Food and Agriculture Organization
of the United Nations

FAO SPECIFICATIONS AND EVALUATIONS

FOR PLANT PROTECTION PRODUCTS

PARATHION-METHYL

O,O-dimethyl O-4-nitrophenyl phosphorothioate

2001

TABLE OF CONTENTS

PARATHION-METHYL

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FAO specifications are developed with the basic objective of ensuring that pesticides complying with them are satisfactory for the purpose for which they are intended so that they may serve as an international point of reference. The specifications do not constitute an endorsement or warranty of the use of a particular pesticide for a particular purpose. Neither do they constitute a warranty that pesticides complying with these specifications are suitable for the control of any given pest, or for use in a particular area. Owing to the complexity of the problems involved, the suitability of pesticides for a particular application must be decided at the national or provincial level.

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INTRODUCTION

FAO establishes and publishes specifications* for technical material and related formulations of plant protection products 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 Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent."
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 Panel of Experts. 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 not necessarily apply to nominally similar products of other manufacturer(s), nor to those where the active ingredient is produced by other methods of synthesis. FAO has the possibility to extend the scope of the specifications to similar products, but only when the Panel of Experts has been satisfied that the additional products are equivalent to those which formed the basis of the reference specification.

* Footnote: The publications are available on the Internet under (http://www.fao.org/pest-and-pesticide-management/en/) or as hardcopy from the Plant Protection Information Officer.

PART ONE

SPECIFICATIONS

PARATHION-METHYL

PARATHION-METHYL TECHNICAL MATERIAL **(Note 1)**

FAO Specification 487/TC (2001)

*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 (*487/2001*). It should be applicable to relevant products of 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 the products of other manufacturers. The evaluation report (*487/2001*) as PART TWO forms an integral part of this publication.*

1 Description

The material shall consist of parathion-methyl together with related manufacturing impurities and shall be in the form of tan-coloured amorphous lumps, free from visible extraneous matter and added modifying agents (Note 2).

2 Active ingredient

2.1 **Identity tests** (10.a/TC/(M1)/2, CIPAC 1B, p. 1879, or 10.a /TC/(M2)/2, CIPAC 1B, p. 1881)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test (Note 3).

2.2 **Parathion-methyl content** (10.a/TC/(M1)/2, CIPAC 1B, p. 1879, or 10.a /TC/(M2)/2, CIPAC 1B, p. 1881)

The parathion-methyl content shall be declared (not less than 950 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

3 Relevant impurities

3.1 **Paraoxon-methyl** (CAS No. 950-35-6, phosphoric acid, dimethyl 4-nitrophenyl ester) (Note 3)

Maximum: 1 g/kg.

3.2 **S-methyl-parathion-methyl** (CAS No. 597-89-7, phosphorothioic acid, *O*,*S*-dimethyl *O*-(4-nitrophenyl) ester) (Note 3)

Maximum: 15 g/kg.

3.3 **Parathion** (CAS No. 56-38-2, Phosphorothioic acid, *O*,*O*-diethyl *O*-(4-nitrophenyl) ester) (Note 3)

Maximum: 3 g/kg.

Note 1 International trade of certain formulations of parathion-methyl is subject to the provisions of the Rotterdam Convention on Prior Informed Consent (PIC).

Note 2 The technical material tends to set to a solid of melting point about 29°C. It must be heated to melting point before formulating. A suitable temperature is 55°C, maintained on a water bath for example. **Technical parathion-methyl may explode violently if heated above 100°C**. Accordingly, local overheating **must** be avoided.

Note 3 The analytical method (Cheminova analytical method AM 448) is available from the Pesticide Management Group, Plant Production and Protection Division, FAO, Viale delle Terme di Caracalla, 00100Rome, Italy, fax 0039 06-5705-6347. Alternatively, S-methyl-parathion-methyl may be determined by the draft CIPAC method (CIPAC handbook E, 1993, p 169).

PARATHION-METHYL TECHNICAL CONCENTRATE (Note 1)

FAO Specification 487/TK (2001)

*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 (*487/2001*). It should be applicable to relevant products of 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 the products of other manufacturers. The evaluation report (*487/2001*) as PART TWO forms an integral part of this publication.*

1 Description

The material shall consist of parathion-methyl together with related manufacturing impurities and shall be a light to dark tan-coloured liquid at temperatures above the congelation point (Notes 2 and 3), free from visible extraneous matter and added modifying agents except for the diluent.

2 Active ingredient

2.1 **Identity tests** (10.a/TC/(M1)/2, CIPAC 1B, p. 1879, or 10.a /TC/(M2)/2, CIPAC 1B, p. 1881)

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 **Parathion-methyl content** (10.a/TC/(M1)/2, CIPAC 1B, p. 1879, or 10.a /TC/(M2)/2, CIPAC 1B, p. 1881)

The parathion-methyl content shall be declared (g/kg or g/l at 20 ± 2°C) and, when determined, the mean measured content shall not differ from that declared by more then the FAO proposed tolerance as given below (Note 4):

Declared content in g/kg, or g/l at 20 ± 2°C	**Tolerance**
Above 500	± 25 g/kg, or g/l at 20 ± 2°C

3 Relevant impurities

3.1 **Paraoxon-methyl** (CAS No. 950-35-6, phosphoric acid, dimethyl 4-nitrophenyl ester) (Note 5)

Maximum: 0.1% of the parathion-methyl content found under 2.2.

