Food and Agriculture Organization
of the United Nations

FAO SPECIFICATIONS AND EVALUATIONS

FOR AGRICULTURAL PESTICIDES

CHLORFENAPYR

4-bromo-2-(4-chlorophenyl)-1-ethoxymethyl-5-trifluoromethyl-1*H*-pyrrole-3-carbonitrile

2014

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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.

From 2002, the development of WHO specifications follows the **New Procedure**, described in the 1st edition of "Manual for Development and Use of FAO and WHO Specifications for Pesticides" (2002) and amended with the supplement of this manual (2006), which is available only on the internet through the FAO and WHO web sites. 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/pest-and-pesticide-management/en/) OR IN HARDCOPY FROM THE PLANT PROTECTION INFORMATION OFFICER.

PART ONE

SPECIFICATIONS

CHLORFENAPYR

INFORMATION

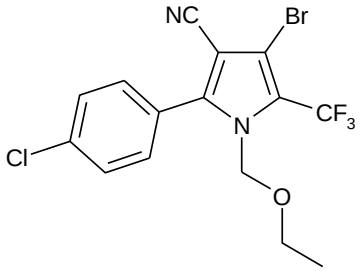
ISO common name
Chlorfenapyr (ISO 1750 approved)

Synonyms
None

Chemical names

IUPAC 4-bromo-2-(4-chlorophenyl)-1-ethoxymethyl-5-trifluoromethyl-*1H*-pyrrole-3-carbonitrile
CA 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-*1H*-pyrrole-3-carbonitrile

Structural formula



Molecular formula
$C_{15}H_{11}BrClF_3N_2O$

Relative molecular mass
407.6

CAS Registry number
122453-73-0

CIPAC number
570

Identity tests
HPLC retention time, IR spectrum

CHLORFENAPYR TECHNICAL MATERIAL

FAO Specification 570 / TC (December 2014[*])

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 (570/2014). It should be applicable to TC produced by this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for TC produced by other manufacturers. The evaluation report (570/2014), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of chlorfenapyr together with related manufacturing impurities and shall be an off-white to tan halide-smelling solid, free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 **Identity tests** (570/TC/M/2 CIPAC/4826) (Note 1)

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 **Chlorfenapyr content** (570/TC/M/3 CIPAC/4826) (Note 1)

The chlorfenapyr content shall be declared (not less than 940 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

Note 1 The method of analysis for identification and determination of chlorfenapyr content in TC and SC, was adopted as CIPAC Method in 2011 and became a full method in 2012. Prior to its publication in CIPAC Handbook O, copies of the method may be obtained via the CIPAC pre-published methods scheme https://www.cipac.org/index.php/methods-publications/pre-published-methods

[*] Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/pest-and-pesticide-management/expert-bodies-conventions/faowho-joint-meeting-on-pesticide-specifications-jmps/en/

CHLORFENAPYR AQUEOUS SUSPENSION CONCENTRATE

FAO Specification 570 / SC (December 2014*)

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 (570/2014). It should be applicable to SC produced by this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for SC produced by other manufacturers. The evaluation report (570/2014), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of a suspension of fine particles of technical chlorfenapyr, complying with the requirements of FAO specification 570/TC (December 2014), in the form of off-white to tan, mildly sweet smelling liquid, in an aqueous phase together with suitable formulants. After gentle agitation the material shall be homogeneous (Note 1) and suitable for further dilution in water.

2 Active ingredient

2.1 **Identity tests** (570/SC/M/2 CIPAC/4826) (Note 2)

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

2.2 **Chlorfenapyr content** (570/SC/M/3 CIPAC/4826) (Note 2)

The chlorfenapyr content shall be declared (g/kg or g/l at 20 ± 2ºC, Note 3) 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 25 up to 100 above 100 up to 250 Note in each range the upper limit is included	± 10% of the declared content ± 6% of the declared content

3 Physical properties

3.1 **Pourability** (MT 148.1, CIPAC Handbook J, p. 133, 2000)

Maximum "residue": 5%.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/pest-and-pesticide-management/en/

3.2 **Spontaneity of dispersion** (MT 160, CIPAC Handbook F, p. 391, 1995) (Notes 4 & 5)

A minimum of 80% of the chlorfenapyr content found under 2.2 shall be in suspension after 5 min in CIPAC Standard Water D at 30 ± 2°C (Note 6).

3.3 **Suspensibility** (MT 184, CIPAC Handbook K, p. 142, 2003) (Note 4)

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

3.4 **Wet sieve test** (MT 185, CIPAC Handbook K, p. 149, 2001) (Note 6)

Maximum: 2 % of the formulation shall be retained on a 75 µm test sieve.

3.5 **Persistent foam** (MT 47.3) (Notes 7 & 8)

Maximum: 50 ml after 1 min.

4 Storage stability

4.1 **Stability at 0°C** (MT 39.3, CIPAC Handbook J, p. 128, 2000)

After storage at 0 ± 2°C for 7 days, the formulation shall continue to comply with clauses for:
- suspensibility (3.3),
- wet sieve test (3.4)

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

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 95% relative to the determined average content found before storage (Note 9) and the formulation shall continue to comply with the clauses for:
- pourability (3.1),
- spontaneity of dispersion (3.2),
- suspensibility (3.3),
- wet sieve test (3.4)

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

Note 2 The method of analysis for identification and determination of chlorfenapyr content in TC and SC, was adopted as CIPAC Method in 2011 and became a full method in 2012. Prior to its publication in CIPAC Handbook O, copies of the method may be obtained via the CIPAC pre-published methods scheme https://www.cipac.org/index.php/methods-publications/pre-published-methods

Note 3 Unless homogenization is carried out carefully, it is possible for the sample to become aerated. This can lead to errors in the determination of the mass per millilitre and in the calculation of the active

ingredient content (in g/l) if methods other than MT 3.3 are used. If the buyer requires both g/kg and g/l at 20 °C, then in case of dispute the analytical results shall be calculated as g/kg.

