FAO SPECIFICATIONS AND EVALUATIONS

FOR AGRICULTURAL PESTICIDES

CHLOROTHALONIL

tetrachloroisophthalonitrile

FOOD AND AGRICULTURE ORGANIZATION of THE UNITED NATIONS

TABLE OF CONTENTS

DISCLAIMER[1]

FAO specifications are developed with the basic objective of promoting, as far as practicable, the manufacture, distribution and use of pesticides that meet basic quality requirements.

Compliance with the specifications does not constitute an endorsement or warranty of the fitness of a particular pesticide for a particular purpose, including its suitability for the control of any given pest, or its suitability for use in a particular area. Owing to the complexity of the problems involved, the suitability of pesticides for a particular purpose and the content of the labelling instructions must be decided at the national or provincial level.

Furthermore, pesticides which are manufactured to comply with these specifications are not exempted from any safety regulation or other legal or administrative provision applicable to their manufacture, sale, transportation, storage, handling, preparation and/or use.

FAO disclaims any and all liability for any injury, death, loss, damage or other prejudice of any kind that may be arise as a result of, or in connection with, the manufacture, sale, transportation, storage, handling, preparation and/or use of pesticides which are found, or are claimed, to have been manufactured to comply with these specifications.

Additionally, FAO wishes to alert users to the fact that improper storage, handling, preparation and/or use of pesticides can result in either a lowering or complete loss of safety and/or efficacy.

FAO is not responsible, and does not accept any liability, for the testing of pesticides for compliance with the specifications, nor for any methods recommended and/or used for testing compliance. As a result, FAO does not in any way warrant or represent that any pesticide claimed to comply with a FAO specification actually does so.

[1] This disclaimer applies to all specifications published by FAO.

INTRODUCTION

FAO establishes and publishes specifications* for technical material and related formulations of public health pesticides with the objective that these specifications may be used to provide an international point of reference against which products can be judged either for regulatory purposes or in commercial dealings.

Since 1999 the development of FAO specifications follows the **New Procedure**, described in the 5th edition of the " Manual on the development and use of FAO specifications for plant protection products" (FAO Plant Production and Protection Page No. 149). This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package, the procedure and evaluation applied by FAO and the Experts of the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS). [Note: prior to 2002, the Experts were of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent, which now forms part of the JMPS, rather than the JMPS.]

FAO Specifications now only apply to products for which the technical materials have been evaluated. Consequently from the year 2000 onwards the publication of FAO specifications under the **New Procedure** has changed. Every specification consists now of two parts namely the specifications and the evaluation report(s):

PART ONE: **The Specification** of the technical material and the related formulations of the plant protection product in accordance with chapter 4, 5 and 6 of the 5th edition of the "Manual on the development and use of FAO specifications for plant protection products".

PART TWO: **The Evaluation Report(s)** of the plant protection product reflecting the evaluation of the data package carried out by FAO and the JMPS. The data are to be provided by the manufacturer(s) according to the requirements of Appendix A, annex 1 or 2 of the "Manual on the development and use of FAO specifications for plant protection products" and supported by other information sources. The Evaluation Report includes the name(s) of the manufacturer(s) whose technical material has been evaluated. Evaluation reports on specifications developed subsequently to the original set of specifications are added in a chronological order to this report.

FAO specifications under the **New Procedure** do <u>not</u> necessarily apply to nominally similar products of other manufacturer(s), nor to those where the active ingredient is produced by other routes of manufacture. FAO has the possibility to extend the scope of the specifications to similar products but only when the JMPS has been satisfied that the additional products are equivalent to that which formed the basis of the reference specification.

Specifications bear the date (month and year) of publication of the current version. Dates of publication of the earlier versions, if any, are identified in a footnote. Evaluations bear the date (year) of the meeting at which the recommendations were made by the JMPS.

* NOTE: PUBLICATIONS ARE AVAILABLE ON THE INTERNET AT
(http://www.fao.org/ag/agp/agpp/pesticid/)
OR IN HARDCOPY FROM THE PLANT PROTECTION INFORMATION OFFICER.

PART ONE

SPECIFICATIONS

CHLOROTHALONIL

INFORMATION

ISO common name

chlorothalonil (E-ISO, (m) F-ISO)

Synonyms

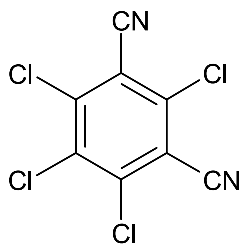
TPN (JMAF)

Chemical names

IUPAC: tetrachloroisophthalonitrile

CA: 2,4,5,6-tetrachloro-1,3-benzenedicarbonitrile

Structural formula



Molecular formula

$C_8Cl_4N_2$

Relative molecular mass

265.9

CAS Registry number

1897-45-6

CIPAC number

288

Identity tests

GC retention time, IR spectrum

CHLOROTHALONIL

TECHNICAL MATERIAL

FAO Specification 288/TC (December 2005*)

This specification, which is PART ONE of this publication, is based evaluations of data submitted by the manufacturers whose names are listed in evaluation reports 288/2004 and 288/2005*. It should be applicable to relevant products of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation reports* 288/2004 and 288/2005, *as PART TWO, form an integral part of this publication.*

1 Description

The material shall consist of chlorothalonil together with related manufacturing impurities, in the form of an off-white powder free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 **Identity tests** (CIPAC 288/TC/M/2, CIPAC Handbook K, p.13, 2003)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 **Chlorothalonil** (CIPAC 288/TC/M/3, CIPAC Handbook K, p.13, 2003)

The chlorothalonil content shall be declared (not less than 985 g/kg) and when determined, the average measured content obtained shall not be lower than the declared minimum content.

3 Relevant impurities

3.1 **Hexachlorobenzene** (Note 1)

Maximum: 0.04 g/kg.

3.2. **Decachlorobiphenyl** (Note 1)

Maximum: 0.03 g/kg.

Note 1 The method for determination of hexachlorobenzene and decachlorobiphenyl in technical and formulated chlorothalonil are available from the Pesticide Management Group of the FAO Plant Protection Service or can be downloaded here.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/ag/agp/agpp/pesticid/.

CHLOROTHALONIL

WETTABLE POWDER

FAO Specification 288/WP (December 2005*)

This specification, which is PART ONE of this publication, is based evaluations of data submitted by the manufacturers whose names are listed in evaluation reports 288/2004 and 288/2005*. It should be applicable to relevant products of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation reports* 288/2004 and 288/2005, *as PART TWO, form an integral part of this publication.*

1 Description

The material shall consist of an homogeneous mixture of technical chlorothalonil, complying with the requirements of FAO specification 288/TC (December 2005), together with filler(s) and any other necessary formulants. It shall be in the form of a fine powder free from visible extraneous matter and hard lumps.

2 Active Ingredient

2.1 **Identity tests** (CIPAC 288/TC/M/2, CIPAC Handbook K, p.13, 2003)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 **Chlorothalonil content** (CIPAC 288/WP/M/2, CIPAC Handbook K, p.13, 2003)

The chlorothalonil content shall be declared (g/kg) and, when determined, the average content measured shall not differ from that declared by more than the tolerance given below.

Declared content, g/kg	Permitted tolerance
Above 250 up to 500 g/kg Above 500 g/kg Note: the upper limit is included in the lower range	± 5% of the declared content ± 25 g/kg

3 Relevant Impurities

3.1 **Hexachlorobenzene** (Note 1)

Maximum: 0.004% of the chlorothalonil content found under 2.2.

3.2 **Decachlorobiphenyl** (Note 1)

Maximum: 0.003% of the chlorothalonil content found under 2.2.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/ag/agp/agpp/pesticid/.

4 Physical Properties

4.1 **Wet sieve test** (MT 185)

Maximum: 0.5% retained on a 75 μm test sieve.

4.2 **Suspensibility** (MT 15.1) (Notes 2 & 3)

A minimum of 70% of the chlorothalonil content found under 2.2. shall be in suspension after 30 minutes in CIPAC Standard Water D at 30 ± 2°C.

4.3 **Persistent foam** (MT 47.2) (Note 4)

Maximum: 60 ml after 1 minute.

4.4 **Wettability** (MT 53.3.1)

The product shall be completely wetted in 1 minute without swirling.

5 Storage Stability

5.1 **Stability at elevated temperature** (MT 46.3) (Note 5)

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 97% relative to the determined average content found before storage and the formulation shall continue to comply with the clauses for:

- wet sieve test (4.1);
- suspensibility (4.2);
- wettability (4.4).

Note 1 The method for determination of hexachlorobenzene and decachlorobiphenyl in technical and formulated chlorothalonil are available from the Pesticide Management Group of the FAO Plant Protection Service or can be downloaded here.

Note 2 The product should be tested at highest and lowest rates of use recommended by the supplier, provided this does not exceed the conditions given in method MT 15.1.

Note 3 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric determination or solvent extraction determination may be used on a routine basis provided, that these methods have been shown to give equal results to those of the chemical assay method. In case of dispute, the chemical method shall be the “referee method”.

Note 4 The mass of the sample to be used in the test should be specified at the highest rate of use recommended by the supplier.

Note 5 Samples of the product taken before and after the storage stability test should be analysed together after the test in order to reduce the analytical error.

