Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Tralopyril

Product type: 21

ECHA/BPC/002/2014

Adopted

9 April 2014

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance tralopyril for product type 21

In accordance with Article 90(2) of Regulation (EU) No 528/2012 (BPR) 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 application for approval in product type 21 of the following active substance:

Common name:	**Tralopyril**
Chemical name:	**4-bromo-2-(4-chlorophenyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile**
EC No.:	**N/A**
CAS No.:	**122454-29-9**
New active substance	

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority and Technical Meeting. The assessment report (AR) and conclusions, as a supporting document to the opinion, contain the detailed grounds for the opinion.

Process for the adoption of opinions

Following the submission of an application by Janssen Pharmaceutica NV, the evaluating Competent Authority (UK) submitted an assessment report and the conclusions of its evaluation to the Commission on 1 September 2009.

Adoption of the opinion

Rapporteur: BPC member for United Kingdom

The BPC opinion on the approval of the active substance tralopyril in product type 21 was adopted on 9 April 2014.

The BPC opinion was adopted by consensus.

Detailed opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the active substance tralopyril in product type 21 may be approved. The detailed grounds for this conclusion are described in the Assessment Report.

2. Opinion

2.1. 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 tralopyril in product type 21 (antifouling products). Tralopyril is an arylpyrrole that acts by uncoupling mitochondrial oxidative phosphorylation. Specifications for the reference source are established. The specifications of the reference source are covered by the batches used in toxicology and ecotoxicology 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 analysis of tralopyril as manufactured and for the determination of impurities. Further validation data are required for the analytical methods in sediment, seawater (which will also cover drinking water) and for residues in fish and shellfish. An analytical method for the analysis of tralopyril in air is required, while analytical methods are not required for soil and freshwater for the intended use.

There is currently no harmonised classification under CLP. This active substance is included in the Rapporteur Member State's harmonised classification work programme and will be progressed as soon as is possible.

The proposed classification and labelling by the evaluating Competent Authority of the active substance tralopyril based on the Regulation (EC) No 1272/2008 (the CLP Regulation) is shown below.

Proposed classification according to CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 2 H300 Acute Tox. 3 H311 Acute Tox. 2 H330 STOT RE 1 H372 (oral) STOT RE 2 H373 (inhalation) Acute Aquatic 1 H400 Chronic Aquatic 1 H410
Labelling	
Pictograms	GHS06, GHS08, GHS09
Signal Word	Danger
Hazard Statement Codes	H300: Fatal if swallowed H311: Toxic in contact with skin H330: Fatal if inhaled H372: Causes damage to organs through prolonged or repeated oral exposure H373: May cause damage to organs through prolonged or repeated inhalation exposure H400: Very toxic to aquatic life

	H410: Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	M = 1000 (acute) and 100 (chronic)

b) Intended use, target species and effectiveness

The intended use of tralopyril in product type 21 is application by professional users via airless spray, brush or roller in a paint that can be applied to hulls and other immersed parts of large marine-going vessels such as commercial boats and ships, navy and other government vessels and super-yachts (25 meter or more in overall length) against marine barnacles, hydroids, slime, adherent slime, weed and brown felt.

The data on the active substance and the reference antifouling product (International Copper Free) have demonstrated sufficient efficacy against a range of animal and algal fouling organisms for approval to be recommended. Evidence is available to demonstrate that development of resistance is not an issue. It is considered that the submitted data and information on resistance are sufficient to support approval.

c) Overall conclusion on the risks for human health and environment including the need for risk management measures

The overall conclusion from the evaluation of tralopyril for use in product type 21 (antifouling products) is, that it may be possible for Member States to issue authorisations of products containing tralopyril for professional use on ships in accordance with the conditions laid down in the BPR.

It should be noted that assessments carried out for human health and the environment for the limited number of substances under product type 21 (antifouling products) often indicate unacceptable risks to certain end users and/or environmental compartments exposed to these substances. These assessments also indicate the need for risk mitigation measures, such as technical controls and/or personal protective equipment (PPE), in order to protect end-users using these substances and minimise exposure of the relevant environmental compartments.

