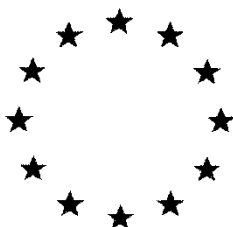


# **European Commission**



**Acetamiprid**

**LIST OF INFORMATION, TESTS AND  
STUDIES WHICH ARE CONSIDERED  
AS RELIED UPON BY THE RMS FOR  
THE EVALUATION WITH A VIEW TO  
THE RENEWAL OF THE ACTIVE  
SUBSTANCE**

**October 2016**

**Rapporteur Member State: The Netherlands**

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## **B.1 Identity**

### **References for the active substance acetamiprid**

Reference is made to Volume 4 of the RAR.

### **References for the PPP Acetamiprid 20 SC**

Reference is made to Volume 4 of the RAR.

## B.2 Physical and chemical properties

### References for the active substance acetamiprid

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 2.1/02	Higashida, S.	1999a	Thermal Stability of NI-25 Generated by: Nisso Chemical Analysis Service Co., LTD Source: Nippon Soda Report/file: Nisso No. NCAS 98-311 Study No.: RD-01414 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 2.6/02	Higashida, S.	2001a	Acetamiprid-Solubility in Ethyl Acetate Generated by: Nisso Chemical Analysis Service Co., LTD Source: Nippon Soda Report/file: Nisso No. NCAS 00-201 Study No.: RD-II01206 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 2.7/02	Higashida, S.	2001b	Partition Coefficient ( <i>n</i> -octanol/water) of IC-0) Generated by: Nisso Chemical Analysis Service Co., LTD Source: Nippon Soda Report/file: Nisso No. NCAS 01-127	N	Y	New data for AIR3 renewal	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Study No.: RD-II01223  GLP, not published				
CA 2.7/03	Higashida, S.	2001c	Partition Coefficient ( <i>n</i> -octanol/water) of IM-1-2 Generated by: Nisso Chemical Analysis Service Co., LTD Source: Nippon Soda Report/file: Nisso No. NCAS 01-126 Study No.: RD-II01224 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 2.7/04	Miya, K	2014a	Partition Coefficient ( <i>n</i> -octanol/water) of IM-1-4 Generated by: Nisso Chemical Analysis Service Co., LTD Source: Nippon Soda Report/file: Nisso No. NCAS 14-004 Study No.: RD-02927 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 2.7/05	Miya, K	2014b	Partition Coefficient ( <i>n</i> -octanol/water) of IM-1-5 Generated by: Nisso Chemical Analysis Service Co., LTD Source: Nippon Soda Report/file: Nisso No. NCAS 14-006 Study No.: RD-02939 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 2.7/06	Miya, K	2014c	Partition Coefficient ( <i>n</i> -octanol/water) of IM-2-1	N	Y	New data for AIR3 renewal	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Generated by: Nisso Chemical Analysis Service Co., LTD Source: Nippon Soda Report/file: Nisso No. NCAS 14-007 Study No.: RD-02895 GLP, not published				
CA 2.7/07	Miya, K	2014d	Partition Coefficient ( <i>n</i> -octanol/water) of IB-1-1 Generated by: Nisso Chemical Analysis Service Co., LTD Source: Nippon Soda Report/file: Nisso No. NCAS 14-005 Study No.: RD-02922 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda

**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 point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 2.1/01	Morishima, Y	1997a	NI-25 (TGAI) – Melting point Generated by: Production Technology Laboratory, Source: Nippon Soda Report/file: Nisso Amended Report No PTL 2-9406-1 Study No.: RD-95148N	N	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP, not published In DAR (2001)				
CA 2.2/01	Gomyo, T., Kobayashi, S	1997a	NI-25 – Vapor pressure Generated by: Nisso Chemical Analysis Service Co., LTD Source: Nippon Soda Report/file: Nisso Amended Report No EC-372-2 Study No.: RD-95115N GLP, not published In DAR (2001)	N	N		Nippon Soda
CA 2.2/02	Ishihara, K.	1997	NI-25 – Henry's Law Constant Generated by: Nisso Chemical Analysis Service Co., LTD Source: Nippon Soda Report/file: Nisso No NCAS 96-173 Study No.: RD-09751 GLP, not published In DAR (2001)	N	N		Nippon Soda
CA 2.3	Morishima, Y	1997c	NI-25 – Color, physical state and odor of technical grade active ingredient and analytical standard Generated by: Production Technology Laboratory, Source: Nippon Soda Report/file: Nisso No 2-9619 Study No.: RD-09743 GLP, not published In DAR (2001)	N	N		Nippon Soda
CA 2.4/01	Morishima, Y	1997d	NI-25 (PAI) – Spectra (UV/VIS, IR,NMR,MS) of NI-25	N	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Generated by: Production Technology Laboratory, Source: Nippon Soda Report/file: Nisso No PTL 2-9713 Study No.: RD-09786 GLP, not published In DAR (2001)				
CA 2.4/02	Morishima, Y	1997e	NI-25 (TGAI) – Spectra of UV/VIS, NMR,MS and IR for impurities of NI-25 Generated by: Production Technology Laboratory, Source: Nippon Soda Report/file: Nisso No PTL 2-9620 Study No.: RD-9747 GLP, not published In DAR (2001)	N	N		Nippon Soda
CA 2.5	Gomyo, T., Kobayashi, S	1997b	NI-25 – Solubility in water Generated by: Nisso Chemical Analysis Service Co., LTD Source: Nippon Soda Report/file: Nisso Amended Report No EC-377-3 Study No.: RD-95124N GLP, not published In DAR (2001)	N	N		Nippon Soda
CA 2.6/01	Gomyo, T., Kobayashi, S	1997c	NI-25 – Solubility in organic solvents Generated by: Nisso Chemical Analysis Service Co., LTD Source: Nippon Soda	N	N		Nippon Soda



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report/file: Nisso Amended Report No EC-376-3 Study No.: RD-95113N GLP, not published In DAR (2001)				
CA 2.7/01	Gomyo, T., Kobayashi, S	1997d	NI-25 – Octanol/water Partition Coefficient Generated by: Nisso Chemical Analysis Service Co., LTD Source: Nippon Soda Report/file: Nisso Amended Report No EC-378-2 Study No.: RD-95112N GLP, not published In DAR (2001)	N	N		Nippon Soda
CA 2.8	Gomyo, T., Kobayashi, S	1997f	NI-25 – Dissociation Constant in water (pKa) Generated by: Nisso Chemical Analysis Service Co., LTD Source: Nippon Soda Report/file: Nisso Amended Report No EC-371-2 Study No.: RD-95114N GLP, not published In DAR (2001)	N	N		Nippon Soda
CA 2.9	Betteley, J.M.T	1997f	Acetamiprid (Code No NI-25) Physicochemical properties Generated by: Huntingdon Life Sciences Ltd., England Source: Nippon Soda Report/file: No NOD 005/971239 Study No.: RD-09762	N	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP, not published In DAR (2001)				
CA 2.10	Morishima, Y	1997f	NI-25 (PAI) – Spectra (UV/VIS, IR,NMR,MS) of NI-25 Generated by: Production Technology Laboratory, Source: Nippon Soda Report/file: Nisso No PTL 2-9713 Study No.: RD-09748 GLP, not published In DAR (2001)	N	N		Nippon Soda
CA 2.11	Betteley, J.M.T	1997	Acetamiprid (Code No NI-25) Physicochemical properties Generated by: Huntingdon Life Sciences Ltd., England Source: Nippon Soda Report/file: No NOD 005/971239 Study No.: RD-09762 GLP, not published In DAR (2001)	N	N		Nippon Soda
CA 2.12	Betteley, J.M.T	1997	Acetamiprid (Code No NI-25) Physicochemical properties Generated by: Huntingdon Life Sciences Ltd., England Source: Nippon Soda Report/file: No NOD 005/971239 Study No.: RD-09762 GLP, not published In DAR (2001)	N	N		Nippon Soda
CA 2.13	Morishima, Y	1997g	NI-25 (TGA1) – Assessment for the determination of the	N	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			oxidizing properties Generated by: Production Technology Laboratory, Source: Nippon Soda Report/file: Nisso No PTL AG-97051 Study No.: RD-09749 Non-GLP, not published In DAR (2001)				

#### **References for the PPP Acetamiprid 20 SC**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 2.1, 2.4, 2.7/2, 2.8.2, 2.8.5.1/1, 2.8.7	Pointer, C	2014	Acetamiprid 20SG: Accelerated Storage Stability Huntingdon Life Sciences, Report No. LGG0102, Document No. RD-02921 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CP 2.2/1	Smeykal, H.	2001	EXP61884A (Acetamiprid 200 g/kg Soluble Granule) Explosive Properties, Siemens Axiva GmbH, Germany, Report No. 20011073.02, Nippon-	N	Y	New data for AIR3 renewal	Nippon Soda

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
			Soda Report No. RD-01188 GLP, not published				
CP 2.2/2	Smeykal, H.	2001	EXP61884A (Acetamidrid 200 g/kg Soluble Granule) Oxidising Properties, Siemens Axiva GmbH, Germany, Report No. 20011073.04, Nippon- Soda Report No. RD-01189 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CP 2.3/1	Smeykal, H.	2001	EXP61884A (Acetamidrid 200 g/kg Soluble Granule) Flammability (Solids), Siemens Axiva GmbH, Germany, Report No. 20011073.01, Nippon- Soda Report No. RD-01190 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CP 2.3/2	Smeykal, H.	2001	EXP61884A (Acetamidrid 200 g/kg Soluble Granule) Auto-flammability (Solids – Determination of Relative Self Ignition Temperature), Siemens Axiva GmbH, Germany, Report No. 20011073.03, Nippon- Soda Report No.	N	Y	New data for AIR3 renewal	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			RD-01191 GLP, not published				
CP 2.6, 2.8.1, 2.8.4, 2.8.5.1/2, 2.8.5.2, 2.8.5.3	Woolley, A.J., Mullee, D.M.	2005	Acetamidiprid 20SG: Determination of general physico-chemical properties. Safepharm Laboratories Ltd., Report No. 235/476, Document No. RD-00694 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CP 2.7/1	Woolley, A & Mullee, D.	2005b	Acetamidiprid 20SG: Determination of Accelerated Storage Stability and Physico-Chemical Characteristics, Safepharm Laboratories 235/476, Nippon-Soda Report No. RD-00695 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CP 2.7/2	Atwal, S	2010a	Acetamidiprid 20SG: Determination of Long-Term Storage Stability and Physico-Chemical Characteristics – Amendment to Final report, Safepharm Laboratories 235/491, Nippon-Soda Report No. RD-01284N GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda

### **B.3 Data on application**

#### **References for the active substance acetamiprid**

No specific references.

#### **References for the PPP Acetamiprid 20 SC**

No specific references.

## **B.4 Further information**

### **References for the active substance acetamiprid**

No specific references.

### **References for the PPP Acetamiprid 20 SC**

No specific references.

## B.5 Methods of analysis

### References for the active substance acetamiprid

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 4.1.2/01	Kellner, T.	2012a	Soil Dissipation study with Acetamiprid and its Soil Metabolite IM-1-5, in or on Soil in Spain in 2010-2011, Eurofins, Germany, Report No.: S10-01209, Document ID RD-02404 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.1.2/02	Kellner, T.	2012b	Soil Dissipation study with Acetamiprid and its Soil Metabolite IM-1-5, in or on Soil in Southern France in 2010-2011, Eurofins, Germany, Report No.: S10-01210, Document ID RD-02405 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.1.2/03	Kellner, T.	2012c	Soil Dissipation study with Acetamiprid and its Soil Metabolite IM-1-5, in or on Soil in Hungary in 2011-2012, Eurofins, Germany, Report No.: S10-01212, Document ID RD-02406 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.1.2/04	Finger, N.	2013	Soil Dissipation study with Acetamiprid and its Soil Metabolite IM-1-5, in or on	N	Y	New data for AIR3 renewal	Nippon Soda



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Soil in Hungary in 2011-2012, Eurofins, Germany, Report No.: S10-00874, Document ID RD-02599 GLP, not published				
CA 4.1.2/05	Tanguy, M. & Weber, H.	2012	Storage Stability of Residues of Acetamiprid and Acetamiprid Metabolite IM-1-5 in four different Calcareous Soils, Eurofins, Germany, Report No.: S10-03186, Document ID RD-02407 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.1.2/06	Rodgers, E.	2012	Validation of Methodologies for the Formulation and analysis of IM-1-5 in Genetox Dosing Formulations, Charles River, UK, Report No. 32668, Document ID RD-02353 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.1.2/07	Beck, I., Class, T.	2009	Acetamiprid: Development and Validation of an Analytical Method(s) for the Determination of Residues on Operator Exposure Dosimeters from Field Studies, PTRL Europe, Germany, Report No. P/B 1603 G, Document ID RD-01863 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA	Pollmann,	2005	Determination of Residues	N	Y	New data for	Nippon

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
4.1.2/08	B.		of Acetamiprid after Three Applications of Acetamiprid 20% SP (containing 20% Acetamiprid) in Potatoes, Northern and Southern Europe 2004, GAB Biotechnologie GmbH, Germany, Report No. 20041020/E1-FPPO, Document ID RD-00619 GLP, not published			AIR3 renewal	Soda
CA 4.1.2/09	Sonder, K-H	2002	Residue Behaviour in Tomatoes (Indoor) European Union (Southern Zone) 2001 Acetamiprid, AE F124370 Water Soluble Powder (SP) 20% w/w, Bayer CropScience GmbH, Germany, Report No.: 01 R 617, Document ID RD-01019 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.1.2/10	Raufer, B.	2013	Residue Study on Rotational Crops after one Application of Acetamiprid on Bare Soil at 2 Sites in Europe in 2010 to 2012 Eurofins Report No. S10-02822, Document ID RD-02495N2 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.1.2/11	Weber, H.	2010	Validation of an Analytical Method for the Determination of Residues of the Acetamiprid	N	Y	New data for AIR3 renewal	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Metabolite IM-1-2 and IM - 1-4 in Calcareous Soil using LC-MS/MS, Eurofins, Germany, Report No. S10-03189, Document ID RD-02197 GLP, not published				
CA 4.1.2/12	Weber, H.	2011	Validation of an Analytical Method for the Determination of Residues of the Acetamiprid Metabolite IM-1-4 and IM - 1-5 in Crops using LC-MS/MS, Eurofins, Germany, Report No. S10-03188, Document ID RD-02234 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.1.2/13	██████████ ██████████	1994	NI-25 Acute Oral Toxicity (LD50) to the Bobwhite Quail, ██████████ ██████████ ██████████ ██████████, Document ID RD-9434N GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.1.2/14	██████████ ██████████ ██████████ ██████████ ██████████	1998	5-Day Dietary Toxicity Test with IM-1-4 in the Mallard Duck ( <i>Anas platyrhynchos</i> ), ██████████ ██████████ ██████████ Document ID RD-9935 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA	██████████	2014	Acetamiprid: Reproductive	N	Y	New data for	Nippon

