FAO SPECIFICATIONS AND EVALUATIONS FOR AGRICULTURAL PESTICIDES

PROPAMOCARB

propyl 3-(dimethylamino)propylcarbamate

FOOD AND AGRICULTURE ORGANIZATION *of* THE UNITED NATIONS

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

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

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

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

INTRODUCTION

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

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

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

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

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

FAO specifications under the **New Procedure** do 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. FAO has the possibility to extend the scope of the specifications to similar products but only when the JMPS has been satisfied that the additional products are equivalent to that which formed the basis of the reference specification.

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

*NOTE: publications are available on the internet at
http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmps/en/

PART ONE

SPECIFICATIONS

PROPAMOCARB

INFORMATION

ISO common name (ISO 1750 published[2])

Propamocarb

Chemical names

IUPAC Propyl 3-(dimethylamino)propylcarbamate
Propyl 3-(dimethylamino)propylcarbamate hydrochloride

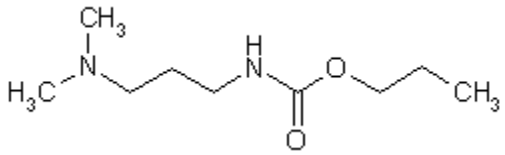
CA Propyl [3-(dimethylamino)propyl]carbamate
Propyl [3-(dimethylamino)propyl]carbamate hydrochloride

Synonyms

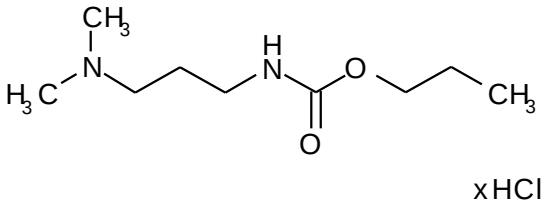
AE B039744 (Propamocarb)
AE B066752 (Propamocarb hydrochloride)

Structural formula

Propamocarb:



Propamocarb hydrochloride:



x HCl

Molecular formulae

Propamocarb: $C_9H_{20}N_2O_2$
Propamocarb hydrochloride: $C_9H_{21}ClN_2O_2$

Relative molecular masses

Propamocarb: 188.3
Propamocarb hydrochloride: 224.7

CAS Registry numbers

Propamocarb: 24579-73-5
Propamocarb hydrochloride: 25606-41-1

[2] when this substance is used as a salt, its identity should be stated, for example propamocarb hydrochloride

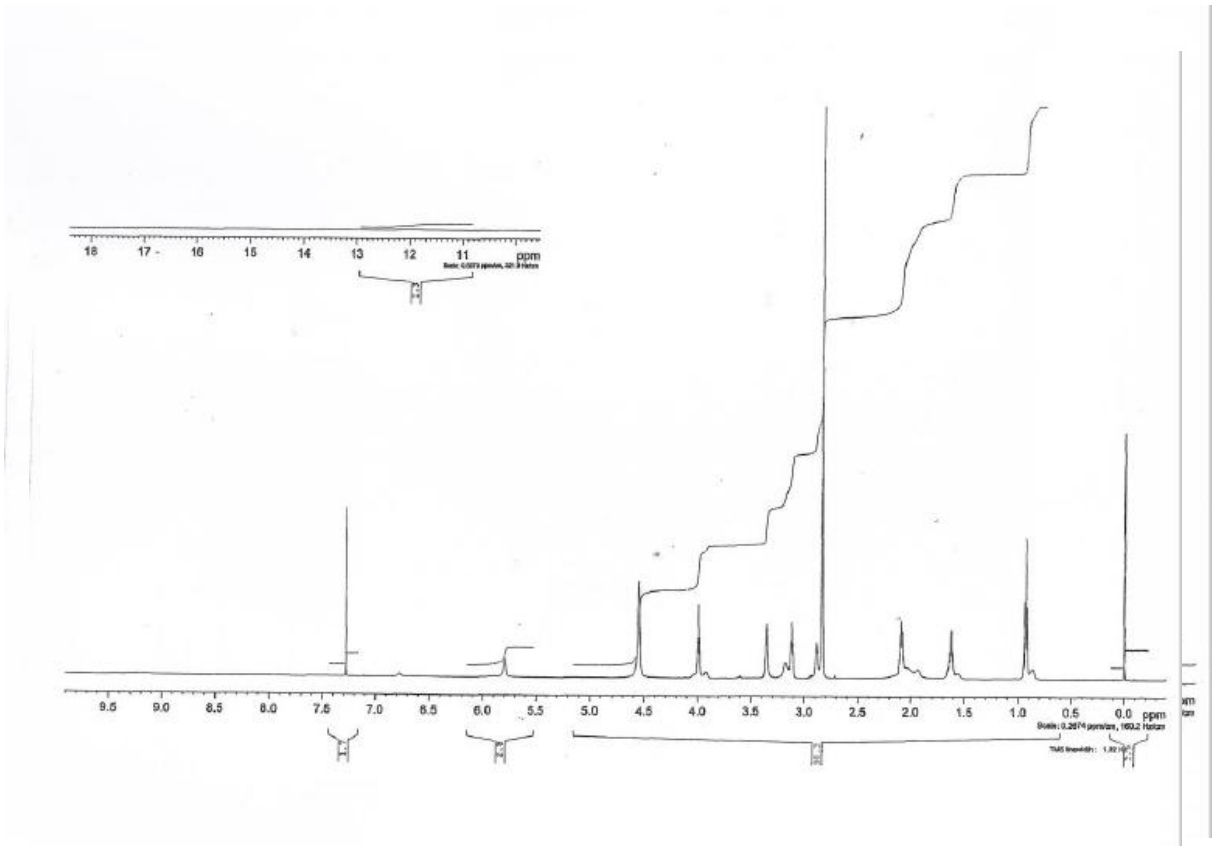
CIPAC numbers

Propamocarb: 399

Propamocarb hydrochloride: 399.601

Identity tests

IR spectrum, retention in normal phase HPLC, ^{1}H NMR spectrum



PROPAMOCARB HYDROCHLORIDE TECHNICAL CONCENTRATE

399.601/TK (May 2013*)

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 (399.601/2012). 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 (399.601/2012) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of propamocarb hydrochloride together with related manufacturing impurities, and shall be a colourless to yellowish clear and viscous liquid free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 **Identity tests** (399/SL/M2, CIPAC Handbook E, p. 184, 1993)
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 **Propamocarb hydrochloride content** (399/SL/M3, CIPAC Handbook E, p. 184, 1993)

The propamocarb hydrochloride content shall be declared (not less than 690 g/kg or 920 g/kg when expressed as theoretical water-free material) and, when determined, the average measured content shall not be lower than 690 g/kg or higher than 740 g/kg.

3 Physical properties

3.1 **pH range** (MT 75.3) (Note 1)

2.0 to 4.0

Note 1 pH measured undiluted.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmps/ps-new/en/

PROPAMOCARB HYDROCHLORIDE SOLUBLE CONCENTRATE

399.601/SL (May 2013*)

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 (399.601/2013). 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 (399.601/2012) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of technical concentrate propamocarb hydrochloride, complying with the requirements of FAO specification 399.601/TK (May 2013), dissolved in suitable solvents, together with any other necessary formulants. It shall be in the form of a clear or opalescent liquid, free from visible suspended matter and sediment, to be applied as a true solution of the active ingredient in water.

2 Active ingredient

2.1 Identity tests (399/SL/M2, CIPAC Handbook E, p. 184, 1993)

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 Propamocarb hydrochloride content (399/SL/M3, CIPAC Handbook E, p. 184, 1993)

The propamocarb hydrochloride content shall be declared (g/kg or g/L at 20 ± 2 ºC, Note 1) and, when determined, the average content measured shall not differ from that declared by more than the appropriate tolerance, given in the table of tolerances:

Declared content in g/kg or g/L at 20 ± 2 °C	Tolerance
above 500	± 25 g/kg or g/L of the declared content

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmps/ps-new/en/

3 Physical properties

3.1 **Solution stability** (MT 41.1)

The formulation following dilution (Note 2) with CIPAC standard water D and standing at 30 °C ± 2 °C for 24 h, shall give a clear solution, free from any separation.
Any visible sediment or particles produced shall pass through a 75 µm test sieve.

