



COMMISSION STAFF WORKING DOCUMENT¹

Basic Substance
diammonium phosphate
SANTE/12351/2015– rev. 1
8 March 2016

Review report for the basic substance diammonium phosphate finalised
in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 8 March 2016
in view of the approval of diammonium phosphate as basic substance in accordance with
Regulation (EC) No 1107/2009

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of diammonium phosphate made in the context of the assessment of the substance provided for in Article 23 of Regulation (EC) No 1107/2009² concerning the placing of plant protection products on the market, with a view to the possible approval of this substance as basic substance.

In accordance with the provisions of Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 29 September 2014 an application from ITAB, hereafter referred to as the applicant, for the approval of the substance diammonium phosphate as basic substance.

The application and attached information were distributed to the Member States and European Food Safety Authority (EFSA) for comments. The applicant was also allowed to address collated comments and provide further information to complete the application, which was finalised in the new version of August 2015.

In accordance with the provisions of Article 23(4) of Regulation (EC) No 1107/2009 the Commission required scientific assistance on the evaluation of the application to EFSA, who delivered its views on the specific points raised in the commenting phase.

EFSA submitted to the Commission the results of its work in the form of a technical report for diammonium phosphate on 6 October 2015³.

The Commission examined the application, the comments by Member States and EFSA and the EFSA Technical report on the substance together with the additional information and comments provided on it by the applicant, before finalising the current draft review report, which was referred to the Standing Committee on Plants, Animals, Food and Feed for examination. The draft review report was finalised in the meeting of the Standing Committee of 8 March 2016.

¹ Does not necessarily represent the views of the Commission.

² OJ L 309, 24.11.2009, p. 1-50.

³ EFSA (European Food Safety Authority), 2015. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for diammonium phosphate for use in plant protection as a non-lethal food attractant for fruit flies. EFSA supporting publication 2015:EN-873. 34 pp.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the EFSA technical report, and the comments and clarifications submitted (background document C), all 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 in support of the **Commission Implementing Regulation (EU) 2016/548⁴** concerning the approval of diammonium phosphate as basic substance under Regulation (EC) No 1107/2009.

The review report will be made available for public consultation by any interested parties.

Without prejudice to the provisions of Regulation (EC) No 178/2002⁵, in particular with respect to the responsibility of operators, following the approval of diammonium phosphate as basic substance, operators are responsible for using it for plant protection purposes in conformity with the legal provisions of Regulation (EC) No 1107/2009 and with the conditions established in the sections 4, 5 and Appendixes I and II of this review report.

EFSA will make available to the public all background documents and the final Technical Report of EFSA, as well as the application without the Appendixes and excluding any information for which confidential treatment is justified in accordance with the provisions of Article 63 of Regulation (EC) No 1107/2009.

Products containing exclusively one or more basic substances do not require authorisation in line with derogation set under Article 28 of Regulation (EC) No 1107/2009. As a consequence, no further assessment will be carried out on such products. However, the Commission may review the approval of a basic substance at any time in conformity with the provisions of Article 23(6) of Regulation (EC) No 1107/2009.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion based on the application, including the results of the evaluation carried out with the scientific assistance of EFSA, is that there are clear indications that it may be expected that diammonium phosphate fulfils the criteria of Article 23.

Diammonium phosphate is authorised to be used in oenology to encourage yeast development by Regulation (EC) No 606/2009⁶ up to a concentration of 1g/L.

The conditions of use are not expected to lead to the presence of residues of concern in food or feed commodities.

⁴ OJ L 95, 9.4.2016, p. 1–3.

⁵ OJ L 31, 1.2.2002 p. 1-24 - Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

⁶ OJ L 193, 24.7.2009, p1-59 - Regulation (EC) No 606/2009 of the European Parliament and of the Council of 10 July 2009 laying down detailed rules for implementing Council Regulation (EC) 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions.

Diammonium phosphate does not have an inherent capacity to cause endocrine disrupting (according to the interim criteria in Regulation 1107/2009), neurotoxic or immunotoxic effects and is not predominantly used for plant protection purposes but nevertheless is useful in plant protection in a product consisting of the substance and water. Finally, it is not placed on the market as a plant protection product.

It can be concluded that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment when used in accordance with the supported uses as described in Appendix II.

In fact, these indications were reached within the framework of the uses which were supported by the applicant and mentioned in the list of uses supported by available data (attached as Appendix II to this review report) and therefore, they are also subject to compliance with the particular conditions and restrictions in sections 4 and 5 of this report.

Extension of the use pattern beyond those described above will require an evaluation at Community level in order to establish whether the proposed extensions of use can still satisfy the requirements of Article 23 of Regulation (EC) No 1107/2009.

The following point is considered as open by the EFSA (2015) for diammonium phosphate, however the risk is considered acceptable for the following reasons:

- *The operator and worker risk assessment has not been addressed.*

Diammonium phosphate will only be used in traps as an attractant for fruit flies which limits exposure. Diammonium phosphate is authorised to be used in oenology to encourage yeast development by Regulation (EC) No 606/2009. Diammonium phosphate is used as an agricultural fertiliser. The exposure for operators and workers from the use of diammonium phosphate is regarded to be equal to or lower than the use of this product in oenology or as a fertiliser. Moreover, the supported basic substance use is referring to products currently on the market to be used in oenology and packaged and labelled in accordance with Regulation (EC) No 1272/2008⁷ including among others necessary information with respect to specific precautionary measures to apply proper risk mitigation measures.

