Section A1 Applicant

Annex Point IIA, I 1

1.1	**Applicant**	Name: Contact person: Address: Telephone number: Fax number: E-mail address:	[redacted] 0049 214 3[redacted] 0049 214 3[redacted]
1.2	**Manufacturer of Active Substance** (if different)	Name: Contact person: Address: Telephone number: Fax number: E-mail address: Name of plant: Address:	[redacted] Germany 0049 2173 3[redacted] 0049 2173 3[redacted]
1.3	**Manufacturer of Product(s)** (if different)	LANXESS Deutschland GmbH Contact person:	as applicant
	1) Product 1		
	2) Product n		

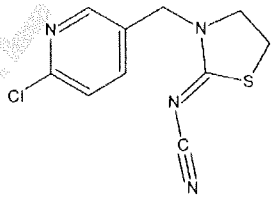
Section A1 Applicant

Annex Point IIA, I 1

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	11/04/2007
Materials and methods	N/A
Conclusion	N/A
Reliability	N/A
Acceptability	N/A
Remarks	Applicants version is considered acceptable
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A2
Annex point IIA, II 2

Identity of Active Substance

Subsection (Annex point)				Official use only
2.1	**Common name (IIA, II)**	ISO name:	Thiacloprid	
		Commercial name:	Calypso; YRC 2894	
2.2	**Chemical name (IIA, II 2.2)**	IUPAC name:	(Z)-N-{3-[(6-Chloro-3-pyridinyl)methyl]-1,3-thiazolan-2-yliden}cyanamide	X
		CAS name:	Cyanamide, [3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene]-	
2.3	**Manufacturer's development code number(s) (IIA, II 2.3)**	YRC 2894		
2.4	**CAS-No and EC numbers (IIA, II 2.4)**	-		
2.4.1	**CAS-No**	111988-49-9		
	Isomer I	-		
	Isomer II	-		
2.4.2	**EC-No**	Not allocated		
	Isomer I	-		
	Isomer II	-		
2.4.3	**Other**	CIPAC No.: 631		
2.5	**Molecular and structural formula, molecular mass (IIA, II 2.5)**	-		
2.5.1	**Molecular formula**	$C_{10}H_9ClN_4S$		
2.5.2	**Structural formula**			
2.5.3	**Molecular mass**	252.73 g/mol		
2.6	**Method of manufacture of the active substance (IIA, II 2.6)**	Refer to Confidential File IIIA TNG Section 2.6		
2.7	**Specification of the purity of the active**	Thiacloprid has a specified minimal purity of [redacted]%.		

Section A2 Identity of Active Substance
Annex point IIA, II 2

	substance, as appropriate (IIA, II 2.7)	
2.8	**Identity of impurities and additives, as appropriate (IIA, II 2.8)**	Refer to Confidential File IIIA TNG Section 2.8
2.8.1	**Isomeric composition**	Refer to Confidential File IIIA TNG Section 2.8.1
2.9	**The origin of the natural active substance or the precursor(s) of the active substance (IIA, II 2.9)**	Not applicable. The active substance has no natural origin (organic synthesis)

Section A2 Identity of Active Substance

Annex point IIA, II 2

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	08/2006
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A2 **Subsection A2.4** **Annex Point IIA, II 2.4**	**Identity** CAS-NO AND EC NUMBERS	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier. If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable.	Official use only
Other existing data [...]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	EC number is not submitted for the active ingredient thiacloprid since such a number is not allocated for it.	
Undertaking of intended data submission [ ]	-	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	07/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A2.8 **Subsection A2.8** **Annex Point IIA, II 2.8**	**Identity of impurities and additives (active substance)** 2.8.5 OTHER NUMBERS	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier. If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable.	Official use only
Other existing data [...]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	CAS and EC numbers, respectively, are given for the impurities of thiacloprid where possible. Other numbers, for example CIPAC numbers, are not submitted for the different impurities since such numbers are not allocated for them.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	07/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A2 **Subsection A2.9** **Annex Point IIA, II 2.9**	**Identity** THE ORIGIN OF THE NATURAL ACTIVE SUBSTANCE OR THE PRECURSOR(S) OF THE ACTIVE SUBSTANCE	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier. If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable.	Official use only
Other existing data [...]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	Since thiacloprid is neither a natural active substance itself nor any precursors of the molecule are natural products this point does not apply to thiacloprid.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	07/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A3 Annex point IIA, III 3	Physical and Chemical Properties of Active Substance							
Subsection (Annex point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1 **Melting point, boiling point, relative density (IIA, III 3.1)**								
3.1.1 **Melting point**	Directive 92/69/EC, method A.1	Purity: [redacted] Specification: as given in Section 2 of dossier.	136 °C An instable second modification with a melting point of 128 °C was observed on one occasion.	–	[redacted]	[redacted]	Krohn, 1996;	
3.1.2 **Boiling point**	OECD guideline 113 (DTA-/TGA-method)	Purity: [redacted] Specification: as given in Section 2 of dossier.	–	[redacted]	[redacted]	[redacted]	Krohn, 1996	X
3.1.3 **Bulk density/ relative density**								
Density	OECD guideline 109 Directive 92/69/EC, method A.3	Purity: [redacted] Specification: as given in Section 2 of dossier.	1.46 g/cm^3 at 20 °C	–	[redacted]	[redacted]	Krohn, 1996	X
Bulk density	CIPAC MT 186	Thiacloprid technical, Specification: as given in Section 2 of dossier.	0.532 g/mL	–	[redacted]	[redacted]	Bogdoll, 2006	

Section A3 Annex point IIA, III 3	Physical and Chemical Properties of Active Substance							
Subsection (Annex point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.2 Vapour pressure and Henry's Law Constant (IIA, III 3.2)								
Vapour pressure	OECD guideline 104 Directive 92/69/EC, method A.4	Purity: [redacted] Specification: as given in Section 2 of dossier.	Results: 1.6-4.5 · 10^{-8} Pa at 50 °C 1.2-1.6 · 10^{-7} Pa at 60 °C 1.7-6.3 · 10^{-7} Pa at 70 °C Conclusion: 3 · 10^{-10} Pa at 20 °C (extrapolated) 8 · 10^{-10} Pa at 25 °C (extrapolated)	–	[redacted]	[redacted]	Krohn, 1996	
Henry's Law Constant	Calculation (ratio between vapour pressure and water solubility (refer to Sections 3.2 and 3.5))	Purity: [redacted] Specification: as given in Section 2 of dossier.	5 · 10^{-10} Pa m^3 mol^{-1} at 20 °C Very low volatile	–	[redacted]	[redacted]	Krohn, 1996	
3.3 Appearance (IIA, III 3.3)								
3.3.1 Physical state	Visual and olfactory inspection	Purity: [redacted] Specification: as given in Section 2 of dossier.	Solid	–	[redacted]	[redacted]	Krohn, 1996	

Section A3 Annex point IIA, III 3	Physical and Chemical Properties of Active Substance							
Subsection (Annex point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.3.2 Colour	Visual and olfactory inspection	Thiacloprid technical, Specification: as given in Section 2 of dossier.	Yellowish to slightly brownish	–	[redacted]	[redacted]	Wanner, 2006	X
3.3.3 Odour	Visual and olfactory inspection	Thiacloprid technical, Specification: as given in Section 2 of dossier.	Weak characteristic odour	–	[redacted]	[redacted]	Wanner, 2006	X
3.4 Absorption spectra (IIA, III 3.4)								
UV/VIS, IR, NMR, MS	UV/VIS, IR, ^{1}H-NMR, ^{13}C-NMR and MS spectrophotometer	Purity: [redacted] Specification: as given in Section 2 of dossier.	UV absorb 242 nm (ε = 18034 l mol^{-1} cm^{-1}) No UV absorbance above 290 nm	–	[redacted]	[redacted]	Stupp, 1995; Grohs, 1995; Etzel, 1995; Thielking, 1995	
	UV/VIS, IR, ^{1}H-NMR, ^{13}C-NMR and MS spectrophotometer	Purity: [redacted] Specification: as given in Section 2 of dossier.	UV absorb 242 nm (ε = 18195 l mol^{-1} cm^{-1}) No UV absorbance above 290 nm.	–	[redacted]	[redacted]	Etzel, 1999 (Addendum I to PPP-Monograph: Table B.2.1)	

Section A3 Annex point IIA, III 3	Physical and Chemical Properties of Active Substance							
Subsection (Annex point)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
A3.5 **Solubility in water (IIA, III 3.5)**	OECD TG 105 ≅ Directive 92/69/EC, method A6	Purity: [redacted] Specification: as given in Section 2 of dossier.	Results at 20 °C: 186 mg/L at pH 4 185 mg/L at pH 5.5-7* 184 mg/L at pH 7 185 mg/L at pH 9 *Unbuffered water		[redacted]	[redacted]	Krohn, 1996	X
	OECD TG 105 ≅ Directive 92/69/EC, method A6	[redacted]. Specification: as given in Section 2 of dossier.	Results at 10 °C: 105 mg/L pure water 095 mg/L at pH 5 093 mg/L at pH 7 102 mg/L at pH 9 Results at 20 °C: 153 mg/L pure water 136 mg/L at pH 5 136 mg/L at pH 7 150 mg/L at pH 9 Results at 30 °C: 233 mg/L pure water 210 mg/L at pH 5 210 mg/L at pH 7 232 mg/L at pH 9		[redacted]	[redacted]	Jungheim, 2006	

Section A3 Annex point IIA, III 3	Physical and Chemical Properties of Active Substance							
Subsection (Annex point)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.7 **Solubility in organic solvents, including the effect of temperature on solubility (IIIA, III 1)**	CIPAC MT 157	Purity: [redacted]. Specification: as given in Section 2 of dossier.	Results: at 20 °C n-Heptane: < 0.1 g/l, Xylene: 0.30 g/l, Dichloromethane: 160 g/l, 1-Octanol: 1.4 g/l, 1-Propanol: 3.0 g/l, Acetone: 64 g/l, Ethyl acetate: 9.4 g/l, Polyethylene glycol: 42 g/l, Acetonitrile: 52 g/l, Dimethyl sulfoxide: 150 g/l		[redacted]	[redacted]	Krohn, 1996	

Section A3 Annex point IIA, III 3	Physical and Chemical Properties of Active Substance							
Subsection (Annex point)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.7 **Solubility in organic solvents, including the effect of temperature on solubility (IIIA, III 1) cont.**	CIPAC MT 157, CIPAC MT 181	Purity: [redacted], Specification: as given in Section 2 of dossier.	Results in g/L at 10 / 20 / 30 °C Cyclohexanone 60 / 86 / 106 Benzyl alcohol 130 / 172 / 215 1-Methyl-2-pyrrolidinone 281 / 315 / 356 1-Octanol 0.75 / 1.21/ 1.73 Texanol 4.27 / 5.65 / 6.97 Diethylene glycol butyl ether 13.4 / 16.2 / 19.8 p-Xylene n.a.* / 0.6 / 0.824 n-Hexane < 0.0005 (10/20 °C) 0.0006 (30 °C) Shellsol D 60 < 0.02 (at all temperatures) * = frozen mixture		[redacted]	[redacted]	Jungheim 2006a	X

Section A3 Annex point IIA, III 3	Physical and Chemical Properties of Active Substance							
Subsection (Annex point)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA, III 2)	–	–	–	[redacted]	–	–	–	
A3.9 Partition coefficient n-octanol/water (IIA, III 3.6)	OECD TG 107 ≅ Directive 92/69/EC, method A8 (Shake flask method)	Purity: [redacted]. Specification: as given in Section 2 of dossier.	Log Pow = 1.26 at 20 °C The effect of pH was not investigated because there is no influence of pH on the water solubility.	[redacted]	[redacted]	[redacted]	Krohn, 1996	X
	OECD TG 117	[redacted] Specification: as given in Section 2 of dossier.	Log Pow = 0.74 in unbuffered water Log Pow = 0.73 at pH 4 Log Pow = 0.73 at pH 7 Log Pow = 0.74 at pH 9	[redacted]	[redacted]	[redacted]	Gruener, 2001 (Addendum I to PPP-Monograph: Table B.2.1)	

Section A3 Annex point IIA, III 3	Physical and Chemical Properties of Active Substance							
Subsection (Annex point)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
	OECD 107/117 Deviation: The partition coefficient is calculated based on the 1 octanol solubility and the water solubility in order to establish its pH and temperature dependence	Purity: [redacted] Specification: as given in Section 2 of dossier (compound used in the related solubility studies)	Based on the solubility data proesented in [redacted] 2006 and 2006a the following 1 octanol / water partition coefficients were calculated at 10, 20 and 30 °C: Pure water: 0.85 / 0.90 / 0.87 pH 5 0.90 / 0.95 / 0.92 pH 7 0.91 / 0.95 / 0.92 pH 9 0.87 / 0.91 / 0.87 Conclusion: Neither a temparature nor pH dependence of the octanol water partition coefficient was found.		[redacted]	[redacted]	Jungheim 2006b	

Section A3 Annex point IIA, III 3	Physical and Chemical Properties of Active Substance							
Subsection (Annex point)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.10 **Thermal stability and identity of relevant breakdown products (IIA, III 3.7)**	OECD guideline 113 (DTA-/TGA-method)	Purity: [redacted]%, Specification: as given in Section 2 of dossier.	- DTA-measurement: Exothermal reaction above 270°C. - TGA-measurement: A weight loss was observed above 280°C.	Thiacloprid is thermally stable at ambient temperature under air	[redacted]	[redacted]	Krohn, 1996	
3.11 **Flammability, including auto-flammability and identity of combustion products (IIA, III 3.8)**								
Flammability	Directive 92/69/EC, method A.10	Purity: [redacted] Specification: as given in Section 2 of dossier.	Thiacloprid is not considered highly flammable.	–	[redacted]	[redacted]	Mix, 1995	
Evolution of flammable gases when contact with water	Directive 92/69/EC, method A.12	Purity: [redacted]. Specification: as given in Section 2 of dossier.	Thiacloprid does not liberate gases in hazardous amounts.	–	[redacted]	[redacted]	Mix, 1995	
Pyrophoric properties	Directive 92/69/EC, method A.13	Purity: [redacted] Specification: as given in Section 2 of dossier.	Thiacloprid has no pyrophoric properties.	–	[redacted]	[redacted]	Mix, 1995	

Section A3 Annex point IIA, III 3	Physical and Chemical Properties of Active Substance							
Subsection (Annex point)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
Auto-flammability	Directive 92/69/EC, method A.16 (BCC test)	Purity: [redacted] Specification: as given in Section 2 of dossier.	Thiacloprid shows no self-ignition.	–	[redacted]	[redacted]	Mix, 1995	
3.12 Flash-point (IIA, III 3.9)	–	–	–	[redacted]	[redacted]	[redacted]	Mix, 1995	
3.13 Surface tension (IIA, III 3.10)	OECD TG 115 ≅ Directive 92/69/EC, method A.5	Purity: [redacted] Specification: as given in Section 2 of dossier.	66 mN/m (80% saturated aqueous solution)	[redacted]	[redacted]	[redacted]	Krohn, 1996	X
3.14 Viscosity (-)	–	–	–	Not applicable since thiacloprid is solid.	–	–	–	
3.15 Explosive properties (IIA, III 3.11)	Directive 92/69/EC, method A.14	Purity: [redacted] Specification: as given in Section 2 of dossier.	Thiacloprid is non-explosive.	–	[redacted]	[redacted]	Mix, 1995	

