

**FAO SPECIFICATIONS AND EVALUATIONS
FOR PLANT PROTECTION PRODUCTS**

FLUAZIFOP-P-BUTYL

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

2000



FOOD AND AGRICULTURE ORGANIZATION *of* THE UNITED NATIONS

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Disclaimer¹

FAO specifications are developed with the basic objective of ensuring that pesticides complying with them are satisfactory for the purpose for which they are intended so that they may serve as an international point of reference. The specifications do not constitute an endorsement or warranty of the use of a particular pesticide for a particular purpose. Neither do they constitute a warranty that pesticides complying with these specifications are suitable for the control of any given pest, or for use in a particular area. Owing to the complexity of the problems involved, the suitability of pesticides for a particular application must be decided at the national or provincial level.

Furthermore, the preparation and use of pesticides complying with these specifications are not exempted from any safety regulation or other legal or administrative provision applicable thereto. FAO shall not be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of the preparation, transportation, sale or use of pesticides complying with these specifications.

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FAO is not responsible for ensuring that any product claimed to comply with FAO specifications actually does so.

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INTRODUCTION

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

Since 1999 the development of FAO specifications has followed the **New Procedure**, described in the 5th edition of the “Manual on the development and use of FAO specifications for plant protection products” (FAO Plant Production and Protection Page No. 149). This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package required for evaluation, the procedures to be applied in the evaluation process by FAO and the Experts of the “FAO Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent.”

FAO Specifications now only apply to the products of manufacturers whose data have been evaluated as satisfactory and to whose products the specifications are thus known to be appropriate. Consequently from the year 2000 onwards the publication of FAO specifications under the **New Procedure** has changed. Every specification document consists now of two parts, namely the specifications and the evaluation report(s):

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

Part Two: The Evaluation Report(s) of the plant protection product, reflecting the evaluation of the data package carried out by FAO and the Panel of Experts, and providing the justification for any deviation in the specifications from requirements of the 5th edition of the Manual. The data have been provided by the manufacturer(s) according to the requirements of Appendix A, Annex 1, of the 5th edition of the “Manual on the development and use of FAO specifications for plant protection products”. The Evaluation Report includes the name(s) of the manufacturer(s) whose technical pesticide has been evaluated.

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

* Footnote: The publications are available on the Internet under (<http://www.fao.org/waicent/faoinfo/agricult/agp/>) or as hardcopy from the Plant Protection Information Officer.

PART ONE – SPECIFICATIONS

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FAO SPECIFICATIONS AND EVALUATIONS FOR PLANT PROTECTION
PRODUCTS

FLUAZIFOP-P-BUTYL

INFORMATION

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

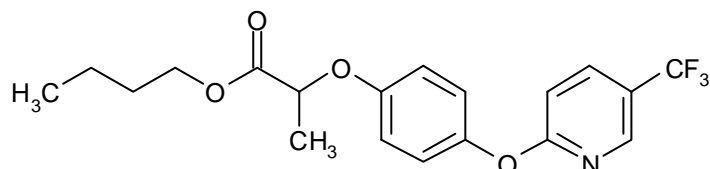
CAS Registry number

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.

FLUAZIFOP-P-BUTYL TECHNICAL MATERIAL

FAO specification 467.205/TC (2000)

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 (467.205/2000). It should be applicable to relevant products of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (467.205/2000) as PART TWO forms 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** (Method 467/TC/M/-)

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** (Method 467/TC/M/-)

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

3 Physical properties

3.1 **Acidity** (MT 31)

Maximum acidity: 4 g/kg calculated as H₂SO₄.

FLUAZIFOP-P-BUTYL EMULSIFIABLE CONCENTRATE

FAO specification 467.205/EC (2000)

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 (467.205/2000). It should be applicable to relevant products of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (467.205/2000) as PART TWO forms an integral part of this publication.

1 Description

The formulation shall consist of technical fluazifop-P-butyl, complying with the requirements of FAO specification 467.205/TC (2000), in the form of a clear to slightly hazy brown liquid, dissolved in suitable solvents (note 1) 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 (Method 467/TC/M/-)

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 (Method 467/TC/M/-)

The fluazifop-P-butyl content shall be declared (g/l) (Note 2) and when determined, the content obtained shall not differ from that declared by more than the following amounts:

Declared content (g/l at 20 ±2°C or g/kg)	Permitted tolerance
above 100 g/l up to 250 g/l Note the upper limit is included in the range	± 6 % of the declared content

3 Physical properties

3.1 pH Range (1% aqueous dispersion) (MT 75) (Note 3)

pH range: 6.0 to 6.5

3.2 Emulsion stability and re-emulsification (MT 36.1) (Notes 4 and 5)

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

Time after dilution	Limits of stability
0 h	Initial emulsion complete
0.5 h	'Cream', maximum: 0.5 ml
2.0 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

3.3 Persistent Foam (MT 47.2) (Note 6)

Maximum: 20 ml after 1 min.

4 Storage stability

4.1 Stability at 0°C (MT 39.3)

After storage at $0 \pm 2^\circ \text{C}$ for 7 days, the volume of solid or liquid which separates shall not be more than 0.3 ml.

4.2 Stability at elevated temperature (MT 46.3)

After storage at $54 \pm 2^\circ \text{C}$ for 14 days, the determined average active ingredient content shall not be lower than 95% relative to the determined average content found under 2.2 before storage and the formulation shall continue to comply with the clauses for pH range (3.1) and Emulsion stability and re-emulsification (3.2) (Note 5).

Note 1 The flash point should not be lower than 38°C (MT 12).