It was agreed at the 55th meeting of the representatives of Member State Competent Authorities for the implementation of the BPR to utilise generic conditions in approval regulations (as outlined in section 2.3 below) for all product type 21 substances evaluated as part of the EU Review Programme for existing active substances to reduce the risks for human health and for the environment from use of these substances[1].

[1] See document: Antifouling (PT21); the way forward for the management of active substances and the authorisation of biocidal products. (CA-March14-Doc.4.2 - Final).

Human health

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios		
Scenario	**Primary or secondary exposure Description of scenario**	**Exposed group**
mixing/loading	**primary exposure:** mixing and loading antifouling product into reservoirs for airless spraying	professionals (potman)
spray application	**primary exposure:** spray application of antifouling product via airless sprayer	professionals (sprayman)
application by brush/roller	**primary exposure:** application of antifouling product by brush and roller	professionals
cleaning of brushes/rollers	**primary exposure:** cleaning of brushes/rollers used to apply antifouling product	professionals
paint removal	**primary exposure:** removal of antifouling paint by abrasive blasting	professionals
No **secondary exposure** should occur as the sites of application and removal of International Copper Free will be inaccessible to the general public and other unprotected persons should be kept out of these sites.		

A quantitative risk assessment was undertaken for systemic effects following exposures via the inhalation and dermal routes. The overall conclusions of the risk characterisation for systemic effects are based on the predicted total systemic body burden. All of the scenarios identified represent medium-term exposure.

A quantitative risk assessment was undertaken for local effects arising from inhalation exposure scenarios (medium-term).

Systemic effects

With regard to the risk assessment for systemic effects, workers should carry out tasks using the appropriate PPE (gloves, boots, eye/face protection, single impermeable coveralls or double coveralls).

No unacceptable risks were identified for mixing and loading of tralopyril in the reference product, application by brush and roller (e.g. around structures such as rudders and propeller shaft exits and as spot repairs to existing coating) and removal by abrasive blasting. Although no unacceptable risks were identified for airless spraying as a result of systemic effects, it is anticipated that professional workers performing this task would be wearing suitable RPE. Although no unacceptable risks were identified for professional workers cleaning brushes or rollers as a result of systemic effects, it is recommended that gloves should be worn.

Combined exposure occurs to an individual taking into account time/duration of exposure, the place of exposure and demographics (e.g. age/gender) for that individual. The operations undertaken in spray and brush or roller application of International Copper Free and its removal from treated surfaces will be undertaken by different individuals. The combined exposure exposures and risks are acceptable.

Local effects

With regard to local effects arising from inhalation, no unacceptable risks were identified for mixing and loading, application by brush/roller and removal by abrasive blasting of tralopyril in the reference productwithout use of RPE. A risk was identified for application of tralopyril in the reference productby airless spraying. However, when performing this task the professional workers will be wearing suitable respiratory protective equipment (RPE). Therefore, the risks to human health as a result of local toxicity under these conditions are acceptable.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario**
Application – new build	Direct losses to marine surface water following spray application to commercial vessels
Maintenance and repair – removal	High pressure washing resulting in waste water containing antifouling paint particulates or physical scraping of painted surfaces to remove solid waste, both resulting in direct environmental exposure of marine surface water
In-service life stage	Three scenarios were evaluated: Commercial harbour Adapted marina (super yacht) Shipping lane
Aggregated exposure	Application losses plus in-service leaching in a commercial harbour resulting in direct exposure of marine surface water
For all four scenarios evaluated the exposure is estimated within the harbour or marina and adjacent to the harbour or marina (defined as the wider marine environment scenario). In addition, a worst and typical case situation was evaluated.	

For the environmental exposure scenarios identified in the table above, the environmental compartments assessed were surface water and sediment in marine systems, where risks were similar in both compartments.

For the "Application – new build" and "Aggregated exposure" scenarios, unacceptable risks were identified. Introduction of a refinement of the application factor and use of appropriate risk mitigation measures, leads to acceptable risks in the wider marine environment scenario but not in the harbour/marina scenario.