3.2 **S-methyl-parathion-methyl** (CAS No. 597-89-7, phosphorothioic acid, *O*,*S*-dimethyl *O*-(4-nitrophenyl) ester) (Note 5)

Maximum: 2% of the parathion-methyl content found under 2.2.

3.3 **Parathion** (Note 5)

Maximum: 0.3% of the parathion-methyl content found under 2.2.

Note 1 International trade of certain formulations of parathion-methyl is subject to the provisions of the Rotterdam Convention on Prior Informed Consent (PIC).

Note 2 The congelation temperature range should be nominated.

Note 3 **Parathion-methyl may explode violently if heated above 100°C**. Stored under cold conditions, however, parathion-methyl will crystallize out from the concentrate, forming a hard cake. In order to reconstitute the technical concentrate, the product must be heated above the crystallization temperature and stirred to achieve a uniform material. A suitable temperature for this purpose is 55°C, maintained on a water bath for example. Local overheating **must** be avoided. It should be noted that it is not sufficient merely to liquefy the crystallized material.

Note 4 If the buyer requires both g/kg and g/l at 20ºC, then in case of dispute the analytical results shall be calculated as g/kg.

Note 5 The analytical method (Cheminova analytical method AM 448) is available from the Pesticide Management Group, Plant Production and Protection Division, FAO, Viale delle Terme di Caracalla, 00100Rome, Italy, fax 0039 06-5705-6347. Alternatively, S-methyl-parathion-methyl may be determined by the draft CIPAC method (CIPAC handbook E, 1993, p 169).

PARATHION-METHYL EMULSIFIABLE CONCENTRATE (Note 1)

FAO Specification 487/EC (2001)

*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 (*487/2001*). It should be applicable to relevant products of 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 the products of other manufacturers. The evaluation report (*487/2001*) as PART TWO forms an integral part of this publication.*

1 Description

The material shall consist of technical parathion-methyl, complying with the requirements of FAO draft specification 487/TC (2001), 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** (10.a/TC/(M1)/2, CIPAC 1B, p. 1884, or 10.a/TC/(M2)/2, CIPAC 1B, p. 1884)

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 **Parathion-methyl content** (10.a/TC/(M1)/2, CIPAC 1B, p. 1884, or 10.a/TC/(M2)/2, CIPAC 1B, p. 1884)

The parathion-methyl content shall be declared (g/kg or g/l at 20 ± 2°C) and, when determined, the mean measured content shall not differ from that declared by more then the FAO proposed tolerance as given below (Note 2):

Declared content in g/kg, or g/l at 20 ± 2°C	**Tolerance**
above 100 up to 250	± 6% of the declared content
above 250 up to 500	± 5% of the declared content
Note: In each range, the upper limit is included	

3 Relevant impurities

3.1 **Paraoxon-methyl** (CAS No. 950-35-6, phosphoric acid, dimethyl 4-nitrophenyl ester) (Note 3)

Maximum: 0.1% of the parathion-methyl content found under 2.2.

3.2 **S-methyl-parathion-methyl** (CAS No. 597-89-7, phosphorothioic acid, *O*,*S*-dimethyl *O*-(4-nitrophenyl) ester) (Note 3)

Maximum: 2% of the parathion-methyl content found under 2.2.

3.3 **Parathion** (Note 3)

Maximum: 0.3% of the parathion-methyl content found under 2.2.

4 Physical properties

4.1 **Emulsion stability and re-emulsification** (MT 36.1.1, CIPAC F, p. 108, standard water MT: 18.1, CIPAC F, p. 59) (Note 4)

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, MT 36.1
0 h	Initial emulsification complete
0.5 h	"Cream", maximum: 2 ml
2.0 h	"Cream", maximum: 4 ml "Free oil", maximum: nil
24 h	Re-emulsification complete
24.5 h	"Cream", maximum: 4 ml "Free oil", maximum: 0.5 ml
Note: tests after 24 h are required only where results at 2 h are in doubt	

4.2 **Persistent foam** (MT 47.2, CIPAC F, p. 152 (Note 5)

Maximum: 25 ml after 1 minute.

5 Storage stability

5.1 **Stability at 0 ºC** (MT 39.3, CIPAC F, p. 128)

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

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

After storage at 54 ± 2ºC for 14 days, the determined active ingredient shall not be lower than the determined average content found before storage (Note 6) and the formulation shall continue to comply with the clauses for:

- S-methyl-parathion-methyl (3.2)

- emulsion stability and re-emulsification (4.1).

