



Basic Substance
Vitis vinifera L. seed extract
PLAN/2024/800 RR rev 3
5 December 2024

FINAL Review report for the basic substance *Vitis vinifera* L. seed extract (grape seed extract)
finalised by the Standing Committee on Plants, Animals, Food and Feed on 5 December 2024 in view of the approval of *Vitis vinifera* L. seed extract (grape seed extract) 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 *Vitis vinifera* L. seed extract, 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 August 2020 an application from Cérence (formerly Jouffray-Drillaud), hereafter referred to as the applicant, for the approval of the substance *Vitis vinifera* L. seed extract as basic substance. This application was not complete and a revised application has been received in December 2020. The final revision of the application was received in February 2023.

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.

In accordance with the provisions of Article 23(4) of Regulation (EC) No 1107/2009 the Commission requested scientific assistance on the evaluation of the application to the 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 *Vitis vinifera* L. seed extract on 30 October 2023³.

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 by the applicant, before finalising the current review report, which was

¹ Review Report established in accordance with Art. 13 of Regulation (EU) No 1107/2009; it 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), 2023. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for approval of grape seed extract as a basic substance to be used in plant protection as a fungicide on grapevines, apples, potatoes and lettuce. EFSA supporting publication 2023:EN-8435. 150 pp. doi:10.2903/sp.efsa.2023.EN-8435.

referred to the Standing Committee on Plants, Animals, Food and Feed for examination. The review report was finalised by the Standing Committee on 5 December 2024.

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 **Commission Implementing Regulation (EU) 2025/96 of 21 January 2025**⁴ concerning the approval of *Vitis vinifera* L. seed extract as basic substance under Regulation (EC) No 1107/2009.

The review report will be published and made available to any interested party.

Without prejudice to the provisions of Regulation (EC) No 178/2002⁵, in particular with respect to the responsibility of operators, following the approval of *Vitis vinifera* L. seed extract 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 sections 4 and 5, and Appendices I and II of this review report.

EFSA has made available to the public all background documents and its final Technical Report as well as the application without the Appendices 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. 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, and the comments and further additional information provided by the applicant to address the open points identified in the Technical Report from EFSA, is that there are clear indications that it may be expected that *Vitis vinifera* L. seed extract fulfils the criteria of Article 23 for the uses specified in Appendix II.

Vitis vinifera L. seed extract is used as a dietary supplement, as food and feed additive and as cosmetic ingredient. Food supplements containing *Vitis vinifera* L. seed extract are allowed to be used as in some Member States (e.g. France, Italy, Belgium) without particular specifications and restrictions. In the EU, dry grape extract of *Vitis vinifera* spp. *vinifera* consisting of a mixture of two extracts from seeds and skin, respectively, is

⁴ OJ L, 2025/96, 22.1.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/96/oj

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.

authorised according to Commission Implementing Regulation (EU) 2017/3075⁶ in the category of ‘flavouring compounds’ for all animal species, except dogs, at the maximum proposed use level of 100 mg/kg complete feed (EFSA FEEDAP Panel, 2016). In the US, grape seed extract has a Generally Recognized as Safe (GRAS) status approved by the Food and Drug Administration (FDA).

The specifications for *Vitis vinifera* L. seed extract for approval as basic substance should be set according to the ones as described by the US Pharmacopoeia Convention Official 2017 (Dietary Supplements: Grape Seeds Oligomeric Proanthocyanidins USP40–NF35 Page 7030), as proposed by EFSA.

The EFSA FEEDAP Panel reviewed in 2016⁷ some tests regarding the irritant properties of *Vitis vinifera* L. seed extract, which showed mild irritant properties to the skin and eyes. The applicant did not provide information on inhalation toxicity. Considering the long-term use of this extract as a dietary supplement, as food and feed additive and as cosmetic ingredient where no immediate or delayed harmful effects on human or animal health have been reported; the absence of a harmonised classification according to ECHA’s Classification and Labelling Inventory⁸ and the limited exposure to the powder form of the substance; it can reasonably be assumed that *Vitis vinifera* L. seed extract should not be considered as a substance of concern.

EFSA also concluded that based on the available information, there is no evidence that *Vitis vinifera* L. seed extract has endocrine disrupting, neurotoxic or immunotoxic potential.

The proposed use as basic substance is as a fungicide on grapevines, apples, potatoes (field spray application) and on lettuce (field and greenhouse applications).

With regard to residues in food and feed, EFSA indicated that the use of *Vitis vinifera* L. seed extract on grapes, apples, potatoes and lettuce is unlikely to be of concern to consumers under the proposed GAP.

Even though a quantification of the background level of *Vitis vinifera* L. seed extract in the environment as well as its occurrence in vineyards due to unharvested grapes were not provided by the applicant, the *Vitis vinifera* L. seed extract is composed of natural substances and exposure in the environment would be lower than that resulting from equivalent material when grape pomace is potentially used as fertiliser.

