Modification of the existing maximum residue level for bifenazate in elderberries

European Food Safety Authority (EFSA)
Maria Anastassiadou, Alba Brancato, Luis Carrasco Cabrera, Lucien Ferreira, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnar Pedersen, Hermine Reich, Alejandro Rojas, Angela Sacchi, Miguel Santos, Alois Stanek, Anne Theobald, Benedicte Vagenende and Alessia Verani

Abstract
In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Landwirtschaftliches Technologiezentrum Augustenberg submitted a request to the competent national authority in Germany to modify the existing maximum residue level (MRL) for the active substance bifenazate in elderberries. The data submitted in support of the request were found to be sufficient to derive an MRL proposal for the crop concerned. Adequate analytical methods for enforcement are available to control the residues of bifenazate and its metabolite in elderberries at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the dietary intake of residues resulting from the use of bifenazate according to the intended agricultural practice is unlikely to present a risk to consumer health.

© 2019 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: bifenazate, elderberries, pesticide, MRL, consumer risk assessment

Requestor: European Commission
Question number: EFSA-Q-2019-00397
Correspondence: pesticides.mrl@efs.europa.eu
Acknowledgments: EFSA wishes to acknowledge the contribution of Marianna Raczyk and Silvia Ruocco to this opinion.

Suggested citation: EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2019. Reasoned Opinion on the modification of the existing maximum residue level for bifenazate in elderberries. EFSA Journal 2019;17(11):5878, 22 pp. https://doi.org/10.2903/j.efsa.2019.5878

ISSN: 1831-4732

© 2019 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.
Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Landwirtschaftliches Technologiezentrum Augustenberg submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance bifenazate in elderberries. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 20 June 2019. To accommodate for the intended use of bifenazate in elderberries, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.02 mg/kg to 0.4 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

Based on the conclusions derived by EFSA in the framework of the renewal of approval Regulation (EC) No 1107/2009, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of bifenazate following foliar application was investigated in fruit crops, root crops, cereals/grass crops and pulses/oilseeds. Studies investigating the effect of processing on the nature of bifenazate (hydrolysis studies) demonstrated that the active substance is stable. As the proposed use of bifenazate is on permanent crops, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and the capability of the analytical method, the residue definitions for plant products were proposed as the ‘sum of bifenazate and bifenazate-diazene expressed as bifenazate’ for enforcement and risk assessment. A comparable residue definition for enforcement is set in Regulation (EC) No 396/2005. These residue definitions are applicable to primary crops, rotational crops and processed products.

EFSA concluded that for the crops assessed in this application the metabolism of bifenazate in primary crops has been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (LOQ).

Specific studies investigating the magnitude of bifenazate residues in processed commodities are not required due to a low consumer exposure.

Residues of bifenazate in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock.

The toxicological profile of bifenazate was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary. During the process of renewal of the approval under Regulation (EC) No 1107/2009 (EFSA, 2017a), the same ADI was agreed while an ARfD of 0.1 mg/kg bw has been set. Although this ARfD has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee), an acute dietary intake calculation considering the ARfD of 0.1 mg/kg bw has been performed.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The most recent long-term consumer exposure conducted by EFSA was updated with median residue value derived for the commodity under assessment. No long-term intake concerns were identified for the authorised and intended use of bifenazate. When considering the ARfD set during the recent EU pesticide peer review, no short-term intake concerns were identified for the intended use of bifenazate in elderberries.

EFSA concluded that the proposed use of bifenazate on elderberries will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

EFSA proposes to amend the existing MRL as reported in the summary table below.

Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.
| Code\(^{(a)}\) | Commodity     | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------------|---------------|-------------------------|------------------------|-----------------------|
| 154080        | Elderberries | 0.02\(^{*}\)           | 0.4                    | The intended use in NEU is sufficiently supported by extrapolation from residue data on currants. Risk for consumers unlikely |

**Enforcement residue definition:** Bifenazate (sum of bifenazate plus bifenazate-diazene expressed as bifenazate)\(^{(F)}\)

---

MRL: maximum residue level; NEU: northern Europe.

\(^{*}\): Indicates that the MRL is set at the limit of analytical quantification (LOQ).

