

**B.8 Environmental fate and behaviour**

**MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE<sup>1</sup> APPROVAL OF ACETAMIPRID**

|                     |                       |  |                      |
|---------------------|-----------------------|--|----------------------|
| <b>Member State</b> | <b>Month and year</b> | <b>Active Substance<sup>2</sup> (Name)</b> | <b>Notifier</b>      |
| The Netherlands     | May 2018              | Acetamiprid                                | Sharda Cropchem Ltd. |

Active substance source = Sharda CropChem Ltd.

**References for the active substance acetamiprid**

**New studies**

| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |      |   |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|------|---|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not   | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
| CA<br>7.1.2.1.1/01<br>7.1.2.1.2/02        | 5.1 lid 2 e  | 2014 | Re-calculation of laboratory aerobic degradation rates of acetamiprid and its metabolites, according to FOCUS (2006, 2011) guidance Exponent International Ltd., UK<br>Nippon-Soda Report No.: RD-02913<br>Non-GLP<br>Not published | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |

| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |      |   |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|------|---|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not                       | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
| CA<br>7.1.2.1.2/0<br>1                    | 5.1 lid 2 e  | 2014 | Rate of Degradation of [ <sup>14</sup> C]-IM-1-5 in Three Soils at 20°C<br>Nippon-Soda Report No.: RD-02811<br>GLP<br>Not published | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |

| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |      |   |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|------|---|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
|   |  |      |   |                         |  |      |   |  |                          |                     | 5.1 lid 1 c<br>[Redacted]   |

| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |       |   |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|-------|---|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year  | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not   | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
|   |  |       |   |                         |  |      |   |  |                          |                     | 5.1 lid 1 c<br>[Redacted]   |
| CA 7.1.2.1.3/01                           | 5.1 lid 2 e<br>[Redacted]  | 2014a | Re-calculation of laboratory anaerobic degradation rate of acetamiprid according to FOCUS (2006, 2011) guidance Exponent International Ltd., UK<br>Nippon-Soda Report No.: RD-02910<br>Non-GLP<br>Not published | N                       |  |      |   | 5.1 lid 1 c<br>[Redacted]                                |                          |                     | 5.1 lid 1 c<br>[Redacted]   |
| CA 7.1.3.1.2/01                           | 5.1 lid 2 e<br>[Redacted]  | 2010  | Adsorption / desorption study of IM-1-5 on soils Nippon Soda Co. Ltd. (NSM), Japan, Report  | N                       |  |      |   | 5.1 lid 1 c<br>[Redacted]                                | Y                        | June 2019           | 5.1 lid 1 c<br>[Redacted]   |

| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |      |   |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|------|---|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
|   |  |      | No. NSM10- 013<br>Document No. RD- 02101<br>GLP<br>Not published  |                         |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |



| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |      |   |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|------|---|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
|   |  |      |   |                         |  |      |   |  |                          |                     | 5.1 lid 1 c<br>[Redacted]   |

| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |      |  |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|------|--|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
|   |  |      |  |                         |  |      |   |  |                          |                     | ( 5.1 lid 1 c<br>[Redacted]   |
| CA 7.2.2.2/01                             | 5.1 lid 2 e  | 2014 | [pyridine-2,6-14C]-Acetamidrid: "Aerobic Degradation in Natural Water"<br>RLP Agrosience, Germany<br>Nippon-Soda<br>Report No.:RD- 02800<br>GLP<br>Not published | N                       |  |      |   | 5.1 lid 1 c<br>[Redacted]                                | Y                        |                     | [Redacted]  |



| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |       |   |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|-------|---|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year  | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not   | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
|   |  |       |   |                         |  |      |   |  |                          |                     | 5.1 lid 1 c<br>[Redacted]   |
| CA 7.2.2.3/01                             | 5.1 lid 2 e<br>[Redacted]  | 2014c | Recalculation of acetamiprid sediment water kinetics according to FOCUS (2006, 2011) guidance Exponent International Ltd., UK<br>Nippon-Soda Report No.: RD-02911<br>Non-GLP<br>Not published | N                       |  |      |   | 5.1 lid 1 c<br>[Redacted]                                |                          |                     | 5.1 lid 1 c<br>[Redacted]   |

