FAO SPECIFICATIONS AND EVALUATIONS FOR PLANT PROTECTION PRODUCTS

QUINCLORAC

3,7-dichloroquinoline-8-carboxylic acid

2002

FOOD AND AGRICULTURE ORGANIZATION *of* THE UNITED NATIONS

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INTRODUCTION

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

Since 1999 the development of FAO specifications follows the **New Procedure**, described in the 5th edition of the " Manual on the development and use of FAO specifications for plant protection products" (FAO Plant Production and Protection Page No. 149). This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package, the procedure and evaluation applied by FAO and the Experts of the "FAO Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent."
FAO Specifications now only apply to products for which the technical materials have been evaluated. Consequently from the year 2000 onwards the publication of FAO specifications under the **New Procedure** has changed. Every specification consists now of two parts namely the specifications and the evaluation report(s):

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

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

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

* Footnote: The publications are available on the Internet under (http://www.fao.org/AG/AGP/AGPP/Pesticid/) or as hardcopy from the Plant Protection Information Officer.

PART ONE

SPECIFICATIONS

QUINCLORAC

FAO SPECIFICATIONS AND EVALUATIONS FOR
PLANT PROTECTION PRODUCTS

QUINCLORAC

INFORMATION

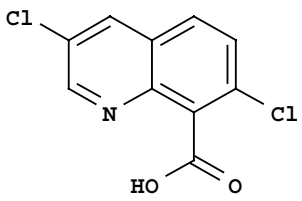
ISO common name
quinclorac (BSI; draft E-ISO, (m) draft F-ISO)

Synonyms
none

Chemical names
IUPAC and CA

3,7-dichloroquinoline-8-carboxylic acid

Structural formula



Molecular formula
$C_{10}H_5Cl_2NO_2$

Relative molecular mass
242.1

CAS Registry number
84087-01-4

CIPAC number
493

EEC number
402-780-1

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QUINCLORAC TECHNICAL MATERIAL

FAO Specification 493/TC (200)

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 (493/2002). 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 (493/2002) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of quinclorac together with related manufacturing impurities and shall be an off-white powder with a characteristic odour, free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 **Identity tests** (493/TC/M/2, CIPAC H, p. 245)

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 **Quinclorac content** (493/TC/M/3, CIPAC H, p. 245)

The quinclorac content shall be declared (not less than 960 g/kg) and, when determined, the mean measured content shall not be lower than the declared minimum content.

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QUINCLORAC WETTABLE POWDER

FAO Specification 493/WP (2002)

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 (493/2002). 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 (493/2002) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of an homogeneous mixture of technical quinclorac, complying with the requirements of FAO specification 493/TC (2002), in the form of a white to grey, nearly odourless solid together with fillers and any other necessary formulants. It shall be in the form of a fine powder free from visible extraneous matter and hard lumps.

2 Active ingredient

2.1 **Identity tests** (493/WP/M/2, CIPAC H, p. 248)

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 **Quinclorac content** (493/WP/M/3, CIPAC H, p. 248)

The quinclorac content shall be declared (g/kg at 20±2°C) and, when determined, the mean measured content shall not differ from that declared by more than the following tolerances:

Declared content in g/kg	Tolerance
above 250 up to 500 above 500 Note in each range the upper limit is included	± 5% of the declared content ± 25 g/kg

3. Physical properties

3.1 **pH range:** (MT 75.2, CIPAC F, p. 206)

pH range: pH 3 to pH 6

3.2 **Wet sieve test** (MT 167, CIPAC F, p. 416)

Maximum: 1 % of the formulation shall be retained on a 75 µm test sieve.

3.3 **Suspensibility**(MT 177, CIPAC F, p. 445) (Notes 1&2)

A minimum of 75 % of the quinclorac content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2 °C (Notes 3&4).

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

Maximum: 30 ml after 1min.

3.5 **Wettability:** (MT 53.3, CIPAC F, p. 164)

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

4. Storage stability

4.1 **Stability at elevated temperature** (MT 46, CIPAC F, p.148)

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 6) and the formulation shall continue to comply with the clauses for pH range (3.1), wet sieve test (3.2), suspensibility (3.3) and wettability (3.5), as required.

