Food and Agriculture Organization
of the United Nations

FAO SPECIFICATIONS AND EVALUATIONS

FOR AGRICULTURAL PESTICIDES

AZIMSULFURON

1-(4,6-dimethoxypyrimidin-2-yl)-3-[1-methyl-4-(2-methyl-2H-tetrazol-5-yl)pyrazol-5-ylsulfonyl]urea

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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 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

AZIMSULFURON

AZIMSULFURON

INFORMATION

ISO common name

Azimsulfuron (E-ISO)

Synonyms

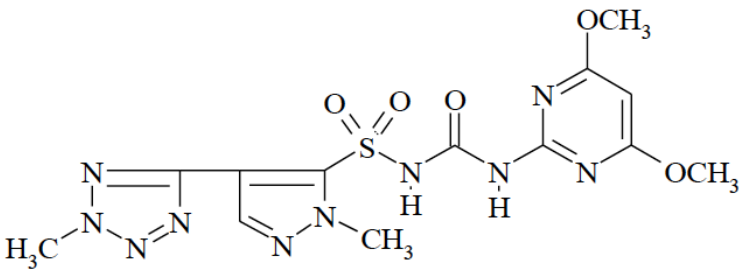
None

Chemical names

IUPAC 1-(4,6-dimethoxypyrimidin-2-yl)-3-[1-methyl-4-(2-methyl-2*H*-tetrazol-5-yl)pyrazol-5-ylsulfonyl]urea

CA *N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-1-methyl-4-(2-methyl-2*H*-tetrazol-5-yl)-1*H*-pyrazole-5-sulfonamide

Structural formula



Molecular formula

$C_{13}H_{16}N_{10}O_5S$

Relative molecular mass

424.40

CAS Registry number

120162-55-2

CIPAC number

584

Identity tests

HPLC relative retention time, IR spectrum

AZIMSULFURON TECHNICAL MATERIAL

FAO Specification 584 / TC (February 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 (*584/2004 & 584/2022*). 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 specification. The specification may not be appropriate for the products of other manufacturers. The evaluation reports (*584/2004 & 584/2022*), as PART TWO, form an integral part of this publication.*

1 Description

The material shall consist of azimsulfuron together with related manufacturing impurities, in the form of a white crystalline solid, free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 **Identity tests** (584/TC/M/2, CIPAC Handbook L, p.24, 2005)

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 **Azimsulfuron content** (584/TC/M/3, CIPAC Handbook L, p.24, 2005)

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

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* 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/

AZIMSULFURON WATER DISPERSIBLE GRANULES

FAO Specification 584 / WG (February 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 (*584/2004 & 584/2022*). 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 specification. The specification may not be appropriate for the products of other manufacturers. The evaluation reports (*584/2004 & 584/2022*), as PART TWO, form an integral part of this publication.*

1 Description

The material shall consist of an homogeneous mixture of technical azimsulfuron, complying with the requirements of FAO specification 584/TC (February 2023), together with carriers and any other necessary formulants. It shall be in the form of granules for application after disintegration and dispersion in water. The formulation shall be dry, free-flowing, essentially non-dusty and free from visible extraneous matter and hard lumps.

2 Active Ingredient

2.1 **Identity tests** (584/WG/M/2, CIPAC Handbook L, p.27, 2005)

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 **Azimsulfuron content** (584/WG/M/3, CIPAC Handbook L, p.27, 2005)

The azimsulfuron content shall be declared (above 500 g/kg) and, when determined, the average content measured shall not differ from that declared by more than ± 25 g/kg.

3 Physical properties

3.1 **Wettability** (MT 53.3.1, CIPAC Handbook F, p.164, 1995)

The formulation shall be completely wetted in 10 seconds.

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

Maximum: 2% retained on a 75 µm test sieve.

3.3 **Dispersibility** (MT 174, CIPAC Handbook F, p.435, 1995)

Minimum: 75% after 1 minute of stirring.