\((a)\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

\((F)\): Fat soluble.
**Table of contents**

Abstract ................................................................................................................................................... 1  
Summary ............................................................................................................................................. 3  
Assessment ........................................................................................................................................ 6  
1. Residues in plants ........................................................................................................................ 7  
   1.1. Nature of residues and methods of analysis in plants .............................................................. 7  
   1.1.1. Nature of residues in primary crops ....................................................................................... 7  
   1.1.2. Nature of residues in rotational crops .................................................................................... 7  
   1.1.3. Nature of residues in processed commodities ........................................................................ 7  
   1.1.4. Methods of analysis in plants ................................................................................................. 7  
   1.1.5. Storage stability of residues in plants ..................................................................................... 7  
   1.1.6. Proposed residue definitions .................................................................................................. 8  
1.2. Magnitude of residues in plants ................................................................................................. 8  
   1.2.1. Magnitude of residues in primary crops .................................................................................. 8  
   1.2.2. Magnitude of residues in rotational crops ............................................................................. 8  
   1.2.3. Magnitude of residues in processed commodities .................................................................... 8  
   1.2.4. Proposed MRLs .................................................................................................................... 8  
2. Residues in livestock ..................................................................................................................... 9  
3. Consumer risk assessment ............................................................................................................ 9  
4. Conclusion and Recommendations ............................................................................................... 9  
References ........................................................................................................................................... 10  
Abbreviations ....................................................................................................................................... 10  
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs ................. 12  
Appendix B – List of end points ........................................................................................................... 13  
Appendix C – Pesticide Residue Intake Model (PRIMo) .................................................................. 19  
Appendix D – Input values for the exposure calculations ................................................................... 20  
Appendix E – Used compound codes ............................................................................................... 22
Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for bifenazate in elderberries. The detailed description of the intended use of bifenazate in elderberries, which is the basis for the current MRL application, is reported in Appendix A.

Bifenazate is the ISO common name for isopropyl 3-(4-methoxybiphenyl-3-yl)carbazate or isopropyl 2-(4-methoxybiphenyl-3-yl)hydraziniformate (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Bifenazate was first approved1 for the use as an acaricide on 1 December 2005; its approval has been extended until 31 July 2020.2 The process of renewal of the approval is ongoing. Bifenazate was evaluated for renewal of the first approval in the framework of Regulation (EC) No 1107/20093 with Sweden designated as rapporteur Member State (RMS) for the representative uses as foliar spray applications on strawberries, fruiting vegetables (tomatoes, peppers, aubergines, cucumbers, courgettes, melons and watermelons), flowering and ornamental plants, and nursery of ornamentals. The renewal assessment report (RAR) prepared by the RMS has been peer reviewed by EFSA and the EFSA conclusion has been published in 2017 (EFSA, 2017a); a final decision concerning the renewal of approval of bifenazate has not yet been taken.

The EU MRLs for bifenazate are established in Annexes II of Regulation (EC) No 396/20054. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2011) and the proposed modifications have been implemented in the MRL legislation. In the framework of the MRL review, certain Codex MRLs have been taken over in the EU MRL legislation.5 After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of the MRLs for bifenazate. The proposals from these reasoned opinions have been considered in the MRL legislation.6

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant (Landwirtschaftliches Technologiezentrum Augustenberg) submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing MRL for bifenazate in elderberries. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 20 June 2019. To accommodate for the intended use of bifenazate in elderberries, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.02* mg/kg to 0.4 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2019), the RAR (Sweden, 2016a,b) prepared under Regulation (EC) 1107/2009, the Commission review report on bifenazate for the first approval of bifenazate (European Commission, 2005), the conclusion on the peer review of the pesticide risk assessment for the renewal of approval of the active substance bifenazate (EFSA, 2017a) as well as the conclusions from previous EFSA opinions on bifenazate, including the Reasoned Opinion on the review of the existing MRLs for bifenazate under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011, 2012a,b, 2015, 2017b).

For this application, the data requirements established in Regulation (EU) No 544/20117 and the guidance documents applicable at the date of submission of the application to the EMS are applicable

---

1 Commission Directive 2005/58/EC of 21 September 2005 amending Council Directive 91/414/EEC to include bifenazate and milbemectin as active substances. OJ L 246, 22.9.2005, p. 17–19
2 Commission Implementing Regulation (EU) 2019/707 of 7 May 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, biflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, desmedipham, dimethoate, dimethomorph, diuron, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, foramsulfuron, formanate, metalaxyl-m, methiocarb, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, s-metolachlor and tebuconazole. OJ L 120, 8.5.2019, p. 16–19
3 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
4 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.
5 Commission Regulation (EU) No 441/2012 of 24 May 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, bifenthrin, boscalid, cysafos, chlorantraniliprole, chlorothalonil, clothianidin, cyproconazole, deltamethrin, dicamba, difenoconazole, dinocap, etoxazole, fenpyroximate, flubendiamide, fluoxidionil, glyphosate, metalaxyl-M, meptyldinocap, novaluril, thiamethoxam, and triazophos in or on certain products. OJ L 135, 25.5.2012, p. 4–56
6 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eur-pesticides-database/public/?event=pesticide.residue.selection&language=EN
7 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
Modification of the existing MRL for bifenazate in elderberries

European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously, are presented in Appendix B.