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Note 1 The formulation should be tested at the highest and the lowest rates of use recommended by the supplier, provided this does not exceed the conditions given in method MT 177.

Note 2 This test will normally only be carried out after the heat stability test 4.1.

Note 3 Unless other temperature is specified.

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

Note 6 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.

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QUINCLORAC WATER DISPERSIBLE GRANULES

FAO Specification 493/WG (2002)

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 (493/2002). 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 (493/2002) as PART TWO forms an integral part of this publication.

1. Description

The material shall consist of an homogeneous mixture of technical quinclorac, complying with the requirements of FAO specification 493/TC (2002), in the form of a light beige to brownish solid together with carriers and any other necessary formulants. It shall be in the form of spherical granules for application after disintegration and dispersion in water. The formulation shall be dry, free-flowing, essentially non-dusty, and free from visible extraneous matter and hard lumps.

2. Active ingredient

2.1 **Identity tests** (493/WG/M/2, CIPAC H, p. 249)

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 **Quinclorac content** (493/WG/M/3, CIPAC H, p. 249)

The quinclorac content shall be declared (g/kg at 20±2°C) and, when determined, the mean measured content shall not differ from that declared by more than the following tolerances:

Declared content in g/kg	Tolerance
above 250 up to 500	± 5 % of the declared content
above 500	± 25 g/kg
Note in each range the upper limit is included	

3. Physical properties

3.1 **pH range** (MT 75.2, CIPAC F, p. 206)

pH range: pH 3 to pH 6.

3.2 **Wettability** (MT 53.3, CIPAC F, p. 164)

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

3.3 **Wet sieve test**(MT 167, CIPAC F, p. 416)

Maximum: 1 % of the formulation shall be retained on a 75 µm test sieve.

3.4 **Degree of dispersion** (MT 174, CIPAC F; p. 435)

Dispersibility: minimum 70 % after 1 minute of stirring.

3.5 **Suspensibility**(MT 168, CIPAC F, p. 417) (Notes 1 & 2)

A minimum of 70 % of the quinclorac content found under 2.2 shall be in the suspension after 30 min in CIPAC Standard Water D at 30 ± 2 °C (Note 3).

3.6 **Persistent foam** (MT 47.2, CIPAC F, p. 152) (Note 4)

Maximum: 30 ml after 1min.

3.7 **Dustiness** (MT 171, CIPAC F, p. 425, gravimetric)(Note 5)

Essentially non-dusty.

3.8 **Flowability** (MT 172, CIPAC F, p. 430)

At least 99.9 % of the formulation shall pass through a 5 mm test sieve after 20 liftings of the sieve.

4. **Storage stability**

4.1 **Stability at elevated temperature** (MT 46, CIPAC F, p.148)

After storage at 54 ± 2 °C for 14 days (Note 6), the determined average active ingredient content must not be lower than 95 % relative to the determined average content found before storage (Note 7) and the formulation shall continue to comply with the clauses for pH range (3.1), wet sieve test (3.3), degree of dispersion (3.4), suspensibility (3.5), dustiness (3.7) and flowability (3.8), as required.

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Note 1 The formulation should be tested at the highest and lowest rates of use recommended by the supplier, provided it does not exceed the conditions given in method MT 168.

Note 2 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler gravimetric method, MT 168, may be used on a routine basis provided that these methods have been shown to give results equal to those of chemical assay. In case of dispute, the chemical method shall be the "referee method".

Note 3 Unless other temperature is specified.

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

Note 5 Measurements of dustiness must be carried out on the sample "as received" and, where practicable, the sample should be taken from a newly opened container, because changes in the water content of samples may influence dustiness significantly. The optical method, MT 171, usually shows good correlation with the gravimetric method and can, therefore, be used as an alternative where equipment is available. Where the correlation is in doubt, it must be checked with the formulation to be tested. In case of dispute the gravimetric method shall be used.

Note 6 Unless other temperatures and/or times are specified.

Note 7 Analysis of the formulation, before and after the storage stability test, should be carried out concurrently (i.e. after storage) to reduce the analytical error.