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

Note 5 The test should be carried out at the maximum application rate of use recommended by the supplier.

Note 6 This test detects coarse particles (e.g. caused by crystal growth) or agglomerates (crust formation) or extraneous materials, which could cause blockage of spray nozzles or filters in the spray tank.

Note 7 MT 47.3 is a revised version of MT 47.2 using a standard measuring cylinder. Prior to publication of the method in a Handbook, copies of the method may be obtained through the CIPAC website, https://www.cipac.org/index.php/methods-publications/pre-published-methods .

Note 8 The mass of sample to be used in the test should be at the application rate of use recommended by the supplier.

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

PART TWO

EVALUATION REPORTS

CHLORFENAPYR

CHLORFENAPYR

FAO/WHO EVALUATION REPORT 570/2014

Recommendations

The Meeting recommended that the specifications for chlorfenapyr TC and SC, proposed by BASF Agro B.V. and as amended, should be adopted by FAO.

Appraisal

The data for chlorfenapyr were evaluated in support of new FAO and WHO specifications for TC and SC. The supporting data and draft specifications were provided by BASF Agro B.V. (BASF) in 2010 and a revised submission in September 2011. As the recommendation of the 16th WHOPES working group meeting on the use of the chlorfenapyr SC formulation in public health was to further evaluate the potential of product indoor residual spraying, the Meeting recommended to publish the FAO specification for chlorfenapyr TC and SC formulation.

Chlorfenapyr is not under patent.

Chlorfenapyr has not been evaluated by the FAO/WHO JMPR and WHO/IPCS. The US EPA has completed a review of the toxicological data submitted for this compound. [EPA 2001]

Chlorfenapyr was evaluated by the European Commission as a Biocidal Product Type 8 (wood preservative), with Portugal as the Rapporteur Member State, and approved for inclusion into Annex I of the Biocidal Products Directive, 98/8/EC. It is currently under evaluation under the Biocidal Products Regulation No.528/2012 as an insecticide active substance (Biocidal Product Type 18). Chlorfenapyr was not included in Annex I of the Council Directive 91/414/EEC. [CD, 2001]

The data submitted were in accordance with the requirements of the revised (revision June 2009) 1st edition of the Manual on development and use of FAO and WHO specifications for pesticides [FAO/WHO Manual] and supported the proposed specifications.

The confidential data provided on the manufacturing process of chlorfenapyr are very similar to the information supplied to EPA OPP. It is however noted that a higher alkylated benzene instead of a related one with lower boiling was specified. The impurities and QC limits for chlorfenapyr TC produced by BASF agree exactly between the information submitted to FAO and to the US EPA, with the exception for the declared minimum content of the active substance which is lower in the US than in the FAO submission (930 g/kg instead of 940 g/kg) [Funk, 2011]

The confidential data submitted by the proposer on the manufacturing process of chlorfenapyr, the data summary in support of the physical-chemical, toxicological and ecotoxicological properties were in accordance with those evaluated by Portugal as part of the European review programme under the Biocide Products Directive 98/8/EC. The only difference is that in the manufacturing process an alkylated aromatic solvent was replaced by a related one with lower boiling point.

Chlorfenapyr is a white to pale yellow solid. It has a low vapour pressure. The compound does not have ionizable groups - therefore, the low water solubility and the octanol/water partition coefficient are not pH dependent. The active ingredient is stable to hydrolysis at pH 4, 7 and 9 at 50°C. In simulated sunlight there is degradation with half-lives of 5-8 days at pH 5, 7 and 9.

The main formulation types available are aqueous suspension concentrates (SC).

The Meeting was provided with commercially confidential information on the manufacturing process and batch analysis data on all impurities present below or above 1 g/kg and their manufacturing limits in the TC. Mass balances were 98.6 – 99.8 % in the 5-batch data.

Based on JMPS standard estimation of relative toxicity of the impurity and the active ingredient, the impurity CL 303,268 (tralopyril) could be considered as relevant. The Meeting considered, that exposure to even pure chlorfenapyr would actually lead to exposure to tralopyril generated in the metabolism and hence the contribution of tralopyril to the hazard would be covered in the toxicity studies.

The justification was accepted and tralopyril is not considered as a relevant impurity in the technical material.

The identity of chlorfenapyr is confirmed by comparing the retention time in the HPLC method and by IR spectroscopy. The analytical method for the determination of the active ingredient in chlorfenapyr technical and SC formulations is reversed-phase HPLC with UV detection. Impurities were determined by HPLC-UV and HRGC. The LOQs for chlorfenapyr and the impurities were 0.1 g/kg in the TC. Test methods for determination of physical-chemical properties of the technical active ingredient and formulations were OECD, EPA, EC and CIPAC, as indicated in the specifications and supporting data, respectively.

The Meeting recommended amendment of the suspensibility specification clause for chlorfenapyr SC and to replace MT 161 with MT 184 - the harmonization of methods MT 15, MT 161 and MT 168. [CIPAC K]

The Meeting also recommended amendment of the low temperature stability clause for chlorfenapyr SC, and to replace MT 39.2 with MT 39.3 [CIPAC J].

