



Chlorothalonil

SANCO/4343/2000 final (revised)

28 September 2006

Review report for the active substance **chlorothalonil**

finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 February 2005
in view of the inclusion of chlorothalonil 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 chlorothalonil, 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. Chlorothalonil 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, Vischim Srl on 08 July 1993, United Phosphorus Ltd on 26 July 1993, K & N Efthymiadis SA on 19 July 1993, Gharda Chemicals Ltd on 19 July 1993, ISK Biotech Europe on 26 July 1993, Barclay Chemicals on 27 July 1993, SANC on 23 July 1993, Iberotam on 26 July 1993, Pilar Ibérica SL on 23 July 1993, AgriChem on 15 July 1993, Portman Agrochemicals on 26 July 1993, Helm AG on 23 July 1993, Industrias Afrasa on 27 July 1993, SA John & Stephen B. on 29 July 1993, B.V. Luxan on 21 July 1993, and Calliope SA on 21 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance chlorothalonil 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 The Netherlands as rapporteur Member State to carry out the assessment of chlorothalonil 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

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.

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 chlorothalonil this deadline was 31 October 1995.

ISK Biotech Europe and Vishim Srl submitted in time each a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore ISK Biotech Europe and Vishim Srl were considered to be the main data submitters. Information has furthermore been submitted by Gharda Chemicals Ltd.

By letter 6 March 1998 Zeneca (now Syngenta) informed the Commission and the rapporteur Member State that the chlorothalonil business of ISK Biosciences (ISK) was purchased by Zeneca Inc/Zeneca Ltd (Zeneca) on February 4th 1998. As a result of this purchase, Zeneca has taken over from and replaced ISK as a notifier for chlorothalonil. Further on in the procedure it has been decided to consider only Syngenta as the main data submitter.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, The Netherlands submitted on 31 January 2000 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 chlorothalonil 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 chlorothalonil from Zeneca Agrochemicals, on 31 July 2000.

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 Zeneca Agrochemicals being the main data submitter, on 20 April 2000.

The Commission organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review), in particular on each of the following disciplines:

- identity and physical /chemical properties ;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from March to September 2001.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 16 November 2001 for comments and further clarification.

In accordance with the provisions of Article 6(4) of Directive 91/414/EEC the Commission organised a tripartite meeting with the main data submitter and the rapporteur Member State for this active substance on 12 December 2002.

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 25 Member States. This final examination took place from July 2001 to September 2004, and was finalised in the meeting of the **Standing Committee** on 15 February 2005.

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 2005/53/EC⁵ concerning the inclusion of chlorothalonil in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing chlorothalonil 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 chlorothalonil 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

⁵ OJ L 241, 17.9.2005, p. 51-56.

the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each chlorothalonil 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).

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 1.4 % 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.

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 chlorothalonil 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 Zeneca Agrochemicals, two of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

On the basis of the information currently available, it has been established that the substances notified by the other data submitters Vischim Srl and Gharda Chemicals Ltd. do, in the meaning of Article 13(2) and (5) of the Directive, differ significantly in degree of purity and/or nature of impurities from the composition registered in the dossier submitted by the main data submitter.

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 chlorothalonil

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 pay particular attention to the protection of:

- aquatic organisms;
- groundwater, in particular with regards to the active substance and its metabolites R417888 and R611965 (SDS46851), when the substance is applied in regions with vulnerable soil and/or climate conditions.

Conditions of use should include risk mitigation measures, 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 chlorothalonil in Annex I under the current inclusion conditions.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. This may particularly be the case for

- A sublethal earthworm study with the lead formulation should be performed by Syngenta and used as confirmatory data.
- The main notifier will submit a new study to set a new ARfD. This study can be evaluated at a later stage because there is a safe use with the current ArfD of 0.015 mg/kg bw/day.

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.

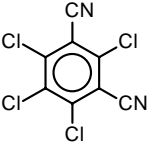
9. Updating of this review report

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 chlorothalonil in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

CHLOROTHALONIL

Common name (ISO)	Chlorothalonil
Chemical name (IUPAC)	Tetrachloroisophthalonitrile
Chemical name (CA)	2,4,5,6-Tetrachloro-1,3-benzenedicarbonitrile
CIPAC No	288
CAS No	1897-45-6
EEC No	217-588-1
FAO SPECIFICATION	Chlorothalonil not less than 985 g/kg Hexachlorobenzene max. 0.04 g/kg Decachlorobiphenyl: max. 0.03 g/kg
Minimum purity	985 g/kg
Molecular formula	C ₈ Cl ₄ N ₂
Molecular mass	265.9
Structural formula	

Melting point	252 °C (99.6 / 99.8 %)
Boiling point	> 350 °C
Appearance	Pure: white crystalline solid or powder Techn.: white or tan powder
Relative density	$D_4^{20} = 1.735$ (99.8%)
Vapour pressure	7.62×10^{-5} Pa at 25 °C
Henry's law constant	2.5×10^{-2} Pa m ³ mol ⁻¹ at 25 °C
Solubility in water	pH (neutral): 0.81 mg/l at 25 °C
Solubility in organic solvents	In g/l at 20 °C: acetone 20.6; dichloroethane 22.4; ethyl acetate 13.8; n-heptane 0.20; xylene 74.4; methanol 1.36
Partition co-efficient (log P_{ow})	pH effectively neutral (ASTM type II water): Log P _{o/w} = 2.94 at 25 °C
Hydrolytic stability (DT₅₀)	pH 5: stable pH 7 : stable pH 9 : DT 50 = 16.1 days at 20 °C
Dissociation constant	No dissociation
Quantum yield of direct photo-transformation in water at $\lambda > 290$ nm	1.4×10^{-3}
Flammability	Not highly flammable
Explosive properties	No explosive properties
UV/VIS absorption (max.)	232 nm, 312 nm and 324 nm ($\epsilon = 62390, 1116$ and 1507 , resp.)
Photostability in water (DT₅₀)	At pH 5 and 25 °C is DT 50 = 64.7 days with 12 hours sunlight/day

APPENDIX II

END POINTS AND RELATED INFORMATION

CHLOROTHALONIL

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	rat: 32% (within 48 h, bile and urine), dog :8% (within 48 h, bile and urine), mice: minimal 10% (within 168 h, urine)
Distribution:	widely distributed, highest tissue residues in kidneys
Potential for accumulation:	no potential for accumulation
Rate and extent of excretion:	mainly via faeces (65-90% in mice, > 80% in rats, 89-99% in dogs)
Toxicologically significant compounds:	parent, thiol metabolites and SDS 3701 (relevant plant and soil metabolite)
Metabolism in animals:	extensive metabolism via glutathion conjugation and subsequently β -lyase pathways

Acute toxicity

Rat LD ₅₀ oral:	> 5000 mg/kg bw
Rat LD ₅₀ dermal:	> 2000 mg/kg bw (rabbit)
Rat LC ₅₀ inhalation:	0.1 mg/l
Skin irritation:	not irritating
Eye irritation:	irritant
Skin sensitization (test method used and result):	skin sensitizer (Maximisation test)

Short term toxicity

Target / critical effect:	stomach and kidneys (histopathological changes and increased organ weights in kidneys)
Lowest relevant oral NOAEL / NOEL:	1.5 mg/kg bw/day (90-day rat)
Lowest relevant dermal NOAEL / NOEL:	< 60 mg/kg bw (21-day rat)
Lowest relevant inhalation NOAEL / NOEL:	no data; not required

Genotoxicity

Some positive response in vitro (without activation). No convincing evidence for genotoxicity in vivo

Long term toxicity and carcinogenicity

Target / critical effect:

kidney and (fore)stomach (pre-neoplastic and neoplastic lesions)
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Lowest relevant NOAEL:

chronic study, rat :1.8 mg/kg bw/day Most relevant NOAEL for setting the AOEL: 2.7 mg/kg bw/day
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Carcinogenicity:

fore-stomach tumours in rats and mice, kidney tumours in rats

Reproductive toxicity

Target / critical effect - Reproduction:

decreased pup weight and histopathological changes in stomach at parental toxic doses.
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Lowest relevant reproductive NOAEL / NOEL:

22.6 mg/kg bw/day, rat

Target / critical effect - Developmental toxicity:

decreased number of live fetuses (rat), increased number of rudimentary ribs (rabbit).
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Lowest relevant developmental NOAEL / NOEL:

10 mg/kg bw/day, rabbit

Delayed neurotoxicity

no data; not required

Other toxicological studies

Toxicological data on three environmental metabolites were submitted: SDS 3701, SDS 46851 and R417888.
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R182281 (SDS 3701):

- | |
|---|
| <ul style="list-style-type: none"> - Oral absorption 26-30% (urine and tissue residues (rat)) - Acute oral toxicity: LD50:242 mg/kg bw - Short-term toxicity: overall NOAEL (90-day/1-year dog): 50 ppm (1.25 mg/kg bw/day) - Genotoxicity:clastogenic in vitro, no genotoxic potential in vivo - Chronic toxicity in rats: NOAEL 3.0 mg/kg bw/day, no indications for carcinogenicity - Reproductive toxicity (rat): decreased body weight pups (without parental toxicity) NOAEL: 1.5 mg/kg bw/day - Teratogenicity (rabbit): increased post implantation loss and decreased foetal weight at maternal toxic |
|---|

R611965 (SDS 46851):

doses NOAEL: 2.5 mg/kg bw/day.
<ul style="list-style-type: none"> - Oral absorption: 22-26% (urinary excretion, rat) - Acute oral toxicity: LD₅₀> 5000 mg/kg bw - Short-term toxicity: Overall NOAEL 50 mg/kg bw/day. - Genotoxicity: Several <i>in vitro</i> and <i>in vivo</i> genotoxicity studies were performed with SDS-46851. All studies, including two point mutation assays, a sister chromatid exchange assay (in CHO-cells), a forward mutation assay (TK, mouse lymphoma cells), an unscheduled DNA synthesis assay (rat hepatocytes), and two micronucleus tests <i>in vivo</i> (mice) were negative. Overall, it is concluded that SDS-46851 is non-genotoxic. - Chronic toxicity in rats: Overall NOAEL: 200 mg/kg bw/day, no carcinogenic potential. - Reproductive toxicity (rat): no reproductive toxicity at parental toxic doses, reproductive NOAEL: > 20.000 ppm (911 mg/kg bw/day) - Teratogenicity (rabbit): decreased live fetuses and decreased fetal weight at maternal toxic doses, developmental NOAEL: 500 mg/kg bw/day.

R417888:

<ul style="list-style-type: none"> - Acute oral toxicity: LD₅₀> 2000 mg/kg bw - 90-d toxicity study: NOAEL > 59 mg/kg bw/d - Genotoxicity: no pointmutations in bacteria and mammalian cells, no chromosome aberrations

Mechanistic data

<p>Kidney effects:</p> <ul style="list-style-type: none"> - the data indicate that kidney lesions are probably caused by thiol metabolites leading to cell-degeneration and subsequent cell-proliferation. - acute kidney effects (ARfD study rat): NOAEL= 60 mg/kg bw/d. <p>Stomach-effects: the data indicate that stomach effects are caused by the irritating properties of the parent compound and were eliminated by glutathion conjugation</p>

Medical data

In case of occupational exposure skin and eye irritation might occur.

Summary (Annex IIA, point 5.10)

Chlorothalonil

ADI

Value	Study	Safety factor
0.015 mg/kg bw/day	90-day rat	100

AOEL	0.009 mg/kg bw/day	Chronic study rat; 30% oral absorption	100
ARfD (acute reference dose)	0.6 mg/kg bw	28-day rat ARfD-study rat	100

R182281 (SDS-3701)

	Value	Study	Safety factor
ADI	0.01 mg/kg bw/day	90-day/1-year dog	100
AOEL	Not relevant		
ARfD (acute reference dose)	0.01 mg/kg bw/day	90-day/1-year dog	100

R611965 (SDS-46851)

	Value	Study	Safety factor
ADI	0.5 mg/kg bw/day	90-day dog	100
AOEL	Not relevant		
ARfD (acute reference dose)	0.5 mg/kg bw/day	90-day dog	100

R417888

	Value	Study	Safety factor
ADI	0.06 mg/kg bw/day	90-day rat	1000
AOEL	Not relevant		
ARfD (acute reference dose)	Not relevant		

Dermal absorption

liquid formulation:
 Concentrate liquid formulation:
 0.02% based on in vivo rat and in vitro human/rat data
 Spray dilution liquid formulation:
 0.34% based on in vivo rat and in vitro human/rat data
 granular formulation:
 Concentrate formulation:
 0.1% based on in vivo rat and in vitro human/rat data
 Spray dilution:
 1.2% based on in vivo rat and in vitro human/rat data

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

max. 23.8% (92 days)

Non-extractable residues after 100 days:

max. 63% (90 days)

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

SDS-3701, max. 32% after 60d, 31-30% after 90-181d
R417888, max 20% after 62-181 days.
SDS-19221, max. 10% after 7 and after 60 days.
SDS-46851, max. 13.2% after 30 days.
R471811 (Compound 13), max. 11%: (max. 55.4% after 121 days incubation of R417888 (end))
R419492, max 12.4% after 120 days.

Supplemental studies

Anaerobic:

SDS-3701, max. 43%
identical metabolic profile as in aerobic studies

Soil photolysis:

No photodegradation of both chlorothalonil and SDS-3701

Remarks:

none

Rate of degradation

Laboratory studies

DT₅₀lab (20 °C, aerobic):

chlorothalonil DT₅₀lab (20°C, aerobic): 0.3; 1.0; 1.3; 1.9; 3; 7; 9; 14, 16; 18; 21; 24; 87 days, mean 15.7 days, range 0.3-87 days (r₂ >0.7)
SDS-3701 DT₅₀lab (20°C, aerobic): 20; 38; 48; 63; 81; 82; 84; 152; 248; 278; 343 days, mean 130.6 days, range 20-343 days (r₂ >0.7)
R417888 DT₅₀lab (20°C, aerobic): 59; 63; 64; 68; 134; 212; 248 days, mean 121.1 days, range 59 – 248 days (r₂ >0.7)
SDS-46851 DT₅₀lab (20°C, aerobic): 103 days
R419492 DT₅₀lab not available, not required

DT₉₀lab (20 °C, aerobic):

chlorothalonil DT₉₀lab (20°C, aerobic): 1.0; 3.3; 4.3; 6.3; 10; 23; 30; 46, 53; 59; 69; 79; 287 days, mean 51.6 days, range 1.0-287 days (extrapolated from DT₅₀,lab)
 SDS-3701 DT₉₀lab (20°C, aerobic): 66; 125; 158; 208; 267; 271; 277; 502; 818; 917; 1132 days, mean 431 days, range 66-1132 days (extrapolated from DT₅₀,lab)
 R417888 DT₉₀lab (20°C, aerobic): 195; 208; 211; 224; 442; 700; 818 days, mean 400 days, range 195 – 818 days (extrapolated from DT₅₀,lab)
 SDS-46851 DT₉₀lab (20°C, aerobic): 340 days
 R419492 DT₉₀lab not available, not required

DT₅₀lab (10 °C, aerobic):

chlorothalonil DT₅₀lab (10°C, aerobic): 33 days (n=1; r²=0.94)
 SDS-3701 DT₅₀lab (10°C, aerobic): longer than study duration - 120 days.

DT₅₀lab (20 °C, anaerobic):DT₅₀lab (20°C, anaerobic): 9,13 days (n=2, r²>0.96)**Field studies (country or region)**DT_{50f} from soil dissipation studies:

DT_{50f}: locations relevant for EU;
 range chlorothalonil: 18-70 days
 range SDS-3701: not available

DT_{90f} from soil dissipation studies:

DT_{90f}: locations relevant for EU;
 range chlorothalonil: 60-300 days, mean 197 days.
 range SDS-3701: longer than study duration - ≥222 - ≥544 days.

Soil accumulation studies:

SDS-3701: accumulation was demonstrated over three years in one experiment; too short to evaluate plateau concentration.

Soil residue studies:

Not available, not required

Remarks:

e.g. effect of soil pH on degradation rate

none

Adsorption/desorptionK_f / K_{oc}:K_d:

pH dependence:

Chlorothalonil	K _{oc} ≥300, 330, 390, ≥640, 850, 900, 1100, 1400, 7000, l/kg; median 850 l/kg.
SDS-3701	K _{oc} 95, 190, <240, 250, 250, 260, 270, 300, 350, 380, 430, 440, 490, 560, 590, 720, 850, 890, 1100 l/kg; median 380 l/kg.
R417888	K _{oc} 6, 6, 7, 11, 13, 17 l/kg; mean 10 l/kg.
SDS-46851	K _{oc} 77 l/kg, required for 2 soils

Mobility**Laboratory studies:**

Column leaching:

Aged residue leaching:

Chlorothalonil	K _{oc} ≥300 - ≥640 l/kg, (n = 2) No leaching, >98% r.a. remained in top 5 cm.
	After 7-60 days aging followed by 2-45 days leaching, r.a. was leached in amounts up to 30% of applied. In case r.a. was identified, chlorothalonil, SDS-3701, SDS-19221 and SDS-46851 were present, the latter in higher amounts than found after ageing. However, in the study with the highest amounts of identified compounds, the water flux was too high. In several studies r.a. was not identified.
SDS-3701	K _{oc} 95 – 1100 l/kg (n = 9)

Field studies:

Lysimeter/Field leaching studies:

A 3 year field groundwater monitoring study in North Carolina (USA): application is 2.5 kg/ha, 8 times with 14 day interval, annual average precipitation is approx. 1700 mm. In this study chlorothalonil remained in the upper soil layer (0-15 cm) and SDS-3701 was found to a depth of 31 cm. Chlorothalonil, SDS-3701, SDS-47525, and SDS-19221 were not found in the groundwater. However, SDS-46851 was found in groundwater at depths of 5.8-10.4 m in max. concentrations from 1.8 to 10.1 µg/l.

A 2 year lysimeter study in Munster (Germany): application is 0,99 kg/ha, annual average precipitation is 910 mm, annual average leachate is approx. 360 mm. In this study the highest concentration measured in the leachate could be attributed to R417888 in a maximum of 24% of radioactivity present in the leachate during the first year. Mean annual measured concentrations are 9.3 µg/l and 7.4 µg/l a.i. equivalent for the two lysimeters respectively. Based on the relative molar mass of 1.23, the averaged annual concentration amounts to 10.3 µg/l.

