Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the single biocidal product:

Neporex 2SG

ECHA/BPC/418/2024

Adopted

29 February 2024

Opinion of the Biocidal Products Committee

on the Union authorisation of Neporex 2SG

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:	**Neporex 2SG**
Authorisation holder:	**Elanco Animal Health Inc.**
Active substance common name:	**cyromazine (CAS No. 66215-27-8)**
Product type:	**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 13 December 2017, recorded in R4BP3 under case number BC-NA035887-38, 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 September 2023. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-50) and its Working Groups (WG-IV-2023). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Germany

The BPC opinion on the Union authorisation of the biocidal product was reached on 29 February 2024.

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(1)(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 Neporex 2SG 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

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product.

General

The biocidal product Neporex 2SG contains the active substance cyromazine (2 % w/w) for use as a larvicide (PT18) in animal housing by professional users. The user category "trained professional" was also applied for. Since the assessment showed no unacceptable risks for professional users without specified training, the additional category "trained professional" is not included in the use as proposed for authorisation.

The following uses have been assessed:

Use	Application method	eCA assessment
#1	Dry scattering of undiluted product	**Not** proposed for authorisation (see efficacy evaluation)
#2	Manual low-pressure spraying of diluted product	**Not** proposed for authorisation (see efficacy evaluation)
#3	Power-operated or automatic equipment low-pressure spraying of diluted product	**Not** proposed for authorisation (see efficacy evaluation)
#4	Pouring of diluted product using a watering can	Acceptable with RMM

Identified substances of concern

No substance of concern was identified.

Endocrine disrupting properties

According to the CAR for cyromazine, the substance is not considered to have endocrine disrupting properties.

There are no indications that a non-active substance of the product may have endocrine disrupting properties on humans and on environmental non-target organisms.

In conclusion there are no indications for endocrine disrupting properties of the biocidal product.

Physico-chemical properties

Neporex 2SG is a white granule with an intensive odour. The pH of a 1 % aqueous solution is 7.7 and the tap and pour density are both 0.755 g/ml.

Accelerated and long-term storage stability studies confirm a shelf-life of 5 years.

According to the CLP criteria, classification of the biocidal product with regard to physical hazards is not required.

The analytical methods for detection and identification for the biocidal product are deemed acceptable.

Efficacy

The submitted efficacy studies are suitable to support the claim "larvicide against house flies (*Musca domestica*) for use in animal housings by pouring the diluted product (2.5% biocidal product in water) onto fly breeding sites (25g biocidal product /m² = 0.5 g active ingredient/m²) using a watering can" (**Use #4**).

A sufficient population reduction of at least 80% was not demonstrated in a field test with the application methods "dry scattering of the undiluted product" (**Use #1**) and "Spraying of the diluted product" (**Use #2 and #3**) therefore, these uses cannot be authorized.

Resistance

Resistance of field fly populations against Cyromazine has been reported in the literature. Therefore, it can be assumed that the use of Cyromazine applied directly to fly-breeding sites may entail a risk of resistance development. In cases where the population has not been reduced, the development of resistance should be suspected.

The following general resistance management measures are included in the SPC:

- If the development of resistance is suspected, a change to another product with an active substance with a different mode of action is then required.
- In order to avoid the occurrence of resistance to any active substance, use products with different modes of action in alternation and avoid the frequent repeated use of the same active substance.
- It is recommendable to complement the treatment in livestock facilities with an adulticide product.
- The use of biocidal products can be combined with other sanitation measures (e.g. frequent removal of dung) or non-chemical means of control (for example biological including the use of parasitoids, where this is commercially viable) within an integrated fly control program.

Always read the label or leaflet before use and follow all the instructions provided.

Human health

According to the Classification, Labelling and Packaging (CLP) criteria, classification of the biocidal product with regard to human health is not required.

The metabolite melamine (formed during degradation in soil and potentially found in groundwater) is considered toxicologically relevant due to its classification by The

Committee for Risk Assessment (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 acceptable daily intake (ADI)) of 0.06 mg/kg bw/d for cyromazine), only cyromazine is considered for the dietary risk evaluation of the biocidal product.

