Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Clothianidin

Product type: 18

ECHA/BPC/026/2014

Adopted

2 October 2014

Opinion of the Biocidal Products Committee

on the application for approval of the active substance clothianidin 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:	**clothianidin**
Chemical name(s):	**(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2- Nitroguanidine**
EC No.:	**433-460-1**
CAS No.:	**210880-92-5**
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 Sumitomo Chemical Company Ltd., United Kingdom on 28 April 2006 and 29 April 2006, the evaluating Competent Authority Germany submitted a Competent Authority Report (CAR) to the Commission on 27 May 2009. In order to review the CAR and the conclusions of the evaluating Competent Authority, the European Commission organised consultations via the Technical Meeting II/2010. Revisions agreed upon were presented and the CAR was 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/fi/addressing-chemicals-of-concern/biocidal-products-regulation/potential-candidates-for-substitution-previous-consultations 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 Germany

The BPC opinion on the approval of the active substance clothianidin in product type 18 was adopted on 2 October 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 clothianidin 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 clothianidin in product type 18. Clothianidin belongs to the chemical class of insecticides known as neonicotinoids or chloronicotinyls, which interfere with the nicotinic acetylcholine receptors at the postsynaptic membrane. The compound acts agonistically on insect nicotinic acetylcholine receptors located in the central nervous system. Clothianidin has an insecticidal effect by contact and ingestion (systemic insecticide). Specifications for the reference source are established. The specification is covered by all (eco)toxicological studies.

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, for the relevant and significant impurities as well as for its relevant transformation products. Validated analytical methods are required and available for the relevant matrices soil, water, air and plant materials.

The harmonised classification and labelling for clothianidin according to Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, table 3.1 (ATP01, index number 613-307-00-5) is presented in the following table. The M-factor for chronic toxicity was added additionally.

Proposed Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 4 Aquatic acute 1 Aquatic chronic 1
Labelling	
Pictograms	GHS07, GHS09
Signal Word	Warning
Hazard Statement Codes	H302: Harmful if swallowed H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	M-Factors: 10 (acute) and 100 (chronic)

b) Intended use, target species and effectiveness

Products in PT 18 containing clothianidin are intended for use in paint-on formulations for controlling insects such as house flies (Musca spp) in animal housings (professional indoor use, application by spraying and brushing) and for domestic premises (non-professional indoor use, application by brushing on cards).

The data on clothianidin and the representative biocidal product have demonstrated sufficient efficacy against the target species against house and face flies (Musca domestica and Musca autumnalis). Resistance and cross-resistance against neonicotinoids (chloronicotinyls like thiamethoxam, acetamiprid and imidacloprid), a group of insecticides acting agonistically on insect nicotinic acetylcholine receptors (nAChRs) have been found in relevant susceptible pests in Europe.

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

Human health

The evaluation of the active substance has indicated that clothianidin has no carcinogenic and mutagenic potential. Clothianidin exhibits moderate acute oral toxicity and is not acutely toxic after dermal and inhalation exposure. It is not irritating to skin or eye and does not display skin-sensitising potential. Clothianidin is unlikely to affect fertility and developmental parameters in humans at doses below a range that elicits other toxic effects in adults. Neurobehavioral effects observed after oral exposure to clothianidin are consistent with nicotinic CNS-stimulation and depression.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios		
Scenario	**Primary or secondary exposure and description of scenario, exposed group**	**Acceptable/ Unacceptable**
Brushing application in animal housing	Exposed group: Professionals Primary occupational exposure: Product is ready-to-use paste, applied by smearing of the undiluted product to small surface patches on walls, piles, windowsills etc. using a brush during the fly season Scenario 2a: Mixing & loading phase, opening can only Scenario 2b: Application, brushing in animal housing (indoors) Scenario 2c: Post-application, cleaning of the brush by rinsing and squeezing/ disposal	Acceptable without PPE (gloves with a 90% protection factor)

