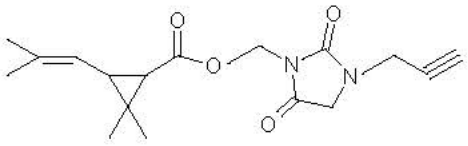
Section A1 Applicant

Annex Point IIA1

1.1	**Applicant**	Name: Dr. Kevan Gartland, Sumitomo Chemical (UK) plc Address: Hythe House, 200 Shepherds Bush Road, London, W6 7NL, UK Telephone: +44 20 7471 3734 Fax number: +44 20 7471 3749 E-mail address: gartland@scuk.sumitomo-chem.co.uk
1.2	**Manufacturer of Active Substance** (if different)	See Confidential Appendix 2.1
1.3	**Manufacturer of Product(s) (if different)**	See Document IIIB, Section 1.2.
	1) Product 1	
	2) Product n	

Section A2 Identity of Active Substance

Subsection (Annex Point)			Official use only
2.1	**Common names (IIA2.1)**	Imiprothrin, Pralle®	x
2.2	**Chemical name (IIA2.2)**	2,5-Dioxo-3-prop-2-ynyl imidazolidin-1-ylmethyl (1RS)-*cis, trans*-2,2-dimethyl-1-(2-methylprop-1-enyl)cyclopropane carboxylate (IUPAC) [2,5-Dioxo-3-(2-propynyl)-1-imidazolidinyl]methyl (1RS)-cis, trans-chrysanthemate	x
2.3	**Manufacturer´s development code number(s) (IIA2.3)**	[redacted]	
2.4	**CAS No and EC numbers (IIA2.4)**		
2.4.1	**CAS-No**	72963-72-5	x
	Isomer 1	-	
	Isomer n	-	
2.4.2	**EC-No**	428-790-6	
	Isomer 1	-	
	Isomer n	-	
2.4.3	**Other**	None	x
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**		
2.5.1	**Molecular formula**	$C_{17}H_{22}N_2O_4$	
2.5.2	**Structural formula**		
2.5.3	**Molecular mass**	318.38	x
2.6	**Method of manufacture of the active substance (IIA2.1)**	See Confidential Appendix	

2.7	**Specification of the purity of the active substance, as appropriate (IIA2.7)**	g/kg	g/L	% w/w	% v/v	x
		-	-	See Confidential Appendix	-	

Section A2 Identity of Active Substance

2.8	**Identity of impurities and additives, as appropriate (IIA2.8)**	See Confidential Appendix
2.8.1	**Isomeric composition**	See Confidential Appendix
2.9	**The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)**	Not applicable

Evaluation by Competent Authorities

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

EVALUATION BY RAPPORTEUR MEMBER STATE

Date *17/05/2010*

Materials and methods *Acceptable with the following amendments:*

2.1 Delete "Pralle"

2.2 Imiprothrin is defined as a mixture of 2 isomers (of a possible 4).

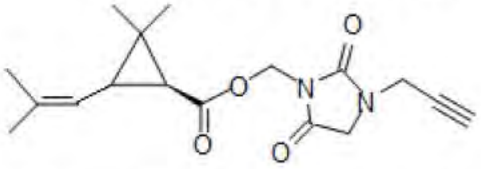
The IUPAC name is given as;

reaction mass of; 2,5-dioxo-3-prop-2-ynylimidazolidin-1-ylmethyl (1R)-cis-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate; 2,5-dioxo-3-prop-2-ynylimidazolidin-1-ylmethyl (1R)-trans-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate (ca 20:80)

2.2 Include CAS name; Cyclopropanecarboxylic acid, 2,2-dimethyl-3-(2-methyl-1-propenyl)-[2,5-dioxo-3-(2-propynyl)-1-imidazolidinyl] methyl ester

2.4.1The CAS number 72963-72-5 refers to the unspecific substance i.e. all 4 isomers rather than the 2 major isomers and is therefore not strictly correct. However the substance has been marketed under this CAS number for over 10 years and this number is quoted in the ISO common name definition.

