Section A1
Annex Point II A1

<table>
<thead>
<tr>
<th>1.1 Applicant</th>
</tr>
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<tbody>
<tr>
<td><strong>Product 1</strong></td>
</tr>
<tr>
<td>(called <em>Nitrogen Controlled Atmosphere Treatment</em>)</td>
</tr>
<tr>
<td>- As above.</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>1.2 Manufacturer of Active Substance (if different)</th>
</tr>
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<tbody>
<tr>
<td><strong>Product 1</strong></td>
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<tr>
<td>(called <em>Nitrogen Controlled Atmosphere Treatment</em>)</td>
</tr>
<tr>
<td>- As above.</td>
</tr>
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</table>

<table>
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<tr>
<th>1.3 Manufacturer of Product(s) (if different)</th>
</tr>
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<tr>
<td><strong>Product 1</strong></td>
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<tr>
<td>(called <em>Nitrogen Controlled Atmosphere Treatment</em>)</td>
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<td>- As above.</td>
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### Section A2
#### Identity of Active Substance

**Annex Point IIA II**

<table>
<thead>
<tr>
<th>Subsection</th>
<th>Description</th>
</tr>
</thead>
</table>
| **2.1 Common name** (IIA2.1) | Nitrogen  
Synonyms: Dinitrogen, diatomic nitrogen, diazyn. |
| **2.2 Chemical name** (IIA2.2) | IUPAC Name: Nitrogen |
| **2.3 Manufacturer’s development code number(s)** (IIA2.3) | Manufacturer’s development code number is not applicable, since Nitrogen is a naturally occurring gas. |
| **2.4 CAS no. and EC numbers** (IIA2.4) |  
2.4.1 CAS No. 7727-37-9  
2.4.2 EC-No 231-783-9 |
| **2.5 Molecular and structural formula, molecular mass** (IIA2.5) |  
2.5.1 Molecular formula N₂  
2.5.2 Structural formula N=N (smiles code)  
2.5.3 Molecular mass 28.01 |
| **2.6 Method of manufacture of the active substance** (IIA2.6) | [Redacted] |
### Section A2  
**Annex Point IIA II**

<table>
<thead>
<tr>
<th>2.7</th>
<th>Specification of the purity of the active substance, as appropriate (IIA2.7)</th>
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<tbody>
<tr>
<td>2.8</td>
<td>Identity of impurities and additives, as appropriate (IIA2.8)</td>
</tr>
<tr>
<td>2.8.1</td>
<td>Isomeric composition</td>
</tr>
<tr>
<td>2.9</td>
<td>The origin of the natural active substance or the precursor(s) of the active substance. (IIA2.9)</td>
</tr>
</tbody>
</table>

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**Evaluation by Competent Authorities**

Use separate “evaluation boxes” to provide transparency as to the comments and views submitted.

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**EVALUATION BY RAPPORTEUR MEMBER STATE**

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<th>Give date of action</th>
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</thead>
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</table>

**Materials and Methods**

*State if applicants version is acceptable, or indicate relevant discrepancies referring to the (sub)heading numbers and to applicant’s summary and conclusion.*

**Results and discussion**

*Adopt applicant’s version or include revised version. If necessary, discuss relevant deviations from applicant’s view referring to the (sub)heading numbers.*

**Conclusion**

*Other conclusions:*

*(adopt applicant’s version or include revised version)*

**Reliability**

*Based on assessment of materials and methods include appropriate reliability indicator.*

**Acceptability**

*Acceptable / not acceptable*

*(give reasons if necessary e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary).*

**Remarks**

**COMMENTS FROM .....**

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<td>Section A2</td>
<td>Identity of Active Substance</td>
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<td>------------------------------</td>
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<tr>
<td>Annex Point IIA II</td>
<td>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant’s summary and conclusion. Discuss if deviating from view of rapporteur member state.</td>
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<td>Materials and Methods</td>
<td>Discuss if deviating from view of rapporteur member state.</td>
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<td>Conclusion</td>
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<tr>
<td>Acceptability</td>
<td>Discuss if deviating from view of rapporteur member state.</td>
</tr>
<tr>
<td>Remarks</td>
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</tbody>
</table>
2.10.1 Human exposure towards active substance
2.10.1.1 Production
   i) Description of process

   ii) Workplace description

   iii) Inhalation exposure

   iv) Dermal exposure

2.10.1.2 Intended uses
   1. Professional users
      i) Description of application process

         Nitrogen gas is intended for use in the insecticidal fumigant product, Nitrogen Controlled Atmosphere Treatment (PT18).

