Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Acetamiprid

Product type: 18

ECHA/BPC/185/2017

Adopted on

14 December 2017

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance acetamiprid for product type 18

In accordance with Article 89(1) 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 (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the application for approval in product type 18 of the following active substance:

Common name:	**Acetamiprid**
Chemical name:	(E)-N1-[(6-chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamide
EC No.:	None
CAS No.:	135410-20-7
Existing active substance	

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by Nisso Chemical Europe GMBH on 24 February 2006, the evaluating Competent Authority Belgium submitted an assessment report and the conclusions of its evaluation to ECHA on 27 July 2015. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via BPC (BPC-18 and BPC-23) and its Working Groups (WG-II-2016). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Information on the fulfilment of the conditions for considering the active substance as a candidate for substitution was made publicly available at https://echa.europa.eu/addressing-chemicals-of-concern/biocidal-products-regulation/public-consultation-on-potential-candidates-for-substitution on 18 November 2016, in accordance with the requirements of Article 10(3) of Regulation (EU) No 528/2012. Interested third parties were invited to submit relevant information by 17 January 2017.

Adoption of the BPC opinion

Rapporteur: Belgium

The BPC opinion on the application for approval of the active substance acetamiprid in product type 18 was adopted on 14 December 2017.

The BPC opinion takes into account the comments of interested third parties provided in accordance with Article 10(3) of BPR.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA webpage at:

http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the acetamiprid in product type 18 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of acetamiprid in product type 18. Acetamiprid acts by affecting the central nervous system of insects, causing paralysis and death. Acetamiprid is a neonicotinoid insecticide which acts on harmful organisms by contact and ingestion. Specifications for the reference source are established.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities. Validated analytical methods are required and available for the relevant matrices: soil, water, blood, tissues muscles, air, plants.

Acetamiprid has been assessed under another European Regulatory Framework(s): Commission Implementing Regulation (EU) No 844/2012 lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012. Acetamiprid is one of the active substances listed in Regulation (EU) No 686/2012. The renewal of acetamiprid for the PPP was approved on 17 October 2016 (EFSA Journal: doi: 10.2903/j.efsa.2016.4610).

A harmonised classification is available. The current harmonised classification for acetamiprid according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Current classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox 4 * Aquatic Chronic 3
Labelling	
Pictogram codes	GHS07
Signal Word	Warning
Hazard Statement Codes	H302: harmful if swallowed H412: harmful to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	None

Based on the evaluation the eCA (Belgium) will prepare an amendment to the current harmonised classification. The proposed amended classification and labelling for acetamiprid according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox 3 Aquatic acute 1

	Aquatic chronic 1
Labelling	
Pictogram codes	GHS06 GHS09
Signal Word	Danger
Hazard Statement Codes	H301: toxic if swallowed H410: very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	M acute: 10M chronic: 10
Justification for the proposal	
H302→ H301 Based on the oral LD50 for rats. H400: Based on the most sensitive aquatic species *Chironomus riparius* H412→ H410 Based on the most sensitive aquatic species *Chironomus riparius*	

b) Intended use, target species and effectiveness

Acetamiprid is intended to be included as an active substance in insecticides (product type 18) to be used by professionals and non-professional to control crawling insects, flying insects and dust mites in indoor conditions (residential and other buildings, in stables and animal transport utilities) and in outdoor conditions i.e. terraces and external (non-garden) perimeters of buildings.

Acetamiprid is a neonicotinoid insecticide which acts on the target organisms by contact and ingestion. The neonicotinoids are a class of insecticides with a common mode of action that affects the central nervous system of insects, causing paralysis and death.

Efficacy tests have demonstrated the effectiveness of acetamiprid based on products at application rates from 2 mg/m² to 200 mg/m² against *Lepisma saccharina* and *Blattella germanica, Dermatophagoïdes pteronyssinus, Dermatophagoïdes farinae, Lepisma saccharina, Lasius niger and Musca domestica*, depending on the formulated products.

