2025

oekotoxzentrum
centre ecotox
Schweizerisches Zentrum für angewandte Ökotoxikologie
Centre Suisse d'écotoxicologie appliquée

SGV – Proposal by the Ecotox Centre for

Fluazinam

First proposal: 28.02.2025 (last bibliographic research)
22.09.2025 (implementation of the expertise)

Imprint

Publisher

Swiss Centre for Applied Ecotoxicology, 8600 Duebendorf/1015 Lausanne

Commissioned by

FOEN, Federal Office for the Environment, Soil and Biotechnology Division, 3003 Bern

Authors

Eva Lauber, Fabian Balk, Mathieu Renaud, Marion Junghans, Swiss Centre for Applied Ecotoxicology

Scientific Support

Stephan Jänsch, ECT Oekotoxikologie GmbH, Böttgerstraße 2-14, 65439 Flörsheim/Main, Germany

External reviewer is not responsible for the final published SGV or the contents of this dossier that is the sole responsibility of the authors.

Acknowledgement

This project was funded by the Swiss Federal Office for the Environment. The authors would like to thank Sophie Campiche (EnviBioSoil) and the people listed under scientific support for the exchange we had and the advice they provided.

Contact

Eva Lauber: eva.lauber@oekotoxzentrum.ch
Marion Junghans: marion.junghans@oekotoxzentrum.ch

Citation Proposal

Lauber E, Balk F, Renaud M, Junghans M. 2025. SGV – Proposal by the Ecotox Centre for Fluazinam. Swiss Centre for Applied Ecotoxicology, Dübendorf, Switzerland; 82 pp.

Policy disclaimer

According to the Action Plan for PPP (AP-PPP) (measure 6.3.3.7), pesticides in soil should be monitored in order to verify the evaluation carried out within the framework of the registration regarding the persistence of pesticides in the environment and their effect on soil organisms and soil functions. Therefore, a suitable method (indicator) for effects of PPP on soil fertility has to be developed and applied in field studies. Risk-based reference values for PPP residues should be available by 2025, and bioindicators for the effects of PPP residues on soil fertility should be developed by 2027.

In response to the AP-PPP and tasked by FOEN and FOAG, experts from the Ecotox Centre and EnviBioSoil have been working since 2018 on an integrative concept to assess the effects of PPP residues in soil. The following dossier represents the full evaluation, derivation and proposal of a Soil Guideline Value (a risk-based reference value), according to the recommended methodology developed within the AP-PPP project (Marti-Roura *et al.* 2023), and does not have a regulatory nature that goes beyond their intended use within the ongoing AP-PPP project. Further information on the ConSoil project and its framework can be found at: https://www.ecotoxcentre.ch/projects/soil-ecotoxicology/monitoring-concept-for-plant-protection-products-in-soils?_ga=2.170121120.1893072167.1726132886-1891293576.1686657912.

The data on the metabolites (Section 5 and Appendix 3) are included only as supporting information and have not been peer reviewed externally.

Oekotoxzentrum | Eawag | Überlandstrasse 133 | 8600 Dübendorf | Schweiz
T +41 (0)58 765 55 62 info@oekotoxzentrum.ch | www.oekotoxzentrum.ch

Centre Ecotox | EPFL-ENAC-IIE-GE | Station 2 | CH-1015 Lausanne | Suisse
T +41 (0)21 693 62 58 | info@centreecotox.ch | www.centreecotox.ch

Executive summary

As part of the Federal Action Plan on Plant Protection Products (Bundesrat, 2017), the Ecotox Centre develops proposals for Soil Guideline Values (SGV). These values are intended to provide an initial screening tool for assessing the potential risk for the long-term fertility of agricultural soils and for the soil ecosystem in general. Based on relevant and reliable effect data and applying the methodology described in the EU Technical Guidance Document on risk assessment (EC TGD 2003), with adaptations described in Marti-Roura *et al.* (2023), **it is not possible to derive a robust SGV for fluazinam.**

Zusammenfassung

Im Rahmen des Aktionsplans Pflanzenschutzmittel (Bundesrat, 2017) erarbeitet das Oekotoxzentrum Vorschläge für Bodenrichtwerte (SGV). Diese Werte sollen ein erstes Screening-Instrument zur Bewertung der potenziellen Risiken für die langfristige Fruchtbarkeit landwirtschaftlicher Böden und für das Ökosystem Boden im Allgemeinen darstellen. Auf der Grundlage relevanter und zuverlässiger Wirkungsdaten und unter Anwendung der im Technischen Leitfaden der EU zur Risikobewertung beschriebenen Methodik (EC TGD 2003) mit den in Marti-Roura *et al.* (2023) beschriebenen Anpassungen ist es **nicht möglich, einen robusten SGV für Fluazinam abzuleiten.**

Résumé

Dans le cadre du plan d'action Produits phytosanitaires (Conseil fédéral, 2017), le Centre Ecotox élabore des propositions de valeurs guides pour les sols (SGV). Ces valeurs sont destinées à fournir un outil de dépistage initial pour évaluer le risque potentiel pour la fertilité à long terme des sols agricoles et pour l'écosystème du sol en général. Sur la base des données pertinentes et fiables relatives aux effets et en appliquant la méthodologie décrite dans le document d'orientation technique de l'UE sur l'évaluation des risques (EC TGD 2003), avec les adaptations décrites dans Marti-Roura *et al.* (2023), **il n'est pas possible de dériver une SGV robuste pour le fluazinam**.

Sommario

Nell'ambito del Piano d'azione dei prodotti fitosanitari (Consiglio federale svizzero, 2017), il Centro Ecotox sviluppa proposte di valori guida per il suolo (SGV). Questi valori sono destinati a fornire uno strumento di screening iniziale per valutare il rischio potenziale per la fertilità a lungo termine dei suoli agricoli e per l'ecosistema del suolo in generale. Sulla base dei dati rilevanti e affidabili sugli effetti e applicando la metodologia descritta nel documento tecnico di orientamento dell'UE sulla valutazione del rischio (EC TGD 2003), con gli adattamenti descritti in Marti-Roura *et al.* (2023), **non è possibile ricavare un SGV robusto per il fluazinam.**

Table of content

1 General information

Information on the pesticide active substance fluazinam in relation to the soil environment is presented in this chapter. Registration information and risk assessments referred to are as follows:

- *EC (2006): Draft Assessment Report (DAR) - public version. Initial risk assessment provided by the rapporteur Member State Austria for the existing active substance fluazinam of the third stage (part A) of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC. European Commission, July 2006.*
- *EFSA (2008): Conclusion regarding the peer review of the pesticide risk assessment of the active substance fluazinam. Scientific Report, European Food Safety Authority. Finalised: 26 March 2008.*
- *EC (2019): Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009: Fluazinam. Rapporteur Member State: Austria, Co-Rapporteur Member State: Denmark. European Commission, June 2019.*
- *EC (2024): Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009: Fluazinam. Rapporteur Member State: Austria, Co-Rapporteur Member State: Denmark. European Commission, July 2024 (RAR updated after ED additional information).*
- *US EPA (2013): Environmental Fate and Ecological Effects Preliminary Risk Assessment for the Registration Review of Fluazinam. June 4, 2013. PC Code 129098. DP Barcode: D411177. Doc ID: EPA-HQ-OPP-2009-0039-0019.*[1]
- *(EFSA 2025a): Answer to "Your application for public access to documents of 5 May 2025 Ref. No.: PAD 2025/098 (00016036)". Legal Affairs Services, Parma, 4 July 2025, Ref. LV/PU/mm (2025) – out–35719985.*
- *(EFSA 2025b): Answer to "Your application for public access to documents of 9 July 2025" Ref. No.: PAD 2025/098 (00020470). Legal Affairs Services, Parma, 13 August 2025, Ref. LV/PU/rl (2025) - out-35840029.*

A draft assessment report (DAR; EC 2006) is available for the active substance and a representative product, on which the EFSA conclusion was based (EFSA 2008). Fluazinam got included in the framework of the 4th European program for the renewal of approvals of pesticide active substances (AIR IV, Group 1– *Substances with expiry date before 30 April 2019*) under Regulation (EC) No 1107/2009, for which a new dossier was submitted in the EU. The first public version of the draft Renewal Assessment Report (dRAR) was subjected to public consultation in 2019 (EC 2019), and later got updated with additional information and an assessment on endocrine disruptive (ED) properties (EC 2024).

In the latest version of the dRAR (see Version history and the coloured highlights in EC (2024) several changes and updates were implemented. However, in this latest version, only the sections that are related to the ED assessment are publicly available (i.e. active substance related sections with regard to the methods of analysis, toxicology and metabolism data and ecotoxicology data as well as the summary sections of Volume 1, Volume 2 and the List of Endpoints). For the product related documents, only the

[1] US EPA document is included for checking the completion of the data that were submitted to the EU or found through literature search. Recently it has been revealed that some manufacturers did not hand in all the studies to EFSA that they handed in to EPA (Mie & Rudén, 2023). However, data presented in US EPA documents are usually of limited use as these documents do not contain enough details to consider the relevance and reliability of a study.

initial dRAR sections are publicly available before the public consultation, the commenting period and the expert meetings (EC 2019).

Due to several changes to the endpoints and the inclusion of new endpoints in the updated List of Endpoints (LoEP), we requested access from EFSA under the EU regulation about public access to documents (PAD regulation, EC (2001)) to the updated ecotoxicology sections of the dRAR for the products (EC 2024), however, this was not granted. Then we requested access from EFSA to A) the new study reports that were submitted and evaluated after the initial dRAR (EC 2019) and B) the study reports for which the reliability of the effect concentration(s) could not be fully considered based on the study summaries in the initial dRAR and the updated study summaries were not available. From this request partial access[2] was granted to two study reports and after the external peer-review of this dossier, in a renewed application, to another four of the 15 requested study reports (EFSA 2025a, 2025b). The repeated follow up requests for the remaining nine studies have to date not been granted. As a result, no reliable prediction for the availability of these study reports can be made and in total, the time allocated for retrieving these reports has exceeded six months.

We also tried to get access to the study reports in question from BLV (Bundesamt für Lebensmittelsicherheit und Veterinärwesen – Federal Food Safety and Veterinary Office) via BLW (Bundesamt für Landwirtschaft – Federal Office for Agriculture), so far without success.

Without the details of the requested study reports, the derivation of a robust SGV for fluazinam is hindered as elaborated below. When all the study reports in question are available, the SGV for fluazinam can be reconsidered.

1.1 Identity and physico-chemical properties

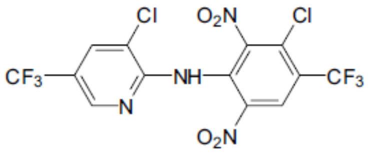
Fluazinam (CAS 79622-59-6) is a dinitroaniline fungicide (NCBI 2025). The pure material is a yellow solid, the technical material has a minimum purity of 960-980 g/kg as manufactured with the relevant impurity of 5-chloro-N-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-4,6-dinitro-o-toluidine (IUPAC name; code No. B-1457 / impurity 5 / impurity X / IMP.4 MW-464; CAS No. 169327-87-1) at maximum 2 g/kg level in the EU (EC 2024, FAO 2023, EC 2019). Another impurity/metabolite (Impurity 6; code No. G-624) was also mentioned in the updated dRAR, without specifying its amount (EC 2024); it was specified as 2,3,4-trichlor-α,α,α-trifluor-5-nitrotoluen in the Registration Report for the fluazinam-containing product, Shirlan (BVL 2011). For the EU renewal assessment, three applicants submitted dossiers with one representative product for each; in all cases a suspension concentrates (SC) containing nominally 500 g fluazinam/L (EC 2024). It is noted that currently the so-called fluazinam task force (FTF) comprises only Adama Makteshim Ltd. (ADM); the other independent applicants are ISK Biosciences Europe N.V. (ISK) and Finchimica SpA (FIN) (EC 2024). Previously Cheminova A/S (CHE) and Nufarm SAS (NUF) were also included in FTF.

The physical-chemical properties of fluazinam are summarised in Table 1 below.

Table 1: Identification and physico-chemical properties of fluazinam. Notes: ISK – ISK Biosciences Europe N.V., FIN – Finchimica SpA, ADM – Adama Makteshim Ltd.

Characteristics	Values	References
Common name	Fluazinam	EC (2006, 2019a and 2024) and EFSA (2008)

[2] Partial access means that personal data (i.e. "*names, signatures, contact details as well as other information allowing the identification of data subjects*") in the documents were masked in line with the relevant EU regulations.

Characteristics	Values	References
Producer's development code number	IKF-1216, B-1216, PP192 (ISK) None (FIN) MCW 465 (ADM)	EC (2024)
IUPAC name	3-chloro-N-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-2,6-dinitro-p-toluidine	EC (2024)
Chemical group	2,6-dinitroaniline fungicide	Lewis (2016)
Structural formula		EC (2024)
Molecular formula	$C_{13}H_4Cl_2F_6N_4O_4$	EC (2024)
CAS	79622-59-6	EC (2024)
EC Number	616-712-5	EC (2024)
SMILES code (canonical SMILES)	C1=C(C=NC(=C1Cl)NC2=C(C=C(C(=C2[N+](=O)[O-])Cl)C(F)(F)F)[N+](=O)[O-])C(F)(F)F	Lewis (2016)
International Chemical Identifier key (InChIKey)	UZCGKGPEKUCDTF-UHFFFAOYSA-N	Lewis (2016)
Molecular weight [g/mol]	465.1	EC (2024)
Melting point [°C]	117 (99.8 % w/w purity)	EC (2024)
Boiling point [°C]	Not applicable Test substance is not stable > 150°C (99.8 % w/w purity)	EC (2024)
Solubility		
Water solubility [mg/L]	0.106, 0.135 and 2.72 at pH 5, 7 and 9 (20°C, 99.8 % purity)	EC (2024)
Solubility in organic solvents [g/L]	ISK (96.8 % w/w purity, 25°C):	EC (2024)

acetone	853
dichlormethane	675
ethyl ether	231
ethyl acetate	722
heaxane	8
methanol	192
octanol	41
toluene	451

ADM (99.0 % w/w purity):

	15 °C	20 °C	25 °C
n-heptane	5.85	6.96	7.00
ethyl acetate	578	634	497
methanol	146	164	168
acetone	643	631	648
xylene	>250 *)	>250 *)	>250 *)
1,2-dichlorethane	>250 *)	>250 *)	>250 *)

*) determined in preliminary test

Characteristics	Values	References
Dissociation constant (pKa)	ISK: pKa = 7.34 at 20 ± 1 °C, (99.9 % w/w) FIN: pKa = 7.09 at 20 °C (99.5 % w/w) ADM: -	EC (2024)
Stability		
Aqueous hydrolysis [d]	DT50: at pH 4: stable (50°C) at pH 7: 7.6 (geometric mean, 25°C) pH 9: 4.6 (arithmetic mean, 25°C)	EC (2024)
Aqueous photolysis [d]	DT50: 2.5 (light, 25°C) no significant degradation (dark, 25°C)	EC (2024)
Photochemical degradation in air [d]	DT50 > 2 days derived by the Atkinson model (AOPWIN version 1.91)	EC (2024)

Characteristics	Values	References
Volatilisation		
Vapour pressure [Pa]	Overall median of data of 3 applicants: 1.38 x 10^{-5} (n = 8, 20°C, 99.5 % w/w purity) 3.3 x 10^{-5} (n = 7, 25°C, 99.5 % w/w purity)	EC (2024)
Henry's law constant [Pa·m^3·mol^{-1}]	Overall median of 3 applicants: 0.0475 (pH 7, 20°C)	EC (2024)
Partition/Adsorption		
Octanol-water partition coefficient (log Kow)	ISK (comparable method to OECD 107) : 4.03 (25°C, pH 5.5-7.0, 99.8 % w/w purity) ISK (method OECD 107): 4.99 at 20 °C (pH: 4.4), (99.7 %w/w) 4.82 at 20 °C (pH: 7.1), (99.7 %w/w) 4.05 at 20 °C (pH: 9.0), (99.7 %w/w) FIN (method OECD 107): 4.56 at 20 °C (pH: 4), (99.5 %w/w) 4.50 at 20 °C (pH: 7), (99.5 %w/w) 2.99 at 20 °C (pH: 9), (99.5 %w/w) FIN (method OECD 117): 4.89 at 20°C (pH: 4), (99.5 % w/w) 4.89 at 20°C (pH: 7), (99.5 % w/w) ADM (method OECD 107): 4.95 at 22-23 °C (pH: 4), (99.5 %w/w) 4.87 at 22-23 °C (pH: 7), (99.5 %w/w) 3.91 at 22-23 °C (pH: 9), (99.5 %w/w)	EC (2024)
Organic carbon normalised Freundlich partitioning coefficient (Kfoc)	See section 1.5.3, Table 3	

1.2 Mode of action

Fluazinam is a lipophilic weak acid acting as a potent uncoupler of oxidative phosphorylation in mitochondria and also having high reactivity with thiols (NCBI 2025). As a result, it acts as an inhibitor of the germination of fungal spores and of the development of fungal structures. Its activity against the zoospores of *Phytophtora infestans* makes it a widely used agent to control late blight in potato. The broad-spectrum activity can also be used against other diseases, such as *Sclerotinia* on turf, *Botrytis* on grapes and beans as well as *Plasmodiophora* in brassicas.

Its broad-spectrum activity is protectant, but it is neither systemic nor curative (NCBI 2025). It belongs to the FRAC C5 resistance group (uncouplers of oxidative phosphorylation): due to its multi-site activity, no development of wide-spread resistance by pathogens is expected (EC 2024).

Fluazinam also belongs to the per- and polyfluoroalkyl substances (PFAS) class containing two trifluoromethyl (-CF_3) groups. For pesticides, fluorination is used to modify chemical attributes of the active substance (e.g. to increase stability, lipophilicity or residual activity) (Donley *et al.* 2024). PFAS are known to be persistent chemicals in the environment and they are linked to various toxic effects (e.g. immunotoxic, carcinogenic, reproductive and developmental effects, metabolic and thyroid issues). Although fluazinam itself is only moderately persistent (see DissT50 in soil, Section 1.5.2), the metabolites are also fluorinated. No accumulation is expected for fluazinam, while the major aerobic soil metabolite HYPA – with field DT50 up to 556 days – is expected to reach a plateau concentration of 0.035-0.037 mg/kg soil following the EU representative use in potato (EC 2024).

The updated renewal assessment report contains the latest results of fluazinam evaluation with regard to the potential endocrine disrupting (ED) effects (EC 2024). Concerning humans, the thyroid-related criteria were considered met; the estrogen-, androgen- and steroidogenesis-related ED criteria were not met (Vol. 1, p.435 and 495). Regarding wildlife, the thyroid-related criteria were considered met for wild mammals but not for other vertebrate non-target organisms, while the estrogen-, androgen- and steroidogenesis-related ED criteria were not met for wild mammals but were met for other vertebrate non-target organisms (Vol. 1, p.494 and 495). However, it is noted that in the proposed decision (Vol. 1, Level 3, 3.1.1.4, p.513 and 515 in the dRAR updated after ED assessment; EC (2024)), the previously indicated data gap has not been updated and no overall conclusion was drawn on the ED properties of fluazinam and no further decision was proposed.

It should be noted that the current evaluation of ED properties focuses on vertebrates, however, the endocrine system of soil invertebrates displays substantial differences. With this in mind, extrapolation of the endocrine mode of action from vertebrates to soil invertebrates is not possible. At present, no validated tools are available for the determination of any invertebrate endocrine mode of action (OECD 2018, Crane *et al.* 2022). Additionally, a systematic literature search on fluazinam yielded no data on specific endocrine-relevant endpoints for in-soil organisms (status 02.2025).

With regard to human toxicology, the potential of genotoxic, carcinogenic, neurotoxic and reproductive effects of fluazinam were investigated (EC 2024). In a battery of genotoxicity assays, fluazinam showed genotoxic potential *in vitro* but not *in vivo*. It was not found to be carcinogenic or neurotoxic. Generational studies with rat and developmental toxicity studies with rat and rabbit indicated certain reproductive effects resulting in the respective classification of the substance (see Section 1.4).

1.3 Use and emissions

Fluazinam is a broad-sprectum fungicide that is authorised in the EU in several plant protection products (solo or in combination with other active substances) for use in various crops, for instance in potato (e.g. 4-10 x 200 g a.s./ha with 7-10 d intervals), winegrape (e.g. 5 x 750 g a.s./ha with 7 d intervals), herbaceous and woody ornamental plants (e.g. 4 x 200 g a.s./ha with 7 d intervals), root and tuber vegetables (e.g. 2 x 100 g a.s./ha with 7-10 d interval) and onion (e.g. 3-4 x 250 g a.s./ha with 7 d intervals) (EPPO 2025).

The representative use for the European authorisation procedure and now for the renewal assessment of the active substance is in potato against potato late blight disease (maximum 10 applications x 200 g a.s./ha with 7-10 days intervals (EFSA 2008, EC 2024).

In Switzerland, fluazinam is authorised in 21 products as a single active substance and in 9 products in combination with another active substance. It is not available for home garden uses (BLV 2025). The products containing fluazinam alone are authorised for uses in winegrape (e.g. 2 x 600 g a.s./ha, interval between applications is not listed), onion (e.g. 3 x 250 g a.s./ha with 7-10 d intervals), potato (e.g. 200 g a.s./ha with 7-10 d intervals, number of applications is not listed) and ornamental plants (e.g. 3 x as a 0.04 % solution, maximum amount of use per hectare is not listed).

1.4 Classification and environmental limit values

During the last finalised EU assessment (EFSA 2008), the following classification and labelling was proposed for fluazinam in line with the previous legistlations (Directive 67/548/EEC and 1999/45/EC):

- *Xn, R20 Harmful by inhalation*
- *Xi, R41 Severely irritating to the eyes*
- *Xi, R43 May cause sensitisation by skin contact*
- *Xi, R38 Irritating to skin*
- *Xn, Toxic to reproduction category 3*
- *R63 Possible risk of harm to the unborn child*
- *R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment*

According to the current harmonised classification and labelling approved by the European Union ((EC) No 1272/2008; ECHA (2025)), the substance is considered as

- *H317 (May cause an allergic reaction)*; Skin sensitisation category 1A
- *H318 (Causes serious eye damage)*; Eye damage category 1
- *H332 (Harmful if inhaled)*; Acute toxicity category 4
- *H400 (Very toxic to aquatic life)*; Aquatic acute category 1
- *H410 (Very toxic to aquatic life with long lasting effects)*; Aquatic chronic category 1
- *H361d (Suspected of damaging the unborn child)*; Reproduction category 2
- *GHS05 [Corrosion]*
- *GHS07 [Exclamation mark]*
- *GHS08 [Health hazard]*
- *GHS09 [Hazardous to the aquatic environment]* and requires the
- Signal word: *Danger*

In the latest dRAR the following classification and labelling are proposed (Vol.1 in EC (2024)):

- *H317*; Skin sensitisation category 1
- *H318*; Eye damage category 1
- *H332*; Acute toxicity category 4
- *H361d*; Reproduction category 2
- *H400*; Aquatic acute category 1
- *H410*; Aquatic chronic category 1
- Signal word: *Danger*

GHS pictograms were not included in the dRAR as their use is specified in the regulation in conjunction with the prescribed hazard signs and statements.

In addition to the above listed harmonised classificiation and labelling, the following hazard classes and categories were also notified by stakeholders (ECHA 2025):

- *H315 (Causes skin irritation)*; Skin irritation category 2
- *H319 (Causes serious eye irritation)*; Eye irritation category 2
- *H330 (Fatal if inhaled)*; Acute toxicity category 2
- *H373 (May cause damage to organs through prolonged or repeated exposure)*; Specific target organ toxicity after repeated exposure category 2

Fluazinam is not listed as a candidate for substitution in the EU (EC 2011, 2015) or in Switzerland (PSMV 2010).

Fluazinam is not considered to be a persistent organic pollutant (POP), a persistent, bioaccumulative and toxic (PBT) substance or a very persistent and very bioaccumulative (vPvB) substance as further considered in section 1.5.2 (also see Vol. 1 in EC (2024)).

Up to now, no soil protection value for retrospective analysis could be found for fluazinam. Please note that the information included here may have changed since the finalisation of this dossier.

1.5 Environmental fate in soil

Volatilisation from soil surface

Considering the physico-chemical properties of fluazinam (see vapour pressure and Henry's law constant in Table 1), volatilisation from soil surface can be considered medium to low (EC 2008, 2019, 2024).

Photodegradation

Photolysis on soil surface can contribute to the degradation of fluazinam; as a result, HYPA and AMPA-fluazinam were found as minor metabolites (Vol. 3CA B.8 in EC (2019).

1.5.1 Route of degradation

Route of degradation was tested via labelling the ^{14}C-*phenyl* and the ^{14}C-*pyridyl* groups; the results given below cover the broadest range combining both types of labelling.

Aerobic degradation in soil

In the aerobic degradation studies only HYPA was found as a major soil metabolite with 5.5 to 13.9 % of the applied radioactivity (AR; LoEP in EC (2024).

Anaerobic degradation in soil

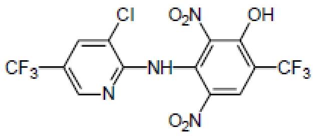
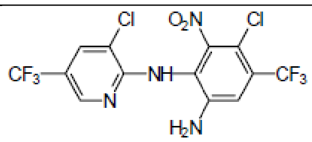
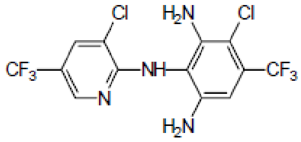
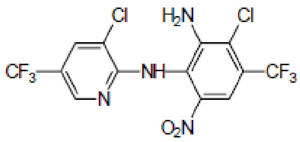
In one soil, the anaerobic degradation of fluazinam resulted in three major soil metabolites: AMPA-fluazinam, DAPA and MAPA (LoEP in EC (2024). It was noted that in the case of the representative use on potato, anaerobic soil conditions were not expected.

The transformation products of fluazinam in soil are summarised in Table 2 below.

Mineralisation and non-extractable residues

Aerobic mineralisation resulted in 0.4-5.0 % AR with non-extractable residues of 15.8-39.0 % after 90-128 days (EC 2024).

Table 2: Fluazinam major soil metabolites. Abbreviation: AR – applied radioactivity

Code/trivial name (synonyms)	**Chemical name**	**Structural formula**	**Route of degradation: maximum occurrence** **[% AR]**	**Reference**
HYPA (G-450, REF 301)	5-(3-chloro-5-trifluoromethyl-2-pyridylamino)-α,α,α-trifluoro-4,6-dinitro-o-cresol		Aerobic: 13.9	EC (2024), LoEP
AMPA-fluazinam (AMPA, AMPAF, REF 302)	4-chloro-6-(3-chloro-5-trifluoromethyl-2-pyridylamino)-α,α,α-trifluoro-5-nitro-m-toluidine		Anaerobic: 8.7	EC (2024), LoEP
DAPA	4-chloro-2-(3-chloro-5-trifluoromethyl-2-pyridylamino)-5-trifluoromethyl-m-phenylenediamine		Anaerobic: 12.0	EC (2024), LoEP
MAPA (G-525)	2-chloro-6-(3-chloro-5-trifluoromethyl-2-pyridylamino)-α,α,α-trifluoro-5-nitro-m-toluidine		Anaerobic: 31.2	EC (2024), LoEP

1.5.2 Rate of degradation

<u>Laboratory degradation studies</u>

For calculating the degradation of fluazinam under aerobic laboratory conditions, various degradation methods were used as best-fitting models (e.g. SFO – single first-order, DFOP – double first-order in parallel, FOMC – first-order multi-compartment, HS – Hockey-Stick). The resulting non-normalised DT50 values (persistence endpoints) ranged between 3.9 and 215 days (pH 5.4-7.38; various sandy loam and loamy sand soils) indicating ***low to high persistence of fluazinam in soil under aerobic conditions*** with no pH-dependence.

The non-normalised aerobic degradation half-lives indicated ***high persistence*** (DT50 values of 109-273 days; dosed as the parent compound; sandy loam soil; pH 6.4-7.23) as well as ***moderate to very high persistence*** (DT50 of 10.8-396 d; dosed as metabolite; sand, loamy sand, sandy loam and clay loam soils; pH 5.1-7.4) ***of the aerobic soil metabolite HYPA under aerobic conditions*** with no pH-dependence.

During the renewal review, anaerobic degradation of fluazinam and in turn its soil metabolites was not considered relevant as anaerobic conditions were not expected to occur for the proposed representative uses (EC 2024). The previously submitted and evaluated anaerobic degradation study indicated low persistence of fluazinam (DT50 of 3.8 d) and moderate to high persistence of HYPA (DT50 of 54-148 d) (EC 2006). The degradation rates of the anaerobic metabolites of AMPA-fluazinam, DAPA and MAPA (see Table 2 above) were not investigated.

Field dissipation studies

Under field conditions the dissipation half-lives of ***fluazinam*** were significantly shorter (non-normalised DissT50 values of 13.5-43.7 d; UK, Germany, northern France and Spain; sandy clay loam, sandy loam, loam and silt loam soils; pH 5.9-7.5) indicating ***moderate persistence*** (EC 2024).

In the same field studies as for fluazinam, i.e. dosed as the parent compound, ***HYPA showed medium to very high persistence*** (non-normalised DissT50 values of 62.4-556 d).

Additional studies

In a field dissipation study, fluazinam was investigated in two locations in China (Feng *et al.* 2015). The application of 375 g a.s./ha rate to bare soils resulted in initial concentrations of 7.89 and 1.11 mg a.s./kg soil (not reported if wet or dry weight of soil; sampled 2 hours after treatment, 15 cm soil layer, clay loam soils with organic matter (OM) content of 2.1 and 2.7 %, pH of 7.4 and 6.4, respectively). The DissT50 values were determined as 4.7 and 13 days that are somewhat lower than reported in the regulatory field dissipation studies. The results indicated that the degradation of fluazinam in soil may be enhanced by alkaline conditions and that the degradation was more influenced by the soil pH than the OM content.

In another field study, dissipation of fluazinam was investigated together with dimetomorph in two locations in China (Chen *et al.* 2018). For the dissipation experiment, a 35 % SC formulation containing 17.5 % fluazinam and 17.5 % dimetomorph was used. The application of 630 g a.s./ha rate (presumably this a.s. amount was meant as the sum of the two a.s. together) to growing potato plants (no growth stages were reported) resulted in an initial fluazinam concentration of 0.252 and 0.708 mg a.s./kg soil (not reported if wet or dry weight of soil; sampled 2 hours after treatment, 10 cm soil layer, the soil parameters were not reported). The DissT50 values of fluazinam were 9.4 and 9.5 days. It should be noted that the degradation of fluazinam could be affected by the presence of dimethomorph therefore these results cannot be compared to the results gained with fluazinam alone.

1.5.3 Adsorption/desorption properties and bioavailability

Adsorption

Based on laboratory adsorption tests, ***fluazinam*** can be classified as ***low to slightly mobile*** in soil. The mobility of the metabolites varies between the categories of immobile and medium mobile (Table 3).

Leaching

A column leaching study resulted in fluazinam residues below the limit of detection (LOD; 2 µg/L for the study) (EC 2006). During the field dissipation studies, no residues above the LOQ were detected below 20 cm in any sample at any time. Aged residues leaching and field leaching studies were not submitted and not required (EC 2006, 2024).

