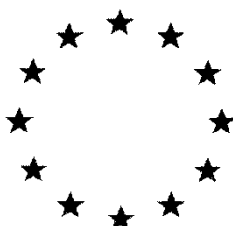


European Commission



**List of information, tests and studies which are considered as relied upon
by the RMS for the evaluation with a view to the approval of the active
substance, in accordance with Article 60 of Commission Regulation (EU) N°
1107/2009**

[NOTE – Tests and studies on Vertebrates are highlighted]

Active Substance Esfenvalerate

Rapporteur Member State : United Kingdom
Co-Rapporteur Member State :

December 2015

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1. IDENTITY

Data Point	Author(s)	Year	Title Compagny 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
IIA 1.10.2/01	Anonymous	2014a	DEREK Nexus Report: Impurity No. 3 Sumitomo Chemical Co., Ltd., Report No.: LLT-0237 Not GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 1.10.2/02	Anonymous	2014b	DEREK Nexus Report: Impurity No. 4 Sumitomo Chemical Co., Ltd., Report No.: LLT-0238 Not GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 1.10.2/03	Anonymous	2014c	DEREK Nexus Report: Impurity No. 5 Sumitomo Chemical Co., Ltd., Report No.: LLT-0239 Not GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 1.10.2/04	Anonymous	2014d	DEREK Nexus Report: Impurity No. 6 Sumitomo Chemical Co., Ltd., Report No.: LLT-0240 Not GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 1.10.2/05	Anonymous	2014e	DEREK Nexus Report: Impurity No. 7 Sumitomo Chemical Co., Ltd., Report No.: LLT-0241 Not GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
IIA 1.10.2/06	Anonymous	2014f	DEREK Nexus Report: Impurity No. 8 Sumitomo Chemical Co., Ltd., Report No.: LLT-0242 Not GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 1.10.2/07	Anonymous	2014g	DEREK Nexus Report: Impurity No. 9 Sumitomo Chemical Co., Ltd., Report No.: LLT-0243 Not GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 1.10.2/08	Anonymous	2014h	DEREK Nexus Report: Impurity No. 10 Sumitomo Chemical Co., Ltd., Report No.: LLT-0244 Not GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 1.10.2/09	Anonymous	2014i	DEREK Nexus Report: Impurity No. 11 Sumitomo Chemical Co., Ltd., Report No.: LLT-0245 Not GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 1.11.1/01	Mukumoto, M.	2010a	Analysis of Esfenvalerate, and its Production Process Impurities, in Esfenvalerate Technical Material Sumitomo Chemical Co., Ltd., Report No.: LLP-0095 GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
IIA 1.11.1/02	Mukumoto, M.	2011a	Supplement to 'Analysis of Esfenvalerate, and its Production Process Impurities, in Esfenvalerate Technical Material' (Contents of Individual Isomers) Sumitomo Chemical Co., Ltd., Report No.: LLP-0102 Non-GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 4.2.3/01	Mukumoto, M.	2010b	Enforcement Analytical Methods of Esfenvalerate Technical Material Sumitomo Chemical Co., Ltd., Report No. LLA-0112 GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 4.2.3/02	Yanagisawa, Y.	2011b	Confirmation of Identification of Active Substance, Isomers and Impurities in Esfenvalerate Technical Material Sumitomo Chemical Co., Ltd., Report No. LLP-0101 Non-GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

2. PHYSICAL AND CHEMICAL PROPERTIES

Data Point	Author(s)	Year	Title Compagny 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
IIA 2.1.2/01	Leslie S., Moseley R.H.	2011	Esfenvalerate: Evaluation of selected physical chemical properties Covance Laboratories Limited Company report No.: LLP-0100 GLP, Unpublished Data gap identified from first EU evaluation	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 2.1.3/01	Leslie S., Moseley R.H.	2011	Esfenvalerate: Evaluation of selected physical chemical properties Covance Laboratories Limited Company report No.: LLP-0100 GLP, Unpublished Data gap identified from first EU evaluation → IIA 2.1.2/01	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 2.2	Leslie S., Moseley R.H.	2011	Esfenvalerate: Evaluation of selected physical chemical properties Covance Laboratories Limited Company report No.: LLP-0100 GLP, Unpublished Previous study not GLP → IIA 2.1.2/01	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
IIA 2.5.1/01	Leslie S., Moseley R.H	2011	Esfenvalerate: Evaluation of selected physical chemical properties Covance Laboratories Limited Company report No.: LLP-0100 GLP, Unpublished Previous study not GLP → IIA 2.1.2/01	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 2.7/01	Leslie S., Moseley R.H	2011	Esfenvalerate: Evaluation of selected physical chemical properties Covance Laboratories Limited Company report No.: LLP-0100 GLP, Unpublished Previous study not GLP → IIA 2.1.2/01	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 2.9.1/01	Graham, R., Gilbert, J	2012	[¹⁴ C]-Esfenvalerate: Hydrolytic Stability Covance Laboratories Limited Company report No.: LLM-0068 GLP, Unpublished Previous study not GLP → IIA 7.5/01	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 2.9.2/01	Graham, R., Dove, R.	2012	[¹⁴ C]-Esfenvalerate: Photodegradation and Quantum Yield in Sterile, Aqueous Solution Covance Laboratories Limited Company report No.: LLM-0065 GLP, Unpublished Previous study not	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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 → IIA 7.6/01				
IIA 2.9.3/01	Graham, R., Dove, R.	2012	[¹⁴ C]-Esfenvalerate: Photodegradation and Quantum Yield in Sterile, Aqueous Solution Covance Laboratories Limited Company report No.: LLM-0065 GLP, Unpublished Data gap identified from first EU evaluation → IIA 7.6/01	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 2.9.4/01	Suzuki, Y., Fujisawa, T., Katagi, T.	2012	Esfenvalerate: Calculation of Aqueous Photolysis Rates in Near Surface Water at North Latitudes 10° to 80° using GCSOLAR Programme Sumitomo Chemical Co., Ltd. Report LLP-0103 Non-GLP, Unpublished. Data gap identified from first EU evaluation	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 2.9.5/01	Leslie S., Moseley R.H	2011	Esfenvalerate: Evaluation of selected physical chemical properties Covance Laboratories Limited Company report No.: LLP-0100 GLP, Unpublished Data gap identified from first EU evaluation	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			→ IIA 2.1.2/01				
IIA 2.11.1/01	Leslie S., Moseley R.H	2011	Esfenvalerate: Evaluation of selected physical chemical properties Covance Laboratories Limited Company report No.: LLP-0100 GLP, Unpublished Previous study not GLP → IIA 2.1.2/01	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 2.15/01	Leslie S., Moseley R.H.	2011	Esfenvalerate: Evaluation of selected physical chemical properties Covance Laboratories Limited Company report No.: LLP-0100 GLP, Unpublished Data gap identified from first EU evaluation → IIA 2.1.2/01	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

3. FURTHER INFORMATION

Data Point	Author(s)	Year	Title Compagny 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
IIA 3.7/01	Sumitomo Chemical Agro Europe	2011	Esfenvalerate TG Safety Data Sheet Company Report No.: SATG/F/500gb Not GLP, Unpublished SDS required based on new guidance	N	N		SUM

4. METHODS OF ANALYSIS

Data Point	Author(s)	Year	Title Compagny 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
IIA 4.2.1/01	Mukumoto , M.	2010b	Enforcement Analytical Methods of Esfenvalerate Technical Material Sumitomo Chemical Co., Ltd., Report No. LLA-0112 GLP, Unpublished Study required to support specification Confidential Information, Document J, IIA 4.2.3/01	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 4.2.1/02	Yanagisawa, Y.	2011b	Confirmation of Identification of Active Substance, Isomers and Impurities in Esfenvalerate Technical Material Sumitomo Chemical Co., Ltd., Report. LLP-0101 Non-GLP, Unpublished Study required to support specification Confidential Information, Document J, IIA 4.2.3/02	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 4.3/01	Weeren, R.D. & Pelz, S.	1998a	Validation of DFG method S19 with modified extraction for the determination of residues of esfenvalerate in field samples of cereals and other dry plant material (Dry peas)	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Submitted but not previously peer reviewed.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			Dr Specht & Partner, Germany Sumitomo Chemical Co., Ltd. Report No. LLA-0091 GLP, Unpublished Study required based on new guidance/data requirement				
IIA 4.3/02	Weeren, R.D. & Pelz, S.	2000	Validation of DFG method S19 with modified extraction for the determination of residues of esfenvalerate in samples of fruits with high water content (Apple) Dr Specht & Partner, Germany Sumitomo Chemical Co., Ltd., Report No LLA-0097 GLP, Unpublished Study required based on new guidance/data requirement	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Submitted but not previously peer reviewed.	SUM
IIA 4.3/03	Weeren, R.D. & Pelz, S.	1998b	Validation of DFG method S19 with modified extraction for the determination of residues of esfenvalerate in field samples of starch containing plant material (potatoes) Dr Specht & Partner, Germany Sumitomo Chemical Co., Ltd., Report No. LLA-0090 GLP, Unpublished Study required	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Submitted but not previously peer reviewed.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			based on new guidance/data requirement				
IIA 4.3/04	Anding, C.	1998	Validation of modified DFG method S19 with modified extraction for the determination of residues of esfenvalerate in field specimens of water containing plant material (Tomato) Defitraces, France Sumitomo Chemical Co., Ltd., Report No. LLA-0093 GLP, Unpublished Study required based on new guidance/data requirement	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Submitted but not previously peer reviewed.	SUM
IIA 4.3/05	Weeren, R.D. & Pelz, S	1998c	Validation of DFG method S19 with DFG cleanup method 5 for the determination of residues of esfenvalerate in field samples of fat containing plant material (rapeseed) Dr Specht & Partner, Germany Sumitomo Chemical Co., Ltd., Report No. LLA-0089 GLP, Unpublished Study required based on new guidance/data requirement	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Submitted but not previously peer reviewed.	SUM