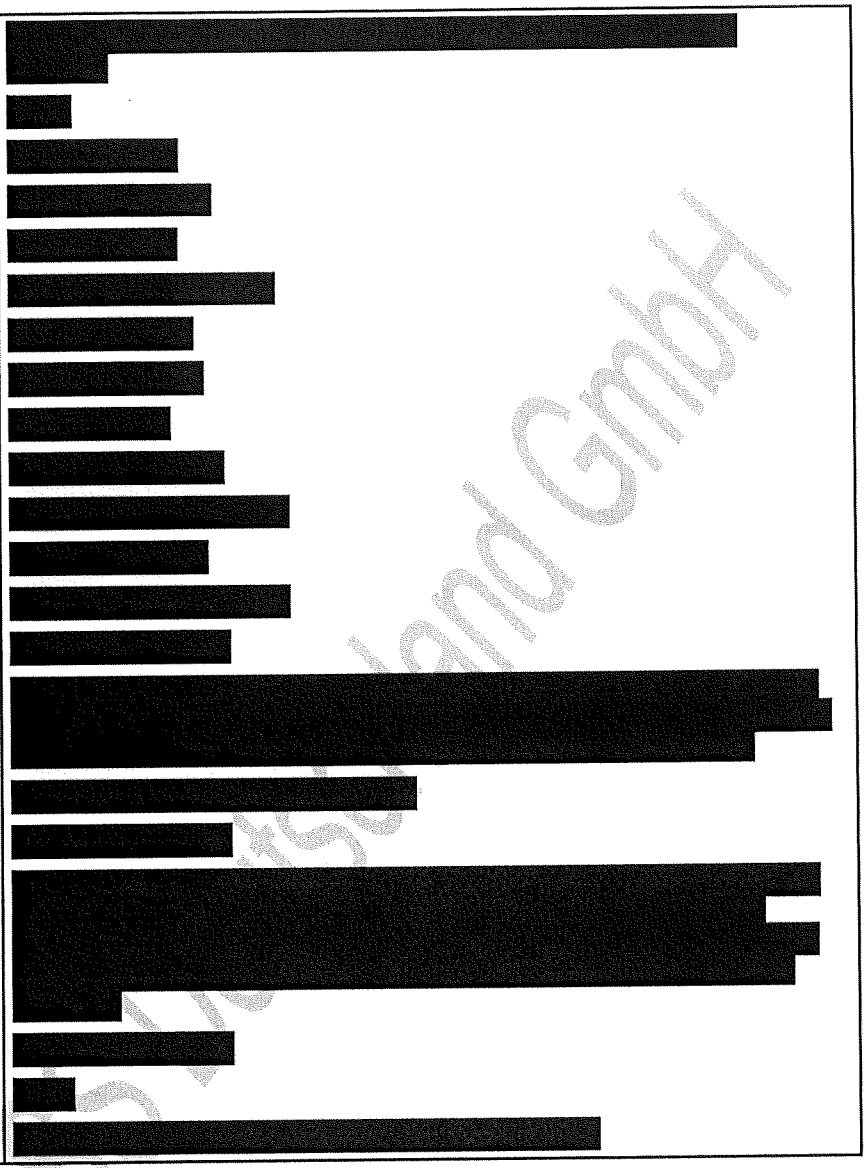
Section A3 Annex point IIA, III 3	Physical and Chemical Properties of Active Substance							
Subsection (Annex point)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.16 Oxidizing properties (IIA, III 3.12)	–	–	Examination of the chemical structure of thiacloprid establishes that it does not contain any chemical groups typical for oxidizing agents such as peroxy or nitro groups, positive halogens (e.g. halogen bonded to nitrogen) or metals in a high oxidation step. Thus the active substance can be regarded as incapable of reacting exothermically with a combustible material such as powdered cellulose.		[redacted]	[redacted]	Mix, 1995	
3.17 Reactivity towards container material (IIA, III 3.13)	US-EPA guideline 830.6313	Purity: [redacted] Specification: as given in Section 2 of dossier.	Recommended container materials for the direct contact with the active substance: plain steel, aluminium, stainless steel #316, copper, brass and HDPE. Metal ions like iron and aluminium acetate had an effect on thiacloprid (about 6% relative active substance weight loss)	–	[redacted]	[redacted]	Swan, 1997	

Section A3 Annex point IIA, III 3	Physical and Chemical Properties of Active Substance							
Subsection (Annex point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
	Not relevant (supplementary information to Swan, 1997)	Thiacloprid, technical Specification: as given in Section 2 of dossier.	Based on experience by the packaging of thiacloprid technical, the following packaging materials are recommended for the direct contact with this substance: HDPE, LDPE and Polypropylene.	–	[redacted]	[redacted]	Wittmann, 2006	

Section A3
Annex point IIA, III 3

Physical and Chemical Properties of Active Substance

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	07/2006
Evaluation of data submitted under section A3	[redacted]

Evaluation of data submitted under section A3	

Section A3 **Subsection A3.8** **Annex Point IIIA, III 2**	**Physical and chemical properties of the active substance** STABILITY IN ORGANIC SOLVENTS
	JUSTIFICATION FOR NON-SUBMISSION OF DATA Official use only As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier. If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable.
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [X]
Detailed justification:	Since the active substance thiacloprid as manufactured does not include an organic solvent a study regarding stability in organic solvents does not apply. For data regarding storage stability of the thiacloprid containing formulations (solvent-based and water-miscible) please refer to Document III B, Section 3.7.
Undertaking of intended data submission [ ]	–
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	07/2006
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A3 **Subsection A3.14** **Annex Point (-)**	**Physical and chemical properties of the active substance** VISCOSITY
	JUSTIFICATION FOR NON-SUBMISSION OF DATA Official use only As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier. If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable.
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [X]
Detailed justification:	Because thiacloprid is solid the determination of viscosity does not apply.
Undertaking of intended data submission [ ]	–
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	07/2006
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4.2 Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid residues in air

Official use only

1 REFERENCE

1.1 Reference

Riegner, K. and Hellpointner, E. (1996): Method for the Determination of YRC 2894 in Air (including the confirmatory method M 00436). Bayer AG, unpublished Report No.: MR-326/96, date: 1996-04-25; (Amendment Report No.: MR-111/99, 1999-02-26).

PPP-Monograph Chapter B.5.3 Analytical methods (residue) in soil, water and air. B.5.3.3 Residues in air

1.2 Data protection

1.2.1 Data owner

1.2.2 Companies with letter of access

1.2.3 Criteria for data protection

[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

No,

no guideline available

2.2 GLP

[redacted]

2.3 Deviations

[redacted]

3 MATERIALS AND METHODS

Method validation of the residues in air method included recoveries obtained from both spray mist application and direct fortification of the TENAX collection tubes. Both recoveries were identical.

For the determination of Thiacloprid (YRC 2894) in air, method 00436 can be used. Air containing Thiacloprid (YRC 2894) is sucked through TENAX adsorption tubes at a rate of 2 L/min over a period of 6 hours. The absorbed active substance is extracted with acetonitrile/water and determined after reversed-phase liquid chromatographic separation by means of an UV detector at 244 nm.

The adsorption capacity was checked at a temperature of 35°C and a relative humidity of 80 %.

Method 00436 (Riegner; Hellpointner 1996) was confirmed by analysing a sample blank extract spiked with 0.28 mg as/L (corresponding to 2 µg as/m3) on an analytical column with different polarity, a cyano-phase and using a different gradient elution. No interference in the control sample and a recovery of 100 % as derived from evaluation against standard calibration curve proves an excellent confirmation of active substance in sample extracts from air.

Validation data for analytical methods for the determination of residues of thiacloprid in air are given in Table 4_2-1.

Section A4.2 **Analytical Methods for Detection and Identification**

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid residues in air

4 CONCLUSION

4.1 Conclusion

The method permits the determination of thiacloprid in air in a concentration range from 0.0018 mg as/m3 (LOQ) to 0.186 mg as/m3.

The systems were validated under 35°C and a relative humidity of 80 %.

4.1.1 Reliability [redacted]

Section A4.2 Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid residues in air

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*07/2006*
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table 4_2-1: Validation data for analytical methods for the determination of residues of thiacloprid (YRC 2894) in air

Type of method; developed by	Matrix	Fortification level (µg/m³)	LOQ (mg/m³)	Recovery rate (%) mean	range	RSD (%)	n
HPLC-UV (Riegner and Hellpointner, 1996)	Air	1.8 a) 186 b)	0.0018 mg as/m³	81.9 99.1	81.4 - 82.4 97.9 - 100.3	0.53 0.94	5 5

a) total recovery

b) desorption recovery

Section A4.2 Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid and metabolite residues in soil

Official use only

1 REFERENCE

1.1 Reference

Sommer, H. (1998a *[Monograph:1998d]*): Method 0532 for liquid chromatographic determination of YRC 2894 and the metabolite YRC 2894-amide in soil. Bayer AG, Report No. MR-535/98, date: 1998-07-29.

PPP-Monograph Chapter B.5.3 Analytical methods (residue) in soil, water and air. B.5.3.1 Residues in soil

1.2 Data protection [redacted]

1.2.1 Data owner [redacted]

1.2.2 Companies with letter of access [redacted]

1.2.3 Criteria for data protection [redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study No,

no guideline available

2.2 GLP [redacted]

2.3 Deviations [redacted]

3 MATERIALS AND METHODS

X

A method using a conventional UV detector for the determination of parent thiacloprid (YRC 2894) and the YRC 2894-amide (M02) can be used (method no. 0532; Sommer, 1998) as primary method. Samples from standard soils spiked with both analytes are extracted with an acidic mixture of methanol/water on a mechanical shaker. The extract is filtered and evaporated to dryness in a Turbo-Vap evaporator. The residues are redissolved in 2 mL of methanol/water. After treatment in an ultra-sonic water bath and subsequent centrifugation to remove fine soil particles, quantification is performed by reversed-phase HPLC with an UV-detector at 242 nm. For confirmatory reasons chromatographic separation is done on a cyano-phase as compared to a RP-18 phase in the primary method. Additionally, the gradient for the mobile phase (acid buffered water/acetonitrile) was changed. Fortification trials were conducted at two fortification levels (10 µg/kg and 100 µg/kg) with two different standard soils. Recoveries for thiacloprid (YRC 2894) were in a range between 85 % and 119 % with an overall recovery of 93 % and a RSD of 9.1 % (n = 20). Recoveries for M02 were in a range between 89 % and 107 %. The overall recovery for M02 was 95 % with a RSD of 5.3 % (n = 20). In the control samples no interferences were found with both primary and confirmatory method.

With regard to the confirmatory method, recoveries for thiacloprid (YRC 2894) ranged from 88 % to 110 % and for M02 from 82 % to 111 %. The overall recovery was 96 % (n = 20) for thiacloprid (YRC 2894) and 98 % (n = 20) for M02. Relative standard deviations (overall RSD) were 6.6 % for YRC 2894 and 8.9 % for M02.

Section A4.2 **Analytical Methods for Detection and Identification**

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid and metabolite residues in soil

A summary on validation data for analytical methods for the determination of residues of thiacloprid and M02 in soil are given in table 4_2-1.

4 CONCLUSION

4.1 Conclusion

Methods for the determination of residues of thiacloprid and M02 are presented.

4.1.1 Reliability [redacted]

Section A4.2 Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2

Analytical method for the determination of thiacloprid and metabolite residues in soil

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*07/2006*
Materials and methods	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table 4_2-1: Validation data for analytical methods for the determination of residues of thiacloprid and M02 in soil

Substrate	Fortification levels (µg/kg)	LOQ (µg/kg)	Analyte; type of method; developed by	Recovery (%) mean	range	RSD (%)	N
Two types of soil (soil 2.2 and Höfchen 4011)	10, 100	10	Parent compound:				
			HPLC-UV[a]	93[a]	85-119	9.1[a]	20
			CM[b]	94[b]	88-107	7.6[b]	20
			M02:				
			HPLC-UV[a]	95[a]	89-107	5.3[a]	20
			CM[b]	99[b]	82-114	8.9[b]	20
			(Sommer, 1998a)				

[a]Primary method
[b]Confirmatory method

Section A4.2 **Annex Point IIA, IV 4.2**	**Analytical Methods for Detection and Identification** ANALYTICAL METHOD FOR THE DETERMINATION OF THIACLOPRID RESIDUES IN ANIMAL AND HUMAN BODY FLUIDS AND TISSUES
	JUSTIFICATION FOR NON-SUBMISSION OF DATA (Official use only) As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier. If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable.
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]
Limited exposure [ ]	**Other justification** [X]
Detailed justification:	Since thiacloprid is not classified as toxic or highly toxic no analytical method for its determination in animal and human body fluids and tissues must be submitted.
Undertaking of intended data submission [ ]	–
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	07/2006
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4.2 Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2

Analytical method for the determination of thiacloprid residues in sediment

Thiacloprid & M02

Official use only

1 REFERENCE

1.1 Reference

Sommer, H. (1997): Method 00467, (MR-873/96) for liquid chromatographic determination of YRC 2894 in sediment Bayer AG, Report No. MR-873/96, date: 1997-01-29.

PPP-Monograph Chapter B.5.3 Analytical methods (residue) in soil, water and air. Table B.5.1 Summary of method description and method validation (Page 52)

1.2 Data protection [redacted]

1.2.1 Data owner [redacted]

1.2.2 Companies with letter of access [redacted]

1.2.3 Criteria for data protection [redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

No,

no guideline available

2.2 GLP [redacted]

2.3 Deviations [redacted]

3 MATERIALS AND METHODS

Essentially the same method as Sommer (1998d) for the determination of thiacloprid in soil.

Sediment samples are extracted two times with methanol/water acidified with 1n hydrochloric acid on a mechanical shaker and filtered. The combined filtrates are concentrated in a rotary evaporator to dryness and the residue is reconstituted in water/acetonitrile/acetic acid and centrifuged. The quantification was done by UV-detection at 244 nm after reversed-phase HPLC-separation. The detector linearity was tested for both analytes within a range of 0.2 to 12 mg/L and yields a correlation coefficient of 1.000, each. X

The mean overall recovery for thiacloprid (YRC 2894), resulting from individual recoveries at fortification levels of 10 and 100 µg/kg, was 72 % with a RSD of 2.9 % (n = 10). The LOQ for YRC 2894 is 10 µg/kg.

For M02 recovery experiments were conducted the same way as for thiacloprid (YRC 2894). The mean overall recovery for M02 was 67 % with a RSD of 16.7 % (n = 10). The LOQ for M02 is 10 µg/kg.

Section A4.2 **Analytical Methods for Detection and Identification**

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid residues in sediment

Thiacloprid & M02

		4 CONCLUSION	
4.1	**Conclusion**	The method is valid for the determination of residues of thiacloprid (YRC 2894) in sediment and its main metabolite M02 down to LOQ 10 µg/kg.	X
4.1.1	Reliability	[redacted]	

Section A4.2 Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2

Analytical method for the determination of thiacloprid residues in sediment

Thiacloprid & M02

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	07/2006
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table 4_2-1: Validation data for analytical methods for the determination of residues of thiacloprid in sediment

Type of method; developed by	Substrate	Fortification level (µg/l)	LOQ (µg/kg)	Analyte	Recovery (%) mean	Recovery (%) range	RSD (%)	N
HPLC-UV (Sommer, 1997c)	Sediment	10, 100	10	Thiacloprid	72	69-76	2.9	5 for each analyte and fortification level
		10, 100	10	M02	67	52-81	16.7	

Section A4.2 Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid and metabolite residues in soil

Official use only

1 REFERENCE

1.1 Reference

Sommer, H. (1998a *[Monograph:1998d]*): Method 0532 for liquid chromatographic determination of YRC 2894 and the metabolite YRC 2894-amide in soil. Bayer AG, Report No. MR-535/98, date: 1998-07-29.

PPP-Monograph Chapter B.5.3 Analytical methods (residue) in soil, water and air. B.5.3.1 Residues in soil

1.2 Data protection [redacted]

1.2.1 Data owner [redacted]

1.2.2 Companies with letter of access [redacted]

1.2.3 Criteria for data protection [redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

No,

no guideline available

2.2 GLP [redacted]

2.3 Deviations [redacted]

3 MATERIALS AND METHODS

X

A method using a conventional UV detector for the determination of parent thiacloprid (YRC 2894) and the YRC 2894-amide (M02) can be used (method no. 0532; Sommer, 1998) as primary method. Samples from standard soils spiked with both analytes are extracted with an acidic mixture of methanol/water on a mechanical shaker. The extract is filtered and evaporated to dryness in a Turbo-Vap evaporator. The residues are redissolved in 2 mL of methanol/water. After treatment in an ultra-sonic water bath and subsequent centrifugation to remove fine soil particles, quantification is performed by reversed-phase HPLC with an UV-detector at 242 nm. For confirmatory reasons chromatographic separation is done on a cyano-phase as compared to a RP-18 phase in the primary method. Additionally, the gradient for the mobile phase (acid buffered water/acetonitrile) was changed. Fortification trials were conducted at two fortification levels (10 µg/kg and 100 µg/kg) with two different standard soils. Recoveries for thiacloprid (YRC 2894) were in a range between 85 % and 119 % with an overall recovery of 93 % and a RSD of 9.1 % (n = 20). Recoveries for M02 were in a range between 89 % and 107 %. The overall recovery for M02 was 95 % with a RSD of 5.3 % (n = 20). In the control samples no interferences were found with both primary and confirmatory method.

With regard to the confirmatory method, recoveries for thiacloprid (YRC 2894) ranged from 88 % to 110 % and for M02 from 82 % to 111 %. The overall recovery was 96 % (n = 20) for thiacloprid (YRC 2894) and 98 % (n = 20) for M02. Relative standard deviations (overall RSD) were 6.6 % for YRC 2894 and 8.9 % for M02.