Note 1 International trade of certain formulations of parathion-methyl is subject to the provisions of the Rotterdam Convention on Prior Informed Consent (PIC).

Note 2 If the buyer requires both g/kg and g/l at 20ºC, then in case of dispute the analytical results shall be calculated as g/kg.

Note 3 The analytical method (Cheminova analytical method AM 448) is available from the Pesticide Management Group, Plant Production and Protection Division, FAO, Viale delle Terme di Caracalla, 00100Rome, Italy, fax 0039 06-5705-6347. Alternatively, S-methyl-parathion-methyl may be determined by the draft CIPAC method (CIPAC handbook E, 1993, p 169).

Note 4 This test will normally only be carried out after the heat stability test, 5.2

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

Note 6 Samples of the formulation taken before and after the storage stability should be analyzed concurrently after the test in order to reduce the analytical error.

PART TWO

EVALUATION REPORT(S)

PARATHION-METHYL

2001 Evaluation report based on submission of data from Cheminova (TC, TK, EC, CS)

FAO SPECIFICATIONS AND EVALUATIONS FOR
PLANT PROTECTION PRODUCTS

PARATHION-METHYL

EVALUATION REPORT 487/2001

Explanation

The data for parathion-methyl were evaluated in support of a review of existing FAO specifications 10.a/TC/S (1989), 10.a/TK/S (1989) and 10.a/EC/S (1989). The existing specifications 10.a/DP/S (1989), 10.a/WP/S (1989) and 10.a/OL/S (1989) were no longer supported. A new specifications was also proposed for CS (aqueous capsule suspension). It should be noted that the original CIPAC number for parathion-methyl was 10.a, which was subsequently changed to 487.

Parathion-methyl is not under patent.

Parathion-methyl had been evaluated by the FAO/WHO JMPR (most recently in 1995 for toxicology and 2000 for residues in the CCPR Periodic Review Programme) and WHO/IPCS. It is currently under review or evaluation by NRA, Australia, by the European Commission and by US EPA.

The draft specification and the supporting data were provided by Cheminova in 2000.

Uses

Parathion-methyl is a non-systemic organophosphorus insecticide and acaricide, with contact, stomach and some respiratory action. It is a cholinesterase inhibitor. Parathion-methyl is registered in many countries for control of insect pests on fruit, vegetables, ornamentals, cereals, oilseeds and forage crops.

Identity

ISO common name

Parathion-methyl (E-ISO, (m) F-ISO)

Synonyms

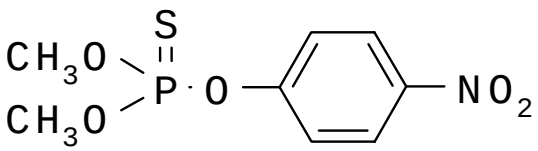
Parathion-methyl (BSI), methyl parathion (ESA, JMAF)

Chemical names

IUPAC O,O-Dimethyl O-4-nitrophenyl phosphorothioate

CA Phosphorothioic acid, O,O-dimethyl O-(4-nitrophenyl) ester

Structural formula



Molecular formula

$C_8H_{10}NO_5PS$

Relative molecular mass

263.2

CAS Registry number

298-00-0

CIPAC number

487
Note: The previous CIPAC number for parathion-methyl was 10.a, which appears in the numbering of CIPAC analysis and test methods published at the time.

Identity tests

HPLC retention time, GC retention time

Physico-chemical properties of pure parathion-methyl (*Table 1*)

Parameter	Value(s) and conditions	Purity %	Method reference
Vapour pressure	2.0×10^{-4} Pa at 20°C 4.1×10^{-4} Pa at 25°C	not stated	Tomlin, 1997 no method ref
Vapour pressure	1.33×10^{-3} Pa at 20°C	not stated	Gückel *et al,* 1982. evaporation-gravimetric
Vapour pressure	1.72 (±0.09) × 10-5 mm Hg at 25°C (=2.3×10^{-3} Pa).	not stated	JMPR, 2000 no method ref
Melting point or boiling point	Melting point: 35-36 °C	not stated	Tomlin, 1997
Temperature of decomposition	Decomposition temperature: 100-120°C Depends on time and temperature: dimethyl sulphide, sulphur dioxide and polyaryl metaphosphates are produced	99.5% or greater	McPherson and Johnson, 1956
Temperature of decomposition	Heating at 150°C for 6.5 hours resulted in 91% isomerization to S-methyl-parathion-methyl followed by generation of dimethyl sulphide, sulphur dioxides and other substances. Parathion-methyl should not be heated above 55ºC.	not stated	Information provided to JMPR 2000
Solubility in water	70.3±2.73 mg/l at 25°C in Milli-Q pure water	98.6% radio-purity ^{14}C and 99.5% unlabelled	Carpenter, 1988 ^{14}C analysis of centrifuged solution over 4 days
Octanol/water partition coefficient	log P_{OW} = 2.8 at 25±1°C	97.8% radio-purity ^{14}C and 99.5% unlabelled	Kabler, 1988 ^{14}C analysis of octanol and aqueous phases
Hydrolysis characteristics	Half-life = 68 days at 25°C at pH 5 Half-life = 40 days at 25°C at pH 7 Half-life = 33 days at 25°C at pH 9 Hydrolysis under dark, sterile conditions at initial conc. of 4 mg/l. The dominant product of acid hydrolysis was desmethyl parathion-methyl and for alkaline hydrolysis it was 4-nitrophenol. In neutral conditions, nearly equal amounts of both products were formed.	>99% radio-purity ^{14}C + 98.1% (by HPLC) unlabelled	EPA 161-1 Wilmes, 1987a HPLC analysis of solutions for 1 month
Hydrolysis characteristics	Half life = 60 days at room temp at pH 2.0 Half life = 63 days at room temp at pH 7.5 Half life = 39 days at room temp at pH 8.5 Hydrolysis rates were measured for 16 months with aqueous ethanol solutions under the influence of light and room temperature (15-31°C) at an initial concentration of 0.1 mg/ml.	not stated	Garcia-Repetto *et al*, 1994
Photolysis characteristics	Environmental half-life of about 9 days at 40 degrees latitude, with no cloud and in the top layer of water. (see more details below).	not stated	Wilmes, 1987b JMPR, 2000.
Dissociation characteristics	Does not dissociate		