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
4.1.2/15	█		Toxicity Test with the Mallard Duck ( <i>Anas platyrhynchos</i> ), █ █ █ Document ID. RD-02797 GLP, not published			AIR3 renewal	Soda
CA 4.1.2/16	█	1998a	Acetamiprid Technical: Acute Toxicity to Sheepshead Minnow ( <i>Cyprinodon variegatus</i> ) Under Flow-Through Conditions, █ █ █ Document ID RD-00726 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.1.2/17	█ █ █ █	2013	Acetamiprid: Amphibian Metamorphosis Assay for the Detection of Thyroid Active Substances, █ █ █ Document ID. RD-02574 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.1.2/18	Putt, A. E.	2003a	Acetamiprid Technical – Acute Toxicity to Midge ( <i>Chironomus riparius</i> ) Under Static Conditions, Springborn Smithers Laboratories, Massachusetts, USA, Report No. 12681.6104, Document ID RD-03144	N	Y	New data for AIR3 renewal	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP, not published				
CA 4.1.2/19	Putt, A. E.	2003b	Acetamiprid Technical – Acute Toxicity to Gammarids ( <i>Gammarus fasciatus</i> ) Under Static Conditions, Springborn Smithers Laboratories, Massachusetts, USA, Report No. 12681.6105, Document ID RD-03143 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.1.2/20	Putt, A. E.	2003c	Acetamiprid Technical – Acute Toxicity to Mysids ( <i>Mysidopsis bahia</i> ) Under Flow-Through Conditions, Springborn Laboratories, Inc., Massachusetts, USA, Report No. 97-9-7100, Document ID RD-00720 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.1.2/21	Kley, A. & Wydra, V.	2012a	Acute Toxicity of IM-1-2 to Larvae of <i>Chironomus riparius</i> in a Static 48-hour Immobilisation Limit Test, IBACON GmbH, Germany, Report No. 67751251, Document ID RD-02374 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.1.2/22	Kley, A. & Wydra, V.	2012b	Acute Toxicity of IC-0 to Larvae of <i>Chironomus riparius</i> in a Static 48-hour Immobilisation Limit Test, IBACON GmbH, Germany, Report No. 67741251, Document ID RD-02375	N	Y	New data for AIR3 renewal	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP, not published				
CA 4.1.2/23	Kley, A. & Wydra, V.	2012c	Acute Toxicity of IB-1-1 to Larvae of <i>Chironomus riparius</i> in a Static 48-hour Immobilisation Limit Test, IBACON GmbH, Germany, Report No. 67731251, Document ID RD-02373 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.1.2/24	Putt, A. E.	1998b	IM-1-4 – Acute Toxicity to Mysids ( <i>Mysidopsis bahia</i> ) Under Static Conditions, Springborn Laboratories, Inc., Massachusetts, USA, Report No. 98-3-7276, Document ID RD-00719 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.1.2/25	Putt, A. E.	2003d	IM-1-5 – Full Life-Cycle Toxicity Test with Water Fleas, <i>Daphnia magna</i> , Under Static-Renewal Conditions, Springborn Smithers Laboratories, Massachusetts, USA, Report No. 13798.6112, Document ID RD-03057 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.1.2/26	Hoberg, J.R.	1997	Acetamiprid Technical – Toxicity to the Freshwater Blue-Green Alga, <i>Anabaena flos-aquae</i> , Springborn Laboratories, Inc., Massachusetts, USA, Report No. 97-6-7008, Document ID RD-00154	N	Y	New data for AIR3 renewal	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP, not published				
CA 4.2/01	Schwarz, T.	2008	Acetamiprid: Validation of an Enforcement Method for Plant Materials, PTRL Europe Study P/B1447G Nippon-Soda Report No. RD-01937 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.2/02	Weber, H	2013	Validation of a Multiresidue Method (Fillion) with Modified Cleanup and Detection for the Determination of Acetamiprid in Potato, Eurofins Agrosience Services, Study No. S13-02134, Document ID RD-02603 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.2/03	Giesau, A. & Weber, H.	2013	Independent Laboratory Validation of an Enforcement Method ("QuEChERS") for the Determination of Residues of Acetamiprid in Crops using LC-MS/MS, Eurofins Agrosience Services, Study No. S12-02718, Document ID RD-02454 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.2/04	Miya, K.	2010	Validation Study of the Analytical Method for the Determination of the Residues of Acetamiprid and Its Metabolite (IM-2-1)	N	Y	New data for AIR3 renewal	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			in Animal Commodities, Nisso Chemical Analysis Service Co., Japan, Report No. NCAS 10-144, Document ID RD-02080 GLP, not published				
CA 4.2/05	Knoch, E.	2010	Independent Laboratory Validation: Analytical Method for the Determination of the Residues of Acetamiprid and its Metabolite (IM-2-1) in Animal Commodities, SGS Institut Fresenius GmbH, Report No. IF-10/01687868, Document ID RD-02156 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.2/06	Täufer, A. & Weber, H.	2010	Validation of an Analytical Method for the Determination of Residues of Acetamiprid and Acetamiprid Soil Metabolite IM-1-5 in Calcareous Soil using LC-MS/MS, Eurofins Dr. Specht, Germany, Report No. S09-03287, Document ID RD-02062N GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.2/07	Miya, K.	2007	Validation Study of the Confirmatory Method for the Determination of Acetamiprid in Water, Nisso Chemical Analysis	N	Y	New data for AIR3 renewal	Nippon Soda



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Service Co., Japan, Report No. NCAS 06-209, Document ID RD-01204 GLP, not published				
CA 4.2/08	Senciuc, M	2014a	Independent Laboratory Validation (ILV) of a Residues Analytical Method for the Determination of Acetamiprid in Drinking Water, PTRL Europe GmbH, Germany, Report No. P 3244 G, Document ID RD-02951 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.2/09	Giesau, A. & Weber, H.	2012	Validation of an Analytical Method for the Determination of Residues of Acetamiprid Metabolite IM-1-5 in Water using LC-MS/MS, Eurofins Agrosience Services, Germany, Report No. S12-02719, Document ID RD-02604 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.2/10	Senciuc, M	2014b	Independent Laboratory Validation (ILV) of a Residues Analytical Method for the Determination of Acetamiprid Metabolite IM-1-5 in Drinking Water, PTRL Europe GmbH, Germany, Report No. P	N	Y	New data for AIR3 renewal	Nippon Soda

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
			3245 G, Document ID RD-02952 GLP, not published				
CA 4.2/11	Beck, I. & Class, T.	2009	Acetamiprid: Development and Validation of an Analytical Method(s) for the Determination of Residues on Operator Exposure Dosimeters from Field Studies, PTRL Europe, Germany, Report No. P/B 1603 G, Document ID RD-01863 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CA 4.2/12	Senciuc, M	2014c	Development and Validation of an Analytical Method for the Determination of Acetamiprid in Blood, PTRL Europe, Germany, Report No. P 3208 G, Document ID RD-02943 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda

**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**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
CA 4.1.1/01	Morishima, Y.	1997h	NI-25 (TGAI)-Validation of Analytical Method for Active Ingredient in NI-25	N	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			(TGA), Document ID RD-09741 GLP, not published				
CA 4.1.2/34	Teixeira, D	1999	Acetamiprid – Determination of Effects on Seedling Emergence and Vegetative Vigor of Ten Plant Species, Springborn Laboratories, Inc., Massachusetts, Report No. 97-12-7184, Document ID RD-II02121 GLP, not published	N	N		Nippon Soda

#### **References for the PPP Acetamiprid 20 SC**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 5.1.2/01	Stäbler, D	2005	Assessment on the Acute Toxicity of Acetamiprid 20% SP on the Midge <i>Chironomus riparius</i> , GAB Biotechnologie GmbH & GAB Analytik GmbH, Germany, Report No. 20041020/01-AACr, Document ID RD-00894 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CP 5.1.2/02	Boksch S., Kreidler, D.	2013	Assessment of Side Effects of Acetamiprid 20 SG on the Honeybee ( <i>Apis mellifera</i> L.) in the Semi-Field after two Applications in <i>Phacelia tanacetifolia</i> in Germany 2012, Eurofins	N	Y	New data for AIR3 renewal	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Agroscience Services, Germany, Report No. S12-02219, Document ID RD-02573 GLP, not published				
CP 5.1.2/03	Hamnerger, R.	2004	Determination of Residues of Acetamiprid in Pollen, Germany 2002, GAB Biotechnologie GmbH & GAB Analytik GmbH, Germany, Report No. 20011073/01-RPN, Document ID RD-00479 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CP 5.1.2/04	Rexer, H.U.	2010a	Acetamiprid 20 SG: A Semi-Field Study with Acetamiprid 20 SG in Winter Oil-Seed Rape, Investigating Residues in Plants, Honey Collected from Combs, and Nectar and Pollen Prepared from Forager Bees in Germany in 2009, Eurofins-GAB GmbH, Germany, Report No. S09-00043, Document ID RD-02042 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CP 5.1.2/05	Rexer, H.U.	2010b	Acetamiprid 20 SG: Assessment of Side Effects and Investigating Residues of Acetamiprid 20 SG on the Honeybee <i>Apis mellifera</i> L. ( <i>Hymenoptera, Apidae</i> ) in the Field Following Application on Winter Oil-Seed Rape in Germany in 2010, Eurofins Agroscience Services, Germany, Report No. S10-01355, Document ID RD-02168 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CP 5.1.2/06	Barth, M.	2014	Acetamiprid 20 SG and Acetamiprid 20 SG plus Folicur®: A study to evaluate potential side effects on the honeybee ( <i>Apis mellifera</i> L.) under field conditions after application in <i>Phacelia</i>	N	Y	New data for AIR3 renewal	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			<i>tanacetifolia</i> B. in Germany in 2013, BioChem agrar, Germany, Report No. 13 10 48 049 B, Document ID RD-02950 GLP, not published				
CP 5.1.2/07	Schulz, L	2012	Effects of Acetamiprid 20 SG on Earthworms under field conditions, BioChem agrar, Germany, Report No. 09 10 48 011 F, Document ID RD-02386 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CP 5.1.2/08	Friedrich, S.	2011	Terrestrial (non-target) plant test with Acetamiprid 20 SG: Vegetative Vigour Test, BioChem agrar, Germany, Report No. 11 10 48 003 P, Document ID RD-02339 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda
CP 5.1.2/09	Teixeira, D.	1999	Acetamiprid – Determination of Effects on Seedling Emergence and Vegetative Vigor of Ten Plant Species, Springborn Laboratories, Inc., Massachusetts, Report No. 97-12-7184, Document ID RD-II02121 GLP, not published	N	Y	New data for AIR3 renewal	Nippon Soda

## B.6 Toxicology and metabolism

### References for the active substance acetamiprid

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.1.1/01	[REDACTED]	1997a	<sup>14</sup> C-NI-25 - Metabolism in Rats [REDACTED] Document No. RD-95127 GLP, not published	Y	N		Nippon Soda
CA 5.1.1/02	[REDACTED]	2003	Metabolism study of Acetamiprid in rat (Determination of IM-1-5) [REDACTED] Document No. RD-03028 GLP, not published	Y	N		Nippon Soda
CA 5.1.1/03	[REDACTED]	1995	[ <sup>14</sup> C]-NI-25 - Biliary Excretion in Rat [REDACTED] Document No. RD-09575 GLP, not published	Y	N		Nippon Soda
CA 5.1.1/04	[REDACTED]	1995	Absorption, Distribution, Metabolism, Elimination, and Pharmacokinetics after Chronic Dosing of [ <sup>14</sup> C]-NI-25 in Rat [REDACTED] Document No. RD-09576 GLP, not published	Y	N		Nippon Soda
CA 5.1.1/05	[REDACTED]	1997b	<sup>14</sup> C-NI-25 - Metabolism Study in Rats (Qualitative and Quantitative Analysis of Metabolites in Group C) [REDACTED] Document No. RD-09654N GLP, not published	Y	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.1.1/06	[REDACTED]	1997c	<sup>14</sup> C-NI-25 - Metabolism in Rats (A Summary Report) [REDACTED] Document No. RD-09785 No GLP, not published	Y	N		Nippon Soda
CA 5.2.1/01	[REDACTED]	1997a	NI-25: Acute Oral Toxicity Study in Rats [REDACTED] Document No. RD-9760 GLP, not published	Y	N		Nippon Soda
CA 5.2.1/02	[REDACTED]	2002a	Acetamidiprid suspended in corn oil: Acute oral toxicity study in rats. [REDACTED] Document No. RD-II 02425 GLP, not published	Y	N		Nippon Soda
CA 5.2.1/03	[REDACTED]	1998	Acetamidiprid*- Acute oral toxicity study in rats (*Proposed ISO Common Name, Code No.: NI-25) [REDACTED] Document No. RD-9528N GPL, Not published	Y	Y	Study generated for registration outside of EU	Nippon Soda
CA 5.2.2/01	[REDACTED]	1997b	NI-25: Acute Dermal Toxicity Study in Rats [REDACTED], Document No. RD-9761 GLP, not published	Y	N		Nippon Soda
CA 5.2.3/01	[REDACTED]	1997	Acetamidiprid : Acute (four-hour) Inhalation Study in Rats [REDACTED] Document No. RD-09782N GLP, not published	Y	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.2.4/01	[REDACTED]	1997a	Acetaminiprid - Primary Dermal Irritation Study in Rabbits [REDACTED] Document No. RD-9533N GLP, not published	Y	N		Nippon Soda
CA 5.2.5/01	[REDACTED]	1997b	Acetaminiprid - Primary Eye Irritation Study in Rabbits [REDACTED] Document No. RD-9532N GLP, not published	Y	N		Nippon Soda
CA 5.2.6/01	[REDACTED]	1997	Acetaminiprid (CodeN° : NI-25) Skin Sensitisation in the Guinea-Pig [REDACTED] Document No. RD-09779 GLP, not published	Y	N		Nippon Soda
CA 5.3.1/01	[REDACTED]	1992	A 4-Week Oral Toxicity Study of NI-25 in the Dog via Dietary Administration [REDACTED] Document No. RD-09444N GLP, not published	Y	N		Nippon Soda
CA 5.3.2/01	[REDACTED]	1997a	Acetaminiprid - Thirteen Week Dietary Subchronic Toxicity in Rats. [REDACTED], Document No. RD-9535N GLP, not published	Y	N		Nippon Soda
CA 5.3.2/02	[REDACTED]	1997b	Acetaminiprid - Thirteen Week Dietary Subchronic Toxicity Study in Mice. [REDACTED], Document No. RD-09536N GLP, not published	Y	N		Nippon Soda



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.3.2/03	[REDACTED]	1998a	A Sub-chronic (3-month) Oral Toxicity Study of NI-25 in the Dog via Dietary Administration [REDACTED] Document No. RD-09445N GLP, not published	Y	N		Nippon Soda
CA 5.3.2/04	[REDACTED]	1998b	A Chronic (12-month) Oral Toxicity Study of NI-25 in the Dog via Dietary Administration [REDACTED] Document No. RD-09446N GLP, not published	Y	N		Nippon Soda
CA 5.3.2/05	Mondal, S. et al	2009	In vivo subacute oral acetamiprid toxicity in haematological indices in Rattus Norvegicus. Environment and Ecology, Vol 27(4A), pp. 1767-1769	N	N		-
Ca 5.3.2/06	Mondal, S. et al	2012	Studies on the electrolytes and microelements in Wistar rat following multiple exposures to acetamiprid. Toxicology and Industrial Health, Vol. 28(5), pp. 422-7	N	N		-
CA 5.3.3/01	[REDACTED]	1997	21-Day Dermal Toxicity Study in Rabbits with Acetamiprid. [REDACTED], Document No. RD-09861 GLP, not published	Y	N		Nippon Soda
CA 5.4.1/01	Kanaguchi, Y.	1997a	Acetamiprid - Reverse Mutation Study on Bacteria Odawara Research Center, Nippon Soda Co. Ltd., Report No. G-0831, Document No. RD-09539N GLP, not published	N	N		Nippon Soda
CA 5.4.1/02	Adams, K.	1998	Acetamiprid. Mammalian Cell Mutation Assay Huntingdon Life Sciences Ltd., Report No. NOD 006/971139, Document No. RD-09766N GLP, not published	N	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.4.1/03	Kanaguchi, Y.	1997b	Acetamidrid - Chromosomal Aberration Study on Chinese Hamster Ovary (CHO) Cells Odawara Research Center, Nippon Soda Co. Ltd., Report No. G-800, Document No. RD-09540N GLP, not published	N	N		Nippon Soda
CA 5.4.1/04	Ham, A.L.	1998	Genotoxicity Test on NI-25 in the Assay for Unscheduled DNA Synthesis in Rat Liver Primary Cell Cultures with a Confirmatory Assay Hazleton Washington, Inc. (HWA), Report No. 15901-0-447R, Document No. RD-09439N GLP, not published	N	N		Nippon Soda
CA 5.4.1/05	Çavaş, T. et al	2012	In vitro genotoxicity evaluation of acetamidrid in CaCo-2 cells using the micronucleus, comet and cH2AX foci assays. Pesticide Biochemistry and Physiology Vol. 104, pp. 212–217	N	N		-
CA 5.4.2/01	[REDACTED]	1998	Mutagenicity Test on NI-25 in an <i>in vivo</i> Mouse Micronucleus Assay [REDACTED] Document No. RD-9441N2 GLP, not published	Y	N		Nippon Soda
CA 5.4.2/02	[REDACTED]	1998	NI-25: Metaphase Analysis in the Rat Bone Marrow <i>in vivo</i> . [REDACTED] Document No. RD-09443N GLP, not published	Y	N		Nippon Soda
CA 5.4.2/03	[REDACTED]	1997	Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells <i>in vivo</i> [REDACTED] Document No. RD-09767N GLP, not published	Y	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.5/01	[REDACTED]	1999	Two-Year Dietary Toxicity and Oncogenicity Study in rats. [REDACTED] Document No. RD-99104 GLP, not published	Y	N		Nippon Soda
CA 5.5/02	[REDACTED]	1999	18-Month Dietary Oncogenicity Study in Mice. [REDACTED] Document No. RD-99103 GLP, not published	Y	N		Nippon Soda
CA 5.6.1/01	[REDACTED]	1999	Two-Generation Reproduction Study with NI-25 in Rats (Reproduction and Fertility Effects). [REDACTED] Document No. RD-99102N GLP, not published	Y	N		Nippon Soda
CA 5.6.2/01	[REDACTED]	1997a	Acetamiprid - Teratogenicity Study in Rats [REDACTED] Document No. RD-09537N GLP, not published	Y	N		Nippon Soda
CA 5.6.2/02	[REDACTED]	1997b	Acetamiprid - Teratogenicity Study in Rabbits [REDACTED] Document No. RD-09538N GLP, not published	Y	N		Nippon Soda
CA 5.6.2/03	Gu, Y. et al	2013	Reproductive effects of two neonicotinoid insecticides on mouse sperm function and early embryonic development <i>In vitro</i> . PLoS one July 2013, Volume 8, Issue 7, e70112	N	N		-
CA 5.6.2/04	Zhang, J.-J. et al	2011	Oxidative stress: Role in acetamiprid-induced impairment of the male mice reproductive system. Agricultural Sciences in China Vol. 10(5), pp. 786-796	N	N		-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.7.1/01	[REDACTED]	1997	Acetamiprid Dose Range Finding Neurotoxicity to Rats by Acute Oral Administration (including determination of time to peak effect) [REDACTED] Document No. RD-09927 GLP, not published	Y	N		Nippon Soda
CA 5.7.1/02	[REDACTED]	1997a	Acetamiprid - Neurotoxicity to Rats by Acute Oral Administration [REDACTED] Document No. RD-09928 GLP, not published	Y	N		Nippon Soda
CA 5.7.1/03	[REDACTED]	1997b	Acetamiprid - Neurotoxicity to Rats by Dietary Administration for 13 Weeks [REDACTED] Document No. RD-09929 GLP, not published	Y	N		Nippon Soda
CA 5.7.1/04	[REDACTED]	2008	An oral developmental neurotoxicity study of acetamiprid in rats [REDACTED] Document No.: RD-01310 GLP, Not published	Y	Y	Study generated for registration outside of EU	Nippon Soda
CA 5.7.1/05	[REDACTED]	2006	Rebuttal of Data Evaluation Record for Acetamiprid (WIL No. 21193, EPA Acetamiprid 099050, MRID 46255619) [REDACTED] Document No. RD-00952 Not GLP, Not published	N	N		Nippon Soda

