PROPICONAZOLE

Dossier for Directive 98/8/EC
Document IIIA

Section 1: Applicant
Section 2 : Identity

From
Tier I - Section 1 - Annex II
of 91/414 dossier :
Identity and general information

Document IIIA – BPD 98/8	**Section 1**	**APPLICANT**
91/414 Annex Point addressed	**II 1**	**Identity of the Active Substance**

1.1 Applicant :

Syngenta European Center
Priestley Road
GU2 7YH Guildford
United Kingdom

Contact person : [redacted]

1.2 Manufacturer :

Syngenta Crop Protection AG
CH - 4002 Basle
Switzerland

Location of plant : [redacted]

Document IIIA – BPD Section 2 IDENTITY 98/8

2.1 Common name : propiconazole

2.2 Chemical name :

IUPAC nomenclature :

1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole

CAS nomenclature :

1H-1,2,4-Triazole, 1-[[2-(2,4-dichloro phenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-

2.3 SYNGENTA's code number : CGA 64250

2.4 CAS and EC number :

2.4.1 CAS number : 60207-90-1

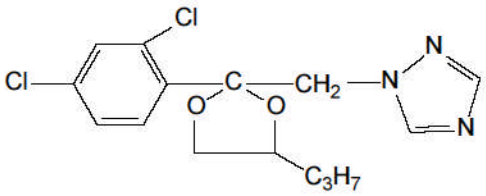
2.4.2 EINECS number : 262-104-4

2.4.3 CIPAC number : 408

2.5 Molecular and structural formula, molecular mass

2.5.1 Molecular formula : $C_{15}H_{17}Cl_2N_3O_2$

2.5.2 Structural formula :



2.5.3 Molecular mass : 342.2

2.6 Method of manufacture of the active substance

CONFIDENTIAL information - data provided separately

2.7 Specification of purity of the active ingredient

CONFIDENTIAL information - data provided separately

2.8 Identity of impurities and additives

CONFIDENTIAL information - data provided separately

2.9 The origin of the natural active substance or the precursor(s) of the active substance

Not applicable

Justification : propiconazole is not a natural active substance

2.10 Exposure data

RMS remark: See Doc III A2.10

Reliability indicator	1

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*6 March 2006, 9 October 2012*
Materials and methods	-
Conclusion	-
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM THE NEW APPLICANT
Date	October 02, 2012

Results and discussion

The applicant has changed in 2011. Syngenta is no applicant any longer.

New applicant:

LANXESS Deutschland GmbH
Business Unit Material Protection Products
ChemPark Leverkusen
D-51369 Leverkusen
Germany

[redacted]

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		
i) Description of process	see confidential part of dossier	
ii) Workplace description	The principles of good occupational hygiene practice set a clear hierarchy of control which places primacy to removing the hazard or controlling it by engineering or procedural means, before the use of personal protective equipment (PPE) and respiratory protective equipment (RPE). This hierarchy of control is clearly followed in Syngenta and includes consideration of aspects such as design and construction of the plant, the cleanliness of the workplace and equipment, working practices and personal hygiene. For exposure to any substance that can be hazardous by ingestion, absorption or inhalation control must be to a standard that eliminates any health effects.	
iii) Inhalation exposure	The plant design aims to contain, as far as is possible, chemical exposure by use of total or partial enclosure and appropriate extraction systems. The plant is designed using the Occupational Exposure Limits (OEL) (see below). The material is practically non-volatile according to data sheet classification (i.e. 0.056 mPa at 25°C).	
iv) Dermal exposure	The plant design aims to contain, as far as is possible, chemical exposure by use of total or partial enclosure. Suitable PPE is worn by operators where there is potential for skin exposure.	
2.10.1.2 Intended use(s)		
1. Professional Users		
i) Description of application process	Connecting/Disconnecting transfer lines	
ii) Workplace description	Industrial formulation of paints and adhesives	
iii) Inhalation exposure	Negligible	
iv) Dermal exposure	0.0083 / 0.00083 mg/kg/day (–/+ gloves)	

