

FAO SPECIFICATIONS AND EVALUATIONS FOR AGRICULTURAL PESTICIDES

LUFENURON

(*RS*)-1-[2,5-dichloro-4-(1,1,2,3,3,3-hexafluoro-propoxy)-phenyl]-3-(2,6-difluorobenzoyl)-urea



FOOD AND AGRICULTURE ORGANIZATION *of* THE UNITED NATIONS

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DISCLAIMER¹

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.

FAO disclaims any and all liability for any injury, death, loss, damage or other prejudice of any kind that may arise as a result of, or in connection with, the manufacture, sale, transportation, storage, handling, preparation and/or use of pesticides which are found, or are claimed, to have been manufactured to comply with these specifications.

Additionally, FAO wishes to alert users to the fact that improper storage, handling, preparation and/or use of pesticides can result in either a lowering or complete loss of safety and/or efficacy.

FAO is not responsible, and does not accept any liability, for the testing of pesticides for compliance with the specifications, nor for any methods recommended and/or used for testing compliance. As a result, FAO does not in any way warrant or represent that any pesticide claimed to comply with a FAO specification actually does so.

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.

From 1999, the development of FAO specifications has followed 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 pesticide in accordance with chapters 4 to 9 of the “Manual on development and use of FAO and WHO specifications for pesticides”.

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/ag/agp/agpp/pesticid/> OR IN HARDCOPY FROM THE PLANT PROTECTION INFORMATION OFFICER.

PART ONE

SPECIFICATIONS

LUFENURON

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LUFENURON

INFORMATION

ISO common name

Lufenuron

Synonyms

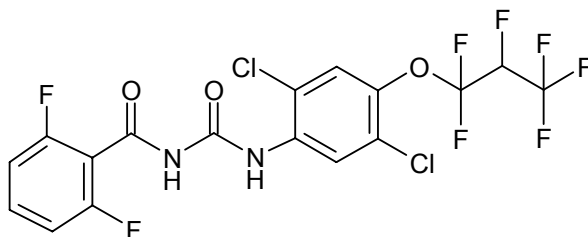
CGA184699

Chemical names

IUPAC (RS)-1-[2,5-dichloro-4-(1,1,2,3,3,3-hexafluoro-propoxy)-phenyl]-3-(2,6-difluorobenzoyl)-urea

CA (RS)-N-[[[2,5-dichloro-4-(1,1,2,3,3,3-hexafluoro-propoxy)phenyl]amino]carbonyl]-2,6-difluoro-benzamide

Structural formula



Empirical formula

C₁₇H₈Cl₂F₈N₂O₃

Relative molecular mass

511.2

CAS Registry number

103055-07-8

CIPAC number

704

Identity tests

HPLC retention time, IR spectrum.

LUFENURON TECHNICAL MATERIAL

FAO Specification 704/TC (May 2008*)

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 (704/2007). 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 (704/2007), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of lufenuron together with related manufacturing impurities, in the form of a white to pale yellow powder free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 Identity tests (CIPAC 704/TC/M/-, 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 Lufenuron content (CIPAC 704/TC/M/-, Note 1)

The lufenuron content shall be declared (not less than 980 g/kg) and when determined, the average measured content obtained shall not be lower than the declared minimum content.

Note 1 Methods for the identification and determination of lufenuron content were adopted by CIPAC in 2007 but are not yet published in a Handbook. Prior to publication of the Handbook, copies of the methods may be obtained through the CIPAC website, <http://www.cipac.org>.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: <http://www.fao.org/ag/agp/agpp/pesticid/>.

LUFENURON EMULSIFIABLE CONCENTRATE

FAO Specification 704/EC (May 2008*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturer whose names is listed in the evaluation report (704/2007). It should be applicable to relevant products of this manufacturer, and those of any other formulators who use only TC from the evaluated source. The specification is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers who use TC from other sources. The evaluation report (704/2007), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of technical lufenuron, complying with the requirements of FAO specification 704/TC (May 2008), dissolved in suitable solvents, together with any other necessary formulants. It shall be in the form of a clear to slightly hazy, stable homogeneous liquid, free from visible suspended matter and sediment, to be applied as an emulsion after dilution with water.

