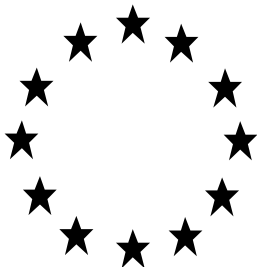
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATION

(submitted by the competent authority)



Nitrogen, *in situ* generated

Product type 18
(Insecticides, acaricides and products to control other arthropods)

"Nitrogen generated from ambient air" as included in Annex I of Regulation (EU) No 528/2012

Case Number in R4BP: BC-MJ074874-21

Competent Authority: DE (BAuA)

Date: 10.08.2023[1]

[1] *Date will be entered when DE CA takes decision in R4BP*

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Changes history table

Application type	refMS/ eCA	Case number in the refMS	Decision date[2]	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
NA-APP	DE	BC-MJ074874-21	10.08.2023	Initial assessment	1 - 59

[2] Date is entered when DE CA takes decision in R4BP

1 Conclusion

"Nitrogen, *in situ* generated" is a gaseous biocidal product of case-type 4 according to the document "CA-July19-Doc.4.1-Final".[3] Consequently, the biocidal product equals the active substance. It does not contain any non-active substances (so called "co-formulant").

The overall conclusion of the evaluation is, that the biocidal product meets all conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 execpt Article 19(1)(a):

"the active substances are included in Annex I or approved for the relevant product-type and any conditions specified for those active substances are met;"

Nitrogen, supplied in gas cylinders, is included in Annex I of Regulation (EU) No 528/2012 and, therefore, can be rightfully used as an active substance in biocidal products in the European Union. Meanwhile *in situ* generated nitrogen is neither included in Annex I nor approved for product type 18 (insecticides).

Nevertheless, in this specific case, product authorisation is possible because of Article 55(3) of the Regulation (EU) No 528/2012 in combination with Commission implemention decision (EU) 2020/1265. Thus, "nitrogen, *in situ* generated" can be authorised for the uses 1, 2 and 3 for professional users, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

Note, that by the time of autohrisation of this biocidal product, the inclusion of the active substance in Annex I is already in process (R4BP case type: AN-APP, R4BP case number: BC-CT074345-22, Substance name: Nitrogen generated from ambient air).

The product is used as an insecticide (product-type 18) by professional users for the control of a variety of insects for the protection of cultural heritage.

General

Detailed information on the intended uses of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

The biocidal product should be considered not to have endocrine-disrupting properties.

The biocidal product contains the active substance "Nitrogen, generated from ambient air", which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

The biocidal product is based on the active substance "Nitrogen generated from ambient air" which does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered as a candidate for substitution.

Composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. As the product does not contain any non-active substances information on the full-composition of the biocidal product can be found in section 2.3 of the PAR.

[3] NOTE AGREED BY MEMBER STATES' COMPETENT AUTHORITIES FOR BIOCIDAL PRODUCTS: Management of product authorisation for *in situ* cases

The manufacturers of the biocidal product are usually listed in section 1.4 of the SPC. However, information about the manufacturers of the biocidal product are not relevant for *in situ* biocidal products of case-type 4. The biocidal product is generated *in situ* during the application. Thus, there are no product manufacturers.

The manufacturers of the active substance are usually listed in section 1.5 of the SPC. However, information about the manufacturers of the active substance are not relevant for *in situ* biocidal products of case-type 4. The active substance is generated *in situ* during the application. Thus, there are no active substance manufacturers.

Conclusions of the assessments for each area

The intended uses as applied for by the applicant have been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

Physical hazards were not identified. More information is available in section 3.3 of the PAR.

Methods for detection and identification

A validated analytical method for quantification of the active substance is not available. It is not possible to detact nitrogen gas itself. The purity of the generated nitrogen during use is usually monitored by analysing and monitoring the residual oxygen content via oxygen sensors (e.g. ZrO_2 type). Due to the specific measurement method a normal validation of the method is considered not feasible and the provided information for analytical method is regarded as sufficient. More information on the analytical methods for the active substance(s) is available in section 3.4 of the PAR.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against all development stages of *Acanthoscelides obtectus, Callosobruchus maculatus, Araecerus fasciculatus, Anthrenus flavipes, Attagenus smirnovi, Attagenus unicolor, Dermestes haemorrhoidalis, Dermestes lardarius, Dermestes maculatus, Trogoderma angustum, Trogoderma granarium, Tribolium confusum, Tribolium destructor, Cryptolestes ferrugineus, Oryzaephilus surinamensis, Prostephanus truncatus, Stegobium paniceum, Plodia interpunctella, Tinea pellionella, Tineola bisselliella* for use 1*;* all development stages of *Thermobia domestica, Kalotermes flavicollis, Sitophilus granaries, Sitophilus zeamais, Anthrenocerus australis, Niptus hololeucus, Anobium punctatum, Lyctus brunneus, Ctenolepisma longicaudata* for use 2; all development stages of *Trogoderma parabile Gibbium psylloides, Mezium affine, Hylotrupes bajulus, Lasioderma serricorne* for use 3. More information is available in section 3.5 of the PAR.

Risk assessment for human health

A human health risk assessment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.6 of the PAR.

Since no substance of concern has been identified, the human health risk assessment is

based on the active substance "Nitrogen generated from ambient air".

Based on the risk assessment, it is unlikely that the intended uses cause any unacceptable acute or chronic risk to professional users, professional bystanders and non-professional bystanders/general public, if the directions for use, as specified in the SPC, are followed.

Dietary risk assessment

Considering the uses, food, or feed contamination is not expected. As a consequence, the exposure via food, via livestock exposure or via transfer of the active substance is considered as negligible, and no dietary risk assessment has been performed.

Risk assessment for animal health

Considering the uses, exposure to animals is not expected. Therefore, no risk assessment for animal health has been performed.

Risk assessment for the environment

A risk assessment for the environment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.8 of the PAR.

Since no substance of concern has been identified, the risk assessment for the environment is based on "Nitrogen generated from ambient air".

2 Information on the biocidal product

2.1 Product type and type of formulation

Table 2.1 Product type and type of formulation

Product type	18 (Insecticides, acaricides and products to control other arthropods)
Type of formulation	GA – Gas (*in situ*)

2.2 Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2.2 Overview of uses of the biocidal product

Use number	Use description	PT	Target organisms	Application method	Application rate (min-max)	User category	Conclusion (eCA/ refMS)	Comment (eCA/ refMS)
1	Professional use indoor	18	*Ctenolepisma longicaudata* *Acanthoscelides obtectus* *Callosobruchus maculatus* *Araecerus fasciculatus* *Anthrenus flavipes* *Attagenus smirnovi* *Attagenus unicolor* *Dermestes haemorrhoidalis* *Dermestes lardarius* *Dermestes maculatus* *Trogoderma angustum* *Trogoderma granarium* *Tribolium confusum* *Tribolium destructor* *Cryptolestes ferrugineus* *Oryzaephilus surinamensis* *Prostephanus truncatus* *Stegobium paniceum* *Plodia interpunctella* *Tinea pellionella* *Tineola bisselliella*	**Method:** Closed system: pressure process **Treatment parameters:** Temperature: 20°C Rel. humidity: 50% Duration: 21 days **Detailed description:** Nitrogen is extracted from the ambient air and pumped into the treatment tents or chambers so that the nitrogen content of the atmosphere rises to about 99% and the oxygen saturation consequently drops towards zero. The humidity of the nitrogen pumped into the treatment area is regulated according to the needs of the object to be treated.	not applicable	Trained professional Professional	R	The target organism *Ctenolepisma longicaudata* was only authorised for use 2 not for use 1. RMMs for human health were added. Use description was adjusted.
2	Professional use indoor	18	*Thermobia domestica* *Kalotermes flavicollis* *Sitophilus granaries* *Sitophilus zeamais* *Anthrenocerus australis* *Niptus hololeucus* *Anobium punctatum* *Lyctus brunneus*	**Method:** Closed system: pressure process **Treatment parameters:** Temperature: 24°C Rel. humidity: 50% Duration: 21 days **Detailed description:**	not applicable	Trained professional Professional	R	The target organism *Ctenolepisma longicaudata* was only authorised for use 2 not for use 1.

				Nitrogen is extracted from the ambient air and pumped into the treatment tents or chambers so that the nitrogen content of the atmosphere rises to about 99% and the oxygen saturation consequently drops towards zero. The humidity of the nitrogen pumped into the treatment area is regulated according to the needs of the object to be treated.				RMMs for human health were added. Use description was adjusted.
3	Professional use indoor	18	*Trogoderma parabile* *Gibbium psylloides* *Mezium affine* *Hylotrupes bajulus* *Lasioderma serricorne*	**Method:** Closed system: pressure process **Treatment parameters:** Temperature: 27°C Rel. humidity: 50% Duration: 21 days **Detailed description:** Nitrogen is extracted from the ambient air and pumped into the treatment tents or chambers so that the nitrogen content of the atmosphere rises to about 99% and the oxygen saturation consequently drops towards zero. The humidity of the nitrogen pumped into the treatment area is regulated according to the needs of the object to be treated.	not applicable	Trained professional Professional	R	RMMs for human health were added. Use description was adjusted.

Codes for indicating the acceptability for each use

A	Acceptable
R	Acceptable with further restriction or risk mitigation measures (RMM)
N	Not acceptable

2.3 Identity and composition

The identity and composition of the biocidal product are

identical ☐
not identical ☒

to the identity and composition of the product(s) evaluated in connection with the inclusion of nitrogen, supplied in gas cylinders, as an active substance in category 6 of Annex I of Directive 98/8/EC. *In situ* generated nitrogen is not yet included in Annex I of Regulation (EU) No 528/2012 nor approved for as an active substance product type 18 (insecticides).

According to the information provided the product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation (EU) No 528/2012.

2.4 Qualitative and quantitative information on the full composition of the biocidal product

The composition of the *in situ* biocidal product "Nitrogen *in situ* generated" is not strictly defined, because the device parameters and the general conditions at the point of use can vary. Additionally, the nitrogen content cannot be measured directly. However, the oxygen content is monitored during use as it is the decisive factor for efficacy and to control correct operation of the devices. Based on submitted information of 105 users of such devices the purity of nitrogen is > 98.85% and the max. Amount of oxygen is 1.0%. In addition it was also indicated by the applicant that up to 1 % residual inert gases are contained in the generated gas.

