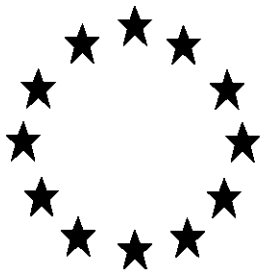
Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Propiconazole

Product-type 9

(Fibre, leather, rubber and polymerised materials preservatives)

12 July 2013

Finland

Propiconazole (PT9)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 12 July 2013

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1 PRINCIPLE OF EVALUATION

This assessment report has been established as a result of the evaluation of propiconazole as product-type 9 (fibre, leather, rubber and polymerised materials preservatives), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with the original view to the possible inclusion of this substance into Annex I or IA to that Directive.

The evaluation has therefore been conducted in the view to determine whether it may be expected, in light of the common principles laid down in Annex VI to Directive 98/8/EC, that there are products in product-type 9 containing propiconazole that will fulfill the requirements laid down in Article 5(1) b), c) and d) of that Directive.

1.2. PURPOSE OF THE ASSESSMENT

The aim of the assessment report is to support a decision on the approval of propiconazole for product-type 9, and should it be approved, to facilitate the authorisation of individual biocidal products in product-type 9 that contain propiconazole. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

The conclusions of this report were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Regulation (EU) No 528/2012.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

[1] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

1.3. PROCEDURE FOLLOWED

This assessment report has been established as a result of the evaluation of propiconazole as product-type 9 (fibre, leather, rubber and polymerised materials preservatives), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[2].

Propiconazole (CAS no. 60207-90-1) was notified as an existing active substance, by Syngenta European Center, hereafter referred to as the applicant, in product-types 8 (wood preservatives), 7 (film preservatives) and 9 (fibre, leather, rubber and polymerised materials preservatives).

Commission Regulation (EC) No 1451/2007 of 4 December 2007[3] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 7(1) of that Regulation, Finland was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for propiconazole as an active substance in Product Type 9 was 31 October 2008, in accordance with Annex V of Regulation (EC) No 1451/2007.

On 30 October 2008, Finnish competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 19 December 2008.

On 11 February 2011, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 1 March 2011. The competent authority report included a recommendation for the inclusion of propiconazole in Annex I to the Directive for PT 9.

On 3 May 2011, the Rapporteur Member State received a notification from the applicant, informing that the role of the participant and the applicant for the active substance propiconazole in the named product types (incl. PT 9) was transferred to Lanxess Deutschland GmbH as of 6 April 2011. However, Syngenta Crop Protection AG still remains the study owner for the active substance. All information of confidential nature on the active substance should be thus directed to Syngenta Crop Protection AG in Switzerland.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on the [date to be inserted]. This

[2] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

[3] Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly.

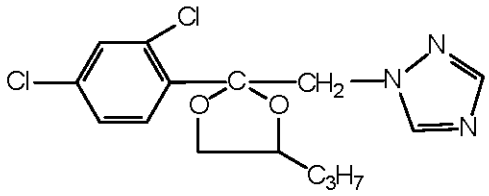
In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 17 May 2013.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1 PRESENTATION OF THE ACTIVE SUBSTANCE

2.1.1 IDENTITY

Identification of the active substance

CAS-No.	60207-90-1
EINECS-No.	262-104-4
Other No. (CIPAC, ELINCS)	CIPAC number 408
IUPAC Name	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
Common name, synonyms	CGA 64250 - Wocosen
Molecular formula	$C_{15}H_{17}Cl_2N_3O_2$
Structural formula	
Molecular weight (g/mol)	342.2
Minimum purity	93 % w/w

The active substance consists of four isomers which all are biocidal active. The applicant has submitted reports on the field performance of these isomers in Plant Protection Product uses. Obviously, there is no biocide specific information available. The full details on the identity of the active substance (i.e. impurities and isomers) are confidential and can be found in the Annex of Confidential Data and Information. None of the manufacturing impurities of propiconazole considered is, on the basis of information currently available, of toxicological or environmental concern. In addition, based on their chemical structure there is no need to believe that they would be more toxic than the active substance itself.

Identification of the representative product

Trade name	Mystox IP	
Manufacturer of the biocidal product	Catomance Technologies Ltd.	
Ingredient of preparation	Function	Content
Propiconazole	active ingredient (fungicide)	25 % w/w
IPBC	active ingredient (fungicide)	25 % w/w
Physical state of preparation	Clear amber free-flowing odourless liquid	
Nature of preparation	Technical concentrate	

The full detail of identity of the representative product is confidential and can be found in the Annex of Confidential Data and Information. None of those ingredients kept confidential is, on the basis of information currently available, of toxicological or environmental concern.