The evaluation report submitted by the EMS (Germany, 2019) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and thus, are made publicly available as background documents to this reasoned opinion.

1. **Residues in plants**

1.1. **Nature of residues and methods of analysis in plants**

1.1.1. **Nature of residues in primary crops**

The metabolism of bifenazate in primary crops has been investigated on fruit crops (apples, oranges, grapes), root crops (radishes), cereals/grass crops (corn) and pulses/oilseeds (cotton) during the MRL review and a previous EFSA opinion (EFSA, 2011, 2012b). These metabolism studies have also been assessed in the framework of the EU pesticides peer review for the renewal of the approval (EFSA, 2017a). Bifenazate was the major residue; the metabolite bifenazate-diazene (D3598) was also observed at different extent depending on the tested crop (up to 40% of total radioactive residue (TRR)).

For the intended use on elderberries, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. **Nature of residues in rotational crops**

Studies on the magnitude of bifenazate residues in rotational crops are not required, since elderberries are a permanent crop.

1.1.3. **Nature of residues in processed commodities**

The effect of processing on bifenazate has been investigated in the framework of a previous EFSA reasoned opinion and during the EU pesticides peer review for the renewal of the approval (EFSA, 2012a, 2017a). Bifenazate was hydrolytically stable under all the conditions tested. Bifenazate-diazene is a metabolite that may occur in the crop under consideration. The behaviour of bifenazate-diazene under processing was not tested and further data were requested by the experts during the EU pesticides peer review for the renewal of the approval (EFSA, 2017a). Since elderberries are normally processed before consumption, the possible degradation of the metabolite bifenazate-diazene should be investigated. However, considering that elderberries are a minor contributor to the total chronic dietary exposure (see also Section 3), it would be desirable but not mandatory to get more information on the hydrolytic stability of bifenazate-diazene.

1.1.4. **Methods of analysis in plants**

Analytical methods for the determination of bifenazate and bifenazate-diazene residues were assessed during the MRL review and EU pesticides peer review for the renewal of the approval (EFSA, 2011, 2017a). The methods are sufficiently validated to analyse the residues of the sum of bifenazate and bifenazate-diazene (determined as bifenazate equivalents) in all plant matrices at the LOQ of 0.01 mg/kg for the total residue, except hops, in which the LOQ is 0.1 mg/kg.

1.1.5. **Storage stability of residues in plants**

The storage stability of bifenazate and bifenazate-diazene residues in various commodities stored under frozen conditions was investigated in the MRL review, the EU pesticides peer review renewal of the approval and in a previous EFSA reasoned opinion (EFSA, 2011, 2017a,b).

Storage stability of residues of bifenazate (assessed as ‘sum of bifenazate and bifenazate-diazene, expressed as bifenazate’) was demonstrated for 6 months for commodities with high acid content.

---

8 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
In separate storage stability studies with bifenazate (parent) and bifenazate-diazene, stability was limited. Since the samples from the residue trials were analysed according to the residue definition as the ‘sum of bifenazate and bifenazate-diazene expressed as bifenazate’, EFSA concluded that the total residues are expected to be stable if samples are stored under frozen conditions for no longer than 6 months.

Hence, for elderberries, a commodity classified as high acid content commodity, storage stability was sufficiently addressed.

1.1.6. Proposed residue definitions

Based on the results of the metabolism studies, the hydrolysis studies and the capabilities of enforcement analytical methods, the MRL review proposed the residue definition for monitoring and for risk assessment as the ‘sum of bifenazate and bifenazate-diazene, expressed as bifenazate’ (EFSA, 2011). The residue definitions are applicable to primary crops, rotational crops and processed products. A comparable residue definition for enforcement is set in Regulation (EC) No 396/2005.

In the framework of the EU pesticides peer review renewal process the above residue definition for risk assessment was confirmed but restricted to fruit crops, pending confirmation that the same toxicological reference values can be used for bifenazate and bifenazate-diazene. Regarding the possibility of setting a global plant residue definition for risk assessment, the EU pesticide peer review decided to further consider the relevance of the major metabolites A1530S and carbamate observed in the cereals’ metabolism study (EFSA, 2017a).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

The applicant provided five residue trials on currants conducted in 2015 in Germany according to the intended Good Agricultural Practice (GAP) for elderberries. Samples were analysed for the total residues (sum of bifenazate and bifenazate-diazene) and results were expressed as bifenazate equivalents.