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

2. Non-professional Users including the general public

(i) via inhalational contact	0.0431 mg/kg bw/day (spray painting)
(ii) via skin contact	0.107 mg/kg bw/day (spray painting)
(iii) via drinking water	Not relevant
(iv) via food	Not relevant
(v) indirect via environment	Not relevant

2.10.2 Environmental exposure towards active substance

2.10.2.1 Production

[redacted]

2.10.2.2 Intended use(s)

The a.s. is blended into paints or adhesives to protect the paint or adhesive film against fungal infestation. It will be used in coatings on wood.

Affected compartment(s):	Water and sediment (via STP), soil
water	Surface water as indirect target via STP, no direct emissions
sediment	Emission of sediment via STP, no direct emission
air	Emission to atmosphere are not relevant due to low volatility (vapour pressure at 25°C is approximately 5.6×10^{-5} Pa and Henry's law constant is 9.2×10^{-5} Pa m³ mol^{-1}) and a very fast atmospheric degradation (half-life in the atmosphere ranging from 2 and 3.5 hours).
soil	For the industrial use of propiconazole in coating on wooden surfaces emissions to soil are only possible during on-site storage of pre-treated timber. For the use the a.s. on mineral surfaces soil compartment is only regarded assuming the countryside scenario
Predicted concentration in the affected compartment(s)	
water	30days time step, worst case PEC_{STP} [µg x L^{-1}]: 2.2 (amateur), 2.1 (professional) $PEC_{surface\ water}$ [µg x L^{-1}]: 0.2 (amateur), 0.2 (professional)

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

sediment	30days time step, worst case $PEC_{Sediment}$ [µg/kg $_{wwt}$]: 4.8 (amateur), 4.5 (professional)
air	Not relevant due to the vapour pressure and the Henry's law constant of propiconazole
soil	30days time step, countryside approach, worst case PECsoil (10) [mg/kg wwt]: 0.0461 (amateur), 0.0293 (professional)

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

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*3April2013*
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
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	

PROPICONAZOLE

Dossier for Directive 98/8/EC
Document IIIA

Section 3 : Physical & Chemical Properties

From
Tier I - Section 1 - Annex II
of 91/414 dossier :
Identity, chemistry data and
general information

Document IIIA – BPD 98/8	**Section 3**	**PHYSICAL AND CHEMICAL PROPERTIES**
91/414 Annex **Point addressed**	**II** **2**	**Physical and Chemical Properties of the Active Substance**

3.1 Melting Point, Boiling Point, Relative density

3.1.1 Freezing point

General Information	
Title of the study:	**Report on freezing temperature**
Project number: Author: Syngenta file number (SAM):	PP-94 / 37P.MPR A. Geoffroy 64250 - 2441
Name and address of testing facility:	SYNGENTA., CH-4002 Basle, Switzerland
Date of report:	September 9, 1994
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Test guidelines used:	EEC A.1
Test substance: Batch identification: Purity of the test substance:	CGA 64250 pure [redacted]

Reliability indicator	1
Data Protection Claim	Yes

Findings :

The **freezing temperature** of the test substance (glass transition temperature of a liquid sample) was determined to be :

-23°C

Evaluation by Competent Authorities
1 December 2005[redacted]

3.1.2 Boiling point

General Information	
Title of the study:	**Report on boiling point / boiling range**
Project number: Author: Syngenta file number (SAM):	16313 R. Das 64250 - 2290
Name and address of testing facility:	SYNGENTA Münchwilen AG, CH-4333 Münchwilen, Switzerland
Date of report:	November 8, 1993
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Test guidelines used:	EEC A.2, OECD No. 103
Test substance: Batch identification: Purity of the test substance:	CGA 64250 tech. [redacted]

Reliability indicator	1
Data Protection Claim	Yes

Findings :

The **boiling point** of the active substance was determined to be :

