FAO SPECIFICATIONS AND EVALUATIONS FOR AGRICULTURAL PESTICIDES

MEFENPYR-DIETHYL

Diethyl (*R,S*) 1-(2,4-dichlorophenyl)-5-methyl-2-pyrazoline-3,5-dicarboxylate

FOOD AND AGRICULTURE ORGANIZATION *of* THE UNITED NATIONS

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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.

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.

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/agriculture/crops/core-themes/theme/pests/pm/jmps/en/

PART ONE

SPECIFICATIONS

MEFENPYR-DIETHYL

INFORMATION

ISO common names

mefenpyr (ISO 1750, published, referring to the racemate),
variant: mefenpyr-diethyl (modified ISO 1750, published)

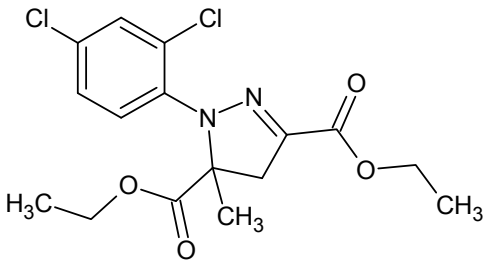
Chemical names

IUPAC: Diethyl (*R,S*) 1-(2,4-dichlorophenyl)-5-methyl-2-pyrazoline-3,5-dicarboxylate
CA: 1-(2,4-dichlorophenyl)-4,5-dihydro-5-methyl-1*H*-pyrazole-3,5-dicarboxylic acid, diethyl ester

Synonyms

AE F107892

Structural formula



Molecular formula

$C_{16}H_{18}Cl_2N_2O_4$

Relative molecular mass

373.2

CAS Registry numbers

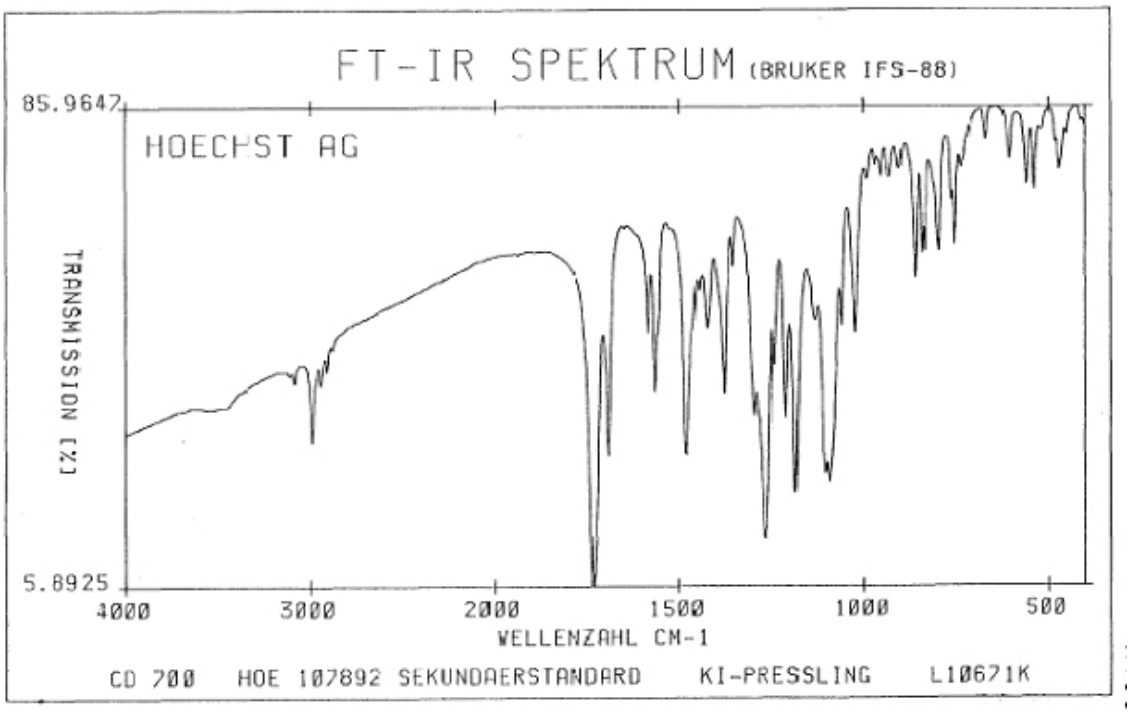
mefenpyr-diethyl:	135590-91-9 (racemate)
mefenpyr:	135591-00-3

CIPAC numbers

mefenpyr-diethyl:	651.229
mefenpyr:	651

Identity tests: retention time in HPLC, UV spectrum

IR-Spectrum



MEFENPYR-DIETHYL TECHNICAL MATERIAL

FAO Specification 651.229/TC (May 2011*)

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 (651.229/2010). 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 (651.229/2010) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of mefenpyr-diethyl together with related manufacturing impurities, in the form of white to beige crystalline powder, and shall be free from visible extraneous matter and added modifying agents.

2 Active ingredient

2.1 **Identity tests** (CIPAC CIPAC/4627/A, Note 1)

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

2.2 **Mefenpyr-diethyl content** (CIPAC CIPAC/4627/A, Note 1)

The mefenpyr-diethyl content shall be declared (not less than 940 g/kg) and, when determined, the average measured content shall not be lower than the declared minimum content.

3 **Relevant impurities** (Note 2)

Note 1: The reversed phase HPLC method (CIPAC/4627/A) for the determination of mefenpyr-diethyl in TC, and the normal phase HPLC method (CIPAC/4627/B) for the determination of mefenpyr-diethyl in WG, OD, EW and EC were adopted by CIPAC in 2008. Prior to their publication in Handbook N, copies of the methods may be obtained through http://www.cipac.org/cipacpub.htm

Note 2 There are no relevant impurities to be controlled in products of the manufacturer identified in evaluation report 651.229/2010. However, ethyl-2-chloro-2-(2,4-dichloro-phenyl-hydrazono)acetate may occur as a result of certain manufacturing processes. If this impurity would occur at ≥ 1 mg/kg (relative to mefenpyr-diethyl) in the products of other manufacturers, it would be designated as relevant impurity and a clause would be required to limit its concentration.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/ps/en/

MEFENPYR-DIETHYL EMULSIFIABLE CONCENTRATE

FAO Specification 651.229/EC (May 2011*)

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 (651.229/2010). 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 (651.229/2010) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of technical mefenpyr-diethyl, complying with the requirements of FAO specification 651.229/TC (May 2011), dissolved in suitable solvents, together with active substance(s) and any other necessary formulants. It shall be in the form of a stable homogeneous liquid, free from visible suspended matter and sediment, to be applied as an emulsion after dilution in water.

2 Active ingredient

2.1 **Identity tests** (CIPAC CIPAC/4627/B, Note 1)

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

2.2 **Mefenpyr-diethyl content** (CIPAC CIPAC/4627/B, Note 1)

The mefenpyr-diethyl content shall be declared (g/kg or g/l at 20 ± 2ºC, Note 2) and, when determined, the average content measured shall not differ from that declared by more than the following tolerances:

Declared content in g/kg or g/l at 20 ± 2°C	Tolerance
up to 25	± 15 % of the declared content
above 25 up to 100	± 10 % of the declared content
Note In each range the upper limit is included	

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/ps/en/

3 Physical properties

3.1 **Emulsion stability and re-emulsification** (MT 36.3, CIPAC Handbook K, p. 136, 2003)

The formulation, when diluted at 30 ± 2°C (Note 3) with CIPAC Standard Waters A and D, shall comply with the following:

Time after dilution	Limits of stability, MT 36.3
0 h	Initial emulsification complete
0.5 h	"Cream", maximum: 2 ml
	"Free oil", maximum: traces
2 h	“Free oil”: maximum traces
24 h	Re-emulsification complete
24.5 h	"Cream", maximum: 2 ml
	"Free oil", maximum: traces

3.2 **Persistent foam** (MT 47.2, CIPAC Handbook F, p. 152, 1995) (Note 4)

Maximum: 40 ml after 1 min.

