FAO SPECIFICATIONS AND EVALUATIONS FOR AGRICULTURAL PESTICIDES

RIMSULFURON

1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-ethylsulfonyl-2-pyridylsulfonyl)urea

FOOD AND AGRICULTURE ORGANIZATION of THE UNITED NATIONS

TABLE OF CONTENTS

RIMSULFURON

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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.

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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.

Since 1999 the development of FAO specifications follows 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, the procedure and evaluation applied by FAO and the Experts of the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS). [Note: prior to 2002, the Experts were of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent, which now forms part of the JMPS, rather than the JMPS.]

FAO Specifications now only apply to products for which the technical materials have been evaluated. Consequently from the year 2000 onwards the publication of FAO specifications under the **New Procedure** has changed. Every specification consists now of two parts namely the specifications and the evaluation report(s):

PART ONE: **The Specification** of the technical material and the related formulations of the plant protection product in accordance with chapter 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 JMPS. The data are to be provided by the manufacturer(s) according to the requirements of Appendix A, annex 1 or 2 of the "Manual on the development and use of FAO specifications for plant protection products" and supported by other information sources. The Evaluation Report includes the name(s) of the manufacturer(s) whose technical material has been evaluated. Evaluation reports on specifications developed subsequently to the original set of specifications are added in a chronological order to this report.

FAO specifications under the **New Procedure** do not necessarily apply to nominally similar products of other manufacturer(s), nor to those where the active ingredient is produced by other routes of manufacture. FAO has the possibility to extend the scope of the specifications to similar products but only when the JMPS has been satisfied that the additional products are equivalent to that which formed the basis of the reference specification.

Specifications bear the date (month and year) of publication of the current version. Dates of publication of the earlier versions, if any, are identified in a footnote. Evaluations bear the date (year) of the meeting at which the recommendations were made by the JMPS.

* NOTE: PUBLICATIONS ARE AVAILABLE ON THE INTERNET AT (http://www.fao.org/ag/agp/agpp/pesticid/)

OR IN HARDCOPY FROM THE PLANT PROTECTION INFORMATION OFFICER.

PART ONE

SPECIFICATIONS

RIMSULFURON

RIMSULFURON

INFORMATION

ISO common names

Rimsulfuron (BSI, E-ISO, ANSI)

Synonyms

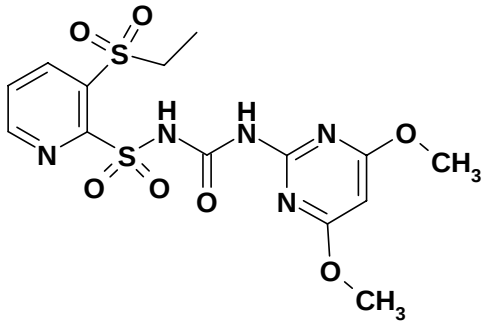
DPX-E9636, IN-E9636, Titus®

Chemical names

IUPAC 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-ethylsulfonyl-2-pyridylsulfonyl)urea

CA *N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-3-(ethylsulfonyl)-2-pyridinesulfonamide

Structural formula



Empirical formula

$C_{14}H_{17}N_5O_7S_2$

Relative molecular mass

431.40

CAS Registry number

122931-48-0

CIPAC number

716

Identity tests

HPLC retention time, IR spectrum.

RIMSULFURON TECHNICAL MATERIAL

FAO specification 716/TC (February 2006*)

*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 (*716/2005*). It should be applicable to relevant products of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (*716/2005*) as PART TWO forms an integral part of this publication.*

1 Description

The material shall consist of rimsulfuron together with related manufacturing impurities and shall be a white homogeneous powder, free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 **Identity tests** (716/TC/M/2, CIPAC Handbook, Note 1)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

2.2 **Rimsulfuron content** (716/TC/M/3, CIPAC Handbook, Note 1)

The rimsulfuron content shall be declared (not less than 960 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

Note 1 Methods for the identification and determination of rimsulfuron content were adopted by CIPAC in 2005 but are not yet published in a Handbook. Prior to publication of the Handbook, copies of the methods may be obtained through the CIPAC website, http://www.cipac.org or from the Secretary, Dr László Bura, Central Service for Plant Protection and Soil Conservation, Budaörsi út 141-145, 1118 Budapest, Hungary.