         The representative product Nitrogen Controlled Atmosphere Treatment is a gas tight area (e.g., a CAT bubble) into which the infested commodities and/or artefacts are placed. The atmosphere within the CAT bubble is then flushed with nitrogen to create an controlled atmosphere of oxygen at <0.2% v/v and nitrogen at >99.8% v/v. It is used to control stored products pests, wood-destroying insects, textile pests and other arthropods.

         Please refer to Document IIIB, Section B6.6 for full details of the tasks and expected levels of nitrogen gas exposure expected from the normal use of Nitrogen Controlled Atmosphere Treatment by professional users.

      ii) Workplace description

         Nitrogen gas is intended for use in the insecticidal fumigant product, Nitrogen Controlled Atmosphere Treatment (PT18). Please refer to Document IIIB, Section B6.6 for full details of the tasks, situations and expected levels of exposure to nitrogen gas from the normal use of Nitrogen Controlled Atmosphere Treatment by professional users.

      iii) Inhalation exposure

         Nitrogen gas is intended for use in the insecticidal fumigant product, Nitrogen Controlled Atmosphere Treatment (PT18). Please refer to Document IIIB, Section B6.6 for full details of the tasks and expected levels of exposure to nitrogen gas from the normal use of Nitrogen Controlled Atmosphere Treatment by professional users.
### Section A2.10
### Annex Point IIA, II, 2.10


2. **Non-professional users including the general public**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>iv) Dermal exposure</td>
<td>Nitrogen is a gas, therefore inhalation is the principle route of exposure. Because of this, the dermal route has not been considered.</td>
</tr>
</tbody>
</table>

#### 2. Non-professional users including the general public

i) **via inhalation**

Nitrogen gas is intended for use in the insecticidal fumigant product, Nitrogen Controlled Atmosphere Treatment (PT18). It is intended for use by professional users only, so primary exposure to nitrogen gas to non-professional users e.g. the general public, is not applicable for the exposure assessment.

ii) **via skin contact**

Nitrogen gas is intended for use in the insecticidal fumigant product, Nitrogen Controlled Atmosphere Treatment (PT18). It is intended for use by professional users only, so primary exposure to nitrogen gas to non-professional users e.g. the general public, is not applicable for the exposure assessment.

iii) **via drinking water**

Nitrogen gas is intended for use in the insecticidal fumigant product, Nitrogen Controlled Atmosphere Treatment (PT18). It is not intended for application directly to water courses. Therefore, exposure to nitrogen gas via drinking water is nil. Notwithstanding this, the environmental exposure assessment for Nitrogen Controlled Atmosphere Treatment shows that there is no likelihood of nitrogen gas entering water courses during normal use as a biocide (see Document IIIB, Section B7.1 for further details).

Full details of the expected levels of exposure to the aquatic compartment are given in section 2.10.2 (below).

iv) **via food**

Nitrogen gas is intended for use in the insecticidal fumigant product, Nitrogen Controlled Atmosphere Treatment (PT18). It can be used to treat food and animal feeding stuffs.

For further details, please refer to Document IIIB, Section B6 7.1.1.

v) **indirect via the environment**

Nitrogen gas is intended for use in the insecticidal fumigant product, Nitrogen Controlled Atmosphere Treatment (PT18). The environmental exposure assessment (as given in section 2.10.2, below) shows that the use of nitrogen gas as a biocide does not change the amount of nitrogen in the environment. Indirect human exposure to nitrogen gas via the environment has not been considered further.

### 2.10.2 Environmental exposure towards the active substance

#### 2.10.2.1 Production

- **(i) Releases into water**

  ![ASCII Art Diagram]

  ![ASCII Art Diagram]
Section A2.10
Annex Point IIA, II, 2.10


(ii) Releases into air

(iii) Waste disposal

2.10.2.2 Intended use(s)

Affected compartment(s):

None. The environmental exposure assessment for nitrogen gas and the representative product, Nitrogen Controlled Atmosphere Treatment, show that there will be zero exposure to the environmental compartments.

For further details, please refer to Document IIIB, Section B7.1.

Predicted concentration in the environmental compartment(s):

Zero.

Nitrogen gas is intended for use in the insecticidal fumigant product, Nitrogen Controlled Atmosphere Treatment (PT18). The environmental exposure assessment for nitrogen gas and the representative product, Nitrogen Controlled Atmosphere Treatment, show that there will be zero exposure to the environmental compartments.

For further details, please refer to Document IIIB, Section B7.1.

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted.

EVALUATION BY RAPPORTEUR MEMBER STATE

Date
Give date of action

Materials and Methods
State if applicants version is acceptable, or indicate relevant discrepancies referring to the (sub)heading numbers and to applicant’s summary and conclusion.