3.2 **Persistent foam** (MT 47.2)

Maximum: 10 ml after 1 min.

4 Storage stability

4.1 **Stability at 0 °C** (MT 39.3)

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

4.2 **Stability at elevated temperature** (MT 46.3)

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 3) and the formulation shall continue to comply with the clause for:

- solution stability (3.1)

Note 1 If the buyer requires both g/kg and g/L at 20 °C, then in case of dispute the analytical results shall be calculated in g/kg.

Note 2 The concentration used for the test should not be higher than the highest concentration recommended in the instructions for use.

Note 3 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

PROPAMOCARB

2012 FAO/WHO evaluation reports based on submission of information from

Propamocarbhydrochloride

FAO EVALUATION REPORT 399.601 / 2012

Recommendations

The meeting recommended that:

(I) the specifications for propamocarb hydrochloride TK and SL, proposed by Bayer CropScience, as amended, should be adopted by FAO.

Appraisal

The Meeting considered data submitted by Bayer CropScience in September 2011 for the development of new FAO specifications for propamocarb hydrochloride TK and SL formulations. The data were broadly in accordance with the requirements of the 2010 revision of the FAO/WHO manual.

Due to the fact that propamocarb hydrochloride, the salt of the base compound propamocarb, is used in most of the formulated products, it should be noted that the evaluated data belong to the variant propamocarb hydrochloride, unless otherwise specified.

Propamocarb and its salt propamocarb hydrochloride are no longer under patent.

Propamocarb was evaluated by the FAO/WHO JMPR for Residues several times (in 2006, 1987, 1986 and in 1984) and for toxicology in 2005, in 1986 and in 1984.

Propamocarb had been reviewed in Europe and included into the positive list of active ingredients effective from 01 October 2007 (Rapporteur Member State: Ireland).

Propamocarb was reviewed by the US EPA in 2004, the latest review started in September 2011.

The Meeting was provided with commercially confidential information on the manufacturing process and five batch analytical data on impurities present at or above 1 g/kg in the TK and their manufacturing limits.

Mass balances ranged from 988 to 1011 g/kg. None of the manufacturing impurities are considered as toxicological or environmental relevant. The impurities and their QC limits in the specification were identical to those submitted in Europe.

Bayer CropScience also submitted the calculated manufacturing limits for a hypothetical TC, which will be the basis for future assessments on equivalence.

The analytical method for determination of propamocarb hydrochloride is a CIPAC method from 1991, published in Handbook E. This method is intended for SL

formulations, but was considered applicable to the TK as well for the following reasons: The SL covers a concentration range of up to 655 g/kg, so the maximum concentration of 710 g/kg is in within the range of tolerance as in the CIPAC Guideline for method extension. The TK as well as the SL are based on freely water miscible solvents or water.

The 5-batch data were generated using an analytical method that is similar to the CIPAC method, with exception of the particle size of the column filling.

No TC specification was proposed for the following reason: Pure propamocarb hydrochloride is a very hygroscopic and highly water soluble substance. In theory it would be possible to produce a material that is higher in purity than the minimum purity declared in the TK specification; however such a material would readily absorb moisture from the surrounding atmosphere resulting in a fast and significant decrease of the initial high content. Consequently, the propamocarb hydrochloride technical material manufactured by Bayer CropScience from which formulated products are manufactured is not isolated as a dry material (TC) but as an aqueous concentrate (TK).

The Meeting noted that in the TK specification the expression of the content of the active ingredient deviates from the specification guideline for a TK as provided in the Manual. The company explained, that their propamocarb has many registrations worldwide for the hydrochloride which are based on a minimum content of 690 g/kg. Changing the description of the content (e.g. to 715 g/kg with allowed tolerance ± 25 g/kg) would lead to numerous questions from national authorities. So in the actual description an upper and lower content is given, while it is explicitly referred to 690 g/kg as minimum content. The Meeting considered these arguments and, being aware of the low toxicity of propamocarb, agreed to accept the justification in such a particular case.

The Meeting discussed the need to specify a pH range in the TK specification. The draft specification did not contain such a clause. Although propamocarb is stable in the pH range 4 – 9, the last step in the TK manufacturing process is a pH adjustment to 2 – 4 that is necessary to keep propamocarb in the hydrochloride form. Therefore it was agreed to add a pH range to the specification.

Some of the studies in the data package supporting the specifications and evaluation of propamocarb submitted by BCS belong to Agriphar (see Annex 2, References). The Meeting questioned the validity of the hazard studies without having access to the manufacturing specification of propamocarb supplied by Agriphar. BCS provided a statement that they have an agreement to use these studies supported by a letter of access from Agriphar. Furthermore, the two companies had formed a Regulatory Task Force for the inclusion of the active ingredient propamocarb into Annex I of the Commission Directive 91/414/EEC.

Under these special conditions and noting, that according to the EFSA Scientific Report (2006) 78, 1-80, “two complete data packages had been provided” for the Annex I inclusion Review Process and “always the relevant endpoint was used for the risk assessment”, the material used in those hazard studies owned by Agriphar can be considered to fully support the BCS specifications.
Moreover, as propamocarb supplied by BCS and Agriphar do not contain relevant impurities and thus both qualities have been deemed comparable, the Meeting accepted the explanation.

SUPPORTING INFORMATION

FOR

EVALUATION REPORT 399.601 / 2012

USES

The substances propamocarb and its salt propamocarb hydrochloride are systematic fungicides with specific activity against a wide range of *Oomycete* species (including *Pythium spp., Peronospora spp., Pseudoperonospora spp., Phytophthora spp*. and *Bremia spp*.), causing seed, seedling, root, foot and stem rots and foliar diseases in several edible crops, predominantly vegetables and potatoes, and in ornamental plants.

IDENTITY OF THE ACTIVE INGREDIENT

ISO common name (ISO 1750 published[3])

Propamocarb

Chemical names

IUPAC Propyl 3-(dimethylamino)propylcarbamate
Propyl 3-(dimethylamino)propylcarbamate hydrochloride

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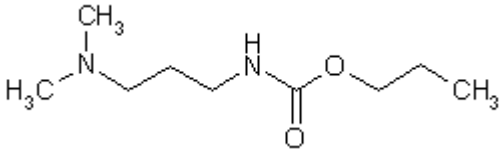
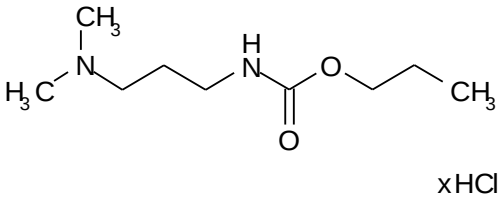


Propamocarb hydrochloride:



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Molecular formulae

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[3] when this substance is used as a salt, its identity should be stated, for example propamocarb hydrochloride

Relative molecular masses

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CIPAC numbers

Propamocarb:	399
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Identity test