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

RIMSULFURON WATER DISPERSIBLE GRANULES

FAO specification 716/WG (February 2006*)

*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 (*716/2005*). It should be applicable to relevant products of these manufacturers but it is not an endorsement of those products, nor a guarantee that they comply with the specifications. The specification may not be appropriate for the products of other manufacturers. The evaluation report (*716/2005*) as PART TWO forms an integral part of this publication.*

1 Description

The material shall consist of an homogeneous mixture of technical rimsulfuron, complying with the requirements of the FAO specification 716/TC (February 2006), 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** (716/WG/M/2, CIPAC Handbook, Notes 1 & 2)

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 **Rimsulfuron content** (716/WG/M/3, CIPAC Handbook, Notes 1 & 2)

The rimsulfuron content shall be declared (g/kg) and, when determined, the average measured content shall not differ from that declared by more than the following tolerances:

Declared content, g/kg	Tolerance
above 100 up to 250 Note: the upper limit is included in the range	± 6% of the declared content

3 Physical properties

3.1 **Wettability** (MT 53.3.1, CIPAC Handbook F, p.165, 1995)

The formulation shall be completely wetted in 10 sec. without swirling.

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

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

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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/ag/agp/agpp/pesticid/.

3.4 **Degree of dispersion** (MT 174, CIPAC Handbook F, p.435, 1995)

Dispersibility: minimum 70% after 2 min. stirring.

3.5 **Suspensibility** (MT 184, CIPAC Handbook K, p.142, 2003) (Notes 3 & 4)

A minimum of 70% shall be in suspension after 30 minutes in CIPAC Standard Water D at 30 ± 2°C.

3.6 **Persistent foam** (MT 47.2, CIPAC Handbook F, p.152, 1995)

Maximum: 60 ml after 1 min.

3.7 **Dustiness** (MT 171, CIPAC Handbook F, p.425, 1995) (Note 5)

Essentially non-dusty.

3.8 **Flowability** (MT 172, CIPAC Handbook F, p.430, 1995)

After the test of storage stability (4.1), at least 99% of the formulation shall pass through a 5 mm test sieve after 20 drops of the sieve.

4 Storage stability

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

After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower that 95% 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 (3.3);
- degree of dispersion (3.4);
- suspensibility (3.5);
- dustiness (3.7).

Note 1 The collaboratively tested method for analysis of wettable powders (WP) is applicable to water dispersible granules (WG). It is, however, recommended that samples be ground to a powder prior to analysis.

Note 2 Methods for the identification and determination of rimsulfuron content were adopted by CIPAC in 2004 but are not yet published in a Handbook. Prior to publication of the Handbook, copies of the methods may be obtained through the CIPAC website, http://www.cipac.org or from the Secretary, Dr László Bura, Central Service for Plant Protection and Soil Conservation, Budaörsi út 141-145, 1118 Budapest, Hungary.

Note 3 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, the simpler gravimetric method, MT 168, 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 4 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 the method.

Note 5 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, MT 171, 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 6 Samples of the formulation taken before and after the storage stability test should be analyzed concurrently after the test in order to reduce the analytical error.

PART TWO

EVALUATION REPORTS

RIMSULFURON

RIMSULFURON

FAO/WHO EVALUATION REPORT 716/2005

Recommendations

The Meeting recommended that the proposed specifications for rimsulfuron TC and WG should be adopted by FAO.

Appraisal

Data provided by E.I. du Pont de Nemours for rimsulfuron were evaluated in support of proposed new FAO specifications for TC and WG.

Rimsulfuron has not been evaluated by the FAO/WHO JMPR or IPCS. A complete EU dossier was submitted to Germany in 2001 and is currently under review by the European Commission.

Rimsulfuron is under patent in many countries until 2007 to 2009.

Rimsulfuron is a herbicide which is used post-emergence on crops such as maize and potatoes, against a variety of annual and perennial grasses and broadleaved weeds.

Rimsulfuron has low acute toxicity via oral, dermal and inhalation routes of exposure, it is not a eye or skin irritant, nor a skin sensitizer, and there is no evidence of genotoxic, carcinogenic or teratogenic properties. As may be expected for a selective herbicide, rimsulfuron is highly toxic to some non-target plants, including duckweed, but it is rather less toxic towards algae and is of low toxicity towards most other wildlife.