* 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 **Suspensibility** (MT 184.1, CIPAC Handbook P, p.245, 2021) (Notes 1 & 2)

A minimum of 60% of the azimsulfuron content found under 2.2. shall be in suspension after 30 minutes in CIPAC Standard Water D at 25 ± 5°C.

3.5 **Persistent foam** (MT 47.3, CIPAC Handbook O, p.177, 2017) (Note 3)

Maximum: 60 ml after 1 minute.

3.6 **Dustiness** (MT 171.1 CIPAC Handbook P, p.235, 2021) (Note 4)

The formulation shall have a maximum collected dust of 30 mg by the gravimetric method or a maximum dust factor of 25 by the optical method of MT 171.1.

3.7 **Flowability** (MT 172.2, CIPAC Handbook P, p.241, 2021)

At least 99% of the formulation (after the test of storage at elevated temperature) shall pass through a 5 mm test sieve after 20 drops of the sieve.

4 Storage Stability

4.1 **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 must not be lower than 97% relative to the determined average content found before storage (Note 5) and the formulation shall continue to comply with the clauses for:

- wet sieve test (3.2);
- dispersibility (3.3);
- suspensibility (3.4);
- dustiness (3.6).

Note 1 The formulation should be tested at the highest and lowest rates of use recommended by the supplier, provided this does not exceed the conditions given in method MT 184.1.

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

Note 3 The mass of the sample to be used in the test should be specified at the highest rate of use recommended by the supplier.

Note 4 Measurement of dustiness must be carried out on the sample "as received" and, where practicable, the sample should be taken from a newly opened container because changes in the water content of samples may influence dustiness significantly. The optical method of MT 171.1 usually shows good correlation with the gravimetric method and can, therefore, be used as an alternative where the equipment is available. Where the correlation is in doubt, it must be checked with the formulation to be tested. In case of dispute, the gravimetric method shall be used.

Note 5 Samples of the formulation taken before and after the storage stability test may be analysed concurrently after the test in order to reduce the analytical error.

PART TWO

EVALUATION REPORTS

AZIMSULFURON

AZIMSULFURON

FAO/WHO EVALUATION REPORT 584/2022

Recommendations

The Meeting recommended the following:

(i) The change of manufacturer of the reference specifications for azimsulfuron TC and WG from E.I. du Pont de Nemours and Company to FMC Inc. should be noted by FAO.

(ii) The editorially updated and confirmed FAO specifications for azimsulfuron TC and WG by FMC Inc. should be adopted by FAO.

Appraisal

The Meeting noted that in a press release dated of March 31, 2017, FMC Inc. (FMC)[1] (USA), announced the acquisition of a significant portion of DuPont's Crop Protection business. Part of this acquisition included azimsulfuron TC and WG formulations.

As such a transition may raise some concerns on the continued validity of the FAO specifications for azimsulfuron TC and WG (see also Manual on the development and use of FAO and WHO specifications for chemical pesticides, Section 3.6), FMC was contacted by FAO and a statement on the support of the reference specifications and possible changes therein was requested.

FMC later on provided a confirmation in writing (FMC, 2018)[2] to FAO confirming the continued support for the FAO reference specifications for azimsulfuron TC and WG. FMC explained that both manufacturing site and - process for azimsulfuron were not affected by the transition from DuPont to their company and confirmed the continued validity of the published specifications and stewardship for them.

The Meeting also noted that the specifications needed some editorial update with regard to certain physical-chemical test methods - for several MT methods newer versions are available and references to meanwhile published analytical methods. These newer versions of MT methods are deemed to be equivalent to previous ones in terms of results but easier to implement in the laboratory (such as MT 184.1, suspensibility) where a standard cylinder and a temperature range of 25 ± 5 °C are used, thus avoiding the use of a thermostated water bath. Therefore, no changes in limits were deemed to be necessary. The analytical

[1] https://www.prnewswire.com/news-releases/fmc-corporation-announces-acquisition-of-significant-portion-of-duponts-crop-protection-business-simultaneous-sale-of-health-and-nutrition-to-dupont-300432498.html

[2] e-mail of Mrs. R. McKenna, FMC to FAO AGP, Mrs. YongZhen Yang dated 19 December 2018.

