

Biocidal Products Committee (BPC)

Opinion on a request according to Article 38 of Regulation (EU)
No 528/2012 on

**Questions on unresolved objections during the mutual recognition
procedure of a PT 18 biocidal product against poultry red mite,
stable fly and darkling beetle**

ECHA/BPC/404/2023

Adopted

23 November 2023



BPC
BIOCIDAL PRODUCTS
COMMITTEE

Opinion of the Biocidal Products Committee

On unresolved objections during the mutual recognition procedure of a PT 18 biocidal product against poultry red mite, stable fly and darkling beetle

In accordance with Article 38 of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on questions concerning unresolved objections during the mutual recognition procedure of a PT 18 biocidal product against poultry red mite, stable fly and darkling beetle.

This document presents the opinion adopted by the BPC.

Process for the adoption of the opinion

ECHA received a request from the Commission on 2 August 2023. ECHA acts as the rapporteur in this type of procedures as agreed at BPC-3. The rapporteur presented the draft opinion to the BPC-49 meeting of 23 November 2023. Following the adoption of the opinion at BPC-49, the opinion was amended according to the outcome of the discussion.

Adoption of the opinion

Rapporteur: European Chemicals Agency (ECHA)

The BPC opinion was reached on 23 November 2023.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA website at: <https://echa.europa.eu/bpc-opinions-on-article-38>

Further details of the opinion and background

1. Request for the opinion

Article 38 of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (the "BPR") establishes that, if so requested by the Commission, pursuant to Article 36(2) or Article 37(2) of the BPR, the Agency shall issue an opinion within 120 days from the date on which the question was referred to it.

On 2 August 2023, ECHA received a request for a BPC opinion from the Commission to address the questions relative to unresolved points of disagreement, regarding the use of PNECsoil values based on data from the information available in the plant protection product area for the environmental risk assessment and on the risk assessment to be performed for the co-formulant octamethylcyclotetrasiloxane that has been identified as a substance of very high concern (SVHC).

The Commission has requested ECHA to formulate an opinion via the BPC on the following questions in order to decide on the authorisation of the product:

1. Determine the values for the PNECsoil spinosad, PNECsoil spinosyn, PNECsoil N-demethylated spinosyn D, to be used for the risk assessment of the biocidal product "Elector".
2. Based on the appropriate PNEC values, determine whether the biocidal product complies with the conditions of Article 19(1) (b) (iv) as regards the risks for the soil compartment.

The Commission further indicated that, when addressing the above-mentioned questions, the following elements should be taken into account by the BPC:

- (a) The product assessment report (PAR) of the biocidal product Elector;
- (b) The assessment report of the active substance (spinosad) under the BPR;
- (c) The studies used by the refMS to refine the PNEC values, for which a letter of access was provided in the application for renewal of the product and submitted by the authorisation holder to ECHA;
- (d) The discussions on the assessment of Elector that took place during the Coordination Group;
- (e) Any other information that ECHA considers relevant.

Background

The authorisation of the biocidal product Elector was renewed by the reference Member State (rMS) CZ under the National authorisation procedure in accordance with Articles 4 and 5(3) of the Regulation (EU) No. 492/2014. It is an insecticide (PT18) which may be used to treat animal production facilities including intensive poultry, swine and cattle housing. This product contains three authorised uses.

The product is reported to work by the following mode of action: nicotinic acetylcholine receptor (nAChR) and gamma-aminobutyric acid (GABA) agonist, killing insects by hyper-excitation of the insect nervous system.