Rimsulfuron is a solid which decomposes at its melting point of 172-173^{0}C. It is an acid, pKa 4.0, and its water solubility increases from about 0.1 g/l at pH 5 to about 6-7 g/l at pH 7 and 9. Under most field conditions, and in its formulations, it is therefore largely dissociated or effectively present in the form of salts, but the salts are not specifically manufactured as such. It has a low vapour pressure and Henry's constant, therefore significant volatilization is not expected. The octanol/water partition coefficient is low, indicating a low potential for bioaccumulation. Rimsulfuron hydrolyzes rapidly in aqueous solution at pH 9 and more slowly at pH 5-7. In contrast, photolysis in aqueous solution in simulated sunlight contributes to the rate of degradation at pH 5 but not at pH 7-9.

The Meeting was provided with details of the manufacturing process, 5 batch analysis data from the current site of production, and manufacturing limits for purity and all impurities at or above 1 g/kg. Mass balances were high (99.62-100.43%), no unknowns were detected and the minimum active ingredient content in technical materials was 960 kg/kg. These data were confirmed as identical to those submitted to Germany for registration of rimsulfuron in the European Union. In the process of the comparison, two minor editorial errors in the impurity data submitted to FAO were corrected by the manufacturer.

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

The analytical method for determination of rimsulfuron has been subjected to collaborative study and was adopted by CIPAC in 2005. Test methods for determination of physico-chemical properties of the formulation are CIPAC, as indicated in the specification.

The proposed specifications for TC and WG complied with the requirements of the manual.

SUPPORTING INFORMATION

FOR

EVALUATION REPORT 716/2005

Patent and review status

Rimsulfuron is under patent in Australia, Austria, Belgium, Brazil, France, Germany, Greece, Hungary, Israel, Italy, Japan, Kazakstan, Luxembourg, Netherlands, Mexico, Russia, South Africa, South Korea, Spain, Sweden, Switzerland, United Kingdom and Ukraine until 2007. Rimsulfuron is also under patent in Chile, China, and Taiwan until 2005; Bulgaria, Yugoslavia, and Zimbabwe until 2008; and Canada, Portugal and USA until 2009.

Rimsulfuron has not been evaluated by the FAO/WHO, JMPR or IPCS. A complete EU dossier was submitted to Germany in 2001 and is currently under review by the European Commission.

Uses

Rimsulfuron is a herbicide, which affects sensitive weeds through inhibition of the plant enzyme acetolactate synthase (ALS), which then blocks the synthesis of essential, branched-chain amino acids. The first symptom of activity is in the meristematic tissues of sensitive species. Growth inhibition is followed by yellow and/or brown colouring and plant death.

It is used post-emergence in maize (corn) under field conditions against a variety of annual and perennial grasses and weeds.

Identity of the active ingredient

ISO common names

Rimsulfuron (BSI, E-ISO, ANSI)

Synonyms

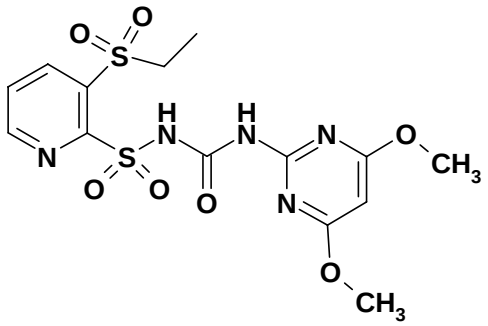
DPX-E9636, IN-E9636, Titus®

Chemical names

IUPAC 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-ethylsulfonyl-2-pyridylsulfonyl)urea

CA *N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-3-(ethylsulfonyl)-2-pyridinesulfonamide

Structural formula



Empirical formula

$C_{14}H_{17}N_5O_7S_2$

Relative molecular mass

431.40

CAS Registry number

122931-48-0

CIPAC number

716

Identity tests

HPLC retention time, IR spectrum.