2.5.2 Replace structure with that of the specific 1R structure below:



2.5.3 Delete entry and replace with "318.37 $gmol^{-1}$"

2.7 Add minimum 87 % w/w

Conclusion *Adopt applicant's version with the amendments detailed above .*

Reliability *0 (no studies have been conducted)*

Acceptability acceptable

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

Section A2.10

Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Subsection		Official use only
2.10.1 Human exposure towards active substance		
2.10.1.1 Production	Imiprothrin is produced outside of the EU. Formulation processes are as follows:	
i) Description of process	Imiprothrin is added to the mixing vessel along with the other components of the formulation. The concentration of imiprothrin within the formulation will either be 0.1% or 0.5% w/w. It is then mixed for specified time, until all components are properly blended and transferred from the mixing vessel and filled into the containers (note that can filling may be conducted by a specialist filling company). Estimated worker exposure scenarios are provided below: A) <u>Transfer of new chemical substance to mixing vessel.</u> 2 workers, exposed for less <1 hour on 300 days per year. The substance is transferred to the mixing vessels (approximately 1-1.75 m^3) by suction (hose connected to drum). B) <u>Mixing</u> 2 workers, exposed for 2 hours on 300 days per year. The concentration of the substance during mixing will be 0.1% w/w. The mixing process is conducted in an automated closed system (under nitrogen). Potential points of release have been identified as volatilisation during mixing, however the volatility of imiprothrin is extremely low. C) <u>Cleanup of mixing vessel</u> 2 workers, exposed for 2 hours on 300 days per year. The concentration of the substance during cleanup will be significantly less than 0.1% w/w. Simple water rinsing will be sufficient for cleaning. Small amounts of imiprothrin may be present in washings from the mixing vessel cleanup. However, these small quantities will either be recycled internally or incinerated in accordance with local and national regulations. D) <u>Filling of end-use containers, valve crimped on and propellant added.</u> 2 workers, exposed for 2 hours on 300 days per year. The concentration of the substance will either be 0.1% or 0.5% w/w. The process is carried out in an enclosed system and workers would not be exposed to the preparation. The environmental impact will be negligible due to the low concentration within the preparation and extremely low volatility of imiprothrin.	
ii) Workplace description	Appropriate PPE and local exhaust ventilation will be provided according to SOP's where there is any potential for exposure.	
iii) Inhalation exposure	Occupational exposure to vapour/aerosol was estimated using EASE2 as 100-200 ppm and is therefore very low. See Document II Risk Assessment for further details.	

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Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

iv) Dermal exposure	Dermal occupational exposure was estimated using EASE2 as 0.1-1 $mg.cm^{-2}.d^{-1}$. [redacted] See Document II Risk Assessment for further details.

2.10.1.2 Intended use(s)

1. Professional Users

i) Description of application process	Public health insecticide. Indoor surface treatment. Use by Pest Control Operators (PCO) treatment for spot, crack and crevice treatment.
ii) Workplace description	The product is intended for surfaces, as a spot crevice spray, applied at distances of 25 to 30 cm. Short bursts are to be applied onto crawling insects (e.g. cockroaches) or into cracks and crevices to flush out crawling insects or on to surfaces where they are likely to run. Prolonged bursts for band treatments are possible and considered to consist of a series of consecutive 1-2 second bursts, with a total spray time of 15-20 seconds. The usage is estimated at twice a week per PCO, at no more than 15 minutes of intermittent spraying, using short bursts of 1-2 seconds. Usage of 2 cans per week would be considered high and 1 can per week would be considered normal for a PCO (reasonable worst case estimate).
iii) Inhalation exposure	[redacted] See Document II Risk Assessment for further details.
iv) Dermal exposure	[redacted] See Document II Risk Assessment for further details.

2. Non-professional Users including the general public

i) Description of application process	Public health insecticide. Indoor surface treatment. Use by the general public for spot, crack and crevice treatment.
ii) Workplace description	Recommended as a 1-2 second spray from 25-30 cm height for a duration of up to 15 -20 seconds per area being treated. It is not thought that Pesguard® LG OBA or Pralle® 0.5% aerosol will be used frequently by the general public. The TGD on Human Exposure to Biocidal Products indicates that 9 times per year is a reasonable worst case estimation of the number of times a member of the general public who routinely uses insecticide products will use crack and crevice aerosols.
(i) via inhalational contact	[redacted] See Document II Risk Assessment for further details.

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Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

(ii) via skin contact	[redacted] See Document II Risk Assessment for further details.
(iii) via drinking water	Significant levels of exposure are not anticipated due to the nature of the area of use as a crack and crevice residual aerosol.
(iv) via food	Significant levels of exposure are not anticipated due to the nature of the area of use as a crack and crevice residual aerosol.
(v) indirect via environment	Significant levels of exposure are not anticipated due to the nature of the area of use as a crack and crevice residual aerosol.

2.10.2 Environmental exposure towards active substance

Imiprothrin is produced outside of the EU. Environmental exposures following formulation are estimated as follows.

2.10.2.1 Production

(i) Releases into water	A standard STP as detailed within the TGD (2003) is assumed. The PEClocal in surface water from formulation of Pesguard LG OBA to be 1.48 x 10^{-5} mg/l. (see Document II: Risk Assessment and EUSES 2.02 printout).
(ii) Releases into air	All of the exhaust from formulation is collected and disposed of in a thermal purification plant, followed by flue-gas scrubbing. This is the reason why no introduction into the atmosphere occurs. Based on the above assumptions and incorporating the available test data the EUSES 2.02 model calculates the PEClocal in air from formulation of Pesguard LG OBA to be 2.34 x 10^{-7} mg/m^3 (see Document II: Risk Assessment and EUSES 2.02 printout).
(iii) Waste disposal	Soil residues following disposal via landfill are calculated to be 0.00115 mg/kg immediately after the application (see Document II: Risk Assessment).

