massenot, F.	1996	Procymidone: Residues in head cabbages, cauliflower, broccoli and Brussels sprouts SOPRA Owner: Sumitomo Chemical Co., Ltd BR-0483 GLP, Unpublished	
IIA, 6.3	Massenot, F.	1997	Procymidone: Residues in head cabbages, cauliflower, broccoli and Brussels sprouts SOPRA Owner: Sumitomo Chemical Co., Ltd BR-0491 GLP, Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 6.3	Benet, F.	1994	Etude des residus de procymidone dans des choux pommes de choux-fleurs SOPRA Owner: Sumitomo Chemical Co., Ltd BR-41-0460F GLP, Unpublished	
IIA, 6.3	Macdonald, I.A., Gillis, N.A., Howie, D.	1992	Determination of Residual Concentrations in Lettuce from Field Trials in France Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0266 GLP, Unpublished	
IIA, 6.3	Benet, F.	1995	Etude de residus de procymidone en culture d'endives (Chicons et racines) SOPRA Owner: Sumitomo Chemical Co., Ltd BR-51-0474F GLP, Unpublished	
IIA, 6.3	Benet, F.	1995	Procymidone: Residues in witloof chicory SOPRA Owner: Sumitomo Chemical Co., Ltd BR-0479 GLP, Unpublished	
IIA, 6.3	Macdonald, I.A., Gillis, N.A., Howie, D.	1991	Determination of Residual Concentrations in Haricot Beans from Field Trials in France Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0265 GLP, Unpublished	
IIA, 6.3	Anonymous (residue form)	1992	Residue Trials with SUMISCLEX 500 WP formulation on Beans in Belgium BEAGx Owner: Sumitomo Chemical Co., Ltd BR-31-0333 Not GLP, Unpublished	
IIA, 6.3	Benet, F., Massenot, F.	1992	Residue Trials with SUMISCLEX 500 SC formulation on Peas in France ICI SOPRA Owner: Sumitomo Chemical Co., Ltd BR-21-0336 GLP, Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 6.3	Benet, F.	1995	Procymidone: Residues in peas SOPRA Owner: Sumitomo Chemical Co., Ltd BR-0476 GLP, Unpublished	
IIA, 6.3	Benet, F., Massenot, F.	1992	Residue Trials with SUMISCLEX 500 SC formulation on Sunflower in France ICI SOPRA Owner: Sumitomo Chemical Co., Ltd BR-11-0255F Not GLP, Unpublished	
IIA, 6.3	Macdonald, I.A., Gillis, N.A., Howie, D.	1992	Determination of Residual Concentrations in Shallots from Field Trials in France Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0324 GLP, Unpublished	
IIA, 6.3	Macdonald, I.A., Gillis, N.A., Howie, D.	1992	Determination of Residual Concentrations in Onion from Field Trials in Spain Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0267 GLP, Unpublished	
IIA, 6.3	Grolleau, G.	2002	Magnitude of the residue of procymidone in plum raw agricultural commodity northern and southern Europe – 2001 Owner: Sumitomo Chemical Co., Ltd. BR-0519 GLP, Unpublished	
IIA, 6.3	Rzepka, S.	2003	Magnitude of the residue of procymidone and its metabolite 3,5-dichloroaniline in plum raw agricultural commodity Owner: Sumitomo Chemical Co., Ltd. BR-0543 GLP. Unpublished	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 6.3 6.5.2,	Grolleau, G	2003	Magnitude of the residue of procymidone and its metabolites in plum raw agricultural commodity and processed fractions, and of procymidone in weeds at the orchard, STAPHYT Study Number: X-03-080-510/027 **Ongoing study**	