Based on this information the following composition of the biocidal product respectively generated nitrogen is proposed:

Table 2.3 Qualitative and quantitative information on the full composition of the biocidal product

Common name	Chemical name	Function	CAS number	EC number	Content (% v/v)
Nitrogen	-	Active substance	7727-37-9	231-783-9	≥98.85
Oxygen	-	Residual oxygen from ambient air	7782-44-7	231-956-9	≤1
Inert gases (mostly Argon)	-	Residual gases from ambient air	-	-	≤1

Nitrogen is generated from ambient air via Pressure Swing Adsorption (PSA) or by using Membrane Gas Separation (MGS). The principles of both generation methods are described below. The possible maximum concentration of pure active substance generated *in situ* is for both systems 99.99% and the release per time unit for continues processes is up to 400 m^3/h (depending on type of installation and mode of gas generation).

Pressure Swing Adsorption (PSA)

Nitrogen generators with pressure swing adsorption technology incorporate carbon molecular sieves (CMS) that adsorb oxygen molecules from the compressed air. As the air flows over the carbon molecular sieves, oxygen and other particles are caught in the sieves, but the nitrogen passes right through.

The generator has to be set in a well ventilated indoor room and the room temperature should be in the range of +5°C to 40°C. In addition, also the compressed air inlet temperature at the nitrogen generator has to be below 40°C.

Before using the ambient air for generation of nitrogen it may be filtered and dried using fine filter, activated carbon filter and a drain valve. The nitrogen purity will be adjusted by regulating the pressure.

Membrane Gas Separation (MGS)

The generator separates compressed air produced by an on-board compressor into nitrogen and an oxygen enriched air stream. The separation system is based on membranes.

A	Pressurised air inlet
B	Hollow fibre membrane
C	Nitrogen outlet
F	Fast permeation
S	Slow permeation

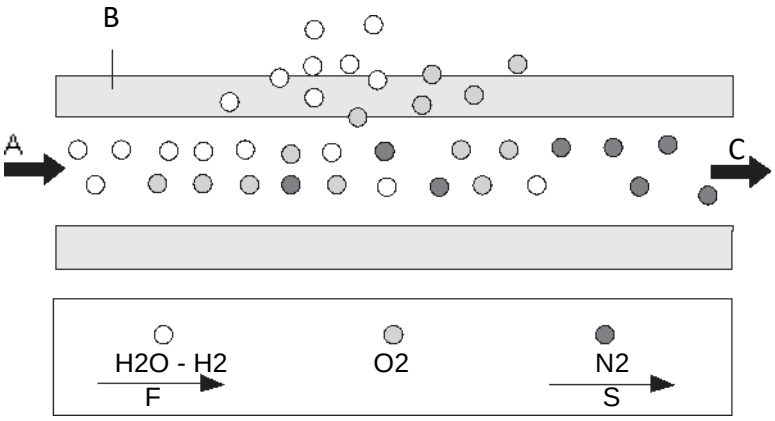


Figure 1: Separation principle

Ambient air contains nitrogen (78.1%), oxygen (20.9%), argon (1%), carbon dioxide, water vapour and traces of other inert gases. Pressurised air (A) is led through hollow fibre membranes (B). The various air components diffuse through the porous wall of the membranes.

The diffusion rate differs for the various gases:

- Oxygen and water vapour have a high diffusion rate and diffuse rapidly through the membrane wall.
- Nitrogen has a low diffusion rate and diffuses slowly through the membrane wall.

Pressurised nitrogen enriched air is released at the outlet of the membranes (E) which can be stored in a nitrogen storage vessel.

The generator has to be set in a well ventilated indoor room and no continuous direct irradiation by sunlight. Normal clean ambient air with a relative humidity < 90% is used at temperatures of +5°C to + 40°C. The generated purity of nitrogen is depending of the pressure used:

Table 2.4 Capacity data

Generator	Nominal production capacity Nlpm*								
Purity%	99.9	99.7	99.5	99	98	97	96	95	93
LP**	10	15	18	24	31	35	40	43	50
HP**	7.6	12	13	18	23	26	30	32	38

* Capacity at nominal conditions:
. Ambient temperature: 20 °C / 68 °F
. Ambient pressure: 1013 mbar(a)

** LP = Low Pressure, max. 2 bar(g) / 29 psig nitrogen pressure

** HP = High Pressure, max. 8 bar(g) / 116 psig nitrogen pressure

In addition, to the possibility to control the residual oxygen content depending on the device settings, the purity of the generated nitrogen during use is usually monitored by analysing and monitoring the residual oxygen content via oxygen sensors (e.g. ZrO_2 type)

2.5 Qualitative and quantitative information on the composition of the premix of the active substance(s)

Not relevant (BP does not contain a premix).

2.6 Qualitative and quantitative information on the composition of the non-active substance mixture

Not relevant (BP does not contain mixtures where composition should be reported).

2.7 Information on the tested product

Not relevant (only the product to be authorised was tested).

2.8 Identification of substance(s) of concern

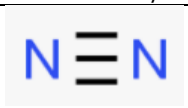
Not relevant (no substance of concern identified).

2.9 Comparison of composition in case of change of composition

Not relevant (no change in composition).

2.10 Identity of the active substance(s)

Table 2.5 Identity of the active substance(s)

Main constituent(s)	
Common name	Nitrogen, generated from ambient air
Chemical name	-
EC number	Not applicable for an *in situ* generated active substance
CAS number	Not applicable for an *in situ* generated active substance
Index number in Annex VI of CLP	-
Minimum purity / content	≥98.85 % v/v
Structural formula	

2.11 Information on the source(s) of the active substance(s)

Not applicable for this *in situ* generated active substance as it is generated directly at the point of use from ambient air.

2.12 Candidate(s) for substitution

No candidate for substitution has been identified.

2.13 Assessment of the endocrine-disrupting properties of the biocidal product

The biocidal product does not contain any active substances having endocrine-disrupting properties.

According to document 'CA-July19-Doc.4.1-Final', the active substance 'nitrogen, generated from ambient air' belongs to case-type 4, where the *in situ* generated active substance equals the biocidal product. Thus, no co-formulants are present in the biocidal product and a corresponding assessment of endocrine-disrupting properties is not required, since the biocidal product is not considered to have endocrine disrupting properties.

2.14 Classification and labelling

The *in situ* generated active substance "nitrogen, generated from ambient air" does not have an existing entry in Annex VI of Regulation (EC) No. 1272/2008 and no classification for the active substance is proposed in the final CAR (DE, 2023) and the BPC opinion (ECHA, 2023) for inclusion in Annex I of Regulation (EU) No 528/2012..

According to document "CA-July19-Doc.4.1-Final", the active substance "nitrogen,

generated from ambient air" belongs to case-type 4, where the *in situ* generated active substance equals the biocidal product. Thus, classification of the biocidal product pursuant to the Regulation (EC) 1272/2008 is not required.

Since the biocidal product has no classification, no labelling according to Regulation (EC) No 1272/2008 is required.

2.15 Letter of access

The applicant did not provide a letter of access with the application for national authorisation. However, because the data protection period pursuant Article 60(2) of the Regulation (EU) No 528/2012 expired, references to the dossier are possible, which was assessed for the inclusion of the active substance nitrogen, supplied in gas cylinders, into Annex I of the Directive 98/8/EC (asset number EU-0012349-0000). A reference list can be found in the corresponding Assessment Report.

2.16 Data submitted in relation to product authorisation

Not relevant (no new data on the active substance(s) and substance(s) of concern was submitted).

2.17 Similar conditions of use across the Union

Not relevant (national authorisation).

3 Assessment of the biocidal product

3.1 Packaging

This Section is not relevant, because ”Nitrogen, *in situ* generated” is an *in situ* biocidal product of case-type 4 as defined in the document “CA-July19-Doc4.1 - Management of product authorisation for *in situ* cases”.