CHLOROTHALONIL

WATER DISPERSIBLE GRANULES

FAO Specification 288/WG (December 2005*)

This specification, which is PART ONE of this publication, is based evaluations of data submitted by the manufacturers whose names are listed in evaluation reports 288/2004 and 288/2005*. It should be applicable to relevant products of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation reports* 288/2004 and 288/2005, *as PART TWO, form an integral part of this publication.*

1 Description

The material shall consist of a homogeneous mixture of technical chlorothalonil, complying with the requirements of FAO specification 288/TC (December 2005), together with carriers and any other necessary formulants. It shall be in the form of nearly spherical granules,produced by an agglomeration process, for application after disintegration and dispersion in water. The formulation shall be dry, free-flowing, essentially non-dusty and free from visible extraneous matter and hard lumps.

2 Active Ingredient

2.1 **Identity tests** (CIPAC 288/TC/M/2, CIPAC Handbook K, p.13, 2003)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 **Chlorothalonil content** (CIPAC 288/WG/M/2, CIPAC Handbook K, p.13, 2003)

The chlorothalonil content shall be declared (g/kg) and, when determined, the average content measured shall not differ from that declared by more than the appropriate tolerance:

Declared content, g/kg	Permitted tolerance
Above 250 up to 500 g/kg	± 5% of the declared content
Above 500 g/kg	± 25 g/kg
Note: the upper limit is included in the lower range	

3 Relevant Impurities

3.1 **Hexachlorobenzene** (Note 1)

Maximum: 0.004% of the chlorothalonil content found under 2.2.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/ag/agp/agpp/pesticid/.

3.2 **Decachlorobiphenyl** (Note 1)

Maximum: 0.003% of the chlorothalonil content found under 2.2.

3.3 **Water** (MT 30.5)

Maximum: 25 g/kg.

4 Physical Properties

4.1 **Wettability** (MT 53.3.1)

The formulation shall be completely wetted in 1 minute without swirling.

4.2 **Wet sieve test** (MT 185)

Maximum: 0.5% retained on a 75 µm test sieve.

4.3 **Degree of dispersion** (MT 174)

Dispersibility : minimum 90% after 1 minute of stirring.

4.4 **Suspensibility** (MT 168) (Notes 2 & 3)

A minimum of 80% of the chlorothalonil content found under 2.2. shall be in suspension after 30 minutes in CIPAC Standard Water D at 30 ± 2°C.

4.5 **Persistent foam** (MT 47.2) (Note 4)

Maximum: 25 ml after 1 minute.

4.6 **Dustiness** (MT 171, gravimetric method)

Essentially non-dusty.

4.7 **Flowability** (MT 172)

At least 99% of the formulation shall pass through a 5 mm test sieve after 5 drops of the sieve.

5 Storage Stability

5.1 **Stability at elevated temperature** (MT 46.3) (Note 5)

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 97% relative to the determined average content found before storage and the formulation shall continue to comply with the clauses for:

- wet sieve test (4.2);
- degree of dispersion (4.3);
- suspensibility (4.4);
- dustiness (4.6).

Note 1 The method for determination of hexachlorobenzene and decachlorobiphenyl in technical and formulated chlorothalonil are available from the Pesticide Management Group of the FAO Plant Protection Service or can be downloaded here.

Note 2 The product should be tested at the highest and lowest rates of use recommended by the supplier, provided this does not exceed the conditions given in method MT 168.

Note 3 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric determination or solvent extraction determination may be used on a routine basis provided, that these methods have been shown to give equal results to those of the chemical assay method. In case of dispute, the chemical method shall be the “referee method”.

Note 4 The mass of the sample to be used in the test should be specified at the highest rate of use recommended by the supplier.

Note 5 Samples of the product taken before and after the storage stability test should be analysed together after the test to reduce the analytical error.

CHLOROTHALONIL

AQUEOUS SUSPENSION CONCENTRATE

FAO Specification 288/SC (December 2005*)

This specification, which is PART ONE of this publication, is based evaluations of data submitted by the manufacturers whose names are listed in evaluation reports 288/2004 and 288/2005. *It should be applicable to relevant products of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation reports* 288/2004 and 288/2005, *as PART TWO, form an integral part of this publication.*

1 Description

The material shall consist of a suspension of fine particles of technical chlorothalonil, complying with the requirements of FAO specification 288/TC (December 2005), in an aqueous phase together with suitable formulants. After gentle agitation the material shall be homogenous (Note 1) and suitable for further dilution in water.

2 Active Ingredient

2.1 **Identity tests** (CIPAC 288/TC/M/2, CIPAC Handbook K, p.13, 2003)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 **Chlorothalonil content** (CIPAC 288/SC/M/2, CIPAC Handbook K, p.13, 2003)

The chlorothalonil content shall be declared (g/kg or g/l at 20 ± 2°C, Note 2) and, when determined, the average content measured shall not differ from that declared by more than the tolerance given below.

Declared content, g/kg	Permitted tolerance
Above 250 up to 500 g/kg Above 500 g/kg Note: the upper limit is included in the lower range	± 5% of the declared content ± 25 g/kg

3 Relevant Impurities

3.1 **Hexachlorobenzene** (Note 3)

Maximum: 0.004% of the chlorothalonil content found under 2.2.

3.2 **Decachlorobiphenyl** (Note 3)

Maximum: 0.003% of the chlorothalonil content found under 2.2.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/ag/agp/agpp/pesticid/.

4 Physical Properties

4.1 **Pourability** (MT 148.1)

Maximum “residue”: 6%.

4.2 **Spontaneity of dispersion** (MT 160) (Note 4)

A minimum of 80% of the chlorothalonil content found under 2.2. shall be in suspension after 5 minutes in CIPAC standard water D at 30 ± 2°C.

4.3 **Suspensibility** (MT 161) (Note 4)

A minimum of 80% of the chlorothalonil content found under 2.2. shall be in suspension after 30 minutes in CIPAC Standard Water D at 30 ± 2°C.

4.4 **Wet sieve test** (MT 185)

Maximum: 0.5% retained on a 75 µm test sieve.

4.5 **Persistent foam** (MT 47.2) (Note 5)

Maximum: 60 ml after 1 minute.

5 Storage Stability

5.1 **Stability at 0°C** (MT 39.3)

After storage at 0 ± 2°C for 7 days, the formulation shall continue to comply with the clauses for:
- suspensibility (4.3);
- wet sieve test (4.4).

5.2 **Stability at elevated temperature** (MT 46.3) (Note 6)

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 97% relative to the determined average content found before storage and the formulation shall continue to comply with the clauses for:
- pourability (4.1);
- spontaneity of dispersion (4.2);
- suspensibility (4.3);
- wet sieve test (4.4).

Note 1 Before sampling to verify the product quality, inspect the commercial container carefully. On standing, suspension concentrates usually develop a concentration gradient from the top to the bottom of the container. This may even result in the appearance of a clear liquid on the top and/or of sediment on the bottom. Therefore, before sampling, homogenise the formulation according to the instructions given by the manufacturer or, in the absence of such instructions, by gentle shaking of the commercial container (for example by inverting the closed container several times). Large containers must be opened and stirred adequately. After this procedure, the container should not contain a sticky layer of non-dispersed matter at the bottom. A suitable and simple method of checking for a non-dispersed sticky layer “cake” is by probing with a glass rod or similar device adapted to the size and shape of the container. All the physical and chemical tests must be carried out on a laboratory sample taken after the recommended homogenisation procedure.

Note 2 In case of dispute, the tolerance shall be applied to the content expressed in g/kg.

Note 3 The method for determination of hexachlorobenzene and decachlorobiphenyl in technical and formulated chlorothalonil are available from the Pesticide Management Group of the FAO Plant Protection Service or can be downloaded here.

Note 4 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric determination or solvent extraction may be used on a routine basis provided that these methods have been shown to give equal results to those of the chemical assay method. In case of dispute, the chemical method shall be the "referee method".

Note 5 The mass of the sample to be used in the test should be specified at the highest rate of use recommended by the supplier.

Note 6 Samples of the product taken before and after the storage stability test should be analysed together after the test to reduce the analytical error.

PART TWO

EVALUATION REPORT(S)

CHLOROTHALONIL

CHLOROTHALONIL

EVALUATION REPORT 288/2005

Recommendations

The Meeting recommended that:

(i) the limit for hexachlorobenzene, in the FAO specification for chlorothalonil TC, should be changed from 0.01 to 0.04 g/kg;

(ii) the limit for hexachlorobenzene, in the FAO specifications for chlorothalonil WP, WG and SC, should be changed from 0.001 to 0.004% of the chlorothalonil content measured;

(iii) the existing FAO specifications for chlorothalonil should be extended to encompass the products of SDS Biotech KK and Vischim.

Appraisal

Data for chlorothalonil were evaluated in support of extension of existing FAO specifications for TC, WP, WG and SC, developed under the New Procedure during 2004 and published by FAO in February 2005.

The specifications for chlorothalonil published by FAO in February 2005 had introduced: (i) a lower limit (10 mg/kg) for the relevant impurity hexachlorobenzene (the limit in the previous (1998) FAO specifications was 300 mg/kg); and (ii) a limit for decachlorobiphenyl which was not previously specified. The new limits for the two relevant impurities were introduced partly as a consequence of the requirement of the Stockholm Convention to restrict the release of persistent organic pollutants (POPs) into the environment.

Data were submitted by SDS Biotech KK, Japan, and Vischim, Italy, in 2004. With the written approval of Syngenta, the non-confidential data submitted by SDS Biotech KK were identical to those submitted by Syngenta in 2003, in support of the existing (February 2005) specifications. For these reasons, Annex 1 to this evaluation report presents only the additional information provided by Vischim. The data from Syngenta (and hence SDS Biotech KK) are given in evaluation report 288/2004, pages 27-37 of this document.