Data Point	Author(s)	Year	Title Compagny 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
IIA 4.3/06	Rzepka, S., Klimmek, A.	2006	Validation of DFG method S19 (extended and revised version) for the determination of residues of esfenvalerate in bulb onion Eurofins/Dr Specht & Partner, Germany Sumitomo Chemical Co., Ltd., Report No. LLA-0105 GLP, Unpublished Study required based on new guidance/data requirement	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 4.3/07	Rzepka, S.	2009	Validation of DFG method S19 (extended and revised version) for the determination of residues of esfenvalerate in citrus Eurofins/Dr Specht & Partner, Germany Sumitomo Chemical Co., Ltd., Report No. LLA-0108 GLP, Unpublished Study required based on new guidance/data requirement	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 4.3/08	Mewis, A	2012	Independent Laboratory Validation (ILV) of Analytical Method DFG S 19 (With Modified Extraction) for the Determination of Residues of Esfenvalerate in Food of Plant	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			Origin Eurofins Agroscience Services Eco Chem GmbH, Sumitomo Chemical Co., Ltd., Report No. LLA-0117 GLP, Unpublished Study required based on new guidance/data requirement				
IIA 4.3/09	Class, T.	2003	Esfenvalerate: Independent Laboratory Validation of the Analytical Methods CLE 333/107 and CLE 333/108 Used for the Determination of the Residues of Esfenvalerate in Materials of Animal Origin PTRL Europe Sumitomo Chemical Co., Ltd., Report No. LLA-0101 GLP, Unpublished Study required based on new guidance/data requirement	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 4.3/10	Class, T., Wilde, N.	2012a	Validation of an Analytical Method for the Determination of Esfenvalerate in Bovine Liver for Post-Registration Control and Monitoring Purpose PTRL Europe Sumitomo Chemical Co., Ltd, Report No. LLA-0119 GLP,	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			Unpublished Study required based on new guidance/data requirement				
IIA 4.3/11	Class, T., Wilde, N.	2012b	Validation of an Analytical Method for the Determination of Chlorophenyl Isovaleric Acid (CPIA, Metabolite of Esfenvalerate) in Bovine Liver for Post-Registration Control and Monitoring Purpose PTRL Europe Sumitomo Chemical Co., Ltd., Report No. LLA-0118 GLP, Unpublished Study required based on new guidance/data requirement	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 4.3/12	Lindner, M., and Giesau, A	2012	Independent Laboratory Validation of an Analytical Method for the Determination of Chlorophenyl Isovaleric Acid (CPIA, Metabolite of Esfenvalerate) in Bovine Liver for Post Registration Control and Monitoring Purposes. Sumitomo Chemical Co., Ltd., Report No. LLA-0120. GLP – Yes	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

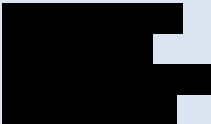

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
IIA 4.3/13	Croucher, A.	1998c	Esfenvalerate: Validation of an Analytical Method for the Determination of Residue in Hen Tissues. Covance Laboratory Report No. CLE 333/107-D2149 Sumitomo Chemical Co., Ltd., Report No. LLA-0083. GLP – Yes Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Submitted but not previously peer reviewed.	SUM
IIA 4.3/14	Croucher, A.	1998d	Esfenvalerate: Validation of an Analytical Method for the Determination of Residue in Cattle Tissues. Covance Laboratory Report No. CLE 333/108-D2140. Sumitomo Chemical Co., Ltd., Report No. LLA-0084. GLP – Yes Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal Submitted but not previously peer reviewed.	SUM
IIA4.4/01 .	Lindner, M.	2011a	Validation of an analytical extraction method for the determination of esfenvalerate in/on soil using two different detection modules Eurofins Agrosience Services Chem, GmbH Germany Sumitomo Chemical Company Co., Ltd., Report No. LLA-0115 GLP –Yes Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA4.4/02	Lindner, M.	2011b	Validation of an analytical method for the determination of	N	Y	Data submitted under Article 15 and 59 of the Regulation	SUM


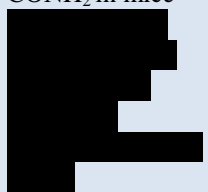
Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			the four isomers of fenvalerate or esfenvalerate in/on soil Eurofins Agroscience Services Chem, GmbH Germany Sumitomo Chemical Company Co., Ltd., Report No. LLA-0116 GLP, Unpublished Study required to support field trials			Necessary for renewal. Not previously submitted.	
IIA4.4/03	Lindner, M.	2011c	Validation of an analytical method for the determination of the esfenvalerate metabolite CONH ₂ -Fen in/on soil Eurofins Dr. Specht GLP GmbH Germany Sumitomo Chemical Company Co., Ltd., Report No. LLA-0114 GLP, Unpublished Study required to support field trials	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 4.5/01	Wolf, S.	2003	Validation of a multi-residue method for the determination of esfenvalerate in surface water RCC Ltd Switzerland Sumitomo Chemical Company Co., Ltd., Report No. LLA-0102 GLP, Unpublished Study required based on new guidance/data	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not requirement	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
IIA 4.8/01	Bacher, R.	2004	Esfenvalerate: Analytical method for the determination of esfenvalerate in blood PTRL Europe, Germany Sumitomo Chemical Company Co., Ltd., Report No. LLA-0103 GLP, Unpublished Data gap identified after first EU evaluation	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM


5. TOXICOLOGY AND METABOLISM DATA

Data Point	Author(s)	Year	Title Compagny 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
IIA 5.3.7/01	[REDACTED]	2000	Esfenvalerate technical: Repeated dose dermal toxicity 21-day study in rats [REDACTED] Unpublished report no.: LLT-0207 GLP, Unpublished Not evaluated during initial procedure. This study was conducted in response to a US EPA Data-Call-In.	Y	Y	Data submitted under Article 15 and 59 of the Regulation Submitted but not previously peer reviewed.	SUM
IIA 5.5.2/01	[REDACTED]	2011	Esfenvalerate TG: Combined chronic / oncogenicity (feeding) study in the Wistar rats [REDACTED] Unpublished report no: LLT-0226 GLP, Unpublished Previous studies were conducted on fenvalerate and this study was conducted to provide a robust study for the assessment of esfenvalerate. The chronic toxicity / carcinogenicity study is a critical study which is seen as necessary to complete the core toxicology	Y	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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 on esfenvalerate to replace the data on fenvalerate. Furthermore, The SCP commented that studies on esfenvalerate would have been preferable to studies on fenvalerate in the assessment of carcinogenicity in the rat (SCP/ESFEN/002/final).				
IIA 5.7.1/01		2000a	Esfenvalerate: acute oral neurotoxicity study in rats  Unpublished report no: LLT-0206 GLP, Unpublished Not evaluated during initial procedure. This study was conducted in response to a US EPA Data-Call-In.	Y	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 5.7.4/01		2000b	Esfenvalerate: subchronic oral neurotoxicity study in rats  Unpublished report no: LLT-0205 GLP, Unpublished Not evaluated during initial	Y	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Submitted but not previously peer reviewed.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			procedure. This study was conducted in response to a US EPA Data-Call-In.				
IIA 5.8.1/01	Kitamoto, S.	2009	Reverse mutation test of Dec-Fen in bacterial systems Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd, Osaka, Japan Unpublished report no: LLT-0216 GLP, Unpublished New study conducted to assess the mutagenic potential of this plant metabolite.	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 5.8.1/07		1980	Acute oral toxicity study of S-5602-CONH ₂ in mice  Unpublished report AT-00-0482, non-GLP, unpublished Not evaluated during initial procedure. This study was conducted to assess the mutagenic potential of this plant/soil/sediment/water metabolite.	Y	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
IIA 5.8.1/08	Yamada T, Kitamoto S	1995	Reverse mutation test of CONH ₂ -Fenvalerate in bacterial systems Laboratory, Sumitomo Chemical Co., Ltd, Osaka, Japan Unpublished report no: AT-50-0486 GLP, Unpublished Not evaluated during initial procedure. This study was conducted to assess the mutagenic potential of this plant/soil/sediment/water metabolite.	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 5.9.1/01	Nishioka, K.	2011	Report on health status of factory workers engaged in manufacturing of esfenvalerate technical material Registration and Regulatory Affairs Department Crop Protection Division – International Sumitomo Chemical Co., Ltd. Japan Unpublished report no: LLT-00225 Non-GLP, Unpublished Updated report of medical surveillance in the years 2001 to 2010	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 5.10.1/01	Willoughby, J.A	2012	Esfenvalerate (DPX-YB656) Technical: Estrogen Receptor Transcriptional	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for	SUM