IIA, 6.5.1	Lewis, C.J.	2003	[^{14}C]Procymidone: Nature of the residue study Owner: Sumitomo Chemical Co., Ltd. BM-0080 GLP, Unpublished	To check
IIA, 6.5.2	Macdonald, I.A., Gillis, N.A., Howie, D.	1992	Procymidone: Determination of Residual Concentrations in Grape, Wine, Must and Pomace from Field Trials in France (Study A) Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0297 GLP, Unpublished	
IIA, 6.5.2	Macdonald, I.A., Gillis, N.A., Howie, D.	1992	Procymidone: Determination of Residual Concentrations in Grape, Wine, Must and Pomace from Field Trials in France (Study B) Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0301 GLP, Unpublished	
IIA, 6.5.2	Macdonald, I.A., Gillis, N.A., Burgin, M.J.	1992	3,5-Dichloroaniline: Determination of Residual Concentrations in Stored Wine Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0319 GLP, Unpublished	
IIA, 6.5.2	Roberts, N.L., Macdonald, I.A., Gillis, N.A., Howie, D.	1992	Procymidone and 3,5-Dichloroaniline: Determination of Residual Concentrations in Cellar Stored Wine following Field Trials in Europe (1991 Trials) Huntingdon Research Centre Ltd Owner: Sumitomo Chemical Co., Ltd BR-21-0316 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, 6.5.2	Ambrus, A.	1992	Determination of Procymidone Residues in Crude and Refined Sunflower Seed Oil Plant Health and Soil Conservation Station (FNTA) Owner: Sumitomo Chemical Co., Ltd BR-21-0282 GLP, Unpublished	
IIA, 6.5.2	Rzepka, S., Milhan, C.	2003	Magnitude of the residue of procymidone and its metabolites in processed plum fractions 2003 Owner: Sumitomo Chemical Co., Ltd. BR-0544 GLP, Unpublished	
IIA, 6.6	Schnoder, F.	2001	[14C]-Procymidone: Potential uptake on succeeding crops Covance Laboratories GmbH Owner: Sumitomo Chemical Co., Ltd BM-0071 GLP, Unpublished	To check

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
IIA, 7.1.1.1.1, 7.1.1.2.1	Purser, D.	1999	(^{14}C)-Procymidone: soil metabolism and degradation Covance Laboratories Ltd. Owner: Sumitomo Chemical Co., Ltd BM-0068 GLP, Unpublished	
IIA, 7.1.1.1.2	Purser, D.	1996	Procymidone: Photodegradation on a soil surface Corning Hazleton (Europe) Owner: Sumitomo Chemical Co., Ltd BM-0061 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, 7.1.1.2.1	Wimbush, J.	2002	PCM-NH-COOH: Degradation in three soils. Covance Laboratories Ltd. Owner: Sumitomo Chemical Co., Ltd BA-0077 GLP, Unpublished	
IIA, 7.1.1.2.2	Benwell, L.	1999	Procymidone: dissipation from six field soils Covance Laboratories Ltd. Owner: Sumitomo Chemical Co., Ltd BR-0504 GLP, Unpublished	
IIA, 7.1.2	Purser, D.	1999	(^{14}C)-PCM-NH-COOH: Adsorption in soil Covance Laboratories Ltd. Owner: Sumitomo Chemical Co., Ltd BM-0069 GLP, Unpublished	
IIA, 7.1.3.3	Schnoder, F.	2002	[14C]-procymidone: Lysimeter study according to BBA Guideline IV, 4-3, 1990. Covance Laboratories Ltd. Owner: Sumitomo Chemical Co., Ltd BA-0074 GLP, Unpublished	
IIA, 7.2.1.2	Brodsky, J.	1997	Determination of the Direct Phototransformation of Procymidone in Water C.A.U. GmbH Owner: Sumitomo Chemical Co., Ltd BP-0053 GLP, Unpublished	