>250°C (> 523 K) at 101.325 kPa
120°C (= 392.2 K) at 1.9 Pa.
Thermal decomposition begins around 355°C

Evaluation by Competent Authorities
[redacted] 20 April 2007. [redacted]

3.1.3 Relative density

General Information	
Title of the study:	**Report on density**
Project number: Author: Syngenta file number (SAM):	16314 R. Das 64250 - 2289
Name and address of testing facility:	SYNGENTA Münchwilen AG, CH-4333 Münchwilen, Switzerland
Date of report:	November 8, 1993
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Test guidelines used:	EEC A.3, OECD No. 109
Test substance: Batch identification: Purity of the test substance:	CGA 64250 tech. [redacted]
Reliability indicator	1
Data Protection Claim	Yes

Findings :

The **density** of the test substance is

1289 kg / m³ (= 1.289 g / cm³) at 20°C

Evaluation by Competent Authorities
[redacted] 20 April 2007. [redacted]

3.2 Vapour pressure, volatility

3.2.1 Henry's law constant

General Information	
Title of the study:	**Report on vapour pressure curve**
Project number: Author: Syngenta file number (SAM):	AG - 88 / 02 P B.F. Rordorf / N. Burkhard 64250 - 2087, 64250 - 2403
Name and address of testing facility:	SYNGENTA Ltd., CH-4002 Basle, Switzerland
Date of report:	June 15, 1988 / September 12, 1994
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Test guidelines used:	OECD No. 104
Test substance: Batch identification: Purity of the test substance:	CGA 64250 pure [redacted]

Reliability indicator	1
Data Protection Claim	Yes

Findings :

The **vapour pressure** of propiconazole was determined to be

$5.6 \cdot 10^{-5}$ Pa at 25°C

The **Henry's Law Constant**, H, is calculated from the following equation:

$$H = P_{VP} / S_W \quad [Pa \cdot m^3 / mol]$$

P_{VP} = vapour pressure [Pa]

S_W = water solubility [mol / m^3]

The following data are used for the calculation of Henry's Law Constant for CGA 64250, propiconazole (mol. weight MW = 342.2 g /mol).

water solubility at 20°C : 100 g / m^3
vapour pressure at 20°C : $2.7 \cdot 10^{-5}$ Pa

Based on these results **Henry's Law Constant** was estimated to be

$9.2 \cdot 10^{-5}$ Pa · m^3 / mol

Evaluation by Competent Authorities
20 April 2007. [redacted]

3.3 Appearance (physical state, colour and odour)

General Information	
Title of the study:	**Report on general physico-chemical properties**
Project number: Author: Syngenta file number (SAM):	20751 (pure active ingredient) / 16311 (technical grade active ingredient) R. Das 64250- 2334 (pure a.i.) / 64250 - 2083 (technical grade a.i.)
Name and address of testing facility:	SYNGENTA Münchwilen AG, CH-4333 Münchwilen, Switzerland
Date of report:	March 22, 1994 (pure a.i.) / November 8, 1993 (technical grade a.i.)
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Test guidelines used:	visual and organoleptic test
Test substance: Batch identification: Purity of the test substance:	CGA 64250 [redacted]

Reliability indicator	1
Data Protection Claim	Yes

Findings :

Substance	Property		
	Colour	**Aspect**	**Odour**
Pure active ingredient	colourless	clear, viscous liquid	weak, slightly sweet
Technical grade active ingredient	yellowish	clear, viscous liquid	very slight mild odour

Evaluation by Competent Authorities
1 December 2005 [redacted]

3.4 Spectra (UV /VIS, IR, NMR, MS), Molecular extinction at relevant wavelengths

General Information	
Title of the study:	**Report on spectra**
Project number: Author: Syngenta file number (SAM):	28042 W. Käser 64250 - 2097
Name and address of testing facility:	SYNGENTA Münchwilen AG, CH-4333 Münchwilen, Switzerland
Date of report:	December 20, 1994
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Test guidelines used:	--
Test substance: Batch identification: Purity of the test substance:	CGA 64250 pure [redacted]