Data Point	Author(s)	Year	Title Compagny 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
			Activation (Human Cell Line (HeLa-9903)) CeeTox, Inc., Kalamazoo, USA. Unpublished report No.: LLT-0232 GLP, Unpublished New study submitted for US EPA EDSP Tier 1			renewal. Not previously submitted.	
IIA 5.10.1/02	Nabb, D.L.	2012	Esfenvalerate (DPX-YB656) Technical: H295R Steroidogenesis Assay. E. I. du Pont de Nemours and Company, Newark, Delaware, USA. Unpublished report No.: LLT-0233 GLP, Unpublished New study submitted for US EPA EDSP Tier 1	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 5.10.1/03	Snajdr, S.I.	2011	Esfenvalerate (DPX-YB656) Technical: <i>In Vitro</i> Aromatase Inhibition Using Human Recombinant Microsomes. E. I. du Pont de Nemours and Company, Newark, Delaware, USA. Unpublished report No.: LLT-0229 GLP, Unpublished New study submitted for US EPA EDSP Tier 1	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 5.10.1/04		2011	Esfenvalerate (DPX-YB656) Technical: 10-Day Hershberger	Y	Y	Data submitted under Article 15 and 59 of the Regulation	SUM

Data Point	Author(s)	Year	Title Compagny 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
			Bioassay for Detecting Androgenic Activity. [REDACTED] Unpublished report No.: LLT-0228 GLP, Unpublished New study submitted for US EPA EDSP Tier 1			Necessary for renewal. Not previously submitted.	
IIA 5.10.1/05	[REDACTED]	2012	Pubertal Development and Thyroid Function in Intact Juvenile/Peripubertal Male Rats following Oral Administration of Esfenvalerate (DPX-YB656) Technical. [REDACTED] Unpublished report No.: LLT-0230 GLP, Unpublished New study submitted for US EPA EDSP Tier 1	Y	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 5.10.1/06	[REDACTED]	2012	Pubertal Development and Thyroid Function in Intact Juvenile/Peripubertal Female Rats following Oral Administration of Esfenvalerate (DPX-YB656) Technical. [REDACTED]	Y	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			<div></div> Unpublished report No.: LLT-0231 GLP, Unpublished New study submitted for US EPA EDSP Tier 1				
IIA 5.10.1/07	Saito, K.	2001	Evaluation of hormonal activity (effects on human estrogen receptor alpha, androgen receptor and progesterone receptor) of fenvalerate using a suite of three <i>in vitro</i> assays. Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd, Osaka, Japan. Unpublished report No.: LLT-0217 Non-GLP, Unpublished New study submitted for US EPA EDSP Tier 1	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 5.10.1/08	<div></div>	2001	<i>In vivo</i> assessment for androgen receptor- and estrogen receptor-mediated effects of esfenvalerate and fenvalerate: the Hershberger and Uterotrophic assays using rats. <div></div>	Y	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			Unpublished report No.: LLT-0218 Non-GLP, Unpublished New study submitted for US EPA EDSP Tier 1				
IIA 5.10.2/01	Mani, U.; Islam, F.; Prasad, A. K.; Kumar, P.; Kumar, V. Suresh; Maji, B. K.; Dutta, K. K.	2002	Steroidogenic alterations in testes and sera of rats exposed to formulated fenvalerate by inhalation. Human & Experimental Toxicology, 21: 593-597. Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0532 Publication submitted for literature review of reproductive toxicity	Y	N	-	-
IIA 5.10.2/02	Mani, U.; Prasad, A. K.; Kumar, P.; Kumar, V. S.; Lal, K; Maji, B. K.; Dutta, K. K.	2003	Effects of formulated fenvalerate (20% EC) on male mediated fertility parameters in rats exposed by nose only inhalation. Journal of Ecophysiology and Occupational Health, 3: 71-78 Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0533	Y	N	-	-

Data Point	Author(s)	Year	Title Compagny 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
			Publication submitted for literature review of reproductive toxicity				
IIA 5.10.2/03	Arena, A. C.; Fernandez, C. D. B.; Porto, E. M.; Bissacot, D. Z.; Pereira, O.C.M.; Kempinas, W. G.	2008	Fenvalerate, a pyrethroid insecticide, adversely affects sperm production and storage in male rats. Journal of Toxicology and Environmental Health, Part A, 71: 1550-1558 Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0534 Publication submitted for literature review of reproductive toxicity	Y	N	-	-
IIA 5.10.2/04	Nassr, A. C. C.; Arena, A. C.; Toledo, F. C.; Bissacot, D. Z.; Fernandez, C. D. B.; Spinardi-Barbisan, A. L. T.; Pires, P. W.; Kempinas, W. G.	2010	Effects of gestational and lactational fenvalerate exposure on immune and reproductive systems of male rats. Journal of Toxicology and Environmental Health, Part A, 73: 952-964. Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0535 Publication	Y	N	-	-

Data Point	Author(s)	Year	Title Compagny 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
			submitted for literature review of reproductive toxicity				
IIA 5.10.2/05	Zhang H, Wang H, Ji YL, Ning H, Yu T, Zhang C, Zhang Y, Zhao XF, Wang Q, Liu P, Meng XH, Xu DX.	2009	Lactational fenvalerate exposure permanently impairs testicular development and spermatogenesis in mice. Toxicology Letters, 191: 47-56. Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0536 Publication submitted for literature review of reproductive toxicity	Y	N	-	-
IIA 5.10.2/06	Zhang H, Wang H, Wang Q, Zhao XF, Liu P, Ji YL, Ning H, Yu T, Zhang C, Zhang Y, Meng XH, Xu DX.	2010	Pubertal and early adult exposure to fenvalerate disrupts steroidogenesis and spermatogenesis in mice at adulthood. Journal of Applied Toxicology, 30 (4):369-377. Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0537 Publication submitted for literature review of reproductive toxicity	Y	N	-	-
IIA 5.10.2/07	Zhang, H, Wang, H; Ji, YL;	2010	Maternal fenvalerate exposure during	Y	N	-	-

Data Point	Author(s)	Year	Title Compagny 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
	Zhang, Y; Yu, T; Ning, H; Zhang, C; Zhao, XF; Wang, Q; Liu, P; Xu, DX.		pregnancy persistently impairs testicular development and spermatogenesis in male offspring. Food and Chemical Toxicology, 48, 1160-1169. Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0538 Publication submitted for literature review of reproductive toxicity				
IIA 5.10.2/08	Shi, X-D; Bi, H-J; Fu, H-L; Li, L-Y; Liu, D-K; Li, J-M.	2011	Effect of low-dose fenvalerate on semen quality capacitation in adult mice. Chinese Medical Journal (Beijing, China, English Edition), 124(10): 1529-1533 Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0539 Publication submitted for literature review of reproductive toxicity	Y	N	-	-
IIA 5.10.2/09	Zhao, X-F; Wang, Q; Ji, Y-L; Wang, H; Liu, P; Zhang, C;	2011	Fenvalerate induces germ cell apoptosis in mouse testes through the Fas/FasL	Y	N	-	-

Data Point	Author(s)	Year	Title Compagny 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
	Zhang, Y; Xu, D-X.		signalling pathway. Archives of Toxicology, 85: 1101-1108. Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0540 Publication submitted for literature review of reproductive toxicity				
IIA 5.10.2/10	Gao, X; Wang, Q; Wang, J; Wang, C; Lu, L; Gao, R; Huan, F; Dixon, D; Xiao, H.	2012	Expression of calmodulin in germ cells is associated with fenvalerate-induced male reproductive toxicity. Archives of Toxicology, 86: 1443-1451. Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0541 Publication submitted for literature review of reproductive toxicity	Y	N	-	-
IIA 5.10.2/11	Tan, L; Wang, S; Ji, J; Sun, X; Li, Y; Wang, Q; Chen, L.	2006	Effects of fenvalerate exposure on semen quality among occupational workers. Contraception 73: 92-96 Non-GLP, Published Sumitomo	N	N	-	-

Data Point	Author(s)	Year	Title Compagny 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
			Chemical Co., Ltd., Report No.: AT-0542 Publication submitted for literature review of reproductive toxicity				
IIA 5.10.2/12	Song, L; Wang, Y-B; Sun, H; Yuan, C; Hong, X; Qu, J-H; Zhou, J-W; Wang, X-R.	2008	Effects of fenvalerate and cypermethrin on rat sperm motility patterns <i>in vitro</i> as measured by computer –assisted sperm analysis. Journal of Toxicology and Environmental Health, Part A, 71: 325-332 Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0543 Publication submitted for literature review of reproductive toxicity	N	N	-	-
IIA 5.10.2/13	Moniz, A.C; Cruz-Casallas, P. E; Salzgeber, S.A; Varoli, F. M; Spinosa, H. S; Bernardi, M.M.	2005	Behavioral and endocrine changes induced by perinatal fenvalerate exposure in female rats. Neurotoxicology and Teratology, 27: 609-614. Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-	Y	N	-	-

Data Point	Author(s)	Year	Title Compagny 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
			0544 Publication submitted for literature review of reproductive toxicity				
IIA 5.10.2/14	Guerra, M. T.; de Toledo, F. C; Kempinas, W. De G.	2011	<i>In utero</i> and lactational exposure to fenvalerate disrupts reproductive function in female rats. Reproductive Toxicology (2011), 32: 298-303. Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0545 Publication submitted for literature review of reproductive toxicity	Y	N	-	-
IIA 5.10.2/15	Qu, J-H; Fei, J; Hong, X; Chen, J-F; Gu, A-H; Sun, H; Xu, X-L; Song, L; Wang, S-L; Wang, X-R.	2012	Involvement of IGF-I signalling pathway in the regulation of steroidogenesis in mouse Leydig cells treated with fenvalerate. Toxicology, 292: 151-155. Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0546 Publication submitted for literature review of reproductive toxicity	Y	N	-	-

