Food and Agriculture Organization
of the United Nations

FAO SPECIFICATIONS AND EVALUATIONS

FOR AGRICULTURAL PESTICIDES

FLUAZIFOP-P-BUTYL

butyl(R)-2-[4-(5-trifluoromethyl-2-pyridinyloxy)phenoxy]propionate

TABLE OF CONTENTS

FLUAZIFOP-P-BUTYL

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.

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 onward, the development of FAO specifications follows the **New Procedure**, described first in the 5th edition of the "Manual on the development and use of FAO specifications for plant protection products" and later in the 1st edition of "Manual for Development and Use of FAO and WHO Specifications for Pesticides" (2002) - currently available as the 2nd edition of the "Manual on development and use of FAO and WHO specifications for chemical pesticides (2022)"-, 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 1999 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 8 of the "Manual on development and use of FAO and WHO specifications for chemical 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. 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 - Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/pest-and-pesticide-management/guidelines-standards/faowho-joint-meeting-on-pesticide-specifications-jmps/pesticide-specifications/pesticide-specifications-list/en/

PART ONE

SPECIFICATIONS

FLUAZIFOP-P-BUTYL

FLUAZIFOP-P-BUTYL

INFORMATION

ISO common name Fluazifop-P-butyl (E-ISO, (m) F-ISO, BSI, ANSI)

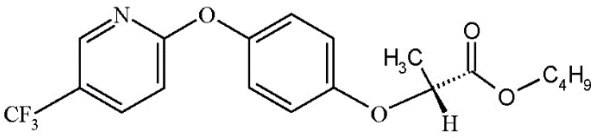
Synonyms None

Chemical names

IUPAC butyl(R)-2-[4-(5-trifluoromethyl-2-pyridinyloxy)phenoxy]propionate

CA (+)-butyl 2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate

Structural formula



Fluazifop-P-butyl consists of a mixture of enantiomers in an approximate ratio of 97% *R* to 3% *S*

Empirical formula	$C_{19}H_{20}F_3NO_4$
Relative Molecular mass	383.4
CAS Registry number	79241-46-6
CIPAC number	467
Identity tests	Chiral HPLC with UV detection for determination of enantiomeric purity or GC with FID for chemical purity.

FLUAZIFOP-P-BUTYL TECHNICAL MATERIAL

FAO Specification 467 / TC (May 2023*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (467/2000 & 467/2023). It should be applicable to relevant products of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers. The evaluation reports (467/2000 & 467/2023) as PART TWO form an integral part of this publication.

1 Description

The material shall consist of fluazifop-P-butyl, together with related manufacturing impurities, in the form of a dark-brown liquid, containing not more than a trace of insoluble material, and free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 **Identity tests** (467/TC/M/2, CIPAC Handbook G, p. 72, 1995)

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 **Fluazifop-P-butyl content** (467/TC/M/3, CIPAC Handbook G, p. 72, 1995)

The fluazifop-P-butyl content shall be declared (not less than 900 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

3 Physical properties

3.1 **Acidity** (MT 31.2.1, CIPAC Handbook F, p. 98, 2007)

Maximum acidity: 4 g/kg calculated as H_2SO_4.

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

FLUAZIFOP-P-BUTYL EMULSIFIABLE CONCENTRATE

FAO Specification 467 / EC (May 2023*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (467/2000 & 467/2023). It should be applicable to relevant products of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers. The evaluation reports (467/2000 & 467/2023) as PART TWO form an integral part of this publication.

1 Description

The formulation shall consist of technical fluazifop-P-butyl, complying with the requirements of FAO specification 467/TC (May 2023), in the form of a clear to slightly hazy brown liquid, dissolved in suitable solvents together with any other necessary formulants. It shall be in the form of a stable homogeneous liquid, free from visible suspended matter and sediment, to be applied as an emulsion after dilution in water.

