Food and Agriculture Organization
of the United Nations

FAO SPECIFICATIONS AND EVALUATIONS

FOR AGRICULTURAL PESTICIDES

TRIFLUMURON

1-(2-chlorobenzoyl)-3-(4-trifluoromethoxyphenyl)urea

TABLE OF CONTENTS

DISCLAIMER[1]

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

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

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

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

INTRODUCTION

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

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) - currently available as 3rd revision of the 1st edition (2016) - , 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 JMPM, 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 pesticide, reflecting the evaluation of the data package carried out by FAO and the JMPS. The data are provided by the manufacturer(s) according to the requirements of chapter 3 of the "FAO/WHO Manual on Pesticide Specifications" 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 developed 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.

* NOTE: PUBLICATIONS ARE AVAILABLE ON THE INTERNET AT (http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmps/ps-new/en/) OR IN HARDCOPY FROM THE PLANT PROTECTION INFORMATION OFFICER.

PART ONE

SPECIFICATIONS

INFORMATION

TRIFLUMURON

ISO common name Triflumuron (ISO 1750, published)

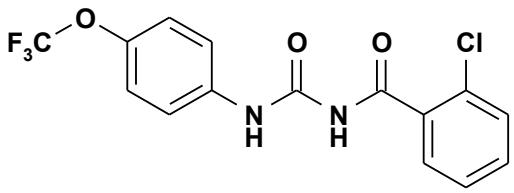
Chemical names

IUPAC 1-(2-chlorobenzoyl)-3-(4-trifluoromethoxyphenyl)urea
CA 2-chloro-N-[[[4-(trifluoromethoxy)phenyl]amino]carbonyl]benzamide

Synonyms

Alsystin®

Structural formula



Molecular formula

C_{15} H_{10} Cl F_3 N_2 O_3

Relative molecular mass

358.7

CAS Registry number

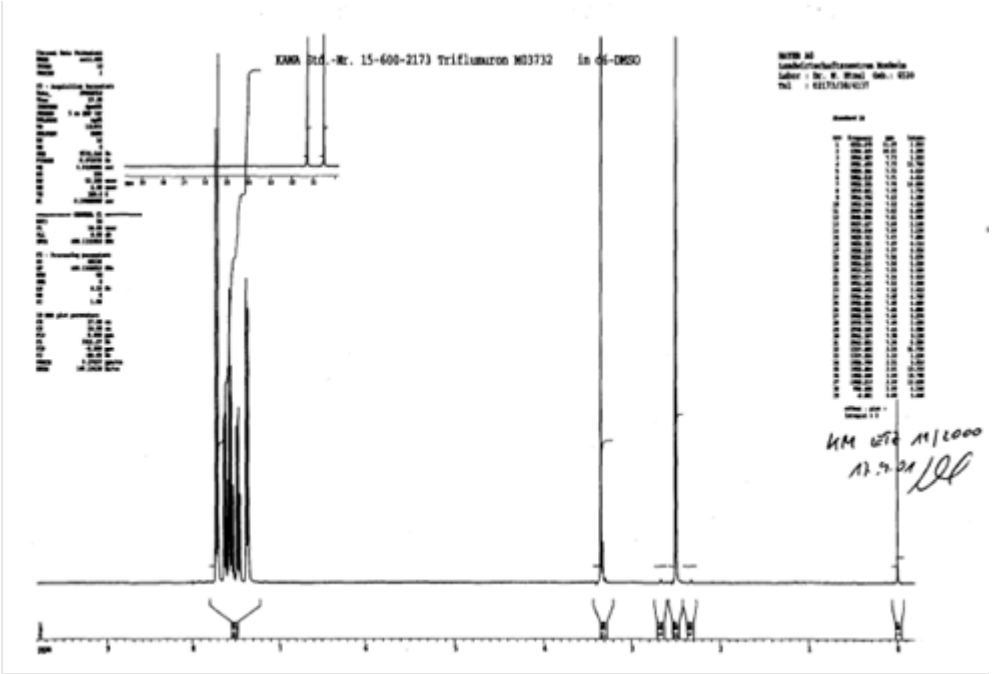
64628-44-0

CIPAC number

548

Identity tests

Retention time in reversed phase HPLC, 1H-NMR-spectrum


KAMA Std.-Nr. 15-600-2173 Triflumuron M03732 in d6-DMSO

TRIFLUMURON TECHNICAL MATERIAL

FAO Specification 548 / TC (July 2018*)

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 (548/2017). It should be applicable to relevant products of these manufacturers 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 (548/2017) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of triflumuron together with related manufacturing impurities, in the form a colourless powder free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 Identity tests (548/TC/M/2, CIPAC Handbook J, 2000, p 115)

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 Triflumuron content (548/TC/M/3, CIPAC Handbook J, 2000, p 115)

The triflumuron content shall be declared (not less than 990 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

3 Relevant impurities

3.1 N,N'-bis-[4-(trifluoromethoxy)phenyl]urea (Note 1)
Maximum: 1.0 g/kg.

3.2 4-Trifluoromethoxyaniline (Note 1)

Maximum: 1.0 g/kg.

Note 1 The peer validated method for determination of N,N'-bis-[4-(trifluoromethoxy) phenyl]urea and 4-trifluoromethoxyaniline in technical and formulated triflumuron was noted by CIPAC in 2017 and adopted. Prior to its publication by CIPAC, a copy of the method is provided in Appendix 1.

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

TRIFLUMURON SUSPENSION CONCENTRATE

FAO Specification 548 / SC (July 2018*)

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 (548/2017). 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 (548/2017), as PART TWO, forms an integral part of this publication.

1 Description

The material shall consist of a suspension of fine particles of technical triflumuron, complying with the requirements of FAO specification 548/TC (July 2018), 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 (548/TC/M2, CIPAC Handbook J, p 115, 2000)

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 Triflumuron content (548/TC/M3, CIPAC Handbook J, p 115, 2000)

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

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

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

3 Relevant impurities

3.1 N,N'-bis-[4-(trifluoromethoxy)phenyl]urea (Note 3)

Maximum: 1.0 g/kg of the triflumuron content found under 2.2

3.2 4-Trifluoromethoxyaniline (Note 3)

Maximum: 1.0 g/kg of the triflumuron content found under 2.2.

4 Physical properties

4.1 **pH range** (MT 75.3, CIPAC Handbook J, p. 131, 2000)

pH range: 6.0 to 8.5

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

Maximum "residue": 5 %

4.3 **Spontaneity of dispersion** (MT 160, CIPAC Handbook F, p. 391, 1995) (Note 4)

A minimum of 90 % of the triflumuron content found under 7.2.2 shall be in suspension after 5 min in CIPAC Standard Water D at 30 ± 2°C.

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

A minimum of 95 % of the triflumuron content found under 2.2 shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2°C.

4.5 **Wet sieve test** (MT 185, CIPAC Handbook K, p. 149, 2003)

Maximum: 0.1 % of the formulation shall be retained on a 75 µm test sieve.

4.6 **Persistent foam** (MT 47.3, CIPAC Handbook K, p. 177, 2017) (Note 5)

Maximum: 40 mL after 1 min.

5 Storage stability

5.1 **Stability at 0°C** (MT 39.3)

After storage at 0 ± 2°C for 7 days, the formulation shall continue to comply with clauses for:

- suspensibility (4.4),
- wet sieve test (4.5),

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

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 95 % relative to the determined average content found before storage (Note 6) and the formulation shall continue to comply with the clauses for:

- pH range (4.1),
- pourability (4.2),
- spontaneity of dispersion (4.3),
- suspensibility (4.4),
- wet sieve test (4.5),

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 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 The peer validated method for determination of N,N'-bis-[4-(trifluoromethoxy)phenyl]urea and 4-Trifluoromethoxyaniline in technical and formulated triflumuron is provided in Appendix 1.

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 equal results 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 correspond to the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.

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

PART TWO

EVALUATION REPORTS

TRIFLUMURON

TRIFLUMURON
FAO/WHO EVALUATION REPORT 548/2017

Recommendations

The Meeting recommended the following:

i) the new specifications for triflumuron TC and SC, proposed by BayerCropScience and as amended, should be adopted by FAO, subject to adoption of the peer validated method for determination of the relevant impurites and clarification of some points.

ii) the FAO specifications for triflumuron TC, SC and WP, developed under the "Old procedure", should be withdrawn.

Appraisal

The Meeting considered data submitted in 2013 by Bayer CropScience, in support of development of new FAO specifications for triflumuron TC and SC and WP. Bayer CropScience (BCS), initially submitted data in 2010, in order to revise the FAO specifications (FAO, 2000).

Triflumuron is the ISO common name for 1-(2-chlorobenzoyl)-3-(4-trifluoromethoxy phenyl)urea. The compound belongs to the chemical group of benzoylurea compounds and to the class of chitin synthesis inhibitors. It is no longer under patent.

Triflumuron has not been evaluated by FAO/WHO JMPR or WHO/IPCS. Triflumuron has been evaluated by the European Commission (RMS Italy) and included in the positive list of active ingredients with a minimum purity of 955 g/kg maximum limits for *N,N'-bis*-[4-(trifluoromethoxy)phenyl]urea (1 g/kg) and 4-trifluoromethoxyaniline (5 g/kg) as relevant impurities. The comparison of the confidential data package submitted to JMPS and that for the evaluation of the active substance in the European Union was done by the authority in Greece and an e-mail was received in 2018 confirming the similarity of the two data packages (Karassali E., 2018).

The Meeting was provided with commercially confidential information on the manufacturing process and five batch analysis data on impurities present at or above 1g/kg and their manufacturing limits in the TC. Mass balances ranged from 995.6 to 998.8 g/kg in the five batch data and no unidentified impurities exceeding 1 g/kg were reported. The declared minimum active ingredient content (990 g/kg) based on the 5-batch analysis data provided, has been set higher than that of the former FAO specification (2000) with 955 g/kg.