Data Point	Author(s)	Year	Title Compagny 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
IIA 5.10.2/16	Xiao, H; Zhang, XC; Zhang, L; Dai, XQ; Gong, W; Cheng, J; Gao, R; Wang, X.	2006	Fenvalerate modifies T-type Ca ²⁺ channels in mouse spermatogenic cells. Reproductive Toxicology, 21: 48-53 Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0547 Publication submitted for literature review of reproductive toxicity	Y	N	-	-
IIA 5.10.2/17	Du, G; Shen, O; Sun, H; Fei, J; Lu, C; Song, L; Xia, Y; Wang, S; Wang, X.	2010	Assessing hormone receptor activities of pyrethroid insecticides and their metabolites in reporter gene assays. Toxicological Sciences 116(1): 58-66 Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0548 Publication submitted for literature review of reproductive toxicity	N	N	-	-
IIA 5.10.2/18	Fei, J; Qu, J-H; Ding, X-L; Xue, K; Lu, C- C; Chen, J- F; Song, L;	2010	Fenvalerate inhibits the growth of primary cultured rat preantral ovarian follicles. Toxicology, 267:	Y	N	-	-

Data Point	Author(s)	Year	Title Compagny 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
	Xia,Y-K; Wang, S-L; Wang, X-R.		1-6. Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0549 Publication submitted for literature review of reproductive toxicity				
IIA 5.10.2/19	Qu, JH; Hong, X; Chen, JF; Wang, YB; Sun, H; Xu, XL; Song, L; Wang, SL; Wang, XR.	2008	Fenvalerate inhibits progesterone production through cAMP-dependent signal pathway. Toxicology Letters, 176, 31-39 Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0550 Publication submitted for literature review of reproductive toxicity	Y	N	-	-
IIA 5.10.2/20	Petr, J; Chmelílová, E; Žalmanová, T; Tůmová, L; Kheilová, K; Kučerová-Chrpová, V; Jílek, F.	2013	Pyrethroids cypermethrin, deltamethrin and fenvalerate have different effects on <i>in vitro</i> maturation of pig oocytes at different stages of growth. Animal, 7(1): 134-142 Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0551 Publication	N	N	-	-

Data Point	Author(s)	Year	Title Compagny 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
			submitted for literature review of reproductive toxicity				
IIA 5.10.2/21	Gao, X; Yu, L; Castro, L; Moore, AB; Hermon, T; Bortner, C; Sifre, M; Dixon, D.	2010	An endocrine-disrupting chemical, fenvalerate, induces cell cycle progression and collagen type 1 expression in human uterine leiomyoma and myometrial cells. Toxicology Letters 196: 133-141. Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0552 Publication submitted for literature review of reproductive toxicity	N	N	-	-
IIA 5.10.2/22	Xu, LC; Sun, H; Chen, JF; Bian, Q; Song, L; Wang, XR.	2006	Androgen receptor activities of <i>p,p'</i> -DDE, fenvalerate and phoxim detected by androgen receptor reported gene assay. Toxicology Letters, 160: 151-157. Non-GLP, Published Sumitomo Chemical Co., Ltd., Report No.: AT-0553 Publication submitted for literature review of reproductive	N	N	-	-

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

6. RESIDUE DATA

Data Point	Author(s)	Year	Title Compagny 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
IIA 6.1.1/01	Schneider, G.E., Orescan, D.B.	1995	Freezer Storage Stability of Esfenvalerate in Various Matrices E. I. DuPont de Nemours and Company Sumitomo Chemical Co., Ltd. Report No. LLR-0273 GLP, Unpublished Study submitted for first EU evaluation but not peer reviewed	N	N		SUM
IIA 6.1.1/02	Burden, A., Benwell, L.	1997	Esfenvalerate: The Evaluation of Residues Stability in Wheat Grain and Straw under Deep Freeze Storage Conditions Covance Laboratories Sumitomo Chemical Co., Ltd. Report No. LLR-0274 GLP, Unpublished Study submitted for first EU evaluation but not peer reviewed	N	N		SUM
IIA	Benwell,	1998	Esfenvalerate: The	N	N		SUM

Data Point	Author(s)	Year	Title Compagny 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
6.1.1/03	L.		Evaluation of Residues Stability in Cabbage under Deep Freeze Storage Conditions Covance Laboratories Sumitomo Chemical Co., Ltd. Report No. LLR-0276 GLP, Unpublished Study submitted for first EU evaluation but not peer reviewed				
IIA 6.3.1/01	Grolleau, G.	1999a	Magnitude of the Residue of Esfenvalerate in Potato Raw Agricultural Commodity Northern & Southern Europe 1998 European Agricultural Services Sumitomo Chemical Co., Ltd. Report No. LLR-0288 GLP, Unpublished Study required based on representative use	N	N		SUM
IIA 6.3.1/02	Grolleau, G.	2000a	Magnitude of the Residue of Esfenvalerate in Potato Raw Agricultural Commodity Northern & Southern Europe 1999 European Agricultural Services Sumitomo Chemical Co., Ltd. Report No. LLR-0297 GLP, Unpublished Study required	N	N		SUM

Data Point	Author(s)	Year	Title Compagny 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
			based on representative use				
IIA 6.3.2/01	Grolleau, G.	1999b	Magnitude of the Residue of Esfenvalerate in Rapeseed Raw Agricultural Commodity Southern France & Italy 1998 European Agricultural Services Sumitomo Chemical Co., Ltd. Report No. LLR-0287 GLP, Unpublished Study required based on representative use	N	N		SUM
IIA 6.3.2/02	Grolleau, G.	2000b	Magnitude of the Residue of Esfenvalerate in Rapeseed Raw Agricultural Commodity Southern France and Italy 1999 European Agricultural Services Sumitomo Chemical Co., Ltd. Report No. LLR-0296 GLP, Unpublished Study required based on representative use	N	N		SUM
IIA 6.3.2/03	Grolleau, G.	2011a	Magnitude of the Residue of Esfenvalerate in Winter Rape Seed Raw Agricultural Commodity Northern Europe - 2011 STAPHYT Sumitomo Chemical Co., Ltd. Report No. LLR-0384 GLP,	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			Unpublished Study required based on representative use				
IIA 6.3.3/01	Grolleau, G.	1999c	Magnitude of the Residue of Esfenvalerate in Winter Wheat Raw Agricultural Commodity Southern France & Spain 1998 European Agricultural Services Sumitomo Chemical Co., Ltd. Report No. LLR-0281 GLP, Unpublished Study required based on representative use	N	N		SUM
IIA 6.3.3/02	Grolleau, G.	2000c	Magnitude of the Residue of Esfenvalerate in Winter Wheat Raw Agricultural Commodity Spain 1999 European Agricultural Services Report No.: LLR-0294 GLP, Unpublished Study required based on representative use	N	N		SUM

Data Point	Author(s)	Year	Title Compagny 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
IIA 6.3.3/03	Grolleau, G.	2011b	Magnitude of the Residue of Esfenvalerate in Winter Wheat Raw Agricultural Commodity Northern & Southern Europe - 2010 STAPHYT Sumitomo Chemical Co., Ltd. Report No. LLR-0378 GLP, Unpublished Study required based on representative use	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 6.3.3/04	Grolleau, G.	2011c	Magnitude of the Residue of Esfenvalerate in Winter Wheat Raw Agricultural Commodity Northern & Southern Europe - 2011 STAPHYT Sumitomo Chemical Co., Ltd. Report No. LLR-0382 GLP, Unpublished Study required based on representative use	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 6.3.4/01	Grolleau, G.	1999d	Magnitude of the Residue of Esfenvalerate in Winter Barley Raw Agricultural Commodity Southern France & Italy 1998 European Agricultural Services Sumitomo Chemical Co., Ltd. Report No. LLR-0282 GLP, Unpublished Study required	N	N		SUM

Data Point	Author(s)	Year	Title Compagny 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
			based on representative use				
IIA 6.3.4/02	Grolleau, G.	2011d	Magnitude of the Residue of Esfenvalerate in Winter Barley Raw Agricultural Commodity Northern Europe - 2010 STAPHYT Report No.: LLR-0379 GLP, Unpublished Study required based on representative use	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 6.3.4/03	Grolleau, G.	2011e	Magnitude of the Residue of Esfenvalerate in Winter Barley Raw Agricultural Commodity Northern & Southern Europe - 2011 STAPHYT Sumitomo Chemical Co., Ltd. Report No. LLR-0383 GLP, Unpublished Study required based on representative use	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 6.5.3/01	Zietz, E.	2000a	The magnitude of residues of esfenvalerate in processed fractions of brewing barley (malt and beer) following treatment with Sumi Alpha 5EC Institut Fresenius Sumitomo Chemical Co., Ltd. Report No. LLR-0308 GLP, Unpublished Study required based on	N	N		SUM

