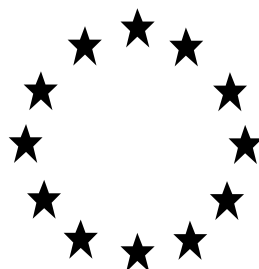


Competent Authority Report



DOCUMENT III-A

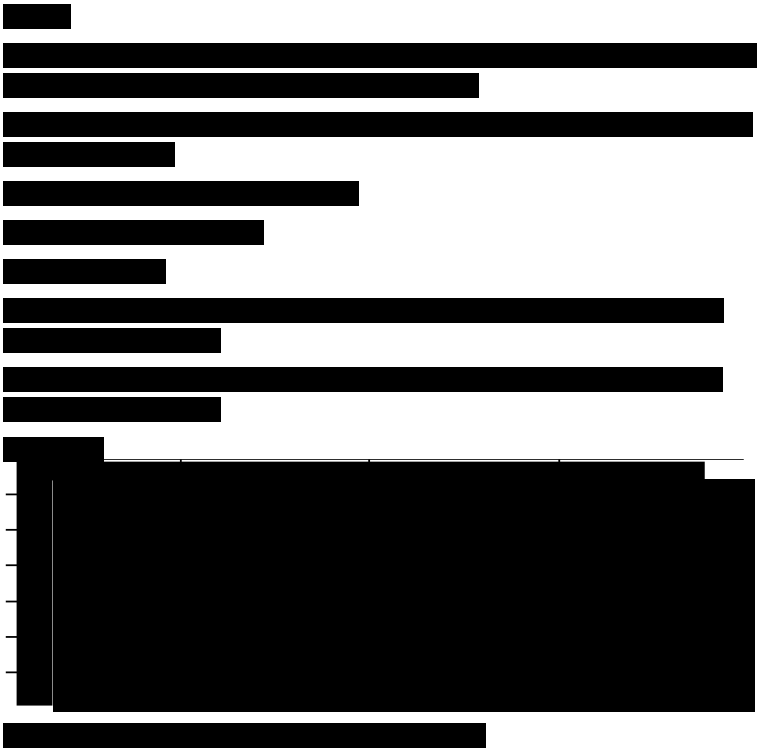






Study Summaries Active Substance

Addendum to Section 4

Rapporteur Member State: Italy

April 2021

| | | |
|--|--|--------------------------|
| BPR: Ann II 5.2.1 BPD: Section A4.2_01 Annex Point IIA4.1/4.2 & IIIA-IV.1 | Analytical Methods for Detection and Identification Bardap 26 Matrix: Soil | |
| | 1 REFERENCE | Official use only |
| 1.1 Reference | ██████████ (2016) Validation of an Analytical Method for the Determination of Bardap 26 in Soil. ██████████ ██ ██ ██ | |
| 1.2 Data protection | Yes | |
| 1.2.1 Data owner | ██████████ | |
| 1.2.2 Companies with letter of access | None | |
| 1.2.3 Criteria for data protection | Article 60 of Regulation 528/2012, on data protection periods for data submitted for the purposes of Directive 98/8/EC or Regulation 528/2012. | |
| | 2 GUIDELINES AND QUALITY ASSURANCE | |
| 2.1 Guideline | SANCO/825/00 rev. 8.1 | |
| 2.2 GLP | Yes, including certificate | |
| 2.3 Deviations | None | |
| | 3 MATERIALS AND METHODS | |
| 3.1 Preliminary treatment | | |
| 3.1.1 Extraction | ██ ██ ██ ██ ██ ██ | |
| 3.1.2 Cleanup | ██ ██ ██ ██ | X |

| | | |
|--|---|--|
| BPR: Ann II 5.2.1 BPD: Section A4.2_01 Annex Point IIA4.1/4.2 & IIIA-IV.1 | Analytical Methods for Detection and Identification Bardap 26 Matrix: Soil | |
| 3.2 Detection | | |
| 3.2.1 Separation method |  | |
| 3.2.2 Detector |  | |
| 3.2.3 Standard(s) |  | |
| 3.2.4 Interfering substance(s) |  | |
| 3.3 Linearity | | |
| 3.3.1 Calibration range |  | |
| 3.3.2 Number of measurements |  | |
| 3.3.3 Linearity |  | |