2.10.2.2 Intended use(s)

Affected compartment(s):	
water	86.8%
air	10.1%
sludge	3.17%
Predicted concentration in the affected compartment(s)	
water	A standard STP as detailed within the TGD (2003) is assumed. The EUSES 2.02 model calculates the PEClocal in surface water from formulation to be 6.62 x 10^{-6} mg/L (see Document II: Risk Assessment and EUSES 2.02 printout).

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Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

air	The EUSES 2.02 model calculates the PEClocal in air from use of [redacted] (see Document II: Risk Assessment and EUSES 2.02 printout).
soil	The EUSES 2.02 model calculates the PEClocal in agricultural soil (total) averaged over 30 days from use of [redacted] (see Document II: Risk Assessment and EUSES 2.02 printout).

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and methods	*State if the applicant's version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Conclusion	*Adopt applicant´s version or include revised version*
Reliability	*Based on the assessment of the method include appropriate reliability indicator*
Acceptability	acceptable / not acceptable *(give reasons if necessary, e.g. if a study is acceptable despite a poor reliability indicator). Discuss the relevance of deficiencies.*
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	

Section A3 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 Appearance (IIA3.1)								
3.1.2 Physical state Physical state 1	Physical state was determined at 25°C by three observers	[redacted]	Clear viscous liquid	The test material was technical grade. As both the purified and technical materials are of a high purity ([redacted]), repeating the test would not provide any significant new information.	Y	(2) Reliable with restrictions	Wojcieck BC (1993). [redacted] Technical Grade active Ingredient – Color, Physical State, Odor. [redacted]	x
Physical state 2	Physical state was determined at 25°C by three observers	[redacted]	Clear liquid	None	Y	(1) Valid without restriction	Wojcieck BC (1993). [redacted] Manufacturing Use Product – Color, Physical State, Odor. [redacted]	x
3.1.3 Colour Colour 1	Colour was determined using the Munsell system	[redacted]	Amber 10YR 7/10 (Munsell)	The test material was technical grade. As both the purified and	Y	(2) Reliable with restrictions	Wojcieck BC (1993). [redacted] Technical Grade active Ingredient –	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
		[redacted]		technical materials are of a high purity ([redacted]), repeating the test would not provide any significant new information.			Color, Physical State, Odor. Ricerca Inc., Doc. No. 4067-93-0133-AS-001 (unpublished).	
Colour 2	Colour was determined using the Munsell system	[redacted]	Golden yellow 5Y 8/12 (Munsell)	None	Y	(1) Valid without restriction	Wojcieck BC (1993). S41311 Manufacturing Use Product – Color, Physical State, Odor. Ricerca Inc., Doc. No. 4067-93-0127-AS-001 (unpublished).	x
3.1.4 Odour Odour 1	Odour was determined at 25°C by three observers	[redacted]	Slightly sweet	The test material was technical grade. As both the purified and technical materials are of a high purity ([redacted]), repeating the test would not provide any	Y	(2) Reliable with restrictions	Wojcieck BC (1993). S41311 Technical Grade active Ingredient – Color, Physical State, Odor. [redacted]	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
				significant new information.				
Odour 2	Odour was determined at 25°C by three observers	[redacted]	Sweet	None	Y	(1) Valid without restriction	Wojcieck BC (1993). [redacted] Manufacturing Use Product – Color, Physical State, Odor. [redacted]	x
3.2 Melting point/ freezing point (IIA 3.2)								
Melting pt.	Not applicable			The study is not required as the substance is a liquid at room temperature.				
Freezing point	ISO 3016 equivalent to 92/69/EEC A1 (pour point)	[redacted]	298 +/- 3 K		Y	1	Evans A J , Mullee D M. (2002). Determination of Melting/freezing temperature. SafePharm	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
							Laboratories. Sumitomo Chemical (UK) Plc. [redacted]	
3.3 Acidity, alkalinity (IIA3.3)								
3.4 Boiling point (IIA3.4) Boiling pt.	The method involved boiling the test material is a round-bottom flask, with the boiling point compared to that of a standard material, toluene. Although the method of determination of boiling point is not described within EC A2, it provides a scientifically valid determination of the physical chemical properties of the test substance.	[redacted]	**result:** decomposes before boiling at 128-144°C **pressure:** 746 mm Hg	As both the purified and technical materials are of a high purity ([redacted]), repeating the test using purified material would not provide any significant new information.	Y	(2) Reliable with restrictions	Wojcieck BC (1993). [redacted] Technical Grade Active Ingredient – Boiling Point. [redacted]	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.5 Relative density (IIA3.5) relative density 1	Capilliary pycnometry using pycnometers of known water equivalence. Pycnometry methodology is fully described in method EC A3	[redacted]	Relative density = 1.122	The method followed is as described in EC A3. The study was conducted on technical grade material, rather than purified active substance. As imiprothrin will not be transported in the form in which it is manufactured ([redacted]), a new study using purified ai should not be required as this will not provide information useful to the handling and risk assessment	Y	(2) Reliable with restrictions	Wojcieck BC (1993). [redacted] Technical Grade Active Ingredient – Density. [redacted].	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
				of imiprothrin.				