Physico-chemical properties of rimsulfuron

Table 1. Physico-chemical properties of rimsulfuron

Parameter	Value(s) and conditions	Purity %	Method	Reference
Vapour pressure	$<10^{-5}$ Pa at 25°C (extrapolated)	99.23	Knudsen gas effusion method	1334-88.63-9
Melting point, boiling point and/or temperature of decomposition	Melting point: 172-173°C Boiling point: not applicable Decomposition temperature: decomposes at melting point	98.8	EEC A.1 capillary method, OECD 102; U.S. EPA OPPTS 830.7200	DuPont-3923
Relative density	1.50 g/cm^3 at 20°C	98.8	EEC A.3, OECD 109, pycnometer method, U.S. EPA OPPTS 830.7300	DuPont-3920
Solubility in water	0.135 g/l at 25°C at pH 5 7.30 g/l at 25°C at pH 7 5.56 g/l at 25°C at pH 9 0.0235 g/l at 20°C (distilled water)	99 98.8	U.S. EPA guidelines subdiv. D, series 63-8 EEC A.6, OECD 105; OPPTS 830.7840	1198-88 DuPont-4710
Octanol/water partition coefficient	K_{OW} at 25°C: 1.94 at pH 5 0.0344 at pH 7	96.23	U.S. EPA guidelines subdiv. D, series 63-11	1334-88.63-11

Table 1. Physico-chemical properties of rimsulfuron

Parameter	Value(s) and conditions	Purity %	Method	Reference
Hydrolysis characteristics	Half-life at 25°C: 4.7 d at pH 5 7.3 d at pH 7 4.2 h at pH 9 4.5 d at pH 5 7.1 d at pH 7 10.9 h at pH 9	99.6 (pyridine label) 98.6 (pyrimidine label)	U.S. EPA Guidelines Subdiv. D, Series 161-1	1221-88
Photolysis characteristics	Natural sunlight, half life: 1.1 d at pH 5 12.4 d at pH 7 12 h at pH 9 1.1 d at pH 5 11 d at pH 7 10.2 h at pH 9	99.6 (pyridine label) 98.6 (pyrimidine label)	U.S. EPA guidelines subdiv. N, series 161-2	1220-88
Dissociation characteristics	pKa = 4.0	99.3	OECD 112 U.S. EPA guidelines subdiv. N, series 63-10 spectrophotometric method	2031-91

Table 2. Chemical composition and properties of technical rimsulfuron (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 99.62–100.43%, no unknowns were detected.
Declared minimum rimsulfuron content	960 g/kg
Relevant impurities ≥ 1 g/kg and maximum limits for them	None
Relevant impurities < 1 g/kg and maximum limits for them	None
Stabilisers or other additives and maximum limits for them	None
Melting temperature of the TC	172-173°C (with decomposition)

Hazard summary

The proposer provided written confirmation that the toxicological and ecotoxicological data included in Annex 1 were derived from rimsulfuron having impurity profiles similar to those referred to in Table 2, above.

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

Rimsulfuron has been submitted to the European Commission in support of an application for inclusion of rimsulfuron in Annex I of Directive 91/414/EEC. In accordance with Directive 67/548/EEC, it is proposed that rimsulfuron should not be classified, which is consistent with the classification proposed in the notification document submitted under Article 4 of Commission Regulation 451/2000.

The WHO hazard classification of rimsulfuron is: U, unlikely to present acute hazard in normal use (WHO 2002).

Formulations

The main formulation type available is water dispersible granules (WG) and the formulations are registered and sold in many countries throughout the world.

Methods of analysis and testing

The analytical method for determination of rimsulfuron (including identity tests) reversed-phase HPLC, using UV detection at 254 nm and internal standardization with diphenyl sulfone. The method was adopted by CIPAC in 2005, for analysis of TC and WG.

The method for determination of impurities is based on reversed-phase HPLC, using UV detection at 230 nm and external standardization.

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

Physical properties

The physical properties, the methods for testing them and the limits proposed for the WG specification, comply with the requirements of the Manual (FAO/WHO 2002).

Containers and packaging

No special requirements for containers and packaging have been identified.

Expression of active ingredient

The active ingredient is expressed as rimsulfuron, in g/kg.

ANNEX 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER

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

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

Species	Test	Duration and conditions	Result	Reference
Rat, m & f	Acute oral	14 d. Rimsulfuron technical, 98.8% purity. EEC method B.1; Directive 92/69/EEC; USEPA subdiv. F, 81-1	LD_{50} >5000 mg/kg bw	757-88
Rabbit, NZ white, m & f	Acute dermal	14 d. Rimsulfuron technical 98.8% purity). EEC method B.3; Directive 92/69/EEC; USEPA subdiv. F, 81-2	LD_{50} >2000 mg/kg bw	745-88
Rat m & f	Acute inhalation	4 h. Rimsulfuron technical 98.8% purity. EEC method B.2; Directive 92/69/EEC; USEPA subdiv. F, 81-3	LC_{50} >5.4 mg/l	628-89 RV1
Rabbit, NZ white, m & f	Acute skin irritation	72 h. Rimsulfuron technical 98.8% purity. EEC method B.4; Directive 92/69/EEC; USEPA Subdiv. F, 81-5	Non-irritant	733-88
Rabbit, NZ white, m & f	Acute eye irritation	72 h. Rimsulfuron technical 98.8% purity. Directive 92/69/EEC; EEC method B.5	Non-irritant	712-88 SU1
Guinea pig, Duncan Hartley albino, m & f	Acute skin sensitization	48 h. Magnusson and Kligman method. Rimsulfuron technical 98.8% purity. EEC method B.6; OECD 406; Directive 92/69/EEC; USEPA subdiv. F, 81-6	Not a sensitizer	444-90 RV1