There is no cross resistance between acetamiprid and organo-phosphate, carbamate and pyrethroid insecticides as recorded in laboratory experiments. Concerning cross resistant effects with nicotinic insecticides, no test has been performed due to the lack of resistant strains. With a mono-site activity the development of resistance to acetamiprid may occur. It could be likely that such a cross resistance with nicotinic insecticide will appear.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

For the acute toxicity, acetamiprid is classified as harmful if swallowed and fulfils the criteria to be classified as toxic if swallowed. It has a low dermal and inhalation acute toxicity. It is non-irritant in contact with eyes or skin and has no sensitizing properties. The toxicity of acetamiprid resulting from repeated exposure has been evaluated by various routes of exposure and in various animal species. Acetamiprid has no genotoxic effect nor carcinogenic or reprotoxic effect.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Spraying, indoor	Primary exposure: Crack and crevices, targeted spot (cockroach/fly control) Residential PPE /RPE (Coated coverall/RPE type 2)	Professionals	Acceptable
Spraying, indoor	Primary exposure: Crack and Crevices, targeted spot (cockroach /fly control) Stables. PPE/RPE (Coated coverall/RPE type 2)	Professionals	Acceptable
Painting by brush, indoor	Primary exposure: Fly control in stables. PPE and RPE (Coated coverall/RPE type 2)	Professional animal breeders	Acceptable
Spraying, outdoor	Primary exposure: Crack and crevices, targeted spot (ants and other crawling insects control) Terraces PPE and RPE (Coated coverall/RPE type 2)	Professionals	Acceptable
Indoor and outdoor	Primary exposure: Spraying: Crack and Crevices, Targeted Spot (cockroach/fly control) using RTU product. Residential in house and surrounding terraces	Non-professional	Acceptable
Infants and toddlers crawling and mouthing on treated surfaces	Secondary exposure post application: toddlers and infants crawling over the treated surface and mouthing following targeted spot or crack and crevice applications by professionals or non-professional users. Upper and lower (18% and 8% of the disloageable fraction) bands assessed. End-use concentration of product sprayed is 0.2% and 0.4%.	Toddlers/ infants	Acceptable, except following professional use at 0.4% for upper band

There is no concern for the professional operators, using the biocidal product acetamiprid (20 %) at mixing and loading, and during spraying (0.4 %) outdoor and indoor, brush-painting (8.7 %) indoor and outdoor, provided appropriate PPE and RPE are worn (i.e. coated coverall and RPE type 2)

There is no concern for the non-professional users during spraying (RTU at 0.2 %) indoor and surrounding terraces.

The secondary exposure after application is considered relevant for the residential indoor scenarios professional and non-professional. Infants, aged between 6 months and 2 years, which are crawling on floor spaces, are considered to be the exposure group with the potentially highest exposure. The main pathway is dermal but oral exposure is considered as well. Due to the non-volatility of acetamiprid inhalative exposure is not considered relevant in the post-application phase.

There is concern with the use at 0.4 % in the acute secondary exposure of infant and toddler at upper range for both targeted spot and crack and crevice applications. However, given that the product is a targeted spot, crack and crevice treatment and thus children, toddlers and infants are not expected to routinely gain access to the exposed areas.
Post application exposure following non-professional use (i.e. 0.2%) will not pose a risk both for acute and chronic. Toddler exposure following non-professional does not pose a risk.

Indirect secondary exposure via food and products from animal origin is acceptable for the general public.