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
relative density 2	As above	[redacted]	Relative density = 0.979	The active ingredient, as manufactured, will not be transported. [redacted] Thus a density study has been conducted on the MUP.	Y	(1) Valid without restriction	Wojcieck BC (1993). [redacted] (Manufacturing Use Product) – Density. Ricerca Inc., [redacted]	x
3.6 Absorption spectra (IIA3.6)								
UV/VIS	UV-Visible absorption spectra were obtained using a Hitachi Model U-3400 spectrometer. [redacted] was dissolved in ethanol (*ca.* 0.01 mg/ml)	[redacted]	No spectral maximum was observed between 201 nm and 360 nm	The data generated were consistent with the structure of [redacted] The test material was technical grade. As both	N	(2) Reliable with restrictions.	Takashima Y (1993). Spectral studies of [redacted] technical grade. Sumitomo Chemical Co. Environmental Health Science	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
				the purified and technical materials are of a high purity ([redacted]), repeating the test would not provide any significant new information.			Laboratory. [redacted]	
IR	Liquid film method using sodium chloride plates. The IR Spectrophotometer was a Nicolet model 205.	[redacted]	≡C-H(str) 3269cm^{-1} C-H(str) 2969-2874cm^{-1} C≡C (str) 2124cm^{-1} C=O(str) 1792cm^{-1} C=O(str) 1732cm^{-1} C-H(str) 1112cm^{-1} C-H(bend) 854cm^{-1}	The data generated were consistent with the structure of [redacted] The test material was technical grade. As both the purified and technical materials are of a high purity ([redacted]), repeating the test would not provide any significant new information.	N	(2) Reliable with restrictions.	Takashima Y (1993). Spectral studies of [redacted] technical grade. Sumitomo Chemical Co. Environmental Health Science Laboratory. [redacted]	x
NMR	The NMR spectrum was obtained using a Jeol	[redacted]	The proton NMR spectrum consists of the	The data generated were	N	(2) Reliable with	Takashima Y (1993). Spectral	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
	JNM-GSX 270J spectrometer. TMS was used as internal standard	[redacted]	following Chemical Shifts, δ ppm: [redacted]	consistent with the structure of [redacted] The test material was technical grade. As both the purified and technical materials are of a high purity ([redacted]), repeating the test would not provide any significant new information.		restrictions.	studies of [redacted] technical grade. Sumitomo Chemical Co. Environmental Health Science Laboratory. [redacted]	
MS	The mass spectrometer was a Hitachi Model M-80B. The electron ionisation mass spectrum was obtained at 70eV, probe temperature 80-200°C and source temperature 180°C. The accelerating voltage was 3kV.	[redacted]	[redacted]. The mass spectrum shows a molecular ion signal at m/z 318, consistent with active substance.	The data generated were consistent with the structure of [redacted] The test material was technical grade. As both the purified and technical materials are of a high purity ([redacted]), repeating the test would not provide any	N	(2) Reliable with restrictions.	Takashima Y (1993). Spectral studies of [redacted] technical grade. Sumitomo Chemical Co. Environmental Health Science Laboratory. [redacted]	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
				significant new information.				

Section A3 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 Vapour pressure (IIA3.7) Vapour pressure	Gas Saturation Procedure. The Gas Saturation Procedure is fully described in EC A4	[redacted]	**temperature:** 25°C, 35°C, 45°C **result:** 1.86 x 10^{-6} Pa, 1.15x10^{-5} Pa, 9.64 x 10^{-5} Pa respectively	The Gas Saturation Procedure is a well accepted method for the determination of vapour pressures in compounds which have very low vapour pressures Although the test was conducted on technical material, a further test on purified material should not result in a significantly differing result as the vapour pressure is very low.	Y	(2) Reliable with restrictions	Lorence PJ (1994). S41311 – Vapour pressure. [redacted]	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.7.1 Henry´s Law Constant (Pt. I-A3.2)	Calculated using the ratio of the vapour pressure of a solute (Pa) and its solubility in water (mol m^{-3})	Not applicable	**Calculated Result:** 6.33 x 10^{-6} Pa m^3 mol^{-1}	Both the solubility and the vapour pressure were measured values. The test material was technical grade material. As both the purified and technical materials are of a high purity ([redacted]), repeating the test would not provide any significant new information.	Y	(2) Reliable with restrictions	Okada Y (2000). Henry's Law Constant for Imiprothrin (Pralle®). Environmental Health Science Laboratory, [redacted]	x

