



COMMISSION STAFF WORKING DOCUMENT¹

Basic Substance
Lecithins

SANCO/12798/2014– rev. 2
30 March 2015

Final

Review report for the basic substance lecithins finalised in the Standing Committee on the Plants, Animals, Food and Feed at its meeting on 29 May 2015

in view of the approval of lecithins 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 lecithins, 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 18 November 2013 an application from ITAB (Institut Technique de l'Agriculture Biologique), hereafter referred to as the applicant, for the approval of the substance lecithins 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 June 2014.

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 the EFSA, who delivered its views on the specific points raised in the commenting phase.

¹ Does not necessarily represent the views of the Commission.

² OJ L 309, 24.11.2009, p. 1-50.

EFSA submitted to the Commission the results of its work in the form of a technical report for lecithins on 25 August 2014³.

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 on 29 May 2015.

Given the importance of the EFSA technical report, the comments, additional information 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 **Commission Implementing Regulation (EU) 2015/1116**⁴ concerning the approval of lecithins 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 lecithins 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 the conditions established in the sections 4, 5 and Appendices 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 Appendices 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 the 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 Outcome of the consultation with Member States and EFSA on the basic substance application for lecithins for use in plant protection as a fungicide on vineyards, fruit trees, vegetables and ornamentals. 2014:EN-643.34 pp.

⁴ OJ L 182, 10.7.2015, p. 26–28.

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.

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 lecithins fulfil the criteria of Article 23.

Lecithins fulfil the criteria of a ‘foodstuff’ as defined in Article 2 of Regulation (EC) No 178/2002. Lecithins are approved as a food additive, under the number E322, by Regulation (EU) No 231/2012⁶.

Considering the EFSA technical report on the basic substance application for lecithins, the rate of application and the conditions of use, which are described in detail in Appendix I and II, it is concluded that the use of lecithins would not lead to concerns for human health. Furthermore, no residues are expected as the conditions of use would not significantly increase the background level due to the natural occurrence of the substance.

Lecithins is not a substance of concern and does not have an inherent capacity to cause endocrine disrupting (according to the interim criteria in Regulation 1107/2009), neurotoxic or immune-toxic 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 was considered as open by EFSA (2014) for lecithins, however the risk is considered small or negligible for the following reason:

- Insufficient information to address fate and behaviour in the environment and to characterise environmental exposure. It is considered that the conditions of use would not significantly increase the background level due to the natural occurrence of the substance and the low application dose per hectare.

4. Identity and chemical properties

The main properties of lecithins are given in Appendix I.

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

⁶ OJ L 83, 22.3.2012, p 1.

Specifications laid down in Regulation (EU) No 231/2012 must be complied with.

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

Lecithins must be identified by given specifications in Appendix I and must be used in compliance with method of preparation and condition of use as reported in Appendices 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 a fungicide are approved.

Use of lecithins 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 lecithins 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 Article 23 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection, as appropriate, with any amendment of the approval conditions for lecithins in Part C of Annex of the Regulation (EC) No 540/2011⁷.

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 not be placed on the market as a plant protection product and 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 of the substance 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.

⁷ OJ L 153, 11.6.2011, p. 1–186.

APPENDIX I

Identity and biological properties

LECITHINS

Common name (ISO)	Not available.
Chemical name (IUPAC)	Not available.
Chemical name (CA)	Not available.
Botanical classification	Not applicable.
Part used	Not applicable.
CAS No	8002-43-5
CIPAC No and EEC No	E322 Einecs: 232-307-2
FAO SPECIFICATION	Not available.
Purity	As defined in Regulation (EC) No 231/2012
Molecular formula	Not applicable.
Molecular mass and structural formula	Not applicable.
Mode of Use	Lecithins as specified above to be used in cold water solution for application on various crops as listed in Appendix II.
Preparation to be used	Lecithins to be diluted in compliance with rate of application reported in Appendix II.
Function of plant protection	Fungicide.

APPENDIX II
List of uses supported by available data LECITHINS

Crop and/or situation (a)	F G I (b)	Target (c)	Product		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (*)
			Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season** (j)	Number min max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	g a.i./ha min max (g/ha) (l)			
Fruit trees Apple fruit <i>Malus pumila</i> Peach-tree <i>Prunus persica</i>	F	Powdery mildews: <i>Podosphaera leucotricha</i> Peach leaf curl <i>Taphrina deformans</i>	Emulsifiable Concentrate (EC)	990 to 1030	Spray application	From BBCH 03 to BBCH 79	3 to 12	5 days	75	500 to 1000	375 to 750	1.125 to 9	5	
Gooseberry <i>Ribes uva-crispa</i>		Powdery mildews: <i>Microsphaera grossulariae</i>				From BBCH 10 to BBCH 85	2 to 4							
Market vegetables gardening like Cucumber <i>Cucumis sativus</i>	Powdery mildews: <i>Podosphaera xhantii</i>	2 to 6				150	1000 to 1500	1500 to 2250	3 to 13.5					
Lettuce <i>Lactuca sativa</i>	<i>Erysiphe cichoracearum</i>	2								7 days	3 to 4.5			
Mash <i>Valerianella locusta</i>	<i>Erysiphe polyphaga</i>	1								-	1.5 to 2.5			
Tomato <i>Lycopersicum esculentum</i>	Tomato late blight <i>Phytophthora infestans</i>	2 to 6								7 days	3 to 13.5			
Endive <i>Cichorium endivia L.</i>	Fungus <i>Alternaria cichorii</i>													
Ornamentals, especially roses	powdery mildew and other fungal diseases													
Grapevine <i>Vitis vinifera</i>	F	Powdery mildews: <i>Plasmopara viticola</i> , <i>Erysiphe necator</i>			From BBCH 11 to BBCH 85					3 to 12	5 days	75	100 to 300	75 to 225

- * For uses where the column „Remarks. As above or other conditions to take into account
- (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,
 - (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 between the plant – type of equipment used must be indicated