Spraying application in animal housing	Exposed group: Professionals Primary occupational exposure: Product is a paste, diluted in water before low pressure spraying to small surface patches, on walls, piles, windowsills etc. during the fly season Scenario 3a: Mixing & Loading, opening can and diluting biocidal product with water, loading sprayer with biocidal product, priming pump and spray line Scenario 3b: Application, spraying in animal housing (indoors) Scenario 3c: Post-application, unblock spray nozzle and cleaning	Acceptable with PPE
Working in animal housing	Exposed group: Professionals Secondary exposure: Exposure via inhalation of contaminated dust as well as via dermal contact to treated surfaces during cleaning or any other typical work in animal housings	Acceptable without PPE
Acute exposure (internal dose) during application by brushing	Exposed group: Non-professionals (adults and infants) Primary internal exposure, only dermal exposure assessed: Treatment of 20 m^2 using 6 painted patches, 50 ml of product 30 s per patch 15, 5 and 5 min for placing, removal of cards and disposal of emptied cans respectively (28 min in total for acute exposure at one day and 5 times per year)	Acceptable
Medium-term exposure (internal dose) during application by brushing	Exposed group: Non-professionals (adults and infants) Primary internal exposure, only dermal exposure assessed: Worst case assessment by assuming that a non-professional is exposed each day over the whole season of 180 d (e.g treating several different rooms per season, application in the neighbourhood etc.)	Acceptable
Indirect exposure of general public during use	Exposed group: Non-professionals Secondary exposure: Not expected	Acceptable

The risk characterisation for professional use of clothianidin, especially for the spraying scenario, is exclusively triggered by dermal contact. For the potential exposure (without

PPE) the risk characterisation for the brushing scenario and the secondary exposure is of no concern. For the spraying scenario risk characterisation is of no concern only if appropriate protective measures are taken.

The risk due to primary exposure of non-professionals by the use of the biocidal product is in all cases acceptable. Secondary exposure of infants and adults is not expected if the biocidal product is used as intended according to the label instructions.

Residues in food or feed are not expected for the representative uses.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Professional use; Animal housing categories (according to ESD) without poultry	Application by smearing/painting as ready-to-use paste and low-pressure spraying with a water diluted solution Releases via manure to soil, groundwater, surface water and sediment
Professional use; Animal housing categories (according to ESD), poultry included	Application by smearing/painting as ready-to-use paste and low-pressure spraying with a water diluted solution Release via manure and STP to soil, groundwater, surface water and sediment
Non-professional use; household	The product will be coated onto a carrier material. A collecting pan for dead insects will be included in the product, enabling disposal of killed target insects via domestic waste. Releases of the a.s. and/or of the coating from the carrier material are not foreseen. Upon desiccation after a few weeks, the coating may be renewed by the user, as appropriate, using a disposable smearing tool added to the packaging, which shall not be washed out. At the end of its service life, the product (i.e. carrier material including original and possibly supplemented coating, smearing tool) is foreseen to be disposed of via domestic waste.

Based on the available data for the representative product and the results of the risk characterisation no risks for the aquatic compartment were identified with the exception of poultry stables with a wastewater discharge to sewage treatment plants or with a direct release to surface water, where a risk for surface water and sediment was identified.

Furthermore, in case of manure application on agricultural soils (arable land, grassland) the majority of the scenarios show a risk to the soil compartment. These results show that a safe use may exist for the specific animal (sub-) categories beef cattle (cat. 2) and laying hens battery - belt drying (cat. 8), only. However, it is concluded that a label restriction is necessary preventing the use of products containing clothianidin in animal housings where exposure to the STP or surface water occurs. This is also the case for laying hens battery - belt drying (cat. 8).

Consequently, the authorisation of biocidal products containing clothianidin against flies in animal housings has to be restricted to animal category 2 (beef cattle) unless data are provided at product authorisation showing that a safe use also exists for other animal categories.

Considering the prospective intended use for control of flies in domestic premises (e.g. product is coated on carrier material, disposal of the carrier material including original and possibly supplemented coating and smearing tools via domestic waste) it was concluded that due to the intended application practice laid down by the applicant the exposure to the environment is negligible. Therefore, no risk characterisation for clothianidin as a "household insecticide" has been carried out. As conclusion, no risk for the environment is expected.

