

**B.6 Toxicology and metabolism**

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

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

Active substance source = Sharda CropChem Ltd.

**References for the active substance acetamiprid**

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
CA 5.1.1/01		1997a	<sup>14</sup> C-NI-25 - Metabolism in Rats Document No. RD-95127 GLP, not published.	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.1.1/02		2003	Metabolism study of Acetamiprid in rat (Determination of IM-1-5) , Document No. RD-03028 GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
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CA 5.1.1/03		1995	[ <sup>14</sup> C]-NI-25 – Biliary Excretion in Rat Document No. RD-09575 GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.1.1/04		1995	Absorption, Distribution, Metabolism, Elimination, and Pharmacokinetics after Chronic Dosing of [ <sup>14</sup> C]-NI-25 in Rat Document No. RD-09576 GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.1.1/05		1997b	<sup>14</sup> C-NI-25 - Metabolism Study in Rats (Qualitative and Quantitative Analysis of Metabolites in Group C) Document No. RD 09654N GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.1.1/06		1997c	<sup>14</sup> C-NI-25 - Metabolism in Rats. (A Summary Report). Document No. RD-09785 No GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.2.1/01		1997a	NI-25: Acute Oral Toxicity Study in Rats. Document No. RD-9760 GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c

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CA 5.2.1/02		2002a	Acetamidrid suspended in corn oil: Acute oral toxicity study in rats. Document No RD-II 02425 GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.2.1/03		1998	Acetamidrid*- Acute oral toxicity study in rats (*Proposed ISO Common Name, Code No.: NI-25. Document No. RD-9528N GPL, Not published	Y	5.1 lid 2 e	2008	Acute oral toxicity of acetamidrid technical in rats. Report No. 7531 Jai research foundation, India GLP, not published	5.1 lid 1 c			5.1 lid 1 c
CA 5.2.2/01		1997b	NI-25: Acute Dermal Toxicity Study in Rats. Document No. RD-9761 GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.2.3/01		1997	Acetamidrid : Acute (four-hour) Inhalation Study in Rats. Document No. RD-09782N GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c

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CA 5.2.4/01		1997a	Acetamidrid - Primary Dermal Irritation Study in Rabbits Document No. RD-9533N GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.2.5/01		1997b	Acetamidrid - Primary Eye Irritation Study in Rabbits Document No. RD-9532N GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.2.6/01		1997	Acetamidrid (Code No. : NI-25) Skin Sensitisation in the Guinea-Pig GLP, not published Document No. RD-09779	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.3.1/01		1992	A 4-Week Oral Toxicity Study of NI-25 in the Dog via Dietary Administration. Document No. RD-09444N GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.3.2/01		1997a	Acetamidrid - Thirteen Week Dietary Subchronic Toxicity in Rats. Document No. RD-9535N GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c

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CA 5.3.2/02		1997a	Acetamidrid - Thirteen Week Dietary Subchronic Toxicity Study in Mice Document No. RD-09536N GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.3.2/03		1998a	A Sub-chronic (3-month) Oral Toxicity Study of NI-25 in the Dog via Dietary Administration. Document No. RD-09445N GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.3.2/04			A Chronic (12-month) Oral Toxicity Study of NI-25 in the Dog via Dietary Administration. Document No. 09446N GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.3.2/05	5.1 lid 2 e	2009	In vivo subacute oral acetamidrid toxicity in haematological indices in <i>Rattus norvegicus</i> . Environment and Ecology, Vol 27(4A), pp. 1767-1769	Y				5.1 lid 1 c			5.1 lid 1 c

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CA 5.3.2/06	5.1 lid 2 e	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	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.3.3/01		1997	21-Day Dermal Toxicity Study in Rabbits with Acetamiprid. Document No. RD-09861 GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.4.1/02	5.1 lid 2 e	1998	Acetamiprid - Reverse Mutation Study on Bacteria Odawara Research Center, Nippon Soda Co. Ltd., Report No. G-0831, Document No. RD-09539N GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c

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CA 5.4.1/03	5.1 lid 2 e	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				5.1 lid 1 c			5.1 lid 1 c
CA 5.4.1/04	5.1 lid 2 e	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				5.1 lid 1 c			5.1 lid 1 c
CA 5.4.1/05	5.1 lid 2 e	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				5.1 lid 1 c			5.1 lid 1 c