Referrals of the disagreement on the evaluation of the renewal of the product "Elector" were submitted on 25 and 27 November 2019, 2 and 4 December 2019 by the initiating concerned Member States (icMSs) to the Coordination Group (CG), in accordance with Article 35(2) of the BPR. The referral was discussed during a teleconference on 21 January 2020 and the CG-39 meeting on 3 February 2020. During the discussions, eight points of disagreement were resolved, while another two remained unresolved. One of the unresolved disagreement points is related to the product containing the non-active substance octamethylcyclotetrasiloxane (CAS 556-67-2) that is a substance included in the "List of Substances of Very High Concern" (SVHC) of Regulation (EC) No 1907/2006 for PBT and vPvB concerns and therefore its consideration as a Substance of Concern (SoC). Another unresolved point of disagreement is related to the PNECsoil values derived from new ecotox data from the dossier submitted under Regulation (EC) No 1107/2009 (PPPR) being used for the refinement of the risk assessment. As the CG did not reach a consensus agreement for the above mentioned two disagreement points, the rMS referred the unresolved objections to the Commission in accordance with Article 36(1) of the BPR.

During the referral discussions, the Member States agreed that the non-active substance octamethylcyclotetrasiloxane (CAS 556-67-2) is considered as a SoC, but no agreement was reached on the outcome of the risk assessment. As the co-formulant is present in the product at a concentration of $\leq 0.01\%$, the rMS CZ argued no risk assessment is needed.

During the referral discussions, the rMS CZ considered that the previous PNEC should not be used but that the applicant should be able to refine the PNECsoil based on the submitted new studies (already accepted under PPPR). In particular, the rMS pointed out also that, according to the Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017: "a refined assessment is possible, for example by including more specific information on releases and improved data on substance properties, if the use of default exposure estimates does not lead to a conclusion on the safe use" and that the applicant has a letter of access to the new spinosad studies from the data owner. However, the icMSs contested the use of the new studies, as the submitted studies do not completely fulfil the BPR requirements and no harmonized guideline exists at EU level on how to refine the PNEC value.

2. Answers to the questions from the Commission

The opinion of the BPC has considered the background information provided by the Commission in the opinion request, the Product Assessment Report (PAR) of the product in question and the conclusion reached during the Environmental Working Group (ENV WG) meeting that took place on 27 September 2023 (ENV WG III 2023).

Question 1: Determine the values for the PNECsoil spinosad, PNECsoil spinosyn, PNECsoil N-demethylated spinosyn D, to be used for the risk assessment of the biocidal product "Elector".

Current information in the CAR

Currently, in the CAR, the assessment of the terrestrial compartment assessment is based on equilibrium partitioning (EPM). Based on this, the PNECsoil,EP for spinosad is 2.27 $\mu\text{g}/\text{kg}$ ww soil (2.57 $\mu\text{g}/\text{kg}$ dw soil). The PNECsoil,EP for major metabolites spinosyn B and N-demethylated spinosyn D is 1.43 and 0.35 $\mu\text{g}/\text{kg}$ ww, respectively (1.62 and 0.40 $\mu\text{g}/\text{kg}$ dw). No effects were observed on the inhibition of N-transformation.

New data after first approval

As stated in the Guidance on BPR: Vol IV Environment Parts B+C, the strategy to assess the soil compartment focuses on the assessment of the protection of all organisms playing a leading role in establishing and maintain the structure and functioning of the ecosystem. Therefore, the soil assessment typically focuses on results from tests that represent different and significant ecological function in the soil system and should be aimed at data relevant to:

- Primary producers (plants)
- Consumers
- Decomposers

After the first active substance approval in 2010, new soil ecotoxicological data of the active substance spinosad and its two metabolites, spinosyn B and N-demethylated spinosyn D, were generated. This new data is reported in the Draft Assessment Report (DAR) for spinosad in the framework of PPPR. The new ecotoxicological data have been evaluated by the rapporteur Member State in the DAR and is found to be acceptable for the risk assessment to derive a more reliable assessment of soil organisms.

Table 1. New information available for the assessment of the soil compartment.