Professional use

A human health risk assessment has been carried out for professional use of the biocidal product for all intended uses.

The occupational risk assessment for the biocidal product takes into account systemic effects of the active substance cyromazine.

In summary, a risk for professional users resulting from the assessed uses #1-4 of of the biocidal product is unlikely for all intended uses.

The following risk mitigation measures have to be taken into account in order to ensure safe use of the biocidal product:

- Use an applicator (e.g. measuring spoon or beaker) for mixing and loading.
- The following risk mitigation measures shall be applied without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work:
    - The wearing of chemical resistant gloves meeting the requirements of European Standard EN 374 is required during product handling phase (glove material to be specified by the authorisation holder within the product information).
    - Wear a protective coverall [type 4, EN 14605[1] or type 5, EN ISO 13982-1[2]] (coverall material to be specified by the authorisation holder within the product information).
    - Wear suitable protective footwear against chemicals (EN 13832) when applying the product.
    - For subsequent handling of treated manure, chemical resistant gloves (EN 374), a protective coverall (at least type 6, EN 13034) and suitable protective footwear against chemicals (EN 13832) is recommended.

Following risk mitigation measures for the professional user are included in the SPC for the only authorised use #4 "Pouring of diluted product using a watering can":

1) Use an applicator (e.g. measuring spoon or beaker) for mixing and loading.

2) The following risk mitigation measures shall be applied without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work:

[1] Use #2 and Use #3
[2] Use #1

a) The wearing of chemical resistant gloves meeting the requirement of European Standard EN 374 is required during product handling phase (glove material to be specified by the authorisation holder within the product information).

b) Wear suitable protective footwear against chemicals (EN 13832) when applying the product.

c) For subsequent handling of treated manure, chemical resistant gloves (EN 374), a protective coverall (at least type 6, EN 13034) and suitable protective footwear against chemicals (EN 13832) is recommended.

Non-professional bystanders and residents (general public)

The uses of the biocidal product are limited to indoor areas. These areas are inaccessible for the general public and therefore bystander exposure during application is not expected.

Exposure of bystanders and residents during and after spreading of liquid manure contaminated with the active substance to grassland or lawn is acceptable.

The following risk mitigation measures have to be included in the SPC:

- Keep out of reach of children.
- Do not apply in areas accessible for the general public.

Dietary exposure / consumer risk assessment

Dietary risks for consumers due to the consumption of animal products are acceptable and additional information on the nature of residues is not required.

As the major part of the used product will end up in manure which will then be spread on the farmland, residues in edible part of the crops for human consumption and for animal feed that are treated with manure containing cyromazine after application of the products in animal housing are to be assessed. The submitted data support the assumption that relevant cyromazine residues in food and feed following uptake with contaminated manure are not expected.

Nevertheless, the results of the refined exposure assessment show also, that the existing default maximum residue level (MRL) of 0.01 mg/kg for products of animal origin according to Regulation (EU) No. 396/2005 is exceeded for almost all evaluated livestock animal species (ruminants, pigs and poultry) and eggs, except for milk. This result indicates that a MRL evaluation for animal commodities may be necessary. However, the few data available from the German food monitoring from 2015 for sheep cheese, and from 2017 for lamb, sheep, chicken and goose and from 2019 for milk show no results above the limit of quantification (LOQ) for cyromazine (0.01 mg/kg). These data support compliance with existing MRLs. Therefore, an MRL evaluation for animal commodities is not necessary.

The following risk mitigation measures have to be included in the SPC:

- Do not apply directly on animals.
- Do not treat feed, drinks and feeding troughs.

Animal health:

Based on the additional dermal exposure pathway and the relatively low margin of exposure (MoE) for adult poultry, application of the biocidal product in breeding housings or

corresponding areas in animal housings for chicks is not supported.

The following risk mitigation measure has to be included in the SPC:

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

Environment

According to the CLP criteria, the biocidal product needs to be classified with regard to the environment as follows:

Aquatic Chronic 3, H412

For all uses applied for, the environmental risk assessment was conducted for the active substance cyromazine and its relevant metabolite melamine.