Reliability indicator	1
Data Protection Claim	Yes

Findings :

IR spectrum

- Operating procedures

  Sample preparation : tel quel, between 2 NaCl plates
  Instrument : Perkin Elmer 1420

- Peak list :

3000 - 3100 cm^{-1}	(C - H) stretch	(aromatic)
2900 - 3000 cm^{-1}	(C - H) stretch	(aliphatic)
1460 / 1500 / 1580 cm^{-1}	(C - C) stretch	(aromatic)
1270 / 1130 / 1020 cm^{-1}	(C - O -C) stretch	(asymmetric)

UV / VIS spectrum

- Operating procedures

  Instrument : Hitachi U-3200 Concentration and solvent : 3.11 mg in 100 ml methanol
  Quartz cell : 10 mm pathlength Reference solvent : methanol

- List of characteristic bands

Wavelength [nm]	Molecular extinction coefficient [$l \cdot mol^{-1} \cdot cm^{-1}$]
220.4	11666

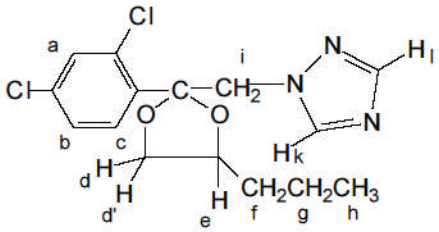
No absorption was observed between 340 nm and 750 nm

H-NMR spectrum

- Operating procedures

Operating temperature :	room temperature	Instrument :	Bruker ACF 300
Solvent :	DMSO	Nucleus :	^{1}H (300 MHz)
		Internal standard :	TMS

Structural formula



- Table of chemical shifts

Chemical shift (ppm)	No. of Protons	Assignment	Multiplicity
0.85	3	h	two triplets (not resolved)
1.3	4	f, g	multiplet
3.25 / 3.35	1	d'	multiplets of diastereomeric forms
3.9 / 4.1	2	d,e	multiplets of diastereomeric forms
4.75	2	I	multiplets (not resolved)
7.45	2	b, c	multiplets
7.65	1	a	multiplets
7.85	1	l	two singlets of the diastereomeric forms
8.4	1	k	two singlets of the diastereomeric forms

Mass spectrum

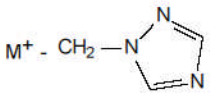
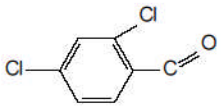
- Operating Procedures

Instrument :	Finigan 4500	Type of analyzer : quadrupole	
Ionization mode :	electron impact		Detection : scan mode
Ionizing energy :	70 eV		

- Peak List

m / z

341 M^+ (not detected)

298/300	$M^+ - C_3H_7$
259 / 261	
191 / 193	$259 - C_5H_8$
173 / 175	
69	C_5H_9
55	$69 - CH_2$

Evaluation by Competent Authorities
1 December 2005. [redacted]

3.5 Solubility in water including effect of pH on solubility

General Information	
Title of the study:	**Report on water solubility**
Project number: Author: Syngenta file number (SAM):	AG-87 / 22P K. Jäkel 64250 - 2085
Name and address of testing facility:	SYNGENTA Ltd., CH-4002 Basle, Switzerland
Date of report:	November 19, 1987
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Test guidelines used:	EEC A.6, OECD No. 105
Test substance: Batch identification: Purity of the test substance:	CGA 64250 pure [redacted]

Reliability indicator	1
Data Protection Claim	Yes

Findings :

The **solubility** of the pure active ingredient in **pure water** was determined to be :

100 mg / l at 20°C and pH 6.9

In aqueous solution the neutral form of propiconazole is predominantly present at pH > 1.1 (pK_a= 1.09). That means the pH should have no appreciable effect on the water solubility of propiconazole in the pH range 4 to 10.