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QUINCLORAC AQUEOUS SUSPENSION CONCENTRATE

FAO Specification 493/SC (2002)

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 (493/2002). 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 (493/2002) as PART TWO forms an integral part of this publication.

1. Description

The material shall consist of a suspension of fine particles of technical quinclorac, complying with the requirements of FAO specification 493/TC (2002), in the form of a white, aromatic smelling aqueous liquid, 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** (493/SC/M/2, CIPAC H, p. 249)

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 **Quinclorac content** (493/SC/M/3, CIPAC H, p. 249)

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

Declared content in g/kg or g/l at 20 ± 2°C	Tolerance
above 25 up to 100 above 100 up to 250 above 250 up to 500 Note in each range the upper limit is included	± 10% of the declared content ± 6% of the declared content ± 5% of the declared content

3. Physical properties

3.1 **pH range** (MT 75.2, CIPAC F, p. 206)

pH range: pH 2.5 to pH 5.5

3.2 **Pourability** (MT 148, CIPAC F, p. 348)

Maximum "residue": 6 %

3.3 **Spontaneity of dispersion** (MT 160, CIPAC F, p. 391)(Note 3)

A minimum of 75 % of the quinclorac content found under 2.2 shall be in the suspension after 5 min in CIPAC Standard Water D at 30 ± 2 °C (Note 4).

3.4 **Suspensibility** (MT 161, CIPAC F, p. 394) (Note 3)

A minimum of 70 % of the quinclorac content found under 2.2 shall be in the suspension after 30 min in CIPAC Standard Water D at 30 ± 2 °C (Note 4).

3.5 **Wet sieve test** (MT167, CIPAC F, p. 416) Note 5)

Maximum: 0.2 % of the formulation shall be retained on a 75 µm test sieve.

3.6 **Persistent foam** (MT 47.2, CIPAC F, p. 152) (Note 6)

Maximum: 30 ml after 1min.

4. **Storage stability**

4.1 **Stability at 0°C** (MT 39.2, CIPAC F, p. 128)

After storage at 0 ± 2 °C for 7 days, the formulation shall continue to comply with the clauses for suspensibility (3.5) and wet sieve test (3.6), as required.

4.2 **Stability at elevated temperature** (MT 46, CIPAC F, p.148)

After storage at 54 ± 2 °C for 14 days (Note 4), the determined average active ingredient content must not be lower than 95 % relative to the determined average content found before storage (Note 7) and the product shall continue to comply with the clauses for pH range (3.1), pourability (3.2), spontaneity of dispersion (3.3), suspensibility (3.4) and wet sieve test (3.5), as required.

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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 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 3 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric 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 4 Unless other temperatures and /or times are specified.

Note 5 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 6 The mass of sample to be used in the test should be at the application rate of use recommended by the supplier.

Note 7 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.

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PART TWO

EVALUATION REPORT(S)

QUINCLORAC

2002 Evaluation report based on submission of data from BASF AG. (TC, WP,WG,SC)

FAO SPECIFICATIONS AND EVALUATIONS FOR
PLANT PROTECTION PRODUCTS

QUINCLORAC

EVALUATION REPORT 493/2002

Explanation

The data for quinclorac were evaluated in support of new FAO specifications.

Quinclorac is under patent in many countries until 2002. In Canada and Bolivia it is patented until 2003.

Quinclorac is registered and sold in USA, Canada and many countries in Central- and South-America, Asia and Europe.
Quinclorac was reviewed by the US EPA in 1999 for tolerance approval.

The draft specification and the supporting data were provided by BASF AG in 2002.

Uses

Quinclorac, a herbicide showing auxin activity similar to that of indolylacetic acid, belongs to the auxin-type class of herbicides that includes the phenoxy-acids, benzoic acids and pyridine compounds. It acts as an inhibitor of cell wall biosynthesis. Quinclorac is mainly adsorbed via the root system and partly through foliage, mainly for the pre- and post-emergence control of *Echinochloa* spp. but also other weeds like *Aeschynomene* spp., *Sesbania* spp., and *Ipomoea* spp., occurring in direct-seeded and transplanted rice.