SUPPORTING INFORMATION
FOR
EVALUATION REPORT 570/2014

USES

Chlorfenapyr is a broad-spectrum insecticide and acaricide acting through ingestion and by contact. It is used in agriculture against leafminers, thrips, mites and other pests, and in non-crop and public health against termites, cockroaches, ants, bedbugs, flies, spiders, centipedes and other insect pests.

BASF chlorfenapyr is currently registered in Brazil [since 1997], Australia [since 1998], Japan [since 1996], Mexico [since 1997] and the USA [since 2001], as well as in several other countries, for agricultural and/or non-crop uses.

IDENTITY OF THE ACTIVE INGREDIENT

ISO common name

Chlorfenapyr (ISO 1750 approved)

Synonyms

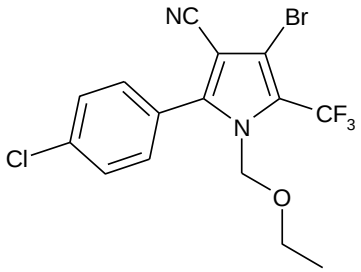
None

Chemical names

IUPAC 4-bromo-2-(4-chlorophenyl)-1-ethoxymethyl-5-trifluoromethyl-*1H*-pyrrole-3-carbonitrile

CA 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-*1H*-pyrrole-3-carbonitrile

Structural formula



Molecular formula

$C_{15}H_{11}BrClF_3N_2O$

Relative molecular mass

407.6

CAS Registry number

122453-73-0

CIPAC number

570

Identity tests

HPLC retention time, IR spectrum

Table 1: Physico-chemical properties of pure chlorfenapyr

Parameter	Values and conditions	Purity % Note[2]	Method reference (and technique if the reference gives more than one)	Study number
Vapour pressure	5.40E-6 Pa at 25 °C (extrapolated from measurements at 60, 70 and 80°C)	99.7	OPPTS 830.7950, EC Annex V method A.4	CK-306-003, 1997/7000836
Melting point.	101.4 - 102.3 °C	99.0	EC Annex V Method A.2, OECD 102	CK-303-002, 1994/7000817
Temperature of decomposition	~183°C	93.6	OPPTS 830.6316	CK-334-001, 1993/7001056
Solubility in water	0.11 mg/l at 20°C, pH=5 0.11 mg/l at 20°C, pH=7 0.14 mg/l at 20°C, pH=9 0.11 mg/l at 10°C, unbuffered deionized water 0.14 mg/l at 20°C, unbuffered deionized water 0.20 mg/l at 30°C, unbuffered deionized water	99.0	EC Annex V method A.6, Shake Flask	CK-311-001, 1994/7000775
Octanol/water partition coefficient	log P_{OW} = 5.28 at 20°C , pH=5 log P_{OW} = 5.21 at 20°C , pH=7 log P_{OW} = 5.24 at 20°C , pH=9 log P_{OW} = 5.28 at 20°C , deionized water	99.0	OECD 107	CK-315-002, 1995/7000648
Hydrolysis characteristics	Half-life = stable at 50 °C at pH 4 Half-life = stable at 50 °C at pH 7 Half-life = stable at 50 °C at pH 9	99.0	EC Annex II section 2.9.1, OECD 111	CK-322-005, 1993/7002659
Photolysis characteristics	Half-lives under conditions that approximate a summer day in Princeton, NJ, USA (40.3°N) were 5 to 8 days Predicted half-lives for Central Europe (52ºN), using the method of Frank and Klöpffer, were 2.3 hours in June and 1.0 day in December	97.0 99.7	US EPA 161-2 BBA Guideline IV, 6-1, July 1990	CK-630-003, 1994/7000719 CK-630-006, 1995/7000721
Dissociation characteristics	The active substance does not contain any ionisable groups	-	Waiver	CK-322-001, 1994/7001669

[2] Purity is the content of pure active ingredient in the technical material, expressed as a percentage

Parameter	Values and conditions	Purity % Note[2]	Method reference (and technique if the reference gives more than one)	Study number
Solubility in organic solvents	Temperature: 20°C (mg/L) hexane: 6850 methanol: 50600 acetonitirile: 394000 toluene: 490000 acetone: 697000 dichloro-methane: 744000 ethyl acetate: 514000	99.0	EC Annex V, A.6	CK-311-001, 1994/7000775

Table 2: Chemical composition and properties of chlorfenapyr technical material

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 98.6 – 99.8 % and percentages of unknowns were < 0.1 %.
Declared minimum chlorfenapyr content	940 g/kg
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
Melting temperature range of the TC	100 - 101°C (98.8%)

HAZARD SUMMARY

Chlorfenapyr has not been evaluated by the WHO IPCS or FAO/WHO JMPR.

The IPCS hazard classification of chlorfenapyr is: moderately hazardous, class II. [WHO, 2009]

EU classification of chlorfenapyr according to Regulation No 1272/2008/EC (Annex VI Table 3.2):

T; R23 Toxic by inhalation.
Xn; R22 Harmful if swallowed.
N; R50-53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Hazard class and category codes (Annex VI Table 3.1):

Acute Tox. 3 H331 Toxic if inhaled
Acute Tox. 4 H302 Harmful if swallowed
Aquatic Acute 1 H400 Very toxic to aquatic life
Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects [CLP, 2009]

FORMULATIONS

The main formulation type available is SC.