Data Point	Author(s)	Year	Title Compagny 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
			representative use				
IIA 6.5.3/02	Zietz, E.	2000b	The magnitude of residues of esfenvalerate in processed fractions of pearl barley (pot barley) following treatment with Sumi Alpha 5EC Institut Fresenius Sumitomo Chemical Co., Ltd. Report No. LLR-0309 GLP, Unpublished Study required based on representative use	N	N		SUM

7. ENVIRONMENTAL FATE AND BEHAVIOUR

Data Point	Author(s)	Year	Title Compagny 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
IIA, 7.1.2/01	Graham, R., Dixon, K. & Dove, R.	2012	[¹⁴ C]- Esfenvalerate: Anaerobic Soil Metabolism and Degradation Covance Laboratories Ltd, Study No. 8244257 Sumitomo Chemical Co., Ltd. LLM-0066 GLP, Unpublished. To replace existing study with fenvalerate	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA, 7.1.3/01	Dixon, K., Dove, R. & Graham, R.	2012	[¹⁴ C]- Esfenvalerate: Photodegradation on Soil Surface Covance Laboratories Ltd, Study No. 8244258 Sumitomo Chemical Co., Ltd. LLM-0067 GLP, Unpublished. To replace existing studies that have methodological deficiencies	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA, 7.2.1/ 01	Jarvis, T. & Mamouni, A.	2011a	Recalculation of Esfenvalerate soil degradation kinetics according to FOCUS (2006) Guidance. Exponent International Ltd. Sumitomo	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			Chemical Co., Ltd. LLM-0061. Non-GLP, Unpublished To update results following FOCUS guidance				
IIA 7.2.3/01	Lewis, C. & Troth, K.	2007a	[Chlorophenyl- ¹⁴ C]CONH ₂ - fenvaterate: Aerobic Degradation in Three Soils. Covance Laboratories Ltd, Study No. 0333/271 Sumitomo Chemical Co., Ltd. LLM-0051 GLP, Unpublished. National requirement during EU re- registration	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA, 7.2.3/02	Jarvis, T. & Mamouni, A.	2012	Calculation of CONH ₂ - fenvaterate soil degradation kinetics from Lewis & Troth (2007) according to FOCUS (2006) Guidance. Exponent International Ltd. Sumitomo Chemical Co., Ltd. LLM-0064 Non-GLP, Unpublished To update results following FOCUS guidance	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
IIA, 7.2.4/	Frische, K. & Hellstern, J.	2011	AE F109036: Aerobic Degradation on Three European Soils. Bayer CropScience AG. Ref no. M- 413119-01-1 GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	Bayer Crop Scienc e AG.
IIA, 7.2.4/01	Graham, R. Dixon, K. & Dove, R.	2012	[¹⁴ C]- Esfenvalerate: Anaerobic Soil Metabolism and Degradation Covance Laboratories Ltd, Study No. 8244257 Sumitomo Chemical Co., Ltd. LLM-0066 GLP, Unpublished. To replace existing study with fenvalerate ⇒ IIA 7.1.2/01	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA, 7.3.1/ 01	Jarvis, T. & Mamouni, A.	2011a	Recalculation of Esfenvalerate soil degradation kinetics according to FOCUS (2006) Guidance. Exponent International Ltd. Sumitomo Chemical Co., Ltd. LLM-0061 Non-GLP, Unpublished To update results following FOCUS guidance ⇒ IIA 7.2.1/01	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
IIA, 7.3.1/ 02	Roussel, C-H	2012a	Soil Dissipation Study after Application of Esfenvalerate to Bare Soils. Northern & Southern Europe – 2010 – 2011. STAPHYT Study Number FLN-10- 6237 Sumitomo Chemical Co., Ltd. Report No. LLR-0385 GLP, Unpublished To address potential for persistence of esfenvalerate	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA, 7.3.1/ 05	Roussel, C-H	2012b	Soil Dissipation Study after Application of Esfenvalerate to Bare Soils. Southern Europe – 2011 – 2012. Sumitomo Chemical Co., Ltd. Report No. LLR-0386 GLP, Unpublished To address potential for persistence of esfenvalerate	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA, 7.3.1/ 03	Jarvis, T. & Mamouni, A.	2011b	Calculation of esfenvalerate field dissipation kinetics from study FLN-10- 6237 according to FOCUS (2006) Guidance. Exponent International Ltd. Sumitomo	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			Chemical Co., Ltd. LLM-0060 Non-GLP, Unpublished To address potential for persistence of esfenvalerate				
IIA, 7.3.1/06	Jarvis, T. & Montesano , V	2012	Calculation of esfenvalerate field dissipation kinetics from study CHR-11- 8882 according to FOCUS (2006) Guidance. Sumitomo Chemical Co. Ltd Report No.: LLM-0069. Non GLP, Unpublished To address potential for persistence of esfenvalerate	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA, 7.3.1/ 04	Lindner, M	2011	Storage Stability Study of Esfenvalerate Metabolite CONH ₂ -Fen in Soil Eurofins Dr. Specht Report No.: STA-1008. Sumitomo Chemical Co., Ltd. Report No. LLR-0381. GLP, Unpublished To support the analysis of CONH₂-Fen in the new dissipation study	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
IIA, 7.4.1/ 01	Ohm, M.	2001	Adsorption/Desorption of [¹⁴ C]-Esfenvalerate at a single concentration in Six Soils E.I. du Pont de Nemours and Company Study No.: 3438 Sumitomo Chemical Co., Ltd. Report No. LLM-0046 GLP, Unpublished National requirement during EU re-registration	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 7.4.2/01	Lewis, C. & Troth, K.	2007b	[Chlorophenyl- ¹⁴ C]CONH ₂ -fenvalerate: Adsorption/Desorption in Soil. Covance Laboratories Ltd, Study No. 0333/270 Sumitomo Chemical Co., Ltd. Report No. LLM-0050 GLP, Unpublished. National requirement during EU re-registration	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 7.4.2/02	Foster, B.	2013	Dec-Fen: Estimation of Soil Adsorption Coefficient (Koc) using High Performance Liquid Chromatography (HPLC)	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			Sumitomo Chemical Co Ltd. LLM-0070 GLP, Unpublished.				
IIA, 7.5/ 01	Graham, R. & Gilbert, J.	2012	[¹⁴ C]- Esfenvalerate: Hydrolytic Stability Covance Laboratories Ltd, Study No. 8244259 Sumitomo Chemical Co., Ltd. Report No. LLM-0068 GLP, Unpublished. To clarify possible epimerisation	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA, 7.6/ 01	Graham, R. & Dove, R.	2012	[¹⁴ C]- Esfenvalerate: Photodegradation and Quantum Yield in Sterile, Aqueous Solution Covance Laboratories Ltd, Study No. 8244255 Sumitomo Chemical Co., Ltd. Report No. LLM-0065 GLP, Unpublished. To clarify possible epimerisation	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA, 7.7/ 01	Graham, R. & Flenley, A.	2011	Esfenvalerate: Assessment of Ready Biodegradability by Measurement of CO ₂ Evolution Covance	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously	SUM

Data Point	Author(s)	Year	Title Compagny 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
			Laboratories Ltd, Study No. 8244256 Sumitomo Chemical Co., Ltd. Report No. LLM-0058 GLP, Unpublished. To replace existing study with fenvalerate			submitted.	
IIA, 7.8.3/ 01	Jarvis, T. & Mamouni, A.	2011c	Recalculation of esfenvalerate sediment water kinetics according to FOCUS (2006) Guidance Exponent International Ltd. Sumitomo Chemical Co., Ltd. Report No. LLM-0059 Non-GLP, Unpublished To update results following FOCUS guidance	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA.7.8.3/ 02	Lewis, C	1995	[14C]Esfenvalera te: Biodegradation in Natural Water- sediment systems at 10°C Sumitomo Chemical Co., Ltd., Report No. LLM-0040 Proposed UK guideline for the Conduct of Biodegradability Tests on Pesticides in Natural	N	N	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			Sediment-Water Systems GLP, Unpublished				
IIA.7.8.3/ 03	Takahashi, N. & Oshima, M.	1988	Degradation of Esfenvalerate in Sediment-water systems Sumitomo Chemical Co., Ltd., Report No. LLM-0024 GLP, Unpublished	N	N	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Previously submitted.	SUM

8. ECOTOXICOLOGY DATA

Data Point	Author(s)	Year	Title Compagny 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
IIA 8.1.4/01	[REDACTED]	2009	Esfenvalerate: Reproductive toxicity test with Northern Bobwhite (<i>Colinus virginianus</i>) following OPPTS 850.2300 and OECD 206 [REDACTED] Unpublished report no.: LLW-0137 GLP, Unpublished Study with esfenvalerate required, conducted to current guidelines	Y	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 8.2.1.3/01	[REDACTED]	2005	3-Phenoxybenzoic acid: Acute toxicity test with rainbow trout (<i>Oncorhynchus mykiss</i>) under static conditions [REDACTED] Unpublished report no: LLW-0114 GLP, Unpublished Study with potentially relevant metabolite required	Y	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 8.2.1.3/02	[REDACTED]	2009	Acute toxicity test of Dec-Fen with rainbow trout (<i>Oncorhynchus</i>	Y	Y	Data submitted under Article 15 and 59 of the Regulation	SUM