The Meeting deemed that the impurities N,N'-bis-[4-(trifluoromethoxy) phenyl]urea (also called bisaylurea) and 4-trifluoromethxyaniline should be considered as relevant and toxicity

studies for both of them were requested. On May 2013, BCS replied that these putative relevant impurities should not be considered as relevant according to the rules laid down in the FAO/WHO Manual (overall hazard would increase less than 10%) and for that reason no toxicity studies were provided. At the same time, updated specifications were submitted regarding the maximum limit of one of these impurities (bisarylurea <1g/kg) and the minimum purity of the TC (new minimum purity raised to 990g/kg). Regarding the other impurity (4-trifluoromethxyaniline) the maximum limit remained at <1g/kg.

The following considerations with regard to the two impurities were made by the Meeting:

N,N'-bis-[4-(trifluoromethoxy)phenyl]urea

N,N'-bis-[4-(trifluoromethoxy)phenyl]urea is more toxic to rats than triflumuron (acute oral LD_{50} 133 mg/kg vs > 5000 mg/kg (EFSA 2011). Thus considering the minimum content of the a.i. (990 g/kg), these LD_{50} values, and applying the standard JMPS calculation, N,N'-bis-[4-(trifluoromethoxy)phenyl]urea should be considered relevant (MTIHaz 1.38), and the maximal acceptable impurity concentration, ImpMax, 2.6 g/kg. The present FAO specification lists 1 g/kg as the maximum concentration, and it would seem justifiable to use this same value in the new specification. This is also the EU maximum limit (SANCO 2011). In addition, BSC provided data which seemed to show that N,N'-bis-[4-(trifluoromethoxy)phenyl]urea is 5000 times more toxic to golden orfe than triflumuron, and that all the toxicity of triflumuron TC toward this fish species could be explained by this impurity. Although there are concerns of the validity of this study (concentrations which were studied greatly exceed the water solubility of triflumuron), these findings corroborate the conclusion that N,N'-bis-[4-(trifluoromethoxy)phenyl]urea should be considered relevant. Noting that triflumuron is very toxic to other aquatic species (48 h EC_{50}, semistatic, to *Daphnia* 1.6 µg/L, approx.. 1/10 of the EC_{50} of N,N'-bis-[4-(trifluoromethoxy)phenyl]urea to golden orfe) (EFSA 2007) and it is thus considered to be clearly toxic to aquatic fauna, the proposed limit for N,N'-bis-[4-(trifluoromethoxy)phenyl]urea content in triflumuron should be conservative enough also from the ecotoxicity point of view.

The method used for the determination of N,N'-bis-[4-(trifluoromethoxy)phenyl]urea is a reverse phase HPLC with UV detection at 258 nm and external standardization. The method was fully validated with respect to linearity, specificity, accuracy, precision and LOQ. The identity of N,N'-bis-[4-(trifluoromethoxy)phenyl]urea had been demonstrated by comparison of the UV-spectra and its retention time with that of the certified reference material.

4-Trifluoromethoxyaniline

4-Trifluoromethoxyaniline is toxic by the dermal route of exposure (LD_{50} in rats < 50 mg/kg) (EFSA 2011). Applying the minimum a.i content of 990 g/kg, and the limits of dermal LD_{50} (<50 mg /kg for 4-trifluoromethoxyaniline and >5000 mg/kg for triflumuron), the standard JMPS calculation indicates that the MTIHaz is > 2.01, and the impurity is thus relevant –

notwithstanding that 4-trifluoromethoxyaniline is a metabolic intermediate of triflumuron (dermal application apparently renders 4-trifluoromethoxyaniline more toxic than metabolic formation from triflumuron). The ImpMax is < 0.99 g/kg. It may be considered justifiable to set the maximal impurity content at 1 g/kg, the concentration proposed by BSC. The EU limit for 4-trifluoromethoxyaniline is 5 g/kg.

The method used for the determination of 4-trifluoromethoxyaniline is reversed phase HPLC with UV detection at 226 nm and external standardization. The method was adequately validated with respect to linearity, specificity, accuracy, precision and LOQ. The identity of 4-trifluoromethoxyaniline had been demonstrated by comparison of the UV-spectra and its retention time with that of the certified reference material.

Triflumuron is a colorless to white crystalline powder with a melting point of 194° C. The compound has a low volatility (vapour pressure: $<10^{-3}$Pa at 20°C) and is only slightly soluble in water (solubility: 0.04mg/L) with no pH dependence.

The compound is readily soluble (> 1g/L) in all organic solvents tested except n-heptane where its solubility is < 0.1 g/L. The octanol/water partition coefficient (log P_{ow}=4.68, at 25° C) is not pH dependent and indicates that the molecule is lipophilic and has a potential for bioaccumulation. Triflumuron is stable to hydrolysis at all pH values tested. Photolysis may contribute to degradation in water with a half life of approx. one month.

The analytical method used for the determination of the active ingredient is a full CIPAC method published in Handbook J. The triflumuron content is determined by reversed phase high performance liquid chromatography using UV detection at 250 nm and external standardisation. The identity of triflumuron is verified by comparing the retention times of an authentic standard with a sample in reversed phase HPLC and ^{d}H-NMR.

The main formulation type available is suspension concentrate (SC) and BCS explained, that the WP is no longer supported.

The physicochemical properties, the methods for testing them and the limits proposed for SC formulations, generally complied with the requirements of the FAO/WHO Manual but the meeting considered the following issues.

SC formulation, physical-chemical properties

Whereas most of the clauses in the physical-chemical properties section were quite straightforward and essentially complied with the Manual (FAO/WHO Manual on development and use of pesticide specifications, 2nd Revision, 2010), some clauses required further clarifications. These were:

pH-range: The Meeting considered the pH range proposed for the SC as excessively wide and asked BCS for a justification. The company explained that due to hydrolytic instability

of triflumuron in alkaline media the upper pH limit is necessary but the value 6.0 instead of 4.5 is more appropriate. The Meeting accepted this justification.

Pourability: That property of the SC was determined by CIPAC MT 148.1 and also specified a rinsed residue. The Meeting recommended that in such case (5 % residue) a result for rinsed residue is not required, as the generic limit is 5 %. The company agreed and agreed to remove the rinsed residues. The Meeting agreed.

The peer validated analytical methods for the determination of the two relevant impurities in TC and SC formulations were presented at the CIPAC Meeting 2017 in Rome and noted. With the availability of the analytical methods, all conditions for publication of the new FAO specifications were met. Copies of the the methods are provided in Appendix 1.

SUPPORTING INFORMATION
FOR
EVALUATION REPORT 548/2017

USES

Triflumuron is a benzoylurea insecticide with non-systemic insect growth regulatory activity for control of leptidopteran insects, especially in top-fruit, citrus, vegetables, forestry, and is also active against migratory locusts and grasshoppers. Triflumuron inhibits the chitin synthesis in insect-larvae about to the moult by interfering with the moulting hormone system. It acts mainly as stomach-poison particularly on larvae of biting insects, and has ovicidal activities.

Identity of the active ingredient

ISO common name Triflumuron (ISO 1750, published)

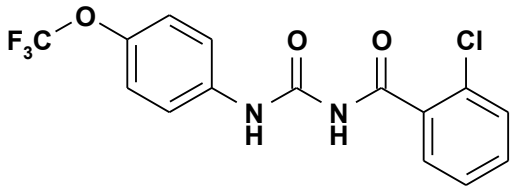
Chemical names

IUPAC 1-(2-chlorobenzoyl)-3-(4-trifluoromethoxyphenyl)urea
CA 2-chloro-N-[[[4-(trifluoromethoxy)phenyl]amino]carbonyl]benzamide

Synonym

Alsystin®

Structural formula



Molecular formula

C_{15} H_{10} Cl F_3 N_2 O_3

Relative molecular mass

358.7

CAS Registry number

64628-44-0

CIPAC number

548

Identity tests

Retention time in reversed phase HPLC, ^{1}H-NMR

Table 1: Physical-chemical properties of pure triflumuron

Parameter	Value(s) and conditions	Purity %	Method reference (and technique if the reference gives more than one)	Study reference
Vapour pressure	< 10^{-3} Pa at 20 °C (extrapolated) < 10^{-3} Pa at 25 °C (extrapolated)	99.8	OECD 104, EC A4	M-052058-01-1
Melting point.	Melting point: 194 °C	99.6	OECD 102	M-300905-01-1
Boiling point	Boiling point can not be determined due to decomposition	-	OECD 103	M-300905-01-1
Temperature of decomposition	> 360 °C	99.6	OECD 113 DSC	M-300905-01-1
Solubility in water	0,04 mg/L at 20 ° C in un-buffered water	99.8	OECD 105 Column saturation method,	M-060752-01-1
Octanol/water partition coefficient	log P_{OW} = 4.68 at 25 ° C	99.1	OPPTS 830.7570 EC A8, OECD 117	M-076649-02-1
Hydrolysis characteristics	No degradation after 30 days at pH 5.0 at 25 °C. Half-life = 465 days at 25 °C at pH 7.0. Half-life = 57 days at 25 °C at pH 9.0	99.0	EPA 161-1 OECD 111	M-019861-02-1
Photolysis characteristics	Half-life = 32.8 days at 25 °C for irradiated samples in sterile solution (pH 7.0) Half-life calculated at 119.2 solar summer days at Phoenix (AZ, USA) or 184.8 2 solar summer days at Athens (Greece)	> 98.0	SETAC 1995	M-088318-01-1
Dissociation characteristics	Triflumuron has no basic properties. It is not possible to specify a pK value due to poor water solubility	99.5	OECD 112	M-025794-01-2

Parameter	Value(s) and conditions	Purity %	Method reference (and technique if the reference gives more than one)	Study reference
Solubility in organic solvents	< 0.1 g/L n-heptane at 20 °C 11.7 g/L dichloromethane at 20 °C 1.3 g/L 2-propanol at 20 °C 1.7 g/L xylene at 20 °C 1.2 g/L n-octanol at 20 °C 26.6 g/L acetone at 20 °C 4.5 g/L acetonitrile at 20 °C 23.3 g/L ethyl acetate at 20 °C 9.6 g/L poly ethylene glycol at 20 °C 127.4 g/L dimethylsulfoxide at 20 °C	99.8[1]	OECD 105	M-091466-01-1

Table 2: Chemical composition and properties of triflumuron 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 995.6 – 998.8kg/kg.
Declared minimum [a.i.] content	990/kg
Relevant impurities ≥ 1 g/kg and maximum limits for them	None
Relevant impurities < 1 g/kg and maximum limits for them:	N,N'-bis[4-(trifluoromethoxy)phenyl]-urea (also called bisarylurea), 1 g/kg 4-trifluoro-methoxyaniline, 1 g /kg.
Stabilisers or other additives and maximum limits for them:	None

Parameter	Value and conditions	Purity %	Method reference	Study reference
Melting temperature range of the TC and/or TK	See Table 1			
Solubility in organic solvents	See Table 1			

[1] Available information has been provided on the solubility of pure active ingredient in organic solvents.