Photolysis

Wilmes (1987b) used a xenon lamp to simulate the irradiation of [^{14}C-phenyl]parathion-methyl dissolved in a sterile aqueous buffer (pH 5) at a concentration of 5 mg/l at 25°C. The measured half-life for disappearance of parathion-methyl was 48 hours, equivalent to an environmental half-life of about 9 days at 40 degrees latitude with no cloud cover and in the top layer of water. The main photoproduct was *p*-nitrophenol. Paraoxon-methyl was detected in the water, accounting for up to 2% of the applied ^{14}C. In a second experiment where volatiles were collected, after 212 hours irradiation the ^{14}C accountability was: 5.9% parathion-methyl, 3.4% *O*-desmethyl-parathion-methyl, 1.6% *p*-nitrophenol, 41.7% polar compounds and 24.7% CO_2. The *O*-desmethyl-parathion-methyl was probably a product of hydrolysis rather than photolysis because it was also detected in the non-irradiated controls.

Chemical composition and properties of parathion-methyl technical material (TC and TK) (*Table 2*)

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 98.2 – 98.9% and percentages of unknowns were negligible.
Declared minimum [a.i.] content	950 g/kg
Relevant impurities ≥ 1 g/kg and maximum limits for them	paraoxon-methyl: maximum 1.2 g/kg [i.e. phosphoric acid, dimethyl 4-nitrophenyl ester] [950-35-6] S-methyl-parathion-methyl: maximum 15.0 g/kg [i.e. phosphorothioic acid, *O*,*S*-dimethyl *O*-(4-nitrophenyl) ester] [597-89-7] parathion: maximum 3.0 g/kg
Relevant impurities **<** 1 g/kg and maximum limits for them:	none
Stabilisers or other additives and maximum limits for them:	none
Melting temperature range of the TC	approx 29 °C

Toxicological summaries

Notes.

(i) The proposer confirmed that the toxicological and ecotoxicological data included in the summary below were derived from parathion-methyl having unreported or unknown impurity profiles, especially for data generated on Bayer's and Monsanto's technical parathion-methyl. The impurity profile of Cheminova's technical material used in the tests is not known exactly. However, because Cheminova production has not changed significantly during the years the proposer believes that the impurity profiles are similar to those referred to in the 5-batch analyses.

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

(iii) More than one form of the active ingredient has been used in the tests. See explanation under (i).

Table 3. Toxicology profile of parathion-methyl technical or formulated material, based on acute toxicity, irritation and sensitization.

Species	Test	Duration and conditions or guideline adopted	Result	Purity	Ref
Rat M	Oral	acute	LD_{50} = 25 mg/kg bw	80% technical	JMPR, 1995 Cuthbert and Carr, 1986a
Rat F	Oral	acute	LD_{50} = 62 mg/kg bw	80% technical	JMPR, 1995 Cuthbert and Carr, 1986a
Rat M	Dermal	acute	LD_{50} = 483 mg/kg bw	80% technical	JMPR, 1995 Cuthbert and Carr, 1986b
Rat F	Dermal	acute	LD_{50} = 481 mg/kg bw	80% technical	JMPR, 1995 Cuthbert and Carr, 1986b
Rat M	Inhalation	acute	LC_{50} = 135 mg/m^3	80% technical	JMPR, 1995 Greenough and McDonald, 1986
Rabbit MF	topical	abraded skin	NOAEL : 10 mg/kg bw/day	96.3%	JMPR, 1995
Rabbit MF	eye irritation	0.1 ml instil into eye	redness 1 hour after treatment, normal by 48 hours	80% technical	JMPR, 1995 Cuthbert and Carr, 1986d
Guinea pig F	intradermal	skin sensitization	not sensitizing	80% technical	JMPR, 1995 Cuthbert and Carr, 1986e
Rabbit	Topical	skin irritation	slightly irritating	80% technical	JMPR, 1995 Cuthbert and Carr, 1986c
Rat MF	oral gavage, neurotoxicity	single	NOAEL: 0.025 mg/kg bw	93.1% technical	JMPR, 1995 Minnema, 1994a
Hen	Intubation	2 doses at 250 (exceeds LD_{50}) and 215 mg/kg bw, 21 days between	Surviving hens recovered in about 7 days - no indications of delayed neurotoxicity	95.8%	JMPR, 1995 Beavers *et al*, 1990
Rat MF	Dermal	acute, 5 daily doses	NOAEL: 2-3 mg/kg bw/day	43.9% EC	Weiler, 1999[2]