Data Point	Author(s)	Year	Title Compagny 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
			mykiss) [REDACTED] Unpublished report no: LLW-0129 GLP, Unpublished Study with potentially relevant metabolite required			Necessary for renewal. Not previously submitted.	
IIA 8.2.1.3/03	[REDACTED]	2009	Acute toxicity test of CONH ₂ -Fen with rainbow trout (<i>Oncorhynchus mykiss</i>) [REDACTED] Unpublished report no: LLW-0133 GLP, Unpublished Study with potentially relevant metabolite required	Y	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 8.2.1.3/04	[REDACTED]	2012	PA-Fen: Acute toxicity to <i>Oncorhynchus mykiss</i> [REDACTED] Unpublished report no: LLW-0143 GLP, Unpublished Study with potentially relevant metabolite required	Y	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 8.3.1.1/01	Sayers, L.E.	2005	Esfenvalerate: Acute toxicity to water fleas, <i>Daphnia magna</i> ,	N	Y	Data submitted under Article 15 and 59 of the Regulation	SUM

Data Point	Author(s)	Year	Title Compagny 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
			under static-renewal conditions Springborn Smithers Laboratories, Wareham, Massachusetts, USA Unpublished report no: LLW-0120 GLP, Unpublished Study conducted according to current guidelines			Necessary for renewal. Not previously submitted.	
IIA 8.3.1.1/0 2	Sayers, L.E.	2011	Esfenvalerate A β isomer - acute toxicity to water fleas, <i>Daphnia magna</i> , under static-renewal conditions Smithers Viscient, Wareham, Massachusetts, USA Unpublished report no: LLW-0142 GLP, Unpublished Study with isomer required for risk assessment	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 8.3.1.1/0 3	van der Kolk, J.	2005	3-Phenoxybenzoic acid: Acute immobilisation test with daphnids (<i>Daphnia magna</i>) under static conditions Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland Unpublished report no: LLW-0115 Non-GLP, Unpublished Study with potentially relevant	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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 required				
IIA 8.3.1.1/04	van der Kolk, J.	2005	(+)CPIA: Acute immobilisation test with daphnids (<i>Daphnia magna</i>) under static conditions Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland Unpublished report no: LLW-0116 Non-GLP, Unpublished Study with potentially relevant metabolite required	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 8.3.1.1/05	Matsuura, Y.	2009	Acute toxicity test of Dec-Fen with <i>Daphnia magna</i> Sumika Technoservice Corporation, Takarazuka, Japan Unpublished report no: LLW-0130 GLP, Unpublished Study with potentially relevant metabolite required	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 8.3.1.1/06	Matsuura, Y.	2009	Acute toxicity test of CONH ₂ -Fen with <i>Daphnia magna</i> Sumika Technoservice Corporation, Takarazuka, Japan Unpublished report no: LLW-0134 GLP, Unpublished Study with potentially	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			relevant metabolite required				
IIA 8.3.1.1/07	Anderson, M MacDougall A	2012	PA-Fen: Acute toxicity to <i>Daphnia magna</i> Smithers Viscient (ESG) Ltd. Harrogate, North Yorkshire, UK Unpublished report no: LLW-0144 GLP, Unpublished Study with potentially relevant metabolite required	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 8.4/01	van der Kolk, J.	2005	3-Phenoxybenzoic acid: Alga growth inhibition test with <i>Pseudokirchneriella subcapitata</i> (syn <i>Selenastrum capricornutum</i>) Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland Unpublished report no: LLW-0117 Non-GLP, Unpublished Study with potentially relevant metabolite required	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 8.4/02	van der Kolk, J.	2005	(+)CPIA: Alga growth inhibition test with <i>Pseudokirchneriella subcapitata</i> (syn <i>Selenastrum capricornutum</i>) Springborn Smithers	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			Laboratories (Europe) AG, Horn, Switzerland Unpublished report no: LLW-0118 Non-GLP, Unpublished Study with potentially relevant metabolite required				
IIA 8.4/03	Fujii, A.	2009	Growth inhibition test of Dec-Fen with the freshwater green alga <i>Pseudokirchneriella subcapitata</i> Sumika Technoservice Corporation, Takarazuka, Japan Unpublished report no: LLW-0131 GLP, Unpublished Study with potentially relevant metabolite required	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 8.4/04	Fujii, A.	2009	Growth inhibition test of CONH ₂ -Fen with the freshwater green alga <i>Pseudokirchneriella subcapitata</i> Sumika Technoservice Corporation, Takarazuka, Japan Unpublished report no: LLW-0135 GLP, Unpublished Study with potentially relevant metabolite required	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
IIA 8.4/05	Anderson, M MacDougall A	2012	PA-Fen: Inhibition of growth to the Alga <i>Pseudokirchneriella subcapitata</i> Smithers Viscient (ESG) Ltd. Harrogate, North Yorkshire, UK Unpublished report no: LLW-0145 GLP, Unpublished Study with potentially relevant metabolite required	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 8.5.2/01	Putt, A.E.	1997	[14C]esfenvalerate - the full life-cycle toxicity to midge (<i>Chironomus riparius</i>) under static-renewal conditions Springborn Laboratories Inc., Wareham, Massachusetts, USA Unpublished report no: LLW-0085 GLP, Unpublished Study with sediment-dwelling organism required	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 8.8.1.2/01	Waterman, L.	2006	A rate-response laboratory test to determine the effects of Sumicidin Alpha EC (50 g/L esfenvalerate) on the predatory mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) Mambo-Tox Ltd., Southampton, UK Unpublished report	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			no: LLW-0123 GLP, Unpublished Study conducted to confirm risk assessment at request of national authority				
IIA 8.8.1.3/0 1	Fussell, S.	2006	A rate-response laboratory test to determine the effects of Sumicidin Alpha EC (50 g/L esfenvalerate) on the ground-active beetle <i>Tachyporus hypnorum</i> (Coleoptera: Staphylinidae) Mambo-Tox Ltd., Southampton, UK Unpublished report no: LLW-0124 GLP, Unpublished Study conducted to confirm risk assessment at request of national authority	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 8.8.1.3/0 2	Fussell, S.	2006	A rate-response laboratory test to determine the effects of Sumicidin Alpha EC on the ground-active spider <i>Erigone atra</i> (Araneae: Linyphiidae) Mambo-Tox Ltd., Southampton, UK Unpublished report no: LLW-0125 GLP, Unpublished Study conducted to confirm risk assessment at request of national authority	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Previously submitted in Germany only.	SUM

Data Point	Author(s)	Year	Title Compagny 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
IIA 8.8.1.4/0 1	Spincer, D.	2006	A rate-response laboratory test to determine the effects of Sumicidin Alpha EC (50 g/L esfenvalerate) on the ladybird beetle <i>Coccinella septempunctata</i> L. (Coleoptera: Coccinellidae) Mambo-Tox Ltd., Southampton, UK Unpublished report no: LLW-0126 GLP, Unpublished Study conducted to confirm risk assessment at request of national authority	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Previously submitted in Germany only.	SUM
IIA 8.8.2.5/0 1	Lührs, U.	2010	Effects of esfenvalerate TG on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil test with 5% peat IBACON GmbH, Rossdorf, Germany Unpublished report no: LLW-0139 GLP, Unpublished Study with soil macro-arthropods conducted to meet Data requirements	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 8.8.2.5/0 2	Lührs, U.	2010	Effects of esfenvalerate TG on reproduction of the collembola <i>Folsomia candida</i> in artificial soil test with 5% peat IBACON GmbH, Rossdorf, Germany Unpublished report	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			no: LLW-0140 GLP, Unpublished Study with soil macro-arthropods conducted to meet Data requirements				
IIA 8.9.1/01	Stäbler, D.	2009	Acute toxicity of CONH ₂ -Fen on earthworms <i>Eisenia fetida</i> using an artificial soil test Eurofins-GAB GmbH, Niefern Öschelbronn, Germany Unpublished report no: LLW-0132 GLP, Unpublished Study with potentially relevant metabolite required	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 8.10.1/01	Moser, F.	2011	Esfenvalerate TG: Determination of effects on soil microflora activity Smithers Viscient, Horn, Switzerland Unpublished report no: LLW-0141 GLP, Unpublished Study conducted to current guidelines required	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIA 8.16/01		2012	Esfenvalerate Technical (DPX-YB656): Short Term Reproduction Assay with the Fathead Minnow, <i>Pimephales promelas</i> , Determined Under Flow-Through Conditions	Y	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			<div></div> Unpublished report no: LLW-0149 GLP, Unpublished Study conducted to meet US EPA's Endocrine Disruptor Screening Program				
IIA 8.16/02	<div></div>	2012	Esfenvalerate (DPX-YB656) Technical: 21-d Amphibian Metamorphosis Assay (AMA) with South African Clawed Frog, <i>Xenopus laevis</i> <div></div> Unpublished report no: LLW-0148 GLP, Unpublished Study conducted to meet US EPA's Endocrine Disruptor Screening Program	Y	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

REPRESENTATIVE PRODUCT DATA – ESFENVALERATE 5EC

IDENTITY

Data Point	Author(s)	Year	Title Compagny 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