FORMULATIONS AND CO-FORMULATED ACTIVE INGREDIENTS

The main formulation type currently available is SC. The proposer provided information (2017) that WP formulations are not supported anymore and only few remaining countries outside Europe still having it sold and this sales being stopped soon.

Triflumuron is co-formulated with *beta*-cyfluthrin and thiacloprid.

These formulations are registered and sold in Latin-American countries (Brazil, Argentina, Chile Peru, Ecuador, Bolivia, Paraguay, Uruguay, Colombia, Venezuela) South Africa, Saudi Arabia, and Egypt.

METHODS OF ANALYSIS AND TESTING

The analytical method for the active ingredient (including identity tests) is CIPAC 548/TC/M/-. The triflumuron content is determined by reversed phase high performance liquid chromatography using UV detection at 250 nm and external standardisation.

The method has been adopted by CIPAC and published in CIPAC Handbbok J.

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

The physical properties, the methods for testing them and the limits proposed for the SC and WP formulations, comply with the requirements of the FAO/WHO manual (2010 2nd edition).

CONTAINERS AND PACKAGING

No special requirements for containers and packaging have been identified.

EXPRESSION OF THE ACTIVE INGREDIENT

The active ingredient triflumuron is expressed as triflumuron in g/L for liquid formulations and as g/kg for solid formulations.

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

Species	Test	Purity % Note[1]	Guideline, duration, doses and conditions	Result	Study reference
rat, male & female	acute oral	98.9	Guideline not stated single application, fasted, non-fasted non-fasted: 1,000 – 2,500 – 5,000 mg/kg bw fasted: 500 – 1,000 – 2,500 – 5,000 mg/kg bw batch 1, rcvd. 1/77	LD_{50} = [> 5,000] mg/kg bw fasted, non-fasted)	M-087278-01-1
rat, female	acute oral	95.2	Guideline not stated single application, fasted 2,5000 – 5,000 mg/kg bw batch no. 16002/79, received 3/79	LD_{50} = [> 5,000] mg/kg bw	M-087551-01-1
rat, male	acute oral	not stated	Guideline not stated single application, fasted 5,000 mg/kg bw batch no. 16003/81	LD_{50} = [> 5,000] mg/kg bw	M-087915-01-2
rat, male	acute oral	not stated	Guideline not stated single application, non-fasted 5,000 mg/kg bw batch 16001/80	LD_{50} = [> 5,000] mg/kg bw	M-037360-01-1
rat, male & female	acute oral	99.1	US-EPA OPPTS 870.1100, OECD 401 single application, fasted 0 – 5,000 mg/kg bw batch 234108012	LD_{50} = [> 5,000] mg/kg bw	M-064546-01-1
rat, male & female	acute oral	99.3	Draft guideline document ENV/JM/PEST (2002) 11 single application, non-fasted 0 – 10 – 70 – 500 mg/kg bw batch EDCI001521	NOAEL = [500] mg/kg bw	M-255456-01-1
mouse, male & female	acute oral	98.9	Guideline not stated single application, fasted 500 – 1,000 – 2,500 – 5,000 mg/kg bw batch 1, rcvd. 1/77	LD_{50} = [> 5,000] mg/kg bw	M-087278-01-1

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

Species	Test	Purity % Note[1]	Guideline, duration, doses and conditions	Result	Study reference
dog, female	acute oral	98.9	Guideline not stated single application, fasted 500 – 1,000 mg/kg bw batch 1, rcvd. 1/77	LD_{50} = [> 1,000] mg/kg bw	M-087278-01-1
sheep, male & female	acute oral	96.7	Guideline not stated single application, 1,000 – 2,500 – 5,000 – 10,000 mg/kg bw batch 16002/78, received 1/79	LD_{50} = [> 10,000] mg/kg bw	M-087599-01-1
rat, male & female	acute dermal	98.9	Guideline not stated; reference made to Noakes and Sanderson (1969) Brit. J. Industr. Med. 26, 59 24h exposure, semi-occlusive conditions 5,000 mg/kg bw batch 1, rcvd. 1/77	LD_{50} = [> 5,000] mg/kg bw	M-087278-01-1
rat, male & female	acute dermal	99.1	US-EPA OPPTS 870.1200; OECD 402 24h exposure, semi-occlusive conditions 0 – 5,000 mg/kg bw batch 234108012	LD_{50} = [> 5,000] mg/kg bw	M-064572-01-1
rat, male & female mouse, male golden hamster, male	acute inhalation	98.9	Guideline not stated description of the exposure system implies nose-only exposure exposure: 1h, 4h, 5x6h rat, 1h: 150 mg/m³ rat, 4h: 39 – 91 – 119 mg/m³ rat, 5x6h: 74 - 133 mg/m³ mouse, hamster, 4h: 166 mg/m³ batch 1, rcvd. 1/77	LC_{50} rat, 1h = [> 150] mg/m³ rat, 4h = [> 119] mg/m³ rat, 5x6h = [> 133] mg/m³ mouse, 4h = [> 166] mg/m³ hamster, 4h = [> 166] mg/m³	M-087278-01-1
rat, male & female	acute inhalation	94.0	Guideline not stated exposure: 4h 0 – 1,550 mg/m³ air batch 9030034	LC_{50} = [> 1,550] mg/m³	M-086890-01-1
rat, male & female	acute inhalation	99.1	OECD 403; Directive 92/69/EEC, Method B.2.; US-EPA 712C-98-193, OPPTS 870.1300 exposure: 4h 0 – 2,108 – 5,030 mg/m³ air (max. techn. attainable.concentration) batch 234108012	LC_{50} = [> 5,030] mg/m³	M-078710-01-1

Species	Test	Purity % Note[1]	Guideline, duration, doses and conditions	Result	Study reference
rat, male & female	acute intraperitoneal	98.9	Guideline not stated single application 250 – 500 – 1,000 – 2,500 – 5,000 mg/kg bw batch 1, rcvd. 1/77	LD_{50} = [> 5,000] mg/kg bw	M-087278-01-1
mouse, male & female	acute subcutaneous	98.9	Guideline not stated single application 500 – 1,000 – 2,500 – 5,000 mg/kg bw batch 1, rcvd. 1/77	LD_{50} = [> 5,000] mg/kg bw	M-087278-01-1
rabbit	skin irritation	98.9	Guideline not stated, method recormended by the U.S. Department of Agriculture (§1500.41, Federal Register 38 (187) 27019 (1973) dose not stated batch 1, rcvd. 1/77	not irritating	M-087278-01-1
rabbit, male, female	skin irritation	99.1	US-EPA OPPTS 870.2500; OECD 404; JMAFF 59 NohSan No. 4200 exposure: 4h 0.5 g batch #02TAP002	not irritating	M-075928-02-1
rabbit	eye irritation	98.9	Guideline not stated method recommended by the U.S. Department of Health, Education and Welfare (Fed. Reg. 37, (83), 8534, 1972). dose not stated batch 1, rcvd. 1/77	slightly irritating, classification not triggered	M-087278-01-1
rabbit, male, female	eye irritation	99.1	US-EPA OPPTS 870.2400; OECD 405; JMAFF 59 NohSan No. 4200 single application 0.2 mL batch # 02TAP002	slightly irritating, classification not triggered	M-075936-01-1
guinea pig, male	skin sensitisation (maximization test, Magnusson-Kligman protocol)	94.0	Guideline not stated intradermal injection: 0.1 mL topical induction, challenge: not stated, 24h batch 9030034	not sensitising	M-086893-01-1

Species	Test	Purity % Note[1]	Guideline, duration, doses and conditions	Result	Study reference
guinea pig, female	skin sensitisation (maximization Test according Magnusson and Kligman)	99.7	OECD 406; Guideline 96/54/EC, Method B.6.; US-EPA FIFRA §81-6 intradermal induction: 2.5% topical induction: 50%, 48h challenge: 50%, 24h batch 234608012	not sensitising	M-087125-01-1

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

Species	Test	Purity % Note[1]	Guideline, duration, doses and conditions	Result	Study reference
rat, male & female	subacute, oral (gavage)	98.9	Guideline not stated 4 weeks + 4 week observation 0 – 30 – 100 – 300 mg/kg bw/day batch 1, rcvd. 1/77	NOEL = [30] mg/kg bw/day LOEL: [100] mg/kg bw/day	M-087319-01-1
rabbit, male & female	subacute, dermal	98.9	Guideline not stated 7h/day, 15 consecutive working days 0 – 50 – 250 mg/kg bw/day batch 1, rcvd. 1/77	NOEL = [50] mg/kg bw/day LOEL = [250] mg/kg bw/day	M-087328-01-1
rabbit, male & female	subacute, dermal	99.5	US-EPA FIFRA Series 82-2; OECD 410 6h/day, 15 consecutive working days + 2 week restitution 0 – 100 – 300 – 1,000 mg/kg bw/day batch 7250121/7030127	NOEL = [100] mg/kg bw/day LOEL = [300] mg/kg bw/day	M-086772-01-1