[2] This report has not been evaluated by the FAO/WHO JMPR. The summary in the table is taken directly from the study report; it has not been subject to expert review.

Table 4. Toxicology profile of parathion-methyl technical material based on repeated administration (subacute to chronic)

Species	Test	Duration and conditions or guideline adopted	Result	Purity	Ref
Human	Oral	increasing from 14 to 20 mg over 30 days	no effect on cholinesterase activity	not reported	JMPR, 1995
Human (3x5)	Oral	4.5 mg for 30 days, followed by 5 mg for 29 days or 5.5 mg for 24 days, then 6 mg/day for 29 days or 6.5 mg/day for 35 days and finally 7 mg/day for 24 days.	no significant inhibition of plasma or erythrocyte cholinesterase activity	not reported	JMPR, 1995
Human M	Oral	up to 19 mg for 30 days	no evidence of toxicity	not reported	JMPR, 1995
Human M	Oral	24 mg/day for 4 weeks	significant inhibition of plasma and erythrocyte cholinesterase activity	not reported	JMPR, 1995
Human M (5)	Oral	3 mg for 28 days, 3.5 mg for next 28 days, 4 mg for next 43 days	no signs of toxicity, no effects on plasma or erythrocyte cholinesterase activity	not reported	JMPR, 1995
Dog MF	Oral	14 days	NOEL: 2.5 mg/kg bw/day	94.3%	JMPR, 1995
Rabbit MF	repeat dermal	21 days (6 hours/day)	NOAEL (F): 5 mg/kg bw/day	93.1%	JMPR, 1995 Goad, 1992
Dog MF	Oral	90 days	NOAEL: 1 mg/kg bw/day	94.32%	JMPR, 1995 Tegeris and Underwood, 1978
Dog MF	Oral	13 weeks	NOAEL: 0.3 mg/kg bw/day	94.9%	JMPR, 1995 Daly, 1992a
Mouse MF	Oral	91-92 days	NOAEL: 10 ppm, 1.5 mg/kg bw/day	93.65%	JMPR, 1995 Daly and Rinehart, 1980b

Species	Test	Duration and conditions or guideline adopted	Result	Purity	Ref
Rat MF	Oral	91-94 days	NOAEL: 2.5 ppm, 0.125 mg/kg bw/day	93.65%	JMPR, 1995 Daly and Rinehart, 1980a
Rat MF	Oral	13 weeks dosing + 3 weeks on untreated diet	NOEL: 5 ppm behavioural NOEL: 0.5 ppm cholinesterase activity	93.1%	Minnema, 1994b[3]
Rat MF	Dermal	13 weeks dosing at 2.5, 8 and 25 mg/kg bw (5 days/ week)+ 13 weeks recovery	cholinesterase depression at all doses no clear behavioural changes or neuropathological lesions at any dose	47.5% liquid formulation	Beyrouty, 1999[4]
Dog MF	Oral	1 year	NOAEL: 0.3 mg/kg bw/day (highest dose tested)	93.65%	JMPR, 1995 Ahmed *et al*, 1981
Dog MF	Oral	1 year dosing at 0.3, 1.0, 3.5 and 4 mg/kg bw/day	NOEL: <0.3 mg/kg bw/day cholinesterase inhibition NOEL: 1 mg/kg bw/day clinical signs	96.5%	Hatch, 1998[4]
Rat MF	Oral	1 year	NOAEL: 2.5 ppm, 0.11 mg/kg bw/day	94.6%	JMPR, 1995 Daly, 1992b
Mouse MF	Oral	2 years, carcinogenicity	NOAEL: 7 ppm, 1.6 mg/kg bw/day - no carcinogenicity	95.5%	JMPR, 1995 Eiben, 1991
Rat MF	Oral	2 years	NOAEL: 2 ppm, 0.1 mg/kg bw/day	94.8%	JMPR, 1995 Bomhard *et al*, 1981
Rat MF	Oral	2 years	NOAEL: 5 ppm, 0.25 mg/kg bw/day	93.65%	JMPR, 1995 Daly, 1983
Rabbit F	oral, FIFRA F 83-3	dosing from day 6 to day 18 of gestation	NOEL: 0.3 mg/kg bw/day cholinesterase inhibition NOEL: 9 mg/kg bw/day (highest dose) development toxicity	95.7% technical	Hoberman, 1991[4]

[3] This report has not been evaluated by the FAO/WHO JMPR. The summary in the table is taken directly from the study report; it has not been subject to expert review.