TG	Species	Endpoint	Test substance	Reference
OECD TG 232	<i>Folsomia candida</i>	Reproduction	GF-976 (43.1% a.s.)	Vinall, S., 2010a. Report nr. 080184
OECD 226	<i>Hypoaspis aculeifer</i>	Reproduction	GF-976 (43.1 % a.s.)	Vinall, S., 2010b. Report nr. 080185
OECD 226	<i>Hypoaspis aculeifer</i>	Reproduction	GF-976 (43.8% a.s.)	Ganßmann, M., 2012. Report nr. 120362
OECD TG 232	<i>Folsomia candida</i>	Reproduction	Spinosyn B	Witte, B., 2015. Report nr. 140821
OECD 226	<i>Hypoaspis aculeifer</i>	Reproduction	Spinosyn B	Witte, B., 2014a. Report nr. 140822
OECD TG 232	<i>Folsomia candida</i>	Reproduction	N-Demethylated spinosyn D	Witte, B., 2014b. Report nr. 140823,
OECD 226	<i>Hypoaspis aculeifer</i>	Reproduction	N-Demethylated Spinosyn D	Witte, B., 2014c. Report nr. 140824

Consideration for deriving the assessment factor

Spinosad is an active substance for use in PT18 (insecticides, acaricides and products to control other arthropods). For their insecticidal mode of action, the spinosyns act as nAChR and GABA receptor agonists in insects.

The newly generated data is limited to two species: *Hypoaspis aculeifer* (OECD TG 226) and *Folsomia candida* (OECD G 232). Both species are recommended species to be tested for insecticidal substances (BPR Guidance Part A, Volume IV Environment, ECHA, 2014).

However, since all new data are part of the invertebrates that are necessary for the breakdown of organic matter and formation of soil structure, all should be considered part of the same trophic level (see e.g. Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7c: Endpoint specific guidance¹).

No information is available on toxicity to terrestrial plants in the CAR (information is available on *Lemna minor* for spinosad for the aquatic compartment). It is important to note however, that under the PPPR spinosad is used as an insecticide to control by spraying a variety of pests in bulb onions, maize (fodder and grain) and sweet corn, grapes (table and wine), lettuce, potato, aubergine, pepper and tomato, and spray applications in greenhouse on lettuce, aubergine and tomato in the EU. Therefore, given its use as an insecticide to protect terrestrial crops, and its known mode of action, it could be assumed that plants are not the potentially most sensitive species², though concrete data using on terrestrial plants (e.g. OECD TG 208, OECD TG 227 or ISO 22030:2005) are not available in the CAR. Note that additional information on terrestrial plants is available in the plant protection product (PPP) dossier, based on EPA guideline subdivision J 122-1 (on the germination emergence and vegetative vigor of non-target terrestrial plants). In this study, no adverse effects were observed for 10 species. Based on the overall results, EFSA³ concluded a low risk to soil macroorganisms (including earthworms) and microorganisms for spinosad and its pertinent metabolites and for non-target terrestrial plants and to organisms involved in the biological methods of sewage treatment for spinosad. This study is however not present in the CAR and has not been included in the newly submitted data and hence cannot be used to lower the assessment factor.

On the assessment of the PNEC_{soil}, the BPR guidance distinguishes three situations for deriving a PNEC_{soil} (ECHA Guidance on BPR, Volume IV Parts B+C, 2017, p. 146):

- *"terrestrial toxicity data are a product-type specific information requirement for some of the PT. However, when no toxicity data are available for soil organisms, or if experimental data are missing for the potentially most sensitive species group, the equilibrium partitioning method is applied to identify a potential risk to soil organisms. This method is regarded as a "screening approach" and is explained in **section 3.6.2.1** of this guidance (see also **section 3.5.2** of this guidance);*
- *when toxicity data are available for a producer, a consumer and/or a decomposer the PNEC_{soil} is calculated using assessment factors as presented in **section 3.6.2.2** of this guidance; provided that the potentially most sensitive taxon is not included in the test species; the previous bullet point still applies.*
- *When only test results for a single soil dwelling species are available the risk assessment is performed both on the basis of this result using assessment factors and on the basis of the EPM. From both PEC_{soil}/PNEC_{soil} ratios the highest one is chosen for the risk characterisation."*

Based on the mode of action (PT18: insecticides, acaricides and products to control other arthropods), the potentially most sensitive taxon is included and basing the PNEC_{soil} on the toxicity data should be considered more reliable compared to the EPM (screening) method

¹https://echa.europa.eu/documents/10162/17224/information_requirements_r7c_en.pdf/e2e23a98-adb2-4573-b450-cc0dfa7988e5?t=1498465307907

² See also Info-box 12 of the ECHA Guidance on BPR, Volume IV Parts B+C, 2017, p. 146

³ EFSA (2018) Peer review of the pesticide risk assessment of the active substance spinosad. doi:10.2903/j.efsa.2018.5252

currently used in the CAR. Hence, the $PNEC_{soil}$ should be derived on the toxicity information by applying the appropriate assessment factor as presented in the table below.