R419492 was detected in the leachate as well in a concentration of 11% of the applied r.a.. Based on the relative molar mass of 1.4, the averaged annual concentration amounts to 4.4 µg/l.

At least five other (polar) metabolites are found in amounts >0.1 µg/l as chlorothalonil equivalents.

Total amounts of radioactivity equivalents (annual average) amounted to: 31.8 and 25.6 µg/l for both lysimeters respectively in the first year and 4.94 and 4.86 µg/l in the second year. Maximum individual concentrations of a.i. equivalents were 79 and 59 µg/l for the two lysimeters respectively in the first year. No parent compound and none of the main metabolites available as reference substance (SDS-3701; SDS-19221; SDS-47523; SDS-47524; SDS-47525; SDS-66882 and SDS-67042) were detected by radio HPLC, except for SDS-46851, detected in a selected sample (19-11-96) at 0.2 µg/l.

Remarks:

none

2.2 Fate and behaviour in water**Abiotic degradation**

Hydrolytic degradation:

pH 5: no hydrolysis (n=3)
pH 7: no hydrolysis (n=3)
pH 9: DT50 (20°C) 16-38 days. (n=3)

Major metabolites:

none

Photolytic degradation:

Photolysis of chlorothalonil is not an important route in the environment. DT50 65 days, non-validated method DT50 10.5 h, with acetonitrile acting as photosensitiser
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Major metabolites:

SDS-3701: DT50 47.5 min at 40°C and 53.7 min at 18°C
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Biological degradation

Readily biodegradable:

no

Water/sediment study:

DT₅₀ water:DT₉₀ water:DT₅₀ whole system:DT₉₀ whole system:

2.5 hours; This value also applies for the whole system (study 7)

Distribution in water / sediment systems (active substance)

major part of r.a. in water phase. Max. in water: 72% at 0 day. Max in sediment: 4.7% at 0,25 day and after day 14 remains <1%.

Distribution in water / sediment systems (metabolites)

No metabolites were present in the water at levels >10% of applied radioactivity. In the sediment bound residues amounted to 33-37% after 100 days; CO ₂ reached 5-9%. In the sediment trichloro-1,3-cyanobenzene reached 20% at day 1 and declined to 12% at day 14. The unknown metabolite C1 in sediment reached 17% at day 0.25 and declined to 5,8% at day 14. The unknown metaboliet C2 never exceeded 10% in the sediment in the HM ditch.
--

Accumulation in water and/or sediment:

Not available, not required

Degradation in the saturated zone

Not available, not required

Remarks:

none

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

7.62×10^{-5} Pa at 25 °C

Henry's law constant:

2.5×10^{-2} Pa m ³ mol ⁻¹ at 25 °C

Photolytic degradation

Direct photolysis in air:

not available, not required

Photochemical oxidative degradation in air

DT₅₀:

DT ₅₀ : 4.7 years (Atkinson calculation)

Volatilisation:

from plant surfaces: not available, not required
--

from soil: not available, not required
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Remarks:

none

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:

chlorothalonil LD50 >5000 mg/kg bw
SDS-3701 LD50 242 mg/kg bw

Acute toxicity to birds:

chlorothalonil LD50 >2000 mg/kg bw
SDS-3701 LD50 158 mg/kg bw

Dietary toxicity to birds:

chlorothalonil LC50 >5200 mg/kg fd
SDS-3701 LC50 1780 mg/kg fd

Reproductive toxicity to birds:

chlorothalonil NOEC 160 mg/kg fd
SDS-3701 NOEC 50 mg/kg fd

Long term toxicity to mammals:

chlorothalonil NOEC 330 mg/kg fd
(developmental NOAEL)
SDS-3701 NOEC 30 mg/kg fd (reproductive
NOAEL (decreased body weight pups))

Aquatic Organisms

Acute toxicity

Species	time	effect	value mg a.i./L	
<i>Oncorhynchus mykiss</i>		LC50	0.038	geometric mean
<i>Lepomis macrochirus</i>		LC50	0.052	geometric mean
<i>Cyprinus carpio</i>		LC50	0.076	geometric mean
<i>Ictalurus punctatus</i>	96 hours	LC50	0.047	
<i>Cyprinodon variegatus</i>	96 hours	LC50	0.033	
<i>Galaxias maculatus</i>	96 hours	LC50	0.016	
<i>Galaxias truttaceus</i>	96 hours	LC50	0.0189	
<i>Galaxias auratus</i>	96 hours	LC50	0.0292	
<i>Pimephales promelas</i>	96 hours	LC50	0.023	
<i>Gasterosteus aculeatus</i>	96 hours	LC50	0.027	
<i>Leiostomus xanthurus</i>	48 hours	LC50	0.032	
<i>Daphnia magna</i>		EC50	0.084	geometric mean
<i>Bracionus calyciflorus</i>	24 hours	EC50	0.024	
<i>Leptocerus</i>	48 hours	EC50	0.038	
<i>Crangonyx pseudogracillis</i>	48 hours	EC50	0.064	
<i>Chydorus</i>	48 hours	EC50	0.074	
<i>Crassostrea virginica</i>	96 hours	EC50	0.011	geometric mean
<i>Lymnea stagnalis</i>	48 hours	EC50	0.26	
<i>Planorbis</i>	48 hours	EC50	0.12	
<i>Erpobdella</i>	48 hours	EC50	0.16	
<i>Planaria</i>	48 hours	EC50	0.2	
<i>Macrocylops fuscus</i>	48 hours	EC50	0.26	
<i>Gammarus pulex</i>	48 hours	EC50	0.24	
<i>Hyaella azteca</i>	48 hours	EC50	0.25	

Species	time	effect	value mg a.i./L	
<i>Chironomus riparius</i>		EC50	0.061	geometric mean
Ostracoda	48 hours	EC50	0.39	
<i>Asellus aquaticus</i>	48 hours	EC50	0.45	
<i>Cloeon dipterum</i>	48 hours	EC50	0.6	
<i>Ischnura elegans</i>	48 hours	EC50	0.56	
<i>Penaeus duorarum</i>		LC50	0.228	geometric mean
<i>Parataya australiensis</i>	96 hours	LC50	0.016	
<i>Astacopsis gouldi</i>	96 hours	LC50	0.012	
<i>Selenastrum capricornutum</i>		EC50	0.116	geometric mean
<i>Scenedesmus subspicatus</i>	96 hours	EbC50	0.31	
<i>Navicula pelliculosa</i>	120 hours	EbC50	0.0096	
<i>Anabaena flos-aquae</i>	120 hours	EbC50	0.074	
Sensitivity distribution		HC5 95% cf	0.01 (0.005-0.016)	of L(E)C50 values
Mean of the log toxicity values	-1.1382			
Sample standard deviation	0.5219			
Sample size	36			

Long term toxicity

Species	time	effect	value in mg a.i./L	
<i>Pimephales promelas</i>	2-generation	NOEC	0.003	
<i>Oncorhynchus mykiss</i>	21 days	NOEC	0.003	geometric mean
<i>Navicula pelliculosa</i>	120 hours	NOEC	0.0035	
<i>Daphnia magna</i>	21 days	NOEC	0.0085	geometric mean
<i>Scenedesmus subspicatus</i>	96h	NOEC	0.020	geometric mean
<i>Anabaena flos-aquae</i>	120 hours	NOEC	0.020	
<i>Selenastrum capricornutum</i>	72-96h	NOEC	0.033	geometric mean
<i>Chironomus riparius</i>	28 days	NOEC	0.040	
<i>Lemna gibba</i>	14 days	NOEC	0.29	
Sensitivity distribution	normal distribution	HC5 (95% cf)	0.001 (0.0002-0.003)	of NOEC values
Mean of the log toxicity values	1.1792			
Sample standard deviation	0.6540			
Sample size	9			

- the average HC5 for the L(E)C50 is 0.01 mg/l (n=36); the average HC5 for the NOECs is 1 µg/l (n=9)
- The number of acute samples vs. chronic samples (36 vs 9) and the spread of the HC5 estimates indicates that the acute HC5 is statistically the more reliable value. Given the rapid dissipation in the aquatic systems, chronic exposure due to the agricultural applications is considered less likely. The initial PEC is the protective estimation for the acute effects, because many toxicity data are based on nominal concentrations and because it cannot be excluded that

pronounced effects may appear already after a short-term exposure.

Outdoor microcosm study (without fish)

- On basis of the most sensitive endpoints studied the overall NOEC in the microcosms is 10 µg chlorothalonil/L;
- In shallow freshwater ecosystems an EAC of 30 µg chlorothalonil/L may allow sustainable populations of sensitive algae and invertebrates, since recovery of affected populations of algae and invertebrates was observed a few weeks after the last application.

Bioconcentration

Bioconcentration factor
(BCF)

2300 l/kg based on r.a. In the fish BCF study r.a. in fish consisted of large number of components, only two were >10% of applied (whole fish based): di- and triglutathione conjugates, 18% and 12% of total r.a. residue. Metabolite SDS-3701 was detected as a minor component, and no unmetabolised chlorothalonil was detected. The BCF for chlorothalonil is estimated <100 l/kg.

Annex VI Trigger for the
bioconcentration factor

100

Clearance time (CT₅₀)
(CT₉₀)

2-7 days for r.a.

Honeybees

Acute oral toxicity:

>40 µg/bee

Acute contact toxicity:

>63 µg/bee

Other arthropod species

Laboratory tests				
type	crop type	species tested	Bravo 500	Bravo 720SC [kg a.i./ha]
Dosage			2.2 [l/ha]	Dosage a: 0.173 Dosage b: 6.0 Dosage c: 7.7 Dosage d: 10.5
Predacious mite	base set	Typhlodromus pyri		Dosage b: moderately harmful (94% effect)
Aphid parasitoid	base set	Aphidius rhopalosiphii Aphidius spp.		Dosage a, b and c: slightly harmful (41-62% effect)

ground dwelling predator		Aleochara bilineata or Poecilus cupreus	harmless	Dosage d: harmless																					
leaf dwelling predator		Chrysoperla carnea		Dosage c: harmless																					
Extended laboratory tests																									
Predacious mite		Typhlodromus pyri		<table> <thead> <tr> <th>Dosage (kg as/ha)</th> <th>Mortality (%)</th> <th>Fecundity*</th> </tr> </thead> <tbody> <tr> <td>1.50</td> <td>0</td> <td>5.0</td> </tr> <tr> <td>1.88</td> <td>0</td> <td>4.6</td> </tr> <tr> <td>5.63</td> <td>9</td> <td>3.8</td> </tr> <tr> <td>12.0</td> <td>17</td> <td>4.4</td> </tr> <tr> <td>18.75</td> <td>13</td> <td>3.1</td> </tr> <tr> <td>control</td> <td></td> <td>8.6</td> </tr> </tbody> </table> <p>There were significant effects on fecundity at every dose, so the NOER < 1.50 kg as/ha.</p> <p>* mean number of eggs per female (7 – 14 DAT)</p>	Dosage (kg as/ha)	Mortality (%)	Fecundity*	1.50	0	5.0	1.88	0	4.6	5.63	9	3.8	12.0	17	4.4	18.75	13	3.1	control		8.6
Dosage (kg as/ha)	Mortality (%)	Fecundity*																							
1.50	0	5.0																							
1.88	0	4.6																							
5.63	9	3.8																							
12.0	17	4.4																							
18.75	13	3.1																							
control		8.6																							
Aphid parasitoid		Aphidius rhopalosiph		<table> <thead> <tr> <th>Dosage (kg as/ha)</th> <th>Mortality (%)</th> </tr> </thead> <tbody> <tr> <td>4.33</td> <td><u>20</u></td> </tr> <tr> <td>7.70</td> <td><u>20</u></td> </tr> <tr> <td>18.75</td> <td><u>44</u></td> </tr> </tbody> </table> <p><u>No effects on fecundity at dosages up to 7.70 kg as/ha (at 18.75 kg as/ha fecundity is not assessed)</u></p>	Dosage (kg as/ha)	Mortality (%)	4.33	<u>20</u>	7.70	<u>20</u>	18.75	<u>44</u>													
Dosage (kg as/ha)	Mortality (%)																								
4.33	<u>20</u>																								
7.70	<u>20</u>																								
18.75	<u>44</u>																								

Earthworms

Acute toxicity:

chlorothalonil: LC50 268.5 mg/kg (at 5% o.m.)
 SDS-3701: LC50 585 mg/kg
 R417888: LC50 >1000 mg/kg
 SDS-46851: LC50 > 1000 mg/kg

Reproductive toxicity:

chlorothalonil: NOEC 25 mg/kg (at 5% o.m.)
 Chlorothalonil 500 g/L SC: NOEC 1.65 mg as/kg (at 5% o.m.)*
 SDS-3701: NOEC 25 mg/kg
 R417888: NOEC 100 mg/kg

* endpoint based on a study from Vischim carried out with the formulation

Effects on other soil non-target macro-organisms

Litter bag study: no negative effects of metabolite SDS-3701 at a concentration of 2.0 mg/kg soil

Soil micro-organisms

Nitrogen mineralization:

Chlorothalonil: <25% effect after 100 days at 4.8 mg/kg
SDS-3701: <25% effect after 28 days at 4.8 mg/kg
SDS-46851: <25% effect after 28 days at 2.8 mg/kg
R417888: <25% effect after 28 days at 3.3 mg/kg

Carbon mineralization:

Chlorothalonil: <25% effect after 100 days at 4.8 mg/kg
SDS-3701: <25% effect after 28 days at 4.8 mg/kg
SDS-46851: <25% effect after 28 days at 2.8 mg/kg
R417888: <25% effect after 28 days at 3.3 mg/kg

Effects on biological methods of sewage treatment

EC50 >100 mg/L .

APPENDIX IIIA**CHLOROTHALONIL**

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.⁶

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	Reports⁷ on previous use in granting national authorizations
IIA, 1.11	Lorence, P.J.	1995	Chlorothalonil- Analytical profile of batches. Generated by: Ricera Inc Submitted by: Zeneca Report no.:1081-94-0121-AS-001 Date: 28-02-95 GLP, Unpublished	
IIA, 1.11	Vargyas, L.D.	1994	Characterization of technical Chlorothalonil: SDS-2787-2401-0201 Generated by: Ricera Inc Submitted by: Zeneca Report no.:1081-94-0094-AS-001 Date: 07-07-94 GLP, Unpublished	
IIA, 1.11	Vargyas, L.D.	1995	Chlorothalonil- Analytical Profile of Batches from the Contract Manufacturing Plant in Yokohama, Japan Generated by: Ricera Inc Submitted by: Zeneca Report no.:1081-95-0030-AS-001 Date: April 95 GLP, Unpublished	

⁶ The data submitter Vischim srl has also claimed data protection for a number of studies. For references see the monograph and the addenda.