METHODS OF ANALYSIS AND TESTING

The analytical method for the active ingredient in TC and in SC formulations is a full CIPAC method. Chlorfenapyr is determined by reverse phase HPLC chromatography and UV detection. [CIPAC 570].

The method for determination of impurities are based on HPLC and HRGC and are adequately validated.

Test methods for determination of physical-chemical properties of the technical active ingredient were OECD, EPA or EC, while those for the formulations are CIPAC.

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

PHYSICAL PROPERTIES

The physical properties, the methods for testing them and the limits proposed for the SC formulation, comply with the requirements of the FAO/WHO Manual.

CONTAINERS AND PACKAGING

No special requirements for containers and packaging have been identified.

EXPRESSION OF THE ACTIVE INGREDIENT

The active ingredient is expressed as chlorfenapyr.

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 chlorfenapyr 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 chlorfenapyr technical material, based on acute toxicity, irritation and sensitization

Species	Test	Purity % Note[3]	Guideline, duration, doses and conditions	Result	Study number
Rat (m, f)	oral	94.5	Single exposure. Study conducted according to U.S. EPA Guideline No: 81-1. Doses: 156.25, 312.5, 625, 1250 and 2500 mg/kg b.w.	LD_{50} ♂: 441 mg/kg b.w. ♀ 1152 mg/kg b.w.	CK-411-001 1993/7001133
Mouse (m, f)	oral	94.5	Single exposure. Study conducted according to JMAFF Guideline No: 59 NohSan No. 4200. Doses: 35, 70 and 140 mg/kg b.w.	LD_{50} ♂ 45 mg/kg b.w. ♀ 78 mg/kg b.w.	CK-411-004 1994/7000707
Rabbit (m, f)	dermal	94.5	Single exposure. Study conducted according to U.S. EPA Guideline No.: 81-2. Dose: 2000 mg/kg b.w.	LD_{50} > 2000 mg/kg b.w.	CK-412-001 1992/7001140
Rat (m, f)	inhalation	94.5	Single 4-hour exposure. Study conducted according to U.S. EPA Guideline No.: 81-3 Doses: 0, 0.34, 0.71, 1.8 and 2.7 mg/L.	LC_{50} ♂: 0.83 mg/L ♀ > 2.7 mg/L	CK-413-001 1993/7001115
Rabbit (m)	skin irritation	94.5	Single exposure, Study conducted according to U.S. EPA Guideline No.: 81-5. Dose: 0.5 g.	Not irritating	CK-415-004 1993/7001137
Rabbit (m)	eye irritation	94.5	Single exposure, Study conducted according to U.S. EPA Guideline No.: 81-4. Dose: 0.1 mg.	Not irritating	CK-415-003 1993/7001138
Guinea pig (f)	skin sensitisation	95.2	Maximisation test. Study conducted according to JMAFF Guideline No: 59 NohSan No. 4200, OECD guideline No.406, 1992, U.S. EPA Guideline No.: 81-6. Doses: 0.05 mL of 2 w/v% suspension in live oil intradermal and 0.2 mL of 10 w/v% suspension in olive oil topical (induction); 0.5 mL of 0.4 w/v% suspension in olive oil topical (challenge).	Not a skin sensitizer	CK-416-002 1999/7000754

Technical chlorfenapyr is moderately toxic in rats via the oral route and inhalation. Mice were found to be more susceptible towards the acute oral effects of chlorfenapyr technical than the rat. Chlorfenapyr has a low magnitude of toxicity by dermal route of exposure. It is not irritating to the skin or eye in rabbits. It does not cause delayed contact hypersensitivity in guinea pigs by testing according to the maximisation test.

[3] Purity is the content of pure active ingredient in the technical material, expressed as a percentage

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

Species	Test	Purity % Note[4]	Guideline, duration, doses and conditions	Result	Study number
Rat (m, f)	Oral dietary	98.4	28-day study conducted according to OECD Method 407. Doses: 0, 600, 900, 1200, 1600, 2000 ppm. (approx. 0, 72, 108, 139, 185, 246 mg/kg b.w./day).	NOAEL < 71.6 mg/kg b.w./day.	CK-420-003, 1991/7001094
Mouse (m, f)	Oral dietary	98.4	28-day study conducted according to OECD Method 407. Doses: 0, 160, 240, 320, 480, 640 ppm. (approx. 0, 32, 51, 67, 112, 144 mg/kg b.w./day).	NOAEL < 32 mg/kg b.w./day.	CK-420-004, 1991/7001093
Rat (m, f)	Oral dietary	93.6	90-day study conducted according to U.S. EPA Guideline No.: 82-1. Doses: 0, 150, 300, 600, 900, 1200 ppm. (approx. 0, 12, 24, 48, 73, 98 mg/kg b.w./day).	NOAEL = 11.7 mg/kg b.w./day.	CK-425-002, 1993/7001148
Mouse (m, f)	Oral dietary	93.6	90-day study conducted according to U.S. EPA Guideline No.: 82-1. Doses: 0, 40, 80, 160, 320 ppm. (approx. 0, 8, 17, 34, 70 mg/kg b.w./day).	NOAEL = 8.2 mg/kg b.w./day.	CK-425-003, 1994/7000836
Dog, Beagle (m, f)	Oral dietary	94.5	90-day study conducted according to U.S. EPA Guideline No.: 82-1. Doses: 60, 120, 300 ppm. (approx. 0, 2, 4, 4/6/7 mg/kg b.w./day for males and 0, 2, 5, 6/6/7 mg/kg b.w./day for females).	NOAEL = 4.2 mg/kg b.m/day	CK-425-001, 1993/7001149
Dog, Beagle (m, f)	One year dietary toxicity	94.5	12-month study conducted according to U.S. EPA Guideline No.: 83-1. Doses: 0, 60, 120, 240 ppm. (approx. 0, 2, 4, 9 mg/kg b.w./day for males and 0, 2, 5, 10 mg/kg b.w./day for females).	NOAEL = ♂: 4.0 mg/kg b.m/day ♀: 4.5 mg/kg b.m/day	CK-427-004, 1994/7000794