2 Active ingredient

2.1 Identity tests (CIPAC 704/EC/M/-, 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 Lufenuron content (CIPAC 704/EC/M/-, Note 1)

The lufenuron content shall be declared (g/kg or g/l at $20 \pm 2^\circ\text{C}$, Note 2) and, when determined, the content obtained shall not differ from that declared by more than the following tolerances:

Declared content, g/kg or g/l at $20 \pm 2^\circ\text{C}$	Permitted tolerance
above 25 g/l up to 100 g/l	$\pm 10\%$ of the declared content
Note: the upper limit is included in the range	

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: <http://www.fao.org/ag/agp/agpp/pesticid/>.

3 Physical properties

3.1 Emulsion stability and re-emulsification (MT 36.3, CIPAC Handbook K, p.137, 2003)

The formulation, when diluted at $30 \pm 2^\circ\text{C}$ with CIPAC standard waters A and D, shall comply with the following:

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

3.2 Persistent foam (MT 47.2, CIPAC Handbook F, p.152, 1995) (Note 3)

Maximum: 60 ml after 1 minute.

4 Storage stability

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

After storage at $0 \pm 2^\circ\text{C}$ for 7 days, the volume of solid and/or liquid which separates shall not be more than 0.1 ml.

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

After storage at $54 \pm 2^\circ\text{C}$ 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 4) and the formulation shall continue to comply with the clause for:

- emulsion stability and re-emulsification (3.1).

Note 1 Methods for the identification and determination of lufenuron content were adopted by CIPAC in 2007 but are not yet published in a Handbook. Prior to publication of the Handbook, copies of the methods may be obtained through the CIPAC website, <http://www.cipac.org>.

Note 2 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 The mass of the sample to be used in the test should be specified at the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.

Note 4 Samples of the product 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

LUFENURON

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LUFENURON

FAO/WHO EVALUATION REPORT 704/2007

Recommendation

The Meeting recommended that the specifications for lufenuron TC and EC, proposed by Syngenta Crop Protection AG, should be adopted by FAO.

Appraisal

Data provided by Syngenta Crop Protection AG were evaluated in support of proposed new FAO specifications for lufenuron TC and EC.

Patent protection for lufenuron has expired in most countries.

Lufenuron is an insecticide which has not been evaluated by the FAO/WHO JMPR or WHO/IPCS. An EU review (according to EU directive 91/414/EEC) is expected to be completed by the end of 2008.

Lufenuron is a racemic mixture of two enantiomers. It is a solid of low vapour pressure, having low solubility in water and a high octanol/water partition coefficient. Hydrolysis occurs slowly at pH 9 and very slowly at pH 5 and 7. Photolysis occurs slowly.

The Meeting was provided with details of the manufacturing process, 5 batch analysis data from the current site of production, and manufacturing limits for purity and all impurities ≥ 1 g/kg. Mass balances were high (99.2 – 100.2%), no unknowns were detected and the minimum lufenuron content of the TC was 980 g/kg. These data were confirmed as identical to those submitted to Portuguese authorities for the registration of lufenuron in the European Union.

The Meeting agreed that none of the impurities should be designated as relevant.

The proposed specifications were in accordance with the requirements of the manual (FAO/WHO 2006) but the Meeting questioned the proposed limit of 60 ml persistent foam in the EC specification, this being the maximum acceptable. The manufacturer stated that there are several EC products on the market and confirmed that the limit of 60ml foam is required to cover all of them. The Meeting accepted the proposed limit.

Analytical methods for determination of lufenuron (including identity tests) are based on a reversed-phase HPLC with external standardization and UV detection, and were adopted by CIPAC in 2007, with provisional status.

SUPPORTING INFORMATION
FOR
EVALUATION REPORT 704/2007

Uses

Lufenuron is a selective insecticide, which provides control of the larvae of insect pests, including various species of Lepidoptera, Coleoptera, some Thysanoptera, some Diptera (leaf miners & fruit flies), some Homoptera (Psyllids & flocculent whitefly), and rust mites of the family Eriophiidae. It is used on a wide range of crops, including cotton, maize, sugar beet, potatoes, other vegetables, grapes, citrus, other fruit, and ornamentals.