Scattering application (use #1)

Unacceptable risks to the environment from use #1 of the biocidal product were determined for the release pathway via sewage treatment plant (STP). Consequently, the use does not meet the requirements for granting an authorisation according to Article 19(1)(b)(iv) of the Biocidal Products Regulation (BPR) for poultry facilities, which are connected to the STP. For this reason, the RMM is assigned to the use:

- Do not use in animal housings where exposure to a STP or direct emission to surface water cannot be prevented.

For releases via slurry/manure application on agricultural land, risk for the environment is acceptable when Neporex 2 SG is applied by scattering in animal housings for all animal sub-categories 1 to 2 and 4 to 18 as given in the Emission Scenario Document (ESD) PT18, No. 14[3], as well as for small ruminants and rabbits. However, the acceptable maximum number of applications per year differs among the main animal categories:

5 applications: Dairy cows (1); Beef cattle (2); small ruminants; non-chicken poultry: turkeys (16), ducks (17), geese (18); rabbits;

1 application: Pigs: sows in individual pens (4), sows in groups (5), fattening pigs (6); chicken and broilers (battery cages and free range) (7-15);

For the animal category 'veal calves', the applicant withdrew the application at a late stage of the authorisation process.

As the scattering application cannot be authorised due to lacking proof of efficacy, these indications are not contained in the SPC.

Spraying and pouring applications (uses #2, #3 and #4)

Unacceptable risks to the environment from the uses #2, #3 and #4 of the biocidal product were determined for the release pathway via STP. Consequently, the uses do not meet the requirements for granting authorisation according to Article 19(1)(b)(iv) of the BPR for poultry facilities, which are connected to the STP. For this reason, the following RMM is assigned to the respective uses:

[3] https://echa.europa.eu/documents/10162/983773/pt18_insecticides_for_stables_and_manure_en.pdf/cc437f66-35ef-4116-a281-026c4f2fb6d0?t=1377104815277

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

For releases via slurry/manure application on agricultural land, risk for the environment is acceptable when Neporex 2 SG is applied by spraying or pouring in animal housings for all animal sub-categories 1 to 2 and 4 to 18 as given in the Emission Scenario Document (ESD) PT18, No. 14[3] as well as for small ruminants and rabbits. However, the acceptable maximum number of applications per year differs among the main animal categories:

5 applications: Dairy cows (1); beef cattle (2); small ruminants; non-chicken poultry: turkeys (16), ducks (17), geese (18); rabbits;

1 application: Pigs: sows in individual pens (4), sows in groups (5), fattening pigs (6); chicken and broilers (battery cages and free range) (7-15)

The maximum number of applications per year per animal category are defined in the section "application rates and frequency" of the SPC.

For the animal category 'veal calves', the applicant withdrew the application at a late stage of the authorisation process.

As the spraying application for uses #2 and #3 cannot be authorised due to lacking proof of efficacy, these indications are not contained in the SPC.

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

Based on new data indicating that its metabolite melamine fulfils two of the three PBT criteria, the active substance cyromazine fulfils the scientific criteria for the identification as a candidate for substitution.

However, the status of cyromazine has not been identified as meeting the substitution criteria in Commission Implementing Regulation (EU) 2016/1068. According to the document "CA-June22-Doc.4.2 - New info available-consequences for BP authorisationsrev1", a comparative assessment in accordance with Article 23 should be carried out only when the active substance is identified as meeting the substitution criteria in the renewal of approval Regulation in accordance with Article 10 (5) of the BPR.

Therefore, no comparative assessment for Neporex 2SG has to be conducted at this point.

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 uses 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, according to Article 19(1)(b) of Regulation (EU) No 528/2012, 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 use 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) of Regulation (EU) No 528/2012 are met it is proposed that the single biocidal product shall be authorised[4], for the use described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

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[4] This is without prejudice of any specific conditions that might apply in the territory of Member States in accordance with Article 44(5) of the BPR.