Bioavailability

The bioavailability of a chemical compound and in turn the actual toxicity of a substance to in-soil organisms is dependent on various factors including the soil physical and chemical properties (e.g. organic matter content, texture/clay content, pH and/or cation exchange capacity) as well as the physiology and behaviour of the organism considered (e.g. surface:volume ratio, anatomy, feeding strategy and/or preferences in habitat) (Peijnenburg 2020, Marti-Roura *et al.* 2023). Proper consideration of bioavailability can help with reducing the overestimation of the actual risk. In order to account only for the bioavailable portion of the tested substance, the test results need to be normalised to the above mentioned soil properties. In the absence of appropriate equations that can mirror the whole complex system, in regulatory context normalisation usually takes place only to the organic matter (OM) content that is considered the main factor influencing bioavailability for non-ionised organic compounds (Marti-Roura *et al.* 2023).

However, fluazinam is a lipophilic weak acid (experimental pKa = 7.09-7.34, see Table 1). In general, the bioavailability of weak acids (pKa 3 to 7) is the highest in acidic to neutral environment. It is expected that at pH lower than the dissociation constant (pKa), the neutral fraction (protonated form) of a weak acid is higher than that of the ionised fraction (deprotonated form). At pH equal to the pKa, the non-ionised and ionised forms occur approximately at equal parts. If the pH is above the pKa, the fraction of the ionised form is higher and can undergo repulsion by the negatively charged surfaces of the soil particles (e.g. OM, clay) resulting in a higher likelihood of leaching (reviewed in Kah & Brown 2006). The top-soil pH of Swiss agricultural soils ranges between pH 4 and 8 as the broadest (Reusser *et al.* 2023) but mainly between pH 4.5 and 7.5 (median 6.0), whereas clay content ranges between 5 % and 50 % (median 20 %; Marti-Roura *et al.* 2023, Reusser *et al.* 2023). When an ionisable organic chemical occurs mostly in its neutral form in the common soil pH range, the sorption to soils is most likely dominated by the neutral form partitioning to soil organic matter (defined by Koc, the organic carbon-normalised adsorption coefficient). For partially ionised chemicals, adsorption can be described by a weighted approach of the neutral form's sorption via Koc and the ionised species' sorption via its own Koc (Droge 2020). In the case of fluazinam, the neutral form dominates with about 99 to 90 % at a soil pH of 4 to 6 and it decreases to about 50 % at a soil pH of 7, where the other 50 % fluazinam occurs in the ionised form. A pH dependence in soil adsorption should be observable, if the OM content of a soil is considered alone as the sorbing matrix. Therefore, a pH-dependent Kow (termed Dow), which is a fraction-weighted calculation of Kow values from the neutral and ionised forms, would give more insights into the soil sorption behaviour of fluazinam. Theoretically, the listed Kow values in Table 1 are such Dow values (determined experimentally). Modelled Kow of the neutral and ionised fluazinam gave log Kow values of 6.93 and 4.02, respectively (partitioning calculations; MarvinSketch, version 23.14.0, date of version release 17.10.2023, ChemAxon, http://www.chemaxon.com.). Since these values are relatively close to each other, both forms may adsorb to the OM particles in soil, which may lead to less pronounced differences in fluazinam adsorption in the natural pH range of agricultural soils.

Two adsorption studies were submitted for the evaluation conducted at EU-level: only the older one was evaluated and agreed upon by the RMS (Galicia & Völkl 1991); although for the newer one (Geffke 2007a) also a detailed summary can be found in the relevant dRAR section.

In the first study (Galicia & Völkl 1991, please find the more detailed summary in B.8.2.1.1, p.43, EC (2006); briefly summarised in Vol. 3CA B.8.1.3.1, p.234, EC (2019)), adsorption and desorption were investigated in four soils in a narrow pH range of 6.0-7.7 (0.48-2.55 % organic carbon (OC) content; 7.2-38.0 % clay; Table 3), around the pKa of fluazinam. In the study summary, it was concluded that *the results* indicated *that a large percentage of fluazinam* was *strongly/irreversibly adsorbed* and that *increasing adsorption (Kf) was observed with increasing organic matter content.* It is noted that the statistical methods and results were not included in the study summary. The partition coefficients normalised to organic carbon content of the soil (Kfoc) seem to be inversely proportional to the soil OC content, though the differences in Kfoc are small (Table 3). Soil pH, clay content and texture did not seem to have an effect on fluazinam adsorption in the studied soil.

The second study (Geffke (2007a) summarised in Vol. 3CA B.8.1.3.1, p.235, EC (2019)) was not evaluated and the results were not agreed upon by the RMS. Also, the results were not included in the respective mean values that were considered further for the exposure assessment. Adsorption and desorption were investigated in five soils (pH 3.2-7.2, 1.36-4.43 % OC and 6.0-75.0 % clay content;

Table 3). The study is mostly well summarised with details on the materials and methods as well as the results. It was noted in the summary that a "*significant correlation between the degree of adsorption and the organic carbon content of the soil is indicated. Likewise, a pH dependency of adsorption was observed, which, however, was not significant*." Unfortunately, the statistical methods and results were not included in the study summary. The Kf and Kfoc values in the silty loam soil (pH 7.2) seem to contradict a correlation between the soil OC content as well as the soil pH and fluazinam adsorption. These values might merely represent outliers but the possible reasons for this are unclear and cannot be assessed with the information at hand.

Overall, the compiled results for both adsorption studies together could indicate a correlation between the soil OC content and fluazinam adsorption (Kf or Kfoc) (exception: silty loam soil, pH 7.2, Kfoc of 79 304 mL/g from the study of Geffke (2007a); figure is not shown). The indication of the compiled results for a pH-dependence of fluazinam adsorption, however, is less clear.

For non-ionised organic compounds, it is assumed that bioavailability is mainly driven by the OM content of the soil (EC TGD 2003). Although fluazinam is a weak acid, the experimental adsorption data overall could indicate a direct relationship between the soil OC content and the Kf or Kfoc values. Consequently, the toxicity test results are normalised to a standard organic matter content (see Section 3).

It should be noted that for the prospective environmental risk assessment for pesticides, no specific normalisation takes place with regard to the OM/OC content of the test soil or for other soil parameters. The EU terrestrial guidance (EC 2002) – that is still in place for evaluating soil micro- and macro-organisms – requires to account for the availability of lipophilic organic contaminants to earthworms as the "*toxicity of lipophilic organic contaminants to soil organisms usually depends on the organic carbon content (foc) of the substrate as this governs adsorption and thus pore water concentration*." The difference should be accounted for "*by dividing the LC50 and the NOEC values by 2 where log Kow is greater than 2 unless it can be demonstrated by soil sorption data or other evidence that the toxicity is independent of foc"*. This provision was not used consequently later on, only for earthworms, even after the compulsory data requirements were broadened to include *Folsomia* and *Hypoaspis*; also, sometimes the EPPO scheme (EPPO 2003) was followed – that was referenced in the terrestrial guidance – meaning that the correction was used only for test soils with 10 % peat content but not with 5 % peat content. The issue was further discussed in an EFSA expert meeting on general recurring issues in ecotoxicology (EFSA 2015). It was agreed upon that the correction factor of 2 should be applied in case of artificial test soils containing both 5 and 10 % peat and for all Tier 1 soil macro-organism tests. As a refinement, the independence of toxicity from soil OM content can be shown and/or sufficiently representative natural soils can be used for testing. Instead of applying this EU correction, for the SGV derivation the ecotoxicological data are normalised to a standard organic matter content as explained above (also see Section 3).

In the absence of physical-chemical parameters, the ionisability of the soil metabolites were investigated via estimating their dissociation constants (pKa), possible ionised forms and the resulting speciation at a wide pH range (pKa calculations; MarvinSketch, version 23.14.0, date of version release 17.10.2023, ChemAxon, http://www.chemaxon.com.). In Switzerland, arable lands and grasslands – that may be involved in pesticide treatments – have a top-soil pH of 4-8 (Reusser *et al.* 2023). Therefore, this range is investigated for the metabolite speciation (Table 4). Based on the modelled pKa values, HYPA occurs mostly in ionised form at natural pH, while AMPA-fluazinam, DAPA and MAPA in their neutral forms. The adsorption of the ionised form of HYPA is pH-dependent with no correlation between the OC and Kf/Kfoc, thus the toxicity test results are not normalised for this metabolite. While DAPA and MAPA

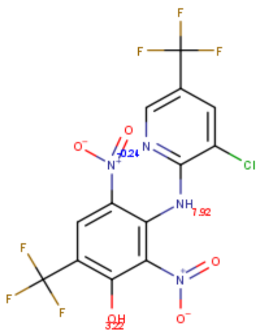
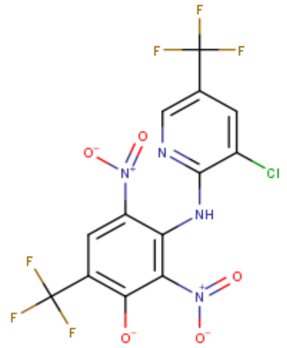
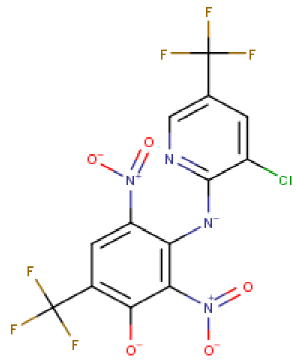
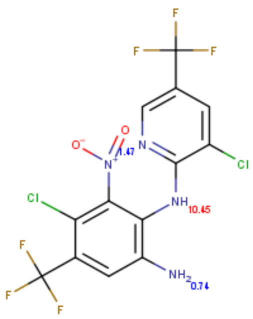
Table 3: Summary of soil adsorption of the active substance fluazinam and the major soil metabolites. Abbreviations: Kfoc – organic carbon-normalised Freundlich distribution coefficients; 1/n – Freundlich exponent. Source: EC (2006, 2019, 2024), Lists of endpoints and Vol. 3CA B.8.1.3.1, p.241-242 (for AMPA-fluazinam, DAPA and MAPA erroneous data are included in LoEP). Data in square brackets are calculated by OZ.

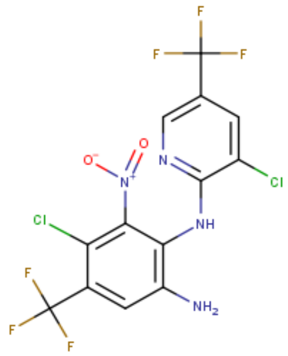
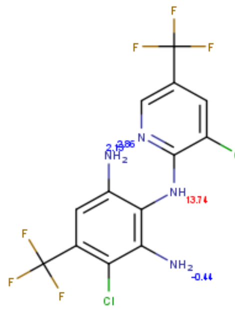
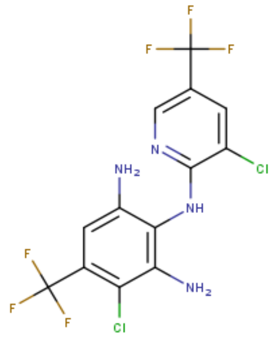
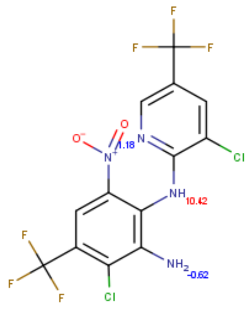
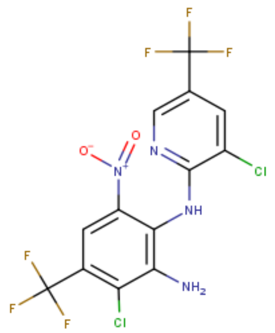
Substance	Soil type	Soil OC content [%]	Soil pH	Clay content [%]	Kf	Kfoc [mL/g]	Geometric mean Kfoc [mL/g]	Arithmetic mean 1/n	pH dependence	Mobility category
Fluazinam[#1]	sand	0.48	6.0	7.2	11.12	2316	1945 [A]	0.650 [A]	no	slightly
	silt loam	1.42	7.7	23.4	27.19	1915				low
	clay loam	2.0	7.1	38.0	37.88	1894				low
	loamy sand	2.55	6.0	8.8	43.48	1705				low
Fluazinam[#2]	silt	1.36	6.8	20.3	61.35	4511	[29 748	[0.989	[yes]	slightly
	silty loam	2.39	7.2	22.6	1895.37	79 304	(23 281) [C]]	(0.957) [C]]		immobile
	clay	3.29	5.7	75.0	1055.98	32 097				immobile
	loam	3.32	5.9	17.0	928.20	27 958				immobile
	loamy sand	4.43	3.2	6.00	3214.66	72 566				immobile
HYPA		pH ≤ 5.7: 0.5-1.6 pH <5.7: 1.8-3.1	4.7-5.7 7.7-8.1			pH ≤ 5.7: 942-1696 pH > 5.7: 453-705	pH ≤ 5.7: 1277 pH > 5.7: 526	pH ≤ 5.7: 0.757 pH > 5.7: 0.830	yes	pH ≤ 5.7: low pH > 5.7: low to medium
AMPA-fluazinam		0.8-2.46	5.33-7.71			5697-12388	7989	0.908	yes, but not applicable	immobile
DAPA		0.8-2.46	5.33-7.71			1047-2102	1047 [B]	0.873 [B]	yes, but not applicable	slightly to low
MAPA		0.8-2.46	5.33-7.71			4209-10392	6708	0.927	no	immobile to slightly mobile

Notes: The mobility categories are based on the classification scheme of McCall *et al.* (1980): Koc of 0-50 very high, 50-150 high, 150-500 medium, 500-2000 low, 2000-5000 slightly, > 5000 immobile. [A] The non-agreed additional results were not included in the mean calculations (EC 2024). It is noted that the mean values for fluazinam were changed in the 2024 version to the geometric mean Kfoc of 1849.1 and the arithmetic mean 1/n of 0.645, but these values do not reflect the agreed individual values (n = 4) and their origin is not clear. [B] Worst-case values as agreed in the LoEP (EC 2024). [C] Calculated without the possible outlier silty loam soil (pH 7.2) – see explanation in the test. [#1] Agreed adsorption results in the updated LoEP (EC 2024); see also Galicia & Völkl (1991) cited in EC (2019), Vol. 3CA B.8.1.3.1 p.234); [#2] Additional results rejected by the RMS, not included in the mean calculations (EC (2024); similar but not exactly the same results were included in Geffke (2007a) cited in EC (2019), Vol. 3CA B.8.1.3.1 p.235, no updated version is available).

occur mostly in their neutral forms at natural top-soil pH, the measured Kfoc values do not show clear correlation with the soil OC content. It is assumed that factors other than the soil OC/OM content can contribute to their adsorption. The adsorption of DAPA also showed pH-dependence, but with negligible effects on the Kfoc values (remaining in the slightly to low mobility category). Altogether, the toxicity values of DAPA and MAPA are also not normalised to a standard soil OM content. There is no soil toxicity data for AMPA-fluazinam, therefore it is not considered further.

***Table 4** Estimation results for the ion speciation of the soil metabolites. Software: MarvinSketch, version 23.14.0, date of version release: 17.10.2023, ChemAxon, http://www.chemaxon.com.*

Soil metabolite	Structural formula	pKa values	No. of forms	The most dominant form(s) between pH 4 and 8
HYPA		-0.24 (N in pyridine ring)* **3.22** (–OH group) **7.92** (=NH group)	Four	**Mostly ionised forms at natural pH** • 85.7-45.6 % estimated occurrence at pH 4-8 (max. 99.1 % at pH 5.6):  • 0.01-54.4 % estimated occurrence at pH 4-8 (max. 100 % at pH ≥ 12.4): 
AMPA-fluazinam		0.74 (–NH_2 group)* 1.47 (N in pyridine ring)* **10.45** (=NH group)	Five	**Mostly neutral form at natural pH** • 99.7 % estimated occurrence at pH 4-8 (max. 99.99 % at pH 5.4-6.6):

Soil metabolite	Structural formula	pKa values	No. of forms	The most dominant form(s) between pH 4 and 8
				
DAPA		-0.44 (–NH_2 group)* 2.13 (–NH_2 group)* 2.86 (N in pyridine ring)* **13.74** (=NH group)	Nine	**Mostly neutral form at natural pH** • 93.2-100 % estimated occurrence at pH 4-8 (max. 100 % at pH 7.2-9.4): 
MAPA		-0.62 (–NH_2 group)* 1.18 (N in pyridine ring)* **10.42** (=NH group)	Five	**Mostly neutral form at natural pH** • 99.9-99.6 % estimated occurrence at pH 4-8 (max. 100 % at pH 5.8): 

Notes: * Not relevant.

1.6 Bioaccumulation and biomagnification

Substances, such as lipophilic organic compounds, can potentially accumulate along the food chain resulting in a risk for higher vertebrates, such as worm-eating birds and mammals. Especially compounds with octanol-water partition coefficients greater than three can pose a risk of secondary poisoning to animals at higher trophic levels. Fluazinam has log Kow values of 2.99-4.99 (direct relationship with pH; 4.03-4.89 at pH 7; Table 1), and thus there is a potential for bioaccumulation and biomagnification that should be considered in a separate assessment. The current SGV derivation consideres only effects to in-soil organisms and plants and a detailed assessment of secondary poisoning is out of the scope.

2 Chemical analysis and environmental concentrations

Comprehensive techniques are necessary for the extraction of plant protection product residues from soil and for their analysis. Through a recent development, a new multi-residue method has been developed and will be used for soil monitoring in Switzerland (Acosta-Dacal *et al.* 2021, Rösch *et al.* 2023). Pesticides are extracted using an optimised QuEChERS (quick, easy, cheap, effective, rugged and safe) approach followed by chemical analysis *via* liquid chromatography coupled to tandem mass spectrometry with electrospray ionisation (LC-ESI-MS/MS, triple quadrupole). In the case of fluazinam, the limit of quantification for the method (MLOQ) was determined as 0.1 ng a.s./g (corresponding to 0.0001 mg a.s./kg soil; Rösch *et al.* 2023).[3]

The soil guideline value that is derived in this dossier for fluazinam will be used in conjunction with the actual soil concentrations monitored in Swiss soils by using the above-described measurement method. The initial measurements on some selected, partly agricultural, Swiss soils resulted in fluazinam concentrations between < 0.0001 mg a.s./kg soil (< MLOQ) and 0.0002 mg a.s./kg soil (Rösch *et al.* 2023, Table S12).

At EU level, the initial predicted environmental concentrations in soil (PECsoil) was calculated as 0.040 mg a.s./kg soil, following the EU GAP (Good Agricultural Practices; potato, maximum 1 x 150 and 9 x 200 g a.s./ha with 7 d intervals and various plant interceptions according to the growth stages of potato; EC (2024)).

3 Effect data on fluazinam

Effect data for soil organisms were collected from studies retrieved from the European registration information (EC 2006, 2019, 2024). Additionally, a bibliographic search was performed for fluazinam and its CAS number (CAS 79622-59-6) in the ECOTOX Knowledgebase (US EPA 2025) and in the database of the German Federal Environment Agency (UBA 2025). Furthermore, a literature search was performed on Scopus by using a combination of key words (Soil, EC50, LC50, NOEC, LOEC, LCx, ECx, toxicity and the English and Latin names of various soil organisms such as earthworm, Collembola or mite) and the compound's name or CAS number. Studies performed with formulated products were included in the dataset unless the amount of active substance within the formulation was unknown or the formulation contained other active substances in addition to fluazinam.

In general, only reliable and relevant data should be used for SGV derivation. Different approaches to assessment and classification of (eco)toxicological data have been published. An established method introduced by Klimisch *et al.* (1997) uses four levels of quality: (1) reliable, (2) reliable with restrictions, (3) not reliable, (4) not assignable. The CRED approach (criteria for reporting and evaluating ecotoxicity data; Moermond *et al.* 2016) is based on a similar classification scheme but takes into account the relevance of test results in a more detailed way. This assessment method was originally developed for the aquatic environment and therefore in order to assess and classify (eco)toxicological studies performed in the soil compartment, the CRED approach needed to be adapted by incorporating soil specific aspects (Casado-Martinez *et al.* 2024). This modified approach is applied for the assessment of

[3] Unless it is specified otherwise, active substance concentrations in soil are meant per kg soil dry weight.

the studies in this dossier and used for evaluating the reliability and relevance of the studies (see scores for "R" and "C", respectively, in Table 5 and Table A1-Table A5).

A short summary of the main points of considerations are given below. For further details on the consideration with regard to the study evaluation and the SGV derivation, please refer to Appendix 1 as well as to the above mentioned soil CRED article (Casado-Martinez *et al.* 2024) and the methodological proposal for deriving soil guideline values (Marti-Roura *et al.* 2023).

Although fluazinam is a weak acid, the experimental adsorption data could indicate a direct relationship between the soil OC content and the Kf/Kfoc values. Consequently, the effect data should be normalised to a standard organic matter content in order to make the results comparable among different soil types. The recommendation of the EC TGD (2003, p.116) for non-ionic organic compounds (normalisation to a standard organic matter content of 3.4 % corresponding to 2 % organic carbon) is in line with the findings in Swiss agricultural soils (Meuli *et al.* (2014); personal communication from NABO) and as such, it is also used here. The normalisation has been performed according to the following equation:

$$Effect\ concentration\ [standard] = Effect\ concentration\ [exp] \times \frac{Fom\ soil\ (standard)}{Fom\ soil(exp)}$$

Where:
Effect concentration [standard] – effect concentration in standard soil [mg/kg]
Effect concentration [exp] – effect concentration in experiment [mg/kg]
Fom soil (standard) – fraction of organic matter in standard soil (0.034) [kg/kg]
Fom soil (exp) – fraction of organic matter in experimental soil [kg/kg]

Studies, where the information about the organic matter (or carbon) content is missing are classified as "*not assignable*" (R4) in accordance with the CRED criteria. Besides the organic matter content, other soil properties such as pH and texture (clay content) need to be also considered. The pH ($CaCl_2$ method) of Swiss agricultural soils mainly ranges between 4.5 and 7.5 (median 6.0) whereas clay content ranges between 5 % and 50 % (median 20 %; Marti-Roura *et al.* 2023). There is no evidence that adsorption and in turn bioavailability of fluazinam is affected by clay content and the pH-dependence is unclear in the natural pH range of agricultural soils.

In the course of the evaluation, reproduction endpoints are considered the most relevant endpoints as they are good indicators of the long-term sustainability of the population. Other chronic endpoints affecting survival and growth (biomass) of individuals are also accepted, since they are traditionally measured endpoints frequently extrapolated to represent the impact at population level (Marti-Roura *et al.* 2023). If multiple comparable toxicity values for the same species and the same measured effect are available, the geometric mean of the effect values is calculated.

Regulatory studies and their endpoints are either accepted without additional assessment (at face value, although without applying the additional divison of the endpoint by two in case of log Kow ≥ 2) or partially/fully re-considered if needed to set the endpoints in line with our criteria as summarised in Appendix 1. This is the case, for example, when organisms were not exposed through soil (e.g. plant vegetative vigour tests *via* foliar application); normalisation to a standard organic matter content was not possible due to lack of data or not the most statistically robust effect concentration was proposed/agreed upon as a final endpoint.

If more than one endpoint is available from the same study for the same effect, the statistically more robust one is preferred. This means that the statistically more robust endpoint is chosen even if it is higher than another one or it includes more than 10 % effect (choosing non-significant endpoints with < 10 % effects is a precautionary approach that is often used at European level). If the latter is the case, it will be highlighted and discussed further in the uncertainty analysis (see later below). If both NOEC and EC10 are available from the same study and statistically both are equally robust, due to the inherent uncertainties of the NOEC, the EC10 is preferred over the NOEC (for further explanation, please refer to Appendix 1).

Complete lists of laboratory and field studies reporting soil effect values for fluazinam and its transformation products are shown in Appendix 2 (for fluazinam, Table A1 with laboratory and Table A2 with field studies) and in Appendix 3 (for the major soil metabolites, Table A3, Table A4 and Table A5). If necessary, some clarifications and/or justifications of the assessment are provided in form of Notes to those tables (see

Notes A1 and Notes A2) in Appendix 2 and 3, respectively) and also the same respective notes for Table 5. In Table 5 of the main text, all the reliable and relevant results are summarised. The lowest values per species per measured effects with the same duration are shown in bold. If there are only greater-than values, the highest one is shown in bold as they mean that up to the highest tested concentration no adverse effects were observed. The geomean, if it is possible to calculate from the results (i.e. there are equal-to values for the same species/effect/duration/type of effect concentration), is used for choosing the lowest value rather than the individual effect concentrations. This sifting procedure helps to choose the lowest effect concentrations per species/group for the SGV derivation (see Table 6).

3.1 Comparison between data for active substance and formulated products

A statistical analysis of potential differences in the toxicity of the active substance and the tested formulations was not possible due to the scarcity of data. Therefore, toxicity data obtained with the active ingredient and the formulations were merged (see data for the parent in Table 5 and Table A1). It is noted that the soil-related endpoints that were newly included in the updated dRAR (see LoEP with coloured highlights in EC (2024)) might indicate some differences between the formulations used by different applicants and/or the different batches that were used by the same applicant previously and recently (for further details, please refer to the uncertainty analysis in Section 7).

When multiple comparable toxicity values for the same species and the same endpoint were available, the geometric mean of the effect values was calculated, irrespective of whether the data was obtained with the active ingredient or formulation.

Table 5: Fluazinam – All reliable (R1-R2) and relevant (C1-C2) effect data. The lowest reliable and relevant effect data per species per test setup are shown in bold. Calculated data are rounded to three significant figures. Abbreviations: n.r. – not reported; n.a. – not applicable; cc. – concentration; WHC – water holding capacity; OC – organic carbon; OM – organic matter; CFU – colony forming units. The full set of studies can be found in Appendix 1 (Table A1). Data were evaluated for reliability and relevance according to the modified CRED criteria (see R/C scores) or taken at face value from regulatory dossiers (Assessment score 1-3). The explanation of notes are included after this table (Notes 1).

Species (Taxonomic group)[4]	Test substance	Measured effect[5]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Eisenia fetida (Earthworm)	Fluazinam (purity 97.3 %)	adult mortality	14 and 28 d	LC50	> 1000	7.95	> 428	Artificial soil: 70 % sand, 20 % kaolinite clay, 10 % sedge peat (with 79.5 % OM content), 10 mg/kg $CaCO_3$, pH 7.0 ± 0.2, 35 % water content of soil dry weight	A, F	R2/C2	Edwards & Coulson (1985) cited in EC (2024), Vol. 3CA B.9.4, p.423
Eisenia fetida (Earthworm)	Fluazinam 500 g/L SC (38.4 % w/w, 495 g a.s./L)	adult mortality	14 d	LC50	> 528 (1376 mg product/kg soil)	10	> 528	Artificial soil: 70 % sand, 20 % kaolinite clay, 10 % peat, 0.5 % $CaCO_3$, pH 6.0 ± 0.2, max. 50 % moisture	EE, F	1	Yearsdon *et al.* (1991) cited in EC (2019), Vol. 3CP (ISK) B.9.7.1 p.145
***Eisenia fetida* (Earthworm)**	**Fluazinam (purity 97.3 %)**	**adult mortality**	**14 and 28 d**	**NOEC**	**≥ 10 (< 100)**	**7.95**	**≥ 4.28 (< 42.8)**	**Artificial soil: 70 % sand, 20 % kaolinite clay, 10 % sedge peat (with 79.5 % OM content), 10 mg/kg $CaCO_3$, pH 7.0 ± 0.2, 35 % water content of soil dry weight**	**A, F**	**R2/C2**	**Edwards & Coulson (1985) cited in EC (2024), Vol. 3CA B.9.4, p.423**
Eisenia fetida (Earthworm)	Fluazinam 500 g/L SC (38.4 % w/w, 495 g a.s./L)	adult mortality	14 d	NOEC	≥ 528 (1376 mg product/kg soil)	10	≥ 180	Artificial soil: 70 % sand, 20 % kaolinite clay, 10 % peat, 0.5 % $CaCO_3$, pH 6.0 ± 0.2, max. 50 % moisture	EE, F	1	Yearsdon *et al.* (1991) cited in EC (2019), Vol. 3CP (ISK) B.9.7.1 p.145
Eisenia fetida (Earthworm)	Fluazinam (purity 97.3 %)	biomass (adult weight)	14 and 28 d	EC50	> 1000	7.95	> 428	Artificial soil: 70 % sand, 20 % kaolinite clay, 10 % sedge peat (with 79.5 % OM content), 10 mg/kg $CaCO_3$, pH 7.0 ± 0.2, 35 % water content of soil dry weight	A, F	R2/C2	Edwards & Coulson (1985) cited in EC (2024), Vol. 3CA B.9.4, p.423

4 M – monocotyledonous, D – dicotyledonous plant species

5 DE – diversity endpoint, EE – enzymatic endpoint, FE – functional endpoint

Species (Taxonomic group)[4]	Test substance	Measured effect[5]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Eisenia fetida **(Earthworm)**	**Fluazinam 500 g/L SC (38.4 % w/w, 495 g a.s./L)**	**biomass (adult weight)**	**14 d**	**NOEC**	**< 53.0 (138 mg product/kg soil)**	**10**	**< 18.0**	**Artificial soil: 70 % sand, 20 % kaolinite clay, 10 % peat, 0.5 % $CaCO_3$, pH 6.0 ± 0.2, max. 50 % moisture**	**EE, F**	**1**	**Yearsdon *et al*. (1991) cited in EC (2019), Vol. 3CP (ISK) B.9.7.1 p.145**
Eisenia fetida **(Earthworm)**	**Fluazinam (purity 97.3 %)**	**biomass (adult weight)**	**28 d**	**NOEC**	**≥ 10 (< 100)**	**7.95**	**≥ 4.28 (< 42.8)**	**Artificial soil: 70 % sand, 20 % kaolinite clay, 10 % sedge peat (with 79.5 % OM content), 10 mg/kg $CaCO_3$, pH 7.0 ± 0.2, 35 % water content of soil dry weight**	**A, F**	**R2/C2**	**Edwards & Coulson (1985) cited in EC (2024), Vol. 3CA B.9.4, p.423**
Eisenia andrei (Earthworm)	Fluazinam 500 g/L SC (YF8053, 39.4 % w/w)	adult mortality	28 d	NOEC	≥ 35	10	≥ 11.9	Artificial soil: 68-69 % quartz sand, 20 % kaolinite clay, 10 % sphagnum peat, approx. 1 % $CaCO_3$, pH 5.7-6.4, 40.6-52.6 % water content of dry weight	F	1	Römbke & Moser (1999) cited in EC (2019), Vol. 3CP (ISK) B.9.7.1 p.146
Eisenia fetida **(Earthworm)**	**MCW 465 500 SC (490 g a.s./L)**	**adult mortality**	**28 d**	**NOEC**	**≥ 3.79 (10 mg product/kg soil)**	**10**	**≥ 1.29**	**Artificial soil: 69 % quartz sand, 20 % kaolinite clay, 10 % sphagnum peat, 0.38 % $CaCO_3$, pH 5.75-6.02, 23.8-30.2 % water content of dry weight**	**F, Z**	**1**	**Winkelmann (2016) cited in EC (2019), Vol. 3CP (ADM) B.9.7.1 p.180**
Eisenia andrei (Earthworm)	Fluazinam 500 g/L SC (YF8053, 39.4 % w/w)	biomass (adult weight change)	28 d	NOEC	≥ 35	10	≥ 11.9	Artificial soil: 68-69 % quartz sand, 20 % kaolinite clay, 10 % sphagnum peat, approx. 1 % $CaCO_3$, pH 5.7-6.4, 40.6-52.6 % water content of dry weight	F	1	Römbke & Moser (1999) cited in EC (2019), Vol. 3CP (ISK) B.9.7.1 p.146
Eisenia fetida **(Earthworm)**	**MCW 465 500 SC (490 g a.s./L)**	**biomass (adult weight change)**	**28 d**	**NOEC**	**≥ 3.79 (10 mg product/kg soil)**	**10**	**≥ 1.29**	**Artificial soil: 69 % quartz sand, 20 % kaolinite clay, 10 % sphagnum peat, 0.38 % $CaCO_3$, pH 5.75-6.02, 23.8-30.2 % water content of dry weight**	**F, Z**	**1**	**Winkelmann (2016) cited in EC (2019), Vol. 3CP (ADM) B.9.7.1 p.180**