3.2 Physical, chemical, and technical properties

Table 3.1 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.1.	Appearance at 20 °C and 101.3 kPa				
3.1.1.	Physical state at 20 °C and 101.3 kPa	Read-across to information provided for Annex I inclusion of nitrogen	n.a.	Gaseous	See Reference List for CAR of Nitrogen (Ireland, 2009).
3.1.2.	Colour at 20 °C and 101.3 kPa	Read-across to information provided for Annex I inclusion of nitrogen	n.a.	Colourless	See Reference List for CAR of Nitrogen (Ireland, 2009).
3.1.3.	Odour at 20 °C and 101.3 kPa	Read-across to information provided for Annex I inclusion of nitrogen	n.a.	Odourless	See Reference List for CAR of Nitrogen (Ireland, 2009).
3.2.	Acidity, alkalinity and pH value	Data waiving		Nitrogen is an inert gas that is nearly insoluble in water and does neither dissociate nor donate or accept protons. Therefore, experimental testing is regarded as obsolete.	
3.3.	Relative density / bulk density	Read-across to information provided for Annex I inclusion of nitrogen	pure nitrogen	Relative density = 0.967 at 0 °C and 101.3 kPa (STP)	See Reference List for CAR of Nitrogen (Ireland, 2009).
3.4.1.1.	Storage stability test – **accelerated storage**	Data waiving		Not relevant. Nitrogen is generated from ambient air in situ directly at the point of	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				use and not intended to be stored before application. Also, no substances with a potential to decompose over time are involved in the process.	
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**	Data waiving		Not relevant. Nitrogen is generated from ambient air in situ directly at the point of use and not intended to be stored before application. Also, no substances with a potential to decompose over time are involved in the process.	
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	Data waiving		Not relevant, BP is a gas.	
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	Data waiving		Nitrogen is widely known to be an inert molecule that does not react under exposure to light.	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Data waiving		Nitrogen is widely known to be stable towards humidity and higher temperatures. No effects on the BP are expected.	
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**		The product is in-situ Nitrogen, purified from ambient air via Pressure Swing Adsorption (PSA) or by using Membrane Technology. No packaging is foreseen for the product.		
3.5.1.	Wettability [indicate the concentration tested]	Data waiving		Not relevant, BP is a gas.	
3.5.2.	Suspensibility, spontaneity, and dispersion stability [indicate the concentration tested]	Data waiving		Not relevant, BP is a gas.	
3.5.3.	Wet sieve analysis and dry sieve test [indicate the concentration tested]	Data waiving		Not relevant, BP is a gas.	
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability [indicate the concentration tested]	Data waiving		Not relevant, BP is a gas.	
3.5.5.	Disintegration time	Data waiving		Not relevant, BP is a gas.	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability [the particle size distribution of droplets (MMAD) should be reported for RTU products if sprayed.]	Data waiving		Not relevant, BP is a gas.	
3.5.7.	Persistent foaming [indicate the concentration tested]	Data waiving		Not relevant, BP is a gas.	
3.5.8.	Flowability/pourability/dustability	Data waiving		Not relevant, BP is a gas.	
3.5.9.	Burning rate — smoke generators	Data waiving		Not relevant, BP is a gas.	
3.5.10.	Burning completeness — smoke generators	Data waiving		Not relevant, BP is a gas.	
3.5.11.	Composition of smoke — smoke generators	Data waiving		Not relevant, BP is a gas.	
3.5.12.	Spraying pattern — aerosols / spray	Data waiving		Not relevant, BP is a gas.	
3.6.1.	Physical compatibility	Data waiving		Not relevant, BP is not intended to be used in combination with other products.	
3.6.2.	Chemical compatibility	Data waiving		Not relevant, BP is not intended to be used in combination with other products.	
3.7.	Degree of dissolution and dilution stability (indicate the concentration tested)	Data waiving		Not relevant, BP is a gas.	
3.8.	Surface tension [indicate the conditions of the test and the concentration tested]	Data waiving		Not relevant, BP is a gas that is nearly insoluble in water and	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				also not intended to form aqueous solutions during use.	
3.9.	Viscosity [indicate the shear rate and the temperature tested]	Data waiving		Not relevant, BP is a gas.	

Table 3.2 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
Nitrogen, *in situ* generated is an in situ generated colourless, odourless gas with a relative density of 0.967. The majority of the endpoints regarding physical, chemical and technical properties are not relevant for this product. **Implications for labelling:** None

3.3 Physical hazards and respective characteristics

Table 3.3 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.1.	Explosives	Data waiving. Nitrogen is an inert gas that is not explosive.		
4.2.	Flammable gases	Data waiving. Nitrogen is an inert gas that is not flammable.		
4.3.	Flammable aerosols	N/A – Product is a gas.		
4.4.	Oxidising gases	Data waiving. Nitrogen is an inert gas that is not oxidising.		
4.5.	Gases under pressure	Data waiving. Hazard class does not apply as the active substance/biocidal product is generated in situ and not stored under pressure.		
4.6.	Flammable liquids	N/A – Product is a gas.		
4.7.	Flammable solids	N/A – Product is a gas.		
4.8.	Self-reactive substances and mixtures	Data waiving. Nitrogen is an inert gas that is not self-reactive.		
4.9.	Pyrophoric liquids	N/A – Product is a gas.		
4.10.	Pyrophoric solids	N/A – Product is a gas.		
4.11.	Self-heating substances and mixtures	N/A – Product is a gas.		
4.12.	Substances and mixtures which in contact with water emit flammable gases	Data waiving. Nitrogen is an inert gas that does not react with water.		
4.13.	Oxidising liquids	N/A – Product is a gas.		
4.14.	Oxidising solids	N/A – Product is a gas.		
4.15.	Organic peroxides	N/A – Product is not an organic peroxide.		
4.16.	Corrosive to metals	N/A – Product is a gas.		
4.17.1.	Auto-ignition temperatures of products	Data waiving. Nitrogen is an inert		

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
	(liquids and gases)	gas that does not ignite.		
4.17.2.	Relative self-ignition temperature for solids	N/A – Product is a gas.		
4.17.3.	Dust explosion hazard	N/A – Product is a gas.		

Table 3.4 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The product is not classified for physical hazards.

3.4 Methods for detection and identification

No method for direct quantification of the active substance Nitrogen is available. As the principle of the biocidal product is to create a nearly oxygen-free atmosphere causing anoxia to target insects, instead the oxygen content is measured and monitored. Knowing the actual oxygen content, the nitrogen concentration is calculated considering the percentage composition of ambient air. The quantification of oxygen is done with a Zirconium dioxide sensor.

The principle of operation of these sensors is not based on the percentage determination of the oxygen, but rather it measures partial pressure of oxygen in a gas or mixture of gases (air). ZrO_2 behaves like an electrolyte. If two different oxygen pressures exist on either side of a piece of ZrO_2, a voltage (Nernst voltage) is generated across it. Measuring this voltage allows the oxygen content to be plotted. This method is very sensitive and resistant to limitations caused by temperature and air humidity. The oxygen measuring system used in the nitrogen chambers has a measuring accuracy of ± 0.001 vol. % (10 vol. ppm) of oxygen.

The sensitivity of this sensor is guaranteed by the manufacturer for a certain period and should be replaced regularly. Using this type of sensor based on the phenomena of electrochemical processes does not require any analytical method that could be validated in the common way. The accuracy and repeatability of the results are achieved by regular calibration of the sensor. The recommended daily recalibration is due to the fluctuations in air pressure as well as a deviation of the measurement signal (drift) occurring during the first hours of operation of the sensor. After the sensor calibration, the normal oxygen content of 20.7% vol. (not 20.95%, which applies only to dry air) is set as a reference value and subsequent measurements are related to the measurement under given conditions. Having another sensor at disposal, it is possible to enter the reference readings from an independent measurement.

Due to the specific measurement method a normal validation of the method is considered not feasible and the provided information for analytical methods is regarded as sufficient.

Table 3.5 Analytical methods for air

The applicant refers for this endpoint to the Nitrogen Assessment Report Ireland (2009). Here, the following is mentioned: "It is not possible to detect nitrogen gas itself. The method of analysis for the nitrogen gas extracted from the atmosphere determines the levels of impurities (oxygen, argon, carbon monoxide, carbon dioxide, total hydrocarbons and water), the balance must be nitrogen. This gives a minimum purity of nitrogen gas." The purity of the generated nitrogen during use is usually monitored by analysing and monitoring the residual oxygen content via oxygen sensors (e.g. ZrO_2 type).

Table 3.6 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
Analytical methods for detection and identification The applicant refers for this endpoint to the Nitrogen Assessment Report Ireland (2009). Here, the following is mentioned: "It is not possible to detect nitrogen gas itself. The method of analysis for the nitrogen gas extracted from the atmosphere determines the levels of impurities (oxygen, argon, carbon monoxide, carbon dioxide, total hydrocarbons and water), the balance must be nitrogen. This gives a minimum purity of nitrogen gas." The purity of the generated nitrogen during use is usually monitored by analysing and monitoring the residual oxygen content via oxygen sensors (e.g. ZrO_2 type). Due to the specific measurement method (calculation of N_2 content by electrochemical oxygen measurement) a classical validation of the method is considered not feasible and the provided information for analytical methods is regarded as sufficient. Analytical methods for the quantification of residues of the active substance in environmental media (soil, drinking water, surface water), in food and feeding stuffs as well as in body fluids and tissues are not necessary. A direct release into soil and water is not expected from the biocidal use. Residues in food and feeding stuffs are not expected from the biocidal use. The product is not intended to be used in food /feed of plant or animal origin. The use of the product will not increase the levels of nitrogen beyond natural atmospheric ranges.

3.5 Assessment of efficacy against target organisms

3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected)

Main Group 03: Pest Control
Product type 18: Insecticide, acaricides and products to control other arthropods

In situ generated nitrogen is an broad-spectrum insecticide for the eradication of stored goods attacking insects, wood destroying insects, textile attacking insects and other arthropods. The use of nitrogen produced *in situ* from air is intended to control arthropod pests that can damage cultural heritage. These harmful organisms cannot only cause the loss of the cultural object itself, but there is also a risk that they will spread to other objects in the vicinity. Without proper treatment, objects can be irreparably damaged, posing a great risk to cultural heritage. The applications intended for use are:

a) Use #1: Treatment parameters: 20°C, 50% relative humidity, 21 days
Target organisms (all developmental stages):
Ctenolepisma longicaudata, Acanthoscelides obtectus, Callosobruchus maculatus , Araecerus fasciculatus, Anthrenus flavipes, Attagenus smirnovi, Attagenus unicolor, Dermestes haemorrhoidalis, Dermestes lardarius, Dermestes maculatus, Trogoderma angustum, Trogoderma granarium, Tribolium confusum, Tribolium destructor, Cryptolestes ferrugineus, Oryzaephilus surinamensis, Prostephanus truncatus, Stegobium paniceum, Plodia interpunctella, Tinea pellionella, Tineola bisselliella

b) Use #2: Treatment parameters:24°C, 50% relative humidity, 21 days
Target organisms (all developmental stages):
Thermobia domestica, Kalotermes flavicollis, Sitophilus granaries, Sitophilus zeamais, Anthrenocerus australis, Niptus hololeucus, Anobium punctatum, Lyctus brunneus

c) Use #3: Treatment parameters:27°C, 50% relative humidity, 21 days
Target organisms (all developmental stages):
Trogoderma parabile, Gibbium psylloides, Mezium affine, Hylotrupes bajulus, Lasioderma serricorne

Based on the submitted efficacy studies nitrogen, *in situ* generated from air, is effective to control a wide range of pests including stored-goods attacking insects (*Plodia interpunctella, Dermestes* sp., *Trogoderma* sp., *Lasioderma serricorne*, *Stegobium paniceum*, *Oryzaephilus surinamensis*, *Tribolium* sp., *Acanthoscelides obtectus*, *Callosobruchus maculatus, Araecerus fasciculatus, Sitophilus* sp.), wood-destroying insects (*Kalotermes flavicollis , Hylotrupes bajulus, Lyctus brunneus, Anobium punctatum*), textile-attacking insects (*Tineola bisselliella, Tinea pellionella, Anthrenocerus australis, Anthrenus flavipes, Attagenus smirnovi, Attagenus unicolor*) and other arthropods (*Ctenolepisma longicaudata, Thermobia domestica, Cryptolestes ferrugineus, Gibbium psylloides, Mezium affine, Niptus hololeucus, Prostephanus truncatus)* following the specific treatment parameters for the different pests. Based on the submitted study the efficacy against the target organism *Ctenolepisma longicaudata* is demonstrated for Use #2 instead of Use #1.