Environment

Acetamiprid is toxic for aquatic organisms (tested on *Chironomus riparius*, insect larvae) and was found to be persistent in water and sediment. It is highly mobile and considering its vapour pressure and Henry constant, acetamiprid will preferably remain in the water phase.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Scenario 1: stables	Application by spraying and brushing: 18 categories of animals/housings (in and out the grazing period) Sewage treatment plant, soil, water, sediment, groundwater	Acceptable for STP and unacceptable for water, sediment, groundwater and for soil for several animal categories
Scenario 2: Household, indoor professionals	• mixing and loading phase • application by spraying: surface (targeted spot), crack and crevices • cleaning phase Sewage treatment plant, soil, water, sediment, groundwater	Acceptable
Scenario 3: Household, indoor general public	• application by spraying: surface (targeted spot), crack and crevices • Cleaning phase Sewage treatment plant, soil, water, sediment, groundwater	Acceptable
Scenario 4: Household, outdoor professionals	a) <u>Countryside</u> • mixing and loading phase • application by spraying: wall application (flying insects), chemical barrier and crawling space (crawling insects). • Wash-off by rainfall b) <u>Cities</u> • mixing and loading phase • application by spraying: wall application (flying insects), chemical barrier and crawling space (crawling insects). • Wash-off by rainfall • Sewage treatment plant, soil, water, sediment, groundwater, bees, birds and mammals (first tier)	Acceptable for STP and not acceptable for soil, surface water, sediment and groundwater
Scenario 5: Household, outdoor general public	a) <u>Countryside</u> • Application by spraying: walls application (flying insects), chemical barrier and crawling space (crawling insects). • Wash-off by rainfall b) <u>Cities</u> • Application by spraying: walls application (flying insects), chemical barrier and crawling space (crawling insects). • Wash-off by rainfall Sewage treatment plant, soil, water, sediment, groundwater, bees, birds and mammals (first tier)	Acceptable for STP and not acceptable for soil, surface water, sediment and groundwater

No unacceptable risks were identified for two scenarios for all compartments: household, indoor for professionals and non-professionals (= general public).

Scenario 1: stables – No risk for the STP was identified. For the use of the professional product was identified as safe use for some animal categories (categories laying hens and parent broilers in free range with grating floor) and as a risk for other categories for soil. For surface water, the sediment and the groundwater, no safe use was identified when considering the exposure assessment with this product.

Scenario 4: Household, outdoor professionals – No risk for the STP. No safe use for the surface water (calculated only for cities), the sediment, the soil and the groundwater.

Scenario 5: Household, outdoor general public – No risk for the STP. No safe use for the surface water (calculated only for cities) and the sediment. For the soil two safe uses were identified: treatment against flying insect and chemical barrier in cities. The others uses were not identified as safe uses for soil. For the groundwater only the chemical barrier in cities was identified as safe use. The other uses were not identified as safe uses for groundwater.

As acetamiprid is a neonicotinoid for scenario 4 and 5 a first tier quantitative assessment for bees was performed as well as a qualitative assessment. Considering the available information it was concluded that there are no unacceptable risks for bees.

For the non-targeted arthropods the qualitative assessment was based on a study presented in the PPP dossier and showed despite the insecticidal properties of acetamiprid and despite that some of the species tested are relatively sensitive, effects are not expected to be severe or persistent.

For scenario 4 and 5 primary and secondary poisoning were assessed. The risks were all acceptable.

Overall conclusion

The use of acetamiprid has been evaluated as acceptable when applied indoor by small scale applications by spraying (cracks and crevices) against flying and crawling insects by professional and non-professional users. Unacceptable risks were identified for stables and outdoor uses as well as for surface application via spraying or brushing. In order to avoid risk to infants and toddlers, professional users should avoid to spray acetamiprid on surfaces where infants and toddlers may have access to for products containing >0.2%.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	no classification required	Acetamiprid does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	no classification required	
	Toxic for reproduction (R)	no classification required	
BT and vPvB properties	Persistent (P) or very Persistent (vP)	Acetamiprid:vP IC-0: potential vP IM 1-2: Not P IM-1-4: vP IM-1-5: vP IB-1-1: not P	Acetamiprid does not fulfil criterion (e) of Article 5(1) and does fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B and vB	
	Toxic (T)	Acetamiprid: T Metabolites IC-0,IM-1-2, IM-1-5 are not T IM-1-4 is potentially T IB-1-1: not T	
Endocrine disrupting properties	Acetamiprid is not considered to have endocrine disrupting properties. Acetamiprid does not fulfil criterion (d) of Article 5(1).		
Respiratory sensitisation properties	No classification required. Acetamiprid does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects	Acetamiprid does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Acetamiprid does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