For the "In-service life stage" scenario, unacceptable risks were identified for commercial harbours and adapted marinas (super yacht) within the harbour or marina, but acceptable risks were found for the wider marine environment scenario. No unacceptable risks were identified for the shipping lane.

For the "Maintenance and repair – removal" scenario unacceptable risks were identified. This will need additional consideration at national level and the available best practice shall be applied to mitigate these risks.

These conclusions are also based on the acceptance of adverse risks identified for areas within adapted marinas (superyachts) and within commercial harbours, where the flow of water is restricted but the activity of treated vessels highly concentrated. The acceptance

of risks within such environments has been agreed for the purposes of approval of PT21 active substances. However there may be the need to further address specific national conditions and/or protections goals at product authorisation stage.

The environmental risk assessment indicates that for the scenarios investigated, the use of tralopyril in the reference productwould result in acceptable risks to shipping lanes and to the wider marine environment represented by the scenarios for the areas adjacent to the OECD-EU commercial harbour and adjacent to the adapted marina (super yacht). These acceptable risks are identified for cumulative exposure scenarios that combine in-service and application losses where the application losses based on the typical case defaults are reduced by appropriate risk mitigation. Risk mitigation could be employed via appropriate label phrases to ensure that application only takes place in dry docks where adequate dock floor discipline measures are employed.

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 or vP
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B or vB
	Toxic (T)	T
Endocrine disrupting properties	Tralopyril is not considered to have endocrine-disrupting properties as no classification is required for C and R and no effects on endocrine organs and/or reproduction observed in standard toxicity studies raise a concern for potential endocrine disruption.	

Consequently, the following is concluded:

Tralopyril does not meet the exclusion criteria laid down in Article 5 of the BPR.

Tralopyril does not meet the conditions laid down in Article 10 of the BPR and is therefore not considered as a candidate for substitution.

The exclusion and substitution criteria were assessed in line with the principles for taking decisions on the approval of active substances under the BPR agreed at the 55th meeting of the representatives of Member State Competent Authorities for the implementation of the BPR[2]. This implies that the assessment of the exclusion criteria is based on Article

[2] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (CA-March14-Doc.4.1 - Final - Principles for the approval of AS.doc)

5(1) using the temporary criteria for the determination of endocrine-disrupting properties in Article 5(3) and the assessment of the substitution criteria is based on Article 10(1)(a, b and d).

2.2.2 POP criteria

The criteria for a substance being a persistent organic pollutant (POP) are P, B and having the potential for long range transport. In addition, high toxicity can breach the B criterion, in which case a substance will be a persistent organic pollutant if it is P, demonstrates the potential for long range transport and is either B or T. Tralopyril has been identified as T, but is not considered to be P or B.

Theoretically, tralopyril does pose a possible risk of long-range transport, on the basis of an estimated atmospheric half-life of 6.5 days. However, when taking into account the very low vapour pressure and low Henry's Law constant, likely limited environmental exposure and rapid degradation in the main exposed environmental compartment, it is concluded that the risk of long-range transport will be very low.

Given the above, tralopyril does not meet the criteria for being a persistent organic pollutant.

2.3. BPC opinion on the application for approval of the active substance tralopyril in product type 21

In view of the conclusions of the evaluation, it is proposed that tralopyril shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification- the minimum purity of the active substance has been evaluated to be 97.5 %;

2. The product assessment shall pay particular attention to exposures, risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance;

3. In the event that products containing tralopyril are subsequently authorised for use in non-professional antifouling products, persons making products containing tralopyril available on the market for non-professional users shall ensure that the products are supplied with appropriate gloves;

4. Authorisations are subject to the following conditions:

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

    b. Labels and, where provided, instructions for use shall indicate that children shall be kept away until treated surfaces are dry;

    c. Labels and, where provided, safety data sheets of products authorised shall indicate that application, maintenance and repair activities shall be conducted within a contained area, on impermeable hard standing with bunding or on soil covered with an impermeable material to prevent losses and minimize emissions to the environment, and that any losses or waste containing tralopyril shall be collected for reuse or disposal;

    d. 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[3] or Regulation (EC) No 396/2005[4] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

The active substance gives rise to some concerns according to Article 28(2) of the BPR and therefore inclusion in Annex I of Regulation (EU) 528/2012 is not acceptable at this time.

