Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Dinotefuran

Product type:18

ECHA/BPC/006/2014

Adopted

17 June 2014

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance dinotefuran for product type PT18

In accordance with Article 90(2) 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 the approval in product type PT18 of the following active substance:

Common name:	**Dinotefuran**
Chemical name:	**(RS)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine**
EC No.:	**Not available**
CAS No.:	**165252-70-0**

New active substance

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report (AR) and conclusions, 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 LKC UK Ltd. on 29 March 2012, the evaluating Competent Authority UK submitted an assessment report and the conclusions of its evaluation to the Agency on 15 October 2013. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and its Working Groups. 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 http://echa.europa.eu/addressing-chemicals-of-concern/biocidal-products-regulation/potential-candidates-for-substitution on 29 November 2013, 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 28 January 2014.

Adoption of the BPC opinion

Rapporteur: BPC member for United Kingdom

The BPC opinion on the approval of the active substance dinotefuran in product-type PT18 was adopted on 17 June 2014.

No comments were received from interested third parties during the public consultation in accordance with Article 10(3) of BPR.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the dinotefuran in product type PT18 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. Opinion

2.1. Conclusions of the evaluation

a) Presentation of the active substance and representative biocidal product including classification of the active substance

This evaluation covers the use of dinotefuran in product type 18. Dinotefuran is a neonicotinoid in the nitroguanidine class. Dinotefuran acts as an agonist of insect nicotinic acetylcholine receptors, but it is postulated that dinotefuran affects the nicotinic acetylcholine binding in a mode that differs from other neonicotinoid insecticides. Dinotefuran is a mixture of isomers R and S (1:1) and consists of two tautomers which can be regarded as E/Z isomers where the protons are in equilibrium. Specifications for the reference source are established.

The physico-chemical properties of the active substance and representative biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and representative biocidal product. The addition of a bittering agent at a level of 0.01 % was agreed as unlikely to have any adverse effects on the storage stability of the representative product. Acceptable partially or fully validated analytical methods are available for the determination of dinotefuran in the technical material, impurities in the technical material, and dinotefuran in soil, drinking water, ground water and surface water. No analytical methods were required for air, animal and human body fluids and tissues, or residues in food or feeding stuffs.

There is no harmonised classification for dinotefuran. The evaluating Competent Authority (eCA) intends to submit the following proposal on harmonised classification to ECHA during 2015:

Classification according to Regulation (EC) No 1272/2008	
Hazard Class and Category Codes	Aquatic Acute; 1 H400 Aquatic Chronic; 1 H410
Labelling	
Pictograms	GHS09
Signal Word	Warning
Hazard Statement Codes	H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	Aquatic Acute: 10 Aquatic Chronic: 10

b) Intended use, target species and effectiveness

Dinotefuran is intended to be used by professionals in products to control insects and other arthropods including cockroaches.

The data on dinotefuran and the representative biocidal product have demonstrated sufficient efficacy against the target species. The possibility of the development of a cross-resistance or a specific resistance to dinotefuran cannot be discounted. Strategies to reduce the risk of

resistance developing can be implemented at product authorisation. Similarly, monitoring programs to confirm that target pests remain susceptible to dinotefuran will need to be implemented.

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

The overall conclusion from the evaluation of dinotefuran for use in Product Type 18 (insecticides, acaricides and products to control other arthropods) is that it may be possible to issue authorisations of products containing dinotefuran in accordance with the conditions laid down in Article 19 of Regulation (EU) No. 528/2012.

Human health

The table below summarises the exposure scenarios assessed:

Summary table: human health scenarios		
Scenario	**Primary or secondary exposure Description of scenario**	**Exposed group**
Application	Primary exposure. Dermal exposure of professional applying insecticidal gel bait product as a spot or crack and crevice treatment (long-term). Tier 1: no PPE Tier 2: PPE (gloves)	Professionals
Post-application	Secondary inhalation exposure to occupants of premises (long-term).	Bystanders (Adults, Children, Infants)
Post-application	Secondary dermal exposure to dislodged or applied insecticidal gel bait product (acute).	Bystanders (Adults, Children, Infants)
Post-application	Secondary oral exposure to dislodged or applied insecticidal gel bait product (acute).	Bystanders (Infants)

For the human health risk assessment, one primary exposure scenario has been identified, which is the application of insecticidal gel bait product using spot treatment and crack and crevice application by professionals. The risk assessment indicates that the risks from primary exposure to dinotefuran as formulated in the representative product are acceptable, without the use of PPE. The risk assessment also indicates that the risks from secondary exposure to dinotefuran are acceptable. Nevertheless, secondary exposure scenarios considered using the reverse reference method indicate that contact with, or the consumption of, a relatively low number of spots of insecticidal product by infants and companion animals would result in the acute systemic AEL being achieved, so it is recommended that the product is labelled with the following phrases: i) "Prevent access to baits by children and animals"; and ii) "Keep in a safe place."