| | | |
|--|---|--|
| BPR: Ann II 5.2.1 BPD: Section A4.2_01 Annex Point IIA4.1/4.2 & IIIA-IV.1 | Analytical Methods for Detection and Identification Bardap 26 Matrix: Soil | |
| 3.5 Recovery rates at different levels | [Redacted] | |
| 3.5.1 Relative standard deviation | [Redacted] | |
| 3.6 Limit of determination | [Redacted] | |
| 3.7 Precision | | |
| 3.7.1 Repeatability | [Redacted] | |
| 3.7.2 Independent laboratory validation | No | |

| | | |
|--|---|--|
| BPR: Ann II 5.2.1 BPD: Section A4.2_01 Annex Point IIA4.1/4.2 & IIIA-IV.1 | Analytical Methods for Detection and Identification Bardap 26 Matrix: Soil | |
| | 4 APPLICANT'S SUMMARY AND CONCLUSION | |

4.1 **Materials and methods**

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| | | |
|---|---|--|
| <p>BPR: Ann II 5.2.1 BPD: Section A4.2_01 Annex Point IIA4.1/4.2 & IIIA-IV.1</p> | <p>Analytical Methods for Detection and Identification Bardap 26 Matrix: Soil</p> | |
| | <p>[REDACTED]</p> | |
| <p>4.2 Conclusion</p> | <p>The method was found to be valid according to the guidance document SANCO/825/00 rev 8.1 for the determination of Bardap 26 in soil with the tested LOQ of 0.01 mg/kg.</p> | |
| <p>4.2.1 Reliability</p> | <p>■</p> | |
| <p>4.2.2 Deficiencies</p> | <p>None</p> | |
| <p>Evaluation by Competent Authorities</p> | | |
| <p>EVALUATION BY RAPPORTEUR MEMBER STATE</p> | | |
| <p>Date</p> | <p>January 2019/Feb 2021</p> | |
| <p>Materials and methods</p> | <p>[REDACTED]</p> | |

| | | |
|--|---|--|
| BPR: Ann II 5.2.1 BPD: Section A4.2_01 Annex Point IIA4.1/4.2 & IIIA-IV.1 | Analytical Methods for Detection and Identification Bardap 26 Matrix: Soil | |
| Conclusion | <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> | |
| Reliability | <p>[REDACTED]</p> | |
| Acceptability | <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> | |
| Remarks | <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> | |
| | COMMENTS FROM ... | |
| Date | <i>Give date of comments submitted</i> | |
| Results and discussion | <i>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</i> | |
| Conclusion | <i>Discuss if deviating from view of rapporteur member state</i> | |
| Reliability | <i>Discuss if deviating from view of rapporteur member state</i> | |
| Acceptability | <i>Discuss if deviating from view of rapporteur member state</i> | |
| Remarks | | |

| | | |
|--|---|--------------------------|
| BPR: Ann II 5.2.3 BPD: Section A4.2_03 Annex Point IIA4.1/4.2 & IIIA-IV.1 | Analytical Methods for Detection and Identification Bardap 26 Matrix: drinking water and surface water | |
| | | |
| | 5 REFERENCE | Official use only |
| 5.1 Reference | ██████████ Validation of an Analytical Method for the Determination of Bardap 26 in Drinking Water and Surface Water. ██ ██ ██ | |
| 5.2 Data protection | Yes | |
| 5.2.1 Data owner | Lonza AG | |
| 5.2.2 Companies with letter of access | None | |
| 5.2.3 Criteria for data protection | Article 60 of Regulation 528/2012, on data protection periods for data submitted for the purposes of Directive 98/8/EC or Regulation 528/2012. | |
| | 6 GUIDELINES AND QUALITY ASSURANCE | |
| 6.1 Guideline | SANCO/825/00 rev. 8.1 | |
| 6.2 GLP | Yes, including certificate | |
| 6.3 Deviations | None | |
| | 7 MATERIALS AND METHODS | |
| 7.1 Preliminary treatment | | |
| 7.1.1 Extraction | ██ ██ | |
| 7.1.2 Cleanup | ██ ██ ██ | |

