Biocidal Products Committee (BPC)

Opinion on the application for inclusion into Annex I,

Category 2 of the active substance:

Nitrogen generated from ambient air

ECHA/BPC/372/2023

Adopted

01 March 2023

Opinion of the Biocidal Products Committee

on the application for inclusion into Annex I, category 2 of the active substance nitrogen generated from ambient air

In accordance with Article 4 of Regulation (EU) No. 88/2014 in conjunction with Article 28 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 (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the inclusion in category 2 of Annex I of the following active substance:

Common name:	**Nitrogen generated from ambient air**
Chemical name:	**Nitrogen**
EC No.:	**Not applicable for an *in situ* generated active substance**
CAS No.:	**Not applicable for an *in situ* generated active substance**

New active substance submitted under Article 1 of Regulation (EU) No 88/2014

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of the BPC opinion

Following the submission of an application by Stiftung Preussischer Kulturbesitz on 4 April 2022 the evaluating Competent Authority Germany submitted an assessment report and the conclusions of its evaluation to ECHA on 14 October 2022. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-46) and its Working Groups (WG-IV-2022). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: Germany

The BPC opinion on the application for inclusuion in category 2 of Annex I of Regulation (EU) No 528/2012 of the active substance nitrogen generated from ambient air was adopted on 1 March 2023.

The BPC opinion was adopted by consensus.

The opinion is published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that nitrogen generated from ambient air may be included in category 2 of Annex I of Regulation (EU) No 528/2012 with the recommendation to add the following restriction in the Annex I entry: “If necessary, during use, measures have to be taken to avoid exposure of the user and the general public to a hypoxic atmosphere”. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of nitrogen generated from ambient air.

Nitrogen is generated from ambient air *in situ*, using a device. Two different generation principles are possible, the Pressure Swing Adsorption (PSA) and the Membrane Gas Separation (MGS). Both generation principles enrich the nitrogen concentration to ≥ 98.85 % (v/v) mainly by separation of oxygen. This results in the purification of nitrogen without generation of any impurities that lead to concern and of impurities that are not already present in ambient air (e. g. inert gases such as argon). Inside these devices, the active substance is generated with a pressure of 2 to 11 bar.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable. There is no cause for concern regarding physical hazards.

Analytical methods are not a data requirement for the inclusion in Annex I. As no validated analytical methods are required to establish the identity of the active substance, no data was provided.

No harmonised classification and labelling exist for the active substance. However, given the inert nature of nitrogen gas and the ubiquitous exposure that does not indicate any adverse effects on human health, no human health hazards and no environmental hazards were identified.

No classification and labelling for nitrogen according to Regulation (EC) No 1272/2008 (CLP Regulation) is proposed.

b) Intended use

Nitrogen generated from ambient air is intended to be used as a broad-spectrum insecticide for the eradication of stored product pests, wood destroying insects, textile pests and other arthropods.

The substance is used for control of arthropod pests that affect commodities, such as museum artefacts (wooden items, textiles, etc), food storage areas, machinery, etc. It is particularly important for very high value commodities such as certain museum artefacts, which may be adversely affected by other fumigants.

In these uses, nitrogen generated from ambient air will be used indoors by professional users; national conditions may exist that are applicable to the user. The nitrogen is used to create a

controlled atmosphere with a very low oxygen concentration (anoxia) in permanently or temporarily sealed treatment tents or chambers.

The treatment results are usually influenced by duration, temperature, humidity and residual oxygen content.

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

Human health

Nitrogen is an inert gas present ubiquitously in ambient air at a concentration of 78.1 %. Humans are exposed constantly throughout their lifetime to high concentrations of the active substance.

The main route of entry and excretion of nitrogen gas is via inhalation and exhalation, respectively. Nitrogen is not metabolised and only poorly soluble in tissues. Therefore, excretion occurs unchanged via exhaled air to almost 100 %.

Nitrogen acts by oxygen replacement lowering the oxygen content of the air, thus leading to asphyxiation of target organisms. This indirect mechanism would also apply to humans exposed to any atmosphere with higher-than-normal nitrogen concentration, i.e. in a hypoxic atmosphere. However, no relevant intrinsic toxicological properties of nitrogen gas could be identified. While exposure to high nitrogen (> 78.1 %) and thus to a hypoxic atmosphere in itself is associated with adverse effects on human health, these cannot be attributed to a direct effect of the active substance but rather to physiological reactions to a lack of oxygen. Therefore, to avoid adverse effects on human health it must be ensured that the oxygen level for the operator and bystanders will remain at a safe level: depending on the specific use, appropriate measures might be necessary to prevent exposure to a hypoxic atmosphere. These measures should be considered during product authorisation.

Nitrogen generated from ambient air does not meet the criteria for endocrine disrupting properties with respect to human health according to Section A of Regulation (EU) 2017/2100.