4 Storage stability

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

After storage at 0 ± 2°C for 7 days, the volume of solid and/or liquid which separate shall not be more than 0.3 ml.

4.2 **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 content of mefenpyr diethyl 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 clause for:

- emulsion stability and re-emulsification (3.1).

Note 1: The reversed phase HPLC method (CIPAC/4627/A) for the determination of mefenpyr-diethyl in TC, and the normal phase HPLC method (CIPAC/4627/B) for the determination of mefenpyr-diethyl in WG, OD, EW and EC formulations were adopted by CIPAC in 2008. Prior to their publication in Handbook N, copies of the methods may be obtained through http://www.cipac.org/cipacpub.htm

Note 2 If the buyer requires both g/kg and g/l at 20°C, then in case of dispute the analytical results shall be calculated as g/kg.

Note 3 Unless another temperature is specified.

Note 4 The mass of sample to be used in the test should correspond to the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.

Note 5 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.

MEFENPYR-DIETHYL EMULSION, OIL IN WATER

FAO Specification 651.229/EW (May 2011*)

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 (651.229/2010). 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 (651.229/2010) as PART TWO forms an integral part of this publication.

1 Description

The formulation shall consist of an emulsion of technical mefenpyr-diethyl, complying with the requirements of FAO specification 651.229/TC (May 2011), in an aqueous phase together with active substance(s) and suitable formulants. After gentle agitation, the formulation shall be homogeneous (Note 1) and suitable for dilution in water.

2 Active ingredient

2.1 **Identity tests** (CIPAC CIPAC/4627/B, Note 2)

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

2.2 **Mefenpyr-diethyl content** (CIPAC CIPAC/4627/B, Note 2)

The mefenpyr-diethyl content shall be declared (g/kg or g/l at 20 ± 2ºC, Note 3) and, when determined, the average content measured shall not differ from that declared by more than the following tolerances:

Declared content in g/kg or g/l at 20 ± 2°C	Tolerance
up to 25	± 15 % of the declared content
above 25 up to 100	± 10 % of the declared content
Note In each range the upper limit is included	

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/ps/en/

3 Physical properties

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

pH range: 6.5 to 8.5

3.2 **Pourability** (MT 148.1, CIPAC Handbook J, p. 133, 2000)

Maximum "residue": 9 %
Maximum rinsed residue: 0.5 %

3.3 **Emulsion stability and re-emulsification** (MT 36.3, CIPAC Handbook K, p.136, 2003)

The formulation, when diluted at 30 ± 2°C (Note 4) with CIPAC Standard Waters A and D, shall comply with the following:

Time after dilution	Limits of stability, MT 36.3
0 h	Initial emulsification complete
0.5 h	"Cream", maximum: 2 ml
	"Free oil", maximum: traces
2 h	"Free oil", maximum: traces
24 h	Re-emulsification complete
24.5 h	"Cream", maximum: 2 ml
	"Free oil", maximum: traces

3.4 **Persistent foam** (MT 47.2, CIPAC Handbook F, p. 152, 1995) (Note 5)

Maximum: 60 mL after 1 min.

4 Storage stability

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

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

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

After storage 54 ± 2°C for 14 days, the determined average content of mefenpyr-diethyl must not be lower than 95 % relative to the determined average content found before storage (Note 6) and the formulation shall continue to comply with the clauses for:
- pH range (3.1),
- emulsion stability and re-emulsification (3.3).

Note 1 All physical and chemical tests listed in this specification are to be performed with a laboratory sample taken after the recommended homogenization procedure.
Before sampling to verify the formulation quality, the commercial container must be inspected carefully. On standing, emulsions may develop a concentration gradient which

could even result in the appearance of a clear liquid on the top (sedimentation of the emulsion) or on the bottom (creaming up of the emulsion). Therefore, before sampling, the formulation must be homogenized according to the instructions given by the manufacturer or, in the absence of such instructions, by gentle shaking of the commercial container (for example, by inverting the closed container several times). Large containers must be opened and stirred adequately.

Note 2 The reversed phase HPLC method (CIPAC/4627/A) for the determination of mefenpyr-diethyl in TC, and the normal phase HPLC method (CIPAC/4627/B) for the determination of mefenpyr-diethyl in WG, OD, EW and EC were adopted by CIPAC in 2008. Prior to their publication in Handbook N, copies of the methods may be obtained through http://www.cipac.org/cipacpub.htm

Note 3 If the buyer requires both g/kg and g/l at 20°C, then in case of dispute the analytical results shall be calculated as g/kg.

Note 4 Unless another temperature is specified.

Note 5 The mass of sample to be used in the test should correspond to the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D.

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.

MEFENPYR-DIETHYL WATER DISPERSIBLE GRANULES

FAO specification 651.229/WG (May 2011*)

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 (651.229/2010). 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 (651.229/2010) as PART TWO forms an integral part of this publication.

1 Description

The material shall consist of an homogeneous mixture of technical mefenpyr-diethyl, complying with the requirements of the FAO specification 651.229/TC (May 2011), together with active substance(s), carriers and other necessary formulants. It shall be in the form of granules from light beige to brown colour 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** (CIPAC CIPAC/4627/B, Note 1)

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

2.2 **Mefenpyr-diethyl content** (CIPAC CIPAC/4627/B, Note 1)

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

Declared content in g/kg at 20 ± 2°C	Tolerance
above 25 up to 100	±10% of the declared content
above 100 up to 250	± 6% of the declared content
Note In each range the upper limit is included	

3 Physical properties

3.1 **Wettability** (MT 53.3, CIPAC Handbook F, p. 164, 1995)

The formulation shall be completely wetted in 30 sec without swirling.

* Specifications may be revised and/or additional evaluations may be undertaken. Ensure the use of current versions by checking at: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/ps/en/

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

The formulation shall be completely wetted in 30 sec without swirling.

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

Dispersibility: minimum 90 % after 1 minute of stirring.

3.4 **Suspensibility** (MT 184, CIPAC Handbook K, p. 142, 2003) (Note 2 & 3)

A minimum of 75 % shall be in suspension after 30 min in CIPAC Standard Water D at 30 ± 2°C.

3.5 **Persistent foam** (MT 47.2, CIPAC Handbook F, p. 152, 1995) (Note 4)

Maximum: 20 ml after 1 minute.

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

Essentially non-dusty.

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

At least 98 % of the formulation shall pass through a 5 mm test sieve after 20 drops of the sieve.

4.8 **Attrition resistance** (MT 178.2, CIPAC Handbook K, p. 140, 2003)

Minimum: 98 % attrition resistance.

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 content of mefenpyr-diethyl must not be lower than 95 % relative to the determined average content found before storage (Note 6) and the formulation shall continue to comply with the clauses for:

- wet sieve test (3.2),
- degree of dispersion (3.3),
- suspensibility (3.4),
- dustiness (3.6),
- attrition resistance (3.8).