| | | |
|---|--|--|
| <p>BPR: Ann II 5.2.3 BPD: Section A4.2_03 Annex Point IIA4.1/4.2 & IIIA-IV.1</p> | <p>Analytical Methods for Detection and Identification Bardap 26 Matrix: drinking water and surface water</p> | |
| | | |
| <p>7.2 Detection</p> | | |
| <p>7.2.1 Separation method</p> | <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>Gradient:</p> <p>[Redacted]</p> <p>[Redacted]</p> | |
| <p>7.2.2 Detector</p> | <p>[Redacted]</p> <p>[Redacted]</p> | |
| <p>7.2.3 Standard(s)</p> | <p>[Redacted]</p> | |
| <p>7.2.4 Interfering substance(s)</p> | <p>[Redacted]</p> | |
| <p>7.3 Linearity</p> | | |
| <p>7.3.1 Calibration range</p> | <p>[Redacted]</p> | |
| <p>7.3.2 Number of measurements</p> | <p>[Redacted]</p> | |

| | | |
|--|---|--|
| BPR: Ann II 5.2.3 BPD: Section A4.2_03 Annex Point IIA4.1/4.2 & IIIA-IV.1 | Analytical Methods for Detection and Identification Bardap 26 Matrix: drinking water and surface water | |
| | | |
| 7.3.3 Linearity |  <p>The content of this cell is almost entirely redacted with black bars. Visible text includes:</p> <ul style="list-style-type: none">Two large rectangular redaction blocks, each with the vertical text "Area counts" on its left side.Several smaller horizontal redaction bars of varying lengths. | |

| | | |
|--|--|--|
| <p>BPR: Ann II 5.2.3 BPD: Section A4.2_03 Annex Point IIA4.1/4.2 & IIIA-IV.1</p> | <p>Analytical Methods for Detection and Identification Bardap 26 Matrix: drinking water and surface water</p> | |
| | | |
| <p>7.4 Specificity: interfering substances</p> | <p>[Redacted]</p> | |
| <p>7.5 Recovery rates at different levels</p> | <p>[Redacted]</p> <p style="text-align: center;">Bardap 26</p> <p>[Redacted]</p> | |
| <p>7.5.1 Relative standard deviation</p> | <p>[Redacted]</p> | |
| <p>7.6 Limit of determination</p> | <p>[Redacted]</p> | |
| <p>7.7 Precision</p> | | |
| <p>7.7.1 Repeatability</p> | <p>[Redacted]</p> | |

| | | |
|--|---|--|
| BPR: Ann II 5.2.3 BPD: Section A4.2_03 Annex Point IIA4.1/4.2 & IIIA-IV.1 | Analytical Methods for Detection and Identification Bardap 26 Matrix: drinking water and surface water | |
| | | |
| 7.7.2 Independent laboratory validation | ■ | |

| | | |
|--|---|--|
| BPR: Ann II 5.2.3 BPD: Section A4.2_03 Annex Point IIA4.1/4.2 & IIIA-IV.1 | Analytical Methods for Detection and Identification Bardap 26 Matrix: drinking water and surface water | |
| | | |
| | 8 APPLICANT'S SUMMARY AND CONCLUSION | |

| | | |
|---|--|--|
| <p>8.1 Materials and methods</p> | <p>[Redacted text]</p> | |
| <p>8.2 Conclusion</p> | <p>The method was found to be valid according to the guidance document SANCO/825/00 rev 8.1 for the determination of</p> | |

| | | |
|--|---|--|
| BPR: Ann II 5.2.3 BPD: Section A4.2_03 Annex Point IIA4.1/4.2 & IIIA-IV.1 | Analytical Methods for Detection and Identification Bardap 26 Matrix: drinking water and surface water | |
| | | |
| | [REDACTED] | |
| 8.2.1 Reliability | [REDACTED] | |
| 8.2.2 Deficiencies | None | |
| | Evaluation by Competent Authorities | |
| | EVALUATION BY RAPPORTEUR MEMBER STATE | |
| Date | January 2019/February 2021 | |

Materials and methods

[Redacted text block containing multiple paragraphs of obscured content]

| | |
|-------------------------------|---|
| Conclusion | [REDACTED] |
| Reliability | [REDACTED] |
| Acceptability | [REDACTED] |
| Remarks | [REDACTED] |
| | COMMENTS FROM ... |
| Date | <i>Give date of comments submitted</i> |
| Results and discussion | <i>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</i> |
| Conclusion | <i>Discuss if deviating from view of rapporteur member state</i> |
| Reliability | <i>Discuss if deviating from view of rapporteur member state</i> |
| Acceptability | <i>Discuss if deviating from view of rapporteur member state</i> |
| Remarks | |