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

Species	Test	Purity % Note[1]	Guideline, duration, doses and conditions	Result	Study reference
rat, male & female	subacute, inhalation	99.2 – 97.4	Guideline not stated 15x6h, 15 consecutive working days 0 – 9 – 29 – 92 mg/m³ air/day 0 – 3 – 8 mg/m³ air/day 0 – 9.3 – 94.3* mg/m³ air/day (* max. techn. producible concentration) batch 1, received 1/77	NOEL = 94.3 mg/m³ air/day	M-087340-01-1
rat, male & female	subacute, inhalation	not stated	Guideline not stated 15x6h, 15 consecutive working days formulation SIR 8514 065 EC 059 B 0 – 71 – 282 – 1,692 mg/m³ air/day (equivalent to 0 – 4.2 – 18.05 – 108.29 mg/m³ air/day a.i.)	NOEL = 71 mg/m³ air/day [4.2 mg a.i./m³ air/day] LOEL = 282 mg/m³ air/day [18.05 mg a.i./m³ air/day]	M-087619-01-1
rat, male & female	subchronic, feeding	96.7	Guideline not stated 3 months 0 – 50 – 500 – 5000 ppm (equivalent to 0 – 3.6 – 35-5 – 349.2 / 0 – 4.5 – 47.0 – 448.7mg/kg bw/day, males/females) batch 16002/78, received 1/79	NOAEL = 50 ppm [3.6/4.5] mg/kg bw/day LOEL = 500 ppm [35.5/47.0] mg/kg bw/day	M-087617-01-1
rat, male & female	subchronic, feeding	94.9	Guideline not stated 3 months 0 – 5 – 15 – 45 ppm (equivalent to 0 – 0.34 – 1.02 – 3.12 / 0 – 0.39 – 1.18 – 3.63mg/kg bw/day, males/females) batch Eg. 1 /80-5/80	NOEL = 45 ppm [3.12/3.63] mg/kg bw/day	M-087254-01-1
rat, male & female	subchronic, feeding	[a)]95.1 [b)]95.6	Guideline not stated 3 months 0 – 20 – 200 – 2,000 ppm (equivalent to 0 – 1.34 – 13.85 – 141.98 / 0 – 1.52 – 15.87 – 148.94mg/kg bw/day, males/females) batch [a)]16002/78, Eg. 1/79 (for 14 days), [b)]mixed batch Eg. 1-5/80	NOAEL = 20 ppm [1.34/1.52] mg/kg bw/day LOEL = 200 ppm [13.85/15.87] mg/kg bw/day	M-086368-01-1

Species	Test	Purity % Note[1]	Guideline, duration, doses and conditions	Result	Study reference
dog, male & female	subchronic, feeding	95.1	Guideline not stated 13 weeks 0 – 100 – 500 – 2,500 ppm (equivalent to 0 – 2.68 – 13.55 – 67.22 mg/kg bw/day) batch 1616001/78, rcvd. 2/78	NOEL = 100 ppm [2.68] mg/kg bw/day LOEL = 200 ppm [13.55] mg/kg bw/day	M-087344-01-1
dog, male & female	subchronic, feeding	95.3	Guideline not stated 12 months 0 – 40 – 200 – 1,000 ppm (equivalent to 0 – 1.42 – 6.83 – 33.07 mg/kg bw/day) composite sample of batches Eg. 1-5/80	NOEL = [1.42] mg/kg bw/day LOEL = 200 ppm [6.83] mg/kg bw/day	M-087430-02-1
dog, male & female	subchronic, feeding	95.3	Guideline not stated 12 months 0 – 20 ppm (equivalent to 0 – 0.72 mg/kg bw/day) composite sample of batches Eg. 1-5/80	NOEL = 20 ppm [0.72] mg/kg bw/day	M-087261-02-1
rat, male & female	combined long-term& carcinogenicity, feeding	95.3	Guideline not stated 2 years 0 – 20 – 200 – 2,000 ppm (equal to 0 – 0.82 – 8.45 – 86.12 / 0 – 1.11 – 11.19 – 110.03 mg/kg bw/day, males/females) 5 batch mixture, Eg. 1-5/80	NOEL = 20 ppm [0.82/1.11] mg/kg bw/day LOEL = 200 ppm [8.45/11.19] mg/kg bw/day. The number, type, location and distribution of the neoplasms found in the study groups did not provide any indications of carcinogenic action of triflumuron (EFSA 2007)	M-087155-02-1

Species	Test	Purity % Note[1]	Guideline, duration, doses and conditions	Result	Study reference
mouse, male & female	carcinogenicity, feeding	94.9	Guideline not stated 2 years 0 – 20 ppm – 200 – 2,000 ppm (equal to 0 – 5.19 – 49.04 – 523.28 / 0 – 6.68 – 67.93 – 691.63 mg/kg bw/day, males/females) 5 batch mixture, Eg. 1-5/80	NOAEL = 20 ppm [5.19/6.68] mg/kg bw/day LOEL = 200 ppm [49.04/67.93] mg/kg bw/day. The number, type, location and distribution of the neoplasms found in the study groups did not provide any indications of carcinogenic action of triflumuron (EFSA 2007)	M-086996-02-1
rat, male & female	multi-generation, feeding	95.3	Guideline: recommendations published by the FDA approx. 670 days 0 – 20 – 200 – 2,000 ppm (2000 ppm equal to 142.54/150.44 mg/kg bw /day, males/females, calculated) 5 batch mixture, rcvd. 1-5/80	NOELparental+repro +neonat = 2,000 ppm [142.54/150.44] mg/kg bw /day	M-087241-02-1
rat, female	developmental, oral (gavage)	91.7	Guideline not stated gestation day 6 to 15 0 – 10 – 30 – 100 mg/kg bw/day batch 1616001/78 (rcvd. 2/78)	NOEL = [100] mg/kg bw/d	M-087602-01-1
rat, female	developmental, oral (gavage)	99.4	US-EPA FIFRA 83-3; US-EPA OPPTS 870.3700; Health Canada PMRA DACO No. 4.5.2 gestation day 6 to 15 0 – 100 – 300 – 1,000 mg/kg bw/day batch EPA-EST 3125-1101	NOEL = [300] mg/kg bw/d LOEL = [1,000] mg/kg bw/d	M-086940-02-1
rabbit, female	developmental, oral (gavage)	91.7	Guideline not stated gestation day 6 to 18 0 – 10 – 30 – 100 mg/kg bw/day batch 1616001/7S (rcvd. 2/78)	NOEL = [100] mg/kg bw/d	M-087600-01-1

Species	Test	Purity % Note[1]	Guideline, duration, doses and conditions	Result	Study reference
rabbit, female	developmental, oral (gavage)	99.4 – 99.5	US-EPA FIFRA 83-3; US-EPA OPPTS 870.3700; Health Canada PMRA DACO No. 4.5.3 gestation day 6 to 18 0 – 100 – 300 – 1,000 mg/kg bw/day batch EPA-EST 3125-1101	NOEL = [300] mg/kg bw/d LOEL = [1,000] mg/kg bw/d	M-086549-02-1

Table 5: Mutagenicity profile of technical triflumuron based on *in vitro* and *in vivo* tests

Species	**Test**	**Purity % Note**[1]	**Guideline, duration, doses and conditions**	**Result**	**Study reference**
Salmonella typhimurium	Reverse mutation assay in vitro	95.1	Guideline not stated S. typhimurium TA1535, TA1537, TA100, TA98 (+/- S9 mix) 4 – 2,500 µg/plate batch 1616001/78, received 2/78	negative	M-087335-01-1
Salmonella typhimurium	Reverse mutation assay in vitro	99.6	US-EPA-FIFRA Sec. 158.135, 81-3 S. typhimurium TA98, TA100, TA1535, TA1537 and TA1538 (+/- S9 mix) 100 – 10,000 µg/plate batch 1030121	negative	M-068903-01-1
Salmonella typhimurium	Reverse mutation assay in vitro	99.3	Directive 84/449/EEC, Method B.14.; OECD 471, US-EPA New and Revised Health Effects Test Guidelines (PB 84-233295) S. typhimurium TA1535, TA100, TA1537, TA98 (+/- S9 mix) 8 – 5,000 µg/plate batch 234912512	negative	M-086848-01-1
Escherichia coli	DNA repair test in vitro	99.8	Guideline not stated E. coli (K12)p 3478, W 3110 625 – 2,500 µg/plate (+/- S9 mix) batch 16003/82	negative	M-087148-01-1

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

Species	Test	Purity % Note[1]	Guideline, duration, doses and conditions	Result	Study reference
Saccharomyces cervisiae	Reverse mutation assay in vitro	99.8	Guideline not stated strains S138, S211α 33 – 10,000 µg/mL (+/- S9 mix) batch 16003/82	negative	M-087498-01-1
Saccharomyces cerevisiae	Mitotic crossing over, gene conversion in vitro	99.8	Guideline not stated strains D7 33 – 10,000 µg/mL (+/- S9 mix) batch 16003/82	negative	M-087504-01-1
Chinese hamster ovary cells	Gene mutation in mammalian cells in vitro	99.0	US-EPA FIFRA §84-2 CHO-K_1-BH_4 cells 100 – 300 µg/mL (+/- S9 mix) batch 1030121	negative	M-068802-01-1
Chinese hamster ovary cells	Gene mutation in mammalian cells in vitro	99.5	Guideline not stated CHO-K_1-BH_4 cells 50 – 100 µg/mL (+/- S9 mix) batch 7250121/7030127	negative	M-086712-01-1
Rat hepatocytes	Unscheduled DNA synthesis in vitro	99.0	US-EPA Guideline 84-2 0.03 – 1,000 µg/mL batch 1030121	negative	M-068891-01-1
Chinese hamster ovary cells	Sister chromatid exchange in vitro	99.0	US-EPA-FIFRA, Sec. 158.135, 84-2 6.3 – 50 µg/mL. (+/- S9 mix) batch 1030121	negative	M-068830-01-1