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CA 5.4.2/01		1998	Mutagenicity Test on NI-25 in an <i>in vivo</i> Mouse Micronucleus Assay Document No. RD-9441N2 GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.4.2/02		1998	NI-25: Metaphase Analysis in the Rat Bone Marrow <i>in vivo</i> . Document No. RD-09443N GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.4.2/03		1997	Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells <i>in vivo</i> Document No. RD-09767N GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.5/01		1999	Two-Year Dietary Toxicity and Oncogenicity Study in rats. Document No. RD-99104 GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.5/02		1999	18-Month Dietary Oncogenicity Study in Mice. Document No. RD 99103 GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c



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CA 5.6.1/01		1999	Two-Generation reproduction Study with NI-25 in Rats (Reproduction and Fertility Effects). Document No. RD-99102N GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.6.2/01		1997a	Acetamiprid - Teratogenicity Study in Rats Document No. RD-09537N GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.6.2/02		1997b	Acetamiprid - Teratogenicity Study in Rats Document No. RD-09538N GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.6.2/03	5.1 lid 2 e	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,	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.6.2/04	5.1 lid 2 e	2013	Oxidative stress: Role in acetamiprid-induced impairment of the male mice reproductive system. Agricultural Sciences in China Vol. 10(5), pp. 786-796	Y				5.1 lid 1 c			5.1 lid 1 c



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CA 5.7.1/05		2006	Rebuttal of Data Evaluation Record for Acetamiprid (WIL No. 21193, EPA Acetamiprid 099050, MRID 46255619) Document No. RD-00952 Not GLP, Not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.7.1/06	5.1 lid 2 e	2007	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	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.7.1/07	5.1 lid 2 e	2007	Acetamiprid DNT Study (WIL- 21193): Statistical analysis for auditory startle response. DP Barcode 341525 CEB memo dated July 24, 2007 Not GLP, Published	Y				5.1 lid 1 c			5.1 lid 1 c

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CA 5.7.1/08	5.1 lid 2 e [REDACTED]	2007 b	Acetamidrid 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	Y				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.7.1/09	5.1 lid 2 e [REDACTED]	2008	Acetamidrid: Data evaluation record for Acetamidrid developmental neurotoxicity study and EPA response to rebuttals submitted by Nisso America. PC Code 099050 Not GLP, Published	Y				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.7.1/10	5.1 lid 2 e [REDACTED]	2013	EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Scientific Opinion on the developmental neurotoxicity potential of acetamidrid and imidacloprid. EFSA Journal 2013;11(12):3471. [51 pp.] doi:10.2903/j.efsa.2013.3471. Not GLP, Published	Y				5.1 lid 1 c [REDACTED]			5.1 lid 1 c

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CA 5.7.1/11	5.1 lid 2 e	2014a	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	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.7.1/12	5.1 lid 2 e	2014b	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	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.7.1/13	5.1 lid 2 e	2015	EFSA PPR Panel 2015. Response of EFSA PPR Panel to the Nippon Soda Co., Ltd. Report on the potential DNT of acetamiprid.	N				5.1 lid 1 c			5.1 lid 1 c

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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				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.1/01		1997c	IM-0 - Acute Oral Toxicity Study In Rats. Document No. RD-9585N GLP, not published	Y				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.1/02		1997c	IM-0 - Thirteen Week Dietary Subchronic Toxicity Study in Rats. Document No. RD-97108 GLP, not published	Y				5.1 lid 1 c [REDACTED]			5.1 lid 1 c

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CA 5.8.1/03		1997a	IM-0 - Reverse Mutation Study on Bacteria Document No. RD-09586N GLP, not published	N				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.1/04		1997d	IM-1-2 - Acute Oral Toxicity Study In Rats. Document No. RD-95133N GLP, not published	Y				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.1/05	5.1 lid 2 e [REDACTED]	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				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.1/06		1997e	IM-1-3 : Acute Oral Toxicity Study In Rats. Document No. RD-95142N GLP, not published	Y				5.1 lid 1 c [REDACTED]			5.1 lid 1 c