As clothianidin is a systemic insecticide and has been shown to be highly toxic to bees, a risk assessment for bees was performed. As currently no harmonized scenario is available, the assessment was based on a comparison of the $PNEC_{bee}$ and the PEC_{soil}. As a worst-case approach it was assumed that the concentration in nectar and pollen is equivalent to the concentration in soil, i.e. a 100 % uptake of clothianidin from soil by plants and a 100 % transfer in nectar and pollen occurs. For the assessment the highest PEC_{soil} values for arable land and grassland was used. The PEC/PNEC values for bees are below one. Therefore, it can be concluded that manure application contaminated with clothianidin to arable land as well as grassland will pose no risk to bees exposed to clothianidin via nectar and pollen. However, as currently no agreed concept for the assessment of the risk to bees is available, at product authorisation a revised risk assessment for bees might be necessary using the agreed assessment concept if available.

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)	not B or vB
	Toxic (T)	T
Endocrine disrupting properties	Clothianidin is not considered to have endocrine disrupting properties	

Consequently, the following is concluded:

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

Clothianidin 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 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"

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[1]. 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 and d).

No comments were received during public consultation. 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

Clothianidin fulfils the criteria for being a vP substance. It is neither B nor does it show a potential for long range transport. Hence, clothianidin does not meet the criteria for being a persistent organic pollutant.

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

In view of the conclusions of the evaluation, it is proposed that clothianidin 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: 93 % w/w

2. Clothianidin is considered a candidate for substitution in accordance with Article 10 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 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[2] or Regulation (EC) No 396/2005[3] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

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

6. Products shall not be authorized for uses in animal housings where exposure to a STP or direct emission to surface water cannot be prevented, unless data are submitted demonstrating that the product will meet the requirements of Article 19 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

7. Due to the risks identified for the soil compartment, products shall not be authorized for uses in animal housings others than for beef cattle, unless data are submitted demonstrating that the product will meet the requirements of Article 19 and Annex VI, if necessary by the application of appropriate risk mitigation

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

measures.

The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012 as it is fulfils the substitution criteria and is toxic to aquatic life of acute category 1.

2.4. Elements to be taken into account when authorising products

1. The active substance clothianidin 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. E.g. if the product claim includes use in stables and animal houses also efficacy against stable flies (*Stomoxys calcitrans*) should be tested.

3. The potential resistance of target insects to clothianidin 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. Good sanitation procedures and all other measures that prevent infestations from developing (i.e. non-chemical measures) have to be established.

    b. Products should always be used in accordance with label recommendations, in terms of dose to be applied and treatment intervals. The effective dose must be applied and no higher or lower doses.

    c. Treatments should be alternated with products with different modes of action, i.e avoid rotating different neonicotinoids.

    d. Levels of effectiveness should be monitored (periodic checks), and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refugia can contribute to the risk of re-infestation.

    e. In cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product with the same mode of action especially neonicotinoids should be avoided.

    f. If signs of resistance begin to appear (as indicated either by control failures or through the test procedure) then every effort should be made to eradicate the population. The measures necessary for eradication will vary in different situations; they may involve a number of procedures using both chemical and non-chemical measures.

4. Residues in food and feed are not expected. However, this assumption may not be true for biocidal products other than the representative product. Therefore, at product authorisation level a dietary risk assessment has to be conducted according to agreed guidance. In case the use leads to residues, analytical methods for food and feed must be provided.

5. As clothianidin is a neonicotinoid and only a very limited non-professional use (indoor, brushing on cards with disposal only to domestic waste) has been assessed for this substance, special attention needs to be paid to bees at the product authorisation stage. This especially applies to biocidal products for non-professional use with different use patterns (e.g. spray application, outdoor use).

Furthermore, as currently no agreed concept for the assessment of the risk to bees is available, at product authorisation a revised risk assessment for bees might be necessary using the agreed assessment concept if available.

6. For products intended for use in domestic premises, emissions to the STP shall be addressed in line with the OECD Emission Scenario Document (ESD) No. 18. If unacceptable risks occur for any environmental compartment, labels and, where provided, safety data sheets of products for use in domestic premises shall indicate that the smearing tool must not to be cleaned by washing. Information must be provided that the smearing tool as well as the carrier material, including original and possibly supplemented coating, must be disposed via the domestic waste to prevent any emissions to the sewer.
7. OECD ESD No. 18 is being revised. At product authorisation the revised ESD, if available, has to be considered.

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 clothianidin.

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