Both manufacturers submitted confidential data on their manufacturing processes, together with manufacturing specifications and 5-batch analysis data on purity, impurities ≥1 g/kg and the two relevant impurities <1 g/kg. Mass balances were high: Vischim, 99.6-101.4% and 99.9-100.3% with no unknowns; SDS Biotech KK, 98.5-99.2% with no reported unknowns. The confidential data were confirmed as essentially similar to those submitted in support of registration in Germany.

In the case of Vischim, two sets of 5-batch analysis data, together with the manufacturing specifications, were submitted, the 2nd of which took into account the newly-published (February 2005) FAO specifications for the relevant impurities occurring at <1 g/kg. The Meeting noted that the two sets of 5-batch analysis data submitted by Vischim represented different manufacturing batches. The newer data represented current production and the earlier data (which did not include information on decachlorobiphenyl) represented materials used to generate the data in tables 1 and 3-6 of this evaluation report. The confidential and non-confidential (tables 1 and 3-6 of this evaluation report) data provided by Vischim were confirmed as essentially similar to those submitted by the company to The Netherlands, as rapporteur member state for the EU review of chlorothalonil.

With the written approval of Syngenta for access to them, SDS Biotech KK submitted non-confidential data which were identical to those submitted by Syngenta in 2003 (i.e. tables 1 and 3-6 of evaluation report 288/2004). On the basis that SDS Biotech KK chlorothalonil TC complies with the existing (February 2005) specification, and because their confidential data clearly indicated equivalence, the Meeting agreed that the SDS Biotech KK TC should be considered equivalent to that of Syngenta (the source of the reference profiles). A January 2005 evaluation by the Dutch Board for Authorization (CTB) also concluded that the SDS Biotech KK TC is equivalent to the Syngenta TC and permitted Syngenta to use SDS Biotech KK material as a second source of chlorothalonil in The Netherlands.

Determination of equivalence was more complex in the case of Vischim. The 5-batch analysis data and manufacturing specification initially submitted by the company in 2004 (which were identical to those submitted in support of the 2004-5 EU review) did not take into account the limits for relevant impurities introduced in the February 2005 FAO specification. The limit for hexachlorobenzene (HCB) initially proposed by Vischim was 0.072 g/kg and no limit was proposed for decachlorobiphenyl (DCB). The Meeting acknowledged that the 1998 FAO specification for chlorothalonil was in force at the time of the initial submission of data by Vischim and that the company could not be expected to know about the clauses and limits for relevant impurities which would subsequently be published by FAO in February 2005.

In response to publication of the revised FAO specification, Vischim produced a revised manufacturing specification and 5-batch analysis data, which specifically addressed the limits for HCB and DCB (008/2005, S05/010 & 011). The revised data were submitted to registration authorities in Germany and the UK. The manufacturer stated that the revised data will also be submitted to other countries in which chlorothalonil is registered by the company and to the European Commission in support of the EU review of chlorothalonil.

The Meeting considered the revised data set for the determination of equivalence. Vischim had initially proposed that a third impurity (>1 g/kg) should be considered relevant but the Meeting agreed that none of the impurities ≥1 g/kg should be considered relevant. The Meeting noted that, by some criteria (including a higher limit for purity of the TC and a 10-fold lower limit for DCB), the Vischim chlorothalonil was equivalent to that of the reference profiles (Syngenta). However, with a proposed limit for HCB of 0.04 g/kg, compared with the 0.01 g/kg limit in the existing (February 2005) FAO specification, the Vischim TC did not appear to be equivalent to that of the reference impurity profile.

The Meeting therefore considered the equivalence of the toxicity and ecotoxicity profiles. Superficially, the data from certain tests suggested that Vischim chlorothalonil might be more toxic than Syngenta chlorothalonil (≥2-fold difference for toxicity and ≥5-fold difference for ecotoxicity, as stipulated in the FAO/WHO manual).

The tests involved were (i) long-term study of toxicity and carcinogenicity in rats; (ii) long-term studies in dogs; and (iii) reproduction study in bobwhite quail. These data were reviewed by WHO/PCS secretariat, using the full study reports from Vischim and from the IPCS (IPCS 1996) and US EPA (EPA 1999) reviews of chlorothalonil. In each case, the PCS secretariat concluded (PCS 2005) that the apparent differences did not reflect a real difference in the toxicity of the chlorothalonil from the two sources. The PCS secretariat therefore concluded that, on the basis of toxicity and ecotoxicity profiles, the Vischim chlorothalonil should be considered equivalent to that of Syngenta and the Meeting concurred.

The Meeting then considered the acceptability of the proposed limits for the relevant impurities.

The WHO/PCS secretariat (PCS 2005) advised that the (withdrawn) ADI for HCB allocated by FAO/WHO JMPR was 0-0.0006 mg/kg, while the ADI for chlorothalonil is 0-0.03 mg/kg, indicating an approximate long-term toxicity ratio of 50:1. Thus, at 10 and 40 mg/kg, respectively, neither Syngenta (and SDS Biotech KK) nor Vischim limits approached the level at which HCB might be expected to contribute to the overall toxicological hazard of chlorothalonil. Both limits are also more stringent than either the GHS guideline (GHS 2003) lower limit for labelling of an impurity on the basis of carcinogenicity (1 g/kg) or the maximum acceptable to the JMPS (2 g/kg), which is based on a 10% limit for increase in estimated hazard (≤10% being taken as negligible). The Meeting recognized that, although it is desirable to minimize the levels of all POPs in agricultural pesticides, the 0.04 g/kg limit for HCB in chlorothalonil TC, proposed by Vischim, was well below the maximum acceptable and could therefore be adopted. The Meeting also recognized that the existing 0.03 g/kg limit for DCB in chlorothalonil TC was also well below the maximum acceptable and agreed that it should be retained, instead of adopting either the 0.003 g/kg limit utilized by Vischim or the 0.002 g/kg limit utilized by SDS Biotech KK.

Both manufacturers stated that the analytical and physical methods referenced in existing specifications, and the clauses and limits (with the exception of the clauses for HCB, as discussed above), were applicable to their products.

SUPPORTING INFORMATION FOR EVALUATION REPORT 288/2005

Physico-chemical properties of chlorothalonil

Table 1. Physico-chemical properties of pure chlorothalonil (Vischim data only)

Parameter	Value(s) and conditions	Purity %	Method	Reference
Vapour pressure	2.2×10^{-4} Pa at 25°C	99.84	EEC A4	32/942392
Melting point	252.5-254.5°C	99.84	EEC A1	32/942392
Solubility in water	5.42×10^{-4}g/l at 25 °C, pH 7.0, distilled water	99.84	EEC A6	32/942392
Octanol/water partition coefficient, Log P K_{ow} at 25°C	2.91 at pH 4 2.94 at pH 7 2.94 at pH 9 2.90 (unbuffered)	99.84	EEC A8	32/942392
Hydrolysis characteristics	Half-life at 50°C pH 5: >62 d pH 7: 14 d pH 9: 0.28 d Half-life at 20°C pH 5: stable pH 7: stable pH 9: 16.1 d	99.84 99.84	EEC C7 EEC C7	57/950744 32/942392
Photolysis characteristics	Half-life = 10.5 h at equivalent of continuous summer sunlight, at 30°N)	99.84	EPA 161-2	42/951419

Table 2. Chemical composition and properties of technical chlorothalonil

Manufacturing process, maximum limits for impurities ≥ 1 g/kg, 5 batch analysis data	Confidential information supplied and held on file by FAO. Mass balances in 2 sets of 5-batch analysis data were 99.6-101.4% and 99.9-100.3%. No unknowns were detectable (<0.01%) by GC-FID. (Vischim)
	Confidential information supplied and held on file by FAO. Mass balances were 98.5-99.2%. Unknowns not reported. (SDS Biotech KK)
Declared minimum chlorothalonil content	990 g/kg. (Vischim)
	985 g/kg. (SDS Biotech KK)
Relevant impurities >1 g/kg and maximum limits for them	None. (Vischim)
	None. (SDS Biotech KK)
Relevant impurities <1 g/kg and maximum limits for them:	Hexachlorobenzene, 40 mg/kg. Decachlorobiphenyl, 3 mg/kg. (Vischim)
	Hexachlorobenzene, 10 mg/kg. Decachlorobiphenyl, 2 mg/kg. (SDS Biotech KK)
Stabilizers or other additives and maximum limits for them:	None. (Vischim)
	None. (SDS Biotech KK)
Melting temperature range of the TC	252.5-254.5°C, without decomposition (Vischim)
	248-253ºC (SDS Biotech KK)

Background information on toxicology/ecotoxicology

Vischim confirmed that the toxicological and ecotoxicological data included in Annex 1, below, were derived from chlorothalonil having impurity profiles similar to those referred to in table 2, above.
Chlorothalonil was under review by the EU in 2004-5, according to the requirements of Directive 91/414/EEC.

Formulations and co-formulated active ingredients

The main formulation types available are SC, WG and WP. Chlorothalonil is co-formulated with other fungicides, such as cymoxanil, copper salts, triazoles or acylalanines. These formulations are registered and sold in many countries throughout the world.

Methods of analysis and testing

SDS Biotech KK and Vischim confirmed that the CIPAC method for determination of chlorothalonil in TC and formulations, and the GC-MS method for determination of the impurities hexachlorobenzene (HCB) and decachlorobiphenyl(DCP), are satisfactory for analysis of their products.