Species	Test	Purity % Note[1]	Guideline, duration, doses and conditions	Result	Study reference
Human lymphocytes	Gene mutation in mammalian cells in vitro	99.3	OECD 473; Directive 84/449/EEC; US-EPA Subpart F-Genetic Toxicity, "In vitro mammalian cytogenetics" without S9 mix: 24 h: 10.0; 30.0; 80.0 µg/mL 48 h: 80.0 µg/mL with S9 mix: 24 h: 10.0; 30.0; 80.0 µg/mL 48 h: 80.0 µg/mL batch 234912512	negative	M-087510-01-1
Mouse, male & female	Micronucleus test in vivo	95.1	Guideline not stated 2x 200 mg/kg bw, 2x 400 mg/kg bw batch 1616001/78, rcvd. 2/78	negative	M-087291-01-1
Mouse, male	Dominant-lethal test in vivo	95.1	Guideline not stated single oral administration (gavage) of 400 mg/kg bw batch 1616001/78, rcvd. 2/78	negative	M-087331-01-1

Table 6: Ecotoxicology profile of technical triflumuron

Species	Test	Purity % Note[1]	Guideline, duration, doses and conditions	Result	Study reference
Colinus virginianus (Bobwhite quail)	acute	94.0	Method described in report, single oral administration, 86, 400, 560, 784, 1098, 1537, 2151 or 3012 mg a.s./kg b.w, batch 9030035	LD_{50} 561 mg a.s./kg bw	M-076686-01-1
Anas platyrhynchos (Mallard duck)	5 d dietary	94.0	Method described in report, 5 days dietary exposure, 0, 600, 1020, 1734, 2948, 5011 or 8519 mg a.s./kg feed, batch 9030035	LC_{50} 2018 mg a.s./kg diet	M-076734-01-1

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

Species	Test	Purity % Note[1]	Guideline, duration, doses and conditions	Result	Study reference
Colinus virginianus (Bobwhite quail)	5 d dietary	94.0	Method described in report, 5 days dietary exposure, 0, 500, 1000, 2000, 4000 or 8000 mg a.s./kg feed, batch 9030035	LC_{50} 1000 mg a.s./kg diet	M-076740-02-1
Colinus virginianus (Bobwhite quail)	5 d dietary	99.4	EPA 71-2, 5 days dietary exposure, 0, 313, 625, 1250, 2500 or 5000 mg a.s./kg feed, batch 234908023	LC_{50} > 5626 mg a.s./kg diet	M-085747-01-1
Colinus virginianus (Bobwhite quail)	reproduction 23 w dietary	98.0	Method described in report, 23 weeks dietary exposure, 0, 20, 80 and 320 mg a.s./kg feed, batch 1030121	NOEC 80 mg a.s./kg diet	M-076600-01-1
Anas platyrhynchos (Mallard duck)	reproduction 23 w dietary	98.0	Method described in report, 23 weeks dietary exposure, 0, 20, 80 and 320 mg a.s./kg feed, batch 1030121	NOEC 80 mg a.s./kg diet	M-076678-01-1
Oncorhynchus mykiss (Rainbow trout)	acute	99.8	Directive 92/69/EEC, C.1 (1992), OECD No. 203 (rev.1992), OPPTS 850.1075 (EPA, 1996) and the EPA § 72-1 (EPA, 1985), 96h, exposed under flow-through conditions to a mean measured concentration of 24.2 µg a.s./L, batch M03732	LC_{50} > 24.2 µg a.s./L	M-065080-01-1
Lepomis macrochirus (Bluegill sunfish)	acute	99.0	EPA-FIFRA § 72-1/SEP-EPA-540/9-85-006 (1982/1985); OPPTS 850.1075 (Public Draft, 1996); Directive 92/69/EEC, C.1 (1992); OECD No. 203 (rev.1992), 96h, exposed under flow-through conditions to a mean measured concentration of 20.8 µg a.s./L., batch 234908023	LC_{50} > 20.8 µg a.s./L	M-066789-01-1
Pimephales promelas (Fathead minnow)	chronic, Early Life–Stage Test	99.8	OECD 210, U.S. EPA-FIFRA § 72-4, U.S. EPA-OPPTS 850.1400, 36 d, exposed under flow-through conditions to a	NOEC ≥ 22.8 µg a.s./L	M-065096-01-1

Species	Test	Purity % Note[1]	Guideline, duration, doses and conditions	Result	Study reference
	(ELS)		mean measured concentration of 22.8 µg a.s./L., batch M03732		
Lepomis macrochirus (Bluegill sunfish)	chronic, Bioconcentration (BCF)	> 99.5	EPA 72-6 and EPA 165-4, 42 d, A dosing system was used to maintain mean water concentrations (nominal) of 2.5 µg mixture of [14C] and cold triflumuron/L for a 28-day exposure period, batch 850322ELB00,	BCF parent (whole fish) 612	M-137472-01-1
Daphnia magna (water flea)	acute	99.4	OECD 202, adopted version 4 April, 1984, OECD Draft document, October 2000 and EEC Directive 92/69/EWG, part C.2. EPA § 72.2, OPPTS 850.1010, public draft, 1996 (modified), 48 h, exposed under semi-static conditions to nominal measured concentration of 0, 0.10, 0.22, 0.48, 1.1, 2.3, 5.2, 11.4 and 25 µg a.s./L, batch 234908023,	EC_{50}1.6 µg a.s./L	M-058835-01-1
Scenedesmus subspicatus (green alga)	sub-chronic	99.5	OECD 201, ISO 8692, 72h, exposed under static conditions to nominal concentrations 1, 10 and 25 µg a.s./L , batch 7-25-0220	E_bC_{50} > 25 µg a.s./L E_rC_{50} > 25 µg a.s./L	M-078062-01-1

Species	Test	Purity % Note[1]	Guideline, duration, doses and conditions	Result	Study reference
Chironomus riparius (freshwater dipteran)	chronic	99.1	BBA-draft ('Effects of plant protection products on the development of sediment-dwelling larvae of Chironomus riparius in a water-sediment system'), January 1996, 28 d, first instar larvae per test container were transferred into a stabilised water-sediment system and exposed for 28 days to nominal concentrations of 0 (control), 0 (solvent control), 0.10, 0.18, 0.32, 0.56, 1.0, 1.8, 3.2, 5.6 and 10 µg a.s./L (measured concentrations 95 – 123 % of nominal, batch 234 402 501	EC_{15} 0.32 µg a.s./L	M-078025-01-1
Apis mellifera (honey bee)	acute, oral	99.4	OECD 213 and 214 (1998), 48h oral exposure to a dose of 226.0 µg a.s./bee and a contact exposure to a dose of 200.0 µg a.s./bee, batch 234908023	LD_{50} oral > 226 µg a.s./bee LD_{50} contact > 200 µg a.s./bee	M-088529-01-1
Eisenia fetida (earthworm)	acute	99.6	OECD 207, 14d exposure in artificial soil to nominal concentrations of 0, 0.1, 1, 10, 100 and 1000 mg a.s./kg d.wt. soil, batch Eg 1/85	LC_{50} > 1000 mg a.s./kg d.wt. soil	M-076742-01-1

Background Information on toxicology/ecotoxicology

Triflumuron has very low acute toxicity [oral: (LD_{50}> 5000mg/kg bw), dermal: (LD_{50}> 5000mg/kg bw) and inhalation: (LC_{50} >5 mg/L)]. It is not irritating to skin while it is slightly irritating to eyes (not triggering GHS classification). Based on the available M&K maximization test triflumuron does not cause skin sensitization.

Due to consistently negative results of the studies *in vitro* and *in vivo*, triflumuron has no potential for genotoxicity.

Triflumuron is not carcinogenic to experimental animals. There is no evidence of teratogenic activity.

It has not been evaluated by WHO IPCS or by FAO/WHO JMPR. The EU agreed Acceptable Daily Intake (ADI) for triflumuron is 0.014 mg/kg bw/day and AOEL is 0.036 mg/kg bw/day.