Section A4.2 Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid and metabolite residues in soil

A summary on validation data for analytical methods for the determination of residues of thiacloprid and M02 in soil are given in table 4_2-1.

4 CONCLUSION

4.1 Conclusion

Methods for the determination of residues of thiacloprid and M02 are presented.

4.1.1 Reliability

Section A4.2 Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid and metabolite residues in soil

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*07/2006*
Materials and methods	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table 4_2-1: Validation data for analytical methods for the determination of residues of thiacloprid and M02 in soil

Substrate	Fortification levels (µg/kg)	LOQ (µg/kg)	Analyte; type of method; developed by	Recovery (%) mean	range	RSD (%)	N
Two types of soil (soil 2.2 and Höfchen 4011)	10, 100	10	Parent compound:				
			HPLC-UV[a]	93[a]	85-119	9.1[a]	20
			CM[b]	94[b]	88-107	7.6[b]	20
			M02:				
			HPLC-UV[a]	95[a]	89-107	5.3[a]	20
			CM[b]	99[b]	82-114	8.9[b]	20
			(Sommer, 1998a)				

[a]Primary method
[b]Confirmatory method

Section A4.2 Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid and metabolites residues in soil

Official use only

1 REFERENCE

1.1 Reference

Sommer, H. (1995): Validation of the method 00389 (MR-235/95) for liquid chromatographic determination of YRC 2894 and the metabolites YRC 2894-amide and YRC-sulfonic acid in soil. Bayer AG, Report No. MR-235/95, date: 1995-06-09.

PPP-Monograph Chapter B.5.3 Analytical methods (residue) in soil, water and air. B.5.3.1 Residues in soil

1.2 Data protection [redacted]

1.2.1 Data owner [redacted]

1.2.2 Companies with letter of access [redacted]

1.2.3 Criteria for data protection [redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

No,

no guideline available

2.2 GLP [redacted]

2.3 Deviations [redacted]

3 MATERIALS AND METHODS

A method using a conventional UV detector for the determination of parent thiacloprid (YRC 2894) and the soil metabolites M02 and M30 can be used (method no. 00389; Sommer, 1995). Spiked soil samples are extracted with methanol/water acidified with hydrochloric acid on a mechanical shaker and filtered. From the filtrate an aliquot is concentrated in a Turbo-Vap to dryness and the residues are redissolved in water/methanol and centrifuged.

The samples are cleaned by HPLC using a column switching system with two columns. On the first column (Zorbax SB-CN) the analytes are cleaned up from the impurities. At the time the amide compound (M02) and the sulfonic acid (M30) are eluted from the first column, the mobile phase is switched to a second column (Alltima-C18) where a peak compression for enhancement of the concentration and the final separation are carried out. The parent compound is determined after gradient elution on the first column without column switching. The quantification for M02 and M30 is done by HPLC with UV-detection at 215 nm. The quantification of thiacloprid (YRC 2894) is done at 244 nm on a separate detector which is connected to the first column. Recovery tests at the lowest spiking level of around 10 µg/kg gave satisfactory results for four different soil types with an overall (comprising all of the three analytes) recovery range of 82 to 114 %. RSDs were between 6.7 and 9.6 %. Testing was also successful for the other two levels of around 50 and 200 µg/kg, with recovery ranges of 62 to 115 % resp. 69 to 97 % and RSDs of 5.3 to 11.3 % resp. 3.7 to 11.0 % (all analytes included). Repeatability was proven for all analytes

Section A4.2 **Analytical Methods for Detection and Identification**

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid and metabolites residues in soil

and levels.

A summary on validation data for analytical methods for the determination of residues of thiacloprid, M02 and M30 in soil are given in table 4_2-1.

4 CONCLUSION

4.1 Conclusion

Methods for the determination of residues of thiacloprid, M02 and M30 are presented.

4.1.1 Reliability

[redacted]

Section A4.2 Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid and metabolites residues in soil

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	07/2006
Materials and methods	[redacted]
Conclusion **Reliability** **Acceptability** **Remarks**	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table 4_2-1: Validation data for analytical methods for the determination of residues of thiacloprid, M02 and M30 in soil

Type of method; developed by	Substrate	Fortification level (µg/kg)	LOQ (µg/kg)	Analyte	Recovery (%) Mean	range	RSD (%)	N
HPLC-UV (Sommer, 1995)	Four soil types (soil 2.1, 2.2, 2.3 and Höfchen 4011)	10, 50, 200	10	Parent compound	91	81-110	7.8	35
				M02	98	86-115	6.8	35
				M30	83	62-102	13.6	35

Section A4.2 Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid and metabolites residues in soil

Official use only

1 REFERENCE

1.1 Reference

Sommer, H. (1997a): Method 00440 (MR-368/96) for liquid chromatographic determination of YRC 2894 and the metabolites YRC 2894-amide and YRC 2894-sulfonic acid in soil. Bayer AG, Report No. MR-368/96, date: 1997-01-20.

Sommer, H. (1997b): Method 00440, M001 (MR-21/97) for liquid chromatographic determination of YRC 2894 and the metabolites YRC 2894-amide and YRC 2894-sulfonic acid in soil. Bayer AG, Report No. MR-21/97, date: 1997-11-07

PPP-Monograph Chapter B.5.3 Analytical methods (residue) in soil, water and air. B.5.3.1 Residues in soil

1.2 Data protection [redacted]

1.2.1 Data owner [redacted]

1.2.2 Companies with letter of access [redacted]

1.2.3 Criteria for data protection [redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

No,

no guideline available

2.2 GLP [redacted]

2.3 Deviations [redacted]

3 MATERIALS AND METHODS

A highly specific LC/MS/MS method for the determination of thiacloprid (YRC 2894) and the soil metabolites M02 and M30 is described under method no. 00440 (Sommer, 1997 a).

Spiked soil samples are extracted with methanol/water acidified with hydrochloric acid on a mechanical shaker and filtered. From the filtrate an aliquot is concentrated in a Turbo-Vap to dryness and the residue is reconstituted in 2 mL of the internal standard solution and centrifuged. The quantification of thiacloprid (YRC 2894), M02 and M30 is done by reversed-phase HPLC using Electrospray MS/MS in the multiple reaction monitoring mode (MRM). For quantification, isotopically labelled internal standards were used.

The original method 00440 was slightly modified concerning instrumental parameters so that levels down to around 5 µg/kg (LOQ) could be successfully validated for all analytes of interest (00440 M001, Sommer, 1997 b). The detector linearity was tested for all analytes within a range of 0.1 to 7 mg/L and yields correlation coefficients between 0.996 and 1.000.

Recovery tests at the lowest spiking level of around 5 µg/kg gave satisfactory results for four different standard soil types with an overall (comprising all of the three analytes) range of 73 % to 109 % (n = 30). RSDs (per level) were between 4.1 and 11.2 %. Testing was also

successful for the additional four levels for each analyte ranging from around 10 to around 200 µg/kg. All individual recoveries were in a range from 74 % to 111 % with level-related RSDs between 2.0 and 11.9 %. Repeatability was guaranteed for all analytes and levels.

A summary on validation data for the analytical method for the determination of residues of thiacloprid, M02 and M30 in soil are given in table 4_2-1.

4 CONCLUSION

4.1 Conclusion

Methods for the determination of residues of thiacloprid, M02 and M30 are presented.

4.1.1 Reliability

[redacted]

Section A4.2 Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid and metabolites residues in soil

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*07/2006*
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table 4_2-1: Validation data for analytical methods for the determination of residues of thiacloprid, M02 and M30 in soil

Type of method; developed by	Substrate	Fortification level (µg/kg)	LOQ (µg/kg)	n	Analyte	Recovery (%) Mean	range	RSD (%)
HPLC/MS/MS (Sommer, 1997a)	Four soil types (soil 2.1, 2.2, 2.3 and Höfchen 4011)	10, 50, 200	**10**	**24**	Thiacloprid	94	85-101	5.7
					M02	95	89-102	4.2
					M30	88	74-111	11.1
HPLC/MS/MS (Sommer, 1997b)	Four soil types (soil 2.1, 2.2, 2.3 and Höfchen 4011)	5, 80	**5**	**20**	Thiacloprid	97	89-109	3.8
					M02	90	78-104	9.0
					M30	87	73-104	9.9

Section A4.2 Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid residues in drinking water

Official use only

1 REFERENCE

1.1 Reference

König, Th. and Sommer, H. (1995): Method for determination of YRC 2894 in drinking water by HPLC with on-line solid phase. Bayer AG, Report No. MR-109/95 (Method 00383), date: 1995-01-31. Amendment Report No. MR-122/99 (MOA 610) dated: 1999-03-03.

PPP-Monograph Chapter B.5.3 Analytical methods (residue) in soil, water and air. B.5.3.2 Residues in water (Study 1)

1.2 Data protection [redacted]

1.2.1 Data owner [redacted]

1.2.2 Companies with letter of access [redacted]

1.2.3 Criteria for data protection [redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study No,

no guideline available

2.2 GLP [redacted]

2.3 Deviations [redacted]

3 MATERIALS AND METHODS

Method 00383 (König, 1995) can be used for the determination of thiacloprid (YRC 2894) in drinking water. The residues are concentrated (factor: ca. 200) by on-line solid phase extraction (C_{18}-cartridge) and determined by reversed-phase HPLC with UV-detection at 244 nm. For the experiments the automated manufacturer-validated OSP-2A (On-line Sample Preparation Unit) of Merck was used. The limit of quantitation of the method was 0.05 µg/L.

The applicability of the methodology was tested by proving linearity of concentrating/eluting of active substance with milliQ water samples spiked with active substance between 0.05 µg/L and 5.03 µg/L (duplicate determinations for each level with a total of 7 levels). A coefficient of 0.9999 shows excellent linearity for the tested working range.

A response comparison for thiacloprid (YRC 2894) has been performed to determine the recovery rates during automatic on-line extraction.

Validation data for this analytical method for the determination of residues of thiacloprid (YRC 2894) in water are given in table 4_2-1.

4 CONCLUSION

4.1 Conclusion The method is valid for the determination of thiacloprid (YRC 2894) residues in drinking water down to LOQ 0.05 µg/l.

4.1.1 Reliability [redacted]

Section A4.2 Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid residues in drinking water

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	07/2006
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table 4_2-1: Validation data for analytical methods for the determination of residues of thiacloprid in water

Type of method; developed by	Substrate	Fortification level (µg/l)	LOQ (µg/l)	Recovery (%) mean	RSD (%)	N
HPLC-UV (König and Sommer, 1995)	Drinking water	0.05	0.05	100	5	10
		5.3	0.05	103	0.2	10

Section A4.2 Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid residues in drinking and surface water

Official use only

1 REFERENCE

1.1 Reference

Sommer, H. (1999): Enforcement and Confirmatory Method for Determination of YRC 2894 in Drinking Water and Surface Water by HPLC. Bayer AG, Report No. MR-384/99, date: 1999-10-25.

PPP-Monograph Chapter B.5.3 Analytical methods (residue) in soil, water and air. B.5.3.2 Residues in water (Study 2)

1.2 Data protection [redacted]

1.2.1 Data owner [redacted]

1.2.2 Companies with letter of access [redacted]

1.2.3 Criteria for data protection [redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

No,

no guideline available

2.2 GLP [redacted]

2.3 Deviations [redacted]

3 MATERIALS AND METHODS

Water samples were concentrated on a C18 solid phase extraction cartridge, air dried and eluted with methanol. The methanol extracts were evaporated to dryness and reconstituted in milli-Q water and analysed by reversed phase HPLC (Luna 3µ C18 column) with UV (DAD) detection at 244 nm and external calibration (positive results were confirmed using a Luna 3µ CN column).

Validation data for the analytical method for the determination of residues of thiacloprid (YRC 2894) in water are given in table 4_2-1.

4 CONCLUSION

4.1 Conclusion

The method is valid for the determination of thiacloprid (YRC 2894) residues in surface as well as in drinking water down to LOQ 0.05 µg/l.

4.1.1 Reliability [redacted]

Section A4.2 Analytical Methods for Detection and Identification

Annex Point IIA, IV 4.2 Analytical method for the determination of thiacloprid residues in drinking and surface water

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*07/2006*
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table 4_2-1: Validation data for analytical methods for the determination of residues of thiacloprid in water

Type of method; developed by	Substrate	Fortification level (µg/l)	LOQ (µg/l)	Recovery (%) mean	RSD (%)	N
HPLC-UV (Sommer, 1999)	Surface and drinking water	0.05	0.05	101	5.1	Not specified
		0.5	0.05	91	7.9	

Section A4.3 **Annex Point IIIA, IV 1**	**Analytical Methods for Detection and Identification** ANALYTICAL METHOD FOR THE DETERMINATION OF THIACLOPRID RESIDUES IN/ON FOOD OR FEEDSTUFFS	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier. If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable.	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [X]	
Detailed justification:	[redacted] Since exposure to food and feedstuffs is not intended it is justified not to submit analytical methods for the determination of thiacloprid residues in / on food and feedstuffs.	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	07/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A5 Effectiveness against target organisms and intended uses

Subsection (Annex Point)			Official use only
5.1	**Function (IIA5.1)**	Generally thiacloprid formulations have been examined for efficacy against insects in a wide range of applications from agriculture use to incorporation in wood preservatives (biocidal use). In wood preservation (product type 8 of the EU Biocidal Product Directive), thiacloprid is used for the protective or remedial treatment of wood in service against wood damage either in primers or incorporated in low binder containing paints (e.g. glazes).	X
5.2	**Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)**		
5.2.1	**Organism(s) to be controlled (IIA5.2)**	Thiacloprid is applied against species of insects which attack (they bore) wood products. Thiacloprid is particularly effective against termites, coleopteres i.e. house longhorn beetle, and common furniture beetles. Efficacy tests are available for the main target organisms. Detailed data on efficacy are summarised in Table A5.1.	
5.2.2	**Products, organisms or objects to be protected (IIA5.2)**	Protection of wooden articles and structures.	
5.3	**Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)**		

Section A5 Effectiveness against target organisms and intended uses

5.3.1 Effects on target organisms (IIA5.3)

The specific efficacy against wood-destroying insects is tested in Europe using EN 46, 47, 49 (part 2), and 117.

Prevention of the growth of wood-destroying insects such as *Reticulitermes santonesis* De Feytaud (termites), larvae of *Hylotrupes bajulus (L)* (house borer), *Anobium punctatum* de Geer (common furniture beetle). See attached Summary Table A5.1 for efficacy data. Lowest non-preventive concentrations are given as well as efficacy data for formulated actives. x

For more detailed information confer the separated study summaries for section 5.3.1 (Effects on target organisms). See also Study Summaries in section 5.10 of Document III-B of dossier (Effects of formulated product on target organisms).

Concerning the remedial treatment, LANXESS has initiated the necessary curative efficacy tests (against *Hylotrupes b.* and *Anobium p.)* with thiacloprid, however, the test reports will not be available before the end of this year. x

Nevertheless, considering on the one hand that there are strong efficacy data for its preventive action against *Hylotrupes b.*, and *Anobium p.* (and termites) and on the other hand the mode of action of thiacloprid (contact and stomach poison), there is a strong evidence that thiacloprid is going to be suitable for remedial applications as well. As usual for all insecticides the effective concentrations will be most likely somewhat higher for the remedial treatment compared to the preventive applications which were considered in the risk assessment. The determination of the exact effective concentration to be approved by the authorities should be part of the biocidal product (wood preservative) approval.

5.3.2 Likely concentrations at which the A.S. will be used (IIA5.3)

PT8 0.5 and 0.02 % thiacloprid in formulated wood preservatives (water based and solvent-based formulations, respectively) x

PTn

5.4 Mode of action (including time delay) (IIA5.4)

5.4.1 Mode of action

Thiacloprid belongs to the chloronicotinyl group of insecticides.

Thiacloprid interacts with insect nicotinic acetylcholine receptors, a class of neurotransmitter-gated cation channels that are involved in excitatory neurotransmission. Like the naturally occurring neurotransmitter acetylcholine, thiacloprid acts as an agonist i.e. the binding of thiacloprid to the receptor protein induces a depolarising ion current causing excitation of the nerve cell. In contrast to acetylcholine, thiacloprid cannot be inactivated by acetylcholinesterase. This results in continuous excitation of nerve cells leading to disorder of the nervous system and subsequent death of treated insects.