IIA, 7.2.1.3.1	Nagasawa, S., Kikuchi, R.	1976	Biodegradability of Procymidone Owner: Sumitomo Chemical Co., Ltd BM-60-0043 Not GLP, Unpublished	
IIA, 7.2.1.3.2	Lewis, C.J.	1996	(^{14}C)-Procymidone Degradation and Retention in Water-Sediment systems Corning Hazleton (Europe) Owner: Sumitomo Chemical Co., Ltd BW-0060 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, 7.2.1.3.2	Lewis, C.J.	2003	[Carbonyl-^{14}C]Procymidone: Degradation and retention in water-sediment systems Owner: Sumitomo Chemical Co., Ltd BM-0060 GLP, Unpublished	
IIA, 7.2.2	Betteley, J.M.T.	1996	Procymidone Physicochemical Properties Huntingdon Life Sciences Ltd. Owner: Sumitomo Chemical Co., Ltd. BP-0050 GLP, Unpublished ⇒ Annex II, 2.1.1	

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, 8.1.2	Rodgers, M.H., Maltby, K., Dawe, I.S.	1996	Procymidone - Subacute dietary toxicity (LC_{50}) to the Bobwhite quail Huntingdon Life Sciences Ltd Owner: Sumitomo Chemical Co., Ltd BW-0050 GLP, Unpublished	
IIA, 8.1.3	Rodgers, M.H.	1997	Procymidone - Effects on reproduction in Bobwhite quail after dietary administration Huntingdon Life Sciences Ltd Owner: Sumitomo Chemical Co., Ltd BW-0064 GLP, Unpublished	
IIA, 8.2.1	Machado, M.W.	2002	PCM-NH-COONa – Acute toxicity to Rainbow trout (Oncorhynchus mykiss) under static-renewal conditions. Springborn Laboratories (Europe) AG Owner: Sumitomo Chemical Co., Ltd BW-0075 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, 8.2.1	Machado, M.W.	2003	CCA – Acute toxicity to rainbow trout (*Oncorhynchus mykiss*) under static-renewal conditions Springborn Smithers Laboratories; Owner: Sumitomo Chemical Co., Ltd. BW-0083 GLP, Unpublished	
IIA, 8.2.2.2	Sousa, J.V.	1996	Procymidone TG - Early life stage toxicity test with rainbow trout (Oncorhynchus mykiss) Springborn Laboratories, Inc. Owner: Sumitomo Chemical Co., Ltd BW-0055 GLP, Unpublished	
IIA, 8.2.2	Cafarella, M.A.	2003	Procymidone – Short-Term Reproduction Test with Medaka (*Oryzias latipes*). Owner: Sumitomo Chemical Co., Ltd, BW-0086 GLP, Unpublished	
IIA, 8.2.2	Kagoshima, M.	2003	Long-term toxicity study of procymidone T.G. to Medaka (*Oryzias latipes*) – **Interim report** Sumitomo Study Number: 0301EFL GLP, Unpublished **Ongoing study**	
IIA, 8.2.3	Panthani, A., Herczog, K.J.S.	2003	Bioconcentration of [^{14}C]Procymidone by Bluegill Sunfish (*Lepomis macrochirus*). Owner: Sumitomo Chemical Co., Ltd. BM-0084 GLP, Unpublished	
IIA, 8.2.4	Bell, G., Groom, S.N., Smith, B.	1996	Procymidone - Acute toxicity to Daphnia magna Huntingdon Life Sciences Ltd Owner: Sumitomo Chemical Co., Ltd BW-0051 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	Putt, A.E.	1999	PCM-NH-COONa – Acute toxicity to Daphnids (Daphnia magna) under static conditions Springborn Laboratories, Inc. Owner: Sumitomo Chemical Co., Ltd BW-0069 GLP, Unpublished	
IIA, 8.2.4	Machado, M.W.	2003	CCA – Acute toxicity to water fleas, *Daphnia magna*, under static conditions; Springborn Smithers Laboratories Owner: Sumitomo Chemical Co., Ltd. BW-0084 GLP, Unpublished	
