



EUROPEAN COMMISSION  
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate E – Safety of the food chain  
Unit E.3 - Chemicals, contaminants, pesticides

Mepiquat  
SANCO/106/08 – rev. 2  
20 May 2008

## FINAL

### Review report for the active substance **mepiquat**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on  
20 May 2008  
in view of the inclusion of mepiquat in Annex I of Directive 91/414/EEC

#### 1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of mepiquat, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC<sup>1</sup> concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EC) No 451/2000<sup>(2)</sup> laying down the detailed rules for the implementation of the second and third stages of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and Regulation (EC) No 1490/2002<sup>(3)</sup>, have laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Mepiquat is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 10 of Regulation (EC) No 451/2000, BASF notified to the Commission of their wish to secure the inclusion of the active substance mepiquat in Annex I to the Directive.

In accordance with the provisions of Article 6(1) of Regulation (EC) No 1490/2002, the Commission, designated United Kingdom as rapporteur Member State to carry out the assessment of mepiquat on the basis of the dossiers submitted by the notifier. In Regulation (EC) No 1490/2002 the Commission specified furthermore that the deadline for the notifier with regard to the submission to the rapporteur Member States of the dossiers required under Article 7(2) of Regulation (EC) No 1490/2002, as well as for other parties with regard to further technical and scientific information was 30 November 2003.

<sup>1</sup> OJ L 230, 19.8.1991, p. 1. Directive as last amended by OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2007/76/EC (OJ L 337, 21.12.2007, p. 100)

<sup>2</sup> OJ L 55, 29.2.2000, p. 25. Regulation as last amended by Regulation (EC) No 1044/2003 (OJ L 151, 19.6.2003, p.32).

<sup>3</sup> OJ L 224, 21.8.2002, p. 23. Regulation as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19).

BASF submitted by the deadline a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore BASF was considered to be the sole data submitter.

In accordance with the provisions of Article 10(1) of Regulation (EC) No 1490/2002, United Kingdom submitted on 5 April 2005 to the EFSA the report of their examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of mepiquat in Annex I to the Directive. Moreover, in accordance with the provisions of Article 10(2) of Regulation (EC) 1490/2002, the Commission and the Member States received also the summary dossier on mepiquat from BASF.

In accordance with the provisions of Article 11 of Regulation (EC) No 1490/2002, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by BASF being the sole data submitter, on 20 January 2006 by making it available.

The EFSA organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review).

In accordance with the provisions of Article 11 c of Regulation 1490/2002 the EFSA sent to the Commission its conclusion on the risk assessment [Conclusions regarding the peer review of the pesticide risk assessment of the active substance mepiquat (finalised 14 April 2008)<sup>4</sup>]. This conclusion refers to background document A (draft assessment report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 12 of Regulation (EC) No 1490/2002, the Commission referred on 20 May 2008 a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 20 May 2008.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA (background document C), these documents are also considered to be part of this review report.

## **2. Purposes of this review report**

This review report, including the background documents and appendices thereto, has been developed and finalised in support of the Directive **2008/108/EC**<sup>5</sup> concerning the inclusion of mepiquat in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing mepiquat they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

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<sup>4</sup> EFSA Scientific Report (2008) 14, 1-86, Conclusion regarding the peer review of the pesticide risk assessment of the active substance mepiquat (finalised 14 April 2008).

<sup>5</sup> Commission Directive 2008/108/EC (OJ L 317, 27.11.2008, p. 6)

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 13 of Regulation (EC) No 1490/2002, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

### **3. Overall conclusion in the context of Directive 91/414/EEC**

The overall conclusion from the evaluation is that it may be expected that plant protection products containing mepiquat will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each mepiquat containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the main data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

The following reference values have been finalised as part of this re-evaluation:

ADI 0.2mg/Kg bw/day

ARfD 0.3mg/Kg bw/day .

AOEL 0.3 mg/Kg bw/day

In particular with regard to residues, further information is required to confirm the risk assessment concerning animal origin products. The review has established that the residues arising from the proposed use, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; including barley and products of animal origin) did not exceed the 6 % of the Acceptable Daily Intake (ADI) in examined populations of consumers, based on the FAO/WHO European Diet (August 1994).