According to the EU guidance document (European Commission, 2017), residue trials on currants (4 trials) can be used to derive an MRL proposal for the whole subgroup of small fruits and berries. Although a specific extrapolation from currants to elderberries is not mentioned in the guidance document, EFSA considered four residue trials in currants as sufficiently representative to derive an MRL proposal by extrapolation for the single crop elderberries. The fact that residue trials are available only from 1 year is a minor deviation which may be acceptable for this minor crop, considering that the location of the trials were sufficiently spread to ensure independency of the trials. According to the EMS, the method of analysis used, which determined the sum of bifenazate and bifenazate-diazene, was sufficiently validated and fit for purpose (Germany, 2019). Samples from the residue trials were stored deep frozen for a period of 3 months for which storage stability was demonstrated.

1.2.2. Magnitude of residues in rotational crops

Not required. Elderberries are permanent crops.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies to address the magnitude of residues for the crop under assessment are not available. Due to expected low consumer exposure to residues resulting from the intended use of bifenazate in elderberries, processing studies are not required.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for elderberries (see Appendix B.1.2.1). In Section 3, EFSA assessed whether residues on this crop resulting from the intended use are likely to pose a consumer health risk.

---

9 The residue definition for bifenazate in Regulation (EC) No 396/2005 is ‘sum of bifenazate plus bifenazate-diazene expressed as bifenazate’. At time of implementation of Regulation (EU) No 79/2014, risk managers did not take into consideration EFSA proposal to change the residue definition for enforcement (to replace ‘plus’ with ‘and’). Anyway, the two words have the same meaning in this sentence.
2. Residues in livestock

Residues of bifenazate in commodities of animal origin were not assessed in the framework of this application, since elderberries are not fed to livestock.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological profile of bifenazate was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary. During the process of renewal of the approval under Regulation (EC) No 1107/2009, the same ADI was agreed while an ARfD of 0.1 mg/kg bw has been set (EFSA, 2017a). Although this ARfD has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee), EFSA performed an acute dietary intake calculation considering the ARfD of 0.1 mg/kg bw.

The most recent long-term consumer exposure (EFSA, 2017b) was updated with median residue value (STMR) derived for the commodity under assessment. The estimated long-term dietary intake accounted for a maximum of 55% ADI (DE child). The contribution of residues in elderberries to the overall long-term exposure is very small 0.015% of ADI. No long-term intake concerns were identified for the authorised and intended use of bifenazate.

When considering the ARfD set during EU pesticide peer review, no short-term intake concerns were identified for the intended use of bifenazate in elderberries.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for elderberries. Adequate analytical methods for enforcement are available to control the residues of bifenazate and its metabolite in the commodity under consideration at the validated LOQ of 0.01 mg/kg.

Based on the risk assessment results, EFSA concluded that the dietary intake of residues resulting from the use of bifenazate according to the intended agricultural practice is unlikely to present a risk to consumer health.

The MRL recommendations are summarised in Appendix B.4.

References

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers’ health arising from proposed temporary EU MRLs. EFSA Journal 2007;5(3):32r, 1141 pp. https://doi.org/10.2903/j.efsa.2007.32r

EFSA (European Food Safety Authority), 2011. Review of the existing maximum residue levels for bifenazate according to Article 12 of Regulation (EC) No 396/2005, 6 December 2011. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2012a. Reasoned opinion on the modification of the existing MRLs for bifenazate in currants (red, black and white), blackberries and raspberries. EFSA Journal 2012;10(2):2577, 24 pp. https://doi.org/10.2903/j.efsa.2012.2577

EFSA (European Food Safety Authority), 2012b. Reasoned opinion on the modification of the existing MRLs for bifenazate in citrus fruit, pome fruit, stone fruit, grapes, hops, strawberries, tomatoes, peppers, aubergines, melons, watermelons. EFSA Journal 2012;10(10):2920, 45 pp. https://doi.org/10.2903/j.efsa.2012.2920

EFSA (European Food Safety Authority), 2015. Reasoned opinion on the modification of the existing MRLs for bifenazate in blueberries, cranberries, gooseberries and azaroles (kiwiberries). EFSA Journal 2015;13(3):4047, 20 pp. https://doi.org/10.2903/j.efsa.2015.4047

EFSA (European Food Safety Authority), 2017a. Conclusion on the peer review of the pesticide risk assessment of the active substance bifenazate. EFSA Journal 2017;15(1):4693, 27 pp. https://doi.org/10.2903/j.efsa.2017.4693
EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Janossy J, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Molnar T, Nougadere A, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Styrm J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2017b. Reasoned opinion on the modification of the existing maximum residue level for bifenazate in soy bean. EFSA Journal 2017;15(9):4983, 22 pp. https://doi.org/10.2903/j.efsa.2017.4983

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev., 22 July 1996.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/V/95-rev. 6, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/V/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/V/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/V/95-rev. 3, 22 July 1997.