4. Identity and biological properties

The main properties of diammonium phosphate are given in Appendix I.

The active substance shall have a purity as oenological grade.

It has been established that for diammonium phosphate as notified by the applicant, no relevant impurities are considered, on the basis of information currently available, of toxicological, ecotoxicological or environmental concern.

⁷ O.J. L. 353, 31.12.2008

5. Particular conditions to be taken into account in relation to the uses as basic substance of diammonium phosphate

Diammonium phosphate must be identified by the specifications given in Appendix I and must be used in compliance with conditions of supported uses as reported in Appendixes I and II.

The following conditions for use deriving from assessment of the application have to be respected by users:

- Only uses as basic substance being an attractant in traps are approved.
- Users shall respect the conditions of use and precautionary statements reported on the products safety data sheet, which has to be available at purchase phase, and in particular, use the prescribed adequate personal protective equipment.

Use of diammonium phosphate must be in compliance with conditions specified in the Appendixes I and II of this review report.

On the basis of the proposed and supported uses (as listed in Appendix II), no particular issues have been identified.

The identification of diammonium phosphate as food ingredient implies that the Regulation (EC) No 178/2002 on food safety applies.

6. List of studies to be generated

No further studies were identified which were at this stage considered necessary.

7. Updating of this review report

The information in this report may require to be updated from time to time 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 23 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, as appropriate, in connection with any amendment of the approval conditions for diammonium phosphate in Part C of Annex of the Regulation (EC) No 540/2011.

8. Recommended disclosure of this review report

Considering the importance of the respect of the approved conditions of use and the fact that a basic substance will be not placed on the market as plant protection product, hence, no further assessment will have to be carried out on it, it is very important to inform not only applicants but also potential users on the existence of this review report.

It is therefore recommended that the competent authorities of Member States will make available such report to the general public and operators by means of their national relevant websites and by any other appropriate form of communication to ensure that the information reaches potential users.

APPENDIX I

Identity and biological properties

DIAMMONIUM PHOSPHATE

| | |
|--|---|
| Common name | Diammonium phosphate (diammonium hydrogen phosphate) |
| Chemical name (IUPAC) | Diammonium hydrogen phosphate |
| Chemical Name. (CA) | Diammonium phosphate |
| CAS No | 7783-28-0 |
| CIPAC No and EEC No | 231-987-8 |
| FAO SPECIFICATION | Not available. |
| Purity | Oenological grade. |
| Molecular formula | $(\text{NH}_4)_2\text{HPO}_4$ |
| Relevant impurities | None. |
| Molecular mass and structural formula | $\left[\begin{array}{c} \text{O} \\ \\ \text{O} - \text{P} - \text{O}^- \\ \\ \text{OH} \end{array} \right] \left[\text{NH}_4^+ \right]_2$ <p>Molecular mass: 132.07 [g/mol]</p> |
| Mode of Use | Diammonium phosphate as specified above to be used in water solution for application as listed in Appendix II. |
| Preparation to be used | Diammonium phosphate to be diluted in compliance with rate of application reported in Appendix II. |
| Function of plant protection | Attractant. |

APPENDIX II
DIAMMONIUM PHOSPHATE

| Crop and/or situation (a) | F G I (b) | Pests or group of pests controlled (c) | Formulation | | Application | | | Application rate per treatment | | | Total rate | PHI (days) (m) | Remarks | |
|---|-----------|--|-------------|----------------------|--------------------------|-----------------------------|--|-------------------------------------|----------------------------|---------------------------|--------------------------------|-------------------------|--------------|--------------------------------|
| | | | Type (d-f) | Conc of a.s. g/L (i) | Method kind (f-h) | Growth stage and season (j) | Number min max (k) | Interval between applications (min) | kg a.s./hl min max (kg/hl) | Water l/ha min max | kg a.s./ha min max (kg/ha) (l) | | | kg a.s./ha min max (kg/ha) (l) |
| Orchards Including cherry tree <i>Prunus spp</i> | F | Mediterranean Fruit fly <i>Ceratitis capitata</i> Cherry fly <i>Rhagoletis cerasi</i> | VP | 40 | Placed in physical traps | | Mass trapping: 1 trap per tree up to 100 traps/ha | Approx. 6 to 8 Weeks* | max 4 | Mass trapping: max 100 | Mass trapping: max 4 | Mass trapping: max 4 | Not relevant | |
| Olive trees <i>Olea europaea</i> | | Olive fly <i>Bactrocera oleae</i> | | | | | | | | Mass trapping: max 100 | Mass trapping: max 4 | Mass trapping: max 4 | | |
| Citrus spp | | Mediterranean Fruit fly <i>Ceratitis capitata</i> | | | | | | | | Mass trapping: max 100 | Mass trapping: max 4 | Mass trapping: max 4 | | |
| Other crops where <i>C. capitata</i> cause damage | | Mediterranean Fruit fly <i>Ceratitis capitata</i> | | | | | | | | Mass trapping: max 100 | Mass trapping: max 4 | Mass trapping: max 4 | | |

* depending upon environmental factors such as climate and topography

- (a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
- (c) e.g. pests as biting and sucking insects, soil born insects, foliar fungi, weeds or plant elicitor
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..
- (e) GCPF Codes – GIFAP Technical Monograph N° 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 plant – type of equipment used must be indicated
- (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO)
- (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) Indicate the minimum and maximum number of application possible under practical conditions of use
- (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)
- (m) PHI - minimum pre-harvest interval