Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Triflumuron

Product type: 18

ECHA/BPC/45/2015

Adopted

3 February 2015

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance Triflumuron 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, the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 18 of the following active substance:

Common name:	**Triflumuron**
Chemical name:	**1-(2-chlorobenzoyl)-3-(4-trifluoromethoxyphenyl) urea**
EC No.:	**264-980-3**
CAS No.:	**64628-44-0**
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 (AR), 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 Bayer Environmental Science AG on 30th April 2006, the evaluating Competent Authority Italy submitted an assessment report and the conclusions of its evaluation to the Commission on 30 September 2008. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-6, BPC-7 and BPC-9) and its Working Groups and the Commission via the Biocides Technical Meetings (TMIII2011; TMII2012). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: BPC member for Italy

The BPC opinion on the non-approval of the active substance Triflumuron in product-type 18 was reached on 3 February 2015.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that Triflumuron in product type 18 may not be approved.

2. BPC Opinion

2.1. BPC 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 Triflumuron in product type 18. Triflumuron belongs to the chemical class of benzoylphenylureas (BPUs). Triflumuron is a broad spectrum insect growth regulator (IGR) that inhibits the synthesis of chitin and acts on insect larvae. Specifications for the reference source are established.

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

Validated analytical methods are available for the active substance as manufactured and for significant impurities. Validated analytical methods are required and are available for the relevant matrices soil, air and water, but additional validation data are still required.

No harmonised classification exists for Triflumuron under the CLP Regulation. The evaluating Competent Authority (Italy) intends to submit the following harmonized classification proposal to ECHA.

Classification according to Regulation 1272/2008	
Hazard Class and Category Codes Hazard Statement Code(s)	Aquatic Acute 1 H400 Aquatic Chronic 1 H410
Labelling	
Signal Word	Warning
Hazard Statement Codes	H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects
M-Factors	M = 100
Precautionary Statement Codes	P273: Avoid release to the environment. P391: Collect spillage P501: Dispose of contents/container to …
Justification for the proposal	
Triflumuron is not readily biodegradable.	

b) Intended use, target species and effectiveness

Triflumuron is an insecticide, for the control of the house fly (*Musca domestica*) and litter beetle (*Alphitobius diaperinus*) indoors for professional users, in livestock and poultry houses. It is applied to locations in livestock and poultry houses where insects breed such as litter, the surface of manure, cesspools and bedding materials. The data on Triflumuron and the representative biocidal product have demonstrated sufficient efficacy against the target species. Cases of resistance in house fly (*Musca domestica*) have been recorded. Triflumuron is intended to be used by means of two different application methods: spraying and watering can. The latter is used only in small farms therefore can be considered as a "marginal use".

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

Human health

The table below summarises the exposure scenarios assessed.

Summary table scenarios		
Scenario	**Primary or secondary exposure Description of scenario**	**Exposed group**
Spray application (including mixing and loading phase)	Primary exposure: application of 5 g/l (0.5%) in-use solution Tier 1: without PPE and RPE Tier 2: with PPE (gloves and impermeable coveralls with a protection factor of 95%) and RPE (masks with a protection factor of 90%)	Professionals
Watering can application	Primary exposure: application of 5 g/l (0.5%) in-use solution Tier 1: without PPE Tier 2: with PPE (gloves and coated coveralls with a protection factor of 80%)	Professionals
Post-application	Secondary exposure: Spraying treatment	Bystanders (Calves; Laying hens)

Risks following exposure to triflumuron as formulated in the biocidal product were unacceptable in the absence of suitable Personal Protective Equipments (PPEs) and/or Respiratory Protective Equipment (RPE).

For the spray application, a safe use was demonstrated when PPE (gloves and impermeable coveralls ensuring a high degree of protection against heavy contamination *i.e.*, protection factor of 95%) and RPE (mask with a protection factor of 90%) are worn.

For the watering can application, a safe use was also demonstrated when professional users wear gloves and coated coveralls with a protection factor of 80%. RPE was not necessary.

Due to the use of triflumuron-based products in animal housing a dietary risk assessment is required. However, guidance on how to undertake such an assessment is under development and therefore, this can only be considered at a later stage once the guidance is available.

Environment

The table below summarises the exposure scenarios assessed.

Summary table scenarios	
Scenario	**Description of scenario**
Spray application (including mixing and loading phase)	Application to the floor area (2 g formulation/m^2) of animal houses as a course spray used to treat areas where flies or other insects may lay eggs.
Watering can application	Application of 5 g/l (0.5%) in-use solution. The biocidal product is intended as insecticide for treatment to manure inside animal houses at a dose rate of 0.5 g active substance per m^2. No harmonized scenario for the watering can application is available. According to the use description provided by the applicant, the watering can application is only used in small stables. In the exposure assessment, the scenario with the smallest stable surface (160 m^2 animal houses for veal calves) provided in the Emission Scenario Document (ESD) for PT 18 was used.
Treatement of manure heaps in poultry farms with laying hens in battery cages with aeration followed by composting	Treatment with Triflumuron occurs in the manure storage room, where the product is applied directly to the manure heaps. Due to the heat of the compost process inside the manure heap, the development of fly maggots is possible only around the bottom of the heap, and treatment is therefore made to a 0.5 m wide band around the base of the manure.
Post-application	Following use of the formulated product in an animal house, potential exposure of the active substance to soil could arise via land applications of manure following storage. Subsequent leaching from affected areas could then result in loadings to groundwater. In line with the emission scenario outlined in the ESD, following use of the formulated product in animal houses and subsequent land application of manure, exposure of the active substance to surface water could potentially occur as a result of run-off from the land treated with manure.