Identity of the active ingredient

ISO common name

quinclorac (BSI, draft E-iso, *(m*) draft F-iso)

Chemical name(s)

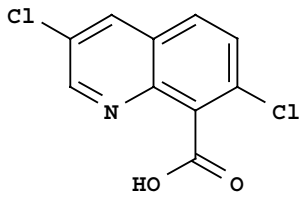
IUPAC and CA

3,7-dichloroquinoline-8-carboxylic acid

Synonyms

None

Structural formula



Molecular formula

$C_{10}H_5Cl_2NO_2$

Relative molecular mass

242.1

CAS Registry number

84087-01-4

CIPAC number

493

EEC number

402-780-1

Identity tests

The test relies on the HPLC method for quinclorac analysis. The retention time of quinclorac in the sample solution should not deviate by more than 10 s from that of authentic quinclorac in the calibration solution [CIPAC Handbook H, p. 245]. IR and TLC form additional identity tests.

Physico-chemical properties of pure quinclorac (*Table 1*)

Parameter	Value(s) and conditions	Purity %	Method reference)
Vapour pressure	1 x 10^{-12} Pa at 20 °C (extrapolated) 4 x 10^{-12} Pa at 25 °C (extrapolated)	99.8	OECD 104, by extrapolation
Melting point, boiling point and/or temperature of decomposition	Melting point: 272.4 - 274.9 °C Decomposition temperature: ca. 272 °C (colour change to brown, with gas evolution beginning)	99.8	OECD 102
Solubility in water	0.072 g/l at 20 °C at pH 5.5 (deionized water) 75.9 g/l at 20 °C at pH 10.3 (NaOH , 0.1 Mol/l)	99.8	EEC A6
Octanol/water partition coefficient	log P_{OW} = 1.76 at 20 °C at pH 4 log P_{OW} = -0.74 at 20 °C at pH 7 log P_{OW} = -3.74 at 20 °C at pH 10	99.8	EEC A8, by extrapolation
Hydrolysis characteristics	Half-life > 30 days at 25 °C at pH 5, pH 7 and pH 9.	>99 % (radiochemical purity)	US-EPA Assessment Guidelines, Subdiv. N, § 161-1 (1982)
Photolysis characteristics	Half life = ca. 100 days (non-sensitized, sterile solution, calculated for continuous illumination) Half life = ca. 43 days (sensitized , sterile solution, calculated for continuous illumination) Experimental setup: solution in water (sterile), pH 7, 25°C, simulated sunlight at 805 w/m², for 660 h over 35 d (15 h light, 9 h dark, illuminated at weekends). Result: Half life > 30 days (dark control solution, non-sensitized, sterile, see hydrolysis) The results were used to extrapolate the half life values above.	99.6% (radiochemical purity)	US-EPA Assessment Guidelines, Subdiv. N, § 161-2 (1982)
Dissociation characteristics	pKa = 4.34 at 20 °C pKa = 4.35 at 25 °C	99.4	OECD 112, titration method

Chemical composition and properties of quinclorac technical material (TC) (*Table 2*)

Manufacturing process, maximum limits for impurities **≥** 1 g/kg, 5 batch analysis data	Confidential information was supplied and is held on file by FAO. Mass balances were 99.2 – 100.0 % and percentages of unknowns were < 0.1.% each.
Declared minimum quinclorac content	960 g/kg
Relevant impurities **≥**1 g/kg and maximum limits for them	None.
Relevant impurities **<** 1 g/kg and maximum limits for them:	None.
Stabilizers or other additives and maximum limits for them:	None.
Melting temperature range of the TC	272.4 - 274.9 °C

Hazard summary

Notes.

(i) The proposer confirmed that the toxicological and ecotoxicological data included in the summary below were derived from quinclorac 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 quinclorac technical material, based on acute toxicity, irritation and sensitization.