Chapter R.7c: Endpoint specific guidance

Version 3.0 – June 2017

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Table R.7.11–1 Major groups of soil organisms to be considered in effect assessment

Organism group	Ecological process	Soil exposure pathway	Important taxa
Plants	Primary production	Mainly soil pore water (by root uptake)	All higher plants
Invertebrates	Breakdown of organic matter Formation of soil structure	Diverse and multiple uptake routes (soil pore water, ingestion of soil material, soil air, secondary poisoning)	Earthworms, springtails, mites
Micro-organisms	Re-cycling of nutrients	Mainly soil pore water	Bacteria, protozoa, fungi

In this case, the dataset allows for selection of an assessment factor⁴ of 100, since chronic studies are available for one trophic level (ECHA Guidance on BPR, Volume IV Parts B+C, 2017, p. 148).

⁴ The assessment factors suggested for the soil compartment are not based on comprehensive experience. The choice of taxonomic groups for which toxicity data are necessary (conform to the core data set of algae, invertebrate and fish for the aquatic environment), is a point of discussion. A dataset comprising of toxicity data for primary producers, consumers and decomposers is preferred (ECHA Guidance on BPR, Volume IV Parts B+C, 2017, p. 148).

Derivation of PNECsoil

Spinosad

Method, Guideline, GLP status, Reliability	Species	End point/ Type of test	Design	Duration	Results (NOEC)	Re- marks	Refere nce
ISO 11268-2 (1996)	<i>Eisenia foetida</i>	Reproductio n toxicity	Laborator y test	56 days	NOEC \geq 2700 g as/ha \approx 14.2 mg as/kg dw soil (10 % OM) 4.828 mg/kg soil dw (corrected for 3.4% OM)	-	GHE-T-986, Lührs, U., 2000 ⁵
OECD 232	<i>Folsomia candida</i>	Repro- duction test	Laborator y test	14 days	13.4 mg/kg (5% peat) 9.112 mg/kg soil dw (corrected for 3.4% OM)	Tested with product GF-976	Vinall, 2010a 080184
OECD 226	<i>Hypoaspis aculeifer</i>	Repro- duction test	Laborator y test	14 days	4.31 mg/kg (5% peat) 2.9301 mg/kg soil dw (corrected for 3.4% OM)	Tested with product GF-976	Vinall, 2010b 080185
OECD 226	<i>Hypoaspis aculeifer</i>	Repro- duction test	Laborator y test	14 days	10.95 mg/kg (5% peat) 7.446 mg/kg soil dw (corrected for 3.4% OM)	Tested with product GF-976	Ganß- mann, 2012

Value to be used in risk assessment

Taking into account the ecotoxicological data presented in the CAR for the first biocidal active substance approval of spinosad (May 2010) and the new ecotoxicological studies reported in the current PPP dossier (March 2017), the following chronic toxicity studies for terrestrial organisms are now available for the active substance spinosad: earthworm, *Hypoaspis aculeifer* and *Folsomia candida*.

The assessment is based on the most sensitive NOEC of ≥ 2.93 mg/kg soil dw determined in the chronic toxicity study on *Hypoaspis aculeifer* and an assessment factor of 100.

