Official Journal
of the European Union

EN
L series

2025/221

7.2.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/221

of 6 February 2025

granting a Union authorisation for the single biocidal product 'Neporex 2SG' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 44(5), first subparagraph, thereof,

Whereas:

(1) On 13 December 2017, Elanco Animal Health Inc. submitted an application to the European Chemicals Agency ('the Agency') in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a single biocidal product named 'Neporex 2SG' of product-type 18, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Germany had agreed to evaluate the application. The application was recorded under case number BC-NA035887-38 in the Register for Biocidal Products.

(2) 'Neporex 2SG' contains cyromazine as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 18.

(3) On 25 September 2023, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.

(4) On 20 March 2024, the Agency submitted to the Commission its opinion ([2]), the draft summary of the biocidal product characteristics ('SPC') of 'Neporex 2SG' and the final assessment report on the single biocidal product, in accordance with Article 44(3) of Regulation (EU) No 528/2012.

(5) The opinion concludes that 'Neporex 2SG' is a single biocidal product within the meaning of Article 3(1), point (r), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) of that Regulation.

(6) On 5 April 2024, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the single biocidal product 'Neporex 2SG'.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) ECHA opinion of 29 February 2024 on the Union authorisation of 'Neporex 2SG' (ECHA/BPC/418/2024), https://echa.europa.eu/opinions-on-union-authorisation.

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0032480-0000 is hereby granted to Elanco Animal Health Inc. for the making available on the market and use of the single biocidal product 'Neporex 2SG' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 27 February 2025 until 31 January 2035.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 February 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Neporex 2SG

Product type(s)

PT18: Insecticides, acaricides and products to control other arthropods

Authorisation number: EU-0032480-0000

R4BP asset number: EU-0032480-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Neporex 2SG MS Madendood Plus Larvokill LarvEx Raxon Rae

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Elanco Animal Health Inc.
	Address	Mattenstrasse 24A 4058 Basel CH
Authorisation number	EU-0032480-0000	
R4BP asset number	EU-0032480-0000	
Date of the authorisation	27 February 2025	
Expiry date of the authorisation	31 January 2035	

1.3. Manufacturer(s) of the product

Name of manufacturer	Schirm GmbH
Address of manufacturer	Dieselstrasse 8 85107 Baar-Ebenhausen Germany
Location of manufacturing sites	Schirm GmbH site 1 Dieselstr. 8 85107 Baar-Ebenhausen Germany

Name of manufacturer	Ipanema Industria de Produtos Veterinários Ltda
Address of manufacturer	Rodovia Raposo Tavares KM 113 – Araçoiaba da Serra – SP Brazil
Location of manufacturing sites	Ipanema Industria de Produtos Veterinários Ltda site 1 Rodovia Raposo Tavares KM 113 – Barreiro 18190-000 Araçoiaba da Serra SP Brazil

Name of manufacturer	Chemical Process Technologies (Pty) Ltd.
Address of manufacturer	Unit 21, Second Floor, 1 Melrose Boulevard – Melrose Arch South Africa
Location of manufacturing sites	Chemical Process Technologies (Pty) Ltd. site 1 45 Battery St 0184 Waltloo, Ext1 South Africa

1.4. **Manufacturer(s) of the active substance(s)**

Active substance	N-cyclopropyl-1,3,5-triazine-2,4,6-triamine (Cyromazine)
Name of manufacturer	Elanco (Shanghai) Animal Health Co., Ltd.
Address of manufacturer	1 Changzhong Road, Wusi Farm, Fengxian County 201423 Shanghai China
Location of manufacturing sites	Elanco (Shanghai) Animal Health Co., Ltd. site 1 1 Changzhong Road, Wusi Farm, Fengxian County 201423 Shanghai China