2 Active ingredient

2.1 **Identity tests** (467/EC/M/2, CIPAC Handbook G, p. 81, 1995)

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 **Fluazifop-P-butyl content** (467/EC/M/3, CIPAC Handbook G, p. 81, 1995)

The fluazifop-P-butyl content shall be declared (above 100 g/l up to 250 g/l or g/kg at 20 ± 2°C) (Note 1) and when determined, the content obtained shall not differ from that declared by more than ± 6 % of the declared content.

3 Physical properties

3.1 **pH range** (MT 75.3, CIPAC Handbook J, p. 131, 2000) (Note 2)

pH range: 6.0 to 6.5.

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

3.2 **Emulsion stability and re-emulsification** (MT 36.3, CIPAC Handbook K, p. 137, 2003) (Note 3)

The formulation, when diluted at 30 ± 2°C with CIPAC Standard Waters A and D, shall comply with the following:

Time after dilution	Limits of stability, MT 36.3
0 h	Initial emulsification complete
0.5 h	"Cream", maximum: 0.5 ml
2 h	"Cream", maximum: 1 ml "Free oil", maximum: trace
24 h	Re-emulsification complete
24.5 h	"Cream", maximum: 1 ml "Free oil", maximum: trace
Note: tests at 24 h are required only where results at 2 h are in doubt	

3.3 **Persistent foam** (MT 47.3, CIPAC Handbook O, p. 177, 2017) (Note 4)

Maximum: 20 ml after 1 min.

4 Storage stability

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

After storage at 0 ± 2°C for 7 days, no separation of particulate or oily matter shall be visible after gentle agitation.

4.2 **Stability at elevated temperature** (MT 46.4, CIPAC Handbook P, p. 232, 2021)

After storage 54 ± 2°C for 14 days, the determined average active ingredient content shall not be lower than 95% relative to the determined average content found before storage (Note 5) and the formulation shall continue to comply with the clauses for

- pH range (3.1) and
- emulsion stability and re-emulsification (3.2)

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

Note 2 The pH range of 6.0 to 6.5 is needed to ensure the stability of the ester. Outside this pH range, higher levels of unesterified acid can cause auto-hydrolysis in water.

Note 3 As outlined in CIPAC MT 36.3, the test concentrations should be based on those in the recommended directions for use supplied with the product. Where several concentrations are recommended, the highest and lowest concentrations within the scope of the method should be used.

Note 4 The mass of sample to be used in the test should be at the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D at 25 ± 5°C.

Note 5 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.

FLUAZIFOP-P-BUTYL EMULSIONS, OIL-IN-WATER

FAO Specification 467 / EW (May 2023*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose names are listed in the evaluation reports (467/2000 & 467/2023). It should be applicable to relevant products of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specification. The specification may not be appropriate for the products of other manufacturers. The evaluation reports (467/2000 & 467/2023) as PART TWO form an integral part of this publication.

1 Description

The formulation shall consist of an emulsion of technical fluazifop-P-butyl, complying with the requirements of FAO specification 467/TC (May 2023), in the form of an off-white emulsion (which may separate on standing), in an aqueous phase together with suitable formulants. After gentle agitation, the formulation shall be homogenous (Note 1) and suitable for dilution in water.

2 Active ingredient

2.1 **Identity tests** (467/EW/M/2, CIPAC Handbook G, p. 81, 1995)

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 **Fluazifop-P-butyl content** (467/EW/M/3, CIPAC Handbook G, p. 81, 1995)

The fluazifop-P-butyl content shall be declared (above 100 g/l up to 250 g/l or g/kg at 20 ± 2°C) (Note 2) and when determined, the content obtained shall not differ from that declared by more than ± 6 % of the declared content.

3 Physical properties

3.1 **Mass per millilitre at 20°C** (MT 3, CIPAC Handbook F, p. 11, 2007)

The range of the mass per millilitre shall be 1.000 to 1.060 g/ml at 20 ± 2°C.