Species	Test	Purity	Duration and conditions or guideline adopted	Result
Rat (m, f)	Oral	93.6	OECD (401),single application	LD_{50} = 2 610 mg/kg bw
Mouse (m, f)	Oral	97.4	OECD, EPA(FIFRA) Subdiv. F, Section 81-1	LD_{50} > 5 000 mg/kg bw
Rat (m, f)	Dermal	93.6	OECD (402), 24 h percutaneous exposure	LD_{50} > 2000 mg/kg bw
Rat (m, f)	Inhalation	93.6	OECD (403), 4 h	LC_{50} = > 5 200 mg/m^3
White rabbit (m, f)	Skin irritation	93.6	Fed.Reg.38, No.187, Sec.1500.41, p 27019 (1973)	Non-irritant
White rabbit (m, f)	Eye irritation	93.6	Fed.Reg.38, No.187, Sec.1500.42, p 27019 (1973)	Non-irritant
Guinea pig (f)	Skin sensitization	97.4	Based on Magnusson, B. and Kligman, A.M.:The Guinea Pig Maximization Test, J. Invest. Dermatol. 52, 268-276 (1969)	Sensitizing
Rat (m, f)	Acute intraperitoneal toxicity	93.6	Single injection into the abdominal cavity, 14 days observation	LD_{50} = 681 mg/kg bw

Quinclorac is characterised by a low acute oral, dermal and inhalation toxicity. The technical active ingredient caused only slight reversible, irritant effects, mainly on the eyes. A possible skin sensitizing potential was indicated in the maximization test.

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

Species	Test	Purity %	Duration and conditions or guideline adopted	Result
Rabbit (m, f)	Dermal	96.5	21 d, EPA Subdiv. F § 82-2, OECD (410), EEC B.9, Japan MAFF	NOEL > 1000 mg/kg bw/d
Dog (m, f)	Oral, subacute	93.6	28 d	NOAEL = 100 mg/kg bw/d LOEL = 300 mg/kg bw/d
Mouse (m, f)	Oral, subacute	96.5	28 d, OECD (407)	NOAEL = 1800 mg/kg bw/d LOEL = 3600 mg/kg bw/d
Rat (m, f)	Oral, subacute	93.6	28 d, OECD (407)	NOAEL = 630 mg/kg bw/d LOEL = 1250 mg/kg bw/d
Rat (m, f)	Oral, subchronic	96.5	3 mo, OECD (408)	NOAEL = 300 mg/kg bw/d LOEL = 900 mg/kg bw/d
Mouse (m, f)	Oral, subchronic	97.4	3 mo, OECD (408), EPA FIFRA Subdiv. F § 82-1, Japan MAFF(1985)	NOAEL = 85 mg/kg bw/d LOEL = 680 mg/kg bw/d
Dog (m, f)	Oral	96.5	12 mo, OECD(452), EPA FIFRA Subdiv. F § 83-1,Japan MAFF (1985)	NOAEL = 34 mg/kg bw/d LOEL = 136 mg/kg bw/d
Rat (m, f)	Feeding, chronic toxicity/ carcinogenicity	97.4	24 mo, OECD (453), EPA FIFRA Subdiv. F § 83-5, Japan MAFF (1985)	NOAEL = 533 mg/kg bw/d not carcinogenic
Mouse (m, f)	Feeding, chronic toxicity/ carcinogenicity	97.4	18 mo OECD (451), EPA FIFRA Subdiv. F § 83-2, Japan MAFF (1985)	NOAEL = 30 mg/kg bw/d not carcinogenic
Rat (m, f)	Feeding, 2 generation reproduction	97.4	OECD (416), EPA FIFRA Subdiv. F § 83-4, Japan MAFF (1985))	Not teratogenic NOAEL >1155 mg/kg bw/d (reproduction) NOAEL = 381 mg/kg bw/d (maternal and fetotoxicity)
Rat (f)	Teratogenicity and developmental toxicity	96.5	OECD (414), EPA FIFRA Subdiv. F § 83-3, Japan MAFF(1985)	Not teratogenic NOAEL = 146 mg/kg bw/d maternal toxicity. NOAEL > 438 mg/kg bw/d embryo/fetotoxicity
Rabbit (f) (Himalayan)	Teratogenicity and developmental toxicity	97.4	OECD (414), EPA FIFRA Subdiv. F § 83-3, Japan MAFF (1985)	Not teratogenic NOAEL = 70 mg/kg bw/d maternal toxicity. NOAEL = 200 mg/kg bw/d embryo/fetotoxicity

The toxicity of quinclorac both after oral and dermal administration is relatively low. Repeated oral administration of high doses targeted the liver, kidneys, and red blood cell counts. Quinclorac was not carcinogenic in long-term studies in rats and mice after administration via the diet. Quinclorac did not lead to any malformations in rats and rabbits. The substance showed developmental toxicity only at doses that were toxic to the dams of rabbits. These effects were not observed in rats. There were no indications of any impairment of fertility in animal studies.