3.5.2 Mode of action and effects on target organisms, including unacceptable suffering

Nitrogen, *in situ* generated from air, is used to create a controlled atmosphere with a very low oxygen concentration (anoxia) in permanently or temporarily sealed treatment tents or chambers to control harmful organisms on cultural objects. Nitrogen is extracted from the ambient air and pumped into the treatment tents or chambers so that the nitrogen content of the atmosphere rises to about 99% and the oxygen saturation consequently drops towards zero. Harmful organisms are not able to survive under low oxygen conditions in the treatment tents or chambers. The mode of action of nitrogen is through the exclusion of oxygen which the target insects require for respiration, and not through any direct effect of nitrogen on the insect's physiology.

3.5.3 Efficacy data

Table 3.7 Efficacy data

<table>
<tr><th>PT and use number</th><th>Test product</th><th>Function / Test organism(s)</th><th>Test method / Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th><th>Number in IUCLID section 6.7/Test report title</th></tr>
<tr>
<td>PT18

Use 1, Use 2, Use 3</td>
<td>In-situ generated nitrogen

Low oxygen atmosphere / Anoxia</td>
<td>Kill

All developmental stages

Ctenolepisma longicaudata

Thermobia domestica

Kalotermes flavicollis

Acanthoscelides obtectus

Callosobruchus maculatus

Araecerus fasciculatus

Sitophilus granarius

Sitophilus zeamais

Anthrenocerus australis

Anthrenus flavipes

Attagenus</td>
<td>Simulated use tests assessing the efficacy of a low oxygen atmosphere was tested on a total of 34 species.
Controlled atmosphere in a climate chamber (C-40/350, CTS Clima Temperature System GmbH) with these parameters:
- temperature: 20, 24 and 27°C
- relative humidity was kept constant at 50%
- oxygen concentration was 0.5% or 1%
- exposure time: 14, 21 or 28 days

Nitrogen generator was used to produce high-purity nitrogen, oxygen concentration in the chamber was monitored by oxygen measuring system and randomly verified by a second oxygen sensor.

1. Test:</td>
<td>Results after 21 days of exposure (red cells: at least one individual survived):
<table>
<tr><th>Duration</th><th colspan="6">21 days</th></tr>
<tr><th>Temperature</th><th colspan="2">20 °C</th><th colspan="2">24 °C</th><th colspan="2">27 °C</th></tr>
<tr><th>Remaining oxygen content</th><th>0.5% O_2</th><th>1.0% O_2</th><th>0.5% O_2</th><th>1.0% O_2</th><th>0.5% O_2</th><th>1.0% O_2</th></tr>
<tr><td>Ctenolepisma longicaudata</td><td>X</td><td>/</td><td>X</td><td>X</td><td>/</td><td>/</td></tr>
<tr><td>Thermobia domestica</td><td>X</td><td>19; 6</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>Kalotermes flavicollis</td><td>X</td><td>15; 3</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>Acanthoscelides obtectus</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>Callosobruchus maculatus</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>Araecerus fasciculatus</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>Sitophilus granarius</td><td>-</td><td>-</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>Sitophilus zeamais</td><td>-</td><td>-</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>Anthrenocerus australis</td><td>-</td><td>-</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
</table>
</td>
<td>Reiche, Landsberger (2018) Innovative Untersuchungsmethoden zur nachhaltigen Wirksamkeit modellhafter Anoxia-Behandlung gegen Insektenbefall an national bedeutsamen Kulturgütern der Sammlungen der Stiftung Preußischer Kulturbesitz (DBU AZ 31865-45)

Landsberger, Frauendorf, Adler, Plarre (2019) Capability and limitations of anoxic treatments for protecting museum collections</td>
<td>07/

DBU-Abschlussbericht-AZ-31865

Capability and Limitations of Anoxic Treatments</td>
</tr>
</table>

		smirnovi *Attagenus unicolor* *Dermestes haemorrhoidalis* *Dermestes lardarius* *Dermestes maculatus* *Trogoderma angustum* *Trogoderma granarium* *Trogoderma parabile* *Tribolium confusum* *Tribolium destructor* *Cryptolestes ferrugineus* *Oryzaephilus surinamensis* *Gibbium psylloides* *Mezium affine* *Niptus hololeucus* *Anobium punctatum* *Prostephanus truncatus*	Test with different test materials representing characteristic matrices of museum objects or packing material (30 x 20 x 4 cm with a rectangular gap in the center) Test materials: Spruce wood, paper (telephone directories), textile (blankets made of 60:40% cotton-synthetic blend), bubble wrap In each tested material 3 larvae of the old house borer (*Hylotrupes bajulus*) were treated Control: identical specimens were stored under the same climatic conditions in a normal atmosphere 2. Test: Test individuals (all developmental stages) were placed in groups to simulate real pest infestation of museum objects. Groups of insects were placed in test tubes with their respective substrate/culture diet. Larvae of wood decaying beetle species were carefully transferred into prepared wood 10 days prior to treatment to												

Anthrenus flavipes	X	X	X	X	X	X
Attagenus smirnovi	X	X	X	X	X	X
Attagenus unicolor	X	X	X	X	X	X
Dermestes haemorrhoidalis	X	X	X	X	X	X
Dermestes lardarius	/	X	/	/	/	/
Dermestes maculatus	X	X	X	X	X	X
Trogoderma angustum	X	X	X	X	X	X
Trogoderma granarium	/	X	/	/	X	/
Trogoderma parabile	-	-	X	-	X	X
Tribolium confusum	X	X	X	X	X	X
Tribolium destructor	X	X	X	X	X	X
Cryptolestes ferrugineus	X	X	X	X	X	X
Oryzaephilus surinamensis	X	X	X	X	X	X
Gibbium psylloides	/	/	/	/	X	X
Mezium affine	-	-	X	-	X	X
Niptus hololeucus	X	/	/	X	X	X

		Lyctus brunneus *Lasioderma serricorne* *Stegobium paniceum* *Hylotrupes bajulus* *Plodia interpunctella* *Tinea pellionella* *Tineola bisselliella*	ensure stress free conditions. Control: identical speciments were stored under the same climatic conditions in a normal atmosphere (22°C, 40% relative humidity) Data evaluation for species within substrate: qualitatively inspected for adults and larger larval stages, for other developmental stages further incubation in a climatised breeding room and second evaluation after three months.	<table><tr><td>*Anobium punctatum*</td><td>X</td><td>4; 11</td><td>X</td><td>X</td><td>X</td><td>X</td></tr><tr><td>*Prostephanus truncatus*</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr><tr><td>*Lyctus brunneus*</td><td>X</td><td>12; 3</td><td>X</td><td>X</td><td>X</td><td>X</td></tr><tr><td>*Lasioderma serricorne*</td><td>X</td><td>X</td><td>X</td><td>-</td><td>X</td><td>X</td></tr><tr><td>*Stegobium paniceum*</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr><tr><td>*Hylotrupes bajulus*</td><td>4; 2</td><td>0; 6</td><td>X</td><td>4; 2</td><td>X</td><td>X</td></tr><tr><td>*Plodia interpunctella*</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr><tr><td>*Tinea pellionella*</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr><tr><td>*Tineola bisselliella*</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr></table>X: All individuals died during treatment. -: Individual survived treatment /: species was not tested. 19; 6 – Individuals were counted: first value gives number of dead individuals, second value gives number of survivers		

3.5.4 Efficacy assessment

The efficacy evaluation is based on the requirements of the Guidance on the Biocidal Products Regulation (BPR) (Volume II Efficacy - Assessment and Evaluation (Parts B+C); Version 3.0; April 2018). The Guidance on the BPR does not contain requirements for fumigation of cultural heritage to control relevant pest species of cultural heritage. Only the eradication of all pests and all their developmental stages provides sufficient protection of cultural objects. Therefore, a sufficient level of efficacy is demonstrated when at the end of the application 100% of the test individuals are dead. According to the general requirements (Guidance on the BPR, Volume II Efficacy - Assessment and Evaluation (Parts B+C); Version 3.0; April 2018, 5.6.4.1.5.2 Assessment, p. 196: "*If the product was assessed to be sufficiently effective in laboratory and/or field tests, it will be authorised as far as efficacy is concerned.*") a simulated-use test, in which the efficacy is tested according to the real use under controlled laboratory conditions, is sufficient to demonstrate the efficacy. In the simulated-use study by Reiche & Landsberger (2018) efficacy against 34 most important economic pests in museums has been demonstrated (study summary: Table 3.7). The study is sufficient to show 100% mortality across all developmental stages after 21 days of exposure to *in situ* generated nitrogen (1% residual oxygen concentration, 50% relative humidity) for all the following target organisms at the specific temperatures:

a) Temperature: 20°C: *Acanthoscelides obtectus, Callosobruchus maculatus , Araecerus fasciculatus, Anthrenus flavipes, Attagenus smirnovi, Attagenus unicolor, Dermestes haemorrhoidalis, Dermestes lardarius, Dermestes maculatus, Trogoderma angustum, Trogoderma granarium, Tribolium confusum, Tribolium destructor, Cryptolestes ferrugineus, Oryzaephilus surinamensis, Prostephanus truncatus, Stegobium paniceum, Plodia interpunctella, Tinea pellionella, Tineola bisselliella*

b) Temperature:24°C: *Ctenolepisma longicaudata, Thermobia domestica, Kalotermes flavicollis, Sitophilus granaries, Sitophilus zeamais, Anthrenocerus australis, Niptus hololeucus, Anobium punctatum, Lyctus brunneus*

c) Temperature:27°C: *Trogoderma parabile, Gibbium psylloides, Mezium affine, Hylotrupes bajulus, Lasioderma serricorne*

3.5.5 Conclusion on efficacy

The efficacy of *in situ* generated nitrogen was sufficiently demonstrated for 34 target organisms of all developmental stages. Based on the submitted efficacy studies "Nitrogen, *in situ* generated from air" is an effective measure to control harmful organisms that can damage cultural heritage following the specific treatment parameters for the different pests.