3.2 **pH range** (MT 75.3, CIPAC Handbook J, p. 131, 2000) (Note 2)

pH range: 5.6 to 6.6.

3.3 **Pourability** (MT148.1, CIPAC Handbook J, p. 133, 2000)

Maximum residue: 0.8 %.

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

3.4 **Emulsion stability and re-emulsification** (MT 36.3, CIPAC Handbook K, p. 137, 2003) (Note 3)

The formulation, when diluted at 30 ± 2°C with CIPAC Standard Waters A and D, shall comply with the following:

Time after dilution	Limits of stability, MT 36.3
0 h	Initial emulsification complete
0.5 h	"Cream", maximum: 0.5 ml
2 h	"Cream", maximum: 1 ml "Free oil", maximum: trace
24 h	Re-emulsification complete
24.5 h	"Cream", maximum: 1 ml "Free oil", maximum: trace
Note: tests at 24 h are required only where results at 2 h are in doubt	

3.5 **Persistent foam** (MT 47.3, CIPAC Handbook O, p. 177, 2017) (Note 4)

Maximum: 20 ml after 1 min.

4 Storage stability

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

After storage at 0 ± 2°C for 7 days, no separation of particulate or oily matter shall be visible after gentle agitation.

4.2 **Stability at elevated temperature** (MT 46.4, CIPAC Handbook P, p. 232, 2021)

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content shall not be lower than 95% relative to the determined average content found before storage (Note 5) and the formulation shall continue to comply with the clauses for

- pH range (3.2),
- emulsion stability and re-emulsification (3.4),
- persistent foam (3.5)

Note 1 All physical and chemical tests listed in this specification are to be performed with a laboratory sample taken after the recommended homogenization procedure.

Before sampling to verify the formulation quality, the commercial container must be inspected carefully. On standing, emulsions may develop a concentration gradient which could even result in the appearance of a clear liquid on the top (sedimentation of the emulsion) or on the bottom (creaming up of the emulsion). Therefore, before sampling, the formulation must be homogenized 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.

Note 2 In determining active ingredient in g/l at 20 ± 2° C, the actual mass per millilitre shall be measured (as per 3.1 using MT 3) and used in the calculation. In case of a dispute, the content should be expressed as g/kg.

Note 3 As outlined in CIPAC MT 36.3, the test concentrations should be based on those in the recommended directions for use supplied with the product. Where several concentrations are recommended, the highest and lowest concentrations within the scope of the method should be used.

Note 4 The mass of sample to be used in the test should be at the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D at 25 ± 5°C.

Note 5 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

FLUAZIFOP-P-BUTYL

FLUAZIFOP-P-BUTYL

FAO/WHO EVALUATION REPORT 467/2023

Recommendations

The Meeting recommended the following:

(i) The change of manufacturer of the FAO specifications for fluazifop-P-butyl TC, EC and EW from Zeneca Agrochemicals to Syngenta Crop Protection should be noted by FAO.

(ii) The editorially updated and confirmed specifications for fluazifop-P-butyl TC, EC and EW should be adopted by FAO.

Appraisal

JMPS had initiated a systematic review process of published new procedure specifications in 2019. One of the specifications that were identified as having high priority for review was the FAO specifications and evaluation for fluazifop-P-butyl. The proposer was Zeneca Agrochemicals in 1999 submitting one of the first data packages under the "New Procedure" to at that time FAO and its "Panel of Experts on Pesticide Specifications" (see Manual on the development and use of FAO specifications for plant protection products, 5th Edition including the new procedure, FAO Plant Protection Paper 149, Rome 1999).