⁷ 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	Reports⁷ on previous use in granting national authorizations
IIA, 2.5.2	Douglass M. L.	1991	Hexachlorobenzene (SDS-1497-0202) Reference Substance Characterization Generated by: Ricera Inc Submitted by: Zeneca Report no.: 1081-90-0391-AS-001 Date: 26-03-91 GLP, Unpublished	
IIA, 2.5.2	Douglass, M. L	1991	Tetrachloroisophthalonitrile (SDS-2787-1501) Reference Substance Characterization Generated by: Ricera Inc Submitted by: Zeneca Report no.: 1081-90-0402-AS-001 Date: 26-03-91 GLP, Unpublished	
IIA, 2.1.1, 2.2, 2.4, 2.11.1, 2.13, 2.15	Gallancher, A. C.	1994	Chlorothalonil PAI (SDS-2787-1501)-Melting point, relative density, Appearance and Chlorothalonil technical (SDS-2787-2401-0201)-Appearance, Flammability, Auto-flammability, explosive properties, oxidizing properties. Doc. no. 1081-94-0066-AS-001 Date: 16-11-94 GLP, Unpublished Submitted by SYN	
IIA, 2.9.4	Hambrick, A. A.	1995	Chlorothalonil (SDS-2787-1501) - Dissociation Constant Generated by: Ricera Inc Submitted by: Zeneca Report no.: 1081-94-0079-AS-001 Date: 24-02-95 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	Reports⁷ on previous use in granting national authorizations
IIA, 2.3.2	Lorence, P. J.	1994	Chlorothalonil - Volatility (Henry's law constant) EC Agrochemicals Registration Directive 93/71/EEC Annex 1, Section 2.3.2 Generated by: Ricera Inc Submitted by: Zeneca Report no.: none Date: 23-9-94 Not GLP, Unpublished	
IIA, 2.6	Lorence, P. J.	1990 (a)	SDS-2787- Determination of solubility in distilled water and seawater Generated by: Ricera Inc Submitted by: Zeneca Report no.: 1081-90-0034-AS-001 Date: 30-10-90 GLP, Unpublished	
IIA, 2.7	Lorence, P. J.	1990 (b)	Chlorothalonil - Solubility in Organic Solvents Generated by: Ricera Inc Submitted by: Zeneca Report no.: 1081-94-0078-AS-001 Date: 30-10-90 GLP, Unpublished	
IIA, 2.8	Lorence, P. J.	1995	Chlorothalonil - Octanol/water partition coefficient Generated by: Ricera Inc Submitted by: Zeneca Report no.: 1081-94-0079-AS-001 Date: 24-02-95 GLP, Unpublished	
IIA, 2.9	Nelse, T. R. and Marks, A. F.	1987	An aqueous photolysis study with 14C-2,4,5,6-tetrachloroisophalonitril, SDS-2787 Generated by: Ricera Inc. Submitted by: Zeneca Report no: 1185-85-0075-EF-001 Date: 12-04-87 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	Reports⁷ on previous use in granting national authorizations
IIA, 3.7 to 3.9	Bernes, A	1998	Physical and chemical properties. Storage stability test for 2 years at ambient temperature of ISK 375 Generated by: Station de Phytopharmacie Submitted by: Zeneca. Report no.: ISK/P.J./B.A.8961/Ch.872/1995/140 Date: 09-04-1998 GLP, Unpublished	
IIA, 3.7 to 3.9	Brown, S. S., Cochran, R. J., Frawley, R. W.	1996	Bravo 500 Final report on Corrosion Characteristics, Generated by: Ricera Inc Submitted by: Zeneca. Reportno.: ISKB-39-96-428-01 Date: 01-08-1996 GLP, Unpublished	
IIA, 3.7 to 3.9	Brown, S. S., Cochran, R. J., Frawley, R. W.	1996	Final report on Corrosion Characteristics of Bravo 720 Generated by: Ricera Inc Submitted by: Zeneca. Report no.: ISKB-39-96-429-01 Date: 13-08-1996 Not GLP, Unpublished	
IIA, 3.7 to 3.9	Long, M. J., Crosby, K. E., Powers, I. J.	1995	Bravo Ultex Packaging Study, Generated by: Ricera Inc Submitted by: Zeneca. Report no.: 2081 T Date: 12-06-95 Not GLP, Unpublished	
IIA, 3.7 to 3.9	Woods, T. J.	1992	Information Supplement, AWWA Chlorothalonil Data Package Submission. Prepared by: Michigan Technological University and University of Dayton Submitted by: Zeneca Date: 12-08-92 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 ⁷ on previous use in granting national authorizations
IIA, 4.2.2	Kenyon, R.G. Wiedmann, J.L.	1992	Analytical procedure for the determination of residues of tetrachloroisophthalonitrile (chlorothalonil, SDS-2787) and 2,5,6-trichloro-4-hydroxyisophthalonitrile (SDS-3701) in soil -1992. Generated by: Ricerca, Inc. Submitted by: Zeneca Report No.: 5221-92-0073-MD-001 Date: June 15, 1992 GLP, Unpublished	
IIA, 4.2.3	Kenyon, R.G. Wiedmann, J.L.	1992	Analytical procedure for the determination of residues of tetrachloroisophthalonitrile (chlorothalonil, SDS-2787) and 2,5,6-trichloro-4-hydroxyisophthalonitrile (SDS-3701) in water - 1992. Generated by: Ricerca, Inc. Submitted by: Zeneca Report No.: 5221-92-0072-MD-001 Date: July 14, 1992 GLP, Unpublished	
IIA, 4.2.1	Nandihalli, U.B.	1996	Independent laboratory validation of a method for the determination of residues of SDS-3701 in milk and meat CHW 6241-111 Cornington Hazleton Inc. GLP, Unpublished	
IIA, 4.1	Vargyas, L.D.	1994	Characterization of technical Chlorothalonil: SDS-2787-2401-0201 Generated by: Ricera Inc Submitted by: Zeneca Report no.:1081-94-0094-AS-001 Date: 07-07-94 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	Reports⁷ on previous use in granting national authorizations
IIA 1.09	Anonymous	2003	Data Sheet R44686 chlorothalonil, purity and byproducts of technical a.i. Submitted by: Syngenta Reportnumber: not applicable Date: 17.12.2003	
IIA 1.11	Arenas, R.	2003	Analysis of five representative batches of chlorothalonil technical (ASF41) produced at GB Biosciences, Houston, TX, USA. Submitted by: Syngenta Report no.: T001464-03 Date: 23.07.2003 GLP, unpublished	
IIA 1.11	Mishler, M.B.	2001a	The determination of chlorothalonil and associated impurities in technical; material by capillary Gas Chromatography, Submitted by Syngenta Report no.:AMW00044-01B Non GLP, non published	
IIA 1.11	Mishler, M.B.	2001b	Method validation: AMW00044-01B, The determination of Chlorothalonil and associated impurities in technical; material by capillary Gas Chromatography, Submitted by Syngenta Report no.:AMW00044-01B GLP, non published	

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	Reports⁷ on previous use in granting national authorizations
II 2.9	Wollerton, C. Walter, G.P.	2000	Chlorothalonil Quantum Yield and Environmental Lifetime of Pure Material Generated by: Zeneca Submitted by: Zeneca Report no.: RJ2917B Date: 28 January 2000 GLP, unpublished Submitted by SYN	
III A 2.7	Bernes, A.	1998	Chemical and Physical properties and storage stability tests of BRAVO 720 SC Generated by: Depart De Phytopharmacie Submitted by: Zeneca Report no.: 9768 Date: 20 November 1998 GLP, unpublished Submitted by SYN	
IIA 4.2.1	Robinson, N. J.	2000	Residue Analytical Method for the Determination of Chlorothalonil in Crops RAM 320/01 GLP, unpublished Submitted by SYN	
IIA 4.2.1	Lister, N..	2000	Validation of SOP RAM 320/01 for the Determination of Residues in Crops RAM 320/01 GLP, unpublished Submitted by SYN	
IIA 4.2.3	Robinson, N. J.	2000	Validation of a residue Analytical Method for the Determination of Residues in Water RAM 320/01 GLP, unpublished Submitted by SYN	
IIA2.3/II A 2.6/IIA 2.8/IIA 2.9	Wollerton,C. G.P.Walter	2000	Chlorothalonil:Water solubility, dissociation constant, Partition coefficient and Henry's Law constant of the metabolite R417888/Na 21 january 2000 GLP, unpublished Submitted by SYN	

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	Reports⁷ on previous use in granting national authorizations
IIA.2.9	Hayes, S.E	2001	Chlorothalonil – Calculation of Half life by reaction with atmospheric hydroxyl radicals. Syngenta, UK Report no.: CHTL B2.1/023 RIC 7317 Non GLP, not published Submitted by SYN	
IIA 2.8	Evans, A.J.	2002	Extended Storage Stability-initial friability (initial test result of a shelf-life study) Performing laboratory: SafePharm Submitted by: Sygenta Project no. 560/186(a) Non GLP. Not published Submitted by SYN	
IIA 4.2.1	Croucher, A.	2001	Chlorothalonil: Independent laboratory validation of SOP RAM 320/02 Analytical method for the determination of residues in crops (cucumber, wheat grain and whole orange). Generated by: Covance Laboratories Ltd., Harrogate, UK Submitted by: Syngenta Jealott's Hill International Research Centre, Bracknell, UK. Company File No: 1983/025-D2419 Date: October 2001 GLP, Unpublished Submitted by SYN	
IIA 4.2.1	McGill C. & Robinson N.	2002	Validation of Analytical Method 384/01 for the determination of Residues in Bovine Muscle, Fat, Kidney, Liver, Milk and Hen's Eggs Syngenta, Berkshire, UK Report No. RJ3313B GLP, not published Date: 2002 Submitted by SYN	

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	Reports⁷ on previous use in granting national authorizations
IIA 4.2.1	Brice, A.	2003	Chlorothalonil metabolite R182281: independent laboratory validation of SOP RAM 348/01 Analytical Method for the determination of Residues in Bovine Muscle, Milk and Hen's Eggs Generated by: Covance laboratories ltd., North Yorkshire, England Report No. 1983/054-D2149 GLP, not published Date: 8 august 2003 Submitted by SYN	
IIA 4.2.1	Robinson N.J.	2003	Standard Operating Procedure RAM 384/01 Residue Analytical Method for the determination of the Chlorothalonil Metabolite RH182281 (SDS-3701) in Bovine Muscle, Fat, Kidney, Liver, Milk and Hen's Eggs Syngenta, Bekshire, UK Report No. - non-GLP, not published Date: 2003 Submitted by SYN	
IIA, 4.2.2/a	Hargreaves, S.L	2001	Residue analytical method for the determination of chlorothalonil and R182281 (SDS-3701) in soil Syngenta, UK, SOP RAM 335/01 non GLP, Unpublished. Submitted by SYN	
IIA, 4.2.2/b	Robinson, N.J.	2002	Residue analytical method for the determination of residues of the chlorothalonil metabolite R417888 in soil Syngenta, UK, SOP RAM 341/01 Date:14/11/2002 non GLP, Unpublished. Submitted by SYN	
IIA, 4.2.2/c	Emburey, M.	2002	R417888 Validation of a residue analytical method for the determination of residues in soil Syngenta, UK, report no. RJ3309B GLP, Unpublished Submitted by SYN	

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	Reports⁷ on previous use in granting national authorizations
IIA, 4.2.3/a	Robinson, N	2000	Chlorothalonil: residue analytical method for the determination of residues in water Syngenta, UK, SOP RAM 333/01 non GLP, Unpublished Submitted by SYN	
IIA, 4.2.3/b	Emburey, M.	2002	Chlorothalonil Validation of a residue analytical method for the determination of residues in water Syngenta, UK, report no. RJ3080B GLP, Unpublished Submitted by SYN	
IIA, 4.2.4/a	Crook, S.J.	2001	Residue analytical method for the determination of residues of chlorothalonil in air. Syngenta, UK, SOP RAM 361/01 non GLP, Unpublished Submitted by SYN	
IIA, 4.2.4/b	Crook, S.J.	2001	Chlorothalonil Validation of a residue analytical method for the determination of residues in air Syngenta, UK, report no. TMJ4573B GLP, Unpublished Submitted by SYN	
IIA 4.2.5	Hall, M.G.	2001	Chlorothalonil: determination in human and animal plasma by GC-MS Generated by: Central Toxicology Laboratory, Cheshire, UK Submitted by: Syngenta Company File No: CTL/024460/TEC/REPT Date: 08/05/2001 Non-GLP, Unpublished Submitted by SYN	

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	Reports⁸ on previous use in granting national authorizations
IIA, 5.1	Andre, J. C., Marciniszyn, J. P., Killeen, J. C., Jr.	1991	Comparison of the effects of dose level and vehicle on the dermal absorption of ¹⁴ C-chlorothalonil by male rats. Generated by: SDS Biotech Corporation Submitted by: Zeneca Agrochemicals Report no.: 1698-88-007-AM-001 Date: May 10, 1991a GLP, Unpublished	
IIA, 5.1	Andre, J. C., Marciniszyn, J. P., Killeen, J. C., Jr.	1991	Evaluation of mitochondrial function in the presence and absence of sulfur-containing analogs of chlorothalonil. Generated by: Ricerca, Inc. Submitted by: Zeneca Agrochemicals Report no.: 3113-88-0107-AM-001 Date: May 10, 1991b GLP, Unpublished	
IIA, 5.9	Chelsky, M.	1990	Study of chlorothalonil plant workers 1990. Evaluation of potential for persistent effects on eyes of workers. Generated by: Morris Chelsky, M. D. Medical Consultant Submitted by: Zeneca Agrochemicals Report no.: not Applicable Date: November 30, 1990a Not GLP, Unpublished	