⁵ The RAR contains a better study: Lührs, U., 2008 (report nr. 080183)

PNEC_{soil} spinosad = NOEC / 100

= 2.93 mg/kg dw / 100

= 0.0293 mg/kg dw

= **29.3 µg/kg dw / 25.9 µg/kg soil ww**

Spinosyn B

Method, Guideline, GLP status, Reliability	Species	End point/ Type of test	Design	Duration	NOEC	Re- marks	Refere nce
ISO 11268-2 (1998) Revised: OECD 222	<i>Eisenia foetida</i>	Reproduction toxicity	Laboratory test	56 days	3.58 mg/kg dw soil (10 % OM) ≥ 1.218 mg/kg dw (corrected to 3.4% OM)	-	Hayward, J. C, 2003
OECD 232	<i>Folsomia candida</i>	Reproduction test	Laboratory test	14 days	≥ 10 mg/kg (5% peat) ≥ 6.8 mg/kg soil dw (corrected for 3.4% OM)	-	Witte, 2015
OECD 226	<i>Hypoaspis aculeifer</i>	Reproduction test	Laboratory test	14 days	≥ 2 mg/kg (5% peat) ≥ 1.36 mg/kg soil dw (corrected for 3.4% OM)	-	Witte, 2014a

Value to be used in Risk Assessment

Three species belonging to the same trophic level are covered by experimental studies (earthworm, *Folsomia candida*, *Hypoaspis aculeifer*). The assessment is based on the chronic toxicity study on earthworms of the biocidal Assessment report (May 2010). A NOEC of ≥ 1.218 mg/kg dw (corrected to 3.4% OM, NOEC: NOEC: ≥ 3.582 mg/kg dw , 10% OM) was used for the calculation of the PNEC_{soil}, applying an assessment factor of 100.

PNEC_{soil} spinosyn B = NOEC / 100

= 1.218 mg/kg dw / 100

= 0.01218 mg/kg dw

= **12.18 µg/kg dw / 10.77 µg/kg soil ww**

N-demethylated spinosyn D

Method, Guideline, GLP status, Reliability	Species	End point/ Type of test	Design	Duration	NOEC	Remarks	Reference
ISO 11268-2 (1998)	<i>Eisenia fetida</i>	Reproduction	Laboratory test	56 days	≥ 1.93 mg/kg dw soil (10 % OM) 0.656 mg/kg soil dw is (corrected for 3.4% OM)	-	Hayward, J.C., 2003
OECD 232	<i>Folsomia candida</i>	Reproduction test	Laboratory test	14 days	4.3 mg/kg (5% peat) 2.92 mg/kg soil dw (corrected for 3.4% OM)	-	Witte, 2014b
OECD 226	<i>Hypoaspis aculeifer</i>	Reproduction test	Laboratory test	14 days	5 mg/kg (5% peat) 3.4 mg/kg soil dw (corrected for 3.4% OM)	-	Witte, 2014c

Value to be used in Risk Assessment

One trophic level is covered by long-term studies (earthworm, *Hypoaspis aculeifer*). A NOEC of 0.656 mg/kg dw (corrected to 3.4% OM; NOEC: ≥1.928 mg/kg dw, 10% OM) was used for the calculation of the PNEC_{soil}. The assessment is based on the chronic toxicity study on earthworms with a NOEC of 0.656 mg/kg dw and an assessment factor of 100.

PNEC_{soil} N-demethylated spinosyn D = NOEC / 100

$$= 0.656 \text{ mg/kg dw} / 100$$

$$= 0.00656 \text{ mg/kg dw}$$

$$= \mathbf{6.56 \text{ } \mu\text{g/kg dw} / 5.77 \text{ } \mu\text{g/kg soil ww}}$$

Based on the information above, the following values for PNEC_{soil} can be used for the risk assessment of the biocidal product Elector:

- spinosad, 25.9 $\mu\text{g/kg ww}$
- spinosyn, 10.77 $\mu\text{g/kg ww}$
- N-demethylated spinosyn D, 5.77 $\mu\text{g/kg ww}$

It is important to note that these values should not be considered as general PNECs for the soil compartment for the active substance spinosad and should not be used to already revise the PNEC_{soil} in the LoEP for spinosad in the course of this Article 38 request process.

Question 2: Based on the appropriate PNEC values, determine whether the biocidal product complies with the conditions of Article 19(1) (b) (iv) as regards the risks for the soil compartment.