The specifications and the evaluation report were published in the year 2000. When the JMPS reviewed in 2022 the specifications and the evaluation report, the main conclusions after contacting Syngenta Crop Protection (Syngenta) were:

- Zeneca Agrochemicals, the former holder of the reference specifications for fluazifop-P-butyl TC, EC and EW, merged with the Agribusiness of Novartis to form Syngenta in late 2000[1].
- The successor company of Zeneca Agrochemicals, Syngenta Crop Protection, still owns and produces fluazifop-P-butyl TC at the same site and using the same manufacturing process as did Zeneca.
- The impurity profile and the minimum purity of fluazifop-P-butyl has not changed since 2000.

However, it became evident that the editorial style and several physical-chemical methods had been updated with newer versions providing equivalent results. In addition, the model specifications had been revised and are now published in the 2nd Edition of the Manual, and the references for analytical methods were largely incomplete. The Meeting also noted an issue with the CIPAC coding system: as the hypothetical fluazifop-P free acid has the code 467, it would need a designation for the so called radical, the butyl group, to make 467.205.

[1] https://www.syngenta.com/en/innovation-agriculture/our-stories/today-marks-major-milestone-us-20-years-founding-syngenta

Yet the coding used in Handbook G for the analytical method for chemical and enantiomeric purity has the designation 467/TC/M - for the technical material and formulations. In order to avoid confusion with the users of specifications and methods, the code 467 now replaces 467.205 throughout the 2023 specifications.

In particular, the following editorial updates were introduced without changing any of the limits:

- The correct references for all analytical and physical-chemical methods were introduced.
- The updated physical-chemical methods now replace the previous older versions wherever possible. These newer versions are deemed to provide equivalent results but represent harmonised versions. These methods include pH range (MT 75.3 replacing MT 75), persistent foam (MT 47.3 instead of MT 47.2), pourability (MT 148.1 replacing MT 148) and stability at elevated temperature (MT 46.4 instead of MT 46.3).
- All footnotes were adjusted according to the last model specifications including the general footnote to check for updates on the FAO website.
- The 2000 EC specification had a footnote on flash point ("The flash point should not be lower than 38°C (MT 12)". That footnote was removed because no longer required in the 2022 model specification for EC. Flammability is considered to be a risk management issue to be dealt with by national registration authorities.
- Some of the MT methods referenced did not indicate a particular sub-method like the density (MT 3 - 3 sub-methods, all deemed applicable) but some MTs needed more specific references like acidity in the TC, where MT 31.2.1 was chosen because the electrometric method is considered to be generally available and robust after dilution of the TC with acetone.

In conclusion, the reconfirmed and updated specifications for fluazifop-P-butyl TC, EC and EW do represent the actual status and are in line with the 2nd Edition of the Manual. The Meeting therefore recommends that FAO should adopt these reconfirmed and updated specifications.

FLUAZIFOP-P-BUTYL

FAO EVALUATION REPORT 467.205/2000

based on submission from Zeneca

Explanation

The data for fluazifop-P-butyl were evaluated in support of new FAO specifications.

Fluazifop-P-butyl is under patent in the USA until 2006, but patents in EU expired in 1999.

Fluazifop-P-butyl has not been evaluated by the FAO/WHO JMPR or WHO/IPCS.

The draft specification and the supporting data were provided by Zeneca, United Kingdom, in 1999.

Uses

Fluazifop-P-butyl is a herbicide. It is used for the post-emergence control of wild oats, volunteer cereals, and annual and perennial grass weeds in oilseed rape, sugar beet, fodder beet, potatoes, vegetables, cotton, soya beans, pome fruit, stone fruit, bush fruit, vines, citrus fruit, pineapples, bananas, strawberries, sunflowers, alfalfa, ornamentals and other broad-leaved crops. It is non-phytotoxic to broad-leaved crops.