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CA 5.8.1/07	5.1 lid 2 e [REDACTED]	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				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.1/08		1998a	IM-1-4 - Acute Oral Toxicity Study In Rats. Document No. RD-9828N GLP, not published	Y				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.1/09		1998b	IM-1-4 - Acute Oral Toxicity Study In Rats. Document No. RD-9829N GLP, not published	Y				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.1/10		1999	13-Week Dietary Subchronic Toxicity Study with IM-1-4 in Rats. Document No. RD-9903 GLP, not published	Y				5.1 lid 1 c [REDACTED]			5.1 lid 1 c



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CA 5.8.1/11	5.1 lid 2 e [REDACTED]	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				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.1/12		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	5.1 lid 2 e		<u>Study Plan</u> Kadam, SB. [6-chloropyridin-3-yl methyl] (methyl) amine (Acetamidiprid Metabolite IM-1-4) Study No. P/17784/CGMT/18 Intox Pvt. Ltd., India GLP, not published	5.1 lid 1 c [REDACTED]	Y	8 months	5.1 lid 1 c [REDACTED]
CA 5.8.1/13		1998	Mutagenicity Test on IM-1-4 in the <i>in vivo</i> Mouse Micronucleus Assay Document No. RD-9835 GLP, not published	Y				5.1 lid 1 c [REDACTED]			5.1 lid 1 c [REDACTED]
CA 5.8.1/14		1997	IM-1-5*HCl: Acute oral toxicity study in rats. Document No. RD-97109 GLP, not published	Y				5.1 lid 1 c [REDACTED]			5.1 lid 1 c

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CA 5.8.1/15		2002b	IM-1-5: Acute oral toxicity study in rats. Document No. RD-II 02424 GLP, not published	Y				5.1 lid 1 c ██████████			5.1 lid 1 c
CA 5.8.1/16	5.1 lid 2 e ██████████	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				5.1 lid 1 c ██████████			5.1 lid 1 c

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
CA 5.8.1/17	5.1 lid 2 e	2012a	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	5.1 lid 2 e	2019	Study plan Kamarkar, AA. N-[6-chloropyridin-3-yl)methyl]-N-methyl ethanimidamide hydrochloride (Acetamiprid IM-1-5) Study No. P/17785/AMES/18 Intox Pvt. Ltd., India GLP, not published  Soman Y.A N-[6-chloropyridin-3-yl)methyl]-N-methyl ethanimidamide hydrochloride (Acetamiprid IM-1-5) <i>Salmonella typhimurium</i> Reverse Mutation Assay Study No. R/17785/AMES/19 Intox Pvt. Ltd., India GLP, not published	5.1 lid 1 c	Y	8 months	5.1 lid 1 c

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
						2019					

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
CA 5.8.1/18	5.1 lid 2 e	2012b	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	5.1 lid 2 e		<u>Study plan</u> Kadam, SB. N-[6-chloropyridin-3-yl)methyl]-N-methyl ethanimidamide hydrochloride (Acetamiprid IM-1-5) Study No. P/17786/CGMT/18 Intox Pvt. Ltd., India GLP, not published	5.1 lid 1 c	Y	8 months	5.1 lid 1 c
CA 5.8.1/19		1997f	IM-2-1 - Acute Oral Toxicity Study In Rats. Document No. RD-95135N GLP, not published Nippon-Soda Report No.: RD-02372 GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
CA 5.8.1/20	5.1 lid 2 e [REDACTED]	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				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.1/21		1997g	IM-2-3: Acute Oral Toxicity Study In Rats. Document No. RD-95144N GLP, not published	Y				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.1/22	5.1 lid 2 e [REDACTED]	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				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.1/23		1997h	IS-1-1: Acute Oral Toxicity Study In Rats. Document No. RD-95140N GLP, not published	Y				5.1 lid 1 c [REDACTED]			5.1 lid 1 c

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
CA 5.8.1/24	5.1 lid 2 e [REDACTED]	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				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.1/25		1997i	IS-2-1: Acute Oral Toxicity Study In Rats Document No. RD-95141N GLP, not published	N				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.1/26	5.1 lid 2 e [REDACTED]	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				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.1/27		1997j	IC-0 - Acute Oral Toxicity Study In Rats. Document No. RD-95137N GLP, not published	Y				5.1 lid 1 c [REDACTED]			5.1 lid 1 c

