

Basic Substance
Mustard seeds powder
SANTE/11309/2017– rev. 2
6 October 2017

Final Review report for the basic substance mustard seeds powder
Finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on 6 October 2017
in view of the approval of mustard seeds powder as basic substance in accordance with
Regulation (EC) No 1107/2009¹

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of mustard seeds powder 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 4 June 2016 an application from Institut Technique de l'Agriculture Biologique (ITAB), hereafter referred to as the applicant, for the approval of the substance mustard seeds powder as basic substance.

The application and attached information were distributed to the Member States and the European Food Safety Authority (EFSA) for comments. The applicant was also allowed to address collated comments and provide further information to complete the application.

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 mustard seeds powder on 20 January 2017³.

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

¹ Report established in accordance with Art. 13 of Regulation (EC) No 1107/2009; does not necessarily represent the views of the European Commission.

² OJ L 309, 24.11.2009, p. 1-50.

³ EFSA (European Food Safety Authority), 2017. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for mustard seeds powder from *Sinapis alba* (*Brassica alba*), *Brassica juncea* and *Brassica nigra* for use in plant protection as fungicide. EFSA supporting publication 2017:EN-1169. 35 pp. doi:10.2903/sp.efsa.2017. EN-1169.

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 6 October 2017.

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, 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) 2017/2066⁴** concerning the approval of mustard seeds powder 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 mustard seeds powder 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 mustard seeds powder fulfils the criteria of Article 23.

Mustard seeds powder fulfils the criteria of a ‘foodstuff’ as defined in Article 2 of Regulation (EC) No 178/2002. According to Regulation (EU) No 1169/2011 on the provision of food

⁴ OJ L 295, 14.11.2017, p. 43.

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.

information to consumers, mustard seeds powder is listed in Annex II of substances or products causing allergies or intolerances. As noted by EFSA, given the specific use as a seed treatment, the probability for translocation or contamination of aerial plant parts by residual mustard seeds powder for human consumption is considered very low.

Considering the EFSA conclusions on the basic substance application for mustard seeds powder, 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 mustard seeds powder would not lead to concerns for human health. Furthermore, the conditions of use are not expected to lead to the presence of residues of concern in food or feed commodities.

Mustard seeds powder does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects. Mustard seeds powder is not predominantly used for plant protection purposes but nevertheless is useful in plant protection. 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 points were considered as open by EFSA (2017) for mustard seeds powder, followed by the reason why the risk is considered negligible:

- *Information on the fate and behaviour in the environment is not available in the application. Insufficient information was available to assess the risk to soil microorganisms from the intended uses.*

As was noted by the applicant, mustard is widely used as a cover crop or green manure. No adverse effects of such use have been reported. It can therefore be assumed that the use of mustard seeds powder as seed treatment would not lead to unacceptable risks to the environment.

4. Identity and biological properties

The main properties of mustard seeds powder are given in Appendix I.

The mustard seeds powder used shall be of food grade quality.

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

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

Mustard seeds powder 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 for as a fungicide for seed treatment are approved.

Use of mustard seeds powder 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.

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 mustard seeds powder 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 not be 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

MUSTARD SEEDS POWDER

Common name (ISO)	There is no ISO common name for this substance
Chemical name (IUPAC)	Not relevant, the substance is a complex mixture
Chemical name (CA)	Not relevant, the substance is a complex mixture
Botanical classification	<i>Sinapis alba (Brassica alba), Brassica juncea and Brassica nigra.</i>
Common names	White mustard, Indian mustard, Chinese mustard, black mustard seed powder
CAS No	84929-33-9 (Brassica alba seed extract) 93062-78-3 (Brassica juncea seed extract) 90064-15-6 (Brassica nigra seed extract)
CIPAC No and EEC No	284-517-9 (Brassica alba seed extract) 296-833-4 (Brassica juncea seed extract) 290-076-3 (Brassica nigra seed extract)
FAO specification	Not available
Minimum purity	Not relevant
Relevant impurities	Purity is depending on the origin
Molecular mass and structural formula	none
Mode of Use	Mix 1,5 kg of mustard seeds powder with 4,5 L water. Treat 100 kg seeds with the slurry created.
Preparation to be used	Water dispersible powder for slurry seed treatment (WS)
Function of plant protection	Fungicide for seed treatment

APPENDIX II
List of uses supported by available data
MUSTARD SEEDS POWDER

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			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)	kg a.i./hl min max (kg/h l)	Water l/ha min max	kg a.i./100 kg seeds		
Wheat seeds <i>Triticum vulgare</i> <i>Triticum aestivum</i> Durum wheat <i>Triticum durum</i> Spelt <i>Triticum spelta</i>	All MS		F	fungi like Common bunt: <i>Tilletia caries</i> <i>Tilletia foetida</i>	Water dispersible powder for slurry seed treatment (WS)	n/a	Seed application before sowing	Summer to Autumn	1	None	-	-	1,5	-	Mix 1,5 kg of mustard seeds powder with 4,5 L water. Treat 100 kg seeds with the slurry created.

(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 suckling 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