Information on temperature effects.

Propiconazole is a non-polar organic compound of high solubility in organic media such as toluene, n-octanol and ethyl acetate, in which it is completely miscible. In contrast, propiconazole exhibits very low solubility in water. As defined in the directive, the water solubility of propiconazole was determined at a temperature of 20 °C where a value of 100 mg/litre was observed. However, due to the very low solubility Syngenta does not consider that it is relevant to determine the water solubility at either 10 or 30°C as such a temperature range will have negligible affect on the solubility of propiconazole.

Evaluation by Competent Authorities
[redacted] 20 April 2007. [redacted]

3.6 Dissociation constant

General Information	
Title of the study:	**Report on dissociation constant in water**
Project number: Author: Syngenta file number (SAM):	EA 133549 K. Jäkel / J. Stulz 64250 - 2287 / 64250 - 2455
Name and address of testing facility:	SYNGENTA Ltd., CH-4002 Basle, Switzerland
Date of report:	August 8, 1990 / October 26, 1994
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Test guidelines used:	OECD No. 112
Test substance: Batch identification: Purity of the test substance:	CGA 64250 pure [redacted]

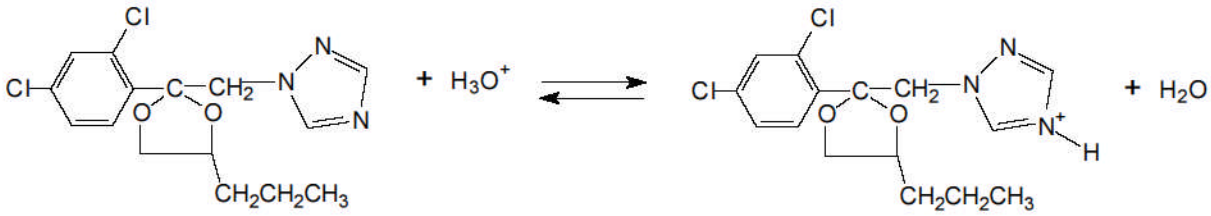
Reliability indicator	1
Data Protection Claim	Yes

Findings :

The **dissociation constant** of propiconazole was determined to be

$$\mathbf{pK_a = 1.09 \text{ at } 20°C}$$

The constant describes the protonation of propiconazole according to the following equation :



I II

II shows one of the possible forms of protonated propiconazole. It can not be decided, which of the nitrogen atoms of the triazole ring is protonated.

In aqueous solutions the neutral form I is predominantly present at pH > 1.09, the protonated form II at pH < 1.09.

Evaluation by Competent Authorities
[redacted]
20 April 2007. [redacted]

3.7 Solubility in organic solvents

General Information	
Title of the study:	**Report on solubility in organic solvents**
Project number: Author: Syngenta file number (SAM):	20752 J. Stulz 64250 - 2084
Name and address of testing facility:	SYNGENTA Münchwilen AG, CH-4333 Münchwilen, Switzerland
Date of report:	March 15, 1994
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Test guidelines used:	SOP 433.1.209
Test substance: Batch identification: Purity of the test substance:	CGA 64250 tech. [redacted]

Reliability indicator	1
Data Protection Claim	Yes

Findings :

The **solubilities** of the technical grade active ingredient in different **organic solvents** at a temperature of 25°C were found to be :

Chemical class	Solvent	Solubility
Aliphatic hydrocarbon	n-hexane	47 g / l
Aromatic hydrocarbon	toluene	completely miscible
Halogenated hydrocarbon	dichloromethane	completely miscible
Alcohol	ethanol	completely miscible
	n-octanol	completely miscible
Ketone	acetone	completely miscible
Ester	ethyl acetate	completely miscible

Evaluation by Competent Authorities
[redacted]
20 April 2007 [redacted]

3.8 Stability in organic solvents :

According to the TNsG on Data Requirements (current version on the ECB web site), stability in organic solvent must be stated if the active ingredient as manufactured includes organic solvent; This is not applicable to propiconazole because it does not contain organic solvents.

