Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Hexaflumuron

Product type: 18

ECHA/BPC/31/2014

Adopted

3 December 2014

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance Hexaflumuron 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 approval in product type 18 of the following active substance:

Common name:	**Hexaflumuron**
Chemical name(s):	**1-[3,5-dichloro-4-(1,1,2,2-tetrafluoroethoxy)phenyl]-3-(2,6-difluorobenzoyl)urea**
EC No.:	**401-400-1**
CAS No.:	**86479-06-3**
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 DowAgroSciences on 26 April 2006, the evaluating Competent Authority Portugal submitted an assessment report and the conclusions of its evaluation to the Commission on 18 July 2011. 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 10 February 2014, 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 11 April 2014.

Adoption of the BPC opinion

Rapporteur: BPC Member for Portugal

The BPC opinion on the approval of the active substance hexaflumuron in product type 18 was adopted on 3 December 2014.

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.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the active substance hexaflumuron 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 Hexaflumuron in product type 18. Hexaflumuron acts by inhibition of chitin synthase enzymes preventing proper chitin deposition in the cuticle and other chitin depended systems of the termite; is an insect growth regulator in the benzyl urea class. 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 in soil, sediment and water.

Hexaflumuron has no entry in Annex VI of the Regulation (EC) No 1272/2008 (CLP Regulation) therefore there is no harmonised classification for this substance. Portugal has submitted a harmonised classification and labelling proposal for hexaflumuron to ECHA on 28 November 2014.

The proposed classification and labelling for hexaflumuron, under consideration by RAC, according to the CLP Regulation is:

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Aquatic Acute; 1 H400 Aquatic Chronic;1 H410
Labelling	
Pictograms	GHS09
Signal Word	Warning
Hazard Statement Codes	H410: Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	M = 1000 for Aquatic Acute M= 10 000 for Aquatic Chronic

b) Intended use, target species and effectiveness

Hexaflumuron is intended to be used by professionals in products to control termites. The data on Hexaflumuron and the representative biocidal product have demonstrated sufficient efficacy against the target species including, though not exclusively: *Reticulitermes* species, *Coptotermes* species and *Heterotemes* species.

Despite the fact that the potential for development of resistance in subterranean termites is considered extremely low, the possibility of the development of cross-resistance or specific resistance to Hexaflumuron cannot be discounted. Strategies to reduce the risk of resistance developing can be implemented at product authorisation.

Hexaflumuron is formulated in solid cellulose baits and is used in two types of tamper resistant bait stations – wall mounted (indoors) and below ground (outdoors). Wall stations are glued and screwed into the walls and can only be opened with a screw driver; ground stations are locked and can only be opened using a dedicated tool.

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

Human health
Increased methemoglobin after repeated exposure was the major finding in all studies and considered as the critical adverse effect for the risk assessment and NOAEL setting.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios		
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**
Installation	Primary exposure: Operator installs bait station. (i.e. mixing & loading of bait)	Professionals
Inspection	Primary exposure: Operator inspects bait station	Professionals
De-installation	Primary exposure: Operator removes bait from bait station	Professionals
Mouthing of poison bait	Secondary exposure: Oral exposure to infant by mouthing of poison bait.	Bystanders (infants)
Accidental ingestion	Secondary exposure: Oral exposure to infant by ingestion of unsecured bait.	Bystanders (infants)
Accidental dermal contact	Secondary exposure: Short-term dermal exposure with bait	Bystanders (infants, children & adults)

Primary exposure assessment for professionals
The relevant professional scenario used for exposure assessment is "Professionals who handle and dispose of the product (installation, inspection and de-installation of in-ground and above ground stations). Safe use was identified with the use of gloves for all tasks.

Secondary exposure assessment
A reverse reference scenario was used as a Tier 1 Assessment for short-term dermal exposure to infant, child or adult that come into contact with the bait and are dermal exposed. However, since the above ground station comtaining the product consists of a rigid plastic housing containing the bait matrix package and this tamper resistant closed bait station is fixed by screws and glued to the wall, such an exposure is unlikely to occur and the risk is considered mitigated.
The scenario used to assess infant acute exposure by mouthing of poisoning bait was similar to that used in rodenticides (PT14) bait box scenario listed in the TNsG, part 3, Appendix 7.2.1. Similarly to the dermal exposure, mouthing and accidental ingestion is unlikely to occur due to the design of the bait station and therefore risks are considered mitigated.