Section A5 Effectiveness against target organisms and intended uses

Cross reference: Thorton (2000)

Statement found in PPP-Monograph Chapter: B.3.1 Data on application relevant to active substance. B.3.1.5 Mode of action

Thiacloprid used as a pesticide is an insecticide whose mode of action can be classified into the group 4 according to the classification of insecticides v4.2.1 (2005) by the Insecticide Resistance Action Committee (IRAC)

Group-class 4: Sub-group: Neonicotinoid. Primary target site of action: Nicotinic Acetylcholine receptor agonists / antagonists (nervous system).

The classification-scheme is available in the web-site www.irac-online.org

Thiacloprid is not included in the above mentioned published classification list but a similar substance (imidacloprid) wiht the same specific chemical group responsible for the mode of action on insects.

Cross reference: IRAC (2005)

5.4.2	**Time delay**	Not relevant for this kind of application (wood preservation)
5.5	**Field of use envisaged (IIA5.5)**	
	MG01: Disinfectants, general biocidal products	
	MG02: Preservatives	Product types PT08 wood preservatives
	MG03: Pest control	
	MG04: Other biocidal products	
	Further specification	
5.6	**User (IIA5.6)**	
	Industrial	See Documents II-B and II-C of the dossier.
	i) Open system	
	ii) Closed system	
	Professional	See Documents II-B and II-C of the dossier.
	i) Open system	
	ii) Closed system	
	General public	See Documents II-B and II-C of the dossier.
5.7	**Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies**	

Section A5 Effectiveness against target organisms and intended uses

(IIA5.7)

5.7.1	**Development of resistance**	Thiacloprid belongs to the chloronicotinyl class of insecticides that interact with insect nicotinic acetylcholine receptors. The only other insecticides that act on this site are cartap and nicotine. For industrial wood preservation using thiacloprid resistance is not an issue. Resistance is usually associated with continued application and resistance is formed between applications such that subsequent applications are less efficacious. Industrial wood preservatives are usually applied only once and there is no evidence to suggest resistance. Also, for other kinds of wood preservation with thiacloprid-containing products, cases of resistances are not reported or known up to the time being. Resistance management of thiacloprid used in plant protection products was extensively addressed in the reference Elbert.A., et al. (2005).
5.7.2	**Management strategies**	Not relevant
5.8	**Likely tonnage to be placed on the market per year (IIA5.8)**	See entries in IUCLID database

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	
Materials and Methods	[redacted]
Results and Discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Table A5.1: Summary Table: Data available on the effectiveness of the active substance against target organisms

Test substance	Test organism(s)	Test system / concentrations applied / exposure time	Test results: lowest non-preventive concentration	Reference (see page 8)
LP OU 28430 (thiacloprid technical)	larvae of *Hylotrupes bajulus (L)* (house longhorn beetle)	Preventive efficacy against larvae of wood destroying house longhorn beetle according to EN 47 (08/90) -Wood species: *Pinus sylvestri* -Treatment: vacuum pressure - Concentrations applied: 0 – 0.023 mass%	The test substance was efficacious at preventing wood destruction by *Hylotrupes bajulus* on pine. The highest non-protective concentration was <1.0 g/m^3 on pine	Schumacher and Fennert. (1999a)
LP OU 28430 (thiacloprid technical)	*Reticulitermis santonesis* De Feytaud (termites)	Preventive efficacy against wood destroying termites according to EN 117 (08/90) -Wood species: *Pinus sylvestri* -Treatment: vacuum pressure - Concentrations applied: 0 – 0.023 mass%	The test substance was efficacious at preventing wood destruction by *Reticulitermis santonesis* De Feytaud on pine. The highest non-protective concentration was <1.1 g/m^3 on pine	Schumacher and Fennert. (1999b)
LP OU 28430 (thiacloprid technical)	*Reticulitermis santonesis* De Feytaud (termites)	Preventive efficacy against wood destroying termites according to EN 117 (08/90) after ageing by leaching procedure (EN 84, 05/97) -Wood species: *Pinus sylvestri* -Treatment: vacuum pressure - Concentrations applied: 0 – 0.023 mass%	The test substance was efficacious at preventing wood destruction by *Reticulitermis santonesis* De Feytaud on artificially aged pine. The highest non-protective concentration was <1.1 g/m^3 on pine	Schumacher and Fennert. (1999c)
LP OU 28430 (thiacloprid technical)	larvae of *Hylotrupes bajulus (L)* (house longhorn beetle)	Preventive efficacy against recently hatched larvae of wood destroying house longhorn beetle according to EN 47 (08/90) after ageing by leaching procedure (EN 84, 05/97) -Wood species: *Pinus sylvestri* -Treatment: vacuum pressure - Concentrations applied: 0 – 0.002 mass%	The test substance was efficacious at preventing wood destruction by *Hylotrupes bajulus* on artificially aged pine. The highest non-protective concentration was between 0.53-0.96 g/m^3 on pine	Schumacher and Fennert (2001a)

Table A5.1: Summary Table: Data available on the effectiveness of the active substance against target organisms (continued)

Test substance	Test organism(s)	Test system / concentrations applied / exposure time	Test results: lowest non-preventive concentration	Reference (see page 8)
LP OU 28430 (thiacloprid [redacted]	*Reticulitermes santonesis* De Feytaud (termites)	Preventive efficacy against wood destroying termites according to EN 117 (08/90) after evaporative ageing (EN 73, 04/90) -Wood species: *Pinus sylvestri* -Treatment: vacuum pressure - Concentrations applied: 0 – 0.0011 mass%	The test substance was efficacious at preventing wood destruction by *Reticulitermes santonesis* on artificially aged pine. The highest non-protective concentration was between 0.66-1.02 g/m^3 on pine	Schumacher and Fennert. (2001b)
LP OU 28430 (thiacloprid [redacted]	larvae of *Hylotrupes bajulus (L)* (house longhorn beetle)	Preventive efficacy against recently hatched larvae of wood destroying house longhorn beetle according to EN 47 (08/90) after evaporative ageing (EN 73, 04/90) -Wood species: *Pinus sylvestri* -Treatment: vacuum pressure - Concentrations applied: 0 – 0.0011 mass%	The test substance was efficacious at preventing wood destruction by *Hylotrupes bajulus* on artificially aged pine. The highest non-protective concentration was <0.32 g/m^3 on pine	Schumacher and Fennert. (2001c)
LP OU 28430 (thiacloprid [redacted]	*Anobium punctatum* (de Geer) (common furniture beetle)	Preventive efficacy against wood destroying furniture beetle according to EN 49 part 2 after ageing by leaching procedure (EN 84, 05/97) -Wood species: *Quercus petraea* -Treatment: vacuum pressure - Concentrations applied: 0 – 0.013 mass%	The test substance was efficacious at preventing wood destruction by *Anobium punctatum* on artificially aged sessile oak. The highest non-protective concentration was <1.87 g/m^3 on sessile oak	Schumacher and Fennert. (2002c)
*Thiacloprid-containing formulation: JJT 3091 ([redacted] thiacloprid)	*Hylotrupes b.* (house longhorn beetle, recently hatched larvae)	EN 46 (04/90) + EN 84 (05/97) EN 46 (04/90) + EN 73 (04/90)	<0.01 g/m^2 <0.01 g/m^2	Schumacher and Fennert (2002a, b)

Table A5.1: Summary Table: Data available on the effectiveness of the active substance against target organisms (continued)

Test substance	Test organism(s)	Test system / concentrations applied / exposure time	Test results: lowest non-preventive concentration	Reference (see page 8)
Thiacloprid	Insects in general	Classification of mode of action on insects according to IRAC-scheme	Thiacloprid used as a pesticide is an insecticide whose mode of action can be classified into the group 4 according to the classification of insecticides v4.2.1 (2005) by the Insecticide Resistance Action Committee (IRAC) Group-class 4: Sub-group: Neonicotinoid. Primary target site of action: Nicotinic Acetylcholine receptor agonists / antagonists (nervous system). The classification-scheme is available in the web-site www.irac-online.org Thiacloprid is not included in the above mentioned published classification list but a similar substance (imidacloprid) wiht the same specific chemical group responsible for the mode of action on insects.	IRAC, 2005
Thiacloprid	Not applicable	Based on the structural formula of thiacloprid	Thiacloprid belongs to the chloronicotinyl group of insecticides. Thiacloprid interacts with insect nicotinic acetylcholine receptors, a class of neurotransmitter-gated cation channels that are involved in excitatory neurotransmission. Like the naturally occurring neurotransmitter acetylcholine, thiacloprid acts as an agonist i.e. the binding of thiacloprid to the receptor protein induces a depolarising ion current causing excitation of the nerve cell. In contrast to acetylcholine, thiacloprid cannot be inactivated by acetylcholinesterase. This results in continuous excitation of nerve cells leading to disorder of the nervous system and subsequent death of treated insects.	Thorton (2000)

*Study highlighted in grey is non-key and not relevant to Document III-A (active substance).

References:

Elbert, A., Bailo-Schleiermacher, I., Brüggen, K.-U., Nauen, R., and Rogers, D. (2005): Bayer CropScience Guidelines on Resistance Management for Neonicoitnoids. Pflanzenschutz-Nachrichten Bayer 58 (76), Special edition.

IRAC (2005): Online available classification scheme on mode of action of insecticides, v4.2.1.

Schumacher, P., and Fennert, E-M. (1999a): Bestimmung der Giftwerte von LP OU 28430 gegenüber Larven von *Hylotrupes bajulus L.* gemäß DIN EN 47 – (08/90). Materialprüfungsamt des Landes Brandenburg, Germany, Report No. 3.2/7693/3, unpublished, date: 1999-11-10.

Schumacher, P., and Fennert, E-M. (1999b): Bestimmung der Grenze der Wirksamkeit von LP OU 28430 gegenüber Termiten (*Reticulitermis santonesis* De Feytaud) – gemäß DIN EN 117 – (08/90). Materialprüfungsamt des Landes Brandenburg, Germany, Report No. 3.2/7693/1, unpublished, date: 1999-12-16.

Schumacher, P., and Fennert, E-M. (1999c): Bestimmung der Grenze der Wirksamkeit von LP OU 28430 gegenüber Termiten (*Reticulitermis santonesis* De Feytaud) – gemäß DIN EN 117 – (08/90). Kombiniert mit einer Auswaschbeanspruchung – gemäß EN 84 – (05/97). Materialprüfungsamt des Landes Brandenburg, Germany, Report No. 3.2/7693/2, unpublished, 1999-12-16.

Schumacher, P., and Fennert, E-M. (2001a): Determination of the toxic values of LP OU 28430 against larvae of *Hylotrupes bajulus (L.)* according to EN 47 (08/90) after leaching procedure according to EN 84 (05/97). Materialprüfungsamt des Landes Brandenburg, Germany, Report No. 3.2/00/8105/03, unpublished, date: 2001-05-15.

Schumacher, P., and Fennert, E-M. (2001b): Determination of the toxic values of LP OU 28430 against *Reticulitermes santonesis* De Feytaud according to EN 117 (08/90) after evaporative ageing procedure according to EN 73 (04/90). Materialprüfungsamt des Landes Brandenburg, Germany, Report No. 3.2/00/8105/01, unpublished, date: 2001-06-18.

Schumacher, P., and Fennert, E-M. (2001c): Determination of the toxic values of LP OU 28430 against larvae of *Hylotrupes bajulus (L)* according to EN 47 (08/90) after evaporative ageing procedure according to EN 73 (04/90). Materialprüfungsamt des Landes Brandenburg, Germany, Report No. 3.2/00/8105/02, unpublished, date: 2001-07-03.

Schumacher, P., and Fennert, E-M. (2002a): Determination of the preventive action of JJT 3091 (water based) against recently hatched larvae of *Hylotrupes bajulus (L.)* according to EN 46 (04/90) after leaching procedures according to EN 84 (05/97). Materialprüfungsamt des Landes Brandenburg, Germany, Report No. 3.2/01/8246/01, unpublished, date: 2002-03-08.

Schumacher, P., and Fennert, E-M. (2002b): Determination of the preventive action of JJT 3091 (water based) against recently hatched larvae of *Hylotrupes bajulus (L.)* according to EN 46 (04/90) after evaporative ageing procedure according to EN 73 (04/90). Materialprüfungsamt des Landes Brandenburg, Germany, Report No. 3.2/01/8246/02, unpublished, date: 2002-04-08.

Schumacher, P., and Fennert, E-M. (2002c): Determination of the protective effectiveness of LP OU 28430 against *Anobium punctatum* (de Geer) by egg-laying and larval survival according to EN 49 part 2 – Application by impregnation treatment after leaching procedure according to EN 84 (05/97). Materialprüfungsamt des Landes Brandenburg, Germany, Report No. 3.2/01/8160/01, unpublished, date: 2002-06-11.

Thornton, H.M. (2000): BIOLOGICAL OVERVIEW (EFFICACY) - A summary of information supporting the claims made for YRC 2894 SC 480 an SC formulation containing 480 g/l YRC 2894 for the control of aphids in apples [Revised].Bayer AG, Report No. RD. 113/2, unpublished, date: 31.01.2000

Section A5.3
Annex Point IIA5.3

Efficacy Data (1)

Efficacy of Thiacloprid on wood against the house longhorn beetle *Hylotrupes bajulus (L).*

			Official use only
		1 REFERENCE	
1.1	**Reference**	Schumacher, P., and Fennert, E.-M. (1999a): Bestimmung der Giftwerte von LP OU 28430 gegenüber Larven von *Hylotrupes bajulus L.* gemäß DIN EN 47 – (08/90). Materialprüfungsamt des Landes Brandenburg, Germany, Report-No. 3.2/7693/3, unpublished, dated: 1999-11-10.	X
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
1.3	**Guideline study**	Yes; EN 47 (08/90)	
1.4	**Deviations**	[redacted]	
		2 METHOD	
2.1	**Test Substance (Biocidal Product)**		
2.1.1	Trade name/ proposed trade name	**LP OU 28430 (developmental code)**	
2.1.2	Composition of Product tested	**Composition of LP OU 28430** **%** [redacted]	
2.1.3	Physical state and nature	Solid	
2.1.4	Monitoring of active substance concentration	No	X
2.1.5	Method of analysis	-	
2.2	**Reference substance**	None	X
2.2.1	Method of analysis for reference substance	-	
2.3	**Testing procedure**	-	
2.3.1	Test population / inoculum / test organism	Test organism: larvae of house longhorn beetle *Hylotrupes bajulus (L)* (6 larvae/test block with a maximum of 3 days of hatching)	X
2.3.2	Test system	Scots pine sapwood (*Pinus sylvestris*) was treated with a defined amount of the product carried by butanone. Product was applied by vacuum pressure. The wood article was conditioned during 28 days after the application. The duration of the biological test was 4 weeks.	X
		Conditions in the culturing chamber: 27-29 °C±1°C; 85%± 5 % r.h with air circulation. Conditions in the conditioning chamber: 20 °C±2°C; 65 ± 5 % r.h.; well ventilated. And in the testing chamber: 21-23 °C±1°C;	

Section A5.3
Annex Point IIA5.3

Efficacy Data (1)

Efficacy of Thiacloprid on wood against the house longhorn beetle *Hylotrupes bajulus (L).*

		70-75 ± 5 % r.h. Dimensions of test specimens: approx. 50 mm x 25 mm x 15 mm. Number of survivors was registered. Larvae that before dying made some wood damage were counted.	
2.3.3	Application of TS	Vacuum pressure.	
2.3.4	Test conditions	The test substance was solved in butanone and then applied to the samples by vacuum pressure. 5 wood blocks were tested per treatment concentration. 30 larvae were used. Concentrations tested: 0, 0.00025, 0.0025, 0.0075, 0.012, 0.023 %.	X
2.3.5	Duration of the test / Exposure time	Test duration: 28 days Exposure time: Single application	X
2.3.6	Number of replicates performed	5	
2.3.7	Controls	Negative control: The damaging activity of the insects is verified by exposure untreated wood to the insects. Solvent control: butanone influence in efficacy testing was checked	
2.4	**Examination**		
2.4.1	Effect investigated	Gnawing and mortality rate of the larvae	
2.4.2	Method for recording / scoring of the effect	The number of surviving larvae and number of dead gnawing larvae are registered	
2.4.3	Intervals of examination	Test wood samples were assessed at the 4th week after incubation	
2.4.4	Statistics	The arithmetic mean was calculated from all 5 wood samples per treatment concentration.	
2.4.5	Post monitoring of the test organism	No	X
		3 RESULTS	
3.1	**Efficacy**		
3.1.1	Dose/Efficacy curve	No	
3.1.2	Begin and duration of effects	-	
3.2	**Effects against organisms or objects to be protected**	In negative control samples that did not receive a protective coating, all test wood articles were strongly bored at the time of testing.	X
3.3	**Other effects**	None	
3.4	**Efficacy of the reference substance**	Not applicable	

Section A5.3
Annex Point IIA5.3

Efficacy Data (1)

Efficacy of Thiacloprid on wood against the house longhorn beetle *Hylotrupes bajulus (L).*

3.5	**Tabular and/or graphical presentation of the summarised results**	See attached Table A5_3-1	X
3.6	**Efficacy limiting factors**	None	
3.6.1	Occurrences of resistances	–	
3.6.2	Other limiting factors	–	
		4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1	**Reasons for laboratory testing**	Testing according to EN 47 is a standard procedure for efficacy assessment for wood preservatives.	
4.2	**Intended actual scale of biocide application**	The applied amount of wood preservative and active substance is comparable with the intended scale of product to be applied in practice.	
4.3	**Relevance compared to field conditions**	-	
4.3.1	Application method	Vacuum pressure application is one of the intended application methods envisaged.	
4.3.2	Test organism	Yes, the test organisms are among the intended target organisms.	
4.3.3	Observed effect	Yes, the protective effect was significant.	
4.4	**Relevance for read-across**	Yes	X
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The protective effectiveness of the active substance thiacloprid against house longhorn beetle *Hylotrupes bajulus (L)* in service was assessed according to DIN EN 47 (08/90). The substrate was Scots pine (*Pinus sylvestris*). The test formulation was applied at different concentrations; the test blocks were inoculated with the longhorn beetle and incubated for 4 weeks. The test blocks were scored for gnawing and surviving larvae were counted.	
5.2	**Reliability**	[redacted]	
5.3	**Assessment of efficacy, data analysis and interpretation**	Thiacloprid applied by vacuum pressure, provided substantial protection against the wood-destroying action of the house longhorn beetle *Hylotrupes bajulus (L)* at the lowest tested concentration (1.0 g/m^3). The test meets the criteria of EN 47.	X X
5.4	**Conclusion**	The test is valid.	X
5.5	**Proposed efficacy specification**	The test formulation applied by vacuum pressure provided substantial protection against the wood-destroying action of the test beetles.	X

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 19/12/06

Materials and Methods

[redacted]

Evaluation by Competent Authorities

Results and Discussion

3.2 any adverse effects observed in the test should be reported in this section.