2.4. Elements to be taken into account when authorising products

With regard to operator exposure, labelling should indicate the level of PPE that must be worn during handling, application and removal of products containing tralopyril. The following risk mitigation measures for professional use are proposed:

1. Where exposure cannot be reduced to an acceptable level by other means, professional operators (sprayers) exposed to antifouling products containing tralopyril must wear RPE. Appropriate RPE includes air-fed respiratory equipment with combined protective helmet and visor to protect the skin of the head and neck. Impairment of vision should be avoided. They should also wear a second overall beneath the coverall. The second overall should be changed regularly and whenever product break-through has been detected.

2. Professional operators (non-sprayers) exposed to antifouling products containing tralopyril should wear an overall of a contrasting colour to the antifouling product being applied. All bare skin should be covered. The overall should be changed regularly. The need for RPE should be informed by a suitable risk assessment.

3. Professional operators working with antifouling products containing tralopyril should wear impermeable gloves of a type recommended by the antifouling manufacturer as suitable for use with the formulation. These gloves should be changed regularly based on the information given by the supplier. Operators should wear impermeable (and non-slip) footwear that protects the lower leg and eye/face protection.

Safe uses to the environment have only been identified for scenarios representative of shipping lanes and the wider environment (i.e. areas adjacent to commercial harbours and adapted marinas (super yacht) provided that adequate risk mitigation measures are in place for professional application and removal activities on commercial ships. A risk has been identified within adapted marinas (super yacht) and commercial harbours. These areas may need additional consideration at national level and the available best practice shall be applied to mitigate these risks.

With regard to the environment, the need to address any specific national conditions and protection goals and/or undertake regional assessments should be considered at product authorisation stage, as environmental risk assessments in this evaluation have been based on generic EU scenarios.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the approval of tralopyril. However, further data shall be required as detailed below.

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

2.5.1 Technical material of the reference source

Quality Control (QC) data are required from a sufficient number of batches to verify the representativeness of the batches analysed in a GLP batch analysis study. The QC data must cover the active substance and a number of impurities. In addition, details of the methods of analysis used to generate the QC data must be provided, and if different from those used to generate the GLP batch analysis data, then appropriate validation data must be provided. This information must be provided to the evaluating Competent Authority (UK).

2.5.2 Residues monitoring method

Air

A method for analysis of tralopyril in air is necessary for monitoring purposes.

Seawater

A further ion transition for the LC-MS/MS method provided must be fully validated. Alternatively, a fully validated confirmatory method of analysis must be provided. The validation data must cover the LOQ required.

Sediment

The method of analysis must be fully validated to cover the required LOQ of 0.079 mg/kg (dry weight). The linearity must also cover this lower LOQ.

A further ion transition for the LC-MS/MS method provided must be fully validated. Alternatively, a fully validated confirmatory method of analysis must be provided. The validation data must cover the LOQ required.

Fish and shell fish

The linearity for the LC-MS/MS method provided must be fully addressed. Example chromatograms must be provided.

A further ion transition for the LC-MS/MS method provided must be fully validated. Alternatively, a fully validated confirmatory method of analysis must be provided. The validation data must cover the LOQ required.

The additional validation data required must be provided as soon as possible but no later than at the date of approval to the evaluating Competent Authority (UK).

2.5.3 Environment

In order to address a potentially severe underestimation of the risk to sediment dwelling organisms from exposure via suspended matter, caused by the fact that sorption data (Koc) has only been studied at concentrations that are not fully relevant in the marine environment, a new study on sorption at environmentally relevant conditions (concentrations µg/l to ng/l, pH ~8, DOC not too high, etc.) is to be performed before the antifouling active substances are evaluated for a potential renewal of the approval.

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