Identity

ISO common name

Fluazifop-P-butyl (BSI, Draft E-ISO, ANSI)

Synonyms

None

Chemical names

IUPAC

butyl(R)-2-[4-(5-trifluoromethyl-2-pyridinyloxy)phenoxy]propionate

CA

(+)-butyl 2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate

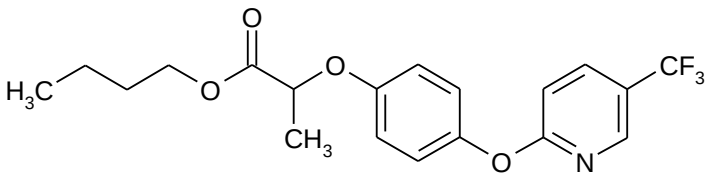
CAS Registry number

79241-46-6

CIPAC number

467

Structural formula



It is 97% of the *R*-isomer and 3% of the *S*-isomer

Molecular formula

$C_{19}H_{20}F_3NO_4$

Relative molecular mass

383.4

Identity tests

Chiral HPLC with UV detection to determine (R) - to (S) – isomers ratio or GC with FID for total fluazifop-butyl. CIPAC Handbook G, 1995, 71-81.

Physical and chemical properties of pure fluazifop-P-butyl

Parameter	Value(s) and conditions	Purity %	Method reference
Vapour pressure	3.3×10^{-8} kPa at 20^0C	99.9%	Wollerton & Walter 1999 (unpublished Zeneca method)
Volatility	1×10^{-7} atm-m^3/mol	99.9%	Wollerton & Walter 1999 (unpublished Zeneca method)
Freezing point	Glass-like at -20^0C	99.9%	Wollerton & Walter 1999 (unpublished Zeneca method)
Melting point and temperature of decomposition	Melting point: -20^0C Decomposition temperature: approximately 100^0C	99.9%	Wollerton & Walter 1999 (unpublished Zeneca method)
Solubility in water	1.1mg/l at 20^0C in purified water ASTM Type II	99.9%	Wollerton & Walter 1999 (unpublished Zeneca method)
Octanol / water partition coefficient	Log P_{ow} 4.5 at 20^0C	99.9%	Wollerton & Walter 1999 (unpublished Zeneca method)
Hydrolysis characteristics	Half-life 29 hours at pH 9 Half-life 78 days pH 7 Stable at pH 5 Tests conducted in the dark	97.1%	McCarron & Heath 1989 (unpublished Zeneca method)
Photolysis characteristics	Half-life 6 days at 25^0C in Florida sun. Degradation products were also metabolites and not considered of environmental importance	98.4%	Jessop, Embury, Leahy 1991 Embury & Leahy 1994 (unpublished Zeneca methods)
Dissociation characteristics	Not determined		

Pure fluazifop-P-butyl is a colourless liquid with no characteristic odour, whereas the technical material (minimum purity of 90% w/w) is a dark brown liquid with a weakly aromatic odour.

Chemical composition and properties of fluazifop-P-butyl technical material (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 99.8 to 100.2%.
Declared minimum fluazifop-P-butyl content	900 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 or boiling temperature range / freezing point	About – 20°C (freezing point).

Hazard summary

Notes.

(i) The proposer provided written confirmation that the toxicological and ecotoxicological data included in the summary below were derived from fluazifop-P-butyl (ester) 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.

(iii) The evaluation is based on data relating to one form of the a.i.

Table 1. Toxicology profile of the fluazifop-P-butyl technical material, based on acute toxicity, irritation and sensitisation

Species	Test	Duration and conditions	Result
Rat (male) (female)	oral	Not provided	LD_{50} = 3680 mg/kg LD_{50} = 2451 mg/kg
Rat	Dermal	Not provided	LD_{50} > 2110 mg/kg
Rat	Inhalation	Not provided	LC_{50} > 5.24 mg/l
Rabbit	Skin irritation	Not provided	Slight
Rabbit	Eye irritation	Not provided	Mild
Guinea pig	Skin sensitisation	Not provided	Negative

Table 2. Toxicology profile of the technical material based on repeated administration (subacute to chronic)