Evaluation by Competent Authorities
31 January 2011. [redacted]

3.9 Partition coefficient n-octanol / water including effect of pH

General Information	
Title of the study:	**Report on partition coefficient**
Project number: Author: Syngenta file number (SAM):	AG-87 / 22P K. Jäkel 64250 - 2086
Name and address of testing facility:	SYNGENTA Ltd., CH-4002 Basle, Switzerland
Date of report:	November 20, 1987
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Test guidelines used:	EEC A.8, OECD No. 107
Test substance: Batch identification: Purity of the test substance:	CGA 64250 pure [redacted]

Reliability indicator	1
Data Protection Claim	Yes

Findings :

The logarithm of the **octanol / water partition coefficient** of the pure active ingredient was determined to be:

$$\log P_{ow} = 3.72 \text{ at pH } 6.6 \text{ and } 25°C$$

Information on temperature effects required.

As already stated (3.5), due to the high solubility of propiconazole in n-octanol, in which it is completely miscible, and the very low solubility of the compound in water, the octanol-water partition coefficient will not be significantly affected by temperature, over the range 10 or 30 °C i.e. both parameters are essentially unchanged and therefore the log of their ratio will also effectively remain constant. Syngenta therefore considers that it is not relevant to measure the coefficient at the noted additional temperatures.

Evaluation by Competent Authorities
[redacted] 20 April 2007. [redacted]

3.10 Thermal Stability :

General Information	
Title of the study:	**Report on thermal stability and stability in air**
Project number: Author: Syngenta file number (SAM):	20753 H. Schürch 64250 - 2335
Name and address of testing facility:	SYNGENTA Werke Schweizerhalle AG, CH-4133 Schweizerhalle, Switzerland
Date of report:	April 18, 1994
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Test guidelines used:	OECD 113
Test substance: Batch identification: Purity of the test substance:	CGA 64250 tech. [redacted]

Reliability indicator	1
Data Protection Claim	Yes

Findings :

The sample shows no exothermic peak between room temperature and 150°C.

Evaluation by Competent Authorities
[redacted]
20 April 2007. [redacted]

3.11 Flammability including auto-flammability

General Information	
Title of the study:	**Report on auto-flammability of liquids**
Project number: Author: Syngenta file number (SAM):	PP - 94 / 10T.AFG H. Schürch 64250 - 2338
Name and address of testing facility:	SYNGENTA Werke Schweizerhalle AG, CH-4133 Schweizerhalle, Switzerland
Date of report:	April 18, 1994
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Test guidelines used:	EEC A.10
Test substance: Batch identification: Purity of the test substance:	CGA 64250 tech. [redacted]

Reliability indicator	1
Data Protection Claim	Yes

Findings :

The **self-ignition temperature** of propiconazole was determined to be

430°C

Evaluation by Competent Authorities
20 April 2007 [redacted]

3.12 Flash point

General Information	
Title of the study:	**Report on determination of flash point**
Project number: Author: Syngenta file number (SAM):	PP - 94 / 10T.FLP H. Schürch 64250 - 2336
Name and address of testing facility:	SYNGENTA Werke Schweizerhalle AG, CH-4133 Schweizerhalle, Switzerland
Date of report:	April 18, 1994
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Test guidelines used:	EEC A.9
Test substance: Batch identification: Purity of the test substance:	CGA 64250 tech. [redacted]

Reliability indicator	1
Data Protection Claim	Yes

Findings :

The **flash point** of propiconazole was determined to be

200 °C (1013 mbar)

Evaluation by Competent Authorities
20 April 2007 [redacted]

3.13 Surface tension

General Information	
Title of the study:	**Report on surface tension of aqueous solutions**
Project number: Author: Syngenta file number (SAM):	PP - 94 / 21T.SUR M. Ryser 64250 - 2413
Name and address of testing facility:	SYNGENTA Ltd. , CH-4002 Basle, Switzerland
Date of report:	September 19, 1994
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Test guidelines used:	OECD No. 115
Test substance: Batch identification: Purity of the test substance:	CGA 64250 tech. [redacted]