Species (Taxonomic group)[4]	Test substance	Measured effect[5]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Eisenia andrei **(Earthworm)**	**Fluazinam 500 g/L SC (YF8053, 39.4 % w/w)**	**reproduction (number of juveniles)**	**56 d**	**NOEC**	**< 0.35**	**10**	**< 0.119**	**Artificial soil: 68-69 % quartz sand, 20 % kaolinite clay, 10 % sphagnum peat, approx. 1 % $CaCO_3$, pH 5.7-6.4, 40.6-52.6 % water content of dry weight**	**F**	**1**	**Römbke & Moser (1999) cited in EC (2019), Vol. 3CP (ISK) B.9.7.1 p.146**
Eisenia fetida **(Earthworm)**	**MCW 465 500 SC (490 g a.s./L)**	**reproduction (number of juveniles)**	**56 d**	**NOEC**	**≥ 3.79 (10 mg product/kg soil)**	**10**	**≥ 1.29**	**Artificial soil: 69 % quartz sand, 20 % kaolinite clay, 10 % sphagnum peat, 0.38 % $CaCO_3$, pH 5.75-6.02, 23.8-30.2 % water content of dry weight**	**F, Z**	**1**	**Winkelmann (2016) cited in EC (2019), Vol. 3CP (ADM) B.9.7.1 p.180**
Folsomia candida **(Collembola)**	**IKF-1216 500 SC (Fluazinam 500 SC, 39.4 % w/w, 500.7 g a.s./L)**	**adult mortality**	**28 d**	**NOEC**	**< 1.23 (3.13 mg product/kg soil)**	**10**	**< 0.418**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinit clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.6-5.8, 50-53 % MWCH**	**F, W**	**1**	**Klein (2002) cited in EC (2019), Vol. 3CP (ISK) B.9.7.2 p.166**
Folsomia candida **(Collembola)**	**TIFC 500 SC (40.2 % w/w, analysed)**	**adult mortality**	**28 d**	**NOEC**	**6.91 (17.2 mg product/kg soil)**	**5**	**4.70**	**Artificial soil: 75 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, pH 6.26-7.40, approx. 40 % of MWHC**	**F, X**	**1**	**Neri & Ponti (2015) cited in EC (2019), Vol. 3CP (FIN) B.9.7.2 p.100**
Folsomia candida **(Collembola)**	**MCW 465 500 SC (500 g a.s./L, nominal)**	**adult mortality**	**28 d**	**NOEC**	**5.58 (13.5 mg product/kg soil)**	**5**	**3.79**	**Artificial soil: 74.8 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, approx. 0.2 % $CaCO_3$, pH 5.9-6.4, 47.3-53.5 % of MWHC**	**F, BB**	**1 (R2/C1)**	**Lührs (2008) and Lührs (2016) cited in EC (2019), Vol. 3CP (ADM) B.9.7.3 p.211**
		geomean			*6.21*		*4.22*				
Folsomia candida (Collembola)	MCW 465 500 SC (500 g a.s./L, nominal)	adult mortality	28 d	LC50	> 11.2 (27.1 mg product/kg soil)	5	> 7.62	Artificial soil: 74.8 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, approx. 0.2 % $CaCO_3$, pH 5.9-6.4, 47.3-53.5 % of MWHC	F, BB	1 (R1/C2)	Lührs (2008) and Lührs (2016) cited in EC (2019), Vol. 3CP (ADM) B.9.7.3 p.211

Species (Taxonomic group)[4]	Test substance	Measured effect[5]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Folsomia candida (Collembola)	IKF-1216 500 SC (Fluazinam 500 SC, 39.4 % w/w, 500.7 g a.s./L)	adult mortality	28 d	LC50	13.9 (35.4 mg product/kg soil)	10	4.73	Artificial soil: 10 % sphagnum peat, 20 % kaolinit clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.6-5.8, 50-53 % MWCH	F, W	1	Klein (2002) cited in EC (2019), Vol. 3CP (ISK) B.9.7.2 p.166
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	adult mortality at 20°C	28 d	LC50	19.8	2.82 (1.66 % OC)	23.9	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R2/C2	Wehrli *et al.* (2024)
		geomean			*16.6*		*10.6*				
Folsomia candida **(Collembola)**	**IKF-1216 500 SC (Fluazinam 500 SC, 39.4 % w/w, 500.7 g a.s./L)**	**reproduction (number of juveniles)**	**28 d**	**NOEC**	**< 1.23 (3.13 mg product/kg soil)**	**10**	**< 0.418**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinit clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.6-5.8, 50-53 % MWCH**	**F, W**	**1**	**Klein (2002) cited in EC (2019), Vol. 3CP (ISK) B.9.7.2 p.166**
Folsomia candida **(Collembola)**	**TIFC 500 SC (40.2 % w/w, analysed)**	**reproduction (number of juveniles)**	**28 d**	**NOEC**	**6.91 (17.2 mg product/kg soil)**	**5**	**4.70**	**Artificial soil: 75 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, pH 6.26-7.40, approx. 40 % of MWHC**	**F, X**	**1**	**Neri & Ponti (2015) cited in EC (2019), Vol. 3CP (FIN) B.9.7.2 p.100**
Folsomia candida **(Collembola)**	**MCW 465 500 SC (500 g a.s./L, nominal)**	**reproduction (number of juveniles)**	**28 d**	**NOEC**	**5.58 (13.5 mg product/kg soil)**	**5**	**3.79**	**Artificial soil: 74.8 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, approx. 0.2 % $CaCO_3$, pH 5.9-6.4, 47.3-53.5 % of MWHC**	**F, BB**	**1 (R1/C1)**	**Lührs (2008) and Lührs (2016) cited in EC (2019), Vol. 3CP (ADM) B.9.7.3 p.211**
		geomean			*6.21*		*4.22*				
Folsomia candida (Collembola)	IKF-1216 500 SC (Fluazinam 500 SC, 39.4 % w/w, 500.7 g a.s./L)	reproduction (number of juveniles)	28 d	EC50	11.9 (30.3 mg product/kg soil)	10	4.05	Artificial soil: 10 % sphagnum peat, 20 % kaolinit clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.6-5.8, 50-53 % MWCH	F, W	1	Klein (2002) cited in EC (2019), Vol. 3CP (ISK) B.9.7.2 p.166

Species (Taxonomic group)[4]	**Test substance**	**Measured effect**[5]	**Duration**	**Type of effect concentration**	**Effect concentration [mg a.s./kg soil]**	**Total OM [%]**	**Normalised effect value [mg a.s./kg soil] 3.4 % OM**	**Test soil**	**Notes**	**Assessment score**	**Source**
Folsomia candida (Collembola)	TIFC 500 SC (40.2 % w/w, analysed)	reproduction (number of juveniles)	28 d	EC50	9.13 (22.7 mg product/kg soil)	5	6.21	Artificial soil: 75 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, pH 6.26-7.40, approx. 40 % of MWHC	F, X	1	Neri & Ponti (2015) cited in EC (2019), Vol. 3CP (FIN) B.9.7.2 p.100
Folsomia candida (Collembola)	MCW 465 500 SC (500 g a.s./L, nominal)	reproduction (number of juveniles)	28 d	EC50	9.05	5	6.15	Artificial soil: 74.8 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, approx. 0.2 % $CaCO_3$, pH 5.9-6.4, 47.3-53.5 % of MWHC	F, BB	(1) R2/C2	Lührs (2008) and Lührs (2016) cited in EC (2019), Vol. 3CP (ADM) B.9.7.3 p.211
Folsomia candida **(Collembola)**	**Fluazinam (purity ≥ 98 %)**	**reproduction (number of juveniles) at 22°C**	**28 d**	**EC50**	**10.1**	**2.82 (1.66 % OC)**	**12.2**	**Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC**	GG	**R2/C2**	**Wehrli *et al.* (2024)**
		geomean			*9.42*		*7.75*				
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	reproduction (number of juveniles) at 20°C	28 d	EC50	10.4	2.82 (1.66 % OC)	12.5	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R2/C2	Wehrli *et al.* (2024)
Hypoaspis aculeifer **(Mite)**	**Fluazinam (purity 99.52 %)**	**adult mortality**	**14 d**	**LC50**	**> 110**	**5**	**> 74.8**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % quartz sand, 0.2 % $CaCO_3$, pH 5.6-5.9, 40.58-48.25 % of MWHC**	**F, H**	**1**	**Schulz (2016a) cited in EC (2024), Vol. 3CA B.9.4.2, p.435**
Hypoaspis aculeifer (Mite)	TIFC 500 SC (40.2 % w/w, analysed)	adult mortality	14 d	NOEC	≥ 3015 (7500 mg product/kg soil)	5	≥ 2050	Artificial soil: 75 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, pH 6.10-6.95, approx. 50 % of MWHC	Y	R1/C1	Colli (2015) cited in EC (2019), Vol. 3CP (FIN) B.9.7.2 p.103
Hypoaspis aculeifer (Mite)	Fluazinam (purity 99.52 %)	reproduction (number of juveniles)	14 d	EC50	> 110	5	> 74.8	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 %	F, H	1	Schulz (2016a) cited in EC (2024), Vol. 3CA B.9.4.2, p.435

Species (Taxonomic group)[4]	Test substance	Measured effect[5]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
								quartz sand, 0.2 % $CaCO_3$, pH 5.6-5.9, 40.58-48.25 % of MWHC			
Hypoaspis aculeifer (Mite)	TIFC 500 SC (40.2 % w/w, analysed)	reproduction (number of juveniles)	14 d	EC50	2594.5	5	1764	Artificial soil: 75 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, pH 6.10-6.95, approx. 50 % of MWHC	F, Y	1	Colli (2015) cited in EC (2019), Vol. 3CP (FIN) B.9.7.2 p.103
***Hypoaspis aculeifer* (Mite)**	**Fluazinam (purity 99.52 %)**	**reproduction (number of juveniles)**	**14 d**	**NOEC**	**≥ 110**	**5**	**≥ 74.8**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % quartz sand, 0.2 % $CaCO_3$, pH 5.6-5.9, 40.58-48.25 % of MWHC**	**F, H**	**1**	**Schulz (2016a) cited in EC (2024), Vol. 3CA B.9.4.2, p.435**
***Hypoaspis aculeifer* (Mite)**	**TIFC 500 SC (40.2 % w/w, analysed)**	**reproduction (number of juveniles)**	**14 d**	**NOEC**	**124.91 (310.72 mg product/kg soil)**	**5**	**84.9**	**Artificial soil: 75 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, pH 6.10-6.95, approx. 50 % of MWHC**	**Y**	**R1/C1**	**Colli (2015) cited in EC (2019), Vol. 3CP (FIN) B.9.7.2 p.103**
Microorganisms	**Fluazinam 500 SC (39.49 % w/w, 516.1 g/ a.s.L)**	**nitrogen transformation[FE]**	**28 d**	**≤ 25 % effect**	**< 0.270 (0.684 mg product/kg soil)**	**2.28 (1.34 % OC)**	**< 0.403**	**Natural soil (Germany; loamy sand): 10.3 % clay, 37.5 % silt, 52.2 % sand, pH 7.4, MWCH 48 %**	**F**	**1**	**Reis (2002) cited in EC (2019), Vol. 3CP (ISK) B.9.9 p.181**
Microorganisms	**Fluazinam 500 SC (39.49 % w/w, 516.1 g a.s./L)**	**carbon transformation[FE]**	**28 d**	**≤ 25 % effect (< 10 % effect)**	**≥ 2.27 (5.748 mg product/kg soil)**	**2.28 (1.34 % OC)**	**≥ 3.39**	**Natural soil (Germany; loamy sand): 10.3 % clay, 37.5 % silt, 52.2 % sand, pH 7.4, MWCH 48 %**	**(F)**	**R2/C2**	**Reis (2002) cited in EC (2019), Vol. 3CP (ISK) B.9.9 p.181**

Notes 1: Notes on soil studies for fluazinam (reliable and relevant data).

A	Acute earthworm test conducted to the OECD 207 guideline (OECD 1984) with the following deviations: • Only three test concentrations with three replicates were used instead of five concentrations with four replicates. • The test duration was longer, 28 instead of 14 days. • The soil pH was not adjusted to 6.0 ± 0.5, but to 7.0 ± 0.2. • The test was conducted under a 16:8 h of light:dark photoperiod instead of continuous light. Fluazinam was mixed into the soil. There was no mortality in the control, thus the validity criterion was met. The test concentrations were 10, 100 and 1000 mg a.s./kg soil. Due to the wide spacing, the NOEC values are considered as greater-than/equal to values that are less than the next highest test concentration.
F	The summarised results were accepted without additional assessment (i.e. at face value). The results may have been re-calculated according to the actual measured active substance content of the applied formulation (if it was available) thus slight differences to the EU-listed endpoints may occur (if they used the nominal a.s. content).
H	Test item technical fluazinam had a purity of 99.52 %. There was no control mortality, thus the validity criterion was met. Due to the high purity of the test item, the results are accepted at nominal levels.
W	The study is referenced as Klein (2002) in Vol. 1 and Vol. 3 documents, but authors are listed as Klein and Meister (Report No. 13781016) in Vol. 2. The study was conducted to the outdated ISO guideline (ISO 1999a) and it was evaluated by the RMS to the currently valid OECD guideline (OECD 2016a). The study results were statistically re-evaluated by the RMS. A new LC50 was determined much lower than the one proposed in the study report. Also, the reproduction NOEC, along with the mortality NOEC, was lower than the lowest test concentration based on a more robust statistical test. The RMS also calculated an EC10, but not an EC20, and the robustness of the EC10 was not evaluated as recommended in EFSA (2019) – likely the evaluation was conducted before the EFSA publication came out. The normalised width of the confidence interval (CI) of the EC10 is "fair" (< 1.0) and based on the ratio of the EC10 and EC50 values, the steepness of the fitted curve is borderline shallow (= 0.33). In the absence of an EC20, the overlap of the CIs of the EC10 and EC20 cannot be checked. It should be noted that the EC10 of 11.49 mg product/kg soil falls between the 2^{nd} and 3^{rd} lowest test concentrations. At the lowest concentrations (3.13, 6.25 and 12.5 mg product/kg soil), there were 7.7, 25.5 and 22.5 % reduction in the number of juveniles as compared to the control. Considering the unclear dose-response, the consideration of the EC20 and its CI cannot be dismissed for a proper decision on the robustness of the EC10. As a result the reliability of the EC10 is considered as *not assignable* (R4). It is noted that for the products only the initial versions of the dRAR documents with summary of the ecotoxicology data and risk assessments are available (EC 2019) before the public consultation, commenting period and expert meetings. In the updated LoEP (EC 2024), the NOECcorr. of < 1.23 mg a.s./kg (in a corrected form, i.e. divided by two) stayed as agreed both for mortality and reproduction.
X	According to the RMS the only difference to the OECD 232 guideline (OECD 2016a) was the photoperiod. Instead of the preferable 16:8 h light:dark, in the test 12:12 h light:dark photoperiod was used. All the validity criteria were met, so it was concluded that this deviation probably did not have considerable effects on the results. The results were statistically re-evaluated by the RMS as follows: • mortality and reproduction NOEC = 17.2 mg prod./kg soil dw [corresponding to 6.91 mg a.s./kg soil] • EC50 = 22.7 mg prod./kg soil dw (95 % CI: 14.39-35.50 mg prod./kg soil dw) [corresponding to 9.13 mg a.s./kg soil] • EC10 = 14.0 mg prod./kg soil dw (95 % CI: 9.60-20.49 mg prod./kg soil dw) [corresponding to 5.63 mg a.s./kg soil] However, the RMS did not report the EC20 value with its CI. The EC10 has a normalised width classified as "fair" and the fitted curve an intermediate steepness (0.33-0.66; neither too steep, nor too shallow). In the absence of an EC20, the overlap of the CIs of the EC10 and EC20 cannot be checked. There were 12.0, 22.9 and 80.5 % reduction in reproduction at 9.6, 17.2 and 30.9 mg product/kg soil concentrations with coefficient of variations (CV) of 35.7, 41.9 and 39.5 %, respectively. Due to the rapid changes in the effects along with the high standard deviation/CV, the lower end of the EC50 CI (14.39 mg product/kg soil) was just slightly higher than the median EC10 (14.0 mg product/kg soil) and the lower end of the EC20 CI can be expected to be lower than the median EC10. As a result the reliability of the EC10 is considered as *not assignable* (R4). It is noted that for the products only the initial versions of the dRAR documents are available (EC 2019) before the public consultation, commenting period and expert meetings. In the updated LoEP (EC 2024), the NOECcorr. of 3.45 and the EC10corr. of 2.8 mg a.s./kg (in corrected forms, i.e. divided by two) are agreed for reproduction.

Y	The study was conducted to the 2009 version of the OECD 226 guideline (OECD 2016b). All validity criteria were met. The RMS re-calculated the ECx values: • EC50 = 2594.5 mg a.s./kg soil dw (95 % CI: 2027-3582 mg a.s./kg soil dw) • EC10 = 47.0 mg a.s./kg soil dw (95 % CI: 21.78-91.10 mg a.s./kg soil dw) The normalised width of the EC10 is “poor” and the steepness of the fitted curve is very shallow (0.018). Thus even without considering the overlap of the CIs of the EC10 and EC20 values, it can be concluded that the EC10 is *not reliable* (R3). However, the RMS considered that still the EC10 should be used as at the level of the statistically significant NOEC and at the lowest test concentration (at 124.91 and 73.48 mg a.s./kg soil, respectively), biologically relevant effects (effects > 15%) were observed. It is noted that for the products only the initial versions of the dRAR documents are available (EC 2019) before the public consultation, commenting period and expert meetings. In the updated LoEP (EC 2024), no effect concentrations are agreed upon/used in the risk assessment from this study. OZ is of the opinion that the statistically significant reproduction NOEC value (20.2 % reduction in reproduction as compared to the control) is suitable for further consideration in the SGV.
Z	The test substance MCW 465 500 SC contained 490 g a.s./L (not specified if nominal or measured) with 1.2928 g/mL density that corresponds to 37.9 % w/w fluazinam content. The validity criteria were met. There were no statistically significant effects or clear dose-response for any of the measured effects at any tested concentration.
BB	The test substance MCW 465 500 SC contained 500 g a.s./L (nominal) with 1.2529 g/mL density that corresponds to 39.9 % w/w nominal fluazinam content. It seems that the Applicant and the RMS used the nominal 39.9 % of a.s. content for conversion, however, we prefer and thus use the analysed a.s. content of the formulation for calculating the test results in terms of a.s. (as reported in Lührs (2008) accessed through EFSA (2025a)). The study was conducted to the ISO 11267 guideline (ISO 1999a), but was evaluated by the RMS to the currently valid OECD 232 guideline (OECD 2016a). The following deviations were noted by the RMS: • Only five concentrations were tested, although 12 are recommended in the guideline for determining ECx values (with minimum 2 replicates in the treatments and 6 in the control). There were five replicates in the control, while even for determining NOEC/LOEC at least 5 concentrations with four replicates in the treatments and eight replicates in the control are recommended in the OECD guideline. It was noted that the test design was in line with the ISO guideline. There were no effects on reproduction up to and including 13.5 mg product/kg soil concentration (corresponding to 5.39 mg a.s./kg soil based on nominal and 5.58 mg a.s./kg soil, based on analysed a.s. content of the formulation) and 71 % decrease in the mean number of juveniles as compared to the control at the highest test concentration (27.1 mg product/kg soil, i.e. 10.8 or 11.2 mg a.s./kg soil based on nominal or analysed a.s. content of the test item, respectively). The study results were statistically re-evaluated by the RMS with the following results (based on nominal a.s. content of the test item): • 28-d EC50 = 8.74 mg a.s./kg soil dw (95 % CI: 6.123-12.576 mg a.s./kg soil dw) • 28-d EC10 = 5.617mg a.s./kg soil dw (95 % CI: 4.090-7.715 mg a.s./kg soil dw) • mortality and reproduction NOEC = 5.4 mg a.s./kg soil dw The normalised width of the EC10 CI fell in the category of “fair” (0.645) and the steepness of the fitted curve was intermediate (0.643; but not far from the steep trigger of > 0.66). Based on the detailed results in the original study reports that were accessed through EFSA (2025a), the ECx calculations were repeated by the Ecotox Centre. This confirmed the RMS calculations, i.e. that the actual CIs are much broader than indicated by the Applicant. Also the lower end of the CI of the EC20 falls below the median EC10. This means that the EC10 cannot be considered statistically robust and it is *not reliable* (R3). The details of the RMS’ statistical analysis were not provided. Using a more robust method, also the 26 % corrected mortality at the highest test concentration proved to be statistically significant setting the NOEC at the second highest test concentration (13.5 mg product/kg soil concentration corresponding to 5.39 mg a.s./kg soil based on nominal and 5.58 mg a.s./kg soil, based on analysed a.s. content of the formulation). The EC50 corresponds to 9.05 mg a.s./kg soil based on analysed a.s. content of the tested formulation. It is noted that for the products only the study summaries in the initial versions of the dRAR documents are available (EC 2019) before the public consultation, commenting period and expert meetings. In the updated LoEP (EC 2024), the NOECcorr. of 2.7 mg a.s./kg (in corrected form, i.e. divided by two) is agreed for reproduction, not the EC10.

	OZ considers the statistically robust NOEC values as suitable for further consideration in the SGV.
EE	The study results in terms of active substance have been re-calculated (and corrected) based on the 38.4 % w/w fluazinam content of the formulation used in the test. (In the study summary, the results as active substance were calculated based on the 495 g a.s./L fluazinam content without considering the density of the product.)
GG	The study of Wehrli *et al.* (2024) investigated the combined effects of fluazinam and heat stress. They applied eight different concentrations at five different temperatures. The test at the standard 20°C and at 22°C followed or can be considered fulfilling the OECD 232 guideline requirements (required: *mean temperature should be 20 ± 1°C with a temperature range of 20 ± 2°C*; OECD (2016a)) and as such are considered here as potentially relevant. For comparability with the standard laboratory tests, the tests conducted at 24, 26 and 28°C are considered *not relevant* (C3). In contrast to what is stated in the article, based on the control results reported in the supporting information, the validity criteria were not fulfilled for the following tests and thus they are considered *not reliable* (R3): • In tests at 24 and 28°C: the coefficient of variation of the number of juveniles in the control were 40.5 and 225 %, respectively, instead of ≤ 30 %. • In test at 26°C: the control mortality was 25 % instead of ≤ 20 %. • In test at 28°C: the number of juveniles per 10 females in the control was 3 instead of ≥ 100. For the following LCx/ECx values the normalised width of the confidence intervals were poor or bad (≥ 1) and thus these are considered *not reliable* (R3): • LC10 and LC50 at 22°C (and the lower end of the LC50 CI < median LC10) • EC10 at 20, 22, 24 and 26°C In addition, even for the LC10 value at 20°C with acceptable normalised width and steepness of the curve, the reliability cannot be fully considered in the absence of the respective LC20 value that is needed for checking the possible overlap of the confidence intervals (EFSA 2019). As a result, the LC10 at 20°C is considered as *not assignable* (R4). EC50 and LC50 values are not the most relevant endpoints for considering the long-term toxicity of fluazinam for an SGV derivation (*relevant with restrictions*; C2). In the absence of enough details (results per treatment with standard deviation and statistical significance, goodness of fit and residuals for the fitted effect curves etc.) the otherwise acceptable results are considered *reliable with restrictions* (R2; see LC50 at 20°C and EC50 at 20 and 22°C). Statistically significant NOEC/LOEC values were not reported. The growth of adults and the body length of juveniles were shown only graphically and as such no quantitative results can be included here.

3.2 Graphic representation of effect data

The lowest relevant and reliable data (R1-2/C1-2) per test setup – normalised to a standard organic matter content of 3.4 % – are plotted in Figure 1. If more values for the same endpoint from the same test are available (e.g. EC10 vs NOEC), the statistically more robust one is shown in the figure. If both EC10 and NOEC are equally robust, EC10 is preferred (for further explanation, please refer to Appendix 1 Considerations for the evaluation of the studies). If values for more measured effects for the same species from the same test are available (e.g. reproduction, biomass, mortality etc.), the lowest one is included in the figure.

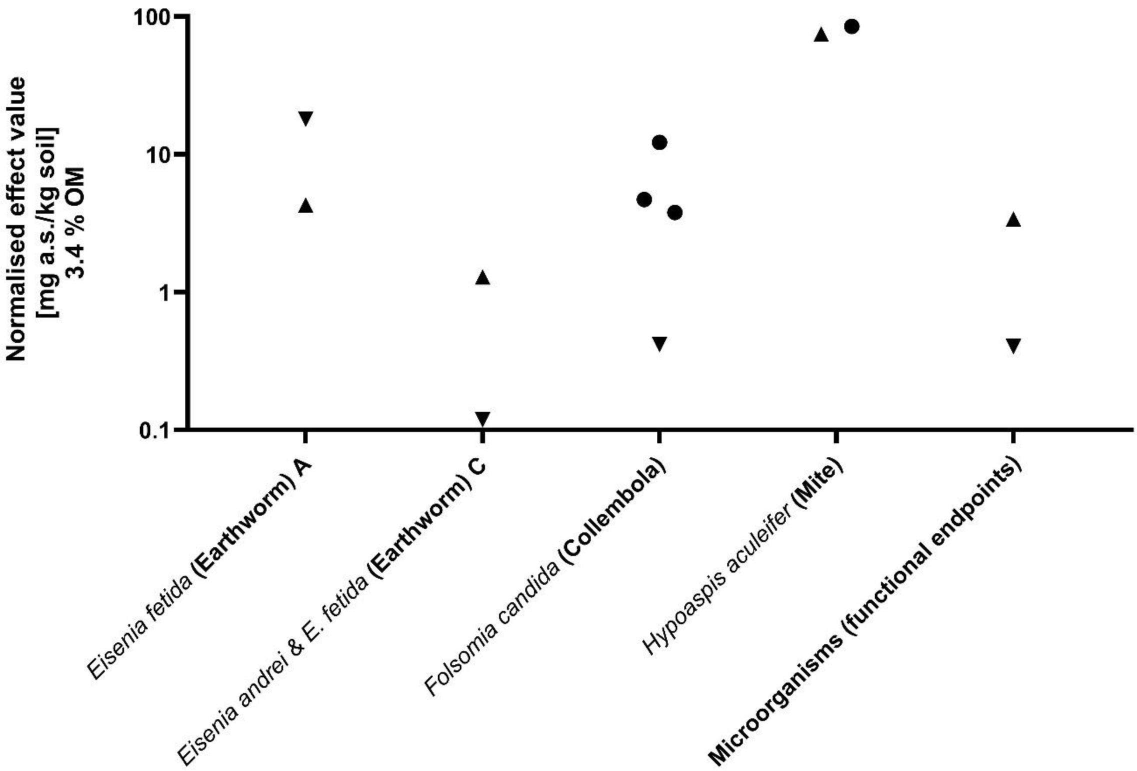


Figure 1: Effect data for fluazinam after normalisation to a standard organic matter content of 3.4 % − the lowest effect concentrations of the relevant and reliable endpoints per species per test setup. For earthworms the acute (A; 14- and 28-d NOEC) and chronic (C; 28- and 56-d NOEC) data are shown separately. For* F. candida*, the highest value shown is a 28-d EC50, while the other values are 28-d NOECs. For* H. aculeifer *chronic data (14-d NOEC), for microorganisms ≤ 25 % effect concentrations are presented. Triangles represent unbound data with the triangle facing up symbolising ≥ or > values and the triangle facing down symbolising ≤ or < values.

This figure aims to provide an overview of the distribution of the effect concentrations, i.e. to indicate the most sensitive species/group. The lowest effect concentrations for *Eisenia andrei* (earthworm, 56-d reproduction NOEC < 0.119 mg a.s./kg soil), microorganisms (≤ 25 % effect at < 0.403 mg a.s./kg soil after 28 d) and *Folsomia candida* (Collembola, 28-d mortality NOEC < 0.418 mg a.s./kg soil) are less-than values that fall in the same order of magnitude. The lowest equal-to effect concentration is a 28-d NOEC of 3.79 mg a.s./kg for mortality and reproduction of *F. candida*. The other chronic effect concentrations are either higher equal-to values (for *F. candida* and *Hypoaspis aculeifer*) or higher-than/equal-to values (for *E. fetida*, *H. aculeifer* and microorganisms).

4 Derivation of SGV

For the SGV derivation for fluazinam, the relevant and reliable effect concentrations of the active substance were normalised to a standard organic matter content of 3.4 %. Data on formulations were re-calculated to the active substance content. Then the lowest toxicity endpoints per species/group were summarised (Table 6).

Table 6: The lowest relevant and reliable acute and chronic data for fluazinam per species/group, rounded to three significant figures, summarised from Table 5. Effect concentrations are expressed as concentrations normalised to 3.4 % soil organic matter content.

Trophic level	Species, family (Group)	Type of effect concentration	Effect concentration [mg a.s./kg soil] (Effect size)	Reference
Decomposers (nutrient transformers)	Microorganisms (Functional endpoint)	≤ 25 % effect	< 0.403 (54.9 %)	Reis (2002) cited in EC (2019), Vol. 3CP (ISK) B.9.9, p.181
Decomposers (litter transformers/ primary consumers)	*Eisenia fetida, Lumbricidae* (Earthworm)	LC50	> 428 (10 %) *	Edwards & Coulson (1985) cited in EC (2024), Vol. 3CA B.9.4, p.423
		NOEC	< 0.119 (54.3 %)	Römbke & Moser (1999) cited in EC (2019), Vol. 3CP (ISK) B.9.7.1, p.146
	Folsomia candida, Isotomidae (Collembola)	NOEC	< 0.418 (17 % and 7.7 %) **	Klein (2002) cited in EC (2019), Vol. 3CP (ISK) B.9.7.2, p.166
Secondary consumers	*Hypoaspis aculeifer, Laelapidae* (Mite)	NOEC	≥ 74.8 (0.0-7.1 %)	Schulz (2016a) cited in EC (2024), Vol. 3CA B.9.4.2, p.435

Notes: * 10 % mortality occurred after 14 d and 23 % after 28 d – the official test duration is 14 d (OECD 1984). ** 17 % mortality and 7.7 % decrease in the number of juveniles occurred in the lowest treatment as compared to the control.

4.1 Derivation of SGV using the assessment factor (AF) method

In general, the SGV_{AF} is determined using assessment factors applied to the lowest valid toxicity endpoint (e.g. NOEC, EC10) from long-term toxicity tests. The magnitude of the AF is selected according to the adapted methods of the European guidance document on environmental risk assessment (EC TGD 2003, Marti-Roura *et al.* 2023).

For fluazinam, the second lowest effect concentration available in the dataset is the ≤ 25 % effect at < 0.403 mg a.s./kg soil value for microorganisms – **decomposers (nutrient transformers)** – where 54.9 % increase occurred in the nitrate-N formation rate after 28 days as compared to the control (Reis (2002) cited in EC (2019), Vol. 3CP (ISK) B.9.9, p.181). At 8.4 times higher concentration 112 % increase was observed. Although the results might indicate a dose-response, the two treatment concentrations are not enough for further consideration, i.e. to estimate the concentration where actually

≤ 25 % effect would have occurred. It is noted that no specific data on non-target soil fungi – the potentially most sensitive group of organisms to fluazinam – is available. Overall, a ***data gap*** needs to be considered for microorganisms.

The overall lowest effect concentration is available for earthworm – **decomposers (litter transformers/primary consumers)** – as a reproduction NOEC of < 0.119 mg a.s./kg soil, where 54.3 % inhibition occurred in the number of juveniles as compared to the control (Römbke & Moser (1999) cited in EC (2019), Vol. 3CP (ISK) B.9.7.1 p.146).