IR spectrum, retention in normal phase HPLC, ^{1}H NMR spectrum

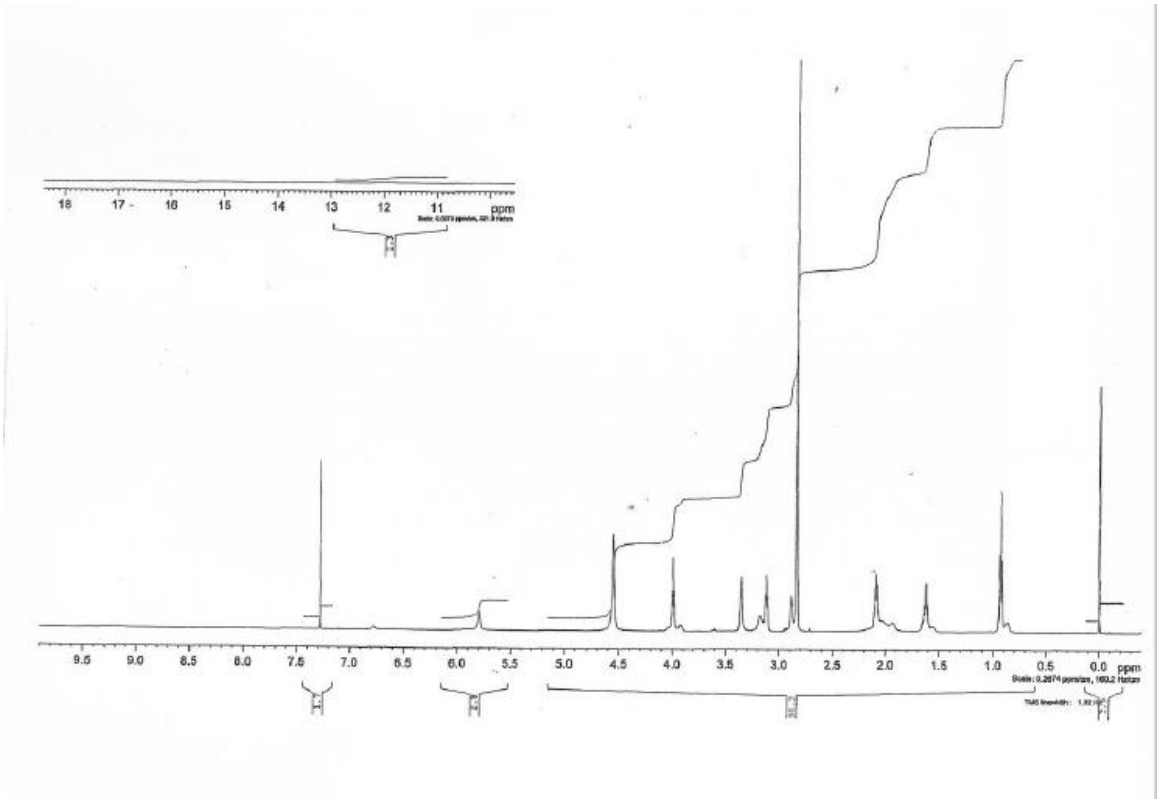

Table 1. Physico-chemical properties of pure propamocarb hydrochloride

Parameter	Value(s) and conditions	Purity %	Method reference (and technique if the reference gives more than one)	Study reference
Vapour pressure	3.8×10^{-5} Pa at 20 °C 8.1×10^{-5} Pa at 25 °C extrapolated from measurements at 46 … 76 °C	97.7	OECD 104	M-157253-01-1
Melting point, boiling point and/or temperature of decomposition	Melting point: 64.2 °C (inert atmosphere) Boiling point: not applicable Decomposition temperature: not applicable: 150 °C	100.3 99,1	CIPAC MT 2	M-164549-01-1
Solubility in water	> 900 g/L at pH 7.0 (base)	99.2	OECD 105	M-157228-01-1
Octanol/water partition coefficient	pH 2.0: log P_{OW} = - 2.87 at 22 °C pH 7.0: log P_{OW} = - 1.21 at 22 °C pH 9.0: log P_{OW} = 0.67 at 22 °C	97.2	OECD 107	M-203110-01-1
Hydrolysis characteristics	No hydrolysis at 50°C at pH 4, 7 and 9 over a five day period	99.4	OECD 111 EPA, Subdivision N § 161-1	M-240450-01-1
Photolysis characteristics	Photochemically stable	96.1	EPA, Subdivision N § 161-1	M-157849-01-1 M-157698-01-1
Dissociation characteristics	pK_a = 9.3 at 20 °C	97.7	OECD 112	M-157256-01-1
Solubility in organic solvents	< 0.01 g/L in n-hexane > 626 g/L in dichloromethane 0.14 g/L in toluene > 656 g/L in methanol 560 g/L in acetone 4.34 g/L in ethylacetate, all at 20 °C	100.3	CIPAC MT 157	M-157242-01-1

Table 2. Chemical composition and properties of propamocarb hydrochloride technical materials (TK)

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 98.8 – 101.1 % and no unidentified impurities were reported
Declared minimum content	690 g/kg for technical concentrate (TK) (or 920 g/kg for TC)
Relevant impurities ≥ 1 g/kg and maximum limits for them	None
Relevant impurities < 1 g/kg and maximum limits for them	None
Stabilisers or other additives and maximum limits for them	None

Parameter	Value and conditions	Purity %	Method reference	Study number
Melting temperature range of the TK	not applicable for TK	-	-	-
Solubility in organic solvents	see table above			

HAZARD SUMMARY

The following conclusions were drawn by the JMPR in the re-evaluation process of the toxicology of propamocarb in 2005:

The acute toxicity of propamocarb is low. Propamocarb is not irritating to the eye or skin. It induced skin sensitization in a Magnusson & Kligman maximization test (and in a local lymph node assay (LLNA)), but gave negative results in a Buehler test.

Propamocarb is not carcinogenic in rodents. As propamocarb gave negative results in an adequate range of tests for genotoxicity in vitro and in vivo, Propamocarb is unlikely to be genotoxic. In view of the lack of genotoxicity and the absence of carcinogenicity in mice and rats, Propamocarb is unlikely to pose a carcinogenic risk to humans.

The JMPR established an ADI of 0–0.4 mg/kg bw based on a NOAEL of 39 mg/kg bw per day, on the basis of vacuolization observed in a range of organs in a 52-week study in dogs, and using a safety factor of 100.

An ARfD of 2 mg/kg bw was established based on a NOAEL of 200 mg/kg bw, on the basis of a decreased activity in rats 1 h after dosing and using a safety factor of 100. This ARfD is adequately protective for effects observed in studies of developmental toxicity.

Following reference values have been finalised as part of the evaluation in the EU:

ADI: 0.29 mg propamocarb hydrochloride/kg bw/day

ARfD: 1 mg propamocarb hydrochloride/kg bw/day

AOEL: 0.29 mg propamocarb hydrochloride/kg bw/day

According to the European classification criteria the hazard classification of Propamocarb is Category 1A, H317: “May cause an allergic skin reaction”.

FORMULATIONS AND CO-FORMULATED ACTIVE INGREDIENTS

The main formulation type available is SL (soluble concentrate).

Propamocarb hydrochloride may be co-formulated with chlorothalonil, fenamidone, fluopicolide and mancozeb in the form of SC.

The free base compound propamocarb may be co-formulated with fosetyl – as propamocarb fosetyl – as an SL.

These formulations are registered and sold in numerous countries around the world.

METHODS OF ANALYSIS AND TESTING

The analytical method for the active ingredient (including identity tests) is AL051/97 [M-183416-01-1]. Propamocarb hydrochloride is determined by HPLC, using UV detection at 210 nm and external standardisation.

The method(s) for determination of impurities are based on ion chromatography with conductivity detection and on gas chromatography with FID detection.

There is a CIPAC method available for SL formulations, published in Handbook E. The sample is dissolved in methanol and separated by liquid chromatography on a silica column. The content of propamocarb hydrochloride is determined from peak areas using external standard calibration.

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

PHYSICAL PROPERTIES

The physical properties, the methods for testing them and the limits proposed for the SL formulations, comply with the requirements of the FAO/WHO Manual (2010).

CONTAINERS AND PACKAGING

No special requirements for containers and packaging have been identified.

EXPRESSION OF THE ACTIVE INGREDIENT

The active ingredient is either expressed as propamocarb or as propamocarb hydrochloride, as required.

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 propamocarb hydrochloride having impurity profiles similar to those referred to in the table above.