Conclusion
Adopt applicant’s version or include revised version

Reliability
Based on assessment of materials and methods include appropriate reliability indicator.

Acceptability
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(give reasons if necessary e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies.)
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Section A2.10
Annex Point II A, II, 2.10
### Section A3  Physical and Chemical Properties of Active Substance

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<th>Purity/Specification</th>
<th>Results</th>
<th>Remarks/Justification</th>
<th>GLP (Y/N)</th>
<th>Reliability</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 Melting point, boiling point, relative density (IIA3.1)</td>
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<td>--</td>
<td>--</td>
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<td>3.1.1 Melting point</td>
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<td>See footnote (below)</td>
<td>N</td>
<td>3</td>
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</tbody>
</table>

Reference: [Link to reference](#)
### Physical and Chemical Properties of Active Substance

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<th>Subsection (Annex point)</th>
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<th>GLP (Y/N)</th>
<th>Reliability</th>
<th>Reference</th>
<th>Official use only</th>
</tr>
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<tbody>
<tr>
<td>3.1.2 Boiling point</td>
<td>Not reported</td>
<td>Not reported</td>
<td>-195.8°C</td>
<td>See footnote (below)</td>
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<td>3</td>
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</table>
### Section A3  
**Physical and Chemical Properties of Active Substance**

<table>
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<th>Reliability</th>
<th>Reference</th>
<th>Official use only</th>
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<tbody>
<tr>
<td>3.1.3 Bulk density/relative density</td>
<td>Not reported Refer to Remarks / Justification.</td>
<td>See footnote (below)</td>
<td>Density: 1.25 g/L</td>
<td>See footnote (below)</td>
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</table>

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Page 1 of 1
Section 3.2
Annex Point IIA 3.2

Vapour Pressure

**JUSTIFICATION FOR NON-SUBMISSION OF DATA**

As outlined in the TN&G on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier. If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable.

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<thead>
<tr>
<th>Other existing data [ ]</th>
<th>Technically not feasible [3]</th>
<th>Scientifically unjustified [ ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limited exposure [ ]</td>
<td>Other justification [ ]</td>
<td></td>
</tr>
</tbody>
</table>

**Detailed justification:**

The vapour pressure of a substance is defined as the saturation pressure above a solid or liquid substance. At the thermodynamic equilibrium, the vapour pressure of a pure substance is a function of temperature only.

Based on the above definition, it is not technically feasible to measure the vapour pressure of nitrogen when used as a biocide. This is because it will only be used under ambient temperature and pressure. Under these conditions nitrogen will be completely in the gaseous form and not present as a liquid or solid (please see also the melting and boiling points quoted within the dossier).

**Undertaking of intended data submission [ ]**

Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)

**Evaluation by Competent Authorities**

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted.

**EVALUATION BY RAPPORTEUR MEMBER STATE**

Date

Give date of action

Evaluation of applicant's justification

Discuss applicant's justification and, if applicable, deviating view

Conclusion

Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data

Remarks

**COMMENTS FROM OTHER MEMBER STATE (specify)**

Date

Give date of comments submitted

Evaluation of applicant's justification

Discuss if deviating from view of rapporteur member state
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**Conclusion**

Discuss if deviating from view of rapporteur member state

**Remarks**
**Section 3.2.1**
Annex Point Pt.1-A3.2

**Henry’s Law Constant**

**JUSTIFICATION FOR NON-SUBMISSION OF DATA**

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<tbody>
<tr>
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<td>Other justification [ ]</td>
<td></td>
</tr>
</tbody>
</table>

**Detailed justification:**

The Technical Guidance Document in Support of the Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance for Data Requirements for Active Substances and Biocidal Products, Version 4.3.2 dated October 2000 states that the Henry’s Law Constant depends on the water solubility and vapour pressure of a substance, and expresses the tendency of a substance to evaporate from aqueous solutions.

Measuring of this parameter is scientifically unjustified, since nitrogen makes up 78.1% v/v (an estimated 4000 trillion tons) of the Earth’s atmosphere and the use of nitrogen as a biocide will never elevate levels beyond normal atmospheric ranges. Also, it is only slightly soluble in water (see elsewhere in this dossier) and the use of nitrogen as a biocide will never elevate levels beyond normal aquatic ranges.

**Undertaking of intended data submission [ ]**

Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)

---

**Evaluation by Competent Authorities**

Use separate “evaluation boxes” to provide transparency as to the comments and views submitted.