Active substance	N-cyclopropyl-1,3,5-triazine-2,4,6-triamine (Cyromazine)
Name of manufacturer	Shandong Guobang Pharmaceutical Co., LTD
Address of manufacturer	F12th, Trendyway Building, No 3688, Jiangnan Road, Binjiang District – Hangzhou, Zhejiang Province China
Location of manufacturing sites	Shandong Guobang Pharmaceutical Co., LTD site 1 NO.02131 Xiangjiangxiyi Street, Advanced Manufacturing Industrial Park, Binhai Economic Development Zone – Weifang City, Shandong Province China

2. **PRODUCT COMPOSITION AND FORMULATION**

2.1. **Qualitative and quantitative information on the composition of the product**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
N-cyclopropyl-1,3,5-triazine-2,4,6-triamine (Cyromazine)		active substance	66215-27-8	266-257-8	2 % (w/w)

2.2. **Type(s) of formulation**

SG Water soluble granule

3. **HAZARD AND PRECAUTIONARY STATEMENTS**

Hazard statements	H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P273: Avoid release to the environment. P501: Dispose of contents in accordance with national regulation. P501: Dispose of container in accordance with national regulation.

4. **AUTHORISED USE(S)**

4.1. **Use description**

Table 1

Pouring with watering can

Product type	PT18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: *Musca domestica* Common name: house fly Development stage: larvae
Field(s) of use	indoor use In animal housing.
Application method(s)	Method: pouring Detailed description: Pouring of diluted product using a watering can.
Application rate(s) and frequency	Application rate: Apply 25 g biocidal product/m^2 = 0,5 g active ingredient/m^2; this equals 1 litre application solution per m^2 2,5 % (w/w); For preparation of the application solution dilute 25 g biocidal product in 1 litre water to treat 1 m^2 Number and timing of application: Stables for dairy cows and small ruminants: maximum (max.) 5 applications per year Stables for beef cattle: max. 5 applications per year Stables for pigs: max. 1 applications per year Stables for chicken: max. 1 application per year Stables for other poultry (turkeys, ducks, geese): max. 5 applications per year Stables for rabbits: max. 5 applications per year In case more applications per year are necessary for an animal category due to repeated infestation, alternative products with a different active substance must be used. Reapplication in case of multiple applications: At least 6 weeks and up to several months between applications.

Category(ies) of users	professional
Pack sizes and packaging material	The product is in direct contact with polyethylene (PE) regardless of the container. — Jar (PE): 100 g – 20 kg — Closure: PE with induction heat sealing foil (Aluminium) — Sachet (Multilayer aluminium foil with PE as primary packaging): 20 g – 100 g — Closed by heat sealing process — Flexible pack (multilayer material (polyethylene terephthalate (PET) and PE)): 3 kg – 5 kg — Closed by heat sealing process — Drum (primary packaging: multilayer material (PET and PE): 4 kg – 20 kg — closed with polypropylene (PP) zip tie — secondary packaging: a rigid container (Fibre / card-board / PE / PP / other similar polymer with a lid on the top)

4.1.1. *Use-specific instructions*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE**[1]

5.1. **Instructions for use**

General

Not authorised for use in veal calve housings.

Dilute the granules in water (25 g biocidal product in 1 litre water to treat 1 m^2). Only watering can application is allowed.

Fly population reduction can be observed starting from 2 weeks after product application.

The following general resistance management measures shall be applied:

— If the development of resistance is suspected, a change to another product with an active substance with a different mode of action is 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 recommended 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 the use of parasitoids, where this is viable) within an integrated fly control program.

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

Cattle and small ruminant (e.g. sheep and goats) facilities

Deep litter: Conduct the treatment within the first few days (up to 3 days) of starting a rearing cycle or within the first 3 days after dung removal and the build-up of new breeding material has started. Use treatment along walls, edges and spillage areas around feeders, drinkers and where manure accumulates. Fly breeding sites are likely to be where manure is not compacted, particularly along walls or fences, because in well-trodden litter limited fly larvae develop.

Slatted floor: Treat the entire floor area within the first few days (up to 3 days) after cleaning out the dung pit but only after the new manure starts to pile up again.