3.5.6 Occurrence of resistance and resistance management

The mode of action of nitrogen is through the exclusion of oxygen which the target insects require for respiration, and not through any direct effect on the insect's physiology. Given this mode of action, it is highly unlikely that the target insects would be able to develop a mechanism for resistance. Furthermore, a resistance to nitrogen is unlikely to occur, because the application as a biocide is designed to be 100% effective against the target organisms and thus they are never exposed to sub-lethal concentrations of nitrogen.

The following general resistance management measures are proposed:

- Good sanitation procedures, proper storage conditions, insect resistant packaging and all other measures that prevent infestations from developing can do much to reduce the need for insecticides.

- Where fumigation have to be used on a regular basis, close guard should be kept against control failures. Complete control of all insects (disinfestation of all stages) in a treatment is the best insurance against resistance.

- In high-volume storage areas, a sufficient level of effectiveness strongly depends on the distribution of the fumigants. Good penetration properties of the gas then ensure an effective gas concentration in all areas.

- The permeability of goods has always to be tested before fumigation. Only when the level of permeability is a known factor and sufficient penetration can be ensured, the fumigation could be performed.

3.5.7 Known limitations

No undesirable or unintended side effects are reported in efficacy studies.

3.5.8 Relevant information if the product is intended to be authorised for use with other biocidal products

The biocidal product is not intended to be used with other products including other biocidal products.

3.6 Risk assessment for human health

3.6.1 Assessment of effects on human health

Nitrogen was included in Annex I of Directive 98/8/EC for product-type 18, however the approval has since expired. In addition, nitrogen is included in category 6 of Annex I to Regulation (EU) No 528/2012.

In 2022, an assessment of the *in situ* generated active substance 'nitrogen, generated from ambient air' for product-type 18 was carried out by the German Competent Authority in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market, with the aim of a possible inclusion of this substance into Annex I or IA to the Directive (IRL-CA 2009).

As defined in document 'CA-July19-Doc.4.1-Final', the active substance 'nitrogen, generated from ambient air' belongs to case-type 4, where the *in situ* generated active substance equals the biocidal product. Thus, classification of the biocidal product is based on the classification of the active substance and the assessment is based on the data and conclusions presented in the CAR (DE, 2022).

According to the corresponding CAR, the active substance 'nitrogen generated from ambient' air is obtained from ambient air by physical separation processes, like Pressure Swing Adsorption (PSA) or Membrane Gas Separation (MGS). Therefore, it can only contain impurities that have already been present in the ambient air before, in largely reduced concentrations. These components of ambient air were considered not relevant for the assessment and subsequently not included in the assessment of the active substance 'nitrogen generated from ambient air'. Thus, the assessment of effects on human health is based solely on the substance nitrogen.

Nitrogen is an inert gas, ubiquitously present in the atmosphere at a concentration of 78.1 %. Hence, humans are constantly exposed to high concentrations of the active substance throughout their lifetime.

When used as a biocide, the inert nitrogen does not exert toxicological effects itself, but leads to asphyxiation of target organisms in a hypoxic atmosphere, as consequence of replacing oxygen and thereby reducing the oxygen content in the air significantly below normal atmospheric levels (20.8 %).

Overall, no relevant intrinsic toxicological properties of nitrogen gas could be identified. While exposure to high nitrogen (> 78.1 %) in hypoxic atmospheres in itself is associated with adverse effects on human health (e.g. hyperventilation, tachycardia, fatigue, blurred vison, tunnel vision, dizziness, breathlessness, light dimming, and tingling), these effects cannot be attributed to the active substance but rather to a lack of oxygen.

No studies and no human health data on possible human health hazards of nitrogen gas are available. However, due to the high background exposure to the substance it can be safely concluded that nitrogen gas does not pose any concern for human health. Therefore, no classification of the biocidal product is proposed.

3.6.1.1 Skin corrosion and irritation

Table 3.8 Conclusion used in Risk Assessment – Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not corrosive or irritant to the skin.
Justification for the value/conclusion	Acceptable waivers have been submitted for endpoints covering the dermal route of exposure. Moreover, no validated test guidelines exist for the testing of gases via the dermal route. Although a gas may theoretically lead to eye or skin irritation, no such effects are observed with nitrogen at ambient air concentrations and to the knowledge of the eCA no cases have been reported other than possible burn or frost bite from rapidly expanding compressed nitrogen gas (Airgas 2021). However, this effect is not intrinsic to nitrogen gas but rather a physical phenomenon caused by the so called Joule-Thompson effect, i.e. falling temperature of expanding gases that pass through a throttle valve. Since nitrogen forms 78.1 % v/v of the earth's atmosphere, all non-aquatic life on earth is constantly exposed, including their skin and mucous membranes, to an atmosphere containing 78.1% v/v nitrogen gas for their entire life cycle. This demonstrates that atmospheric levels of nitrogen do not exhibit any adverse toxicological effects. Hence, no human health associated toxic effects are to be expected from the active substance 'nitrogen, generated from ambient air'. In conclusion, there is robust expert consensus that the active substance 'nitrogen, generated from ambient air' does not give rise to concern in accordance with Article 28(2) of Regulation (EU) No 528/2012 and no classification according to Regulation (EC) No 1272/2008 is warranted.
Classification of the product according to CLP	No classification required.

3.6.1.2 Eye irritation

Table 3.9 Conclusion used in Risk Assessment – Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating to the eye.
Justification for the value/conclusion	Acceptable waivers have been submitted for endpoints covering the dermal route of exposure. Moreover, no validated test guidelines exist for the testing of gases via the dermal route. Although a gas may theoretically lead to eye or skin irritation, no such effects are observed with nitrogen at ambient air concentrations and to the knowledge of the eCA no cases have been reported other than possible burn or frost bite from rapidly expanding compressed nitrogen gas (Airgas 2021). However, this effect is not intrinsic to nitrogen gas but rather a physical phenomenon caused by the so called Joule-Thompson effect, i.e. falling temperature of expanding gases that pass through a throttle valve. Since nitrogen forms 78.1 % v/v of the earth's atmosphere, all non-aquatic life on earth is constantly exposed, including their skin and mucous membranes, to an atmosphere containing 78.1 % v/v nitrogen gas for their entire life cycle. This demonstrates that atmospheric levels of nitrogen do not exhibit any adverse toxicological effects. Hence, no human health associated toxic effects are to be expected from the active substance `nitrogen, generated from ambient air'. In conclusion, there is robust expert consensus that the active substance 'nitrogen, generated from ambient air' does not give rise to concern in accordance with Article 28(2) of Regulation (EU) No 528/2012 and no classification according to Regulation (EC) No

	1272/2008 is warranted.
Classification of the product according to CLP	No classification required.

3.6.1.3 Respiratory tract irritation

Table 3.10 Conclusion used in the Risk Assessment – Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritant to the respiratory tract.
Justification for the conclusion	Acceptable waivers have been submitted for endpoints covering the dermal route of exposure. Moreover, no validated test guidelines exist for the testing of gases via the dermal route. Although a gas may theoretically lead to eye or skin irritation, no such effects are observed with nitrogen at ambient air concentrations and to the knowledge of the eCA no cases have been reported other than possible burn or frost bite from rapidly expanding compressed nitrogen gas (Airgas 2021). However, this effect is not intrinsic to nitrogen gas but rather a physical phenomenon caused by the so called Joule-Thompson effect, i.e. falling temperature of expanding gases that pass through a throttle valve. Moreover, according to the CAR (DE, 2022), there are no indications that the active substance would meet the criteria for STOT SE 3, H335 (respiratory tract irritation). Since nitrogen forms 78.1 % v/v of the earth's atmosphere, all non-aquatic life on earth is constantly exposed, including their skin and mucous membranes, to an atmosphere containing 78.1 % v/v nitrogen gas for their entire life cycle. This demonstrates that atmospheric levels of nitrogen do not exhibit any adverse toxicological effects. Hence no human health associated toxic effects are to be expected from the active substance 'nitrogen, generated from ambient air'. In conclusion, there is robust expert consensus that the active substance 'nitrogen, generated from ambient air' does not give rise to concern in accordance with Article 28(2) of Regulation (EU) No 528/2012 and no classification according to Regulation (EC) No 1272/2008 is warranted.
Classification of the product according to CLP	No classification required.

3.6.1.3 Skin sensitization

Table 3.11 Conclusion used in Risk Assessment – Skin sensitisation

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to the skin.
Justification for the value/conclusion	Acceptable waivers have been submitted for endpoints covering the dermal route of exposure. Moreover, no validated test guidelines exist for the testing of gases via the dermal route. Since nitrogen forms 78.1 % v/v of the earth's atmosphere, all non-aquatic life on earth is constantly exposed, including their skin and mucous membranes, to an atmosphere containing 78.1 % v/v nitrogen gas for their entire life cycle. This demonstrates that atmospheric levels of nitrogen do not exhibit any adverse toxicological effects. Hence, no human health associated toxic effects are to be expected from the active substance 'nitrogen, generated from ambient air'. In conclusion, there is robust expert consensus that the active substance 'nitrogen, generated from ambient air' does not give rise to concern in accordance with Article 28(2) of Regulation (EU) No 528/2012 and no classification according to Regulation (EC) No 1272/2008 is warranted.
Classification of the product according to CLP	No classification required.

3.6.1.4 Respiratory sensitization

Table 3.12 Conclusion used in Risk Assessment – Respiratory sensitisation

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to the respiratory tract.
Justification for the value/conclusion	Acceptable waivers have been submitted for endpoints covering the inhalation route of exposure. It is scientifically unjustified to conduct further toxicity studies by the inhalation route for nitrogen, since it is inert and not intrinsically hazardous. No validated test methods exist for respiratory sensitisation. There are no indications that nitrogen gas could be expected to be a respiratory sensitiser given the ubiquitous exposure to the substance. Hence, the active substance 'nitrogen, generated from ambient air' does not meet the criteria for classification as respiratory sensitizer according to Regulation (EC) No 1272/2008 and does not give rise to concern as laid out in Art. 28(2)(a) of the BPR.
Classification of the product according to CLP	No classification required.