Note 2 In determining active ingredient in g/l at $20 \pm 2^\circ \text{C}$, the actual mass per millilitre shall be measured (using MT 3) and used in the calculation. Where doubt remains, the content should be expressed as g/kg.

Note 3 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 4 In applying MT 36.1, tests after 24 hours are required only where results at 2 hours are in doubt.

Note 5 Samples taken before and after this test should be analysed concurrently to reduce analytical error.

Note 6 This test should be carried out at the highest application concentration.

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

FAO specification 467.205/EW (2000)

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 (467.205/2000). It should be applicable to relevant products of this manufacturer but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (467.205/2000) as PART TWO forms 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 467.205/TC (2000), 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/-)

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/-)

The fluazifop-P-butyl content shall be declared (g/l) (Note 2) and when determined, the content obtained shall not differ from that declared by more than the following amounts:

Declared content (g/l at 20 ±2°C or g/kg)	Permitted tolerance
above 100 g/l up to 250 g/l Note the upper limit is included in the range	± 6 % of the declared content

3 Physical properties

3.1 Mass per millilitre at 20° C (MT 3)

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)

pH range: 5.6 to 6.6.

3.3 Pourability (MT148)

Maximum residue: 0.8 %.

3.4 Emulsion stability and re-emulsification (MT 36.1) (Notes 3 and 4)

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

Time after dilution	Limits of stability
0 h	Initial emulsion complete
0.5 h	'Cream', maximum: 0.5 ml
2.0 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

3.5 Persistent Foam (MT 47.2) (Note 5)

Maximum: 20 ml after 1 minute.

3 Storage stability

3.1 Stability at 0°C (MT 39.3)

After storage at $0 \pm 2^\circ\text{C}$ for 7 days, no separation of particulate or oily matter shall be visible after gentle agitation.

3.2 Stability at elevated temperature (MT 46.3)

After storage at $54 \pm 2^\circ\text{C}$ for 14 days, the determined average active ingredient content shall not be lower than 95% relative to the determined average content found under 2.2 before storage and the formulation shall continue to comply with the clauses for pH range (3.2), emulsion stability and re-emulsification (3.4) and persistent foam (3.5) (Note 4).

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 $20 \pm 2^\circ \text{C}$, 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 In applying MT 36.1, tests after 24 hours are required only where results at 2 hours are in doubt.

Note 4 Samples taken before and after this test should be analysed concurrently to reduce analytical error.

Note 5 This test should be carried out at the highest application concentration.

PART TWO - EVALUATIONS

FLUAZIFOP-P-BUTYL 2000

Evaluation based on submission from Zeneca 2000

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FAO SPECIFICATIONS AND EVALUATIONS FOR PLANT PROTECTION
PRODUCTS

FLUAZIFOP-P-BUTYL

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

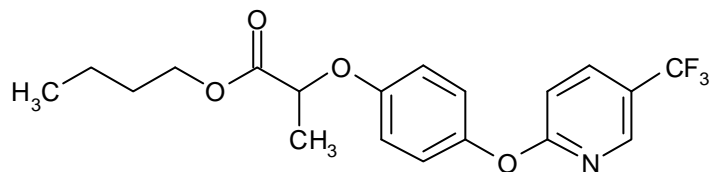
CAS Registry number

79241-46-6

CIPAC number

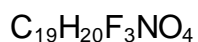
467

Structural formula



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

Molecular formula



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 fluzifop-butyl. CIPAC Handbook G, 1995, 71-81.

Physical and chemical properties of pure fluzifop-P-butyl

Parameter	Value(s) and conditions	Purity %	Method reference
Vapour pressure:	3.3×10^{-8} kPa at 20°C	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°C	99.9%	Wollerton & Walter 1999 (unpublished Zeneca method)
Melting point and temperature of decomposition:	Melting point: -20°C Decomposition temperature: approximately 100°C	99.9%	Wollerton & Walter 1999 (unpublished Zeneca method)
Solubility in water:	1.1mg/l at 20°C 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°C	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°C 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		
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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 ³ 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 [a.i.] content:	900 g/kg.
Relevant impurities ³ 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
<i>In Vitro</i>				
Bacterial mutation assay	Salmonella typhimurium TA15355, TA1537, TA1538, TA98, TA100	1.6-5000 µg/plate +/-S9	93.8% w/w	Negative
Mammalian cell cytogenetics	Human lymphocytes	1-1000 µg/ml +/-S9	95.8% w/w	Negative
Mammalian cell mutation assay	L5178Y mouse lymphoma	100-1000 µg/ml +/-S9	91.9% w/w	Negative
<i>In Vivo</i>				
Mouse bone marrow micronucleus	Bone marrow (micronucleated polychromatic 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
<i>Daphnia magna</i> (water flea)	48h	Immobilisation	>1.0	EC ₅₀
<i>Oncorhynchus mykiss</i> (rainbow trout)	96h	Mortality	1.411 ^a	LC ₅₀
<i>Cyprinus carpio</i> (Common carp)	96h	Mortality	1.31 ^a	LC ₅₀
<i>Selenastrum capricornutum</i> (green alga)	72h	Biomass	>1.8	EC ₅₀
<i>Navicula pelliculosa</i> (freshwater diatom)	72h	Biomass	0.51	EC ₅₀
<i>Lemna gibba</i> (duckweed)	14 days	Growth	>1.4	EC ₅₀
<i>Daphnia magna</i> (water flea)	21 days	Reproduction	0.25 ^a	NOEC
<i>Pimephales promelas</i> (Fathead minnow)	28 days	Early life stage	0.077	NOEC

^(a) fluazifop-butyl tested

EC₅₀ – media effective concentration, LC₅₀ – 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 254nm.

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 (5th 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.