As in this earthworm test five treatment concentrations were used resulting in clear dose-response relationship for the effects on the number of juveniles, we tried to extrapolate the EC50 (GraphPad Prism 10 Version 10.2.2) and EC10 values (Microsoft Excel 2016). The best fit in GraphPad Prism was provided by the non-linear fit of non-logarithmic data (variable slope; four parameters; constraints: Bottom = 0, Top = 100, IC50 > 0; based on non-normalised data; see details in Table 7).

Table 7: Statistical results of the best-fit regression for the earthworm reproduction study (Römbke & Moser (1999) cited in EC (2019)). Software: GraphPad Prism 10 Version 10.2.2. Best fit: non-linear fit of non-logarithmic data (variable slope; four parameters; n = 6). The statistical evaluation was conducted with non-normalised data.

Best-fit values	
Bottom	= 0.000
Top	= 100.0
EC50	**0.2748 [mg a.s./kg soil]**
Hill Slope	0.6175
logEC50	-0.5609
Span	= 100.0
95% CI (profile likelihood)	
EC50	0.1904 to 0.3645 [mg a.s./kg soil]
Hill Slope	0.5136 to 0.7351
logEC50	-0.7202 to -0.4383
Goodness of Fit	
Degrees of Freedom	4
R squared	0.9983
Sum of Squares	11.37
Sy.x	1.686
Constraints	
Bottom	Bottom = 0
Top	Top = 100
EC50	EC50 > 0 [mg a.s./kg soil]

The generated non-normalised EC50 of 0.2748 mg a.s./kg soil was used to re-calculate the logEC50 with higher accuracy (8 decimal places instead of 4). This logEC50 and the Hill Slope value were then substituted into the Hill equation to fit a curve for the whole effect spectrum (1-99 %) and estimate the EC10 value (Figure 2). The Hill equation is as follows (referenced in Motulsky & Christopoulos (2023)):

$$Y=\mathrm{Bottom}+\frac{\mathrm{Top}-\mathrm{Bottom}}{1+\left(\frac{10^{\mathrm{LogEC}_{50}}}{10^{X}}\right)^{\mathrm{HillSlope}}}$$

The resulted non-normalised EC10 was 0.00783 mg a.s./kg soil. The extrapolated EC50 normalised to 3.4 % standard OM content is equal to 0.0934, the normalised EC10 is 0.00266 mg a.s./kg soil. As the test results consist of only effects > 50 %, the extrapolated EC10 is surrounded by a high level of uncertainty and it is not considered suitable for deriving a robust SGV.

The third lowest effect concentration appeared to be for Collembola, **decomposers (litter transformers/primary consumers)**. Statistically significant mortality and decrease in the number of juveniles occurred at the lowest test concentration resulting in a NOEC of < 0.418 mg a.s./kg soil for mortality (Klein (2002) cited in EC (2019), Vol. 3CP (ISK) B.9.7.2 p.166). The observed 22 % mortality is very close to the limit determined as a validity criterion for control mortality (required: ≤ 20 %) in a test conducted according to the OECD 232 guideline (OECD 2016a), and the survival was 83 % of the control survival. The 7.7 % reduction in reproduction was proven to be statistically significant in the RMS' re-evaluation. There was no clear dose-response in the effects, so the actual NOEC is expected to not be much lower than the lowest test concentration and as such likely covered by the NOEC estimated for earthworms.

The reproduction NOEC of ≥ 74.8 mg a.s./kg soil for predatory mite – **secondary consumers** – is two orders of magnitude higher than the other lower values for the previously discussed groups/species and as such, it is not critical.

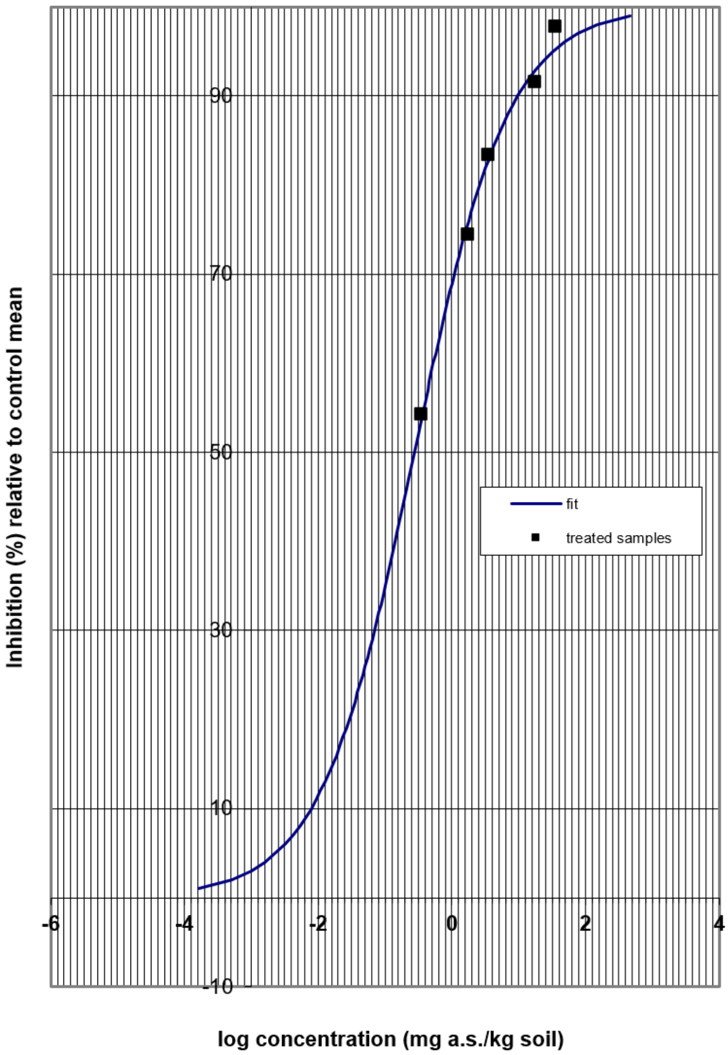


Figure 2: Sigmoid curve fitted to the earthworm reproduction study results (Römbke & Moser (1999) cited in EC (2019)) substituting the EC50 of 0.2748 mg a.s./kg and the Hill Slope value of 0.6175 from the best-fit non-linear fit (GraphPad Prism 10 Version 10.2.2) into the Hill equation. Software: Microsoft Excel 2016.

When relevant and reliable long-term test results with equal-to effect concentrations (NOEC or EC10 values) are available, depending on the number of species/groups and trophic levels, an AF of 100/50/10 can be applied to the lowest effect concentration. If no reliable and suitable chronic data is available, the lowest equal-to acute value (LC50 or EC50) can be used with an AF of 1000 (Table 20 in EC TGD (2003)). In the case of fluazinam, the lowest effect concentrations are not equal-to values for any species/groups at any trophic levels. This means that **no robust SGV, neither definitive nor preliminary, can be derived for fluazinam based on the available and verifiable ecotoxicological data.**

4.2 Derivation of SGV using the species sensitivity distribution (SSD) method

The minimum data requirement recommended for the application of the SSD approach for SGV_{SSD} is at least ten exact data points ($NOEC/EC_{10}$) from three taxonomic groups whereas data from microbial functional processes should not be used in the distribution (Marti-Roura *et al.* 2023). In the case of fluazinam, no equal-to effect concentration is available for any species/groups. Thus, the minimum data requirement for an SSD is not met.

4.3 Derivation of SGV using the equilibrium partitioning (EqP) approach

If no reliable data on terrestrial organisms is available, the equilibrium partitioning utilising aquatic toxicity data can be used to estimate the SGV_{EqP} (EC TGD 2003). For fluazinam, no relevant and reliable equal-to data on soil organisms – that would be suitable for deriving an SGV – is available, therefore the possibility of using the EqP approach was considered. However, no robust aquatic PNEC (predicted no-effect concentration) is available for fluazinam (NORMAN Ecotoxicology Database, Quality Target for fluazinam, https://www.norman-network.com/nds/ecotox/qualityTargetShow.php?susID=8648). Thus, the derivation of SGV_{EqP} for fluazinam using the equilibrium partitioning approach is not feasible.

4.4 Determination of SGV using mesocosm/field data

Three potentially relevant field studies, two on earthworms and one study on micro-arthropods, could be obtained for fluazinam (see Table A2 in Appendix 2). There was no analytical verification in the earlier earthworm study (Mills (2001) and Sharples (2006) cited in EC (2019), Vol. 3CP (ISK) B.9.7.1 p.148) that would have been a critical requirement for further consideration of the results (see Appendix 1). From the other two study summaries it seems that the other earthworm study (Krück (2009) cited in EC (2019), Vol. 3CP (ADM) B.9.7.1 p.183) was conducted together with the micro-arthropod study (Schulz (2009) cited in EC (2019), Vol. 3CP (ADM) B.9.7.1 p.216). The main concerns that emerged in the summarised results are as follows. Although the same analytical results were listed for both studies, 14-d intervals were given for the earthworm and 7-d and 9-d intervals for the micro-arthropod study. Also, the 60-80 % crop coverage that occurred in the field broadens the range of the expected concentrations of the treatments in the soil so much, that it is not possible to consider with certainty if the required 50-150 % nominal concentrations were achieved in the earthworm study. There were eight applications in both studies at three rates, but the first two were not accepted by the RMS/EFSA for the earthworm study, while all eight treatments were found acceptable for the micro-arthropod study. The analytical verification took place after the last application; however, the earthworms were sampled three months, the micro-arthropods approximately two months after that. Considering the relatively short DissT50 of fluazinam (see Section 1.5.2) and the general considerations that are followed for field studies in the SGV dossiers (see Appendix 1), as well as the other uncertainties as explained above, no reliable endpoint could be derived from either of these studies for the SGV derivation (for further details, please refer to the respective notes to Table A2 in Appendix 2).

5 Toxicity of major transformation products

It is noted that this section and the tables with the metabolite data in Appendix 3 (Table A3, Table A4 and Table A5) were not subjected to external peer-review.

Effect data are available for three major soil metabolites of fluazinam: HYPA (aerobic), DAPA (anaerobic) and MAPA (anaerobic). The full effect data tables are presented in Appendix 3 (Table A3, Table A4 and Table A5), whereas Table 8 below summarises the lowest effect concentrations for these metabolites with regard to the lowest relevant and reliable effect concentration available per species/group. In the dRAR, in the definition of residues in the environment that require further assessment (Section 2.1.42 in Volume 1 – Level 2 of EC (2024)), only fluazinam and HYPA were included for the soil compartment; AMPA-fluazinam needs to be considered only for the surface water and sediment compartments. As DAPA and MAPA are anaerobic soil metabolites, they were not found relevant for the representative use in potato at EU level (EC 2024); here they are included for completeness.

Table 8: Lowest reliable and relevant soil effect data for fluazinam soil metabolites HYPA, MAPA and DAPA. Endpoints are shown without normalisation to 3.4 % soil organic matter content (for explanation, please refer to Section 1.5.3).

Species	Type of effect concentration	HYPA concentration [mg/kg soil]	MAPA concentration [mg/kg soil]	DAPA concentration [mg/kg soil]	References
Eisenia fetida (Earthworm)	NOEC	≥ 14.2	≥ 30	≥ 30	Krome (2009) cited in EC (2024), Vol. 3CA B.9.4.1, p.425 Friedrich (2016a) cited in EC (2024), Vol. 3CA B.9.4.1, p.428. Friedrich (2016b) cited in EC (2024), Vol. 3CA B.9.4.1, p.430.
Folsomia candida (Collembola)	NOEC	≥ 6.08	≥ 30	≥ 30	Lührs (2004) cited in EC (2024), Vol. 3CA B.9.4.2, p.438. Friedrich (2016c) cited in EC (2024), Vol. 3CA B.9.4.2, p.449. Friedrich (2016d) cited in EC (2024), Vol. 3CA B.9.4.2, p.452.
Hypoaspis aculeifer (Mite)	NOEC	12.5	≥ 28.6	≥ 30	Lührs (2017) cited in EC (2024), Vol. 3CA B.9.4.2, p.442. Schulz (2016c) cited in EC (2024), Vol. 3CA B.9.4.2, p.458. Schulz (2016d) cited in EC (2024), Vol. 3CA B.9.4.2, p.460.
Microorganisms	≤ 25 % effect (< 10 % effect)	-	≥ 3.0	≥ 1.5	Schulz (2016e) cited in EC (2024), Vol. 3CA B.9.5, p.472. Schulz (2016b) cited in EC (2024), Vol. 3CA B.9.5, p.475.

All the effect concentrations are greater-than/equal-to values with the exception of the *H. aculeifer* NOEC of 12.5 mg/kg soil for HYPA. The effect concentrations for the metabolites are approximately one to two orders of magnitude higher than the effect concentrations for fluazinam. It should be noted that there is no relevant and reliable microorganism effect concentration for HYPA, though that is one of the most sensitive groups of organisms to fluazinam based on the available data (Table 6). As a result, it remains unclear if this metabolite would require further evaluation in a mixture risk assessment or if the risk from HYPA is covered by an SGV derived and a risk assessment conducted for the parent compound.

6 Proposed SGV to protect soil organisms

Depending on the degree of uncertainty or the representativeness of the derivation method and/or the assessment factor used for the SGV derivation, the final SGV can be classified as preliminary or definitive.

Based on the available relevant and reliable data, no robust SGV – neither definitive nor preliminary – can be derived for fluazinam.

7 Protection of soil organisms and uncertainty analysis

For fluazinam, the lowest relevant and reliable data per species/groups comprises **only unbound values for** microorganisms, earthworms (*Eisenia andrei* and *E. fetida*), collembolans (*Folsomia candida*) and mites (*Hypoaspis aculeifer*). Fluazinam is a fungicide, thus according to its mode of action, it is expected that fungi would be the most sensitive taxonomic group. However, relevant and reliable toxicity data on **fungi** are lacking. The potentially most sensitive group of organisms with the lowest less-than effect concentration is **earthworms** (NOEC < 0.119 mg a.s./kg soil with 54.3 % effects on reproduction) but the lowest effect concentrations for microorganisms and collembolans are also less-than values. Hence, the most sensitive group for effects of fluazinam on soil organisms cannot be determined based on the available data. The statistical extrapolation indicated a normalised EC10 of 0.00266 mg a.s./kg soil for earthworms; however, this value is surrounded by a high level of uncertainty and thus it is not suitable and appropriate to be used for deriving a robust SGV. For **microorganisms**, 54 % effect on nitrogen transformation occurred at 0.403 mg a.s./kg soil (the lower tested concentration) and based on the two tested concentrations it is not possible to estimate at which concentration the effects would sink to/below the acceptable ≤ 25 % effect that is specified for agrochemicals in the respective guideline (OECD 2000b). The lowest relevant and reliable NOEC for **collembolans** is < 0.418 mg a.s./kg soil with 17 % effects on adult mortality and 7.7 % decrease in the number of juveniles as compared to the control.

There are several **newly added effect concentrations for various soil species/group in the updated LoEP** (EC 2024; see the coloured highlights in the document). These study results as additional information from the applicants were included later in the updated dRAR (in 2021, according to the document history of the updated LoEP) but only the initial version of the dRAR (EC 2019) was made publicly available in full length. After the ED assessment, the summary documents and the active substance sections related to the ED assessment were made publicly available, but not the documents for the products. The Oekotoxzentrum (OZ) requested the updated product documents from EFSA, but only a link to the documents related to the ED assessment was provided. Requests for access to the original study reports were only granted for six of the 15 requested reports (for further details on the PAD requests, please refer to Section 1). In the absence of detailed study summaries and/or the original study reports, the reliability of the newly added effect concentrations in the updated LoEP cannot be considered. These values, summarised in Table 9 below, are potentially relevant but their reliability currently cannot be considered and thus they are scored as *not assignable* (R4/C1) in Appendix 2 (Table A1).

The new NOEC values **for earthworms** are much more consistent and higher than the previously included ones (see data in Table 9 vs Table 5). However, without any information on the underlying studies they cannot be used for refining the older very low less-than value. The new, potentially acceptable reproduction NOEC values (Table 9) are approximately 24-55 times higher than the lowest relevant and reliable less-than reproduction NOEC (Römbke & Moser 1999). However, the effect sizes at the levels of the newly added NOEC values are not presented in the updated LoEP (and if they are statistically or biologically significant) and it is also not reported whether there were test concentrations above the NOEC values or they were the highest tested concentrations, in which case they would actually be greater-than/equal-to values. The test items and the test conditions would also need to be investigated further, especially for the studies submitted by the applicant ISK Biosciences Europe N.V. (ISK), to find out more about the possible reason(s) behind the sizable differences between the initially evaluated and the later added earthworm results (see detailed discussion below).

The details of the new reproduction studies **for Collembola** would also require further investigation as previously adult mortality proved to be the most sensitive type of effect, but mortality results are not listed in the updated LoEP for the newly added data. The newly listed reproduction NOEC values are surrounded by the same issues as discussed for earthworms above (effect size, type of significance, tested concentrations resulting in bound/unbound values etc.).

The **new microorganism data** is largly variable on their own and also in comparison with the previous results. For N-transformation, the already evaluated relevant and reliable as well as the potentially reliable new effect concentrations (all non-normalised) with ≤ 25 % effects are ~0.108, ~1.32 and ~38.8 mg a.s./kg soil, while at the same time > 25 % effects were observed at 0.270 and at ~1.20 mg a.s./kg soil concentrations using various SC formulations (all results were measured after 28 d, except the result at ~1.20 mg a.s./kg soil concentration that was measured after 100 d; see Table 5 in Section 3.1 and Table 9 below).

Due to the insufficient amount of data for a statistical evaluation, it has been assumed that there was no significant **<u>difference between the toxicity of fluazinam as technical-grade active ubstance and the tested SC formulations containing fluazinam as single active substance</u>** (see Section 3.1). However, the relevant and (potentially) reliable data might indicate otherwise: there is a possible difference in the toxicity of the different formulations used for the tests by different applicants and even between batches/lots used by the same applicant. The most obvious differences can be seen for the studies submitted by ISK: an earlier study resulted in the normalised **earthworm reproduction NOEC** of **< 0.119 mg a.s./kg soil** (54.3 % effect on *E. andrei*, Fluazinam 500 SC/YF8053, Römbke & Moser (1999)), a later one in **3.24 mg a.s./kg soil** (effect size on *E. fetida* is not listed, IKF-1216 500 SC, Wagenhoff (2020a); no study summary available, the reliability is not assignable); as well as 54.9 % effect on **N-transformation** was observed at a non-normalised **0.27 mg a.s./kg soil** concentration in an earlier study (Fluazinam 500 SC/IKF-1216, Reis (2002)), while < 25 % effect at a non-normalised **~38.8 mg a.s./kg soil** concentration in the study conducted later (Frowncide 500 SC, Barbosa (2017); no study summary available, the reliability is not assignable). These studies indicate approx. one to two orders of magnitude differences in toxicity of the previously and recently tested ISK formulations. It is noted in the updated Vol. 1 (EC 2024) – but not in the updated LoEP – that Frowncide 500 SC, the formulation recently used for microorganism testing by ISK, is not considered comparable to the intended formulation IKF-1216 500 SC, the formulation previously used for testing by the same applicant. This may explain the differences between the ISK results on microorganisms, but not on earthworms. In addition, the differences in the effects on N-transformation are also high amongst the formulations used by the different applicants for testing (see discussion above). Such differences could occur for the same type of formulations (here all are suspension concentrates, SC) when these contain different types and/or amounts of safeners, synergists or other co-formulants. Or, for a certain formulation, when for example the types and/or the amounts of co-formulants were changed with time; or when the manufacturing process was improved resulting in different/lower amount of unintentional (toxic) impurities. Without knowing more about the reasons behind the differences in toxicity amongst the formulations/batches, none of the test results can be sensibly dismissed. It is noted that all studies, the older and the newer ones as well, were considered in the course of the EU renewal assessment (EC 2019, 2024).

All of these uncertainties and discrepancies can be further investigated and may be refined after getting access to the original study reports.

In the absence of a robust SGV for fluazinam, the possible protectiveness of such an SGV over the metabolites cannot be considered.

Table 9: Effect concentrations as summarised in the updated LoEP (highlighted there in yellow; EC 2024), for which no study summary or study report is available. The effect concentrations are included here without the EU "correction" (see explanation in Section 1.5.3). The references and the study results are matched based on comparing the existing results and references to the new studies. These studies are also included in the respective appendices below (see Table A1 in Appendix 2). Abbreviations: FTF – Fluazinam Task Force, CHE – Cheminova A/S, NUF – Nufarm SAS, ISK – ISK Biosciences Europe N.V., FIN – Finchimica SpA.

No.	Test organism	Test substance	Application method / OM content [%]	Time scale	Type of endpoint	Toxicity	Normalised effect concentrations [mg a.s./kg soil]	Reference; applicant
1.	*Eisenia fetida* (Earthworm)	IKF-1216 500 SC	Mixed into soil / 10 % peat	Chronic	Reproduction	NOEC = 9.53 mg a.s./kg soil	3.24	Wagenhoff (2020a) cited in EC (2024), LoEP, p.388 and Vol. 2; ISK
2.	*Eisenia fetida* (Earthworm)	Fluazinam 500 SC	Mixed into soil / 5 % peat	Chronic	Biomass (bodyweight)	NOEC = 2.98 mg a.s./kg soil	2.03	Krome (2010) cited in EC (2024), LoEP, p.389 and Vol. 2; FTF (CHE)
2.	*Eisenia fetida* (Earthworm)	Fluazinam 500 SC	Mixed into soil / 5 % peat	Chronic	Reproduction	NOEC = 9.54 mg a.s./kg soil	6.49	Krome (2010) cited in EC (2024), LoEP, p.389 and Vol. 2; FTF (CHE)
3.	*Eisenia fetida* (Earthworm)	Fluazinam 500 SC (limit test)	Mixed into soil / 10 % peat	Chronic	Reproduction	NOEC < 9.5 mg a.s./kg soil	< 3.23	Goodband & Hill (2006) cited in EC (2024), LoEP, p.388 and Vol. 2; FTF (CHE)
4.	*Eisenia fetida* (Earthworm)	TIFC 500 SC	Mixed into soil / 10 % peat	Chronic	Reproduction	NOEC = 8.34 mg a.s./kg soil	2.84	Dini (2020) cited in EC (2024), LoEP, p.389 and Vol. 2; FIN
5.	*Folsomia candida* (Collembola)	IKF-1216 500 SC	Mixed into soil / 10 % peat	Chronic	Reproduction	NOEC = 0.754 mg a.s./kg soil	0.255	Wagenhoff (2020b) cited in EC (2024), LoEP, p.389 and Vol. 2; ISK
6.	*Folsomia candida* (Collembola)	Fluazinam 500 SC	Mixed into soil / 5 % peat	Chronic	Reproduction	NOEC = 6.68 mg a.s./kg soil	4.54	Lührs (2007a) cited in EC (2024), LoEP, p.389 and Vol. 2; FTF (NUF)
7.	Microorganisms	Frowncide 500 SC	n.r.	28 d	N-transformation	< 25 % effect at 20 and 100 mg product/kg soil (~7.75 and 38.8 mg a.s./kg) *	n.a.	Barbosa (2017) cited in EC (2024), LoEP, p.391 and Vol. 2; ISK
8.	Microorganisms	Fluazinam 500 SC	n.r.	28 d	N-transformation	< 25 % effect at 0.27 mg product/kg soil (~0.108 mg a.s./kg) * > 25 % effect at 2.27 mg product/kg soil (~0.906 mg a.s./kg) *	n.a.	Feil (2009) cited in EC (2024), LoEP, p.392 and Vol. 2; FTF (CHE)** and Reis (2007a) cited in EC (2024), LoEP, p.392 and Vol. 2; FTF (NUF)**
9.	Microorganisms	Fluazinam 500 SC	n.r.	28 d	N-transformation	< 25 % effect at 0.332 and 3.32 mg product/kg soil (~0.132 and 1.32 mg a.s./kg) *	n.a.	
10.	Microorganisms	TIFC 500 SC	n.r.	100 d	N-transformation	> 25 % effect at 3.0 and 30 mg product/kg soil (~1.20 and 12.0 mg a.s./kg) *	n.a.	Tediosi (2020) cited in EC (2024), LoEP, p.388 and Vol. 2; FIN

Note: * For the newly added microorganism studies, the effect concentrations in terms of active substance are estimated considering the nominal fluazinam content of the formulations as reported previously (Vol. 3CP B.9, p.5 for ISK, FIN and FTF/ADM/CHE/NUF in EC (2019)). ISK: IKF-1216 500 SC, 38.76 % w/w; FIN: TIFC 500 SC, 40.15 % w/w; FTF: MCW 465 500 SC: 39.90 % w/w. ** Based on the study titels in Volume 2 and the listed results in the LoEP, it is not possible to determine, which reference belongs to which result(s).

8 References

Acosta-Dacal, A., Rial-Berriel, C., Díaz-Díaz, R., Bernal-Suárez, M.d.M. and Luzardo, O.P. (2021) Optimization and validation of a QuEChERS-based method for the simultaneous environmental monitoring of 218 pesticide residues in clay loam soil. Science of The Total Environment 753, 142015. https://doi.org/10.1016/j.scitotenv.2020.142015

Anderson, R.H., Prues, A.G. and Kravitz, M.J. (2010) Determination of the biologically relevant sampling depth for terrestrial ecological risk assessments. Geoderma 154(3), 336-339. https://doi.org/10.1016/j.geoderma.2009.11.004

Azimonti, G., Galimberti, F., Marchetto, F., Menaballi, L., Ullucci, S., Pellicioli, F., Alessandra, C., Lidia, C., Alessio, I., Angelo, M., Boer, W.d. and Voet, H.v.d. (2015) Comparison of NOEC values to EC10/EC20 values, including confidence intervals, in aquatic and terrestrial ecotoxicological risk assessment. EFSA Supporting Publications 12(12), EN-906. https://doi.org/10.2903/sp.efsa.2015.EN-906

BASF (2021) Dossier for the renewal of the active substance Pendimethalin (BAS 455 48 H), BASF Agro B.V. Arnhem (NL) Freienbach Branch. https://open.efsa.europa.eu/question/EFSA-Q-2022-00041

BLV (2025) Bundesamt für Lebensmittelsicherheit und Veterinärwesen – Pflanzenschutzmittelverzeichnis, https://www.psm.admin.ch/de/wirkstoffe.

BVL (2011) PSM-Zulassungsbericht (Registration Report): Shirlan, 034092-00/00, Wirkstoff(e): Fluazinam. Stand: 2011-04-19. Budesamt für Verbraucherschutz und Lebensmittelsicherheit, Braunschweig. https://www.bvl.bund.de/SharedDocs/Downloads/04_Pflanzenschutzmittel/01_zulassungsberichte/034092-00-00.pdf?__blob=publicationFile&v=4

Casado-Martinez, M., Dell'Ambrogio, G., Campiche, S., Kroll, A., Lauber, E., Marti-Roura, M., Mendez-Fernandez, L., Renaud, M., Tierbach, A., Wildi, M., Wong, J.W.Y., Werner, I., Junghans, M. and Ferrari, B.J.D. (2024) Incorporation of sediment- and soil-specific aspects in the Criteria for Reporting and Evaluating Ecotoxicity Data (CRED). Integr Environ Assess Manag https://doi.org/10.1002/ieam.4948

Chen, L., Jia, C., Li, F., Jing, J., Yu, P., He, M. and Zhao, E. (2018) Dissipation and residues of fluazinam and dimethomorph in potatoes, potato plants, and soil, determined by QuEChERS ultra-performance liquid chromatography tandem mass spectrometry. Environmental Science and Pollution Research 25(32), 32783-32790. https://doi.org/10.1007/s11356-018-3281-7

Crane, M., Dungey, S., Lillicrap, A., Thompson, H., Weltje, L., Wheeler, J.R. and Lagadic, L. (2022) Commentary: Assessing the endocrine disrupting effects of chemicals on invertebrates in the European Union. Environmental Sciences Europe 34, 36. https://doi.org/10.1186/s12302-022-00613-3

Donley, N., Cox, C., Bennett, K., Temkin, A.M., Andrews, D.Q. and Naidenko, O.V. (2024) Forever Pesticides: A Growing Source of PFAS Contamination in the Environment. Environmental Health Perspectives 132(7), 075003. https://doi.org/10.1289/EHP13954

Droge, S.T.J. (2020) Sorption of polar and ionogenic organic chemicals. In Ortega-Calvo, J. J. and Parsons, J. R. (eds.), Bioavailability of organic chemicals in soil and sediment, Handbook of Environmental Chemistry, 100: 43-80, Springer Nature Switzerland AG, Published online: 30 April 2020. https://link.springer.com/book/10.1007/978-3-030-57919-7

EC (2001) Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32001R1049&qid=1605024886432.

EC (2002) Draft working Document - Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev 2 final, 17 October 2002. https://food.ec.europa.eu/system/files/2016-10/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf.

EC (2006) Draft Assessment Report (DAR) - public version. Initial risk assessment provided by the rapporteur Member State Austria for the existing active substance fluazinam of the third stage (part A) of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC. European Commission, July 2006. https://www.efsa.europa.eu/en/consultations/call/public-consultation-active-substance-fluazinam-0

EC (2008) Pesticides in air: Considerations for exposure asssessment. Report prepared by the FOCUS Working Group on pesticides in air (FOCUS Air Group). . European Commission, Health & Consumer Protection Directorate-General, Directorate E - Food Safety: plant health, animal health and welfare, international questions, E1 - Plant health. SANCO/10553/2006 Rev 2 June 2008. https://esdac.jrc.ec.europa.eu/public_path/projects_data/focus/air/docs/FOCUS_AIR_GROUP_REPORT-FINAL.pdf

EC (2011) Consolidated text (02.12.2024): Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011R0540-20240901.

EC (2015) Consolidated text (24.11.2024): Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution. https://eur-lex.europa.eu/eli/reg_impl/2015/408/2023-07-31.

EC (2019) Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009: Fluazinam. Rapporteur Member State: Austria, Co-Rapporteur Member State: Denmark. European Commission, June 2019. https://www.efsa.europa.eu/en/consultations/call/public-consultation-active-substance-fluazinam

EC (2022) Updated draft Renewal Assessment Report prepared according to the Commission Regulation (EU) No. 1107/2009, provided by the Rapporteur Member State Sweden for the existing active substance pirimicarb. https://open.efsa.europa.eu/consultations/a0c09000008TWrwAAG?search=pirimicarb.

EC (2024) Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009: Fluazinam. Rapporteur Member State: Austria, Co-Rapporteur Member State: Denmark. European Commission, July 2024 (RAR updated after ED additional information). https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000001icx5/pc1067

EC TGD (2003) Technical Guidance Document on Risk Assessment (Part II). European Commission. Joint Research Centre. EUR 20418 EN/2. https://op.europa.eu/s/y4d4.

ECHA (2017) European Chemical Agency - Guidance on Biocidal Products Regulation: Volume IV Environment - Assessment and Evaluation (Parts B+C). ECHA-17-G-23-EN; Cat. Number: ED-01-17-897-EN-N; ISBN: 978-92-9020-151-9. https://doi.org/10.2823/033935

ECHA (2025) Substance Infocard, fluazinam (ISO); 3-chloro-N-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)pyridin-2-amine. European Chemicals Agency https://echa.europa.eu/de/substance-information/-/substanceinfo/100.114.073

EFSA (2008) Conclusion regarding the peer review of the pesticide risk assessment of the active substance fluazinam. *Scientific Report*, European Food Safety Authority. Finalised: 26 March 2008. . EFSA Journal 137, 1-82. https://doi.org/10.2903/j.efsa.2008.137r

EFSA (2015) Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology. European Food Safety Authority. EFSA Supporting Publications 12(12), 924E. https://doi.org/10.2903/sp.efsa.2015.EN-924

EFSA (2019) Technical report on the Outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology. European Food Safety Authority. EFSA supporting publication 16(7), EN-1673. https://doi.org/10.2903/sp.efsa.2019.EN-1673

EFSA (2025a) Answer to "Your application for public access to documents of 5 May 2025 Ref. No.: PAD 2025/098 (00016036)". Legal Affairs Services, Parma, 4 July 2025, Ref. LV/PU/mm (2025) – out–35719985 (Fluazinam).