IIA, 8.2.5	Putt, A.E.	1996	Procymidone TG - The full life-cycle toxicity test with water fleas (Daphnia magna) under flow through conditions Springborn Laboratories, Inc. Owner: Sumitomo Chemical Co., Ltd BW-0056 GLP, Unpublished	
IIA, 8.2.6	Hoberg, J.R.	1999	PCM-NH-COONa – Toxicity to the freshwater green alga, Pseudokirchneriella subcapitata Springborn Laboratories, Inc. Owner: Sumitomo Chemical Co., Ltd BW-0070 GLP, Unpublished	
IIA, 8.2.6	Hoberg, J.R.	2003	CCA – Toxicity to the freshwater green alga, *Pseudokirchneriella subcapitata*; Springborn Smithers Laboratories; Owner: Sumitomo Chemical Co., Ltd. BW-0085 GLP, Unpublished	
IIA, 8.2.7	Putt, A.E.	2003	Procymidone – The full life cycle toxicity to midge (*Chironomus riparius*) under static conditions. Owner: Sumitomo Chemical Co., Ltd. BW-0082 GLP, Unpublished	
IIA, 8.2.7	Putt, A.E.	2003	Procymidone – Bioconcentration and depuration study with Oligochaetes (*Lumbriculus variegatus*). Owner: Sumitomo Chemical Co., Ltd. BM-0083 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, 8.3.1.1	Bell, G., Barrett, K.	1996	Procymidone TG - Acute toxicity to Honey bees (Apis mellifera) Huntingdon Life Sciences Ltd Owner: Sumitomo Chemical Co., Ltd BW-0054 GLP, Unpublished	
IIA, 8.3.2	Schmuck, R.	1993	Acute effects of Sumisclex WG50 on Carabid Beetles (Poecilus cupreus) under Laboratory Conditions Bayer AG Owner: Sumitomo Chemical Co., Ltd BW-31-0028 GLP, Unpublished	
IIA, 8.3.2	Peto, R.	1993	Effects of Sumisclex WG50 on Trichogramma caoeciae Marchal (Hymenoptera, Trichogrammatidae) in Laboratory RCC Umweltchemie GmbH & Co. KG Owner: Sumitomo Chemical Co., Ltd BW-31-0029 GLP, Unpublished	
IIA, 8.3.2	Kleiner, R.	1993	Testing toxicity to Beneficial Arthropods Parasitic wasp - Aphidius matricariae Hal./ Adults according to IOBC Guideline (Polgar, 1988) Sumisclex WG50 Bayer AG Owner: Sumitomo Chemical Co., Ltd BW-31-0027 GLP, Unpublished	
IIA, 8.3.2	Kast, W.K.	1989	Versuchsbericht der LVWO Weinsberg für die Prüfung im Zulassungverfahren Bayer AG Owner: Sumitomo Chemical Co., Ltd BE-91-1420G Not GLP, Unpublished	
IIA, 8.4.1	Rodgers, M.H., Cameron, D.M., Gillham, A.M.	1995	Procymidone - Acute toxicity (LC_{50}) to the earthworm (Eisenia foetida) Huntingdon Life Sciences Ltd Owner: Sumitomo Chemical Co., Ltd BW-0049 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	Nienstedt, K.M.	2002	PCM-NH-COONa: a 14-day acute toxicity test with the earthworm Eisenia fetida. Springborn Laboratories (Europe) AG Owner: Sumitomo Chemical Co., Ltd BW-0077 GLP, Unpublished	
IIA, 8.4.2	Nienstedt, K. M.,	2002	A chronic toxicity and reproduction test exposing Eisenia fetida to Kimono 50 SC in OECD artificial soil. Springborn Smithers Laboratories (Europe) AG Owner: Sumitomo Chemical Co., Ltd BW-0078 GLP, Unpublished	
IIA, 8.5	van der Kolk, J.	2002	PCM-NH-COONa (sodium salt of a metabolite of procymidone): Determination of effects on soil microflora activity. Springborn Laboratories (Europe) AG Owner: Sumitomo Chemical Co., Ltd BW-0076 GLP, Unpublished	