methods for confirmation of the identity of azimsulfuron and determination of its content are meanwhile published in Handbook L. In addition, some typos were corrected like the references to MT tests after the accelerated storage test and minor wordings adjusted, for example, samples after the accelerated storage test “*may”* be analyzed concurrently was revised instead to the stronger "*should*". Also, the former "essentially non-dusty" in the dustiness clause was replaced by the standard wording: "The formulation shall have a maximum collected dust of 30 mg by the gravimetric method or a maximum dust factor of 25 by the optical method of MT 171.1." This provides suitable limits for both the gravimetric and optical method, respectively.

For these reasons, the Meeting recommended that FMC should be noted as new holder of the reference specifications for azimsulfuron TC and WG, and that these specifications with FMC as holder should be considered as the new reference specifications.

AZIMSULFURON

FAO/WHO EVALUATION REPORT 584/2004

Explanation

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

Azimsulfuron is under patent in Taiwan until 2004; Canada until 2005; Australia, Brazil, France, Greece, Israel, Italy, New Zealand, Portugal and Turkey until 2006; Spain, South Korea and Thailand until 2007; and Japan until 2009.

Azimsulfuron has not been evaluated by the FAO/WHO JMPR or IPCS. It was reviewed by the European Commission in 1998 and has achieved Annex 1 listing.

The draft specification and the supporting data were provided by E.I. du Pont de Nemours and Company in October 2003.

Uses

Azimsulfuron is a herbicide which affects sensitive weeds through inhibition of the enzyme acetolactate synthase (ALS). Inhibition of ALS leads to the cessation of cell division and subsequent growth processes in plants. Azimsulfuron is taken up mainly by leaves and shoots and, to a lesser extent, roots. Once taken up, it is translocated via both xylem and phloem.

It is used post-emergence in rice fields against a variety of annual weeds.

Identity of the active ingredient

ISO common name

Azimsulfuron (E-ISO)

Synonyms

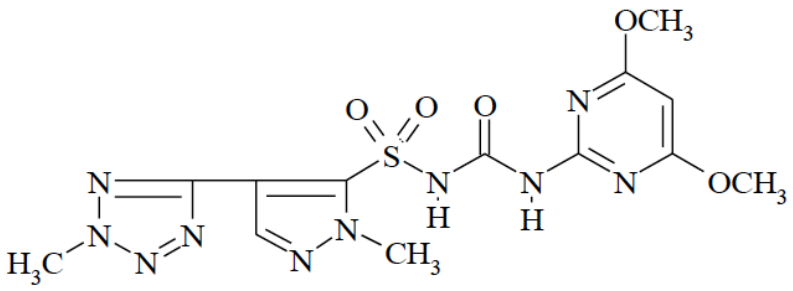
None

Chemical names

IUPAC 1-(4,6-dimethoxypyrimidin-2-yl)-3-[1-methyl-4-(2-methyl-2*H*-tetrazol-5-yl)pyrazol-5-ylsulfonyl]urea

CA *N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-1-methyl-4-(2-methyl-2*H*-tetrazol-5-yl)-1*H*-pyrazole-5-sulfonamide

Structural formula



Molecular formula

$C_{13}H_{16}N_{10}O_5S$

Relative molecular mass

424.40

CAS Registry number

120162-55-2

CIPAC number

584

Identity tests

HPLC relative retention time, IR spectrum

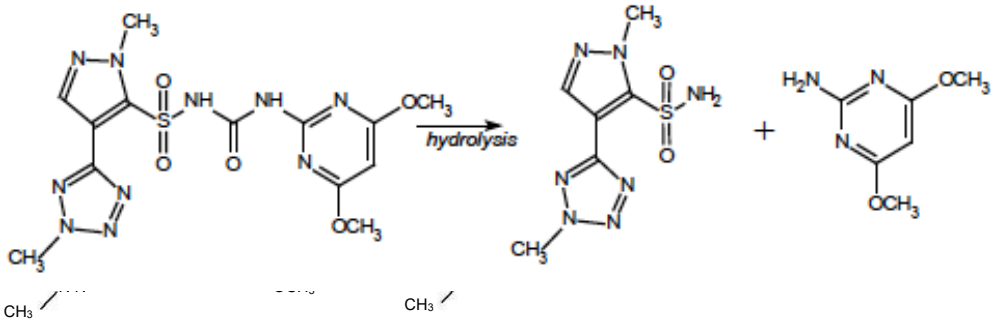
Physico-chemical properties of pure azimsulfuron