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/V/95-rev. 5, 22 July 1997.

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/V/95-22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev. 4.

European Commission, 2005. Review report for the active substance bifenazate. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 3 June 2005 in view of the inclusion of bifenazate in Annex I of Council Directive 91/414/EEC. SANCO/10158/2005-rev.3, 3 June 2005.

European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/V/95-Rev. 10.3, 13 June 2017

FAO (Food and Agriculture Organization of the United Nations), 2016. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd Edition. FAO Plant Production and Protection Paper 225, 298 pp.

Germany, 2019. Evaluation report on the modification of MRLs for bifenazate in elderberries. May 2019, 24 pp.

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org

Sweden, 2016a. Renewal Assessment Report (RAR) on the active substance bifenazate prepared by the rapporteur Member State Sweden, in the framework of Commission Implementing Regulation (EU) No 844/2012, January 2016.

Sweden, 2016b. Revised Renewal Assessment Report (RAR) on bifenazate prepared by the rapporteur Member State Sweden in the framework of Commission Implementing Regulation (EU) No 844/2012, November 2016.

**Abbreviations**

| Abbreviation | Definition |
|--------------|------------|
| a.i.         | active ingredient |
| a.s.         | active substance |
| ADI          | acceptable daily intake |
| ARfd         | acute reference dose |
| BBCH         | growth stages of mono- and dicotyledonous plants |
| bw           | body weight |
| CF           | conversion factor for enforcement to risk assessment residue definition |
| CXL          | Codex maximum residue limit |
| DAR          | draft assessment report |
| DAT          | days after treatment |
| EMS          | evaluating Member State |
| FAO          | Food and Agriculture Organization of the United Nations |
| GAP          | Good Agricultural Practice |
| HR           | highest residue |
| IEDI         | international estimated daily intake |
| IESTI        | international estimated short-term intake |
ISO  International Organisation for Standardisation
IUPAC  International Union of Pure and Applied Chemistry
LC-MS/MS  liquid chromatography tandem mass spectrometry
LOQ  limit of quantification
MRL  maximum residue level
MS  Member States
NEU  northern Europe
OECD  Organisation for Economic Co-operation and Development
PAFF  Standing Committee on Plants, Animals, Food and Feed
PBI  plant-back interval
PF  processing factor
PHI  preharvest interval
PRIMo  (EFSA) Pesticide Residues Intake Model
RA  risk assessment
RD  residue definition
RMS  rapporteur Member State
SANCO  Directorate-General for Health and Consumers
SC  suspension concentrate
SEU  southern Europe
SMILES  simplified molecular-input line-entry system
STMR  supervised trials median residue
TRR  total radioactive residue
WHO  World Health Organization

Modification of the existing MRL for bifenaze in elderberries
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F G or I(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|-------------------------|------------|-----------------------------------|-------------|----------------|-------------------------------|---------|
|                       |                         |            |                                   | Type(b) Conc. a.s. Method kind Range of growth stages & season(c) Number min-max Interval between application (min) g a.s./hl min-max Water L/ha min-max Rate Unit PHI (days)(d) |          |
| Elderberries          | NEU                     | F          | Red spider mites                  | SC 240 g/L Foliar treatment – broadcast spraying BBCH 11–97 2 7 days – 1,000 11.5 g/ha 14 |          |

GAP: Good Agricultural Practice; MRL: maximum residue level; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SC: suspension concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to 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.
(d): PHI: minimum pre-harvest interval.
Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

| Primary crops (available studies) | Crop groups | Crop(s) | Application rate (kg a.s./ha) | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|---------|-------------------------------|----------------|----------------|
| Fruit crops                       | Oranges     | 1× 0.42 and 2.24 | Fruits: 43, 184, 274, and 442 Leaves: 43 and 184 | EFSA (2011)  |
|                                  | Apples      | 1× 0.42 and 2.24 | Fruits: 31 and 101 Leaves: 0 and 101 | EFSA (2011)  |
|                                  | Grapes      | 1× 0.56 and 1.12 | Fruits and leaves: 0 and 30 | EFSA (2011)  |
| Root crops                        | Radishes    | 1× 1.12 and 2.24 | Leaves and roots: 7 | EFSA (2012b) |
| Leafy crops                       | --          | --       | --                            | --            |
| Cereals/grass crops               | Corn        | 1× 0.85 and 5.6 | Forage: 5 Stover and grains: 103 | EFSA (2012b) |
| Pulses/Oilseeds                   | Cotton      | 1× 0.56 and 2.24 | Leaves: 0 Seed and gin trash: 112 | EFSA (2012b) |