Section A3 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 Surface tension (IIA3.8) Surface tension	EC Method A5 The surface tension of a 90% saturated aqueous solution was determined with a surface tension/torsion balance using the OECD harmonised ring method	[redacted]	**result:** Test solution 1 = 46.51 mN/m Test solution 2 = 46.75 mN/m Mean = 46.63 mN/m **temperature:** 21±1°C	[redacted] is considered to be a surface active material at 21°C	Y	(1) Reliable without restrictions	Betteley J.M.T. 1997. [redacted] Physicochemical Properties. Huntingdon Life Sciences Ltd., P.O. Box 2, Huntingdon, Cambridgeshire. (unpublished) [redacted]	x
3.9 Solubility in water (IIA3.9) Water solubility	Shake Flask Method. The Shake Flask Method is fully described in EC A6	[redacted]	**result:** 0.0935 g/l **temperature:** 25°C **pH:** 6.5	Imiprothrin has no ionisable groups and undergoes hydrolysis in basic conditions, so the effect of pH on water solubility is not required. The test material	Y	(2) Reliable with restrictions	Lorence PJ (1994). [redacted] –Water solubility. Ricerca Inc., [redacted]	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
				was technical grade. As both the purified and technical materials are of a high purity ([redacted]), repeating the test would not provide any significant new information. Since only one water solubility at an appropriate temperature is adopted to the assessment of predicted environmental concentration (PEC) and Henry's law constant, together with the determination of the design of other studies, e.g. hydrolysis, we believe that the submitted water solubility at 25°C be				

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
				sufficient to the objective of this study as well as the requirement of this guideline.				
3.10 Partition coefficient n-octanol/water (IIA3.10)								

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
log Pow	Shake Flask Method. The Shake Flask Method is fully described in EC A8	[redacted]	**result:** 2.9 **temperature:** 25°C **pH:** 6.2 – 6.6	Since there are no ionisable moieties associated with [redacted], a change in pH will have no effect on the octanol:water coefficient. Since only one partition coefficient (*n*-octanol/water) at an appropriate temperature is adopted to the assessment for bioaccumulation potential of chemical, we believe that the submitted partition coefficient at 25°C be sufficient to the objective of this study as well as the requirement of this guideline.	Y	(1) Reliable without restrictions	Lorence PJ (1994). [redacted] – Octanol/water partition coefficient. [redacted]	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.11 Thermal stability, identity of relevant breakdown products (IIA3.11)	Accelerated Storage Stability based on CIPAC MT 46, where the test material is maintained at 54 °C for a period of 14 days. The percent active ingredient is measured at zero time and at the end of the test. In this test the active ingredient content was also measured after 7 days.	[redacted]	[redacted]	Under the criteria in OECD 113 (1981), for the accelerated storage stability test, if the active substance content decreases by less than 5%, the material is considered to be stable in air.	Y	(1) Reliable without restrictions	Furuta R., Okada Y. (1995). Stability of [redacted] technical grade. Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd. [redacted]	x
	One-year storage stability based on US EPA Guidelines, subdivision D, 63-17. Active ingredient content was measured after 3, 6 and 12 months. The temperature and relative humidity during storage ranged from 18 to 31°C and from 17 to 74% respectively.	[redacted]	[redacted]	The MUP is considered to be stable in air.	Y	(1) Reliable without restrictions	Furuta R., Okada Y. (1995). Storage stability of [redacted] manufacturing use product. Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd. [redacted]	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.12 Reactivity towards container material (IIA3.12)	Storage in a steel can inner-coated with resin (120 mm x 60mm, 50 mm height) and sealed with a lid. Storage was in the dark at ambient temperature (18 to 31°C) and relative humidity ranging from 17 to 74%. Samples were removed for analysis by GC at intervals of 3, 6 and 12 months. In addition to the above-mentioned test, the corrosion characteristics of [redacted] MUP were determined by visual inspection of the storage containers.	[redacted]	There was no detectable degradation of the imiprothrin MUP. The physical state of the material was unchanged, there were no degradation products detected and the active ingredient content did not change by more that 1.2% Visual inspection before storage and after one year's storage was conducted. The storage containers were not affected by storage of the three lots of [redacted] MUP.	The active ingredient as manufactured will not be transported. [redacted] For this reason, a stability study has been conducted on the MUP.	Y	(1) Reliable without restrictions	Furuta R., Okada Y. (1995. Corrosion characteristics of [redacted] Manufacturing Use Product. Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd. [redacted] Furuta R., Okada Y. (1995). Storage stability of [redacted] Manufacturing Use Product at ambient for one year. Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd. [redacted]	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.13 Dissociation constant (-)	OECD 112 (spectrophotometric method)	[redacted]	No measurable dissociation constant could be obtained. S-41311 does not dissociate	None	Y	(1) Reliable without restrictions	Furuta R (1995). Preliminary test for the determination of dissociation constant of [redacted] Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd. [redacted]	x
3.14 Granulometry			Not required	Active substance is a liquid				