In addition it has been agreed that the representative product will contain a bittering agent that may discourage ingestion.

Overall, if dinotefuran in the representative product is used in the manner described by professional operators then the risk to human health is acceptable.

Environment

The table below summarises the exposure scenarios assessed:

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Application	None
Post-application	Surface water through losses to STP via drains after wet cleaning
Post-application	Sediment through losses to STP via drains after wet cleaning
Post-application	Soil through losses to STP via drains after wet cleaning and following limited sorption to sewage sludge
Post-application	Atmosphere through losses to STP via drains after wet cleaning
Post-application	*In-situ* contact with foraging bees

The indoor scenario used for the environmental risk assessment (based upon relevant Emission Scenarios and modified by refinements agreed at various Technical Meetings) has assumed treatment onto hard surfaces not prone to frequent wet cleaning using a targeted crack and crevice or spot treatment for cockroach control in domestic dwellings and commercial, public or municipal buildings. Application of the representative product is made only by professional operators using a syringe based delivery system capable of delivering 0.1 g spots of gel bait. It should be noted that assessment of the representative product has assumed application either for spot treatment or crack and crevice treatment into difficult to access areas (for the purposes of cleaning by householders) behind fixtures, structures and in cavities where cockroaches feed, congregate and seek harbourage. Professional operators would be recommended to apply 0.2 g of product per m^2 for infestations of small cockroach species and 0.4 g of product per m^2 for large cockroach species. However, in cases of heavy infestations, a maximum rate of 0.8 g per m^2 (equivalent to 0.016 g m^{-2} of dinotefuran) would be recommended regardless of species size.

The risk assessment assumed that treatment would be applied on a small scale with treated areas in a domestic dwelling equivalent to 2 m^2 (equivalent to maximum treatment of 16 x 0.1 g spots of Dinotefuran 2 % Bait per house) and a treated area of 9.3 m^2 in public / commercial buildings (equivalent to maximum treatment of 74 x 0.1 g spots of product per large building). Infestations of greater severity would need alternative and more radical control measures.

Although the representative product will be delivered into cavities and ducting, behind kitchen cabinets or cupboards etc, under cooking appliances and into cracks or crevices where cockroaches will congregate, feed and seek harbourage, it is assumed that rooms where treatment occurred would be subject to wet cleaning (but where cleaning efficiency would only reach 3 % as product has been applied to areas not prone to frequent wet cleaning).

Overall, if dinotefuran as formulated in the representative product is used in the manner prescribed, with targeted indoor application into areas not prone to frequent wet cleaning against cockroaches by professional operators, the risk to surface waters through losses to STP via drains is acceptable. Furthermore, potential risks to sediment and non-target biota are also considered acceptable. Although no obvious direct route to the soil compartment can be demonstrated, negligible concentrations of dinotefuran could be applied to agricultural land following limited sorption to sewage sludge. However, acceptable risks were demonstrated to local soil. Due to the lack of volatility of the compound (5.0×10^{-5} Pa at 25 °C), no losses to the air compartment were predicted from use of the representative product.

The attractiveness to bees of ingredients other than the active substance is unknown. However, it should be noted that the use of the representative product is indoors in cracks and other difficult to reach places. These situations are not typically sought out by foraging bees and it is considered that the representative product placement would limit any potential increase in the attractiveness of the bait that these other ingredients may have. Consequently, the risk to bee colonies from direct exposure to the product is likely to be minimal.

However, it must be noted that any future increase in application or use pattern of dinotefuran based products would likely result in significantly increased emissions to environmental compartments and these should be assessed for risk by MS at product authorisation. Furthermore, additional supporting data may also be required on the active substances in order to support these new assessments.