Radiolabelled active substance: phenyl-UL-14C-bifenazate. The results show that bifenazate is the major residue, but also bifenazate-diazene (D3598) occurs to different extent depending on the crop (up to 40% of TRR). Other metabolites were detected. Reference: (EFSA, 2011, 2012b, 2017a)

| Rotational crops (available studies) | Crop groups | Crop(s) | Application rate (kg a.i./ha) | PBI (days) | Comment/Source |
|-------------------------------------|-------------|---------|------------------------------|------------|----------------|
| Root/tuber crops                    | Carrots     | Bare soil, 0.56 and 5.6 | 30 and 125 | Label position: 1-phenyl ring. Low total radioactive residues (TRR) were detected in all samples from rotational crops. 'Bound' residues made up the majority of the TRR for most samples. The extractable portion of the TRR consisted of a number of products, suggesting extensive degradation and metabolism of bifenazate. Neither bifenazate nor any of the reference metabolites were detected in any of the extracts analysed (EFSA, 2011, 2017a) |
| Leafy crops                         | Lettuce     | Bare soil, 0.56 and 5.6 | 30 and 125 |
| Cereal (small grain)                | Wheat       | Bare soil, 0.56 and 5.6 | 30, 125, 360 |
| Processed commodities (hydrolysis study) | Conditions | Investigated? | Comment/Source |
|-----------------------------------------|------------|--------------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)     | Yes        | The hydrolysis study showed that bifenazate is stable under these processing conditions. (EFSA, 2012a) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | The only other residue observed was bifenazate-diazene (D3598), which is the major metabolite in raw commodities. D3598 was not studied separately in a hydrolysis study and it is not known whether it will have a similar stability as parent (data gap of the EU Pesticide Peer Review). Reference: (EFSA, 2017a) |
| Sterilisation (20 min, 120°C, pH 6)     | Yes        | |

Can a general residue definition be proposed for primary crops?

- Yes (EFSA, 2011)

Rotational crop and primary crop metabolism similar?

- Yes (EFSA, 2011)

Residue pattern in processed commodities similar to residue pattern in raw commodities?

- Yes (EFSA, 2011)

Plants residue definition for monitoring (RD-Mo)

- Reg 396/2005: Sum of bifenazate plus bifenazate-diazene, expressed as bifenazate
- EFSA, 2017a: Sum of bifenazate and bifenazate-diazene (D3598), expressed as bifenazate

Plants residue definition for risk assessment (RD-RA)

- Sum of bifenazate and bifenazate-diazene (D3598), expressed as bifenazate (EFSA, 2011)
- Fruit crops: Sum of bifenazate and bifenazate-diazene (D3598), expressed as bifenazate (pending confirmation that the same toxicological reference values can be used for bifenazate and bifenazate-diazene) (EFSA, 2017a)

Conversion factor (monitoring to risk assessment)

- 1

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

- Matrices with high water content, high oil content, high acid content and dry matrices, except hops: LC–MS/MS, LOQ 0.01 mg/kg (EFSA, 2011)
- Hops: LC–MS/MS, LOQ 0.1 mg/kg (EFSA, 2017a)

DAT: days after treatment; a.s: active substance; PBI: plant-back interval; a.i.: active ingredient; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category               | Commodity                              | T (°C) | Stability | Compounds covered | Comment/Source |
|-----------------------------------|------------------------|----------------------------------------|--------|-----------|-------------------|----------------|
|                                   | High water content     | Tomato paste and puree                | –18    | 1 Month   | Bifenazate        | EFSA (2017a)   |
|                                   | High water content     | Cucumber fruits and leaves            | –20    | < 0.5 Month | Bifenazate        | EFSA (2017a)   |
|                                   | High water content     | Cotton whole plant                    | –18    | 37 Days   | Bifenazate        | EFSA (2017b)   |
|                                   | High acid content      | not specified                         | –18    | 6 Months  | (Total bifenazate and bifenazate-diazene) | EFSA (2011)   |
|                                   |                        | Strawberries                           | –18    | 6 Months  | Bifenazate        | EFSA (2017a)   |
|                                   | High oil content       | Cotton seed                            | –18    | 56 Days   | Bifenazate        | EFSA (2017b)   |
|                                   | Processed products     | Cotton seed refined oil               | ≤ −18  | 28 Days   | Bifenazate        | EFSA (2017b)   |
|                                   |                        | Cotton seed hulls                      | ≤ −18  | 52 Days   | Bifenazate        | EFSA (2017b)   |
|                                   |                        | Cotton seed meal                       | ≤ −18  | 42 Days   | Bifenazate        | EFSA (2017b)   |
### B.1.2. Magnitude of residues in plants