ANNEX 2

REFERENCES

Study number	Author(s)	year	Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study.
	FAO and WHO JMPS	2006	Manual on development and use of FAO and WHO specifications for pesticides. February 2006 Revision of First Edition. FAO Plant Production and Protection Paper. Revised. www.fao.org/ag/AGP/AGPP/Pesticid/Default.htm and http://whqlibdoc.who.int/publications/2006/9251048576_eng_update2.pdf
M-019861-02-1		1984	Hydrolysis of Alsystin in sterile aqueous buffer solutions Bayer CropScience, Stilwell, Kansas, U.S.A. Unpublished
M-025794-01-2		1987	Dissociation constant of triflumuron at 20 degree C Bayer AG, Wuppertal, Germany Unpublished
M-037360-01-1		1982	FCR 1272 and SIR 8514 - Study for acute combination toxicity
M-052058-01-1		2002	Vapour pressure, physical-chemical properties – Trilumuron Bayer AG, Leverkusen, Germany Unpublished
M-058835-01-1		2002	Acute toxicity of triflumuron (tech.) to water fleas (Daphnia magna) under semistatic test conditions
M-060752-01-1		2002	Water Solubility of SIR 8514 (Triflumuron) Bayer AG, Leverkusen, Germany Unpublished
M-064546-01-1		2002	Triflumuron technical (Alsystin) - An acute oral LD50 study in the rat Unpublished
M-064572-01-1		2002	Triflumuron technical (Alsystin) - An acute dermal LD50 study in the rat Unpublished
M-065080-01-1		2002	Triflumuron (SIR 8514): Acute toxicity limit test with rainbow trout (Oncorhynchus mykiss) under flow-through conditions Report 1022.014.103 Unpublished
M-065096-01-1		2002	Triflumuron (SIR 8514): Early life-stage limit test with fathead minnow (Pimephales promelas) under flow-through conditions Report: 1022.014.122 Unpublished
M-066789-01-1		2002	Acute toxicity of triflumuron to fish (*Lepomis macrochirus*) Report: DOM 22019 Unpublished

M-068802-01-1	1988	Alsystin technical - CHO/HGPRT mutation assay Unpublished
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M-068891-01-1	1988	Alsystin technical - Unscheduled DNA synthesis in rat primary hepatocytes Unpublished
M-068903-01-1	1988	Alsystin technical (Bay SIR 8514) - Salmonella/mammalian-microsome plate incorporation mutagenicity assay (Ames test) Unpublished
M-075928-02-1	2002	Technical Triflumuron - Primary skin irritation study in rabbits Unpublished
M-075936-01-1	2002	Technical Triflumuron - Primary eye irritation study in rabbits Unpublished
M-076600-01-1	1983	Effect of triflumuron on bobwhite quail reproduction Unpublished Unpublished
M-076649-02-1	2002	Determination of octanol-water partition coefficient of triflumuron Unpublished
M-076678-01-1	1983	Effects of triflumuron on mallard duck reproduction Report 441 Unpublished
M-076686-01-1	1982	Acute oral LD50 of BAY SIR 8514 to bobwhite quail Report 257 Unpublished
M-076734-01-1	1981	Acute dietary LC50 of SIR 8514 technical to mallard ducks Unpublished
M-076740-02-1	1981	Acute dietary LC50 of SIR 8514 technical to bobwhite quail Report 80-175-03 Unpublished
M-076742-01-1	1986	Akute Toxizitaet von Triflumuron (techn.) fuer Regenwuermer Report: HBF/RG 65 Unpublished
M-078025-01-1	1996	Influence of triflumuron (tech.) on development and emergence of larvae of *Chironomus riparius* in a water-sediment system Report: HBF/CH 07 unpublished
M-078062-01-1	1990	Growth inhibition of green algae (*Scenedesmus subspicatus)* by triflumuron (tech.) Report: HBF/AL 73 Unpublished
M-078710-01-1	2002	SIR 8514 (common-name: Triflumuron) - Study on acute inhalation toxicity in rats according to OECD no. 403 Unpublished

M-085747-01-1	2002	Technical triflumuron: a subacute dietary LC50 with northern bobwhite Report 200246 Unpublished
M-086368-01-1	1984	SIR 8514 (proposed common name triflumuron) - Subchronic study of toxicity to rats (three-month feeding study) Bayer CropScience AG, report no.: 12487, Unpublished
M-086549-02-1	1987	SIR 8514 - Study of embryotoxic effects on rabbits after oral administration (proposed common name: Triflumuron) Bayer AG, Wuppertal, Germany Bayer CropScience AG, report no. 15869 Unpublished
M-086712-01-1	1989	SIR 8514 - Mutagenicity study for the detection of induced forward mutations in the CHO-HGPRT assay in vitro Bayer Crop Science AG, report no.17576 Unpublished
M-086772-01-1	1990	SIR 8514 (proposed common name: Triflumuron) - Subacute dermal toxicity study on rabbits Bayer CropScience AG, report no. 18710, Unpublished
M-086848-01-1	1991	SIR 8514 - Salmonella/microsome test Bayer CropScience AG, report no. 20805 Unpublished
M-086890-01-1	1981	Acute inhalation toxicity of SIR 8514 Bayer CropScience AG, report no.: 69843, Unpublished
M-086893-01-1	1982	Delayed dermal sensitization of SIR 8514 Bayer CropScience AG, report no.: BC263, Unpublished
M-086940-02-1	1987	SIR 8514 - Study of embryotoxic effects on rats after oral administration (proposed common name: Triflumuron) Bayer Crop Science AG, report no. 15392 Unpublished
M-086996-02-1	1984	SIR 8514 (suggested common name: Triflumuron) - Chronic toxicity study on mice (2-year feeding experiment) Bayer Crop Science AG, report no. 12919 Unpublished
M-087125-01-1	1997	SIR 8514 - Study for the skin sensitization effect in guinea pigs (guinea pig maximization test according Magnusson and Kligman) Bayer CropScience AG, report no.: 26686, Unpublished
M-087148-01-1	1983	SIR 8514 (proposed c.n. triflumuron) - POL test on E. coli to evaluate for DNA damage Bayer CropScience AG, report no. 12190 Unpublished

M-087155-02-1	1984	SIR 8514 (Triflumuron) - Chronic toxicity study on rats (2-year feeding experiment) Bayer Crop Science AG, report no. 12495 Unpublished
M-087241-02-1	1983	SIR 8514 (c.n. triflumuron; Alsystin active ingredient) - Multigeneration study on rats Bayer Crop Science AG, report no. 11646 Unpublished
M-087254-01-1	1983	SIR 8514 (Triflumuron) - Subchronic toxicological study with rats (feeding study over three months) Bayer CropScience AG, report no.: 12312, Unpublished
M-087261-02-1	1984	SIR 8514 (proposed common name: Triflumuron): Chronic oral toxicity to dogs / supplementary study (12-month feeding experiment) Bayer CropScience AG, report no.: 12460, Unpublished
M-087278-01-1	1977	SIR 8514 - Acute toxicity studies Bayer CropScience AG, report no.: 7139, Unpublished
M-087291-01-1	1978	SIR 8514 - Micronucleus test on mouse to evaluate SIR 8514 for mutagenic potential Bayer Crop Science AG, report no. 7729 Unpublished
M-087319-01-1	1978	SIR 8514 - Subacute oral cumulative toxicity study on rats Bayer CropScience AG, report no.: 7733, Unpublished
M-087328-01-1	1978	SIR 8514 - Subacute dermal cumulative toxicity study on rabbits Bayer CropScience AG, report no. 7773, Unpublished
M-087331-01-1	1978	SIR 8514 - Dominant lethal study on male mouse to test for mutagenic effects Bayer Crop Science AG, report no. 7977 Unpublished
M-087335-01-1	1979	SIR 8514 - Salmonella/microsome test for point mutagenic effects Bayer CropScience AG, report no. 8203, Unpublished
M-087340-01-1	1979	SIR 8514 - Subacute inhalation study on rats Bayer CropScience AG, report no. 8747, Unpublished
M-087344-01-1	1980	SIR 8514 - Subchronic toxicity study on dogs (thirteen-week feeding experiment) Bayer AG, Wuppertal, Germany Bayer CropScience AG, report no.: 8894, Unpublished

M-087430-02-1	1984	SIR 8514 (proposed common name: Triflumuron) - Chronic oral toxicity study on dogs (12- month feeding experiment) Bayer CropScience AG, report no.: 12515, Unpublished
M-087498-01-1	1983	Mutagenicity evaluation of SIR 8514 (c.n. Triflumuron) in the reverse mutation induction assay with Saccharomyces cervisiae strains S138 and S211alpha Bayer Crop Science AG, report no. R2619 Unpublished
M-087504-01-1	1983	Evaluation of SIR 8514 (c.n. Triflumuron) in the induced mitotic crossing over and gene conversion assay in Saccharomyces cervisiae strain D7 Bayer Crop Science AG, report no. R2621 Unpublished
M-087510-01-1	1992	Chromosome aberration assay in human lymphocytes in vitro with SIR 8514 Bayer Crop Science AG, report no.R5482 Unpublished
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M-087599-01-1	1981	SIR 8514 - Acute toxicity for sheep after oral administration Bayer AG, Wuppertal, Germany Bayer CropScience AG, report no.: 9752, Unpublished
M-087600-01-1	1981	SIR 8514 - Evaluation for embryotoxic and teratogenic effects in orally dosed rabbits Bayer CropScience AG, report no. 9769 Unpublished
M-087602-01-1	1981	SIR 8514 - Evaluation for embryotoxic and teratogenic effects in orally dosed rats Bayer Crop Science AG, report no. 9770 Unpublished
M-087617-01-1	1981	SIR 8514 (Triflumuron) - Subchronic toxicological study on rats (feeding experiment over three months) Bayer AG, Wuppertal, Germany Bayer CropScience AG, report no.: 10153, Unpublished
M-087619-01-1	1981	SIR 8514 065 EC 059 B - Subacute inhalational toxicity study on rats Bayer CropScience AG, report no. 10162, Unpublished
M-087915-01-2	1981	SIR 8514 - Determination of acute toxicity (LD50) Bayer AG, Wuppertal, Germany Bayer CropScience AG, report no.: MO-01-021701, Unpublished

M-088318-01-1		2003	Photolysis of triflumuron in sterile aqueous buffer pH 7 Bayer CropScience AG, Monheim, Germany Unpublished
M-088529-01-1		2001	Effects of triflumuron a.i. (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory (limit test) Report: 9941036 Unpublished
M-091466-01-1		2001	Density, Surface Tension, Organic Solubility, Boiling Point and Henry Law Constant of SIR 8514 (Triflumuron)
M-137472-01-1		1990	Triflumuron - Bioconcentration in fish Bayer AG, Leverkusen, Germany Report BF-004 Unpublished
M-255456-01-1		2005	Triflumuron: A 5-day single-dose toxicity testing study in the rat Bayer CropScience AG, report no.: 201336, Unpublished
M-300905-01-1		2008	Melting, boiling point and thermal stability of AE F067232 (triflumuron) Unpublished
M-356428-01-1	FAO	2000	FAO specifications for plant protection products - Triflumuron 1-(2-chlorobenzoyl)-3-(4-trifluoromethoxyphenyl)urea Published
	WHO Regional Office for Europe	2000	Air quality Guidelines for Europe. Second Edition
	EFSA	2007	Draft Assessment Report (DAR) Public version Triflumuron. Vol 3 Annex B, part 2, B.6
	SANCO	2011	Triflumuron SANCO/13544/2010 28 January 2011
	EFSA	2011	Conclusion on pesticide peer review. Conclusion on the peer review of the pesticide risk assessment of the active substance triflumuron. EFSA Journal 2011;9(1)1941
	Karassali E.	2018	E-mail received July 4 2018 from E. Karassali, Benaki Institute of Phytopathology, confirming the similarity of the confidential data packages submitted to JMPS and in the European Union