⁸ 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 ⁸ on previous use in granting national authorizations
IIA, 5.9	Chelsky, M.	1990	Annual employee health screening reports, Greens Bayou Plant, 1986 - 90 - Special reference to chlorothalonil workers and the respiratory system. Generated by: Morris Chelsky, M. D. Medical Consultant Submitted by: Zeneca Agrochemicals Report no.: not Applicable Date: November 30, 1990b Not GLP, Unpublished	
IIA, 5.9	Chelsky, M.	1992	Annual employee health screening reports, Greens Bayou Plant, 1986 - 91 - Special reference to chlorothalonil workers and the respiratory system. Generated by: Morris Chelsky, M. D. Medical Consultant Submitted by: Zeneca Agrochemicals Report no.: not Applicable Date: July 20, 1992 Not GLP, Unpublished	
IIA, 5.9	Chelsky, M.	1990	Published irritation/sensitization report concerning chlorothalonil, notes and comments Generated by: M. Chelsky, M. D., Consultant in Occupational Health Surveillance Submitted by: Zeneca Agrochemicals Report no.: not Applicable Dates: March 5, 1989 and October 22, 1990c 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 ⁸ on previous use in granting national authorizations
IIA, 5.3	Fillmore, G. E., Laveglia, J., Sloane, K.E., Wooding, W.L., Busey, W.M.	1992	A 30-day oral toxicity study in dogs with technical chlorothalonil, T-117-12. Generated by: Ricerca, Inc., Bio/dynamics, Inc., and Experimental Pathology Laboratories, Inc. Submitted by: Zeneca Agrochemicals Report no.: 5092-91-0354-TX-003 Date: June 26, 1992 GLP, Unpublished	
IIA, 5.3	Fillmore, G., Laveglia, J., Auletta, C.S., Busey, W.M.	1993	A 90-day oral toxicity study in dogs with chlorothalonil. Generated by: Ricerca, Inc., Bio/dynamics, Inc., and Experimental Pathology Laboratories Submitted by: Zeneca Agrochemicals Report no.: 5210-92-0103-TX-003 Date: April 6, 1993 GLP, Unpublished	
IIA, 5.1	Griffin, T. B.	1990	Study to evaluate the dermal metabolism of 14C-chlorothalonil (14C-ASC-2787) in male rhesus monkeys. Generated by: Coulston International, Inc. Submitted by: Zeneca Agrochemicals Report no.: 3381-89-0213-AM-001 Date: May 21, 1990 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 ⁸ on previous use in granting national authorizations
IIA, 5.1	Griffin, T. B.	1989	A study to evaluate the metabolism of 14C-chlorothalonil(14C-DS-2787) in male rhesus monkeys. Generated by: Coulston International, Inc. Submitted by: Zeneca Agrochemicals Report no.: 3282-89-0089-AM-001 Date: November 28, 1989 GLP, Unpublished	
IIA, 5.3	Hironanka, M.	1996	Analysis of hyperplastic changes in the stomach and kidney of male rats after 28-day induction by chlorothalonil technical. Generated by: Safety Assessment Center Submitted by: Zeneca Agrochemicals Report no.: 3561 Date: 25 September 1996 GLP, Unpublished	
IIA, 5.8	Ho, M. D., Killeen, J.C., Jr., Marciniszyn, J.	1990	Study of the excretion and distribution of radio-label following oral administration of 14C-SDS-46851 to Sprague Dawley rats. Generated by: Ricerca, Inc. Submitted by: Zeneca Agrochemicals Report no.: 3589-90-0159-AM-001 Date: October 26, 1990 GLP, Unpublished	
IIA, 5.8	Hoberman, A. M., Serrone, D. M., Killeen, J.C., Jr.	1989	A teratology dose range finding study in rabbits with 3-carbamyl-2,4,5-trichlorobenzoic acid (SDS-46851) . Generated by: Argus Res Labs and Ricerca, Inc. Submitted by: Zeneca Agrochemicals Report no.: 1112-86-0056-TX-002/1019-005P Date: February 8, 1989 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 ⁸ on previous use in granting national authorizations
IIA, 5.8	Killeen J.C.D.	1998	SDS 3701: A developmental toxicity study in rats via oral administration. Submitted by: Zenenca Report no.: 97-4112 Date: 12 June 1998 GLP, Unpublished	
IIA, 5.5	Killeen, J. C., Jr., Laveglia, J., Cockrell, B. Y.	1993	Electron microscopic evaluation of kidneys in male Fischer 344 rats following the oral administration of technical chlorothalonil. Generated by: Ricerca, Inc. and Experimental Pathology Laboratories Submitted by: Zeneca Agrochemicals Report no.: 1664-87-0089-TX-002 Date: June 29, 1993 GLP, Unpublished	
IIA, 5.8	Lucas, F.	1993	A two generation reproduction study in rats with SDS-46851. Generated by: Ricerca, Inc. and Experimental Pathology Laboratories, Inc. Submitted by: Zeneca Agrochemicals Report no.: 3822-91-0014-TX-004 Date: September 3, 1993 GLP, Unpublished	
IIA, 5.6	Lucas, F., Killeen, J. C., Jr., Busey, W.	1990	A two generation reproduction study in rats with technical chlorothalonil. Generated by: Ricerca, Inc. and Experimental Pathology Labs Submitted by: Zeneca Agrochemicals Biosciences Corporation Report no.: 1722-87-0121-TX-003 Date: november 9, 1990 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 ⁸ on previous use in granting national authorizations
IIA, 5.8	Lucas, F., Laveglia, J., Isaacs, K. R.	1994	An oncogenicity study in mice with SDS-46851. Generated by: Ricerca, Inc. and Experimental Pathology Laboratories, Inc. Submitted by: Zeneca Agrochemicals Report no.: 3584-91-0071-TX-003 Date: March 10, 1994 GLP, Unpublished	
IIA, 5.1	Magee, T. A., Marciniszyn, J. P., Killeen, J. C., Jr.	1990	Study to evaluate the urinary metabolites of chlorothalonil following dermal application to male rhesus monkeys. Generated by: Ricerca, Inc. Submitted by: Zeneca Agrochemicals Report no.: 3382-89-0214-AM-001 Date: november 2, 1990 GLP, Unpublished	
IIA, 5.1	Magee, T. A., Marciniszyn, J. P., Killeen, J. C., Jr.	1991	Study of the urinary excretion of radiolabel by dogs following oral administration of ¹⁴ C-chlorothalonil by gavage. Generated by: Ricerca, Inc. Submitted by: Zeneca Agrochemicals Report no.: 3086-90-0229-AM-001 Date: December 6, 1991 GLP, Unpublished	
IIA, 5.9	McAmis, R. J.	1994	This letter did not have a title. The subject is clinical cases of exposure to chlorothalonil that were evaluated and treated at the Medical Plaza Industrial Clinic. Generated by: Robert J. McAmis, M.D. Medical Consultant Submitted by: Zeneca Agrochemicals Report no.: not applicable Date: March 14, 1994a 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	Reports⁸ on previous use in granting national authorizations
IIA, 5.9	McAmis, R. J.	1994	Review of respiratory chlorothalonil exposures in humans. Generated by: Robert J. McAmis, M. D. Medical Consultant Submitted by: Zeneca Agrochemicals Report no.: not applicable Date: March 14, 1994b Not GLP, Unpublished	
IIA, 5.9	McAmis, R. J., Ashby, G. P.	1995	Diagnosis of poisoning, specific signs of poisoning, clinical tests. McAmis, R. J., M. D., Ashby, G. P., M. D., 1995a Submitted by: Zeneca Agrochemicals Not GLP, Unpublished	
IIA, 5.9	McAmis, R. J., Ashby, G. P.	1995	Proposed treatment: First aid measures, Antidotes, medical treatment. McAmis, R. J., M. D., Ashby, G. P., M. D., 1995b Submitted by: Zeneca Agrochemicals Not GLP, Unpublished	
IIA, 5.3	Mizens	1996	A 21-day repeated dose dermal toxicity study in rats with technical chlorothalonil. Generated by: Ricera Inc. Submitted by: Zeneca Agrochemicals Report no.: 68-59-96-0113-TX-002 Date: September 5, 1996 GLP, Unpublished	
IIA, 5.5	Mizens	1997	Chlorothalonil: Mechanism of Action and Cell Proliferation. Generated by: Ricera, Inc. Submitted by: Zeneca Agrochemicals Report no.: 5943-97-0041-TX-001 Date: February 12, 1997. 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 ⁸ on previous use in granting national authorizations
IIA, 5.5	Mizens	1996	A 90-day pilot study for the evaluation of cell proliferation in the kidneys of male rats following the oral administration of technical chlorothalonil. Generated by: Ricerca Inc. Submitted by: Zeneca Agrochemicals Report no.: 6704-96-0010-TX-003 Date: 26 September 1996. GLP, Unpublished	
IIA, 5.5	Mizens	1997	Chlorothalonil mechanism of action and cell proliferation. Generated by: Ricerca Inc. Submitted by: Zeneca Agrochemicals Report no.: 5943-97-0041-TX-001 Date: 2 February 1997.	
IIA, 5.8	Mizens, M., Laveglia, J., Curry, P. T.	1994	In vitro mammalian cytogenetic test with SDS-3701. Generated by: Ricerca, Inc. and Microbiological Associates, Inc. Submitted by: Zeneca Agrochemicals Report no.: 6006-94-0048-TX-003 Date: October 17, 1994 GLP, Unpublished	
IIA, 5.8	Mizens, M., Killeen, J.C., Jr., Hamilton, B. F.	1991	A 28-day feeding study in mice with SDS-46851. Generated by: Ricerca, Inc. and Experimental Pathology Laboratories, Inc. Submitted by: Zeneca Agrochemicals Report no.: 3582-90-0155-TX-003 Date: April 17, 199 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 ⁸ on previous use in granting national authorizations
IIA, 5.8	Mizens, M., Fillmore, G. E., Killeen, J.C., Jr., Busey, W. M.	1991	A 90-day feeding study in mice with SDS-46851. Generated by: Ricerca, Inc. and Experimental Pathology Laboratories, Inc. Submitted by: Zeneca Agrochemicals Report no.: 3583-90-0317-TX-003 Date: July 12, 1991 GLP, Unpublished	
IIA, 5.5	Mizens, M., Laveglia, J., Auletta, C. S., Busey, W. M.	1994	5211-92-0457-TX-003 A chronic (12-month) oral toxicity study in dogs technical chlorothalonil. Generated by: Ricerca, Inc., Pharmaco LSR, Inc., and Experimental Pathology Laboratories, Inc. Submitted by: Zeneca Agrochemicals Report no.: 92-0457 Date: December 19, 1994 GLP, Unpublished	
IIA, 5.8	Proudlock, R.J. Taylor, K.H. Elmore, E.A.	1995	In vivo bone marrow chromosomal analysis in chinese hamsters with SDS-3701. Generated by: Ricerca Inc. Submitted by: Zeneca Agrochemicals Report no.: 6006-94-0049-TX-003 Date: June 2, 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 ⁸ on previous use in granting national authorizations
IIA, 5.4	Proudlock, R.J., Greer, J.V., Elmore, E.A.	1995	In vivo bone marrow chromosomal analysis in Chinese Hamsters following multiple dose administration of technical chlorothalonil. Generated by: Ricerca Inc. Submitted by: Zeneca Agrochemicals Report no.: 6005-94-0047-TX-003 Date: 2 June 1995 GLP, Unpublished	
IIA, 5.8	Savides, M. C., Marciniszyn, J. P., Killeen, J.C., Jr.	1990	Pharmacokinetic study to determine the effects of dose level on the metabolism of 14C-SDS-46851 by rats. Generated by: Ricerca, Inc. Submitted by: Zeneca Agrochemicals Report no.: 3043-88-0056-AM-001 Date: July 11, 1990c GLP, Unpublished	
IIA, 5.1	Savides, M. C., Marciniszyn, J. R., Killeen, J. C., Jr.	1990	Study of urinary excretion of radiolabel by catheterized dogs following oral administration of 14C-chlorothalonil by gavage. Generated by: Ricerca, Inc. Submitted by: Zeneca Agrochemicals Report no.: 3086-89-0041-AM-001 Date: April 17, 1990a GLP, Unpublished	
IIA, 5.1	Savides, M. C., Marciniszyn, J. P., Killeen, J. C., Jr.	1990	Study to evaluate the urinary metabolites of chlorothalonil from male rhesus monkeys. Generated by: Ricerca, Inc. Submitted by: Zeneca Agrochemicals Report no.: 3349-89-0179-AM-001 Date: April 16, 1990b. 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 ⁸ on previous use in granting national authorizations
IIA, 5.1	Savides, M. C., Jentoft, N. H., Killeen, J. C., Jr., Laveglia, J.	1995	Study to determine the extent and nature of biliary excretion of chlorothalonil and/or metabolites in the dog. Part I. Generated by: Ricerca, Inc. Submitted by: Zeneca Agrochemicals Report no.: 5521-93-0319-AM-001 Date: April 1995 GLP, Unpublished	
IIA, 5.1	Savides, M. C., Magee, T. A., Marciniszyn, J. P., Killeen, J. C., Jr.	1990	Study to evaluate the metabolic pathway of chlorothalonil (14C-ASC-2787) in germ-free rats. Generated by: Ricerca, Inc. Submitted by: Zeneca Agrochemicals Report no.: 3060-88-0219-AM-001 Date: April 18, 1990c GLP, Unpublished	
IIA, 5.8	Schroeder	1998	SDS-3701: a developmental toxicity study in rats via oral administration. Generated by: Huntingdon Submitted by: Zeneca Agrochemicals Report no.: 97-4112 Date: 12 June 1998 GLP, Unpublished	
IIA, 5.8	Serrone, D. M., Laveglia, J., Isaacs, K. R.	1993	A combined chronic toxicity/oncogenicity study in rats with 3-carbamyl-2,4,5-trichlorobenzoic acid (SDS-46851). Generated by: Ricerca, Inc. and Experimental Pathology Laboratories, Inc. Submitted by: Zeneca Agrochemicals Report no.: 3533-90-0030-TX-005 Date: november 23, 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	Reports⁸ on previous use in granting national authorizations
IIA, 5.2	Shults, S. K., Laveglia, J., Jackson, G. C.	1993	Acute (four-hour) inhalation toxicity (LC50) study in rats with hammermilled technical chlorothalonil (T-117-15). Generated by: Ricerca, Inc. and Huntingdon Research Centre Ltd. Submitted by: Zeneca Agrochemicals Report no.: 5290-92-0160-TX-002 Date: January 25, 1993 GLP, Unpublished	
IIA, 5.1	Ward, R. J., Scott, R. C.	1989	Chlorothalonil: In Vitro absorption from technical material through human epidermis. Generated by: ICI Central Toxicology Laboratory Submitted by: Zeneca Agrochemicals Report no.: CTL/P/2640 Date: October 31, 1989a GLP, Unpublished	
IIA, 5.1	Ward, R. J., Scott, R. C.	1989	Chlorothalonil: In Vitro absorption from "Bravo 720" formulation through human epidermis. Generated by: ICI Central Toxicology Laboratory Submitted by: Zeneca Agrochemicals Report no.: CTL/P/2880 Date: December 7, 1989b 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 ⁸ on previous use in granting national authorizations
IIA, 5.5	Wilkinson and Killeen	1996	A mechanistic interpretation of the oncogenicity of chlorothalonil in rodents and an assessment of human relevance Generated by: Technology Science Group Inc. Submitted by: Zeneca Agrochemicals Regulatory Toxicology and Pharmacology 24, 69-84, 1996. Not GLP, Published	
IIA, 5.1	Wilkinson, C.F., Killeen, J.C.	1996	A mechanistic interpretation of the oncogenicity of chlorothalonil in rodents and an assessment of human relevance. Regulatory Toxicology & Pharmacology 24, 69-84, 1996. Generated by: Ricerca Submitted by: Zeneca Agrochemicals Report no.: - Date: 1996 GLP, Unpublished	
IIA 5.1.3	Jones, B.K.	2000	Chlorothalonil 720g/l SC formulation: In vivo dermal absorption of chlorothalonil in the rat. Generated by: Central Toxicology Laboratory Submitted by: Zeneca Agrochemicals Report No.: CTL/UR0616/REG/REPT Date: 21 March 2000 GLP, unpublished Submitted by SYN	

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	Reports⁸ on previous use in granting national authorizations
IIA 5.1.3	Davies, D.J.	2000	Chlorothalonil 720g/l SC formulation: In vitro absorption of chlorothalonil through rat epidermis. Generated by: Central Toxicology Laboratory Submitted by: Zeneca Agrochemicals Report No.: CTL/JV1584/REG/REPT Date: 10 March 2000a GLP, unpublished Submitted by SYN	
IIA 5.1.3	Davies, D.J.	2000	Chlorothalonil 720g/l SC formulation: In vitro absorption of chlorothalonil through human epidermis. Generated by: Central Toxicology Laboratory Submitted by: Zeneca Agrochemicals Report No.: CTL/JV1585/REG/REPT Date: 13 March 2000b GLP, unpublished Submitted by SYN	
IIA 5.1.3	Ward, R.J.	2000	Chlorothalonil 825g/kg WDG formulation: In vitro absorption of chlorothalonil through rat epidermis. Generated by: Central Toxicology Laboratory Submitted by: Zeneca Agrochemicals Report No.: CTL/JV1586/REG/REPT Date: 7 February 2000a GLP, unpublished Submitted by SYN	
IIA 5.1.3	Ward, R.J.	2000	Chlorothalonil 825g/kg WDG formulation: In vitro absorption of chlorothalonil through human epidermis. Generated by: Central Toxicology Laboratory Submitted by: Zeneca Agrochemicals Report No.: CTL/JV1587/REG/REPT Date: 24 February 2000b GLP, unpublished Submitted by SYN	

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 ⁸ on previous use in granting national authorizations
IIA 5.8.1	Schetter, J.E., Yoshida, M., Watson, M.	2000	A 52-week oral toxicity study in dogs with SDS-3701 Generated by: Ricerca Inc. Submitted by: Zeneca Agrochemicals Report no.: SDS-3701/7181-97-0102-TX-001 Date: January 31, 2000 GLP, unpublished Submitted by SYN	
IIA 5.8.1	Johnson, I. R.	1999	R417888: Acute oral toxicity study in rats Generated by: Central Toxicology Laboratory, Alderly Park Macclesfield Cheshire UK Submitted by: Zeneca Agrochemicals Report no.: CTL/P/6459 Date: 7 December 1999 GLP, unpublished Submitted by SYN	
IIA 5.8.1	Seville, A.	1999	GSH reactivity of chlorothalonil and its metabolite R417888 generated by: Chemistry Design Group, Zeneca Agrochemicals Submitted by: Zeneca Agrochemicals Report no.: - Date: 5 July 1999a Not GLP, unpublished Submitted by SYN	
IIA 5.8.1	Seville, A.	1999	GSH reactivity of chlorothalonil and its metabolite R611965 (SDS-46851 / CTB - MIII) generated by: Chemistry Design Group, Zeneca Agrochemicals Submitted by: Zeneca Agrochemicals Report no.: - Date: 25 October 1999b Not GLP, unpublished Submitted by SYN	

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 ⁸ on previous use in granting national authorizations
IIA 5.8.1	Callander, R. D.	2000	R417888: Bacterial mutation assay in <i>S. typhimurium</i> and <i>E. coli</i> Generated by: Central Toxicology Laboratory, Alderly Park Macclesfield Cheshire UK Submitted by: Zeneca Agrochemicals Report no.: CTL/YV4341/Regulatory/Report Date: 22 March 2000 GLP, unpublished Submitted by SYN	
IIA 5.8.1	Clay, P.	2000	R417888: L5178 TK+/- mouse lymphoma mutation assay Generated by: Central Toxicology Laboratory, Alderly Park Macclesfield Cheshire UK Submitted by: Zeneca Agrochemicals Report no.: CTL/VV0208/Regulatory/Report Date: 12 January 2000 GLP, unpublished Submitted by SYN	
IIA 5.8.1	Ho, M.D. et al.	1990	Study of the excretion and distribution of radiolabel following oral administration of 14C-SDS-46851 to Sprague-Dawley rats Syngenta, UK Report no.: 3589-90-0159-AM-001 GLP, not published Submitted by SYN	
IIA 5.8.1	Noakes, J.P.	2001	R417888: 90 day dietary toxicity study in rats. Central Toxicology Laboratory, Alderley Park Macclesfield, Cheshire, UK. Report No. CTL/PR1164/REG/REPT. GLP, unpublished Submitted by SYN	
IIA 5.8.1	Fox, V.	2000a	R417888: In vitro cytogenic assay in human lymphocytes. Central Toxicology Laboratory, Alderley Park Macclesfield, Cheshire, UK. Report No. CTL/SV1002/REG/REPT. GLP, unpublished Submitted by SYN	

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	Reports⁸ on previous use in granting national authorizations
IIA 5.8.1	Fox, V.	2000b	R417888: In vitro cytogenic assay in human lymphocytes. Central Toxicology Laboratory, Alderley Park Macclesfield, Cheshire, UK. Report No CTL/SV1051/REG/REPT. GLP, unpublished Submitted by SYN	
IIA 5.8.1	Fox, V.	2002	R611965 (SDS 46851): Mouse bone marrow micronucleus test. Central Toxicology Laboratory, Alderley Park Macclesfield, Cheshire, UK. Report No CTL/SM1110/REG/REPT. GLP, unpublished Submitted by SYN	
IIA 5.8.1	Schroeder, R.E.	1998	SDS-3701: A developmental toxicity study in rats via oral administration. Huntingdon Life Sciences, East Millstone, New Jersey, USA. Report No CTL/C/3921. GLP, unpublished Submitted by SYN	

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	Reports⁹ on previous use in granting national authorizations
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⁹ 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 ⁹ on previous use in granting national authorizations
IIA, 6.2/01	Duane, W. C., Doran, T. J.	1990	A study to determine the nature of the residues in meat, milk and tissues from lactating goats fed 14C-Chlorothalonil (2,4,5,6-tetrachloroisophthalonitrile). Generated by: Ricerca, Inc. and Analytical Bio-Chemistry Laboratories, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 1067-85-0080-EF-001 Date: June 15, 1990 GLP, Unpublished	
IIA, 6.5/17	Fitzgerald, T. J., Kenyon, R. G.	1993	Magnitude of residues of tetrachloroisophthalonitrile (chlorothalonil, SDS-2787), SDS-3701 and HCB on process corn fractions - 1992. Generated by: Ricerca, Inc. Report No.: 5528-93-0090-CR-001 Date: September 24, 1993 GLP, Unpublished	
IIA, 6.1/04	Huhtanen, K. L., Doran, T. J.	1992	A plant metabolism study with 14C-Chlorothalonil (2,4,5,6-tetrachloroisophthalonitrile) on celery. Generated by: Ricerca, Inc. Submitted by: ISK Biosciences Corp./Zeneca Company File No.: 3503-90-0184-EF-001 Date: October 6, 1992 GLP, Unpublished	
IIA, 6.1/05	Huhtanen, K. L., Doran, T. J.	1993	A plant metabolism study with 14C-chlorothalonil (2,4,5,6-tetrachloroisophthalonitrile) on snapbeans. Generated by: Ricerca, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 5216-92-0063-EF-001 Date: September 23, 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	Reports⁹ on previous use in granting national authorizations
IIA, 6.3/02	Kenyon, R. G.	1993	Determination of residues of tetrachloroisophthalonitrile (chlorothalonil, SDS-2787), SDS-3701, SDS-46851, HCB, and PCBN in wheat grain from a stability study (field incurred) - 1988 - Four year interim report. Generated by: Ricerca, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 3064-88-0070-CR-002 Date: June 9, 1993 GLP, Unpublished	
IIA, 6.3/03	Kenyon, R. G.	1993	Determination of residues of tetrachloroisophthalonitrile (chlorothalonil, SDS-2787), SDS-3701, SDS-46851, HCB, and PCBN in tomatoes from a stability study (field incurred) - 1988 - Four year interim report. Generated by: Ricerca, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 3064-88-0083-CR-002 Date: June 21, 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	Reports⁹ on previous use in granting national authorizations
IIA, 6.3/07	Kenyon, R. G.	1993	Determination of residues of tetrachloroisophthalonitrile (chlorothalonil, SDS-2787), SDS-3701, SDS-46851, HCB, and PCBN in soybeans from a stability study (field incurred) - 1988 - Four year interim report. Generated by: Ricerca, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 3064-88-0097-CR-002 Date: June 22, 1993 GLP, Unpublished	
IIA, 6.5/13	Kenyon, R. G., Ballee, D. L.	1996	Residues of tetrachloroisophthalonitrile (chlorothalonil, SDS-2787), SDS-3701, SDS-46851 HCB and PCBN on peanuts - Processing study. Generated by: Ricerca, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 1155-86-0006-CR-001 Date: October 14, 1996 GLP, Unpublished	
IIA, 6.3/01	King, C.	1993	Determination of residues of tetrachloroisophthalonitrile (chlorothalonil, SDS-2787), SDS-3701, SDS-46851, HCB, and PCBN in cherries from a stability study (field incurred) - 1988 - Four year interim report. Generated by: Ricerca, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 3064-88-0068-CR-002 Date: June 18, 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 ⁹ on previous use in granting national authorizations
IIA, 6.3/08	King, C.	1993	Determination of residues of tetrachloroisophthalonitrile (chlorothalonil, SDS-2787), SDS-3701, SDS-46851, HCB, and PCBN in celery from a stability study (field incurred) - 1988 - Four year interim report. Generated by: Ricerca, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 3064-88-0136-CR-002 Date: June 25, 1993 GLP, Unpublished	
IIA, 6.3/10	King, C.	1993	Determination of residues of tetrachloroisophthalonitrile (chlorothalonil, SDS-2787), SDS-3701, SDS-46851, HCB, and PCBN in peanuts from a stability study (field incurred) - 1988 - Four year interim report. Generated by: Ricerca, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 3064-88-0160-CR-002 Date: August 2, 1993 GLP, Unpublished	
IIA, 6.5/01	King, C., Prince, P. M.	1993	Magnitude of residues following applications of Bravo 720 to potatoes - processing study Generated by: Ricerca, Inc. and The National Food Laboratory Submitted by: ISK Biosciences Corp./Zeneca Report No.: 5232-92-0105-CR-001 Date: April 2, 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	Reports⁹ on previous use in granting national authorizations
IIA, 6.5/11	King, C., Prince, P. M.	1990	Residues of tetrachloroisophthalonitrile (chlorothalonil, SDS-2787), SDS-3701, SDS-46851, HCB and PCBN on carrots - Processing study - 1988 Generated by: Ricerca, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 3186-89-0286-CR-001 Date: April 26, 1990 GLP, Unpublished	
IIA, 6.5/15	King, C., Prince, P. M.	1990	Residues of tetrachloroisophthalonitrile (chlorothalonil, SDS-2787), SDS-3701, SDS-46851 HCB and PCBN on winter squash - Processing study. Generated by: Ricerca, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 3185-89-0287-CR-001 Date: May 11, 1990 GLP, Unpublished	
IIA, 6.2/02	Ku, H. S.	1990	A study to determine the nature of the residue in meat, milk and tissues from lactating goats dosed with 14C-4-hydroxy-2,5,6-trichloroisophthalonitrile (SDS-3701). Generated by: Ricerca, Inc. and Analytical Bio-Chemistry Laboratories, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 1183-87-0024-EF-001 Date: February 20, 1990 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	Reports⁹ on previous use in granting national authorizations
IIA, 6.6/02	Nelsen, T. R., Marks, A. F.	1995	An indoor crop rotation study with ¹⁴ C-chlorothalonil (2,4,5,6-tetrachloroisophthalonitrile). Generated by: SDS Biotech Corporation Submitted by: ISK Biosciences Corp./Zeneca Report No.: 608-4EF-82-0169-001 Date: December 15, 1995 GLP, Unpublished	
IIA, 6.5/06	Prince, P. M., King, C., Wiedmann, J. L.	1994	Magnitude of chlorothalonil residues in grapes and processed fractions. Generated by: Ricerca, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 5919-94-0017-CR-001 Date: December 27, 1994 GLP, Unpublished	
IIA, 6.5/14	Prince, P. M., King, C.	1993	Determination of the magnitude of residues, tetrachloroisophthalonitrile (chlorothalonil, SDS-2787), SDS-3701 and HCB on prunes - Processing Study - 1992. Generated by: Ricerca, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 5485-93-0022-CR-001 Date: July 23, 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 ⁹ on previous use in granting national authorizations
IIA, 6.3/05	Rose, C. A.	1993	Determination of residues of tetrachloroisophthalonitrile (chlorothalonil, SDS-2787), SDS-3701, SDS-46851, HCB, and PCBN in potatoes from a stability study (field incurred) - 1988 - Four year interim report. Generated by: Ricerca, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 3064-88-0095-CR-002 Date: July 30, 1993 GLP, Unpublished	
IIA, 6.3/06	Rose, C. A.	1993	Determination of residues of tetrachloroisophthalonitrile (chlorothalonil, SDS-2787), SDS-3701, SDS-46851, HCB, and PCBN in carrots from a stability study (field incurred) - 1988 - Four year interim report. Generated by: Ricerca, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 3064-88-0096-CR-002 Date: July 1, 1993 GLP, Unpublished	
IIA, 6.6/03	Rose, C. A., Kenyon, R. G., Dillon, K. A. Wiedmann, J. L., Ballee, D. L.	1991	Rotational crop study: Summary of residues of tetrachloroisophthalonitrile (chlorothalonil, SDS-2787), its metabolites and manufacturing impurities in first season rotated crops and corresponding soils from Bravo® treated areas - 1985 - 1987. Generated by: Ricerca, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 1401-86-0084-CR-019 Date: August 9, 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	Reports ⁹ on previous use in granting national authorizations
IIA, 6.3/09	Wiedmann, J. L.	1993	Determination of residues of tetrachloroisophthalonitrile (chlorothalonil, SDS-2787), SDS-3701, SDS-46851, HCB, and PCBN in almond hulls and nutmeats from a stability study (field incurred) - 1988 - Four year interim report. Generated by: Ricerca, Inc. Submitted by: ISK Biosciences Corp./Zeneca Report No.: 3064-88-0158-CR-002 Date: May 30, 1993 GLP, Unpublished	
IIA 6.3/06	Gill, J.P. and Iniesta, L.	2001	Residue levels in potatoes from trials conducted in Spain during 2000. Generated by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3144B, Study No. 00JH070 Date: 10/08/2001 GLP, unpublished Submitted by SYN	