Acetamiprid does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Acetamiprid does meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore considered as a candidate for substitution. Acetamiprid is vP and T. The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[1] and in line with "Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR"[2] agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

2.2.2. POP criteria

Acetamiprid does not fulfil the criteria to be a POP.

2.2.3. Public consultation for potential candidates for substitution

As acetamiprid is considered a candidate for substitution, ECHA launched the public consultation in accordance with Article 10(3) of Regulation (EU) No 528/2012. The public consultation took place from 18 November 2016 to 17 January 2017. Two contributions were submitted. One referred to the PBT assessment and contained a new water degradation study. This study was evaluated and alter the former conclusion on the P criteria. Acetamiprid is now meeting the vP criterion but is still a candidate for substitution. The other contribution mentioned that the uses claimed for acetamiprid under PT18 are common ones and that there are alternatives to this substance as shown by biocidal products already placed on the market for those uses and against the same organisms.

2.3. BPC opinion on the application for approval of the active substance acetamiprid in product type 18

In view of the conclusions of the evaluation, it is proposed that acetamiprid shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions**:**

1. Specification: minimum purity of the active substance evaluated: minimum purity in 99.0% w/w

2. Acetamiprid is considered a candidate for substitution in accordance with Article 10(d) of Regulation (EU) No 528/2012.

3. The authorisations of biocidal products are subject to the following condition(s):

    a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

[1] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)

[2] See document: Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)

b. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:

   i. Professional users

   ii. Infants and toddlers following secondary exposure when the product is sprayed by professionals at a concentration above 0.2%.

   iii. Surface water, sediment, soil, groundwater for products applied by spray or brush in stables.

   iv. Surface water, sediment, soil, groundwater for products applied by spray outdoors.

c. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009[3] or Regulation (EC) No 396/2005[4] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

4. The person responsible for the placing on the market of a treated article treated with or incorporating the active substance acetamiprid shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.

Acetamiprid cannot be included in Annex I of Regulation (EU) No 528/2012 because it meets the following criteria of Article 28(2)(b) fulfilling the substitution criteria (acetamiprid is vP and T).

2.4. Elements to be taken into account when authorising products

1. The active substance acetamiprid is considered as a candidate for substitution, and consequently the competent authority shall perform a comparative assessment as part of the evaluation of an application for either national or Union authorisation.

2. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

   a. If an unacceptable risk is identified for professional users, safe operational procedures and appropriate organizational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

   b. Unacceptable risk is identified for infants and toddlers during secondary exposure with the highest concentation (0.4%) of professional product. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measure, or by other means, such as labels, and where provided, safety data sheets, indicating that products shall be restricted to areas not accessible to children, these uses should not be authorised.

[3] Regulation (EC) No 470/2009 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11)
[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1)

c. An unacceptable risk is identified for soil (for some animal categories), surface water, sediment and groundwater for products applied by spray or brush in stables. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

d. An unacceptable risk is identified for surface water, sediment, groundwater, soil for products applied by spray outdoor. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

e. As acetamiprid is a neonicotinoid special attention was paid to bees. A quantitative assessment was performed, however currently there is no agreed concept for the assessment of the risk to bees available. At product authorisation a revised risk assessment for bees might be necessary using the agreed assessment concept if available.

3. An assessment of the risk in food and feed areas may be required at product authorisation where use of the product may lead to contamination of food and feeding stuffs.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of acetamiprid.

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