3.6.1.5 Acute oral toxicity

Table 3.13 Value used in the Risk Assessment – Acute oral toxicity

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not acutely orally toxic.
Justification for the value/conclusion	Acceptable waivers have been submitted for endpoints covering the oral route of exposure. Since nitrogen is a gas, oral administration to test animals is technically not feasible and scientifically not justified as the main route of exposure would be the inhalation route. Furthermore, there are no approved test guidelines for the testing of gaseous substances by the oral route. Since nitrogen forms 78.1 % v/v of the earth's atmosphere, all non-aquatic life on earth is constantly exposed to an atmosphere containing 78.1 % v/v nitrogen gas for their entire life cycle. 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, there is robust expert consensus that the active substance 'nitrogen, generated from ambient air' does not give rise to concern in accordance with Article 28(2) of Regulation (EU) No 528/2012 and no classification according to Regulation (EC) 1272/2008 is warranted.
Classification of the product according to CLP	No classification required.

3.6.1.6 Acute inhalation toxicity

Table 3.14 Value used in the Risk Assessment – Acute inhalation toxicity

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not acutely toxic by inhalation.
Justification for the value/conclusion	Acceptable waivers have been submitted for endpoints covering the inhalation route of exposure. It is scientifically unjustified to conduct further toxicity studies by the inhalation route for nitrogen, since it is inert and not intrinsically hazardous. Furthermore, nitrogen acts by simple asphyxia. The exposure to an atmosphere containing very high levels of nitrogen could result in asphyxiation through displacement of oxygen. Therefore, the toxicity that could be observed in such a study would directly be related to the asphyxia of the animals due to the decreasing oxygen and not to a toxic effect of nitrogen. Moreover, 78.1 % of nitrogen that is the normal air concentration (781,000 ppm) already exceeds the upper limit for classification for acute inhalation toxicity (20,000 ppm/4h). Hence, the active substance 'nitrogen, generated from ambient air' does not meet the criteria for classification as acute toxic via the inhalation route of exposure according to Regulation (EC) No 1272/2008 and does not give rise to concern as laid out in Art. 28(2)(a) of the BPR.
Classification of the product according to CLP	No classification required.

3.6.1.7 Acute dermal toxicity

Table 3.15 Value used in the Risk Assessment – Acute dermal toxicity

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not acutely dermally toxic.
Justification for the value/conclusion	Acceptable waivers have been submitted for endpoints covering the dermal route of exposure. Moreover, no validated test guidelines exist for the testing of gases via the dermal route. Since nitrogen forms 78.1 % v/v of the earth's atmosphere, all non-aquatic life on earth is constantly exposed, including their skin and mucous membranes, to an atmosphere containing 78.1 % v/v nitrogen gas for their entire life cycle. This demonstrates that atmospheric levels of nitrogen do not exhibit any adverse toxicological effects. Hence, no human health associated toxic effects are to be expected from the active substance 'nitrogen, generated from ambient air'. In conclusion, there is robust expert consensus that the active substance 'nitrogen, generated from ambient air' does not give rise to concern in accordance with Article 28(2) of Regulation (EU) No 528/2012 and no classification according to Regulation (EC) 1272/2008 is warranted.
Classification of the product according to CLP	No classification required.

3.6.2 Information on dermal absorption

Table 3.16 Value(s) used in the Risk Assessment – Dermal absorption

Conclusion used in Risk Assessment – Respiratory sensitisation	
Substance	Nitrogen generated from ambient air
Value(s)	Not relevant
Justification for the selected value(s)	Acceptable waivers have been submitted for endpoints covering the dermal route of exposure. A dermal absorption study with nitrogen is not available and technically not feasible. The main route of exposure to nitrogen is by inhalation. Nitrogen forms 78.1 % v/v of the earth's atmosphere, all non-aquatic life on earth is constantly exposed, including their skin and mucous membranes, to an atmosphere containing 78.1 % v/v nitrogen gas for their entire life cycle. Since concentration of nitrogen in inhaled and exhaled human breath is not significantly different, no considerable amount of nitrogen is absorbed into the human body via the inhalation route. This demonstrates that atmospheric levels of nitrogen do not exhibit any adverse toxicological effects. Therefore, a dermal absorption value has not been derived, as it is not considered relevant for the assessment and corresponding data waiving has been accepted.

3.6.3 Available toxicological data relating to substance(s) of concern

No substances of concern regarding human health were identified as the biocidal product does not contain any non-active substances. Thus, non of the criteria as specified in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)) are fulfilled. Consequently, only the active substance was addressed in the human health risk assessment.

3.6.4 Other

Not relevant. According to the CAR (DE, 2022), 'nitrogen, generated from ambient air' does not meet the criteria for classification as STOT SE and STOT RE. Further, no concerns were identified regarding carcinogenic, reprotoxic, neurotoxic or immunotoxic properties.

3.6.4.1 Food and feeding stuffs studies

Not relevant.

3.6.4.2 Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product

Not relevant.

3.6.4.3 Other test(s) related to the exposure to humans

None.

3.6.5 Available toxicological data relating to endocrine disruption

In the active substance evaluation (DE, 2022) for inclusion in Annex I of Regulation (EU) No 528/2012, it was concluded that the *in situ* generated active substance 'nitrogen, generated from ambient air' is not considered to have endocrine disrupting properties.

According to document 'CA-July19-Doc.4.1-Final', the active substance 'nitrogen, generated from ambient air' belongs to case-type 4, where the *in situ* generated active substance equals the biocidal product. Thus, no co-formulants are present in the biocidal product and a corresponding assessment of endocrine-disrupting properties is not required, since the biocidal product is not considered to have endocrine disrupting properties.

3.6.6 Exposure assessment and risk characterisation for human health

3.6.6.1 Introductory remarks

The use of nitrogen produced *in situ* is a effective method of controlling harmful organisms that can be used for all types and combinations of materials in cultural facilities without causing damage.

In situ generated nitrogen (a.s.) as a biocide is used to create such a controlled atmosphere with a very low concentration (<1%) of oxygen (anoxia) in sealed permanent chambers or mobile treatment tents/bubbles.

Nitrogen is extracted from the ambient air via Pressure Swing Adsorption (PSA) or by using Membrane Gas Separation (MGS) and pumped into the treatment tents/bubbles or chambers so that the nitrogen content of the atmosphere rises to about 99% and consequently an oxygen deficient atmosphere is generated. The humidity of the nitrogen pumped into the treatment area is regulated according to the needs of the object to be treated. Harmful organisms are not able to survive under the conditions in the treatment tents/bubbles or chambers.

The danger posed by the use of nitrogen is closely related to the reduction of oxygen levels in the surrounding area of the treatment area (tent, bubble, chamber), wich may result, for example, from leackage. However, under normal conditions, professionals are not

exposed to an oxygen reduced atmosphere.

The only times a professional operator may theoretically be exposed to low oxygen levels are during the actual working steps next to the treatment area, i.e., when filling tents/bubbles or chambers for the first time, when refilling (if necessary to maintain oxygen and nitrogen levels), and/or when venting at the end of the treatment phase.

Exposure of professionals that are not involved in the fumigation can be excluded as access to areas surrounding the treatment tents/bubbles/chambers is restricted with the conditions of use.

Since no reference values have been derived for nitrogen, exposure calculations against nitrogen are not necessary. However, qualitative considerations imply that in order to detect and safely address leakage that may have the potential to cause exposure to low oxygen levels, technical or organisational measures have to be stipulated. These are described in the scenarios below.

Relevant guidance documents consulted for human health risk assessment
Please, consider chapter 4.4.2.

Strategy for livestock exposure and/or dietary risk assessment
Not relevant

3.6.6.2 Identification of the main paths of human exposure towards active substance(s) and substance(s) of concern from use in the biocidal product

Table 3.17 Summary table: main paths of human exposure

Summary table: main paths of human exposure					
Exposure path	**Primary (direct) exposure**		**Secondary (indirect) exposure**		
	Professional users	**Non-professional users**	**Professional users**	**Non-professional bystanders/ General public**	**Via food**
Oral	n/a	n/a	no	no	no
Dermal	no	n/a	no	no	n/a
Inhalation	yes *	n/a	no**	no	n/a

* *Only if the system is not correctly working.*

** *Secondary exposure of other professionals that are not involved in the fumigation can be excluded as access to areas surrounding the treatment chambers/bubbles/tents is restricted with the conditions of use.*

3.6.6.3 List of exposure scenarios

Table 3.18 Summary table: exposure scenarios

Summary table: exposure scenarios		
Scenario and task number	**Description of scenario and tasks**	**Exposed group**
Primary exposure		
1	***Fumigation in permanent chambers or mobile tents or bubbles***	

3.6.6.4 Reference values to be used in risk characterisation

Table 3.19 Reference values to be used in risk characterisation

Reference	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	Value
AELshort-term	No data available.	No reference values were derived.	Not applicable, N_2 is a gas
AELmedium-term			Not applicable, N_2 is a gas
AELlong-term			Not applicable, N_2 is a gas
AECdermal			Not applicable, N_2 is a gas
AECinhalation			n.r.
ARfD			n.r.
ADI			n.r.

*n.r. = not relevant

3.6.6.5 Specific reference value for groundwater

No specific reference values for groundwater were derived.