[redacted]

Concentration % w/w	Mean retention of preservative ($g\ m^{-3}$)	Mean number of survivors (after 4 w)
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]

Conclusion

[redacted]

Reliability

[redacted]

Evaluation by Competent Authorities	
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Comments	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Table A5_3-1 Results of the efficacy of thiacloprid against the larvae of house longhorn beetles (*Hylotrupes bajulus L.*) according to the EN 47 without ageing procedure

Test period	Test concentrations	Solution retention per test block (TB)			Preservative retention	Recovered larvae			Not recovered larvae
		Min.	Mean (5TB)	Max.	Mean	Dead		Survivors	
						Not gnawed	Gnawed		
[Weeks]	[%]	[g]	[g]	[g]	[g m^{-3}]	Number	Number	Number	Number
4	0.00025	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	0.0025	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	0.0075	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	0.012	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	0.023	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Control-solvent	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Control-untreated sample	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Section A5.3
Annex Point IIA5.3

Efficacy Data (2)

Efficacy of thiacloprid on wood against the house longhorn beetle *Hylotrupes bajulus* (L).

			Official use only
		1 REFERENCE	
1.1	**Reference**	Schumacher, P., and Fennert, E.-M. (2001a): Determination of the toxic values of LP OU 28430 against larvae of *Hylotrupes bajulus* (L.) according to EN 47 (08/90) after leaching procedure according to EN 84 (05/97). Materialprüfungsamt des Landes Brandenburg, Germany, Report-No. 3.2/00/8105/03, unpublished, date: 2001-05-15.	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
1.3	**Guideline study**	Yes; EN 47 (08/90) and EN 84 (for ageing by leaching procedure, 05/07)	
1.4	**Deviations**	[redacted]	
		2 METHOD	
2.1	**Test Substance (Biocidal Product)**		
2.1.1	Trade name/ proposed trade name	**LP OU 28430 (developmental code)**	
2.1.2	Composition of Product tested	**Composition of LP OU 28430** **%** [redacted]	
2.1.3	Physical state and nature	Solid	
2.1.4	Monitoring of active substance concentration	No	X
2.1.5	Method of analysis	-	
2.2	**Reference substance**	None	X
2.2.1	Method of analysis for reference substance	-	
2.3	**Testing procedure**	-	
2.3.1	Test population / inoculum / test organism	Test organism: larvae of house longhorn beetle *Hylotrupes bajulus* (L.) (6 larvae/test block with a maximum of 3 days of hatching)	X
2.3.2	Test system	Areas of Scots pine sapwood (*Pinus sylvestris*) were treated with a defined amount of the product carried by butanone. Product was applied by vacuum pressure. After application and conditioning period (28 days) the wood article was artificially aged by leaching (14 days). The duration of the biological test was 12 weeks. Conditions in the culturing chamber: 27-29 °C±1°C; 85%± 5 % r.h with	X

Section A5.3 Annex Point IIA5.3 — **Efficacy Data (2)**

Efficacy of thiacloprid on wood against the house longhorn beetle *Hylotrupes bajulus* (L).

		air circulation. Conditions in the conditioning chamber: 20 °C±2°C; 65 ± 5 % r.h.; well ventilated. And in the testing chamber: 21-23 °C±1°C; 70-75 ± 5 % r.h. Dimensions of test specimens: approx. 50 mm x 25 mm x 15 mm. Number of survivors was registered. Larvae that before dying made some wood damage were counted.	
2.3.3	Application of TS	Vacuum pressure.	
2.3.4	Test conditions	The test substance was solved in butanone and then applied to the samples by vacuum pressure. 5 wood blocks were tested per treatment concentration. 30 larvae were used. Concentrations tested: 0, 0.00011, 0.0002, 0.0004, 0.0011, and 0.002 %.	X
2.3.5	Duration of the test / Exposure time	Test duration: 12 weeks Exposure time: Single application	
2.3.6	Number of replicates performed	5	
2.3.7	Controls	Negative control: The damaging activity of the insects is verified by exposure untreated wood to the insects without being subjected to an ageing procedure. Negative control with ageing procedure: same as above but with ageing procedure. Solvent control: butanone influence in efficacy testing was checked	
2.4	**Examination**		
2.4.1	Effect investigated	Gnawing and mortality rate of the larvae	
2.4.2	Method for recording / scoring of the effect	Number of survivors and larvae that had bored were registered	
2.4.3	Intervals of examination	Test wood samples were assessed at the 12th week (at the 4th for some concentrations) after incubation. See Table A5_3-1	
2.4.4	Statistics	The arithmetic mean was calculated from all samples per treatment concentration.	
2.4.5	Post monitoring of the test organism	No	X
		3 RESULTS	
3.1	**Efficacy**		
3.1.1	Dose/Efficacy curve	-	
3.1.2	Begin and duration of effects	-	

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Annex Point IIA5.3

Efficacy Data (2)

Efficacy of thiacloprid on wood against the house longhorn beetle *Hylotrupes bajulus* (L).

3.2	**Effects against organisms or objects to be protected**	In negative control samples that did not receive a protective coating, almost all larvae survived.	X
3.3	**Other effects**	None	
3.4	**Efficacy of the reference substance**	-	
3.5	**Tabular and/or graphical presentation of the summarised results**	See attached Table A5_3-1	X
3.6	**Efficacy limiting factors**	None	
3.6.1	Occurrences of resistances	–	
3.6.2	Other limiting factors	–	
		4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1	**Reasons for laboratory testing**	Testing according to EN 47 and EN 84 are standard procedures for efficacy assessment for wood preservatives.	
4.2	**Intended actual scale of biocide application**	The applied amount of wood preservative and active substance is comparable with the intended scale of product to be applied in practice.	
4.3	**Relevance compared to field conditions**	-	
4.3.1	Application method	Vacuum pressure application is one of the intended application methods envisaged.	
4.3.2	Test organism	Yes, the test organisms are among the intended target organisms.	
4.3.3	Observed effect	Yes, the protective effect was significant.	
4.4	**Relevance for read-across**	Yes	X
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The protective effectiveness of thiacloprid against house longhorn beetle *Hylotrupes bajulus* (L) in service was assessed according to DIN EN 47 (08/90) combined with an ageing procedure by leaching according to EN 84 (50/97). The substrate was blocks of Scots pine (*Pinus sylvestris*). Thialcoprid as applied at different concentrations; the test blocks were inoculated with the longhorn beetle and incubated for 12 weeks. Surviving larvae were counted.	
5.2	**Reliability**	[redacted]	
5.3	**Assessment of efficacy, data analysis and interpretation**	Thiacloprid applied by vacuum pressure, provided substantial protection against the wood-destroying action of the house longhorn beetle *Hylotrupes bajulus* (L). The lowest protective tested concentration was in the range of 0.53-0.96 g/m^3. The test meets the criteria of EN 47 and EN 84.	X

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Efficacy Data (2)

Efficacy of thiacloprid on wood against the house longhorn beetle *Hylotrupes bajulus* (L).

5.4	**Conclusion**	The test is valid.	X
5.5	**Proposed efficacy specification**	Thiacloprid applied by vacuum pressure provided substantial protection against the wood-destroying action of the test beetles even though after wood ageing.	X

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 16/04/07

Materials and Methods

[redacted]

Evaluation by Competent Authorities

Results and Discussion

[redacted]

Concentration % w/w	Mean retention of preservative (g m^{-3})	Mean number of survivors (after 12 w)
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]

Conclusion

[redacted]

Reliability

[redacted]

Evaluation by Competent Authorities	
Acceptability	[redacted]
Remarks	[redacted]

Table A5_3-1 Results of the efficacy of thiacloprid against the larvae of house longhorn beetles (*Hylotrupes bajulus L.*) according to the EN 47 after ageing procedure EN 84 by leaching

Test period	Test concentrations	Solution retention of the 5 test blocks			Preservative retention	Recovered larvae			Not recovered larvae
		Min.	Mean (5TB)	Max.		Dead		Survivors	
						Not gnawed	gnawed		
[Weeks]	[%]	[g]	[g]	[g]	[g/m³]	Number	Number	Number	Number
4	0.002	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	0.0011	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
12	0.0011	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	0.0004	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	0.0002	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	0.00011	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Control-solvent	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Control-untreated sample	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Control after EN 84	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

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Efficacy Data (3)

Efficacy of thiacloprid on wood against the house longhorn beetle *Hylotrupes bajulus* (L).

			Official use only
		1 REFERENCE	
1.1	**Reference**	Schumacher, P., and Fennert, E.-M. (2001c): Determination of the toxic values of LP OU 28430 against larvae of *Hylotrupes bajulus* (L) according to EN 47 (08/90) after evaporative ageing procedure according to EN 73 (04/90). Materialprüfungsamt des Landes Brandenburg, Germany, Report-No. 3.2/00/8105/02, unpublished, 2001-07-03.	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
1.3	**Guideline study**	Yes; EN 47 (08/90) and EN 73 (for ageing by evaporation procedure, 04/90)	
1.4	**Deviations**	[redacted]	
		2 METHOD	
2.1	**Test Substance (Biocidal Product)**		
2.1.1	Trade name/ proposed trade name	**LP OU 28430 (developmental code)**	
2.1.2	Composition of Product tested	**Composition of LP OU 28430** **%** [redacted] [redacted]	
2.1.3	Physical state and nature	Solid	
2.1.4	Monitoring of active substance concentration	No	X
2.1.5	Method of analysis	-	
2.2	**Reference substance**	None	X
2.2.1	Method of analysis for reference substance	-	
2.3	**Testing procedure**	-	
2.3.1	Test population / inoculum / test organism	Test organism: larvae of house longhorn beetle *Hylotrupes bajulus (L)* (6 larvae/test block with a maximum of 3 days of hatching)	X
2.3.2	Test system	Areas of Scots pine sapwood (*Pinus sylvestris*) were treated with a defined amount of the product carried by butanone. Product was applied by vacuum pressure. After treatment and conditioning period (28 days) the wood article was artificially aged by evaporation during 3 months. The duration of the biological test was 12 weeks.	X

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Efficacy Data (3)

Efficacy of thiacloprid on wood against the house longhorn beetle *Hylotrupes bajulus* (L).

		Conditions in the culturing chamber: 27-29 °C±1°C; 85%± 5 % r.h with air circulation. Conditions in the conditioning chamber: 20 °C±2°C; 65 ± 5 % r.h.; well ventilated. And in the testing chamber: 21-23 °C±1°C; 70-75 ± 5 % r.h. Dimensions of test specimens: approx. 50 mm x 25 mm x 15 mm. Number of survivors was registered. Larvae that before dying made some wood damage were counted.	
2.3.3	Application of TS	Vacuum pressure.	
2.3.4	Test conditions	The test substance was solved in butanone and then applied to the samples by vacuum pressure. 5 wood blocks were tested per treatment concentration. 30 larvae were used. Concentrations tested: 0, 0.000065, 0.00013, 0.0002, 0.0004, and 0.0011 %.	X
2.3.5	Duration of the test / Exposure time	Test duration: 12 weeks Exposure time: Single application	
2.3.6	Number of replicates performed	5	
2.3.7	Controls	Negative control: The damaging activity of the insects is verified by exposure untreated wood to the insects without ageing. Negative control with ageing procedure: same as above but with ageing. Solvent control: butanone influence in efficacy testing was checked.	
2.4	**Examination**		
2.4.1	Effect investigated	Gnawing and mortality rate of the larvae	
2.4.2	Method for recording / scoring of the effect	Number of survivors and larvae that had bored were registered	
2.4.3	Intervals of examination	Test wood samples were assessed at the 12th week after incubation (at the 4th for some concentrations). See Table A5_3-1	
2.4.4	Statistics	The arithmetic mean was calculated from all samples per treatment concentration.	
2.4.5	Post monitoring of the test organism	No	X
		3 RESULTS	
3.1	**Efficacy**		
3.1.1	Dose/Efficacy curve	-	
3.1.2	Begin and duration of effects	-	
3.2	**Effects against organisms or objects to be protected**	In negative control samples that did not receive a protective coating, all larvae survived.	X
3.3	**Other effects**	None	

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Annex Point IIA5.3

Efficacy Data (3)

Efficacy of thiacloprid on wood against the house longhorn beetle *Hylotrupes bajulus* (L).

3.4	**Efficacy of the reference substance**	-	
3.5	**Tabular and/or graphical presentation of the summarised results**	See attached Table A5_3-1	X
3.6	**Efficacy limiting factors**	None	
3.6.1	Occurrences of resistances	–	
3.6.2	Other limiting factors	–	
		4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1	**Reasons for laboratory testing**	Testing according to EN 47 and EN 73 are standard procedures for efficacy assessment for wood preservatives.	
4.2	**Intended actual scale of biocide application**	The applied amount of wood preservative and active substance is comparable with the intended scale of product to be applied in practice.	
4.3	**Relevance compared to field conditions**	-	
4.3.1	Application method	Vacuum pressure application is one of the intended application methods envisaged.	
4.3.2	Test organism	Yes, the test organisms are among the intended target organisms.	
4.3.3	Observed effect	Yes, the protective effect was significant.	
4.4	**Relevance for read-across**	Yes	X
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Thiacloprid against house longhorn beetle *Hylotrupes bajulus* (L) in service was assessed according to DIN EN 47 (08/90) combined with an ageing procedure by leaching according to EN 73 (04/90). The substrate was blocks of Scots pine (*Pinus sylvestris*). The test formulation was applied at different concentrations; prior to biological testing wood was exposed to a current of air for artificial ageing and then inoculated with the longhorn beetle and incubated for 12 weeks. Surviving larvae were counted.	
5.2	**Reliability**	[redacted]	
5.3	**Assessment of efficacy, data analysis and interpretation**	Thiacloprid applied by vacuum pressure, provided substantial protection against the wood-destroying action of the house longhorn beetle *Hylotrupes bajulus* (L). The lowest protective tested concentration was 0.32 g/m^3. The test meets the criteria of EN 47 and EN 73.	X
5.4	**Conclusion**	The test is valid.	X
5.5	**Proposed efficacy specification**	Thiacloprid applied by vacuum pressure provided substantial protection against the wood-destroying action of the test beetles even though after wood ageing by evaporation.	X

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	16/04/07
Materials and Methods	[redacted]

Evaluation by Competent Authorities

Results and Discussion

[redacted]

Concentration % w/w	Mean retention of preservative (g m^{-3})	Mean number of survivors (after 12 w)
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]

Evaluation by Competent Authorities	
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Comments	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Table A5_3-1 Results of the efficacy of thiacloprid against the larvae of house longhorn beetles (*Hylotrupes bajulus* L.) according to the EN 47 after ageing procedure EN 73 by evaporation

Test period	Test concentrations	Solution retention of the 5 test blocks			Preservative retention	Recovered larvae			Not recovered larvae
		Min.	Mean (5TB)	Max.		Dead		Survivors	
						Not gnawed	Gnawed		
[Weeks]	[%]	[g]	[g]	[g]	[g m^{-3}]	Number	Number	Number	Number
4	0.0011	[redacted]							
	0.0004								
12	0.0004								
	0.0002								
	0.00013								
	0.000065								
	Control-solvent								
	Control-untreated sample								
	Control after EN 73								

Section A5.3
Annex Point IIA5.3

Efficacy Data (4)

Efficacy of thiacloprid on wood against termites *Reticulitermis santonesis* De Feytaud.