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

Table 3: Toxicology profile of the propamocarb hydrochloride technical material, based on acute toxicity, irritation and sensitization

Species	Test	Purity %[4]	Guideline, duration, doses and conditions	Result	Study reference
Rat, males and females	oral	68.0%	OECD 401 (1987) and US EPA OPPTS 870-1100 (1998)	Male and female LD50 > 5000 mg/kg Previcur N equating to LD50 > 3400 mg/kg propamocarb hydrochloride	M-205214-01-1
Rat, males and females	oral	71.5%	EC Directive 92/69/EEC B.1 (1992) and OECD 420 (1992)	Male and female LD50 > 2000 mg/kg	M-310337-01-1
Rat, males and females	dermal	68.0%	EC Directive 92/69/EEC, B.3 (1992); OECD 402 (1987) and US EPA OPPTS 870.1200 (1998)	Male and female LD50 > 5000 mg/kg Previcur N equating to LD50 > 3400 mg/kg propamocarb hydrochloride	M-205218-01-1
Rat, males and females	dermal	71.5%	EC Directive 92/69/EEC, B.3 (1992) and OECD 402 (1987)	Male and female LD50 > 2000 mg/kg	M-310341-01-1
Rat, males and females	inhalation	71.2%	EC Directive 92/69/EEC, B.2 (1992); OECD 403 (1981), US EPA 81-3 (1984) and JMAFF Nohsan No. 4200 (1985)	Male and female LC50 > 5.54 mg/L	M-167986-01-1
Rat, males and females	inhalation	71.5%	EC Directive 92/69/EEC, B.2 (1992) and OECD 403 (1981)	Male and female LC_{50} > 5.01 mg/L	M-310999-01-1
Rat, males and females	inhalation	68.0%	EC Directive 92/69/EEC, B.2 (1992) and OECD 403 (1981)	Male and female LC_{50} > 4.95 mg/L Previcur N equating to LC_{50} > 3.4 mg/L propamocarb hydrochloride	M-206501-01-1
Rabbit, males	skin irritation	68.0%	EC Directive 92/69/EEC, B.4 (1992); OECD 404 (1992) and US EPA OPPTS 870.2500	Not irritant	M-205222-01-1

[4] Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

Species	Test	Purity %[4]	Guideline, duration, doses and conditions	Result	Study reference
			(1998)		
Rabbit, females	skin irritation	71.5%	EC Directive 92/69/EEC, B.4 (1992); OECD 404 (1992); EPA FIFRA 81-5 and TSCA, E, 798.4470	Not irritant	M-310346-01-1
Rabbit, males	eye irritation	68.0%	EC Directive 92/69/EEC, B.5 (1992); OECD 405 (1987), US EPA OPPTS 870.2400 (1998)	Not irritant	M-205226-01-1
Rabbit, males	eye irritation	71.5%	EC Directive 92/69/EEC, B.5 (1992); OECD 405 (1987); EPA-FIFRA 81-4 and TSCA, E, 798.4500	Not irritant	M-310352-01-1
Guinea pig, females	skin sensitization (Magnusson& Kligman)	71.2%	EC Directive 96/54/EC, B.6 (1996); OECD 406 (1992); US EPA OPPTS 879.2600 (1998) and JMAFF NohSan No. 4200 (1985)	Weak skin sensitizer	M-184379-01-1
Guinea pig, females	skin sensitization (Buehler)	71.5%	EC Directive 92/69/EEC, B.6 (1992) and OECD 406 (1992)	Non sensitizer	M-310356-01-1
Mouse, females	skin sensitization (LLNA)	66.1%	OECD 429 (2002)	Sensitizer	M-252483-01-1
Guinea pig, females	phototoxicity		No need for phototoxicity testing as $\varepsilon < 3$ L/molxcm		
Guinea pig, females	photo-sensitization		No need as $\varepsilon < 3$ L/molxcm		

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

Species	Test	Purity %[4]	Guideline, duration, doses and conditions	Result	Study number
Rat, males and females	4-week feeding study	67.0%	Not applicable (only preliminary and explorative study design); Study not performed under GLP, but laboratory GLP-certified	NOEL = 2500 ppm Proplant equating to 186 and 200 mg/kg bw/day propamocarb hydrochloride in males and females respectively	M-310359-01-1
Rat, males and females	4-week gavage study	70.6%	Not applicable (only preliminary and explorative study design); Study not performed under GLP, but laboratory GLP-certified	NOAEL = 100 mg/kg/day	M-310378-01-1
Rat, males and females	4-week feeding study	64.3%	OECD 407 (1995)	NOAEL = 5000 ppm Previcur N equating to 422 or 459 mg/kg bw/day propamocarb hydrochloride in males and females, respectively	M-157580-01-1
Dog, males and females	4-week feeding study	68.4%	Not applicable (only preliminary and explorative study design); Study not performed under GLP, but laboratory GLP-certified	NOAEL = 3000 ppm Previcur N equivalent to 119 mg/kg bw/day propamocarb hydrochloride	M-157633-01-1
Rat, males and females	3-week dermal study	71.7%	OECD 410 (1981) and US EPA 82-2 (1984)	NOEL for systemic toxicity > 1000 mg/kg/day equivalent to 717 mg/kg/day propamocarb hydrochloride NOEL for irritancy 100 mg/kg/day equivalent to 71.7 mg/kg/day propamocarb hydrochloride	M-157653-01-1
Rat, males and females	4-week dermal study	75.0%	EC Directive 92/69/EEC, B.9 (1992); OECD 410 (1981) and	NOEL of dermal exposure 300 mg/kg bw/day propamocarb hydrochloride	M-310445-01-1

[4] Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

Species	Test	Purity %[4]	Guideline, duration, doses and conditions	Result	Study number
			US EPA 82-2 (1984)		
Rat, males and females	13-week feeding study	66.5%	OECD 408 (1981)	NOAEL = 5000 ppm equivalent to 362 and 396 mg/kg bw/d propamocarb hydrochloride in males and females respectively	M-157612-01-1
Rat, males and females	13-week feeding study	71.2%	OECD 408 (1981); US EPA 83-2 (1984); JMAFF NohSan No. 4200 (1985): Not all tissues preserved were examined histopathologically.	NOAEL = 7020 ppm equivalent to 318 and 363 mg/kg bw/d propamocarb hydrochloride in males and females, respectively	M-168497-02-1
Rat, males and females	13-week feeding study	75.0%	EC Directive 87/302/EEC (1988); OECD 408 (1998) and US EPA OPPTS 870.3100 (1996)	NOEL = 1500 ppm equivalent to 104 and 130 mg/kg bw/d propamocarb hydrochloride in males and females, respectively	M-310432-01-1
Mouse, males and females	13-week feeding study	71.2%	OECD 408 (1981); US EPA 83-2 (1984);JMAFF NohSan No.4200 (1985): No haematology investigations were conducted, but this did not affect the scientific validity of the study.	NOEL = 11232 ppm equivalent to 1349 and 1952 mg/kg bw/d propamocarb hydrochloride in males and females, respectively	M-168498-02-1
Mouse, males and females	13-week gavage study	70.6% (1st batch) and 75.0% (2nd batch)	Not applicable (only preliminary and explorative study design); Study not performed under GLP, but laboratory GLP-certified	NOEL = 1000 mg/kg bw/day	M-310427-01-1
Dog, males and females	13-week feeding study	75.0%	EC Directive 87/302/EEC (1988); OECD 409 (1998) and US EPA OPPTS 870.3150 (1998)	NOEL = 1000 ppm equivalent to 45 and 51 mg/kg bw/day propamocarb hydrochloride	M-310439-01-1
Dog, males and females	1-year feeding study	75.0%	EC Directive 87/302/EEC (1988); OECD 452 (1981) and US EPA OPPTS 870.4100 (1998)	NOEL < 1000 ppm equivalent to 39 and 42 mg/kg bw/day propamocarb hydrochloride	M-310442-01-1
Dog, males and females	2-year feeding study	68.0% to 68.7%	US EPA 83-1 (1982)	NOAEL = 3000 ppm equivalent to 71 and 73 mg/kg bw/day	M-157637-01-1

Species	Test	Purity %[4]	Guideline, duration, doses and conditions	Result	Study number
				propamocarb hydrochloride in males and females respectively	
Rat, males and females	Combined chronic/ oncogenicity feeding study	70.2%	Not stated, but substantially compliant with OECD Guideline 453 (1981) and US EPA 83-5 (1984): Deviations: only 10 males and 10 females from the control and high dose levels examined histopathologically after 52 weeks of treatment.	Not oncogenic NOAEL = 1000 ppm equating to 43 and 55 mg/kg bw/day propamocarb hydrochloride in both males and females after 52 weeks or equating to 37 and 45 mg/kg bw/day propamocarb hydrochloride in both males and females after 104 weeks	M-157599-01-1
Rat, males and females	Combined chronic/ oncogenicity feeding study	71.2%	EC Directive 88/302/EEC, Part B (1987); OECD 453 (1981); US EPA 83-5 (1984) and JMAFF NohSan No. 4200 (1985)	Not oncogenic Based on body weight, food consumption and histopathological findings, NOAEL in males = 2800 ppm equating to 104 mg/kg/day propamocarb hydrochloride after 52 weeks and to 84 mg/kg/day after 2 years NOAEL in females = 2800 ppm equating to 133 mg/kg/day propamocarb hydrochloride after 52 weeks and to 112 mg/kg/day after 2 years	M-183340-01-1
Rat, males and females	Combined chronic/ oncogenicity study	65.1%	OECD 453 (1981) and US EPA OPPTS 870.4300 (1998): No blood sampling for haematological evaluation at week 13.	Not oncogenic Based on multifocal vacuolation of epithelial cells lining the brain choroids plexus, as well as those of the lacrimal glands - no NOAEL in this study	M-310604-01-1
Rat, males and females	chronic feeding study	69.1%	OECD Guideline 452 (1981); US-OPPTS 870.4100 (1998)	NOEL in males = 1500 ppm equating to 84 mg/kg/day propamocarb hydrochloride NOEL in females = 375 ppm equating to 29 mg/kg/day propamocarb hydrochloride Overall NOEL = 375 ppm equating to 21and 29 mg/kg /day propamocarb	M-310609-01-1