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
CA 5.7.1/06	Li, A.A., Lau, E.	2007 a	Characterization of Critical Toxicology Endpoints for Acetamiprid Risk Assessment: Auditory Startle Habituation and Maternal Toxicity from the Developmental Neurotoxicology Study (MRID 47191101) Exponent, USA, dated April 6, 2007. Document No. RD-02833 Not GLP, Not published	N	N		Nippon Soda
CA 5.7.1/07	Nguyen, J.	2007	Acetamiprid DNT Study (WIL-21193): Statistical analysis for auditory startle response. DP Barcode 341525 CEB memo dated July 24, 2007 Not GLP, Published	N	N		U.S. EPA
CA 5.7.1/08	Li, A.A., Lau, E.	2007 b	Acetamiprid DNT Study (WIL-21193; MRID 46255619): Response to EPA CEB Statistical Analyses and Weight of Evidence Supporting NOAEL of 10 mg/kg bwt/day Exponent, Inc., USA, Report dated September 17, 2007, Document No. RD-02486 Not GLP, Not published	N	N		Nippon Soda
CA 5.7.1/09	U.S. EPA	2008	Acetamiprid: Data evaluation record for Acetamiprid developmental neurotoxicity study and EPA response to rebuttals submitted by Nisso America. PC Code 099050 Not GLP, Published	N	N		U.S. EPA
CA 5.7.1/10	EFSA	2013	EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Scientific Opinion on the developmental neurotoxicity potential of acetamiprid and imidacloprid. EFSA Journal 2013;11(12):3471. [51 pp.] doi:10.2903/j.efsa.2013.3471. Not GLP, Published	N	N		EFSA

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verbrat e stud y Y/N	Data prote ction claim ed Y/N	Justification if data protection is claimed	Owner
CA 5.7.1/ 11	Li, A.A. <i>et al.</i>	2014 a	Response to EFSA PPR Scientific Opinion on the Acetamiprid DNT Study Exponent, USA, Doc. no. 1400668.000 – 2130, dated March 2014. Document No. RD-02799 Not GLP, Not published	N	N		Nippon Soda
CA 5.7.1/ 12	Li, A.A.	2014 b	Addendum to Response to EFSA PPR Scientific Opinion on the Acetamiprid DNT Study Previously Submitted March 2014 2014 – Information requested by EFSA and new analysis Exponent, USA, Doc. no. 1400668.000 – 6351, dated July 10 2014. Document No. RD-02892 Not GLP, Not published	N	N		Nippon Soda
CA 5.7.1/ 13	EFSA	2015	EFSA PPR Panel 2015. Response of EFSA PPR Panel to the Nippon Soda Co., Ltd. Report on the potential DNT of acetamiprid.	N	N		EFSA
CA 5.7.2/ 01		1997	NI-25 Acute Delayed Neurotoxicity Study in the Domestic Hen  Nippon-Soda Report No.: RD-9438N GLP Not published	Y	Y	Study generated for registration outside of EU	Nippon Soda
CA 5.8.1/ 01		1997c	IM-0 - Acute Oral Toxicity Study In Rats.  Document No. RD-9585N GLP, not published	Y	N		Nippon Soda
CA 5.8.1/ 02		1997c	IM-0 - Thirteen Week Dietary Subchronic Toxicity Study in Rats.  Document No. RD-97108 GLP, not published	Y	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.8.1/03	[REDACTED]	1997a	IM-0 - Reverse Mutation Study on Bacteria [REDACTED] Document No. RD-09586N GLP, not published	N	N		Nippon Soda
CA 5.8.1/04	[REDACTED]	1997d	IM-1-2 - Acute Oral Toxicity Study In Rats. [REDACTED] Document No. RD-95133N GLP, not published	Y	N		Nippon Soda
CA 5.8.1/05	Mochizuki, N., Kanaguchi, Y.	1997b	IM-1-2 - Reverse Mutation Study on Bacteria Nippon Soda Co. Odawara Research Center Japan, Report No. G-964, Document No. RD-9601N GLP, not published	N	N		Nippon Soda
CA 5.8.1/06	[REDACTED]	1997e	IM-1-3 : Acute Oral Toxicity Study In Rats. [REDACTED] Document No. RD-95142N GLP, not published	Y	N		Nippon Soda
CA 5.8.1/07	Mochizuki, N., Kanaguchi, Y.	1997c	IM-1-3 - Reverse Mutation Study on Bacteria Odawara Research Center, Nippon Soda Co. Ltd., Report No. G-936, Document No. RD-95143N GLP, not published	N	N		Nippon Soda
CA 5.8.1/08	[REDACTED]	1998a	IM-1-4 - Acute Oral Toxicity Study In Rats. [REDACTED] Document No. RD-9828N GLP, not published	Y	N		Nippon Soda
CA 5.8.1/09	[REDACTED]	1998b	IM-1-4: Acute Dermal Toxicity Study in Rats [REDACTED] Document No. RD-9829N GLP, not published	Y	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.8.1/ 10	[REDACTED]	1999	13-Week Dietary Subchronic Toxicity Study with IM-1-4 in Rats. [REDACTED] Document No. RD-9903 GLP, not published	Y	N		Nippon Soda
CA 5.8.1/ 11	Mochizuki, N., Kanaguchi, Y.	1997d	IM-1-4 - Reverse Mutation Study on Bacteria Odawara Research Center, Nippon Soda Co. Ltd., Report No. G-940, Document No. RD-09602N GLP, not published	N	N		Nippon Soda
CA 5.8.1/ 12	Cifone, M.A.	1998	Mutagenicity test on IM-1-4 in the CHO/HGPRT forward mutation assay Covance Laboratories Inc., Report No. 6840-106, 18981-0-435, Document No. RD-9834 GLP, not published	N	Y	Available study not evaluated during the previous evaluation	Nippon Soda
CA 5.8.1/ 13	[REDACTED]	1998	Mutagenicity Test on IM-1-4 in the <i>in vivo</i> Mouse Micronucleus Assay [REDACTED] Document No. RD-9835 GLP, not published	Y	Y	Available study not evaluated during the previous evaluation	Nippon Soda
CA 5.8.1/ 14	[REDACTED]	1997	IM-1-5*HCl: Acute oral toxicity study in rats. [REDACTED] Document No. RD-97109 GLP, not published	Y	N		Nippon Soda
CA 5.8.1/ 15	[REDACTED]	2002b	IM-1-5: Acute oral toxicity study in rats. [REDACTED] Document No. RD-II 02424 GLP, not published	Y	N		Nippon Soda
CA 5.8.1/ 16	Kanaguchi, Y.	1997c	IM-1-5 - reverse mutation study on bacteria Odawara Research Center, Nippon Soda Co. Ltd., Report No. H145, Document No. RD-97101 GLP, not published	N	Y	Available study not evaluated during the previous evaluation	Nippon Soda



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.8.1/ 17	Riach, C.G.	2012 a	IM-1-5: Bacterial Reverse Mutation Test in <i>Salmonella typhimurium</i> TA 1535, TA 100, TA 1537 and TA 98 and <i>Escherichia coli</i> WP2uvrA (OECD 471) Charles River, UK, Report No. 32827, Document No. RD-02354 GLP, not published	N	Y	Study generated to satisfy current data requirements	Nippon Soda
CA 5.8.1/ 18	Riach, C.G.	2012 b	IM-1-5: <i>In vitro</i> Mammalian Cell Gene Mutation Test in Mouse Lymphoma L5178Y Cells (OECD 476) Charles River, UK, report No. 32830, Document No. RD-02372 Nippon-Soda Report No.: RD-02372 GLP, not published	N	Y	Study generated to satisfy current data requirements	Nippon Soda
CA 5.8.1/ 19		1997f	IM-2-1 - Acute Oral Toxicity Study In Rats. Document No. RD-95135N GLP, not published	Y	N		Nippon Soda
CA 5.8.1/ 20	Mochizuki, N., Kanaguchi, Y.	1997e	IM-2-1 - Reverse Mutation Study on Bacteria Odawara Research Center, Nippon Soda Co. Ltd., Report No. G-932, Document No. RD-9587N GLP, not published	N	N		Nippon Soda
CA 5.8.1/ 21		1997g	IM-2-3: Acute Oral Toxicity Study In Rats. Document No. RD-95144N GLP, not published	Y	N		Nippon Soda
CA 5.8.1/ 22	Mochizuki, N., Kanaguchi, Y.	1997f	IM-2-3 - Reverse Mutation Study on Bacteria Odawara Research Center, Nippon Soda Co. Ltd., Report No. G-938, Document No. RD-09603N GLP, not published	N	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verbrat e stud y Y/N	Data prote ction claim ed Y/N	Justification if data protection is claimed	Owner
CA 5.8.1/ 23		1997h	IS-1-1: Acute Oral Toxicity Study In Rats.  Document No. RD-95140N GLP, not published	Y	N		Nippon Soda
CA 5.8.1/ 24	Mochizuki, N., Kanaguchi, Y.	1997g	IS-1-1 - Reverse Mutation Study on Bacteria Odawara Research Center, Nippon Soda Co. Ltd., Report No. G-948, Document No. RD-09606N GLP, not published	N	N		Nippon Soda
CA 5.8.1/ 25		1997i	IS-2-1: Acute Oral Toxicity Study In Rats  Document No. RD-95141N GLP, not published	Y	N		Nippon Soda
CA 5.8.1/ 26	Mochizuki, N., Kanaguchi, Y.	1997h	IS-2-1 - Reverse Mutation Study on Bacteria Odawara Research Center, Nippon Soda Co. Ltd., Report No. G-946, Document No. RD-9607N GLP, not published	N	N		Nippon Soda
CA 5.8.1/ 27		1997j	IC-0 - Acute Oral Toxicity Study In Rats.  Document No. RD-95137N GLP, not published	Y	N		Nippon Soda
CA 5.8.1/ 28	Mochizuki N., Kanaguchi Y.	1997i	IC-0 - Reverse Mutation Study on Bacteria Odawara Research Center, Nippon Soda Co. Ltd., Report No. G-942, Document No. RD-09605N GLP, not published	N	N		Nippon Soda
CA 5.8.1/ 29		1999z	IB-1-1: Acute Oral Toxicity in Rats  Document No. RD-9906 GLP, not published	Y	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.8.1/30	Mochizuki, N., Kanaguchi, Y.	1997	IB-1-1: Reverse Mutation Study on Bacteria Odawara Research Center, Nippon Soda Co. Ltd., Report No. H163, Document No. RD-9915 GLP, not published	N	N		Nippon Soda
CA 5.8.2/01	[REDACTED]	2010	Acetamidrid: 4-Week Dietary Immunotoxicity Study in the Rat [REDACTED] Document No. RD-02011 GLP, not published	Y	Y	Study generated for registration outside of EU	Nippon Soda
CA 5.8.2/02	[REDACTED]	2010	4-Week Acetamidrid: Dietary Immunotoxicity studies in mouse [REDACTED] Document No. RD-02019 GLP, not published	Y	Y	Study generated for registration outside of EU	Nippon Soda
CA 5.8.2/03	[REDACTED]	1997	Acetamidrid: Pharmacological Studies in Experimental Animals. [REDACTED], Document No. RD-09578N GLP, not published	Y	N		Nippon Soda
CA 5.8.2/04	Zhang, J.-J. et al	2012	Nephrotoxicity of acetamidrid on male mice and the rescue role of Vitamin E. Journal of Animal and Veterinary Advances Vol. 11(15), pp. 2721-2726	N	N		-
CA 5.9.1/01	Ota, Y.	2014	Human Handling Experiences From Plant Employees Manufacturing Acetamidrid (No. 3) Nippon Soda Co., Ltd, Document No. RD-02879 Non-GLP, not published	N/A	Y	Required to satisfy data requirement	Nippon Soda
CA 5.9.1/02	Kanaguchi, Y.	2007	Human Handling Experiences From Plant Employees Manufacturing Acetamidrid (No. 2) Nippon Soda Co., Ltd, Document No. RD-01239 Non-GLP, not published	N/A	Y	Required to satisfy data requirement	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 5.9.1/03	Arai, S.	1998	Human Handling Experiences From Plant Employees Manufacturing Acetamiprid Nippon Soda Co., Ltd., Document No. RD-9849 Non-GLP, not published	N/A	N		Nippon Soda
CA 5.9.6/01	[REDACTED]	1998	Acetamiprid: Detoxification Studies for Acute Toxicity of NI-25 [REDACTED], Document No. RD-95108N GLP, not published	Y	N		Nippon Soda

#### References for the PPP Acetamiprid 20 SC

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.1/1	[REDACTED]	1998	Acute Oral Toxicity in Rats - EXP 60707B [REDACTED] [REDACTED] [REDACTED] Document No. RD-9943 GLP, not published	Y	N	-	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.2/01	■■■■■	1998	Acute Dermal Toxicity in Rats - EXP 60707B  ■■■■■ ■■■■■ ■■■■■ Document No. RD-9944  GLP, not published	Y	N	-	Nippon Soda
KCP 7.1.3/01	■■■■■	1999	Acetamidiprid 20% SP - Acute Inhalation Toxicity Study in Rats  ■■■■■ ■■■■■ ■■■■■ Document No.RD-9545N  GLP, not published	Y	N	-	Nippon Soda
KCP 7.1.4/01	■■■■■	1998	Acute Dermal Irritation in Rabbits - EXP 60707B  ■■■■■ ■■■■■ ■■■■■ Document No. RD-9945  GLP, not published	Y	N	-	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.5/01	■■■■■	1998	Acute Eye Irritation in Rabbits - EXP 60707B  ■■■■■ ■■■■■ ■■■■■ Document No. RD-9946  GLP, not published	Y	N	-	Nippon Soda
KCP 7.1.6/01	■■■■■	1998	Skin Sensitisation Test in Guinea Pig. EXP 60707B.  ■■■■■ ■■■■■ ■■■■■ Document No. RD-9947  GLP, not published	Y	N	-	Nippon Soda
KCP 7.3/01	Craig, S.	2014	The <i>In Vitro</i> Percutaneous Absorption of Radiolabelled Acetamiprid in the Concentrate and One In-Use Spray Dilution of Acetamiprid 20SP Through Human Skin  Charles River, UK, Report No. 34871, Document No. RD-02802  GLP, Not published	N	Y	New study to refine exposure of formulation to operators, workers and by-standers	Nippon Soda