Other impurities in the TC were determined by capillary GC with FID detection and their identities confirmed by GC-MS (Vischim); and by capillary GC with FID or MSD (SDS Biotech KK). Xylene insolubles were determined gravimetrically (SDS Biotech KK).

Test methods for determination of physico-chemical properties of the technical active ingredient were essentially OECD methods, while those for the formulations were CIPAC procedures, as indicated in the specifications (Vischim and SDS Biotech KK).

Physical properties

The physical properties, the methods for testing them and the limits proposed for the SC, WG and WP are identical to those in the existing specifications.

ANNEX 1. HAZARD SUMMARY PROVIDED BY THE PROPOSER

Note: The proposer provided written confirmation that the toxicological and ecotoxicological data included in the summary below were derived from chlorothalonil having impurity profiles similar to those referred to in table 2, above.

Table 3. Toxicology profile of chlorothalonil technical material, based on acute toxicity, irritation and sensitization (Vischim data only)

Species	Test	Duration and conditions or guideline adopted	Result	Reference
Rat, CD strain (m/f)	oral	Study conducted prior to issuance of formal test guidelines. Chlorothalonil TC, 98.5% purity	LD_{50} = >5000 mg/kg bw 14 d observation after treatment. No mortalities. During the 1st 5 h after dosing, decreased motor activity and piloerection observed.	88/CFA002/276
Rabbit, New Zealand strain (m/f)	dermal	OECD 402. Chlorothalonil TC, 98.5% purity	LD_{50} = >2000 mg/kg bw 14 d observation after treatment. No mortalities. During the 1st 5 h after dosing, decreased motor activity observed.	88/CFA003/277
Rat, CD strain (m/f)	inhalation	Study conducted in 1985, prior to issuance of formal test guidelines. 4 h exposure time. Chlorothalonil TC, 98.63% purity	LC_{50} = 0.250 (m) to 0.205 (f) mg/l. Mortality observed at two highest exposure levels, 0.223 and 0.376 mg/l. Clinical signs observed during and after exposure were gasping, exaggerated respiratory movements, reduced respiratory rate, turbidity, dark eye, hypothermia, swollen abdomen and emaciation.	88/CFA001/185
Rabbit, new Zealand strain (m/f)	skin irritation	OECD 404. 4 h exposure, 72 h observation. Chlorothalonil TC, 98.63% purity	Non-irritant.	88/CFA004/235
Rabbit, New Zealand strain (m)	eye irritation	Study conducted prior to issuance of formal test guidelines. Chlorothalonil TC, 98.5% purity	Irritant, corrosive. A definite reaction to treatment observed in animals exposed to chlorothalonil for 24 h. After 72 h, corrosive pannus formation seen in an area of 3-5 mm of the cornea of 2 of 3 animals.	083-002/T/012/85
Guinea pig, Dunkin/Hartley strain (f)	skin sensitization	OECD 406. Chlorothalonil TC, 99.18 % purity	Skin sensitizer*. Chlorothalonil produced evidence of skin sensitization (delayed contact hypersensitization) in 9 among 10 animals.	40/940427/SS

* The results of two separate studies of skin sensitization potential (delayed type hypersensitivity), using the Magnusson and Kligmann maximisation test in Guinea pigs, were contradictory. The first study gave equivocal results due to the use of inappropriate irritant challenge concentrations,

whereas the second study was more credible and produced clear evidence of a sensitization potential.

Table 4. Toxicology profile of chlorothalonil technical material, based on repeated administration (sub-acute to chronic) (Vischim data only)

Species	Test	Duration and conditions or guideline adopted	Result	Reference
Rat, CD strain (m/f)	feeding, sub-chronic toxicity, 13 weeks	EPA 82-1. Chlorothalonil TC, 99.18% purity	NOAEL (combined) = 5.1 mg/kg bw/d* LOEL(combined) = 26.2 mg/kg bw/d*	9/920338
Mouse, CD-1 strain, (m/f)	feeding, sub-chronic toxicity, 13 weeks	EPA 82-1. Chlorothalonil TC, 99.18% purity	NOAEL (combined) = 10.5 mg/kg bw/d* LOEL (combined = 44 mg/kg bw/d*	1/92034
Dog, beagle strain, (m/f)	feeding, sub-chronic toxicity, 13 weeks	EPA 82-1. Chlorothalonil TC, 99.18% purity	NOEL (combined) = 5.85 mg/kg bw/d*	12/920413
Rat, CD strain, (m/f)	feeding, carcinogenicity, 104 weeks	EPA 83-2. Chlorothalonil TC, 99.18% purity	NOAEL (combined, overall) = 0.8 mg/kg bw/d*****	15/943286
Mouse, CD-1 strain, (m/f)	feeding, carcinogenicity, 80 weeks	EPA 83-2. Chlorothalonil TC, 99.18% purity	NOAEL combined (overall) = 2.2 mg/kg bw****	16/943065
Dog, beagle strain, (m/f)	feeding, chronic toxicity, 52 weeks	EPA 83-2. Chlorothalonil TC, 99.18% purity	NOAEL = 5.51 mg/kg bw/d**	14/943124
Rat, CD strain (m/f)	feeding, 2-generation reproduction	EPA 83-4, OECD 416. Chlorothalonil TC, 99.18% purity	NOAEL (parents, for mating and reproductive performance) = 261 mg/kg bw/d*** NOAEL (offspring) = 100 mg/kg bw/d No obvious adverse effects on the developing conceptus at any of the dosages investigated***	21/942505
Rat, CD strain (m/f)	teratogenicity and developmental toxicity	EPA 83-3, OECD 414. Chlorothalonil TC, 99.18% purity	NOAEL (maternal) = 200 mg/kg bw/d*** NOAEL (developing conceptus) >500 mg/kg bw/d*** No primary teratogenic/embryotoxic potential at any of the dosages investigated	22/930637
Rabbit, New Zealand strain (m/f)	teratogenicity and developmental toxicity	EPA 83-3, OECD 414. Chlorothalonil TC, 99.18% purity	NOAEL (maternal) = 10 mg/kg bw/d*** NOAEL (developing conceptus) = 10 mg/kg bw/d*** No primary teratogenic/embryotoxic potential at any of the dosages investigated	23/930638

* In addition to the studies listed, a sub-chronic dietary toxicity study was conducted in dogs for 28 d. Hyperplasia/hyperkeratosis was a consistent finding in the non-glandular stomach of rats

and mice in all these studies but was considered to reflect an adaptive response in the presence of an irritant material. No histopathological changes seen in dogs after 28 d but adrenal gland identified as a target organ in the 90-d study in this species.

** In the 52-week dietary study on dogs, 10240 ppm produced adverse effects on bodyweight and food consumption. Death of a single female at this level was considered to be treatment-related. Gastric mucosal irritation observed at 10240 ppm and, to a lesser extent, at 1280 ppm. Increased incidence and degree of brown pigment in the epithelium of cortical tubules of kidney observed microscopically in animals treated with 1280 or 10240 ppm. Animals treated at 10240 ppm had increased incidence and degree of hypertrophy of the cells of the zona fasciculata in the adrenals. At 160 ppm there was no indication of systemic toxicity or gastric irritation.

*** In the 2-generation study in rats, chlorothalonil caused lower body weight gain in parents at 1200 and 3000 ppm, and in offspring at 3000 ppm, but without any adverse effects on fertility or reproductive performance. Maternal toxic responses were induced in teratogenicity studies both in rats and rabbits but without any evidence of any primary teratogenic or embryotoxic effects.

**** The only neoplastic change seen in the 80-week dietary oncogenicity study in mice, at doses of 0, 15, 60, 240 and 960 ppm, was an increase in the incidence (4/50(m) and 5/50(f) compared to 1/50(m) in control group) of squamous cell papilloma of the non-glandular stomach at 960 ppm. Same tumour type noted in 1/50(f) at 60 ppm diet and in 2/50(m) at 240 ppm diet. The finding was considered to be a result of chronic gastric irritation by chlorothalonil. Treatment-related non-neoplastic changes observed in stomach (non-glandular and glandular regions), oesophagus, kidneys, adrenals, and mesentheric lymph nodes. Epithelial hyperplasia of the non-glandular stomach was seen at all dosages and there was an increased incidence of hyperkeratosis at 240 and 960 ppm. Treatment-related changes, consisting of basophilic and dilated renal cortical tubules and cystic atrophic glomeruli, were found in males treated at 60, 240 and 960 ppm. Changes observed in stomach and oesophagus anticipated due to chlorothalonil producing chronic mucosal irritation.

***** There was no evidence of tumorigenic potential in rats dosed for 104 weeks at up to 240 ppm. There was a minor, statistically significantly, increase in the incidence of tumors (benign and malignant) in the non-glandular region of the stomach of males receiving 1200 ppm (equivalent to 54 mg/kg/day). These tumors however were, considered a direct irritant effect of chlorothalonil, as evidenced by macroscopic and non-neoplastic microscopic changes in the non-glandular region. The maximum tolerated dose for this study was considered to be 1200 ppm on the basis of the histopathological treatment-related changes in the stomach, liver and kidneys, which had no effect on mortality. With the exception of the expected irritant response in the stomach at all dose levels, and despite only slightly higher incidence than controls for animals treated with 15 ppm, the NOEL for this study was considered to be 15 ppm (equivalent to 0.7 mg/kg/day for males and 0.9 mg/kg/day for females).

