



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Lenacil
SANCO/833/08 – final¹
11 May 2010

Review report for the active substance **lenacil**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
14 March 2008
in view of the inclusion of lenacil 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 lenacil, 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 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⁽²⁾ 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, as last amended by Regulation (EC) No 1490/2002⁽³⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Lenacil is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EC) No 451/2000, Schirm GmbH notified to the Commission of their wish to secure the inclusion of the active substance lenacil in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EC) No 451/2000, the Commission, designated Belgium as rapporteur Member State to carry out the assessment of lenacil 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.

¹ On 11 May 2010 the Standing Committee on Food Chain and Animal Health has taken note of the amendments of chapter 1, 3, 5, 6 and 7 and appendix II based on the EFSA Journal 2009; 7(9):1326.

² OJ No L 55, 29.02.2000, p.25.

³ OJ No L 224, 21.8.2002, p.23. Regulation as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.09.2007, p. 19).

Schirm GmbH 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 Schirm GmbH was considered to be the sole data submitter.

In accordance with the provisions of Article 10(1) of Regulation (EC) No 1490/2002, Belgium submitted on 30 November 2007 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 lenacil 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 lenacil from the notifier.

In accordance with the provisions of Article 11 of Regulation (EC) No 1490/2002 as last amended by Regulation (EC) 1095/2007, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by Schirm GmbH being the sole data submitter, on 08 January 2008 by making it available.

In accordance with the provisions of Article 11a of Regulation 1490/2002 as last amended by Regulation (EC) 1095/2007 the Commission examined the draft assessment report, the recommendations by the rapporteur Member State and the comments received from other Member States in consultation with experts from a certain number of Member States.

In accordance with the provisions of Article 11b and Article 12 (1) a of Regulation (EC) No 1490/2002 as last amended by Regulation (EC) 1095/2007, the Commission referred on 14 March 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 14 March 2008.

Finally, in compliance with the provisions of Article 12a of Regulation (EC) No 1490/2002 as last amended by Regulation (EC) 1095/2007, EFSA delivered its conclusions on lenacil on 25 September 2009⁴. The Commission referred on 11 May 2010 an updated review report to the Standing Committee on the Food Chain and Animal Health, for examination. The updated review report was finalised in the meeting of the Standing Committee on 11 May 2010 as revision number 3.

The present review report contains the conclusions of the final examination by the Standing Committee.

2. Purposes of this review report

This review report, including the background document appendices thereto, has been developed in support of Directives **2008/69/EC**⁵ and **2010/39/EU**⁶ concerning the inclusion of lenacil in Annex I to Directive 91/414/EEC. The Commission shall request the EFSA to deliver its view on the draft review reports by 31 December 2010 at the latest. When the Member States decide on individual plant protection products containing lenacil they shall take into account this review report 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. However, when the EFSA has delivered its view on the draft review report, the Commission shall revise it.

⁴ EFSA Journal 2009; 7(9):1326. [83 pp.]. doi:10.2903/j.efsa.2009.1326. Available online: www.efsa.europa.eu

⁵ Commission Directive 2008/69/EC (OJ L 172, 02.07.2008, p. 9)

⁶ Commission Directive 2010/39/EC (OJ L 156, 23.06.2010, p. 7-11)

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 lenacil 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 lenacil containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these indications 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: 0.12 mg/kg bw/day

ARfD: not allocated, not necessary.

AOEL: 0.4 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. Using WHO European diet data, a Theoretical Maximum Daily Intake (TMDI) of 0.02% ADI was calculated. A calculation carried out with the EFSA PRAPeR model (PRIMO, rev. 2) showed the diet for UK toddlers (TMDI = 0.4% ADI) as the most critical model for the chronic intake.

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

As an ARfD is not appropriate, the estimates for the acute dietary exposure have not been calculated.

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.

It has also been 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 lenacil is given in Appendix I.

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

It has been 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 lenacil

On the basis of the proposed and supported uses (as listed in Appendix II), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- the risk to aquatic organisms, especially algae and aquatic plants. Conditions of authorisation shall include risk mitigation measures, such as bufferzones between treated areas and surface water bodies;
- the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential

groundwater contamination from the metabolites IN-KF 313, M1, M2 and M3 in vulnerable zones, where appropriate.

7. List of studies to be generated

- The Member States concerned shall ensure that the notifier presents to the Commission not later than 30 June 2012 information to further identify and characterise soil metabolites Polar B and Polars and metabolites M1, M2 and M3 which occurred in lysimeter studies and further trials on rotational crops, including possible phytotoxic effects.

If a decision on the classification of lenacil under Directive 67/548/EEC would identify the need for further information on the relevance of the metabolites IN-KE 121, IN-KF 313, M1; M2, M3, Polar B and Polars, the Member States concerned shall request the submission of such information.

Some other endpoints however may 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 (pag 28-29).

8. Information on studies with claimed data protection

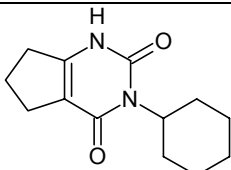
For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I 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 lenacil in Annex I of the Directive.

APPENDIX I**Identity**

LENACIL

Common name (ISO)	Lenacil
Chemical name (IUPAC)	3-cyclohexyl-1,5,6,7-tetrahydrocyclopentapyrimidine-2,4(3H)-dione
Chemical name (CA)	3-cyclohexyl-6,7-dihydro-1Hcyclopentapyrimidine-2,4(3H,5H)-dione
CIPAC No	163
CAS No	2164-08-1
EEC No	218-499-0 (EINECS)
FAO SPECIFICATION	n/a
Minimum purity	975 g/kg
Molecular formula	C ₁₃ H ₁₈ N ₂ O ₂
Molecular mass	345.2
Structural formula	

APPENDIX II

List of uses supported by available data

LENACIL

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		
Sugar beet Fodder beet (BEAVX)	Northern Europe, Southern Europe	Venzar 80 WP	F	Grass and Broad leaf weeds	WP	800 g/kg	Medium-low volume spraying, broadcast application	Post-emergence BBCH 10 (emergence first leaf) – 31 (beginning of crop cover)	1-4	7-14	0.0312 5 - 0.25	200-400	0,125 - 0,5	None*	Maximum of 0,5 kg a.s./ha per season [1] [2]

- 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
 - (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