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
CA 5.8.1/28	5.1 lid 2 e [REDACTED]	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				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.1/29		1999z	IB-1-1: Acute Oral Toxicity in Rats Document No. RD-9906 GLP, not published	Y				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.1/30	5.1 lid 2 e [REDACTED]	1997j	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				5.1 lid 1 c [REDACTED]			5.1 lid 1 c
CA 5.8.2/01		2010	Acetamidrid: 4-Week Dietary Immunotoxicity Study in the Rat. Document No. RD-02011 GLP, not published	Y				5.1 lid 1 c [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]			5.1 lid 1 c



Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
CA 5.8.2/02		2010	4-Week Acetamidiprid: Dietary Immunotoxicity studies in mouse. Document No. RD-02019 GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.8.2/03		1997	Acetamidiprid: Pharmacological Studies in Experimental Animals. Document No. RD-09578N GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.8.2/04	5.1 lid 2 e	2012	Nephrotoxicity of acetamidiprid on male mice and the rescue role of Vitamin E. Journal of Animal and Veterinary Advances Vol. 11(15), pp. 2721-2726	Y				5.1 lid 1 c			5.1 lid 1 c
CA 5.9.1/01	5.1 lid 2 e	2014	Human Handling Experiences From Plant Employees Manufacturing Acetamidiprid (No. 3) Nippon Soda Co., Ltd, Document No. RD-02879 Non-GLP, not published	N				5.1 lid 1 c			5.1 lid 1 c

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
CA 5.9.1/02	5.1 lid 2 e	2007	Human Handling Experiences From Plant Employees Manufacturing Acetamidrid (No. 2). Nippon Soda Co., Ltd, Document No. RD-01239 Non-GLP, not published	N				5.1 lid 1 c			5.1 lid 1 c
CA 5.9.1/03	5.1 lid 2 e	1998	Human Handling Experiences From Plant Employees Manufacturing Acetamidrid Nippon Soda Co., Ltd, , Document No. RD-9849 Non-GLP, not published	N				5.1 lid 1 c			5.1 lid 1 c
CA 5.9.6/01	-	1996	Acetamidrid: Detoxification Studies for Acute Toxicity of NI- 25 Document No. RD-95108N GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c

**References for the PPP Acetamiprid 20 SC**

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCP 7.1.1/1		1998	Acute Oral Toxicity in Rats - EXP 60707B Document No. RD-9943 GLP, not published	Y				5.1 lid 1 c ██████████			5.1 lid 1 c
KCP 7.1.2/1		1998	Acute Dermal Toxicity in Rats - EXP 60707B Document No. RD-9944 GLP, not published	Y				5.1 lid 1 c ██████████			5.1 lid 1 c
KCP 7.1.3/1		1999	Acetamiprid 20% SP - Acute Inhalation Toxicity Study in Rats Document No. RD-9545N GLP, not published	Y				5.1 lid 1 c ██████████			5.1 lid 1 c
KCP 7.1.4/1		1998	Acute Dermal Irritation in Rabbits - EXP 60707B Document No. RD-9945 GLP, not published	Y				5.1 lid 1 c ██████████			5.1 lid 1 c
KCP 7.1.5/1		1998	Acute Eye Irritation in Rabbits - EXP 60707B Document No. RD-9946 GLP, not published	Y				5.1 lid 1 c ██████████			5.1 lid 1 c

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data <sup>5</sup>		RMS Opinion <sup>4,6,7</sup> a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCP 7.1.6/1		1998	Skin Sensitisation Test in Guinea Pig. EXP 60707B. Document No. RD-9947 GLP, not published	Y				5.1 lid 1 c			5.1 lid 1 c
KCP 7.3/01	5.1 lid 2 e	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				5.1 lid 1 c	Y	8 months	5.1 lid 1 c
					5.1 lid 2 e	2019	<u>Study plan</u> In vitro percutaneous absorption of Acetamiprid, formulated as Acetamiprid 20% SG, through human skin. Study No.: P21130/26 Triskelion B.V., The Netherlands GLP, not published	5.1 lid 1 c			5.1 lid 1 c
							<u>In vitro</u> percutaneous absorption of Acetamiprid, formulated as Acetamiprid 20% SG, through human skin <u>Triskelion</u> <u>Report No. V21130/26</u> <u>GLP: Yes</u> <u>Unpublished</u>	5.1 lid 1 c			5.1 lid 1 c