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

Species	Test	Purity % Note[4]	Guideline, duration, doses and conditions	Result	Study number
Rat (m, f)	Chronic dietary toxicity and carcinogenicity	94.5	24-month study conducted according to U.S. EPA. Guideline No.: 83-5 Doses: 60, 300, 600 ppm in the feed. (approx. 0, 3, 15, 31 mg/kg b.w./day for males and 0, 4, 19, 37 mg/kg b.w./day for females)	organ x, type of tumour incidences were generally low, no significant differences between control and treated groups of animals other effects: At 200 ppm, decreases in body weight and body weight gain, decreases in albumin/globulin ratios, increases in total cholesterol and hepatocellular enlargement. NOAEL 60 ppm, 2.9 and 3.6 mg/kg b.m./day for males and females, respectively	CK-427-002, 1994/7000797
Mouse (m, f)	Chronic dietary toxicity and carcinogenicity	94.5	24-month study conducted according to U.S. EPA Guideline No.: 83-2. Doses: 20, 120, 240 ppm in the feed. (approx. 0, 3, 17, 35 mg/kg b.w./day for males and 0, 4, 22, 45 mg/kg b.w./day for females).	organ x, type of tumour no significant differences between control and treated groups of animals other effects: At 240 ppm: Increased mortality, not attributable to any neoplastic changes. At 120 ppm, reduced body weight gain and vacuolization of the white matter of the brain at 120 ppm. NOAEL 20 ppm, 2.8 and 3.7 mg/kg b.m./ day for males and females, respectively	CK-428-002, 1994/7000798
Rat (f)	Oral developmental toxicity (embryo-fetal toxicity/	94.5	Study conducted according to U.S. EPA Guideline No.: 83-3 Doses: 0, 25, 75, 225 mg/kg b.w./day from gestation days 6 to 15.	Ovarian, uterine and fetal observations were unaffected at all dose levels. No external, soft tissue or skeletal malformations or variations were attributed to	CK-432-001, 1993/7001107

Species	Test	Purity % Note[4]	Guideline, duration, doses and conditions	Result	Study number
	teratogenicity)			treatment. NOEL for maternal toxicity: 25 mg/kg b.w./day based on reduced maternal body weight gains, food consumption and water consumption. NOEL for fetal/developmental toxicity: 225 mg/kg b.w./day. Not a developmental toxicant nor a teratogenic agent in the rat.	
Rabbit (f)	Oral developmental toxicity (embryo-fetal toxicity/ teratogenicity)	94.5	Study conducted according to U.S. EPA Guideline No.: 83-3 Doses: 0, 5, 15, 30 mg/kg b.w./day from gestation days 7 to 19.	NOEL for maternal toxicity: 5 mg/kg b.w./day based on reduced maternal body weight gains nad food consumption. NOEL for fetal/developmental toxicity: 30 mg/kg b.w./day. Not a developmental toxicant nor a teratogenic agent in the rabbit.	CK-432-002, 1993/7001106
Rat (m, f)	Two-generation (One-Litter) reproduction study in rat	94.5	Study conducted according to U.S. EPA Guideline No.:83-4. Doses: 0, 60, 300, 600 ppm in the feed (approx. 0, 5, 25, 44 mg/kg b.w./day) for two successive generations (P_1 and F_1).	Parental toxicity (reduced mean body weights and body weight gains) was noted at the 300 and 600 ppm dietary levels. There was no evidence of any parental toxicity at the 60 ppm dietary level. Reproductive performance was not affected at any dietary dose level. No adverse effects at the 60, 300 or 600 ppm dietary levels were evident from reproductive indices, gestation indices or parturition data during either litter interval. The only neonatal parameters	CK-430-002, 1994/7000839

Species	Test	Purity % Note[4]	Guideline, duration, doses and conditions	Result	Study number
				significantly affected by treatment were reductions in pup body weights (at the 300 ppm and 600 ppm) and reductions in pup survival (at 600 ppm in the F2 litters from postnatal day 0 to 4). NOEL for general maternal toxicity and toxicity to the offspring = 60 ppm (equivalent to approximately 5 mg/kg b.w./day)	
Rat (m, f)	Acute neurotoxicity	94.9	Single exposure. Study conducted according to U.S. EPA Guideline No.:81-8. Doses: 45, 90, 180 mg/kg b.w.	Increased mortality noted at 180 mg/kg b.w. Clinical signs of toxicity (changes in gait, locomotion and arousal, lethargy) noted at 180 and 90 mg/kg b.w. LOAEL = 90 mg/kg b.w. NOAEL = 45 mg/kg b.w. Not considered to be an acute neurotoxicant.	CK-451-001, 1996/7001081
Rat (m, f)	One-year dietary neurotoxicity	94.5	12-month study conducted according to U.S. EPA Guideline No.: 83-1. Doses: 60, 800, 600 ppm in the feed (approx. 0, 3, 15, 30 mg/kg b.w./day)..	Reduced body weights, body weight gains and feed efficiency. Vacuolation and/or myelin sheath swelling of the brain and spinal cord in males at 300 ppm and above. This process was not associated with any evidence of myelin or axon degeneration and was not evident after the recovery period. LOAEL = 300 ppm NOAEL = 60 ppm (equivalent to daily intake of 2.6 mg/kg b.w./day for males and 3.4 mg/kg b.w./day	CK-451-002, 1994/7000730