[4] This report has not been evaluated by the FAO/WHO JMPR. The summary in the table is taken directly from the study report; it has not been subject to expert review.

Species	Test	Duration and conditions or guideline adopted	Result	Purity	Ref
Rabbit F	Oral	days 6-18 gestation	NOAEL: 1 mg/kg bw/day maternal NOAEL: 3 mg/kg bw/day developmental	95.7%	JMPR, 1995 Renhof, 1984
Rat F	oral, reproductive and developmental	days 6-15 of gestation	NOAEL: 1 mg/kg bw/day	97%	JMPR, 1995 Becker *et al*, 1987
Rat F	oral, reproductive and developmental	days 6-15 of gestation	NOAEL: 0.3 mg/kg bw/day	94.4%	JMPR, 1995 Machemer, 1977
Rat MF	oral, multigeneration	repeat dose	NOAEL: 2 ppm, 0.1 mg/kg bw/day	95%	JMPR, 1995 Löser and Eiben, 1982
Rat MF	oral, 2-generation	14 weeks F_0 parents 18 weeks F_1 parents	NOAEL: 5 ppm, 0.25 mg/kg bw/day	93.65%	JMPR, 1995 Daly, 1982

Table 5. Mutagenicity profile of parathion-methyl technical material based on in vitro and in vivo tests

Species	Test	Duration and conditions or guideline adopted	Result	Purity	Ref
Chinese hamster ovary cells	OECD guideline 475 EEC Directive 87/302/EEC	*in vitro* mammalian cell gene mutation test	no demonstration of mutagenic potential	96.9% technical	Brendler-Schwaab, 1993[5]
Chinese hamster ovary cells	OECD guideline 473	*in vitro* mammalian chromosome aberration test	no increases in chromosome aberrations at any dose level, with or without metabolic activation	96.9% technical	Gahlmann, 1995[5]
Mouse	*in vivo*, 10 mg/kg bw	dominant lethal mutation	negative	95.7%	JMPR, 1995 Herbold, 1984
Mouse	*In vivo*, 2x5, 2x10 mg/kg bw	micronucleus formation	negative	95.6%	JMPR, 1995 Herbold, 1982
Rat hepatocytes	*In vitro*, $3x10^{-5}$ - $3x10^{-2}$ ul/ml	unscheduled DNA synthesis	negative	not measured	JMPR, 1995 Curren, 1989

[5] This report has not been evaluated by JMPR. The summary in the table is taken directly from the study report; it has not been subject to expert review.

Species	Test	Duration and conditions or guideline adopted	Result	Purity	Ref
Salmonella typhimurium	*In vitro*, 2-12500 ug/plate	reverse mutation	positive	94%	JMPR, 1995 Herbold, 1986b
Salmonella typhimurium, TA98, TA100, TA1535, TA1537	*In vitro*, 2-12500 ug/plate	reverse mutation	positive in TA100 at ≥ 900 ug/plate	96%	JMPR, 1995 Herbold, 1986a

Table 6. Ecotoxicology profile of parathion-methyl technical material and formulations.

Species	Test	Duration and conditions	Result	Purity	Reference
Anas platyrhynchos (mallard duck)	short-term toxicity FIFRA E71-2	5 days, in feed	LC_{50} 374 ppm ai NOEC: 12.3 ppm ai	43.2% EC	Grimes and Jaber, 1988
Anas platyrhynchos (mallard duck)	one generation, reproduction. FIFRA E71-4	20 weeks dosing, 21.7±2.4°C	NOEC: 14.7 ppm (highest level tested)	not reported	Beavers *et al*, 1988
Colinus virginianus (bobwhite quail)	one generation, reproduction. FIFRA E71-4	20 weeks dosing, 22.4±2°C	NOEC: 6.27 ppm	technical	Beavers *et al*, 1989
Cyprinodon variegatus (sheepshead minnow)	acute toxicity, flow-through system	96 hours	24 hour LC_{50} 7.4 mg ai/l 48 hour LC_{50} 7.3 mg ai/l 72 hour LC_{50} 5.3 mg ai/l 96 hour LC_{50} 3.4 mg ai/l no NOEC established	43.2% formulation	Surprenant, 1988a
Cyprinodon variegatus (sheepshead minnow) fertilised embryos, 24 hours old	acute toxicity, flow-through system FIFRA E72-4	35 days at 25°C	NOEC: 12ug ai/l	95.8% technical	Surprenant, 1989