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

Species	Test	Purity %	Conditions	Result
Salm Salmonella typhiurium	Point mutation, Ames test	96.5	Dose range: 20 - 5000µg/plate with (S-9 from S.D. rats) and without metabolic activation in TA 98, TA 100, TA 1535, TA 1537 strain	Not mutagenic
Chinese hamster ovary (CHO) cell line	Point mutation, CHO/HGPRT test	96.5	Dose range: 0.0464 - 2.15 mg/ml with (S-9 from S.D. rats) and without metabolic activation	Not mutagenic
Human lymphocytes	Chromosome aberration, cytogenic investigation, in vitro	96.5	Dose range: 250- 1000 µg/ml without metabolic activation Dose range: 500 - 2000 µg/ml with metabolic activation (S9-mix from Sprague Dawley rats)	Mutagenic both with and without S-9 mix at dose levels showing clear cytotoxicity
Bone marrow cells (NMRI mice)	Chromosome aberration, micronucleus test, in vivo	96.5	Oral administration, dose range: 500 - 2000 mg/kg bw	Not mutagenic
Bone marrow cells (Chinese hamster)	Chromosome aberration, cytogenic investigation, *in vivo*	98.3	Oral administration, dose range: 2000 - 8000 mg/kg bw	Not mutagenic
Bacillus subtilis	DNA damage and repair, Rec assay (H 17 (REC^+) and M 45 (REC^-)	97.4	Dose range: 1 - 10000 µg/plate without metabolic activation with metabolic activation (S9-mix from Sprague Dawley rats)	Not mutagenic Not mutagenic
Primary hepatocytes (Fisher rats)	DNA damage and repair Unscheduled DNA synthesis, *in vitro*	96.5	Dose range: 101 - 2020 µg/ml	Not mutagenic
Rat hepatocytes	DNA damage and repair Unscheduled DNA synthesis, *in vivo/in vitro*	97.4	Oral administration Dose: 1000 mg/kg bw (4 h) Doses 100 , 1000 mg/kg bw (16h) ^{3}HTdR treatment of primary hepatocytes	Not mutagenic

The genotoxic potential of quinclorac was tested covering the endpoints gene mutation, chromosome damage as well as DNA damage and repair.

When tested in an *in vitro* system at biologically unachievable and cytotoxic concentrations in human lymphocytes, chromosome-damaging properties were found. However, *in vivo* studies performed with NMRI mice, and Chinese hamsters gave no indication of chromosome aberration. No DNA damage and repair were observed in the studies. Quinclorac was thus found to be devoid of mutagenic activity on the basis of the studies performed.