APPENDIX 1

PEER VALIDATED ANALYTICAL METHOD FOR DETERMINATION OF THE RELEVANT IMPURITIES *N,N*'-BIS-[4-(TRIFLUOROMETHOXY) PHENYL]UREA AND 4-TRIFLUOROMETHOXYANILINE IN TRIFLUMURON TECHNICAL AND SC FORMULATIONS PROPOSED BY BAYER CROPSCIENCE

(CIPAC DOCUMENT NR. 5091/m)

Triflumuron

rel. Impurities

1,3-bis(4-trifluoromethoxyphenyl)urea
and
4-(trifluoromethoxy)aniline

HPLC Method 5091/m

CIPAC Peer Validation

by

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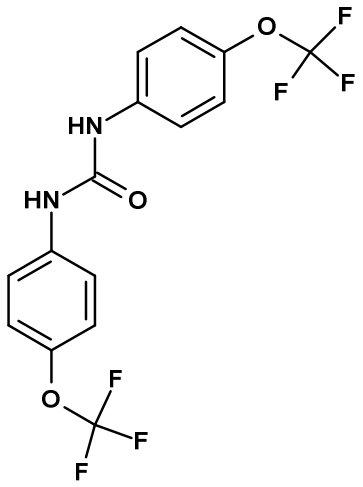
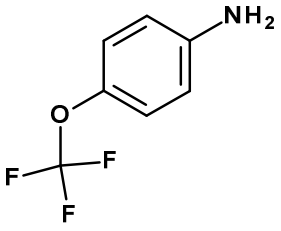
May 2017

TRIFLUMURON, rel. Impurities

1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline

Report Name	1,3-bis(4-trifluoromethoxyphenyl)urea
Synonyms	N,N'-bis-[4-(trifluoromethoxy)phenyl]urea, AE B143886, BCS-AD26894
Three letter code	-
Structural formula	
Empirical Formula	C_{15} H_{10} F_6 N_2 O_3
Molecular Weight	380.2 g/mol
CAS no	78015-49-3

Report Name	4-(trifluoromethoxy)aniline
Synonyms	AE F069069, BCS-AC49934
Three letter code	-
Structural formula	
Empirical Formula	C_7 H_6 F_3 N O
Molecular Weight	177.1 g/mol
CAS no	461-82-5

TRIFLUMURON TECHNICAL
5091/TC/M/-

1 Sampling. Take at least 100 g*. Grind the sample thoroughly in a mortar.
*(for this trial less amount is provided; please grind the entire sample)

2 Identity tests.
2.1 HPLC. Use the HPLC method described below. The relative retention time of 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline in the sample solution should not deviate by more than 2% from that of the calibration solution.

2.2 UV spectrometry. Record the UV spectrum during the HPLC determination. The UV spectrum obtained from the sample should not differ significantly from that of the standard. (Fig. 1 and Fig. 2)

3 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline.

OUTLINE OF THE METHOD.
1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline contents are determined (g/kg) by reversed phase high performance liquid chromatography using UV detection at 226 nm and 258 nm and external standard calibration.

3.1 Determination of 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline by reversed phase HPLC

REAGENTS
1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline reference standards of known content
Acetonitrile (HPLC grade)
Purified water (HPLC grade)
Eluent A: purified water 40% (*v/v*)
Eluent B: acetonitrile 60% (*v/v*)

APPARATUS
High performance liquid chromatograph equipped with an injection system capable to inject 5 µL and an UV spectrophotometric detector operated at 226 nm and 258 nm.
Liquid chromatography column, stainless steel, 125 x 4 (i.d.) mm, packed with Nucleosil 120-3 C 18; 3 µm or equivalent with the same selectivity.
Electronic integrator or data system
Ultrasonic bath

PROCEDURE

(a) Operating conditions (typical):

Flow rate:	1 mL/min
Column temperature:	40℃
Injection volume:	5 µL
Detector wavelength:	0.0 – 3.0 min: 226 nm (for 4-(trifluoromethoxy)aniline) 3.0 – 3.7 min: 258 nm 3.7 – 5.0 min: 300 nm (for triflumuron) 5.0 – 9.0 min: 258 nm (for 1,3-bis(4-trifluoromethoxyphenyl)urea)
Retention time:	approx. 2.2 min for 4-(trifluoromethoxy)aniline approx. 5.2 min for 1,3-bis(4-trifluoromethoxyphenyl)urea
Total run time:	approx. 8 min

(b) Equilibration of the system. Pump sufficient mobile phase through the column to equilibrate the system. Inject 5 µL portions of the calibration solution C1 and repeat the injections until retention times and peak areas deviate by less than ± 1 % from the mean for three successive injections.

(c) Calibration solution. Weigh in duplicate (to the nearest 0.1 mg) approximately 20 mg (*s* mg) of the reference standard of 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline into separate volumetric flasks (50 mL). Add 20 mL acetonitrile and place the flasks in an ultrasonic bath for 15 min. Make up the flasks with acetonitrile to just below the calibration mark and allow to cool to ambient temperature. Fill to the mark with acetonitrile and mix thoroughly.

Transfer 5 mL of this solution into a separate volumetric flask (50 mL) and make up the flasks with acetonitrile to just below the calibration mark. Allow to cool to ambient temperature, fill to the mark with acetonitrile and mix thoroughly.

Depending on the final concentrations of the analytes in the sample solution, transfer 3 mL of this solution into a separate volumetric flask (50 mL) and make up the flasks with acetonitrile to just below the calibration mark. Allow to cool to ambient temperature, fill to the mark with acetonitrile and mix thoroughly (Calibration solutions C1, C2) (Fig. 3).

(d) Sample preparation. Prepare sample solutions in duplicate for each sample. Weigh (to the nearest 0.1 mg) sufficient sample (*w* mg) to contain about approximately 0.12 mg (*w* mg) of 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline into separate volumetric flasks (50 mL). Add 20 mL acetonitrile and place the flasks in an ultrasonic bath for 15 min. Make up the flasks with acetonitrile to just below the calibration mark and allow to cool to ambient temperature. Fill to the mark with acetonitrile and mix thoroughly (Sample solutions S1, S2) (Fig. 4).

(e) Determination. Inject in duplicate each sample solution and bracket a series of sample solution injections by injections of the calibration solutions as follows: calibration solution 1, calibration solution 2, calibration solution 1, sample solution 1, sample solution 1, sample solution 2, sample solution 2, calibration solution 1, … (C1, C2, C1, S1, S1, S2, S2, C1, …).

Determine the peak areas of 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline.

(f) Calculation

Calculate the response factors from the calibration solutions bracketing the injections of the sample solutions. Average the response factors of the calibration solutions preceding and following the sample solution injections. These must agree within ±1 % of the average otherwise repeat the determination. Calculate the content of the sample solutions.

$$f_i = \frac{s \times P}{H_S}$$

1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline

$$\text{content (g/kg)} = \frac{H_W \times f}{w}$$

Where:

f_i = single response factor
f = average response factor
H_S = peak area of 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline standard in the calibration solution
H_W = peak area of 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline in the sample solution
s = weight of the 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline standard in the calibration solution (mg)
w = weight of the sample (mg)
P = purity of the 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline standard (g/kg)

TRIFLUMURON SUSPENSION CONCENTRATE
5091/SC/M/-

1 Sampling. Take at least 500 mL*. Shake the sample well prior to weighing.
*(for this trial less amount is provided)

2 Identity tests.

2.1 HPLC. As for 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline in Triflumuron 5091/TC/M/-

2.2 UV spectrometry. As for 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline in Triflumuron 5091/TC/M/-

3 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline.
Same approach as for 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline in Triflumuron 5091/TC/M/-

3.1 Determination of 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline by reversed phase HPLC
As for 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline in Triflumuron 5091/TC/M/- except

Disposable PTFE syringe filter compatible with organic solvents and a 0.45 µm pore diameter or centrifuge.

(d) Sample preparation. As for 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline in Triflumuron 5091/TC/M/- except filter the sample solution through a disposable filter or centrifuge the sample solution (Sample solutions S3, S4) (Fig. 5).