Identity of the active ingredient

ISO common name

Lufenuron

Synonyms

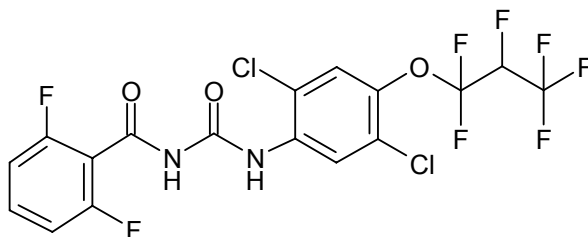
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Chemical names

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Relative molecular mass

511.2

CAS Registry number

103055-07-8

CIPAC number

704

Identity tests

HPLC retention time, IR-Spectrum

Physico-chemical properties of lufenuron

Table 1. Physico-chemical properties of pure lufenuron

Parameter	Value(s) and conditions	Purity %	Method	Reference
Vapour pressure	<4 x 10 ⁻⁶ Pa at 25°C	99.5%	EEC A.4	CGA 184699/0249
Melting point	168.7 to 169.4°C	99.7%	EEC A.1	CGA 184699/0548
Boiling point, temperature of decomposition	Starts at about 242°C, before the boiling point is reached	99.7%	EEC A.2	CGA 184699/0548
Solubility in water	48 µg/l at 25°C	99.7%	OECD 105, EEC A.6	CGA 184699/0675
Partition coefficient	log P _{OW} = 5.12 (± 0.14) at 25°C	99.5%	OECD 107	CGA 184699/0247
Hydrolysis characteristics	Half-live at 25°C: pH 5 = >>30 days pH 7 = >>30 days pH 9 = 512 hours (21.3 days)	96.3% 94.4 98.5	OECD 111	CGA 184699/0230
Photolysis characteristics	Half-life at 25°C in sterile aqueous solutions (c ₀ = 0.05 ppm in pH 7 buffer) using xenon arc light: dichlorophenyl ring ¹⁴ C-labelled lufenuron = 16 days difluorophenyl ring ¹⁴ C-labelled lufenuron = 10.3 days No degradation in dark controls. Averages 93.5-99.1% applied radioactivity recovered. Up to 15% CO ₂ (photolytic mineralization of chlorophenyl ring moiety) occurred, with two other photolysis products at >10%.	96.8% 98%	USEPA 161-2 (and in accordance with EU guidelines)	CGA 184699/0362 CGA 184699/0361
Dissociation characteristics	pK _a = 10.18 ± 0.05 (acidic)	99.7%	OECD 112	CGA 184699/0672

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

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 99.2–100.2%, with no unknowns ≥1 g/kg.
Declared minimum lufenuron content	980 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	168.7°C to 169.4°C

Hazard summary

Lufenuron has not been evaluated by the IPCS or by the FAO/WHO JMPR. The WHO hazard classification of lufenuron is class III (slightly hazardous) (WHO 2002). Lufenuron is classified in Annex I to Directive 67/548/EEC (Commission Directive 2000/32/EC of 19 May 2000 adapting the technical progress for the 26th time the Council Directive 67/548/EEC): lufenuron is not classified as dangerous if swallowed, in contact with skin or by inhalation, and is not irritating to skin or eyes. Lufenuron is classified as sensitizing. An EU review (according to EU directive 91/414/EEC) is expected to be completed by 2008.

Formulations and co-formulated active ingredients

The only formulation type available is EC, which is registered and sold in many countries throughout the world.

Lufenuron may be co-formulated with profenofos or fenoxycarb.

Methods of analysis and testing

The analytical methods for determination of lufenuron (including identity tests) are based on a reversed-phase HPLC with external standardization and UV detection. The methods were adopted by CIPAC in 2007, with provisional status.

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

Physical properties

The physical properties, the methods for testing them and the limits proposed for the EC formulations, comply with the requirements of the manual (FAO/WHO 2006).

Containers and packaging

No special requirements for containers and packaging have been identified.

Expression of the active ingredient

The active ingredient is expressed as lufenuron.

ANNEX 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER

Note: the proposer provided written confirmation that the toxicological data included in the following summary were derived from lufenuron having impurity profiles similar to those referred to in Table 2, above.

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

Species	Test	Duration and conditions	Result	Reference
Rat (m,f)	Acute oral	OECD 401; 14-d observation; purity 95.2%; 1 dose level, 2000 mg/kg bw.	LD ₅₀ >2000 mg/kg bw	CGA 184699/0080
Rat (m,f)	Acute dermal	OECD 402; 14-d observation; purity 95.2%; limit dose, 2000 mg/kg bw	LD ₅₀ >2000 mg/kg bw	CGA 184699/0432
Rat (m,f)	Acute inhalation	OECD 403; 4-h exposure, 14-d observation; purity 95.2%; Actual mean concentration, 2350 mg/m ³ (highest achievable concentration)	LC ₅₀ >2350 mg/m ³	CGA 184699/0083
Rabbit	Skin irritation	OECD 404; 1 to 72-h; purity 95.2%; dose, 0.5g/ml	Non-irritating	CGA 184699/0084
Rabbit	Eye irritation	OECD 405; 1 to 72-h; purity 95.2%; 70 mg/eye	Non-irritating	CGA 184699/0085
Guinea pig	Skin sensitization	OECD 406 (optimization test); 48-h; purity 95.2%; dose 10% in Vaseline (petroleum jelly)	Sensitizer	CGA 184699/0086