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

Species	Test	Duration and conditions	Result	Reference
Rat (Cr1:CD), m & f	Oral and reproductive toxicity (1 generation)*	90 d. Rimsulfuron technical 97.5% and 98.12% purity. USEPA subdiv. F, 82-1; Directive 87/302/EEC part B, 90-day oral rodent	NOEL = 50 ppm (3.35 & 4.11 mg/kg/day, m & f, respectively)	43-89 & 43-89 SU1
Mouse, Cr1:CD-1 (ICR), m & f	Oral	90 d. Rimsulfuron technical 97.5% and 98.12% purity, USEPA subdiv. F, 82-1 part B, 90-day oral rodent; Directive 87/302/EEC	NOAEL = 375 & 7500 ppm (56.0 & 1575 mg/kg bw/day, m & f, respectively	3-89
Dog (Beagle), m & f	Oral	90 d. Rimsulfuron technical 98.8% purity. USEPA subdiv. F, 82-1 part B, 90-day oral non-rodent; Directive 87/302/EEC	NOAEL = 250 ppm (9.63 & 10.6 mg/kg/day, m & f, respectively)	604-89

* The minimum requirements for EEC & USEPA guidelines were met. However, the study also included a 45-day clinical pathology examination and a satellite group of 10 rats/sex/dose as a 1-generation reproductive range-finding study. Following the 90-day feeding phase, these animals were mated and allowed to deliver offspring, which were observed through weaning.

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

Species	Test	Duration and conditions	Result	Reference
Dog (Beagle), m & f	Carcinogenicity	1 year. Rimsulfuron technical 98.8% purity. USEPA subdiv. F, 83-1 part B, chronic toxicity test non-rodent; Directive 87/302/EEC	NOAEL = 2500 ppm (81.8 & 86.5 mg/kg/day, m & f, respectively) Not carcinogenic	659-90; 659-90 SU1 & 659-90 SU2
Rat Cr1:CD® (BR), m & f	Carcinogenicity	2 year. Rimsulfuron technical 98.8% purity. USEPA subdiv. F, 83-5; OECD 453; Directive 87/302/EEC Part B	NOAEL = 300 ppm (m) (11.8 mg/kg bw/day) NOAEL = 3000 ppm (f) (163 mg/kg bw /day) Not carcinogenic	559-90 & 559-90
Mouse Cr1:CD®-1(ICR), m & f	Carcinogenicity	18-month. Rimsulfuron technical 98.8% purity. USEPA subdiv. F, 83-2; OECD 451; Directive 87/302/EEC part B	NOAEL = 2500 ppm (351 mg/kg bw/day (m), 488 mg/kg bw /day (f)) Not carcinogenic	732-90 RV1 & 732-90 SU1
Rat Cr1:CD® (BR), m & f	Teratogenicity	Rimsulfuron technical 98.8% purity. USEPA subdiv. F, 83-3; Directive 87/302/EEC part B, teratogenicity test in rodents	NOAEL = 2000 mg/kg bw/day maternal 6000 mg/kg bw/day foetal	170-89
Rabbit Hra: (NZW) SPF, f	Teratogenicity	Rimsulfuron technical 98.8% purity. USEPA subdiv. F, 83-3; Directive 87/302/EEC part B, teratogenicity test in non-rodent; OECD 414	NOAEL = 170 mg/kg by/day maternal NOAEL = 500 mg/kg bw/day foetal	403-89 & 403-89 SU1