Table 1. Physico-chemical properties of pure azimsulfuron

Parameter	Value(s) and conditions	Purity %	Method reference	Study reference
Vapour pressure	4 x 10^{-9} Pa at 25°C (extrapolated) measurements from 86°C to 124°C	99.62%	EEC 2.3.1, Knudsen gas effusion method	Cobranchi and Schmuckler, 1994
Melting point, boiling point and/ or temperature of decomposition	Melting point: 170°C Boiling point: not applicable Decomp. temp.: 180 - 250°C	99.62%	EEC 2.1, capillary, oil bath method EEC 2.12 DSC, TGA	Moore, 1994a Lesieur, 1994
Relative density	1.12 at 20°C	99.62%	EEC 2.2, OECD 109, displaced mineral oil - pycnometer method	Moore, 1994b
Solubility in water	72.3 mg/l at 20°C at pH 5 1050 mg/l at 20°C at pH 7 6536 mg/l at 20°C at pH 9	>97% a	CIPAC MT 157 Part 2, Shake flask method	Schmuckler, 1991

Parameter	Value(s) and conditions	Purity %	Method reference	Study reference
Octanol/water partition coefficient	Log K_{OW} = 0.646 at 25°C at pH 5 Log K_{OW} = -1.37 at 25°C at pH 7 Log K_{OW} = -2.08 at 25°C at pH 9	96.95% [a]	Shake flask method, OTS Guideline CG1400	Smyser, 1991
Volatility	Henry's Law Constants (calculated) (Pa x ^{m3} x mol $^{-1}$) 8 x 10^{-9} at 20°C at pH5 5 x 10^{-10} at 20°C at pH7 9 x 10^{-11} at 20°C at pH9	Not applicable	Calculated	Schmuckler, 1995
Hydrolysis characteristics [b]	Half-life = 89 days (mean of 83 and 95) at 25°C at pH 5 Half-life = 124 days (mean of 117 and 132) at 25°C at pH 7 Half-life = 132 days (mean of 126 and 139) at 25°C at pH 9	Radiochem purity 97.4% (pyrazole label); 97.3% (pyrimidine label)	U.S. EPA Pesticide Assessment Guidelines (Hitch, 1982a)	Hausmann, 1991a
Photolysis characteristics [c]	Simulated sunlight: Half-life = 103 days at pH 5 Half-life = 164 days at pH 7 Half-life = 225 days at pH 9	see Hausmann, 1991b	US EPA model GCSOLAR (EPA, 1985)	Barefoot, 1998
Dissociation characteristics	pKa = 3.6	96.95% [a]	OECD 112, spectrophoto-metric method	Cooke, 1993

[a] Tests were conducted between 1989 and 1992. Process was optimized in 1994 to yield technical of ≥98% purity.



[b] Hydrolysis test in dark and sterile conditions at a concentration of 25 mg/l for 30 days. Hydrolysis cleaved the sulfonylurea bridge.

[c] Photolysis test in sterile conditions at a concentration of 25 mg/l for 30 days.

Chemical composition and properties of azimsulfuron technical material (TC)

Table 2. Chemical composition and properties of azimsulfuron 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 were100.3-101.4%.
Declared minimum azimsulfuron content	980 g/kg.
Relevant impurities ≥1 g/kg and maximum limits for them	None.
Relevant impurities <1 g/kg and maximum limits for them:	None
Stabilizers or other additives and maximum limits for them:	None.
Melting temperature range of the TC	170ºC (decomposition occurs at 180-250ºC.