In case of small ruminants (e.g. sheep and goats) kept on soft bedding: larvae can be found on the whole surface of the cubicle / pen; therefore, application of the product to the entire surface is required. Apply in corners or around drinking and feeding troughs if necessary.

Pigs facilities

All-in, all-out system: Conduct the treatment within the first few days (up to 3 days) after cleaning out the dung pit but only after the new manure starts to build up.

Slatted floors: Treat the entire floor area within the first few days (up to 3 days) after cleaning out the dung pit but only after the new manure starts to build up.

Deep litter: Conduct the treatment within the first few days (up to 3 days) after dung removal but only after the manure starts to build up. Use treatment along walls, edges and spillage areas around feeders, drinkers and where manure accumulates. Fly breeding sites are likely to be where manure is not compacted, particularly along walls or fences, because in well-trodden litter limited fly larvae develop.

Chicken poultry facilities (layers, broilers, breeders)

Deep pits, slatted floor, floor-manure-piling operations: Conduct the treatment to the entire dung area within the first few days (up to 3 days) after manure removal but only after the manure starts to build up.

Bedding operations: Apply onto the humid points where larvae develop, such as in areas around drinkers and feeders or in points where a leakage of water occurs (fall of steam condensation, leakage from water pipes etc.).

Operations with manure removal belts: Remove manure outside the operations at intervals sufficient enough to avoid the development of larvae. Spillage of manure on the floor or accumulation of manure in corners may occur and facilitate the development of larvae. Conduct the treatment by pouring the application solution onto these points.

Other poultry (turkeys, ducks, geese)

Bedding operations: Apply the application solution onto the humid points where larvae develop, such as in areas around drinkers and feeders or in points where a leakage of water occurs (fall of steam condensation, leakage from water pipes etc.).

Slatted areas: Apply the application solution to the entire dung area within the first few days (up to 3 days) after manure removal but only after the manure starts to build up. Re-apply whenever the level of manure increases by 10 cm.

Rabbit facilities

Deep pits, floor-manure-piling operations: Apply the application solution to the entire dung area within the first few days (up to 3 days) after manure removal but only after the first manure starts to build up. Re-apply whenever the level of manure increases by 10 cm.

Operations with mechanical removal systems: Remove Manure outside the operations at intervals sufficient enough to avoid the development of larvae. Spillage of manure on the floor or accumulation of manure on corners may occur and facilitate the development of larvae. Conduct the treatment by pouring the application solution onto these points.

5.2. **Risk mitigation measures**

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:

   a) The wearing of chemical resistant gloves meeting the requirement of European Standard EN 374 or equivalent 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 in accordance with European Standard EN 13832 or equivalent when applying the product.

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

3) Do not apply directly on animals.

4) Do not treat feed, drinks and feeding troughs.

5) Keep out of reach of children.

6) Do not apply in areas accessible for the general public.

7) Do not use in breeding stations or other breeding areas for chicks.

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

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

1) Do not discharge the biocidal product nor the diluted solution of the biocidal product into the sewage system or waters.

2) Dampen solid material carefully to prevent it being blown away.

3) Take up mechanically and collect in suitable container for disposal.

4) IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

5) IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

6) IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

7) IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.

5.4. **Instructions for safe disposal of the product and its packaging**

1) Residues of the biocidal product must be disposed of in accordance with national and regional regulations.

   Containers containing residues of the product have to be handled accordingly.

2) Leave biocidal products in original containers. Do not mix with other wastes.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

1) Shelf-life: 60 months

2) Do not store near food, drink and feed.

6. **OTHER INFORMATION**

With respect to the 'Category(ies) of users' note: Professionals (including industrial users) means trained professionals if this is required by national legislation.

Full titles of EN standards and legislation referred to in section 5.2

EN 374 – Protective gloves against dangerous chemicals and micro-organisms.

EN 13832 – Footwear protecting against chemicals

EN 13034 – Protective clothing against liquid chemicals. Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment).

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

(1) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.