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

Species	Test	Duration and conditions	Result	Reference
Rat, Tif:RAIf, Sprague-Dawley	Short-term toxicity	3-m dietary; OECD 408; purity 95.2%; doses: 0, 25, 150, 1500, 15000 ppm	NOEL = 150 ppm (9.7/10.2 mg/kg bw/d, m/f)	CGA 184699/0090
Dog, beagle	Short-term toxicity	3-m dietary; OECD 409; FIFRA 82-1; purity 95.2%; doses: 0, 200, 3000, 50000 ppm	NOAEL = 50000ppm (2023/1933 mg/kg bw/d, m/f)	CGA 184699/0091
Dog, beagle	Short-term toxicity	1-year dietary; FIFRA 83-1, OECD 452; purity 95.3%; doses: 0, 100, 2000, 50000 ppm	NOAEL = 100ppm (3.97/3.64 mg/kg bw/d, m/f)	CGA 184699/0206
Dog, beagle	Short-term toxicity	1-year dietary; FIFRA 83-1, OECD 452; purity 97.1%; doses: 0, 100, 2000, 50000 ppm	NOAEL = 250ppm (7.02/7.72 mg/kg bw/d, m/f)	CGA 184699/0434
Mouse, Tif:MAGf	Carcinogenicity	18-m dietary; FIFRA 83-2, OECD 451; purity 96.2%; doses: 0, 2, 20, 200, 400 ppm	Not carcinogenic NOEL = 20ppm (2.25/2.12 mg/kg bw/d, m/f)	CGA 184699/0288
Rat, Tif:RAIf	Chronic toxicity, carcinogenicity	2-year dietary, FIFRA 83-5, OECD 453, 1981; purity 96.2%; doses: 0, 5, 50, 500, 1500 ppm	Not carcinogenic NOAEL = 50 ppm (1.93/2.34 mg/kg bw/d, m/f)	CGA 184699/0287
Rat, Tif:RAI	Reproductive toxicity	2-generation, dietary; OECD 416, FIFRA 83-4; purity 96.2%; doses: 0, 5, 25, 100, 250 ppm	No effects on reproductive parameters NOAEL reproductive, parental, offspring = 250 ppm (20.9/22.2 mg/kg bw/d, m/f)	CGA 184699/0213

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

Species	Test	Duration and conditions	Result	Reference
Rat, Crl: CD (SD) BRAVAF/Plus	Developmental toxicity	Gavage feeding; OECD 414, FIFRA 83-3; purity 94.7%; doses: 0, 100, 500, 1000 mg/kg bw/d	Not teratogenic NOAEL maternal toxicity = 500 mg/kg bw/d NOAEL developmental toxicity = 1000 mg/kg bw/d	CGA 184699/0088
Rabbit, Hra: New Zealand white SPF	Developmental toxicity	Gavage feeding; OECD 414, FIFRA 83-3; purity 94.7%; doses: 0, 100, 500, 1000 mg/kg bw/d	Not teratogenic NOEL for maternal and developmental toxicity = 1000 mg/kg bw/d	CGA 184699/0089