3.6.6.6 Professional users

Scenario 1: Fumigation in permanent chambers or mobile tents or bubbles

Table 3.20 Description

Description of Scenario 1
A controlled atmosphere with very low oxygen concentration is created in sealed permanent chambers or mobile treament tents/bubbles. According to information provided by the applicant, these application variants are distributed in the EU as follows - 51 % permanently installed chambers with sizes 1.5-171 m^3 (75^{th} perc. 37.5 m^3) - 49 % mobile tents, bubbles (plastic cover/stationary) with sizes up to 3000 m^3 (75^{th} perc. 200 m^3) The fumigation duration are several days (7 to 56 days). As the working procedures and the resulting risk mitigation measures for professional users are essentially identical, these three application variants are covered by this scenario. The following activities are carried out during treatment with nitrogen, according to information from the applicant. At the beginning of the treatment cycle, at the treatment chambers a warning light is turned on and the door is locked. The treatment units are equipped with oxygen measuring devices as part of their system control unit. At the end of the treatment cycle, the units must be ventilated to return to normal oxygen levels and enable safe opening of the units. Therefore first, the nitrogen supply is mechanically stopped by closing a valve. For the venting, fresh air from surrounding environment is supplied e.g. by a ventilation fan with blower engine. Once normal oxygen levels are reached, the warning light turns off and the system for acoustic warning signals are deactivated. To ensure that normal oxygen levels have been reached inside the unit, a gas sample is taken at a hose outlet of the chamber with a handheld oxygen measuring device. Fumigations with nitrogen in temporarily mobile established fumigation bubbles/tents are basically carried out in the same way. After setting them up, their integrity is checked. The applicant describes that the atmosphere in such a bubble is slightly lower than ambient atmosphere so that the atmosphere inside the bubble is unlikely to flow out during the treatment duration. Nevertheless, it is theoretically possible for leaks to occur, which could lead to nitrogen escaping and thus a decrease in the oxygen concentration in surrounding areas. Two worst-case scenarios are possible: 1. Sudden release of nitrogen from the enclosure into the surrounding room air. This could be caused by a sudden significant leakage of the enclosure (e.g., due to a large tear in the sealing foil). 2. A leak in the enclosure in addition to continuous nitrogen generation into the enclosure could lead to continued nitrogen flow into the surrounding room and potentially causing a dangerous oxygen deficiency to develop. In the first worst-case situation, the entire nitrogen atmosphere of the enclosure could be released into the surrounding room air. For this scenario, the applicant made an estimation on the required surrounding room size. The calculation is based on the assumption of a fumigated enclosure with the volume $V_{enclosure}$ located in a room with a total room volume of V_{room}. The oxygen concentration in

the room outside the enclosure (Volume is V_{tot} – $V_{enclosure}$) is expected to be 21%, the concentration inside the enclosure is nearly 0%.
If the nitrogen in the enclosure escapes instantaneously into the outer volume, the final concentration in the room would be
$C_{room}[\%] = (V_{room} - V_{enclosure}) \cdot 21\% / V_{room}$
Considering that the sitation would be safe until at least 19% oxygen in the room air, the required relation of the enclosure volume to the room volume would be
$V_{room} / V_{enclosure} = 1/(21\text{-}19\%/21\%) = 10.5$

Consequently, following this calculation, the room has to be at least 10-fold the size of the enclosure to ensure no risk arising from a potential leakage of the entire nitrogen atmosphere from the enclosure to the surrounding room. For instance, a 50 m^3 big enclosure can, therefore, safely be placed in a room with a minimum volume of 500 m^3.

For scenario 2 a small leak and continuous nitrogen generation into the enclosure could lead to continued nitrogen flow into the surrounding room area. An estimation from the applicant was made on the required surrounding room size in ratio to the highest possible nitrogen flow of generators in order to ensure that no dangerous oxygen atmosphere can develop as it is sufficiently compensated by the supply of fresh air through normal room ventilation.
It is assumed that due to natural ventilation the air exchange rate Q in the room is at least 0.5 per hour, the nitrogen generation rate is expressed by $\dot{V}_{N_2}$. The two flows of ventilation air ($Q \cdot V_{room}$) with an assumed oxygen concentration of 21% and the generated nitrogen flow $\dot{V}_{N_2}$ with an assumed oxygen concentration of 0% result after prolonged durations into an equlibrium concentration in the room air of

$$c_{room} = \frac{Q \cdot V_{room} \cdot 21\% + \dot{V}_{N_2} \cdot 0\%}{Q \cdot V_{room} + \dot{V}_{N_2}} = \frac{Q \cdot V_{room} \cdot 21\%}{Q \cdot V_{room} + \dot{V}_{N_2}}$$

Considering that the situation would be safe until at least 19% oxygen in the room air (c_{room}), the resulting maximum allowable nitrogen generation is then given by

$$\dot{V}_{N_2} = \left(\frac{21\%}{19\%} - 1\right) \cdot 0.5h^{-1} \cdot V_{room} = 0.0526 \cdot V_{room} = 1/19 \cdot V_{room}$$

Following this calculation, the nitrogen flow per hour must not exceed 1/19 of the room volume. For instance, a 13.8 m^3/h nitrogen flow can be safely used when the surrounding room is at least 262.5 m^3.

These two risk mitigation measures focusing on restriction of enclosure to room size ratio as well as nitrogen flow rate per hour to room ratio has to be considered. With these risk mitigation measures in place, no harm is foreseen for operators or professional bystanders being in the vicinity of the enclosure even if both worst case scenarios as outlined would occur.
For simplification, for the RMMs the above derived values will be rounded, i.e., a restriction to an enclosed treated voulme of 1/10 of the room volume and a flow rate of 1/20 of the room volume per hour will be stipulated.

In order to detect and address cases of emerging low oxygen levels

- an area in the surrounding of the nitrogen treatment chamber/bubble/tent is defined. This area is labelled with appropriate warning signs and secured so that only authorised personnel can enter this area.
- Aeration should preferrably be performed with fresh air from outside. In cases where this is not possible, good ventilation of the sourrounding area must be ensured.

- The surrounding room must have at least 10-fold the volume of the fumigated enclosure to ensure no risk (oxygen level >19 Vol.%) from a potential leakage of the enclosure.
- The maximum nitrogen flow of the generator per hour must not exceed 1/20 of the volume of the surrounding room to ensure no risk (oxygen level >19 Vol.%) from a continuous nitrogen generation into the surrounding room.

In addition to the authorised conditions of use, there are several national guidelines listing measures to ensure safe working practices related to low oxygen level atmospheres. In Germany, there are available guidelines by the DGUV (Deutsche Gesetzliche Unfallversicherung, German public accident insurance, DGUV Information 205-006 for activities in rooms with an oxygen-reduced atmosphere); and in the German Technical Rules for Workplaces (Technische Regel für Arbeitsstätten; ASR A3.6).

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 hazards are expected for nitrogen. Therefore, no quantitative exposure and risk assessment have been performed. Regarding occupational safety, there are no objections against the use, when the following risk mitigation measures are adhered to in order to ensure safety to low level of oxygen:

Risk mitigation measures should be considered such as appropriate warning signs and good ventilation after treatment.
The surrounding room must have at least 10-fold the volume of the fumigated enclosure. The maximum nitrogen flow of the generator per hour must be at least 20-fold smaller than the size of the surrounding room.

In the opinion of the refMS DE, these measures will ensure that oxygen level for the operator and professional bystander will remain at a safe level.

3.6.6.7 Non-professional users

Not relevant. The biocidal product is not intended for non-professional use.

3.6.6.8 Secondary exposure to professional bystanders and non-professional bystanders/general public

The biocidal product 'nitrogen, *in situ* generated' is intended to be used by professionals only, to create a controlled atmosphere with an oxygen concentration <1 % (anoxia) in sealed permanent chambers or mobile treatment tents/bubbles in order to control harmful organisms for all types and combinations of materials in cultural facilities.

Potential risk during the use of the biocidal product may arise from exposure to the oxygen deficient (hypoxic) atmosphere, leading to adverse effects on human health ranging from increased breathing rates, accelerated heartbeat, nausea, vomiting to asphyxiation.

However, such exposure of the general public is not expected, since the access to areas surrounding the treatment tents/bubbles/chambers is restricted with the conditions of use. In addition to adequate warning signs, appropriate aeration/ventilation, restrictions of enclosure to room size ratio as well as nitrogen flow rate per hour to room ratio have been

stipulated to address the potential risk following a possible leakage from the enclosure (see 3.6.11).

Thus, no additional assessment of non-professional bystanders/general public is required. Secondary exposure of the general public to the biocidal product 'nitrogen, *in situ* generated' is not relevant, if the biocidal product is used as intended and access of bystanders/general public to treatment-related areas is excluded by the following risk mitigation measure:

- An area in the surrounding of the nitrogen treatment shall be defined. This surrounding area is labelled with appropriate warning signs and secured so that only authorised personnel can enter this area.

Conclusion

In conclusion, no health risk for the general public is expected, if the biocidal product is used as intended and the following risk mitigation measure is included in the SPC:

- An area in the surrounding of the nitrogen treatment shall be defined. This surrounding area is labelled with appropriate warning signs and secured so that only authorised personnel can enter this area.

3.6.7 Monitoring data

Not relevant.

3.6.8 Dietary risk assessment

The nitrogen containing biocidal product „nitrogen – *in situ* generated" for which authorisation is sought is intended to be used for the protection of cultural objects from storage pests. No direct or indirect contact with food or feed is intended. In the unlikely event that residue transfer into food items does occur, residue levels are expected to be low compared to the naturally occurring levels of nitrogen in food. Therefore, there is no dietary risk to consumers from the intended use.

3.6.8.1 Information of non-biocidal use of the active substance and residue definitions

Not relevant.

3.6.8.2 Estimating livestock exposure to active substances used in biocidal products and Worst Case Consumer Exposure (WCCE)

Not relevant.

3.6.8.3 Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s) and consumer exposure

Not relevant.

3.6.8.4 Estimating transfer of biocidal active substances into foods as a result of non-professional use and consumer exposure

Not relevant.

3.6.8.5 Maximum residue limits or equivalent

Not relevant.

3.6.9 Aggregated exposure and risk characterisation

Not relevant.

3.6.10 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not relevant.