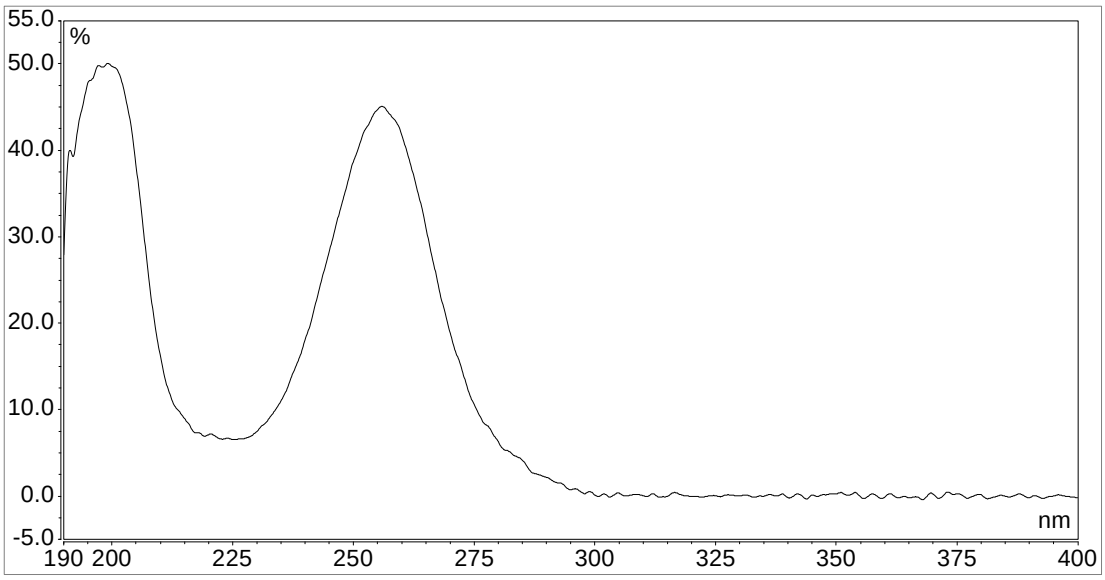


Fig. 1 UV-Spectrum of 1,3-bis(4-trifluoromethoxyphenyl)urea

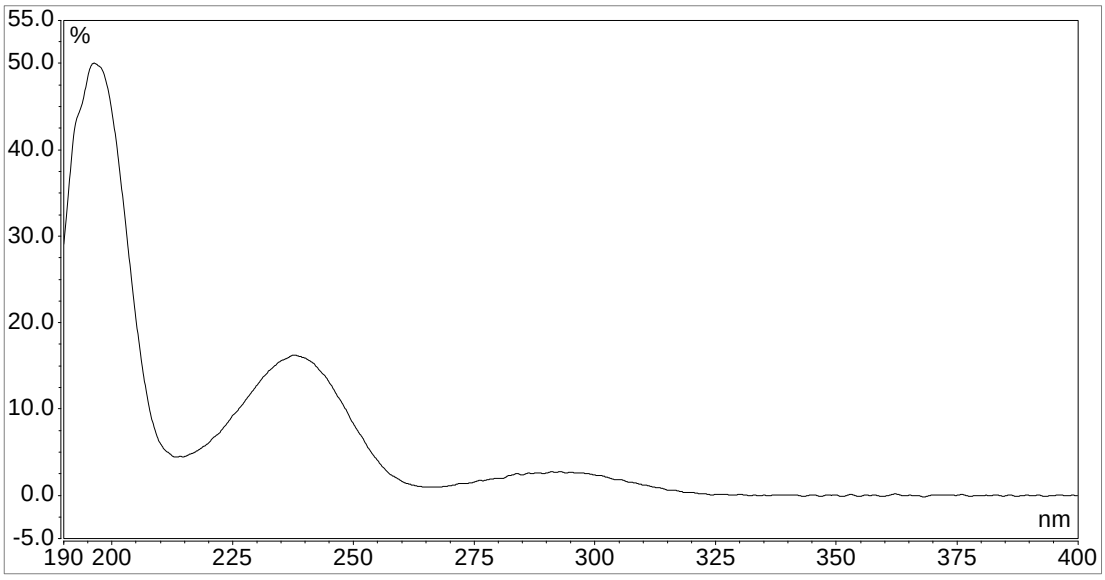


Fig. 2 UV-Spectrum of 4-(trifluoromethoxy)aniline

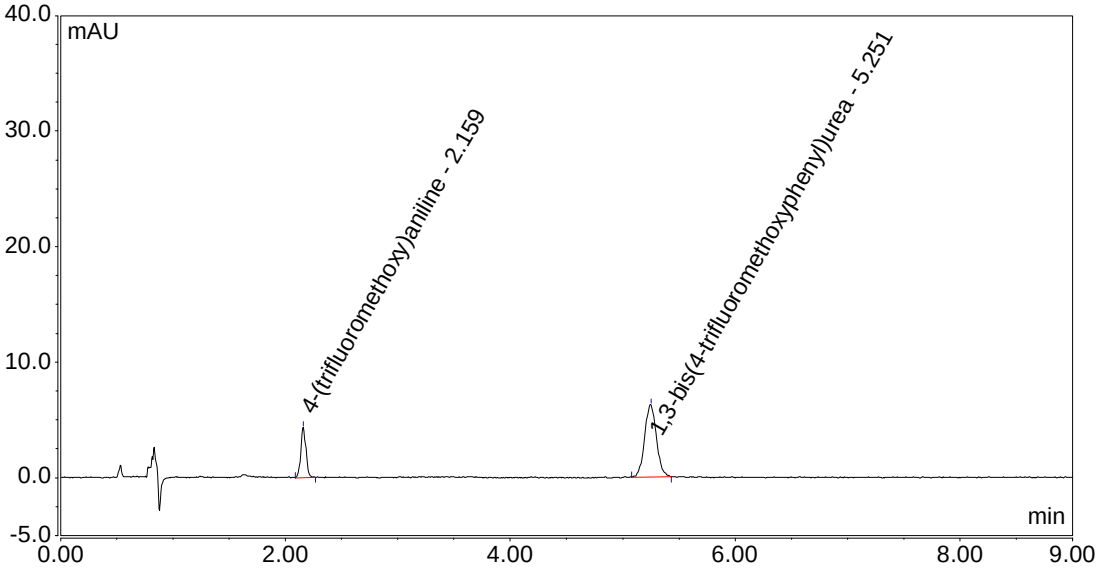


Fig. 3 Chromatogram of 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline Analytical Standards

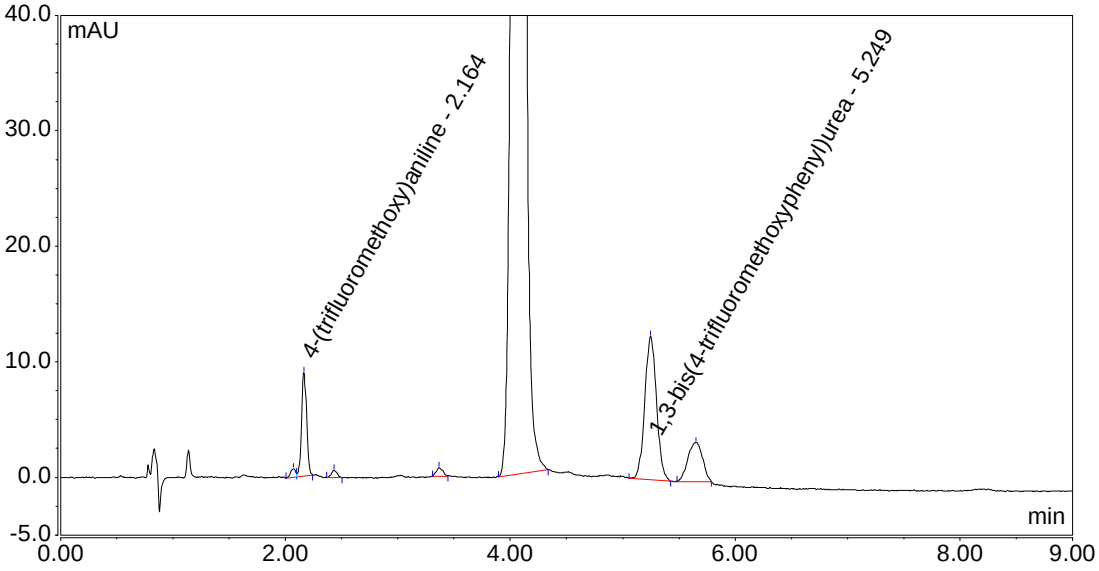


Fig. 4 Chromatogram of Triflumuron TC spiked with 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline

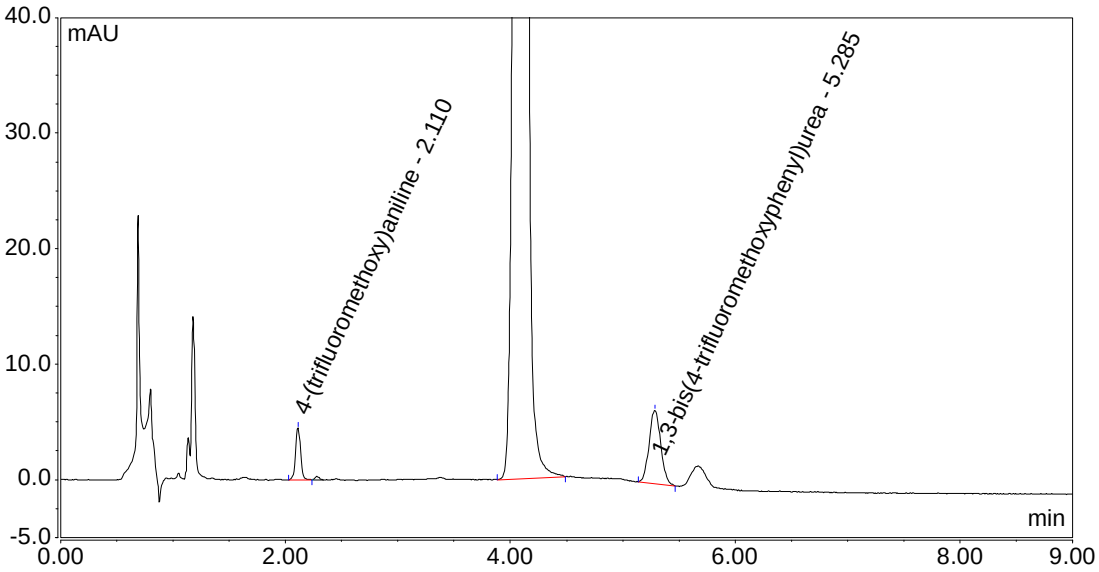


Fig. 5 Chromatogram of Triflumuron SC spiked with 1,3-bis(4-trifluoromethoxyphenyl)urea and 4-(trifluoromethoxy)aniline