Reliability indicator	1
Data Protection Claim	Yes

Findings:

The surface tension of an aqueous suspension at 20°C by the **Wilhelmy plate method** was determined to be :

δ = 46.6 - 48.4 mN / m. (filtrates of 10.0 g / l suspensions)
δ = 55.8 - 62.3 mN / m (filtrates of 1.0 g / l suspensions)

Evaluation by Competent Authorities
20 April 2007. [redacted]

3.14 Viscosity :

General Information	
Title of the study:	**Report on viscosity of liquids**
Project number: Author: Syngenta file number (SAM):	PP - 96 / 32T.VIL M. Ryser 64250 - 3017
Name and address of testing facility:	SYNGENTA Ltd. , CH-4002 Basle, Switzerland
Date of report:	June 24, 1996
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Test guidelines used:	OECD No. 114
Test substance: Batch identification: Purity of the test substance:	CGA 64250 tech. [redacted]

Reliability indicator	1
Data Protection Claim	Yes

Findings:

At 20°C : 69.630 +/- 0.379 Pa*s at shear rate D = 0.10 < D < 10.0 sec^{-1}
At 40°C : 3.509 +/- 0.39 Pa*s at shear rate D = 0.10 < D < 10.0 sec^{-1}

Evaluation by Competent Authorities
[redacted]
20 April 2007. [redacted]

3.15 Explosive properties

General Information	
Title of the study:	**Report on explosive properties**
Project number: Author: Syngenta file number (SAM):	PP - 94 / 10T.EXP H. Schürch 64250 - 2337
Name and address of testing facility:	SYNGENTA Werke Schweizerhalle AG, CH-4133 Schweizerhalle, Switzerland
Date of report:	April 18, 1994
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Test guidelines used:	EEC A.14
Test substance: Batch identification: Purity of the test substance:	CGA 64250 tech. [redacted]

Reliability indicator	1
Data Protection Claim	Yes

Findings:

The substance **is not considered an explosive,** as concluded from test results on :

- Thermal sensitivity (effect of a flame)
- Mechanical sensitivity (shock)

Mechanical sensitivity (friction) : not tested
The testing method is not suitable for liquids.

Evaluation by Competent Authorities
[redacted] 20 April 2007. [redacted]

3.16 Oxidizing properties

General Information	
Title of the study:	**Oxidizing properties (liquids) of CGA 64250 tech**
Project number: Author: Syngenta file number (SAM):	81905 H. Angly 64250 - 4299
Name and address of testing facility:	SYNGENTA Institute of Safety and Security, Testing Laboratory, Basle, Switzerland
Date of report:	March 31, 2000
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Test guidelines used:	section 34, UN 1999
Test substance: Batch identification: Purity of the test substance:	CGA 64250 tech. [redacted]

Reliability indicator	1
Data Protection Claim	Yes

Findings:

The substance is not considered an oxidizing substance.

Evaluation by Competent Authorities
1 December 2005. [redacted]

3.17 Reactivity towards container material

The corrosion characteristics of propiconazole technical material were assessed for; tin plate, iron steel and stainless steel. For all three test materials no weight change was observed over the test period and it was therefore concluded that technical propiconazole is not corrosive to these packaging materials.

In addition, technical propiconazole is not oxidizing, not explosive, is thermally stable to at least 150 °C and has a flash point of 200 °C demonstrating its low reactivity.

Furthermore, technical propiconazole has been in large-scale manufacture and storage for in excess of twenty years without significant incident in relation to reactivity to its packaging material.