Based on the predicted environmental concentrations by the rMS CZ in the PAR, the highest PEC/PNEC_{soil} (i.e. 0.4) is found for N-demethylated spinosyn D for Red mites (0.36 g product/m²) (Animal category 11). The difference in the proposed PNEC_{soil} will increase the maximum PEC/PNEC to 0.8; all other calculated PEC/PNEC are lower, with the majority of the PEC/PNEC value ≤ 0.1 .

As the non-active substance octamethylcyclotetrasiloxane is present in the product at a concentration of $\leq 0.01\%$, no additional risk assessment is needed. Nonetheless, the risk assessment performed by the rMS CZ for all environmental compartments demonstrated no risk for surface water, sediment and soil (PEC/PNEC 6.35e-10, 2.70e-5 and 2.7e-5 respectively).

Overall, no unacceptable risk was calculated for the soil upon use of Elector as PT18 insecticide in animal stables.

3. Overall conclusion

The following values for the PNEC_{soil} spinosad, PNEC_{soil} spinosyn, PNEC_{soil} N-demethylated spinosyn D can be used for the risk assessment of the biocidal product "Elector":

- spinosad, 25.9 $\mu\text{g}/\text{kg ww}$
- Spinosyn, 10.77 $\mu\text{g}/\text{kg ww}$
- N-demethylated spinosyn D, 5.77 $\mu\text{g}/\text{kg ww}$

Based on the appropriate PNEC values, no unacceptable risk was calculated for the soil upon use of Elector as PT18 insecticide in animal stables. The biocidal product complies with the conditions of Article 19(1)(b)(iv) of the BPR as regards the risks for the soil compartment.

4. Annexes

Background material provided by the applicant on the request of the Commission

As the applicant only provided a letter of access to the relevant studies, the following original study reports were provided by the applicant on the request of the Commission for this assessment:

- Witte, B.; 2015; Spinosyn B: Effects on Reproduction of the Collembola *Folsomia candida* in Artificial Soil with 5% Peat; Institut für Biologische Analytik und Consulting IBACON GmbH; Lab Study No. 93351016; DAS Study No. 140821; 20 January 2015; Unpublished
- Witte, B.; 2014; Spinosyn B: Effects on Reproduction of the Predatory Mite *Hypoaspis aculeifer* in Artificial Soil with 5% Peat; Institut für Biologische Analytik und Consulting IBACON GmbH; Lab Study No. 93351089; DAS Study No. 140822; 17 December 2014; Unpublished
- Witte, B.; 2014; N-demethyl Spinosyn D: Effects on Reproduction of the Collembola *Folsomia candida* in Artificial Soil with 5% Peat; Institut für Biologische Analytik und Consulting IBACON GmbH; Lab Study No. 93341016; DAS Study No. 140823; 10 December 2014; Unpublished
- Witte, B.; 2014; N-demethyl Spinosyn D: Effects on Reproduction of the Predatory Mite *Hypoaspis aculeifer* in Artificial Soil with 5% Peat; Institut für Biologische Analytik und Consulting IBACON GmbH; Lab Study No. 93341089; DAS Study No. 140824; 19 November 2014; Unpublished
- Vinall S. (2010). A laboratory test to determine the effects of fresh residues of two formulations of spinosad (GF-976 and GF-1872) on the springtail, *Folsomia candida* (Collembola, Isotomidae). Dow AgroSciences unpublished report number DOW-09-31, 23 March 2010.
- Vinall S. (2010). A laboratory test to determine the effects of fresh residues of two formulations of spinosad (GF-976 and GF-1872) on the predatory mite, *Hypoaspis aculeifer* (Acari, Laelapidae). Dow AgroSciences unpublished report number DOW-09-32, 23 March 2010.
- Ganßmann, M. (2012): Effects of GF-976 on Reproduction of the Predatory Mite *Hypoaspis aculeifer* in Artificial Soil with 5% Peat. Institut für Biologische Analytik und Consulting IBACON GmbH, Lab Study ID: 73281089. Dow AgroSciences unpublished report, DAS Study Number 120362. Study Report Completion Date: September 17, 2012.