**EVALUATION BY RAPPORTEUR MEMBER STATE**

Date

Evaluate date of action

Evaluation of applicant’s justification

Discuss applicant’s justification and, if applicable, deviating view

Conclusion

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Remarks

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**Evaluation of applicant's justification**  
*Discuss if deviating from view of rapporteur member state*

**Conclusion**  
*Discuss if deviating from view of rapporteur member state*
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<th>Reliability</th>
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<td>3.3 Appearance (IIA3.3)</td>
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### Section A3  Physical and Chemical Properties of Active Substance

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<td>Absorption spectra</td>
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Page 1 of 1
**Section 3.4.2IR**  
**Annex Point IIA 3.4**  
Absorption Spectra - IR

**JUSTIFICATION FOR NON-SUBMISSION OF DATA**  
As outlined in the TNSG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.  
If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable.

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<tbody>
<tr>
<td>Limited exposure</td>
<td>Other justification [ ]</td>
<td></td>
</tr>
</tbody>
</table>

**Detailed justification:**  
Infrared spectroscopy is used to determine functional groups of compounds in the vapour phase, as pure liquids, in solution or in a solid state.  
It is not technically feasible to measure the IR spectra of nitrogen since it is transparent through the entire infrared spectral region.  
Also, the structure of the nitrogen molecule has already been established by other means.

**Undertaking of intended data submission** [ ]  
Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)

**Evaluation by Competent Authorities**  
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted.

**EVALUATION BY RAPPOREUR MEMBER STATE**

**Date**

Give date of action

**Evaluation of applicant's justification**

Discuss applicant's justification and, if applicable, deviating view

**Conclusion**

Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data

**Remarks**

**COMMENTS FROM OTHER MEMBER STATE (specify)**

**Date**

Give date of comments submitted

**Evaluation of applicant's justification**

Discuss if deviating from view of rapporteur member state

**Conclusion**

Discuss if deviating from view of rapporteur member state

**Remarks**
**Absorption Spectra - NMR**

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### Detailed justification:

Nuclear Magnetic Resonance spectroscopy is used to determine the structure of liquid organic chemicals. It is also typically conducted on molecules containing the Carbon\(^{13}\) or Hydrogen\(^{1}\) nuclei. Also, NMR on Nitrogen\(^{14}\) or Nitrogen\(^{15}\) nuclei give unclear results. Therefore it is not technically feasible to measure the NMR since the nitrogen molecule is not an organic compound (which are defined as molecules containing hydrocarbon groups). Also, the structure of the nitrogen molecule has already been established by other means.

### Undertaking of intended data submission

Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)

### Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted.

#### EVALUATION BY RAPPORTEUR MEMBER STATE

- **Date**: Give date of action
- **Evaluation of applicant's justification**: Discuss applicant's justification and, if applicable, deviating view
- **Conclusion**: Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data
- **Remarks**

#### COMMENTS FROM OTHER MEMBER STATE (specify)

- **Date**: Give date of comments submitted
- **Evaluation of applicant's justification**: Discuss if deviating from view of rapporteur member state
- **Conclusion**: Discuss if deviating from view of rapporteur member state
- **Remarks**
### Section A3  Physical and Chemical Properties of Active Substance

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<tr>
<td>3.4</td>
<td>Absorption Spectra (IIA, III, 3.4)</td>
<td></td>
<td></td>
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<td>MS</td>
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</tr>
</tbody>
</table>
### Section A3: Physical and Chemical Properties of Active Substance

<table>
<thead>
<tr>
<th>Subsection (Annex point)</th>
<th>Method</th>
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<th>Results</th>
<th>Remarks/ Justification</th>
<th>GLP (Y/N)</th>
<th>Reliability</th>
<th>Reference</th>
<th>Official use only</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5 Solubility in water (IIA3.5)</td>
<td>Not reported</td>
<td>Refer to Remarks / Justification.</td>
<td>See footnote.</td>
<td>Nitrogen is sparingly soluble in water: - 0.00198% w/w at 20°C</td>
<td>N</td>
<td>3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Effects of pH on water solubility**

No data has been found showing the effect of pH on solubility of nitrogen. However, the amount of dissociation of water is unlikely to have a significant effect on its interaction with the inert nitrogen molecule and therefore its solubility. On this basis, experimental determination of the effect in pH on solubility of the nitrogen prescribed in this application will not add any significant information to this application.
### Section 3.6

**Annex Point IIIA, IIIB**

#### Dissociation Constant

**JUSTIFICATION FOR NON-SUBMISSION OF DATA**

As outlined in the TNmG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.

If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable.

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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
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</table>

**Limited exposure**

<table>
<thead>
<tr>
<th></th>
<th>Other justification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[ ]</td>
</tr>
</tbody>
</table>

**Detailed justification:**

It is not technically possible to determine the dissociation constant of nitrogen in water. This is because nitrogen has been shown to be insoluble in water. Refer to data end point Document IIIA, section A3.5 solubility in water (IIA3.5). The EPA approved test guideline for determining dissociation constant in water (Guideline OPPTS 830.7370) states that dissociation constant can only be measured if the test material is soluble in water.

