

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the single biocidal product:

Hokoex

ECHA/BPC/297/2021

Adopted

14 October 2021

Opinion of the Biocidal Products Committee

on the Union authorisation of Hokoex

In accordance with Article 44(3) 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 Union authorisation of:

Name of the biocidal product:	Hokoex
Authorisation holder:	Hokochemie GmbH
Active substances common name:	Cyromazine
Product type:	PT 18

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority (eCA).

Process for the adoption of BPC opinions

Following the submission of an application on 12 December 2017, recorded in R4BP3 under case number BC-TH035808-24, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 25 March 2021. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-40) and its Working Groups (WG II 2021). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Switzerland

The BPC opinion on the Union authorisation of the biocidal product was reached on 14 October 2021.

The BPC opinion was adopted by consensus.

The opinion is published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the single biocidal product is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012, as defined in Article 3(r).

The single biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore may be authorised for the uses specified in this opinion. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of Hokoex referred to in Article 22(2) of Regulation (EU) No 528/2012.

2. BPC Opinion

2.1 BPC Conclusions of the evaluation

a) Summary of the evaluation and conclusions of the risk assessment

General

Hokoex is a PT18 biocidal product containing the active substance cyromazine (2% w/w). Hokoex was evaluated as representative product during active substance approval. The active substance cyromazine is not a candidate for substitution. The product does not contain any substances of concern. None of the co-formulants are expected to have endocrine disrupting properties. One co-formulant needs to be considered as a nanomaterial and a corresponding product label is required.

The biocidal product Hokoex is formulated as water soluble granules. The uses applied for by the applicant are the following (see section 2.2.1 of the PAR for a full description of the intended uses as applied for by the applicant):

Use No.	User	Application method	Use description
1	Professionals	Spraying or pouring of product dissolved in water, direct dispersal of granules	<p>Larvicide to control nuisance and biting flies in professional livestock:</p> <p>Indoors for use in housings of all types of animals (pigs, cattle, horses, poultry, sheep, goats, rabbits, mink farms, zoological gardens) in places where manure and / or other excrements are not compressed.</p> <p>Outdoors in slurry reservoirs and on manure heaps.</p>
2	Non-professionals	Spraying of product dissolved in water, direct dispersal of granules	<p>Larvicide to control nuisance and biting flies in animal husbandry:</p> <p>Indoors in housings of animals not destined for food production (horses, sheep, goats, rabbits, ferrets, and mink).</p>

Use No.	User	Application method	Use description
			Outdoors on manure heaps and in slurry tanks.
3	Professionals	Spraying of product dissolved in water, direct dispersal of granules	<p>Larvicide to control nuisance flies in waste management facilities:</p> <p>Application indoors and outdoors on waste management facilities contaminated by organic matter.</p> <p>Waste transfer stations, landfill sites, MBT (mechanical biological treatment) facilities, composting sites.</p>
4	Professionals	Spraying of product dissolved in water, direct dispersal of granules	<p>Prevention of flea infestation in mink farms:</p> <p>Indoors (mink farms are half-open spaces), application to mink nests.</p>

Physico-chemical properties

Hokoex is formulated as water soluble granules. The granules are white and free flowing with a particle size that lies mostly in the range of 1-4 mm. The biocidal product was stable for 14 weeks at 54±2°C in a glass bottle with screw cap and for 60 months at 20±2°C in polypropylene containers. The technical characteristics of the biocidal product remained unchanged during storage. The container was stable. A shelf life of 60 months (5 years) is proposed.

Wettability of the product is acceptable. The product is freely flowable, nearly dust free and attrition resistance is acceptable. The product dissolves readily in water and forms stable solutions; it does not foam when dissolved in water. The product is not intended for use together with other products.

The effects of light and humidity on the stability of the biocidal product have not been investigated. Therefore, the following label instructions are required:

- *Do not expose to direct sunlight;*
- *Store in a dry place and protect from humidity.*

The biocidal product was assessed with regard to physical hazards. The product is not explosive, not flammable and has no oxidising properties. No self-ignition occurred in the tested range of 25-400°C.

Based on the physicochemical and technical properties and the assessment of physical hazards, no classification of the biocidal product is required.