Studies relied upon for the first inclusion of Acetamiprid in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) No 1107/2009

| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |      |  |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|------|--|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
| CA 7.1.1.1 /01                            | 5.1 lid 2 e  | 1997 | 14C-NI-25: Metabolism in One Soil Incubated under Aerobic Conditions<br>Report/file:RCC Project 373994 Amended final report<br>Nippon Soda Doc No. RD-09624N<br>GLP, Not published           | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.1.1.1 /02                            | 5.1 lid 2 e  | 1998 | Acetamiprid (NI-25): Metabolism in Collombey Soil<br>Report/file RPAC Report N° EC-97- 406<br>Nippon Soda Doc No. RD-09961<br>Non-GLP , Not published  | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.1.1.1 /03                            | 5.1 lid 2 e  | 1997 | [14C]-NI-25: Rate of Aerobic Degradation in Three Soil Types at 20°C and One Soil Type at 10°C<br>Report/file: RPAL Study Report 11256<br>Nippon Soda Doc No. RD-09962<br>GLP, Not published | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.1.1.1 /04                            | 5.1 lid 2 e  | 2002 | [14C]-Acetamiprid: Rate of Degradation in Three Calcareous Soils at 20°C<br>Aventis CropScience SA.,   | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |

| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |      |  |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|------|--|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
|   |  |      | report C019428<br>Nippon Soda Doc No.<br>RD-00168<br>GLP not published   |                         |  |      |   |  |                          |                     |   |
| CA 7.1.1.2 /01                            | 5.1 lid 2 e  | 1997 | [14C]-NI-25: Anaerobic Soil Degradation<br>Report/file: RPAL Study Report 11444<br>Nippon Soda Doc No. RD-09860<br>GLP, Not published  | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.1.1.3 /01                            | 5.1 lid 2 e  | 1998 | Acetamiprid (NI-25) Soil Photolysis<br>Report/file: RPAC Study N° EC-97- 359<br>Nippon Soda Doc No. RD-09833<br>GLP, Not published   | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.1.2.1 .1/02                          | 5.1 lid 2 e  | 1997 | 14C-NI-25: Metabolism in One Soil Incubated under Aerobic Conditions<br>Report/file:RCC Project 373994 Amended final report<br>Nippon Soda Doc No. RD-09624N<br>GLP, Not published | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.1.2.1 .1/03                          | 5.1 lid 2 e  | 1997 | [14C]-NI-25: Rate of Aerobic Degradation in Three Soil Types at 20°C and One Soil Type at 10°C<br>Report/file: RPAL Study Report 11256<br>Nippon Soda Doc No.                      | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |

| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |      |  |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|------|--|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
|   |  |      | RD-09962<br>GLP, Not published   |                         |  |      |   |  |                          |                     |   |
| CA 7.1.2.1.1/04                           | 5.1 lid 2 e  | 2002 | [14C]-Acetamiprid: Rate of Degradation in Three Calcareous Soils at 20°C<br>Aventis CropScience SA., report C019428<br>Nippon Soda Doc No. RD-00168<br>GLP not published                     | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.1.2.1.2/03                           | 5.1 lid 2 e  | 1997 | 14C-NI-25: Metabolism in One Soil Incubated under Aerobic Conditions<br>Report/file:RCC Project 373994 Amended final report<br>Nippon Soda Doc No. RD-09624N<br>GLP, Not published           | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.1.2.1.2/04                           | 5.1 lid 2 e  | 1997 | [14C]-NI-25: Rate of Aerobic Degradation in Three Soil Types at 20°C and One Soil Type at 10°C<br>Report/file: RPAL Study Report 11256<br>Nippon Soda Doc No. RD-09962<br>GLP, Not published | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.1.2.1.2/05                           | 5.1 lid 2 e  | 2002 | [14C]-Acetamiprid: Rate of Degradation in Three Calcareous Soils at 20°C<br>Aventis CropScience SA., report C019428<br>Nippon Soda Doc No.   | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |

| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |      |  |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|------|--|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
|   |  |      | RD-00168<br>GLP<br>not published   |                         |  |      |   |  |                          |                     |   |
| CA 7.1.2.1.2/06                           | 5.1 lid 2 e  | 1997 | NI-25: Rate of Degradation of the Acid Metabolite, [14C]-IC-0 in Three Soils<br>Report/file: RPAL Study Report 11257<br>Nippon Soda Doc No. RD-9963<br>GLP, Not published                  | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.1.2.1.3/02                           | 5.1 lid 2 e  | 1997 | [14C]-NI-25: Anaerobic Soil Degradation<br>Report/file: RPAL Study Report 11444<br>Nippon Soda Doc No. RD-09860<br>GLP, Not published  | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.1.4/01                               | 5.1 lid 2 e  | 2003 | [ <sup>14</sup> C]-Acetamiprid: Aged Residue Column Leaching Study in Two Calcareous Soils<br>Nippon Soda Doc No. RD-03061<br>GLP<br>not published   | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.1.4/02                               | 5.1 lid 2 e  | 1997 | <sup>14</sup> C-NI-25: Leaching Characteristics of Aged Residues in one Soil<br>Source: Nippon Soda Generated by: RCC Umweltchemie AG<br>Nippon Soda Doc No. RD-9566<br>GLP, Not published | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.1.3.1                                | 5.1 lid 2 e  | 1997 | Adsorption/Desorption of 14C-  | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |

| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |      |  |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|------|--|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
| .1/01                                     |  |      | NI-25 on Five Soils Report/file:RCC Project 374016 Nippon Soda Doc No. RD-09564N GLP, Not published  |                         |  |      |   |  |                          |                     |   |
| CA 7.1.3.1.2/02                           | 5.1 lid 2 e  | 1997 | Adsorption/Desorption of IM-1-4 on Five Soils Report/file:RCC Project 383826 Nippon Soda Doc No. RD-09567N GLP, Not published  | N                       |  |      |   | 5.1 lid 1 c  |                          | 5.1 lid 1 c         |   |
| CA 7.1.3.1.2/03                           | 5.1 lid 2 e  | 1997 | 6-Chloronicotinic Acid (Acetamiprid Metabolite) Soil Adsorption/Desorption Study. Report/file: RPAC Study N° EC-97- 370 Nippon Soda Doc No. RD-9973 GLP, Not published | N                       |  |      |   | 5.1 lid 1 c  |                          | 5.1 lid 1 c         |   |
| CA 7.1.3.1.2/04                           | 5.1 lid 2 e  | 2003 | [14C]-IM-1-2 : Adsorption to and Desorption from Four Soils and One Sediment BayerCropScience SA, report C030079 Nippon Soda Doc No. RD-03056 GLP not published        | N                       |  |      |   | 5.1 lid 1 c  |                          | 5.1 lid 1 c         |   |
| CA 7.2.1.1/01                             | 5.1 lid 2 e  | 1997 | NI-25 - Hydrolysis Source: Nippon Soda Report/file: Nisso Amended Report N° EC-375-2   | N                       |  |      |   | 5.1 lid 1 c  |                          | 5.1 lid 1 c         |   |

| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |      |   |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|------|---|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not   | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
|   |  |      | Nippon Soda Doc No. RD-95122N<br>GLP, Not published   |                         |  |      |   |  |                          |                     |   |
| CA 7.2.1.1 /02                            | 5.1 lid 2 e  | 1997 | Hydrolysis of IM-1-4 and IC-0 (Two Degradates of Acetamidrid) as a Function of pH<br>Report/file: PTRL Study Report P 225G<br>Nippon Soda Doc No. RD-00252<br>GLP, Not published  | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.2.1.1 /03                            | 5.1 lid 2 e  | 2002 | Hydrolysis of IM-1-5<br>Nippon Soda CO., LTD, report C028667<br>Nippon Soda Doc No. RD-II 02448<br>GLP, not published   | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.2.1.2 /01                            | 5.1 lid 2 e  | 1998 | Aqueous Photodegradation of [ <sup>14</sup> C]-Acetamidrid at pH 7 and Determination of Quantum Yield.<br>Report/file: PTRL Europe Study N° P 196 G,<br>RPA Study N°96-82<br>Nippon Soda Doc No. RD-00403<br>GLP, Not published | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.2.1.2 /02                            | 5.1 lid 2 e  | 1998 | Acetamidrid - Verification of the Identity of the Photolyte obtained at pH 7 - Study 96-82<br>Extension Report/file: RPA Study N° 98-47 Nippon Soda   | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |

| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |      |   |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|------|---|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not   | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
|   |  |      | Doc No. RD-9965N<br>GLP, Not published  |                         |  |      |   |  |                          |                     |   |
| CA 7.2.1.2 /03                            | 5.1 lid 2 e  | 1997 | Aqueous Photolysis of 14C-IM-1-4 under Laboratory Conditions.<br>Report/file: CC Project N°671332 Nippon Soda Doc No. RD-09967<br>GLP, Not published                | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.2.1.2 /04                            | 5.1 lid 2 e  | 1997 | Aqueous Photolysis of [14C]-IC-0 under Laboratory Conditions<br>Report/file: CC Project N°671343 Nippon Soda Doc No. RD-09966<br>GLP, Not published                 | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.2.1.2 /05                            | 5.1 lid 2 e  | 2003 | Photodegradation of IM-1-5 in Water<br>Nippon Soda CO., LTD, report C030709<br>Nippon Soda Doc No. RD-03041<br>GLP, not published                                   | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.2.2.1 /01                            | 5.1 lid 2 e  | 1999 | Acetamidiprid : Assessment of Ready Biodegradability<br>CO2 Evolution Test.<br>Report/file: SPL Project N°238/046 Nippon Soda Doc No. RD-9993<br>GLP, Not published | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.2.2.3 /02                            | 5.1 lid 2 e  | 1997 | [14C]-NI-25 : Degradation in Two Water/Sediment Systems.<br>Report/file: RPAL Study   | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |



| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |      |  |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|------|--|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
|   |  |      | 11263 Nippon Soda Doc No. RD-9968<br>GLP, Not published  |                         |  |      |   |  |                          |                     |   |
| CA 7.3.1/01                               | 5.1 lid 2 e  | 2000 | Estimation of the degradation of Acetamiprid by photo-oxidation in air, Model calculation according to Atkinson.<br>Report/file: RCC Study No 788714 Nippon Soda Doc No. RD-00981<br>Non GLP, Not published                        | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CA 7.3.1/02                               | 5.1 lid 2 e  | 1997 | Investigation of the Volatilization of 14C-Acetamiprid Formulated Corresponding to EXP60707B from Plant and Soil Surfaces under laboratory Conditions.<br>Report/file: RPA24<br>Nippon Soda Doc No. RD-00249<br>GLP, Not published | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |

### References for the PPP Acetamiprid 20 SC

#### New studies

| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |       |   |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|-------|---|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year  | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not   | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
| CP 9.1.1.2/01                             | 5.1 lid 2 e  | 2014  | Re-calculation of acetamiprid field dissipation rates from Wicks (1999) according to FOCUS (2006, 2011) guidance Exponent International Ltd., UK<br>Nippon-Soda Report No.: RD-02912<br>Non-GLP<br>Not published            | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CP 9.1.1.2/02                             | 5.1 lid 2 e  | 2012a | Soil Dissipation study with Acetamiprid and its Soil Metabolite IM- 1-5, in or on Soil in Spain in 2010-2011<br>Eurofins Agroscience Services<br>Nippon Soda Co. Ltd Report No.: RD-02404<br>GLP<br>Not published           | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CP 9.1.1.2/03                             | 5.1 lid 2 e  | 2012b | Soil Dissipation study with Acetamiprid and its Soil Metabolite IM- 1-5, in or on Soil in Southern France in 2010-2011<br>Eurofins Agroscience Services<br>Nippon Soda Co. Ltd Report No.: RD-02405<br>GLP<br>Not published | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |

| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |       |  |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|-------|--|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year  | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
| CP 9.1.1.2/04                             | 5.1 lid 2 e  | 2012c | Soil Dissipation study with Acetamiprid and its Soil Metabolite IM- 1-5, in or on Soil in Northern France in 2010-2011<br>Eurofins Agrosience Services<br>Nippon Soda Co. Ltd Report No.: RD-02406<br>GLP<br>Not published   | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CP 9.1.1.2/05                             | 5.1 lid 2 e  | 2013  | Soil Dissipation study with Acetamiprid and its Soil Metabolite IM- 1-5, in or on Soil in Hungary in 2011-2012<br>Eurofins Agrosience metabolite IM-1-5 in four different Calcareous Soils<br>Eurofins Agrosience Services<br>Nippon Soda Co. Ltd Report No.: RD-02407Services<br>Nippon Soda Co. Ltd Report No.: RD-02599<br>GLP<br>Not published | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |

| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |       |  |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|-------|--|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year  | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
| CP 9.1.1.2/06                             | 5.1 lid 2 e  | 2012  | Storage Stability of Residues of Acetamiprid and Acetamiprid metabolite IM-1-5 in four different Calcareous Soils. Eurofins Agrosience Services Nippon Soda Co. Ltd Report No.: RD-02407 | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CP 9.1.1.2/07                             | 5.1 lid 2 e  | 2014b | Calculation of Acetamiprid soil DT50 values from new field dissipation studies in 2010 and 2011 using FOCUS kinetics.  | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |

Studies relied upon for the first inclusion of Acetamiprid in Annex I to Directive 91/414/EEC and for renewal of approval under Regulation (EC) No 1107/2009

| Data requirement point / reference number | Study or test considered as relied upon and for which data protection has been claimed |      |   |                         | Title of alternative study or case referenced / submitted by applicant |      |   | Reason for equivalence / justification for non-provision | Cat. 4 data <sup>5</sup> |                     | RMS Opinion <sup>4,6,7</sup><br>a) GLP-compliant?<br>b) Guideline-compliant?<br>c) Equivalent endpoint? |
|---|--|------|---|-------------------------|--|------|---|--|--------------------------|---------------------|---|
|   | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not   | Vertebrate study<br>Y/N | Author(s)  | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not |  | Y/N                      | Submission deadline |   |
| CP 9.1.1.2 /08                            | 5.1 lid 2 e  | 1999 | Acetamiprid : Field Soil Dissipation Study in Europe RPA Study 11258, Doc 202052 Nippon Soda Doc No. RD-9997<br>GLP, Not published  | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |
| CP 9.1.1.2 /09                            | 5.1 lid 2 e  | 1999 | Acetamiprid (NI-25) and Metabolites : Storage Stability in Soils from the European Terrestrial Field Soil Dissipation Study 11258<br>Report/file:<br>R&D/CRLD/AN/mr/9915587, Study 98-07<br>Nippon Soda Doc No. RD-9998<br>GLP, Not published | N                       |  |      |   | 5.1 lid 1 c  |                          |                     | 5.1 lid 1 c   |