Species	Test	Purity % Note[4]	Guideline, duration, doses and conditions	Result	Study number
				for females)	

Results observed following long-term dietary administration of chlorfenapyr technical to rats, mice and dogs were similar to those noted following short-term oral administration. The NOAELs for all three species were in the same range, with the lowest NOAEL in rodents: 60 ppm in rats (2.9 and 3.6 mg/kg b.w./ day for males and females, respectively) and 20 ppm in mice (2.8 and 3.7 mg/kg b.w./ day for males and females, respectively). Long-term dietary administration of chlorfenapyr technical resulted in no treatment-related oncogenic findings in either rats or mice.
Results from developmental toxicity studies in rats and rabbits showed that chlorfenapyr technical is neither a teratogen nor a developmental toxicant. The NOAELs for developmental toxicity were the highest doses tested in the respective studies, when tested up to maternally toxic doses (30 and 225 mg/kg b.w./day for rabbits and rats, respectively). The NOAELs for maternal toxicity were 5 and 25 mg/kg b.w./day for rabbits and rats, respectively.
Results from a 2-generation reproductive toxicity study in rats showed that chlorfenapyr technical is not selectively toxic to the fertility or the developing offspring. The NOAEL for general maternal toxicity and toxicity to the offspring was 60 ppm (equivalent to approximately 5 mg/kg b.w.).
Results from a one-year neurotoxicity study in rats showed myelin sheath swelling in the spinal nerve roots after 13 weeks of treatment and myelinopathy of the brain and spinal cord after 52 weeks of treatment at doses of 300 and 600 ppm. The NOAEL was 60 ppm (2.6 and 3.4 mg/kg b.m./day for males and females, respectively). The findings were consistent with the neuropathological findings observed in the short-term rodent and long-term mouse studies. The effects were shown to be completely reversible following a 4-month recovery period. The alterations occurred in the absence of direct, degenerative damage to myelin (such as demyelination) or axons (such as axonal degeneration), and were not associated with any clinical behavioral effects (as evidenced by negative findings in the functional observation battery and motor activity tests).

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

Species	Test	Purity % Note[5]	Guideline, duration, doses and conditions	Result	Study number
Salmonella typhimurium and *Escherichia coli*	Bacterial Reverse Gene Mutation *in vitro* test	94.5	Study conducted according to U.S. EPA Guideline No.: 84-1 and 84-2. Doses: 0, 0.5, 1, 5, 10, 15, 20 and 25 μg/plate with and without S-9 (3 replicates each).	Does not induce either base-pair substitution or frame-shift mutation in any of the tester bacterial strains. Not mutagenic.	CK-435-001, 1994/7000799
Chinese Hamster lung cell culture	Chromosome aberrations, cytogenic investigation *in vitro* test	93.8	Study conducted according to OECD 473. Doses: 0, 0.9, 1.8, 3.5, 7.0, 14.1, 28.1, 56.3, 112.5, 225, 450, 900 and 1800 μg/ml with and without S-9.	Not clastogenic or polyploidy-inducing agent.	CK-435-007, 1994/7000803
Chinese Hamster Ovary cell culture	Chromosome aberrations, cytogenic investigation *in vitro* test	94.5	Study conducted according to EPA Guideline No.: 84-2. Doses: 0, 6.25, 12.5, 25 and 50 μg/ml with S-9; 0, 12.5, 25, 50 and 100 μg/ml without S-9.	Not clastogenic or polyploidy-inducing agent.	CK-435-006, 1994/7000835
Primary rat hepatocytes	Unscheduled DNA Synthesis *in vitro* test	94.5	Study conducted according to U.S. EPA Guideline No.: 84-4. Doses: 0, 0.05, 0.075, 0.1, 0.125, 0.15 and 0.3 μg/ml.	Because of excessive toxicity at 0.30 μg/ml, the highest dose evaluated was 0.15 μg/ml. No significant increase in the incorporation of tritiated thymidine into nuclear DNA of the cultured cells was found at any dose level. No induction of DNA damage in cultured rat hepatocytes.	1993/7001146, CK-435-003
Chinese Hamster Ovary cell culture	Mammalian Cell CHO/HGPRT Mutagenicity *in vitro* test	94.5	Study conducted according to U.S. EPA Guideline No.: 84-1 and 84-2. Doses: 0, 5, 10, 50, 100, 250 and	Because of excessive toxicity at 500 μg/ml, the highest dose evaluated was 250 μg/ml. No induced mutations at the HGPRT locus in	CK-435-004, 1994/7000834

[5] Purity is the content of pure active ingredient in the technical material, expressed as a percentage

Species	Test	Purity % Note[5]	Guideline, duration, doses and conditions	Result	Study number
			500 μg/ml with metabolic activation; 0, 2.5, 5, 10, 50, 100, and 250 μg/ml without metabolic activation.	CHO cells. Not mutagenic.	
Mouse (m, f)	*in vivo* Micronucleus Assay in Mouse Bone Marrow Cell	94.5	Single exposure. Study conducted according to U.S. EPA Guideline No.: 84-2. Doses: 0, 7.5, 15, 30 mg/kg b.w. (males); 0, 5, 10, 20 mg/kg b.w. (females).	No effect on the number of micronucleated polychromatic erythrocytes in the bone marrow at any dose level at any sacrifice interval for males or females. Does not cause chromosomal damage *in vivo*. Not genotoxic.	CK-435-002, 1992/7001141

Results from a battery of *in vitro* and *in vivo* genotoxicity studies showed no indication of a mutagenic or genotoxic potential of chlorfenapyr technical material.