Estimates of acute dietary exposure of various groups of consumers populations revealed that the Acute Reference Dose (ARfD) would not be exceeded (UK diet all less than 3 %).

The review has identified acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 6 of this report.

#### **4. Identity**

The identity of mepiquat is given in Appendix I.

At the time of the evaluation no FAO specification was allocated.

The review has established that for the active substance notified by the main data submitter none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

#### **5. Endpoints and related information**

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of the EFSA, and at section 3 of this report.

#### **6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing mepiquat**

In assessing applications to authorise plant protection products containing mepiquat for uses other than barley, Member States shall pay particular attention to the criteria in Article 4(1) (b), and shall ensure that any necessary data and information is provided before such an authorisation is granted.

The Member States must pay particular attention to the residues in food of plant and animal origin and evaluate the dietary exposure of consumers.

#### **7. List of studies to be generated**

No further studies were identified which were at this stage considered necessary in relation to the inclusion of mepiquat in Annex I under the current inclusion conditions.

Some other endpoints however, require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. The list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Scientific report (page 27).

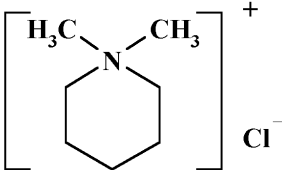
## **8. Information on studies with claimed data protection**

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC and neither does it commit the Commission.

## **9. Updating of this review report**

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Any such adaptation will be finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for mepiquatin Annex I of the Directive.

**APPENDIX I****Identity****MEPIQUAT**

<b>Common name (ISO)</b>	Mepiquat
<b>Chemical name (IUPAC)</b>	<i>1,1-dimethylpiperidinium chloride (mepiquat chloride)</i>
<b>Chemical name (CA)</b>	<i>1,1-dimethylpiperidinium chloride (mepiquat chloride)</i>
<b>CIPAC No</b>	440.302 (mepiquat chloride) 440 (mepiquat)
<b>CAS No</b>	24307-26-4 (mepiquat chloride) 15302-91-7 (mepiquat)
<b>EEC No</b>	246-147-6 (mepiquat chloride)
<b>FAO SPECIFICATION</b>	None
<b>Minimum purity</b>	615-665 g/l in the technical concentrate (TK)*, corresponding to a minimum purity in the theoretically dry technical material (TC) of 990 g/kg.
<b>Molecular formula</b>	C <sub>7</sub> H <sub>16</sub> ClN (mepiquat chloride) C <sub>7</sub> H <sub>16</sub> N (mepiquat)
<b>Molecular mass</b>	149.7
<b>Structural formula</b>	Mepiquat chloride 

**APPENDIX II**  
**List of uses supported by available data**

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	Number* min/ max (k)	interval between applications (min)	kg as/hL min – max (l)	water L/ha min – max	kg as/ha min – max (l)		
<b>Barley</b>	Belgium, Denmark, Finland France, Ireland, Luxembourg, Sweden, United Kingdom	Terpal Terpal Terpal Terpal Terpal Terpal	F	Stem stabilisation	SL	<b>305**</b> <b>155**</b> *	SP	31 – 49	1	-	<b>0.127 - 0.508**</b> 0.065 - 0.258***	150 - 600	<b>0.7625**</b> 0.3875** *	[2]	[1]

There are more products/uses available or under preparation which will be supported on the national level.

\* splitting not particularly displayed here - (\*Max 0.458 (ww&wb): Maximum 2 litres/product/hectare/crop (0.610 kg ai/ha/crop) must not be exceeded when applying split dose applications).

\*\* mepiquat chloride

\*\*\* ethephon

<p>For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).</p> <p>(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>	<p>(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxyppyr). <b>In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialdicarb-isopropyl).</b></p> <p>(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application</p> <p>(k) Indicate the minimum and maximum number of application possible under practical conditions of use</p> <p>(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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[1] Residue trial data base for cereals incomplete, consumer risk assessment and MRL proposal for the use in the broad category of cereals cannot be finalised. Complete data is available only to support a use in barley; and based on this data no risk to consumers is expected.

[2] covered by conditions of use