PHYSICAL AND CHEMICAL PROPERTIES

Data Point	Author(s)	Year	Title Compagny 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
IIIA 2.1.1/01	Lecocq, V.	2013	Physical and chemical properties and shelf-life storage stability tests for Esfenvalerate 5EC, CRA-W, Gembloux, Belgium Report no: LLF-0195 GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIIA 2.1.2/01	Lecocq, V	2013	Physical and chemical properties and shelf-life storage stability tests for Esfenvalerate 5EC, CRA-W, Gembloux, Belgium Report no: LLF-0195 GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIIA 2.3.1/01	Lecocq, V	2013	Physical and chemical properties and shelf-life storage stability tests for Esfenvalerate 5EC, CRA-W, Gembloux,	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			Belgium Report no: LLF-0195 GLP, Unpublished				
IIIA 2.4.1/01	Lecocq, V	2013	Physical and chemical properties and shelf-life storage stability tests for Esfenvalerate 5EC, CRA-W, Gembloux, Belgium Report no: LLF-0195 GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIIA 2.4.2/01	Lecocq, V	2013	Physical and chemical properties and shelf-life storage stability tests for Esfenvalerate 5EC, CRA-W, Gembloux, Belgium Report no: LLF-0195 GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIIA 2.5.1/01	Lecocq, V	2013	Physical and chemical properties and shelf-life storage stability tests for Esfenvalerate 5EC, CRA-W, Gembloux, Belgium Report no: LLF-0195 GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIIA 2.5.3/01	Lecocq, V	2013	Physical and chemical properties and shelf-life storage stability tests for Esfenvalerate 5EC,	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not	SUM

Data Point	Author(s)	Year	Title Compagny 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
			CRA-W, Gembloux, Belgium Report no: LLF-0195 GLP, Unpublished			previously submitted.	
IIIA 2.6.1/01	Lecocq, V	2013	Physical and chemical properties and shelf-life storage stability tests for Esfenvalerate 5EC, CRA-W, Gembloux, Belgium Report no: LLF-0195 GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIIA 2.7.1/01	Lecocq, V	2013	Physical and chemical properties and shelf-life storage stability tests for Esfenvalerate 5EC, CRA-W, Gembloux, Belgium Report no: LLF-0195 GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIIA 2.7.4/01	Lecocq, V	2013	Physical and chemical properties and shelf-life storage stability tests for Esfenvalerate 5EC, CRA-W, Gembloux, Belgium Report no: LLF-0195 GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIIA 2.7.5/01	Lecocq, V	2013	Physical and chemical properties and shelf-life storage stability tests for Esfenvalerate 5EC, CRA-W, Gembloux, Belgium Report no: LLF-0195 GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			tests for Esfenvalerate 5EC, CRA-W, Gembloux, Belgium Report no: LLF-0195 GLP, Unpublished			Necessary for renewal. Not previously submitted.	
IIIA 2.8.2/01	Lecocq, V-	2013	Physical and chemical properties and shelf-life storage stability tests for Esfenvalerate 5EC, CRA-W, Gembloux, Belgium Report no: LLF-0195 GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIIA 2.8.7/01	Lecocq, V	2013	Physical and chemical properties and shelf-life storage stability tests for Esfenvalerate 5EC, CRA-W, Gembloux, Belgium Report no: LLF-0195 GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIIA 2.14/01	Lecocq, V	2013	Physical and chemical properties and shelf-life storage stability tests for Esfenvalerate 5EC, CRA-W, Gembloux, Belgium Report no: LLF-0195 GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIIA 4.4/01	Sumitomo Chemical	2011	Esfenvalerate 5EC Safety Data Sheet	N	N		SUM

Data Point	Author(s)	Year	Title Compagny 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
	Agro Europe		Sumitomo Chemical Co., Ltd., Report No.: SA5EC/bGr/500gb Not GLP, Unpublished SDS required based on new guidance				
IIIA 2.2.1/01	Mak, W.A.	2011	Some physico-chemical properties of Esfenvalerate 5 EC TNO Defense, Security and Safety Sumitomo Chemical Co., Ltd., report No.: LLF-0194 GLP, Unpublished	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIIA 2.2.2/01	Mak, W.A.	2011	Some physico-chemical properties of Esfenvalerate 5 EC TNO Defense, Security and Safety Sumitomo Chemical Co., Ltd., report No.: LLF-0194 GLP, Unpublished → IIIA 2.2.1/01	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIIA 2.3.3/01	Mak, W.A.	2011	Some physico-chemical properties of Esfenvalerate 5 EC TNO Defence, Security and Safety Sumitomo Chemical Co., Ltd., report No.: LLF-0194 GLP, Unpublished → IIIA 2.2.1/01	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

FURTHER INFORMATION

Data Point	Author(s)	Year	Title Compagny 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
IIIA 4.4/01	Sumitomo Chemical Agro Europe	2011	Esfenvalerate 5EC Safety Data Sheet Sumitomo Chemical Co., Ltd., Report No.: SA5EC/bGr/500gb Not GLP, Unpublished SDS required based on new guidance	N	N		SUM

METHODS OF ANALYSIS

Data Point	Author(s)	Year	Title Compagny 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
IIIA 5.2.1/01	Bernes, A.	2012	Physical and chemical properties and shelf-life storage stability tests for Esfenvalerate 5 EC, Second Interim Report Centre Walloon de Recherches agronomiques Sumitomo Chemical Co., Ltd., Report No. LLF-0193 GLP, Unpublished Study required to support technical characteristics/stability data ⇒ IIIA 2.1.1/01	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

TOXICOLOGY AND METABOLISM DATA

Data Point	Author(s)	Year	Title Compagny 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
IIIA 7.6.2/01	Johnson, I.R	2009	Esfenvalerate 5 EC: <i>In vitro</i> absorption of esfenvalerate through human epidermal membranes Dermal Technology Laboratory Ltd Report No.: LLM-0056 GLP, Unpublished New study conducted to refine the estimate of dermal absorption for risk assessment	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM


ENVIRONMENTAL FATE AND BEHAVIOUR

Data Point	Author(s)	Year	Title Compagny 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
IIIA, 9.6.1/01	Jarvis, T. & Schwarz, N.	2012a	Predicted Environmental Concentrations (PEC) of Esfenvalerate in groundwater for Annex I renewal in the EU using the FOCUS groundwater scenarios. Sumitomo Chemical Co. Ltd Report No. LLM- 0062 Non-GLP, Unpublished. New exposure assessment	N	N		SUM
IIIA, 9.6.2/01	Jarvis, T. & Schwarz, N.	2012a	Predicted Environmental Concentrations (PEC) of Esfenvalerate in groundwater for Annex I renewal in the EU using the FOCUS groundwater scenarios. Sumitomo Chemical Co. Ltd Report No. LLM- 0062 Non-GLP, Unpublished. New exposure assessment ⇒ IIIA 9.6.1/01	N	N		SUM
IIIA, 9.6.2/02	Jarvis, T. & Montesano , V.	2014	Predicted Environmental Concentrations (PEC) of the metabolites of	N	N		SUM

Data Point	Author(s)	Year	Title Compagny 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
			Esfenvalerate in groundwater for Annex I renewal in the EU using the FOCUS groundwater scenarios Sumitomo Chemical Co. Ltd. Report No.: LLM-0073. Non-GLP, Unpublished.				
IIIA, 9.7/01	Jarvis, T. & Schwarz, N.	2012b	Predicted Environmental Concentrations (PEC) of Esfenvalerate in surface water for Annex I renewal in the EU using the FOCUS surface water scenarios. Sumitomo Chemical Co. Ltd Report No. LLM-0063 Non-GLP, Unpublished. New exposure assessment	N	N		SUM

ECOTOXICOLOGY DATA

Data Point	Author(s)	Year	Title Compagny 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
IIIA 10.2.3/01	Schanné, C.	2005	[¹⁴ C]-esfenvalerate 50 g/L EC: Assessment of the ecological effects on aquatic communities using outdoor aquatic mesocosms Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland Unpublished report no: LLW-0109 GLP, Unpublished Study required to refine risk assessment	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIIA 10.2.3/02	Schanné, C.	2005	[¹⁴ C]-esfenvalerate 50 g a.s./L EC: Assessment of the ecological effects on aquatic communities using outdoor aquatic mesocosms after triplicate treatment at 14-day intervals Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland Unpublished report no: LLW-0110 GLP, Unpublished Study required to refine risk assessment	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIIA 10.2.3/03	██████	2005	[¹⁴ C]-esfenvalerate 50 g/L EC: Assessment of the acute and chronic toxicity on <i>Oncorhynchus mykiss</i> using outdoor aquatic	Y	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM

Data Point	Author(s)	Year	Title Compagny 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
			mesocosms  Unpublished report no: LLW-0111 GLP, Unpublished Study required to refine risk assessment				
IIIA 10.2.7/01	Ford, S. & Lewis, G	2014	An investigation of the potential biomagnification using a simple food chain mode Sumitomo Chemical Co. Ltd. Unpublished report No.: LLM-0074 Non-GLP, Unpublished. Response to EFSA request January 2014	N	Y		SUM
IIIA 10.4.4/01	Viel, A.J.	1988	Evaluation Of The Toxicity Of Esfenvalerate (S1844 - SUMI-ALPHA) For The Domestic Bee (<i>Apis mellifera</i>) On Eared Wheat In The Presence Of Honeydew (1985) And On Flowering White Mustard (1986) France 1985 - 1986 INRA, Bures-sur-Yvette, France Unpublished report no: Unpublished report No.: LLW-61-0015 Non-GLP, Unpublished Not new study but summary	N	N		SUM