Table 6. Ecotoxicology profile of technical chlorfenapyr

Species	Test	Purity % Note[6]	Guideline, duration, doses and conditions	Result	Study number
Lepomis macrochirus (bluegill fish)	Acute toxicity	94.5	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-1. Doses: 0, 5.03, 9.53, 14.7, 26.5, and 43.6 μg/L.	LC_{50} = 11.6 μg/L NOEC = 5.03 μg/L	CK-511-001; 1992/7001143
Oncorhynchus mykiss (rainbow trout)	Acute toxicity	94.5	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-1. Doses: 0, 2.61, 4.68, 8.01, 18.4, and 32.4 μg/L.	LC_{50} = 7.4 μg/L NOEC = 2.61 μg/L	CK-511-002; 1992/7001128
Ictalurus punctatus (channel catfish)	Acute toxicity	94.9	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-1. Doses: 0, 7.23, 11.7, 24.9, 39.5, and 56.2 μg/L.	LC_{50} = 12.3 μg/L NOEC = 7.23 μg/L	CK-511-005; 1996/7000986
Cyprinodon variegatus (sheepshead minnow)	Acute toxicity	94.5	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-1. Doses: 0, 16.2, 30.7, 48.4, 84.9, and 155 μg/L.	LC_{50} = 60.2 μg/L NOEC = 30.7 μg/L	CK-511-004; 1993/7001166
Daphnia Magna (water flea)	Acute toxicity: immobility	94.5	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-2. Doses: 0, 1.40, 2.52, 3.86, 6.31, and 10.7 μg/L.	EC_{50} = 6.1 μg/L NOEC = 2.52 μg/L	CK-521-001; 1992/7001127
Mysidopsis bahia (mysid shrimp)	Acute toxicity	96.8	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-3 (c). Doses: 0, 0.32, 0.73, 0.89, 1.52, 2.52, and 5.08 μg/L.	LC_{50} = 2.0 μg/L NOEC = 0.32 μg/L	CK-521-004; 1994/7000842

[6] Purity is the content of pure active ingredient in the technical material, expressed as a percentage

Species	Test	Purity % Note[6]	Guideline, duration, doses and conditions	Result	Study number
Lepomis macrochirus (bluegill fish)	Acute toxicity	94.5	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-1. Doses: 0, 5.03, 9.53, 14.7, 26.5, and 43.6 μg/L.	LC_{50} = 11.6 μg/L NOEC = 5.03 μg/L	CK-511-001; 1992/7001143
Oncorhynchus mykiss (rainbow trout)	Acute toxicity	94.5	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-1. Doses: 0, 2.61, 4.68, 8.01, 18.4, and 32.4 μg/L.	LC_{50} = 7.4 μg/L NOEC = 2.61 μg/L	CK-511-002; 1992/7001128
Ictalurus punctatus (channel catfish)	Acute toxicity	94.9	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-1. Doses: 0, 7.23, 11.7, 24.9, 39.5, and 56.2 μg/L.	LC_{50} = 12.3 μg/L NOEC = 7.23 μg/L	CK-511-005; 1996/7000986
Cyprinodon variegatus (sheepshead minnow)	Acute toxicity	94.5	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-1. Doses: 0, 16.2, 30.7, 48.4, 84.9, and 155 μg/L.	LC_{50} = 60.2 μg/L NOEC = 30.7 μg/L	CK-511-004; 1993/7001166
Daphnia Magna (water flea)	Acute toxicity: immobility	94.5	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-2. Doses: 0, 1.40, 2.52, 3.86, 6.31, and 10.7 μg/L.	EC_{50} = 6.1 μg/L NOEC = 2.52 μg/L	CK-521-001; 1992/7001127
Mysidopsis bahia (mysid shrimp)	Acute toxicity	96.8	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-3 (c). Doses: 0, 0.32, 0.73, 0.89, 1.52, 2.52, and 5.08 μg/L.	LC_{50} = 2.0 μg/L NOEC = 0.32 μg/L	CK-521-004; 1994/7000842
Lepomis macrochirus (bluegill fish)	Acute toxicity	94.5	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-1. Doses: 0, 5.03, 9.53, 14.7, 26.5, and 43.6 μg/L.	LC_{50} = 11.6 μg/L NOEC = 5.03 μg/L	CK-511-001; 1992/7001143