#### B.1.2.1. Summary of residues data from the supervised residue trials

| Commodity   | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|-------------|-----------------------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|--------------------------|--------------------------|----------------|
| Elderberries | NEU                         | 0.014; 0.04; 0.042; 0.098; 0.17                                    | Residue trials on currants compliant with GAP (±25% tolerance in application rate) Extrapolation to elderberries possible | 0.4                    | 0.17                     | 0.04                     | 1              |

MRL: maximum residue level; GAP: Good Agricultural Practice.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Not triggered | Elderberries are not grown in rotation with other crops |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Not triggered |

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application and are not required.

B.2. Residues in livestock

Not relevant

B.3. Consumer risk assessment

| ARfD | Not necessary (European Commission, 2005) 0.1 mg/kg bw (EFSA, 2017a) |
| Highest IESTI, according to EFSA PRIMo | Scenario 1: not necessary |
| | Scenario 2: Elderberries: 0.1% of ARfD Elderberry juice: 2.7% of ARfD |
| Assumptions made for the calculations | Scenario 1: not necessary |
| | Scenario 2: Calculations performed with PRIMo revision 2 |
| | The calculation in Scenario 2 is based on the highest residue level expected in the raw agricultural commodity under assessment using the ARfD of 0.1 mg/kg bw per day set in the EU pesticide peer review renewal of the approval (EFSA, 2017a) |
Modification of the existing MRL for bifenazate in elderberries

ADI

0.01 mg/kg bw per day (European Commission, 2005; EFSA, 2017a)

Highest IEDI, according to EFSA PRIMo

55% ADI (DE child)
Contribution of crops assessed:
Elderberries: 0.015% of ADI

Assumptions made for the calculations

Calculations performed with PRIMo revision 2
The calculation is based on the median residue levels derived for the raw agricultural commodity for the intended use on elderberries and for the authorised uses assessed during the MRL review and the EFSA reasoned opinions published after the MRL review
The contributions of commodities where no GAP or safe Codex limit (CXL) was reported in the framework of the MRL review were not included in the calculation

B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------------------|-----------|------------------------|-------------------------|-----------------------|
| Enforcement residue definition: Bifenazate (sum of bifenazate plus bifenazate-diazene expressed as bifenazate)<sup>(F)</sup> |
| 154080 Elderberries | 0.02* | 0.4 | The intended use in NEU is sufficiently supported by extrapolation from residue data on currants. Risk for consumers unlikely |

MRL: maximum residue level; NEU: northern Europe.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.
Appendix C – Pesticide Residue Intake Model (PRIMo)

### Bifenazate

| Status of the active substance: | approved | Code no. | LOQ (mg/kg bw): | 0.01 | Proposed LOQ: | 0.01 |
|-------------------------------|----------|----------|-----------------|------|--------------|------|
| ADI (mg/kg bw per day):       | 0.01     | ARfD (mg/kg bw): | 0.1 |
| Source of ADI:                | EC       | Source of ARfD:  | EFSA |
| Year of evaluation:           | 2005     | Year of evaluation: | 2017 |

No of diets exceeding ADI: ---

### Highest calculated TMDI values in % of ADI

| Commodity/group of commodities | No of diets exceeding ADI |
|--------------------------------|--------------------------|
|                                 | 1 2 3 ... 55             |

### Highest contributor to MS diet (in % of ADI)

| Commodity/group of commodities | 2nd contributor to MS diet (in % of ADI) | 3rd contributor to MS diet (in % of ADI) | pTMRLs at LOQ (in % of ADI) |
|--------------------------------|----------------------------------------|----------------------------------------|-----------------------------|
|                                 | 1 2 3 ... 55                          | 1 2 3 ... 55                          | 1 2 3 ... 55                |

**Conclusion:**

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Bifenazate is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

For processed commodities, no exceedance of the ARfD/ADI was identified.

| Commodity | ARfD/ADI | pTMRL/Threshold MRL (mg/kg) |
|-----------|----------|-----------------------------|
| Elderberries | 0.17/- | 0.17/- |

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

Conclusion:

For Bifenazate, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

For processed commodities, no exceedance of the ARfD/ADI was identified.
## Appendix D – Input values for the exposure calculations