Table 5. Mutagenicity profile of chlorothalonil technical material based on *in vitro* and *in vivo* tests (Vischim data only)

Species	Test	Conditions	Result	Reference
Salmonella typhimurium	*in vitro* gene mutation assay	With and without exogenous metabolic activation system. EEC 79/831 Annex V Part B; OECD 471; Notification 118, Pharmaceutical Affairs Board, Ministry of Health and Welfare, Japan, 1984. Chlorothalonil TC, 98.74% purity	Negative	128006-M-10587
L5178Y mouse lymphoma cells	*in vitro* gene mutation in mammalian cells	OECD 476; EEC 87/302/EEC; US EPA detection of gene mutation in somatic cells in culture. Chlorothalonil TC, 99.10% purity	Negative	82/962528

Species	Test	Conditions	Result	Reference
Human lymphocytes	*in vitro* cytogenetic assay. Chromosome aberrations	With and without exogenous metabolic activation system. EEC 79/83, Annex V, Part B; TSCA guideline (US EPA 40 CFR part 798, 1985-1986, Section 798.5375. Chlorothalonil TC, 98.74% purity	Negative	128008-M-10787
Rat primary hepatocytes	*in vitro* unscheduled DNA synthesis	EEC and TSCA guidelines(EPA in 40 CFR part 798, 1985). Chlorothalonil TC 98.74% purity	Negative	128007-M-10687
Mouse, CD-1 strain	*in vivo* micronucleus test	OECD 474 (1982); EEC Annex V, L251B, 1984. Chlorothalonil TC, 98.74% purity	Negative	27/920705

Table 6. Ecotoxicology profile of chlorothalonil technical material (Vischim data only)

Species	Test	Duration and conditions	Result	Reference
Daphnia magna (water flea)	48-hour acute toxicity	OECD 202 Part 1. Chlorothalonil TC, 99.18% purity	EC_{50} = 59 µg/l	8(a)/920231
Daphnia magna (water flea)	21-day chronic toxicity	OECD 202 Part 2. Chlorothalonil TC, 99.18% purity	EC_{50} immobilization = 45 µg/l EC_{50} reproduction = 130 µg/l lowest NOEC = 1 µg/l, based on parental generation survival	8(e)920814
Oncorrhyncus mykiss (rainbow trout)	96-hour short-term toxicity, flow-through	OECD 203. Chlorothalonil TC, 99.18% purity	LC_{50} = 12 µg/l*	8(b)/920232
Oncorrhyncus mykiss (rainbow trout)	21-day prolonged toxicity	OECD 204. Chlorothalonil TC, 99.18% purity	LC_{50} <24 µg/l	8(d)920696
Cyprinus carpio (common carp)	96-hour short-term toxicity, flow-through	OECD 203. Chlorothalonil TC, 99.18% purity	LC_{50} = 55 µg/l	8(c)/920233
Scenedesmus subspicatus (green alga)	Growth inhibition. 96-h continuous illumination, orbital shaker	OECD 201. Chlorothalonil TC, 99.18% purity	EC_{50} = 480 µg/l NOEC = 620 µg/l, calculated using AUC	8(f)920437
Chironomus riparius (sediment-dwelling midge)	28-day static test system	Long-term toxicity (BBA 1995). Chlorothalonil TC, 99.18% purity	EC_{50} = 400 µg/l NOEC = 125 µg/l (initial water concentration) or 0.95 mg/kg (sediment concentration at end of study)	89/973322
Eisenia foetida (earthworm)	Acute toxicity	OECD 207. Chlorothalonil TC, 99.18% purity	LC_{50} 14-d = 516 mg/kg dry soil	4/921046

Species	Test	Duration and conditions	Result	Reference
Soil micro-organisms	Effects on non-target micro-organisms, 28-d	EPPO Guideline. Recommended laboratory tests for assessing hazard to soil microflora. Chlorothalonil TC, 99.10% purity	No effects on nitrogen transformation and carbon mineralization in soil treated with chlorothalonil TC at 2x maximum application concentration.	3a/943068
Activated sludge micro-organisms	Respiration rate of activated sludge.	EC Directive "Biodegradation-Activated sludge respiration inhibition test"; OECD 209. Chlorothalonil TC, 99.18% purity	EC_{50} and EC_{80} >0.1 g/l No inhibitory effect on respiration rate of activated sludge.	096/983843
Apis mellifera (honey bee sterile females)	Acute oral toxicity	US EPA, Subdiv. L Series 14-1. Chlorothalonil TC, 99.18% purity	LD_{50} >40 µg/bee	7/911157
Mallard duck	Acute oral toxicity.	EPA-FIFRA 71-1. Chlorothalonil TC, 99.18% purity	LD_{50} >2000 mg/kg bw**	6/911468
Mallard duck	Sub-acute, 5-d dietary toxicity.	EPA-FIFRA 71-2. Chlorothalonil TC, 99.18% purity	LC_{50} >5200 ppm diet NOEL >5200 ppm diet	5/911414
Bobwhite quail	Sub-acute, 5-d dietary toxicity.	EPA-FIFRA 71-2. Chlorothalonil TC, 99.18% purity	LC_{50} >5200 ppm diet NOEL = 650 ppm diet	2/911413
Bobwhite quail	Dietary reproduction and tolerance.	EPA-FIFRA 71-4. Chlorothalonil TC, 99.18% purity	NOEL = 160 ppm diet***	10/11/930496

* Acute toxicity of chlorothalonil to rainbow trout in the presence of sediment produced an LC_{50} value >10x that obtained with no sediment, indicating that toxicity is significantly reduced in natural water systems by sediment and suspended material. Bioconcentration factors (BCF) up to 310 were determined in the edible fraction, 4500 in the non-edible fraction, and a whole fish BCF of 2700, indicating relatively low potential for bioconcentration (depuration half-life 7 to 13 d). In natural water-sediment systems, chlorothalonil rapidly transfers to the sediment, where it is degraded with a DT_{50} <0.25 d.

** There was a slight decrease in body weight and food consumption at 2000 ppm.

*** Tested at up to 640 ppm. No clinical signs of toxicity; no effect on survival of parent or offspring; body weights and food consumption not influenced by treatments. However, at the highest concentration tested, the number of eggs laid and therefore the number of 14-d survivors per female was lower than the control group. No treatment-related effects at necropsy.

ANNEX 2. REFERENCES

008/2005	2005. Chlorothalonil technical material. Analytical profile.
083-002/T/012/85	1985. Chlorothalonil. Eye irritation study in rabbits.
096/983843	1998. Chlorothalonil. Activated sludge - respiration inhibition test.
1/92034	1992. Chlorothalonil. Subacute toxicity to mice by dietary administration for 13 weeks.
10/11/930496	1993. Chlorothalonil. Bobwhite quail dietary reproduction and tolerance studies. vol. I-II.
12/920413	1994. Chlorothalonil. Toxicity to dogs by dietary administration for 13 weeks.
128006-M-10587	1988. Reverse mutation in Salmonella typhymurium. Test substance: chlorothalonil technical.
128007-M-10687	1988. Unscheduled DNA synthesis in primary rat hepatocytes. Test substance: chlorothalonil technical.
128008-M-10787	1988. Chromosome aberrations in human lymphocytes cultured in vitro. Test substance: chlorothalonil technical.
14/943124	1995. Chlorothalonil. Toxicity to dogs by repeated dietary administration for 52 weeks. Vol. 1–2.
15/943286	1996. Chlorothalonil. Potential tumorigenic effects in prolonged dietary administration to rats. vol. 1–14.
16/943065	1995. Chlorothalonil. Potential tumorigenic effects in prolonged dietary administration to mice. vol. 1-9.
2/911413	1991. Chlorothalonil. Subacute dietary toxicity (LC_{50}) to bobwhite quail.
21/942505	1995. Chlorothalonil. A study of the effect on reproductive function of two generations in rat.
22/930637	1994. Chlorothalonil. A study of the effect on pregnancy of the rat.
23/930638	1994. Chlorothalonil. A study of the effect on pregnancy of the rabbit.
27/920705	1992. Chlorothalonil. Mouse micronucleus test.
32/942392	1995. Chlorothalonil (pure). Physical and chemical properties.
3a/943068	1995. Chlorothalonil technical. Effects on soil non-target organisms. Nitrogen transformation-carbon mineralisation.
4/921046	1992. Chlorothalonil. Acute toxicity (LC_{50}) to earthworm (Eisenia foetida).
40/940427/SS	1995. Technical Chlorothalonil. Skin sensitization in the Guinea-pig.
42/951419	1996. C^{14}-Chlorothalonil. Photo-degradation in water.
5/911414	1992. Chlorothalonil. Subacute dietary toxicity (LC_{50}) to mallard duck.
57/950744	1995. Chlorothalonil. Physico-chemical properties - vol. I.
6/911468	1992. Chlorothalonil. Acute oral toxicity (LD_{50}) to mallard duck.
7/911157	1992. The acute contact and oral toxicity to honey bees of chlorothalonil technical.
8(a)/920231	1992. The acute toxicity of chlorothalonil to Daphnia magna.
8(b)/920232	1992. The acute toxicity of chlorothalonil to rainbow trout (Oncorrhynchus mykiss).
8(c)/920233	1992. The acute toxicity of chlorothalonil to common carp (Cyprinus carpio).
8(d)920696	1992. The prolonged toxicity of chlorothalonil to rainbow trout (Oncorhynchus mykiss).
8(e)920814	1992. An assessment of the effect of chlorothalonil on the reproduction of Daphnia magna.
8(f)920437	1992. The algistatic activity of chlorothalonil.
82/962528	1996. Chlorothalonil. Mammalian cell mutation assay.
88/CFA001/185	1988. Chlorothalonil technical. Inhalatory toxicity study in rat.
88/CFA002/276	1988. Chlorothalonil technical. Acute oral toxicity study in rat.
88/CFA003/277	1988. Chlorothalonil technical. Acute percutaneous toxicity study in rabbit.