Notwithstanding this, it is also not scientifically necessary to determine the dissociation constant of nitrogen in water. Since the “Technical Guidance Document in Support of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products” states that dissociation constant only needs to be measured if water solubility cannot be measured.

#### Undertaking of intended data submission

Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)

#### Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted.

**EVALUATION BY RAPPORTEUR MEMBER STATE**

**Date**

Give date of action

**Evaluation of applicant's justification**

Discuss applicant's justification and, if applicable, deviating view

**Conclusion**

Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g., submission of specific test/study data.

**Remarks**
<table>
<thead>
<tr>
<th>Section 3.6</th>
<th>Dissociation Constant</th>
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</thead>
<tbody>
<tr>
<td>Annex Point IIIA, III0§</td>
<td>COMMENTS FROM OTHER MEMBER STATE (specify)</td>
</tr>
<tr>
<td>Date</td>
<td>Give date of comments submitted</td>
</tr>
<tr>
<td>Evaluation of applicant's justification</td>
<td>Discuss if deviating from view of rapporteur member state</td>
</tr>
<tr>
<td>Conclusion</td>
<td>Discuss if deviating from view of rapporteur member state</td>
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<td>Remarks</td>
<td></td>
</tr>
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<th>Reliability</th>
<th>Reference</th>
<th>Official Use only</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA, III, I)</td>
<td>Not reported. Refer to Remarks/Justification</td>
<td>Results presented in terms of %w/w (all measured at the same pressure of 0.101325 MPa).</td>
<td>-60°C 0.04200 %w/w  -50°C 0.04233 %w/w  -40°C 0.04298 %w/w  -30°C 0.04330 %w/w  -20°C 0.04363 %w/w  -10°C 0.04395 %w/w  0°C 0.04428 %w/w  10°C 0.04460 %w/w  20°C 0.04493 %w/w  25°C 0.04526 %w/w</td>
<td>These results show that nitrogen is virtually insoluble in hexane, and that the solubility stays approximately constant between -60°C to 25°C. Note that it is not possible to express the solubility of nitrogen in hexane in mg/L. This is because the amount of gas dissolved was not reported.</td>
<td>N</td>
<td>3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Section A3: Physical and Chemical Properties of Active Substance

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<th>Reliability</th>
<th>Reference</th>
<th>Official Use only</th>
</tr>
</thead>
</table>
| 3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA, III, I) | Not reported. | Refer to Remarks / Justification | Results presented in terms of %w/w (all measured at the same pressure of 0.101325 MPa). | | \[ \begin{align*}
-60^\circ C & : 0.02485 \%w/w \\
-50^\circ C & : 0.02433 \%w/w \\
-40^\circ C & : 0.02398 \%w/w \\
-30^\circ C & : 0.02380 \%w/w \\
-20^\circ C & : 0.02363 \%w/w \\
-10^\circ C & : 0.02363 \%w/w \\
0^\circ C & : 0.02363 \%w/w \\
10^\circ C & : 0.02371 \%w/w \\
20^\circ C & : 0.02380 \%w/w \\
25^\circ C & : 0.02389 \%w/w \\
30^\circ C & : 0.02398 \%w/w \\
40^\circ C & : 0.02324 \%w/w \\
50^\circ C & : 0.02350 \%w/w \\
\end{align*} \] | N | 3 | |

These results show that nitrogen is virtually insoluble in methanol, and that the solubility stays approximately constant between -60°C to 50°C. Note that it is not possible to express the solubility of nitrogen in methanol in mg/L. This is because the amount of gas dissolved was not reported.
### Stability in organic solvents

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Limited exposure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Detailed justification:** The Technical Guidance Document in Support of the Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance on Data Requirements for Active Substances and Biocidal Products (dated October 2000) states that stability in organic solvents must only be determined if the active ingredient, as manufactured, includes an organic solvent. Nitrogen will be supplied as a 100% gas when it is marketed as a biocide. It does not contain any organic solvents, therefore stability data for nitrogen in organic solvents is not required.

