



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: Production and distribution chain
Unit D.3 - Chemicals, contaminants and pesticides

1-methylcyclopropene
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**COMMISSION WORKING DOCUMENT - DOES NOT NECESSARILY REPRESENT
THE VIEWS OF THE COMMISSION SERVICES**

Review report for the active substance **1-methylcyclopropene**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 23 September 2005 in view of the inclusion of 1-methylcyclopropene in Annex I of Directive 91/414/EEC.

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of the new active substance 1-methylcyclopropene, made in the context of the work provided for in Articles 5 and 6 of Directive 91/414/EEC 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.

In accordance with the provisions of Article 6(2) of Directive 91/414/EEC, the British authorities received on 28 February 2002 an application from Rohm and Haas France S.A.S., hereafter referred to as the applicant, for the inclusion of the active substance 1-methylcyclopropene in Annex I to the Directive. The British authorities indicated to the Commission on 17 May 2002 the results of a first examination of the completeness of the dossier, with regard to the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive. Subsequently, and in accordance with the requirements of Article 6(2), a dossier on 1-methylcyclopropene was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on the Food Chain and Animal Health in the meeting of the working group 'legislation' thereof on 11 June 2002, during which the Member States confirmed the receipt of the dossier.

In accordance with the provisions of Article 6(3), which requires the confirmation at Community level that the dossier is to be considered as satisfying, in principle, the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive and in accordance with the procedure laid

down in Article 20 of the Directive, the Commission confirmed in its Decision 2003/35/EC¹ of 10 January 2003 that these requirements were satisfied.

Following an agreement between the Commission and the European Food Safety Authority (EFSA), the latter organised a peer review for those active substances for which the decision on completeness has been published after June 2002.

Within the framework of that decision and with a view to the further organisation of the works related to the detailed examination of the dossier provided for in Article 6(2) and (4) of Directive 91/414/EEC, it was agreed between the Member States and the Commission that the United Kingdom would, as rapporteur Member State, carry out the detailed examination of the dossier and report the conclusions of its examination accompanied by any recommendations on the inclusion or non-inclusion and any conditions relating thereto, to the EFSA as soon as possible and at the latest within a period of one year.

In analogy with the provisions of Article 8(1) of Regulation (EC) No 451/2000² for existing active substances, the United Kingdom submitted on 30 May 2003 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 1-methylcyclopropene in Annex I to the Directive.

In analogy with the provisions of Article 8 of Regulation (EC) No 451/2000 for existing active substances, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by Rohm and Haas France S.A.S. being the main data submitters, on 14 August 2003 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 analogy with the provisions of Article 8 (7) of Regulation 451/2000 for existing active substances the EFSA sent to the Commission its conclusion on the risk assessment (Ref D(2005) HK/nb/482)³. This conclusion refers to background document A (draft assessment report) and background document B (EFSA peer review report).

In analogy with the provisions of Article 8 (7) of Regulation (EC) No 451/2000 for existing active substances, the Commission referred on 15 July 2005 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 23 September 2005.

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.

¹ OJ L11, 16. 1.2003, p.52.

² OJ L 55, 29.2.2000, p. 25. Regulation as last amended by Regulation (EC) No 1490/2002 (OJ L 224, 21.8.2002, p. 23).

³ *EFSA Scientific Report* (2005) 30, 1-46

2. Purposes of this review report

This review report, including the background documents and appendices thereto, have been developed and finalised in support of the Directive **2006/19/EC**⁴ concerning the inclusion of 1-methylcyclopropene in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing 1-methylcyclopropene 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.

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 analogy with the provisions of Article 8(9) of Regulation 451/2000 for existing active substances, 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 possession of 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 1-methylcyclopropene 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 1-methylcyclopropene containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the following uses which were proposed and supported by the sole 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.

⁴ OJ No L 44, 15.02.2006, p. 15-17

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

ADI:	0.0009 mg/kg bw/day
ArfD:	0.07 mg/kg bw/day
AOEL:	0.009 mg/kg bw/day

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is $\leq 1\%$ of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994).

Additional intake from water and products of animal origin are not expected to give rise to intake problems.

Estimates of acute dietary exposure of adults and toddlers revealed that the Acute Reference Dose (ARfD) would not be exceeded (European diet $< 1\%$ for all considered population subgroups).

The review has identified several 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 and Physical/chemical properties

The main identity and the physical/chemical properties of 1-methylcyclopropene are given in Appendix I.

The active substance shall have a minimum purity of 960g/kg technical product.

As 1-methylcyclopropene is a gas, the manufacturing process produces it in an encapsulated form as a cyclodextrin complex containing 3.3% active substance. This was the representative formulation in the review.

The review has established that for the active substance notified by the main data submitter the manufacturing impurities 1-chloro-2-methylpropene and 3-chloro-2-methylpropene are of toxicological concern and each of them must not exceed 0.5 g/kg in the technical material. None of the other 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 1-methylcyclopropene

On the basis of the proposed and supported uses, no particular issues have been identified as requiring short term attention from the Member States.

7. List of studies to be generated

No further studies were identified which were considered at this stage, and under the current inclusion conditions necessary in relation to the inclusion of 1-methylcyclopropene in Annex I.


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 1-methylcyclopropene in Annex I of the Directive.

APPENDIX I**Identity, physical and chemical properties****1-METHYLCYCLOPROPENE**

Common name (ISO)	1-methylcyclopropene (an ISO Common Name will not be considered for this active substance)
Chemical name (IUPAC)	1-methylcyclopropene
Chemical name (CA)	1-methylcyclopropene
CIPAC No	Not allocated
CAS No	3100-04-7
EEC No	Not allocated
FAO SPECIFICATION	Not allocated
Minimum purity	960 g/kg
Molecular formula	C ₄ H ₆
Molecular mass	54
Structural formula	

APPENDIX II

List of uses supported by available data

1-METHYLCYCLOPROPENE

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					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	water l/ha min max	kg as/ha min max		
Apples	Belgium France Germany Italy Spain The Netherlands United Kingdom <i>Austria</i> <i>Ireland</i> <i>Greece</i> <i>Portugal</i>	Smart-Fresh	I	N/A (Plant growth regulator)	Vapour releasing product (VP)	3.3%	Proprietary generator	After harvest (not later than 7 days after harvest)	One per stored batch of apples	N/A	N/A (see Remarks)	N/A (see Remarks)	518-1000	0	(See Nota Bene below) Critical GAP considered for risk assessment = 1000 ppb as in the air = 2.24 mg as / m ³ = 0.009 mg as./ kg apples

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					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	water l/ha min max	kg as/ha min max		
															Minimum use rate = 545 ppb as in the air = 1.22 mg as / m ³ = 0.0049 mg as./ kg apples
<p>NB: -The relationship between 1-MCP in ppb vs. mg is expressed by the law of gases, thus following the formula: milligrams 1-MCP/cubic meter = selected concentration of 1-MCP in the air in ppm x molecular weight 1-MCP (=54 g/mol)/volume occupied by 1 mole of gas at 20°c (24.06 liters). Minimum use rate is 545 ppb 1-MCP, equivalent to $0.545 \times 54 / 24.06 = 1.22 \text{ mg/m}^3$ Critical use rate is 1000 ppb 1-MCP, equivalent to $1 \times 54 / 24.06 = 2.24 \text{ mg/m}^3$ -Storage room filling density considered is 250 kg of fruit/m³</p>															

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
 - (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
 - (f) All abbreviations used must be explained
 - (g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (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
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) Remarks may include: Extent of use/economic importance/restrictions