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		Classification
CMR properties	Carcinogenicity (C)	No classification required
	Mutagenicity (M)	No classification required
	Toxic for reproduction (R)	No classification required
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	vP
	Bioaccumualtive (B) or very Bioaccumulative (vB)	Not B and vB
	Toxic (T)	T
Endocrine disrupting properties	Not considered to have endocrine disrupting properties	

Consequently, the following is concluded:

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

Dinotefuran does meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore considered as a candidate for substitution, by being very persistent (vP) and toxic (T). No comments were received during public consultation. 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" agreed at the 54th meeting of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products (CA-March14-Doc.4.1 - Final - Principles for the approval of AS.doc). This implies that the assessment of the exclusion criteria is based on Article 5(1) using the temporary criteria for the determination of endocrine-disrupting properties in Article 5(3) and the assessment of substitution criteria is based on Article 10(1)(a, b and d).

There are several other active substances intended for use in the same product type that have already been approved or are currently being reviewed under Regulation (EU) No 528/2012.

2.2.2. POP criteria

Dinotefuran fulfils the criteria for being vP and T. However dinotefuran does not demonstrate the potential for long range transport. In view of this, dinotefuran does not meet the criteria for being a persistent organic pollutant.

2.3. BPC opinion on the application for approval of the active substance dinotefuran in product type PT18

In view of the conclusions of the evaluation, it is proposed that dinotefuran 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 is 991 g/kg. Dinotefuran is a racemic mixture.

2. Dinotefuran is considered a candidate for substitution in accordance with Article 10(1)(d) of Regulation (EU) No 528/2012.

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

4. For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment

Dinotefuran gives rise to concern according to Article 28(2) and so inclusion in Annex I of Regulation (EU) No 528/2012 is not possible. Grounds for non-inclusion in Annex I are the fulfilment of substitution criteria including toxicity to aquatic life of acute category 1.

2.4. Elements to be taken into account when authorising products

1. Whilst the efficacy data provided is sufficient to recommend approval of the substance, data demonstrating the efficacy of the product at the minimum application rate against the range of proposed target organisms using the recommended application equipment must be provided at the product authorisation stage.

2. The potential resistance of target insects to dinotefuran could be of concern and, as such, resistance management measures should be included in the authorisation of products. These could include (but should not be restricted to) the following factors:

a. The population size of the target insect should be evaluated before a control campaign. The dose and frequency of applications and the timing of the control campaign should be in proportion to the size of the infestation.
b. A complete elimination of insects in the infested area should be achieved.
c. The use instruction of products should contain guidance on resistance management for insecticides.
d. Resistant management strategies should be developed, and dinotefuran should not be used in an area where resistance to this substance is suspected.
e. The authorisation holder and professional end-users shall report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management.

3. Appropriate risk mitigation measures must be taken to minimise the potential exposure of humans and of non-target species. In particular, Member States should consider that labels and/or safety-data sheets of products authorised clearly indicate that: ”Products shall not be placed in areas accessible to infants, children and companion animals”.

4. Products authorised should contain a bittering agent that may discourage ingestion.

5. Dinotefuran is a mixture of isomers R and S (1:1). There is no information available on the efficacy of the different isomers and therefore it is not known whether it fulfils Article 10(1) (f) on the substitution criteria, namely 'contains a significant proportion of non-active isomers'. However, there are currently no clear rules, methodology or guidance for the assessment of this criterion and this issue cannot be considered further at this time. The efficacy of the dinotefuran isomers will have to be considered when such guidance does become available.

6. Only a limited environmental risk assessment was performed on dinotefuran as formulated in the representative product due to its controlled and targeted indoor use pattern against cockroaches. Special attention should be paid to the potential risks to bees. No products containing dinotefuran should be authorised unless it can be demonstrated that the product will meet the requirements of Article 19 of Regulation (EU) No 528/2012, if necessary by the application of appropriate risk mitigation measures. Additional supporting environmental effects plus fate and behaviour data may also be required on both the active substance and relevant metabolites. The exposure assessement in the CAR is based on a very limited exposure. If in future applications (product authorisation) additional uses with soil exposure are claimed these need to be further assessed and additional data on soil living insects and other NTOs are triggered.

7. With regard to aqueous photolysis, this route of degradation should be considered on a case-by-case basis by individual Member States depending upon local conditions, especially if use patterns were to be extended / changed and could potentially lead to direct exposure of surface waters.

8. 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.

9. Where there will be an application for product authorisation containing a use of dinotefuran in treated articles, a risk assessment should be performed for that use considering in particular its classification as very Persistent (vP) and Toxic (T).

10. The active substance dinotefuran 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.

2.5. Requirement for further information

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

Palatability studies following accelerated storage of the product to be submitted at the product authorisation stage.

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