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IIA 6.3/07	Gill, J.P. and Sutra, G.	2001	Residue levels in wheat and processed wheat products from Trials carried out in France during 1999. Generated by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3094B, Study No. 99JH076 Date: 29/01/2001 GLP, unpublished Submitted by SYN	
IIA 6.3/08	Gill, J.P. and Myles, P.	2001	Residue levels in wheat and processed wheat products from Trials carried out in the UK during 1999. Generated by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3095B, Study No. 99JH077 Date: 31/01/2001 GLP, unpublished Submitted by SYN	
IIA 6.3/09	McGill, C. and Griehl, T.	2001	Residue levels in wheat from a Study Conducted in the Germany during 2000. Generated by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3135B, Study No. 00JH045 Date: 21/06/2001 GLP, unpublished Submitted by SYN	

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 ⁹ on previous use in granting national authorizations
IIA 6.3/12	McGill, C. and Barnaud, C.	2000	Chlorothalonil: Residue levels in potatoes from trials carried out in France during 1999. Generated by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3051B, Study No. 99JH074 Date: 18/09/2000 GLP, unpublished Submitted by SYN	
IIA 6.3/13	McGill, C., Giacomelli, G. and S.R: Burke	2001	Residue levels in potatoes from trials conducted in Italy during 2000. Generated by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3136B, Study No. 00JH073 Date: 21/06/2001 GLP, unpublished Submitted by SYN	
IIA 6.3/14	McGill, C. and Volpi, E.	2000	Residue levels in wheat from trials conducted in Italy during 1999. Generated by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3024B, Study No. 99JH078; Date: 30/08/2000 GLP, unpublished Submitted by SYN	

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	Reports⁹ on previous use in granting national authorizations
IIA 6.3/15	McGill, C. and Volpi, E.	2001	Residue levels in wheat from trials conducted in Italy during 2000. Generated by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3134B, Study No. 00JH044 Date: 25/06/2001 GLP, unpublished Submitted by SYN	
IIA 6.3/16	McGill, C., Iniesta, L. and Burke, S.R.	2001	Residue levels in wheat from trials conducted in Spain during 2000. Generated by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3139B, Study No. 00JH046 Date: 05/10/2001 GLP, unpublished Submitted by SYN	
IIA 6.3/17	Richards, S. and Iniesta, L.	2001	Residue levels in potatoes from trials conducted in Spain during 2000. Generated by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3190B, Study No. 00JH143 Date: 19/12/2001 GLP, unpublished Submitted by SYN	

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	Reports⁹ on previous use in granting national authorizations
IIA 6.4/01	King C. and Pince P.	1995	Freezer storage stability of SDS-3701 in milk and cow tissue Syngenta, UK Report no.: 5927-93-0329-CR-001 GLP, not published Submitted by SYN	
IIA 6.2/01	Guirguis A.S. and Yu, C.C.	1994	Metabolism of dicamba in lactating goats Syngenta, UK Report no.: project 580065, report no.28 GLP, not published	
IIA 6.2/02	Nietschmann, D.A. and Yu, C.C.	1994	Dicamba: Metabolism in laying hens Syngenta, UK Report no.: project 580065, report no.25 GLP, not published	
IIA 6.3.3/01	Gasser, A.	2001	Residues of NOA 405873 in milk, blood and tissues (muscle, fat, liver, kidney) of dairy cattle resulting from feeding of NOA 405873 (metabolite of dicamba, SAN 837) at three dose levels Syngenta, UK Report no.: 324/00 GLP, not published	

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	Reports¹⁰ on previous use in granting national authorizations

¹⁰ 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 ¹⁰ on previous use in granting national authorizations
IIA, 7.1.2/02	Archer, G., Doran, T. J.	1991	Adsorption and desorption of SDS-3701 to soils. Generated by: Ricerca, Inc. Submitted by: Zeneca Report No.: 3606-90-0375-EF-001 Date: May 3, 1991 GLP, Unpublished	
IIA, 7.2.1	Frazier, H. W.	1995	CTL - A Summary of Aerobic Aquatic Degradation Data (Half-Life Values) in Natural Water (Includes Appendix - CTL (SDS-2787): 90 Hour Aquarium Study, by Kent Kabler, Toxikon Env. Sciences) Generated by Ricerca Submitted by Zeneca Company File No. 5980-95-0263-EF-001 date. 4 December 1995 Not GLP, Unpublished	
IIA, 7.2.1.3.2/01	Hatzenbeler, C. J., Doran, T. J.	1991	An aerobic aquatic metabolism study with 14C-Chlorothalonil. Generated by: Ricerca, Inc. Submitted by: Zeneca Report No.: 3161-90-0240-EF-001 Date: August 19, 1991 GLP, Unpublished	
IIA, 7.1.1/03	Jacobson, B. M., Schollenberger, J. M.	1992	Dissipation of 4-hydroxy-2,5,6-trichloroisophthalonitrile (SDS-3701) in soil: A re-analysis of chlorothalonil soil. Dissipation data. Generated by: Ricerca, Inc. Submitted by: Zeneca Report No.: 1874-92-0517-EF-001 Date: September 11, 1992 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 ¹⁰ on previous use in granting national authorizations
IIA, 7.1.2/03	Waller, R. L.	1992	Adsorption and desorption of SDS-46851 to soils. Generated by: Ricerca, Inc. Submitted by: Zeneca Report No.: 3605-90-0374-EF-001 Date: January 30, 1992 GLP, Unpublished	
IIA 7.1.1.2.1	J.Emburry	1999	Degradation of R417888 in soil. Generated by: Zeneca Submitted by: Zeneca Company file No.: RJ2863B date: 03 December 1999 GLP, unpublished Submitted by SYN	
IIA 7.1.2	P.K.Thomas	1999	Chlorothalonil: Adsorption and desorption properties of R417888 in seven soils Generated by: Zeneca Research Submitted by: Zeneca Company file No.: RJ2803B date: 13 October 1999 GLP, unpublished Submitted by SYN	
IIA 7.1.2	S.F.Kuet	2000	The effect of ageing on the adsorption properties of a metabolite, SDS-3701, in soil Generated by: Zeneca Research Submitted by: Zeneca Company file No.: RJ2880B date: 04 January 2000 GLP, unpublished Submitted by SYN	

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 ¹⁰ on previous use in granting national authorizations
IIA 7.1.3.3	F. Schnöder	1999	14C-SDS-2787 (chlorothalonil): Lysimeter study according to BBA Guideline IV, 4-3, 1990. Generated by: Covance Laboratories GmbH Submitted by: Zeneca. Company file No.: CLE 1483-1077-003 date: 11 June 1999 GLP, unpublished Submitted by SYN	
IIA 7.2.1.4	C.J. Hatzenbeler, T.J.Doran	1991	An aerobic aquatic metabolism study with 14C-chlorothalonil Generated by: Ricerca. Inc. Submitted by: Zeneca Company file No.: 3161-90-0240-EF-001 date: 19 August 1991 GLP, unpublished Submitted by SYN	
IIA 7.2.1.4	W.E.Gentle,	1999	Chlorothalonil: Dissipation in a 30 cm deep indoor aquatic microcosm. Generated by: Zeneca Research Submitted by: Zeneca Company file No.: TMJ 4216B date: 8 April 1999 GLP, unpublished Submitted by SYN	
IIA 7.2.1.4	W.E. Gentle, L.J.Tattersfield	1999	Chlorothalonil: Preliminary dosing study in varied depth aquatic microcosms. Generated by: Zeneca Research Submitted by: Zeneca. Company file No.: TMJ4342B date: 15 December 1999 GLP, unpublished Submitted by SYN	

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	Reports¹⁰ on previous use in granting national authorizations
IIA, 7.1.1.1.1/01	Gibbings, E., Bramley, Y.	2001	Chlorothalonil: degradation in aerobic soil Report No. RJ3099B GLP, Unpublished Submitted by SYN	
IIA, 7.1.1.1.2.3/01	Kenyon, R.G.	1995	Residues of tetrachloroisophthalonitrile, its degradation products and manufacturing impurities in soil from a stability study (final report) Report No. 3436-890375-CR-002 GLP, Unpublished Submitted by SYN	
IIA, 7.1	Emburey, S.N.	2001	Further analysis of lysimeter study leachate Report No. RJ3255B GLP, Unpublished Submitted by SYN	
IIA, 7.2.2/01	Kuet, S.F. and A. Morrow	2001	Chlorothalonil. Volatilisation from soil and leaf surface, RJ3221B Submitted by SYN	
IIA 7.4/01	Marks, A.	1986	Determination of tetrachloroisophthalonitrile (Chlorothalonil, SDS-2787), SDS-3701 and SDS-46851 in water from Long Island wells Report No. 1149-86-0010-AS-002 GLP, Unpublished Submitted by SYN	
IIA 7.1.3.3	Vonk, J.W.	2000	Expert Opinion on the nature of unknown metabolites of chlorothalonil in lysimeter leachate. EPP Consultancy ; Report no. 001201 December 17, 2000 Submitted by SYN	

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	Reports¹¹ on previous use in granting national authorizations
IIA, 8.6	Backus, P.	1992	Effect of chlorothalonil on seed germination/seedling emergence (Tier I). Generated by: Ricerca, Inc. Submitted by: Zeneca Report No.: 5234-92-0119-BE-001 Date: July 31, 1992 GLP, Unpublished	
IIA, 8.6	Backus, P.	1992	Effect of chlorothalonil on vegetative vigor of plants (Tier I). Generated by: Ricerca, Inc. Submitted by: Zeneca Report No.: 5234-92-0120-BE-001 Date: July 31, 1992 GLP, Unpublished	
IIA, 8.2.7	Forster A.	1998a	To assess the toxicity of chlorothalonil to the sediment dwelling phase of the midge <i>Chironimus riparius</i> . Generated by Huntingdon Life Sciences Submitted by Zeneca Report No: RIA974025 Date: 24 June 1998 GLP, Unpublished	

¹¹ 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 ¹¹ on previous use in granting national authorizations
IIA, 8.2.5/02	Shults, S. K., Hoberg, J. R.	1991	Flow-through life-cycle toxicity study in mysid shrimp with technical chlorothalonil. Generated by: Ricerca, Inc. and Springborn Laboratories, Inc. Submitted by: Zeneca Report No.: 3228-89-0043-TX-002/90-05-3330 Date: December 11, 1991 GLP, Unpublished	
IIA, 8.2.6/01	Williams, T. L., Hughes, J. S.	1992	The toxicity of technical chlorothalonil fungicide to <i>Selenastrum capricornutum</i> . Generated by: Malcolm Pirnie, Inc. Submitted by: Zeneca Report No.: B038-001-1 Date: August 5, 1992 GLP, Unpublished	
IIA, 8.4.1	Wuthrich, W.	1990	Acute toxicity (LC50) study of Daconil 2787 Extra to earthworms. Generated by: R C C UMWELTCHEMIE AG Submitted by: Zeneca Report No.: RCC Project 282971 Date: November 29, 1990 GLP, Unpublished	
IIA 8.2.6	D.V. Smith, N. Shillabeer.	1998	Chlorothalonil: Toxicity to freshwater diatom <i>Navicula pelliculosa</i> Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6423/B date: December 1998 GLP, unpublished Submitted by SYN	
IIA 8.2.6	D.V. Smith, N. Shillabeer.	1998	Chlorothalonil: Toxicity to the blue-green alga <i>Anabaena flos-aquae</i> . Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6413/B date: December 1998 GLP, unpublished Submitted by SYN	

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	Reports¹¹ on previous use in granting national authorizations
IIA 8.2.6	D.V. Smith, N. Shillabeer.	2000	Chlorothalonil: Toxicity to the freshwater diatom <i>Navicula pelliculosa</i> in the presence of sediment Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6776/B date: January 2000 GLP, unpublished Submitted by SYN	
IIA 8.2.6	D.V. Smyth, S.E. Magor, N. Shillabeer	1999	Chlorothalonil: Acute toxicity to the green alga <i>Selenastrum capricornutum</i> of a 750 g/l WG formulation Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6761/B date: December 1999 GLP, unpublished Submitted by SYN	
IIA 8.2.6	S.E. Magor, N.Shillabeer	2000	SDS-46851: Toxicity to the green alga <i>Selenastrum capricornutum</i> Generated by: Zeneca Research Submitted by: Zeneca Company file No.: AG0596/D date: 27 January 2000 GLP, unpublished Submitted by SYN	
IIA 8.2.6	S.E. Magor, N.Shillabeer	1999	R417888: Toxicity to the green alga <i>Selenastrum capricornutum</i> Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6584/B date: May 1999 GLP, unpublished Submitted by SYN	
IIA 8.2.4	M.J. Hamer, W.E. Gentle	1999	Acute toxicity to aquatic invertebrates Generated by: Zeneca Research Submitted by: Zeneca. Company file No.: TMJ4135B date: July 1999 GLP, unpublished Submitted by SYN	

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 ¹¹ on previous use in granting national authorizations
IIA 8.2.4	S.E. Magor, N. Shillabeer	1999	Chlorothalonil: Acute Toxicity to Daphnia magna of a 750 g/l WG formulation. Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6763/B date: December 1999 GLP, unpublished Submitted by SYN	
IIA 8.2.4	S.E. Magor, N. Shillabeer	2000	SDS-46851: Acute toxicity to Daphnia magna Generated by: Zeneca Research Submitted by: Zeneca Company file No.: AG0596/C date: May 2000 GLP, unpublished Submitted by SYN	
IIA 8.2.4	S.E. Magor, N. Shillabeer	1999	SDS-46851: Acute toxicity to Daphnia magna Generated by: Zeneca Research. Submitted by: Zeneca Company file No.: AG0193/C date: May 1999 GLP, unpublished Submitted by SYN	
IIA 8.2.4	S.E. Magor, N. Shillabeer	1999	SDS-19221: Acute Toxicity to Daphnia magna Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6482/B date: January 1999 GLP, unpublished Submitted by SYN	
IIA 8.2.4	S.E. Magor, N. Shillabeer	1999	Chlorothalonil: Evaluation of a lysimeter leachate for toxicity to Daphnia magna Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6599/B date: June 1999 GLP, unpublished Submitted by SYN	