The risk characterization is based on exposure scenarios dealing with the spraying application, the watering can application and treatment of manure heaps in poultry farms with laying hens in battery cages with aeration followed by composting.

Risk characterization for Triflumuron

Terrestrial compartment including groundwater

Spraying application
For the spraying application, unacceptable risks for the soil compartment post-application were identified following use of Triflumuron in animal houses.

Watering can application
As concerns the watering can application, unacceptable risks for the soil compartment post-application were identified.

Treatement of manure heaps in poultry farms with laying hens in battery cages with aeration followed by composting
Acceptable risks were identified for the soil compartment only when Triflumuron is applied once per year and the resulting manure is applied to arable land. More applications per year or if the resulting manure is applied to grassland lead to an unacceptable risk. In addition, the composting of the manure heaps must include a hot phase.
The composting process is complex and a distinction can be made between two phases: an initial, 'hot' phase with elevated temperatures created by the heat during the aerobic, microbial decomposition of organic matter, followed by a secondary, 'curing' phase at ambient temperatures.

No risk unacceptable risk was identified for the groundwater compartment for any assessed application type.

Aquatic compartment

Spraying application
For the sediment and surface water compartments, an unacceptable risk has been identified for all the identified scenarios following the grassland application. As far as the application on arable land is concerned, an unacceptable risk has been identified for the scenarios related to all animal categories except for the scenario concerning beef cattle housed during the grazing season.

Watering can application
The risks to the aquatic compartment are not acceptable.

Treatment of manure heaps in poultry farms with laying hens in battery cages with aeration followed by composting
Acceptable risks have been identified for surface water and sediment.

Secondary poisoning

Triflumuron does not present a risk for secondary poisoning in the environment for any assessed application type.

Risk characterization for metabolites

Spraying application
Concerning the metabolites, an unacceptable risk was identified in surface water. No unacceptable risk was identified in the sediment or in the soil compartment.

Watering can application
No unacceptable risks were identified for metabolites.

Treatement of manure heaps in poultry farms with laying hens in battery cages with aeration followed by composting

Regarding metabolites, no unacceptable risks were identified in any compartment with or without composting including or not a hot phase.

Conclusion

With regard to the environmental risk assessment the following can be concluded:

- For the spraying and watering can application unacceptable risks are identified for several compartments for triflumuron as well as for the metabolites. Consequently, these applications cannot be regarded as safe uses. No risk mitigation measures can be applied to refine these unacceptable risks.
- For the treatment of manure heaps in poultry farms with laying hens in battery cages with aeration followed by composting the use is considered too limited for approval because:
    - The risk is acceptable only for one application per year. Because the active substance degrades in manure re-colonisation is possible when the concentrations drop below efficacious levels. Re-application with the same substance or a substance with a similar action acting on insect larvae is therefore required considering that flies rapidly develop from egg to adult (the default value used in similar evaluations according to the "Emission Scenario Document for Insecticides for stables and manure Storage System" is 4). Therefore one application per year is not realistic.
    - The risk is acceptable only if a hot phase is assumed in the composting process. It cannot be guaranteed that this will occur in practice in poultry farms. For other active substances no unacceptable risks were identified without including the hot phase.
    - The risk is acceptable only if the resulting manure is applied to arable land. It cannot be guaranteed that in practice the resulting manure will not be applied to grassland.

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		Conclusion
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)	not P
	Bioaccumualtive (B) or very Bioaccumulative (vB)	not B
	Toxic (T)	T
Endocrine disrupting properties	Triflumuron is not considered to have endocrine disrupting properties	
Respiratory sensitisation properties	No classification required	

Consequently, the following is concluded:

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

Triflumuron does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

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).

2.2.2. POP criteria

Triflumuron is considered T. Triflumuron was concluded to be neither P nor B. No potential for long-range environmental transport is expected. Subsequently, it is concluded that Triflumuron does not meet the POP criteria.

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

In view of the conclusions of the evaluation, that:

1. for the spraying and watering can application unacceptable risks, which cannot be mitigated, are identified for several compartments for triflumuron as well as for the metabolites. Consequently, these applications cannot be regarded as safe uses;

2. for the treatment of manure heaps in poultry farms with laying hens in battery cages with aeration followed by composting the limitations for the risks to be acceptable are not realistic and therefore the conditions of use for the biocidal product cannot be considered representative;

it is concluded that biocidal products containing Triflumuron as an active substance may not be expected to meet the criteria laid down in point (b) of Article 19(1)(b)(iv). Subsequently, it is proposed that Triflumuron shall not be approved and included in the Union list of approved active substances.

Triflumuron meets the criteria for classification according to Regulation (EC) 1272/2008 as toxic to aquatic life of acute category 1. Therefore, Triflumuron does not meet the conditions in Article 28(2) to allow inclusion in Annex I of Regulation (EU) 528/2012.

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[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)