			Official use only
		1 REFERENCE	
1.1	**Reference**	Schumacher, P., and Fennert, E-M. (1999b): Bestimmung der Grenze der Wirksamkeit von LP OU 28430 gegenüber Termiten (*Reticulitermis santonesis* De Feytaud) – gemäß DIN EN 117 – (08/90). Materialprüfungsamt des Landes Brandenburg, Germany, Report-No. 3.2/7693/1, unpublished, 1999-12-16.	X
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
1.3	**Guideline study**	Yes; EN 117 (08/90)	
1.4	**Deviations**	[redacted]	
		2 METHOD	
2.1	**Test Substance (Biocidal Product)**		
2.1.1	Trade name/ proposed trade name	**LP OU 28430 (developmental code)**	
2.1.2	Composition of Product tested	**Composition of LP OU 28430** **%** Thiacloprid tech. [redacted]	
2.1.3	Physical state and nature	Solid	
2.1.4	Monitoring of active substance concentration	No	X
2.1.5	Method of analysis	-	
2.2	**Reference substance**	None	X
2.2.1	Method of analysis for reference substance	-	
2.3	**Testing procedure**	-	
2.3.1	Test population / inoculum / test organism	Test organism: termites *Reticulitermis santonesis* De Feytaud (250 workers plus an amount of soldiers and nymphs corresponding to the proportion found in the colony culture, per test block)	X
2.3.2	Test system	Scot pine sapwood (*Pinus sylvestris*) was treated with a defined amount of the product carried by butanone. Product was applied by vacuum pressure. The wood article was conditioned during 28 days after the application. The duration of the biological test was 8 weeks. Conditions in the culturing chamber and in the testing chamber: 26-28 °C±1°C; >75% r.h. with air circulation. Conditions in the	X

Section A5.3 Annex Point IIA5.3 — **Efficacy Data (4)**

Efficacy of thiacloprid on wood against termites *Reticulitermis santonesis* De Feytaud.

		conditioning chamber: 20 °C±2°C; 65 ± 5 % r.h.; well ventilated. Dimensions of test specimens: approx. 50 mm x 25 mm x 15 mm. Number of survivors was registered (differentiating between soldiers, nymphs and workers). The samples were also visually assessed and scored.	
2.3.3	Application of TS	Vacuum pressure.	
2.3.4	Test conditions	The test substance was solved in butanone and then applied to the samples by vacuum pressure. Three wood blocks were tested per treatment concentration. Concentrations tested: 0, 0.00025, 0.0013, 0.00375, 0.012, 0.023 %.	
2.3.5	Duration of the test / Exposure time	Test duration: 8 weeks Exposure time: Single application	
2.3.6	Number of replicates performed	3	
2.3.7	Controls	Negative control: Survivors and aspect of the untreated wood was also assessed. Solvent control: Butanone influence on efficacy testing was checked	
2.4	**Examination**		
2.4.1	Effect investigated	Mortality and attack suffered	
2.4.2	Method for recording / scoring of the effect	The number of surviving termites and degree of damage caused was registered. Additionally, the following scoring was used: 0 = No attack 1 = Attempted attack 2 = Slight attack 3 = Average attack 4 = Strong attack	
2.4.3	Intervals of examination	Test wood samples were assessed at the 8th week after incubation	
2.4.4	Statistics	The arithmetic mean was calculated from all samples per treatment concentration.	
2.4.5	Post monitoring of the test organism	No	X
		3 RESULTS	
3.1	**Efficacy**		
3.1.1	Dose/Efficacy curve	-	
3.1.2	Begin and duration of effects	-	

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Annex Point IIA5.3

Efficacy Data (4)

Efficacy of thiacloprid on wood against termites *Reticulitermis santonesis* De Feytaud.

3.2	**Effects against organisms or objects to be protected**	In negative control samples that did not receive a protective coating, all test wood articles were strongly bored at the time of testing.	X
3.3	**Other effects**	None	
3.4	**Efficacy of the reference substance**	-	
3.5	**Tabular and/or graphical presentation of the summarised results**	See attached Table A5_3-1	X
3.6	**Efficacy limiting factors**	None	
3.6.1	Occurrences of resistances	–	
3.6.2	Other limiting factors	–	
		4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1	**Reasons for laboratory testing**	Testing according to EN 117 is a standard procedure for efficacy assessment for wood preservatives.	
4.2	**Intended actual scale of biocide application**	The applied amount of wood preservative and active substance is comparable with the intended scale of product to be applied in practice.	
4.3	**Relevance compared to field conditions**	-	
4.3.1	Application method	Vacuum pressure application is one of the intended application methods envisaged.	
4.3.2	Test organism	Yes, the test organisms are among the intended target organisms.	
4.3.3	Observed effect	Yes, the protective effect was significant.	
4.4	**Relevance for read-across**	Yes	X
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The protective effectiveness of the active substance thiacloprid against termites *Reticulitermis santonesis* De Feytaud in service was assessed according to DIN EN 117 (08/90). The substrate was blocks of Scots pine (*Pinus sylvestris*). The test formulation was applied at different concentrations; the test blocks were inoculated with the termites and incubated for 8 weeks. Damage on the test blocks was visually assessed and surviving individuals were counted.	
5.2	**Reliability**	[redacted]	
5.3	**Assessment of efficacy, data analysis and interpretation**	Thiacloprid applied by vacuum pressure, provided substantial protection against the wood-destroying action of the termites *Reticulitermis santonesis* De Feytaud at the lowest tested concentration (1.1 g/m^3). The test meets the criteria of EN 117.	X

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Efficacy Data (4)

Efficacy of thiacloprid on wood against termites *Reticulitermis santonesis* De Feytaud.

5.4	**Conclusion**	The test is valid.	X
5.5	**Proposed efficacy specification**	Thiacloprid applied by vacuum pressure provided substantial protection against the wood-destroying action of the test termites.	X

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 17/04/07

Materials and Methods

[redacted]

Evaluation by Competent Authorities

Results and Discussion

[redacted]

Concentration % w/w	Mean retention of preservative ($g\ m^{-3}$)	Mean number of survivors		Average extent of attack
		Workers (%)	Soldiers/ Nymphs	
[redacted]				

[redacted]

Conclusion

[redacted]

Reliability

[redacted]

Evaluation by Competent Authorities	
Acceptability	[redacted]
Remarks	[redacted]

Table A5_3-1 Results of the efficacy of thiacloprid against the larvae of termites (*Reticulitermis s.*) according to the EN 117 without ageing procedure

Test conc. [%]	Number of wood sample	Preservative retention per test block		Results		
			Mean	Survivors		Visual assessment
				Workers	Soldiers/ Nymphs	
		[g m^{-3}]	[g m^{-3}]	Number	Number	
0.00025	361 362 363					
0.0013	390 939 395					
0.00375	403 405 407					
0.012	521 523 524					
0.023	501 502 506					
Control-solvent	468 469 470					
Control-untreated sample	566 567 568					

Section A5.3
Annex Point IIA5.3

Efficacy Data (5)

Efficacy of thiacloprid on wood against termites *Reticulitermis santonesis* De Feytaud.

			Official use only
		1 REFERENCE	
1.1	**Reference**	Schumacher, P., and Fennert, E.-M. (1999c): Bestimmung der Grenze der Wirksamkeit von LP OU 28430 gegenüber Termiten (*Reticulitermis santonesis* De Feytaud) – gemäß DIN EN 117 – (08/90). Kombiniert mit einer Auswaschbeanspruchung – gemäß EN 84 – (05/97). Materialprüfungsamt des Landes Brandenburg, Germany, Report-No. 3.2/7693/2, unpublished, 1999-12-16.	X
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
1.3	**Guideline study**	Yes; EN 117 (08/90) and EN 84 (for ageing by leaching procedure, 05/07)	
1.4	**Deviations**	[redacted]	
		2 METHOD	
2.1	**Test Substance (Biocidal Product)**		
2.1.1	Trade name/ proposed trade name	**LP OU 28430 (developmental code)**	
2.1.2	Composition of Product tested	**Composition of LP OU 28430** **%** Thiacloprid tech. [redacted]	
2.1.3	Physical state and nature	Solid	
2.1.4	Monitoring of active substance concentration	No	X
2.1.5	Method of analysis	-	
2.2	**Reference substance**	None	X
2.2.1	Method of analysis for reference substance	-	
2.3	**Testing procedure**	-	
2.3.1	Test population / inoculum / test organism	Test organism: termites *Reticulitermis santonesis* De Feytaud (250 workers plus an amount of soldiers and nymphs corresponding to the proportion found in the colony culture, per test block)	X
2.3.2	Test system	Scots pine sapwood (*Pinus sylvestris*) was treated with a defined amount of the product carried by butanone. Product was applied by vacuum pressure. After application and conditioning period (28 days) the wood article was artificially aged by leaching (14 days). The duration of the biological test was 8 weeks.	X

Section A5.3
Annex Point IIA5.3

Efficacy Data (5)

Efficacy of thiacloprid on wood against termites *Reticulitermis santonesis* De Feytaud.

		Conditions in the culturing chamber and in the testing chamber: 26-28 °C±1°C; >75% r.h. with air circulation. Conditions in the conditioning chamber: 20 °C±2°C; 65 ± 5 % r.h.; well ventilated. Dimensions of test specimens: approx. 50 mm x 25 mm x 15 mm. Number of survivors was registered (differentiating between soldiers, nymphs and workers). The samples were also visually assessed and scored.	
2.3.3	Application of TS	Vacuum pressure.	
2.3.4	Test conditions	The test substance was solved in butanone and then applied to the samples by vacuum pressure. Three wood blocks were tested per treatment concentration. Concentrations tested: 0, 0.00025, 0.0013, 0.00375, 0.012, 0.023 %.	
2.3.5	Duration of the test / Exposure time	Test duration: 8 weeks Exposure time: Single application	
2.3.6	Number of replicates performed	3	
2.3.7	Controls	Negative control: Survivors and aspect of the untreated wood was also assessed without being subjected to an ageing procedure. Negative control with ageing procedure: same test as above but is subjected to artificial ageing. Solvent control: Butanone influence on efficacy testing was checked.	
2.4	**Examination**		
2.4.1	Effect investigated	Mortality and attack suffered	
2.4.2	Method for recording / scoring of the effect	The number of surviving termites and degree of damage caused was registered. Additionally, the following scoring was used: 0 = No attack 1 = Attempted attack 2 = Slight attack 3 = Average attack 4 = Strong attack	
2.4.3	Intervals of examination	Test wood samples were assessed at the 8th week after incubation	
2.4.4	Statistics	The arithmetic mean was calculated from all samples per treatment concentration.	
2.4.5	Post monitoring of the test organism	No	X
		3 RESULTS	
3.1	**Efficacy**		

Section A5.3
Annex Point IIA5.3

Efficacy Data (5)

Efficacy of thiacloprid on wood against termites *Reticulitermis santonesis* De Feytaud.

3.1.1	Dose/Efficacy curve	-	
3.1.2	Begin and duration of effects	-	
3.2	**Effects against organisms or objects to be protected**	In negative control samples that did not receive a protective coating, all test wood articles were strongly gnawed at the time of testing	X
3.3	**Other effects**	None	
3.4	**Efficacy of the reference substance**	-	
3.5	**Tabular and/or graphical presentation of the summarised results**	See attached Table A5_3-1	X
3.6	**Efficacy limiting factors**	None	
3.6.1	Occurrences of resistances	–	
3.6.2	Other limiting factors	–	
		4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1	**Reasons for laboratory testing**	Testing according to EN 117 and ageing with EN 84 are standard procedures for efficacy assessment for wood preservatives.	
4.2	**Intended actual scale of biocide application**	The applied amount of wood preservative and active substance is comparable with the intended scale of product to be applied in practice.	
4.3	**Relevance compared to field conditions**	-	
4.3.1	Application method	Vacuum pressure application is one of the intended application methods envisaged.	
4.3.2	Test organism	Yes, the test organisms are among the intended target organisms.	
4.3.3	Observed effect	Yes, the protective effect was significant.	
4.4	**Relevance for read-across**	Yes	X
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The protective effectiveness of thiacloprid against termites *Reticulitermis santonesis* De Feytaud in service was assessed according to DIN EN 117 (08/90) combined with an ageing procedure by leaching according to EN 84 (50/97). The substrate was blocks of Scots pine sapwood (*Pinus sylvestris*). The test formulation was applied at different concentrations; leached for artificial ageing and finally the test blocks were exposed to the termites during 8 weeks. The damage on the test blocks was scored and surviving individuals were counted.	
5.2	**Reliability**	[redacted]	

Section A5.3 Annex Point IIA5.3

Efficacy Data (5)

Efficacy of thiacloprid on wood against termites *Reticulitermis santonesis* De Feytaud.

5.3	**Assessment of efficacy, data analysis and interpretation**	Thiacloprid applied by vacuum pressure, provided substantial protection against the wood-destroying action of the termites *Reticulitermis santonesis* De Feytaud at the lowest tested concentration (1.1 g/m^3). The test meets the criteria of EN 117 and EN 84.	X
5.4	**Conclusion**	The test is valid.	X
5.5	**Proposed efficacy specification**	Thiacloprid applied by vacuum pressure provided substantial protection against the wood-destroying action of the test termites even though after ageing.	X

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17/04/07
Materials and Methods	[redacted]

Evaluation by Competent Authorities

Results and Discussion

[redacted]

Concentration % w/w	Mean retention of preservative ($g\ m^{-3}$)	Mean number of survivors		Average extent of attack
		Workers (%)	Soldiers/ Nymphs	
[redacted]				

[redacted]

Evaluation by Competent Authorities	
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Table A5_3-1 Results of the efficacy of thiacloprid against the larvae of termites (*Reticulitermis s.*) according to the EN 117 after ageing procedure EN 84 by leaching

Test conc. [%]	Number of wood sample	Solution retention per test block [g]	Preservative retention per test block [g m^{-3}]	Mean [g m^{-3}]	Results: Survivors Workers Number	Results: Survivors Soldiers/ Nymphs Number	Results: Visual assessment
0.00025	364 365 369						
0.0013	397 400 401						
0.00375	409 412 413						
0.012	507 508 509						
0.023	525 527 528						
Control-solvent	471 472 473						
Control-after EN 84	569 570 571						
Control-untreated sample	572 573 574						

Section A5.3
Annex Point IIA5.3

Efficacy Data (6)

Efficacy of LP OU 28430 on wood against termites *Reticulitermis santonesis* De Feytaud.