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IIA 8.2.1	S.E. Magor, N. Shillabeer	1999	Chlorothalonil: Acute toxicity to rainbow trout (oncorhynchus mykiss) of a 750 g/l WG formulation Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6762/B date: December 1999	
IIA 8.2.1	S.E. Magor, N. Shillabeer	1999	SDS-46851: Toxicity to rainbow trout (Oncorhynchus mykiss) Generated by: Zeneca Research Submitted by: Zeneca Company file No.: AG0569/B date: May 1999 GLP, unpublished Submitted by SYN	
IIA 8.2.1	S.E. Magor, N. Shillabeer	1999	R417888: Acute Toxicity to rainbow trout (Oncorhynchus mykiss) Generated by: Zeneca Research Submitted by: Zeneca Company file No.: AG0193/B date: May 1999 GLP, unpublished Submitted by SYN	
IIA 8.2.1	S.E. Magor, N. Shillabeer	1999	SDS-19221: Acute Toxicity to rainbow trout (Oncorhynchus mykiss) Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6481/B date: January 1999 GLP, unpublished Submitted by SYN	
IIA 8.2.1	S.E. Magor, N. Shillabeer	1999	Chlorothalonil: Evaluation of a lysimeter leachate for toxicity to rainbow trout (Oncorhynchus mykiss) Generated by: Zeneca Research Submitted by: Zeneca. Company file No.: BL6598/B date: June 1999 GLP, unpublished Submitted by SYN	

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 ¹¹ on previous use in granting national authorizations
IIA 8.2.8	D.V. Smyth S.E. Magor, N. Shillabeer	1998	Chlorothalonil: Toxicity to duckweed (Lemna gibba) Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6473/B date: December 1998 GLP, unpublished Submitted by SYN	
IIA 8.3.1.1	H.M. Thompson	2000	Chlorothalonil: Acute contact and oral toxicity of technical material to Honey bees (Apis mellifera) Generated by: National Bee Unit, C.S.L. Submitted by: Zeneca Company file No.: GQ4001 date: 19 January 2000 GLP, unpublished Submitted by SYN	
IIA 8.3.2	H.M. Austin	1999	A laboratory study to evaluate the effects of SDS-3701 on Poecilus cupreus (coleoptera: Carabidae). Generated by: Ecotox limited Submitted by: Zeneca Company file No.: 42278 date: 25 March 1999 GLP, unpublished Submitted by SYN	

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 ¹¹ on previous use in granting national authorizations
IIA 8.3.2	A.Travis	2000	A Tier II laboratory test to assess the effects of the metabolite R417888 on <i>Poecilus cupreus</i> (coleoptera: Carabidae). Generated by: Zeneca Research Submitted by: Zeneca Company file No.: 00JH006 Technical letter date: 16 May 2000 GLP, unpublished Submitted by SYN	
IIA 8.4.1	A.Travis	1999	Toxicity of R417888, a metabolite of chlorothalonil, to the earthworm <i>Eisenia fetida</i> in an artificial soil test. Generated by: Zeneca Research Submitted by: Zeneca Company file No.: RJ2887B date: 9 December 1999 GLP, unpublished Submitted by SYN	
IIA, 8.4.1/01	Moser, Th, Rombke, J.	2000a	Chlorothalonil: acute toxicity of the metabolite SDS-46851 (R611965) to the earthworm <i>Eisenia andrei</i> in an artificial soil test ECT Oekotoxikologie GmbH Report No. F18RA GLP, Unpublished Submitted by SYN	
IIA, 8.4.2/01	Moser, Th, Rombke, J.	2000b	Chlorothalonil: reproduction toxicity of the metabolite SDS-373 (R182281) to the earthworm <i>Eisenia andrei</i> in an artificial soil test ECT Oekotoxikologie GmbH Report No. F11RR GLP, Unpublished Submitted by SYN	

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	Reports¹¹ on previous use in granting national authorizations
IIA, 8.4.2/02	Moser, Th.	2001	Chlorothalonil: reproduction toxicity of chlorothalonil technical material to the earthworm <i>Eisenia andrei</i> according to the International Standard ISO 11268-2 Part 2 (1988) "Soil quality – Effects of pollutants on earthworms (<i>Eisenia fetida</i>) – Part 2: Determination of effects on reproduction ECT Oekotoxikologie GmbH Report No. V1RR GLP, Unpublished Submitted by SYN	
IIA 8.4.2/03	Moser, Th.	2001	Chlorothalonil: reproduction toxicity of the metabolite R417888 to the earthworm <i>Eisenia andrei</i> in an artificial soil test according to the International Standard ISO 11268-2 Part 2 (1988) "Soil quality – Effects of pollutants on earthworms (<i>Eisenia fetida</i>) – Part 2: Determination of effects on reproduction ECT Oekotoxikologie GmbH Report No. V2RR GLP, Unpublished Submitted by SYN	
IIA, 8.5/01	McMurray, A.	2001a	A laboratory assessment of the effects of chlorothalonil metabolites [SDS-3701, SDS-46851, R-417888] on soil microflora respiration and nitrogen transformation Report no. ENV5183 GLP, Unpublished Submitted by SYN	
IIA, 8.6/01	Pierce, A.	2001	GSH Reactivity of chlorothalonil and its metabolite R182281, R419492 and R471811 Report no. RIC7335 Non-GLP, Unpublished Submitted by SYN	

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	Reports¹¹ on previous use in granting national authorizations
IIA, 8.6/02	Seville, A.	1999a	GSH Reactivity of chlorothalonil and its metabolite R611965 Report no. RIC7304 Non-GLP, Unpublished Submitted by SYN	
IIA, 8.6/03	Seville, A.	1999b	GSH reactivity of chlorothalonil and its metabolite R417888 Report no. RIC7303 Non-GLP, Unpublished Submitted by SYN	
IIA, 8.6/04	Collinge, D.	2000b	Chlorothalonil metabolite R417888 – absence of fungicidal activity Report no. RIC7301 Non-GLP, Unpublished Submitted by SYN	
IIA, 8.6/05	Collinge, D.	2001	Chlorothalonil metabolite R611965 – absence of fungicidal activity Report no. RIC7302 Non-GLP, Unpublished Submitted by SYN	
IIA, 8.6/06	Mills, D.	2001	Fungicidal activity – evaluation of chlorothalonil and chlorothalonil metabolite R182281 Report No., RIC7333 Non-GLP, Unpublished Submitted by SYN	
IIA, 8.7/02	Wallace, S.J.	2002	R044686 (Chlorothalonil technical): effect on respiration rate of activated sludge. Report No. BL 7409/B. Submitted by SYN	

APPENDIX IIIB

CHLOROTHALONIL

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

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

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 1.09	Anonymous	2003	Data Sheet R44686 chlorothalonil, purity and byproducts of technical a.i. Submitted by: Syngenta Reportnumber: not applicable Date: 17.12.2003
IIA 1.11	Arenas, R.	2003	Analysis of five representative batches of chlorothalonil technical (ASF41) produced at GB Biosciences, Houston, TX, USA. Submitted by: Syngenta Report no.: T001464-03 Date: 23.07.2003 GLP, unpublished
IIA 1.11	Mishler, M.B.	2001 a	The determination of chlorothalonil and associated impurities in technical; material by capillary Gas Chromatography, Submitted by Syngenta Report no.:AMW00044-01B Non GLP, non published
IIA 1.11	Mishler, M.B.	2001 b	Method validation: AMW00044-01B, The determination of Chlorothalonil and associated impurities in technical; material by capillary Gas Chromatography, Submitted by Syngenta Report no.:AMW00044-01B GLP, non published
IIA 1.11	Garofani, S.	2002 a	Chlorothalonil technical. Determination of the A.I. content validation of the analytical method Generated by: ChemService Submitted by: Vischim S.r.l. Report no.:CH-93/2001 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 1.11	Garofani, S.	2002 b	Chlorothalonil technical. Determination of the A.I. content validation of the analytical method. Amendment no 1 to the Final Report CH-93/2001 Generated by: ChemService Submitted by: Vischim S.r.l. Report no.:CH-93/2001 GLP, unpublished
IIA 1.11	Garofani, S.	2002 c	Chlorothalonil technical. Determination of the impurities validation of the analytical method Generated by: ChemService Submitted by: Vischim S.r.l. Report no.:CH-94/2001 GLP, unpublished
IIA 1.11	Garofani, S.	2002 d	Chlorothalonil technical. Determination of the impurities validation of the analytical method Amendment no 1 to the Final Report CH-93/2001 Generated by: ChemService Submitted by: Vischim S.r.l. Report no.:CH-93/2001 GLP, unpublished
IIA 1.11	Garofani, S.	2002 e	Chlorothalonil technical. Determination of the hexachlorobenzene content of the analytical method Generated by: ChemService Submitted by: Vischim S.r.l. Report no.:CH-95/2001 GLP, unpublished
IIA 1.11	Garofani, S.	2002 f	Chlorothalonil technical. Determination of the hexachlorobenzene content of the analytical method Amendment no 1 to the Final Report CH-93/2001 Generated by: ChemService Submitted by: Vischim S.r.l. Report no.:CH-93/2001 GLP, unpublished
IIA 1.11	Garofani, S.	2002 g	Chlorothalonil technical. Analysis of five batch samples. Generated by: ChemService Submitted by: Vischim S.r.l. Report no.:CH-96/2001 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 1.11	Garofani, S.	2002 h	Chlorothalonil technical. Analysis of five batch samples. Amendment no 1 to the Final Report CH-93/2001 Generated by: ChemService Submitted by: Vischim S.r.l. Report no.:CH-93/2001 GLP, unpublished
IIA 1.11	Terradas, F	2001	Chlorothalonil technical chemical composition Letter Submitted by Gharda
IIA 1.11	Bondre, S.S.	2000	Analysis certification of limits for chlorothalonil technical Gharda chemicals Report no.: GCLQA no. SAL IMDP 27 GLP, unpublished Submitted by Gharda
IIA 1.11	Bondre,S.S.	2000	Analysis certification of limits for chlorothalonil technical Addendum Gharda chemicals Report no.: GCLQA no. SAL IMDP 27 GLP, unpublished Gharda
II 2.9	Wollerton, C. Walter, G.P.	2000	Chlorothalonil Quantum Yield and Environmental Lifetime of Pure Material Generated by: Zeneca Submitted by: Zeneca Report no.: RJ2917B Date: 28 January 2000 GLP, unpublished Submitted by SYN
III A 2.7	Bernes, A.	1998	Chemical and Physical properties and storage stability tests of BRAVO 720 SC Generated by: Depart De Phytopharmacie Submitted by: Zeneca Report no.: 9768 Date: 20 November 1998 GLP, unpublished Submitted by SYN
IIA 4.2.1	Robinson, N. J.	2000	Residue Analytical Method for the Determination of Chlorothalonil in Crops RAM 320/01 GLP, unpublished Submitted by SYN

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	Lister, N..	2000	Validation of SOP RAM 320/01 for the Determination of Residues in Crops RAM 320/01 GLP, unpublished Submitted by SYN
IIA 4.2.3	Robinson, N. J.	2000	Validation of a residue Analytical Method for the Determination of Residues in Water RAM 320/01 GLP, unpublished Submitted by SYN
IIA2.3/IIA 2.6/IIA 2.8/IIA 2.9	Wollerton,C. G.P.Walter	2000	Chlorothalonil:Water solubility, dissociation constant, Partition coefficient and Henry's Law constant of the metabolite R417888/Na 21 january 2000 GLP, unpublished Submitted by SYN
IIA 2.8	Kilgour, J.D.	1998	Chlorothalonil 82.5 g/kg WG: Assessment of apparent aerodynamic particle size distribution by air elutriation Generated by: Central Toxicology Laboratory Submitted by: Zeneca Agrochemicals Report number: CTL/P/5949 Date: 21 December 1998 GLP, unpublished Submitted by SYN
IIA 2.8	Kilgour, J.D.	1998	Chlorothalonil 750 g/kg WG: Assessment of apparent aerodynamic particle size distribution by air elutriation Generated by: Central Toxicology Laboratory Submitted by: Zeneca Agrochemicals Report number: CTL/P/5949 Date: 24 June 1998 GLP, unpublished Submitted by SYN
IIA.2.9	Hayes, S.E	2001	Chlorothalonil – Calculation of Half life by reaction with atmospheric hydroxyl radicals. Syngenta, UK Report no.: CHTL B2.1/023 RIC 7317 Non GLP, not published Submitted by SYN

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 2.8	Evans, A.J.	2002	Extended Storage Stability-intial friability (initial test result of a shelf-life study) Performing laboratory: SafePharm Submitted by: Sygenta Project no. 560/186(a) Non GLP. Not published Submitted by SYN
IIIA 2.7	Fraschini, C.	1999 a	Chlorothalonil 75 WG. Shelf life at ambient temperature. Performing laboratory: SIPCAM. Submitted by: VISCHIM S.R.L. Project no.: 008/97 GLP. Not published Submitted by VIS
IIIA 2.7	Fraschini, C.	1999 b	Chlorothalonil 500 g/l. Active content and stability at 0 0C temperature. Performing laboratory: SIPCAM. Submitted by: VISCHIM S.R.L. Project no.: 006/99 GLP. Not published Submitted by VIS
IIIA 2.7	Freschi, G.	2001	Chlorothalonil 500 g/l. (stability at 0 0C) Performing laboratory: SIPCAM. Submitted by: VISCHIM S.R.L. Project no.: 003/2001 GLP. Not published Submitted by VIS
IIIA 4.6	Flack,I	2001	Chlorothalonil 75 WG– Determination of the efficiency of the normal procedures used for cleaning spray tanks after use. Performing laboratory: Huntingdon Life Science Ltd Submitted by VISCHIM SRL Report no.: VCM 100/012412 GLP, not published Submitted by VIS

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	Croucher, A.	2001	Chlorothalonil: Independent laboratory validation of SOP RAM 320/02 Analytical method for the determination of residues in crops (cucumber, wheat grain and whole orange). Generated by: Covance Laboratories Ltd., Harrogate, UK Submitted by: Syngenta Jealott's Hill International Research Centre, Bracknell, UK. Company File No: 1983/025-D2419 Date: October 2001 GLP, Unpublished Submitted by SYN
IIA 4.2.1	Cordon, C.	2002	Chlorothalonil: Independent laboratory validation of methodology for the determination of residues of chlorothalonil in apples and wheat grain. Generated by: Huntingdon Life Sciences, Alconbury, UK Submitted by: Vischim S.r.l., Milano, Italy Company File No: VCM 104/022546 Date: May 2002 GLP, Unpublished Submitted by VIS
IIA 4.2.1	McGill C. & Robinson N.	2002	Validation of Analytical Method 384/01 for the determination of Residues in Bovine Muscle, Fat, Kidney, Liver, Milk and Hen's Eggs Syngenta, Berkshire, UK Report No. RJ3313B GLP, not published Date: 2002 Submitted by SYN
IIA 4.2.1	Brice, A.	2003	Chlorothalonil metabolite R182281: independent laboratory validation of SOP RAM 348/01 Analytical Method for the determination of Residues in Bovine Muscle, Milk and Hen's Eggs Generated by: Covance laboratories ltd., North Yorkshire, England Report No. 1983/054-D2149 GLP, not published Date: 8 august 2003 Submitted by SYN

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	Robinson N.J.	2003	Standard Operating Procedure RAM 384/01 Residue Analytical Method for the determination of the Chlorothalonil Metabolite RH182281 (SDS-3701) in Bovine Muscle, Fat, Kidney, Liver, Milk and Hen's Eggs Syngenta, Bekshire, UK Report No. - non-GLP, not published Date: 2003 Submitted by SYN
IIA 4.2.1	Cordon, C.	2002	Independent laboratory validation of methodology for the determination of residues of chlorothalonil and its metabolite 4-hydroxy-2,5,6-trichloro-1,3-dicyanaobenzene in animal tissues and produce Generated by: Huntingdon Life Sciences Ltd., Huntingdon, UK Submitted by: Vischim srl, Cesano Maderno (MI), Italy Company File No: VCM 105/022700 Date: 20/05/2002 GLP, Unpublished Submitted by VIS
IIA, 4.2.2/a	Hargreaves, S.L	2001	Residue analytical method for the determination of chlorothalonil and R182281 (SDS-3701) in soil Syngenta, UK, SOP RAM 335/01 non GLP, Unpublished. Submitted by SYN
IIA, 4.2.2/b	Robinson, N.J.	draft	Residue analytical method for the determination of residues of the chlorothalonil metabolite R417888 in soil Syngenta, UK, SOP RAM 341/01 non GLP, Unpublished. Submitted by SYN
IIA, 4.2.2/c	Emburey, M.	2002	R417888 Validation of a residue analytical method for the determination of residues in soil Syngenta, UK, report no. RJ3309B GLP, Unpublished Submitted by SYN
IIA, 4.2.3/a	Robinson, N	2000	Chlorothalonil: residue analytical method for the determination of residues in water Syngenta, UK, SOP RAM 333/01 non GLP, Unpublished Submitted by SYN

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, 4.2.3/b	Emburey, M.	2002	Chlorothalonil Validation of a residue analytical method for the determination of residues in water Syngenta, UK, report no. RJ3080B GLP, Unpublished Submitted by SYN
IIA, 4.2.4/a	Crook, S.J.	2001	Residue analytical method for the determination of residues of chlorothalonil in air. Syngenta, UK, SOP RAM 361/01 non GLP, Unpublished Submitted by SYN
IIA, 4.2.4/0b	Crook, S.J.	2001	Chlorothalonil Validation of a residue analytical method for the determination of residues in air Syngenta, UK, report no. TMJ4573B GLP, Unpublished Submitted by SYN
IIA 4.2.5	Cordon, C.	2002	Validation of methodology for the determination of residues of chlorothalonil and its metabolite 4-hydroxy-2,5,6-trichloro-1,3-dicyanaobenzene in human blood and urine Generated by: Huntingdon Life Sciences Ltd., Huntingdon, UK Submitted by: Vischim srl, Cesano Maderno (MI), Italy Company File No: VCM 105/022703 Date: 20/05/2002a GLP, Unpublished Submitted by VIS
IIA 4.2.5	Hall, M.G.	2001	Chlorothalonil: determination in human and animal plasma by GC-MS Generated by: Central Toxicology Laboratory, Cheshire, UK Submitted by: Syngenta Company File No: CTL/024460/TEC/REPT Date: 08/05/2001 Non-GLP, Unpublished Submitted by SYN