APPENDIX IIIB

PROCYMIDONE

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, 4.1.1	Mukumoto, M.	2003	Analytical method for the determination of active substance in procymidone technical material. Owner: Sumitomo Chemical Co., Ltd. BA-0086 GLP, Unpublished
IIA, 4.1.1	Mukumoto, M.	2003	Determination of procymidone content by current and new analytical methods. Owner: Sumitomo Chemical Co., Ltd. BA-0088 GLP, Unpublished
IIA, 4.2.1	Weeren, R.D., Pelz, S.	2000	Validation of the DFG method S19 (extended revision) for the determination of residues of procymidone in specimens of commodities with high water content (white cabbage). Specht and Partner Owner: Sumitomo Chemical Co., Ltd BA-0076 GLP, Unpublished
IIA, 4.2.1	Weeren, R.D., Pelz, S.	2000	Validation of the DFG method S19 (extended revision) for the determination of residues of procymidone in specimens of fruits with high acid content (currant). Specht and Partner Owner: Sumitomo Chemical Co., Ltd BA-0077 GLP, Unpublished
IIA, 4.2.1	Weeren, R.D., Pelz, S.	2000	Validation of the DFG method S19 (extended revision) for the determination of residues of procymidone in samples of commodities with high fat content (rapeseed). Specht and Partner Owner: Sumitomo Chemical Co., Ltd BA-0078 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, 4.2.1	Weeren, R.D., Pelz, S.	2000	Validation of the DFG method S19 (extended revision) for the determination of residues of procymidone in specimens of cereals and other dry crops (barley grain and straw). Specht and Partner Owner: Sumitomo Chemical Co., Ltd BA-0081 GLP, Unpublished
IIA, 4.2.1	Rzepka, S.	2003	Validation of suitable methods for the determination of residues of CCA, DCA and PCM-NH-COOH in/on commodities with high acid content (plum jam). Owner: Sumitomo Chemical Co., Ltd. BA-0090 GLP, Unpublished
IIA, 4.2.2	Weeren, R.D., Pelz, S.	2000	Validation of the Corning Hazleton (Europe) test method (CHE study number 1482/1) for the determination of residues of procymidone in soil. Specht and Partner Owner: Sumitomo Chemical Co., Ltd BA-0083 GLP, Unpublished
IIA, 4.2.2	Wimbush, J.	2002	PCM-NH-COOH: Degradation in three soils (analytical procedures only) Covance Laboratories Ltd Owner: Sumitomo Chemical Co., Ltd BA-0084 GLP, Unpublished
IIA, 4.2.3	Wais, A.	2001	Development and validation of the residue analytical method for procymidone in surface water. RCC Ltd Owner: Sumitomo Chemical Co., Ltd BA-0079 GLP, Unpublished
IIA, 4.2.3	Wolf, S.	2001	Validation of the multi-residue method F12 for procymidone in drinking water. RCC Ltd Owner: Sumitomo Chemical Co., Ltd BA-0082 GLP, Unpublished
IIA, 4.2.3	Wimbush, J.	2002	PCM-NH-COOH: Validation of an analytical method for the determination of residues in surface water. Covance Laboratories Ltd Owner: Sumitomo Chemical Co., Ltd BA-0085 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
IIA, 5.1	Tarui, H.	2003	Rat *in vitro* metabolism of procymidone. Owner: Sumitomo Chemical Co., Ltd. BM-0085 GLP, Unpublished
	Yamada	1991	??????