A validated analytical method for the quantification of the active substance cyromazine in the biocidal product is available. Validated analytical methods for the monitoring of residues in soil and food are available. Monitoring methods for air and water were submitted as post approval requirements to the eCA of the active substance. Analytical methods for the monitoring of residues of cyromazine in body fluids and tissues is not required since cyromazine is not considered toxic or highly toxic.

A validated analytical method for the monitoring of melamine in soil is available. Monitoring methods for melamine in water were submitted as post approval requirements to the eCA of the active substance.

Efficacy

It is concluded that the biocidal product Hokoex is sufficiently effective to control nuisance and biting flies in animal housings by scattering granules, spraying, and pouring. Further, Hokoex is considered to be sufficiently effective in waste management facilities (indoors in mechanical-biological treatment facilities contaminated by organic matter and at composting sites) by spraying to control nuisance flies.

All outdoor uses, the indoor use in waste transfer stations where general waste is treated ("indoors in reception pits of waste transfer stations"), and the use against fleas in mink farms were not sufficiently supported by efficacy studies and were, thus, removed from the authorised uses.

For all approved applications, the product has to be applied at an application dose of 25 g/m². If the organic substrate is dry, the methods pouring or spraying should be applied to assure efficacy.

According to the CAR of cyromazine and supported by literature, the use of cyromazine applied directly to fly-breeding sites may entail a risk of resistance development. Therefore, general resistance management measures are proposed in the SPC.

Human health

General

Human health effects assessment of the biocidal product Hokoex is based on available animal studies already assessed in the CAR of cyromazine as Hokoex is identical to the representative product. Hokoex is not classified for human health endpoints. It does not contain a substance of concern. The metabolite Melamine (formed during degradation in soil and potentially found in groundwater) is considered toxicologically relevant due to its classification by RAC in December 2020 as "carcinogenic category 2" (H351). However, the recent classification proposal by RAC did not change the tolerable daily intake (TDI). As the toxicological reference dose (TDI) for the metabolite melamine is 0.2 mg/kg bw (compared to the ADI of 0.06 mg/kg bw/d for cyromazine), only cyromazine is considered for the dietary risk evaluation of Hokoex.

Primary exposure to Hokoex was assessed for professional and non-professional users when using the product in animal housings indoors and outdoors on manure heaps and in slurry tanks. Further, exposure was assessed for professionals in waste management facilities.

Secondary exposure was assessed for the general public to spray drift and when reentering treated areas.

(i) Professional users

The risk assessment suggests that no adverse systemic effects are expected for the professional users when gloves are used during mixing and loading operations and during the manual dry scattering of the product.

No adverse systemic effects are expected for the professional users when gloves and a coated coverall are used during the application with watering can.

For the spraying application, the risk for professional users is acceptable when gloves and a coated coverall are used during the application and when the area treated is limited to 600 m² per day per user. The cleaning of the spray equipment or the watering can that follows on the same day must also be carried out while wearing gloves and a coated coverall. No PPE are prescribed during the application by mechanical scattering of granules in waste management facilities (this application method was not authorized due to efficacy reasons).

The following risk mitigation measures (RMMs) are implemented:

- *During the handling of the pure product (manual dry scattering and mixing and loading): wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information);*
- *During the application of the diluted product by spraying or with a watering can and during the cleaning of the spray equipment or watering can: wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and coated coveralls;*
- *The area treated by spraying must be limited to 600 m² per day per user;*
- *Adapt the nozzle and the pressure of the spray equipment to ensure a minimum application rate of 1 L/min;*
- *Use disposable protective coveralls (at least type 6, EN 13034).*

(ii) Non-Professional users and general public

The risk for human health during application of Hokoex by scattering granules and spraying is acceptable for non-professional users if sturdy footwear/boots is worn during the application of the product. As the models for scattering granules consider some kind of device (e.g. shaker) to spread granules, a measuring and scattering device should be included in packaging for non-professional users. The secondary exposure (general public) to spray drift is acceptable for adults and children.

The scenario rubbing-off and mouthing is unacceptable for toddlers. The following risk mitigation measure (RMM) is implemented:

- *For use only in areas that are inaccessible to children.*

Pets are covered by the risk assessment for animal health, there are no risks to pets.