Table 6. Ecotoxicology profile of the technical material

Species	Test	Purity %	Duration and conditions	Result
Daphnia magna (water flea)	Acute toxicity	98.6	48 h, static water , OECD (202),US-EPA OPPTS 850.1010,1996)	EC_{50} > 100 mg/l NOEC $\geq$ 100 mg/l
Daphnia magna (water flea)	Chronic toxicity	96.6	21 d, flow -through EPA. (Subdiv. E § 72-4)	EC_{50} > 110 mg/l NOEC = 110 mg/l
Salmo gairdneri (rainbow trout)	Acute toxicity	98.6	96 h, static water OECD (203), EPA (Subdiv. E § 72-1, p 66, 1982)	NOEC = 100 mg/l
Lepomis macrochirus (bluegill sunfish)	Acute toxicity	98.6	96 h, static water OECD (203), EPA (Subdiv. E § 72-1, p 66, 1982)	NOEC = 100 mg/l
Pimephales promelas (fathead minnow)	Chronic toxicity Early life stage	96.6	38 d, flow -through EPA(Subdiv. E § 72-4(a))	NOEC = 31 mg/l LOEC = 62 mg/l
Pseudokirchneriella subcapitata (green alga)	Acute toxicity	99.2	72 h, static water OECD (201)	EC_{50} >100 mg/l (growth rate) EC_{50} >100 mg/l (biomass)
Anabaena flos-aquae (blue-green alga)	Acute toxicity	99.2	96 h, static water ASTM (E 1218-90), OECD (201), EPA (OPPTS 850.100, 1996)	EC_{50} > 100 mg/l (growth rate) EC_{50} = 69.4 mg/l (biomass)
Lemna gibba (A duckweed)	Acute toxicity	99.2	7 d, static water ASTM (E 1415-91) EPA (OPPTS 850.4400, 1996)	EC_{50} >100 mg/l (growth rate) EC_{50} >100 mg/l (biomass)
Apis mellifera (Honey bee)	Acute oral and contact toxicity	99.8	48 h OECD (213 and 214,1998)	LD_{50} > 102.3 mg/l (oral) LD_{50} > 100 mg/l (contact)
Colinus virginianus (Bobwhite quail)	Acute oral toxicity	96.5	Single application, EPA (protocol PB 83-153908 (1982) Subdiv. E § 71-1), EPA/SEP 540/9-85-007	NOEL= 2000 mg/kg bw
Colinus virginianus (Bobwhite quail)	Dietary toxicity	96.5	5 d EPA (E § 71-2, p 37, 1982)	LC_{50} > 5000 mg/kg food
Anas platyrhynchos (Mallard duck)	Dietary toxicity	96.5	5 d EPA (E § 71-2, p 37, 1982)	LC_{50} > 5000 mg/kg food
Colinus virginianus (Bobwhite quail)	Reproductive toxicity	99.2	27 weeks, EPA (Protocol PB 83-153908 (1982) Subdiv. E § 71-4), EPA/SEP 540/9-86-139	NOEL = 500 mg/kg food
Anas platyrhynchos (Mallard duck)	Reproductive toxicity	99.2	21 weeks, EPA/FIFRA Subdiv. E § 71-4	NOEL = 1000 mg/kg food

Soil microflora	Nitrogen turnover test with BAS 514 46 H (250 g a.s./L)	Formulation, 250g/l	28 days, BBA-guideline part VI, 1-1, 2nd edition (1990)	Negligible effects
Soil microflora	Soil respiration test with BAS 514 46 H (250 g a.s./L)	Formulation, 250g/l	28 days, BBA-guideline part VI, 1-1, 2nd edition (1990)	Negligible effects
Pseudomonas putida (activated sludge)	Acute toxicity	97.4	72 h, static water DIN 38412	EC_{50} = 1580 mg/l

The ecotoxicological effects of quinclorac were investigated using various organisms from major biological groups. The results demonstrated that quinclorac is of low toxicity to aquatic and terrestrial organisms including fish, aquatic invertebrates, algae, birds and terrestrial invertebrates.

Although Quinclorac has not been evaluated by the FAO/WHO JMPR, it has been classified by the WHO IPCS as a “Technical grade active ingredient unlikely to present an acute hazard in normal use” (WHO/PCS/01.5/Rev.1)

It was characterized by the US EPA in 1999 with the signal word 'caution' (EPA review). In the European Union it is additionally described as 'sensitizing' (R 43).

Formulations and co-formulated active ingredients

The main formulation types available are water dispersible granules (WG), wettable powder (WP) and aqueous suspension concentrates (SC). Quinclorac is currently not co-formulated with other pesticides.

These formulations are registered and sold in many countries throughout the world.

Methods of analysis and testing

The analytical method for the active ingredient (including identity tests) is a full CIPAC method (CIPAC Handbook H, pages 244- 247). Quinclorac is determined by reversed phase HPLC (C_{18}, tetrahydrofuran/ water/ sulfuric acid (0.5 M)) using UV detection at 238 nm and external standardization.

There are no relevant impurities and therefore no methods are necessary.