**Undertaking of intended data submission**

Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)

### Evaluation by Competent Authorities

*Use separate "evaluation boxes" to provide transparency as to the comments and views submitted*

**EVALUATION BY RAPPORTEUR MEMBER STATE**

**Date**
Give date of action

**Evaluation of applicant's justification**
Discuss applicant's justification and, if applicable, deviating view

**Conclusion**
Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data

**Remarks**

**COMMENTS FROM OTHER MEMBER STATE (specify)**

**Date**
Give date of comments submitted

**Evaluation of applicant's justification**
Discuss if deviating from view of rapporteur member state

**Conclusion**
Discuss if deviating from view of rapporteur member state

**Remarks**
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</thead>
<tbody>
<tr>
<td>3.9 Partition coefficient n-octanol/water (IIA, III, 3.6)</td>
<td>Not given.</td>
<td></td>
<td>Partition Coefficient $K$ for nitrogen at about 25°C: Isobutanol and water: 8.08 Olive oil and water: 4.66</td>
<td>N</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Section A3

### Physical and Chemical Properties of Active Substance

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<th>Reliability</th>
<th>Reference</th>
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</tr>
</thead>
<tbody>
<tr>
<td>3.10 Thermal stability, identity of relevant breakdown products (IIA, 3.7)</td>
<td>Not reported. Refer to Remarks/Justification.</td>
<td>Not reported. Refer to Remarks/Justification.</td>
<td>Nitrogen gas (N2) is thermodynamically stable. Refer to Remarks/Justification.</td>
<td>Nitrogen gas (N2) is widely known to be an inert molecule that will only react with other chemicals in the presence of a catalyst (e.g., lightning, nitrogen fixing bacteria, etc). The only breakdown product that nitrogen gas can form is elemental nitrogen; this will quickly combine with other chemicals to form other molecules, e.g., together with oxygen to form nitrogen oxides (NOx).</td>
<td>N</td>
<td>3</td>
<td></td>
<td></td>
</tr>
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</table>
Flammability, including auto-flammability and identity of combustion products.

**Justification for non-submission of data**

As outlined in the TnSG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.

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<tbody>
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<td>[ ]</td>
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<td>[3]</td>
</tr>
</tbody>
</table>

**Detailed justification:**

Nitrogen gas is widely known to be inert, therefore it is scientifically unjustified to measure the flammability.

Nitrogen is listed in Annex I of 67/548/EEC as “Not Classified”. One of the classification criteria is flammability, which does not apply to this substance.

**Undertaking of intended data submission**

Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)

**Evaluation by Competent Authorities**

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted.

**EVALUATION BY RAPPORTEUR MEMBER STATE**

Give date of action

Discuss applicant's justification and, if applicable, deviating view

**Conclusion**

Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data

**Remarks**

**Comments from other Member State (specify)**

Give date of comments submitted

Discuss if deviating from view of rapporteur member state

**Conclusion**

Discuss if deviating from view of rapporteur member state

**Remarks**
Section 3.12  
Annex Point IIA 3.9  
Flash Point

**JUSTIFICATION FOR NON-SUBMISSION OF DATA**

As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.

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<tbody>
<tr>
<td>Limited exposure [ ]</td>
<td>Other justification [ ]</td>
<td></td>
</tr>
</tbody>
</table>

**Detailed justification:**

Flash point is defined as the lowest temperature, corrected to a pressure of 101,325 Pa (normal atmospheric pressure), at which a liquid evolves vapours, under specified test conditions, in such an amount that a flammable vapour-air mixture is produced. Nitrogen does not exist as a liquid at normal atmospheric pressure. It is a gas under the conditions it will be marketed as a biocide. It is technically not feasible to determine the flash point of a gas. There is no approved guideline for testing the flash point of a gas. Notwithstanding this, it is also not scientifically necessary to conduct a flash point test for nitrogen on the basis that it is well established and accepted that nitrogen is a non-flammable gas that does not support combustion.

**Undertaking of intended data submission [ ]**

Give date on which the data will be handed in later (Only acceptable if the test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)

**Evaluation by Competent Authorities**

*Use separate "evaluation boxes" to provide transparency as to the comments and views submitted*

**EVALUATION BY RAPPORTEUR MEMBER STATE**

**Date**

Give date of action

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Discuss applicant's justification and, if applicable, deviating view

**Conclusion**

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**Remarks**

**COMMENTS FROM OTHER MEMBER STATE (specify)**

**Date**

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**Evaluation of applicant's justification**

Discuss if deviating from view of rapporteur member state

**Conclusion**

Discuss if deviating from view of rapporteur member state

**Remarks**
### Section 3.13
Annex Point IIA 3.10

**Surface Tension**

**JUSTIFICATION FOR NON-SUBMISSION OF DATA**

As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.

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<td>[ ]</td>
<td>[3]</td>
<td>[3]</td>
</tr>
</tbody>
</table>

**Limited exposure**

[ ]

**Other justification**

[ ]

**Detailed justification:** The test methods described in Directive 92/69/E.E.C. A.5 only apply to the measurement of surface tension of aqueous solutions. Nitrogen does not exist as an aqueous solution at normal atmospheric pressure. It is a gas under the conditions it will be marketed as a biocide. It is technically not feasible to determine the surface tension of a gas. There is no approved guideline for determining the surface tension of a gas. It is also scientifically unjustified, given that nitrogen is a gas under the normal physical conditions it will be used as a biocide. Determining the surface tension of nitrogen (by manipulating the test conditions e.g. temperature and pressure), will not provide any useful information for the risk assessment.