EFSA (2025b) Answer to "Your application for public access to documents of 9 July 2025" Ref. No.: PAD 2025/098 (00020470). Legal Affairs Services, Parma, 13 August 2025, Ref. LV/PU/rl (2025) - out-35840029 (Fluazinam).

EPPO (2003) Environmental risk assessment scheme for plant protection products. Chapter 8: Soil organisms and functions. European and Mediterranean Plant Protection Organization. EPPO Bulletin 33(2), 195-209. https://doi.org/10.1046/j.1365-2338.2003.00654.x

EPPO (2025) List of databases on registered plant protection products in the EPPO region. European and Mediterranean Plant Protection Organisation. Accessed: 2025. https://www.eppo.int/ACTIVITIES/plant_protection_products/registered_products

FAO (2023) FAO specifications and evaluations for agricultural pesticides: fluazinam (3-chloro-N-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-2,6-dinitro-p-toluidine). Food and Agricultural Organization of the United Nations, pp. 70. https://openknowledge.fao.org/server/api/core/bitstreams/6cef39f3-929f-4ff1-bb39-68966e8ec53a/content.

Feng, X., Wang, K., Mu, Z., Zhao, Y. and Zhang, H. (2015) Fluazinam Residue and Dissipation in Potato Tubers and Vines, and in Field Soil. American Journal of Potato Research 92(5), 567-572. http://dx.doi.org/10.1007/s12230-015-9469-1

Filimon, M.N., Voia, S.O., Vladoiu, D.L., Isvoran, A. and Ostafe, A. (2015) Temperature dependent effect of difenoconazole on enzymatic activity from soil. J. Serb. Chem. Soc. 80(9), 1127-1137. http://dx.doi.org/10.2298/JSC141218030F

FOCUS (1997) Soil persistence models and EU registration. The final report of the work of the Soil Modelling Work group of FOCUS (FOrum for the Co-ordination of pesticide fate models and their Use). 77 pp. https://food.ec.europa.eu/system/files/2016-10/pesticides_ppp_app-proc_guide_fate_soil-persistance-1997.pdf.

ISO (1999a) Soil quality - Inhibition of reproduction of Collembola (*Folsomia candida*) by soil pollutants. International Standards Organisation, Geneva, Switzerland (ISO 11267:1999). https://www.iso.org/standard/19245.html

ISO (1999b) Soil quality - Effects of pollutants on earthworms - Part 3: Guidance on the determination of effects in field situations. International Standards Organisation, Geneva, Switzerland (ISO 11268-3:1999). https://www.iso.org/standard/22764.html

ISO (2006) Soil quality - Sampling of soil invertebrates - Part 2: Sampling and extraction of micro-arthropods (Collembola and Acarina). International Standards Organisation, Geneva, Switzerland (ISO 23611-2:2006(E)). https://www.iso.org/standard/37027.html

ISO (2014) Soil quality - Effects of pollutants on earthworms - Part 3: Guidance on the determination of effects in field situations. International Standards Organisation, Geneva, Switzerland (ISO 11268-3:2014). https://www.iso.org/standard/57583.html

Kah, M. and Brown, C.D. (2006) Adsorption of Ionisable Pesticides in Soils. pp. 149-217. *In* Ware, G.W., Whitacre, D.M., Albert, L.A., de Voogt, P., Gerba, C.P., Hutzinger, O., Knaak, J.B., Mayer, F.L., Morgan, D.P., Park, D.L., Tjeerdema, R.S., Yang, R.S.H. and Gunther, F.A. (eds), Reviews of Environmental Contamination and Toxicology, Vol. 188, Springer, New York, NY. https://doi.org/10.1007/978-0-387-32964-2_5

Klimisch, H.J., Andreae, M. and Tillmann, U. (1997) A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data. Regulatory Toxicology and Pharmacology 25, 1-5. https://doi.org/10.1006/rtph.1996.1076

Lewis, K.A., Tzilivakis, J., Warner, D. and Green, A. (2016) An international database for pesticide risk assessments and management. Human and Ecological Risk Assessment 22(4), 1050-1064. https://doi.org/10.1080/10807039.2015.1133242

Liu, C., Yang, Z., He, P., Munir, S., He, P., Wu, Y., Ho, H. and He, Y. (2019) Fluazinam positively affected the microbial communities in clubroot cabbage rhizosphere. Scientia Horticulturae 256, 108519. https://doi.org/10.1016/j.scienta.2019.05.046

Marti-Roura, M., Dell'Ambrogio, G., Campiche, S., Wong, J., Junghans, M., Renaud, M. and Ferrari, B.J.D. (2023) Methodology proposal for the derivation of Soil Guideline Values for Plant Protection Product residues. Part 2 - Recommendations for the derivation of Soil Guideline Values. Swiss Centre for Applied Ecotoxicology, Dübendorf and Lausanne, Switzerland. https://www.oekotoxzentrum.ch/media/czdbwdbi/2023_consoil_sgv_report_part_2.pdf.

McCall, P.J., Laskowski, D.A., Swann, R.L. and Dishburger, H. (1980) Measurements of sorption coefficients of organic chemicals and their use in environmental fate analysis. *In*: Test Protocols for Environmental Fate and Movement of Toxicants. *In*: Proceedings of the 94th Annual Meeting of theAmerican Association of Official Analytical Chemists (AOAC). October 21–22, Washington, DC, pp. 89–109.

Meuli, R.G., Schwab, P., Wächter, D. and Ammann, S. (2014) Nationale Bodenbeobachtung (NABO) 1985-2004. Zustand und Veränderung der anorganischen Schadstoffe und Bodenbegleitparameter. Bundesamt für Umwelt, Bern. Umwelt-Wissen Nr. 1409: 94 S. http://www.bafu.admin.ch/uz-1507-d.

Moermond, C.T.A., Kase, R., Korkaric, M. and Ågerstrand, M. (2016) CRED: Criteria for reporting and evaluating ecotoxicity data. Environmental Toxicology and Chemistry 35(5), 1297-1309. https://doi.org/10.1002/etc.3259

Motulsky, H.J. and Christopoulos, A. (2023) Fitting models to biological data using linear and nonlinear regression. A practical guide to curve fitting., GraphPad Software Inc., San Diego CA, www.graphpad.com.

Muñoz-Leoz, B., Garbisu, C., Charcosset, J.Y., Sánchez-Pérez, J.M., Antigüedad, I. and Ruiz-Romera, E. (2013) Non-target effects of three formulated pesticides on microbially-mediated processes in a clay-loam soil. Sci Total Environ 449, 345-354. https://doi.org/10.1016/j.scitotenv.2013.01.079

NCBI (2025) PubChem Compound Summary for CID 91731, Fluazinam. Retrieved February 4, 2025 from National Center for Biotechnology Information. https://pubchem.ncbi.nlm.nih.gov/compound/Fluazinam.

NEPC (2011) Schedule B5b - Guideline on Methodology to Derive Ecological Investigation Levels in Contaminated Soils. National Environment Protection Council, National Environment Protection (Assessment of Site Contamination) Measure. Australia, April 2011. https://www.nepc.gov.au/sites/default/files/2022-09/schedule-b5b-guideline-methodology-derive-eils-sep10.pdf.

Niemi, R.M., Heiskanen, I., Ahtiainen, J.H., Rahkonen, A., Mäntykoski, K., Welling, L., Laitinen, P. and Ruuttunen, P. (2009) Microbial toxicity and impacts on soil enzyme activities of pesticides used in potato cultivation. Applied Soil Ecology 41(3), 293-304. https://doi.org/10.1016/j.apsoil.2008.12.002

OECD (1984) Test No. 207: Earthworm, Acute Toxicity Tests. OECD Guidelines for the Testing of Chemicals, Section 2, OECD Publishing, Paris. https://doi.org/10.1787/9789264070042-en

OECD (2000a) Test No. 217: Soil Microorganisms: Carbon Transformation Test. OECD Guidelines for the Testing of Chemicals, Section 2, OECD Publishing, Paris. https://doi.org/10.1787/9789264070240-en.

OECD (2000b) Test No. 216: Soil Microorganisms: Nitrogen Transformation Test. OECD Guidelines for the Testing of Chemicals, Section 2, OECD Publishing, Paris. https://doi.org/10.1787/9789264070226-en

OECD (2006) Test No. 208: Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test, OECD Guidelines for the Testing of Chemicals, Section 2, OECD Publishing, Paris. https://doi.org/10.1787/9789264070066-en

OECD (2016a) Test No. 232: Collembolan Reproduction Test in Soil. OECD Guidelines for the Testing of Chemicals, Section 2, OECD Publishing, Paris. https://doi.org/10.1787/9789264264601-en

OECD (2016b) Test No. 226: Predatory mite (*Hypoaspis (Geolaelaps) aculeifer*) reproduction test in soil. OECD Guidelines for the Testing of Chemicals, Section 2, OECD Publishing, Paris. https://doi.org/10.1787/9789264264557-en

OECD (2018) Revised Guidance Document 150 on standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption, OECD Series on Testing and Assessment, OECD Publishing, Paris. https://doi.org/10.1787/9789264304741-en

Peijnenburg, W.J.G.M. (2020) Implementation of bioavailability in prospective and retrospective risk assessment of chemicals in soils and sediments. in Ortega-Calvo, J. J. and Parsons, J. R. (eds.), Bioavailability of organic chemicals in soil and sediment, Handbook of Environmental Chemistry, 100: 391-422, Springer Nature Switzerland AG, Published online: 30 April 2020. https://doi.org/10.1007/698_2020_516

PSMV (2010) SR 916.161, Verordnung vom 12. Mai 2010 über das Inverkehrbringen von Pflanzenschutzmitteln (Pflanzenschutzmittelverordnung, PSMV) Stand am 1. Februar 2025 https://www.fedlex.admin.ch/eli/cc/2010/340/de.

Reusser, J.E., Siegenthaler, M.B., Winkel, L.H.E., Wächter, D., Kretzschmar, R. and Meuli, R.G. (2023) Geochemical Soil Atlas of Switzerland. Distribution of 20 elements in the topsoil. Agroscope (Federal Office for Agriculture), Zürich and Federal Office for the Environment, Bern. https://www.bafu.admin.ch/bafu/en/home/topics/soil/info-specialists/geochemicalsoilatlas.html.

RIVM (2007) Guidance for the derivation of environmental risk limits within the framework of 'International and national environmental quality standards for substances in the Netherlands' (INS). Authors: P.L.A. van Vlaardingen and E.M.J. Verbruggen, National Institute for Public Health and the Environment. Bilthoven, The Netherlands. RIVM report 601782001/2007. https://www.rivm.nl/bibliotheek/rapporten/601782001.pdf.

Rösch, A., Wettstein, F.E., Wächter, D., Reininger, V., Meuli, R.G. and Bucheli, T.D. (2023) A multi-residue method for trace analysis of pesticides in soils with special emphasis on rigorous quality control. Analytical and Bioanalytical Chemistry 415(24), 6009-6025. https://doi.org/10.1007/s00216-023-04872-8

Toschki, A., Hammers-Wirtz, M., Possberg, C., Ross-Nickoll, M., Schäffer, A., Schmidt, B., Scholz Starke, B., Römbke, J., Scheffzyk, A., Klein, M. and Hommen, D. (2020) Evaluation of the risk for soil organisms under real conditions. Development of a national position for amending downstream legislations of the new EU Plant Protection Products Regulation. Texte 201/2020, Report No. EF001129-ENG, German Environment Agency. https://www.umweltbundesamt.de/en/publikationen/evaluation-of-the-risk-for-soil-organisms-under.

UBA (2025) ETOX - Information System, Ecotoxicology and Environmental Quality Targets. Federal Environment Agency (Umweltbundesamt), Dessau-Roßlau, Germany. http://webetox.uba.de/webETOX/index.do.

US EPA (1982) Pesticide Assessment Guideline, Subdivision J, Hazard Evaluation: Nontarget Plants. Prepared by Holst, R. W. and Ellwanger, T. C. EPA-540/9-82-020, October 1982, US Environmental Protection Agency, Office of Pesticides and Toxic Substances, Washington, D.C. https://nepis.epa.gov/

US EPA (2013) Environmental Fate and Ecological Effects Preliminary Risk Assessment for the Registration Review of Fluazinam. June 4, 2013. PC Code 129098. DP Barcode: D411177. Doc ID: EPA-HQ-OPP-2009-0039-0019. https://www.regulations.gov/document/EPA-HQ-OPP-2009-0039-0019

US EPA (2025) ECOTOXicology Knowledgebase - curated toxicity data. US Environmetal Protection Agency. https://cfpub.epa.gov/ecotox/.

Wehrli, M., Slotsbo, S., Fomsgaard, Inge S., Laursen, Bente B., Gröning, J., Liess, M. and Holmstrup, M. (2024) A Dirt(y) World in a Changing Climate: Importance of Heat Stress in the Risk Assessment of Pesticides for Soil Arthropods. Global Change Biology 30(10), e17542. https://doi.org/10.1111/gcb.17542

Appendix 1 Considerations for the evaluation of the studies

General considerations

- ***Effects on target species*** (pests) against which the active substance can be used are not considered (they are not included in any of the data tables in the SGV dossier).
- ***Efficacy studies on terrestrial plants*** with the aim to evaluate the effectiveness of the chemical compound on target species (pests) are not considered for the evaluation (they are not included in any of the data tables). The potential increase of the plant health due to a reduction of the pest is unrelated to the ecotoxicological effects of the substance.
- Only the effects of the substance *via* ***soil exposure*** is considered relevant. Effects resulting from using sand or other material instead of soil, or from direct over spraying of the test organism instead of exposure through soil, are *not* considered *relevant* (**C3**).
- For ***seedling emergence tests*** following the standard OECD 208 guideline, the use of 15-cm containers is recommended and followed by many of the contract labs. A 15-cm pot usually has a depth of approx. 13-14 cm and – based on photos of the test in contract labs (e.g. Ibacon, Eurofins etc.) – the planted pots are usually filled up to the lower end of the brim, i.e. approx. to 10-11-12 cm. In other studies for instance it was specified that they used pots with 11-cm diameter and 10-cm depth (see Anonymous (2016) cited in (BASF 2021) or 7-cm depth trays (Fleming *et al*. (1996a) cited in (EC 2022)). The specific container size/soil depth is used if it is reported/summarised. Otherwise the use of an average soil depth of 10 cm along with 1.5 g/cm^3 soil bulk density for converting the applied rate of the test item to a concentration in the soil is considered reasonable and pragmatic (also see the recommendation in Info-box 13 in (ECHA 2017), p.149). This is based on the above detailed information, i.e. the test guideline recommendation in conjunction with available information in standard regulatory study reports, information available publicly on the methods used by contract laboratories as well as personal communication with experts conducting such studies. While the soil depth can slightly vary depending on the plant species/test facility, ten centimetres soil depth is considered as a reasonable average for studies where the container size is not reported, which also allows comparability of the non-target terrestrial plant results with other studies, where either the test item is mixed into the soil, i.e. the test item concentration in the soil is known (most laboratory studies) or the upper 10-cm layer is sampled for analytical measurements (see e.g. field earthworm studies). If specific information is available for a certain study, the concentrations are calculated accordingly.

  It is noted that the behaviour of the test substances can vary and can result in different distributions in the soil in case of over-spraying. However, choosing and considering a certain soil depth is a pragmatic approach and a pragmatic solution that is already applied for the authorisation/registration of pesticides (but with different depths, i.e. 5 cm for permanent crops and 20 cm for crops where ploughing in the season takes place, even if the substance is actually not mixed into the soil after application, see e.g. (FOCUS 1997) and (EC 2002)) as well as of biocides (ECHA 2017).

  In the study reports, ***phytotoxicity effects*** are usually evaluated qualitatively or semi-quantitatively through a subjective scale. Thus, phytotoxicity results – beyond actual ***mortality*** – are considered not suitable for deriving quantitative endpoints.
- Reproductive endpoints are considered the most relevant endpoints as they are good indicators of the sustainability of the population in the long-term. Other endpoints affecting survival and growth (biomass) of individuals are also accepted, since they were traditionally measured endpoints frequently extrapolated to represent the impact at population level. If multiple comparable toxicity values for the same species and the same measured effect are available, the ***geometric mean*** of the effect values is calculated.

- Following a critical consideration (Azimonti *et al.* 2015, EFSA 2019), the statistically more robust endpoint of ***EC10 vs NOEC*** is chosen. If both endpoints seem to be equally robust (e.g. details of statistical methods and results are reported; clear dose-response; descriptive statistics; NOEC: also statistically significant LOEC is reported; EC10: width/lower/higher limits of confidence intervals for EC10/20/50; steepness of curve etc. are available), then EC10 is preferred due to the general inherent uncertainties a NOEC is surrounded by (Azimonti *et al.* 2015). When no or not statistically robust EC10median is available, the statistically robust NOEC is preferred. It is noted that statistically non-robust (but "biologically significant") NOEC values are often preferred during the EU pesticide authorisation/renewal processes, to provide long-term endpoints with not higher than 10 % effects. However, such endpoint could not account for the variability of data in soil studies (where coefficient of variation in the control is accepted up to 15, 30 or 50 %). The uncertainty in a NOEC value with higher level of effects may need to be highlighted and discussed. In the absence of a statistically robust endpoint, the study results are considered *not reliable* (**R3**) or *not assignable* (**R4**) depending on the actual flaws.
- ***Regulatory studies and their endpoints*** (EU/EFSA) are generally accepted without additional assessment (at face value) or partially re-considered if needed to set the endpoints in line with our criteria as summarised here and detailed above (Moermond *et al.* 2016, Marti-Roura *et al.* 2023). This is the case, for example, when organisms are not exposed through soil (e.g. plant vegetative vigour tests *via* foliar application); normalisation to a standard organic matter content is not possible due to lack of data; not the statistically most robust effect concentration is proposed/agreed upon as an endpoint etc. A full re-assessment may also be carried out for regulatory studies, where the study summary is not sufficiently detailed and we can get access to the original study report.
- Study ***endpoints from authorisation reports*** (e.g. EU/EFSA, US EPA) are subjected to the same scrutiny as open literature data. These include but are not limited to careful consideration of the study design (e.g. number of replicates and test concentrations), the way the tests were conducted (e.g. environmental conditions, observations), their results (e.g. performance of control, validity criteria, dose-response, deviation) as well as the statistical analysis (e.g. methods and reported details). Authorisation reports are accepted at face value and used in the risk assessment if they meet the criteria of reliability and relevance as detailed above (Moermond *et al.* 2016, Marti-Roura *et al.* 2023). If they have flaws in terms of reliability and relevance or other requirements as detailed here and in the above cited documents (e.g. validity criteria of the study were not met; no statistically robust EC10median could be derived; endpoint could not be standardised due to lacking information on OM/OC content of the test soil etc.), the regulatory endpoints are listed at face value and not considered further but not used in deriving an SGV.
- In general, ***biomarker studies*** are not included in the tables since they are based on endpoints, whose relationship to effects at population level is uncertain. However, some exo-enzymes produced by soil microorganisms can be used as biomarkers of soil fertility and are important in the ecological functioning of the soil (e.g. Filimon *et al.* 2015, NEPC 2011, RIVM 2007). For this reason, microbial-mediated enzymatic activities are included in the assessment as "*relevant with restrictions*" (**C2**).
- The relationship between ***microbial biodiversity and function*** is quite complex. Although it cannot be denied that loss of microbial diversity can have an impact on function, the role of biodiversity in supporting microbial functions needs a better understanding (EFSA 2019). For this reason, in this report, microbial endpoints directly involved in soil functions are preferred over microbial diversity endpoints.

- ***Recovery of effects*** – that can be seen e.g. in earthworm field studies – is not considered acceptable within the scope of SGV that is used in relation to long-term pesticide residues, not immediate effects after application of pesticides.
- Long-term endpoints from ***field studies*** are considered as supportive information unless there is analytical verification. A robust effect concentration can only be derived when it is confirmed by analytical verification and it should be within approximately a month of the assessment of the effect endpoint to ensure its reliability with regards to any potential loss of the test substance through degradation/dissipation and as a result to underestimate the risk. In order to derive effect concentration(s) for the whole duration of a field study, the test substance concentration should be monitored regularly until the end of the study. When the test substance concentrations are measured only at the beginning of the study, the derivation of an approx. one-month endpoint is considered reliable enough for a quantitative use (see e.g. field earthworm studies). As the actual degradation/dissipation of a pesticide can be affected by a mixture of various biotic and abiotic factors, without measured residues in the test site it is not possible to calculate a meaningful (time-weighted average) concentration in the soil and derive a robust endpoint (see e.g. concentration-dependent dissipation of pesticides in Muñoz-Leoz *et al.* (2013)). It is noted that, for instance, according to the often used field earthworm study guideline (ISO 2014) 50 % deviation from the nominal concentration is acceptable. However, as we compare the derived effect concentrations – and in turn the derived SGV – directly to the measured environmental concentrations, it is more reasonable to base the effect values on the measured amount of test substance present in the soil during the study. Altogether it is considered a pragmatic approach to use the analytical verification results for the upper 10-cm soil layer. It is noted that the sampled upper 10-cm soil layer does not cover the whole depth where earthworms can occur. However, a) while it is not ideal, it is usually the only analytical information available (see e.g. the respective requirement in ISO (2014)); b) depending on the ecological group (i.e. epigeic, endogeic or anecic species) the exposure of earthworms to pesticides can highly vary anyway. In a pilot study it was shown that even anecic species living usually in deep burrows can be affected by pesticide treatments due to their feeding and mating habits, i.e. gathering food and mating on the contaminated soil surface (Toschki *et al.* 2020). The abundance, diversity and activity of soil biota are in general the highest in the top soil layer (Toschki *et al.* 2020, Anderson *et al.* 2010).

Soil organic matter content

- When only ***total organic carbon*** is reported in a study, the total organic carbon value is transformed to organic matter by using a factor of 1:1.7.
- If only a ***percentage of sphagnum peat*** is reported in laboratory studies with artificial soil, the soil organic matter content is estimated assuming that the only source of organic matter in the soil comes from the sphagnum peat and that the organic matter content of the sphagnum peat is approximately 100 %.
- If ***no organic carbon/matter content*** is reported, the study endpoint cannot be normalised and thus is not suitable for further use. As a result, the study is scored as *not assignable: Information needed to make an assessment of the study is missing* (**R4**; Moermond *et al.* 2016, Casado-Martinez *et al.* 2024).

For the adapted criteria – that were mainly based on the European technical guidance document (EC TGD 2003) – and further details on the parameters and methods that are used for the SGV derivation, please refer to Marti-Roura *et al.* (2023). The criteria beyond these resources will be included in an updated methodological report.

Appendix 2 Data on the active substance

Table A1: Soil effect data for fluazinam from laboratory experiments. The lowest reliable and relevant effect data per species per test setup are shown in bold. Unreliable, not relevant and not assignable data are greyed out. Calculated data are rounded to three significant figures. Abbreviations: n.r. – not reported; n.a. – not applicable; cc. – concentration; MWHC – maximum water holding capacity; OC – organic carbon; OM – organic matter; CFU – colony forming units; FTF – Fluazinam Task Force, CHE – Cheminova A/S, NUF – Nufarm SAS, ISK – ISK Biosciences Europe N.V., FIN – Finchimica SpA. Data were evaluated for reliability and relevance according to the modified CRED criteria (see R/C scores) or taken at face value from regulatory dossiers (Assessment score 1-3). For notes, please refer to the end of Appendix 2 (Notes A1).

Species (Taxonomic group)[6]	Test substance	Measured effect[7]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Eisenia fetida (Earthworm)	Fluazinam (purity 97.3 %)	adult mortality	14 and 28 d	LC50	> 1000	7.95	> 428	Artificial soil: 70 % sand, 20 % kaolinite clay, 10 % sedge peat (with 79.5 % OM content), 10 mg/kg $CaCO_3$, pH 7.0 ± 0.2, 35 % water content of soil dry weight	A, F	R2/C2	Edwards & Coulson (1985) cited in EC (2024), Vol. 3CA B.9.4, p.423
***Eisenia fetida* (Earthworm)**	**Fluazinam (purity 97.3 %)**	**adult mortality**	**14 and 28 d**	**NOEC**	**≥ 10 (< 100)**	**7.95**	**≥ 4.28 (< 42.8)**	**Artificial soil: 70 % sand, 20 % kaolinite clay, 10 % sedge peat (with 79.5 % OM content), 10 mg/kg $CaCO_3$, pH 7.0 ± 0.2, 35 % water content of soil dry weight**	**A, F**	**R2/C2**	**Edwards & Coulson (1985) cited in EC (2024), Vol. 3CA B.9.4, p.423**
Eisenia fetida (Earthworm)	Fluazinam (purity 97.3 %)	biomass (adult weight)	14 and 28 d	EC50	> 1000	7.95	> 428	Artificial soil: 70 % sand, 20 % kaolinite clay, 10 % sedge peat (with 79.5 % OM content), 10 mg/kg $CaCO_3$, pH 7.0 ± 0.2, 35 % water content of soil dry weight	A, F	R2/C2	Edwards & Coulson (1985) cited in EC (2024), Vol. 3CA B.9.4, p.423
***Eisenia fetida* (Earthworm)**	**Fluazinam (purity 97.3 %)**	**biomass (adult weight)**	**28 d**	**NOEC**	**≥ 10 (< 100)**	**7.95**	**≥ 4.28 (< 42.8)**	**Artificial soil: 70 % sand, 20 % kaolinite clay, 10 % sedge peat**	**A, F**	**R2/C2**	**Edwards & Coulson (1985) cited in EC**

6 M – monocotyledonous, D – dicotyledonous plant species
7 DE – diversity endpoint, EE – enzymatic endpoint, FE – functional endpoint

Species (Taxonomic group)[6]	Test substance	Measured effect[7]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
								(with 79.5 % OM content), 10 mg/kg $CaCO_3$, pH 7.0 ± 0.2, 35 % water content of soil dry weight			**(2024), Vol. 3CA B.9.4, p.423**
Eisenia fetida (Earthworm)	Fluazinam 500 g/L SC (38.4 % w/w, 495 g a.s./L)	adult mortality	14 d	NOEC	≥ 528 (1376 mg product/kg soil)	10	≥ 180	Artificial soil: 70 % sand, 20 % kaolinite clay, 10 % peat, 0.5 % $CaCO_3$, pH 6.0 ± 0.2, max. 50 % moisture	EE, F	1	Yearsdon *et al*. (1991) cited in EC (2019), Vol. 3CP (ISK) B.9.7.1 p.145
Eisenia fetida (Earthworm)	Fluazinam 500 g/L SC (38.4 % w/w, 495 g a.s./L)	adult mortality	14 d	LC50	> 528 (1376 mg product/kg soil)	10	> 180	Artificial soil: 70 % sand, 20 % kaolinite clay, 10 % peat, 0.5 % $CaCO_3$, pH 6.0 ± 0.2, max. 50 % moisture	EE, F	1	Yearsdon *et al*. (1991) cited in EC (2019), Vol. 3CP (ISK) B.9.7.1 p.145
***Eisenia fetida* (Earthworm)**	**Fluazinam 500 g/L SC (38.4 % w/w, 495 g a.s./L)**	**biomass (adult weight)**	**14 d**	**NOEC**	**< 53.0 (138 mg product/kg soil)**	**10**	**< 18.0**	**Artificial soil: 70 % sand, 20 % kaolinite clay, 10 % peat, 0.5 % $CaCO_3$, pH 6.0 ± 0.2, max. 50 % moisture**	**EE, F**	**1**	**Yearsdon *et al*. (1991) cited in EC (2019), Vol. 3CP (ISK) B.9.7.1 p.145**
Eisenia andrei (Earthworm)	Fluazinam 500 g/L SC (YF8053, 39.4 % w/w)	adult mortality	28 d	NOEC	≥ 35	10	≥ 11.9	Artificial soil: 68-69 % quartz sand, 20 % kaolinite clay, 10 % sphagnum peat, approx. 1 % $CaCO_3$, pH 5.7-6.4, 40.6-52.6 % water content of dry weight	F	1	Römbke & Moser (1999) cited in EC (2019), Vol. 3CP (ISK) B.9.7.1 p.146
Eisenia andrei (Earthworm)	Fluazinam 500 g/L SC (YF8053, 39.4 % w/w)	biomass (adult weight change)	28 d	NOEC	≥ 35	10	≥ 11.9	Artificial soil: 68-69 % quartz sand, 20 % kaolinite clay, 10 % sphagnum peat, approx. 1 % $CaCO_3$, pH 5.7-6.4, 40.6-52.6 % water content of dry weight	F	1	Römbke & Moser (1999) cited in EC (2019), Vol. 3CP (ISK) B.9.7.1 p.146
***Eisenia andrei* (Earthworm)**	**Fluazinam 500 g/L SC (YF8053, 39.4 % w/w)**	**reproduction (number of juveniles)**	**56 d**	**NOEC**	**< 0.35**	**10**	**< 0.119**	**Artificial soil: 68-69 % quartz sand, 20 % kaolinite clay, 10 % sphagnum peat, approx. 1 % $CaCO_3$, pH 5.7-6.4, 40.6-52.6 %**	**F**	**1**	**Römbke & Moser (1999) cited in EC (2019), Vol. 3CP (ISK) B.9.7.1 p.146**

Species (Taxonomic group)[6]	Test substance	Measured effect[7]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
								water content of dry weight			
Eisenia fetida (Earthworm)	IKF-1216 500 SC	reproduction	n.r.	NOEC	9.53	10	3.24	n.r.	F, FF	R4/C1	Wagenhoff (2020a) cited in EC (2024), LoEP, p.388 and Vol. 2
Eisenia fetida (Earthworm)	Fluazinam 500 SC	biomass (body weight)	n.r.	NOEC	2.98	5	2.03	n.r.	F, FF	R4/C1	Krome (2010) cited in EC (2024), LoEP, p.388 and Vol. 2
Eisenia fetida (Earthworm)	Fluazinam 500 SC	reproduction	n.r.	NOEC	9.54	5	6.49	n.r.	F, FF	R4/C1	Krome (2010) cited in EC (2024), LoEP, p.388 and Vol. 2
Eisenia fetida (Earthworm)	Fluazinam 500 SC (limit test)	reproduction	n.r.	NOEC	< 9.5	10	< 3.23	n.r.	F, FF	R4/C1	Goodband & Hill (2006) cited in EC (2024), LoEP, p.389 and Vol. 2
Eisenia fetida (Earthworm)	TIFC 500 SC	reproduction	n.r.	NOEC	8.34	10	2.84	n.r.	F, FF	R4/C1	Dini (2020) cited in EC (2024), LoEP, p.389 and Vol. 2
***Eisenia fetida* (Earthworm)**	**MCW 465 500 SC (490 g a.s./L)**	**adult mortality**	**28 d**	**NOEC**	**≥ 3.79 (10 mg product/kg soil)**	**10**	**≥ 1.29**	**Artificial soil: 69 % quartz sand, 20 % kaolinite clay, 10 % sphagnum peat, 0.38 % $CaCO_3$, pH 5.64-6.02, 23.8-30.2 % water content of dry weight**	**F, Z**	**1**	**Winkelmann (2016) cited in EC (2019), Vol. 3CP (ADM) B.9.7.1 p.180**
***Eisenia fetida* (Earthworm)**	**MCW 465 500 SC (490 g a.s./L)**	**biomass (adult weight change)**	**28 d**	**NOEC**	**≥ 3.79 (10 mg product/kg soil)**	**10**	**≥ 1.29**	**Artificial soil: 69 % quartz sand, 20 % kaolinite clay, 10 % sphagnum peat, 0.38 % $CaCO_3$, pH 5.64-6.02, 23.8-30.2 % water content of dry weight**	**F, Z**	**1**	**Winkelmann (2016) cited in EC (2019), Vol. 3CP (ADM) B.9.7.1 p.180**
***Eisenia fetida* (Earthworm)**	**MCW 465 500 SC (490 g a.s./L)**	**reproduction (number of juveniles)**	**56 d**	**NOEC**	**≥ 3.79 (10 mg product/kg soil)**	**10**	**≥ 1.29**	**Artificial soil: 69 % quartz sand, 20 % kaolinite clay, 10 % sphagnum peat, 0.38 % $CaCO_3$, pH 5.64-6.02, 23.8-30.2 % water content of dry weight**	**F, Z**	**1**	**Winkelmann (2016) cited in EC (2019), Vol. 3CP (ADM) B.9.7.1 p.180**