88/CFA004/235	1988. Chlorothalonil technical: Acute dermal irritation/corrosion test in the rabbit.
89/973322	1998. Chlorothalonil technical. Toxicity to the sediment dwelling phase of the midge Chironomus riparius.
9/920338	1994. Chlorothalonil. Toxicity to rats by dietary administration for 13 weeks.
EPA 1999	U.S. EPA, Re-registration Eligibility Decision (RED) report. Chlorothalonil. http://www.epa.gov/oppsrrd1/REDs/0097red.pdf
FAO/WHO 2002	Manual on development and use of FAO and WHO specifications for pesticides, 1st edition. FAO plant production and protection paper 173. FAO, Rome, 2002.
GHS 2003	Globally harmonized system of classification and labelling of chemicals, United Nations, New York and Geneva, 2003, http://www.unece.org/trans/danger/publi/ghs/ghs_rev00/english.
IPCS 1996	Chlorothalonil. Environmental Health Criteria, 183. WHO, Geneva, 1996.
PCS 2005	Equivalence of two chlorothalonil products. WHO/PCS AAi/Atr/TMe, dated 18 October 2005. Unpublished. Attachment chlorothalonil.pdf to e-mail RE:equivalence of two chlorothalonil products, sent by A. Aitio (WHO/PCS) to G Vaagt (FAO), M Zaim (WHOPES), R Schreuder and A Hill on 18 October 2005.
S05/010 & 011	2005. Chlorothalonil technical analysis of five batch samples.

CHLOROTHALONIL

EVALUATION REPORT 288/2004

Explanation

The data for chlorothalonil were evaluated in support of a review of existing FAO specifications for TC, WP, WG and SC (AGP:CP/354, Rome,1998).

Chlorothalonil is not under patent.

Chlorothalonil was reviewed by the FAO/WHO JMPR in 1992. In addition, the Core Assessment Group of JMPR also reviewed chlorothalonil in 1994. This was outside the normal JMPR process, taking into account a draft Environmental Health Criteria (EHC) document that had been made available by the International Programme on Chemical Safety (IPCS) and a report (WHO/PCS/95.7) was published by WHO. The EHC document was subsequently published (IPCS 1996).

The US EPA reviewed chlorothalonil in 1997 and a Registration Eligibility Decision (RED) was approved in September 1998 (EPA 738-R-99-004). Chlorothalonil is currently under review in the EU, under Commission Directive 91/414. The rapporteur member state responsible for this review is The Netherlands.

The draft specification and the supporting data were provided by Syngenta Crop Protection AG in 2003.

Uses

Chlorothalonil is a non-systemic fungicide, active against a broad spectrum of fungal diseases. Its mode of action involves binding to free amino groups of amino acids in proteins, which provides multi-site inhibition of fungal enzymes critical to the survival/growth of many fungi.

It is used for the control of a wide variety of fungal diseases in agriculture/horticulture and viticulture.

Identity of the active ingredient

ISO common name

Chlorothalonil (E-ISO, (m)F-ISO, approved)

Chemical names

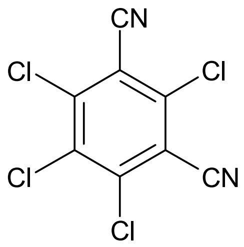
IUPAC: tetrachloroisophthalonitrile

CA: 2,4,5,6-tetrachloro-1,3-benzenedicarbonitrile

Synonyms

TPN (JMAF)

Structural formula



Empirical formula

$C_8Cl_4N_2$

Relative molecular mass

265.9

CAS Registry number

1897-45-6

CIPAC number

288

Identity tests

GC retention; IR spectrum.

Physico-chemical properties of chlorothalonil

Table 1. Physico-chemical properties of pure chlorothalonil

Parameter	Value(s) and conditions	Purity %	Method reference
Vapour pressure	7.62×10^{-8} kPa at 25ºC	99.7	EEC A4
Melting point, boiling point and/or temperature of decomposition	Melting point: 252.1ºC Boiling point: not applicable Decomposition temperature: not applicable	99.6	EEC A1
Solubility in water	0.81mg/l at 25ºC	99.6	EEC A6
Octanol/water partition coefficient	log P_{OW} = 2.94 at 25ºC	99.0	EEC A8
Hydrolysis characteristics	Half-life = 38 days at 25ºC at pH 9 Stable for 49 days at 25ºC at pH 5 and pH 7	98.3	EEC A7, EPA161-1, OECD 111
Photolysis characteristics	Based on 12 h sunlight/day, photolysis at pH 5 and 25ºC resulted in an estimated half-life (DT_{50}) of 64.7days. The environmental half-life in water under mid-European conditions was calculated to be between 3.7 and 260 days, depending upon seasonal sunlight and depth of water.	99.0 99.5	EPA FIFRA Subdiv. N, Guidelines 161-2 and 161-3 Not applicable, company report
Dissociation	Does not dissociate	Not	Not applicable

Parameter	Value(s) and conditions	Purity %	Method reference
characteristics		applicable	

Table 2. Chemical composition and properties of chlorothalonil technical material (TC)

Manufacturing process, maximum limits for impurities ≥1 g/kg, 5 batch analysis data	Confidential information supplied and held on file by FAO. Mass balances were 99.8–100.3% and percentages of unknowns were 0.08 to 0.1%.
Declared minimum chlorothalonil content	985 g/kg.
Relevant impurities ≥1 g/kg and maximum limits for them	None.
Relevant impurities <1 g/kg and maximum limits for them:	Hexachlorobenzene: 0.01g/kg maximum. Decachlorobiphenyl: 0.03g/kg maximum.
Stabilizers or other additives and maximum limits for them:	None.
Melting or boiling temperature range of the TC	248 to 253ºC.

Toxicological summaries

Notes.

(i) The proposer confirmed that the toxicological and ecotoxicological data included in the summary below were derived from chlorothalonil having impurity profiles similar to those referred to in the table above.

(ii) The conclusions expressed in the summary below are those of the proposer, unless otherwise specified.

Table 3. Toxicology profile of chlorothalonil technical material, based on acute toxicity, irritation and sensitization

Species	Test	Duration and conditions or guideline adopted	Result
Rat, SD, (m, f)	Oral	OECD 401	LD_{50} = >5,000 mg/kg bw
Rat, Alpk:Apf SD (m, f)	Dermal	OECD 402	LD_{50} = >5,000 mg/kg bw
Rat, SD, (m, f)	Inhalation	OECD 403	LC_{50} = 0.1 [0.07-0.14] mg/l
Rabbit, New Zealand White, (m)	Skin irritation	OECD 404	Mild skin irritant
Rabbit, Albino, (m, f)	Eye irritation	OECD 405	Severe eye irritant
Guinea pig, Dunkin Hartley, (m, f) Human experience	Skin sensitization (Maximisation) Published case reports	End-point addressed in multiple animal studies with different designs	Skin sensitizer (based on results of animal studies and human experience)

Chlorothalonil has low acute toxicity by the oral and dermal routes but is very toxic by inhalation, following exposure to finely powdered material (2-3 µm). Chlorothalonil is a mild skin irritant following single application and may cause moderate irritation following prolonged or repeated exposure. Chlorothalonil causes marked eye irritation, evident as irreversible corneal opacity. Chlorothalonil has been shown to have skin sensitization potential in animals and in humans.

Table 4. Toxicology profile of technical chlorothalonil based on repeated administration (sub-acute to chronic)

Species	Test	Duration and conditions or guideline adopted	Result [(isomer/form)]
Rat, Fischer 344, (m)	Sub-chronic dermal	OECD 410 21 days at 0, 60, 100, 250 or 600 mg/kg bw/d	NOAEL = 600 mg/kg bw/d (Systemic)
Rat, CD, (m, f)	Sub-chronic oral dietary feeding	28 day range-finder, non-guideline. 0, 80, 175, 375 & 1500 mg/kg bw/d	LOEL = 80 mg/kg bw/d
Rat, Fischer 344, (m)	Sub-chronic oral dietary feeding, investigative	28 day study of renal and forestomach cell proliferation. 0, 1.5, 15 or 175 mg/kg bw/d	NOAEL = 1.5 mg/kg bw/d LOEL = 15 mg/kg bw/d
Rat, CD, (m, f)	Sub-chronic oral dietary feeding	OECD 408, 90 days at 0, 40, 80, 175, 375, 750 or 1500 mg/kg bw/d	LOEL = 40 mg/kg bw/d
Rat, CD, (m, f)	Sub-chronic oral dietary feeding	OECD 408, 90 days at 0, 1.5, 3, 10 or 40 mg/kg bw/d	NOAEL = 10 mg/kg bw/d LOEL = 40 mg/kg bw/d
Rat, Fischer 344, (m)	Sub-chronic oral dietary feeding investigative	90 day study of renal cell proliferation. 0 and 175 mg/kg bw/d	LOEL = 175 mg/kg bw/d
Mouse, CD-1, (m, f)	Sub-chronic oral dietary feeding	90 day range-finder for carcinogenicity study 0, 7.5, 15, 50, 275 or 750 ppm	NOAEL = 2.8 mg/kg bw/d (15 ppm) LOEL = 9.2 mg/kg bw/d (50 ppm)
Dog, Beagle (m, f)	Sub-chronic oral capsule dosing	OECD 409 90 days at 0, 15, 150 or 500 (750)* mg /kg bw/d	NOAEL = 15 mg/kg bw/d LOEL = 150 mg/kg bw/d
Dog, Beagle (m, f)	Chronic oral capsule dosing	OECD 409 1 year at 0, 15, 150 or 500 mg /kg bw/d	NOAEL = 150 mg/kg bw/d LOEL = 500 mg/kg bw/d
Rat, Fischer 344, (m, f)	Chronic toxicity/ carcinogenicity oral dietary feeding	OECD 453, 166 weeks dosing at 0, 40, 80 or 175 mg/kg bw/d	LOEL = 40 mg/kg bw/d Kidney tumours observed at all doses.
Rat, Fischer 344, (m, f)	Chronic toxicity/ carcinogenicity oral dietary feeding	OECD 453, 26-29 months dosing at 0, 1.8, 3.8, 15 or 175 mg/kg bw/d	NOAEL = 1.8 mg/kg bw/d LOEL = 3.8 mg/kg bw/d Renal hyperplasia
Mouse, CD-1, (m, f)	Carcinogenicity oral dietary feeding	OECD 452, 24 months dosing at 0, 750, 1500 or 3000 ppm	LOEL = 125 mg/kg bw/d (750 ppm) Kidney & forestomach tumours at all doses
Mouse, CD-1, (m)	Carcinogenicity oral dietary feeding	OECD 452, 24 months dosing at 0, 0, 10/15 (15 ppm from Week 18), 40, 175 or 750 ppm	NOAEL = 1.9 mg/kg bw/d (15 ppm) LOEL = 5.4 mg/kg bw/d (40 ppm) Hyperplasia & hyperkeratosis of forestomach
Rat, SD, (m, f)	Two-generation reproductive toxicity, oral diet	OECD 416, doses of 0, 500, 1500 or 3000 ppm chlorothalonil	<u>Parental</u> LOEL = 500 ppm (23 mg/kg bw) based on hyperplasia in kidney & forestomach <u>Developmental</u>

Species	Test	Duration and conditions or guideline adopted	Result [(isomer/form)]
			NOAEL = 1500 ppm (68 mg/kg bw/d) LOEL = 3000 ppm (145 mg/kg bw) based on decreased pup body weight at day 21 Reproductive NOAEL = 3000 ppm (145 mg/kg bw/d) LOEL = None
Rat, SD (f)	Developmental toxicity, gavage dosing in 0.5% aqueous methylcellulose	OECD 414 at doses of 0, 25, 100 or 400 mg /kg bw/d on days 6-15	Maternal NOAEL = 100 mg/kg bw/d LOEL = 400 mg/kg bw based on mortality Developmental NOAEL = 100 mg/kg bw/d LOEL = 400 mg/kg bw based on increased number of resorptions
Rabbit, NZW, (f)	Developmental toxicity, gavage dosing in 0.5% aqueous methylcellulose	OECD 414 at doses of 0, 5, 10 or 20 mg/kg bw/day on days 7 to 19	Maternal NOAEL = 10 mg/kg bw/d LOEL =20 mg/kg bw based on mortality Developmental NOAEL = 20 mg/kg bw/d LOEL = None

The principal lesions observed following dietary administration of chlorothalonil to rats and mice for up to 90 days were hyperplasia and hyperkeratosis of the forestomach and hyperplasia of the proximal tubular epithelium of the kidney. These effects were not seen in dogs dosed for up to one year at 500 mg/kg/d. Dermal administration to rats caused no histopathological effects in the rat doses up to 600 mg/kg bw/day. The toxicity findings in the chronic rat and mouse studies were consistent with those seen in the sub-chronic studies, with hyperplasia of the forestomach and renal proximal tubular epithelium being the most prominent effects. Tumours were observed in the forestomach and kidneys of rats and mice. The forestomach tumours were not considered relevant to human health, as humans do not possess this anatomical structure. The NOAEL for chronic toxicity is considered to be 1.8 mg/kg/d and the NOAEL for kidney tumours is 3.8 mg/kg/d. A non-genotoxic mode of action has been demonstrated for kidney tumour formation that demonstrates that these tumours occur as a secondary consequence of renal toxicity. There is no evidence that chlorothalonil is a reproductive or developmental toxicant, at dose levels that do not cause maternal toxicity.

Table 5. Mutagenicity profile of technical chlorothalonil based on *in vitro* and *in vivo* tests

Species	Test	Conditions	Result

Species	Test	Conditions	Result
Bacterial mutation assay	*Salmonella typhimurium* TA1535, TA1537, TA1538, TA98, TA100	20-2000 µg/plate	Negative ± S9
Bacterial mutation assay	*Salmonella typhimurium*TA1535, TA1537, TA1538, TA98, TA100	0.5-50 µg/plate	Negative ± S9
Bacterial mutation assay	*Salmonella typhimurium* TA1535, TA1537, TA1538, TA98, TA100	0.33-6.6 µg/plate	Negative ± S9
Bacterial mutation assay	*Salmonella typhimurium* TA1535, TA1537, TA1538, TA98, TA100 *Escherichia coli* WP2 hcr+, WP2 hcr-	1-500 µg/plate	Negative ± S9
Mammalian cell gene mutation assay	V-79 cells & BALB/3T3	0.3 µg/ml	Negative ± S9
DNA repair assay	*B. subtilis* H17 (wild type) and M45 (repair deficient)	2-200 µg/disc	Negative -S9
DNA repair assay	*Salmonella typhimurium* TA1987, TA1538	20, 10 & 2 µl of a 1 mg/ml solution	Positive ± S9
Mammalian cell cytogenetic assay	CHO-K1 cells (Chinese hamster)	0.03 – 6 µg/ml	Positive –S9 Negative +S9
Micronucleus assay	Chinese hamster bone marrow	2 doses at 4-2500 mg/kg bw/d	Negative
Chinese hamster (m)	Chromosomal aberrations, bone marrow	Single dose at 500-5000 mg/kg bw/d	Negative
Chinese hamster (m)	Chromosomal aberrations, bone marrow	5 doses at 50-350 mg/kg bw/d	Negative
Chinese hamster (m)	Chromosomal aberrations, bone marrow	2 doses at 8-5000 mg/kg bw/d	Negative
Chinese hamster (m)	Chromosomal aberrations, bone marrow	5 doses at 188-750 mg/kg bw/d	Negative
Mouse (m)	Micronucleus assay, bone marrow	2 doses at 4-2500 mg/kg bw/d	Negative
Mouse (m)	Chromosomal aberrations, bone marrow	2 doses at 4-2500 mg/kg bw/d	Negative
Mouse (m)	Chromosomal aberrations, bone marrow	Single dose at 250-2500 mg/kg bw/d	Negative
Mouse (m, f)	Micronucleus assay, bone marrow	Single dose at 500-10000 mg/kg bw/d	Negative
Rat (m)	Micronucleus assay, bone marrow	2 doses at 8-5000 mg/kg bw/d	Negative
Rat (m)	Chromosomal aberrations, bone marrow	5 doses at 500-2000 mg/kg bw/d	Negative
Rat (m)	Chromosomal aberrations, bone marrow	2 doses at 8-5000 mg/kg bw/d	Negative
Rat (m)	Chromosomal aberrations, bone marrow	Single dose at 500-5000 mg/kg bw/d	Negative

Chlorothalonil was extensively tested for genotoxic potential, including several *in vivo* studies in different species and conducted at high dose levels, and was conclusively shown not to be genotoxic *in vivo*.

Table 6. Ecotoxicology profile of technical chlorothalonil

Species	Test	Duration and conditions	Result
Daphnia magna (water flea)	Acute toxicity	48 h, static, 20ºC	EC_{50} = 70 μg/l
Daphnia magna (water flea)	Chronic toxicity	2 generations, each exposed for 21 days, flow-through, 22ºC	NOEC = 35 μg/l
Oncorhynchus mykiss (rainbow trout)	Acute toxicity	96 h, static, 12ºC	LC_{50} = 47 μg/l
Ictalurus punctatus (channel catfish)	Acute toxicity	96 h, static, 22ºC	LC_{50} = 43 μg/l
Pimephales promelas (fathead minnow)	Full life-cycle	297 days, flow-through, 25ºC	NOEC = 3.0 μg/l
Selenastrum capricornutum (green alga)	Effect on growth	120 h, static, 24ºC, 4300 lux	EbC_{50} = 210 μg/l NOEC = 100 μg/l
Eisenia foetida (earthworm)	Acute toxicity	14 days in artificial soil, 20ºC	LC_{50} >404 mg/kg
Eisenia foetida (earthworm)	Reproduction	56 days in artificial soil, 20ºC	NOEC = 50 mg/kg
Apis mellifera (honey bee)	Acute contact toxicity	Single dose in tetrahydrofuran, 48 h observation	LD_{50} >101 μg/bee
Apis mellifera (honey bee)	Acute oral toxicity	Dosed in sucrose solution, 48 h observation	LD_{50} >63 μg/bee
Colinus virginianus (bobwhite quail)	Acute oral toxicity	Single dose in corn oil, 14 days observation	LD_{50} >2000 mg/kg bw
Anas platyrhynchos (mallard duck)	Acute oral toxicity	Single dose in corn oil, 8 days observation	LD_{50} >4640 mg/kg bw
Colinus virginianus (bobwhite quail)	Short-term dietary toxicity	5 day exposure, total 8 days observation	LC_{50} >10000 mg/kg diet
Anas platyrhynchos (mallard duck)	Short-term dietary toxicity	5 day exposure, total 8 days observation	LC_{50} >10000 mg/kg diet
Colinus virginianus (bobwhite quail)	Reproduction	21 weeks exposure	NOEL = 1000 mg/kg diet
Anas platyrhynchos (mallard duck)	Reproduction	18 weeks exposure	NOEL = 1000 mg/kg diet

Chlorothalonil was of low toxicity to terrestrial organisms tested, including birds, earthworms and honey bees. In laboratory studies, chlorothalonil was highly toxic to aquatic organisms. However, in natural environments it was readily dissipated through degradation resulting in no long-term exposure and reducing the potential for short-term effects. Field studies have confirmed that, following agricultural use, the risk to aquatic environments is low.

Chlorothalonil was reviewed by FAO/WHO JMPR in 1992 and by IPCS in the Environmental Health Criteria (EHC) series in 1996. The WHO classification of the acute hazard is: "unlikely to present acute hazard in normal use" (WHO 2002).

The EU has assigned the following hazard classifications (EU 2001):

Hazard symbol: T+N
Risk phrases: R26, very toxic by inhalation;
R37, irritating to the respiratory system;
R40, possible risk of irreversible effects;

R41, risk of serious damage to eyes;
R43, may cause sensitisation by skin contact.

The US EPA has classified chlorothalonil as a “likely human carcinogen” (USEPA 1999).

The International Agency for Research on Cancer assigned chlorothalonil to Category 2b “possibly carcinogenic to humans” (IARC 1999).

Formulations and co-formulated active ingredients

The main formulation types available are SC, WG and WP and chlorothalonil may be co-formulated with other fungicides. These formulations are registered and sold worldwide.

Methods of analysis and testing

The analytical method for determination of the active ingredient (including identity tests) is a provisional CIPAC method (CIPAC K). Chlorothalonil is determined by capillary GC with FID and internal standardization with *n*-butyl phthalate.

The methods for determination of impurities are based on GC- MS. The CIPAC method for published for chlorothalonil incorporated a method for the determination of HCB (CIPAC K) but this method was not validated for support of the proposed new specification limit for HCB, nor for the determination of decachlorobiphenyl. For these reasons, the manufacturer developed a new analytical method for the two relevant impurities and conducted a small-scale study of the method with 5 participating laboratories. The validation data were presented to CIPAC in 2004 but the method could not be adopted by CIPAC, because there was no system for the recognition of peer validated methods.

Test methods for determination of physico-chemical properties of the technical active ingredient were essentially OECD methods, while those for the formulations were CIPAC procedures, as indicated in the specifications.

Physical properties

The physical properties, the methods for testing them and the limits proposed for the SC, WG and WP formulations comply with the requirements of the FAO/WHO manual (FAO/WHO 2002).

Containers and packaging

No special requirements for containers and packaging have been identified.

Expression of the active ingredient

The active ingredient is expressed as chlorothalonil.

Appraisal

The Meeting evaluated data on chlorothalonil for the review of existing (1998) FAO specifications for the TC, WP, WG and SC.

Chlorothalonil has been widely used as a non-systemic fungicide in agriculture for many years. Chlorothalonil is a solid compound with a melting point of 252ºC; it has low water solubility and volatility; it is stable to hydrolysis at pH 4 and 7 but hydrolyses slowly at pH 9; and is relatively stable to photolysis by UV light. Its octanol-water partition coefficient (log P_{ow} 2.9) suggests a potential for moderate bioconcentration but, in practice, it is metabolized or otherwise degraded too quickly for this to occur.

The Meeting was provided with confidential information on the manufacturing process; 5 batch analysis data; and manufacturing specifications for TC purity, for impurities with limits ≥1 g/kg, and for two impurities with limits <1 g/kg. The two impurities controlled to <1 g/kg were hexachlorobenzene (HCB) and decachlorobiphenyl, having manufacturing specifications of 0.01 and 0.03 g/kg, respectively. Mass balances were high (99.8-100.3%) but small proportions (0.08-0.1%) of unknown impurities were also found. These data were confirmed as similar to those presented for registration of chlorothalonil in the Netherlands.

The proposed specification for minimum purity of chlorothalonil TC was 985 g/kg, which was higher than that of the existing FAO specification (985 ± 15 g/kg). The Meeting welcomed the introduction of the higher minimum value.

The Meeting agreed that none of the impurities with limits ≥1 g/kg should be considered relevant.

HCB (which was formerly used as an agricultural fungicide but has now been withdrawn throughout the world) and decachlorobiphenyl (a polychlorinated biphenyl or PCB) are both considered to be persistent organic pollutants (POPs), under the terms of the Stockholm Convention. The Meeting noted that although the toxicity of HCB is well characterized, less is known about decachlorobiphenyl. It is not a "planar" PCB, a group which has toxicological characteristics similar to chlorinated dibenzodioxins. The manufacturer stated that certain other PCBs may be present, but only at much lower concentrations than decachlorobiphenyl in the technical chlorothalonil made by the company, and that planar PCBs have not been detected in their product. The Meeting agreed that both HCB and decachlorobiphenyl are relevant impurities, primarily because of their persistence in the environment and potential for bioaccumulation.

The limit for HCB in the existing FAO specification for chlorothalonil was 0.3 g/kg and manufacturer stated that the company had improved the manufacturing process in order to minimise the content of HCB and introduced the new limit of 0.01 g/kg. The Meeting agreed that, in the interests of minimizing release of HCB into the environment, the proposed 0.01 g/kg limit should be adopted.

Decachlorobiphenyl was not controlled by the existing FAO specifications, though the Meeting accepted that it had probably been present in chlorothalonil manufactured previously. In the absence of specific toxicity and ecotoxicity data, WHO/PCS suggested that the hazards presented by this impurity may be approximately similar to those of other non-planar PCBs, on which basis the proposed limit was expected to be below the maximum acceptable with respect to risks. In the interests of minimizing release of this PCB into the environment, the Meeting agreed that the proposed 0.03 g/kg limit should be adopted.

The Meeting questioned whether the toxicity studies carried out in the past with technical grade chlorothalonil are remain valid for the substance with the low level of the impurity HCB. The manufacturer confirmed that the data available showed that the toxicity of chlorothalonil containing HCB at or below the proposed limit of 0.01 g/kg was not significantly different from that of earlier batches which complied with the existing 0.3 g/kg limit. The Meeting therefore concluded that chlorothalonil complying with the proposed new limits for relevant impurities is unlikely to present greater hazards than earlier TCs which complied with the existing specification.

The acute toxicity of chlorothalonil is low by oral and dermal exposure routes but high by the inhalation route. Chlorothalonil it is a mild skin irritant upon repeated or prolonged exposure, a severe eye irritant, and a skin sensitizer. In long-term studies in rodents, chlorothalonil caused hyperplasia and tumours in the forestomach and/or kidney in rats and mice. Chlorothalonil was negative in a wide variety of studies on genotoxicity and the tumours in the forestomach (an organ that does not exist in humans) were considered to be caused by an irritation mechanisms. The kidney tumours were related to a glutathione conjugation metabolic pathway, which is prominent in rats but of lower activity in humans. Chlorothalonil was not teratogenic and had no adverse effects on reproduction.

Chlorothalonil is very toxic to organisms in the aqueous environment, including *Daphnia*, fish, and green algae, but is of low toxicity to birds and honey bees.

Analytical methods for determination of the chlorothalonil content of the TC, WP, WG and SC are CIPAC methods. A GC-MS method was validated for the determination of HCB and decachlorobiphenyl in chlorothalonil at and about the proposed specification limits. Although the method was not be adopted by CIPAC (for reasons unrelated to the quality of the method or the data presented), the data exceeded the minimum JMPS requirements for peer validation and the Meeting considered the method to be acceptable for support of the proposed specifications.

The physical test methods required for support of the proposed specifications are full CIPAC methods.

Specifications were submitted for TC, WP, WG and SC. The clauses and limits in the proposed specifications were in accordance with the guidelines given in the manual (FAO/WHO 2002). The proposed WG specification included a clause to limit the water content. The manufacturer explained that the clause is not required to ensure stability of the active ingredient but to avoid adverse effects on dispersibility and wet sieve test performance that would otherwise develop during storage of the product. The Meeting accepted the explanation.

Recommendations

The Meeting recommended that FAO should:

- withdraw the existing specifications for chlorothalonil TC, WP, WG and SC.
- adopt the proposed specifications for chlorothalonil TC, WP, WG and SC.

References

CIPAC K	CIPAC Handbook K, p. 13, Dobrat W. and Martjin A. (eds), 2003, Black Bear Press, Cambridge, UK, ISBN 0 902951 15 7.
EU 2001	Minutes of EU Classification and Labelling Working Group for Dangerous Substances [Pesticides] Meeting, held in Arona, Italy, April 25-27, 2001. Published as Directive 2004/73/EC, Journal of European Communities, L152/1, p.48, 29 April 2004.
FAO/WHO 2002	Manual on development and use of FAO and WHO specifications for pesticides, 1st edition, 2002, Rome.
IARC 1999	International Agency for Research on Cancer. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Chlorothalonil (Group 2B), Vol 73, p.183 ff., WHO 1999.
IPCS 1996	Chlorothalonil. Environmental Health Criteria, 183. 145pp. WHO, Geneva, Switzerland. ISBN 92-4-157183-7. C12138 614.7.
USEPA 1999	Re-Registration Eligibility Decision, April 1999, US EPA, Washington DC, USA.
WHO 2002	The WHO recommended classification of pesticides by hazard and guidelines to classification 1998-1999, WHO/PCS/98.21/rev1, 1998.