Species	Test	Purity %[4]	Guideline, duration, doses and conditions	Result	Study number
				hydrochloride in males and females, respectively	
Mouse, males and females	Oncogenicity feeding study	70.2%	Deviations from OECD Guideline 451 (1981): Toxicity was not achieved at highest dose level; no blood smear was taken at 12 and 18 months of treatment. Additional deviations from US EPA Guideline 83-2 (1984): The duration was 2 years, not 18 months; selected organs were not weighed at necropsy; tissues from decedents from intermediate and low dose groups were not examined histopathologically.	NOAEL= 500 ppm equating to 52 and 54 mg/kg/day propamocarb hydrochloride in males and females, respectively	M-157604-01-1
Mouse, males and females	Oncogenicity feeding study	71.2%	Commission Directive 88/302/EEC, Part B (1987); OECD Guideline 451 (1981); US EPA 83-2 (1984); JMAFF NohSan No. 4200 (1985): with an additional control group	Not oncogenic NOEL in males = 6720 ppm equating to 690 mg/kg/day propamocarb hydrochloride NOEL in females = 105 ppm equating to 12 mg/kg/day propamocarb hydrochloride, based on body weight effects seen only in females Overall NOEL = 105 ppm equating to 11 and 12 mg/kg/day propamocarb hydrochloride in males and females, respectively	M-182006-01-1
Mouse, males and females	Oncogenicity feeding study	69.1%	OECD Guideline 451 (1981); US EPA 712-C-98-211 OPPTS 870.4200 (1998)	Not oncogenic Based on body weight effects, NOAEL = 840 ppm equating to 106 and 136 mg/kg/day propamocarb hydrochloride	M-310623-01-1

Species	Test	Purity %[4]	Guideline, duration, doses and conditions	Result	Study number
				in males and females, respectively	
Rat, males and females	2-generation feeding study	71.2%	US EPA OPPTS 870.3800 (draft 1996); OECD Guideline 416 (1983); JMAFF NohSan No. 4200 (1985); Deviation from OPPTS 870.3800 (1998): Specified organ weights were recorded from 1 pup/sex/litter from the surplus F_1 and F_2 weanlings rather than 3 pup/sex/litter.	Based on body weight and food consumption effects, parental and developmental NOAEL = 1250 ppm equating to 58 and 90 mg/kg/day propamocarb hydrochloride in males and females, respectively; Reproduction NOAEL = 8000 ppm equating to 367 and 570 mg/kg/day Propamocarb hydrochloride in males and females, respectively	M-183560-02-1
Rat, males and females	2-generation gavage study	69.1%	OECD Guideline 416 (1999); US EPA OPPTS 870.3800 (1998)	Parental NOAEL: 50 mg/kg bw/day (equivalent to 37.5 mg propamocarb /kg bw/day) based on adverse effects in clinical signs, alterations in body weight gain, food consumption and specific vacuolar changes in the epithelial cells of the choroid plexus. Reproductive NOAEL: 200 mg/kg bw/day (equivalent to 150.1 mg propamocarb /kg bw/day) based on adverse effects on sperm parameters at 1000 mg/kg bw/day Developmental NOAEL: 200 mg/kg bw/day (equivalent to 150.1 mg propamocarb /kg bw/day) based on decreased pup viability at 1000 mg/kg bw/day	M-310681-01-1
Rat, females	Embryo-toxicity study	68.0%	US EPA 83.3 (1978)	NOEL = 0.3 mL/kg PrevicurN equating to 204 mg/kg propamocarb hydrochloride	M-157608-02-1
Rat, females	Embryo-toxicity study	69.1%	Directive 87/302/EEC, Annex V, Part B 1988; OECD Guideline 414 (1981) and EPA OPPTS 870.3700 (1998)	NOAEL= 1500 ppm equating to 123 mg/kg bw/day propamocarb hydrochloride	M-310689-01-1
Rabbit, females	Embryo-	69.4%	Not stated, but compliant with	Maternal and fetal NOEL = 0.2 mL/kg	M-157597-02-1

Species	Test	Purity %[4]	Guideline, duration, doses and conditions	Result	Study number
	toxicity study		OECD Guideline 414 (1981) and US EPA 83-3 (1984)	bw/day Previcur N equating to 140 mg/kg propamocarb hydrochloride	
Species	Test	Purity %	Guideline, duration, doses and conditions	Result	Study number
Rabbit, females	Embryo-toxicity study	69.1%	Dir. 87/302/EEC, Annex V, part B (1988); OECD Guideline 414 (1981); EPA OPPTS 870.3700 (1998): Temperature outside Guideline range.	Maternal NOAEL = 2000 ppm equating to 76 mg/kg bw/day propamocarb hydrochloride Fetal NOAEL = 8000 ppm equating to 269 mg/kg bw/day propamocarb hydrochloride	M-310703-01-1

Table 5: Mutagenicity profile of technical propamocarb hydrochloride based on in vitro and in vivo tests

Species	Test	Purity %[4]	Guideline, duration, doses and conditions	Result	Study number
S. typhimurium TA98, TA 100, TA 1535, TA 1537, TA 1538 and E. coli WP2uvrA	*In vitro* mutagenicity test (Ames test)	66.5%	Not stated, but substantially compliant with OECD Guideline 471 and 472 (1983); Deviation: Only one mutation test conducted in both the presence and absence of metabolic activation. This deviation does not affect the scientific validity of the study.	Negative	M-157610-01-1
S. typhimurium TA98, TA 100, TA 1535, TA 1537, TA 1538	*In vitro* mutagenicity test (Ames test)	-	OECD Guideline 471; Commission Directive 92/69/EEC Method B14; US EPA, Section 84-2	Negative	M-310446-01-1
E. coli WP2uvrA	*In vitro* mutagenicity test (Ames test)	69.1%	OECD Guideline 471; Commission Directive 92/69/EEC Method B13/14; US EPA-OPPTS 870.5100	Negative	M-310449-01-1
S. typhimurium TA98, TA 100, TA 1535, TA 1537, TA 1538 and E. coli WP2uvrA	*In vitro* mutagenicity test (Ames test)	68.6%	OECD Guideline 471 and 472 (1983)	Negative	M-157642-01-1
Human lymhocytes	*In vitro* chromosome	68.6%	OECD Guideline 473 (1983)	Negative	M-157641-01-1

[4] Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

Species	Test	Purity %[4]	Guideline, duration, doses and conditions	Result	Study number
	aberration test				
Human lymhocytes	*In vitro* chromosome aberration test	69.1%	OECD Guideline 473 (1997); US-OPPTS 870.5375 (1998);Directive 67/548/EEC, Annex V, B.10 (2000)	Negative	M-310453-01-1
Mouse lymphoma L5178Y (TK+/-) cells	*In vitro* gene mutation test OECD 476	71.1%	OECD Guideline 476 (1997); Commission Directive 88/302/EEC (1988); US-OPPTS 870.5300 (1998)	Negative	M-197256-01-1
Mouse lymphoma L5178Y (TK+/-) cells	*In vitro* gene mutation test	69.1%	OECD Guideline 476 (1997); Directive 67/548/EEC, Annex V, B.17 (2000); US-OPPTS 870.5300 (1998)	Negative	M-310551-01-1
CD-1 mice	*In vivo* micro-nucleus test OECD 474	70.2%	Not stated, but substantially compliant with OECD Guideline 474 (1983) with deviations concerning the sampling times: First exp.: sacrifice 6 hours after the second dose; Second exp.: sacrifice by cervical dislocation 12, 24, 36 and 48 hours after the second dose	Negative	M-157582-01-1
NMRI mice	*In vivo* micro-nucleus test	69.1%	OECD Guideline 474 (1997); US-OPPTS 870.5395 (1998); Directive 67/548/EEC, Annex V, B.12 (2000)	Negative	M-310555-01-1
ICR/SIM mice	Dominant lethal mutation	69.2%	Not stated, but substantially compliant with OECD Guideline 478 (1984)	Negative	M-157583-01-1