Toxicological summaries

Notes.

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

Species	Test	Duration and conditions or guideline adopted	Result	Study ref
Male and female rat	Acute oral	14 days Azimsulfuron technical (97.9% purity) [a] [b]	LD_{50} >5000 mg/kg bw	Ueda, 1990c
Male and female rat	Acute dermal	14 days Azimsulfuron technical (97.9% purity) [a] [b] MAFF Japan, 1985	LD_{50} = >2000 mg/kg bw	Ueda, 1990a
Male and female rat Fischer (F344/DuCrj)	Acute inhalation	4 hours Azimsulfuron technical (99.1% purity) OECD 403	LC_{50} > 5.94 mg/m^3	Ebino, 1993
Female rabbit (New Zealand white)	Acute skin irritation	72 hours Azimsulfuron technical (97.9% purity) [a] [b] Draize, 1965	Non-irritant	Kosaka, 1990a
Female rabbit (New Zealand white)	Acute eye irritation	24 hours Azimsulfuron technical (97.9% purity) [a] [b] Draize, 1965 Kay *et al*., 1962	Non-irritant	Kosaka, 1990b
Female guinea pig (Crj:Hartley)	Acute skin sensitization	72 hours; Magnusson and Kligman method Azimsulfuron technical (97.9% purity) [a] [b] Magnusson and Kligman, 1969	Not a sensitizer	Ueda, 1990b

[a] Tests were conducted between 1989 and 1992. Process was optimized in 1994 to yield technical of ≥ 98% purity.

[b] This study was conducted in compliance with the GLP standards of MAFF in Japan, FIFRA, EPA in USA and OECD at The Institute of Environmental Toxicology in Tokyo, Japan.

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

Species	Test	Duration and conditions or guideline adopted	Result	Study ref
Male and female rats (Fischer F344/DuCrj)	Oral	13 weeks Azimsulfuron technical (99.1% purity) OECD Guideline 408	NOEL = 1250 ppm (75.3 and 82.4 mg/kg/day for males and females respectively)	Toshishiro, 1993
Male and female mice ICR (Crj:CD-1)	Oral	13 weeks Azimsulfuron technical (99.1% purity) [b]	NOEL = 300 and 3000 ppm (40.62 and 469.9 mg/ kg/day) for males and females respectively)	Harada, 1992
Male and female Beagle dogs	Oral	13 weeks Azimsulfuron technical (99.3% purity) OECD Guideline 409	NOEL = 300 ppm (8.81 and 9.75 mg/kg/day for males and females respectively)	Harada, 1995b
Male and female rat (Fischer F344/DuCrj)	Oral	24 months Azimsulfuron technical (99.0% purity) OECD Guideline 453	NOAEL = 1000 ppm (34.3 and 43.8 mg/kg/day for males and females respectively)	Kosei, 1993
Male and female mice ICR (Crj/CD-1)	Oral oncogenicity	18 months Azimsulfuron technical (99.0% purity) OECD Guideline 451	NOEL = 2500 ppm and 750 ppm (247.5 and 69.9 mg/kg/day) for males and females respectively. No evidence for oncogenicity	Takahashi, 1994
Male and female dogs (Beagle)	Oral feeding	1 year Azimsulfuron technical (99.0% purity) OECD Guideline 452	NOAEL = 750 ppm (17.88 and 19.25 mg/kg/day for males and females respectively)	Harada, 1995a
Male and female rats (Sprague-Dawley)	Reproductive toxicity (2 generations)	2 generations Azimsulfuron technical (99.0% purity) OECD Guideline 416	NOEL(reproduction) = 8000 ppm (601-724 and 663-783 mg/kg/day for males and females respectively) NOEL (systemic toxicity) = 125 ppm (9.59-11.25 and 10.92–2.39 mg/kg/day for males and females, respectively).	Hojo, 1994
Female Rats Crj:CD (SD)	Teratogenicity study	15 days Azimsulfuron technical (99.0% purity) US EPA FIFRA Guideline, Subdivision F, 83-3	Non teratogenic at dose levels up to 1000 mg/kg/day Maternotoxic and fetotoxic at 1000 mg/kg/day.	Fujii, 1994
Female rabbits (Japanese White)	Teratogenicity study	13 days Azimsulfuron 99.0% purity US EPA FIFRA Guideline Subdivision F, 83-3.	NOEL for maternotoxicity 150 mg/kg/day NOEL for fetotoxicity 500 mg/kg/day	Aoyama, 1994