Summary of the assessment of effects on human health regarding Article 28(2)

Endpoint	Brief description
Acute toxicity	Acceptable waivers have been submitted. Nitrogen is an inert gas present ubiquitously in ambient air at a concentration of 78.09 %. Humans are exposed constantly throughout their lifetime to high concentrations of the active substance. High (compared to normal) nitrogen levels cause asphyxiation by oxygen displacement. However, no relevant intrinsic toxicological properties of nitrogen gas could be identified, hence no human health associated toxic effects are to be expected from the active substance nitrogen generated from ambient air. In conclusion, the active substance does not meet the criteria for concern according to Article 28(2)(a-c) of Regulation (EU) No 528/2012 based on expert consensus.
Corrosion and irritation	
Sensitisation	
Repeated dose toxicity	
Genotoxicity	
Carcinogenicity	
Reproductive toxicity	
Neurotoxicity	
Immunotoxicity	
Disruption of the endocrine system	
Other effects	

Environment

Elemental nitrogen is the most abundant atmospheric gas accounting for 78.1% of the atmosphere by volume and is, in its elemental form, largely unreactive owing to strong bonds between nitrogen atoms.

For risk assessment, it should be considered that no meaningful quantitative exposure assessment could be carried out given the natural background concentrations in the environment. The use of nitrogen generated from ambient air as a biocide will never elevate levels beyond normal environmental ranges. Further, nitrogen is already an ultimate degradation compound.

Nitrogen generated from ambient air does not meet the criteria for endocrine disrupting properties with respect to non-target organisms according to Section B of Regulation (EU) 2017/2100.

Summary of the assessment of effects on the environment regarding Article 28(2)

Conclusion on criteria of Article 28	
Conclusion on PBT and vP/vB criteria	Not available as nitrogen is an inorganic substance.
Conclusion on classification criteria of Article 28(2)(a)	The active substance does not meet the criteria for concern according to Article 28(2)(a) of Regulation (EU) No 528/2012 based on expert consensus.
Conclusion on other concern equivalent of Article 28(2)(a-c)	The active substance does not give rise to concern equivalent to Article 28(2)(a-c) of Regulation (EU) No 528/2012 based on expert consensus.

Overall conclusion

Given the inert nature of nitrogen gas and the ubiquitous exposure that does not indicate any adverse effects on human health, no human health or environmental hazards were identified for nitrogen generated from ambient air. Furthermore, no physical hazards have been identified.

In conclusion, based on expert consensus, the active substance does not meet any of the criteria raising concern as specified in Article 28(2) of Regulation (EU) No 528/2012.

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		**Conclusions**	
CMR properties	Carcinogenicity (C)	No classification required.	Nitrogen does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	No classification required.	
	Toxic for reproduction (R)	No classification required.	
PBT and vPvB properties	Persistent (P) or	Not applicable as nitrogen is an	Nitrogen does not fulfil

Property		Conclusions	
	very Persistent (vP)	inorganic substance	any of the PBT or vPvB criteria.
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B or vB	
	Toxic (T)	Not T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No	Nitrogen is not considered to have endocrine disrupting properties and does not fulfil criterion (d) of Article 5(1).
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	No	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s)	No	
Respiratory sensitisation properties	No classification required. No respiratory sensitising properties observed at ambient air concentrations. Nitrogen does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects other than those related to endocrine disrupting properties	Nitrogen does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Not applicable		

Consequently, the following is concluded based on expert consensus:

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

Nitrogen does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is therefore not considered a candidate for substitution and therefore does not meet criterion (b) according to Article 28(2).

2.2.2. POP criteria

Not applicable as nitrogen is an inorganic substance.

2.3. BPC opinion on the Annex I inclusion of the active substance nitrogen generated from ambient air

In view of the conclusions of the evaluation, it is proposed that nitrogen generated from ambient air may be included in category 2 of Annex I of Regulation (EU) No 528/2012 as it is concluded that the active substance does not give rise to concern in accordance with Article 28(2) of that Regulation. However, to ensure that the anoxia issue for users and the general public is adequately taken into account at the stage of product approval, it is proposed to add the following restriction in the Annex I entry: “If necessary, during use, measures have to be taken to avoid exposure of the user and the general public to a hypoxic atmosphere”.

2.4. Elements to be taken into account when authorising products

The following recommendations and measures have been identified during the assessment, based on known uses of the active substance. Authorities should consider these recommendations and measures when authorising products, together with possible other measures, and decide whether these measures are applicable for the concerned product:

Where an exposure to a hypoxic atmosphere is possible, measures might be necessary to ensure that oxygen levels remain at /return to safe levels. Especially in areas accessible for the general public (including children), normal atmospheric oxygen levels have to be ensured, e. g., by suitable oxygen detection methods, access restrictions, appropriate ventilation, etc.

Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the inclusion of nitrogen generated from ambient air into category 2 of Annex I of the BPR.

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