Species (Taxonomic group)[6]	Test substance	Measured effect[7]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
***Folsomia candida* (Collembola)**	**IKF-1216 500 SC (Fluazinam 500 SC, 39.4 % w/w, 500.7 g a.s./L)**	**adult mortality**	**28 d**	**NOEC**	**< 1.23 (3.13 mg product/kg soil)**	**10**	**< 0.418**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinit clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.6-5.8, 50-53 % MWCH**	**F, W**	**1**	**Klein (2002) cited in EC (2019), Vol. 3CP (ISK) B.9.7.2 p.166**
Folsomia candida (Collembola)	IKF-1216 500 SC (Fluazinam 500 SC, 39.4 % w/w, 500.7 g a.s./L)	adult mortality	28 d	LC50	13.9 (35.4 mg product/kg soil)	10	4.73	Artificial soil: 10 % sphagnum peat, 20 % kaolinit clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.6-5.8, 50-53 % MWCH	F, W	1	Klein (2002) cited in EC (2019), Vol. 3CP (ISK) B.9.7.2 p.166
***Folsomia candida* (Collembola)**	**IKF-1216 500 SC (Fluazinam 500 SC, 39.4 % w/w, 500.7 g a.s./L)**	**reproduction (number of juveniles)**	**28 d**	**NOEC**	**< 1.23 (3.13 mg product/kg soil)**	**10**	**< 0.418**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinit clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.6-5.8, 50-53 % MWCH**	**F, W**	**1**	**Klein (2002) cited in EC (2019), Vol. 3CP (ISK) B.9.7.2 p.166**
Folsomia candida (Collembola)	IKF-1216 500 SC (Fluazinam 500 SC, 39.4 % w/w, 500.7 g a.s./L)	reproduction (number of juveniles)	28 d	EC10	4.53 (11.49 mg product/kg soil)	10	1.54	Artificial soil: 10 % sphagnum peat, 20 % kaolinit clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.6-5.8, 50-53 % MWCH	W	R4/C1	Klein (2002) cited in EC (2019), Vol. 3CP (ISK) B.9.7.2 p.166
Folsomia candida (Collembola)	IKF-1216 500 SC (Fluazinam 500 SC, 39.4 % w/w, 500.7 g a.s./L)	reproduction (number of juveniles)	28 d	EC50	11.9 (30.3 mg product/kg soil)	10	4.05	Artificial soil: 10 % sphagnum peat, 20 % kaolinit clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.6-5.8, 50-53 % MWCH	F, W	1	Klein (2002) cited in EC (2019), Vol. 3CP (ISK) B.9.7.2 p.166
Folsomia candida (Collembola)	IKF-1216 500 SC	reproduction	n.r.	NOEC	0.754	10	0.255	n.r.	F, FF	R4/C1	Wagenhoff (2020b) cited in EC (2024), LoEP, p.389 and Vol. 2
Folsomia candida (Collembola)	Fluazinam 500 SC	reproduction	n.r.	NOEC	6.68	5	4.54	n.r.	F, FF	R4/C1	Lührs (2007a) cited in EC (2024), LoEP, p.389 and Vol. 2
***Folsomia candida* (Collembola)**	**TIFC 500 SC (40.2 % w/w, analysed)**	**adult mortality**	**28 d**	**NOEC**	**6.91 (17.2 mg product/kg soil)**	**5**	**4.70**	**Artificial soil: 75 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, pH**	**F, X**	**1**	**Neri & Ponti (2015) cited in EC (2019), Vol. 3CP (FIN) B.9.7.2 p.100**

Species (Taxonomic group)[6]	Test substance	Measured effect[7]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
								6.26-7.40, approx. 40 % of MWHC			
Folsomia candida (Collembola)	TIFC 500 SC (40.2 % w/w, analysed)	reproduction (number of juveniles)	28 d	EC50	9.13 (22.7 mg product/kg soil)	5	6.21	Artificial soil: 75 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, pH 6.26-7.40, approx. 40 % of MWHC	F, X	1	Neri & Ponti (2015) cited in EC (2019), Vol. 3CP (FIN) B.9.7.2 p.100
Folsomia candida (Collembola)	TIFC 500 SC (40.2 % w/w, analysed)	reproduction (number of juveniles)	28 d	EC10	5.63 (14.0 mg product/kg soil)	5	3.83	Artificial soil: 75 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, pH 6.26-7.40, approx. 40 % of MWHC	X	R4/C1	Neri & Ponti (2015) cited in EC (2019), Vol. 3CP (FIN) B.9.7.2 p.100
***Folsomia candida* (Collembola)**	**TIFC 500 SC (40.2 % w/w, analysed)**	**reproduction (number of juveniles)**	**28 d**	**NOEC**	**6.91 (17.2 mg product/kg soil)**	**5**	**4.70**	**Artificial soil: 75 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, pH 6.26-7.40, approx. 40 % of MWHC**	**F, X**	**1**	**Neri & Ponti (2015) cited in EC (2019), Vol. 3CP (FIN) B.9.7.2 p.100**
***Folsomia candida* (Collembola)**	**MCW 465 500 SC (500 g a.s./L, nominal)**	**adult mortality**	**28 d**	**NOEC**	**5.58 (13.5 mg product/kg soil)**	**5**	**3.79**	**Artificial soil: 74.8 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, approx. 0.2 % $CaCO_3$, pH 5.9-6.4, 47.3-53.5 % of MWHC**	**F, BB**	**1 (R2/C1)**	**Lührs (2008) and Lührs (2016) cited in EC (2019), Vol. 3CP (ADM) B.9.7.3 p.211**
Folsomia candida (Collembola)	MCW 465 500 SC (500 g a.s./L, nominal)	adult mortality	28 d	LC50	> 11.2 (27.1 mg product/kg soil)	5	> 7.62	Artificial soil: 74.8 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, approx. 0.2 % $CaCO_3$, pH 5.9-6.4, 47.3-53.5 % of MWHC	F, BB	1 (R1/C2)	Lührs (2008) and Lührs (2016) cited in EC (2019), Vol. 3CP (ADM) B.9.7.3 p.211
Folsomia candida (Collembola)	MCW 465 500 SC (500 g a.s./L, nominal)	reproduction (number of juveniles)	28 d	EC50	9.05	5	6.15	Artificial soil: 74.8 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, approx. 0.2 % $CaCO_3$, pH 5.9-	F, BB	(1) R2/C2	Lührs (2008) and Lührs (2016) cited in EC (2019), Vol. 3CP (ADM) B.9.7.3 p.211

Species (Taxonomic group)[6]	Test substance	Measured effect[7]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
								6.4, 47.3-53.5 % of MWHC			
Folsomia candida (Collembola)	MCW 465 500 SC (500 g a.s./L, nominal)	reproduction (number of juveniles)	28 d	EC10	5.617	5	3.82	Artificial soil: 74.8 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, approx. 0.2 % $CaCO_3$, pH 5.9-6.4, 47.3-53.5 % of MWHC	F, BB	(1) R3/C1	Lührs (2008) and Lührs (2016) cited in EC (2019), Vol. 3CP (ADM) B.9.7.3 p.211
***Folsomia candida* (Collembola)**	**MCW 465 500 SC (500 g a.s./L, nominal)**	**reproduction (number of juveniles)**	**28 d**	**NOEC**	**5.58 (13.5 mg product/kg soil)**	**5**	**3.79**	**Artificial soil: 74.8 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, approx. 0.2 % $CaCO_3$, pH 5.9-6.4, 47.3-53.5 % of MWHC**	**F, BB**	**1 (R1/C1)**	**Lührs (2008) and Lührs (2016) cited in EC (2019), Vol. 3CP (ADM) B.9.7.3 p.211**
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	adult mortality at 20°C	28 d	LC10	9.14	2.82 (1.66 % OC)	11.0	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R4/C1	Wehrli *et al.* (2024)
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	adult mortality at 22°C	28 d	LC10	14.7	2.82 (1.66 % OC)	17.7	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R3/C3	Wehrli *et al.* (2024)
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	adult mortality at 24°C	28 d	LC10	8.17	2.82 (1.66 % OC)	9.85	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R3/C3	Wehrli *et al.* (2024)
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	adult mortality at 26°C	28 d	LC10	8.46	2.82 (1.66 % OC)	10.2	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R3/C3	Wehrli *et al.* (2024)

Species (Taxonomic group)[6]	Test substance	Measured effect[7]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	adult mortality at 28°C	28 d	LC10	8.05	2.82 (1.66 % OC)	9.71	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R3/C3	Wehrli *et al.* (2024)
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	adult mortality at 20°C	28 d	LC50	19.8	2.82 (1.66 % OC)	23.9	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R2/C2	Wehrli *et al.* (2024)
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	adult mortality at 22°C	28 d	LC50	17.9	2.82 (1.66 % OC)	21.6	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R3/C3	Wehrli *et al.* (2024)
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	adult mortality at 24°C	28 d	LC50	13.3	2.82 (1.66 % OC)	16.0	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R3/C3	Wehrli *et al.* (2024)
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	adult mortality at 26°C	28 d	LC50	12.2	2.82 (1.66 % OC)	14.7	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R3/C3	Wehrli *et al.* (2024)
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	adult mortality at 28°C	28 d	LC50	12.0	2.82 (1.66 % OC)	14.5	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R3/C3	Wehrli *et al.* (2024)
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	reproduction (number of juveniles) at 20°C	28 d	EC10	6.08	2.82 (1.66 % OC)	7.33	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-	GG	R3/C1	Wehrli *et al.* (2024)

Species (Taxonomic group)[6]	**Test substance**	**Measured effect**[7]	**Duration**	**Type of effect concentration**	**Effect concentration [mg a.s./kg soil]**	**Total OM [%]**	**Normalised effect value [mg a.s./kg soil] 3.4 % OM**	**Test soil**	**Notes**	**Assessment score**	**Source**
								6.15, 47.2-58.1 % of MWHC			
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	reproduction (number of juveniles) at 22°C	28 d	EC10	4.75	2.82 (1.66 % OC)	5.73	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R3/C3	Wehrli *et al.* (2024)
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	reproduction (number of juveniles) at 24°C	28 d	EC10	4.96	2.82 (1.66 % OC)	5.98	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R3/C3	Wehrli *et al.* (2024)
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	reproduction (number of juveniles) at 26°C	28 d	EC10	2.64	2.82 (1.66 % OC)	3.18	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R3/C3	Wehrli *et al.* (2024)
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	reproduction (number of juveniles) at 20°C	28 d	EC50	10.4	2.82 (1.66 % OC)	12.5	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R2/C2	Wehrli *et al.* (2024)
***Folsomia candida* (Collembola)**	**Fluazinam (purity ≥ 98 %)**	**reproduction (number of juveniles) at 22°C**	**28 d**	**EC50**	**10.1**	**2.82 (1.66 % OC)**	**12.2**	**Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC**	**GG**	**R2/C2**	**Wehrli *et al.* (2024)**
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	reproduction (number of juveniles) at 24°C	28 d	EC50	9.31	2.82 (1.66 % OC)	11.2	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R3/C3	Wehrli *et al.* (2024)

Species (Taxonomic group)[6]	Test substance	Measured effect[7]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Folsomia candida (Collembola)	Fluazinam (purity ≥ 98 %)	reproduction (number of juveniles) at 26°C	28 d	EC50	7.17	2.82 (1.66 % OC)	8.65	Natural soil (LUFA Speyer 2.2; loamy sand): 72.3 % sand, 16.9 % silt, 10.8 % clay, pH 5.23-6.15, 47.2-58.1 % of MWHC	GG	R3/C3	Wehrli *et al.* (2024)
Hypoaspis aculeifer (Mite)	Fluazinam (purity 99.52 %)	adult mortality	14 d	LC50	> 110	5	> 74.8	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % quartz sand, 0.2 % $CaCO_3$, pH 5.6-5.9, 40.58-48.25 % of MWHC	F, H	1	Schulz (2016a) cited in EC (2024), Vol. 3CA B.9.4.2, p.435
Hypoaspis aculeifer (Mite)	Fluazinam (purity 99.52 %)	reproduction (number of juveniles)	14 d	EC50	> 110	5	> 74.8	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % quartz sand, 0.2 % $CaCO_3$, pH 5.6-5.9, 40.58-48.25 % of MWHC	F, H	1	Schulz (2016a) cited in EC (2024), Vol. 3CA B.9.4.2, p.435
***Hypoaspis aculeifer* (Mite)**	**Fluazinam (purity 99.52 %)**	**reproduction (number of juveniles)**	**14 d**	**NOEC**	**≥ 110**	**5**	**≥ 74.8**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % quartz sand, 0.2 % $CaCO_3$, pH 5.6-5.9, 40.58-48.25 % of MWHC**	**F, H**	**1**	**Schulz (2016a) cited in EC (2024), Vol. 3CA B.9.4.2, p.435**
Hypoaspis aculeifer (Mite)	TIFC 500 SC (40.2 % w/w, analysed)	adult mortality	14 d	NOEC	≥ 3015 (7500 mg product/kg soil)	5	≥ 2050	Artificial soil: 75 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, pH 6.10-6.95, approx. 50 % of MWHC	Y	R1/C1	Colli (2015) cited in EC (2019), Vol. 3CP (FIN) B.9.7.2 p.103
Hypoaspis aculeifer (Mite)	TIFC 500 SC (40.2 % w/w, analysed)	reproduction (number of juveniles)	14 d	EC50	2594.5	5	1764	Artificial soil: 75 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, pH 6.10-6.95, approx. 50 % of MWHC	F, Y	1	Colli (2015) cited in EC (2019), Vol. 3CP (FIN) B.9.7.2 p.103

Species (Taxonomic group)[6]	Test substance	Measured effect[7]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Hypoaspis aculeifer (Mite)	TIFC 500 SC (40.2 % w/w, analysed)	reproduction (number of juveniles)	14 d	EC10	47.0	5	32.0	Artificial soil: 75 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, pH 6.10-6.95, approx. 50 % of MWHC	F, Y	R3/C1	Colli (2015) cited in EC (2019), Vol. 3CP (FIN) B.9.7.2 p.103
Hypoaspis aculeifer **(Mite)**	**TIFC 500 SC (40.2 % w/w, analysed)**	**reproduction (number of juveniles)**	**14 d**	**NOEC**	**124.91 (310.72 mg product/kg soil)**	**5**	**84.9**	**Artificial soil: 75 % quartz sand, 20 % kaolinite clay, 5 % sphagnum peat, pH 6.10-6.95, approx. 50 % of MWHC**	**Y**	**R1/C1**	**Colli (2015) cited in EC (2019), Vol. 3CP (FIN) B.9.7.2 p.103**
Microorganisms	**Fluazinam 500 SC (39.49 % w/w, 516.1 g a.s./L)**	**nitrogen transformation[FE]**	**28 d**	**≤ 25 % effect**	**< 0.270 (0.684 mg product/kg soil)**	**2.28 (1.34 % OC)**	**< 0.403**	**Natural soil (Germany; loamy sand): 10.3 % clay, 37.5 % silt, 52.2 % sand, pH 7.4, MWHC 48 %**	**F**	**1**	**Reis (2002) cited in EC (2019), Vol. 3CP (ISK) B.9.9 p.181**
Microorganisms	**Fluazinam 500 SC (39.49 % w/w, 516.1 g a.s./L)**	**carbon transformation[FE]**	**28 d**	**≤ 25 % effect (< 10 % effect)**	**≥ 2.27 (5.748 mg product/kg soil)**	**2.28 (1.34 % OC)**	**≥ 3.39**	**Natural soil (Germany; loamy sand): 10.3 % clay, 37.5 % silt, 52.2 % sand, pH 7.4, MWHC 48 %**	**F**	**R2/C2**	**Reis (2002) cited in EC (2019), Vol. 3CP (ISK) B.9.9 p.181**
Microorganisms	MCW 465 500 SC (500 g a.s./L)	nitrogen transformation[FE]	28 d, 42 d	≤ 25 % effect	n.a	1.73 (1.02 % OC)	n.a.	Natural soil (LUFA standard soil 2.3, loamy sand – DIN): 59.4 % sand, 32.5 % silt, 8.6 % clay, pH 5.8 ± 1.8, 49.9-52.2 % of MWHC	F, DD	3	Scheerbaum (2006 and 2016) cited in EC (2019), Vol. 3CP (ADM) B.9.9 p.227
Microorganisms	Frowncide 500 SC	nitrogen transformation[FE]	28 d	≤ 25 % effect	≥ ~38.8 (≥ 100 mg product/kg soil)	n.r.	n.a.	n.r.	F, MM	(1) R4/C1	Barbosa (2017) cited in EC (2024), LoEP, p.391 and Vol. 2; ISK
Microorganisms	Fluazinam 500 SC	nitrogen transformation[FE]	28 d	≤ 25 % effect	≥ ~ 0.108, < ~0.906 (≥ 0.27 mg product/kg soil, < 2.27 mg product/kg soil)	n.r.	n.a.	n.r.	F, MM	(1) R4/C1	Feil (2009) or Reis (2007a) cited in EC (2024), LoEP, p.391 and Vol. 2; CHE
Microorganisms	Fluazinam 500 SC	nitrogen transformation[FE]	28 d	≤ 25 % effect	≥ ~ 1.32 (≥ 3.32 mg product/kg soil)	n.r.	n.a.	n.r.	F, MM	(1) R4/C1	Feil (2009) or Reis (2007a) cited in EC (2024), LoEP, p.391 and Vol. 2; CHE

Species (Taxonomic group)[6]	Test substance	Measured effect[7]	Duration	Type of effect concentration	Effect concentration [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Microorganisms	TIFC 500 SC	nitrogen transformation[FE]	100 d	≤ 25 % effect	< ~1.20 (< 3.0 mg product/kg soil)	n.r.	n.a.	n.r.	F, MM	(1) R4/C1	Tediosi (2020) cited in EC (2024), LoEP, p.391 and Vol. 2; FIN
Allium cepa[M] *Avena sativa*[M] *Sorghum bicolor*[M] *Zea mays*[M] *Cucumis sativus*[D] *Brassica kaber*[D] *Fagopyrum esculentum*[D] *Glycine max*[D] *Lycopersicon esculentum*[D] *Raphanus sativus*[D] (Terrestrial plants)	Fluazinam (purity 97.3)	seedling emergence	14 d	EC50	> 1.67 > 1.67 > 1.67 > 1.67 > 1.67 > 1.67 > 1.67 > 1.67 > 1.67 > 1.67 (1.5 kg a.s./ha)	n.r.	n.a.	Natural soil amended with 50 % silica sand and supplemental nutrients	S	R4/C2	Backus (1993a) cited in EC (2024), Vol. 3CA B.9.6.1, p.478
Allium cepa[M] *Avena sativa*[M] *Sorghum bicolor*[M] *Zea mays*[M] *Cucumis sativus*[D] *Brassica kaber*[D] *Fagopyrum esculentum*[D] *Glycine max*[D] *Lycopersicon esculentum*[D] *Raphanus sativus*[D] (Terrestrial plants)	Fluazinam (purity 97.3)	biomass (fresh weight)	14 d	EC50	> 1.67 > 1.67 > 1.67 > 1.67 > 1.67 > 1.67 > 1.67 > 1.67 > 1.67 > 1.67 (1.5 kg a.s./ha)	n.r.	n.a.	Natural soil amended with 50 % silica sand and supplemental nutrients	S	R4/C2	Backus (1993a) cited in EC (2024), Vol. 3CA B.9.6.1, p.478
Allium cepa[M] *Avena sativa*[M] *Lolium perenne*[M] *Zea mays*[M] *Cucumis sativus*[D] *Brassica oleracea*[D] *Daucus carota*[D] *Glycine max*[D] *Lactuca sativa*[D]	IKF-1216 500 F (41.5 % fluazinam)	seedling emergence	n.r.	EC25	> 0.583 > 0.583 > 0.583 > 0.583 > 0.583 > 0.583 > 0.583 > 0.583 > 0.583 > 0.583	n.r.	n.a.	n.r.	HH	R4/C1	Stewart (2003) cited in (US EPA 2013), p.58, MRID 46172801

Species (Taxonomic group)[6]	**Test substance**	**Measured effect**[7]	**Duration**	**Type of effect concentration**	**Effect concentration [mg a.s./kg soil]**	**Total OM [%]**	**Normalised effect value [mg a.s./kg soil] 3.4 % OM**	**Test soil**	**Notes**	**Assessment score**	**Source**
Lycopersicon esculentum[D] *Raphanus sativus*[D] (Terrestrial plants)					> 0.583 (874 g a.s./ha)						

Table A2: Soil effect data for fluazinam from field studies. Abbreviations: n.r. – not reported; n.a. – not applicable; WHC – water holding capacity; OC – organic carbon; OM – organic matter; CFU – colony forming units. Values resulting from calculations are rounded to three significant figures.

Species (Taxonomic group)	**Test substance**	**Measured effect**[8]	**Duration**	**Type of effect concentration**	**Effect value [mg a.s./kg soil]**	**Total OM [%]**	**Normalised effect value [mg a.s./kg soil] 3.4 % OM**	**Test soil**	**Notes**	**Assessment score**	**Source**
Earthworms	Fluazinam 500 SC (516.1 g a.s./L, analysed)	population abundance, biomass	approx. 1 year	NOEC	≥ (Application rate: 10 x 200 g a.s./ha, 7 d intervals)	8.4	n.a.	Field study (UK, clay loam soil): 41 % sand, 32 % silt, 27 % clay, pH (water) 7.6, WHC of 102.1 %	V	3	Mills (2001) and Sharples (2006) cited in EC (2019), Vol. 3CP (ISK) B.9.7.1 p.148
Epigeic and endogeic species (Earthworms)	MCW 465 500 SC (MAC 92800 F; 509 g a.s./L, analysed)	population abundance, biomass	approx. 10 months	NOEC	≥ (Application rate: 6 x 814 g a.s./ha, 14 d intervals)	3.40 (2 % OC)	n.a.	Field study (Eastern Germany, medium loam sand soil): pH 5.6, mean 32.3 % (26.48-40.35 %) of MWHC (A-horizon)	AA	(1) R3/C1	Krück (2009) cited in EC (2019), Vol. 3CP (ADM) B.9.7.1 p.183; updated abstract in EC (2024), LoEP, p.390
Micro-arthropods (Mites and collembolans)	MCW 465 500 SC (509 g a.s./L, analysed)	population abundance	approx. 11 months	NOEC	(Application rate: 8 x 204 g a.s./ha, 7-9 d intervals)	3.37 (1.98 % OC)	n.a.	Field study (Eastern Germany, medium loam sand soil): average pH 5.6, average 32.32 % of MWHC (A-horizon)	CC	(1) R3/C1	Schulz (2009) cited in EC (2019), Vol. 3CP (ADM) B.9.7.1 p.216; updated abstract in EC (2024), LoEP, p.391

Notes A1: Notes on soil studies for fluazinam.

A	Acute earthworm test conducted to the OECD 207 guideline (OECD 1984) with the following deviations: • Only three test concentrations with three replicates were used instead of five concentrations with four replicates. • The test duration was longer, 28 instead of 14 days.

[8] [DE] – diversity endpoint, [EE] – enzymatic endpoint, [FE] – functional endpoint

	• The soil pH was not adjusted to 6.0 ± 0.5, but to 7.0 ± 0.2. • The test was conducted under a 16:8 h of light:dark photoperiod instead of continuous light. Fluazinam was mixed into the soil. There was no mortality in the control, thus the validity criterion was met. The test concentrations were 10, 100 and 1000 mg a.s./kg soil. Due to the wide spacing, the NOEC values are considered as greater-than/equal to values that are less than the next highest test concentration.
F	The summarised results were accepted without additional assessment (i.e. at face value). The results may have been re-calculated according to the actual measured active substance content of the applied formulation (if it was available) thus slight differences to the EU-listed endpoints may occur (if they used the nominal a.s. content).
H	Test item technical fluazinam had a purity of 99.52 %. There was no control mortality, thus the validity criterion was met. Due to the high purity of the test item, the results are accepted at nominal levels.
S	Test item technical fluazinam had a purity of 97.3 %. Due to the high purity of the test item, the results are accepted at nominal levels. It is noted that mustard (common name) is specified as *Brassica kaber* (scientific name) in the study summary. *B. kaber* (DC.) Wheeler is a synonym for *Sinapis alba* L. that is wild/field mustard and an invasive weed species. As otherwise crop species were tested, it is assumed that rather a cultivated mustard species was meant, such as white mustard – *Sinapis alba* L. syn. *Brassica alba* (L.) Rabenh. or *B. hirta* Moench; brown mustard – *Brassica juncea* (L.) Czern. syn. *Sinapis juncea* L.; or black mustard – *Brassica nigra* (L.) W.D.J. Koch syn. *Sinapis nigra* L. The study including Tier 1 germination and seedling emergence tests is rather old and was conducted to an outdated US EPA guideline (US EPA 1982). Here only the seedling emergence test is considered relevant as the germination test was conducted on filter papers in Petri dishes. For the seedling emergence test, natural soil was amended with 50 % silica sand and supplemental nutrients without detailing the soil parameters (type, structure, pH, OC/OM content etc.). The soil was placed in growth containers (fiber pans of 25.2 x 20.3 x 7.6 cm; upper surface approx. 1.5 cm below the edge, which means approx. 6 cm soil depth). The treatment was sprayed onto the soil surface. Details of the spraying application (using a solvent for the treatment and including a solvent control) were not summarised in detail, however, the results were given separately for “control”, “solvent control” and “treatment”. The containers were incubated in a greenhouse for 14 days. 4 replicates x 10 seeds were in each treatment/control. The treatment was given as 1.5 kg a.s./ha that corresponds to 1.67 mg a.s./kg soil calculated with 6 cm soil depth and 1.5 g/cm^3 soil bulk density. It was not summarised if the fresh weight was measured in relation to the shoot, the root or the whole plant. No information was summarised if statistical evaluation took place. While the effects were clearly less than 50 %, in the absence of a statistical evaluation, it is unclear if there were any statistically significant effects. The RMS noted that all validity criteria to the OECD 208 guideline (OECD 2006) were met, but this statement cannot be checked based on the summarised data and information. (It should be noted that the original US EPA guideline had no validity criteria.) The following deviations to the OECD 208 guideline were noted by the RMS: • In the test no analytical verification occurred, while the OECD 208 guideline requires analytical verification of the applied test solution. • In the test a photoperiod of 14:10 h of light:dark was applied, while the OECD 208 guideline requires minimum 16 h light to be used during the test. The RMS found the study valid and suitable for use in the risk assessment. Due to the lacking information on the application of the solvent and then its evaporation in the solvent control, on the detailed control and treatment results, on the statistical analysis and on the detailed soil properties, the reliability of the study results are considered *not assignable* (R4).
V	A field study of A) ten applications with 7-d intervals (T1-T10); B) ten applications with 140, 126, 6 x 58, 128 and 128 g a.s./ha. Toxic reference (benomyl) was applied once. Control plot got 10 times water applications when the treatments were made (T1-T10). Earthworms were collected 5 days before T1, 5 d after T4, 4 d after T10, 5 months after T1, 6 months after T1 and 12 months after T1. The study was conducted according to the outdated ISO guideline (ISO 1999b) that did not require analytical verification of the applied test substance. In the summary the following was included: “*The measured concentrations of the test item were within ± 5% of the nominal application rate. No measurements of the concentrations of the test item or its metabolites in the soil were conducted*.” Which probably means that the application solutions were analytically verified, but not the amount in the soil.

	Analytical verification of the application in the soil is a pre-requisite for considering the results reliable for SGV derivation (see detailed consideration in Appendix 1). In the absence of analytical verification of the applications, the results of this study are considered *not reliable* (R3). It is noted that the RMS final conclusion was also low reliability of the results due to the lacking analytical verification of the test item in soil and the partially missing statistical evaluation (EC 2019). In the updated LoEP (EC 2024), the study and its results are not included.
W	The study is referenced as Klein (2002) in Vol. 1 and Vol. 3 documents, but authors are listed as Klein and Meister (Report No. 13781016) in Vol. 2. The study was conducted to the outdated ISO guideline (ISO 1999a) and it was evaluated by the RMS to the currently valid OECD guideline (OECD 2016a). The study results were statistically re-evaluated by the RMS. A new LC50 was determined much lower than the one proposed in the study report. Also, the reproduction NOEC, along with the mortality NOEC, was found being lower than the lowest test concentration based on a more robust statistical test. The RMS also calculated an EC10, but not an EC20, and the robustness of the EC10 was not evaluated as recommended in EFSA (2019) – likely the evaluation was conducted before the EFSA publication came out. The normalised width of the confidence interval (CI) of the EC10 is "fair" (< 1.0) and based on the ratio of the EC10 and EC50 values, the steepness of the fitted curve is borderline shallow (= 0.33). In the absence of an EC20, the overlap of the CIs of the EC10 and EC20 cannot be checked. It should be noted that the EC10 of 11.49 mg product/kg soil falls between the 2nd and 3rd lowest test concentrations. At the lowest concentrations (3.13, 6.25 and 12.5 mg product/kg soil), there were 7.7, 25.5 and 22.5 % reduction in the number of juveniles as compared to the control. Considering the not clear dose-response, the consideration of the EC20 and its CI cannot be dismissed for a proper decision on the robustness of the EC10. As a result the reliability of the EC10 is considered as *not assignable* (R4). It is noted that for the products only the initial versions of the dRAR documents with summary of the ecotoxicology data and risk assessments are available (EC 2019) before the public consultation, commenting period and expert meetings. In the updated LoEP (EC 2024), the NOECcorr. of < 1.23 mg a.s./kg (in a corrected form, i.e. divided by two) stayed as agreed both for mortality and reproduction.
X	According to the RMS the only difference to the OECD 232 guideline (OECD 2016a) was the photoperiod. Instead of the preferable 16:8 h light:dark, in the test 12:12 h light:dark photoperiod was used. All the validity criteria were met, so it was concluded that this deviation probably did not have considerable effects on the results. The results were statistically re-evaluated by the RMS as follows: • mortality and reproduction NOEC = 17.2 mg prod./kg soil dw [corresponding to 6.91 mg a.s./kg soil] • EC50 = 22.7 mg prod./kg soil dw (95 % CI: 14.39-35.50 mg prod./kg soil dw) [corresponding to 9.13 mg a.s./kg soil] • EC10 = 14.0 mg prod./kg soil dw (95 % CI: 9.60-20.49 mg prod./kg soil dw) [corresponding to 5.63 mg a.s./kg soil] However, the RMS did not report the EC20 value with its CI. The EC10 has a normalised width classified as "fair" and an intermediate steepness (0.33-0.66; neither too steep, nor too shallow). In the absence of an EC20, the overlap of the CIs of the EC10 and EC20 cannot be checked. There were 12.0, 22.9 and 80.5 % reduction in reproduction at 9.6, 17.2 and 30.9 mg product/kg soil concentrations with coefficient of variations (CV) of 35.7, 41.9 and 39.5 %, respectively. Due to the rapid changes in the effects along with the high standard deviation/CV, the lower end of the EC50 CI (14.39 mg product/kg soil) was just slightly higher than the median EC10 (14.0 mg product/kg soil) and the lower end of the EC20 CI can be expected to be lower than the median EC10. As a result the reliability of the EC10 is considered as *not assignable* (R4). It is noted that for the products only the initial versions of the dRAR documents are available (EC 2019) before the public consultation, commenting period and expert meetings. In the updated LoEP (EC 2024), the NOECcorr. of 3.45 and the EC10corr. of 2.8 mg a.s./kg (in corrected forms, i.e. divided by two) are agreed for reproduction.
Y	The study was conducted to the 2009 version of the OECD 226 guideline (OECD 2016b). All validity criteria were met. The RMS re-calculated the ECx values: • EC50 = 2594.5 mg a.s./kg soil dw (95 % CI: 2027-3582 mg a.s./kg soil dw) • EC10 = 47.0 mg a.s./kg soil dw (95 % CI: 21.78-91.10 mg a.s./kg soil dw) The normalised width of the EC10 is "poor" and the steepness of the fitted curve is very shallow (0.018). Thus even without considering the overlap of the CIs of the EC10 and EC20 values, it can be concluded that the EC10 is *not reliable* (R3). However, the RMS considered that still the EC10 should be used as at the level of the statistically significant NOEC and at the lowest test concentration (at 124.91 and 73.48 mg a.s./kg soil, respectively), biologically relevant effects (effects > 15%) were observed. It is noted that for the products only the initial versions of the dRAR documents are available (EC 2019) before the public consultation, commenting period and expert meetings. In the updated LoEP (EC 2024), no effect concentrations are agreed upon/used in the risk assessment from this study.