[b] This study was conducted in compliance with the GLP standards of MAFF in Japan, FIFRA, EPA in USA and OECD at The Institute of Environmental Toxicology in Tokyo, Japan.

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

Species	Test	Conditions	Result	Study ref
Salmonella typhimurium	Mutagenicity	Azimsulfuron technical (97.9% purity) [a] U.S. EPA Pesticide Assessment Guidelines, Subdivision F, 84-2	Negative	Reynolds, 1989
Chinese Hamster ovary cells	CHO/HRPT gene mutation	Azimsulfuron technical (98.9% purity) OECD Guideline 476	Negative with and without activation	Gerber,1994b
Rat hepatocytes	*In vitro* Unscheduled DNA synthesis (UDS)	Azimsulfuron technical (98.9% purity) OECD Guideline 482	UDS was not observed	Gerber, 1994a
Chines hamster lung cells	*In vitro* cytogenetics	Azimsulfuron technical (97.9% purity) [a b]	No structural nor numerical chromosome aberrations in the metabolic activation method	Sasaki, 1990

[a] Tests were conducted between 1989 and 1992. Process was optimized in 1994 to yield technical of ≥ 98% purity.

[b] This study was conducted in compliance with the GLP standards of MAFF in Japan, FIFRA, EPA in USA and OECD at The Institute of Environmental Toxicology in Tokyo, Japan.

Table 6. Ecotoxicology profile of technical azimsulfuron

Species	Test	Duration and conditions	Result	Study ref
Lepomis macrochirus (bluegill sunfish)	Acute	96 hr, static Azimsulfuron technical (98.9% purity) OECD Guideline 203	LC_{50} = >1000 mg/l NOEC = 780 mg/l	Kreamer, 1994d
Oncorhynchus mykiss (rainbow trout)	Acute	96 hr, static Azimsulfuron technical (98.9% purity) OECD Guideline 203	LC_{50} = 154 mg/l NOEC = 49 mg/l	Kreamer, 1994e
Oncorhynchus mykiss (rainbow trout)	Sub-chronic	28 days, flow-through Azimsulfuron technical (98.9% purity) ECD Guideline 204	NOEC = 23 mg/l	Kreamer, 1994b
Daphnia magna (water flea)	Acute toxicity	48 hr, static Azimsulfuron technical (98.9% purity) ECD Guideline 202	EC_{50} = 941 mg/l NOEC= 650 mg/l	Kreamer, 1994c
Oncorhynchus mykiss (rainbow trout)	Chronic toxicity	90 days, flow-through Azimsulfuron technical (98.9% purity) OECD Guideline 210	NOEC = 6.3 mg/l	Kreamer, 1994a

Lemna gibba	Growth and reproduction	14 days Azimsulfuron technical (98.9% purity) FIFRA, Subdivision J, 123-2	EC_{50} = 0.8 µg/l NOEC < 0.46 µg/l	Thompson, 1995
Selenastrum capricornutum (green alga)	Growth and reproduction	120 hours Azimsulfuron technical (98.9% purity) FIFRA, Subdivision J, 123-2,122-2	EC_{50} = 12 µg/l NOEC < 8.1 µg/l	Thompson, 1994
Eisenia foetida andrei earthworm	Acute toxicity	14 days Azimsulfuron technical (98.9% purity) OECD Guideline 207	LC_{50} = >1000 ppm	Caley *et al*. 1994
Apis mellifera (honey bee)	Acute oral and contact toxicity	48 hours Azimsulfuron technical (98.9% purity) FIFRA Subdivision L, Series 71-1, Hazard Evaluation: Non-target Insects	LC_{50} = >1000 ppm (oral) and > 25.0 µg/bee (contact)	Beavers & Palmer, 1994 Palmer & Beavers, 1994
Colinus Virginianus and *Anas Platyrhynchos* Bobwhite quail and Mallard duck	Acute oral toxicity	14 days Azimsulfuron technical (98.9% purity) Pesticide Assessment Guidelines, FIFRA Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms	LD_{50} = >2250 mg/kg	Beavers & Campbell, 1994c, 1994a
Colinus Virginianus and *Anas Platyrhynchos* Bobwhite quail and Mallard duck	Dietary toxicity	5 days Azimsulfuron technical (98.9% purity) OECD Guideline 205	LC_{50} = >5620 ppm	Beavers & Campbell, 1994b. Jaber & Campbell, 1994