## B.7 Residues

### References for the active substance acetamiprid

Annex Point / Reference number	Author(s)	Year	Title, Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
IIA 6.0/01	Maestracci, M.	1998	Acetamiprid/Storage Stability Study Generated by : ADME-Bioanalyses Report/title : RPA/NI-25/97051 Study N° RPA 97-75 Source : Nippon Soda GLP, GEP : Yes Date : January 8, 1998 Not published	N	N		Nippon Soda
CA, 6.1	Goller G.	1999	Stability Study of NI-25 (Acetamiprid) in apple and tomato samples after storage in freezer at or below -18 °C - Fortification experiments with active ingredient Nippon-Soda Document No. RD-00340 A.D.M.E. - Bioanalyses, France, Report No. RPA/NI-25/97051, 97-75 GLP, Not published	N	N		Nippon Soda
6.1/01	Gieseke, L.D.	1999	NI-25 (acetamiprid): Freezer storage stability of acetamiprid residues in various raw agricultural commodities and processing fractions (plant matrices). Horizon Laboratories, Inc. Report No. 10201, Document No. RD-00270 GLP, not published	N	N		Nippon Soda

Annex Point / Reference number	Author(s)	Year	Title, Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
6.1/03	Jean-Baptiste C.	2009	Frozen Storage Stability of Residues of Acetamiprid in Fodder Pea. Anadiag Laboratories. Report No. A7125, Document No. RD-01936. GLP, not published	N	N		Nippon Soda
6.1/04	Netzband, D. J.	2003	Stability study of Acetamiprid in potatoes during frozen storage, USA, 2002 in freezer at or below -18°C, 02Y535566, RD-00243; Doc No. 645-002, Test facility: Bayer CropScience, Residue Chemistry Department, Research Triangle Park, North Carolina, USA GLP, self-certified, 20.02.2003	N	Y		Nippon Soda
IIA 6.1/01	Austin, D.J., McMillan-Staff, S.L., Lingwood, A.	1997	[ <sup>14</sup> C]-NI-25 Metabolism in Carrots Generated by: Rhône-Poulenc Agriculture Ltd Report/file: RPAL Study 11253 Source: Nippon Soda GLP, GEP : Yes Date: August 22, 1997 Not published	N	N		Nippon Soda
KIIA 6.1/02	Hobbs, G. Inns, L.	2012	[ <sup>14</sup> C]-IM-1-5: Uptake and Metabolism of Soil Residues in Confined Rotational Crops Report no . RD-02391 GLP: Yes Unpublished	N	Y	New data required to identify the plant uptake of a metabolite unique for calcareous soils	Nippon Soda
IIA 6.1/03	Kawai, T.	1995	NI-25 [CN- <sup>14</sup> C] - Nature of the Residue in Cabbages Plants Generated by: Nisso Chemical Analysis Service Co, Ltd Report/file: NCAS N°:2-	N	N		Nippon Soda



Annex Point / Reference number	Author(s)	Year	Title, Source (where different from company) Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			137 NG Amended Report EC-617-1 Source: Nippon Soda GLP, GEP : Yes Date: October 23, 1997 Not published				
IIA 6.1/04	Saito, H.	1997(1)	NI-25 [Pyridine-2,6- <sup>14</sup> C] - Nature of the Residue in Apples Generated by: Nisso Chemical Analysis Service Co, Ltd Report/file: NCAS N°: 2-98 Amended Report-742-1 Source : Nippon Soda GLP, GEP : Yes Date : November 10, 1997 Not published	N	N		Nippon Soda
IIA 6.1/05	Saito, H.	1997(2)	NI-25 [Pyridine-2,6- <sup>14</sup> C] - Nature of the Residue in Cabbages Plants Generated by: Nisso Chemical Analysis Service Co, Ltd Report/file: NCAS N°: 2-111 Amended Report EC-743-1 Source: Nippon Soda Date: November 10, 1997 GLP, GEP : Yes Not published	N	N		Nippon Soda
IIA 6.1/06	Saito, H.	1997(3)	NI-25 [Pyridine-2,6- <sup>14</sup> C] - Nature of the Residue in Eggplants Generated by: Nisso Chemical Analysis Service Co, Ltd Report/file: NCAS N°: 2-92 Amended Report N° EC-391-3 Source: Nippon Soda Date: November 17, 1997 GLP, GEP : Yes Not published	N	N		Nippon Soda
6.1/02	Miller N.	1999	Foliarly applied 14C-acetamiprid: Metabolic fate and distribution in cotton (Gossypium	N	N		Nippon Soda

Annex Point / Reference number	Author(s)	Year	Title, Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			hirsutum). Rhône-Poulenc Ag Company. Report No. EC-97-367, Document No. RD-00741 GLP, not published				
IIA 6.2/01		1997(1)	<sup>14</sup> C-NI-25 (Acetamidrid): Absorption, Distribution, Metabolism and Excretion after Repeated Oral Administration to Lactating Goats Generated by:  Source: Nippon Soda GLP, GEP : Yes Date: May 23, 1997 Not published	Y	N		Nippon Soda
IIA 6.2/02		1997(2)	<sup>14</sup> C -NI-25 (Acetamidrid): Absorption, Distribution, Metabolism and Excretion after Repeated Oral Administration to Laying Hens Generated by:  Source: Nippon Soda GLP. GEP : Yes Date: July 3, 1997 Not published	Y	N		Nippon Soda
IIA 6.3/01	D'Accriscio , M. Maestracci, M	1997(2)	Acetamidrid (NI-25) - Formulation EXP60707A (SP) - Trial United Kingdom 1996 - Residues in Apple Decline study Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/dbe 9716245, Doc N°442022	N	N		Nippon Soda

Annex Point / Reference number	Author(s)	Year	Title, Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Study N° 96-704 Source: Nippon Soda GLP, GEP : yes Date: 23 September 1997 Not published				
IIA 6.3/02	D'Accriscio , M. Maestracci, M.	1997(5)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - Trials The Netherlands 1996 - Residues in Apple Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/dbe 9716246, Doc N°442023 Study N° 96-784 Source: Nippon Soda GLP, GEP : Yes Date: 12 September 1997 Not published	N	N		Nippon Soda
IIA 6.3/03	D'Accriscio , M. Maestracci, M.	1997(6)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - Trials France 1996 - Residues in Apple Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9715752, Study N° 96-732 Source: Nippon Soda GLP, GEP : Yes Date: 08 December 1997 Not published Amendment n°1/file : R&D/CRLD/AN/ 9915433 (02 April 1999)	N	N		Nippon Soda
IIA 6.3/04	Domenichini, P.	1998(4)	Generation of apple samples suitable for residue analysis (decline curve) following applications of Acetamiprid 20% SP (2 <sup>nd</sup> year of trial) Generated by: Sipcam Spa	N	N		Nippon Soda

Annex Point / Reference number	Author(s)	Year	Title, Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report/file: SIP1129 Source: Nippon Soda GLP, GEP : yes Date: 14 May 1998 Not published				
IIA 6.3/05	Fraschini, C.	1997(4)	Analysis of Acetamiprid Residues on Apple (Whole fruit) Generated by: Sipcam Spa Report/file: SIP1086 Source: Nippon Soda GLP, GEP : Yes Date: 14 July 1997 Not published	N	N		Nippon Soda
IIA 6.3/06	Fraschini, C.	1997(5)	Analysis of Acetamiprid Residues on Pear (Whole fruit) Generated by: Sipcam Spa Report/file: SIP1085 Source: Nippon Soda GLP, GEP : yes Date: 14 July 1997 Not published	N	N		Nippon Soda
IIA 6.3/07	Fraschini, C.	1997(7)	Analysis of NI-25 (Acetamiprid) Residues in Tomato (Whole fruit) Generated by: Sipcam Spa Report/file: SIP1092 Source: Nippon Soda GLP; GEP : yes Date: 14 July 1997 Not published	N	N		Nippon Soda
IIA 6.3/08	Freschi, G.	2000(1)	Analysis of NI-25 (Acetamiprid) Residues in Tomato (Whole fruit) Generated by: Sipcam Spa Report/file: SIP1224 Source: Nippon Soda GLP; GEP : yes Date: 13 July 2000 Not published	N	N		Nippon Soda
KIIA 6.3/09	Pollman, B.	2005	Determination of Residues of Acetamiprid after Three Applications of Acetamiprid 20 % SP (containing 20 % Acetamiprid) Potatoes, Northern and Southern	N	Y	New data required to cover the new claim on potato	Nippon Soda

Annex Point / Reference number	Author(s)	Year	Title, Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Europe 2004. Report no. 20041020/E1-FPPO GLP: Yes  Unpublished				
IIA 6.3/10	Richard, M; Maestracci, M.	1997(4)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - Trial Greece 1996 - Residues in Apple - Decline study Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9715419, Doc N°441468 Study N° 96-653 Source: Nippon Soda GLP, GEP : Yes Date: 27 May 1997	N	N		Nippon Soda
IIA 6.3/11	Richard, M; Maestracci, M	1997(5)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - Trial United Kingdom 1996 - Residues in Apple Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9716024, Study N° 96-703 Doc N°441770 Source: Nippon Soda GLP, GEP : yes Date: 22 August 1997	N	N		Nippon Soda
IIA 6.3/12	Richard, M. Maestracci, M.	1997(9)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - Trials France 1997 - Residues in Apple Decline study Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/db 9716757, Doc N°442873 Study N° 97-611 Source: Nippon Soda GLP, GEP : yes Date: 19 December 1997	N	N		Nippon Soda

Annex Point / Reference number	Author(s)	Year	Title, Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebra te study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Not published				
IIA 6.3/13	Richard, M. Maestracci, M.	1997(10)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - Trials Italy 1997 - Residues in Apple Decline study Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/dbe 9716756, Doc N°442872 Study N° 97-627 Source: Nippon Soda GLP, GEP : yes Date: 17 December 1997 Not published	N	N		Nippon Soda
IIA 6.3/14	Richard, M. Maestracci, M.	1997(11)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - Trials Greece 1997 - Residues in Apple Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/dbe 9716744, Doc N°442860 Study N° 97-737 Source: Nippon Soda GLP, GEP : yes Date: 19 December 1997 Not published	N	N		Nippon Soda
IIA 6.3/15	Richard, M. Maestracci, M.	1997(16)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - Trial France 1996 - Residues in Tomato Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9715973, Doc N°441724 Study N° 96-557 Source: Nippon Soda GLP, GEP : yes Date: 11 July 1997 Not published	N	N		Nippon Soda


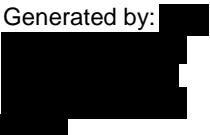
Annex Point / Reference number	Author(s)	Year	Title, Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
IIA 6.3/16	Richard, M. Maestracci, M	1997(17)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - Trial Spain 1996 - Residues in Tomato (Greenhouse) - Decline study Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9716021, Doc N°441762 Study N° 96-629 Source: Nippon Soda GLP, GEP : yes Date: 18 August 1997 Not published	N	N		Nippon Soda
IIA 6.3/17	Richard, M. Maestracci, M	1997(18)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - Trial Italy 1996 - Residues in Tomato (Greenhouse) - Decline study Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9715986, Doc N°441734 Study N° 96-767 Source: Nippon Soda GLP, GEP : yes Date: 11 July 1997 Not published	N	N		Nippon Soda
IIA 6.3/18	Richard, M. Maestracci, M.	1997(19)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - Trial France 1997 - Residues in Tomato (in Greenhouse) Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/dbc 9716514, Doc N°442381 Study N° 97-538 Source: Nippon Soda GLP, GEP : yes Date: 4 November 1997	N	N		Nippon Soda

Annex Point / Reference number	Author(s)	Year	Title, Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Not published				
IIA 6.2/19	Richard, M. Maestracci, M	1997(20)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - Trial France 1997 - Residues in Tomato (in Greenhouse) Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/dbe 9716513, Doc N°442380 Study N° 97-539 Source: Nippon Soda GLP, GEP : yes Date: 4 November 1997 Not published	N	N		Nippon Soda
IIA 6.3/20	Richard, M. Maestracci, M	1997(21)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - Trial France 1997 - Residues in Tomato Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/vt 9716629, Doc N°442749 Study N° 97-587 Source: Nippon Soda Date: 28 November 1997 GLP, GEP : Yes Not published		N		Nippon Soda
IIA 6.3/21	Richard, M. Maestracci, M	1997(22)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - Trial France 1997 - Residues in Tomato Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/dbe 9716627, Doc N°442746 Study N° 97-586 Source: Nippon Soda Date: 27 November 1997 GLP, GEP : Yes Not published	N	N		Nippon Soda



Annex Point / Reference number	Author(s)	Year	Title, Source (where different from company) Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
IIA 6.3/22	Richard, M., Maestracci, M.	1997(29)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - Trial Italy 1996 - Residues in Apple Decline study Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/vg 9715988, Doc N°441771 Study N° 96-769 Source: Nippon Soda GLP, GEP: Yes date : 19 August 1997 Not published	N	N		Nippon Soda
IIA 6.3/23	Richard, M ; Maestracci, M	1997(34)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - Trials France 1996 - Residues in Apple - Decline study Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/kd 9715990, Doc N°441738 Study N° 96-552 Source: Nippon Soda GLP, GEP : Yes Date 11 June 1997 Not published	N	N		Nippon Soda
KIIA 6.3/24	Simek, E.	2013	Determination of acetamiprid residues in cherry tomatoes following 2 applications of Acetamiprid 20% SG under greenhouse conditions in Southern and Northern Europe – 2012. Report no . B2061 GLP: Yes Unpublished	N	Y	New data to cover the claim on small tomato varieties	Nippon Soda
KIIA 6.3/25	Simek, E.	2014	Determination of acetamiprid residues in cherry tomatoes following 2 applications of Acetamiprid 20% SG under greenhouse conditions in Southern	N	Y	New data to cover the claim on small tomato	Nippon Soda

Annex Point / Reference number	Author(s)	Year	Title, Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Europe – 2013 Report no . R B3142 GLP: Yes Unpublished			varieties	
KIIA 6.3/26	Simek, E.	2012	Determination of acetamiprid residues in cherry tomatoes following 2 applications of Acetamiprid 20% SG under greenhouse conditions in Southern and Northern Europe – 2011 Report no . RD-02762 GLP: Yes Unpublished	N	Y	New data to cover the claim on small tomato varieties	Nippon Soda
KIIA 6.3/27	Sonder, KH.	2002	Residue behaviour in tomatoes (indoor) European Union (Southern zone) 2001 Acetamiprid water soluble powder (SP) 20 % w/w. Report no . RD-01019 GLP: Yes Unpublished	N	Y	New data to cover the claim on tomato varieties	Nippon Soda
IIA 6.3/28	Venet, C. Barriere, I.	2000(1)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - Trials France 1999 - Residues in Apple + Processed products Generated by: Aventis CropScience Report/file: R&D/CRLD/AN/mba 0015360, Doc N°447500 Study N° 99-708 Source: Nippon Soda GLP, GEP : yes Date: 30 March 2000 Not published	N	N		Nippon Soda
IIA 6.3/29	Venet, C. Barrière, I	2000(4)	Acetamiprid (NI-25) - Formulation EXP60707A (SP) - South/Italy/1999 - 1 harvest study trial - Residues in Tomato (fruit).(in Greenhouse) Generated by Aventis	N	N		Nippon Soda

