

FAO SPECIFICATIONS AND EVALUATIONS FOR AGRICULTURAL PESTICIDES

RIMSULFURON

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

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DISCLAIMER¹

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

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

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

FAO disclaims any and all liability for any injury, death, loss, damage or other prejudice of any kind that may arise as a result of, or in connection with, the manufacture, sale, transportation, storage, handling, preparation and/or use of pesticides which are found, or are claimed, to have been manufactured to comply with these specifications.

Additionally, FAO wishes to alert users to the fact that improper storage, handling, preparation and/or use of pesticides can result in either a lowering or complete loss of safety and/or efficacy.

FAO is not responsible, and does not accept any liability, for the testing of pesticides for compliance with the specifications, nor for any methods recommended and/or used for testing compliance. As a result, FAO does not in any way warrant or represent that any pesticide claimed to comply with a FAO specification actually does so.

¹ This disclaimer applies to all specifications published by FAO.

INTRODUCTION

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

From 1999 onward, the development of FAO specifications follows the **New Procedure**, described first in the 5th edition of the "Manual on the development and use of FAO specifications for plant protection products" and later in the 1st edition of "Manual for Development and Use of FAO and WHO Specifications for Pesticides" (2002) - currently available as the 2nd edition of the "Manual on development and use of FAO and WHO specifications for chemical pesticides (2022)"-, which is available only on the internet through the FAO and WHO web sites.

This **New Procedure** follows a formal and transparent evaluation process. It describes the minimum data package, the procedure and evaluation applied by FAO and the Experts of the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS). [Note: prior to 2002, the Experts were of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent, which now forms part of the JMPM, rather than the JMPS.]

FAO Specifications now only apply to products for which the technical materials have been evaluated. Consequently, from the year 1999 onwards the publication of FAO specifications under the **New Procedure** has changed. Every specification consists now of two parts namely the specifications and the evaluation report(s):

Part One: **The Specification** of the technical material and the related formulations of the pesticide in accordance with chapters 4 to 8 of the "Manual on development and use of FAO and WHO specifications for chemical pesticides".

Part Two: The Evaluation Report(s) of the pesticide, reflecting the evaluation of the data package carried out by FAO and the JMPS. The data are provided by the manufacturer(s) according to the requirements of chapter 3 of the "FAO/WHO Manual on Pesticide Specifications" and supported by other information sources. The Evaluation Report includes the name(s) of the manufacturer(s) whose technical material has been evaluated. Evaluation reports on specifications developed subsequently to the original set of specifications are added in a chronological order to this report.

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

Specifications bear the date (month and year) of publication of the current version. Evaluations bear the date (year) of the Meeting at which the recommendations were made by the JMPS.

^{*} NOTE: PUBLICATIONS ARE AVAILABLE ON THE INTERNET at <a href="http://www.fao.org/pest-and-pesticide-management/guidelines-standards/faowho-joint-meeting-on-pesticide-specifications-joint-meeting-on-pesticide-specification-specification-specification-specification-specification-spe

PART ONE

SPECIFICATIONS

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RIMSULFURON

INFORMATION

ISO common name

Rimsulfuron (BSI, E-ISO, ANSI)

Synonyms

DPX-E9636, IN-E9636, Titus®

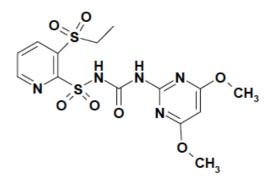
Chemical names

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



Molecular formula C₁₄H₁₇N₅O₇S₂

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 (July 2023*)

This specification, which is PART ONE of this publication, is based on an evaluation of data submitted by the manufacturers whose name are listed in the evaluation reports (716/2005 & 716/2023). 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 reports (716/2005 & 716/2023) as PART TWO form 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 M, p. 190, 2009)

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 M, p. 190, 2009)

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.

^{*} 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/

RIMSULFURON WATER DISPERSIBLE GRANULES

FAO Specification 716 / WG (July 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 (716/2005 & 716/2023). 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 reports (716/2005 & 716/2023) as PART TWO form an integral part of this publication.

1 Description

The material shall consist of a homogeneous mixture of technical rimsulfuron, complying with the requirements of FAO specification 716/TC (July 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 (716/WG/M/2, CIPAC Handbook M, p. 193, 2009)

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 M, p. 193, 2009) (Note 1)

The rimsulfuron content shall be declared (above 100 up to 250 g/kg) and, when determined, the average measured content shall not differ from that declared by more than ± 6% of the declared content.