Azimsulfuron has not been evaluated by the IPCS or by the FAO/WHO JMPR.

Azimsulfuron is classified by WHO as “unlikely to present acute hazard in normal use” (WHO 2002). It does not meet the criteria established in the UN Recommendations on the Transport of Dangerous Goods (published by the United Nations Committee of Experts on the Transport of Dangerous Goods) and, therefore, is not considered as dangerous/hazardous for transportation purposes.

Formulations and co-formulated active ingredients

The main formulation type available is water dispersible granules (WG). Azimsulfuron may be co-formulated with other herbicides including bensulfuron-methyl or metsulfuron-methyl. These formulations are registered and sold in many countries throughout the world.

Methods of analysis and testing

The analytical method for determination of the active ingredient (including identity tests) was validated by collaborative study (Bura 2003) and adopted, with provisional status, by CIPAC in 2004 (CIPAC 2004).

The azimsulfuron content is determined by reversed-phase HPLC using a 15 cm x 4.6 mm i.d. Zorbax® SB-C8 column, 5 µm particle size (or equivalent). The mobile phase is composed of pH 3.0 water and acetonitrile. The compound is detected using a UV detector at 240 nm and quantification is done by internal standardization with 4,4'-biphenol as the internal standard.

Within-laboratory validation data were also provided for an HPLC method (method ESB-22-93) designed for analysis of WG formulations (Blank, 1994). Azimsulfuron is determined on a reversed-phase HPLC system using a Zorbax® cyano column and a mobile phase of 30% acetonitrile and 70% water (adjusted to pH 3 with phosphoric acid), with UV detection at 240 nm. Phenyl sulphone is added as an internal standard. Validation data are summarized in Table 7.

Table 7. Validation data for azimsulfuron content of WG formulations (Blank, 1994)

Substrate	Test	Result
Method ESB-22-93 (HPLC, internal standard) Validation: Blank, 1994.		
WG	linearity	Sensitivity of response from 25% below to 25% above the target assay level (0.1 mg/l) is unchanged
	specificity	no co-elution of the azimsulfuron active ingredient or the internal standard, phenyl sulfone, occurred with impurities of the formulation or components of a formulation placebo.
	precision Note 1	Repeatability S_r = 0.002 at an azimsulfuron level of 49% (n=5). Reproducibility S_r = 0.012 at an azimsulfuron level of 49% (n=5), 2 different analysts on different days.
	LOQ	method as written is valid down to 5% of ai in formulations
	recovery	mean 101.1% (n=4) for spiking placebo at 48% and 51%.

Note 1: S_r is relative standard deviation.

The method for determination of impurities is based on reversed-phase gradient-elution HPLC, using UV detection at 254 nm and external standardisation (Simons, 2003).

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

Physical properties

The physical properties, the methods for testing them and the limits proposed for the WG formulations, comply with the requirements of the FAO/WHO Manual (FAO/WHO 2002). Physical testing of azimsulfuron 50% WG prepared in March 1992 was reported by Metzger and Koehler, 1995 (Table 8).