Table 6: Ecotoxicology profile of technical propamocarb hydrochloride

Species	Test	Purity %[4]	Guideline, duration, doses and conditions	Result	Study number
Bobwhite quail	Acute oral toxicity	66.5%	US EPA FIFRA 71-1	The acute oral LD50 for Bobwhite quail of both sexes was estimated to be >1842 mg propamocarb hydrochloride/kg bw The concentration at which there was No Observed Effect (NOEL) was 460 mg/kg bw	M-157904-01-1
Mallard duck	Acute oral toxicity	66.5%	US EPA FIFRA 71-1	The acute oral LD50 for Mallard duck of both sexes was determined to be >1842 mg Propamocarb hydrochloride/kg bw	M-157906-01-1
Bobwhite quail	Short-term dietary toxicity	73.6%	US EPA FIFRA 71-2, EPA TSCA 797.2050, EPA OPPTS 850.2200 and OECD 205	For both sexes, the oral 5-day $LC_{50,}$ the lowest lethal dose (LLC), and the Lowest Observed Effect Concentration (LOEC) in Bobwhite quail was > 5000 mg propamocarb hydrochloride/kg feed. The No Observed Effect Concentration (NOEC) was 5000 mg/kg feed. The toxicity endpoint (LC50 > 5000 ppm) was converted to the daily dose: LC50 > 962 mg propamocarb hydrochloride/kg bw/day	M-310799-01-1
Mallard duck	Short-term dietary toxicity	67.1%	OECD 205 and US EPA FIFRA 71-2	For both sexes, under the conditions of this study, the oral 5-day LC_{50} and the lowest lethal dose in Mallard duck was established to be >5500 mg propamocarb hydrochloride/kg feed while the Lowest Observed Effect Concentration (LOEC) was 5500 mg/kg feed. The No Observed Effect Concentration (NOEC) was determined to be 2200 mg/kg feed.	M-310796-01-1

[4] Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage.

Species	Test	Purity %[4]	Guideline, duration, doses and conditions	Result	Study number
Bobwhite quail	Subchronic and reproduction toxicity	71.2%	OECD 206; US EPA FIFRA 71-4	Combining the parental and reproductive findings the Lowest Observable Effect Concentration (LOEC) was 6016 mg propamocarb hydrochloride/kg feed. The No Observed Effect Concentration (NOEC) was 1139 mg as/kg feed. The toxicity endpoint (NOEC = 1139 ppm) was converted to the daily dose: NOEC = 105 mg/kg bw/day.	M-167971-01-1
Mallard duck	Subchronic and reproduction toxicity	69.1%	US EPA FIFRA 71-4; OECD 206	At the highest concentration tested propamocarb hydrochloride had an adverse effect on adult female body weight towards the end of the testing period. There was no effect on the reproductive parameters monitored. Therefore the Lowest Observable Effect Concentration (LOEC) for Mallard ducks was 3800 mg propamocarb hydrochloride/kg feed and the No Observed Effect Concentration (NOEC) was 990 mg/kg feed	M-310783-01-1
Rainbow trout	Acute toxicity	71.9%	OECD 203; US EPA 72-1	96 hours LC_{50} of propamocarb hydrochloride to Rainbow trout was greater than 99 mg/L.	M-157858-01-1
Bluegill	Acute toxicity	71.9%	OECD 203; US EPA 72-1:	96 hours LC_{50} of Propamocarb hydrochloride to Bluegill sunfish was greater than 92 mg/L.	M-157853-01-1
Fathead minnow	Chronic toxicity ELS	71.1%	OECD 210, US EPA OPTTS 850.1400	Propamocarb hydrochloride had no statistically significant negative effect on any of the endpoints (summarised above) up to 37.5 mg/L during hatch and 28 days post-hatch (= fish early life stage). Hence, the overall NOEC is 37.5 mg propamocarb hydrochloride/L, and the LOEC has to be concluded as > 37.5 mg Propamocarb hydrochloride/L.	M-310729-01-1
Bluegill sunfish	Bioaccumula-		Guidelines not applicable	In Bluegill sunfish and Channel catfish the	Publication under

Species	Test	Purity %[4]	Guideline, duration, doses and conditions	Result	Study number
and Channel catfish	tion 28d +14d		Bluegill sunfish: Seventy five fish weighing approximately 0.5 g each were held in either a control aquarium, receiving 250 ml/min of clean water, or a dosed aquarium that received 250 mL/min of water containing 1 mg/L of radiolabelled propamocarb (98% pure). After 28 days the propamocarb-hydrochloride dosing was stopped and the fish left to depurate in clean flowing water with five fish being sampled at 1, 3, 7, 10 and 14 days into the depuration period. Channel catfish: A soil/water uptake study was conducted for 28 days with a 14 day depuration period in a clean soil water system. Radiolabelled propamocarb hydrochloride was thoroughly mixed into 5 kg of soil (11% clay, 52% sand and 37% silt) to produce a nominal concentration of 3 mg/kg, which was spread over the bottom of a stainless steel tank and aged aerobically for 14 days. Then 400 L of well water was added to this system followed by 50 catfish (average weight 0.5 g). Analysis of total radioactivity	bioconcentration factors (BCF) after 28 days were below 100. In both species propamocarb residues depurated rapidly with a biological half-life of less than seven days, with tissue levels falling below the limits of detection after 10 days in Bluegills.	M-157741-01-1 M-157742-01-1

Species	Test	Purity %[4]	Guideline, duration, doses and conditions	Result	Study number
			was conducted on water, hydrosoil and three fish after 1, 3, 7, 10, 14, 21 and 28 days exposure. After 28 days 20 fish were transferred to a clean water/soil system and sampled after 1, 3, 7, 10 and 14 days		
Daphnia magna	Acute toxicity	73.6%	Directive 92/69/EEC (part C.2; 1992); OECD Guideline No. 202 (1984)	48h-EC_{50} for immobilisation of Daphnia was found to be >100 mg Propamocarb hydrochloride/L (equivalent to >140 mg Proplant/L) with a NOEC at 100 mg/L	M-310720-01-1
Daphnia magna	Chronic toxicity	68.2%	OECD 202; US EPA FIFRA 72-4(B)	Based on the most sensitive endpoint in this study (growth), the NOEC was 12.3 mg/L propamocarb hydrochloride and the LOEC was 24.7 mg/L	M-165289-01-1
Pseudokirchneriella subcapitata	Chronic	67.8%	US EPA OPPTS 850.5400; OECD 201; EC Annex V Part C.3	Propamocarb hydrochloride has low toxicity to the algae Pseudokirchneriella subcapitata with a 72hr E_rC_{50} and E_bC_{50} > 85 mg/L	M-240390-01-1
Lemna gibba	Chronic	68.2%	US EPA 122-2	Propamocarb hydrochloride was not toxic to *Lemna gibba* at concentrations up to 18 mg/L; thus the 14 days EC50 is > 18 mg/L based on a nominal concentration in respect of frond growth.	M-165250-01-1
Apis mellifera	contact	66.4%	EPPO Guideline 170; US EPA FIFRA 141-1	The contact toxicity of Propamocarb hydrochloride to *Apis mellifera* was greater than 100 μg/bee.	M-155976-01-1
Apis mellifera	acute oral	66.4%	EPPO Guideline 170	The oral LD50 of propamocarb hydrochloride to *Apis mellifera* was greater than 84 μg/bee.	M-167909-01-1
Eisenia fetida	Acute toxicity	66.0%	OECD 207	The LC_{50} of propamocarb hydrochloride to earthworms was greater than 660 mg/kg soil and the No observed effect	M-157838-01-1