			Official use only
		1 REFERENCE	
1.1	**Reference**	Schumacher, P., and Fennert, E.-M. (2001b): Determination of the toxic values of LP OU 28430 against *Reticulitermes santonesis* De Feytaud according to EN 117 (08/90) after evaporative ageing procedure according to EN 73 (04/90). Materialprüfungsamt des Landes Brandenburg, Germany, Report-No. 3.2/00/8105/01, unpublished, date: 2001-06-18.	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
1.3	**Guideline study**	Yes; EN 117 (08/90) and EN 73 (for ageing by evaporation procedure, 04/90)	
1.4	**Deviations**	[redacted]	X
		2 METHOD	
2.1	**Test Substance (Biocidal Product)**		
2.1.1	Trade name/ proposed trade name	**LP OU 28430 (developmental code)**	
2.1.2	Composition of Product tested	**Composition of LP OU 28430** **%** Thiacloprid tech. [redacted]	
2.1.3	Physical state and nature	Solid	
2.1.4	Monitoring of active substance concentration	No	X
2.1.5	Method of analysis	-	
2.2	**Reference substance**	None	X
2.2.1	Method of analysis for reference substance	-	
2.3	**Testing procedure**	-	
2.3.1	Test population / inoculum / test organism	Test organism: termites *Reticulitermis santonesis* De Feytaud (250 workers plus an amount of soldiers and nymphs corresponding to the proportion found in the colony culture, per test block)	X
2.3.2	Test system	Areas of Scots pine sapwood (*Pinus sylvestris*) were treated with a defined amount of the product carried by butanone. Product was applied by vacuum pressure. After application and conditioning period (28 days) the wood article was artificially aged by evaporation (3 months). The	X

		duration of the biological test was 9 weeks. Conditions in the culturing chamber and in the testing chamber: 26-28 °C±1°C; >75% r.h. with air circulation. Conditions in the conditioning chamber: 20 °C±2°C; 65 ± 5 % r.h.; well ventilated. Dimensions of test specimens: approx. 50 mm x 25 mm x 15 mm. Number of survivors was registered (differentiating between soldiers, nymphs and workers). The samples were also visually assessed and scored.	
2.3.3	Application of TS	Vacuum pressure.	
2.3.4	Test conditions	The test substance was solved in butanone and then applied to the samples by vacuum pressure. Three wood blocks were tested per treatment concentration. Concentrations tested: 0, 0.000065, 0.00013, 0.0002, 0.0004, 0.0011 %.	
2.3.5	Duration of the test / Exposure time	Test duration: 9 weeks Exposure time: Single application	
2.3.6	Number of replicates performed	3	
2.3.7	Controls	Negative control: Survivors and aspect of the untreated wood was assessed without being subjected to ageing. Negative control with ageing procedure: same as above but with ageing Solvent control: Butanone influence on efficacy testing was checked	
2.4	**Examination**		
2.4.1	Effect investigated	Mortality and attack suffered	
2.4.2	Method for recording / scoring of the effect	The number of surviving termites and degree of tunnelling caused was registered. Additionally, the following scoring was used: 0 = No attack 1 = Attempted attack 2 = Slight attack 3 = Average attack 4 = Strong attack	
2.4.3	Intervals of examination	Test wood samples were assessed at the 9th week after incubation	
2.4.4	Statistics	The arithmetic mean was calculated from all samples per treatment concentration.	
2.4.5	Post monitoring of the test organism	No	X
		3 RESULTS	
3.1	**Efficacy**		

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Annex Point IIA5.3

Efficacy Data (6)

Efficacy of LP OU 28430 on wood against termites *Reticulitermis santonesis* De Feytaud.

3.1.1	Dose/Efficacy curve	-	
3.1.2	Begin and duration of effects	-	
3.2	**Effects against organisms or objects to be protected**	In negative control samples that did not receive a protective coating, all test wood articles were strongly bored at the time of testing.	X
3.3	**Other effects**	None	
3.4	**Efficacy of the reference substance**	Not applicable	
3.5	**Tabular and/or graphical presentation of the summarised results**	See attached Table A5_3-1	X
3.6	**Efficacy limiting factors**	None	
3.6.1	Occurrences of resistances	–	
3.6.2	Other limiting factors	–	
		4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1	**Reasons for laboratory testing**	Testing according to EN 117 and ageing with EN 73 are standard procedures for efficacy assessment for wood preservatives.	
4.2	**Intended actual scale of biocide application**	The applied amount of wood preservative and active substance is comparable with the intended scale of product to be applied in practice.	
4.3	**Relevance compared to field conditions**	-	
4.3.1	Application method	Vacuum pressure application is one of the intended application methods envisaged.	
4.3.2	Test organism	Yes, the test organisms are among the intended target organisms.	
4.3.3	Observed effect	Yes, the protective effect was significant.	
4.4	**Relevance for read-across**	Yes	X

Section A5.3
Annex Point IIA5.3

Efficacy Data (6)

Efficacy of LP OU 28430 on wood against termites *Reticulitermis santonesis* De Feytaud.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The protective effectiveness of thiacloprid against termites *Reticulitermis santonesis De Feytaud* in service was assessed according to DIN EN 117 (08/90) combined with an ageing procedure by evaporation according to EN 73 (04/90). The substrate was blocks of Scots pine (*Pinus sylvestris*). The test formulation was applied at different concentrations and exposed to a current of air for artificial ageing; the biological test was assessed after 9 weeks-incubation period. The degree of damage was scored and surviving individuals were counted.	
5.2	**Reliability**	[redacted]	X
5.3	**Assessment of efficacy, data analysis and interpretation**	Thiacloprid applied by vacuum pressure, provided substantial protection against the wood-destroying action of the termites *Reticulitermis santonesis* De Feytaud. The lowest protective tested concentration was between the range of 0.66-1.02 g/m^3. The test meets the criteria of EN 117 and EN 73.	X
5.4	**Conclusion**	The test is valid.	X
5.5	**Proposed efficacy specification**	Thiacloprid applied by vacuum pressure provided substantial protection against the wood-destroying action of the test termites even though after wood ageing.	X

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Date	19/12/06

Evaluation by Competent Authorities

Materials and Methods

[redacted]

Evaluation by Competent Authorities

Results and Discussion

[redacted]

Concentration % w/w	Mean retention of preservative ($g\ m^{-3}$)	Mean number of survivors		Average extent of attack
		Workers (%)	Soldiers/ Nymphs	
[redacted]				

[redacted]

Conclusion

[redacted]

Evaluation by Competent Authorities	
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Table A5_3-1 Results of the efficacy of thiacloprid against termites (*Reticulitermis s.*) according to the EN 117 after ageing procedure EN 73 by evaporation

Test concentrations [%]	Number of wood sample	Solution retention per test block [g]	Preservative retention per test block [g m^{-3}]	Mean [g m^{-3}]	Results: Survivors Workers Number	Results: Survivors Soldiers/ Nymphs Number	Results: Visual assessment
0.000065	53 55 56						
0.00013	57 59 60						
0.0002	61 62 64						
0.0004	66 67 68						
0.0011	70 71 72						
Control-solvent	49 50 51						
Control-untreated sample	1 2 3						
Control-after EN 73	4 5 6						

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Annex Point IIA5.3

Efficacy Data (7)

Efficacy of thiacloprid on wood against the common furniture beetle *Anobium punctatum* (de Geer).

			Official use only
		1 REFERENCE	
1.1	**Reference**	Schumacher, P., and Fennert, E.-M. (2002c): Determination of the protective effectiveness of LP OU 28430 against *Anobium punctatum* (de Geer) by egg-laying and larval survival according to EN 49 part 2 – Application by impregnation treatment after leaching procedure according to EN 84 (05/97). Materialprüfungsamt des Landes Brandenburg, Germany, Report-No. 3.2/01/8160/01, unpublished, date: 2002-06-11.	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	X
1.3	**Guideline study**	Yes; EN 49 part 2(08/90) and EN 84 (ageing by leaching procedure, 05/07)	
1.4	**Deviations**	[redacted]	
		2 METHOD	
2.1	**Test Substance (Biocidal Product)**		
2.1.1	Trade name/ proposed trade name	**LP OU 28430 (developmental code)**	
2.1.2	Composition of Product tested	**Composition of LP OU 28430** **%** Thiacloprid tech. [redacted]	
2.1.3	Physical state and nature	Solid	
2.1.4	Monitoring of active substance concentration	No	X
2.1.5	Method of analysis	-	
2.2	**Reference substance**	None	X
2.2.1	Method of analysis for reference substance	-	
2.3	**Testing procedure**	-	
2.3.1	Test population / inoculum / test organism	Test organism: common furniture beetle *Anobium punctatum* (de Geer) (eggs laid and hatched in the control test: 425)	
2.3.2	Test system	Areas of Sessile oak wood (*Quercus petraea*) were treated with a defined amount of the product carried by butanone. Product was applied by vacuum pressure. Previous testing wood was conditioned (28 days) and artificially aged by leaching (14 days). The duration of the	

Section A5.3
Annex Point IIA5.3

Efficacy Data (7)

Efficacy of thiacloprid on wood against the common furniture beetle *Anobium punctatum* (de Geer).

		biological test was 52 weeks. Numbers of surviving larvae, eggs-laid and hatched were registered.	
2.3.3	Application of TS	Vacuum pressure.	
2.3.4	Test conditions	The test substance was solved in butanone and then applied to the samples by vacuum pressure. 5 wood blocks were tested per treatment concentration. A total of 425 eggs were used for testing in the control tests. Concentrations tested: 0, 0.0006, 0.0014, 0.0028, 0.006, and 0.013 %.	
2.3.5	Duration of the test / Exposure time	Test duration: 52 weeks Exposure time: Single application	
2.3.6	Number of replicates performed	5	
2.3.7	Controls	Negative control: The number of egg-laying and hatching, larval survival are verified by exposure of untreated wood to the gravid females of *Anobium punctatum.* Solvent control: butanone influence in efficacy testing was checked	X
2.4	**Examination**		
2.4.1	Effect investigated	Egg-laying and hatching, larval survival	
2.4.2	Method for recording / scoring of the effect	Number of eggs laid and hatched, number of test blocks with living larvae and number of living larvae recovered	
2.4.3	Intervals of examination	Test wood samples were assessed at the 52^th week after incubation. See Table A5_3-1	
2.4.4	Statistics	The arithmetic average was calculated from all samples per treatment concentration.	
2.4.5	Post monitoring of the test organism	No	X
		3 RESULTS	
3.1	**Efficacy**		
3.1.1	Dose/Efficacy curve	-	
3.1.2	Begin and duration of effects	-	
3.2	**Effects against organisms or objects to be protected**	In negative control samples that did not receive a protective coating, almost all larvae survived.	X
3.3	**Other effects**	None	
3.4	**Efficacy of the reference substance**	-	

Section A5.3
Annex Point IIA5.3

Efficacy Data (7)

Efficacy of thiacloprid on wood against the common furniture beetle *Anobium punctatum* (de Geer).

3.5	**Tabular and/or graphical presentation of the summarised results**	See attached Table A5_3-1	X
3.6	**Efficacy limiting factors**	None	
3.6.1	Occurrences of resistances	–	
3.6.2	Other limiting factors	–	
		4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1	**Reasons for laboratory testing**	Testing according to EN 49 part 2 and EN 84 are standard procedures for efficacy assessment for wood preservatives.	
4.2	**Intended actual scale of biocide application**	The applied amount of wood preservative and active substance is comparable with the intended scale of product to be applied in practice.	
4.3	**Relevance compared to field conditions**	-	
4.3.1	Application method	Vacuum pressure application is one of the intended application methods envisaged.	
4.3.2	Test organism	Yes, the test organisms are among the intended target organisms.	
4.3.3	Observed effect	Yes, the protective effect was significant.	
4.4	**Relevance for read-across**	Yes	X
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Thiacloprid against common furniture beetle *Anobium punctatum* (de Geer) in service was assessed according to DIN EN 49 part 2 combined with an ageing procedure by leaching according to EN 84 (05/97). The substrate was blocks of Sessile oak (*Quercus petraea*). The test formulation was applied at different concentrations; the test blocks were inoculated with the common furniture beetle and incubated for 52 weeks. Surviving larvae and number of laid eggs and hatched were counted.	
5.2	**Reliability**	[redacted]	
5.3	**Assessment of efficacy, data analysis and interpretation**	Thiacloprid applied by vacuum pressure, provided substantial protection against the wood-destroying action of the common furniture beetle *Anobium punctatum* (de Geer). The lowest protective tested concentration was 1.87 g/m^3. The test meets the criteria of EN 49 part 2 and EN 84.	X
5.4	**Conclusion**	The test is valid.	X
5.5	**Proposed efficacy specification**	Thiacloprid applied by vacuum pressure provided substantial protection against the wood-destroying action of the test beetles even though after wood ageing.	X

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	19/12/06
Materials and Methods	[redacted]

Evaluation by Competent Authorities

Results and Discussion

[redacted]

Conclusion

[redacted]

Reliability

[redacted]

Evaluation by Competent Authorities	
Acceptability	[redacted]
Remarks	[redacted]

Table A5_3-1 Results of the efficacy of thiacloprid against common furniture beetle *Anobium punctatum* (de Geer) according to the EN 49 part 2 after ageing procedure EN 84 by leaching

Test period	Test concentrations	Solution retention of the 5 test blocks			Preservative retention	Evaluation of the test blocks			
		Min.	Mean (5TB)	Max.		Number of eggs		Number of test blocks with living larvae	Number of living larvae recovered
						laid	hatched		
[Weeks]	[%]	[g]	[g]	[g]	[g/m^3]	Number	Number	Number	Number
52	0 Butanone	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	0.0006	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	0.0014	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	0.0028	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	0.006	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	0.013	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Control-untreated sample	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Section A6.1.1 Acute Toxicity oral (1)

Annex Point IIA6.1.1

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (1996a): YRC 2894 - Study for acute oral toxicity in rats. [redacted] Report No. 25376, date: 1996-08-27. *PPP-Monograph Chapter: B.6.2 Acute toxicity, irritancy and sensitisation. B.6.2.1 Acute oral toxicity (Study 1)*
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes; OECD guideline 401; US-EPA FIFRA § 81-1; Directive 92/69/EEC method B.1
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

Forty fasted Wistar rats were gavaged with a single dose of 62.5-1000 mg/kg bw YRC 2894 (thiacloprid, purity: [redacted]) in demineralised water with 2% v/v Cremophor EL. X

4 RESULTS AND DISCUSSION

The dosing regimen and number of deaths per group are presented in Table A6_1_1-1.

The deaths occurred within 2-8 days after dosing. Clinical signs of systemic toxicity were seen at 100 mg/kg bw and above. The main signs were piloerection, constipation, decreased motility and reactivity, poor reflexes, spastic gait, spasmodic state, convulsions, tremor, tachypnea, dyspnea, laboured breathing, diarrhoea, increased salivation, narrowed palpebral fissure, closed eyelids, red excretion out of the nose and red incrusted snout. These signs were seen within 25 minutes to 6 hours of dosing and lasted up to 5 days in males and up to 8 days in females. There were no clear treatment-related effects on body weight. Gross necropsy of the decedents revealed discoloration of the lungs, liver, spleen, kidneys, stomach, intestines and adrenal glands. No gross changes were observed in the animals sacrificed at the end of the study.

The LD_{50} values were 836 and 444 mg/kg bw in males and females, respectively.

Section A6.1.1 Acute Toxicity oral (1)

Annex Point IIA6.1.1

5 CONCLUSION

5.1 Conclusion

Since LD_{50} values were 836 and 444 mg/kg bw in males and females, respectively, the test material must be classified as 'Harmful' (if swallowed) according to Directive 93/21/EEC.

[redacted]

5.1.1 Reliability

[redacted]

Section A6.1.1 Acute Toxicity oral (1)

Annex Point IIA6.1.1

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14/06/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A6_1_1-1 Mortalities following a single gavage dose to fasted rats

Dose	Deaths	
(mg/kg bw)	Males	Females
62.5	[redacted]	[redacted]
100	[redacted]	[redacted]
300	[redacted]	[redacted]
500	[redacted]	[redacted]
700	[redacted]	[redacted]
1000	[redacted]	[redacted]

Section A6.1.1 Acute oral toxicity (2)

Annex Point IIA6.1.1

Official use only

1 REFERENCE

1.1	**Reference**	[redacted]1995a): YRC 2894 - Pilot toxicity study on rats [redacted] Report No. 23861, date: 1995-03-22. *PPP-Monograph Chapter: B.6.2 Acute toxicity, irritancy and sensitisation. B.6.2.1 Acute oral toxicity (Study 2)*	X
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes; OECD guideline 401; US-EPA FIFRA § 81-1
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

In a 1994 pilot study, 5 non-fasted Wistar rats were gavaged with a single dose of 100-5000 mg/kg bw YRC 2894 (thiacloprid) (purity: [redacted]) in demineralised water with 2% v/v Cremophor EL. The observation period was 48 hours.

4 RESULTS AND DISCUSSION

The dosing regimen and number of deaths per group are presented in Table A6_1_1-1.

The deaths occurred within 3-48 hours after dosing. Clinical signs were seen at all dose levels and included decreased motility and reactivity, poor reflexes, spastic gait, spasmodic state, convulsions, tremor, tachypnea, dyspnea, laboured breathing, diarrhoea, increased salivation, narrowed palpebral fissure, red incrusted margins of eyes. These signs were seen within 59 minutes to 4 hours after dosing and lasted up to 6 days. Transient effects on body weight gain were observed in both sexes. Gross necropsy revealed no clear treatment-related findings.

The LD_{50} values were 621 and 396 mg/kg bw in males and females, respectively.