	OZ is of the opinion that the statistically significant reproduction NOEC value (20.2 % reduction in reproduction as compared to the control) is suitable for further consideration in the SGV.
Z	The test substance MCW 465 500 SC contained 490 g a.s./L (not specified if nominal or measured) with 1.2928 g/mL density that corresponds to 37.9 % w/w fluazinam content. The validity criteria were met. There were no statistically significant effects or clear dose-response for any of the measured effects at any tested concentration.
AA	The field earthworm study was conducted in Eastern Germany according to the ISO 11268-3 guideline (ISO 1999b). The test substance MCW 465 500 SC contained 509 g a.s./L (analysed; 1.2665 g/mL density). It was applied eight times at three rates, 0.4, 0.8 and 1.6 L product/ha (corresponding to 204, 407 and 814 g a.s./application/ha, respectively) <u>with 14-d intervals</u> between the treatments. The test field was a permanent grassland (loam sand soil) with 60-80 % soil coverage. While in Materials and methods (Applications) section of the study summary 14-day intervals between the applications were given, in the Findings (Environmental conditions) it was mentioned that "*The test item was applied on eight application dates in the period between 29.05.2008 and 23.07.2008*." This seems to be the same time period as for the micro-arthropod study (Schulz (2009) cited in EC (2019), Vol. 3CP (ADM) B.9.7.1 p.216; also see Note CC below) and definitely not with 14-d intervals. This assumption is underpinned by the same analytical results reported for both studies (see below). The spray solutions (after application) and soil samples (0-10 cm, after the last application and irrigation) were taken for analytical verification. The spray solutions were within 90-110 % of the nominal concentrations. The soil cores contained **0.136-0.340** (8 x 0.4 L product/ha), **0.308-0.667** (8 x 0.8 L product/ha) and **0.758-1.544** (8 x 1.6 L product/ha) **mg a.s./kg soil dw.** The maximum values for the same treatment were 2.0-2.5 times higher than the minimum values. Without degradation, the maximum expected soil concentrations after 8 applications with 60-80 % interception (10 cm soil depth, 1.5 g/cm^3 soil density) would be **0.218-0.435, 0.434-0.868 and 0.868-1.74 mg a.s./kg soil** at 3.2 L/ha (8 x 204 g a.s./ha), 6.4 L/ha (8 x 407 g a.s./ha) and 12.8 L/ha (8 x 814 g a.s./ha) rates. Considering the 13.5-43.7 d field DissT50 of fluazinam (see Section 1.5.2) along with the 14 (presumably 7-9) days of intervals, the measured concentrations are expected to be considerably lower than the maximum values estimated without degradation. The range of 60-80 % plant coverage (i.e. 20-40 % deposition on soil) results in a wide variation of the expected soil concentrations and it is difficult to consider if the applications could be 50-150 % of the nominal rates (as it is required in the updated version of the earthworm guideline (ISO 2014)). The earthworms were sampled one month before and one month after the 1st application, as well as 3 and 8 months after the last application. This means that there were approximately 3 months between the analytical verification (following the last application) and the earthworm sampling (3 months after the last application). Considering the relatively short field DissT50 of fluazinam (see section 1.5.2) and that recovery is not accepted for the retrospective risk assessment, no endpoint from the study can be reliably derived for the SGV (for further explanation on the consideration of field studies, please refer to Appendix 1). It is noted that the following was added to the updated LoEP (EC 2024): "*Due to uncertainties regarding adequate exposure at the 1st and 2nd application date only 6 applications should be considered for the risk assessment.*" In the absence of an updated product document (Vol. 3CP (ADM) B.9), the reasoning for this consideration has remained unclear. Due to the low number of anecic earthworms in the control, no endpoint was derived for anecic species; for epigeic and endogeic earthworms, a NOEC of 6 x 1.6 L/ha was agreed upon in the updated LoEP (EC 2024). Due to the above detailed uncertainties (unsure intervals between applications, variation in plant interception and in the analytical results as well as 3 months time gap between the analytical verification and the earthworm sampling), no reliable endpoint can be derived for the SGV (*not reliable*, R3).
BB	The test substance MCW 465 500 SC contained 500 g a.s./L (nominal) with 1.2529 g/mL density that corresponds to 39.9 % w/w nominal fluazinam content. It seems that the Applicant and the RMS used the nominal 39.9 % of a.s. content for conversion, however, we prefer and thus use the analysed a.s. content of the formulation for calculating the test results in terms of a.s. (as reported in Lührs (2008) accessed through EFSA (2025a)). The study was conducted to the ISO 11267 guideline (ISO 1999a), but was evaluated by the RMS to the currently valid OECD 232 guideline (OECD 2016a). The following deviations were noted by the RMS: • Only five concentrations were tested, although 12 are recommended in the guideline for determining ECx values (with minimum 2 replicates in the treatments and 6 in the control). There were five replicates in the control, while even for determining NOEC/LOEC at least 5 concentrations with four replicates in the treatments and eight replicates in the control are recommended in the OECD guideline. It was noted that the test design was in line with the ISO guideline.

	There were no effects on reproduction up to and including 13.5 mg product/kg soil concentration (corresponding to 5.39 mg a.s./kg soil based on nominal and 5.58 mg a.s./kg soil, based on analysed a.s. content of the formulation) and 71 % decrease in the mean number of juveniles as compared to the control at the highest test concentration (27.1 mg product/kg soil, i.e. 10.8 or 11.2 mg a.s./kg soil based on nominal or analysed a.s. content of the test item, respectively). The study results were statistically re-evaluated by the RMS with the following results (based on nominal a.s. content of the test item): • 28-d EC50 = 8.74 mg a.s./kg soil dw (95 % CI: 6.123-12.576 mg a.s./kg soil dw) • 28-d EC10 = 5.617mg a.s./kg soil dw (95 % CI: 4.090-7.715 mg a.s./kg soil dw) • mortality and reproduction NOEC = 5.4 mg a.s./kg soil dw The normalised width of the EC10 CI fell in the category of “fair” (0.645) and the steepness of the fitted curve was intermediate (0.643; but not far from the steep trigger of > 0.66). Based on the detailed results in the original study reports that were accessed through EFSA (2025a), the ECx calculations were repeated by the Ecotox Centre. This confirmed the RMS calculations, i.e. that the actual CIs are much broader than indicated by the Applicant. Also the lower end of the CI of the EC20 falls below the median EC10. This means that the EC10 cannot be considered statistically robust and it is *not reliable* (R3). The details of the RMS’ statistical analysis were not provided. Using a more robust method, also the 26 % corrected mortality at the highest test concentration proved to be statistically significant setting the NOEC at the second highest test concentration (13.5 mg product/kg soil concentration corresponding to 5.39 mg a.s./kg soil based on nominal and 5.58 mg a.s./kg soil, based on analysed a.s. content of the formulation). The EC50 corresponds to 9.05 mg a.s./kg soil based on analysed a.s. content of the tested formulation. It is noted that for the products only the study summaries in the initial versions of the dRAR documents are available (EC 2019) before the public consultation, commenting period and expert meetings. In the updated LoEP (EC 2024), the NOECcorr. of 2.7 mg a.s./kg (in corrected form, i.e. divided by two) is agreed for reproduction, not the EC10. OZ considers the statistically robust NOEC values as suitable for further consideration in the SGV.
CC	The field micro-arthropod study (Schulz 2009) was conducted to the ISO 23611-2 guideline (ISO 2006) with regard to the sampling and extraction methods in Eastern Germany at the same time and in the same area as described for the field earthworm study in Krück (2009; see Note AA above). The test substance MCW 465 500 SC contained 509 g a.s./L (analysed; 1.2665 g/mL density). It was applied eight times at three rates, 0.4, 0.8 and 1.6 L product/ha (corresponding to 204, 407 and 814 g a.s./application/ha, respectively) with 7, 7, 7, 7, 9, 9 and 9 days of intervals between the applications. The test field was a permanent grassland (loam sand soil) with 60-80 % soil coverage. It seems as if the field earthworm field study (see Note AA) was conducted together with the micro-arthropod study: the same analytical results were summarised for the micro-arthropod study as for the earthworm study. (The soil cores contained **0.136-0.340** (8 x 0.4 L product/ha), **0.308-0.667** (8 x 0.8 L product/ha) **and 0.758-1.544** (8 x 1.6 L product/ha) mg a.s./kg soil dw.) The maximum values for the same treatment were 2.0-2.5 times higher than the minimum values. In both studies, soil sampling took place after the plots were watered following the last (8^{th}) application, which might have been on day 98 in the earthworm study if it was conducted with 14-d intervals or on day 55 as in the micro-arthropod study if it was conducted with 7-9 day intervals (also see Note AA on the earthworm field study; it is assumed that the earthworm study was also conducted with 7-9 day intervals between the applications). Without degradation, the maximum expected soil concentrations after 8 applications with 60-80 % interception (10 cm soil depth, 1.5 g/cm^3 soil bulk density) would be **0.218-0.435, 0.434-0.868 and 0.868-1.74 mg a.s/kg soil** at 3.2 L/ha (8 x 204 g a.s./ha), 6.4 L/ha (8 x 407 g a.s./ha) and 12.8 L/ha (8 x 814 g a.s./ha), respectively. Considering the 13.5-43.7 d field DissT50 of fluazinam (see Section 1.5.2) along with the 7-9 days of intervals, the measured concentrations are expected to be considerably lower than the maximum values estimated without degradation. With degradation, the ***best-case/worst-case PECsoil,initial values*** after the 8^{th} application on day 55 are as follows: **0.074/0.286 mg a.s./kg soil** for the low rate, **0.147/0.571 mg a.s./kg soil** for the middle rate and **0.295/1.142 mg a.s./kg soil** for the high rate treatment assuming 10 cm soil depth, 1.5 g/cm^3 soil density, 7-9 days of intervals (see details above), 80/60 % plant interception and fluazinam DissT50 of 13.5/43.7 days for best-case/worst-case scenarios, respectively (PECsoil calculator, version 1.0, HSE, UK, 2015, https://www.hse.gov.uk/pesticides/data-requirements-handbook/fate/environmental-fate-models.htm). Due to the wide range of the predicted fluazinam concentrations in the soil, it is difficult to consider if the treatments reached adequate concentrations in the soil.

	It should be noted that in the updated LoEP (EC 2024), the first 2 applications were not considered acceptable for the earthworm study (see Note AA above), while this was not taken into account for the micro-arthropod study that was presumably conducted together with the earthworm study. It is possible that the issues were related only to the highest test rate as that was used for deriving the earthworm endpoint. Here the agreed endpoint relates to the lowest test rate. The micro-arthropods were sampled one day before and 3 weeks after the first application, as well as 2, 5 and 10 months after the last application. This means that there were approximately 2 months between the analytical verification (following the last application) and the micro-arthropod sampling (2 months after the last application). Considering the relatively short field DissT50 of fluazinam (see section 1.5.2) and that recovery is not accepted for the retrospective risk assessment, no endpoint from the study can be reliably derived for the SGV (for further explanation on the consideration of field studies, please refer to Appendix 1). In the updated LoEP (EC 2024) an overall NOEC of 8 x 0.4 L product/ha was agreed upon as adverse effects were observed on mites and collembolans at higher rates. Due to the above detailed uncertainties (variation in plant interception and in the analytical results as well as 2 months time gap between the analytical verification and the micro-arthropod sampling), no reliable endpoint can be derived for the SGV (*not reliable*, R3).
DD	There was no proper nitrate-N formation at the beginning of the study in the control, therefore the study was considered as *not reliable* (R3).
EE	The study results in terms of active substance have been re-calculated (and corrected) based on the 38.4 % w/w fluazinam content of the formulation used in the test. (In the study summary, the results as active substance were calculated based on the 495 g a.s./L fluazinam content without considering the density of the product.)
FF	These studies are included in the LoEP that was updated and made publicly available after including additional information, the outcome of the commenting period and expert consultations as well as the ED evaluation (EC 2024). Similarly updated dRAR documents are not available for the products and thus the details of these studies cannot be checked and confirmed. If the values were tabled in the LoEP as corrected values (for details, please refer to Section 1.5.3), they are included here without any correction.
GG	The study of Wehrli *et al.* (2024) investigated the combined effects of fluazinam and heat stress. They applied eight different concentrations at five different temperatures. The test at the standard 20°C and at 22°C followed or can be considered fulfilling the OECD 232 guideline requirements (required: *mean temperature should be 20 ± 1°C with a temperature range of 20 ± 2°C*; OECD (2016a)) and as such are considered here as potentially relevant. For comparability with the standard laboratory tests, the tests conducted at 24, 26 and 28°C are considered *not relevant* (C3). In contrast to what is stated in the article, based on the control results reported in the supporting information, the validity criteria were not fulfilled for the following tests and thus they are considered *not reliable* (R3): • In tests at 24 and 28°C: the coefficient of variation of the number of juveniles in the control were 40.5 and 225 %, respectively, instead of ≤ 30 %. • In test at 26°C: the control mortality was 25 % instead of ≤ 20 %. • In test at 28°C: the number of juveniles per 10 females in the control was 3 instead of ≥ 100. For the following LCx/ECx values the normalised width of the confidence intervals were poor or bad (≥ 1) and thus these are considered *not reliable* (R3): • LC10 and LC50 at 22°C (and the lower end of the LC50 CI < median LC10) • EC10 at 20, 22, 24 and 26°C In addition, even for the LC10 value at 20°C with acceptable normalised width and steepness of the curve, the reliability cannot be fully considered in the absence of the respective LC20 value that is needed for checking the possible overlap of the confidence intervals (EFSA 2019). As a result, the LC10 at 20°C is considered as *not assignable* (R4). EC50 and LC50 values are not the most relevant endpoints for considering the long-term toxicity of fluazinam for an SGV derivation (*relevant with restrictions*; C2). In the absence of enough details (results per treatment with standard deviation and statistical significance, goodness of fit and residuals for the fitted effect curves etc.) the otherwise acceptable results are considered *reliable with restrictions* (R2; see LC50 at 20°C and EC50 at 20 and 22°C). Statistically significant NOEC/LOEC values were not reported. The growth of adults and the body length of juveniles were shown only graphically and as such no quantitative results can be included here.
HH	The study was not submitted to the EU renewal assessment. The US EPA document does not contain enough details to consider the reliability of this potentially relevant study.

	The applied 0.78 lbs a.s./A is equal to 874 g a.s./ha.
MM	For the newly added microorganism studies, the effect concentrations in terms of active substance are estimated considering the nominal fluazinam content of the formulations as reported previously (Vol. 3CP B.9, p.5 for ISK, FIN and FTF/ADM/CHE/NUF in EC (2019). • ISK: IKF-1216 500 SC, 38.76 % w/w • FIN: TIFC 500 SC, 40.15 % w/w • FTF: MCW 465 500 SC: 39.90 % w/w.

It is noted that the following active substance/product studies were considered potentially relevant but did not meet the most important requirement with regard to the way of exposure through soil and/or application did not happen as a single substance only once (and they may have other deficiencies as well), thus they have not been evaluated and listed in detail (C3):

- Backus (1993a) cited in EC (2024), Vol. 3CA B.9.6.1, p.478; Petri dish seed germination test (Tier 1).
- Backus (1993b) cited in EC (2024), Vol. 3CA B.9.6.1, p.481; Vegetative vigour test (Tier 1).
- Crosby (1995) cited in EC (2024), Vol. 3CA B.9.6.2, p.490; Vegetative vigour test (Tier 2).
- Schmidt (2006) cited in EC (2019a), Vol. 3CP (ISK) B.9.7.2 p.170; Litter bag field test.
- Thompson (2010) cited in EC (2019a), Vol. 3CP (ISK) B.9.7.2 p.172; Litter bag and non-target soil arthropods monitoring field study.
- Lührs & Meinerling (2009) cited in EC (2019a), Vol. 3CP (ADM) B.9.7.3 p.215; Litter bag field test.
- Fiebig (2006) cited in EC (2019a), Vol. 3CP (ADM) B.9.11.2 p.231; Vegetative vigour test.
- Liu *et al.* (2019); Effect of fluazinam on microorganism community in cabbage root zone.
- Niemi *et al.* (2009); Microcosm, mesocosm and field tests with fluazinam formulation on microbial activity

Appendix 3 Data on the metabolites

Table A3: Soil effect data for HYPA, a soil metabolite of fluazinam. Values resulting from calculations are shown with three significant figures. The lowest effect datum per study is shown in bold. Unreliable, not relevant and not assignable data are greyed out. Abbreviations: n.r. – not reported; n.a. – not applicable; MWHC – maxixmum water holding capacity; OC – organic carbon; OM – organic matter; CFU – colony forming units. For notes, please refer to the end of Appendix 3 (Notes A2).

Species (Taxonomic group)	Measured effect[9]	Duration	Type of effect concentration	Effect value [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Eisenia fetida (Earthworm)	adult mortality	14 d	NOEC	≥ 1000	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 6.3-6.5	B, F	1	Lührs (2000) cited in EC (2024), Vol. 3CA B.9.4, p.424
Eisenia fetida (Earthworm)	adult mortality	14 d	LC50	> 1000	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 6.3-6.5	B, F	1	Lührs (2000) cited in EC (2024), Vol. 3CA B.9.4, p.424
***Eisenia fetida* (Earthworm)**	**biomass (adult weight)**	**14 d**	**NOEC**	**269**	**10**	**n.a.**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 6.3-6.5**	**B, F**	**1**	**Lührs (2000) cited in EC (2024), Vol. 3CA B.9.4, p.424**
***Eisenia fetida* (Earthworm)**	**adult mortality**	**28 d**	**NOEC**	**≥ 14.2**	**10**	**n.a.**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69 % quartz sand, 0.4 % $CaCO_3$, pH 5.81-6.68, 52 % of MWHC**	**C, F**	**1**	**Krome (2009) cited in EC (2024), Vol. 3CA B.9.4.1, p.425**
Eisenia fetida (Earthworm)	adult mortality	28 d	EC10	> 14.2	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69 % quartz sand, 0.4 % $CaCO_3$, pH 5.81-6.68, 52 % of MWHC	C, F	1	Krome (2009) cited in EC (2024), Vol. 3CA B.9.4.1, p.425
***Eisenia fetida* (Earthworm)**	**biomass (adult body weight change)**	**28 d**	**NOEC**	**≥ 14.2**	**10**	**n.a.**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69 % quartz sand, 0.4 % $CaCO_3$, pH 5.81-6.68, 52 % of MWHC**	**C, F**	**1**	**Krome (2009) cited in EC (2024), Vol. 3CA B.9.4.1, p.425**

[9] DE – diversity endpoint, EE – enzymatic endpoint, FE – functional endpoint

Species (Taxonomic group)	Measured effect[9]	Duration	Type of effect concentration	Effect value [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
***Eisenia fetida* (Earthworm)**	**reproduction (number of juveniles)**	**56 d**	**NOEC**	**≥ 14.2**	**10**	**n.a.**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69 % quartz sand, 0.4 % $CaCO_3$, pH 5.81-6.68, 52 % of MWHC**	**C, F**	**1**	**Krome (2009) cited in EC (2024), Vol. 3CA B.9.4.1, p.425**
Eisenia fetida (Earthworm)	reproduction (number of juveniles)	56 d	EC10	> 14.2	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69 % quartz sand, 0.4 % $CaCO_3$, pH 5.81-6.68, 52 % of MWHC	C, F	1	Krome (2009) cited in EC (2024), Vol. 3CA B.9.4.1, p.425
Eisenia fetida (Earthworm)	adult mortality	28 d	NOEC	≥ 66.2	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 70 % quartz sand, pH 5.97-6.77	G	R4/C1	Tediosi & Noè (2016) cited in EC (2024), Vol. 3CA B.9.4.1, p.433.
Eisenia fetida (Earthworm)	adult mortality	28 d	LC50	> 66.2	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 70 % quartz sand, pH 5.97-6.77	G, F	1	Tediosi & Noè (2016) cited in EC (2024), Vol. 3CA B.9.4.1, p.433.
Eisenia fetida (Earthworm)	biomass (adult body weight change)	28 d	NOEC	≥ 66.2	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 70 % quartz sand, pH 5.97-6.77	G	R4/C1	Tediosi & Noè (2016) cited in EC (2024), Vol. 3CA B.9.4.1, p.433.
Eisenia fetida (Earthworm)	reproduction (number of juveniles)	56 d	EC50	49.6	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 70 % quartz sand, pH 5.97-6.77	G	R3/C1	Tediosi & Noè (2016) cited in EC (2024), Vol. 3CA B.9.4.1, p.433.
Eisenia fetida (Earthworm)	reproduction (number of juveniles)	56 d	EC10	42.0	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 70 % quartz sand, pH 5.97-6.77	G	R3/C1	Tediosi & Noè (2016) cited in EC (2024), Vol. 3CA B.9.4.1, p.433.
***Eisenia fetida* (Earthworm)**	**reproduction (number of juveniles)**	**56 d**	**NOEC**	**36.8**	**10**	**n.a.**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 70 % quartz sand, pH 5.97-6.77**	**G, F**	**1**	**Tediosi & Noè (2016) cited in EC (2024), Vol. 3CA B.9.4.1, p.433.**
***Folsomia candida* (Collembola)**	**adult mortality**	**28 d**	**NOEC**	**≥ 6.08**	**10**	**n.a.**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 6.0-6.5, 45-51 % of MWHC**	**I, F**	**1**	**Lührs (2004) cited in EC (2024), Vol. 3CA B.9.4.2, p.438.**

Species (Taxonomic group)	Measured effect[9]	Duration	Type of effect concentration	Effect value [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Folsomia candida **(Collembola)**	**reproduction (number of juveniles)**	**28 d**	**EC50**	**≥ 6.08**	**10**	**n.a.**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 6.0-6.5, 45-51 % of MWHC**	**I, F**	**1**	**Lührs (2004) cited in EC (2024), Vol. 3CA B.9.4.2, p.438.**
Folsomia candida (Collembola)	reproduction (number of juveniles)	28 d	EC10	3.95	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 6.0-6.5, 45-51 % of MWHC	I, F	3	Lührs (2004) cited in EC (2024), Vol. 3CA B.9.4.2, p.438.
Folsomia candida **(Collembola)**	**reproduction (number of juveniles)**	**28 d**	**NOEC**	**≥ 6.08**	**10**	**n.a.**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 6.0-6.5, 45-51 % of MWHC**	**I**	**R1/C1**	**Lührs (2004) cited in EC (2024), Vol. 3CA B.9.4.2, p.438.**
Folsomia candida (Collembola)	adult mortality	28 d	LC50	> 100	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 70 % quartz sand, $CaCO_3$, pH 6.20-6.29, approx. 50 % of MWHC	K, F	1	Sharples & Moseley (2009) cited in EC (2024), Vol. 3CA B.9.4.2, p.446.
Folsomia candida (Collembola)	adult mortality	28 d	LC10	4.99	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 70 % quartz sand, $CaCO_3$, pH 6.20-6.29, approx. 50 % of MWHC	K, F	3	Sharples & Moseley (2009) cited in EC (2024), Vol. 3CA B.9.4.2, p.446.
Folsomia candida (Collembola)	adult mortality	28 d	NOEC	40.0	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 70 % quartz sand, $CaCO_3$, pH 6.20-6.29, approx. 50 % of MWHC	K, F	1	Sharples & Moseley (2009) cited in EC (2024), Vol. 3CA B.9.4.2, p.446.
Folsomia candida (Collembola)	reproduction (number of juveniles)	28 d	EC50	60.8	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 70 % quartz sand, $CaCO_3$, pH 6.20-6.29, approx. 50 % of MWHC	K, F	1	Sharples & Moseley (2009) cited in EC (2024), Vol. 3CA B.9.4.2, p.446.
Folsomia candida (Collembola)	reproduction (number of juveniles)	28 d	EC10	36.43	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 70 % quartz	K, F	3	Sharples & Moseley (2009) cited in EC (2024), Vol. 3CA B.9.4.2, p.446.

Species (Taxonomic group)	Measured effect[9]	Duration	Type of effect concentration	Effect value [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
							sand, $CaCO_3$, pH 6.20-6.29, approx. 50 % of MWHC			
***Folsomia candida* (Collembola)**	**reproduction (number of juveniles)**	**28 d**	**NOEC**	**20.0**	**10**	**n.a.**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 70 % quartz sand, $CaCO_3$, pH 6.20-6.29, approx. 50 % of MWHC**	**K, F**	**1**	**Sharples & Moseley (2009) cited in EC (2024), Vol. 3CA B.9.4.2, p.446.**
Hypoaspis aculeifer (Mite)	adult mortality	14 d	NOEC	≥ 200	5	n.a.	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.8 % quartz sand and 0.2 % $CaCO_3$, pH 5.7-5.8, 48.6-52.0 % of MWHC	J, F	1	Lührs (2017) cited in EC (2024), Vol. 3CA B.9.4.2, p.442.
Hypoaspis aculeifer (Mite)	reproduction (number of juveniles)	14 d	EC50	198.19	5	n.a.	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.8 % quartz sand and 0.2 % $CaCO_3$, pH 5.7-5.8, 48.6-52.0 % of MWHC	J, F	1	Lührs (2017) cited in EC (2024), Vol. 3CA B.9.4.2, p.442.
Hypoaspis aculeifer (Mite)	reproduction (number of juveniles)	14 d	EC10	15.26	5	n.a.	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.8 % quartz sand and 0.2 % $CaCO_3$, pH 5.7-5.8, 48.6-52.0 % of MWHC	J, F	1	Lührs (2017) cited in EC (2024), Vol. 3CA B.9.4.2, p.442.
***Hypoaspis aculeifer* (Mite)**	**reproduction (number of juveniles)**	**14 d**	**NOEC**	**12.5**	**5**	**n.a.**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.8 % quartz sand and 0.2 % $CaCO_3$, pH 5.7-5.8, 48.6-52.0 % of MWHC**	**J, F**	**1**	**Lührs (2017) cited in EC (2024), Vol. 3CA B.9.4.2, p.442.**
***Hypoaspis aculeifer* (Mite)**	**adult mortality**	**14 d**	**NOEC**	**≥ 28.5**	**5**	**n.a.**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % quartz sand and 0.2 % $CaCO_3$, pH 5.5-6.0, 44.09-48.25 % of MWHC**	**M, F**	**1**	**Schulz (2016b) cited in EC (2024), Vol. 3CA B.9.4.2, p.455.**
***Hypoaspis aculeifer* (Mite)**	**reproduction (number of juveniles)**	**14 d**	**NOEC**	**≥ 28.5**	**5**	**n.a.**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % quartz sand and 0.2 % $CaCO_3$, pH 5.5-6.0, 44.09-48.25 % of MWHC**	**M, F**	**1**	**Schulz (2016b) cited in EC (2024), Vol. 3CA B.9.4.2, p.455.**

Species (Taxonomic group)	Measured effect[9]	Duration	Type of effect concentration	Effect value [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Hypoaspis aculeifer (Mite)	reproduction (number of juveniles)	14 d	EC50	> 28.5	5	n.a.	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % quartz sand and 0.2 % $CaCO_3$, pH 5.5-6.0, 44.09-48.25 % of MWHC	M, F	1	Schulz (2016b) cited in EC (2024), Vol. 3CA B.9.4.2, p.455.
Microorganisms	nitrogen transformation (nitrification; amended soil)[FE]	28 d	≤ 25 % effect	≥ 0.38	2.28 (1.34 % OC)	n.a.	Natural soil (loamy sand, Rossdorf, Germany): 10.3 % clay, 37.5 % silt, 52.2 % sand, pH 6.0-6.1, 41-46 % of MWHC Amendment: 0.5 % lucerne meal	P	R4/C1	Reis (2002b) cited in EC (2024), Vol. 3CA B.9.5, p.463.
Microorganisms	respiration rate (amended soil)[FE]	28 d	≤ 25 % effect (< 10 % effect)	≥ 0.38	2.28 (1.34 % OC)	n.a.	Natural soil (loamy sand, Rossdorf, Germany): 10.3 % clay, 37.5 % silt, 52.2 % sand, pH 7.0-7.5, 44-47 % of MWHC Amendment: glucose	P	R4/C1	Reis (2002b) cited in EC (2024), Vol. 3CA B.9.5, p.463.
Microorganisms	nitrogen transformation (nitrification; amended soil)[FE]	28 d	≤ 25 % effect	< 0.32	1.84 (1.08 % OC)	n.a.	Natural loamy sand soil (LUFA Speyer 2.3): 58.7 % sand, 31.9 % silt, 9.4 % clay, pH 6.4 ± 0.6, 47.7-55.2 % of MWHC Amendment: 0.5 % lucerne meal	Q	R3/C1	Scheerbaum (2009e) cited in EC (2024), Vol. 3CA B.9.5, p.469.
Avena sativa[M] *Brassica rapa*[D] *Lactuca sativa*[D] (Terrestrial plants)	seedling emergence, biomass (shoot dry weight)	14 d	NOEC	100 100 100	n.r.	n.a.	Natural soil (Japan): 15.2% fine particles (< 20 µm), pH: 5.9, carbon content: 1.09 %	T	R4/C4	Sugimoto & Hayashi (2004) cited in EC (2024), Vol. 3CA B.9.6.1, p.484
Avena sativa[M] *Brassica rapa*[D] *Lactuca sativa*[D] (Terrestrial plants)	seedling emergence, biomass (shoot dry weight)	14 d	EC50	> 100 > 100 > 100	n.r.	n.a.	Natural soil (Japan): 15.2% fine particles (< 20 µm), pH: 5.9, carbon content: 1.09 %	T	R4/C4	Sugimoto & Hayashi (2004) cited in EC (2024), Vol. 3CA B.9.6.1, p.484
Triticum aestivum[M] *Glycine max*[D] *Brassica napus*[D] (Terrestrial plants)	mortality	14 d	NOEC	200 200 50.0	2.04 (1.2 % OC)	n.a.	Natural soil (LUFA 2.3, sandy loam)	U	R4/C1	Bütztler & Meinerling (2008) cited in EC (2024), Vol. 3CA B.9.6.1, p.486

Species (Taxonomic group)	Measured effect[9]	Duration	Type of effect concentration	Effect value [mg a.s./kg soil]	Total OM [%]	Normalised effect value [mg a.s./kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Triticum aestivum[M] *Glycine max*[D] *Brassica napus*[D] (Terrestrial plants)	seedling emergence	14 d	NOEC	200 200 100	2.04 (1.2 % OC)	n.a.	Natural soil (LUFA 2.3, sandy loam)s	U	R4/C1	Bütztler & Meinerling (2008) cited in EC (2024), Vol. 3CA B.9.6.1, p.486
Triticum aestivum[M] *Glycine max*[D] *Brassica napus*[D] (Terrestrial plants)	biomass (shoot fresh weight)	14 d	NOEC	30.4 25.0 40.4	2.04 (1.2 % OC)	n.a.	Natural soil (LUFA 2.3, sandy loam)s	U	R4/C1	Bütztler & Meinerling (2008) cited in EC (2024), Vol. 3CA B.9.6.1, p.486
Triticum aestivum[M] *Glycine max*[D] *Brassica napus*[D] (Terrestrial plants)	biomass (shoot fresh weight)	14 d	EC50	114.6 79.5 79.2	2.04 (1.2 % OC)	n.a.	Natural soil (LUFA 2.3, sandy loam)s	U	R4/C1	Bütztler & Meinerling (2008) cited in EC (2024), Vol. 3CA B.9.6.1, p.486

Table A4: Effect data on MAPA, a soil metabolite of fluazinam. Values resulting from calculations are shown to three significant figures. The lowest effect datum per study is shown in bold. Unreliable, not relevant and not assignable data are greyed out. Abbreviations: n.r. – not reported; n.a. – not applicable; MWHC – maximum water holding capacity; OC – organic carbon; OM – organic matter. For notes, please refer to the end of Appendix 3 (Notes A2).