Annex Point / Reference number	Author(s)	Year	Title, Source (where different from company) Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			CropScience Report/file: R&D/CRLD/AN/bva 0015356, Doc N°447495 Study N° 99-686 Source: Nippon Soda GLP, GEP : yes Date: 24 march 2000 Not published				
IIA 6.3	Maestracci, M.	1997	Acetamiprid (NI-25) – Formulation EXP6070A (SP) – Trial France 1996 – Residues in pear - decline study Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/kd/9716046 Study Number: 96-734 RD-00332 Source: Nippon Soda GLP, GEP : Yes Date 15 December 1997 Not published	N	N		Nippon Soda
IIA 6.3	Maestracci, M.	1997	Acetamiprid (Code No. NI-25) – Formulation EXP60707A (SP) Trials France 1996 – Residues in apple Generated by: Rhône-Poulenc Agro Report/file: R&D/CRLD/AN/kd/9716012 Study Number: 96-553 RD-99112 Source: Nippon Soda GLP, GEP : Yes Date 10 July 1997 Not published	N	N		Nippon Soda
IIA 6.4/01		1999(1)	Acetamiprid : Magnitude of Residues in Dairy Cow Milk and Tissues. Generated by: 	Y	N		Nippon Soda

Annex Point / Reference number	Author(s)	Year	Title, Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Source: Nippon Soda Date: January 6, 1999 Not published				
IIA 6.4	[REDACTED]	1999	Acetamiprid (Code No.: NI-25) – Magnitude of Residues in Poultry Tissue and Eggs. Generated by: [REDACTED] [REDACTED] Source: Nippon Soda Date: July, 1999 Not published	Y	Y	New data required for determination of residue definition for products of animal origin	Nippon Soda
IIA .6.5/01	Kowite, W.J.	1999	NI-25: Magnitude of Residues in Apple Processed Commodities Resulting from Foliar Applications of EXP 80667A Insecticide Generated by: Rhône- Poulenc Agriculture Ltd Report/file: Study No 97512650 Source: Nippon Soda GLP. GEP : yes Date: August 25. 1999 Not published	N	N		Nippon Soda
IIA 6.5/02	McMillan-Staff, Austin, D.J.	1997	[ <sup>14</sup> C]-NI-25 Investigation of the Nature of the Potential Residue in the Products of Industrial Processing or Household Preparation. Generated by: Rhône-Poulenc Agriculture Ltd Report/file:RPAL Study 13442 Source: Nippon Soda Date: October 09, 1997 Not published	N	N		Nippon Soda
KIIA 6.6/01	Raufer, B.	2013	Residue study on rotational crops after one application of Acetamiprid on bare soil at 2 sites in Europe in 2010 to 2012. Report no RD-02495N2	N	Y	New data required to identify the plant uptake of a metabolite	Nippon Soda

<b>Annex Point / Reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title, Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
			GLP: Yes Unpublished			unique for calcareous soils	
KIIA 6.6/02	Raufer, B	2014	Residue study on rotational crop (turnip) after one application of Acetamiprid on bare soil at 1 site in Europe in 2012 to 2013. Report no. RD-02930 GLP: Yes Unpublished	N	Y	New data required to identify the plant uptake of a metabolite unique for calcareous soils	Nippon Soda

## B.8 Environmental fate and behaviour

### References for the active substance acetamiprid

#### New studies

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 7.1.2.1.1/01, 7.1.2.1.2/02	Jarvis, T. & Hilton, M	2014	Re-calculation of laboratory aerobic degradation rates of acetamiprid and its metabolites, according to FOCUS (2006, 2011) guidance Exponent International Ltd., UK Nippon-Soda Report No.: RD-02913 Non-GLP Not published	N	N		Nippon Soda
CA 7.1.2.1.2/01	Jewkes, Y.	2014	Rate of Degradation of [ <sup>14</sup> C]-IM-1-5 in Three Soils at 20°C Nippon-Soda Report No.: RD-02811 GLP Not published	N	Y	Guideline laboratory aerobic soil study to address annex point	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 7.1.2.1.3/01	Jarvis, T. & Montesano, V	2014a	Re-calculation of laboratory anaerobic degradation rate of acetamiprid according to FOCUS (2006, 2011) guidance Exponent International Ltd., UK Nippon-Soda Report No.: RD-02910 Non-GLP Not published	N	N		Nippon Soda
CA 7.1.3.1.2/01	Sugiyama, H.	2010	Adsorption / desorption study of IM-1-5 on soils Nippon Soda Co. Ltd. (NSM), Japan, Report No. NSM10-013 Document No. RD-02101 GLP Not published	N	Y	Guideline batch sorption study to address annex point	Nippon Soda
CA 7.2.2.2/01	Möndel, M.	2014	[pyridine-2,6-14C]-Acetamiprid: "Aerobic Degradation in Natural Water" RLP Agrosience, Germany Nippon-Soda	N	Y	New data requirement under Regulation (EC) 1107/2009	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No.:RD-02800 GLP Not published				
CA 7.2.2.3/01	Jarvis, T. & Montesano, V.	2014c	Recalculation of acetamiprid sediment water kinetics according to FOCUS (2006, 2011) guidance Exponent International Ltd., UK Nippon-Soda Report No.: RD-02911 Non-GLP Not published	N	N		Nippon Soda

**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 point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 7.1.1.1 /01	Morgenroth, U.	1997	14C-NI-25: Metabolism in One Soil Incubated under Aerobic Conditions Report/file:RCC Project 373994 Amended final report Nippon Soda Doc No. RD-09624N GLP, Not published	N	N		Nippon Soda



CA 7.1.1.1 /02	Feung, C.S.	1998	Acetamiprid (NI-25): Metabolism in Collombey Soil  Report/file RPAC Report N° EC-97- 406  Nippon Soda Doc No. RD-09961  Non-GLP , Not published	N	N		Nippon Soda
CA 7.1.1.1 /03	Burr, C.M	1997	[14C]-NI-25: Rate of Aerobic Degradation in Three Soil Types at 20°C and One Soil Type at 10°C  Report/file: RPAL Study Report 11256  Nippon Soda Doc No. RD-09962  GLP, Not published	N	N		Nippon Soda
CA 7.1.1.1 /04	Simmonds M.B.	2002	[14C]-Acetamiprid: Rate of Degradation in Three Calcareous Soils at 20°C  Aventis CropScience SA., report C019428  Nippon Soda Doc No. RD-00168  GLP not published	N	N		Nippon Soda
CA 7.1.1.2 /01	Burr, C.M., Doble, M.L	1997	[14C]-NI-25: Anaerobic Soil Degradation  Report/file: RPAL Study Report 11444  Nippon Soda Doc No. RD-09860  GLP, Not published	N	N		Nippon Soda

CA 7.1.1.3 /01	Mislankar, S.G.	1998	Acetamiprid (NI-25) Soil Photolysis Report/file: RPAC Study N° EC-97-359  Nippon Soda Doc No. RD-09833 GLP, Not published	N	N		Nippon Soda
CA 7.1.2.1 .1/02	Morgenroth, U.	1997	14C-NI-25: Metabolism in One Soil Incubated under Aerobic Conditions Report/file:RCC Project 373994 Amended final report  Nippon Soda Doc No. RD-09624N GLP, Not published	N	N		Nippon Soda
CA 7.1.2.1 .1/03	Burr, C.M	1997	[14C]-NI-25: Rate of Aerobic Degradation in Three Soil Types at 20°C and One Soil Type at 10°C Report/file: RPAL Study Report 11256  Nippon Soda Doc No. RD-09962 GLP, Not published	N	N		Nippon Soda
CA 7.1.2.1 .1/04	Simmonds M.B.	2002	[14C]-Acetamiprid: Rate of Degradation in Three Calcareous Soils at 20°C Aventis CropScience SA., report C019428  Nippon Soda Doc No. RD-00168 GLP not published	N	N		Nippon Soda
CA 7.1.2.1 .2/03	Morgenroth, U.	1997	14C-NI-25: Metabolism in One Soil Incubated under Aerobic Conditions Report/file:RCC Project 373994 Amended final report  Nippon Soda Doc No. RD-09624N GLP, Not published	N	N		Nippon Soda

CA 7.1.2.1 .2/04	Burr, C.M	1997	[14C]-NI-25: Rate of Aerobic Degradation in Three Soil Types at 20°C and One Soil Type at 10°C  Report/file: RPAL Study Report 11256  Nippon Soda Doc No. RD-09962  GLP, Not published	N	N		Nippon Soda
CA 7.1.2.1 .2/05	Simmonds M.B.	2002	[14C]-Acetamiprid: Rate of Degradation in Three Calcareous Soils at 20°C  Aventis CropScience SA., report C019428  Nippon Soda Doc No. RD-00168  GLP not published	N	N		Nippon Soda
CA 7.1.2.1 .2/06	Lowden, P., Oddy, A.M., Jones, M.K.	1997	NI-25: Rate of Degradation of the Acid Metabolite, [14C]-IC-0 in Three Soils  Report/file: RPAL Study Report 11257  Nippon Soda Doc No. RD-9963  GLP, Not published	N	N		Nippon Soda
CA 7.1.2.1 .3/02	Burr, C.M., Doble, M.L	1997	[14C]-NI-25: Anaerobic Soil Degradation  Report/file: RPAL Study Report 11444  Nippon Soda Doc No. RD-09860  GLP, Not published	N	N		Nippon Soda
CA 7.1.4/ 01	Simmonds M.	2003	[ <sup>14</sup> C]-Acetamiprid: Aged Residue Column Leaching Study in Two Calcareous Soils  Nippon Soda Doc No. RD-03061  GLP not published	N	N		

CA 7.1.4/ 02	Morgenroth, U.	1997	14C-NI-25: Leaching Characteristics of Aged Residues in one Soil Source: Nippon Soda Generated by: RCC Umweltchemie AG Nippon Soda Doc No. RD-9566 GLP, Not published	N	N		
CA 7.1.3.1 .1/01	Flückiger, J.	1997	Adsorption/Desorption of 14C-NI-25 on Five Soils Report/file:RCC Project 374016 Nippon Soda Doc No. RD-09564N GLP, Not published	N	N		Nippon Soda
CA 7.1.3.1 .2/02	Mamouni, A	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	N		Nippon Soda
CA 7.1.3.1 .2/03	Liu, A.C.	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	N		Nippon Soda
CA 7.1.3.1 .2/04	Mackenzie E. Price O.	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	N		Nippon Soda

CA 7.2.1.1 /01	Gomyo, T., Kobayas hi, S	1997	NI-25 - Hydrolysis Source: Nippon Soda Report/file: Nisso Amended Report N° EC-375-2 Nippon Soda Doc No. RD-95122N GLP, Not published	N	N		Nippon Soda
CA 7.2.1.1 /02	Class, T	1997	Hydrolysis of IM-1-4 and IC-0 (Two Degradates of Acetamiprid) as a Function of pH Report/file: PTRL Study Report P 225G Nippon Soda Doc No. RD-00252 GLP, Not published	N	N		Nippon Soda
CA 7.2.1.1 /03	Takashi ma, K	2002	Hydrolysis of IM-1-5 Nippon Soda CO., LTD, report C028667 Nippon Soda Doc No. RD-II 02448 GLP, not published	N	N		Nippon Soda
CA 7.2.1.2 /01	Hausma nn, S., Class, T.	1998	Aqueous Photodegradation of [14C]-Acetamiprid at pH 7 and Determination of Quantum Yield Report/file: PTRL Europe Study N° P 196 G, RPA Study N°96-82 Nippon Soda Doc No. RD-00403 GLP, Not published	N	N		Nippon Soda
CA 7.2.1.2 /02	Emeric, G.T.	1998	Acetamiprid - Verification of the Identity of the Photolyte obtained at pH 7 - Study 96-82 Extension Report/file : RPA Study N° 98-47 Nippon Soda Doc No. RD-9965N GLP, Not published	N	N		Nippon Soda

CA 7.2.1.2 /03	Mamouni , A.	1997	Aqueous Photolysis of 14C-IM-1-4 under Laboratory Conditions Report/file: CC Project N°671332 Nippon Soda Doc No. RD-09967 GLP, Not published	N	N		Nippon Soda
CA 7.2.1.2 /04	Mamouni , A	1997	Aqueous Photolysis of [14C]-IC-0 under Laboratory Conditions Report/file: CC Project N°671343 Nippon Soda Doc No. RD-09966 GLP, Not published	N	N		Nippon Soda
CA 7.2.1.2 /05	H. Shiotani	2003	Photodegradation of IM-1-5 in Water Nippon Soda CO., LTD, report C030709 Nippon Soda Doc No. RD-03041 GLP, not published	N	N		Nippon Soda
CA 7.2.2.1 /01	Mead, C.	1999	Acetamidrid : Assessment of Ready Biodegradability CO2 Evolution Test. Report/file: SPL Project N°238/046 Nippon Soda Doc No. RD-9993 GLP, Not published	N	N		Nippon Soda
CA 7.2.2.3 /02	McMillan -Staff, S.L., Austin, D.J.	1997	[14C]-NI-25 : Degradation in Two Water/Sediment Systems. Report/file: RPAL Study 11263 Nippon Soda Doc No. RD-9968 GLP, Not published	N	N		Nippon Soda
CA 7.3.1/0 1	Van der Gaauw, A.	2000	Estimation of the degradation of Acetamidrid by photo-oxidation in air, Model calculation according to Atkinson. Report/file: RCC Study No 788714 Nippon Soda Doc No. RD-00981 Non GLP, Not published	N	N		Nippon Soda

CA 7.3.1/0 2	Kubiak, R.	1997	Investigation of the Volatilization of 14C-Acetamiprid Formulated Corresponding to EXP60707B from Plant and Soil Surfaces under laboratory Conditions.  Report/file: RPA24 Nippon Soda Doc No. RD-00249 GLP, Not published	N	N		Nippon Soda
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### **References for the PPP Acetamiprid 20 SC**

#### **New studies**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
CP 9.1.1.2/01	Jarvis, T. & Hilton, M	2014	Re-calculation of acetamiprid field dissipation rates from Wicks (1999) according to FOCUS (2006, 2011) guidance Exponent International Ltd., UK Nippon-Soda Report No.: RD- 02912 Non-GLP Not published	N	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 9.1.1.2/02	Kellner, T.	2012a	Soil Dissipation study with Acetamiprid and its Soil Metabolite IM-1-5, in or on Soil in Spain in 2010-2011 Eurofins Agrosience Services Nippon Soda Co. Ltd Report No.: RD-02404 GLP Not published	N	Y	Guideline dissipation study to address annex point for IM-1-5	Nippon Soda
CP 9.1.1.2/03	Kellner, T.	2012b	Soil Dissipation study with Acetamiprid and its Soil Metabolite IM-1-5, in or on Soil in Southern France in 2010-2011 Eurofins Agrosience Services Nippon Soda Co. Ltd Report No.: RD-02405 GLP Not published	N	Y	Guideline dissipation study to address annex point for IM-1-5	Nippon Soda



<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
CP 9.1.1.2/04	Kellner, T.	2012c	Soil Dissipation study with Acetamiprid and its Soil Metabolite IM-1-5, in or on Soil in Northern France in 2010-2011 Eurofins Agrosience Services Nippon Soda Co. Ltd Report No.: RD-02406 GLP Not published	N	Y	Guideline dissipation study to address annex point for IM-1-5	Nippon Soda
CP 9.1.1.2/05	Finger, N.	2013	Soil Dissipation study with Acetamiprid and its Soil Metabolite IM-1-5, in or on Soil in Hungary in 2011-2012 Eurofins Agrosience Services Nippon Soda Co. Ltd Report No.: RD-02599 GLP Not published	N	Y	Guideline dissipation study to address annex point for IM-1-5	Nippon Soda
CP 9.1.1.2/06	Tanguy, M. & Weber, H.	2012	Storage Stability of Residues of Acetamiprid and Acetamiprid	N	Y	Supporting data for new dissipation studies	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			metabolite IM-1-5 in four different Calcareous Soils Eurofins Agroscience Services Nippon Soda Co. Ltd Report No.: RD-02407				
CP 9.1.1.2/07	Jarvis, T. & Montesano, V.	2014b	Calculation of Acetamiprid soil DT50 values from new field dissipation studies in 2010 and 2011 using FOCUS kinetics		CA 7.1.2.2.1/06	Jarvis, T. & Montesano, V.	2014b

**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 point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 9.1.1.2/08	Wicks, R.J.	1999	Acetamiprid : Field Soil Dissipation Study in Europe RPA Study 11258, Doc 202052 Nippon Soda Doc No. RD-9997 GLP, Not published	N	N		Nippon Soda