**Undertaking of intended data submission**

[ ]

Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)

### Evaluation by Competent Authorities

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**Conclusion**

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**Remarks**

**COMMENTS FROM OTHER MEMBER STATE (specify)**

**Date**

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Discuss if deviating from view of rapporteur member state

**Conclusion**

Discuss if deviating from view of rapporteur member state

**Remarks**
## Section 3.14  
Annex Point (IIIa, III0§)

### Viscosity

#### JUSTIFICATION FOR NON-SUBMISSION OF DATA

As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier. If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable.

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<tr>
<th>Reason</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technically not feasible</td>
<td>[3] The Technical Guidance Document in Support of the Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market: Guidance for Data Requirements for Active Substances and Biocidal Products, Version 4.3.2 dated October 2000 states that viscosity should be measured for liquid substances only. Nitrogen does not exist as a liquid at normal atmospheric pressure. It is a gas under the conditions it will be marketed as a biocide. It is technically not feasible to determine the viscosity of a gas. There is no approved guideline for testing the viscosity of a gas. It is also scientifically unjustified, given that nitrogen is a gas under the normal physical conditions it will be used as a biocide. Determining the viscosity of nitrogen (by manipulating the test conditions e.g. temperature and pressure), will not provide any useful information for the risk assessment.</td>
</tr>
<tr>
<td>Scientifically unjustified</td>
<td>[3] Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</td>
</tr>
</tbody>
</table>

#### Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted.

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<td>Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data</td>
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</tr>
<tr>
<td>Remarks</td>
<td></td>
</tr>
</tbody>
</table>
# Explosive properties

**JUSTIFICATION FOR NON-SUBMISSION OF DATA**

As outlined in the TnSG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.

If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable.

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</thead>
<tbody>
<tr>
<td>Limited exposure [ ]</td>
<td>Other justification [ ]</td>
<td></td>
</tr>
</tbody>
</table>

**Detailed justification:**
The test method Directive 92/69/E C A.14 Explosive Properties, states that the test for explosive properties need not be performed when available thermodynamic information (e.g. heat of formation, heat of decomposition) and/or absence of certain reactive groups in the structural formula establishes beyond reasonable doubt that the substance does not present any risk of explosion. It is widely known and accepted that nitrogen is thermodynamically stable and therefore does not exhibit explosive properties. Conducting an explosivity test for nitrogen will only confirm this well-established property of nitrogen, and will not provide any new information for the risk assessment.

**Undertaking of intended data submission [ ]**

Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)

---

**Evaluation by Competent Authorities**

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**EVALUATION BY RAPPORTEUR MEMBER STATE**

**Date**

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**Evaluation of applicant’s justification**

Discuss applicant’s justification and, if applicable, deviating view

**Conclusion**

Indicate whether applicant’s justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data

**Remarks**

**COMMENTS FROM OTHER MEMBER STATE (specify)**

**Date**

Give date of comments submitted

**Evaluation of applicant’s justification**

Discuss if deviating from view of rapporteur member state

**Conclusion**

Discuss if deviating from view of rapporteur member state

**Remarks**
**Section 3.16**  
**Annex Point IIA 3.12**  

**Oxidising Properties**

<table>
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<tbody>
<tr>
<td>Limited exposure [ ]</td>
<td>Other justification [ ]</td>
<td></td>
</tr>
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</table>

**Detailed justification:** The test methods described in Directive 92/69/E.E.C A.17 only applies to solid materials. Nitrogen is not a solid at normal atmospheric pressure. It is a gas under the conditions it will be marketed as a biocide. It is not scientifically unjustified to determine whether nitrogen has oxidising properties because there are no approved guidelines for testing the oxidising properties of a gas. Notwithstanding this, examination of the structural formula of nitrogen, along with the fact that it is widely accepted that nitrogen is thermodynamically stable, suggests that nitrogen will not exhibit oxidising properties, even if it could be tested.

**Undertaking of intended data submission [ ]**  
Give date on which the data will be handed in later. (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)

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**Evaluation by Competent Authorities**

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted.

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<td>Discuss applicant's justification and, if applicable, deviating view.</td>
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**Remarks**

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</tbody>
</table>

| Remarks | |
|---------| |
Section 3.17  
Annex Point IIA 3.13  
Reactivity towards container material

JUSTIFICATION FOR NON-SUBMISSION OF DATA

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If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable.