3 Physical properties

3.1 **Wettability** (MT 53.3, CIPAC Handbook F, p. 165, 1995)

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

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)

Dispersibility: minimum 70% after 2 min 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)
 - Minimum: 70% after 30 min in CIPAC Standard Water D at 30 ± 2°C.
- 3.5 **Persistent foam** (MT 47.3, CIPAC Handbook O, p. 177, 2017) (Note 3)

Maximum: 60 ml after 1 min.

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

Essentially non-dusty.

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

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 46.4, CIPAC Handbook P, p. 232, 2021)

After storage at $54 \pm 2^{\circ}$ C for 14 days, the determined average active ingredient content must not be lower than 95% relative to the determined average content found before storage (Note 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 analyzed concurrently after the test in order to reduce the analytical error.

PART TWO

EVALUATION REPORT

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RIMSULFURON

FAO/WHO EVALUATION REPORT 716/2023

Recommendations

The Meeting recommended the following:

- (i) The change of manufacturer of the FAO reference specifications for rimsulfuron TC and WG from E.I. DuPont de Nemours & Co. to Corteva Agriscience should be noted by FAO.
- (ii) The editorially updated FAO specifications for rimsulfuron TC and WG, as confirmed by Corteva Agriscience, should be adopted by FAO.

Appraisal

The Meeting noted that Corteva Agriscience (Corteva) has been formed from the merger of Dow and DuPont in 2017 and became a standalone company in June 2019². The intellectual property rights for rimsulfuron and its formulations previously owned by E.I. DuPont (DuPont) then was integrated into the portfolio of Corteva Agriscience. Its predecessor company, DuPont, had been the proposer and holder of the FAO reference specifications for rimsulfuron TC and WG (FAO/WHO Evaluation Report 716/2005).

As such a transition may raise certain concerns on the continued validity of the FAO specifications for rimsulfuron technical material and formulations (see also Manual on the development and use of FAO and WHO specifications for chemical pesticides, Sections 2.7 and 3.6 on revision of specifications), Corteva was contacted by FAO and a statement on the support of the reference specifications and possible changes therein was requested.

Corteva later on provided a confirmation in writing (Corteva, 2023³) to FAO confirming the continued support for the FAO reference specifications for rimsulfuron TC and WG. Corteva explained, that there were additional manufacturing sites that represent the current manufacturing process and specifications, and that the manufacturing sites and -process for rimsulfuron were not affected by the transition from DuPont to their company. Corteva confirmed the continued validity of the published specifications and stewardship for them.

For these reasons, the Meeting recommended that Corteva should be noted as new holder of the reference specifications for rimsulfuron TC and WG.

² https://www.corteva.ca/en/about-corteva/our-history.html

³ Letter from Jennifer Jones, Corteva, dated July 20, 2023

The Meeting also noted, that the specifications needed some editorial update with regard to analytical and physical-chemical test methods.

The FAO specifications for rimsulfuron TC and WG were considered to require an editorial update as follows :

- TC and WG: The CIPAC analytical methods for determination of rimusulfuron in TC and WG are published in Handbook M. The correct references for identity tests and determination of the content of rimsulfuron were inserted.
- WG specification: certain CIPAC methods like suspensibility (MT 184), persistent foam (MT 47.2), dustiness (MT 171), flowability (MT 172) and stability at elevated temperature (MT 46.3) are available in newer versions that provide equivalent results and are published in recent Handbooks. For these methods, the newer versions for suspensibility (MT 184.1), persistent foam (MT 47.3), dustiness (MT 171.1), flowability (MT 172.2) and accelerated storage stability (MT 46.4) with their corrected footnotes were introduced, but no limits or conditions were changed. In addition, some clauses to be tested after the accelerated test were incorrectly referenced and corrected, and footnotes were adjusted as needed.

The updated and confirmed specifications comply with the latest edition (2022) of the Manual on specifications for chemical pesticides, and the Meeting therefore recommended to FAO to adopt the 2023 specifications for rimsulfuron TC and WG.