CP 9.1.1.2 /09	Kieken, JL., Queyrel, I.	1999	Acetamiprid (NI-25) and Metabolites : Storage Stability in Soils from the European Terrestrial Field Soil Dissipation Study 11258  Report/file: R&D/CRLD/AN/mr/9915587, Study 98-07  Nippon Soda Doc No. RD-9998  GLP, Not published	N	N		Nippon Soda
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## B.9 Ecotoxicology

### References for the active substance acetamiprid

(grey marking: not considered acceptable or only considered as supplemental information for risk assessment)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 8.1.1.1 /02	██████████ ██████████	1994 b	NI-25: Acute oral toxicity (LD <sub>50</sub> ) to the Bobwhite Quail ██ Nippon-Soda Report No: RD-9434N GLP Not published	Y	Y	The only acute avian toxicity study assessed for the initial Annex I inclusion was conducted on mallard duck. The All data requirements (Reg. (EU) No. 283/2013) state the preferred species to be Japanese or Bobwhite quail.	Nippon Soda
CA 8.1.1.1 /03	██████████ ██████████ ██████████ ██████████	2011	Acetamiprid: An acute oral toxicity study with the zebra finch ( <i>Poephila guttata</i> ) ██ ██ Nippon-Soda Report No: RD-02175 GLP Not published	Y	Y	This study gives a lower endpoint than the Annex I agreed endpoint.	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA. 8.1.1.2 /03	██████	2012	Acetamiprid Technical Grade: Dietary toxicity test in zebra finch( <i>Poephila guttata</i> ) ████████████████████ ████████████████████ ████████████████████ Nippon-Soda Report No: RD-02389 GLP Not published	Y	Y	New study conducted for registration of Acetamiprid outside of EU.	Nippon Soda
CA. 8.1.1.2 /04	██████ ██████ ██████ ██████	1988	5-day dietary toxicity test with IM-1-4 in the Mallard Duck ( <i>Anas platyrhynchos</i> ) ████████████████████ Nippon-Soda Report No: RD-09935 GLP Not published	Y	Y	Study not previously considered in the initial Annex I inclusion dossier.	Nippon Soda
CA 8.1.1.3 /02	██████ ██████	2014	Acetamiprid: Reproductive Toxicity Test with the Mallard Duck ( <i>Anas platyrhynchos</i> ) ████████████████████ Nippon-Soda Report No: RD-02797 GLP Not published	Y	Y	New study conducted for registration of Acetamiprid outside of EU.	Nippon Soda
CA 8.2.1/03	██████	1995	Acetamiprid - Acute Toxicity Study in Carp. ████████████████████ ████████████████████ Nippon-Soda Report No: RD-9549 GLP Not published	Y	Y	Study not previously considered in the initial Annex I inclusion dossier.	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 8.2.1/04	[REDACTED]	1998b	Acetamiprid technical - acute toxicity to sheepshead minnow ( <i>Cyprinodon variegatus</i> ) under flow-through conditions [REDACTED] Nippon-Soda Report No: RD-00726 GLP Not published	Y	Y	Study not previously considered in the initial Annex I inclusion dossier.	Nippon Soda
CA 8.2.3/01	[REDACTED]	2013	Acetamiprid: Amphibian metamorphosis assay for the detection of the thyroid active substances [REDACTED] [REDACTED] Nippon-Soda Report No: RD-02574 GLP Not published	Y	Y	Under new data requirements (Reg. (EU) No. 283/2013) available data on amphibians should be submitted and consideration of endocrine disrupting properties required.	Nippon Soda
CA 8.2.4.2/01	Putt, A.E.	2003a	Acetamiprid technical - Acute toxicity to midge ( <i>Chironomus riparius</i> ) under static conditions. Springborn Smithers Laboratories, NC, USA Nippon-Soda Report No: RD-03144 GLP Not published	N	Y	Required in line with new data requirements (Reg. (EU) No. 283/2013).	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 8.2.4.2 /02	Putt, A.E.	2003 b	Acetamiprid technical - Acute toxicity to gammarids ( <i>Gammarus fasciatus</i> ) under static conditions. Springborn Smithers Laboratories, NC, USA Nippon-Soda Report No: RD-03143 GLP Not published	N	Y	Useful as further supportive information, due to insecticidal properties of active substance.	Nippon Soda
CA 8.2.4/03	Putt, A.E.	1998 b	Acetamiprid technical - Acute toxicity to mysids ( <i>Mysidopsis bahia</i> ) under flow-through conditions Springborn Laboratories, Inc. Nippon-Soda Report No: RD-00720 GLP Not published	N	Y	Useful as further supportive information, due to insecticidal properties of active substance.	Nippon Soda
CA 8.2.4/05	Kley, A. & Wydra, V.	2012 a	Acute toxicity of IM-1-2 to larvae of <i>Chironomus riparius</i> in a static 48-hours immobilisation test Ibacon GmbH, Rossdorf, Germany Project No. 67741251 Nippon-Soda Report No: RD-02374 GLP Not published	N	Y	Required as <i>Chironomus</i> is the most sensitive aquatic organism tested.	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 8.2.4/06	Kley, A. & Wydra, V.	2012 b	Acute toxicity of IC-0 to larvae of <i>Chironomus riparius</i> in a static 48-hours immobilisation test Ibacon GmbH, Rossdorf, Germany Nippon-Soda Report No: RD-02375 GLP Not published	N	Y	Required as <i>Chironomus</i> is the most sensitive aquatic organism tested.	Nippon Soda
CA 8.2.4/07	Kley, A. & Wydra, V.	2012 c	Acute toxicity of IB-1-1 to larvae of <i>Chironomus riparius</i> in a static 48-hours immobilisation test Ibacon GmbH, Rossdorf, Germany Nippon-Soda Report No: RD-02373 GLP Not published	N	Y	Required as <i>Chironomus</i> is the most sensitive aquatic organism tested.	Nippon Soda
CA 8.2.4/09	Putt, A.E.	1998 c	IM-1-4 Acute toxicity to mysids ( <i>Mysidopsis bahia</i> ) under static conditions Springborn Laboratories, Inc. Nippon-Soda Report No: RD-00719 GLP Not published	N	Y	Study generated for registration outside of EU	Nippon Soda
CA 8.2.6.2 /01	Hoberg, J.R.	1997 a	Acetamiprid technical - toxicity to the freshwater blue-green alga, <i>Anabaena flos-aquae</i> . Springborn Smithers Laboratories, NC, USA, Nippon-Soda Report No: RD-00154 GLP Not published	N	Y	Study not previously considered in the initial Annex I inclusion dossier.	Nippon Soda



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 8.3.1.2 /01	Harkin, S.	2014	Acetamiprid – Chronic toxicity test for adult honeybees ( <i>Apis mellifera</i> L.) The Food and Environment Research Agency, York, UK. Nippon-Soda Report No: RD-02928 GLP Not published	N	Y	Required in line with new data requirements (Reg. (EU) No. 283/2013).	Nippon Soda
CA 8.3.1.3 /01	Harkin, S.	2015	Acetamiprid: <i>In vitro</i> chronic toxicity to larval stage honeybee ( <i>Apis mellifera</i> L.) The Food and Environment Research Agency, York, UK. Nippon-Soda Report No: RD-02929 GLP Not published	N	Y	Required in line with new data requirements (Reg. (EU) No. 283/2013).	Nippon Soda

**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**

(grey marking: not considered acceptable or only considered as supplemental information for risk assessment)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 8.1.1.1/01	████████	1994a	NI-25 -Acute oral toxicity (LD <sub>50</sub> ) to the mallard duck. ██████████ ██████ Nippon-Soda Report No: RD-9435N GLP Not published	Y	N		Nippon Soda
CA 8.1.1.2/01	████████	1994c	NI-25 -Sub-acute Dietary toxicity (LC <sub>50</sub> ) to the mallard duck. ██████████ ██████ Nippon-Soda Report No: RD-09437N GLP Not published	Y	N		Nippon Soda
CA 8.1.1.2/02	████████	1994d	NI-25 -Sub-acute Dietary toxicity (LC <sub>50</sub> ) to the bobwhite quail. ██████████ ██████ Nippon-Soda Report No: RD-09436N GLP Not published	Y	N		Nippon Soda
CA 8.1.1.3/01	████████ ██████ ██████	1999	Reproduction study with Acetamiprid in the mallard duck ( <i>Anas platyrhynchos</i> ) ██████ Nippon-Soda Report No: RD-09990 GLP Not published	Y	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 8.1.1.3/03	[REDACTED]	1997	Reproduction study with Acetamiprid in the bobwhite quail ( <i>Colinus virginianus</i> ) [REDACTED] Nippon-Soda Report No: RD-09930N GLP Not published	Y	N		Nippon Soda
CA 8.2.1/01	[REDACTED]	1997a	NI-25 -Acute toxicity study in Rainbow trout. [REDACTED] [REDACTED] [REDACTED] Nippon-Soda Report No: RD-09637N GLP Not published	Y	N		Nippon Soda
CA 8.2.1/02	[REDACTED]	1997a	Acetamiprid - Acute toxicity (96 hrs) to bluegill ( <i>Lepomis macrochirus</i> ) under flow through conditions. [REDACTED] [REDACTED] [REDACTED] Nippon-Soda Report No: RD-00232 GLP Not published	Y	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 8.2.1/05	██████████ ████	1998	IM-1-4 -Acute toxicity study in Rainbow trout ( <i>Oncorhynchus mykiss</i> ) under semi-static conditions. ████████████████████ ████████████████████ ██████████ Nippon-Soda Report No: RD-9938 GLP Not published	Y	N		Nippon Soda
CA 8.2.2.1/01	██████ ██████████	1997	Acetamidrid -Early life stage toxicity test to Fathead minnow ( <i>Pimephales promelas</i> ). ████████████████████ ████████████████████ ██████████ Nippon-Soda Report No: RD-00255 GLP Not published	Y	N		Nippon Soda
CA 8.2.4.1/01	Saika, O.	1997b	NI-25 -Acute toxicity study in Daphnids. Nippon Soda Co., Odawara Research Center, Japan. Nippon-Soda Report No: RD-09765 GLP Not published	N	N		Nippon Soda

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
CA 8.2.4.1/02	Mc Elligott A.	1997a	IM-1-4 -Acute toxicity (48 hours) to Daphnids under semi-static conditions. Rhone-Poulenc Secteur Agro, Sophia, Antipolis, France. Nippon-Soda Report No: RD-9939 GLP Not published	N	N		Nippon Soda
CA 8.2.4.1/03	Mc Elligott A.	1997b	IM-1-2 -Acute toxicity (48 hours) to Daphnids under semi-static conditions. Rhone-Poulenc Secteur Agro, Sophia, Antipolis, France. Nippon-Soda Report No: RD-9940 GLP Not published	N	N		Nippon Soda
CA 8.2.4.1/04	Mc Elligott A.	1997c	IC-0 -Acute toxicity (48 hours) to Daphnids under semi-static conditions. Rhone-Poulenc Secteur Agro, Sophia, Antipolis, France. Nippon-Soda Report No: RD-9936 GLP Not published	N	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 8.2.4.1/05	Mc Elligott A.	1998	IB-I-I -Acute toxicity (48 hours) to Daphnids under semi-static conditions. Rhone-Poulenc Secteur Agro, Sophia, Antipolis, France. Nippon-Soda Report No: RD-9941 GLP Not published	N	N		Nippon Soda
CA 8.2.4.1/06	Saito, S.	2002	IM-1-5 (N1-((6-chloro-3-pyridyl)methyl)-N1-methylacetamidine): Acute toxicity to <i>Daphnia magna</i> . Aventis CropScience Nippon-Soda Report No: RD-II02414 GLP Not published	N	N		Nippon Soda
CA 8.2.4.2/04	Putt, A.E.	2001	IM-1-4 Acute toxicity to midge <i>Chironomus riparius</i> under static conditions Generated by:: Springborn Smithers Laboratories, NC, USA, Nippon-Soda Report No: RD-01034 GLP Not published	N	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 8.2.4.2/08	Putt, A.E.	2003c	IM-1-5 - Acute Toxicity to Midge ( <i>Chironomus riparius</i> ) Under Static Conditions. Source : Aventis CropScience Nippon-Soda Report No: RD-03060 GLP Not published	N	N		Nippon Soda
CA 8.2.5.1/01	Suteau, P.	1997b	Acetamidrid - <i>Daphnia magna</i> Life cycle (21 day static renewal) Chronic toxicity study. Rhone-Poulenc Secteur Agro, Sophia, Antipolis, France. Nippon-Soda Report No: RD-00235 GLP Not published	N	N		Nippon Soda
CA 8.2.5.1/02	Putt, A.E.	2003d	IM-1-5 - Full life-cycle toxicity test with water fleas, <i>Daphnia magna</i> , under static-renewal conditions. Springborn Smithers Laboratories, NC, USA, Nippon-Soda Report No: RD-03057 GLP, not published	N	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 8.2.5.3/01	Mc Elligott, A.	1999	Acetamiprid -Toxicity to the sediment dwelling chironomid larvae ( <i>Chironomus riparius</i> ) Rhone-Poulenc Secteur Agro, Sophia, Antipolis, France. Nippon-Soda Report No: RD-II02191 GLP Not published	N	N		Nippon Soda
CA 8.2.6.1/01	Suteau, P.	1996a	Acetamiprid -Freshwater algal growth inhibition study (72 hours) ( <i>Scenedesmus subspicatus</i> ) Rhone-Poulenc Secteur Agro, Sophia, Antipolis, France. Nippon-Soda Report No: RD-09931 GLP Not published	N	N		Nippon Soda
CA 8.2.7/01	Hoberg, J.R.	1997b	Acetamiprid technical - Toxicity to duckweed, <i>Lemna gibba</i> . Springborn Laboratories, Inc. USA. Nippon-Soda Report No: RD-00223 GLP Not published	N	N		Nippon Soda



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 8.3.1.4/01	Collins, M.K.	1997	Evaluation of toxicity of residues of Acetamiprid (NI-25) on alfalfa to honey bees ( <i>Apis mellifera</i> L.) (Hymenoptera, Apidae) Landis International, Valdosta, GA Nippon-Soda Report No: RD-00017 GLP Not published	N	N		Nippon Soda
CA 8.3.2/01	Schmitzer, S.	2003	Effects of IM 1-5 on the Reproduction of Rove beetles <i>Aleochara bilineata</i> in the laboratory. Aventis CropScience Nippon-Soda Report No: RD-03101 GLP: yes Published: no	N	N		Nippon Soda
CA 8.4/01	Johnson, A.J.	1994	NI-25 Acute toxicity (LC <sub>50</sub> ) to Earthworm ( <i>Eisenia foetida</i> ). Huntingdon Research Center, U.K. Nippon-Soda Report No: RD-09520N GLP Not published	N	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 8.4/02	Wetton, P.M.	1999a	IM-1-4 Acute toxicity to Earthworm ( <i>Eisenia foetida</i> ). Safepharm Laboratories Ltd, U.K. Nippon-Soda Report No: RD-00780 GLP Not published	N	N		Nippon Soda
CA 8.4/03	Lührs, U.	2002a	Acute toxicity (14 days) of IM-1-2 to the earthworm <i>Eisenia fetida</i> in artificial soil. Aventis CropScience Nippon-Soda Report No : B004154 GLP Not published	N	N		Nippon Soda
CA 8.4/04	Wetton, P.M.	1999b	IC-0 - Acute toxicity to Earthworm ( <i>Eisenia foetida</i> ). Safepharm Laboratories Ltd, U.K. Nippon-Soda Report No: RD-00781 GLP: Yes Not published	N	N		Nippon Soda
CA 8.4/05	Rogers. M.	2002	IM-1-5: Acute toxicity (LC <sub>50</sub> ) to the earthworm Huntingdon Life Sciences, Ltd. Nippon-Soda Report No: RD-II 02451 GLP Not published	N	N		Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 8.4.1/01	Lührs, U.	2003	Effects of IM-1-5 on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil. Source : Aventis CropScience Report No: C029229, Document No. RD-03096 GLP Not published	N	N		Nippon Soda
CA 8.4.2.1/01	Klein, S. & Rosenkraus, B.	2003	Effects of IM -1-5 on Reproduction of the Collembola Folsomia Candida in Artificial Soil IBACON, Germany Nippon-Soda Report No: RD-03058 GLP Not published	N	N		Nippon Soda
CA 8.5/01	Forster, J.	1997	A laboratory assessment of the effects of NI-25 on soil microflora respiration & nitrogen transformations according to EPPO Bulletin 24, 1-16 (1994). Chemex International plc. Nippon-Soda Report No: RD-09942 GLP Not published	N	N		Nippon Soda