Species	Test	Duration and conditions	Result Obtained
Rat	Oral gavage	90 day toxicity	NOAEL: 100 ppm (9.0 mg/kg/day)
Dog	Oral gavage	13 week and 1 year toxicity (fluazifop-butyl)	NOAEL: 25mg/kg/day
Rat	Oral gavage carcinogenicity	2 year dietary/carcinogenicity (fluazifop-butyl and fluazifop acid)	NOAEL: 1.0 mg/kg/day Not carcinogenic
Mouse	Oral gavage	1 year dietary (fluazifop-butyl and fluazifop-acid)	Not carcinogenic
Rat	Feeding reproduction	Two generation reproduction (fluazifop-butyl)	NOAEL: 10 ppm (0.85 mg/kg/day) Not a reprotoxin
	Feeding reproduction	Three generation reproduction (fluazifop-butyl)	NOAEL: 10 ppm (0.90 mg/kg/day Not a reprotoxin
Rat	Feeding teratogenicity	Maternal toxicity Developmental toxicity	NOAEL: 100 mg/kg/day NOAEL: 5 mg/kg/day Not teratogenic
Rabbit	Feeding teratogenicity	Maternal toxicity Developmental toxicity	NOAEL: 10 mg/kg/day NOAEL: 10 mg/kg/day Not teratogenic

Table 3. Mutagenicity profile of the technical material based on *in vitro* and *in vivo* tests

Test System	Target Cells	Concentration	Purity	Results
In Vitro				
Bacterial mutation assay	Salmonella typhimurium TA15355, TA1537, TA1538, TA98, TA100	1.6-5000 ⌈g/plate +/-S9	93.8% w/w	Negative
Mammalian cell cytogenetics	Human lymphocytes	1-1000 ⌈g/ml +/-S9	95.8% w/w	Negative
Mammalian cell mutation assay	L5178Y mouse lymphoma	100-1000 ⌈g/ml +/-S9	91.9% w/w	Negative
In Vivo				
Mouse bone marrow micronucleus	Bone marrow (micronucleated poly-chromatic erythrocytes)	250, 400 mg/kg	93.8% w/w	negative

Table 4. Ecotoxicology profile of the technical material, aquatic organisms

Species	Test Duration	Test type	Effect concentration, mg/l	Result
Daphinia magna (water flea)	48h	Immobilisation	>1.0	EC_{50}
Oncorhynchus mykiss (rainbow trout)	96h	Mortality	1.411[a]	LC_{50}
Cyprinus carpio (Common carp)	96h	Mortality	1.31[a]	LC_{50}
Selenastrum capricornutum (green alga)	72h	Biomass	>1.8	EC_{50}
Navicula pelliculosa (freshwater diatom)	72h	Biomass	0.51	EC_{50}
Lemna gibba (duckweed)	14 days	Growth	>1.4	EC_{50}
Daphnia magna (water flea)	21 days	Reproduction	0.25[a]	NOEC
Pimephales promelas (Fathead minnow)	28 days	Early life stage	0.077	NOEC

[(a)] fluazifop-butyl tested

EC_{50} – media effective concentration, LC_{50} – median lethal concentration,

NOEC – no observed effect concentration.

Table 5. Ecotoxicology profile of the technical material, birds

Species		Test Type	Test concentrations	Result obtained
Mallard duck		Acute oral	0 ,506, 1030, 2010, 3030 or 3960 mg ai/kg bodyweight	Acute oral LD50 >3960, lowest lethal dose (LLD) and NOEL =3960 mg/kg
Mallard duck		Subacute oral toxicity	0, 412, 667, 1140, 1880, 3080, or 4850 ppm diet	Dietary LC50 >4850 ppm
Bobwhite quail		Subacute oral toxicity	0, 440, 653, 1090, 1820, 2980, or 5320 ppm diet	Dietary LC50 >5230 ppm
Mallard duck		Reproduction	0, 5 or 50 ppm diet	Reproductive NOEL =50 ppm
Bobwhite quail		Reproduction	0, 5 or 50 ppm diet	Reproductive NOEL =50 ppm

Table 6. Ecotoxicology profile of the technical material (honeybees)

Test	Time	LD_{50} (µg ai/bee)
Contact	24 h LD_{50}	>200
Oral	24 h LD_{50}	>200

Fluazifop-P-butyl has not been evaluated by the WHO/IPCS or by the FAO/WHO JMPR. The WHO/IPCS hazard classification of fluazifop-P-butyl a.i. is slightly hazardous, Class III.