Species	Test	Purity % Note[6]	Guideline, duration, doses and conditions	Result	Study number
Oncorhynchus mykiss (rainbow trout)	Acute toxicity	94.5	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-1. Doses: 0, 2.61, 4.68, 8.01, 18.4, and 32.4 μg/L.	LC_{50} = 7.4 μg/L NOEC = 2.61 μg/L	CK-511-002; 1992/7001128
Ictalurus punctatus (channel catfish)	Acute toxicity	94.9	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-1. Doses: 0, 7.23, 11.7, 24.9, 39.5, and 56.2 μg/L.	LC_{50} = 12.3 μg/L NOEC = 7.23 μg/L	CK-511-005; 1996/7000986
Cyprinodon variegatus (sheepshead minnow)	Acute toxicity	94.5	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-1. Doses: 0, 16.2, 30.7, 48.4, 84.9, and 155 μg/L.	LC_{50} = 60.2 μg/L NOEC = 30.7 μg/L	CK-511-004; 1993/7001166
Daphnia Magna (water flea)	Acute toxicity: immobility	94.5	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-2. Doses: 0, 1.40, 2.52, 3.86, 6.31, and 10.7 μg/L.	EC_{50} = 6.1 μg/L NOEC = 2.52 μg/L	CK-521-001; 1992/7001127
Mysidopsis bahia (mysid shrimp)	Acute toxicity	96.8	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-3 (c). Doses: 0, 0.32, 0.73, 0.89, 1.52, 2.52, and 5.08 μg/L.	LC_{50} = 2.0 μg/L NOEC = 0.32 μg/L	CK-521-004; 1994/7000842
Lepomis macrochirus (bluegill fish)	Acute toxicity	94.5	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-1. Doses: 0, 5.03, 9.53, 14.7, 26.5, and 43.6 μg/L.	LC_{50} = 11.6 μg/L NOEC = 5.03 μg/L	CK-511-001; 1992/7001143
Oncorhynchus mykiss (rainbow trout)	Acute toxicity	94.5	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-1. Doses: 0, 2.61, 4.68, 8.01, 18.4, and 32.4 μg/L.	LC_{50} = 7.4 μg/L NOEC = 2.61 μg/L	CK-511-002; 1992/7001128

Species	Test	Purity % Note[6]	Guideline, duration, doses and conditions	Result	Study number
Ictalurus punctatus (channel catfish)	Acute toxicity	94.9	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-1. Doses: 0, 7.23, 11.7, 24.9, 39.5, and 56.2 μg/L.	LC_{50} = 12.3 μg/L NOEC = 7.23 μg/L	CK-511-005; 1996/7000986
Cyprinodon variegatus (sheepshead minnow)	Acute toxicity	94.5	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-1. Doses: 0, 16.2, 30.7, 48.4, 84.9, and 155 μg/L.	LC_{50} = 60.2 μg/L NOEC = 30.7 μg/L	CK-511-004; 1993/7001166
Daphnia Magna (water flea)	Acute toxicity: immobility	94.5	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-2. Doses: 0, 1.40, 2.52, 3.86, 6.31, and 10.7 μg/L.	EC_{50} = 6.1 μg/L NOEC = 2.52 μg/L	CK-521-001; 1992/7001127
Mysidopsis bahia (mysid shrimp)	Acute toxicity	96.8	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-3 (c). Doses: 0, 0.32, 0.73, 0.89, 1.52, 2.52, and 5.08 μg/L.	LC_{50} = 2.0 μg/L NOEC = 0.32 μg/L	CK-521-004; 1994/7000842
Lepomis macrochirus (bluegill fish)	Acute toxicity	94.5	96-h flow-through exposure. Study conducted according to U.S. EPA Guideline 72-1. Doses: 0, 5.03, 9.53, 14.7, 26.5, and 43.6 μg/L.	LC_{50} = 11.6 μg/L NOEC = 5.03 μg/L	CK-511-001; 1992/7001143

ANNEX 2

REFERENCES

Study number	Author(s)	year	Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study.
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EPA 2001		2001	Pesticide Fact Sheet, Chlorfenapyr, EPA-730-F-00-001, January, 2001 http://www.epa.gov/opprd001/factsheets/chlorfenapyr.pdf
CD, 2001		2001	2001/697/EC: Commission Decision of 5 September 2001 concerning the non-inclusion of chlorfenapyr in Annex I to Council Directive 91/414/EEC (Text with EEA relevance) (notified under document number C(2001) 2617) Official Journal L 249 , 19/09/2001 P. 0019 - 0020
FAO/WHO Manual		2009	Manual on development and use of FAO and WHO specifications for pesticides, June 2009 revision of the First edition http://www.fao.org/pest-and-pesticide-management/expert-bodies-coventions/faowho-joint-meeting-on-pesticide-specifications-jmps/pesticide-specifications/en/ and http://whqlibdoc.who.int/publications/2006/9251048576_eng_update2.pdf
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CK-630-003		1994	AC 303,630: Photodegradation in water American Cyanamid Co.; Princeton NJ; United States of America CK-630-003; 1995/7000719 GLP, Unpublished
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CK-412-001	1992	Dermal LD50 study in albino rabbits with AC 303,630 technical CK-412-001; 1992/7001140 GLP, Unpublished
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CK-420-004	1991	AC 303,630: A 28-day mouse feeding study CK-420-004; 1991/7001093 GLP, Unpublished
CK-425-002	1993	AC 303,630: A 13-week dietary toxicity study in the albino rat CK-425-002; 1993/7001148 GLP, Unpublished
CK-425-003	1994	AC 303,630: A 13-week dietary toxicity study in the albino mouse CK-425-003; 1994/7000836 GLP, Unpublished
CK-425-001	1993	90-day dietary toxicity study with AC 303,630 in purebred Beagle dogs CK-425-001; 1993/7001149 GLP Unpublished
CK-427-002	1994	A chronic dietary toxicity and oncogenicity study with AC 303,630 in rats CK-427-002; 1994/7000797 GLP, Unpublished
CK-427-004	1994	One year dietary toxicity study with AC 303,630 in purebred Beagle dogs CK-427-004; 1994/7000794 GLP, Unpublished
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