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Data protection claimed</b> <b>Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
CA 8.6.1/01	Hatano, R.	1999	Insecticidal activity of NI-25 metabolites Nippon Soda Co., Odawara Research Center, Japan. Nippon-Soda Report No: RD-9617N2 GLP Not published	N	N		Nippon Soda
CA 8.8/01	Mead, C.	1999	Acetamiprid: assessment of the inhibitory effect on the respiration of activated sewage sludge. Safepharm Laboratories Ltd, U.K. Nippon-Soda Report No: RD-00221 GLP Not published	N	N		Nippon Soda

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Data protection claimed</b> <b>Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
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<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Data protection claimed</b> <b>Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCA 9/1	Exponent International Limited	2014	Literature review report, Submission of scientific peer-reviewed open literature under Regulation (EC) No 1107/2009. Exponent International Ltd., Harrogate North Yorkshire, HG2 8RE, United Kingdom. Exponent Project Number: 1007618.UK0 EWC 1839. Nippon-Soda Report No: RD-02961 Not GLP, Unpublished	N	Y	New data for AIR3 renewal	Nippon Soda

**Articles from the public literature that were submitted and are mentioned in Vol.3 CA B.9:**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b>  <b>Source</b>
KCA 8.2.4	Beketov, M.A., Liess, M.	2008	Potential of 11 pesticides to initiate downstream drift of stream macroinvertebrates. Arch Environ Contam Toxicol Vol. 55, pp. 247–253
KCA 8.3.1	Aliouane, Y., El Hassani, A.K., Gary, V., Armengaud, C., Lambin, M., Gauthier, M.	2009	Subchronic exposure of honeybees to sublethal doses of pesticides: effects on behavior. Environ. Toxicol. Chem. Vol. 28(1), pp. 113-122

Data point	Author(s)	Year	Title  Source
KCA 8.3.1	Biddinger, D.J., Robertson, J.L., Mullin, C., Frazier, J., Ashcraft, S.A., Rajotte, E.G., Joshi, N.K., Vaughn, M.	2013	Comparative toxicities and synergism of apple orchard pesticides to <i>Apis mellifera</i> (L.) and <i>Osmia cornifrons</i> (Radoszkowski). PLoS ONE Vol. 8(9): e72587. doi:10.1371/journal.pone.0072587
KCA 8.3.1	Costa, E.M., Araujo, E.L., Maia, A.V.P., Silva, F.E.L., Bezerra, C.E.S., Silva, J.G.	2014	Toxicity of insecticides used in the Brazilian melon crop to the honey bee <i>Apis mellifera</i> under laboratory conditions. Apidologie Vol. 45, pp. 34–44
KCA 8.3.1	El Hassani, A.K., Dacher, M., Gary, V., Lambin, M., Gauthier, M., Armengaud, C.	2008	Effects of sublethal doses of acetamiprid and thiamethoxam on the behaviour of the honeybee ( <i>Apis mellifera</i> ). Arch Environ Contam Toxicol Vol. 54, pp. 653–661
KCA 8.3.1	Fanti, M., Maines, R., Angeli, G.	2006	Assessment of levels of repellency and toxicity of neonicotinoid insecticides on <i>Apis mellifera ligustica</i> . ATTI Plant Pathology Days Vol. 1, pp. 51-58
KCA 8.3.1	Iwasa, T., Motoyama, N., Ambrose, J.T., Roe, R.M.	2004	Mechanism for the differential toxicity of neonicotinoid insecticides in the honey bee, <i>Apis mellifera</i> . Crop Protection Vol. 23, pp. 371–378
KCA 8.3.1	Laurino, D., Porporato, M., Patetta, A., Manino, A.	2011	Toxicity of neonicotinoid insecticides to honey bees: laboratory tests. Bulletin of Insectology (2011) Vol. 64(1), pp. 107-113
KCA 8.3.1	Nadaf, H., Yadav, G.S., Kaushik, H.D., Sharma, K.	2013	Toxicity of new molecules of insecticides against honeybee <i>Apis mellifera</i> L. Trends in Biosciences Vol. 6(4), pp. 445-447

Data point	Author(s)	Year	Title  Source
KCA 8.3.1	Sterk, G., Benuzzi, M.	2004	Plant protection product news, proof of toxicity in greenhouse bumblebees. Protected Cultivation Vol. 1, pp. 75-77
KCA 8.3.1	Sterk G., Bolkmans K., De Jonghe R., De Wael L., Vermeulen J. (1995)	1995	Side effects of PreFeRal WG ( <i>Paecylomices fumosoroseus</i> ) (WIZE) Brown and Smith strain Apopka 97) on <i>Bombus terrestris</i> . Medical faculty of Agricultural Sciences, University of Ghent, 60 (3a): 713-717
KCA 8.3.1	Vinothkumar , B., Kumaran, N., Boomathi, N, Saravanan, P.A., Kuttalam, S.	2010	Toxicity of Spirotetramat 150 OD to honeybees. The Madras Agricultural Journal Vol. 97, pp. 86-87
KCA 8.3.1	Wu, J., Li, J-L., Peng, W-J., Hu, F-L.	2010	Sensitivities of three bumblebee species to four pesticides applied commonly in greenhouses in China
KCA 8.3.1	Hawthorne and Dively	2011	Killing them with kindness? Inhive medications may inhibit xenobiotic efflux transporters and endanger honey bees. PLoS One (2011) DOI: 10.1371/journal.pone.0026796
KCA 8.3.2	Pastagia, J.J., Patel, M.B.	2007	Relative contact toxicity of some insecticides to worker bees of <i>Apis cerana</i> F.. Journal of Plant Protection and Environment (2007) Vol. 4(2), pp. 89-92
KCA 8.3.2	Abraham, C.M., Braman, S.K., Oetting, R.D., Hinkle, N.C.	2013	Pesticide compatibility with natural enemies for pest management in greenhouse Gerbera daisies. J. Econ. Entomol. Vol. 106(4), pp. 1590-1601
KCA 8.3.2	Ahmad, M., Rafiq, M., Arif, M.I., Sayyed, A.H.	2011	Toxicity of some commonly used insecticides against <i>Coccinella undecimpunctata</i> (Coleoptera: Coccinellidae). Pakistan J. Zool. Vol. 43(6), pp. 1161-1165

Data point	Author(s)	Year	Title  Source
KCA 8.3.2	Baldessari, M., Malagnini, V., Tolotti, G., Angeli, G.	2010	Field tests on vines and apple trees and in the laboratory. <i>Informatore Agrario</i> Vol. 66(45), pp. 67-70
KCA 8.3.2	Basappa, H.	2007	Toxicity of biopesticides and synthetic insecticides to egg parasitoid, <i>Trichogramma chilonis</i> Ishii and coccinellid predator, <i>Cheilomenes sexmaculata</i> (Fabricius). <i>J. Biol. Control</i> . Vol. 21(1), pp. 31-36
KCA 8.3.2	Beers, E.H., Schmidt, R.A	2014	Impacts of orchard pesticides on <i>Galendromus occidentalis</i> : Lethal and sublethal effects. <i>J. Econ. Entomol.</i> Vol. 106(4), pp. 1590-1601
KCA 8.3.2	Bostanian, N.J., Laurin, M-C.	2008	Effects of ten pesticides to <i>Anystis baccarum</i> (Acari: Anystidae). <i>IOBC/WPRS Bulletin</i> Vol. 35, pp. 96-100
KCA 8.3.2	Bostonian, N.J., Thistlewood, H.A., Hardman, J.M., Laurin, M., Racette, G.	2009	Effect of seven new orchard pesticides on <i>Galendromus occidentalis</i> in laboratory studies. <i>Pest Manag Sci</i> Vol. 65, pp. 635–639
KCA 8.3.2	Bostanian, N.J., Hardman, J.M., Thistlewood, H.A., Racette, G.	2010	Effects of six selected orchard insecticides on <i>Neoseiulus fallacis</i> (Acari: Phytoseiidae) in the laboratory. <i>Pest Manag Sci</i> Vol. 66, pp. 1263–1267
KCA 8.3.2	Bostanian, N.J., Hardman, J.M., Thistlewood, H.A., Racette, G.	2010	The response of <i>Neoseiulus fallacis</i> (Garman) and <i>Galendromus occidentalis</i> (Nesbitt) (Acari: Phytoseiidae) to six reduced risk insecticides in Canada. <i>Pesticides and Beneficial Organisms IOBC/wprs Bulletin</i> Vol. 55, pp. 73-77
KCA 8.3.2	Broufas, G.D., Pappas, M.L., Vassiliou, G., Koveos, D.S.	2008	Toxicity of certain pesticides to the predatory mite <i>Euseius finlandicus</i> (Acari: Phytoseiidae). <i>Pesticides and Beneficial Organisms IOBC/wprs Bulletin</i> Vol. 35, pp. 85-91



Data point	Author(s)	Year	Title  Source
KCA 8.3.2	Chen, S., Song, M., Qi, S., Wang, C.	2013	Safety evaluation of eleven insecticides to <i>Trichogramma nubilale</i> (Hymenoptera: Trichogrammatidae). J. Econ. Entomol. Vol. 106(1), pp. 136-141
KCA 8.3.2	Chorazy, A; Garnis, J.	2011	Impact of selected pesticides used to protect strawberries for predatory mite <i>Amblyseius andersoni</i> (Chant) survival. Progress in Plant Protection Vol. 51(2), pp. 900-904
KCA 8.3.2	Cloyd, R.A., Dickinson, A.	2006	Effect of insecticides on mealybug destroyer (Coleoptera: Coccinellidae) and parasitoid <i>Leptomastix dactylopii</i> (Hymenoptera: Encyrtidae), natural enemies of citrus mealybug (Homoptera: Pseudococcidae). J. Econ. Entomol. Vo l. 99(5), pp. 1596-1604
KCA 8.3.2	Duso, C., Ahmad, S., Tirello, P., Pozzebon, A., Klaric, V., Baldessari, M., Malagnini, V., Angeli, G.	2014	The impact of insecticides applied in apple orchards on the predatory mite <i>Kampimodromus aberrans</i> (Acari: Phytoseiidae). Exp Appl Acarol Vol. 62, pp. 391–414
KCA 8.3.2	Echegaray, E.B., Cloyd, R.A.	2012	Effects of reduced-risk pesticides and plant growth regulators on rove beetle (Coleoptera: Staphylinidae) adults. J. Econ. Entomol. Vol. 105(6), pp. 2097-2106
KCA 8.3.2	Fiedler, Z.	2009	<i>Amblyseius andersoni</i> (Chant) – A new alternative to combat spider mites. Progress in Plant Protection Vol. 49(3), pp. 1469-1473

Data point	Author(s)	Year	Title  Source
KCA 8.3.2	Kutuk, H. Yigit, A.	2009	Residual toxicity of pymetrozine, spiromesifen, spinosad and acetamiprid to the predacious ladybird <i>Serangium parcesetosum</i> (Coleoptera: Coccinellidae), a predator of the whitefly, <i>Bemisia tabaci</i> (Homoptera: Aleyrodidae) on greenhouse crops in the East Mediterranean region of Turkey. IOBC/wprs Bulletin Vol. 49, pp. 353-358
KCA 8.3.2	Lanzoni, A., Sangiorgi, L., Luigi, V. de, Consolini, L., Pasqualini, E., Burgio, G.	2012	Evaluation of chronic toxicity of four neonicotinoids to <i>Adalia bipunctata</i> L. (Coleoptera: Coccinellidae) using a demographic approach. IOBC WPRS Bulletin Vol. 74, pp. 211-217
KCA 8.3.2	Laurin, M-C., Bostanian, N.J.	2007	Laboratory studies to elucidate the residual toxicity of eight insecticides to <i>Anystis baccarum</i> (Acari: Anystidae). Journal of Economic Entomology Vol. 100(4), pp. 1210-1214
KCA 8.3.2	Poletti, M., Maia, A.H.N., Omoto, C.	2007	Toxicity of neonicotinoid insecticides to <i>Neoseiulus californicus</i> and <i>Phytoseiulus macropilis</i> (Acari: Phytoseiidae) and their impact on functional response to <i>Tetranychus urticae</i> (Acari: Tetranychidae). Biological Control Vol. 40, pp. 30-36
KCA 8.3.2	Stara, J., Ourednickova, J., Kocourek, F.	2011	Laboratory evaluation of the side effects of insecticides on <i>Aphidius colemani</i> (Hymenoptera: Aphidiidae), <i>Aphidoletes aphidimyza</i> (Diptera: Cecidomyiidae) and <i>Neoseiulus cucumeris</i> (Acari: Phytoseiidae). Journal of Pest Science Vol. 84, pp. 25-31
KCA 8.3.2	Sugiyama, K., Katayama, H., Saito, T.	2011	Effect of insecticides on the mortalities of three whitefly parasitoid species, <i>Eretmocerus mundus</i> , <i>Eretmocerus eremicus</i> and <i>Encarsia formosa</i> (Hymenoptera: Aphelinidae). Applied Entomology and Zoology Vol. 46, pp. 311-317

Data point	Author(s)	Year	Title  Source
KCA 8.3.2	Wang, Y., Chen, L., Yu, R., Zhao, X., Wu, C., Cang, T., Wang, Q.	2012c	Insecticide toxic effects on <i>Trichogramma ostriniae</i> (Hymenoptera: Trichogrammatidae). Pest Management Science Vol. 68, pp. 1564-1571
KCA 8.3.2	Wang, Y., Chen, L., An, X., Jiang, J., Wang, Q., Cai, L., Zhao, X.	2013b	Susceptibility to selected insecticides and risk assessment in the insect egg parasitoid <i>Trichogramma confusum</i> (Hymenoptera: Trichogrammatidae). Journal of Economic Entomology Vol. 106(1), pp. 142-149
KCA 8.3.2	Jadhav, D.S., Shukla, A.	2013	Relative toxicity of some insecticides to <i>Coccinella transversalis</i> (F.) Indian Journal of Entomology (2013) Vol. 75.4, pp. 301-303
KCA 8.3.2	Mali, A.K., Kurtadikar, J.S., Wadnerkar, D.W., Nemade, P.W.	2008	Studies on the safety of pesticides to grapevine mealy bug predator, <i>Scymnus coccivora</i> Aiyar. Pestology (2008) Vol. 32(1), pp. 37-46
KCA 8.3.2	Mali, A.K., Kurtadikar, J.S., Wadnerkar, D.W., Nemade, P.W.	2008	Studies on the safety of pesticides to grapevine mealy bug predator, <i>Cryptolaemus montrouzieri</i> Aiyar. Pestology (2008) Vol. 32(4), pp. 17-27
KCA 8.3.2	Rezac, M., Pekar, S., Stara, J	2010	The negative effect of some selective insecticides on the functional response of a potential biological control agent, the spider <i>Philodromus cespitum</i> . Biocontrol (2010) Vol. 55(4), pp. 503-510
KCA 8.3.2	Wang, Y., Yu, R., Zhao, X., Chen, L., Wu, C., Cang, T., Wang, Q.	2012	Susceptibility of adult <i>Trichogramma nubilale</i> (Hymenoptera: Trichogrammatidae) to selected insecticides with different modes of action. Crop Protection, (2012) Vol. 34, pp. 76-82
KCA 8.3.2	Zhao, X., Wu, C., Wang, Y., Cang, T., Chen, L., Yu, R., Wang, Q	2012	Assessment of toxicity risk of insecticides used in rice ecosystem on <i>Trichogramma japonicum</i> , an egg parasitoid of rice Lepidopterans. Journal of Economic Entomology (2012) Vol. 105.1, pp. s92-101

Data point	Author(s)	Year	Title  Source
KCA 8.3.2	Bacci, L., Crespo, A.L., Galvan, T.L., Pereira, E.J., Picanço, M.C., Silva, G.A., Chediak, M	2007	Toxicity of insecticides to the sweet potato whitefly (Hemiptera: Aleyrodidae) and its natural enemies. Pest Manag Sci. (2007) Vol. 63(7), pp. 699-706
KCA 8.4	Wang, Y., Cang, T., Zhao, X., Yu, R., Chen, L., Wu, C., Wang, Q.	2012b	Comparative acute toxicity of twenty-four insecticides to earthworm, <i>Eisenia fetida</i> <i>Ecotoxicology and Environmental Safety</i> Volume 79: 122-128.  Non-GLP Published