Note 1 The reversed phase HPLC method (CIPAC/4627/A) for the determination of mefenpyr-diethyl in TC, and the normal phase HPLC method (CIPAC/4627/B) for the determination of mefenpyr-diethyl in WG, OD, EW and EC were adopted by CIPAC in 2008. Prior to their publication in Handbook N, copies of the methods may be obtained through http://www.cipac.org/cipacpub.htm

Note 2 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.

Note 3 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. In case of dispute, chemical assay shall be the "referee method".

Note 4 The mass of sample to be used in the test should be specified at the highest rate recommended by the supplier. The test is to be conducted in CIPAC standard water D.

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

171.2, usually shows good correlation with the gravimetric method, MT 171.1, 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 Analysis of the formulation, before and after the storage stability test, should be carried out concurrently (i.e. after storage) to reduce analytical error.

PART TWO

EVALUATION REPORTS

MEFENPYR-DIETHYL

MEFENPYR-DIETHYL

FAO/WHO EVALUATION REPORT 651.229/2010

Recommendations

The meeting recommended that:

(i) the specifications for mefenpyr-diethyl TC, EC, EW and WG formulations, proposed by Bayer CropScience, as amended, should be adopted by FAO.

Appraisal

Data for mefenpyr-diethyl were submitted by Bayer CropScience in support of new FAO specifications for TC, EC, EW and WG formulations in December 2007, with certain amendments in November 2010.
Mefenpyr-diethyl is not an active ingredient, but a safener for use in combination with certain herbicides. It is under patent in several European countries, Canada, Australia and Russia until 2010 and in the USA until 2014.
Mefenpyr-diethyl has not been evaluated by the FAO/WHO JMPR and WHO/IPCS. It was evaluated under national regulations in several European countries and US EPA under TSCA[2].
The meeting was provided with commercially confidential information of the manufacturing process for mefenpyr-diethyl, the manufacturing specifications for the TC and the 5-batch analytical data on the purity and impurities ≥ 1 g/kg. Mass balances were high (98.5 to 99.4 %), but enclosed in this is a percentage of 1.1 to 1.6 % of a fraction of unidentified high boiling compounds. The manufacturer has initiated studies to identify these compounds. No further compounds at concentrations ≥ 0.1 % were identified.
The data were identical to those submitted in Germany, but due to the fact that mefenpyr-diethyl is not an active substance, the latest data were not evaluated for national authorisation.
The Meeting agreed that none of the impurities should be designated as relevant in specifications. One potentially relevant impurity was identified. The studies to support this were simultaneously submitted in Germany for evaluation and the impurity ethyl-2-chloro-2-(2,4-dichloro-phenyl-hydrazono)acetate was found to be skin sensitizing and genotoxic (in vitro). The content of this impurity in the submitted batches and in quality control is below the limit of quantification of 1.0 ppm. As stipulated in the specification Manual, a precautionary footnote was added in the TC specification.

The molecule of mefenpyr-diethyl carries an asymmetrically substituted carbon atom, C 5. The compund is produced as a racemate. It is a white crystalline solid which melts at 50-52 °C. The water solubility is low (20 mg/L). At high pH values ester hydrolysis will occur, while at pH 4 and 5 hydrolysis is slow. The solubility in organic

[2] TSCA:Toxic Substances Control Act: US-American law to regulate chemicals registration. Mefenpyr has been evaluated under TSCA (including setting of MRLs) rather than under the FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) as a plant protection product.

solvents is moderate in low polarity solvents (n-hexane, sesame oil) to high in polar solvents like methanol.
The safener has some surface active properties, so the conventional shake flask method according to OECD Guideline 107 is not properly applicable. The experimentally determined partition coefficient K_{ow} is around 6800 (P_{ow} = 3.8). The calculated value using a modelling software are in the same order of magnitude (3.24 $\pm$ 0.65). The degradation by photolysis is moderately slow, due to the low quantum yield.
The proposed specifications are generally in accordance with the requirements of the manual (FAO/WHO, 2006 and 2010).
In all specifications the term "active ingredient" was replaced by "safener", as mefenpyr-diethyl is not a proper active ingredient.
The Meeting noticed that OD formulations seem to be a prominent formulation type among the products registered in different countries and asked for a specification for this formulation type. Bayer CropScience agreed to consider an extension for OD formulations, as soon as the product range has been finalized.

Issues specific for certain formulation types only:
EW: A clause for the pH range was considered necessary in the specification because of the limited stability of mefenpyr-diethyl at high and low pH respectively and because the safener is always coformulated with active ingredient, which might also be sensitive to pH. The Meeting noticed that at pH 9 mefenpyr-diethyl undergoes rapid hydrolysis (half life about 0.3 days), so the specified upper pH limit of 8.5 is questionable, even when taking into account the low water solubility of mefenpyr-diethyl of 20 mg/L. The guideline maximum limit of 60 mL foam after one minute is needed because of the variety of products containing mefenpyr diethyl and is supported by data submitted by the manufacturer.
A rinsed residue of 0.5 % is specified, while the stated method MT 148.1 determines no rinsed residue and the basic principle of the Manual is not to specify a rinsed residue due to the lack of an appropriate method. The Meeting suggested following the description in MT 148 to determine the rinsed residue, if this is considered necessary.

For obvious reasons mefenpyr-diethyl as safener is always coformulated with certain herbicide active ingredients. For these “multi active ingredients”-formulation the procedures described in the 2010 Revision of the FAO/WHO Manual (introduction to chapter 4) do apply.

The analytical methods for determination of mefenpyr-diethyl (including identity tests) consist of two separate methods: the TC method is based on reversed phase HPLC using a C_{18}-substituted silica column and UV detection at 300 nm with external standardization (CIPAC/4627/A). The methods for determination of the safener in the formulations (EC, EW, OD and WG) are based on normal phase chromatography on silicagel with UV detection at 227 nm (CIPAC/4627/B) with external standardization as well. Both methods are available through the CIPAC prepublication scheme before their inclusion in Handbook N: both methods are full CIPAC methods..

SUPPORTING INFORMATION

FOR

EVALUATION REPORT 651.229/2010

USES

Mefenpyr-diethyl is not an active substance but is used as a safener in combination with certain herbicides like fenoxaprop-P-ethyl (acetyl-CoA-carboxylase inhibitor) and sulfonylureas e.g. iodosulfuron-methyl-sodium and mesosulfuron-methyl (both are ALS-inhibitors), for improving the tolerance of e.g. cereal crops to these herbicides. The mode of action is to induce e.g. monooxygenase systems contributing to enhanced metabolization of the herbicides in crops but interestingly not in weed species.