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.15 Viscosity (-)	Brookfield Rotational viscometer following method OECD 114 (1981)	[redacted]	**result:** 59 centipoise at 3 rpm 60 centipoise at 6 rpm 60 centipoise at 12 rpm **temperature:** 25 ± 0.2°C	The active ingredient, as manufactured, will not be transported. [redacted] For this reason the viscosity study has been conducted on the MUP.	Y	(1) Reliable without restrictions	Wojcieck BC (1993). [redacted] (Maunfacturing Use product) – Viscosity. [redacted]	x

Section A3 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 Solubility in organic solvents, including the effect of temperature on solubility (IIA3.16)	The study was performed using a method analogus to EC A6. Solubility was determined in n-octanol, methanol, hexane, acetonitrile and acetone	[redacted]	**Result:** Tests were performed at three volume ratios 5/95, 50/50 and 95/5. The test material was soluble in all proportions in n-octanol, methanol, acetonitrile and actone. In hexane the solubility was determined as 0.62g/100 ml **Temperature:** 25 ±1°C	Solvents are representative of polar and non-polar nature organic solvents. Although the test was conducted on technical material, imiprothrin is fully soluble in at least 2 of the solvents (polar and non-polar) so no further testing is required.	Y	(1) Reliable without restrictions	Lorence PJ (1994). [redacted] - Solubility. [redacted]	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.17 Stability in organic solvents used in biocidal product and identity of relevant breakdown products (IIA3.17)	US EPA Guidelines, subdivision D, 63-17	[redacted]	Imiprothrin is stable in the presence of [redacted] for at least one year.	Imiprothrin Manufacturing Use Product contains the solvent isopropyl myristate. A one year stability study is reported under section 3.10/02	Y	(1) Reliable without restrictions	Furuta R., Okada Y. (1995). Storage stability of [redacted] manufacturing use product. Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd. [redacted]	x
4.1 Explosive properties (IIA4.1)	EC Method A14 Koenen test apparatus was used for thermal sensitivity and the fall hammer for determination of mechanical sensitivity	[redacted]	[redacted] does not possess explosive properties.	Mechanical sensitivity: No visible or audible reaction was recorded. Thermal sensitivity: No explosion was observed and there was no deformation to any of the tubes.	Y	(1) Reliable without restrictions	Betteley J.M.T. 1997. [redacted] Physicochemical Properties. Huntingdon Life Sciences Ltd., P.O. Box 2, Huntingdon, Cambridgeshire. (unpublished) [redacted]	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
4.6 Flammable liquids **Flammability, including auto-flammability and identity of combustion products (IIA3.8)**	EC Method A15. ASTM-E659-78	[redacted]	Auto-ignition temperature of [redacted] was determined to be 359°C.	Barometric pressure was 1008 (mbar) Delay was 26 seconds	Y	(1) Reliable without restrictions	Betteley J.M.T. 1997. [redacted] Physicochemical Properties. Huntingdon Life Sciences Ltd., P.O. Box 2, Huntingdon, Cambridgeshire. (unpublished) [redacted]	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
Flammability in contact with water	EC Method A12	Test not conducted. Imiprothrin has not shown any adverse reactions during previous tests performed in water (e.g. solubility, hydrolysis, ready biodegradation) nor have any incidents of adverse reactions occurred during use of the product. This is considered sufficient justification for non-submission of test data.						
Pyrophoric properties	EC Method A13	Test not conducted. Imiprothrin is used in self-pressurised aerosol products and as such by its nature when dispensed is in contact with air. Experience in use, therefore, suggests that a negative result would be obtained for this data point.						