Nonetheless, it is recommended to label the product with "Keep out of reach of children".

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Outdoor application by professionals in bait systems	emission to fresh surface water, soil, and solid waste
Indoor application by professionals in bait systems	emission to air indoors and outdoors, solid waste, and waste water

The vast majority of hexaflumuron released to the environment is predicted to be in the soil compartment. The sediment and suspended sediment are predicted to contain very low1% amounts of hexaflumuron released to the environment, respectively. Surface water, fish, and air are predicted to contain even lower amounts of hexaflumuron.

Since hexaflumuron is applied as a bait formulation and is almost immobile in soil, exposure would be limited to a small area in the close vicinity of the treated buildings.

The emissions from placement of the baits indoors will be negligible. The reasons for such a low indoor emission are that 1) the vapour pressure of hexaflumuron is extremely low, severely limiting the amount of hexaflumuron that could be found in air, 2) partially consumed baits are collected by the professional applicator for eventual incineration. Therefore, there will be negligible release or almost no release to the sewage treatment plant (STP). Furthermore, model calculations have confirmed that only very low amounts of the hexaflumuron present in the environment will be in the air compartment.

There is no difference between indoor or outdoor application, since the termites do not live indoors and the colony is outdoors either around or underneath a structure. The active substance will enter the environment less by emissions from the baits but by the termites itself. A large, mature colony will consume a very low amount of hexaflumuron before the colony is eliminated. A smaller colony, either due to colony age or termite species, will consume even less hexaflumuron before the colony is eliminated. Additionally, the termites would die throughout the foraging area of the colony.

The risk assessment for non compartment specific effects relevant to the food chain (secondary poisoning) has been conducted with the conclusion that hexaflumuron is not expected to enter the food chain.

Considering the small amounts involved, the emission via the termites is very low. Nevertheless, it was proposed that the product should be designed in such a way that the exposure of hexaflumuron to the environment will be negligible by using confined termite bait stations.

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
	Mutagenicity (M)	no classification required
	Toxic for reproduction (R)	no classification required
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	vP
	Bioaccumulative (B) or very Bioaccumulative (vB)	vB
	Toxic (T)	T
Endocrine disrupting properties	hexaflumuron is not considered to have endocrine disrupting properties	

Consequently, the following is concluded:

Hexaflumuron does meet the exclusion criteria laid down in Article 5(1)(e) of Regulation (EU) No 528/2012 by being very persistent (vP), very bioaccumulative (vB) and toxic (T).

Hexaflumuron does meet the conditions laid down in Article 10(1)(a) of Regulation (EU) No 528/2012, and is therefore considered as a candidate for substitution by meeting one exclusion criteria.

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 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).

During public consultation 1 confidential and 19 non-confidential comments were received from third parties. Comments included information on the availability of alternative active substances and on the essentiality of the active substance hexaflumuron for the use of termite control. In addition, there are several other active substances already approved, or reviewed by the BPC, which have been evaluated for the same product type.

2.2.2. POP criteria

Hexaflumuron fulfils the criteria for being vP, vB and T. However hexaflumuron does not demonstrate the potential for long range transport. In view of this, hexaflumuron does

[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)

not meet the criteria for being a persistent organic pollutant.

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

In view of the conclusions of the evaluation, it is proposed that hexaflumuron 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 984 g/kg.

2. Hexaflumuron is considered a candidate for substitution in accordance with Article 10(1)(a) 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 an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

4. For professional users, safe operational procedures and appropriate organizational 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.

5. As hexaflumuron is considered to be very persistent, very bioaccumulative and toxic exposure of non-target animals and the environment should be minimised by considering and applying all appropriate risk mitigation measures. These include the restriction to professional use only and the obligation to use confined bait stations.

Hexaflumuron 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. The active substance Hexaflumuron 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. 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.

3. The potential resistance of target insects to hexaflumuron is low but 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 authorisation holder and professional end-users shall report any observed

resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management.

5. 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: ”Keep out of reach of children”.

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 hexaflumuron.

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