Section A6.1.1 Acute oral toxicity (2)

Annex Point IIA6.1.1

5 CONCLUSION

5.1 Conclusion

Since LD_{50} values were 621 and 396 mg/kg bw in males and females, respectively, the test material must be classified as 'Harmful' (if swallowed) according to Directive 93/21/EEC.

[redacted]

5.1.1 Reliability

[redacted]

Section A6.1.1 Acute oral toxicity (2)

Annex Point IIA6.1.1

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14/06/2006
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A6_1_1-1 **Acute oral toxicity in female rats Mortalities following a single gavage dose to non-fasted rats**

Dose	Deaths	
(mg/kg bw)	Males	Females
100	[redacted]	[redacted]
140	[redacted]	[redacted]
225	[redacted]	[redacted]
370	[redacted]	[redacted]
425	[redacted]	[redacted]
500	[redacted]	[redacted]
600	[redacted]	[redacted]
700	[redacted]	[redacted]
1000	[redacted]	[redacted]
2500	[redacted]	[redacted]
5000	[redacted]	[redacted]

Section A6.1.1 Acute oral Toxicity (3)

Annex Point IIA6.1.1 **M02**

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] 1995b *[Monograph: 1995c]* [redacted] Study for acute oral toxicity in rats [redacted] Report No. 24553, date: 1995-12-01. *PPP-Monograph Chapter: B.6.8 Other toxicological studies. B.6.8.1 Toxicity of metabolites – a) Acute oral toxicity (Study 1)*
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes; OECD guideline 401; US-EPA FIFRA § 81-1; Directive 92/69/EEC method B.1
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

In a 1995 study, Wistar rats (5/sex/dose) were gavaged with a single dose of 2000 mg/kg bw M02 (purity: [redacted]) in demineralised water with 2% v/v Cremophor EL. In addition, 5 males were dosed with 500 mg/kg bw.

4 RESULTS AND DISCUSSION

A single female died in the top dose group. Clinical signs of toxicity were observed in both sexes and included piloerection, decreased motility, spastic and incoordinated gait, tachypnea, laboured breathing, narrowed palpebral fissure, poor reflexes and spontaneous vocalization. These overt signs were evident between 3-6 hours post-treatment and lasted up to 2 days in males and 3 days in females. No gross treatment-related findings were detected at necropsy. The LD_{50} value for the test material was greater than 2000 mg/kg bw for both sexes.

5 CONCLUSION

5.1	**Conclusion**	M02 is of low acute toxicity to rats following oral administration (LD_{50} > 2000 mg/kg bw). [redacted]
5.1.1	Reliability	[redacted]

Section A6.1.1 Acute oral Toxicity (3)

Annex Point IIA6.1.1 **M02**

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27/06/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.1.1 Acute oral Toxicity (4)

Annex Point IIA6.1.1 **M30**

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] 1996d) [redacted] (YRC 2894 metabolite) - Study for acute oral toxicity in rats [redacted] Report No.: 24794, date: 1996-02-15. *PPP-Monograph Chapter: B.6.8 Other toxicological studies. B.6.8.1 Toxicity of metabolites – a) Acute oral toxicity (Study 2)*
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes OECD guideline 401; US-EPA FIFRA § 81-1; Directive 92/69/EEC method B.1
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

In a 1995 limit test, Wistar rats (5/sex/dose) were gavaged with a single dose of 2000 mg/kg bw M30 (purity: [redacted]) in demineralised water with 2% v/v Cremophor EL.

4 RESULTS AND DISCUSSION

No deaths occurred during the study. Clinical signs were observed 4-hour post treatment and included diarrhoea and lack of faeces. All overt signs had resolved within 2 days of treatment. No gross treatment-related findings were detected at necropsy. The LD_{50} value for the test material was greater than 2000 mg/kg bw for both sexes.

5 CONCLUSION

5.1	**Conclusion**	M30 is of low acute toxicity to rats following oral administration (LD_{50} > 2000 mg/kg bw). [redacted]
5.1.1	Reliability	[redacted]

Section A6.1.1 Acute oral Toxicity (4)

Annex Point IIA6.1.1 **M30**

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27/06/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.1.2 Acute dermal Toxicity

Annex Point IIA6.1.2

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] 1996b): YRC 2894 - Study for acute dermal toxicity in rat[redacted] Report No. 24879, date: 1996-03-11. *PPP-Monograph Chapter: B.6.2 acute toxicity, irritancy and sanitation. B.6.2.1 Acute oral toxicity*
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes; OECD guideline 402; US-EPA FIFRA § 81-2; Directive 92/69/EEC method B.3
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

In a 1995 limit test, Wistar rats (5/sex) were dermally administered a single dose of 2000 mg/kg bw YRC 2894 (thiacloprid) (purity: [redacted]). The test substance was moistened with 0.9% NaCl solution to form a paste and applied to shorn dorsal skin under an occlusive dressing for 24 hours.

4 RESULTS AND DISCUSSION

No deaths occurred during the study. There were no clinical signs of toxicity or local skin reactions. Body weights were not affected by treatment. No gross findings were observed at necropsy. The dermal LD_{50} value of the test substance was greater than 2000 mg/kg bw in male and female rats.

5 CONCLUSION

5.1	**Conclusion**	As LD_{50} was > 2000 mg/kg bw, thiacloprid is not classifiable via the dermal route according to Directive 93/21/EEC. [redacted]
5.1.1	Reliability	[redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14/06/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.1.3 Acute inhalation Toxicity

Annex Point IIA6.1.3

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] 1996): YRC 2894 - Acute inhalation toxicity study on rats according to OECD No. 403 [redacted] Report No. 24775, date: 1996-02-09. *PPP-Monograph Chapter: B.6.2 acute toxicity, irritancy and sanitation. B.6.2.3 Acute inhalation toxicity*
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes; OECD guideline 403; US-EPA FIFRA § 81-3; Directive 92/69/EEC method B.2.
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

In a 1994 study, Wistar rats (5/sex/dose) were exposed (directed-flow nose-only) to a solid aerosol of YRC 2894 (thiacloprid) (purity: [redacted]) at concentrations of 80, 481, 1523 or 2535 mg/m3 for 4 hours.

In addition to the clinical observations, body weight measurements and gross necropsy, reflex tests (Functional Observational Battery) were conducted and the rectal temperatures were recorded at the cessation of exposure.

The particle-size distribution of the aerosol is presented in Table A6_1_3-1. The respirability of the particles was adequate at concentrations < 481 mg/m^3. Because of technical difficulties with aerosol generating equipment, the respirability of the aerosol particles was reduced at concentrations exceeding 500 mg/m^3. Despite the lower respirability, female rats died at the higher exposure levels.

4 RESULTS AND DISCUSSION

Deaths occurred between 1 to 7 days post exposure at 1523 (3/5 females) and 2535 mg/m^3 (4/5 females). Clinical signs of systemic toxicity were seen in both sexes at 481 mg/m^3 and above from 4 hours post exposure up to 6 days post exposure. These signs included concentration-dependent bradypnea, dyspnea, laboured breathing, rales, red encrustations around snout and nose, salivation, prostration, blepharospasm, mydriasis, chromodacryorrhea, tremor, reduced motility, apathy, ungroomed hair, hypothermia and piloerection. All animals showed normal reflexes, except some alteration in reflexes at 1523 mg/m^3. Significant body weight reductions were seen at 481 mg/m^3 and above. There were significant concentration-dependent decreases in rectal temperature in

Section A6.1.3 Acute inhalation Toxicity

Annex Point IIA6.1.3

both sexes (Table A6_1_3-2).

Gross necropsy of the decedents revealed reddish coloured lungs with red foci, red intestinal mucosa and red slimy material in the intestine, pale livers with lobulation, and a red colour in the pelvis of the kidneys. No treatment-related findings were seen in the animals killed at the scheduled sacrifice.

The acute inhalation LC_{50} value of the test substance was greater than 2535 mg/m³ air in males and approximately 1223 mg/m³ air in females for a 4 hour exposure.

5 CONCLUSION

5.1 Conclusion

Since LC_{50} values for females were 1223 mg/kg bw, the test material must be classified as 'Harmful' (via the inhalation route) according to Directive 93/21/EEC. X

[redacted]

5.1.1 Reliability [redacted]

Section A6.1.3 Acute inhalation Toxicity

Annex Point IIA6.1.3

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	16/06/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A6_1_3-1 Characterisation of the aerodynanmic particle-size distribution.

Gravimetric Conc mg/m^3	Control	80	481	1523	2535
MMAD (µm)	-	[redacted]	[redacted]	[redacted]	[redacted]
GSD	-	[redacted]	[redacted]	[redacted]	[redacted]
Aerosol mass <3 µm (%)	-	[redacted]	[redacted]	[redacted]	[redacted]

Table A6_1_3-2 Rectal temperatures (°C) immediately after the cessation of exposure.

Gravimetric Conc mg/m^3	0	80	481	1523	2535
Males	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Females	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Section A6.1.4 Acute Toxicity. Skin and eye irritation

Annex Point IIA6.1.4

Official use only

1 REFERENCE

1.1	**Reference**	[redacted]1995c *[Monograph: 1995b]*): YRC 2894 - Study for skin and eye irritation / corrosion in rabbits[redacted]Report No. 24217, date: 1995-08-01. *PPP-Monograph Chapter: B.6.2 acute toxicity, irritancy and sensitation. B.6.2.4 Skin irritancy and B.6.2.5 Eye irritancy*
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes; OECD guidelines 404, 405; US-EPA FIFRA § 81-4, § 81-5; Directive 92/69/EEC method B.4
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

In a 1995 test, 0.5 g YRC 2894 (thiacloprid) (purity: [redacted]) moistened with deionized water was applied to shorn dorso-lateral skin of three New Zealand White rabbits under a semi-occluded dressing for 4 hours. Skin reactions were scored on the Draize scale at 1, 24, 48 and 72 hours post treatment.

In the same study, 100 µl (equivalent to 50 mg) of pulverised YRC 2894 (purity: [redacted]) was instilled into the conjunctival sac of one eye of each of three New Zealand White rabbits. Ocular lesions were scored on the Draize scale at 1, 24, 48 and 72 hours post instillation. Twenty-four hours after instillation, the treated eyes were rinsed with normal saline. A 1% fluorescein solution was applied to the corneal surface to evaluate epithelial damage.

4 RESULTS AND DISCUSSION

Very slight erythema (grade 1) was observed in all three animals but all the skin reactions had resolved by the 72-hour observation point.

No corneal or iridial lesions were evident. Conjunctival redness (grade 1) and swelling (grade 1 & 2) were seen in all three animals at the 1 and 24 hour observation points. All the ocular lesions had resolved by the 48-hour observation point.

Section A6.1.4 Acute Toxicity. Skin and eye irritation

Annex Point IIA6.1.4

5 CONCLUSION

5.1 Conclusion

Thiacloprid (YRC 2894) has no irritant effect to the skin or eyes. X
Therefore, the test substance is not classifiable as an eye irritant according to Directive 93/21/EEC.

[redacted]

5.1.1 Reliability [redacted]

Section A6.1.4 Acute Toxicity. Skin and eye irritation

Annex Point IIA6.1.4

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	16/06/20006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.1.5 Acute Toxicity. Skin sensitisation

Annex Point IIA6.1.5

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] 1996): YRC 2894 - Study for skin-sensitising effects in guinea pigs (Guinea pig Maximization test method according Magnusson and Kligman) [redacted] Report No. 24641, date: 1996-01-16. *PPP-Monograph: B.6.2 Acute toxicity. B.6.2.6 Skin sensitisation*
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes; Magnusson and Kligman maximisation test (OECD guideline 406; US-EPA FIFRA § 81-6; Directive 92/69/EEC method B.6)
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

In a 1995 study, the skin sensitisation potential of YRC 2894 (thiacloprid) (purity: [redacted]) was investigated in female Dunkin-Hartley guinea pigs. The test material was suspended in physiological saline containing 2% Cremophor EL.

Dose levels for the induction and challenge treatments were based on the results of range-finding studies. Intradermal injections of the test material (0.1 ml) at concentrations ranging between 0-5% were evaluated after 24 and 48 hours. Topical induction applications of the test material (0.5 ml) at concentrations of 0, 12.5, 25 and 50% were evaluated at 48 and 72 hours after the start of the application. These injections and topical applications did not induce skin reactions. One week prior to the challenge, the challenge concentrations were evaluated on 5 guinea pigs that were treated in the same manner as the control animals during the induction treatment. Slight localised erythema (grade 1) was observed in 2 guinea pigs with the 50% concentration. The following concentrations were selected for the main study: intradermal induction 5%, topical induction 50% and challenge 25%.

In the main study, one test group of ten animals and two control groups each consisting of 5 animals were used. The second control group was held in reserve in case a second challenge or further investigations were required. Each test animal received 3 pairs of the following intradermal induction injections (0.1 ml) into shorn skin in the scapular region: i) Freunds Complete Adjuvant (FCA) diluted 1:1 with physiological saline solution, ii) 5% YRC 2894 in the vehicle, iii) 5% YRC 2894 formulated in the vehicle and FCA (1:1). Six days after the

injections, topical application of 10% sodium lauryl sulphate in vaseline was applied to the injection sites. Twenty-four hours later, a topical induction application of 50% YRC 2894 (0.5 ml) was applied to the injection sites under an occlusive dressing for 48 hours. The vehicle control animals received the same induction treatment without the test material.

Fourteen days after topical induction, both the test and one vehicle control group were administered topical challenge applications to shorn flank skin for 24 hours under an occlusive dressing. Each animal was administered 25% YRC 2894 (0.5 ml) on the left flank (caudal) and vehicle on the left flank (cranially). At the end of the exposure period, the application sites were cleaned with physiological saline. The skin reactions were scored at 48 and 72 hours after the start of the challenge applications (scale 0-3).

4 RESULTS AND DISCUSSION

Only 1/10 test animal produced a positive response (grade 1) to the topical challenge applications. Although a positive control group was not included in this study, the sensitivity of the animal stock had been tested in contemporary studies. X

5 CONCLUSION

5.1 Conclusion

Thiacloprid (YRC 2894) has no skin sensitizing potential under the conditions of the Maximization test. Therefore, YRC 2894 is not classifiable as a skin sensitiser according to Directive 93/21/EEC.

[redacted]

5.1.1 Reliability [redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	30/06/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.2
Annex Point IIA6.2

Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study (2)

Dermal absorption

Official use only

1 REFERENCE

1.1 References

1 [redacted] 2002a): An exploratory study to determine the rate and route of elimination of YRC2894 (thiacloprid) when administered intravenously or dermally to male Rhesus monkeys. Report No. M-074260-01-1, unpublished

2 [redacted] 2002b): A study to determine the dermal absorption of ^{14}C-thiacloprid in SC 480 formulation when administered dermally to male Rhesus monkeys. Report No. M-0074257-01-1, unpublished

1.2 Data protection [redacted]

1.2.1 Data owner [redacted]

1.2.2 Companies with letter of access [redacted]

1.2.3 Criteria for data protection [redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study Yes;

US EPA-OPPTS Guideline No. 870.7600
Health Canada PMRA DACO No. 5.8

2.2 GLP [redacted]

2.3 Deviations [redacted]

3 MATERIALS AND METHODS

Exploratory study:

X

In a 2002 study (May/June), the rates and routes of excretion of radioactivity following intravenous (i.v.) and dermal administration to non-naïve male rhesus monkeys was investigated (one monkey per group). Group assignments are given in Table A6_2-1.

For Group 1, one male rhesus monkey was intravenously (i.v.) administered ^{14}C-thiacloprid (radiochemical purity [redacted], 28.9 µCi) at a dose of 234 µg. The animal was remained in the metabolism cage for the duration of the study.

For Group 2, one male rhesus monkey was administered a dermal application of Calypso SC 480 containing ^{14}C-thiacloprid (actual dose 222 µg at 9.25 µg/cm^2) to shaved back skin (4 cm × 6 cm) demarcated with a Duoderm patch to isolate the dosing area. The application site was then covered with an aluminium protective device. The animal was anaesthetised and restrained during dosing; it was then placed in a primate chair for an 8-hour dosing period. After 8 hours, the protective dressings were removed and the application site washed with soapy water and dried. The dose site (4 cm × 1.5 cm) was tape-stripped 16 times (4 sets of four strips). The skin was then swabbed with isopropyl alcohol and washed with soapy water.

For the Group 2 animal, a urine pan/screen wash/wipe was conducted at 4 and 8 hours post-dose and a chair wash/wipe was conducted at 8 hours post-dose after the animal was removed from the chair. Urine and