### References for the PPP Acetamiprid 20 SC

#### New studies

(grey marking: not considered acceptable or only considered as supplemental information for risk assessment)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 10.2.1 /01	██████████	1998	Acetamiprid 20% SP acute toxicity study in carp. ████████████████████ Nippon-Soda Report No.: RD-09551N GLP Not published	Y	Y	Required to meet current data requirements.	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 10.2.1 /03	Stäbler, D	2005	Assessment on the acute toxicity of Acetamiprid 20 % SP on the midge <i>Chironomus riparius</i> GAB Biotechnologie GmbH & GAB Analytik GmbH, Germany Nippon-Soda Report No.: RD-00894 GLP Not published	N	Y	Required as <i>Chironomus</i> is the most sensitive aquatic organism tested.	Nippon Soda
IIIA 10.2.3 /01	Hommen U.	2015	Acetamiprid – Outdoor aquatic mesocosm study with two applications. Nippon Soda Co., Ltd., Tokyo, Japan Study Report 239-02 GLP, unpublished	N	Y		Nippon Soda Co
CP 10.3.1 .1.1/0 2	Kling, A.	2003	Acute contact and oral toxicity of EXP 60707 A to the bumble bee <i>Bombus terrestris</i> L. under Laboratory conditions GAB & IFU GmbH, Germany Nippon-Soda Report No.: RD-00975 GLP Not published	N	Y	Study required as effects on bumblebees now covered in new EFSA Guidance Document on Bees (2013).	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 10.3.1 .5/01	Bocksch, S.	2013	Assessment of side effects of Acetamiprid 20 SG on the honeybee ( <i>Apis mellifera</i> L.) in the semi-field after two applications in <i>Phacelia tanacetifolia</i> in Germany 2012 Eurofins-GmbH, Niefern-Oschlebronn, Germany Nippon-Soda Report No.: RD-02573 GLP Not published	N	Y	Required for the bee risk assessment.	Nippon Soda
CP 10.3.1 .5/02	Schur, A.	2002	A semi-field study on the effects on honey bees ( <i>Apis mellifera</i> L.) of ASSAIL 70 WP (EXP61842A, Acetamiprid 70%) Straight and in Combination with the Fungicide PROCURE 50WS (Triflumizole 50%). Arbeitsgemeinschaft GAB Biotechnologie GmbH, Niefen-Oschelbronn, Germany Nippon-Soda Report No.: RD-00595 GLP, not published	N	Y	Required for the bee risk assessment.	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 10.3.1 .5/03	Rentschler, S.	2009	Acetamiprid 20 SP: A semi-field study to evaluate effects on the honeybee ( <i>Apis mellifera carnica</i> : Hymenoptera, Apidae) in <i>Phacelia tanacetifolia</i> in southern Germany 2008 Eurofins-GmbH, Niefern-Oschlebronn Germany. Nippon-Soda Report No.: RD-01749 GLP Not published	N	Y	Required for the bee risk assessment.	Nippon Soda
CP 10.3.1 .5/04	Bocksch, S.	2007	Acetamiprid 20SP: A semi-field study to evaluate effects on the honey bee ( <i>Apis mellifera carnica</i> ; Hymenoptera, Apidae) in <i>Phacelia tanacetifolia</i> in Northern and Southern Germany 2007 Eurofins-GmbH, Niefern-Oschlebronn, Germany Nippon-Soda Report No.: RD-01289 GLP Not published	N	Y	Required for the bee risk assessment.	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 10.3.1 .5/05	Schur, A.	2003	A semi-field study on the effects of a foliar application of EXP60707A (Acetamiprid 20 % SP) on the brood development of the honey bee ( <i>Apis mellifera</i> L.) GAB & IFU GmbH, Germany, Nippon-Soda Report No.: RD-00976 GLP Not published	N	Y	Required for the bee risk assessment.	Nippon Soda
CP 10.3.1 .5/06	Nienstedt, K. M.	2000	A semi-field toxicity test to determine the effects of EXP60707B on the Honeybee ( <i>Apis mellifera</i> ) Springborn Laboratories (Europe) AG, Switzerland Nippon-Soda Report No.: RD-00789 GLP Not published	N	Y	Required for the bee risk assessment.	Nippon Soda



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 10.3.1 .5/07	Rexer, H.U.	2011	A Semi-Field Study on the Effects on Honeybees ( <i>Apis mellifera</i> L.) of Acetamiprid 20 SG and in Combination with the Fungicides Prothioconazole 25 EC and Tebuconazole 25 EW in Winter Oil-Seed Rape in Germany in 2010 Eurofins-GmbH, Niefen-Oschelbronn, Germany Nippon-Soda Report No.: RD-02186 GLP Not published	N	Y	Additional supportive information on bees.	Nippon Soda
CP 10.3.1 .5/08	Rexter, H.U.	2010 a	Acetamiprid 20 SG: A Semi-Field Study with Acetamiprid 20 SG in Winter Oil-Seed Rape, Investigating Residues in Plants, Honey Collected from Combs, and Nectar and Pollen Prepared from Forager Bees in Germany in 2009 Eurofins-GmbH, Niefern-Oschelbronn, Germany Nippon-Soda Report No.: RD-02042 GLP Not published	N	Y	Additional supportive information on bees.	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 10.3.1 .5/10	Callandret, A.*	1994	NI-25 / Beneficial insects / honeybee cage test Rhône-Poulenc Agro, Chazay Research Farm, France, Nippon-Soda Report No.: RD-01196 GEP Not published	N	Y	Additional supportive information on bees.	Nippon Soda
CP 10.3.1 .5/11	Kovács, G.	1999	Cage test of MOSPILAN 20 SP on bee colonies (Apis mellifera carnica). Ecotoxicological Laboratory, Hungary, Nippon-Soda Report No.: RD-00756 Non-GLP Not published	N	Y	Additional supportive information on bees.	Nippon Soda
CP 10.3.1 .5/12	Maurin, G.	2000	Tunnel evaluation of short term toxicity on bees of the active ingredient EXP 60707 ACTA, France Nippon-Soda Report No.: RD-01091 GEP Not published	N	Y	Additional supportive information on bees.	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 10.3.1 .6/01	Rexer, H.U.	2010 b	Acetamiprid 20 SG: Assessment of side effects and investigating residues of Acetamiprid 20 SG on the honeybee <i>Apis mellifera</i> L. (Hymenoptera, Apidae) in the field following applications on winter oil-seed rape in Germany in 2010 Eurofins-GmbH, Niefern-Oschelbronn, Germany Nippon-Soda Report No.: RD-02168 GLP Not published	N	Y	Additional supportive information on bees.	Nippon Soda
CP 10.3.1 .6/02	Szentes, C.	2000	Field test of Mospilan 20 SP on honeybee colonies in flowering oilseed rape Ecotoxicological Laboratory, Fácánkert, Hungary Nippon-Soda Report No.: RD-II 01075 GLP Not published	N	Y	Additional supportive information on bees.	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 10.3.1 .6/03	Barth, M.	2014	Acetamiprid 20 SG and Acetamiprid 20 SG plus FolicurP®:  A study to evaluate potential side effects on the honeybee ( <i>Apis mellifera</i> L.) under field conditions after application in <i>Phacelia tanacetifolia</i> B. in Germany in 2013  BioChem agrar, Gerichshain, Germany  Nippon-Soda Report No.: RD-02950  GLP  Not published	N	Y	Additional supportive information on bees.	Nippon Soda
CP 10.3.2 .2/05	Röhlig, U.	2011	Toxicity of Acetamiprid 20 SG to the parasitic wasp <i>Aphidius rhopalosiphii</i> under extended laboratory conditions (under semi-field conditions aged residues on potted apple trees).  BioChem agrar, Gerichshain, Germany  Nippon-Soda Report No.: RD-02334  GLP  Not published	N	Y	Required to support NTA risk assessment for the proposed GAP.	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 10.3.2 .2/07	Röhlig, U.	2011a	Toxicity of Acetamiprid 20 SG to the ladybird <i>Coccinella septempunctata</i> L. under extended laboratory conditions (under semi-field conditions aged residues on potted apple trees). BioChem agrar, Gerichshain, Germany Nippon-Soda Report No.: RD-02343 GLP Not published	N	Y	Required to support NTA risk assessment for the proposed GAP.	Nippon Soda
CP 10.4.1 .1/03	Schulz, L.	2012	Effects of Acetamiprid 20 SG on earthworms under field conditions BioChem agrar, Gerichshain, Germany Nippon-Soda Report No.: RD-02386 GLP Not published	N	Y	Additional information to support the earthworm risk assessment.	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 10.4.2 .1/01	Friedrich, S.	2011a	Effects of Acetamiprid 20 SG on the reproduction of the collembolans <i>Folsomia candida</i> BioChem agrar, Gerichshain, Germany Project No. 11 10 48 078 S Nippon-Soda Report No.: RD-02342 GLP Not published	N	Y	Required in line with new data requirements (Reg. (EU) No. 284/2013).	Nippon Soda
CP 10.4.2 .1/02	Schulz, L.	2011	Effects of Acetamiprid 20 SG on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> BioChem agrar, Gerichshain, Germany Project No. 11 10 48 077 S Nippon-Soda Report No.: RD-02335 GLP Not published	N	Y	Required in line with new data requirements (Reg. (EU) No. 284/2013).	Nippon Soda
CP 10.6.2 /01	Friedrich, S.	2011b	Terrestrial (non-target) plant test with Acetamiprid 20 SG: vegetative vigour test BioChem agrar, Gerichshain, Germany Nippon-Soda Report No.: RD-02339 GLP Not published	N	Y	Required in line with current data requirements.	Nippon Soda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 10.6.2 /02	Teixeira, D.	1999	Acetamiprid - Determination of effects on seedling emergence and vegetative vigor of ten plant species. Springborn Laboratories Inc., USA Nippon-Soda Report No.: RD-II 02121 GLP Not published	N	Y	Required in line with current data requirements.	Nippon Soda

\* Actually this study was included in the DAR. The summary is given in the DAR, but with this summary, the reference for another study (Tisseur & Robles, 1997, see 10.3.1.5/09 in this RAR) is given.

**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**

(grey marking: not considered acceptable or only considered as supplemental information for risk assessment)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
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CP 10.2.1 /02	Suteau, P.	1997 c	EXP 60707A - Acute toxicity (48 hours) to daphnids ( <i>Daphnia magna</i> ) under static conditions. Rhone-Poulenc Secteur Agro, Sophia, Antipolis, France. Nippon Soda Report No: RD- 00015 GLP Not published	N	N		Nippon Soda
CP 10.2.1 /04	McElligot t, A.	1997 d	EXP 60707B - Freshwater algal growth inhibition study (72 hours) ( <i>Scenedesmus subspicatus</i> ). Rhone-Poulenc Secteur Agro, Sophia, Antipolis, France. Nippon Soda Report No: RD- 00016 GLP Not published	N	N		Nippon Soda
CP 10.3.1 .1.1/0 1	Kling, A.	2001	Assessment of side effects of EXP 60707 A to the honeybee, <i>Apis mellifera</i> L. in the laboratory GAB, Niefern-Oschelbronn, Germany Nippon Soda Report No: RD- II02431 GLP Not published	N	N		Nippon Soda



CP 10.3.1 .5/09	Tisseur, M. & Robles, A.C.*	1997	EXP 60707 – short-term toxicity for bees evaluated in tunnels. Rhone-Poulenc Secteur Agro, Sophia, Antipolis, France. Nippon Soda Report No: RD- 00018 Non-GLP Not published	N	N		Nippon Soda
CP 10.3.2 .1/01	Candolfi, M.P.	1997 a	EXP 60707A - Laboratory contact toxicity test with the predacious mite <i>Typhlodromus</i> <i>pyri</i> Scheuten (Acari: Phytoseiidae) Springborn Laboratories Europe AG. Nippon Soda Report No: RD- 00021 GLP Not published	N	N		Nippon Soda
CP 10.3.2 .1/02	Candolfi, M.P.	1997 b	EXP 60707A - Laboratory acute toxicity test with the parasitic wasp <i>Aphidius</i> <i>rhopalosiphi</i> (Hymenoptera: Braconidae) Springborn Laboratories Europe AG. Nippon Soda Report No: RD- 00020 GLP Not published	N	N		Nippon Soda

CP 10.3.2 .1/03	Candolfi, M.P.	1997 c	EXP 60707A - Laboratory contact toxicity test with the seven spotted Lady Beetle, <i>Coccinella septempunctata</i> L. (Coleoptera: Coccinellidae) Springborn Laboratories Europe AG. Nippon Soda Report No: RD-00022 GLP Not published	N	N		Nippon Soda
CP 10.3.2 .1/04	Candolfi, M.P.	1997 d	EXP 60707A - Laboratory acute toxicity test with the ground beetle <i>Poecilus cupreus</i> L. (Coleoptera: Carabidae) Springborn Laboratories Europe AG. Nippon Soda Report No: RD-00019 GLP Not published	N	N		Nippon Soda
CP 10.3.2 .2/01	Lüehrs, U.	1999	EXP 60707B - Effects on the predacious mite <i>Typhlodromus pyri</i> Scheuten (Acari: Phytoseiidae) - extended laboratory test. IBACON, Rossdorf, Germany. Nippon Soda Report No: RD-03016 GLP No t published	N	N		Nippon Soda

CP 10.3.2 .2/02	Moll, M.	1999	EXP 60707B - Effects on the parasitoid <i>Aphidius rhopalosiphi</i> (Hymenoptera: Aphidiidae) - extended laboratory study. IBACON, Rossdorf, Germany. Nippon Soda Report No: RD-IIM059 GLP Not published	N	N		Nippon Soda
CP 10.3.2 .2/03	Adelberger, I.	2001	EXP 60707 A : Toxicity to the predatory mite <i>Typhlodromus pyri</i> SCHEUTE (Acari, Phytoseiidae) using an extended laboratory test with freshly applied and aged residues following a single application at rates of 13 or 100 g a.s./ha. Nippon Soda Report No: RD-II02082 GLP Not published	N	N		Nippon Soda
CP 10.3.2 .2/04	Schuld, M.	2001	EXP 60707 A : Toxicity to the aphid parasitoid <i>Aphidius rhopalosiphi</i> DeStefani-Perez (Hymenoptera: Braconidae) using an extended laboratory test with freshly applied and aged residues following a single application at rates of 13 or 100 g a.s./ha. Nippon Soda Report No: RD-II02083 GLP Not published	N	N		Nippon Soda

CP 10.3.2 .2/06	Hirth, N.	2002	EXP 60707 A : Toxicity to the ladybird <i>Coccinella septempunctata</i> L. (Coleoptera, Coccinellidae) using an extended laboratory test with freshly applied and aged residues following a single application at rates of 13 or 100 g a.s./ha. Nippon Soda Report No: RD-II02081 GLP Not published	N	N		Nippon Soda
CP 10.3.2 .2/08	Hirth, N.	2001	EXP 60707 A : Toxicity to the green lacewing <i>Chrysoperla carnea</i> Steph. (Neuroptera, Chrysopidae) using an extended laboratory test with freshly applied and aged residues following a single application at rates of 13 or 100 g a.s./ha. Nippon Soda Report No: RD-II02084 GLP Not published	N	N		Nippon Soda
CP 10.4.1 .1/01	Suteau, P.	1996 b	EXP 60707A - Acute toxicity (14-day) to earthworms ( <i>Eisenia foetida</i> ). Rhone-Poulenc Agrochimie, Center de Recherche, Sophia Antipolis. Nippon Soda Report No: RD-00023 GLP Not published	N	N		Nippon Soda

CP 10.4.1 .1/02	Gossma nn, A.	1997	EXP 60707B - effects on reproduction and growth of earthworms ( <i>Eisenia foetida</i> ) in artificial soil. IBACON, Rossdorf, Germany. Nippon Soda Report No: RD- 00024 GLP Not published	N	N		Nippon Soda
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\* This study was not included in the DAR. The reference is cited in the DAR, but with this reference the summary for another study (Callandret, 1994, see 10.3.1.5/10 in this RAR) is given.