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°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 C₁₄H₁₇N₅O₇S₂

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	99	U.S. EPA guidelines subdiv. D, series 63-8 EEC A.6, OECD	1198-88
	0.0235 g/l at 20°C (distilled water)	98.8	105; OPPTS 830.7840	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
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	99.6 (pyridine label)	U.S. EPA Guidelines Subdiv. D, Series 161-1	1221-88
	4.5 d at pH 5 7.1 d at pH 7 10.9 h at pH 9	98.6 (pyrimidin e label)		
Photolysis characteristics	Natural sunlight, half life: 1.1 d at pH 5 12.4 d at pH 7 12 h at pH 9	99.6 (pyridine label)	U.S. EPA guidelines subdiv. N, series 161-2	1220-88
	1.1 d at pH 5 11 d at pH 7 10.2 h at pH 9	98.6 (pyrimidin e label)		
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).

Cont	ainers	and	packa	aina
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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
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 nonrodent; OECD 414	NOAEL = 170 mg/kg by/day maternal NOAEL = 500 mg/kg bw/day foetal	403-89 & 403-89 SU1

^{*} 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 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 <i>in</i> <i>vitro</i> 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 observe d	418-89 RV1
Human lymphocytes	In vitro gene mamm alian	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
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: $EC_{50} = 1.6 \text{ mg/l}$ $NOEC = 0.625 \text{ mg/l}$ $Growth \text{ rate:}$ $EC_{50} = 2.8 \text{ mg/l}$ $NOEC = 0.625 \text{ mg/l}$	90466
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: $EC_{50} = 2.0 \text{ mg/l}$ NOEC = 0.45 mg/l Area under growth curve: $EC_{50} = 1.9 \text{ mg/l}$ NOEC = 0.90 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

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

				Page 20 d
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
104-92	1991. Mutagenicity testing of DPX-E9636-22 in the Salmonella typhimurium plate incorporation assay.
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.
170-89	1989. Teratogenicity study of IN-E9636-22 in rats.
17-89	1988. A dietary LC ₅₀ study with the mallard.
2031-91	1989. Dissociation constant of DPX-E9636 in water.
267-89	1989. An acute contact toxicity study with the honey bee.
346-89 RV1	1990. <i>In vitro</i> evaluation of DPX-E9636-22 for chromosome aberrations in human lymphocytes.
350-89	1989. Static acute 48-hour EC50a of DPX-E9636-22 to Daphnia magna.
351-89	1989. Static acute 96-hour LC_{50} a of DPX-E9636-22 to Rainbow Trout (Salmo gairdneri).
352-89 RV1	1990. Static acute 96-hour LC50a of DPX-E9636-22 to Bluegill Sunfish (Lepomis macrochirus).
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403-89 & 403-89 SU1	1991. Teratogenicity study of IN-E9636-22 in rabbits
411-90	1990. An acute oral toxicity study with the mallard.
418-89 RV1	1990. Assessment of DPX-E9636-22 in the <i>in vitro</i> unscheduled DNA synthesis assay in primary rat hepatocytes.
423-89 RV1	1990. Mutagenicity evaluation of DPX-E9636-22 in the CHO/HPRT assay.
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, <i>Oncorhynchus mykiss</i> .
559-90 & 559-90	1991. Combined chronic toxicity/oncogenicity study with IN-E9636-22 two-year feeding study in rats.
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.
757-88	1988. Acute oral toxicity study with DPX-E9636-2 in male and female rats.

Du Pont document No.	Year and title or published reference
797-88	1988. An acute oral toxicity study with the bobwhite.
90466	1990. The algistatic activity of DPX-E9636 technical.
920708	1992. DPX-E9636-22 technical: An assessment of the inhibitory effect on the growth of duckweed (<i>Lemna minor</i>).
95-90 RV1	1990. Chronic toxicity of IN-E9636-22 to Daphnia magna, DuPont Haskell Laboratory, HLR 95-90 RV1, 5-Nov-90. Unpublished.
DuPont-3777	2000. Rimsulfuron technical: Influence on growth and growth rate of the blue-green alga <i>Anabaena flos-aquae</i> .
DuPont-3920	2000. Determination of density for rimsulfuron (DPX-E9636).
DuPont-3923	2001. Determination of melting point/melting range for rimsulfuron (DPX-E9636).
DuPont-4710	2000. Solubility of rimsulfuron (DPX-E9636) in water.
E9636/ECO 1	1990. DPX-E9636: Determination of toxicity to the earthworm <i>Eisenia foetid</i> .
FAO/WHO 2002	Manual on Development and use of FAO and WHO specifications, 1 st edition. FAO plant production and protection paper 173. FAO, Rome, 2002.
WHO 2002	The WHO recommended classification of pesticides by hazard and guidelines to classification, 2000-2002. WHO, Geneva, 2002.