Species	Test	Duration and conditions	Result	Purity	Reference
Salmo gairdneri (rainbow trout)	acute toxicity, flow-through system	96 hours	24 hour LC_{50} 3.9 mg ai/l 48 hour LC_{50} 2.8 mg ai/l 72 hour LC_{50} 2.4 mg ai/l 96 hour LC_{50} 2.3 mg ai/l no NOEC established	43.2% formulation	Surprenant, 1988b
Apis mellifera (honey bee)	oral and contact toxicity FIFRA 141-1	Oral: 4 hours, sugar solution Contact: acetone solution, 1 ul/bee on thorax	Oral LD_{50}: 0.025 ug product/bee Contact LD_{50}: 0.079 ug product/bee	500 g/l EC	Kovács, 1995
Daphnia magna (water flea) <24 h old	chronic toxicity, flow through	21 days, 20-22°C	7 day EC_{50} >1.7 ug/l 14 day EC_{50} 1.1 ug/l 21 day EC_{50} 0.96 ug/l	95.7% technical	Blasberg *et al*, 1993
Daphnia magna (water flea) 6-24 h old	acute OECD 202 Part 1	48 hours, 21°C	48 hour EC_{50} = 7.3 ug/l	96.5% technical	Heimbach, 1983
Scenedesmus subspicatus (green alga)	effect on growth, static water	96 hours, 20±2°C	EC_{50} 3.0±0.9 mg/l NOEC 0.1 mg/l	96.5% technical	Anderson, 1994
Skeletonema costatum (alga)	effect on growth, static water	96 hours	96 hours EC_{50} 5.3 mg/l NOEC 1.0 mg/l	not reported	ERL, 1981

Under the CCPR Periodic Review Programme, the 1995 FAO/WHO JMPR estimated an acceptable daily intake (ADI) and an acute reference dose (acute RfD) for humans:

ADI, 0 to 0.003 mg/kg bw;

Acute RfD, 0.03 mg/kg bw per day.

Parathion-methyl was previously evaluated by the JMPR in 1963, 1965, 1968, 1972, 1975, 1979, 1980, 1982, 1984.

The IPCS hazard classification of parathion-methyl active ingredient is: "extremely hazardous, class Ia".

Formulations

The main formulation types available are CS and EC. Parathion-methyl is not co-formulated with other pesticides.

Emulsifiable concentrates are registered and sold in: Australia, Bolivia, Cuba, Dominican Republic, El Salvador, France, Ghana, Hungary, Israel, Italy, Mexico, Pakistan and United States.

Aqueous Capsule Suspensions are registered and sold in: Australia, Belize (Central America), Colombia, Costa Rica, El Salvador, France, Greece, Guatemala, Honduras, Hungary, Iraq, Italy, Mexico, Myanmar, Poland, Spain and Venezuela.

Methods of analysis and testing

Method CIPAC 10.a/TC/(M2)/3

The analytical method for the active ingredient (including identity tests) is described in CIPAC Handbook 1B (10.a/TC/(M2)/3). The parathion-methyl is determined by normal phase HPLC, using UV detection at 254 nm with internal standardisation.

The method(s) for determination of impurities are based on reversed phase HPLC with UV detection and external standards.

Method AM 448 (Sørensen, 2000b)

Method AM 448 uses reversed phase HPLC with UV detection and external standards to analyse paraoxon-methyl, S-methyl-parathion-methyl and parathion in parathion-methyl TC, TK, EC and CS products.

The method is undergoing peer laboratory validation.

Method AM 448 is a further development (modification) of the draft method on p 169 of CIPAC Handbook E. The purpose of the modification is to measure the three relevant impurities simultaneously in TC, TK, EC and CS,

Method CIPAC/4183/m (May 2000) (Sørensen, 2000a)

This method was designed to measure free or non-encapsulated parathion-methyl in parathion-methyl CS formulations. Heptane is used to extract the free parathion-methyl while leaving the capsules intact. The concentration of parathion-methyl extracted into the heptane is determined by GC-FID with an internal standard.

The results of collaborative testing were presented at the CIPAC meeting in Granada 2000 but was not adopted because the results were too variable. Collaborative testing of an alternative method is scheduled for 2002-2003.

Physical properties

The physical properties, the methods for testing them and the limits proposed for the TC, TK and EC, complied with the requirements of the FAO Manual (5th edition), with two exceptions. The proposed specification for CS formulations did not comply with the guidelines given in the manual but these issues were not addressed by the meeting, in view of the failure of the collaborative study of the method for free active ingredient, referred to above.

Containers and packaging

No special requirements for containers and packaging have been identified, except that carbon steel containers should not be used unless lined with suitable material.

Expression of the active ingredient

The active ingredient is expressed as parathion-methyl.

Appraisal

The data submitted were in accordance with the requirements of the FAO Manual (5th edition) and supported the draft specifications for TC, TK and EC.

Parathion-methyl is a non-systemic organophosphorus insecticide and acaricide with anti-cholinesterase action. The proposer for parathion-methyl specifications was Cheminova. Data and draft specifications for TC, TK, EC and CS were provided for review in 2001.