A low risk was concluded by EFSA for birds and mammals, non-target arthropods, bees, soil macro-organisms and micro-organisms, other non-target organisms (fauna), and biological methods of sewage treatment for all intended uses. Based on the proposed potential exposure due to the uses as fertilisers, it can be assumed that exposure after application as a fungicide can be lower, not resulting in a substantial increase in the environment, including aquatic organisms. Additionally, the EFSA FEEDAP Panel Opinion (2016) reported that the use of

⁶ Commission Implementing Regulation (EU) 2017/307 of 21 February 2017 concerning the authorisation of dry grape extract of *Vitis vinifera* spp. *vinifera* as a feed additive for all animal species except for dogs. OJ L 44, 22.2.2017, p. 1–5.

⁷ EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2016. Scientific opinion on the safety and efficacy of dry grape extract when used as a feed flavouring for all animal species and categories. EFSA Journal 2016; 14(6):4476, 18 pp. doi: <http://dx.doi.org/10.2903/j.efsa.2016.4476>

⁸ <https://echa.europa.eu/regulations/clp/cl-inventory>

dry grape extract at the maximum proposed level (i.e.: 100 mg/kg complete feed) is not considered to be a risk for the environment.

Therefore, considering the EFSA Technical Report and the conditions of use which are described in detail in Appendices I and II, it is concluded that the use of the *Vitis vinifera* L. seed extract would not lead to concerns for human health. Furthermore, no residues or unacceptable effects on the environment are expected for this use.

Vitis vinifera L. seed extract 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.

Overall, 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 preparation for use in Appendix I and for the uses as described in Appendix II.

These conclusions 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 Union 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.

4. Identity and biological properties

The properties of *Vitis vinifera* L. seed extract are given in Appendix I.

The *Vitis vinifera* L. seed extract should meet the requirements of the US Pharmacopoeia Convention Official 2017 (Dietary Supplements: Grape Seeds Oligomeric Proanthocyanidins USP40–NF35 Page 7030):

Purity: oligomeric proanthocyanidins minimum 75% on the anhydrous basis.

5. Particular conditions to be taken into account in relation to the uses as basic substance of *Vitis vinifera* L. seed extract

Vitis vinifera L. seed extract must be identified by the given specifications in Appendix I and must be used in compliance with the method of preparation and conditions of use as reported in Appendices I and II.

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 the *Vitis vinifera* L. seed extract in Part C of Annex of the Regulation (EC) No 540/2011⁹.

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 of the substance on the existence of this review report.

Further to the publication of this review report, it is recommended that the competent authorities of Member States will make it additionally available 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.

⁹ OJ L 153, 11.6.2011, p. 1–186.

APPENDIX I
Identity and biological properties
Vitis vinifera L. seed extract

Common name (ISO)	N/A
Chemical name (IUPAC)	N/A
Chemical name (CA)	N/A
Common names	Grape seed extract
CAS No	N/A
CIPAC No and EEC No	N/A
FAO specification/ specification in another regulatory context, if available	FAO not available
Minimum purity	oligomeric proanthocyanidins minimum 75% on the anhydrous basis
Relevant impurities	no impurities
Molar mass and structural formula	N/A
Mode of Use	Spray application
Preparation to be used	dustable or wettable powder
Function of plant protection	fungicide

APPENDIX II
List of uses supported by available data
VITIS VINIFERA L. SEED EXTRACT

Crop and/ or situation (a)	Member State or Country	Example product name as available on the market	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate				PHI (days) (m)	Remarks *
					Type (d-f)	Conc of a.i. g/L (i)	Method kind (f-h)	Growth stage & season (j)	No. of Application min max (k)	Interval between applications (min) (days)	g a.i./hl min max (g/ha)	Water l/ha min max	Total rate each application g a.i./ha min max (g/ha) (l)	Total rate each year (g/ha)		
Grapevine <i>Vitis vinifera</i> VITVI	All MS	Grape seed extract	F	Downy mildew <i>Plasmopara viticola</i> PLASVI	WP or DP	100 % grape seed powder	spray treatment	BBCH 13-57 then BBCH 71-79*	6	5 to 7	98	300	294	1764		
Apple tree <i>Malus domestica</i> , MABSD				Apple scab <i>Venturia inaequalis</i> VENTIN				BBCH 11 to BBCH 59*	6		98	500	490	2940		
Potatoes <i>Solanum tuberosum</i> SOLTU				Potato late blight <i>Phytophthora infestans</i> PHYTIN				BBCH 31-BBCH 59* then BBCH 70 to BBCH 90	6		98	300	294	1764		
Lettuce <i>Lactuca sativa</i> LACSA			F/ G	Downy mildew <i>Peronospora</i> sp., <i>Bremia lactucae</i> BREMLA				BBCH 19 to BBCH 50	3		98	500	490	1470		

NOTE: GAP table was updated by EFSA, see Reporting table comment 3(13). It is noted that in the GAP table submitted in the application, the applicant specified the individual crops belonging to the crop groups of pome fruits and leafy vegetables; accordingly, only the specific individual crops belonging to these crop groups, i.e. apples and lettuce, respectively were retained in the GAP table in Appendix E and were considered in the assessment, and the general reference to pome fruits and leaf vegetables was removed. Information to demonstrate usefulness of the intended basic substance as fungicide on pome fruits (i.e. apple), potatoes and leaf vegetables (i.e. lettuce) was not provided.

* 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 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 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
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