3.6.11 Overall conclusion on risk assessment for human health

Table 3.21 Overall conclusion on the risk assessment for human health from systemic and local exposure

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
1/2/3	Professional use indoor, Nitrogen is extracted from the ambient air and pumped into the treatment tents/bubbles or chambers	*acceptable with the following risk mitigation measure*	- An area in the surrounding of the nitrogen treatment shall be defined. This surrounding area is labelled with appropriate warning signs and secured so that only authorised personnel can enter this area. - Aeration should preferably be performed with fresh air from outside. In case where this is not possible, good ventilation of the surrounding area must be ensured. - The surrounding room has to be 10-fold the volume of the fumigated enclosure to ensure no risk (oxygen level >19 Vol.%) from a

			potential leakage from the enclosure. - The nitrogen flow of the generator per hour must not exceed 1/20 of the volume of the surrounding room to ensure no risk (oxygen level >19 Vol.%) from a continuous nitrogen generation into the surrounding room.

3.7 Risk assessment for animal health

Considering the uses of the biocidal product ’nitrogen, *in situ* generated‘, exposure to animals is not expected. Therefore, no risk assessment for animal health has been performed.

3.7.1 Risk for companion animals

Not relevant for the intended use.

3.7.2 Risk for livestock animals

Not relevant for the intended use.

3.8 Risk assessment for the environment

Where applicable, the environmental risk assessment of nitrogen has been carried out according to Guidance on the BPR: Volume IV Environment (Part A) as well as (Parts B+C) (2017) when compiling this section. The guidance is available on the ECHA website at https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation.

3.8.1 Available studies and endpoints applied in the environmental risk assessment

3.8.1.1 Endpoints for the active substance(s), metabolite(s) and transformation product(s)

It is the nature of an application for authorisation of a biocidal product under Article 55 (3) BPR, that the active substance in this product has not been approved yet. Consequently, no assessment report exists for the active substance on which the assessment of the biodical products may be based. The a.s. nitrogen generated in-situ from ambient air is currently under review. However, pure nitrogen (CAS no. 7727-37-9) was notified as an existing active substance and has been already assessed and approved as an biocidal active substance under the BPD. And since no new endpoint studies have been submitted during the application for this product authorisation, the environmental risk assessment is entirely based on the list of endpoints as published in the assessment report for nitrogen (Assessment report for nitrogen PT18, 28/11/2008) for which Ireland was the rapporteur member state. The assessment report is available on the ECHA website.

The endpoints applied in the environmental risk assessment are summarised in the tables below.

Table 3.22 Endpoints and PNEC values for the active substance(s) applied in the environmental risk assessment

Endpoints and PNEC values for the active substance(s) applied in the environmental risk assessment			
	Value	**Unit**	**Remarks**
	In-situ generated nitrogen		
Fate and behaviour in the environment			
Molecular weight	28.01	g/mol	
Melting point	-210	°C	
Vapour pressure (at X°C)	Not applicable (n/a)	Pa	
Water solubility (at 15°C)	0.00216	% w/w	
Log Octanol/water partition coefficient (K_{ow})	8.08	Log 10	(ca. 25°C, isobutanol and water)
Organic carbon/water partition coefficient (K_{oc})	n/a	L/kg	
Henry's Law Constant (at X C)*[if measured data available]*	n/a	$Pa/m^3/mol$	
Characterisation of biodegradability	n/a	-	

Rate constant for STP	n/a	h^{-1}	
Transformation fraction and maximum radioactivity	n/a	- %	
DT_{50} for biodegradation in surface water	n/a	d or hr (at 12ºC)	
Transformation fraction and maximum radioactivity	n/a	- %	
DT_{50} for hydrolysis in surface water	n/a	d or hr (at 12ºC /pH)	
DT_{50} for degradation in soil	n/a	d or hr (at 12ºC)	
Transformation fraction and maximum radioactivity	n/a	- %	
DT_{50} for degradation in air	n/a	d or hr	
DT_{50} for degradation in the sewer system	n/a	d or hr (at 12ºC)	
DT_{50} for degradation in manure	n/a	d or hr (at 12ºC)	
Predicted no effect concentrations (PNEC)			
Sewage treatment plant	n/a	mg/L	
Surface water	n/a	mg/L	
Marine water	n/a	mg/L	
Sediment	n/a	mg/kg wwt	
Marine sediment	n/a	mg/kg wwt	
Soil	n/a	mg/kg wwt	
Bird	n/a		
Mammals	n/a		

3.8.1.2 Endpoints for the product

There are no new additional data available for the product. The exposure assessment and classification and labelling are based on the agreed endpoints for the active substance.

3.8.1.3 Substance(s) of concern

No substances of concern regarding the environment were identified as the product is in-situ generated nitrogen from ambient air and does not contain any other substances. Consequently, only the active substance was addressed in the environmental risk assessment.

3.8.1.4 Screening for endocrine disruption relating to non-target organisms

The biocidal product contains the active substance "Nitrogen, generated from ambient air", which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

3.8.1.5 PBT-Assessment

Not applicable.

3.8.2 Emission estimation

Not applicable.

3.8.3 Exposure calculation and risk characterisation

Waivers have been submitted for all compartments and found acceptable by the eCA on the basis that nitrogen occurs naturally in the environment comprising 78.1 % v/v in the atmosphere and does not exhibit any intrinsic hazardous characteristics nor indications of toxicity, a bioaccumulation potential or endocrine activity. A classical environmental risk assessment on the basis of a PEC/PNEC ratio is therefore not applicable. Taking into account the ubiquitous distribution in the atmosphere, it is concluded that no unacceptable risks to the environment resulting from the use of in-situ generated nitrogen as an insecticidal fumigant in a closed chamber indoors must be assumed.

3.8.4 Primary and secondary poisoning

3.8.4.1 Primary poisoning

Not applicable.

3.8.4.2 Secondary poisoning

Not applicable.

3.8.5 Mixture toxicity

Not applicable.

3.8.6 Aggregated exposure (combined for relevant emission sources)

Not applicable.

3.8.7 Overall conclusion on the risk assessment for the environment

Table 3.23 Overall conclusion on the risk assessment for the environment

Overall conclusion on the risk assessment for the environment			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
1	Nitrogen, *in situ* generated from air, is used by professionals indoor at 20°C to create a controlled atmosphere with a very low oxygen concentration (anoxia) in permanently or temporarily sealed treatment tents or chambers to control harmful organisms on cultural objects	*Acceptable*	none
2	Nitrogen, *in situ* generated from air, is used by professionals indoor at 24°C to create a controlled atmosphere with a very low oxygen concentration (anoxia) in permanently or temporarily sealed treatment tents or chambers to control harmful organisms on cultural objects	*Acceptable*	none
3	Nitrogen, *in situ* generated from air, is used by professionals indoor at 27°C to create a controlled atmosphere with a very low oxygen concentration (anoxia) in permanently or temporarily sealed treatment tents or chambers to control harmful organisms on cultural objects	*Acceptable*	none

3.9 Assessment of a combination of biocidal products

Not relevant (a use with other biocidal products is not intended).

3.10 Comparative assessment

Not relevant (no candidate for substitution was identified).

4 Appendices

4.1 Calculations for exposure assessment

4.1.1 Human health

Not relevant.

4.1.2 Dietary assessment

Not relevant.

4.1.3 Environment

Not relevant..

4.2 New information on the active substance and substance of concern

Not relevant (no new information on the active substance(s) is available).

Not relevant (no substance(s) of concern identified).

4.3 List of studies for the biocidal product

Because the data protection period pursuant Article 60(2) of the Regulation (EU) No 528/2012 expired, references to the dossier are possible, which was assessed for the inclusion of the active substance nitrogen, supplied in gas cylinders, into Annex I of the Directive 98/8/EC (asset number EU-0012349-0000). The reference list can be found in the corresponding Assessment Report. Further studies and reports submitted by the applicant with the application for product authorisation are listed below.

Table 4.1 List of studies for the biocidal product

Author (s)	**Year** **Report date**	**Reference No.** ***(Annex III requirement)*** **/** **IUCLID Section No.**	**IUCLID Document name**	**Title. Report No.**	**Type of publication**	**Source (where different from company)** **Study sponsor**	**GLP (Yes/No)**	**Data Protection Claimed (Yes/No)**
Reiche, I., Landsberger, B.	2018	6	Innovative Untersuchungsmethoden zur nachhaltigen Wirksamkeit modellhafter Anoxia-Behandlung gegen Insektenbefall an national bedeutsamen Kulturgütern der Sammlungen der Stiftung Preußischer Kulturbesitz (DBU AZ 31865-45)	-	Final project report	Rathgen-Forschungslabor, Berlin, Germany	-	No

4.4 References

4.4.1 References other than list of studies for the BP

- DGUV Information 205-006, Arbeiten in sauerstoffreduzierter Atmosphäre, Deutsche Gesetliche Unfallversicherung e.V., Berlin, Juni 2013 aktualisierte Fasssung Januar 2019.

- Technische Regeln für Arbeitstätten, ASR A3.6, Lüftung, Januar 2012, zuletzt geändert Gemeinsames Ministeralbaltt (GMBL) 2018, S.474.

4.4.2 Guidance documents

Packaging
No guidance agreed yet.

Physical, chemical, and technical properties
- Guidance on the BPR: Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. (Parts A+B+C) - Version 2.1, March 2022

Physical hazards and respective characteristics
- Guidance on the BPR: Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. (Parts A+B+C) - Version 2.1, March 2022
- Guidance on the Application of the CLP Criteria – Version 5.0, July 2017

Methods for detection and identification
- Guidance on the Biocidal Products Regulation, March 2022
  - Guidance on the BPR: Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. (Parts A+B+C) - Version 2.1, March 2022

Efficacy
- Guidance on the BPR: Volume II Efficacy – Assessment and Evaluation (Parts B+C), Version 3.0, 2018

Human health
- Guidance on the Biocidal Products Regulation Volume III Human Health -Assessment& Evaluation (Parts B+C), Version 4.0

Animal health
Not relevant.

Environment
- Guidance on the BPR: Volume IV Environment (Part A) as well as (Parts B+C) (2017) https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation.

4.4.3 Legal texts

- Regulation (EU) No 528/2012 of the European Parlament and the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

- Commission Implementing Decision (EU) 2020/1265 of 9 September 2020 allowing Germany to authorise biocidal products consisting of in situ generated nitrogen for the

protection of cultural heritage

- Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

- Commission Directive 2009/89/EC of 30 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include nitrogen as an active substance in Annex I thereto