Formulations

The main formulation types available are emulsifiable concentrate (EC) and oil-in-water emulsions (EW). These formulations are registered and sold in most countries.

Methods of analysis and testing

The analytical method for the active ingredient is CIPAC Handbook G, 1995, pages 71-81. The fluazifop-P-butyl is determined by HPLC using a CHIRA-Chrom-1, 'Pirkle' column and UV detection at 254 nm.

Test methods for physical-chemical properties of technical active ingredient and for the formulation are CIPAC methods, as indicated in the specifications.

Physical properties

The physical properties, the methods for testing them and the limits proposed for the EC and EW formulations, comply with the requirements of the FAO Manual (5^{th} edition).

Containers and packaging

No special requirements apply for containers and packaging.

Expression of the active ingredient

The active ingredient is expressed as fluazifop-P-butyl.

Appraisal

Fluazifop-P-butyl is a herbicide that is patented in some countries and has not previously been the subject of FAO specifications. Technical fluazifop-P-butyl is an isomeric mixture containing 97% *R*- and 3% *S*- isomers.

Fluazifop-P-butyl is of low volatility and water solubility. It is hydrolysed slowly under alkaline conditions, very slowly under neutral conditions and is stable under mildly

acidic conditions. It is subject to slow photolysis, degrading to products that are also metabolites.

Based on the stereochemistry of the molecules, the equivalence of metabolism and sub-

chronic toxicology of fluazifop-butyl and fluazifop-P-butyl, it is considered valid to use data on fluazifop-butyl to assess the toxicity of fluazifop-P-butyl. Fluazifop-P- butyl is not genotoxic. It is considered to be of low acute oral, dermal and inhalation toxicity. Fluazifop-P-butyl was found to be a slight irritant to rabbit skin and was classified as a mild irritant (class 4 on a 1 to 8 point scale) to non-irrigated rabbit eyes. In a maximisation test, fluazifop-P-butyl was determined to be a non- sensitiser to guinea pig skin.

There is some potential confusion in published literature on the common name. Zeneca maintained that the correct ISO common name is fluazifop-P-butyl and that fluazifop-P refers to the acid. Nonetheless ISO only records fluazifop-P which refers to the butyl ester.

The ester is rapidly hydrolysed to the acid, i.e. fluazifop P, which was used in a number of the toxicological studies. This was acceptable as the acid is the phytotoxic agent.

The identification by chiral HPLC is costly to duplicate in most laboratories but is an accepted CIPAC method and there is no alternative. A non-chiral GC method is used to determine the active ingredient content.

The manufacturer proposed that the minimum active ingredient in the technical material be not less than 900 g/kg. This was higher than the concentration previously notified to registration authorities, indicating a refinement in the manufacturing process, but was considered acceptable.

The Meeting was provided with commercially confidential information on the manufacturing process and batch analysis data on all impurities present at or above 1g/kg. These data were identical to those submitted and accepted for registration in South Africa. The five batch analysis of impurities showed that the concentrations of active ingredient and impurities were within narrow ranges and the mass balances were high. None of the impurities was considered by the meeting to be a relevant impurity.

Draft specifications submitted for the technical material, emulsifiable concentrate and oil-in-water emulsion were considered acceptable by the meeting.

Recommendations

The meeting recommended that the evaluation and draft specifications for fluazifop-P-butyl TC, EC and EW proposed by Zeneca should be adopted by FAO.