Evaluation by Competent Authorities
1 December 2005. [redacted]

PROPICONAZOLE

Dossier for Directive 98/8/EC Document IIIA

Section 6: Toxicological and Metabolic Studies

From
Tier I - Section 3 - Annex II
of 91/414 dossier :
Toxicology and metabolism studies on the active substance

98/8 Doc IIIA section No.	**6.1.1/01**	**Acute toxicity – Oral**
91/414 Annex Point addressed	**II 5.2.1 / 01**	Acute toxicity - oral

1.2	**Title**	Acute oral LD_{50} in the rat of technical CGA 64'250
1.3 project N° Syngenta File N° (SAM)	**Report and/or**	78 52 44 64250 / 1528
1.4	**Lab. Report N°**	78 52 44
1.5 Reference to original study / report	**91/414 Cross**	5.2.1 / 01
1.6	**Authors**	Report: [redacted] Summary:
1.7	**Date of report**	December 7, 1978
1.8 owner	**Published /**	Unpublished / Syngenta
2.1	**Testing facility**	[redacted]
2.2 experimental work	**Dates of**	October 19 to November 8, 1978
3.	**Objectives**	Investigation of acute oral toxicity in rats
4.1	**Test substance**	CGA 64'250, technical grade active ingredient
4.2	**Specification**	[redacted]
4.3 stability	**Storage**	not applicable (single treatment only)
4.4 vehicle	**Stability in**	not applicable
4.5 vehicle	**Homogeneity in**	not applicable
4.6	**Validity**	not applicable
5 solvent	**Vehicle /**	2% aqueous carboxymethylcellullose (CMC)
6	**Physical form**	viscous liquid
7.1	**Test method**	not specified
7.2	**Justification**	The procedures followed are in-line with current Guideline requirements.
7.3	**Copy of method**	A description of the method is part of the original study report as submitted under Reference 5.2.1 / 01.
8 method	**Choice of**	Standard procedure for the intended purpose
9	**Deviations**	Only formal deviations (see details below) from EC Directive 92/69 B1.
10.1 laboratory	**Certified**	not applicable
10.2 authority	**Certifying**	not applicable

10.3	**GLP**	no
10.4	**Justification**	When the study was performed, GLP was not compulsory
11.1	**GEP**	not applicable
11.2	**Type of facility (official or officially recognised)**	[redacted]
11.3	**Justification**	not applicable

x12.1	**Test system**	Strain:	Rat, Sprague-Dawley derived. Tif: RAIf (SPF)
		Source	[redacted]
		Age:	young adult (7 to 8 weeks)
12.2	**Procedure**	Dose levels:	500, 1'000, 3'000 and 4'000 mg/kg b.w.
		Group size:	5 males and 5 females
		Dose regimen:	single oral gavage of 10 or 20 ml/kg. The animals were fasted overnight before the treatment.
		Observation period:	14 days. Body weights were measured weekly.

x13 Findings

Dose	Mortality	Onset of death	Clinical signs, Autopsy
Males			
500 mg/kg 1'000 mg/kg 3'000 mg/kg 4'000 mg/kg	0 / 5 1 / 5 3 / 5 5 / 5	 Day 1 Day 1 - 2 Day 1	Sedation, Dyspnea, Abnormal Body Position, Ruffled Fur were observed in all groups with increasing severity. No effects on body weight gain.
Females			
500 mg/kg 1'000 mg/kg 3'000 mg/kg 4'000 mg/kg	0 / 5 3 / 5 4 / 5 5 / 5	 Day 2 Day 1 - 2 Day 1	Sedation, Dyspnea, Abnormal Body Position, Ruffled Fur were observed in all groups with increasing severity. No effects on body weight gain.
LD_{50}: 1'517 mg/kg (958 - 2'291 mg/kg) calculated according to the logit model including 95% confidence limits			All symptoms were reversible within 8 - 14 days. No substance related gross organ changes were seen.

14	**Statistics**	see above
15	**References (published)**	None
16	**Unpublished data**	None
x17	**Reliability Indicator**	1

Data Protection Claim	Yes

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	12.11.2004
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	

PP 2.504/WM/ 24.10.1994