IDENTITY OF THE SAFENER

ISO common name

mefenpyr (ISO 1750 published, refers to the racemate),
Variant: mefenpyr-diethyl (modified ISO 1750 published; the diethyl ester of mefenpyr)

Chemical name(s)

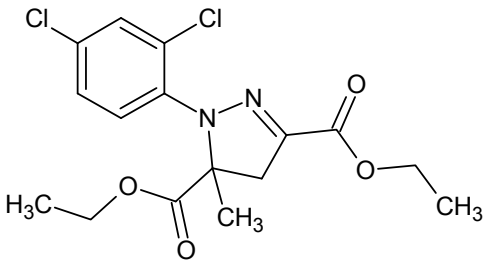
IUPAC: Diethyl (*R,S*) 1-(2,4-dichlorophenyl)-5-methyl-2-pyrazoline-3,5-dicarboxylate

CA: 1-(2,4-dichlorophenyl)-4,5-dihydro-5-methyl-1*H*-pyrazole-3,5-dicarboxylic acid, diethyl ester

Synonyms

AE F107892

Structural formula



Molecular formula

$C_{16}H_{18}Cl_2N_2O_4$

Relative molecular mass

373.2

CAS Registry numbers

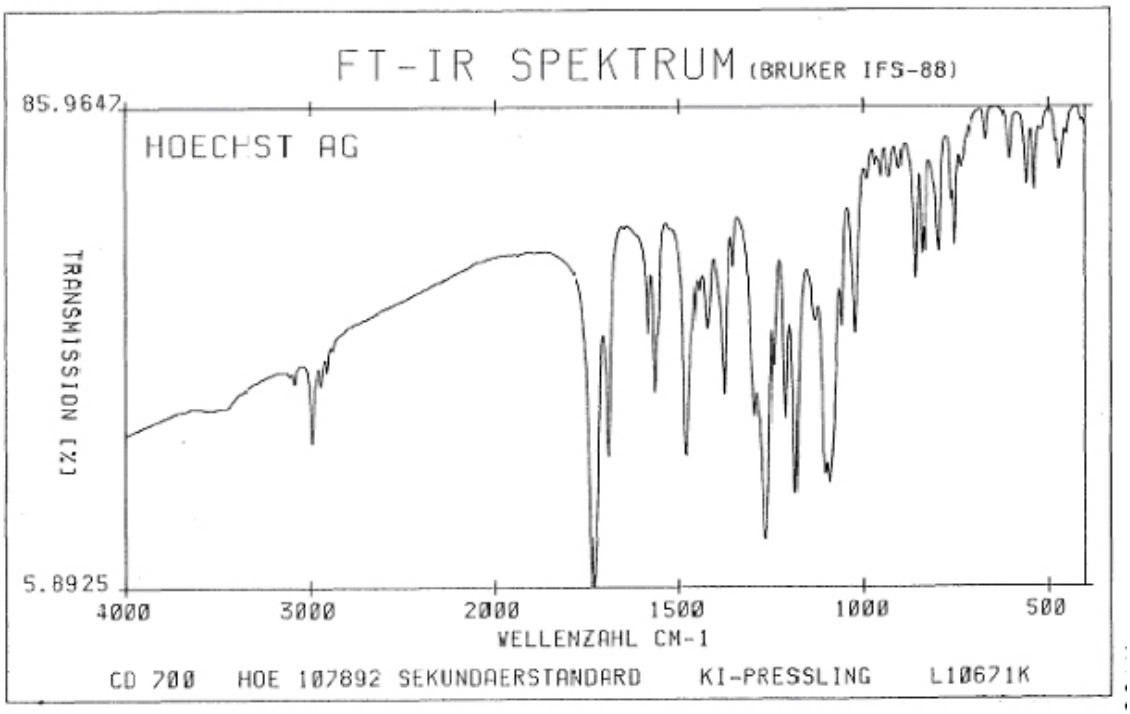
mefenpyr-diethyl: 135590-91-9 (racemate)
mefenpyr: 135591-00-3

CIPAC numbers

mefenpyr-diethyl:	651.229
mefenpyr:	651

Identity tests: Retention time in HPLC, UV spectrum.

IR-Spectrum



PHYSICAL AND CHEMICAL PROPERTIES

Table 1. Physico-chemical properties of pure mefenpyr-diethyl

Parameter	Value(s) and conditions	Purity %	Method	Reference
Vapour pressure	< 6.3 x 10^{-6} Pa at 20 °C (extrapolated) < 1.4 x 10^{-5} Pa at 25 °C (extrapolated) based on measurements at 68 ... 127 °*C (above melting point)*	99.2	EEC A4 vapour pressure balance	M-129281-01-2
Melting point, boiling point	Melting point: 50 - 52 °C	99.2	DSC[3]	M-135569-01-1
Temperature of decomposition	260 °C	99.4	DSC	M-227502-01-1
Solubility in water	20 mg/L at 20 °C (pH 6.2)	99.2	OECD 105	M-127649-01-1
Octanol/water partition coefficient	log P_{OW} = 3.83 at 21 °C (pH 6.3) log P_{OW} = 3.24 ± 0.65 ([1]) (pH 4 ... 10)	99.2 -	OECD 107 Shake flask method Statement, calculated by modelling software	M-127650-01-1 M-234869-01-1
Hydrolysis characteristics	Half-life at 25 °C: > 365 days at pH 4 > 365 days at pH 5 40.9 days at pH 7 0.35 days at pH 9 Hydrolysis at 25 °C in sterile buffer solution: 4 % after 30 d at pH 4, 3,5 ... 5 % after 30 d at pH 5 39 ... 67 % after 30 d at pH 7 86 % after 1 d at pH 9. Concentrations: 0.01, 0.1 and 0.2 mol/L	99.2	EPA, Subdivision N, § 161-1	M-131836-01-1
Photolysis characteristics	Photolysis under sterile conditions (pH 5.1, concentration 9.3 mg/L, 25 °C): Half-life SunTest II = 193.5 h Half-life SunTest III = 200 h Half-live estimated at 3 times the intensity of sunlight in June at 52° North, sea level	radio-chemical purity > 98.0	EPA, Subdivision N, § 161-2	M-133945-01-1

[3] DSC: Differential Scanning Calorimetry

Dissociation characteristics	Does not dissociate	-	Statement	M-129803-01-1
Solubility in organic solvents	35 g/L in n-hexane 56 g/L in sesame oil 151 g/L in 2-propanol 151 g/L in polyethylene glycol > 400 g/L in toluene > 400 g/L in methanol > 400 g/L in ethylacetate > 500 g/L in dichloromethane > 500 g/L in acetone > 500 g/L in dimethylsulfoxide all at 20 °C	96.5	OECD 105	M-127777-01-2

([1]): Mefenpyr-diethyl is a surface active substance. In this case according to OECD 107 there might be difficulties in using the shake flask method. So the value calculated by modelling software is given here in addition.

Table 2. **Chemical composition and properties of mefenpyr-diethyl technical materials (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 98.5 – 99.4 %, including 1.15 – 1.56 % of unidentified high boiling compounds.			
Declared minimum mefenpyr-diethyl content	940 g/kg			
Relevant impurities ≥ 1 g/kg and maximum limits for them	None			
Relevant impurities < 1 g/kg and maximum limits for them:	None One potentially relevant impurity.			
Stabilisers or other additives and maximum limits for them:	None			
Parameter	Value and conditions	Purity %	Method reference	Study reference
Melting temperature range of the TC	43 … 47 °C	93.5 %	DSC	M-133870-01-1
Solubility in organic solvents	See Table 1			

HAZARD SUMMARY

Mefenpyr-diethyl has neither been evaluated by the WHO IPCS nor by the FAO/WHO JMPR.

Mefenpyr diethyl was evaluated in Germany. An ADI of 0.03 mg/kg bw and an AOEL of 0.1 mg/kg bw/d was proposed by the German BfR. The setting of an ARfD was considered to not be justified.

FORMULATIONS AND CO-FORMULATED ACTIVE INGREDIENTS

The safener mefenpyr-diethyl is always co-formulated together with herbicides.

The main formulation types available are EW (oil in water emulsion), EC (emulsifiable concentrate), WG (water dispersible granule) and OD (oil dispersion) formulations.

Mefenpyr-diethyl is co-formulated either with fenoxaprop-P-ethyl or it is co-formulated with iodosulfuron-methyl-sodium, mesosulfuron-methyl or other combinations including one of this active ingredients.