Data Point	Author(s)	Year	Title Compagny 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
			included for risk assessment				
IIIA 10.4.4/02	Pinsdorf, W.	1989a	Results of Official Testing for Harmfulness to Bees - Tent Tests Institut für Landwirtschaftskammer, Saatgutuntersuchung und Bienenkunde, Nevinghoff, Germany Unpublished report no: Unpublished report No.: LLW-91-0047G Non-GLP, Unpublished Not new study but summary included for risk assessment	N	N		SUM
IIIA 10.4.4/03	Pinsdorf, W.	1989b	Results of Official Testing for Harmfulness to Bees - Tent Tests Institut für Landwirtschaftskammer, Saatgutuntersuchung und Bienenkunde, Nevinghoff, Germany Unpublished report No.: LLW-91-0048G Non-GLP, Unpublished Not new study but summary included for risk assessment	N	N		SUM
IIIA 10.4.4/04	Pinsdorf, W.	1989c	Results of Official Testing for Harmfulness to Bees - Tent Tests Institut für	N	N		SUM

Data Point	Author(s)	Year	Title Compagny 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
			Landwirtschaftskammer, Saatgutuntersuchung und Bienenkunde, Nevinghoff, Germany Unpublished report No.: LLW-91-0049G Non-GLP, Unpublished Not new study but summary included for risk assessment				
IIIA 10.4.5/01	Hadházy, A., Zaják, Á.	1987	Bee-toxicological Test Of SUMI-ALPHA 5 % EC Nature and Game Preserve Station, Fácánkert, Hungary Unpublished report no: LLW-71-0014 Non-GLP, Unpublished Not new study but summary included for risk assessment	N	N		SUM
IIIA 10.4.5/02	Nengel, S.	1996	Assessment of side effects of SUMICIDIN ALPHA EC (CYD 30303) on the honey bee (<i>Apis mellifera</i> L.) in the field by application during bee-flight GAB Biotechnologie GmbH, Niefern-Öschelbronn, Germany Unpublished report number: LLW-0102 GLP, Unpublished Study required to refine risk	N	N		SUM

Data Point	Author(s)	Year	Title Compagny 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
			assessment				
IIIA 10.4.5/03	Tornier, I.	1997	Assessment of side effects of SUMICIDIN ALPHA EC (CYD 30303) on the honey bee (<i>Apis mellifera</i> L.) in the field by application during bee-flight Cyanamid Agrar GmbH & Co. KG Unpublished report number: LLW-0103 GLP, Unpublished Study required to refine risk assessment	N	N		SUM
IIIA 10.4.5/04	Kleiner R.	1998	Testing toxicity to Honeybees- <i>Apis mellifera</i> L (under field conditions) according to BBA guideline VI, 23-1 (1991) and EPPO Guideline No 170 (1992): Sumicidin Alpha EC (CYD 30303) BioChem agrar, Cunnersdorf, Germany Unpublished report number: LLW-0097 GLP, Unpublished Study required to refine risk assessment	N	N		SUM
IIIA 10.4.5/05	Mühlen, W.	1998	Assessment of the side effects of SUMICIDIN Alpha EC (CYD 30303) on honeybees (<i>Apis mellifera</i> L) under natural conditions in the field Institut für	N	N		SUM

Data Point	Author(s)	Year	Title Compagny 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
			Pflanzenschutz, Saatgutuntersuchung und Bienenkunde (IPSAB) der Landwirtschaftskammer Westfalen-Lippe. Münster, Germany Unpublished report no: LLW-0098 GLP, Unpublished Study required to refine risk assessment				
IIIA 10.4.5/06	Nengel, S.	1998a	SUMICIDIN Alpha EC: The effects on the honey bee (<i>Apis mellifera</i> L.) in the field following application during bee-flight GAB Biotechnologie GmbH, Niefern-Öschelbronn, Germany Unpublished report no: LLW-0099 GLP, Unpublished Study required to refine risk assessment	N	N		SUM
IIIA 10.4.5/07	Nengel, S.	1998b	SUMICIDIN Alpha EC: The effects on the honey bee (<i>Apis mellifera</i> L.) in the field following application during bee-flight GAB Biotechnologie GmbH, Niefern-Öschelbronn, Germany Unpublished report no: LLW-0101 GLP, Unpublished Study required to	N	N		SUM

Data Point	Author(s)	Year	Title Compagny 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
			refine risk assessment				
IIIA 10.4.5/08	Nengel, S.	1998c	SUMICIDIN Alpha EC: The effects on the honey bee (<i>Apis mellifera</i> L.) in the field following application during bee-flight GAB Biotechnologie GmbH, Niefern-Öschelbronn, Germany Unpublished report no: LLW-0100 GLP, Unpublished Study required to refine risk assessment	N	N		SUM
IIIA 10.4.5/09	Kriszan, M.	2012	Determination of Side-Effects of Esfenvalerate 5 EC on Honeybees (<i>Apis mellifera</i> L.) in <i>Phacelia tanacetifolia</i> in the Field in France 2012. Eurofins Agrosience Services, EcoChem GmbH, Niefern-Öschelbronn, Germany. Sumitomo Chemical Co Ltd. Unpublished report no.: LLW-0146, 27 November 2012. GLP, Unpublished To update results following latest guideline	N	Y	SUM	
IIIA 10.4.7/01	Viel, A.J.	1988	Evaluation Of The Toxicity Of Esfenvalerate (S1844 - SUMI-	N	N		SUM

Data Point	Author(s)	Year	Title Compagny 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
			ALPHA) For The Domestic Bee (<i>Apis mellifera</i>) On Eared Wheat In The Presence Of Honeydew (1985) And On Flowering White Mustard (1986) France 1985 - 1986 INRA, Bures-sur-Yvette, France Unpublished report No.: LLW-61-0015 Non-GLP, Unpublished Not new study but summary included for risk assessment				
IIIA 10.4.7/01	Krizszan, K.	2012	Determination of the side-effects of 'Esfenvalerate 5 EC' on Honeybees (<i>Apis mellifera</i> L.) in Phacelia tanacetifolia in the field in France 2012. Eurofins Agrosience Services, EcoChem GmbH D-75223 Niefern-Öschelbronn, Germany Unpublished report no: LLW-0146 GLP, Unpublished To update results following latest guideline	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIIA 10.5.2/01	Goßmann, A.	1998	Effects of Esfenvalerate 5EC on the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) – extended	N	N		SUM

Data Point	Author(s)	Year	Title Compagny 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
			laboratory study- IBACON GmbH, Rossdorf, Germany Unpublished report no: LLW-0092 GLP, Unpublished Not new study but summary included for risk assessment				
IIIA 10.5.2/02	Goßmann, A.	2000	Effects of Esfenvalerate 5EC on the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) – extended laboratory study on residues- IBACON GmbH, Rossdorf, Germany Unpublished report no: LLW-0095 GLP, Unpublished Not new study but summary included for risk assessment	N	N		SUM
IIIA 10.5.2/03	Moll, M., Bützler, R.	2004	Effects of Sumi-Alpha 5EC on the parasitoid <i>Aphidius rhopalosiphii</i> extended laboratory study - aged residue test - IBACON GmbH, Rossdorf, Germany Unpublished report no: LLW-0107 GLP, Unpublished Study required to refine risk assessment	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM
IIIA 10.5.2/04	Schmitzer, S.	2004	Effects of Sumi-Alpha 5EC on the wolf spider <i>Pardosa</i> spp., extended laboratory study -	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not	SUM

Data Point	Author(s)	Year	Title Compagny 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
			aged residue trial - IBACON GmbH, Rossdorf, Germany Unpublished report no: LLW-0108 GLP, Unpublished Study required to refine risk assessment			previously submitted.	
IIIA 10.5.4/01	Jepson, P.C., Halsall, N., Mead-Briggs, M., Halliwell, E.	1990	The Effects Of A Summer Application Of The Pyrethroid Insecticide Sumi-Alpha On The Non-target Fauna Of A Winter Wheat Crop Agrochemical Evaluation Unit, Southampton, UK Unpublished report no: LLW-0025 GLP, Unpublished Not new study but summary included for risk assessment	N	N		SUM
IIIA 10.5.4/02	Vinall, S., Mead-Briggs, M.	1999	A field study to evaluate the effects of the insecticide Sumi-Alpha, an EC formulation containing 50 g/L esfenvalerate, on the non-target arthropod fauna of winter wheat Mambo-Tox Ltd., Southampton, UK Unpublished report no: LLW-0093 GLP, Unpublished Not new study but summary included for risk assessment	N	N		SUM
IIIA 10.5.4/03	Goßmann, A.	2000	Effects of Sumi-Alpha SEC on predatory mites	N	N		SUM

Data Point	Author(s)	Year	Title Compagny 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
			(Acari, Phytoseiidae) and other beneficial arthropods in apple orchards (field experiment in southern France) IBACON GmbH, Rossdorf, Germany Unpublished report no: LLW-0096 GLP, Unpublished Not new study but summary included for risk assessment				
IIIA 10.6.3/01	Teixeira, D.	2003	Esfenvalerate 5% EC – Chronic toxicity and reproductive effects to earthworms (<i>Eisenia fetida</i>) following exposure in artificial soil Springborn Smithers Laboratories, Wareham, Massachusetts, USA Unpublished report no: LLW-0106 GLP, Unpublished Study required to refine risk assessment	N	Y	Data submitted under Article 15 and 59 of the Regulation Necessary for renewal. Not previously submitted.	SUM