Test methods for determination of physico-chemical properties of the technical active ingredient were OECD, EU or US-EPA, while those for the formulations were CIPAC (pH range, MT 75; accelerated storage stability, MT 46; storage stability at 0°C, MT 39; degree of dispersion, MT 174; persistent foam, MT 47; suspensibility, MT 161, 168 and 177; spontaneity of dispersion, MT 160; wet sieve test, MT 167; wettability, MT 53; dustiness, MT 171; flowability, MT 172; pourability, MT 148), as indicated in the specifications.

Physical properties
The physical properties, the methods for testing them and the limits proposed for the WP, WG and SC formulations, comply with the requirements of the FAO Manual (5th edition).

Containers and packaging

No special requirements for containers and packaging have been identified.

Expression of the active ingredient

The active ingredient is expressed as quinclorac in g/kg or g/l.

Appraisal

The data for quinclorac were submitted by the proposer in accordance with the requirements of the FAO Manual (5th edition), evaluated in support of the new FAO specifications. The proposer stated that the confidential data sets evaluated by the FAO and the EPA were identical. However, this could not be confirmed by the Meeting, due to circumstances beyond the control of the proposer, FAO and the JMPS.

The production of quinclorac is under patent in many countries until 2002, and in Canada and Bolivia it is patented until 2003. It was reviewed by the US EPA in 1999 for tolerance approval.

Quinclorac is an off-white powder with a characteristic odour. It melts in the range 272 - 275°C and is of low water solubility (0,072 g/l, pH 5.5), although this increases considerably at higher pH (75.9 g/l, pH 10.3) . It is formulated as a wettable powder (WP); as water dispersible granules (WG); and as an aqueous suspension concentrate (SC). Quinclorac is stable in water (at pH values 5, 7, and 9) and to photodegradation.

The proposer provided the meeting with commercially confidential information on the manufacturing process and batch analysis data. Impurities were identified at or above 1 g/kg and manufacturing limits were specified for them. The meeting considered none of them to be relevant. The meeting did however question the possible presence of a relevant impurity which could have been derived from a starting material. The company provided a clear case to show that this chemical is too reactive to survive the subsequent stages of manufacture and thus will not be detectable in the TC.

Quinclorac is characterized by a low acute oral, dermal and inhalation toxicity. The technical active ingredient caused only slight reversible, irritant effects, mainly on the eyes. A possible sensitizing potential was indicated in the maximization test .

The toxicity of quinclorac both after oral and dermal administration is relatively low. Repeated oral administration of high doses targeted the liver, kidneys, and red blood cell counts.

Quinclorac was not carcinogenic in long-term studies in rats and mice after administration via the diet. Quinclorac did not lead to any malformations in rats and rabbits, and showed developmental toxicity only at doses that were toxic to the dams of rabbits. These effects were not observed in rats. There were no indications of any impairment of fertility in animal studies.

Quinclorac was found to be devoid of mutagenic activity on the basis of the studies presented.

Quinclorac is of low toxicity to aquatic and terrestrial organisms including fish, aquatic invertebrates, algae, birds and terrestrial invertebrates.

Although quinclorac has not been evaluated by the FAO/WHO JMPR, it has been classified by the WHO IPCS as a “Technical grade active ingredient unlikely to present an acute hazard in normal use” (WHO/PCS/01.5/Rev.1)

The proposer declared that quinclorac produced and commercialised by BASF AG complies with the FAO specifications (2002).

Recommendation

The meeting recommended that the specifications for quinclorac TC, WP, WG, and SC, presented by BASF AG, should be adopted as FAO specifications.

References

CIPAC F	CIPAC Handbook F, Collaborative International Pesticides Analytical Council, 1995, UK
CIPAC H	CIPAC Handbook H, Collaborative International Pesticides Analytical Council, 1998, UK
EPA review	http://www.epa.gov/fedrgstr/EPA-PEST/1998/december/Day-02/p31683.htm
FAO Manual	Manual on the development and use of FAO specifications for plant protection products, 5th edition. FAO Plant production and protection paper 149. FAO, 1999, Rome.
Pesticide Manual	The Pesticide Manual, 12th Edition, British Crop Protection Council, 2000, UK