These formulations are registered and sold in many countries round the world under different trade names.

METHODS OF ANALYSIS AND TESTING

The analytical methods for determination of mefenpyr-diethyl (including identity tests) consist of two separate methods: the TC method is based on reversed phase HPLC using a C_{18}-substituted silica column and UV detection at 300 nm with external standardization (CIPAC/4627/A). The methods for determination of the safener in the formulations (EC, EW, OD and WG) are based on normal phase chromatography on silicagel with UV detection at 227 nm (CIPAC/4627/B). Both methods are available through the CIPAC prepublication scheme before their inclusion in Handbook N: both methods are full CIPAC methods. The methods for determination of impurities are based on reverse phase LC, using UV detection at 220 nm and external standardisation.

Test methods for determination of physico-chemical properties of mefenpyr-diethyl are OECD, EPA or EC, while those for the formulations are CIPAC, as indicated in the specifications.

PHYSICAL PROPERTIES

The physical properties, the methods for testing them and the limits proposed for the EC, EW and WG formulations comply with the requirements of the FAO/WHO manual, 2010 revision.

CONTAINERS AND PACKAGING

No special requirements for containers and packaging have been identified.

EXPRESSION OF THE CONTENT OF THE SAFENER

The safener is expressed as mefenpyr-diethyl.

ANNEX 1

HAZARD SUMMARY PROVIDED BY THE PROPOSER

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

Table 3. Toxicology profile of mefenpyr-diethyl technical material, based on acute toxicity, irritation and sensitization

Species	Test	Purity % Note [4]	Guideline, duration and conditions	Result	Study reference
Rat, males and females	oral	AZ No. 04292, 98.9% w/w	OECD 401	LD_{50} > 5000 mg/kg bw	M-126562-01-1
Mouse, males and females	oral	AZ No. 04292, 98.9% w/w	OECD 401	LD_{50} > 5000 mg/kg bw	M-126339-01-1
Rat, males and females	dermal	AZ No. 04292, 98.9% w/w	OECD 402	LD_{50} > 4000 mg/kg bw	M-126286-01-1
Rat, males and females	inhalation	AZ No. 04432, 94.5%	OECD 403	LC_{50} > 1320 mg/m^3*	M-127729-01-1
Rabbit, males and females	skin irritation	AZ No. 04292, 98.9% w/w	OECD 404	Not irritating	M-126376-01-1
Rabbit, males and females	eye irritation	AZ No. 04292, 98.9% w/w	OECD 405	Not irritating	M-126489-01-1
Guinea pig, females	skin sensiti-zation	AZ No. 04432, 94.5%	OECD 406, Maximization test	Not sensitizing	M-129800-01-1
Guinea pig, females	phototoxi-city	AZ No. 04518, 94.3% w/w	Draft OECD guideline "Phototoxicity after cutaneous application" March 1990	Phototoxic potential down to a conc. of 5%	M-136891-01-1

[4] Note: Purity is the content of pure mefenpyr-diethyl in the technical material, expressed as a percentage.

Species	Test	Purity % Note [4]	Guideline, duration and conditions	Result	Study reference
Guinea pig, females	photosen-sitization	AZ No. 04518, 94.3% w/w	Similar to OECD 406 with an irradiation sequence after each application of the product (induction and challenge)	Not photosensitizing	M-137187-01-1

* Maximum technically attainable concentration

Mefenpyr-diethyl showed very low acute oral and dermal toxicity, no irritation and sensitising effects. Phototoxicity potential was shown but no photosensitisation.

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

Species	Test	Purity % Note [5]	Guideline, duration and conditions	Result	Study reference
Rat, males and females	4-week feeding study	AZ No. 04292, 98.9% w/w	OECD 407 0-10-52-101-249-488-744 mg/kg bw/d (f)	NOAEL = 249 mg/kg bw/d LOEL = 488 mg/kg bw/d	M-136540-01-1 M-138747-01-1
Mouse, males and females	4-week feeding study	AZ No. 04292, 98.9% w/w	OECD 407 0-19-98-211-503-1080-1748 mg/kg bw/d (m)	NOAEL = 503 mg/kg bw/d LOEL = 1080 mg/kg bw/d	M-135826-01-1 M-137592-01-1

[5] Note: Purity is the content of pure mefenpyr-diethyl in the technical material, expressed as a percentage.

Species	Test	Purity % Note [5]	Guideline, duration and conditions	Result	Study reference
Dog, males and females	4-week feeding study	AZ No. 04292, 98.9% w/w	OECD 409 0-48-92-174-375 (m), 0-53-98-184-308 (f) mg/kg bw/d	NOAEL = 92 mg/kg bw/d LOEL = 174 mg/kg bw/d	M-129927-01-1
Rat, males and females	4-week dermal study	AZ No. 04518, 94.3% w/w	OECD 410 100-300-1000 mg/kg bw/d	NOAEL = 300 mg/kg bw/d LOEL = 1000 mg/kg bw/d	M-137769-01-1
Rat, males and females	13-week feeding study	AZ No. 04432, 94.5%	OECD 408 0-8-42-207-661 mg/kg bw/d (m)	NOAEL = 42 mg/kg bw/d LOEL = 207 mg/kg bw/d	M-136542-01-1
Mouse, males and females	13-week feeding study	AZ No. 04432, 94.5%	OECD 408 0-18-89-449-1493 mg/kg bw/d (m)	NOAEL = 89 mg/kg bw/d LOEL = 449 mg/kg bw/d	M-137593-01-1
Dog, males and females	13-week feeding study	AZ No. 04432, 94.5%	OECD 409 0-15-81-339 mg/kg bw/d	NOAEL = 15 mg/kg bw/d LOEL = 81 mg/kg bw/d	M-136357-01-1
Dog, males and females	1-year feeding study	AZ No. 04518, 94.3% w/w	OECD 452 0-2.3-10-51-260 (m), 0-2.1-11-58-282 (f) mg/kg bw/d	NOAEL = 51 mg/kg bw/d LOEL = 260 mg/kg bw/d	M-138113-01-1
Rat, males and females	Combined chronic/carcinogenicity feeding study	AZ No. 04518, 94.3% w/w	OECD 453 0-1.9-9.8-48.5-252 mg/kg bw/d (m)	NOAEL = 48.5 mg/kg bw/d LOEL = 252 mg/kg bw/d No oncogenic effect	M-134048-02-1
Mouse, males and females	Oncogenicity feeding study	AZ No. 04518, 94.3% w/w	OECD 451 0-2.8-14.1-70.6-351 mg/kg bw/d	NOAEL = 70.6 mg/kg bw/d LOEL = 351 mg/kg bw/d	M-133984-02-1

Species	Test	Purity % Note [5]	Guideline, duration and conditions	Result	Study reference
			(m)	No oncogenic effect	
Rat, males and females	2-generation feeding study	AZ No. 04518, 94.3% w/w	OECD 416	NOAEL systemic = 75 mg/kg bw/d LOEL = 396 mg/kg bw/d No effects on reproduction up to 396 mg/kg bw/d (highest dose tested)	M-133451-02-1
Rat, females	Embryotoxicity study	AZ No. 04432, 94.5%	OECD 414, Limit test	NOAEL dams < 1000 mg/kg bw/d NOAEL pups > 1000 mg/kg bw/d No teratogenic effect	M-137035-02-1
Rat, females	Embryo-toxicity study	AZ No. 07172, 94.7 %	OECD 414 0-40-200-1000 mg/kg bw/d	$NOAEL_{dams}$ = 200 mg/kg bw/d $NOAEL_{pups}$ = 200 mg/kg bw/d No teratogenic effect	M-186899-01-1
Rat, females	Embryo-toxicity and post-natal develop-ment toxicity study	AZ No. 04518, 94.3% w/w	OECD 414 (limit test) followed by a 3-week rearing period	$NOAEL_{dams}$ > 1000 mg/kg bw/d $NOAEL_{pups}$ < 1000 mg/kg bw/d No teratogenic effect	M-137883-01-1
Rabbit, females	Embryo-toxicity study	AZ No. 04432, 94.5%	OECD 414 40-100-250 mg/kg bw/d	$NOAEL_{dams}$ = 100 mg/kg bw/d $LOEL_{dams}$ = 250 mg/kg bw/d $NOAEL_{pups}$ = 100 mg/kg bw/d $LOEL_{pups}$ = 250 mg/kg bw/d No teratogenic effect	M-138652-03-1

In repeated administration study, mefenpyr-diethyl proved to be of rather low and unspecific toxicity. The liver was found to be the main target organ together with haematopoietic system in both rodent and non rodent species.