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

Species	Test	Duration and conditions	Result	Reference
<i>Salmonella typhimurium</i> , <i>E. coli</i>	Bacterial gene mutation <i>in vitro</i> (OECD 471)	0-5000 µg/plate, ± activation; purity 95.2%	Not mutagenic	CGA 184699/0096
Chinese hamster, V79 cells	Gene mutation <i>in vitro</i> (OECD 476)	0-500 µg/ml, - activation 0-750 µg/ml, + activation purity 95.2%	Not mutagenic	CGA 184699/0097
Chinese hamster cells	Cytogenetic test <i>in vitro</i> (OECD 473)	0-200 µg/ml, - activation 0-1600 µg/ml, + activation purity 95.2%	Not clastogenic	CGA 184699/0098
Rat hepatocytes	DNA repair <i>in vitro</i> (OECD 482)	0-6900 µg/ml, purity 95.2%	Not genotoxic	CGA 184699/0094
Human fibroblasts	DNA repair <i>in vitro</i> (OECD 482)	0-6900 µg/ml, purity 95.2%	Not genotoxic	CGA 184699/0095
Human fibroblast	DNA repair <i>in vitro</i> (OECD 482)	0-5000 µg/ml, purity 97.1%	Not genotoxic	CGA 184699/0518
Mouse bone marrow somatic cells	Micronucleus test <i>in vivo</i> (OECD 474)	0, 1250, 2500, 5000 mg/kg bw; purity 95.2%	Not clastogenic	CGA 184699/0099
Rat hepatocytes	In vivo/ <i>in vitro</i> DNA repair test (OECD 486)	0, 1250, 2500, 5000 mg/kg bw; purity 97.1%	Not genotoxic	CGA 184699/0353
Rat hepatocytes	In vivo/ <i>in vitro</i> DNA repair test (OECD 486)	0, 1250, 2500, 5000 mg/kg bw; purity 97.1%	Not genotoxic	CGA 184699/0585

No mutagenic effects were noted in any test, *in vitro* or *in vivo*.

Table D. Ecotoxicology profile of lufenuron technical material

Species	Test	Duration and conditions	Result	Reference
<i>Anas platyrhynchos</i> (mallard duck)	Acute oral	14-d observation; EPA Pesticide Assessment Guidelines, E, 1982; purity 94.7%; treatment levels 500, 1000, 2000 mg a.s./kg bw	LD ₅₀ >2000 mg/kg bw	CGA 184699/0102
<i>Colinus virginianus</i> (bobwhite quail)	Acute oral	14-d observation; EPA Pesticide Assessment Guidelines, E, 1982; purity 94.7%; treatment levels 500, 1000, 2000 mg a.s./kg bw	LD ₅₀ >2000 mg/kg bw	CGA 184699/0104
<i>Anas platyrhynchos</i> (mallard duck)	Short-term	5-d treatment, 3-d observation; EPA Pesticide Assessment Guidelines, E, 1982; purity 94.7%; treatment levels 163, 325, 650, 1300, 2600, 5200 mg/kg feed	LC ₅₀ >5200 mg/kg feed (>1183 mg/kg bw/d dietary dose)	CGA 184699/0103
<i>Colinus virginianus</i> (bobwhite quail)	Short-term	5-d treatment, 3-d observation; EPA Pesticide Assessment Guidelines, E, 1982; purity 94.7%; treatment levels 163, 325, 650, 1300, 2600, 5200 mg/kg feed	LC ₅₀ >5200 mg/kg feed (>966 mg/kg bw/d dietary dose)	CGA 184699/0105
<i>Colinus virginianus</i> (bobwhite quail)	Reproduction	EPA Pesticide Assessment Guidelines Section 71-4 (1982); purity 97.1%; treatment levels 200, 400, 600 mg/kg diet	NOEC = 200 mg/kg diet (19.9 mg/kg bw/d dietary dose)	CGA 184699/0105
<i>Anas platyrhynchos</i> (mallard duck)	Long-term toxicity & reproduction	EPA Pesticide Assessment Guidelines Section 71-4 (1982); purity 97.1%; treatment levels 200, 400, 600 mg/kg diet	NOEC = 200 mg/kg diet (32.2 mg/kg bw/d dietary dose)	CGA 189699/0433
<i>Oncorhynchus mykiss</i> (rainbow trout)	Acute	96-h static exposure, freshwater; OECD 203; purity 95.3%; doses 10, 18, 32, 58, 100 mg/l	LC ₅₀ >73 mg a.s./l	CGA 184699/0011
<i>Lepomis macrochirus</i> (bluegill sunfish)	Acute	96-h static exposure, freshwater; OECD 203; purity 95.3%; doses 10, 18, 32, 58, 100 mg/l	LC ₅₀ >29 mg a.s./l	CGA 184699/0010
<i>Cyprinus carpio</i> (carp)	Acute	96-h static exposure, freshwater; OECD 203; purity 95.3%; doses 10, 18, 32, 58, 100 mg/l	LC ₅₀ >63 mg a.s./l	CGA 184699/0012
<i>Ictalurus punctatus</i> (catfish)	Acute	96-h static exposure, freshwater; OECD 203; purity 95.4%; doses 10, 18, 32, 58, 100 mg/l	LC ₅₀ >45 mg a.s./l	CGA 184699/0009
<i>Oncorhynchus mykiss</i> (rainbow trout)	Chronic toxicity	21-d exposure, flow-through; OECD 204; purity 97.8%; doses 0.0020, 0.0043, 0.0090, 0.018, 0.069 mg/l	Lowest lethal concentration >0.069 mg a.s./l; NOEC = 0.069 mg a.s./l	CGA 184699/0198