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

Species	Test	Conditions	Result	Reference
Salmonella typhimurium	Mutagenicity	Rimsulfuron technical 99% purity. OECD 471; EEC Method B.14; Directive 92/69/EEC; U.S. EPA subdiv. F, 84-2	Negative	104-92
Chinese hamster ovary cells	CHO/HRPT gene mutation	Rimsulfuron technical 98.8% purity. U.S. EPA subdiv. F, 84-2; Directive 87/302/EEC *in vitro* mammalian cell mutation test	Negative with and without activation	423-89 RV1
Rat hepatocytes	*In vitro* unscheduled DNA synthesis (UDS)	Rimsulfuron technical 98.8% purity. U.S. EPA subdiv. F, 84-2; Directive 87/302/EEC part B - DNA damage repair - unscheduled DNA synthesis	UDS not observed	418-89 RV1
Human lymphocytes	*In vitro* gene mammalian cytogenetics	Rimsulfuron technical 98.8% purity. U.S. EPA subdiv. F, 84-2; EEC method B.10; Directive 92/69/EEC	Negative with and without activation	346-89 RV1

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

Species	Test	Conditions	Result	Reference
Mouse bone marrow micronucleus	*In vivo* somatic cell assay	Rimsulfuron technical 98.8% purity. U.S. EPA subdiv. F, 84-2; EEC method B.11; Directive 92/69/EEC	Negative	480-89

Table D. Ecotoxicology profile of rimsulfuron technical material

Species	Test	Duration and conditions	Result	Reference
Lepomis macrochirus (bluegill sunfish)	Acute	96 h, static. Rimsulfuron technical 98.8% purity. U.S. EPA subdiv. E, 72-1	LC_{50} >390 mg/l	352-89 RV1
Oncorhynchus mykiss (rainbow trout)	Acute	96 h, static. Rimsulfuron technical 98.8% purity. U.S. EPA subdiv. E, 72-1	LC_{50} >390 mg/l	351-89
Daphnia magna (water flea)	Acute toxicity	48 h, static. Rimsulfuron technical 98.8% purity U.S. EPA subdiv. E, 72-2	EC_{50} = 360 mg/l	350-89
Daphnia magna (water flea)	Chronic toxicity	21 d, static renewal (non-aerated). Rimsulfuron technical 98.8% purity. OECD Guideline 202; U.S. EPA subdiv. E, 72-4	EC_{50} = 450 mg/l NOEC = 0.82 mg/l[*] MATC = 5.6 mg/l	95-90 RV1
Oncorhynchus mykiss (rainbow trout)	Chronic toxicity	90 d, flow-through. Rimsulfuron technical 99% purity. OECD Guideline 210; U.S. EPA subdiv. E, 72-1	NOEC = 110 mg/l	507-94
Lemna minor (duckweed)	Growth and reproduction	14 d. Rimsulfuron technical 98.8% purity. FIFRA, subdiv. J, 122-2, 123-2; Draft OECD Guideline: duckweed, growth inhibition test (1981)	EC_{50} = 4.6 µg/l NOEC <1.0 µg/l	920708
Selenastrum capricornutum (green alga)	Growth and reproduction	120 h. Rimsulfuron technical 97% purity. OECD 201; FIFRA, subdiv. J, 123-2,122-2	Area under growth curve: EC_{50} = 1.6 mg/l NOEC = 0.625 mg/l Growth rate: EC_{50} = 2.8 mg/l NOEC = 0.625 mg/l	90466

[*] NOEC is based on adult immobility with 75% fiducial limits of 320 to 580 mg/l rimsulfuron technical.