Mefenpyr-diethyl did not show any carcinogenic potential, did not have any effect on reproduction nor teratogenicity.

Table 5. Mutagenicity profile of technical mefenpyr-diethyl based on in vitro and in vivo tests

Species	Test	Purity % Note [6]	Guideline, duration and conditions	Result	Study reference
S. typhimurium TA98, TA 100, TA 1535, TA 1537, TA 1538 and E. coli WP2uvrA	*In vitro* mutagenicity test (Ames test) OECD 471 and 472	AZ No. 04292, 98.9% w/w	0, 4, 20, 100, 2500, 5000 or 10000 µg/plate +/- S9 mix Positive controls	Negative (+/- S9 mix)	M-127158-02-1
V79 chinese hamster ovary cells	*In vitro* chromosome aberration test OECD 473	AZ No. 04292, 98.9% w/w	0, 5, 12.5 and 25 µg/ml (without S9 mix) 0, 10, 50 and 100 µg/ml (with S9 mix) Positive controls	Negative (+/- S9 mix)	M-127164-01-1
V79 chinese hamster ovary cells	*In vitro* gene mutation test OECD 476	AZ No. 04292, 98.9% w/w	0, 10, 25, 50, 75 and 100 µg/ml (without S9 mix) 0, 25, 50, 75 and 100 µg/ml (with S9 mix) Positive controls	Negative (+/- S9 mix)	M-127679-01-1
A 549 cell line	*In vitro* unscheduled DNA synthesis OECD 482	AZ No. 04292, 98.9% w/w	0, 0.01, 0.03, 0.1, 0.3, 1, 3, 10, 30, 100 µg/mL +/- S9 mix Positive controls	Negative (+/- S9 mix)	M-127283-01-1

[6] Note: Purity is the content of pure mefenpyr-diethyl in the technical material, expressed as a percentage.

Species	Test	Purity % Note [6]	Guideline, duration and conditions	Result	Study reference
NMRI mice	*In vivo* micronucleus test OECD 474	AZ No. 04292, 98.9% w/w	0 and 5000 mg/kg by gavage Positive control	Negative	M-127162-01-1

No indications of any genotoxic potential of mefenpyr-diethyl were observed.

Table 6. Ecotoxicology profile of technical mefenpyr-diethyl

Species	Test	Purity % Note [7]	Guideline, duration and conditions	Result	Study reference
Birds					
Japanese quail	Acute oral toxicity	AZ 04432, 94.5% w/w	-	LD_{50} > 2 000 mg a.s./kg bw	M-129750-02-1
Mallard duck	Acute oral toxicity	AZ 04432, 94.5% w/w	-	LD_{50} > 2 000 mg a.s. /kg bw	M-129753-01-1
Japanese quail	Short-term dietary toxicity	AZ 04518 94.3% w/w	5 days	LC_{50} > 5 000 mg a.s./kg diet LC_{50} > 1462 mg a.s./kg bw	M-130531-01-1
Mallard duck	Short-term dietary toxicity	AZ 04518 94.3% w/w	5 days	LC_{50} > 5 000 mg a.s./kg diet LC_{50} > 1590 mg a.s./kg bw	M-138587-01-1
Japanese quail	Subchronic and Reproduce-tion toxicity	AZ 04518 94.3% w/w	6 weeks	NOEL= 1000 mg a.s./kg diet NOEL= 106 mg a.s./kg bw	M-133356-01-1
Fish					
Rainbow trout	Acute toxicity	AZ 04432 94.5% w/w	static 96h	LC_{50} = 4 200 [µg t.s./L]	M-130986-01-1
Mirror carp	Acute toxicity	AZ 04432 94.5% w/w	static 96h	LC_{50} = 2 400 [µg t.s./L]	M-136683-01-1
Rainbow trout	Chronic toxicity JFG	no. 05436 94.8 % w/w	dynamic 28 d	NOEC = 100 [µg t.s./L]	M-133862-01-1
Bluegill	Bioaccumu-lation 28d +14d	99.4% spiked with [phenyl-UL-^{14}C] mefenpyr-diethyl. Radiochemical purity: 99 %.	dynamic 28 d	BCF = 232	M-133970-01-1

[7] Note: Purity is the content of pure mefenpyr-diethyl in the technical material, expressed as a percentage.

Aquatic invertebrates					
Daphnia magna	Acute toxicity	AZ 05815 94.5% w/w	static 48h	EC_{50} = 5 900 μg/L	M-141867-01-1
Daphnia magna	Chronic toxicity	no. 05436 94.8 % w/w	semi-static 21 d	NOEC 320 μg/L	M-133863-01-1
Green algae					
Pseudokirch-neriella subcap.		AZ 07172 94.7 % w/w	static 96h	E_bC_{50} 6 610 (μg t.s. /L)	M-181164-01-1
Scenedesmus subspicatus[S]		AZ 04518 94.3 % w/w	static 72h	E_bC_{50} 5 800 (μg t.s. /L)	M-130528-01-1
Diatom algae					
Navicula pelliculosa		AZ 07172 94.7% w/w	static 96h	E_bC_{50} 1650 μg/L	M-183085-01-1
Aquatic macrophytes					
Lemna gibba		AZ 07172 94.7% w/w	semi-static 7d	E_bC_{50} > 12 000 μg/L	M-183121-01-1
Bees					
Apis mellifera	contact	AZ 04518 94.3 % w/w	48 hours	LD_{50} > 700 μg a.s./bee NOEC = 700 μg a.s. /bee	M-135701-01-2
Apis mellifera	acute oral	AZ 04518 - purity 94.3 % w/w	48 hours	LD_{50} > 926 μg a.s./bee NOEC = 900 μg a.s./bee	M-135703-01-2
Earthworms mefenpyr-diethyl (AE F107892)					
Eisenia fetida	Acute toxicity	AZ 04518 94.3 % w/w	14 d	LC_{50}: > 1000 NOEC: 1000 (mg t.s. /kg soil)	M-130768-01-1

Note: earthworm studies were carried out in artificial soil containing 10% peat for reason of comparison.

The environmental profile of mefenpyr-diethyl has been well defined. The substance and its environmental degradates are not persistent in soil or water and there is very low probability that leaching into groundwater will occur. In addition, studies on fish, birds or mammalian species are not indicative of any potential for bioaccumulation.

Based on an extended ecological data basis, mefenpyr-diethyl is toxic to aquatic organisms (fish and daphnids).