IIA, 5.3.3	Ogata, H.	2002	28-day repeated dose dermal toxicity study of procymidone TG in rats. Panapharm Laboratories Co., Ltd Owner: Sumitomo Chemical Co., Ltd BT-0200 GLP, Unpublished
IIA, 5.3.3	Ogata, H.	2001	7-day repeated dose dermal toxicity study of procymidone TG in rats. Panapharm Laboratories Co., Ltd Owner: Sumitomo Chemical Co., Ltd BT-0198 GLP, Unpublished not found
IIA, 5.9.1	Kurihara, T.	2001	A Review on Medical Examinations of Factory Workers Possibly Exposed to Procymidone Technical Materials Owner: Sumitomo Chemical Co., Ltd BT-0197 Not GLP, Unpublished
IIIA, 7.3	Owen, H.M.	2002	Procymidone: in vitro absorption through human and rat epidermis. Central Toxicology Laboratory Owner: Sumitomo Chemical Co., Ltd BM-0076 GLP, Unpublished
IIIA, 7.3	Savides, M.C.	2002	The in vivo dermal absorption of [14C]procymidone SC in rats. Ricerca Owner: Sumitomo Chemical Co., Ltd BM-0075 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

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	Grolleau, G.	2002	Magnitude of the residue of procymidone in protected tomato raw agricultural commodity – Northern and Southern Europe 2001. European Agricultural Service Owner: Sumitomo Chemical Co., Ltd BR-0517 GLP, Unpublished
IIA, 6.3	Grolleau, G.	2002	Magnitude of the residue of procymidone in protected pepper raw agricultural commodity – Northern and Southern Europe 2001. European Agricultural Services Owner: Sumitomo Chemical Co., Ltd BR-0516 GLP, Unpublished
IIA, 6.3	Grolleau, G.	2002	Magnitude of the residue of procymidone in protected cucumber raw agricultural commodity – Northern and Southern Europe 2001. European Agricultural Services Owner: Sumitomo Chemical Co., Ltd BR-0515 GLP, Unpublished
IIA, 6.3	Grolleau, G.	2002	Magnitude of the residue of procymidone in plum raw agricultural commodity northern and southern Europe – 2001 Owner: Sumitomo Chemical Co., Ltd. BR-0519 GLP, Unpublished
IIA, 6.3	Rzepka, S.	2003	Magnitude of the residue of procymidone and its metabolite 3,5-dichloroaniline in plum raw agricultural commodity Owner: Sumitomo Chemical Co., Ltd. BR-0543 GLP. Unpublished
IIA, 6.3 6.5.2, IIIA, 10.3	Grolleau, G	2003	Magnitude of the residue of procymidone and its metabolites in plum raw agricultural commodity and processed fractions, and of procymidone in weeds at the orchard, STAPHYT Study Number: X-03-080-510/027 **Ongoing study**
IIA, 6.5.1	Lewis, C.J.	2003	[^{14}C]Procymidone: Nature of the residue study Owner: Sumitomo Chemical Co., Ltd. BM-0080 GLP, Unpublished
IIA, 6.5.2	Rzepka, S., Milhan, C.	2003	Magnitude of the residue of procymidone and its metabolites in processed plum fractions 2003 Owner: Sumitomo Chemical Co., Ltd. BR-0544 GLP, Unpublished

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA, 7.1.1.2.1	Wimbush, J.	2002	PCM-NH-COOH: Degradation in three soils. Covance Laboratories Ltd. Owner: Sumitomo Chemical Co., Ltd BM-0077 GLP, Unpublished
IIA, 7.1.3.3	Schnoder, F.	2002	[14C]-procymidone: Lysimeter study according to BBA Guideline IV, 4-3, 1990. Covance Laboratories Ltd. Owner: Sumitomo Chemical Co., Ltd BM-0074 GLP, Unpublished
IIA, 7.2.1.1	Lentz, N.R.	2002	A hydrolysis study of [14C]procymidone in water Ricerca, LLC Owner: Sumitomo Chemical Co., Ltd. BM-0073 GLP, Unpublished
IIA, 7.2.1.3.2	Lewis, C.J.	2003	[Carbonyl-^{14}C]Procymidone: Degradation and retention in water-sediment systems Owner: Sumitomo Chemical Co., Ltd BM-0060 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