Parathion-methyl is slightly soluble in water (70 mg/l at 25°C). Its vapour pressure at 25°C is 0.41 mPa. Although relatively slowly hydrolysed, parathion-methyl hydrolyses more quickly with increasing pH, with a half life of 68, 40 or 33 days at pH 5, 7 and 9, respectively, at 25°C in dark sterile conditions. The environmental photolysis half-life is about 9 days, under conditions corresponding to 40 degrees latitude with no cloud cover and in the top layer of water.

The Meeting was provided with commercially confidential information on the manufacturing process and batch analysis data on TC for all impurities present at or above 1 g/kg and some at lower levels. Mass balances for the 5-batch analyses ranged from 981-988 g/kg. The water level in one batch very slightly exceeded the manufacturing quality control limit of 5 g/kg. Duplicate analyses for each impurity in each batch were in excellent agreement. These data were declared to be similar to those reviewed in 1999 for registration in Australia.

Three impurities were proposed as relevant impurities:

paraoxon-methyl (CAS 950-35-6),
phosphoric acid, dimethyl 4-nitrophenyl ester,
maximum 1.2 g/kg in TC;

S-methyl-parathion-methyl (CAS 597-89-7),
phosphorothioic acid, *O*,*S*-dimethyl *O*-(4-nitrophenyl) ester,
maximum 15.0 g/kg in TC;

parathion (CAS 56-38-2),
phosphorothioic acid, *O*,*O*-diethyl *O*-(4-nitrophenyl) ester,
maximum 3.0 g/kg in TC.

Parathion-methyl is acutely toxic at low doses when administered either orally or by inhalation. It is slightly irritating to the skin and eyes but has not been shown to be a sensitizing agent. WHO has classified parathion-methyl as 'extremely hazardous' (JMPR, 1995).

In two-year studies of mice and rats, parathion-methyl was not carcinogenic. In developmental studies of rats and rabbits, no effects on fetuses were observed that could not be attributed to maternal toxicity. There was no evidence of genotoxicity in a limited range of studies in mammalian systems. The ADI for humans is 0-0.003 mg/kg bw and the acute RfD is 0.03 mg/kg bw (JMPR, 1995).

Parathion-methyl is highly toxic to birds, fish, mammals, honey bees and aquatic invertebrates.

CIPAC methods (GC and HPLC) are available for identifying and measuring the parathion-methyl content of technical and EC or CS formulations.

A method was tested for measuring free parathion-methyl in CS formulations (CIPAC/4184) and reported in to CIPAC in 2000. However, it was not sufficiently robust and was not adopted. An alternative method is to be validated in 2002-2003.

Relevant impurities are determined by the Cheminova method, VAM 029-01, or, in the case of S-methyl-parathion-methyl, alternatively by the CIPAC method, 487 (10.a)/TC/(M1 and M2)/- (CIPAC handbook E, p. 169, 1993). The Cheminova method utilizes HPLC with a reversed-phase column, UV detection and external standardization. It is suitable for determination of all three relevant impurities. Good recoveries and precision were demonstrated.

Comparison of the acute RfD for parathion of 0.01 mg/kg bw (JMPR, 1995) with that for parathion-methyl indicates that parathion is a relevant impurity. S-methyl-parathion-methyl and paraoxon-methyl are also more toxic than parathion-methyl and so meet the definition of relevant impurity.

The existing specifications use the name, 'S-methyl parathion', for this impurity but this is misleading. Other names used for this impurity include: isoparathion-methyl, S-methyl-parathion-methyl and alkylisoparathion-methyl. The meeting agreed that the impurity should be identified in specifications by its systematic name and CAS number. The meeting also agreed that, for convenience, such impurities should also be described by a brief name, such as a common name, a generally accepted acronym or a derivative of a common name. In this case S-methyl-parathion-methyl was considered to be a suitable unambiguous name for the impurity.

The meeting agreed that the specifications for parathion-methyl TC and TK should include a note, warning of the possible explosion hazard if these materials are heated to or above 100ºC, for any reason but particularly to melt the solids which may form at lower temperatures in both the TC and the TK.

The meeting agreed that the specification for parathion-methyl CS could be considered when further information and robust test methods become available. The proposer stated that the CS was not intended to be a slow release product but was intended to reduce the risks to users. Information would be required to support the reduction in risk and a suitably robust and validated method would be required to determine the content of "free" active ingredient. Suitable limits, with supporting information, would be required for pourability and freeze/thaw stability.

Recommendations

The meeting recommended that the specifications for parathion-methyl TC, TK and EC proposed by Cheminova, with amendments, should be adopted by FAO.

The meeting recommended that a specification for parathion-methyl CS should be considered for adoption, subject to provision of the limits, information and methods identified in the appraisal.

As a general point for all specifications which include relevant impurities, the meeting recommended that, in the absence of a standard common name, the impurity should be described by its systematic name and CAS number. In addition, for convenience, the impurity should be described by a brief name such as a common name, a generally accepted acronym or a derivative of a common name.

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Note: Some of the references provided by the proposer and those listed by JMPR (1995) do not match exactly in year or study numbers, but the proposer believed that they are the same.