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
6.1.3	Jones, B.K.	2000	Chlorothalonil 720g/l SC formulation: In vivo dermal absorption of chlorothalonil in the rat. Generated by: Central Toxicology Laboratory Submitted by: Zeneca Agrochemicals Report No.: CTL/UR0616/REG/REPT Date: 21 March 2000 GLP, unpublished Submitted by SYN
IIA 6.1.3	Davies, D.J.	2000	Chlorothalonil 720g/l SC formulation: In vitro absorption of chlorothalonil through rat epidermis. Generated by: Central Toxicology Laboratory Submitted by: Zeneca Agrochemicals Report No.: CTL/JV1584/REG/REPT Date: 10 March 2000a GLP, unpublished Submitted by SYN
6.1.3	Davies, D.J.	2000	Chlorothalonil 720g/l SC formulation: In vitro absorption of chlorothalonil through human epidermis. Generated by: Central Toxicology Laboratory Submitted by: Zeneca Agrochemicals Report No.: CTL/JV1585/REG/REPT Date: 13 March 2000b GLP, unpublished Submitted by SYN
6.1.3	Ward, R.J.	2000	Chlorothalonil 825g/kg WDG formulation: In vitro absorption of chlorothalonil through rat epidermis. Generated by: Central Toxicology Laboratory Submitted by: Zeneca Agrochemicals Report No.: CTL/JV1586/REG/REPT Date: 7 February 2000a GLP, unpublished Submitted by SYN
6.1.3	Ward, R.J.	2000	Chlorothalonil 825g/kg WDG formulation: In vitro absorption of chlorothalonil through human epidermis. Generated by: Central Toxicology Laboratory Submitted by: Zeneca Agrochemicals Report No.: CTL/JV1587/REG/REPT Date: 24 February 2000b GLP, unpublished Submitted by SYN

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
6.8.1	Schetter, J.E., Yoshida, M., Watson, M.	2000	A 52-week oral toxicity study in dogs with SDS-3701 Generated by: Ricerca Inc. Submitted by: Zeneca Agrochemicals Report no.: SDS-3701/7181-97-0102-TX-001 Date: January 31, 2000 GLP, unpublished Submitted by SYN
6.8.1	Johnson, I. R.	1999	R417888: Acute oral toxicity study in rats Generated by: Central Toxicology Laboratory, Alderly Park Macclesfield Cheshire UK Submitted by: Zeneca Agrochemicals Report no.: CTL/P/6459 Date: 7 December 1999 GLP, unpublished Submitted by SYN
6.8.1	Seville, A.	1999	GSH reactivity of chlorothalonil and its metabolite R417888 generated by: Chemistry Design Group, Zeneca Agrochemicals Submitted by: Zeneca Agrochemicals Report no.: - Date: 5 July 1999a Not GLP, unpublished Submitted by SYN
6.8.1	Seville, A.	1999	GSH reactivity of chlorothalonil and its metabolite R611965 (SDS-46851 / CTB - MIII) generated by: Chemistry Design Group, Zeneca Agrochemicals Submitted by: Zeneca Agrochemicals Report no.: - Date: 25 October 1999b Not GLP, unpublished Submitted by SYN
6.8.1	Duane, W.C.	1971	Reinvestigation of the degradation of chlorothalonil by bovine rumen fluid Generated by: Diamond Shamrock Corp., T.R. Evans research Centre, Painesville, Ohio Submitted by: Zeneca Agrochemicals Report no.: date: 17 December 1971 Not GLP, unpublished Submitted by SYN

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
6.8.1	Callander, R. D.	2000	R417888: Bacterial mutation assay in <i>S. typhimurium</i> and <i>E. coli</i> Generated by: Central Toxicology Laboratory, Alderly Park Macclesfield Cheshire UK Submitted by: Zeneca Agrochemicals Report no.: CTL/YV4341/Regulatory/Report Date: 22 March 2000 GLP, unpublished Submitted by SYN
6.8.1	Clay, P.	2000	R417888: L5178 TK+/- mouse lymphoma mutation assay Generated by: Central Toxicology Laboratory, Alderly Park Macclesfield Cheshire UK Submitted by: Zeneca Agrochemicals Report no.: CTL/VV0208/Regulatory/Report Date: 12 January 2000 GLP, unpublished Submitted by SYN
6.8.2	Lees, D. (a)	2005	Chlorothalonil: Acute reference dose study in the Fisher 344 rat Generated by: Central Toxicology Laboratory Submitted by: Syngenta Crop Protection Inc. Report No: AR7494-REG Date: 25 November 2005 GLP, unpublished Submitted by SYN
6.8.2	Lees, D. (b)	2005	Chlorothalonil: Preliminary acute reference dose study in the Fisher 344 rat Generated by: Central Toxicology Laboratory Submitted by: Syngenta Crop Protection Inc. Report No: CTL/AR7493/Summary/Report Date: 23 November 2005 GLP, unpublished Submitted by SYN
6.11.1	Kilgour, J.D.	1999	Chlorothalonil 720 g/l SC: 4-Hour acute inhalation toxicity study in rats Generated by: Central Toxicology Laboratory Submitted by: Zeneca Agrochemicals Report No.: CTL/P/6311 Date: 12 July 1999 GLP, unpublished Submitted by SYN

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
6.11.1	Kilgour, J.D.	1999	Chlorothalonil 500 g/l SC: 4-Hour acute inhalation toxicity study in rats Generated by: Central Toxicology Laboratory Submitted by: Zeneca Agrochemicals Report No.: CTL/P/6317 Date: 23 August 1999 GLP, unpublished Submitted by SYN
IIA 5.1/01	Ho, M.D. et al.	1990	Study of the excretion and distribution of radiolabel following oral administration of ¹⁴ C-SDS-46851 to Sprague-Dawley rats Syngenta, UK Report no.: 3589-90-0159-AM-001 GLP, not published Submitted by SYN
IIA 5.8.2/01	Noakes, J.P.	2001	R417888: 90 day dietary toxicity study in rats. Central Toxicology Laboratory, Alderley Park Macclesfield, Cheshire, UK. Report No CTL/PR1164/REG/REPT. GLP, unpublished Submitted by SYN
IIA 5.8.3/01	Fox, V.	2000 a	R417888: In vitro cytogenic assay in human lymphocytes. Central Toxicology Laboratory, Alderley Park Macclesfield, Cheshire, UK. Report No CTL/SV1002/REG/REPT. GLP, unpublished Submitted by SYN
IIA 5.8.3/02	Fox, V.	2000 b	R417888: In vitro cytogenic assay in human lymphocytes. Central Toxicology Laboratory, Alderley Park Macclesfield, Cheshire, UK. Report No CTL/SV1051/REG/REPT. GLP, unpublished Submitted by SYN
IIA 5.8.3/03	Fox, V.	2002	R611965 (SDS 46851): Mouse bone marrow micronucleus test. Central Toxicology Laboratory, Alderley Park Macclesfield, Cheshire, UK. Report No CTL/SM1110/REG/REPT. GLP, unpublished Submitted by SYN
IIA 5.8.5/01	Schroeder, R.E.	1998	SDS-3701: A developmental toxicity study in rats via oral administration. Huntingdon Life Sciences, East Millstone, New Jersey, USA. Report No CTL/C/3921. GLP, unpublished Submitted by SYN

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 6.3/01	Balluff, M.	1994	Final report on testing the fate of residues of SOS 40.793 F.O.WG (ASU 93 390 F) in cereals under field conditions Generated by: GAB Biotechnologie GmbH & UFU Umweltanalytik GmbH, Niefern- <u>schelbronn</u> , Germany Submitted by: Vischim srl, Cesano Maderno (MI), Italy Study No: AGR/RP-F 94?SOS Date: December 1994 GLP, unpublished Submitted by VIS
IIA 6.3/02	Beinhauer, K.	1993	Field trial for determination of residue levels in wheat according to the BBA Guideline IV 3-3 (1990), SOS 40.793 F.O. WG, Pugil 75 WG Generated by: BioChem GmbH, Karlsruhe, Germany Submitted by: Vischim srl, Cesano Maderno (MI), Italy Study No: 93 10 47 103 Date: 29/03/1993 GLP, unpublished Submitted by VIS
IIA 6.3/03	Beinhauer, K.	1994	Field trial for determination of residue levels in winter wheat according to the BBA Guideline IV 3-3 (1990), SOS 40.793 F.O. WG Generated by: BioChem GmbH, Karlsruhe, Germany Submitted by: Vischim srl, Cesano Maderno (MI), Italy Study No: 94 10 47 005 Date: 17/03/1994 GLP, unpublished Submitted by VIS
IIA 6.3/04	Brielbeck, B. and Marx, D	1995	Determination of chlorothalonil and HCB in cereals after treatment with Pugil 75 WG. Generated by: St \ddot{a} hler Agrochemie GmbH & Co. KG, Stade, Germany Submitted by: Vischim srl, Cesano Maderno (MI), Italy Company File No: AB 93390-RU-010, Study No. RU 0194 Date: 28/06/1995 GLP, unpublished Submitted by VIS

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 6.3/05	Brielbeck, B. and Marx, D	1995	Determination of chlorothalonil and HCB in cereals after treatment with Pugal 75 WG according to BBA Guideline IV 3-8 Generated by: Stöhrler Agrochemie GmbH & Co. KG, Stade, Germany Submitted by: Vischim srl, Cesano Maderno (MI), Italy Company File No: AB 93390-RU-010-02, Study No. RU 0194 Date: 28/06/1995a GLP, unpublished Submitted by VIS
IIA 6.3/06	Gill, J.P. and Iniesta, L.	2001	Residue levels in potatoes from trials conducted in Spain during 2000. Generated by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3144B, Study No. 00JH070 Date: 10/08/2001 GLP, unpublished Submitted by SYN
IIA 6.3/07	Gill, J.P. and Sutra, G.	2001	Residue levels in wheat and processed wheat products from Trials carried out in France during 1999. Generated by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3094B, Study No. 99JH076 Date: 29/01/2001 GLP, unpublished Submitted by SYN
IIA 6.3/08	Gill, J.P. and Myles, P.	2001	Residue levels in wheat and processed wheat products from Trials carried out in the UK during 1999. Generated by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3095B, Study No. 99JH077 Date: 31/01/2001 GLP, unpublished Submitted by SYN

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 6.3/09	McGill, C. and Griehl, T.	2001	Residue levels in wheat from a Study Conducted in the Germany during 2000. Generated by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3135B, Study No. 00JH045 Date: 21/06/2001 GLP, unpublished Submitted by SYN
IIA 6.3/10	Hoenzelaers, R.	1994	Final report on testing the fate of residues of SOS 40.793 F.O.WG (ASU 93 390 F) in cereals under field conditions Generated by: Agroplan, Goch-Nierswalde, Germany Submitted by: Vischim srl, Cesano Maderno (MI), Italy Study No. AGR/RP-F 93/SOS 40.793 F.O.WG Date: January 1994 GLP, unpublished Submitted by VIS
IIA 6.3/11	Hoenzelaers, R. and Schulz, J.	1993	Final report about testing the residual behaviour of SOS 40.793 F.O.WG in winter wheat under field conditions (field report) Generated by: Agroplan, Goch-Nierswalde, Germany Submitted by: Vischim srl, Cesano Maderno (MI), Italy Study No: AGR/RP-F 94/SOS 40.793 F.O. WG Date: 29/03/1993 GLP, unpublished Submitted by VIS
IIA 6.3/12	McGill, C. and Barnaud, C.	2000	Chlorothalonil: Residue levels in potatoes from trials carried out in France during 1999. Generated by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3051B, Study No. 99JH074 Date: 18/09/2000 GLP, unpublished Submitted by SYN

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 6.3/13	McGill, C., Giacomelli, G. and S.R: Burke	2001	Residue levels in potatoes from trials conducted in Italy during 2000. Generated by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3136B, Study No. 00JH073 Date: 21/06/2001 GLP, unpublished Submitted by SYN
IIA 6.3/14	McGill, C. and Volpi, E.	2000	Residue levels in wheat from trials conducted in Italy during 1999. Generated by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Zeneca Agrochemicals, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3024B, Study No. 99JH078; Date: 30/08/2000 GLP, unpublished Submitted by SYN
IIA 6.3/15	McGill, C. and Volpi, E.	2001	Residue levels in wheat from trials conducted in Italy during 2000. Generated by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3134B, Study No. 00JH044 Date: 25/06/2001 GLP, unpublished Submitted by SYN
IIA 6.3/16	McGill, C., Iniesta, L. and Burke, S.R.	2001	Residue levels in wheat from trials conducted in Spain during 2000. Generated by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3139B, Study No. 00JH046 Date: 05/10/2001 GLP, unpublished Submitted by SYN

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 6.3/17	Richards, S. and Iniesta, L.	2001	Residue levels in potatoes from trials conducted in Spain during 2000. Generated by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK Submitted by: Syngenta, Jealott's Hill International Research Centre, Bracknell, UK. Company File No: RJ3190B, Study No. 00JH143 Date: 19/12/2001 GLP, unpublished Submitted by SYN
IIA 6.4/01	King C. and Pince P.	1995	Freezer storage stability of SDS-3701 in milk and cow tissue Syngenta, UK Report no.: 5927-93-0329-CR-001 GLP, not published Submitted by SYN
IIA 6.2/01	Guirguis A.S. and Yu, C.C.	1994	Metabolism of dicamba in lactating goats Syngenta, UK Report no.: project 580065, report no.28 GLP, not published
IIA 6.2/02	Nietschmann, D.A. and Yu, C.C.	1994	Dicamba: Metabolism in laying hens Syngenta, UK Report no.: project 580065, report no.25 GLP, not published
IIA 6.3.3/01	Gasser, A.	2001	Residues of NOA 405873 in milk, blood and tissues (muscle, fat, liver, kidney) of dairy cattle resulting from feeding of NOA 405873 (metabolite of dicamba, SAN 837) at three dose levels Syngenta, UK Report no.: 324/00 GLP, not published

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
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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
8.1.2/01	J.Emburry	1999	Degradation of R417888 in soil. Generated by: Zeneca Submitted by: Zeneca Company file No.: RJ2863B date: 03 December 1999 GLP, unpublished Submitted by SYN
8.2.1/01	P.K.Thomas	1999	Chlorothalonil: Adsorption and desorption properties of R417888 in seven soils Generated by: Zeneca Research Submitted by: Zeneca Company file No.: RJ2803B date: 13 October 1999 GLP, unpublished Submitted by SYN
8.2.2/01	S.F.Kuet	2000	The effect of ageing on the adsorption properties of a metabolite, SDS-3701, in soil Generated by: Zeneca Research Submitted by: Zeneca Company file No.: RJ2880B date: 04 January 2000 GLP, unpublished Submitted by SYN
8.2.3/01	F. Schnöder	1999	14C-SDS-2787 (chlorothalonil): Lysimeter study according to BBA Guideline IV, 4-3, 1990. Generated by: Covance Laboratories GmbH Submitted by: Zeneca. Company file No.: CLE 1483-1077-003 date: 11 June 1999 GLP, unpublished Submitted by SYN
8.4.3/01	G. Bell	1998	Chlorothalonil: Assessment of ready biodegradability (CO ₂ evolution test) Generated by: Huntingdon Life Sciences Submitted by: Vischim Company file No.: VCM 53/941209 date: 26 June 1998 GLP, unpublished Submitted by VIS

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
8.4.4/01	Anonymous	1996	14C-Chlorothalonil - Degradability and Fate in Water/sediment Systems Generated by: Huntingdon Research Centre Ltd Submitted by: Vischim Srl Company file no.: VCM 45/962245 date: 1996 GLP, unpublished Submitted by VIS
8.4.4/02	C.J. Hatzenbeler, T.J.Doran	1991	An aerobic aquatic metabolism study with 14C-chlorothalonil Generated by: Ricerca. Inc. Submitted by: Zeneca Company file No.: 3161-90-0240-EF-001 date: 19 August 1991 GLP, unpublished Submitted by SYN
8.4.4/03	T.R. Nelson, A.F.Marks	1985	An anaerobic aquatic metabolism study with 14C-chlorothalonil Generated by: SDS Biotech Corporation Submitted by: Zeneca. Company file No.: 680-3EF-84-0026-001 date: 15 July 1985 GLP, unpublished Submitted by SYN
8.4.5/01	W.E.Gentle,	1999	Chlorothalonil: Dissipation in a 30 cm deep indoor aquatic microcosm. Generated by: Zeneca Research Submitted by: Zeneca Company file No.: TMJ 4216B date: 8 April 1999 GLP, unpublished Submitted by SYN
8.4.5/02	W.E. Gentle, L.J.Tattersfield	1999	Chlorothalonil: Preliminary dosing study in varied depth aquatic microcosms. Generated by: Zeneca Research Submitted by: Zeneca. Company file No.: TMJ4342B date: 15 December 1999 GLP, unpublished Submitted by SYN
IIA, 7.1.1.1.1/ 01	Gibbings, E., Bramley, Y.	2001	Chlorothalonil: degradation in aerobic soil Report No. RJ3099B GLP, Unpublished Submitted by SYN