Other existing data [ ]  
Limited exposure [ ]  
Technically not feasible [ ]  
Scientifically unjustified [3]  
Other justification [ ]

Detailed justification:

Nitrogen is supplied in containers designed and manufactured in accordance with either:-

Containers manufactured to these specifications will ensure that there is no reactivity between the nitrogen and its container. Moreover, nitrogen is widely accepted to be inert.

Undertaking of intended data submission [ ]

Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date

Give date of action
### Section 3.17  
**Annex Point II A 3.13**

<table>
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1. Reference

2. Data protection

3. Data owner
3. **MATERIALS AND METHODS**

3.1 **Preliminary Treatment**

3.1.1 Enrichment  
Not applicable.

3.1.2 Cleanup  
Not applicable.

3.2 **Detection**

3.2.1 Separation method  
Not applicable. The nitrogen gas for use as a biocide will be contained either in the nitrogen gas cylinders or the fumigation containment area (eg. CAT bubble). The test gas will simply be drawn off through a valve / sample port.

3.2.2 Detector  
**Nitrogen**  
Not applicable. After determination of the total content of specified impurities (see list below) the balance shall consist of nitrogen, plus any traces of noble gases present.

**Specified impurities:**
- Oxygen - Please see annex B of reference A4.1/01
- Carbon monoxide and Carbon dioxide - Please see annex C of reference A4.1/01
- Total hydrocarbons - Please see annex D of reference A4.1/01
- Water - Please see annex E of reference A4.1/01

3.2.3 Standards  
Standard gas not necessary.

3.2.4 Interfering substances  
None.
### 3.3 Linearity

#### 3.3.1 Calibration range

**Specified impurities:**
- Oxygen ≤ 0.0015% v/v
- Carbon monoxide ≤ 0.0005% v/v
- Carbon dioxide ≤ 0.0001% v/v
- Total hydrocarbons ≤ 0.0001% v/v
- Water ≤ 0.0010% v/v

- **Total impurities** ≤ 0.0032% v/v
- **Nitrogen** ≥ 99.9968% v/v

This standard is suitable for measuring nitrogen gas to a purity in the range of 99.9968% v/v - 100.0000% v/v.

#### 3.3.2 Number of measurements

Not reported.

#### 3.3.3 Linearity

Not reported.

### 3.4 Specifity: interfering substances

None.

### 3.5 Recovery rates at different levels

Not reported.

#### 3.5.1 Relative standard deviation

Not reported.

### 3.6 Limit of determination

This standard is suitable for measuring nitrogen gas to a purity in the range of 99.9968% v/v - 100.0000% v/v.

### 3.7 Precision

#### 3.7.1 Repeatability

#### 3.7.2 Independent laboratory validation
4 APPLICANT’S SUMMARY AND CONCLUSION

4.1 Materials and methods
Since nitrogen gas cannot be specifically analysed itself, its presence is determined by the absence of the other major atmospheric gases.

4.2 Conclusion
The nitrogen gas used as a biocide is extracted from the atmosphere. The relative composition of the atmosphere is widely known to be remarkably consistent between sea level and 300,000 feet. Therefore, the assumption that nitrogen is left when the other major atmospheric gases have been removed is justified.

This standard is suitable for measuring nitrogen gas to a purity in the range of 99.9968% v/v - 100.0000% v/v.

4.2.1 Reliability
1

4.2.2 Deficiencies
None.

Evaluation by Competent Authorities

Use separate “evaluation boxes” to provide transparency as to the comments and views submitted.

EVALUATION BY RAPPORTEUR MEMBER STATE

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**Section A4.1**
**Annex Point II A, IV, 4.1**
**Analytical Methods for Detection and Identification**
Purity of Active Ingredient
### Section 4.2 (a) Annex Point IIA, IV. 4.2

Analytical methods in all relevant environmental media including recovery rates and the limits of determination for the active substance, and residues thereof, and where relevant in/on the following: (a) Soil

#### JUSTIFICATION FOR NON-SUBMISSION OF DATA

As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.

If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable:

- Other existing data [✓]
- Limited exposure [✓]
- Detailed justification:
  - Technically not feasible [✓]
  - Scientifically unjustified [✓]
  - Other justification [✓]

When used as a biocide, within the fumigation containment area, nitrogen will not enter the soil compartment because there is no mechanism for it to be released directly into the soil. This means that the use of nitrogen as a biocide will never elevate the levels of nitrogen beyond normal atmospheric ranges.

#### Undertaking of intended data submission [✓]

Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)

### Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

#### EVALUATION BY RAPPORTEUR MEMBER STATE

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#### Remarks

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- **Remarks**