Species	Test	Purity %[4]	Guideline, duration, doses and conditions	Result	Study number
				concentration (NOEC) 1000 mg/kg soil.	
Eisenia fetida	Chronic toxicity	67.1%	BBA Guideline Part VI, 2-2, 1994; ISO 11268-2, 1998	There were no significant impacts of propamocarb hydrochloride on the growth or reproduction of *Eisenia fetida* up the maximum rate of 100 L Previcur N/ha equivalent to 72.5 kg propamocarb hydrochloride/ha, which itself is equivalent to approximately 362 mg propamocarb hydrochloride/kg (dry weight) soil.	M-240391-01-1

ANNEX 2

REFERENCES

Study number	Author(s)	Year	Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study	Owner
M-155976-01-1		1997	Contact toxicity (LD 50) to honey bees (Apis mellifera L.) : Propamocarb hydrochloride water soluble 722 g/l; Code: AE B066752 00 SL67 A206- GLP: no Unpublished	BCS
M-157228-01-1	.	1989	Propamocarb-base solubility in water of pH 7 GLP: no Unpublished	BCS
M-157242-01-1	.	1990	Propamocarb hydrochloride - solubility in organic solvents GLP: no Unpublished	BCS
M-157253-01-1		1990	The temperature dependence of the vapor pressure of Propamocarb-HCl (ZK 66752). GLP: no Unpublished	BCS
M-157256-01-1		1991	The acid dissociation constant of ZK 66 752 (Propamocarb-HCl). GLP: no Unpublished	BCS
M-157580-01-1		1986	Previcur N: Subacute systemic tolerance study in rats with dietary administration over a period of 5 weeks. GLP: no Unpublished	BCS
M-157582-01-1	.	1980	Micronucleus test on CP 604 (SN 66 752, Previcur N) propamocarb hydrochloride GLP: no Unpublished	BCS
M-157583-01-1		1979	Dominant lethal study of Previcur N propamocarb hydrochloride GLP: no Unpublished	BCS
M-157597-02-1		1990	Previcur N (CP 604) Embryotoxicity including teratogenecity study in rabbits after daily intragastrical administration from day 6 to day 18 of gestation – Revised final report. GLP: no Unpublished	BCS

M-157599-01-1	.	1982	Previcur N (SN 66 752): Toxicity and potential tumorigenecity in dietary administration to rats for 104 weeks GLP: no Unpublished	BCS
M-157604-01-1		1983	Previcur N (SN 66 752): Potential tumorigenecity to mice in dietary administration for 104 weeks GLP: no Unpublished	BCS
M-157608-02-1	.	1990	Previcur N (CP 604) Embryotoxicity including teratogenicity study in rats after daily intragastrical administration from day 6 to day 19 of gestation – Revised final report. GLP: no Unpublished	BCS
M-157610-01-1	.	1981	Mutagenecity testing in bacteria with Previcur N GLP: no Unpublished	BCS
M-157612-01-1		1982	Previcur N: Three month sub-chronic oral toxicity study in rats GLP: no Unpublished	BCS
M-157633-01-1		1985	28 days toxicity feeding study (range finding) with repetitive administration of Previcur N to Beagle dogs GLP: no Unpublished	BCS
M-157637-01-1		1985	24-month oral (feeding) study with Previcur N in Beagle dogs GLP: no Unpublished	BCS
M-157641-01-1	.	1987	Technical propamocarb hydrochloride (Previcur N): metaphase chromosome analysis of human lymphocytes cultured in vitro. GLP: no Unpublished	BCS
M-157642-01-1		1987	Technical propamocarb hydrochloride: microbial metabolic activation test to assess mutagenic potential GLP: no Unpublished	BCS
M-157653-01-1		1992	Previcur N (Promapmocarb HCl) – Rat 21-day dermal repeat dose study. GLP: no Unpublished	BCS
M-157698-01-1		1980	Photolysis experiments with Propamocarb-HCl (SN 66752) in heated sterilized aqueous solution. GLP: no Unpublished	BCS

M-157741-01-1		1980	Uptake of propamocarb fungicide by bluegills and channel catfishs. GLP: no Unpublished	BCS
M-157742-01-1		1981	Metabolic fate and tissue residues of propamocarb in bluegills and channel catfishs. GLP: no Unpublished	BCS
M-157838-01-1	.	1990	Acute toxicity of Previcur N to earthworms, Eisenia foetida using an artificial soil test GLP: no Unpublished	BCS
M-157849-01-1	.	1978	Photolysis of Propamocarb-HCl (SN 66752) in aqueous solution. GLP: no Unpublished	BCS
M-157853-01-1		1991	The static acute toxicity of propamocarb hydrochloride to the blugill sunfish, Lepomis macrochirus GLP: no Unpublished.	BCS
M-157858-01-1		1991	The static acute toxicity of propamocarb-Hcl to the rainbow trout, Oncorhyncus mykiss GLP: no Unpublished	BCS
M-157904-01-1		1992	Previcur N SL: Bobwhite quail acute oral toxicity (LD50) study GLP: no Unpublished	BCS
M-157906-01-1		1992	Previcur: Mallard duck acute oral LD50 study GLP: no Unpublished	BCS
M-164549-01-1		1990	Propamocarb hydrochloride - melting point Schering AG, Berlin, Germany GLP: no Unpublished	BCS
M-165250-01-1		1996	Toxicity to duckweed (Lemna gibba, G3) in a static renewal system : Propamocarb hydrochloride water-miscible concentrate 68.2% w/w (738 g/l) AE B066752 GLP: yes Unpublished	BCS
M-165289-01-1		1996	Effects on life-cycle of the water flea (Daphnia magna) in a static renewal system : Propamocarb hydrochloride water-miscible concentrate 68.2% w/w (738 g/l) AE B066752 GLP: yes Unpublished	BCS
M-167909-01-1		1997	Oral toxicity (LD 50) to honey bees (Apis mellifera L.); Propamocarb hydrochloride water soluble concentrate 722 g/l; AE B066752 00 SL67 A206 GLP: yes Unpublished	BCS

M-167971-01-1	1998	Bobwhite quail dietary reproduction study Propamocarb HCL liquid concentrate 780g/L Code: AE B066752 00 TK72 A101 GLP: yes Unpublished	BCS
M-167986-01-1	1998	Rat acute (4-hour) inhalation toxicity Propamocarb HCl liquid concentrate 71.2% w/v Code: AE B066752 00 TK72 A1 (CQ 684) GLP: yes Unpublished	BCS
M-168497-02-1	1998 and 2005	Propamocarb hydrochloride liquid concentrate: Rat dietary 90 daytoxicity range finding study Report and Amendment No.1 GLP: yes Unpublished	BCS
M-168498-02-1	1998 and 2005	Propamocarb hydrochloride liquid concentrate: Mouse dietary 90 day toxicity range finding study Report and Amendment No.1 GLP: yes Unpublished	BCS
M-182006-01-1	2005	Propamocarb HCL liquid concentrate: Mouse dietary oncogenicity (18 months) study Code: AE B066752 00 TK72 A101 GLP: yes Unpublished	BCS
M-183340-01-1	1998	Rat combined chronic toxicity and ongenicity (dietary) Propamocarb Hydrochloride liquid concentrate Code: AE B066752 00 TK72 A101 GLP: yes Unpublished	BCS
M-184379-01-1	1999	Guinea pig skin sensitisation study (Magnusson & Kligman Method) Propamocarb Hydrochloride liquid concentrate 71.2% w/w Code: AE B066752 00 TK72 A1 GLP: yes Unpublished	BCS
M-183416-01-1	1998	Analytical method: Determination of Propamocarb hydrochloride (AE B066752) in technical substance and formulations by HPLC Code: AE B066752 AgrEvo GmbH, Product Analysis, Frankfurt am Main, Germany GLP: no Unpublished	BCS
M-183560-02-1	1998 and 2004	Propamocarb hydrochloride liquid concentrate, 780 g/L: Rat dietary two-generation reproductive toxicity study Code: AE B066752 00 TK72 A101 Report and Amendment USA GLP: yes Unpublished	BCS