### D.1. Consumer risk assessment

| Commodity                                      | Chronic risk assessment |Acute risk assessment |
|-----------------------------------------------|-------------------------|----------------------|
| Commodity Input value (mg/kg)                  | Comment                  | Comment              |
| Citrus fruits                                 | 0.23 Median residue (EFSA, 2012b) | Acute risk assessment performed only for the crop under consideration with the ARfD published in the EFSA Conclusions (EFSA, 2017a) |
| Tree nuts                                     | 0.03 Median residue (CXL) (EFSA, 2011) |                      |
| Pome fruits                                   | 0.18 Median residue (CXL) (EFSA, 2011) |                      |
| Stone fruits                                  | 0.34 Median residue (CXL) (EFSA, 2011) |                      |
| Table and wine grapes                          | 0.19 Median residue (CXL) (EFSA, 2011) |                      |
| Strawberries                                  | 0.63 Median residue (CXL) (EFSA, 2011) |                      |
| Cane fruits                                   | 2.25 Median residue (CXL) (EFSA, 2011) |                      |
| Blueberries, cranberries, currants, gooseberries, azarole | 0.23 Median residue (EFSA, 2012a, 2015) |                      |
| Elderberries                                  | 0.04 Median residue |                      |
| Tomatoes                                      | 0.14 Median residue (EFSA, 2012b) |                      |
| Peppers                                       | 1.10 Median residue (CXL) (EFSA, 2011) |                      |
| Aubergines                                    | 0.18 Median residue (CXL) (EFSA, 2011) |                      |
| Cucurbits, edible peel                         | 0.05 Median residue (CXL) (EFSA, 2011) |                      |
| Cucurbits, inedible peel                      | 0.04 Median residue (EFSA, 2012b) |                      |
| Basil                                         | 12.90 Median residue (CXL) (EFSA, 2011) |                      |
| Beans (with and without pods), peas (with and without pods), lentils (fresh) | 0.4 Median residue (CXL) (EFSA, 2012b) |                      |
| Dry beans                                     | 0.01 Median residue (CXL) (EFSA, 2011) |                      |
| Soya beans                                    | 0.01 Median residue (EFSA et al., 2017b) |                      |
| Cotton seed                                   | 0.01 Median residue (CXL) (EFSA, 2011) |                      |
| Hops (dried)                                  | 7.80 Median residue (CXL) (EFSA, 2011) |                      |
| Mammalian*(a), meat*(b), fat, liver, kidney, edible offal, other | 0.01 Median residue (CXL) (EFSA, 2011) |                      |
| Poultry tissues                               | 0.01 Median residue (CXL) (EFSA, 2011) |                      |
| Ruminant milk                                 | 0.01 Median residue (CXL) (EFSA, 2011) |                      |
| Poultry eggs                                  | 0.01 Median residue (CXL) (EFSA, 2011) |                      |

CXL: Codex maximum residue limit.

(a): Swine, bovine, sheep, goats, horses and other farm animals.

(b): Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticide, STMR residue values were calculated considering a 80%/90% muscle and 20%/10% fat content for mammal/poultry meat respectively (FAO, 2016).
## Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|--------------------------------|-------------------------------------------------|---------------------------------|
| **Bifenazate**                | isopropyl 3-(4-methoxybiphenyl-3-yl)carbazateor isopropyl 2-(4-methoxybiphenyl-3-yl) hydrazinoformate COc1ccc(cc1NNC(=O)OC(C)C)c2cccc2 VHLKTXFWDRXILV-UHFFFAOYSA-N | ![Structural formula for Bifenazate](image1) |
| **Bifenazate-diazene (D3598)** | isopropyl (E)-(4-methoxybiphenyl-3-yl) diazenecarboxylate COc1ccc(cc1/N=N/C(=O)OC(C)C)c2cccc2 AGTBLMHQIEASU-VHEBQXMUSA-N | ![Structural formula for Bifenazate-diazene](image2) |
| **A1530S**                    | biphenyl-4-yl hydrogen sulfate OS(=O)(=O)OCccc(cc1)c2cccc2 JATOIOIIORRLF-UHFFFAOYSA-N | ![Structural formula for A1530S](image3) |
| **Carbamate**                 | isopropyl (4-methoxybiphenyl-3-yl)carbamate COc1ccc(cc1NC(=O)OC(C)C)c2cccc2 JPVRHMQFLMLREU-UHFFFAOYSA-N | ![Structural formula for Carbamate](image4) |

<sup>(a)</sup>: The name in bold is the name used in the conclusion.

<sup>(b)</sup>: ACD/Name 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 06 September 2017).

<sup>(c)</sup>: ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 February 2018).