Table D. Ecotoxicology profile of rimsulfuron technical material

Species	Test	Duration and conditions	Result	Reference
Anabaena flos-aquae (blue/green alga)	Growth and reproduction	96 h. Rimsulfuron technical 98.8% purity. U.S. EPA OPPTS 850.5400 (1996)	Cell density: EC_{50} = 2.0 mg/l NOEC = 0.45 mg/l Area under growth curve: EC_{50} = 1.9 mg/l NOEC = 0.90 mg/l Growth rate: EC_{50} = 5.2 mg/l NOEC = 0.45 mg/l	DuPont-3777
Eisenia foetida andrei (Earthworm)	Acute toxicity	14 d. Rimsulfuron technical 98.8% purity. OECD 207; EEC Guideline C(L1)4; Directive 79/831	LC_{50} >1000 mg/kg	E9636/ECO 1
Apis mellifera (honey bee)	Acute contact toxicity	48 h. Rimsulfuron technical 98.8% purity. FIFRA subdiv. L, series 141-1, hazard evaluation: non-target insects	LD_{50} >100 μg a.s./bee	267-89
Apis mellifera (honey bee)	Acute oral toxicity	48 h. Rimsulfuron technical 98.8% purity. FIFRA subdiv. L, series 141-1, hazard evaluation: non-target insects	LD_{50} >1000 mg a.s./bee	469-91
Colinus virginianus (bobwhite quail)	Acute oral toxicity	14 d. Rimsulfuron technical 98.8% purity. FIFRA subdiv. E, 71-1; hazard evaluation: wildlife and aquatic organisms	LD_{50} >2250 mg/kg bw LOEL >2250 mg/kg bw NOEL >2250 mg/kg	797-88
Anas platyrhynchos (mallard duck)	Acute oral toxicity	14 d. Rimsulfuron technical 98.8% purity. FIFRA subdiv. E, 71-1; hazard evaluation: wildlife and aquatic organisms	LD_{50} >2000 mg/kg bw LOEL >2000 mg/kg bw NOEL >2000 mg/kg	411-90
Colinus virginianus (bobwhite quail)	Dietary toxicity	5 d. Rimsulfuron technical 98.8% purity. FIFRA subdiv. E, 71-2; Hazard Evaluation: wildlife and aquatic organisms	LC_{50} >5620 ppm NOEC >5620 ppm	16-89
Anas platyrhynchos (mallard duck)	Dietary toxicity	5 d. Rimsulfuron technical 98.8% purity. FIFRA subdiv. E, 71-2; hazard evaluation: wildlife and aquatic organisms	LC_{50} >5620 ppm NOEC >5620 ppm	17-89

ANNEX 2. REFERENCES

Du Pont document No.	Year and title or published reference
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1198-88	1988. Determination of the solubility of DPX-E9636 in various organic solvents and aqueous organic systems at 25 plus/minus 1 degree C.
1220-88	1989. Photodegradation of [pyridine-2-^{14}C]DPX-E9636 and [pyrimidine-2-^{14}C]DPX-E9636 in water (conducted in sunlight).
1221-88	1989. Hydrolysis of [pyridine-2-^{14}C]DPX-E9636 and [pyrimidine-2-^{14}C]DPX-E9636 in buffer solutions of pH 5, 7 and 9.
1334-88.63-11	1989. n-Octanol/water partition coefficient determination of DPX-E9636 at pH 5 and pH 7.
1334-88.63-9	1989. Vapor pressure of DPX-E9636.
16-89	1988. A dietary LC_{50} study with the bobwhite.
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350-89	1989. Static acute 48-hour EC50a of DPX-E9636-22 to Daphnia magna.
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352-89 RV1	1990. Static acute 96-hour LC50a of DPX-E9636-22 to Bluegill Sunfish (Lepomis macrochirus).
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411-90	1990. An acute oral toxicity study with the mallard.
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43-89 & 43-89 SU1	1991. Subchronic oral toxicity: 90-Day study with IN-E9636-21 feeding study and one-generation reproduction study in rats.
444-90 RV1	1990. Maximization sensitization study (Magnusson-Kligman) with DPX-E9636-22 in Guinea pigs.
469-91	1991. A dietary LC_{50} toxicity study with the honey bee.
480-89	1989. Mouse bone marrow micronucleus assay of DPX-E9636-22.
507-94	1994. Early life-stage toxicity of DPX-E9636-22 (rimsulfuron) with Rainbow Trout, *Oncorhynchus mykiss*.
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604-89	1989. Subchronic oral toxicity: 90-Day study with IN-E9636-22 feeding study in dogs
628-89 RV1	1991. Acute inhalation toxicity study with DPX-E9636-22 (milled) in rats.
659-90; 659-90 SU1 & 659-90 SU2	1991. Chronic toxicity (1 year) oral toxicity study in the dog with IN-E9636-22 via the diet.
712-88 SU1	1990. Primary eye irritation study with DPX-E9636-22 in rabbits.
732-90 RV1 & 732-90 SU1	1991. Oncogenicity study with IN-E9636-22 eighteen-month feeding study in mice.
733-88	1988. Primary dermal irritation study with DPX-E9636-22 in rabbits.
745-88	1988. Acute dermal toxicity study of DPX-E9636-22 in rabbits.
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WHO 2002	The WHO recommended classification of pesticides by hazard and guidelines to classification, 2000-2002. WHO, Geneva, 2002.