Table D. Ecotoxicology profile of lufenuron technical material

Species	Test	Duration and conditions	Result	Reference
<i>Pimephales promelas</i> (fathead minnow)	Fish full life cycle	2-generation; OECD Guideline 210 & US-EPA FIFRA 72-5; purity 97.1%; doses 0.0025, 0.0050, 0.010, 0.020, 0.040 mg/l	NOEC = 0.02 mg a.s./l (based on egg hatch & survival in F1 generation)	CGA 189699/0757
<i>Daphnia magna</i> (water flea)	Acute	Static freshwater, 48-h exposure; EPA Pesticide Assessment Guideline 1982; radiolabelled lufenuron; doses 0.00033, 0.00052, 0.0010, 0.0018, 0.0032, 0.0056, 0.010 mg/l	EC ₅₀ = 0.0013 mg a.s./l	CGA 184699/0013
<i>Daphnia magna</i> (water flea)	Acute	Static, 48-h exposure; EPA Pesticide Assessment Guideline 1982; purity 92.8%; doses 0.00016, 0.00031, 0.00063, 0.00125, 0.00250, 0.00500, 0.010mg/l	EC ₅₀ = 0.0011 mg a.s./l	CGA 184699/0015
<i>Daphnia magna</i> (water flea)	Acute with sediment	Static, 48-h exposure; specially designed test; radiolabelled lufenuron; doses 0.0010, 0.0018, 0.0032, 0.0056, 0.010 mg/l	EC ₅₀ = 0.004 mg a.s./l	CGA 184699/0014
<i>Daphnia magna</i> (water flea)	Chronic	Static, 21-d exposure; OECD 202; purity 92.8%; doses 0.0000010, 0.0000032, 0.000010, 0.000032, 0.00010 mg/l	NOEC = 0.00010 mg a.s./l	CGA 184699/0017
<i>Scenedesmus subspicatus</i> (freshwater green alga)	Growth inhibition	72-h exposure; OECD 201; purity 95.3%; doses 0.074, 0.22, 0.67, 2.0, 6.0, 18 mg/l	EC ₅₀ = 10 mg a.s./l	CGA 184699/0018
<i>Chironomus riparius</i> (midge)	Midge emergence rate & development	28-days exposure, treated water or sediment; OECD test with Chironomidae, 1998; purity 97.1%; water column doses 0.000125-0.004 mg/l; sediment doses 0.010-0.32 mg/kg	Water exposure: NOEC = 0.002 mg a.s./l (emergence) NOEC = 0.004 mg a.s./l (development) Sediment exposure: NOEC = 0.04 mg a.s./kg (emergence) NOEC = 0.08 mg a.s./kg (development)	CGA 184699/0566
<i>Apis mellifera</i> (honeybee)	Oral and contact; mortality & behaviour	48-h exposure; EPPO 170 (1992); purity 97.1%; oral doses 5, 10 g/l (maximum oral dose determined from consumption data) contact doses 100, 200 µg/bee	Oral LD ₅₀ >197 µg a.s./bee Contact LD ₅₀ >200 µg a.s./bee	CGA 184699/0521

Table D. Ecotoxicology profile of lufenuron technical material

Species	Test	Duration and conditions	Result	Reference
<i>Eisenia foetida</i> (earthworm)	Acute toxicity, mortality & behaviour	14-d exposure; OECD 207; purity 95.3%; doses 12.3, 37, 111, 333 and 1000 mg/kg soil	LC ₅₀ >1000 mg a.s./kg soil	CGA 184699/0021
Effects on soil non-target micro-organisms	Soil respiration & nitrification	28-d exposure; (BBA), VI 1-1 (1990) guideline, purity 96.2%; doses 150 g as/ha = 0.2 mg as/kg dry soil, and 1500 g as/ha = 2 mg as/kg dry soil.	No significant effect >25% by day 28 NOEC 2 mg ai/kg	CGA 184699/0312

The results indicate low acute, short- and long-term toxicity to birds; low acute and chronic toxicity to fish and algae; high acute and chronic toxicity to aquatic invertebrates and low acute toxicity to honeybees and earthworms.

ANNEX 2. References

Syngenta document number or other reference	Year and title of report or publication details
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