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, 7.1.1.1.2. 3/01	Kenyon, R.G.	1995	Residues of tetrachloroisophthalonitrile, its degradation products and manufacturing impurities in soil from a stability study (final report) Report No. 3436-890375-CR-002 GLP, Unpublished Submitted by SYN
IIA, 7.1.1.1.2. 3/02	Emburey, S.N.	2001	Further analysis of lysimeter study leachate Report No. RJ3255B GLP, Unpublished Submitted by SYN
IIA, 7.2.1.2/01	Wolfe, A.L.	1972	The effect of ultra-violet radiation on 4-hydroxy-2,5,6-trichloroisophthalonitrile in aqueous solutions Report No. RIC6786 Not GLP, Unpublished Submitted by SYN
IIA, 7.2.1.2/02	Ambrust, K.L.	2000	Photodegradation of hydroxychlorothalonil in aqueous solution, presentation at the 219th ACS National Meeting, San Francisco, USA Not GLP, Published Submitted by SYN
IIA 7.2.1.2/03	Kirkpatrick, D.	2001	¹⁴ C-chlorothalonil photodegradation in water Report No. VCM 42/951419 GLP, Unpublished Submitted by VIS
IIA, 7.2.2/01	Kuet, S.F. and A. Morrow	2001	Chlorothalonil. Volatilisation from soil and leaf surface, RJ3221B Submitted by SYN
IIA 7.4/01	Marks, A.	1986	Determination of tetrachloroisophthalonitrile (Chlorothalonil , SDS-2787), SDS-3701 and SDS-46851 in water from Long Island wells Report No. 1149-86-0010-AS-002 GLP, Unpublished Submitted by SYN
IIA 7	Vonk, J.W.	2000	Expert Opinion on the nature of unknown metabolites of chlorothalonil in lysimeter leachate. EPP Consultancy ; Report no. 001201 December 17, 2000 Submitted by SYN

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
9.2.1/01	D.V. Smith, N. Shillabeer.	1998	Chlorothalonil: Toxicity to freshwater diatom <i>Navicula pelliculosa</i> Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6423/B date: December 1998 GLP, unpublished Submitted by SYN
9.2.1/02	D.V. Smith, N. Shillabeer.	1998	Chlorothalonil: Toxicity to the blue-green alga <i>Anabaena flos-aquae</i> . Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6413/B date: December 1998 GLP, unpublished Submitted by SYN
9.2.1/03	D.V. Smith, N. Shillabeer.	2000	Chlorothalonil: Toxicity to the freshwater diatom <i>Navicula pelliculosa</i> in the presence of sediment Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6776/B date: January 2000 GLP, unpublished Submitted by SYN
9.2.1/04	D.V. Smyth, S.E. Magor, N. Shillabeer	1999	Chlorothalonil: Acute toxicity to the green alga <i>Selenastrum capricornutum</i> of a 750 g/l WG formulation Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6761/B date: December 1999 GLP, unpublished Submitted by SYN
9.2.1/05	S.E. Magor, N. Shillabeer	2000	SDS-46851: Toxicity to the green alga <i>Selenastrum capricornutum</i> Generated by: Zeneca Research Submitted by: Zeneca Company file No.: AG0596/D date: 27 January 2000 GLP, unpublished Submitted by SYN

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
9.2.1/06	S.E. Magor, N.Shillabeer	1999	R417888: Toxicity to the green alga <i>Selenastrum capricornutum</i> Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6584/B date: May 1999 GLP, unpublished Submitted by SYN
9.2.2.1/01	M.J. Hamer, W.E. Gentle	1999	Acute toxicity to aquatic invertebrates Generated by: Zeneca Research Submitted by: Zeneca. Company file No.: TMJ4135B date: July 1999 GLP, unpublished Submitted by SYN
9.2.2.1/02	S.E. Magor, N. Shillabeer	1999	Chlorothalonil: Acute Toxicity to <i>Daphnia magna</i> of a 750 g/l WG formulation. Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6763/B date: December 1999 GLP, unpublished Submitted by SYN
9.2.2.1/03	S.E. Magor, N. Shillabeer	2000	SDS-46851: Acute toxicity to <i>Daphnia magna</i> Generated by: Zeneca Research Submitted by: Zeneca Company file No.: AG0596/C date: May 2000 GLP, unpublished Submitted by SYN
9.2.2.1/04	S.E. Magor, N. Shillabeer	1999	SDS-46851: Acute toxicity to <i>Daphnia magna</i> Generated by: Zeneca Research. Submitted by: Zeneca Company file No.: AG0193/C date: May 1999 GLP, unpublished Submitted by SYN
9.2.2.1/05	S.E. Magor, N. Shillabeer	1999	SDS-19221: Acute Toxicity to <i>Daphnia magna</i> Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6482/B date: January 1999 GLP, unpublished Submitted by SYN

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
9.2.2.1/06	S.E. Magor, N. Shillabeer	1999	Chlorothalonil: Evaluation of a lysimeter leachate for toxicity to <i>Daphnia magna</i> Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6599/B date: June 1999 GLP, unpublished Submitted by SYN
9.2.3.1/01	S.E. Magor, N. Shillabeer	1999	Chlorothalonil: Acute toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>) of a 750 g/l WG formulation Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6762/B date: December 1999
9.2.3.1/02	S.E. Magor, N. Shillabeer	1999	SDS-46851: Toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>) Generated by: Zeneca Research Submitted by: Zeneca Company file No.: AG0569/B date: May 1999 GLP, unpublished Submitted by SYN
9.2.3.1/03	S.E. Magor, N. Shillabeer	1999	R417888: Acute Toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>) Generated by: Zeneca Research Submitted by: Zeneca Company file No.: AG0193/B date: May 1999 GLP, unpublished Submitted by SYN
9.2.3.1/04	S.E. Magor, N. Shillabeer	1999	SDS-19221: Acute Toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>) Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6481/B date: January 1999 GLP, unpublished Submitted by SYN

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
9.2.3.1/05	S.E. Magor, N. Shillabeer	1999	Chlorothalonil: Evaluation of a lysimeter leachate for toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>) Generated by: Zeneca Research Submitted by: Zeneca. Company file No.: BL6598/B date: June 1999 GLP, unpublished Submitted by SYN
9.2.6/01	D.V. Smyth S.E. Magor, N. Shillabeer	1998	Chlorothalonil: Toxicity to duckweed (<i>Lemna gibba</i>) Generated by: Zeneca Research Submitted by: Zeneca Company file No.: BL6473/B date: December 1998 GLP, unpublished Submitted by SYN
9.4.1/01	H.M. Thompson	2000	Chlorothalonil: Acute contact and oral toxicity of technical material to Honey bees (<i>Apis mellifera</i>) Generated by: National Bee Unit, C.S.L. Submitted by: Zeneca Company file No.: GQ4001 date: 19 January 2000 GLP, unpublished Submitted by SYN
9.4.1/02	H.M. Thompson	2000	Chlorothalonil: Acute contact and oral toxicity of a 720SC formulation to Honey bees (<i>Apis mellifera</i>) Generated by: National Bee Unit, C.S.L. Submitted by: Zeneca Company file No.: GQ4002 date: 19 January 2000 GLP, unpublished Submitted by SYN
9.4.1/03	H.M. Thompson	2000	Chlorothalonil: Acute contact and oral toxicity of a 82.5 WDG formulation to Honey bees (<i>Apis mellifera</i>) Generated by: National Bee Unit, C.S.L. Submitted by: Zeneca Company file No.: GQ4003 date: 13 January 2000 GLP, unpublished Submitted by SYN

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
9.5.1/01	S.Vinall	2000	Chlorothalonil 720 g/l SC (YF10938): A laboratory test to determine effects on the predatory mite, Typhlodromus pyri (phytosiidae). Generated by: Agrochemical Evaluation Unit. Submitted by: Zeneca Company file: 41290 date: 27 January 2000 GLP, unpublished Submitted by SYN
9.5.1/02	A. Sankanu	2000	A Tier I laboratory study study to evaluate the effects of Chlorothalonil (YF10938) on the green lacewing, Chrysoperla carnea. Generated by: Ecotox limited. Submitted by: Zeneca Company file: 41292 date: 14 March 2000 GLP, unpublished Submitted by SYN
9.5.1/03	I. Baxter	2000	Chlorothalonil 720 g/l SC (YF10938): A laboratory study to determine the effects on parasitoid, Aphidius rhopalosiphi. Generated by: Agrochemical Evaluation Unit. Submitted by: Zeneca Company file: 41291 date: 31 March 2000 GLP, unpublished Submitted by SYN
9.5.1/04	I.Baxter	2000	Chlorothalonil 720 g/l SC (YF10938): A laboratory test to determine effects on the ground beetle, Poecilus cupreus. Generated by: Agrochemical Evaluation Unit. Submitted by: Zeneca Company file: 41289 date: 31 March 2000 GLP, unpublished Submitted by SYN
9.5.1/05	H.M. Austin	1999	A laboratory study to evaluate the effects of SDS-3701 on Poecilus cupreus (coleoptera: Carabidae). Generated by: Ecotox limited Submitted by: Zeneca Company file No.: 42278 date: 25 March 1999 GLP, unpublished Submitted by SYN

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
9.5.1/06	A.Travis	2000	A Tier II laboratory test to assess the effects of the metabolite R417888 on <i>Poecilus cupreus</i> (coleoptera: Carabidae). Generated by: Zeneca Research Submitted by: Zeneca Company file No.: 00JH006 Technical letter date: 16 May 2000 GLP, unpublished Submitted by SYN
9.6.1/01	A.Travis	1999	Toxicity of R417888, a metabolite of chlorothalonil, to the earthworm <i>Eisenia fetida</i> in an artificial soil test. Generated by: Zeneca Research Submitted by: Zeneca Company file No.: RJ2887B date: 9 December 1999 GLP, unpublished Submitted by SYN
IIA, 8.1.3/01	Barrett, K.	2002	Chlorothalonil an evaluation of the long-term risk to avian species and mammals Submitted by VIS
IIA, 8.2.3/01	Szalkowski, MB.	1980	Accumulation, distribution and depuration of 14C-4-hydroxy-2,5,6-trichloroisophthalonitrile (DS-3701) in bluegill sunfish (<i>Lepomis macrochirus</i>) under flow through aquatic conditions Diamond Shamrock Corporation Report No. 115-3EI-80-0176-001 GLP, Unpublished Submitted by SYN
IIA, 8.2.6/01	Caux, PY, Kent, RA, Fan, GT, Stephenson, GL	1996	Environmental fate and effects of chlorothalonil: a Canadian perspective Critical Reviews Environmental Science and Technology 26 (1) 45-CGA-16393 Non GLP, Published Submitted by SYN
IIA, 8.4.1/01	Moser, Th, Rombke, J.	2000 a	Chlorothalonil: acute toxicity of the metabolite SDS-46851 (R611965) to the earthworm <i>Eisenia andrei</i> in an artificial soil test ECT Oekotoxikologie GmbH Report No. F18RA GLP, Unpublished Submitted by SYN

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, 8.4.2/01	Moser, Th, Rombke, J.	2000 b	Chlorothalonil: reproduction toxicity of the metabolite SDS-373 (R182281) to the earthworm <i>Eisenia andrei</i> in an artificial soil test ECT Oekotoxikologie GmbH Report No. F11RR GLP, Unpublished Submitted by SYN
IIA, 8.4.2/02	Moser, Th.	2001	Chlorothalonil: reproduction toxicity of chlorothalonil technical material to the earthworm <i>Eisenia andrei</i> according to the International Standard ISO 11268-2 Part 2 (1988) "Soil quality – Effects of pollutants on earthworms (<i>Eisenia fetida</i>) – Part 2: Determination of effects on reproduction ECT Oekotoxikologie GmbH Report No. V1RR GLP, Unpublished Submitted by SYN
IIA 8.4.2/03	Moser, Th.	2001	Chlorothalonil: reproduction toxicity of the metabolite R417888 to the earthworm <i>Eisenia andrei</i> in an artificial soil test according to the International Standard ISO 11268-2 Part 2 (1988) "Soil quality – Effects of pollutants on earthworms (<i>Eisenia fetida</i>) – Part 2: Determination of effects on reproduction ECT Oekotoxikologie GmbH Report No. V2RR GLP, Unpublished Submitted by SYN
IIA, 8.4.2/04	Rodgers, M.H.	2003	4-Hydroxy-2,5,6-trichloro-1,3-dicyanobenzene. To determine the effects on reproduction and growth of the earthworm, <i>Eisenia fetida</i> . Report No. VCM 117/024270. Submitted by VIS
IIA, 8.5/01	McMurray, A.	2001 a	A laboratory assessment of the effects of chlorothalonil metabolites [SDS-3701, SDS-46851, R-417888] on soil microflora respiration and nitrogen transformation Report no. ENV5183 GLP, Unpublished Submitted by SYN
IIA, 8.5/02	Seyfried, B.	2003	The effects of chlorothalonil on soil respiration and nitrification The effects of chlorothalonil on soil respiration and nitrification. Report No. 846510. Submitted by VIS

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, 8.5/03	Seyfried, B.	2003	The effects of 4-hydroxy-2,5,6-trichloro-1,3-dicyanobenzene on soil respiration and nitrification. Report No 846511. Submitted by VIS
IIA, 8.6/01	Pierce, A.	2001	GSH Reactivity of chlorothalonil and its metabolite R182281, R419492 and R471811 Report no. RIC7335 Non-GLP, Unpublished Submitted by SYN
IIA, 8.6/02	Seville, A.	1999 a	GSH Reactivity of chlorothalonil and its metabolite R611965 Report no. RIC7304 Non-GLP, Unpublished Submitted by SYN
IIA, 8.6/03	Seville, A.	1999 b	GSH reactivity of chlorothalonil and its metabolite R417888 Report no. RIC7303 Non-GLP, Unpublished Submitted by SYN
IIA, 8.6/04	Collinge, D.	2000 b	Chlorothalonil metabolite R417888 – absence of fungicidal activity Report no. RIC7301 Non-GLP, Unpublished Submitted by SYN
IIA, 8.6/05	Collinge, D.	2001	Chlorothalonil metabolite R611965 – absence of fungicidal activity Report no. RIC7302 Non-GLP, Unpublished Submitted by SYN
IIA, 8.6/06	Mills, D.	2001	Fungicidal activity – evaluation of chlorothalonil and chlorothalonil metabolite R182281 Report No., RIC7333 Non-GLP, Unpublished Submitted by SYN
IIA, 8.7/0.1	Barnes, S.P., Burwood, C.E., Dickinson, R.A., Shanahan, F.O.	1998	Chlorothalonil activated sludge-respiration inhibition test Report No. VCM 096/983843 GLP, Unpublished Submitted by VIS
IIA, 8.7/02	Wallace, S.J.	2002	R044686 (Chlorothalonil technical): effect on respiration rate of activated sludge. Report No. BL 7409/B. Submitted by SYN

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIIA, 10.2.2/01	Ashwell, J., Dark, R., Grant, R. Jones, R. & Tattersfield, L.	2002	Outdoor microcosm study to assess the effects of chlorothalonil on aquatic organisms Syngenta Jealott's Hill International Research Centre Study number 00JH10 Submitted by SYN
IIIA, 10.5/05	Baxter, I. (Study Director)	2000	Chlorothalonil: a Tier II extended laboratory study to evaluate the effects of a 720 g/L SC formulation on the parasitic wasp, <i>Aphidius rhopalosiphii</i> (Hymenoptera, Braconidae) Report No. ZEN-00-14/C Submitted by SYN
IIIA, 10.5/06	Vinall, S. (Study Director)	2000	Chlorothalonil: a Tier II extended laboratory study to evaluate the effects of a 720 g/L SC formulation on the predatory mite, <i>Typhlodromus pyri</i> (Acarina, Phytoseiidae) Report No. ZEN-00-15/C Submitted by SYN
IIIA, 10.5/07	Wainwright, M.	2003	Chlorothalonil 75 WG. An extended laboratory test to evaluate the effects of pesticides on adults of the cereal aphid parasitoid <i>Aphidius rhopalosiphii</i> Report No. VCM 107/023414 Submitted by VIS
IIIA, 10.5/08	Wainwright, M.	2003	Chlorothalonil 500 SC. An extended laboratory test to evaluate the effects of pesticides on the predacious mite <i>Typhlodromus pyri</i> . Report No. VCM 108/023416 Submitted by VIS
IIIA, 10.6.1.2/01	Rodgers, M.H.		Chlorothalonil 500 g/l SC. To determine the effects on reproduction and growth of the earthworm, <i>Eisenia fetida</i> . Report No. VCM 113/024019. Submitted by VIS
IIIA, 10.6.2/a	Galicia, H.F. (study director).	2002	R182281, metabolite of R044686: litterbag test on decomposition of organic material in the field by soil macro and micro organisms Sprinborn Smythers Laboratories, CH, study no. 1047112797 Syngenta project no. 2023513 GLP, Unpublished Submitted by SYN

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIIA, 10.7/01	McMurray, A.	2001 b	A laboratory assessment of the effects of Bravo 720 (YF11524) on soil microflora respiration and nitrogen transformations according to current OECD guidelines 216 and 217 Report No. ENV5110 Chemax International plc GLP, Unpublished Submitted by SYN

APPENDIX IV

List of uses supported by available data

CHLOROTHALONIL

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		
Winter wheat	Northern MS	BRAVO 500/ BRAVO 720	F	puccinia spp. septoria spp. helminthosporium fusarium	SC	500, 720 g/l	overall	last app. at BBC H 51	2	Between BBCH 31 and 51	0.25-0.67	150 - 400	1.0	NA	-
Spring	Northern	BRAVO	F	puccinia	SC	500,	overall	BBC	1	-	0.25-	150 -	1.0	NA	-

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		
wheat	MS	500/ BRAVO 720		a spp. septoria spp. helminthosporium fusarium		720 g/l	1	H 51			0.67	400			

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		
Winter wheat	Southern MS	BRAVO 500/ BRAVO 720	F	puccinia spp. septoria spp. helminthosporium fusarium	SC	500, 720 g/l	overall	last app. at BBCH H 51	2	Between BBCH 31 and 51	0.25-0.67	150 - 600	1.0	NA	-
Spring wheat	Southern MS	BRAVO 500/ BRAVO 720	F	puccinia spp. septoria spp. helminthosporium fusarium	SC	500, 720 g/l	overall	BBCH H 51	1	-	0.25-0.67	150 - 600	1.0	NA	-

- Remarks** :
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.*
 - (b) fumigation of a structure)
 - (c) Outdoor or field use (F), glasshouse application (G) or indoor
 - (d) application (I)
 - (e) *e.g.* biting and suckling insects, soil born insects, foliar fungi,
 - (f) weeds
 - (g) *e.g.* wettable powder (WP), emulsifiable concentrate (EC),
 - (h) granule (GR)
GCPF Codes - GIFAP Technical Monograph No 2, 1989
All abbreviations used must be explained
Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
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) application
The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) PHI - minimum pre-harvest interval
Remarks may include: Extent of use/economic importance/restrictions