Species (Taxonomic group)	Measured effect[10]	Duration	Type of effect concentration	Effect value [mg metabolite/ kg soil]	Total OM [%]	Normalised effect value [mg metabolite/kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Eisenia fetida **(Earthworm)**	**adult mortality**	**28 d**	**NOEC**	**≥ 30**	**10**	**n.a.**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.68-6.11, 54.4-55.6 % of MWHC**	**D, F**	**1**	**Friedrich (2016a) cited in EC (2024), Vol. 3CA B.9.4.1, p.428.**

[10] DE – diversity endpoint, EE – enzymatic endpoint, FE – functional endpoint

Species (Taxonomic group)	Measured effect[10]	Duration	Type of effect concentration	Effect value [mg metabolite/ kg soil]	Total OM [%]	Normalised effect value [mg metabolite/kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Eisenia fetida (Earthworm)	adult mortality	28 d	EC10	> 30	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.68-6.11, 54.4-55.6 % of MWHC	D, F	1	Friedrich (2016a) cited in EC (2024), Vol. 3CA B.9.4.1, p.428.
***Eisenia fetida* (Earthworm)**	**biomass (adult body weight change)**	**28 d**	**NOEC**	**≥ 30**	**10**	**n.a.**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.68-6.11, 54.4-55.6 % of MWHC**	**D, F**	**1**	**Friedrich (2016a) cited in EC (2024), Vol. 3CA B.9.4.1, p.428.**
Eisenia fetida (Earthworm)	biomass (adult body weight change)	28 d	EC10	> 30	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.68-6.11, 54.4-55.6 % of MWHC	D, F	1	Friedrich (2016a) cited in EC (2024), Vol. 3CA B.9.4.1, p.428.
***Eisenia fetida* (Earthworm)**	**reproduction (number of juveniles)**	**56 d**	**NOEC**	**≥ 30**	**10**	**n.a.**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.68-6.11, 54.4-55.6 % of MWHC**	**D, F**	**1**	**Friedrich (2016a) cited in EC (2024), Vol. 3CA B.9.4.1, p.428.**
Eisenia fetida (Earthworm)	reproduction (number of juveniles)	56 d	EC10	> 30	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.68-6.11, 54.4-55.6 % of MWHC	D, F	1	Friedrich (2016a) cited in EC (2024), Vol. 3CA B.9.4.1, p.428.
Folsomia candida (Collembola)	adult mortality	28 d	LC50	> 30	5	n.a.	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.1 % % quartz sand, 0.3 % $CaCO_3$, pH 5.82-6.06, 57.7-59.3 % of MWHC	L, F	1	Friedrich (2016c) cited in EC (2024), Vol. 3CA B.9.4.2, p.449.
***Folsomia candida* (Collembola)**	**adult mortality**	**28 d**	**NOEC**	**≥ 30**	**5**	**n.a.**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.1 % % quartz sand, 0.3 % $CaCO_3$, pH 5.82-6.06, 57.7-59.3 % of MWHC**	**L, F**	**1**	**Friedrich (2016c) cited in EC (2024), Vol. 3CA B.9.4.2, p.449.**

Species (Taxonomic group)	Measured effect[10]	Duration	Type of effect concentration	Effect value [mg metabolite/ kg soil]	Total OM [%]	Normalised effect value [mg metabolite/kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Folsomia candida (Collembola)	reproduction (number of juveniles)	28 d	EC50	> 30	5	n.a.	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.1 % % quartz sand, 0.3 % $CaCO_3$, pH 5.82-6.06, 57.7-59.3 % of MWHC	L, F	1	Friedrich (2016c) cited in EC (2024), Vol. 3CA B.9.4.2, p.449.
Folsomia candida (Collembola)	reproduction (number of juveniles)	28 d	EC10	> 30	5	n.a.	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.1 % % quartz sand, 0.3 % $CaCO_3$, pH 5.82-6.06, 57.7-59.3 % of MWHC	L, F	1	Friedrich (2016c) cited in EC (2024), Vol. 3CA B.9.4.2, p.449.
***Folsomia candida* (Collembola)**	**reproduction (number of juveniles)**	**28 d**	**NOEC**	**≥ 30**	**5**	**n.a.**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.1 % % quartz sand, 0.3 % CaCO3, pH 5.82-6.06, 57.7-59.3 % of MWHC**	**L, F**	**1**	**Friedrich (2016c) cited in EC (2024), Vol. 3CA B.9.4.2, p.449.**
Hypoaspis aculeifer (Mite)	**adult mortality**	**14 d**	**NOEC**	**≥ 28.6**	**5**	**n.a.**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % quartz sand and 0.2 % $CaCO_3$, pH 5.2-5.6, 42.09-49.08 % of MWHC**	**N, F**	**1**	**Schulz (2016c) cited in EC (2024), Vol. 3CA B.9.4.2, p.458.**
Hypoaspis aculeifer (Mite)	adult mortality	14 d	LC50	> 28.6	5	n.a.	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % quartz sand and 0.2 % $CaCO_3$, pH 5.2-5.6, 42.09-49.08 % of MWHC	N, F	1	Schulz (2016c) cited in EC (2024), Vol. 3CA B.9.4.2, p.458.
Hypoaspis aculeifer (Mite)	**reproduction (number of juveniles)**	**14 d**	**NOEC**	**≥ 28.6**	**5**	**n.a.**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % quartz sand and 0.2 % $CaCO_3$, pH 5.2-5.6, 42.09-49.08 % of MWHC**	**N, F**	**1**	**Schulz (2016c) cited in EC (2024), Vol. 3CA B.9.4.2, p.458.**
Hypoaspis aculeifer (Mite)	reproduction (number of juveniles)	14 d	EC50	> 28.6	5	n.a.	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % quartz sand and 0.2 % $CaCO_3$, pH 5.2-5.6, 42.09-49.08 % of MWHC	N, F	1	Schulz (2016c) cited in EC (2024), Vol. 3CA B.9.4.2, p.458.

Species (Taxonomic group)	Measured effect[10]	Duration	Type of effect concentration	Effect value [mg metabolite/ kg soil]	Total OM [%]	Normalised effect value [mg metabolite/kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Microorganisms	**nitrogen transformation (nitrification; amended soil)[FE]**	**28 d**	**≤ 25 % effect (< 10 % effect)**	**≥ 3.0**	**1.84 (1.08 % OC)**	**n.a.**	**Natural loamy sand soil (Canitz, Germany): 58.0 % sand, 33.1 % silt, 8.9 % clay, pH 6.3, 45.97-47.95 % of MWHC Amendment: 0.5 % lucerne meal**	**R, F**	**1**	**Schulz (2016e) cited in EC (2024), Vol. 3CA B.9.5, p.472.**

Table A5: Effect data on DAPA, a soil metabolite of fluazinam. Values resulting from calculations are shown to three significant figures. The lowest effect datum per study is shown in bold. Unreliable, not relevant and not assignable data are greyed out. Abbreviations: n.r. – not reported; n.a. – not applicable; MWHC – maximum water holding capacity; OC – organic carbon; OM – organic matter. For notes, please refer to the end of Appendix 3 (Notes A2).

Species (Taxonomic group)	Measured effect[11]	Duration	Type of effect concentration	Effect value [mg metabolite/ kg soil]	Total OM [%]	Normalised effect value [mg metabolite/kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Eisenia fetida **(Earthworm)**	**adult mortality**	**28 d**	**NOEC**	**≥ 30**	**10**	**n.a.**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.72-6.12, 54.3-55.7 % of MWHC**	**E, F**	**1**	**Friedrich (2016b) cited in EC (2024), Vol. 3CA B.9.4.1, p.430.**
Eisenia fetida (Earthworm)	adult mortality	28 d	EC10	> 30	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.72-6.12, 54.3-55.7 % of MWHC	E, F	1	Friedrich (2016b) cited in EC (2024), Vol. 3CA B.9.4.1, p.430.
Eisenia fetida **(Earthworm)**	**biomass (adult body weight change)**	**28 d**	**NOEC**	**≥ 30**	**10**	**n.a.**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.72-6.12, 54.3-55.7 % of MWHC**	**E, F**	**1**	**Friedrich (2016b) cited in EC (2024), Vol. 3CA B.9.4.1, p.430.**

[11] DE – diversity endpoint, EE – enzymatic endpoint, FE – functional endpoint

Species (Taxonomic group)	Measured effect[11]	Duration	Type of effect concentration	Effect value [mg metabolite/ kg soil]	Total OM [%]	Normalised effect value [mg metabolite/kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
Eisenia fetida (Earthworm)	biomass (adult body weight change)	28 d	EC10	> 30	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.72-6.12, 54.3-55.7 % of MWHC	E, F	1	Friedrich (2016b) cited in EC (2024), Vol. 3CA B.9.4.1, p.430.
***Eisenia fetida* (Earthworm)**	**reproduction (number of juveniles)**	**56 d**	**NOEC**	**≥ 30**	**10**	**n.a.**	**Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.72-6.12, 54.3-55.7 % of MWHC**	**E, F**	**1**	**Friedrich (2016b) cited in EC (2024), Vol. 3CA B.9.4.1, p.430.**
Eisenia fetida (Earthworm)	reproduction (number of juveniles)	56 d	EC10	> 30	10	n.a.	Artificial soil: 10 % sphagnum peat, 20 % kaolinite clay, 69.5 % quartz sand, 0.5 % $CaCO_3$, pH 5.72-6.12, 54.3-55.7 % of MWHC	E, F	1	Friedrich (2016b) cited in EC (2024), Vol. 3CA B.9.4.1, p.430.
Folsomia candida (Collembola)	adult mortality	28 d	LC50	> 30	5	n.a.	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.1 % % quartz sand, 0.3 % $CaCO_3$, pH 5.82-6.19, 57.4-59.1 % of MWHC	L, F	1	Friedrich (2016d) cited in EC (2024), Vol. 3CA B.9.4.2, p.452.
***Folsomia candida* (Collembola)**	**adult mortality**	**28 d**	**NOEC**	**≥ 30**	**5**	**n.a.**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.1 % % quartz sand, 0.3 % $CaCO_3$, pH 5.82-6.19, 57.4-59.1 % of MWHC**	**L, F**	**1**	**Friedrich (2016d) cited in EC (2024), Vol. 3CA B.9.4.2, p.452.**
Folsomia candida (Collembola)	reproduction (number of juveniles)	28 d	EC50	> 30	5	n.a.	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.1 % % quartz sand, 0.3 % $CaCO_3$, pH 5.82-6.19, 57.4-59.1 % of WHC	L, F	1	Friedrich (2016d) cited in EC (2024), Vol. 3CA B.9.4.2, p.452.
Folsomia candida (Collembola)	reproduction (number of juveniles)	28 d	EC10	> 30	5	n.a.	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.1 % % quartz sand, 0.3 % $CaCO_3$, pH 5.82-6.19, 57.4-59.1 % of MWHC	L, F	1	Friedrich (2016d) cited in EC (2024), Vol. 3CA B.9.4.2, p.452.

Species (Taxonomic group)	Measured effect[11]	Duration	Type of effect concentration	Effect value [mg metabolite/ kg soil]	Total OM [%]	Normalised effect value [mg metabolite/kg soil] 3.4 % OM	Test soil	Notes	Assessment score	Source
***Folsomia candida* (Collembola)**	**reproduction (number of juveniles)**	**28 d**	**NOEC**	**≥ 30**	**5**	**n.a.**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.1 % % quartz sand, 0.3 % $CaCO_3$, pH 5.82-6.19, 57.4-59.1 % of MWHC**	**L, F**	**1**	**Friedrich (2016d) cited in EC (2024), Vol. 3CA B.9.4.2, p.452.**
Hypoaspis aculeifer (Mite)	**adult mortality**	**14 d**	**NOEC**	**≥ 30.0**	**5**	**n.a.**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % quartz sand and 0.2 % $CaCO_3$, pH 5.2-5.8, 45.29-49.43 % of MWHC**	**O, F**	**1**	**Schulz (2016d) cited in EC (2024), Vol. 3CA B.9.4.2, p.460.**
Hypoaspis aculeifer (Mite)	adult mortality	14 d	LC50	> 30.0	5	n.a.	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % quartz sand and 0.2 % $CaCO_3$, pH 5.2-5.8, 45.29-49.43 % of MWHC	O, F	1	Schulz (2016d) cited in EC (2024), Vol. 3CA B.9.4.2, p.460.
Hypoaspis aculeifer (Mite)	**reproduction (number of juveniles)**	**14 d**	**NOEC**	**≥ 30.0**	**5**	**n.a.**	**Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % quartz sand and 0.2 % $CaCO_3$, pH 5.2-5.8, 45.29-49.43 % of MWHC**	**O, F**	**1**	**Schulz (2016d) cited in EC (2024), Vol. 3CA B.9.4.2, p.460.**
Hypoaspis aculeifer (Mite)	reproduction (number of juveniles)	14 d	EC50	> 30.0	5	n.a.	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.7 % quartz sand and 0.2 % $CaCO_3$, pH 5.2-5.8, 45.29-49.43 % of MWHC	O, F	1	Schulz (2016d) cited in EC (2024), Vol. 3CA B.9.4.2, p.460.
Microorganisms	**nitrogen transformation (nitrification; amended soil)[FE]**	**28 d**	**≤ 25 % effect (< 10 % effect)**	**≥ 1.5**	**2.41 (1.42 % OC)**	**n.a.**	**Natural loamy sand soil (Canitz, Germany): 58.0 % sand, 33.1 % silt, 8.9 % clay, pH 6.3, 44.54-47.20 % of MWHC Amendment: 0.5 % lucerne meal**	**R, F**	**1**	**Schulz (2016b) cited in EC (2024), Vol. 3CA B.9.5, p.475.**

Notes A2: Notes on soil effect data for fluazinam metabolites.

B	Test item HYPA had a purity of 99.7 %. Due to the high purity of the test item, the results are accepted at nominal levels.The test item was mixed into the soil. The water content of the soil was not included in the study summary. There was no control mortality, thus the validity criterion was met.
C	Test item HYPA had a purity of 94.7 %. The validity criteria were met. The following deviations were noted by the RMS: • The water content in the soil deviated more than 10 % at the end of the study as compared to the start. • For shorter periods, the temperature deviated out of the guideline range of 20 ± 2°C. Due to the lack of effects, the deviations were considered to have no impact on the outcome of the study. The highest nominal test concentration of 15 mg/kg soil has been re-calculated according to the purity of the test item (14.2 mg/kg soil).
D	Test item MAPA had a purity of 99.47 %. The validity criteria were met. Due to the high purity of the test item, the results are accepted at nominal levels.
E	Test item DAPA had a purity of 98.4 %. The validity criteria were met. Due to the high purity of the test item, the results are accepted at nominal levels.
F	The summarised results were accepted without additional assessment (i.e. at face value). The results may have been re-calculated according to the actual measured active substance content of the applied formulation (if it was available) thus slight differences to the EU-listed endpoints may occur (if they used the nominal a.s. content).
G	Test item HYPA had a purity of 99.7 %. The validity criteria were met. Due to the high purity of the test item, the results are accepted at nominal levels. The actual water content of the soil was not summarised properly: it is not clear if the 29.6-38.9 % values were given as of dry weight soil or of MWHC. There was 15 % mean adult mortality at the highest concentration (66.2 mg HYPA/kg soil) and no mortality in the control, but according to the study summary it was statistically not significant. – In the absence of the detailed data, the result cannot be confirmed and is considered *not assignable*. The mean adult body weight change was 30.0 % in the control, 28.0-35.5 % at the lower seven concentrations and 13.2 % at the highest test concentration without being statistically significant. – In the absence of the detailed data, the result cannot be confirmed and is considered *not assignable*. On reproduction there were effects only at the highest concentration (35.8 % inhibition), at the lower concentration there was no inhibition or even a slight increase (-4.5 to 0.5 % effects). The EC10 and EC50 values were summarised as follows: • 56-d EC50 = 49.6 mg HYPA/kg soil dw (95 % CI: 24.3-54.6 mg/kg soil dw) • 56-d EC10 = 42.0 mg HYPA/kg soil dw (95 % CI: na-44.6 mg/kg soil dw) The lower limit of the confidence interval (CI) of the EC10 probably could not be calculated or included zero. As a result the EC10 is not considered reliable. Also, the lower limit of the CI of the EC50 is lower than the median EC10 that questions the reliability of the EC50. The EC20 was not calculated. The RMS did not repeat the statistical evaluation and in the absence of the detailed results, it is not possible to re-run it. The questionable results are thus considered as *not assignable* (R4) and the ECx values as *not reliable* (R3).
I	Test item HYPA had a purity of 99.4 %. The validity criteria were met. Due to the high purity of the test item, the results are accepted at nominal levels. The study was conducted to the ISO guideline 11267 (ISO 1999a), but was evaluated by the RMS to the currently valid OECD 232 guideline (OECD 2016a). The following deviations were noted by the RMS: • Only five concentrations were tested, although 12 are recommended in the guideline for determining ECx values. There were five replicates in the control, while eight are recommended in the OECD guideline. It was noted that the test design was in line with the ISO guideline. • "*No validation of the extraction method was given in the study report*." The study results were statistically re-evaluated by the RMS to derive ECx values with the following outcome: • 28-d EC50 > 6.08 mg HYPA/kg soil dw

	• 28-d EC20 > 6.08 mg HYPA/kg soil dw • 28-d EC10 = 3.95 mg HYPA/kg soil dw (95 % CI: 1.74-8.97 mg HYPA/kg soil dw) The reliability evaluation of the EC10 showed that the fit of the response curve was not good, the normalised width of the confidence interval had to be classified as "poor" and the relationship between the confidence intervals of the EC10 and EC20/EC50 values could be considered acceptable. Altogether the EC10 was considered not reliable and not suitable for use in the risk assessment. Considering the 13 % effect on reproduction at the highest concentration as "ecologically relevant", the RMS agreed the second highest concentration as reproduction NOEC (3.04 mg HYPA/kg soil). This precautionary approach is not followed for the SGV derivation (also see the detailed consideration in Appendix 1).
J	Test item HYPA had a purity of 99.8 %. The validity criteria were met. Due to the high purity of the test item, the results are accepted at nominal levels. The following deviation from the guideline (OECD 2016b) was noted by the RMS: • In the study five concentrations were tested, while the guideline recommends eight for determining NOEC and ECx values. Five concentrations are recommended for determining the NOEC alone. The RMS re-conducted the statistical evaluation with the following results: • EC10 = 15.26 mg test item/kg soil dw (95 % CI 1.055-33.476 mg test item/kg soil dw) • EC20 = 42.376 mg test item/kg soil dw (95 % CI 10.580-68.978 mg test item/kg soil dw) • EC50 = 198.19 mg test item/kg soil dw (95 % CI 129.131-548.151 mg test item/kg soil dw) The reliability evaluation of the EC10 showed that the fit of the response curve was not good, the normalised width of the confidence interval had to be classified as "bad" and the relationship between the confidence intervals of the EC10 and EC20/EC50 values could not be considered acceptable as the EC20low (10.58 mg/kg) was lower than the median EC10 (15.26 mg/kg). Altogether the EC10 was considered unreliable and not suitable for use in the risk assessment.
K	Test item HYPA had a purity of 98.0 %. The validity criteria were met. Due to the high purity of the test item, the results are accepted at nominal levels. The study was conducted to the ISO guideline 11267 (ISO 1999a), but was evaluated by the RMS to the currently valid OECD 232 guideline (OECD 2016a). The following deviations were noted by the RMS: • In the study five concentrations were tested with five replicates for each, while the guideline recommends 12 concentrations with at least two replicates in the treatments and six in the control for determining ECx values or five concentrations with four replicates in the treatments and eight in the control for determining NOEC values. It was noted that the test design was in line with the ISO guideline. • "*No validation of the extraction method was given in the study report*." There were 18 % effect on reproduction in the solvent control, and the water and solvent controls were not pooled in the original study report. The treatment results were compared to the water control in the original study report. The RMS re-conducted the statistical evaluation. According to the OECD guideline, if there are statistical differences between the two controls, the treatment results should be compared to the solvent control. The RMS evaluated the mortality data based on the pooled control and the reproduction data based on the solvent control with the following results: • 28-d LC50 > 100 mg HYPA/kg soil dw • 28-d LC10 = 4.99 mg HYPA/kg soil dw (95 % CI: 1.02-9.92 mg HYPA/kg soil dw), normalised width of the CI: 1.8 (poor reliability) • 28-d EC50 = 60.80 mg HYPA/kg soil dw (95 % CI: 37.82-78.94 mg HYPA/kg soil dw) • 28-d EC10 = 36.43 mg HYPA/kg soil dw (95 % CI: 8.36-50.25 mg HYPA/kg soil dw), normalised width of the CI: 1.1 (poor reliability) • 28-d mortality NOEC = 40.0 mg HYPA/kg soil dw • 28-d reproduction NOEC = 20.0 mg HYPA/kg soil dw It is noted that based on the water control, the reproduction NOEC was determined by the study authors as 10.0 mg HYPA/kg soil, the EC10 as 9.40 mg HYPA/kg soil, the EC50 as 36.34 mg HYPA/kg soil and the LC10 as 43.69 mg HYPA/kg soil.

L	Test item MAPA had a purity of 99.47 %. Test item DAPA had a purity of 99.73 %. The validity criteria were met. Due to the high purity of the test item, the results are accepted at nominal levels. The following deviations were noted by the RMS: • In the study, 9 concentrations with 8 replicates in the control and 4 replicates in the treatments were tested. The guideline recommends 12 concentrations with at least two replicates in the treatments and six in the control for determining ECx values or five concentrations with four replicates in the treatments and eight in the control for determining NOEC values. The applied test concentrations were lower than required for determining ECx values. • In the study 12:12 h light:dark photoperiod was applied, while the guideline recommendation is 16:8 h light:dark photoperiod. • In the study the Abbott's correction was used for the control, although according to the test guideline a correction is not required. It was noted that the deviation from the guideline had no impact on the study results. The RMS considered the study results suitable for use in the risk assessment.
M	Test item HYPA had a purity of 95.14 %. The validity criteria were met. The test results are corrected to the purity of the test item.
N	Test item MAPA had a purity of 95.47 %. The validity criteria were met. The test results are corrected to the purity of the test item.
O	Test item DAPA had a purity of 99.73 %. The validity criteria were met. Due to the high purity of the test item, the results are accepted at nominal levels.
P	Test item HYPA had a purity of 99.7 %. Due to the high purity of the test item, the results are accepted at nominal levels. The RMS evaluated the study to the OECD 216 and 217 guidelines (OECD 2000b, 2000a). The calculation of the percentage differences from the control after 28 days can be repeated and confirmed by OZ. There are some uncertainties, however, e.g. how the respiration test was conducted and reported. The OECD 217 guideline would require glucose-induced respiration rates measured for 12 consequtive hours after 0, 7, 14 and 28 days. It is not included in the study summary (EC 2024) how long the CO_2 measurements took and if the summarised respiration data related to rates per hour. If the hours measuring the CO_2 formation were the same in all cases, it did not have an effect on the outcome. The validity criterion of less than 15 % coefficient of variation (CV) was met for the soil respiration test (based on the OECD 217 guideline) but could not be checked by OZ for the nitrate-N transformation study in the absence of summarised standard deviations or detailed results for the replicates. The RMS noted that the CV was 6.5 % in the control of the nitrogen transformation test (based on the OECD 216 guideline). In their conclusion it was noted by the RMS that the test was conducted "*to an IOBC Bioassay of the side effects of pesticides on* Beauveria brassiana *and* Metarhizium anisopliae *(1992) and a Dutch guideline on effects of pesticides on soil fungi. Therefore, the study is not appropriate to replace the standard toxicity testing. The results of the study might be considered as supportive information in a weight of evidence.*" Considering the lacking detailes and the RMS conclusion, the study is considered as *not assignable* (R4).
Q	Test item HYPA had a purity of 97.85 %. Due to the high purity of the test item, the results are accepted at nominal levels. Based on the summarised data, the calculation of the percentage deviation of the nitrate-N formation rates and the control CV could be repeated by OZ. The OZ results are slightly different than the results provided by the RMS. (see table below) There were effects above 25 % at the lower test concentration after 28 days, while all effects were less than 25 % after 84 days. However, recovery is not accepted for SGV derivation, so the results after the standard test duration of 28 days cannot be considered in this dossier.

Test concentration [mg/kg dry soil]	**Deviation from control [%] for Nitrate-N transformation rate**						
	Intervals in days						
	0-7	0-14	**0-28**	0-42	0-56	0-70	**0-84**
0.32	-33	-11	**32**	31	36	26	**5**
1.60	-33	-9	**9**	12	-6	-10	**7**

	It is unclear what caused the increased nitrate-N formation rates at the lower test concentration following the initial decrease/toxic effects. At the higher concentration, after the initial decrease, there were no deviation from the control more than 12 %. Altogether, the results from this test are not considered reliable for SGV derivation.
R	Test item MAPA had a purity of 99.47 %. Test item DAPA had a purity of 99.73 %. Due to the high purity of the test items, the results are accepted at nominal levels. For both studies our re-calculation confirmed that the summarised results were the nitrate formation rates and not the nitrate content (as was also indicated by the time intervals given in the summary table instead of days). However, the validity criterion should be based on the nitrate concentration measured in the control replicates to get a CV for each sampling day. Consequently, the fulfilment of the validity criterion could not be checked by OZ. According to the RMS, the CV was 6.8 % for both studies.
T	A 14-d seedling emergence study with three concentrations (1.0, 10 and 100 mg HYPA/kg soil) was conducted to the OECD 208 guideline (OECD 2006). The test item was mixed into the soil. The following information was missing from the study summary: • the purity of the test item HYPA • most of the soil property data, such as soil type, structure, moisture and OC/OM content • the quality of the summarised soil carbon content: (total) organic, elemental, inorganic or the sum of all, i.e. total carbon • way of watering • relative humidity • the evaluation of the solvent control as compared to the water control and if there was a difference between them; if not, whether they were pooled for the statistical evaluation and for the presentation of the results (only a “control” group without specification is presented in the result tables) According to the summary as well as the RMS comments, in the study a photoperiod of 10:14 h of light:dark was applied. In the controls, the emergence was 95-100 % for all species, so this deviation probably did not have considerable effects on the outcome of the test. According to the RMS comments, the validity criteria of the OECD 208 guideline were met. While phytotoxicity cannot be evaluated quantitatively, from the summarised results it seems there were dose-response effects at 10 and 100 mg HYPA/kg soil test concentrations. In the absence of the above listed information both the relevance and the reliability of the study results are considered as *not assignable* (R4/C4).
U	A seedling emergence test that was conducted to the OECD 208 guideline (OECD 2006). The test duration was 14 days after 50 % of the control seeds germinated. The test item HYPA had a purity of 99.9 %. Due to the high purity of the test item, the results are accepted at nominal levels. According to the summary, the study was conducted with standard LUFA 2.3 sandy loam soils containing Corg = 1.2 ± 0.15 %. No other soil parameters were summarised. According to the information available on the LUFA Speyer website (the company who provides the standard LUFA Speyer soils; https://www.lufa-speyer.de/images/stories/V8_Analyses_Datashet_for_Standard_Soils.pdf), the type 2.3 soil is indeed a sandy loam soil according to the American USDA classification system (it is silt sand according to the German DIN standard) with 0.76 ± 0.14 % organic carbon content, pH 5.73 ± 0.22, 6.4 ± 1.7 % clay, 33.7 ± 1.4 % silt and 59.9 ± 1.2 % sand content and 1310 ± 59 g/L soil bulk density. The soil used in the test had almost 60 % higher mean organic carbon content than the official value listed by the company. This means that the soil used in the study was either not the standard type 2.3 soil, or the parameters of the used batch deviated from the officially listed parameters. As a result, the company listed parameters cannot be used in lieu of the missing soil parameters of the study. The test substance was dissolved in acetone, mixed with sand (solvent was allowed to evaporate) and then mixed into the soil. It was summarised that the soil samples were taken from all treatments and controls after the 1st and 2nd application. It is not clear what is meant under 1st and 2nd application as according to other information provided on the treatment method, the soil was treated once before sowing the seeds. The mean measured concentrations were 64-74 % of the nominal test concentrations. For all tested species delayed plant development was observed at the highest test concentrations. The origin of the NOEC values summarised in the Conclusion section are not clear: they were based on the biomass results that provided the most of the statistically significant effects at higher concentrations. The results could have been corrected to the analytical results, but then the nominal 50.0 mg HYPA/kg soil should have been corrected to 32 and/or 37 mg HYPA/kg soil. Instead, NOEC values of 30.4 and 40.4 mg HYPA/kg soil were listed for *T. aestivum* and *B. napus*, respectively, and an uncorrected 25.0 mg HYPA/kg soil for *G. max*.

	The RMS found that the validity criteria were met. The agreed EC50 values were based on nominal concentrations. In the absence of the detailed analytical results and no explanation on how the 1st and 2nd applications were meant in the case of a study with one initial application, the results are considered as *not assignable* (R4).
FF	These studies are included in the LoEP that was updated and made publicly available after including additional information, the outcome of the commenting period and expert consultations as well as the ED evaluation (EC 2024). Similarly updated dRAR documents are not available for the products and thus the details of these studies cannot be checked and confirmed. If the values were tabled in the LoEP as corrected values (for details, please refer to Section 1.5.3), they are included here without any correction.

It is noted that the following metabolite study was considered potentially relevant but did not meet the most important requirement with regard to the way of exposure through soil, applied as a single substance (and they may have other deficiencies as well), thus they have not been evaluated and listed in detail (C3):

- Reis (2004) cited in EC (2024), Vol. 3CA B.9.5, p.466; Effect of fluazinam on soil fungi in a mixture of soil and culture media.