(iii) Dietary risk assessment

Considering the use of the biocidal product and the use-specific risk mitigation measures in place, i.e.

- *Do not apply directly on animals.*
- *Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.*
- *Do not store near food, drink and animal feedingstuff.*

direct exposure of food, feed, drinking water and food producing animals is not foreseen. However, transfer of cyromazine into food via secondary livestock exposure or the spreading of treated manure on fields on which food or feed are grown, cannot be excluded. As a consequence, the dietary exposure via livestock exposure and via transfer of cyromazine into food/feed crops was assessed.

Following refined calculation, the worst-case consumer exposure (WCCE) does not exceed 30 % of the acceptable daily intake (ADI) of cyromazine. Hence, no formal maximum residue level (MRL) assessment is triggered according to the guideline of the European Medicines Agency (EMA).

It should be noted that according to the estimation of livestock exposure, the existing default MRLs of 0.01 mg/kg for products of animal origin according to Regulation (EU) No. 396/2005 are exceeded for almost all evaluated livestock animal species. However, Swiss food monitoring data from the years 2014 – 2018 comprising a range of animal species and products, as well as monitoring data of veterinary medicinal product residues from the EU analyzing for cyromazine support the expectation that product use according to the label instructions does not lead to undue cyromazine residues in food from animal origin.

The corresponding assessment supports the assumption, that relevant cyromazine residues in food and feed as a consequence of the uptake from contaminated manure are not expected.

Animal Health

No risk for animal health is expected except for chicks. In contrast to hens, for chicks also the dermal exposure pathway has to be considered, increasing exposure compared to adult animals. The corresponding assessment concluded that an unacceptable health risk cannot be excluded for chicks. Consequently, the following risk mitigation measure, applicable to all modes of product application, was introduced:

- *Do not use in breeding stations or other breeding areas for chicks.*

Environment

The environmental risk assessment was based on the environmental effect and fate data in the CAR of cyromazine. No further information on environmental effects and environmental fate was required for the assessment of the intended uses for the biocidal product Hokoex.

With regard to the environment, the biocidal product Hokoex is classified as Aquatic chronic Cat. 3, the following hazard statement is required: H412 (Harmful to aquatic life with long lasting effects)

The environmental risk assessment was performed for the active substance cyromazine and its metabolite melamine. As a consequence of its classification by RAC in December 2020 as Carc. Cat. 2 (H351) and STOT RE 2 (H373), melamine was considered as a toxicologically relevant metabolite, when following the SANCO Guidance Document (Sanco/221/2000-rev.10-final, 25 February 2003). Therefore, the concentration of melamine in groundwater was compared against the trigger value of 0.1 µg/L according to paragraph 68 of Annex VI of Regulation (EU) No 528/2012.

The product does not contain any substance of concern for the environment.

Use 1 (Larvicide to control nuisance and biting flies in professional livestock):

Risk for the environment is acceptable when Hokoex is applied by professional users via dry scattering in animal housings of the following animal categories. The acceptable number of maximum biocidal applications per fly season differs among the animal main categories:

- 5 applications: Non-chicken poultry: turkeys, ducks, geese; and rabbits*
- 4 applications: Dairy cows; sheep and goats*
- 2 applications: Beef cattle and veal calves; and horses*
- 1 application: Pigs: sows in individual pens; sows in groups, and fattening pigs*

Risk for the environment is not acceptable for fly treatment by scattering in chicken and broilers housings, and in zoological gardens.

Risk for the environment is acceptable when Hokoex is applied by professional users via spraying and pouring in animal housings of all animal sub-categories 1 to 18 as well as for rabbits, horses, sheep and goats. However, the acceptable number of maximum biocidal applications per fly season differs among the animal main categories:

- 5 applications: Dairy cows; sheep and goats; non-chicken poultry: turkeys, ducks, geese; and rabbits*
- 4 applications: Beef cattle and veal calves; and horses*
- 2 applications: Pigs: sows in individual pens, sows in groups, and fattening pigs*

1 application: Chicken and broilers (battery cages and free range)

For the animal category chicken and broilers, risk for surface water and sediment is not acceptable when the housing is connected to the STP. The following RMM is required:

"Do not use in animal housings where exposure to a sewage treatment plant or direct emission to surface water cannot be prevented."

