



**Basic Substance
Onion oil
SANTE/10615/2018– rev.1
20 July 2018**

Final Review report for the basic substance Onion Oil
finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on 20 July 2018
in view of the approval of onion oil 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 Onion oil, 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 12 December 2016 an application from Bionext, hereafter referred to as the applicant, for the approval of the substance Onion oil as basic substance. This application was not complete and a revised application has been received on 20 March 2017.

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 September 2017.

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.

EFSA submitted to the Commission the results of its work in the form of a technical report for Onion oil on 31 October 2017³.

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), 2017. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for onion oil for use in plant protection as repellent. EFSA supporting publication 2017:EN-1315. 36 pp. doi:10.2903/sp.efsa.2017.EN-1315.

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 20 July 2018.

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) 2018/1295⁴** concerning the approval of Onion oil 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 Onion oil 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 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. 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

⁴ OJ L 243, 27.9.2018, p. 7.

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.

report from EFSA, is that there are clear indications that it may be expected that onion oil fulfils the criteria of Article 23.

Onion oil is used as a flavour and fragrance agent in the food industry and also in traditional medicine and phytotherapy.

Onion oil can be used as food flavouring being a component of food as ruled under Regulation (EC) No 1334/2008, therefore it fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002.

The proposed use as basic substance is supported on crops belonging to the Umbelliferae (carrots, celeriac, parsnip, parsley root) against carrot root flies, by masking the scent of the umbelliferous crops.

EFSA indicated in its technical report that the consumer exposure assessment to onion oil residues cannot be concluded. However, considering the method of application (e.g. via dispensers or granules) and volatility of its major components, plus the nature of the components, there is no evidence of toxic residues for consumers.

In addition, considering the rate of application and comparing the potential contamination of the carrot crop to the natural presence of same components in onions crops and their respective dietary exposures, it can be concluded that the exposure of the carrot crop will not cause any concern for consumers' exposure to residues.

Therefore, considering the EFSA conclusions, 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 Onion oil would not lead to concerns for human health. Furthermore, no residues or unacceptable effects on the environment are expected given the conditions of use and its degradation pathway.

Onion oil is not a substance of concern, does not have an inherent capacity to cause endocrine disrupting, 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.

4. Identity and biological properties

The main properties of Onion oil are given in Appendix I.

The onion oil should be of food grade.

It has been established that for onion oil 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 onion oil

Onion oil 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 having a repellent effect are approved;*
- *Only uses in pot and granules dispensers are approved;*

When handling the oil, users shall respect the precautionary statements reported on the product safety data sheet, which has to be available at purchase phase. In particular, users shall use splash goggles, wear overall and oil solvent resistant gloves and if inhalation risk exists wear organic vapour respirator.

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

The quality of the oil should be in accordance with Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods.

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 Onion oil in Part C of Annex of the Regulation (EC) No 540/2011⁶.

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.

It is therefore recommended that the competent authorities of Member States will make available such report to 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.

⁶ OJ L 153, 11.6.2011, p. 1–186.

APPENDIX I
Identity and biological properties
 Onion oil

Common name (ISO)	Onion oil
Chemical name (IUPAC)	Not applicable (complex mixture)
Chemical Name (CA)	Not applicable (complex mixture)
Common names	<i>Allium cepa</i> oil, Onion oil natural, Onion oil organic
CAS No	8002-72-0
CIPAC, EINECS	232-498-2(EINECS)
FAO SPECIFICATION	None
Purity	Food grade Not relevant (complex mixture)
Relevant impurities	None
Molecular mass and structural formula	Not relevant (complex mixture)
Mode of Use	Oil dispensers
Preparation to be used	AL (any other liquid): a liquid to be applied undiluted <ol style="list-style-type: none"> 1. Dispensers (small glass or plastic pots and small plastic containers, both with openings to allow evaporation) are filled with 20 ml onion oil. <li style="text-align: center;">or 2. Dispensers (as above) are filled with 4.4 g of onion oil and then ethylene-vinyl acetate granules (commercially available) are added up to a total of 30 g. This gives a ratio of 1 g oil to 5.8 g granules. The granules improve the release of vapour from the dispenser.
Function of plant protection	Repellent, scent masking

APPENDIX II
List of uses supported by available data
ONION OIL

Crop and/or situation (a)	Member State for use	Example product name as available on the market	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)	kg a.i./hl min max (kg/hl)	g or L product/ha min max	kg a.i./ha min max (kg/ha) (l)				kg a.i./ha min max (kg/ha) (l)
Umbelliferous crops (carrots, celeriac, parsnip, parsley root)	All MS	Onion oil; TOP Onion oil; Onion oil natural; Onion Oil Extender ; BJONIEXT; Onion oil organic; Onion EO	F	Carrot root fly (<i>Psila rosae</i>)	AL	-	Masking the smell of the umbelliferous crop by onion oil evaporated from dispensers	Shortly after planting or crop emergence (around mid- April) until end of November (before harvest)	1			-	Pot dispensers 0.08-0.160 L/ha Granule Dispenser 17.6 – 35.2 g/ha	-	-	Not relevant	4-8 dispense rs per ha Professional use only

- (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