M-197256-01-1		2001	In vitro mammalian cell mutation test with mouse lymphoma cells Propamocarb hydrochloride liquid concentrate, 780 g/L Code: AE B0066752 00 7K72 A101 GLP: yes Unpublished	BCS
M-203110-01-1		2001	Partition coefficient N-octanol / water (Flash-shaking method) Propamocarb hydrochloride Code: AE B066752 00 1B97 0001 GLP: yes Unpublished	BCS
M-205214-01-1		2001	Acute oral toxicity in rats Previcur N (AE B066752 00 SL67 A2 - EXP10382A) GLP: yes Unpublished	BCS
M-205218-01-1		2001	Acute Dermal Toxicity in Rats Previcur N (AE B066752 00 SL67 A2 - EXP10382A) GLP: yes Unpublished	BCS
M-205222-01-1		2001	Acute dermal irritation in rabbits Previcur N (AE B066752 00 SL67 A2 - EXP10382A) GLP: yes Unpublished	BCS
M-205226-01-1		2001	Acute Eye irritation in Rabbits Previcur N (AE B066752 00 SL67 A2 - EXP10382A) GLP: yes Unpublished	BCS
M-206501-01-1	.	2001	Acute inhalation toxicity (nose only) study in the rat Previcur N (AE B06675200 SL67 A2 - EXP10382 A) GLP: yes Unpublished	BCS
M-240390-01-1		2001	Propamocarb Hydrochloride - Toxicity to the Freshwater Green Alga, Pseudokirchneriella Subcapitata GLP: yes Unpublished	BCS
M-240391-01-1		2001	Effects of Propamocarb Hydrochloride on Reproduction and Growth of Earthworms Eisenia Fetida (Savigny 1826) in Artificial Soil GLP: yes Unpublished	BCS
M-240450-01-1		2001	Hydrolysis of [14C]Propamocarb at pH 4,5,7 and 9 PTRL West, Inc., USA GLP Unpublished	BCS
M-252483-01-1		2005	AE B066752 00 SL67 A2 (Previcur N) - Evaluation of potential dermal sensitization in the local lymph node assay in the mouse GLP: yes Unpublished	BCS

M-310337-01-1	1995	Proplant (Propamocarb hydrochloride 722 g/l SL) Acute oral toxicity study in the rat - fixed dose method GLP: yes Unpublished	Agriphar S.A.
M-310341-01-1	1995	Proplant (Propamocarb hydrochloride 722 g/l SL) Acute dermal toxicity (limit test) in the rat GLP: yes Unpublished	Agriphar S.A.
M-310346-01-1	1995	Proplant (Propamocarb hydrochloride 722 g/l SL) Acute dermal irritation test in the rabbit GLP: yes Unpublished	Agriphar S.A
M-310352-01-1	1995	Proplant (Propamocarb hydrochloride 722 g/l SL) Acute eye irritation test in the rabbit GLP: yes Unpublished	Agriphar S.A.
M-310356-01-1	1995	Proplant (Propamocarb hydrochloride 722 g/l SL) - Modified nine-induction Buehler delayed contact hypersensitivity study in the Guinea pig GLP: yes Unpublished	Agriphar S.A
M-310359-01-1	1997	A 28-day range-finding (dietary) toxicity study in rats with Proplant GLP: no Unpublished	Agriphar S.A.
M-310378-01-1	2000	A preliminary 28-day oral (gavage) dose range-finding toxicity study in rats with Proplant GLP: no Unpublished	Agriphar S.A.
M-310427-01-1	2000	A preliminary dose-ranging three-month oral (gavage) dose toxicity study in CD-1 mice with Proplant GLP: no Unpublished	Agriphar S.A.
M-310432-01-1	2001	Propamocarb HCl 722 G/L - 90-day oral dietary toxicity study in wistar rats, followed by a 28-day recovery period GLP: yes Unpublished	Agriphar S.A.
M-310439-01-1	2001	Propamocarb HCL 722 G/L - 90-day oral dietary toxicity study in male and female beagle dogs GLP: yes Unpublished	Agriphar S.A.
M-310442-01-1	2003	52-week oral dietary toxicity study with Proplant (Propamocarb HCl 722 g/l) in male and female beagle dogs GLP: yes Unpublished	Agriphar S.A.
M-310445-01-1	2002	Proplant (Propamocarb HCl 722 g/l) : Repeated dose (28-days) dermal toxicity by daily exposure in the rat. GLP: yes Unpublished	Agriphar S.A.

M-310446-01-1		1997	Propamocarb HCl 722 g/l : Reserve mutation assay "Ames Test" using Salmonella typhimurium GLP: yes Unpublished	Agriphar S.A.
M-310449-01-1	.	2001	Evaluation of the mutagenic activity of Proplant (propamocarb HCl 722 g/l) in the Escherichi coli reverse mutation assay (with independent repeat) GLP: yes Unpublished	Agriphar S.A
M-310453-01-1		2001	Evaluation of the ability of Proplant (Propamocarb HCl 722 g/l) to induce chromosome aberrations in cultured peripheral human lymphocytes GLP: yes Unpublished	Agriphar S.A
M-310551-01-1		2001	Evaluation of the mutagenic activity of Proplant (propamocarb HCl 722 g/l) in an in vitro mammalian cell gene mutation test with L5178Y mouse lymphoma cells (with independant repeat) GLP: yes Unpublished	Agriphar S.A
M-310555-01-1		2001	Micronucleus test in bone marrow cells of the mouse with Proplant GLP: yes Unpublished	Agriphar S.A
M-310604-01-1		2001	A two year oral (dietary) combined chronic toxicity and oncogenicity study in rats with Proplant GLP: no Unpublished	Agriphar S.A
M-310609-01-1		2002	52-week oral dietary toxicity study with Proplant (Propamocarb HCl 722 g/l) in Wistar rats GLP: yes Unpublished	Agriphar S.A
M-310623-01-1		2003	18-months oral dietary carcinogenicity study with Proplant (Propamocarb HCl 722 g/l) in CD-1 mice GLP: yes Unpublished	Agriphar S.A.
M-310681-01-1		2002	An oral (gavage) two-generation reproduction toxicity in rats with Proplant GLP: yes Unpublished	Agriphar S.A
M-310689-01-1	.	2001	Proplant (Propamocarb HCl 722 g/l) : Embryotoxicity and teratogenicity study by dietary administration in female wistar rats GLP: yes Unpublished	Agriphar S.A
M-310703-01-1		2002	Proplant (Propamocarb HCl 722 g/l) : Embryotoxicity and teratogenicity study by dietary administration in female albino NZW rabbits GLP: yes Unpublished	Agriphar S.A
M-310720-01-1		1996	Acute limit study in Daphnia magna with Proplant GLP: yes Unpublished	Agriphar S.A

M-310729-0-1-		2002	Proplant - Early life-stage toxicity test with Fathead minnow (Pimephales promelas) under flow-through conditions GLP: yes Unpublished	Agriphar S.A
M-310783-01-1		2003	Proplant - Reprodutive toxicity test with mallard duck (Anas platyrhynchos) GLP: yes Unpublished	Agriphar S.A
M-310796-01-1		2002	Proplant - Dietary toxicity test with mallard duck (Anas platyrhynchos) GLP: yes Unpublished	Agriphar S.A
M-310799-01-1		2001	5-day dietary toxicity study in bobwhite quail Proplant (propamocarb HCL 722 g/l) GLP: yes Unpublished	Agriphar S.A
M-310999-01-1		1995	Proplant - Acute inhalation toxicity study four - hour exposure (nose only) in the rat GLP: yes Unpublished	Agriphar S.A
M-357736-01-1	FAO/WHO	1984	Pesticide residues in food – 1984. Report of the Joint Meeting on Pesticide Residues, Rome, 24 September to 3 October, 1984 FAO Plant Production and Protection Paper 62 Publication	-
M-357742-01-1	FAO/WHO	1986	Pesticide residues in food – 1986. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues, Rome, 29 September to 8 October, 1986 FAO Plant Production and Protection Paper 77 Publication	-
M-360693-03-1	FAO/WHO	2010	Manual on development and use of FAO and WHO specifications for pesticides - Second revision of the first edition	-