ANNEX 2

References

Study number	Author(s)	year	Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study.
M-126286-01-1		1990	Hoe 107892; substance, technical (Code: Hoe 107892 00 ZC99 0001) Testing for acute dermal toxicity in the male and female Wistar rat GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished
M-126339-01-1		1990	HOE 107892; SUBSTANCE, TECHNICAL (Code: Hoe 107892 00 ZC99 0001) Testing for acute oral toxicity in the male and female NMRI mouse GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished
M-126376-01-1		1990	Hoe 107892; SUBSTANCE, TECHNICAL (Code: Hoe 107892 00 ZC99 0001) Testing for primary dermal irritation in the rabbit GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished
M-126489-01-1		1990	Hoe 107892; substance, technical (Code: Hoe 107892 00 ZC99 0001) Testing for primary eye irritation in the rabbit GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished
M-126562-01-1		1990	Hoe 107892; SUB ANCE, TECHNICAL (Code: Hoe 107892 00 ZC99 0001) Testing for acute oral toxicity in the male and female Wistar rat GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished
M-127158-02-1		1995	Hoe 107892 - substance, technical (Code: Hoe 107892 00 ZC99 0001) Study of the mutagenic potential in strains of Salmonella typhimurium (Ames Test) and Escherichia coli GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished
M-127162-01-1		1990	Hoe 107892 - substance, technical (Code: Hoe 107892 00 ZC99 0001) Micronucleus test in male and female NMRI mice after oral administration GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished

M-127164-01-1	1990	Hoe 107892 - substance, technical (Code: Hoe 107892 00 ZC99 0001) Chromosome aberrations in vitro in V79 Chinese hamster cells GLP Hoechst AG; Pharma Development, , Frankfurt, Germany Unpublished
M-127283-01-1	1990	Evaluation of Hoe 107892 - substance, technical (Code: Hoe 107892 00 ZC99 0001) in the unscheduled DNA synthesis test in mammalian cells in vitro GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished
M-127649-01-1	1990	Hoe 107892 Solubility in water at 3 pH-values GLP Hoechst AG, Frankfurt am Main, Germany
M-127650-01-1	1990	Hoe 107892. Partition coefficient octanol/water GLP Hoechst AG, Frankfurt am Main, Germany Unpublished
M-127679-01-1	1990	Hoe 107892 - substance, technical (Code: Hoe 107892 00 ZC99 0001) Detection of gene mutations in somatic cells in culture HGPRT-test with Y79 cells GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished
M-127729-01-1	1991	Hoe 107892; substance, technical Code: Hoe 107892 00 ZC97 0001 Testing for acute aerosol inhalation toxicity in the male and female SPF Wistar rat 4-hour LC50 GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished
M-127777-01-2	1991	Hoe 107892, solubility in organic solvents and vehicles GLP Hoechst AG, Frankfurt am Main, Germany Unpublished
M-129281-01-2	1991	Determination of the vapour pressure of Hoe 107892 00 ZB99 0001 depending on the temperature GLP Hoechst AG, Frankfurt am Main, Germany Unpublished
M-129750-02-1	1994	Hoe 107892; substance, technical (CODE: Hoe 107892 00 ZC97 0001) Testing for acute oral toxicity in the male and female Japanese quail (Coturnix coturnix japonica) GLP Hoechst AG, Frankfurt am Main, Germany Unpublished
M-129753-01-1	1991	Hoe 107892; SUBSTANCE, TECHNICAL (CODE: Hoe 107892 00 ZC97 0001) Testing for acute oral toxicity in the male and female Mallard duck (Anas platyrhynchos) GLP Hoechst AG, Frankfurt am Main, Germany Unpublished

M-129800-01-1	1991	Hoe 107892; SUBSTANCE, TECHNICAL (Code: Hoe 107892 00 ZC97 0001) Testing for sensitising properties in the Pirbright-White guinea pig in a maximisation test GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished
M-129803-01-1	1991	Hoe 107892, Determination of the Dissociation Constant K_{Diss} Hoechst AG, Frankfurt am Main, Germany GLP: no Unpublished
M-129927-01-1	1991	30-day oral toxicity (feeding) study with Hoe 107892 substance technical (Code: Hoe 107892 00 ZC99 0001) in the dog GLP Unpublished
M-130528-01-1	1991	Hoe 107892 - substance, technical (Hoe 107892 00 ZC94 0001) Effect to Scenedesmus subspicatus (Green alga) in a Growth Inhibition Test (method OECD) GLP Hoechst AG, Frankfurt am Main, Germany Unpublished
M-130531-01-1	1991	Hoe 107892; substance, technical; (Code: Hoe 107892 00 ZC94 0001) 8-day dietary LC50 test in the Japanese quail (Coturnix coturnix japonica) GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished
M-130768-01-1	1991	Hoe 107892; substance, technical (Hoe 107892 00 ZC94 0001) Effect to Eisenia fetida (Earthworm) in a 14 day Artificial Soil Test (method OECD) GLP Hoechst AG, Frankfurt am Main, Germany Unpublished
M-130986-01-1	1991	Hoe 107892 - substance, technical (Hoe 107892 00 ZC94 0001) Effect to Oncorhynchus mykiss (Rainbow trout) in a Static-Acute Toxicity Test (method OECD) GLP Hoechst AG, Frankfurt am Main, Germany Unpublished
M-131836-01-1	1993	Hoe 107892 Determination of the Abiotic Hydrolysis as a Function of pH according to EPA Pesticide Assessment Guideline, Subdivision N, § 161-1 Hoe 107892 00 ZB99 0001 GLP Hoechst AG, Frankfurt am Main, Germany Unpublished

M-133356-01-1	1994	HOE 107892; SUBSTANCE TECHNICAL (Code: Hoe 107892 00 ZC94 0001) Avian subchronic toxicity test - oral toxicity (including effects on reproduction) in the Japanese quail (Coturnix coturnix japonica, Temminck und Schlegel, 1849) following a 6 GLP Hoechst AG; Pharma Development, Corporate Toxicology, Frankfurt, Germany Unpublished
M-133451-02-1	1995	HOE 107892 SUBSTANCE TECHNICAL (CODE: Hoe 107892 00 ZC94 0001) Two-generation reproduction study in the rat GLP Switzerland Unpublished
M-133862-01-1	1994	Hoe 107892 - substance, technical Code: Hoe 107892 00 ZC97 0001 Effect to Oncorhynchus mykiss (Rainbow trout) in a 28-days Juvenile Growth Test under Flow-Through Conditions GLP Hoechst Schering AgrEvo GmbH; Frankfurt, Germany Unpublished
M-133863-01-1 .	1994	Hoe 907892 - substance, technical Code: Hoe 107892 00 ZC97 0001 Effect to Daphnia magna (Waterflea) in a 21-day Reproduction Test (method OECD) GLP Hoechst Schering AgrEvo GmbH; Frankfurt, Germany Unpublished
M-133870-01-1	1994	Hoe 107892 substance, technical (Code: Hoe 107892 00 ZD94 0001) Determination of the Melting Point GLP: no Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Unpublished
M-133945-01-1	1994	Code: Hoe 107892 00 ZE99 0001 14C - Hoe 107892 Direct Photolysis in Aqueous Buffered Solution, Degradation Kinetics and Quantum Yield GLP Hoechst Schering AgrEvo GmbH;Environmental Chemistry Frankfurt, Germany Unpublished
M-133970-01-1	.1995	Code: Hoe 107892 00 ZE99 0003 Hoe 107892 (dichlorophenyl-^{14}C) Flow-through Bioaccumulation and Metabolism Study with Bluegill Sunfish (Lepomis macrochirus) GLP Source: Hoechst Schering AgrEvo GmbH; Frankfurt, Germany Unpublished
M-133984-02-1	1994	Oncogenicity (feeding) study with Hoe 107892 substance technical (Code: Hoe 107892 00 ZC94 0001) in the mouse GLP Unpublished