IIA, 8.2.1	Machado, M.W.	2002	PCM-NH-COONa – Acute toxicity to Rainbow trout (Oncorhynchus mykiss) under static-renewal conditions. Springborn Laboratories (Europe) AG Owner: Sumitomo Chemical Co., Ltd BW-0075 GLP, Unpublished
IIA, 8.2.1	Machado, M.W.	2003	CCA – Acute toxicity to rainbow trout (*Oncorhynchus mykiss*) under static-renewal conditions Springborn Smithers Laboratories; Owner: Sumitomo Chemical Co., Ltd. BW-0083 GLP, Unpublished
IIA, 8.2.2	Cafarella, M.A.	2003	Procymidone – Short-Term Reproduction Test with Medaka (*Oryzias latipes*). Owner: Sumitomo Chemical Co., Ltd, BW-0086 GLP, Unpublished
IIA, 8.2.2	Kagoshima, M.	2003	Long-term toxicity study of procymidone T.G. to Medaka (*Oryzias latipes*) – **Interim report** Sumitomo Study Number: 0301EFL GLP, Unpublished **Ongoing study**
IIA, 8.2.3	Panthani, A., Herczog, K.J.S.	2003	Bioconcentration of [^{14}C]Procymidone by Bluegill Sunfish (*Lepomis macrochirus*). Owner: Sumitomo Chemical Co., Ltd. BM-0084 GLP, Unpublished
IIA, 8.2.4	Machado, M.W.	2003	CCA – Acute toxicity to water fleas, *Daphnia magna*, under static conditions; Springborn Smithers Laboratories Owner: Sumitomo Chemical Co., Ltd. BW-0084 GLP, Unpublished
IIA, 8.2.6	Hoberg, J.R.	2003	CCA – Toxicity to the freshwater green alga, *Pseudokirchneriella subcapitata*; Springborn Smithers Laboratories; Owner: Sumitomo Chemical Co., Ltd. BW-0085 GLP, Unpublished
IIA, 8.2.7	Putt, A.E.	2003	Procymidone – The full life cycle toxicity to midge (*Chironomus riparius*) under static conditions. Owner: Sumitomo Chemical Co., Ltd. BW-0082 GLP, Unpublished
IIA, 8.2.7	Putt, A.E.	2003	Procymidone – Bioconcentration and depuration study with Oligochaetes (*Lumbriculus variegatus*). Owner: Sumitomo Chemical Co., Ltd. BM-0083 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, 8.4.1	Nienstedt, K.M.	2002	PCM-NH-COONa: a 14-day acute toxicity test with the earthworm Eisenia fetida. Springborn Laboratories (Europe) AG Owner: Sumitomo Chemical Co., Ltd BW-0077 GLP, Unpublished
IIA, 8.4.2	Nienstedt, K. M.,	2002	A chronic toxicity and reproduction test exposing Eisenia fetida to Kimono 50 SC in OECD artificial soil. Springborn Smithers Laboratories (Europe) AG Owner: Sumitomo Chemical Co., Ltd BW-0078 GLP, Unpublished
IIA, 8.5	van der Kolk, J.	2002	PCM-NH-COONa (sodium salt of a metabolite of procymidone): Determination of effects on soil microflora activity. Springborn Laboratories (Europe) AG Owner: Sumitomo Chemical Co., Ltd BW-0076 GLP, Unpublished
IIIA, 9.2.1	Jarvis, T.	2002	FOCUS groundwater modelling for procymidone and PCM-NH-COOH Novigen Sciences Report No: SU06902 Owner: Sumitomo Chemical Co., Ltd. BM-0079 Not GLP, Unpublished
IIIA, 10.6.2	Galicia, H.F.	2002	Procymidone: Determination of the effects of pesticides on straw degradation in soil using the litterbag test. Springborn Smithers Laboratories (Europe) AG Owner: Sumitomo Chemical Co., Ltd BW-0079 GLP, Unpublished

APPENDIX IV

List of uses supported by available data

PROCYMIDONE

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Plum	northern countries	Sumisclex	F	*Monilia sp*	WP	500 g/kg	Spray	End of flowering	1-2	**7 d**	0.15-0.1	1200-1500	0.75	7	
Cucumber	indoors	Sumisclex	I	*Botrytis sp* *Sclerotinia sp* *Alternaria sp*	WP	500 g/kg	Spray	**XXX**	1-2	**7 d**	0.1875-0.1	1000-1500	0.75	3	Hydroponics

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions