WHO SPECIFICATIONS AND EVALUATIONS

FOR PUBLIC HEALTH PESTICIDES

FENITROTHION

O,*O*-dimethyl *O*-4-nitro-*m*-tolyl phosphorothioate

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

INTRODUCTION

WHO 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.

From 2002, the development of WHO specifications follows the **New Procedure**, described in the Manual for Development and Use of FAO and WHO Specifications for Pesticides. This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package, the procedure and evaluation applied by WHO and the experts of the "FAO/WHO Joint Meeting on Pesticide Specifications" (JMPS).

WHO Specifications now only apply to products for which the technical materials have been evaluated. Consequently, from the year 2002 onwards the publication of WHO 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 Specifications of the technical material and the related formulations of the pesticide in accordance with chapters 4 to 9 of the "FAO/WHO Manual on Pesticide Specifications."

Part Two: The Evaluation Report(s) of the pesticide, reflecting the evaluation of the data package carried out by WHO and the JMPS. The data are provided by the manufacturer(s) according to the requirements of chapter 3 of the "FAO/WHO Manual on Pesticide Specifications" 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.

WHO specifications under the **New Procedure** do not necessarily apply to nominally similar products of other manufacturer(s), nor to those where the active ingredient is produced by other routes of manufacture. WHO 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.

* Footnote: The publications are available on the Internet under (http://www.who.int/whopes/quality/en/).

PART ONE

SPECIFICATIONS

FENITROTHION

INFORMATION

Common name

fenitrothion (BSI, E-ISO, (*m*) F-ISO, ESA, BAN)

Synonyms

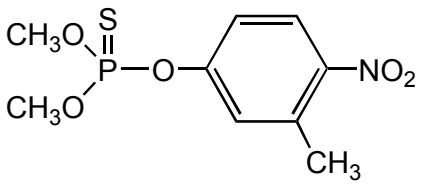
sumithion, MEP

Chemical names

IUPAC: *O*,*O*-dimethyl *O*-4-nitro-*m*-tolyl phosphorothioate

CA: *O*,*O*-dimethyl *O*-(3-methyl-4-nitrophenyl) phosphorothioate

Structural formula



Molecular formula

$C_9H_{12}NO_5PS$

Relative molecular mass

277.25

CAS Registry number

112-14-5

CIPAC number

35

Identity tests

HPLC retention time, IR spectrum.

FENITROTHION TECHNICAL MATERIAL

WHO specification 35/TC (January 2010*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (35/2009). It should be applicable to TC produced by this manufacturer 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 TC produced by other manufacturers. The evaluation report (35/2009), as PART TWO, form an integral part of this publication.

1 Description

The material shall consist of fenitrothion together with related manufacturing impurities and, below its decomposition (boiling) point (Note 1), shall be a pale yellow to yellowish brown oil, faint characteristic odour, free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 **Identity tests** (CIPAC 35/TC/m3/2) (Notes 2 & 3)

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 **Fenitrothion content** (CIPAC 35/TC/m3/3) (Note 2)

The fenitrothion content shall be declared (not less than 930 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

3 Relevant impurities

3.1 **S-methyl fenitrothion** (CIPAC 35/TC/m3/4) (Note 4)

Maximum: 5 g/kg.

3.2 **Tetramethyl pyrophosphorothioate (TMPP)** (CIPAC 35/TC/m3/5) (Note 5)

Maximum: 3 g/kg.

Note 1 The melting point should be in the range −1 − +1°C, the decomposition point is around 210°C (the boiling point cannot be determined). Fenitrothion is always used at temperatures well below the decomposition point.

Note 2 The normal phase HPLC methods (CIPAC/4602) for the determination of fenitrothion in TC and in WP, EC and UL formulations were accepted as full CIPAC methods in 2009. Prior to their publication in Handbook N, copies of the methods may be obtained through the CIPAC website, http://www.cipac.org/prepubme.htm.

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* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.who.int/whopes/quality/en/.

Note 3 In addition to HPLC-UV retention times, the infrared spectrum shown in Figure 1 provides good evidence of the identity of fenitrothion.

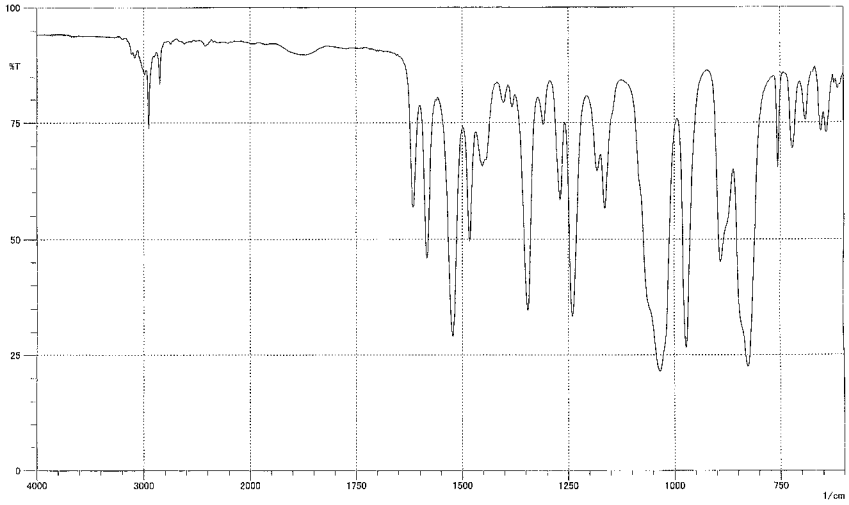

Figure 1. Infrared spectrum of fenitrothion.

Note 4 The independent laboratory validated HPLC-UV method (CIPAC/4602) for the determination of the relevant impurity *S*-methyl fenitrothion in fenitrothion TC and in WP, EC and UL formulations was adopted by CIPAC in 2007 and is available through the CIPAC website, http://www.cipac.org/cipacpub.htm.

Note 5 The independent laboratory validated capillary GC-FID method (CIPAC/4660) for the determination of the relevant impurity tetramethyl pyrophosphorothioate (TMPP) in fenitrothion TC and in WP, EC and UL formulations was adopted by CIPAC in 2009 and is available through the CIPAC website, http://www.cipac.org/cipacpub.htm.

FENITROTHION WETTABLE POWDER

WHO specification 35/WP (January 2010*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (35/2009). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated source. The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation report (35/2009), as PART TWO, form an integral part of this publication.

1 Description

The material shall consist of a homogeneous mixture of technical fenitrothion, complying with the requirements of WHO specification 35/TC (January 2010), 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 35/WP/m3/2) (Notes 1 & 2)

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 **Fenitrothion content** (CIPAC 35/WP/m3/3) (Note 1)

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

Declared content in g/kg	Tolerance
above 250 up to 500 g/kg Note: the upper limit is included in the range.	± 5% of the declared content

3 Relevant impurities

3.1 **S-methyl fenitrothion** (CIPAC 35/WP/m3/4) (Note 3)

Maximum: 2.5% of the fenitrothion content found under clause 2.2.

3.2 **Tetramethyl pyrophosphorothioate (TMPP)** (CIPAC 35/WP/m3/5) (Note 4)

Maximum: 0.3 % of the fenitrothion content found under clause 2.2.

3.3 **Water** (MT 30.5, CIPAC Handbook J, p.120, 2000)

Maximum: 30 g/kg.

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* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.who.int/whopes/quality/en/.

4 Physical properties

4.1 **pH range** (MT 75.3, CIPAC Handbook J, p.131, 2000)

pH range: 4 to 7.

4.2 **Wet sieve test** (MT 185, CIPAC Handbook K, p.149, 2003)

Maximum: 2% retained on a 75 µm test sieve.

4.3 **Suspensibility** (MT 184, CIPAC Handbook K, p.142, 2003) (Notes 5 & 6)

A minimum of 70% of the fenitrothion content found under 2.2 shall be in suspension after 30 min in CIPAC standard water D at 30 ± 2°C (Note 7).

4.4 **Persistent foam** (MT 47.2, CIPAC Handbook F, p.152, 1995) (Note 8)

Maximum: 30 ml after 1 min.

4.5 **Wettability** (MT 53.3, CIPAC Handbook F, p.164, 1995)

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

5 Storage stability

5.1 **Stability at elevated temperature** (MT 46.3, CIPAC Handbook J, p.128, 2000)

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 90%, relative to the determined average content found before storage (Note 9), and the formulation shall continue to comply with the clauses for:

- S-methyl fenitrothion (3.1),
- tetramethyl pyrophosphorothioate (TMPP) (3.2),
- pH range (4.1),
- wet sieve test (4.2),
- suspensibility (4.3),
- wettability (4.5),

Note 1 The normal phase HPLC methods (CIPAC/4602) for the determination of fenitrothion in TC and in WP, EC and UL formulations were accepted as full CIPAC methods in 2009. Prior to their publication in Handbook N, copies of the methods may be obtained through the CIPAC website, http://www.cipac.org/prepubme.htm.

Note 2 In addition to HPLC-UV retention times, the infrared spectrum shown in Figure 1, attached to the specification for fenitrothion TC, provides good evidence of the identity of fenitrothion.

Note 3 The independent laboratory validated HPLC-UV method (CIPAC/4602) for the determination of the relevant impurity *S*-methyl fenitrothion in fenitrothion TC and in WP, EC and UL formulations was adopted by CIPAC in 2007 and is available through the CIPAC website, http://www.cipac.org/cipacpub.htm.

Note 4 The independent laboratory validated capillary GC-FID method (CIPAC/4660) for the determination of the relevant impurity tetramethyl pyrophosphorothioate (TMPP) in fenitrothion TC and in WP, EC and UL formulations was adopted by CIPAC in 2009 and is available through the CIPAC website, http://www.cipac.org/cipacpub.htm.

Note 5 The formulation should be tested at the highest and lowest rates of use recommended by the supplier, provided it does not exceed the conditions given in method MT 184.

Note 6 This test will normally only be carried out after the heat stability test 5.1.

Note 7 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric and solvent extraction determination may be used on a routine basis provided that these methods have been shown to give results equal to those of chemical assay. In case of dispute, the chemical method shall be the "referee method".

Note 8 The mass of sample to be used in the test should be at the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.

Note 9 Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

FENITROTHION EMULSIFIABLE CONCENTRATE

WHO specification 35/EC (January 2010*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose name is listed in the evaluation report (35/2009). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated source. The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation report (35/2009), as PART TWO, form an integral part of this publication.

1 Description

The material shall consist of technical fenitrothion, complying with the requirements of WHO specification 35/TC (January 2010), dissolved in suitable solvents together with any other necessary formulants. It shall be in the form of a stable homogeneous liquid, free from visible suspended matter and sediment, to be applied as an emulsion after dilution in water.

2 Active ingredient

2.1 **Identity tests** (CIPAC 35/EC/m3/2) (Notes 1 & 2)

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 **Fenitrothion content** (CIPAC 35/EC/m3/3) (Note 1)

The fenitrothion content shall be declared (g/kg or g/l at 20 ± 2°C, Note 3) and, when determined, the average content measured shall not differ from that declared by more than the following tolerances.

Declared content in g/kg or g/l at 20 ± 2°C	Tolerance
above 250 up to 500 above 500 Note: the upper limit is included in the range.	± 5% of the declared content ± 25 g/kg or g/l

3. Relevant impurities

3.1 **S-methyl fenitrothion** (CIPAC 35/EC/m3/4) (Note 4)

Maximum: 2.5% of the fenitrothion content found under clause 2.2.

3.2 **Tetramethyl pyrophosphorothioate (TMPP)** (CIPAC 35/WP/m3/5) (Note 5)

Maximum: 0.3 % of the fenitrothion content found under clause 2.2.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.who.int/whopes/quality/en/.

3.3 **Water** (MT 30.5, CIPAC Handbook J, p.120, 2000)

Maximum: 2 g/kg.

4 Physical properties

4.1 **pH range** (MT 75.3, CIPAC Handbook J, p.131, 2000)

pH range: 3 to 6.

4.2 **Emulsion stability and re-emulsification** (MT 36.3, CIPAC Handbook K, p.137, 2003) (Note 6)

The formulation, when diluted at 30 ± 2°C with CIPAC standard waters A and D, shall comply with the following.

Time after dilution	Limits of stability
0 h	Initial emulsification complete
0.5 h	"Cream", maximum: 0.5 ml
2 h	"Cream", maximum: 1 ml "Free oil", maximum: 0.5 ml
24 h	Re-emulsification complete
24.5 h	"Cream", maximum: 0.5 ml "Free oil", maximum: trace
Note: tests after 24 h are required only where results at 2 h are in doubt.	

4.3 **Persistent foam** (MT 47.2, CIPAC Handbook F, p.152, 1995) (Note 7)

Maximum: 50 ml after 1 min.

5 Storage stability

5.1 **Stability at 0°C** (MT 39.3, CIPAC Handbook J, p.126, 2000)

After storage at 0 ± 2°C for 7 days, the volume of solid and/or liquid which separate shall not be more than 0.3 ml.

5.2 **Stability at elevated temperature** (MT 46.3, CIPAC Handbook J, p.128, 2000)

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 95% relative to the determined average content found before storage (Note 8) and the product shall continue to comply with the clauses for:

- S-methyl fenitrothion (3.1),
- tetramethyl pyrophosphorothioate (TMPP) (3.2),
- pH range (4.1),
- emulsion stability and re-emulsification (4.2).

Note 1 The normal phase HPLC methods (CIPAC/4602) for the determination of fenitrothion in TC and in WP, EC and UL formulations were accepted as full CIPAC methods in 2009. Prior to their publication in Handbook N, copies of the methods may be obtained through the CIPAC website, http://www.cipac.org/prepubme.htm.

Note 2 In addition to HPLC-UV retention times, the infrared spectrum shown in Figure 1, attached to the specification for fenitrothion TC, provides good evidence of the identity of fenitrothion.

Note 3 If the buyer requires both g/kg and g/l at 20°C, then in case of dispute the analytical results shall be calculated as g/kg.

Note 4 The independent laboratory validated HPLC-UV method (CIPAC/4602) for the determination of the relevant impurity *S*-methyl fenitrothion in fenitrothion TC and in WP, EC and UL formulations was adopted by CIPAC in 2007 and is available through the CIPAC website, http://www.cipac.org/cipacpub.htm.

Note 5 The independent laboratory validated capillary GC-FID method (CIPAC/4660) for the determination of the relevant impurity tetramethyl pyrophosphorothioate (TMPP) in fenitrothion TC and in WP, EC and UL formulations was adopted by CIPAC in 2009 and is available through the CIPAC website, http://www.cipac.org/cipacpub.htm.

Note 6 The test will normally only be carried out after the heat stability test 5.2. Emulsion stability should be tested with the formulation at 1.0 % concentration.

Note 7 The mass of sample to be used in the test should be at the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.

Note 8 Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

PART TWO

EVALUATION REPORTS

FENITROTHION

FENITROTHION

FAO/WHO EVALUATION REPORT 35/2009

Recommendations

The Meeting recommended the following.

(i) the specifications for fenitrothion TC, WP, EC and UL proposed by Sumitomo Chemical Co. Ltd., as amended, should be adopted by FAO.

(ii) the specifications for fenitrothion TC, WP and EC proposed by Sumitomo Chemical Co. Ltd., as amended, should be adopted by WHO.

(iii) the existing FAO specifications for fenitrothion TC, DP, WP, OL, EC (1988) and UL (1997), and the existing WHO specifications for fenitrothion TC, EC (1999) and WP (1989), should be withdrawn.

Appraisal

The Meeting considered data and supporting information submitted by Sumitomo Chemical Co. Ltd. for the review of existing FAO specifications for fenitrothion TC, DP, WP, OL, EC (1988) and UL (1997), and the existing WHO specifications for fenitrothion TC, EC (1999) and WP (1989).

Fenitrothion is no longer under patent. Fenitrothion formulated as WP has WHOPES recommendation for use as indoor residual spraying against malaria vectors.

Fenitrothion was evaluated by the FAO/WHO JMPR and WHO/IPCS several times (1969, 1974, 1977, 1982, 1983, 1984, 1986, 1988 and 2000) and by WHO/IPCS in 1990. Fenitrothion was also the subject of the "Environmental Health Criteria Monograph 133" published in 1992. It was evaluated and reviewed by the US EPA in 1975 and by Japanese Ministry of Health and Welfare in 1975.

The draft specification and the supporting data were provided by the manufacturer and proposer, Sumitomo Chemical Co., Ltd. in October 2006. The specifications were updated in March 2007. Concurrently, the published and obsolete CIPAC method for determination of fenitrothion in TC and formulations based on packed column GC was replaced by a new fully validated normal phase HPLC method which was adopted by CIPAC in 2008.

The issue of relevant impurities was discussed by the Meeting. The Meeting concluded that, based on the criteria in the Specification Manual and available acute toxicity data, two impurities are considered as relevant in fenitrothion TC and in formulations: S-methyl fenitrothion and tetramethyl pyrophosphorothioate (TMPP). For both compounds, peer validated analytical methods for their determination in TC and formulations are now available.

Fenitrothion is a slightly volatile, non-systemic organophosphorus insecticide of low water solubility. It is not readily hydrolyzed at slightly acidic and neutral pH (half life of several months at pH 4 and 7, somewhat faster hydrolysis at pH 9, respectively) but photolysis is comparatively rapid. It is of short persistence in animals, plants, soil

and water and therefore bioaccumulation is unlikely to occur despite an octanol/water partition coefficient of 3.3.

The proposed minimum purity of the fenitrothion TC is 930 g/kg, which was accepted by the Meeting.

Confidential information on the manufacturing process and impurity profile was provided by the proposer. The impurity data presented by Sumitomo was essentially the same as those presented by the company to the Australian authorities for the purposes of registration. The Australian Pesticide and Veterinary Medicine Authority (APVMA) commented that "*the chemistry and quality control data (manufacturing process, purity and impurities etc.) submitted by Sumitomo in support of the FAO and WHO specifications for fenitrothion active constituent are similar to those assessed by the APVMA for approval of the active constituent*".

The content of the relevant impurity, S-methyl fenitrothion (*O*,*S*-dimethyl *O*-4-nitro-*m*-tolyl phosphorothioate), was ≤ 1 g/kg in all batches and hence lower than the proposed manufacturing limit of 5 g/kg. The content of the relevant impurity tetramethyl pyrophosphorothioate (TMPP) was ≤ 1 g/kg in all batches and hence lower than the proposed manufacturing limit of 3 g/kg.

Fenitrothion is a phosphorothionate and other compounds of this type are known to have the potential to undergo internal transesterification in storage to form a potentially more toxic S-alkyl isomer. S-methyl fenitrothion is not an impurity carried forward from one of the raw materials, due to the design and steps involved in the manufacturing process which is used in the production of fenitrothion TC. S-methyl fenitrothion can increase in concentration during storage of fenitrothion TC or formulations in the presence of compounds such as anionic surfactants and at elevated temperatures.

A small increase in S-methyl fenitrothion concentration was found in the formulations after the accelerated storage test at 54°C for 14 days. As S-methyl fenitrothion can increase during storage, its concentration must be controlled in all formulations after the test of stability at elevated temperature. As with other organophosphorous compounds, fenitrothion shows a somewhat limited stability in the WP formulation, so the minimum content after the storage test at elevated temperature was set at 90 % which is a deviation from the default 95 % as in the Specification Manual. Fenitrothion shows a better stability in the EC, where the general limit of 95% is applicable as compared to the sample before the accelerated stability test.

The methods used to produce the data on the range of physico-chemical properties and chemical composition are all referenced CIPAC, AOAC and OECD or sufficiently validated in-house methods.

The JMPS asked the proposer to evaluate the requirement for the inclusion of clauses for water, as a relevant impurity, and pH as a physical property in the TC and formulations.

A limit for water was not included in the TC specification for the following reasons:

i) fenitrothion is not prone to hydrolysis by water and,
ii) the isolation procedure of fenitrothion in the last step of the synthesis leads to low content of water in the TC, which potentially would cause a problem in the production of oil-based formulations (EC, UL).

However, the limits for water as a relevant impurity in the WP, EC and UL specifications are required due to the possibility of water being present in the formulants and possible adverse effect of residual water on physical-chemical properties of these formulations.

The Meeting concluded that a pH range clause is not required for the TC as well, due to the sufficient hydrolytic stability of the active ingredient and low water content.

A pH range must be specified for the WP, EC and UL formulations. The rate of degradation of fenitrothion could be increased by an acidic pH of less than 3 as quoted in the specifications. Moreover hydrolysis can occur at pH greater than 9 as shown in the study HM-0094. Fenitrothion, like many other organophosphate pesticides, is hydrolysed by strong alkali.

The proposed specification for the TC was in accordance with the requirements of the FAO/WHO Manual. The proposed specifications for the WP, EC and UL were also in accordance with the requirements of the FAO/WHO Manual.

SUPPORTING INFORMATION

FOR

EVALUATION REPORT 35/2009

Uses

Fenitrothion is an insecticide, acetylcholinesterase inhibitor. It is used in agriculture, horticulture, forestry and public health against chewing and sucking insects on rice, cereals, fruits, vegetables, stored grains, cotton, etc., for agriculture and flies, mosquitoes and cockroaches in public health use.

Identity of the active ingredient

Common name

fenitrothion (BSI, E-ISO, (*m*) F-ISO, ESA, BAN)

Synonyms

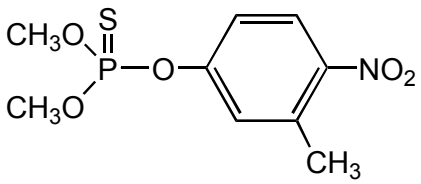
sumithion, MEP

Chemical names

IUPAC: *O*,*O*-dimethyl *O*-4-nitro-*m*-tolyl phosphorothioate

CA: *O*,*O*-dimethyl *O*-(3-methyl-4-nitro-phenyl) phosphorothioate

Structural formula



Molecular formula

$C_9H_{12}NO_5PS$

Relative molecular mass

277.25

CAS Registry number

112-14-5

CIPAC number

35

Identity tests

HPLC retention time, IR spectrum.

Physico-chemical properties of fenitrothion

Table 1. Physico-chemical properties of pure fenitrothion

Parameter	Value(s) and conditions	Purity %	Method reference and study number
Vapour pressure	1.48×10^{-4} Pa at 10°C 6.76×10^{-4} Pa at 20°C 1.57×10^{-3} Pa at 25°C (interpolated) 3.39×10^{-3} Pa at 30°C	99.1%	EPA 830.7950 / OECD 104 / EEC A.4 (HP-0136)
Melting point, boiling point and/or temperature of decomposition	Melting point: -1°C - +1°C	99.2%	OECD 102 / EEC A.1 (HP-0140)
	Boiling point: fenitrothion began to decompose at around 210°C and it was impossible to determine the boiling point. Decomposition temperature: around 210°C	99.1%	OECD 103 (HP-0133)
Solubility in water	19.0 mg/L at 20 ± 0.5 °C (in distilled water)	99.1%	OECD 105 (HP-0137)
Octanol/water partition coefficient	Log Pow = 3.319 ± 0.080 at 25°C	99.3%	OECD 107 (HP-0145)
Hydrolysis characteristics	Half-life = 100-101 days at 25 ± 1°C at pH 9 Half-life = 180-186 days at 25 ± 1°C at pH 7 Half-life = 191-200 days at 25 ± 1°C at pH 5	>99%	EPA 161-1 (HM-0094)
Photolysis characteristics	Half-life = 3.33-3.65 days at 25 ± 1 °C at pH 5 under light condition Half-life = 70.8-140.9 days at 25 ±1°C at pH 5 under dark condition	>99%	EPA 161-2 (HM-0093)
Dissociation characteristics	Not applicable (On basis on the structure of the test material, it is not considered that the reaction of giving or receiving proton will occur in water solution containing fenitrothion)	-	-

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

The chemical composition of the TC, the methods for testing it and the limits proposed for the TC, comply with the requirements of the FAO/WHO manual (March 2006 revision of the 1st edition). These data are confidential and has been evaluated, but only the summarised results are presented in the specification document supplied by Sumitomo.

Manufacturing process, maximum limits for impurities ≥1 g/kg, 5 batch analysis data	Confidential information supplied and held on file by FAO and WHO. Mass balances were 100.4-100.5%. Percentages of unknowns were 0%
Declared minimum fenitrothion content	930 g/kg
Relevant impurities ≥ 1 g/kg and maximum limits for them	S-methyl fenitrothion (*O*,*S*-dimethyl *O*-4-nitro-*m*-tolyl phosphorothiolate) Maximum limit: 5 g/kg tetramethyl pyrophosphorothioate (TMPP) Maximum limit: 3 g/kg
Relevant impurities < 1 g/kg and maximum limits for them	None
Stabilizers or other additives and maximum limits for them	None
Melting or boiling temperature range of the TC	Boiling point: fenitrothion began to decompose at around 210°C and it was impossible to determine the boiling point

Background information on toxicology / ecotoxicology

The data provided by Sumitomo outlined the toxicology (acute, irritation and sensitization and sub-acute to chronic), mutagenicity and ecotoxicological profile of the fenitrothion technical material.

Acute toxicity was low in Rats, Rabbits, Guinea Pigs, in both males and females in general toxicity and neurotoxicity terms, as shown by the LD50, LC50, NOELs and NOAELs. The Hershberger assay in Rats showed no anti-androgenicity or androgenicity.

Fenitrothion is unlikely to pose a carcinogenic risk to humans.

Fenitrothion was not genotoxic in a range of studies *in vitro* and *in vivo*.

Fenitrothion is not persistent in soil and leaching is not significant. Therefore there is negligible risk to following crops or of groundwater contamination. Volatilization is a significant dissipative process in the environment although, once in the vapour phase, fenitrothion is short-lived. Transport to surface water via spray drift poses a risk to aquatic species, although the duration of exposure is brief because fenitrothion dissipates in microbially active natural water systems with a half-life of less than one week. The compound will also tend to migrate to sediment.

Health risks for avian and mammalian species following the consumption of treated vegetation, grain and contaminated insects are likely to be low. The low long-term risk to insectivorous species and birds grazing on treated grassland is not likely to arise due to:

(i) the high acute toxicity of fenitrothion to insects, preventing residue build-up in this food source;

(ii) the generally low persistence of fenitrothion in the environment; and

(iii) the rapid decline of residues in species forming the diet.

Aquatic organisms (fish and invertebrates) are potentially at risk, especially in the event of overspray to static water bodies. However buffer zones appropriate to each crop and monitoring wind direction to prevent spray drift should ensure that aqueous concentrations remain below the environmentally acceptable concentrations even in the event of multiple applications. Although fenitrothion is fat-soluble, the rates of biotransformation and excretion of metabolites largely mitigate bioconcentration. Label warnings are intended to minimise the risks to fish.

The risks to algal species, earthworms, soil micro-organisms and sewage bacteria are considered to be low, even in worst-case scenarios, without taking into consideration the rapid dissipation processes that occur in the environment.

Fenitrothion is extremely toxic to honeybees and highly toxic to non-target arthropods. However, it does not have growth inhibitory activity and the effects of treatment are relatively short-lived. Most beneficial insect populations would recover quite rapidly. Label warnings are intended to minimise the risks to honeybees.

Soil microbiological processes are generally unaffected by use of fenitrothion on agricultural land.

It is used in agriculture and for public health use.

An acceptable daily intake (ADI) of 0-0.005 mg/kg body weight was established in 2000. The IPCS hazard classification of fenitrothion is: moderately hazardous, class II.

Formulations and co-formulated active ingredients

The main formulation types available are EC, WP and UL.

Fenitrothion is not co-formulated with other pesticides in UL and WP formulations.

These UL and WP formulations are registered and sold in Saudi Arabia, Sri Lanka, Thailand, Malaysia, Vietnam, Brazil, Australia, Argentina, Colombia and Venezuela.

Methods of analysis and testing

The previous analytical method for the active ingredient (including identity tests) was Sumitomo Chemical, 1983, HA-0139. The fenitrothion is determined by GC on a 3% Polyphenyl ether (7 Rings) / Chromosorb W (HP, 80-100 mesh) column with FID and with internal standardisation using fluorenthene. The CIPAC method was been adopted as a GC method on packed column.

A new method for fenitrothion, based on HPLC and external standardisation, is used by Sumitomo and are the methods referred to in the specifications for fenitrothion products.

The methods used for the determination of relevant (toxicologically significant) impurities are:

(i) S-methyl fenitrothion, which is based on normal phase HPLC using a µBondapak CN column with UV detection at 254 nm.

(ii) TMPP, which is based on capillary GC using a DB1 column with FID detection and an internal standard.

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

Physical and chemical properties of formulations

The physical properties, the methods for testing them and the limits proposed for the EC, WP and UL formulations, comply with the requirements of the FAO/WHO manual (March 2006 revision of the 1st edition). These results are presented as determined or calculated values in the supporting documents supplied by Sumitomo as shown in the reference section.

Containers and packaging

No special requirements for containers and packing have been identified.

Expression of the active ingredient

The active ingredient is expressed as fenitrothion, in g/kg or alternatively for liquid formulated products, in g/l. In case of dispute, the analytical result is expressed as g/kg.

ANNEX 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER

Notes:

(i) The proposer confirmed that the toxicological and ecotoxicological data included in the summary below were derived from fenitrothion 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.

Notes:

Acute toxicity was low in Rats, Rabbits, Guinea Pigs, in both males and females in general toxicity and neurotoxicity terms, as shown by the LD50, LC50. NOELs and NOAELs. The Hershberger assay in Rats showed no anti-androgenicity or androgenicity.

Fenitrothion is unlikely to pose a carcinogenic risk to humans.

Fenitrothion was not genotoxic in a range of studies *in vitro* and *in vivo*.

Table A. Toxicology profile of the fenitrothion technical material, based on acute toxicity, irritation and sensitization

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study numbe
Rats, male & female	Acute oral	96.6%	Dose levels: 600, 1000, 1400, 1800, 2200, 2600, 3000 mg/kg	LD_{50} = 1700 mg/kg bw for male, 1720 mg/kg bw for female	HT-0353
Rats, male & female	Acute dermal	97.2%	Dose levels: 310, 625, 1250, 2500, 5000 mg/kg	LD_{50} = 890 mg/kg bw for male, 1200 mg/kg bw for female	HT-0187
Rats, male & female	Acute inhalation	96.6%	4 hours whole body exposure, Dose levels: 3.91, 8.90, 38.2, 1010, 2210 mg/m^3	LC_{50} = >2210 mg/m^3 for male, >2210mg/m^3 for female	HT-0352
Rabbits, male & female	Skin irritation	96.5%	Dose levels: 0.5 ml	Negative	HT-0201
Rabbits, male & female	Eye irritation	96.5%	Dose levels: 0.5 ml	Unwashed: Minimal Washed: Negative	HT-0201
Guinea pigs	Skin sensitization	97.2%	Landsteiner-Draize's method	Negative	HT-0181
Rats	Acute neurotoxicity	94.3%	Dose levels: 12.5, 50, 200mg/kg for males, 50, 200, 800mg/kg for female	NOAEL: 12.5 mg/kg/day for male, not demonstrated for female	HT-0512

Table B. Toxicology profile of the technical material based on repeated administration (sub-acute to chronic)

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Rats, male & female	Subacute feeding toxicity	Unknown	6 months Dose levels: 10, 30, 150 ppm	NOAEL:10 ppm (0.59 mg/kg/day for males, 0.64 mg/kg/day for females)	HT-0538
Rats, male & female	Subacute feeding neurotoxicity	94.3%	3 months Dose levels: 6, 20, 60, 200 ppm	General toxicity NOAEL: 20 ppm (1.32 mg/kg/day for males, 1.56 mg/kg/day for females) Neurotoxicity NOAEL: 200 ppm (13.8 mg/kg/day) for males, 60 ppm (4.85 mg/kg/day) for females	HT-0520
Dogs, male & female	Subacute feeding toxicity	96.8%	1 year Dose levels: 5, 10, 50 ppm	NOEL: 10 ppm NOAEL: 50 ppm (1.57 mg/kg/day for males, 1.59 mg/kg/day for females)	HT-0374
Rabbits, male & female	Subacute dermal toxicity	93.7%	21 days Dose levels: 3, 10, 50, 250 mg/kg/day	NOEL (local): <3 mg/kg/day NOAEL (systemic): 3 mg/kg/day	HT-0488

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Rats, male & female	Chronic feeding toxicity	97.2%	92 weeks Dose levels: 2.5, 5, 10 ppm	NOEL:5 ppm (0.270 mg/kg/day for males, 0.283 mg/kg/day for females) NOAEL:10 ppm (0.487 mg/kg/day for males, 0.598 mg/kg/day for females)	HT-0001 HT-1001
Rats, male & female	Chronic feeding toxicity and carcinogenicity	97.0%	2 years Dose levels: 10, 30, 100 ppm	NOEL & NOAEL: 10 ppm (0.5 mg/kg/day) Carcinogenicity: not carcinogenic	HT-0006 HT-0193 HT-0194
Rats, male & female	2 generation reproduction, feeding	94.6%	Dose levels: 10, 40 or 120 ppm	Parental NOAEL: 10 ppm (0.7 mg/kg/day) Pup NOAEL: 40 ppm (2.3-5.4 mg/kg/day) Reproduction NOAEL: 120 ppm (7.4-15.2 mg/kg/day)	HT-0452 HT-0513
Rats, male & female	Teratogenicity and embryotoxicity, oral	96.6%	Dose levels: 3, 8 or 25 mg/kg/day	Maternal NOAEL: 8 mg/kg/day Developmental NOAEL: 25 mg/kg/day Teratogenicity: not teratogenic	HT-0382
Rabbits, male & female	Teratogenicity and embryotoxicity, oral	96.6%	Dose levels: 3, 10 or 30 mg/kg/day	Maternal NOAEL: 10 mg/kg/day Developmental NOAEL: 30 mg/kg/day Teratogenicity: not teratogenic	HT-0367
Rat	Hershberger assay	99.7%	Dose levels: 0.75, 1.5 or 3 mg/kg daily for 5 days	No antiandrogenicity No androgenicity	HT-0551

Table C. Mutagenicity profile of the technical material based on *in vitro* and *in vivo* tests

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Salmonella typhimurium (TA1535, TA1537, TA1538) *Escherichia coli* (W3102)	Reverse mutation	98.5%	10, 100, 1000 (with and without metabolic activation), 10000 (without metabolic activation) μg/plate or 0, 10, 100, 1000 μg/ml	Negative	HT-0142
Salmonella typhimurium (TA100, TA100 nit$^-$, TA98, TA98 nit$^-$)	Reverse mutation	96.8%	10, 100, 1000 (for technical), 0, 100, 500, 1000, 2000 (for purified) μg/plate, with and without S9 mix	Slightly mutagenic in TA100 strain but not in TA100 nit$^-$ strain.	HT-0259
Salmonella typhimurium (TA100, TA98, TA1535, TA1537, TA100NR, TA100 1,8-DNP$_6$) *Escherichia coli* (WP2*uvr*A)	Reverse mutation	94.7%	100, 200, 500, 1000, 2000 or 5000 μg/plate, with and without S9 mix	Slightly mutagenic in TA100 strain but not in TA100 NR strain.	HT-0431
Bacillus subtilis (H17, M45 rec$^-$) *Escherichia coli* (W-3623 *pol* A$^-$, *uvr* A$^-$, *rec* A$^-$, wild type) *Salmonella typhimurium* (TA1538 *uvr*B$^-$, TA1978)	Rec-assay	98.5%	10, 100, 1000 or 10000 μg/disk, without metabolic activation	Negative	HT-0142
The host: Male ICR mouse The indicator organism: *Salmonella typhimurium* G46	Host-mediated assay	98.5%	100 or 200 mg/kg	Negative	HT-0142
Chinese hamster ovary cells (CHO-K1)	*In vitro* chromosomal aberration	96.7%	75, 150 or 300 μg/ml (+S9, 2 +14 and 2+22 h) 0, 3, 10 or 30 μg/ml (-S9 8, 16 and 24 h)	Negative	HT-0420
Chinese hamster lung cells (V79)	Mammalian cel gene mutation	94.7%	10^{-5}, $3x10^{-5}$, 10^{-4} or $3x10^{-4}$ M, with and without S9 mix	Negative	HT-0387
Mouse embryo primary cultured cell	Sister chromatid exchange	98.6%	10^{-5}, $5x10^{-5}$or 10^{-4} M	Negative	HT-0208
Male ICR mice	*In vivo* chromosomal aberration	96.8%	200, 400 or 800 mg/kg (6, 24 and 48 h)	Negative	HT-0235
Male Sprague-Dawley rats	*In vivo* chromosomal aberration	96.8%	100, 200 or 400 mg/kg (6, 24 and 48 h) 20, 40 or 80 mg/kg x 5 (24 h interval, sacrificed 6h after the last dose)	Negative	HT-0258
Male ICR mice	Micronucleus test	96.8%	200, 400, 800 or 1600 mg/kg (24 h)	Negative	HT-0234

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Male Sprague-Dawley rat hepatocytes	*In vivo / in vitro* unscheduled DNA synthesis	94.3%、94.5%	300 mg/kg (3, 12 and 24 h)	Negative	HT-0444
Male ICR mice and male Sprague-Dawley rats	Dominant lethal assay	98.5%	20 or 200 mg/kg (mouse) and 0, 2, 7 or 20 mg/kg (rat) daily for 5 days	Negative	HT-0210

Table D. Ecotoxicology profile of the technical material

Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Daphnia magna (48 hours)	Acute toxicity to aquatic invertebrates (*Daphnia*)	94.5%	0, 0.0020, 0.0043, 0.010, 0.020, 0.040, 0.084, 0.180 and 0.340 mg/l (Measured)	EC_{50} (48 hour): 0.0086 mg/l NOEC (48 hour): < 0.002 mg/l	HW-0328
Rainbow trout *Salmo gairdneri* (96 hours)	Acute toxicity to fish	94.5%	0, 0.26, 0.44, 0.86, 2.0 and 7.0 mg/l (Measured)	LC_{50} (96 hour): 1.3 mg/l NOEC (96 hour): 0.44 mg/l	HW-0329
Bluegill sunfish *Lepomis macrochirus* (96 hours)	Acute toxicity to fish	94.5%	0, 1.0, 0.38, 0.69, 1.2 and 6.4 mg/l (Measured)	LC_{50} (96 hour): 2.5 mg/l NOEC (96 hour): 0.69 mg/l	HW-0330
Selenastrum capricornutum (96 hours)	Effects on algal growth	94.5%	0, 0.24, 0.61, 0.92, 1.9 and 4.8 mg/l (Measured)	EC_{50} (96 hour): 1.3 mg/l NOEC (96 hour): 0.61 mg/l	HW-0327
Honey bee	Acute oral to bee	94.6%	0, 0.021, 0.047, 0.10, 0.23 and 0.50 µg a.s./bee	LD_{50} (48 hours): 0.20 µg a.s./bee	HW-0481
Honey bee	Acute contact to bee	94.6%	0, 0.063, 0.13, 0.25, 0.50 and 1.0 µg a.s./bee	LD_{50} (48 hours): 0.16 µg a.s./bee	HW-0481
Mallard duck	Acute oral toxicity	94.5%	0, 65, 129, 259, 517 and 1034 mg/kg b.w.	LD_{50}: > 1034 mg/kg b.w. NOEL: 129 mg/kg b.w.	HW-0243
Bobwhite quail	Acute oral toxicity	94.5%	0, 16, 32, 65, 129 and 259 mg/kg b.w.	LD_{50}: 23 mg/kg b.w. NOEL: < 16 mg/kg b.w.	HW-0242
Mallard duck	Short-term dietary toxicity	94.5%	0, 313, 625, 1250, 2500 and 5000 ppm	LC_{50}: 1773 ppm NOEC: < 313 ppm	HW-0255
Bobwhite quail	Short-term dietary toxicity	94.5%	0, 39, 78, 156, 313 and 625 ppm	LC_{50}: 126 ppm NOEC: 39 ppm	HW-0254

ANNEX 2

REFERENCES

Author and year or study number	Study title. Study identification number. Report identification number. Company conducting the study.
Sumitomo Chemical Co. Ltd, 10/2006	FAO/WHO Specifications for Pesticides – Proposers (Sumitomo's) completed template with (i) Manufacturing Process and batch test details (Confidential) & (ii) specifications including physico-chemical properties, toxicological summaries, comments & references (Non-confidential)
Sumitomo Chemical Co. Ltd, 03/2007	Proposers (Sumitomo's) specifications - Fenitrothion TC, EC, WP and UL and methods of analysis – March 2007 updated version of October 2006 specifications
Sumitomo Chemical Co. Ltd, 04/2009	Proposers (Sumitomo's) specifications - Fenitrothion TC, EC, WP and UL and methods of analysis – April 2009 updated version of march 2007 specifications
CIPAC 1980	CIPAC Handbook 1A - Analysis of Technical and Formulated Pesticides
CIPAC 1985	CIPAC Handbook 1C - Analysis of Technical and Formulated Pesticides
BCPC – Ed C Tomlin 2002-2003	The e-Pesticide Manual (Twelfth Edition) Version 2.2 (British Crop Protection Council)
RSC, Roberts, T. et al 1999	Metabolic Pathway of Agrochemicals Pt 2 Insecticides and Fungicides Pages 314-325
Report No. HP-0136	Fenitrothion -Vapour Pressure Sumitomo Chemical Co., Ltd.
Report No. HP-0140	Fenitrothion: Determination of the physico-chemical properties Sumitomo Chemical Co., Ltd.
Report No. HP-0133	Determination of boiling point of fenitrothion Sumitomo Chemical Co., Ltd.
Report No. HP-0137	Solubility of fenitrothion in water Sumitomo Chemical Co., Ltd.
Report No. HP-0145	Partition coefficient (n-octanol;water – $K_{o/w}$) of [14C] fenitrothion Sumitomo Chemical Co., Ltd.
Report No. HM-0094	Hydrolysis of fenitrothion in water as a function of pH at 25°C Sumitomo Chemical Co., Ltd.
Report No. HM-0093	Photodegradation of fenitrothion in water Sumitomo Chemical Co., Ltd.
Report No. HT-0353	Acute oral toxicity of Sumithion in rats Sumitomo Chemical Co., Ltd.
Report No. HT-0187	Acute oral, subcutaneous and dermal toxicities of Sumithion technical in mice and rats Sumitomo Chemical Co., Ltd.
Report No. HT-0352	Acute inhalation toxicity of Sumithion in rats Sumitomo Chemical Co., Ltd.
Report No. HT-0201	Primary eye and skin irritation tests of Sumithion^{R} technical in rabbits Sumitomo Chemical Co., Ltd.
Report No. HT-0181	Skin sensitization test of Sumithion technical in guinea pigs Sumitomo Chemical Co., Ltd.
Report No. HT-0512	An acute study of the potential effects of orally administered fenitrothion on behavior and neuromorphology in rats Sumitomo Chemical Co., Ltd.
Report No. HT-0538	Six month feeding study of Sumithion, Sumioxon and p-nitrocresol in rats Sumitomo Chemical Co., Ltd.
Report No. HT-0520	A 3-month dietary study of the potential effects of fenitrothion on behavior, neurochemistry and neuromorphology in rats Sumitomo Chemical Co., Ltd.
Report No. HT-0374	One year dietary toxicity study in dogs Sumitomo Chemical Co., Ltd.

Author and year or study number	Study title. Study identification number. Report identification number. Company conducting the study.
Report No. HT-0488	21-day dermal toxicity study in rabbits with Sumithion T.G. Sumitomo Chemical Co., Ltd.
Report No. HT-0001	Ninety-two week feeding study of Sumithion in rats with special reference to cholinesterase activity Sumitomo Chemical Co., Ltd.
Report No. HT-1001	Sumithion: 92-week feeding study: Individual data Sumitomo Chemical Co., Ltd.
Report No. HT-0006	Two-year dietary administration in the rat Sumitomo Chemical Co., Ltd.
Report No. HT-0193	104-week chronic administration in rats Project No. 343-107:Individual animal data Volume I Sumitomo Chemical Co., Ltd.
Report No. HT-0194	104-week chronic administration in rats Project No. 343-107: Individual histopathology findings Sumitomo Chemical Co., Ltd.
Report No. HT-0452	Reproductive effects of Sumithion administered orally in feed to Crl:CD®(SD)BR rats for two generations Sumitomo Chemical Co., Ltd.
Report No. HT-0513	Reproductive effects of Sumithion administered orally in feed to Crl:CD®(SD)BR rats for two generations Sumitomo Chemical Co., Ltd.
Report No. HT-0382	Teratology study in rats with Sumithion Sumitomo Chemical Co., Ltd.
Report No. HT-0367	Teratology study in rabbits Sumitomo Chemical Co., Ltd.
Report No. HT-0551	Evaluation of a 5-day Hershberger assay using young mature male rats: methyltestosterone and *p,p'*-DDE, but not fenitrothion, exhibited androgenic or antiandrogenic activity *in vivo*. J. Toxicol. Sci. 25, (5), 403-415
Report No. HT-0142	Studies on mutagenicity of Sumithion^{R} with bacterial systems Sumitomo Chemical Co., Ltd.
Report No. HT-0259	Mutagenicity tests of Sumithion with nitroreductase-defective bacteria Sumitomo Chemical Co., Ltd.
Hara, M. *et al*., 1989	Mutagenicity studies on fenitrothion in bacteria and mammalian cells Mutation Research, 222, 53-61, Report No. HT-0431
Report No. HT-0420	*In vitro* chromosomal aberration test of Sumithion in Chinese hamster ovary cells (CHO-K1) in culture Sumitomo Chemical Co., Ltd.
Report No. HT-0387	*In vitro* gene mutation test of Sumithion in V79 Chinese hamster cells in culture Sumitomo Chemical Co., Ltd.
Report No. HT-0208	Effects of fenitrothion on sister chromatid exchanges (SCE) in cultured mouse embryo cells Sumitomo Chemical Co., Ltd.
Report No. HT-0235	*In vivo* chromosomal aberration test of Sumithion^{R} on bone marrow cells of mice Sumitomo Chemical Co., Ltd.
Report No. HT-0258	*In vivo* chromosomal aberration test of Sumithion^{R} on bone marrow cells of rats Sumitomo Chemical Co., Ltd.
Report No. HT-0234	The micronucleus test of Sumithion^{R} Sumitomo Chemical Co., Ltd.
Report No. HT-0444	*In vivo*/*in vitro* unscheduled DNA synthesis (UDS) test of Sumithion in rat hepatocytes Sumitomo Chemical Co., Ltd.
Report No. HT-0210	Dominant lethal test of Sumithion in rats and mice Sumitomo Chemical Co., Ltd.

Author and year or study number	Study title. Study identification number. Report identification number. Company conducting the study.
Report No. HW-0328	Acute toxicity of fenitrothion to *Daphnia magna* Sumitomo Chemical Co., Ltd.
Report No. HW-0329	Acute flow-through toxicity of fenitrothion to rainbow trout (*Salmo gairdneri*) Sumitomo Chemical Co., Ltd.
Report No. HW-0330	Acute flow-through toxicity of fenitrothion to bluegill sunfish (*Lepomis macrochirus*) Sumitomo Chemical Co., Ltd.
Report No. HW-0327	Acute toxicity of fenitrothion to *Selenastrum capricornutum* Prinz Sumitomo Chemical Co., Ltd.
Report No. HW-0481	Fenitrothion -Acute contact and oral toxicity tests with honey bees (*Apis mellifera*) Sumitomo Chemical Co., Ltd.
Report No. HW-0481	Fenitrothion -Acute contact and oral toxicity tests with honey bees (*Apis mellifera*) Sumitomo Chemical Co., Ltd.
Report No. HW-0243	Sumithion technical grade: An acute oral toxicity study with the mallard Sumitomo Chemical Co., Ltd.
Report No. HW-0242	Sumithion technical grade: An acute oral toxicity study with the bobwhite Sumitomo Chemical Co., Ltd.
Report No. HW-0255	Sumithion technical grade: A dietary LC_{50} study with the mallard Sumitomo Chemical Co., Ltd.
Report No. HW-0254	Sumithion technical grade: A dietary LC_{50} study with the bobwhite Sumitomo Chemical Co., Ltd.
Report No. HA-0139	Analysis of the composition of Sumithion technical grade Sumitomo Chemical Co., Ltd.
APVMA March 2007	Comparison of Manufacturing Process, Quality control, specifications and batch analyses information for fenitrothion active constituent submitted to WHO with the information submitted to APVMA (Australian Pesticides and Veterinary Medicines Authority)
Sumitomo Chemical, 9/10/2007, revised 30/04/2008	Proposers reply to the JMPS evaluation questions on the Fenitrothion data submission, both the confidential and non-confidential sections, from JMPS 2007 Closed Meeting
Mikami, N., *et. al.*, 1977	Toxicity Study of S-methylfenitrothion
Toia, R.F., *et. al.,* 1980	Identification and Toxicological Evaluation of Impurities in Technical Malathion and Fenthion
Sumitomo Chemical, 2008	Method of Analysis of the composition (Fenitrothion content) of Sumithion TC and formulations by HPLC, Sumitomo Chemical Co., Ltd. Report No. CIPAC/4602/m
Sumitomo Chemical, 2008	CIPAC Collaborative Trial of the analysis of Fenitrothion in TC and Formulations by HPLC, Sumitomo Chemical Co., Ltd. Report No. CIPAC/4603/R
Sumitomo Chemical, 2007	Method of Analysis of the S-Methyl fenitrothion content of Sumithion TC and formulations by HPLC, Sumitomo Chemical Co., Ltd. Report No. CIPAC/4545/m
Sumitomo Chemical, 2007	CIPAC Peer Validation of the determination of S–methyl fenitrothion in Fenitrothion Technical and Formulations by HPLC Sumitomo Chemical Co., Ltd. Report No. CIPAC/4547/R
Sumitomo Chemical, 2009	Method of analysis of TMPP content of Sumithion TC and formulations by GC, Sumitomo Chemical Co., Ltd. Report No. CIPAC /4660/m
Sumitomo Chemical, 2009	CIPAC Peer Validation of the analysis of TMPP by GC, Sumitomo Chemical Co., Ltd. Report No. CIPAC/4661/R