Table 8. Physical testing of azimsulfuron 50% WG (Metzger and Koehler 1995)

Test	Method	Result		
Appearance		Colour: tan.		
pH of 1% aq soln	CIPAC MT 75	5.7		
Bulk density (tap density)	CIPAC MT 169	0.63 g/ml		
Storage stability at 54°C	CIPAC MT 46	Test	Ambient	54°C
		Assay	49.2% ai	49.2% ai
		pH	5.7	5.6
		Wet sieve	0.6%	0.6%
		Suspensibility	66.1%	64.4%
		Dispersibility	91%	89%
Wettability	CIPAC MT 53.3.1	Wetting time: immediate		
Persistent foaming	CIPAC MT 47	Volume of foam at 1 minute: 0 ml		
Suspensibility	CIPAC MT 168	66%		
Dispersibility	CIPAC MT 174	91%		
Wet sieve test	CIPAC MT 167	0.6% retained on 75 μm sieve		
Nominal size range (dry sieve analysis)	CIPAC MT 170	≥90% retained on 500 μm sieve, ≤10% retained on 1400 μm sieve		
Dustiness	CIPAC MT 171	0.03% dust content		
Flowability	CIPAC MT 172	All of the test substance flowed freely through the sieve spontaneously (without agitation).		

Containers and packaging

No extraordinary container or package issues need be considered.

Expression of the active ingredient

The active ingredient is expressed as azimsulfuron.

Appraisal

The Meeting considered the data and draft specifications in support of the development of new FAO specifications for azimsulfuron TC and WG. The data submitted were in accordance with the requirements of the FAO/WHO Manual (1st edition).

The water solubility of azimsulfuron depends on pH (72.3, 1050 and 6536 mg/l at 20°C at pH 5, 7 and 9 respectively). Azimsulfuron is acidic, with a pKa of 3.6. It is reasonably stable to hydrolysis and photolysis.

The Meeting was provided with commercially confidential information on the manufacturing process and batch analysis data on all impurities present at or above 1 g/kg. The process typically produces azimsulfuron having a minimum assay of 980 g/kg. Analyses of 5 batches of azimsulfuron produced in 2002 accounted for 100.3-101.4% of the material (azimsulfuron 99.9-100.9%, water 0.16-0.18%, total other impurities 0.23-0.32%). The Meeting was informed that several minor

impurities included in the manufacturing specification but which did not appear in the 5-batch data were included on the basis that they were only rarely detectable. The confidential data agreed with those submitted to the Ministry of Health in Italy (Desideri, 2004). The Meeting agreed that none of the impurities of azimsulfuron should be considered as relevant impurities.

The toxicological and ecotoxicological data were derived from azimsulfuron having impurity profiles similar to those described in the 5-batch analyses (manufacturing QC minimum limit 980 g/kg for azimsulfuron) or, for tests conducted between 1989 and 1992, on material of a lesser purity.

Azimsulfuron has not been evaluated by the WHO IPCS or by JMPR. Azimsulfuron

appears to be generally of low mammalian toxicity.

Ecotoxicological study summaries on fish, Daphnia, Lemna gibba, algae, birds, bees and earthworms were provided. Azimsulfuron is generally of low ecotoxicity except for the plants, *Lemna gibba* and green algae, with NOEC values of <0.46 and <8.1 μg/l respectively. In the view of WHO/PCS, as a herbicide it would be classified as very toxic to aquatic organisms.

Azimsulfuron does not meet the criteria established in the UN Recommendations on the Transport of Dangerous Goods (published by the United Nations Committee of Experts on the Transport of Dangerous Goods) and therefore, is not considered as dangerous or hazardous for transportation purposes.

The main formulation type is water dispersible granules (WG).

The analytical method for active ingredient relies on reversed-phase HPLC with internal standard phenyl sulfone and has been adopted by CIPAC. The HPLC method provides one identity test, with IR spectrophotometry for further identification.

The physical properties of azimsulfuron WG comply with the proposed specifications. No special requirements for containers and packaging have been identified.

Recommendations

The Meeting recommended that the draft specifications for azimsulfuron TC and WG proposed by E.I. du Pont de Nemours and Company, as amended by agreement between the company and the Meeting, should be adopted by FAO.

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