Risk for the environment is acceptable for fly treatment at mink farms *with maximum one application per year. Risk for the environment is not acceptable for fly treatment by spraying and pouring in zoological gardens.*

The maximum number of applications per year per animal category are defined in the section "use-specific instructions for use" of the SPC.

Use 2 (Larvicide to control nuisance and biting flies in animal husbandry):

Risk for the environment is acceptable when Hokoex is applied by non-professional users by dry scattering or spraying in housings of horses, sheep and goats, ferrets, and rabbits. The maximum number of applications per year was determined via read-across from the assessment of use 1.

Use 3 (Larvicide to control nuisance flies in waste management facilities):

Application at composting sites

Risk for the environment is acceptable when Hokoex is applied indoors by dry scattering or spraying at composting sites.

Application indoors in mechanical biological treatment facilities:

Unacceptable risks to aquatic and terrestrial compartments were identified when Hokoex is applied indoors by spraying on incoming waste in reception pits of mechanical-biological treatment sites. The risk can be reduced to acceptable level with the following risk mitigation measure:

"Application only with disposable coverall."

"Any losses of the product into water collected in the reception pit should be disposed as hazardous waste."

"Treat waste only indoors at mechanical-biological treatment sites."

"Waste treated indoors should not be stored outdoors."

The first RMM is integrated in the RMM for protective clothing for professional users. The second RMM serves to prevent any discharge of accumulated and contaminated water to the sewer.

In addition, the indoor use at waste transfer stations and the general outdoor use at waste management facilities were removed from the authorised uses because according to the conclusion of the EFF WG-II-2021, efficacy was not sufficiently demonstrated for this use.

And finally, the last RMM serves to prevent any potential discharge to the environment from the outdoor storage of indoor treated waste.

Authorised uses

Based on the conclusions of the assessment of the biocidal product Hokoex, the following uses can be authorized (a full description of the authorised uses is provided in the SPC):

Use No.	User	Application method	Use description
1	Professionals	Spraying or pouring of product dissolved in water, direct dispersal of granules ¹	<p>Larvicide to control nuisance and biting flies in professional livestock:</p> <p>Indoors for use in animal housings (dairy cows, beef cattle, veal calves, sows in individual pens, sows in groups, fattening pigs, laying hens in free range, laying hens in enriched battery cages, broilers, turkeys, ducks, geese, rabbits, horses, goats and sheep) in places where manure and / or other excrements are not compressed. Breeding stations or other breeding areas for chicks are exempt for product use.</p> <p>Fly treatment in mink farms.</p>
2	Non-professionals	Spraying of product dissolved in water, direct dispersal of granules	<p>Larvicide to control nuisance and biting flies in animal husbandry:</p> <p>Indoors in housings of animals (horses, sheep, goats, rabbits, and ferrets).</p>
3	Professionals	Spraying of product dissolved in water	<p>Larvicide to control nuisance and biting flies in waste management facilities:</p> <p>Application indoors in mechanical-biological treatment facilities contaminated by organic matter and at composting sites.</p>
<p>¹ : For chicken poultry (laying hens in free range, laying hens in enriched battery cages, broilers) only application by spraying and pouring (but not by direct dispersal of granules) is authorised.</p>			

b) Presentation of the biocidal product including classification and labelling

The description of the biocidal product is available in the SPC.

The hazard and precautionary statements of the biocidal product according to the Regulation (EC) 1272/2008 is available in the SPC.

c) Description of uses proposed to be authorised

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

The active substance cyromazine contained in the biocidal product does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered a candidate for substitution. Therefore, a comparative assessment of the biocidal product is not required.

e) Overall conclusion of the evaluation of the uses proposed to be authorised

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended use(s) of the biocidal product have been

evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product are met.

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

For the proposed authorised use(s), according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product is sufficiently effective;
2. the biocidal product has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
 - the fate and distribution of the biocidal product in the environment,
 - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
 - the impact of the biocidal product on non-target organisms,
 - the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the uses described in the SPC, may be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product

As the conditions of Article 19(1) are met it is proposed that the single biocidal product shall be authorised¹, for the use(s) described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

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¹ This is without prejudice of any specific conditions that might apply in the territory of Member State(s) in accordance with Article 44(5) of the BPR.