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
Flash-point								
Flash point 1	EC Method A9 Non-equilibrium method using closed cup as ASTM D93-80	[redacted]	Flashpoint. 141°C Pressure. 997 mbar	A thermocouple was used in place of a thermometer A blue halo was observed around the test flame at 121°C	Y	(1) Reliable without restrictions	Betteley J.M.T. 1997. [redacted] Physicochemical Properties. Huntingdon Life Sciences Ltd., P.O. Box 2, Huntingdon, Cambridgeshire. (unpublished) [redacted]	x
Flash point 2	Pensky Martens Closed Cup tester. The Closed Cup Procedure is fully described in EC A9	[redacted]	The mean flash point for two replicates corrected to a barometric pressure of 760 mm Hg was 110° C.	The active ingredient, as manufactured, will not be transported. [redacted]	Y	(1) Reliable without restrictions	Wojcieck BC (1993). [redacted] (Manufacturing Use product) – Flammability. [redacted]	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
				[redacted]. For this reason a flash point study has been conducted on the MUP.				
4.13 Oxidizing properties (IIA4.13)	Aliquots of the test material were exposed to 1% w/w aqueous potassium permanganate and any temperature change measured	[redacted]	There was an initial very slight temperature rise (approx 2°C). There were no fumes, sputtering etc.	There are no functional groups in [redacted] which are capable of exhibiting oxidative capacity. The active ingredient, as manufactured, will not be transported. [redacted]. For this reason the oxidation reduction study	Y	(1) Reliable without restrictions	Wojcieck BC (1993). [redacted] (Maunfacturing Use product) – Oxidation-Reduction. [redacted]	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
				has been conducted on the MUP.				

Section A3 Summary of main results and conclusions

Imiprothrin is a clear, amber, viscous liquid at room temperature, and decomposes before boiling at 128 ºC. It has a slightly sweet odour and a relative density of 1.122.

The vapour pressure of imiprothrin is 1.86 x 10^{-6} Pa at 25ºC, with a calculated Henry's law constant of 6.33 x 10^{-6} Pa m^3 mol^{-1}. It does not dissociate and has a water solubility of 0.0935 g/L (25ºC).

Imiprothrin is soluble in a range of organic solvents (solubility in hexane is 0.62 g /100 mL) and is stable in the presence of XXXXXXX XXXXXX for at least one year. The octanol:water coefficient (log P_{ow}) for imiprothrin is 2.9 (25ºC).

Imiprothrin is considered a surface active material at 21ºC, with a surface tension of 46.63 mN/m. The viscosity of the MUP ([redacted]) was 59 centipoise at 3 rpm, and 60 centipoise at both 6 and 12 rpm.

Imiprothrin is thermally stable at room temperature, has a flash point temperature of 141ºC and an auto-ignition temperature of 359ºC. It does not posess explosive properties and has no functional groups which are capable of exhibitng oxidative capacity.

The data generated during an absorption spectra study (UV/Vis, IR, NMR, MS) were consistent with the structure of imiprothrin.

As the active ingredient as manufactured will not be transported, a stability study (reactivity towards conatiner material) was conducted on the MUP. The physical state of the material was unchanged, no degradation products were observed and the containers were not affected after 12 months storage.

Section A3	**Evaluation by Competent Authorities**
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*17/05/2010*

Materials and methods

Applicants version is acceptable with the following amendments:

For all purities quoted the applicant has stated that the figures refer to the sum of all 4 isomers rather than only the 2 major isomers. According to the applicant they always report the purity this way.

3.1.2 Physical state 1

Remarks – delete

GLP

N

Reliability

[redacted]

***3.1.2 Physical state 2** – delete*

3.1.3 Colour 1

Method

Add "..by 3 people at 25 deg C"

Remarks - delete

GLP

N

Reliability

[redacted]

***3.1.3 Colour 2** – delete*

3.1.4 Odour 1

Remarks – delete

GLP

N

Reliability

[redacted]

***3.1.4 Odour 2** – delete*

3.3 Acidity, alkalinity

Results

Add "no information provided"

Remarks

Add "Active substance does not contain water and is not intended to be used in a product which will be diluted with water"

3.4 Boiling point

Method

Delete entry and replace with the following:

"Test substance was placed into a flask and heated – temperature at which it boiled/decomposed was measured. Reference substance – toluene."

Results

Delete entry and replace with the following:

"Decomposes at 128 deg C"

Remarks

Delete entry and replace with the following:

"At ~ 128 deg C and 746 mmHg, the colour of the sample changed from yellowish-orange to orange-red. Upon further heating, at approximately 144 deg C, the sample turned dark brown."

GLP

N – no QA statement present in the study report, therefore cannot be considered GLP compliant

Reliability

[redacted]

3.5 Relative density 1

Method

Delete "Pycnometry methodology is fully described in method EC A3" with "92/69/EEC, A3"

Remarks

Within the sentence .....(rather it will be a manufacturing use product - see below)..... replace 'manufacturing' with 'manufacturing'.

Add the following:

"All measurements were carried out at 20 deg C. The requirement of 92/69/EEC method A3 is that water density is measured at 4 deg C. Recalculating the result assuming pure water at 4 deg C has a density of 1.000 g/cm^3 and at 20 deg C has a density of 0.9982 then the relative density would be 1.121."