M-134048-02-1	1995	Combined chronic toxicity/oncogenicity (feeding) study with Hoe 107892 substance technical (Code: Hoe 107892 00 ZC94 0001) in the rat GLP Switzerland Unpublished
M-135569-01-1	1992	Melting point of Hoe 107892 substance, pure GLP: no Hoechst AG, Frankfurt am Main, Germany Unpublished
M-135701-01-2	1991	Hoe 107892; substance, technical (Hoe 107892 00 ZC94 0001) Investigating the contact toxicity to the honey bee Apis mellifera L. GLP Hoechst AG, Frankfurt am Main, Germany Unpublished
M-135703-01-2	1991	Hoe 107892; substance, technical (Hoe 107892 00 ZC94 0001) Investigating the oral toxicity to the honey bee Apis mellifera L. GLP Hoechst AG, Frankfurt am Main, Germany Unpublished
M-135826-01-1	1992	Hoe 107892; SUBSTANCE, TECHNICAL (Code: Hoe 107892 00 ZC99 0001) Repeated-dose oral toxicity (4-week feeding study) in the NMRI mouse GLP Hoechst AG; Pharma Development, Corporate Toxicology, Frankfurt, Germany Unpublished
M-136357-01-1	1992	13-week oral toxicity (feeding) study with Hoe 107892 substance technical (Code: Hoe 107892 00 ZC97 0001) in the dog GLP Unpublished
M-136540-01-1	1992	Hoe 107892 - SUBSTANCE TECHNICAL (Code: Hoe 107892 00 ZC99 0001) Repeated-dose oral toxicity (4-week feeding study) in the Wistar rat GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished
M-136542-01-1	1992	HOE 107892 substance technical (Code: HOE 107892 00 ZC97 0001) Sub-chronic oral toxicity 13-week feeding study in rats GLP Unpublished
M-136683-01-1	1992	Hoe 107892 - substance, technical (Hoe 107892 00 ZC94 0001) Effect to Cyprinus carpio (mirror carp) in a static-acute toxicity test (method OECD) GLP Hoechst AG, Frankfurt am Main, Germany Unpublished

M-136891-01-1	1992	HOE 107892; SUBSTANCE TECHNICAL (Code: Hoe 107892 00 ZC94 0001) Testing for phototoxicity after cutaneous application in the Pirbright-White guinea pig GLP Hoechst AG, Frankfurt am Main, Germany Unpublished
M-137035-02-1	1992	Hoe 107892 - substance technical (Code: Hoe 107892 00 ZC97 0001) Testing for embryotoxicity in the Wistar rat after oral administration (limit test) GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished yes
M-137187-01-1	1992	HOE 107892; SUBSTANCE, TECHNICAL; (Code: Hoe 107892 00 ZC94 0001) Testing for photosensitising properties in the Pirbright-White guinea pig GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished
M-137592-01-1	1992	Hoe 107892; SUBSTANCE, TECHNICAL (Code: Hoe 107892 00 ZC99 0001) Repeated-dose oral toxicity (4-week feeding study) in the NMRI mouse Renal glutathione contents and enzyme activities GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished
M-137593-01-1	1991	Hoe 107892 SUBSTANCE TECHNICAL (Code: Hoe 107892 00 ZC97 0001) Sub-chronic oral toxicity 13-week feeding study in mice GLP Unpublished
M-137769-01-1	1992	Hoe 107892 - SUBSTANCE TECHNICAL (Code: Hoe 107892 00 ZC94 0001) Repeated-dose dermal toxicity (21 treatments in 29 days) in the Wistar rat GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished
M-137883-01-1	1992	Hoe 107892 - substance technical (Code: Hoe 107892 00 ZC94 0001) Testing for embryotoxicity and effects on post-natal development in Wistar rats after oral administration (limit test) GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished
M-138113-01-1	1992	52-week oral toxicity (feeding) study with Hoe 107892 substance technical (Code: Hoe 107892 00 ZC94 0001) in the dog GLP Unpublished
M-138587-01-1	1992	Hoe 107892; SUBSTANCE, TECHNICAL (CODE: Hoe 107892 00 ZC94 0001) 8-day dietary LC50 test in the mallard duck (Anas platyrhynchos) GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished

M-138652-03-1	2000	Hoe 107892 - substance technical (Code: Hoe 107892 00 ZC97 0001) Testing for embryotoxicity in the Himalayan rabbit after oral administration GLP Hoechst AG; Pharma Development, Frankfurt, Germany Unpublished
M-138747-01-1	1992	Hoe 107892; SUBSTANCE, TECHNICAL (Code: Hae 107892 00 ZC99 0001) Repeated-dose oral toxicity (4-week feeding study) in the Wistar rat Glutathione contents and enzyme acitivities in liver and kidneys GLP Hoechst AG, Frankfurt am Main, Germany Unpublished
M-141867-01-1	1997	AE F107892 substance technical Code: AE F107892 00 1C97 0001 Acute toxicity to Daphnia magna (Waterflea) GLP Hoechst Schering AgrEvo GmbH; Frankfurt, Germany Unpublished
M-181164-01-1	1998	Mefenpyr-diethyl (Draft ISO), substance, technical Code: AE F107892 00 1 C97 0001 Alga, Growth Inhibition Test (Pseudokirchneriella subcapitata, 96 [h]) GLP Unpublished
M-183085-01-1	1999	Algal growth inhibition - Navicula pelliculosa Mefenpyr-diethyl (draft ISO) substance, technical Code: AE F107892 00 1C97 0001 GLP Hoechst Schering AgrEvo GmbH; Frankfurt, Germany Unpublished
M-183121-01-1	1998	Duckweed (Lemna gibba G3) growth inhibition test Mefenpyr-diethyl (draft ISO) substance, technical Code: AE F107892 00 1C97 0001 GLP Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Unpublished
M-186899-01-1	1999	Rat oral developmental toxicity (teratogenicity) study Mefenpyr-diethyl substance technical Code: AE F107892 00 1C97 0001 GLP Hoechst Marion Roussel, DEU;T Frankfurt, Germany Unpublished
M-227502-01-1	2004	Boiling point Thermal stability Mefenpyr-diethyl; substance, pure Code: AE F107892 00 1B99 0002 GLP Unpublished
M-234626-01-1	2004	Analytical Method Determination of AE F107892 (Mefenpyr-diethyl) in Technical Grade and Pure Active Substance by HPLC Code: AE F107892 GLP: no Bayer CropScience GmbH, Frankfurt, Germany Unpublished

M-234869-01-1		2004	Assessment on the n-octanol/water partition coefficient Mefenpyr-diethyl Code: AE F107892 GLP: no Bayer CropScience S.A., Lyon, France Unpublished
	FAO/WHO	2002 Ammended 2010	Manual on development and use of FAO and WHO specifications for pesticides. February 2006 Revision of First Edition. FAO Plant Production and Protection Paper. Revised. www.fao.org/ag/AGP/AGPP/Pesticid/Default.htm and http://whqlibdoc.who.int/publications/2006/9251048576_eng_update2.pdf