GLP

N – no QA statement present in the study report, therefore cannot be considered GLP compliant

Reliability

[redacted]

3.5 Relative density 2 *– delete this section*

3.6 Absorption spectra

UV/Vis

Results

Delete "201 nm" and replace with "210 nm"

Remarks

Delete second paragraph. Add "Information to address the effects of pH (<2 and >10) has not been provided however intended use is not in an aqueous environment". The molar absorption co-efficient (Ɛ) should be calculated or a case for non-submission provided. A case has subsequently been provided by the applicant concluding that the data indicates that improthrin does not have a maximum absorance in the UV/Vis area of the spectrum between 210nm and 360nm then calculation of the molar absorption co-efficient is not necessary. The supporting information would suggest that there is a degree of absorbance between 210nm and 250nm however the peak absorbance is estimated to be at wavelengths <200nm which are not shown on the spectra.

Reliability

[redacted]

IR

Results

Delete "201 nm" and replace with "210 nm"

Remarks

Delete second paragraph

Reliability

[redacted]

NMR

Method

Add the following text "… at 270 MHz. Test substance was dissolved in deuterated chloroform – 20 mg/ml. Spectrum obtained at ambient temperature."

Remarks

Delete second paragraph

Reliability

[redacted]

MS

Results

m/z = 318, 151, 123 (100 %)

Remarks

Delete second paragraph

Reliability

[redacted]

3.7 Vapour pressure

Reliability

[redacted]

3.7.1 Henry's Law Constant

Results

Add "at 25 deg C"

Remarks – delete

GLP

N

Reliability

[redacted]

3.8 Surface tension

Method

Delete "EC method A5" and replace with "92/69/EEC, A5"

Results – delete

Remarks

Delete "..at 21 deg C." and replace with "Two tests were conducted. The time between preparation of the 90 % saturated aqueous solution and surface tension measurement was 2.5 hours (test 1) and 4.5 hours (test 2)."

3.9 Solubility in water

Method

Delete second paragraph and replace with "92/69/EEC, A6"

Reliability

[redacted]

3.10 Partition coefficient

Method

Replace text with "92/69/EEC, A8"

3.11 Thermal stability 1

Method

Delete text and replace with "OECD 113. Accelerated storage at 54 deg C for a period of 14 days based on CIPAC MT46"

Remarks

Replace "...in air" with "...at RT"

3.11 Thermal stability 2 *– move to section 3.17*

Method

Add "Stored in a sealed can in the dark."

Results

Add "Physical state unchanged"

Remarks

Delete text and replace with "S-41311 MUP does not decompose when stored at ambient temperature in commercial packages for one year"

3.12 Reactivity towards container material

GLP

N – no QA statement present in the study report, therefore cannot be considered GLP compliant.

Reliability

[redacted]

3.13 Dissociation constant

GLP

N

3.15 Viscosity

Results

Delete "result:" and replace with "Dynamic viscosity ="

GLP

N – no QA statement present in the study report, therefore cannot be considered GLP compliant

3.16 Solubility in organic solvents

Results

Add "Solubility in water = 6200 mgl^{-1}"

Remarks

Delete second paragraph and replace with the following:

"As the test substance was determined to be soluble in all proportions with each solvent except, n-hexane, further testing to determine a definitive measured solubility was conducted only on the test substance in n-hexane.

Due to the high solubility value in n-hexane (and even higher solubility in other solvents) the effect of temperature is not likely to be of any consequence."

3.17 Stability in organic solvents

Delete text and replace with that as detailed in section 3.11/02.

4.1 Explosive properties

Method:

Add the following text: 'Test method EC A14 is considered to be comparable to that specified in the context of Regulation 1272/2008 (CLP)'

4.6 Flammability

Method

Delete "EC Method A15" and replace with "92/69/EEC, A15"

Remarks

Delete text and replace with Barometric pressure ~ 1 atmosphere

4.6 Flash-point 1

Method

Delete "EC Method A9" and replace with "92/69/EEC, A9". Add text: 'Test methods for determination of flash point specified under EEC Method A9 are in accordance with those considered appropriate under Regulation 1272/2008 (CLP)'

Results

Pressure = 997 mbar (~1 atm)

4.6 Flash-point 2 *- delete*

4.13 Oxidising Properties

Delete all the text except the first paragraph under the Remarks/Justification column. Add the following text to this paragraph 'This waiver is also considered to address the requirements specified under Regulation 1272/2008 (CLP)'

Summary of main results

In paragraph 5, replace the word 'posess' with 'possess' and the word 'exhibitng' with exhibiting'

In paragraph 6, replace the word 'conatiner' with 'container'.

Conclusion	*Adopt applicant´s version with the above amendments*
Reliability	[redacted]
Acceptability	*acceptable*
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	