2.1.2 PHYSICO-CHEMICAL PROPERTIES

Propiconazole (technical active ingredient) is a yellowish, (purified; clear), viscous liquid with a boiling point > 250 °C at normal pressure. It is only very slightly volatile, with a vapour pressure of $5.6 \cdot 10^{-5}$ Pa (at 25 °C) and Henry's law constant of $9.2 \cdot 10^{-5}$ Pa•m^3/mol. Propiconazole does not absorb visible or ultraviolet light in the range between 290 nm and 750 nm. Due to the small spectral overlap, only a slow direct photochemical degradation can be expected. The water solubility is moderate, 100 mg/l at 20 °C, and is independent of the pH (pK_a = 1.09). Propiconazole is hydrolytically stable in the pH-range between 1 and 13. The log K_{ow} is 3.72 at neutral pH. Propiconazole is completely miscible in many organic solvents, and solubility in n-hexane is 47 g/l. Flammability, explosive and oxidising properties are not critical.

2.1.3 METHODS OF ANALYSIS

The methods of analysis of active substance as manufactured and for determination of impurities which are present at quantities > 0.1 g/kg in the active substance as manufactured have been validated and shown to be sufficiently specific, linear, accurate and precise. The methods for residue analysis in different matrices (soil, surface water, sediment, potable water and air), as appropriate for the assessed uses, have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

2.1.4 INTENDED USES

Propiconazole has been evaluated for its use as a preservative for polymerised materials (PT 9), more specifically in vinyl floors (PT 9.3). The biocide product, Mystox IP, is blended into PVC. This serves to protect the plastic against fungal infestation. In PVC applications, the biocidal product is added to the plastic during manufacturing by means of an automated dosing system.

2.1.5 EFFICACY

According to the applicant propiconazole showed a broad antifungal spectrum in in-vitro assays and was most active against *Penicillium citrinum*, *Chaetomium globosum*, *Cladosproium cladosporioides* and to less extend against *Alternaria tenuissima*, *Aspergillus niger* and *Aureobasidium pullulans*. The obtained results illustrate that the test substance might be useful for mould control on plastics, e.g. PVC floorings. However, on the basis of the efficacy test submitted in the dossier, likely concentration at which the active substance will be used (1000 ppm = 1 g/kg plastic) cannot be fully justified because there was no difference observed in the efficacy for 500 ppm compared with the higher concentrations.

2.1.6 RESISTANCE

As other triazole fungicides propiconazole inhibits the C 14 demethylation step in the ergosterolbiosynthesis of fungi. According to the applicant resistance to fungicides is a normal phenomenon embodied in the natural process of the evolution of biological systems and all DMIs (**de**ethylation **i**nhibitor) including propiconazole have a similar resistance risk but resistance factors may be different. According to the applicant propiconazole as a plant protection product should be strictly used as all DMIs according to the Fungicide Resistance Action Committee guidelines. However, there are no specific resistance prevention measures for biocides identified. The Rapporteur Member State points out that there are no specific resistance cases to propiconazole reported. It is therefore only recommended to pay attention to prevention of the evolution of tolerant fungal strains and report to Competent Authorities any new information on development of fungal resistance to propiconazole.

2.1.7 CLASSIFICATION AND LABELLING

Propiconazole is classified as follows:

Classification	In accordance with Annex I of Directive 67/548/EEC
Class of danger	Xn (Harmful); N (Dangerous for the environment)
R phrases	22-43-50/53 (Harmful if swallowed. May cause sensitization by skin contact. Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.)
S phrases	(2)-36/37-46-60-61 [(Keep out of the reach of children.*) Wear suitable protective clothing and gloves. If swallowed, seek medical advice immediately and show this container or label. This material and its container must be disposed of as hazardous waste. Avoid release to the environment. Refer to special instructions/Safety data sheets.]

*) For preparations sold to general public

In accordance with Regulation 1272/2008/EC on classification, labelling and packaging of chemical substances and mixtures (the CLP regulation) the following classification and labelling are applied to propiconazole:

Hazard class and hazard category	Acute Tox. 4 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1
Pictogram(s)	GHS07; GHS09
Signal word	Warning
Hazard (H) statements	H302 Harmful if swallowed. H317 May cause an allergic skin reaction. [H400 Very toxic to aquatic life.] H410 Very toxic to aquatic life with long lasting effects.
Precautionary (P) statements	To be chosen by the person who places the product on the market.

2.2 SUMMARY OF THE RISK ASSESSMENT

2.2.1 HUMAN HEALTH

2.2.1.1 SUMMARY OF MAMMALIAN TOXICITY STUDIES (INCL. AEL)

Propiconazole is moderately toxic with an oral acute LD_{50} of 1500 mg/kg bw/day and it is as skin sensitizer. Based on the test results propiconazole is a moderate sensitizer according to the potency categorisation described in the Guidance on the Application of the CLP Criteria, 2011.

The liver is the main target organ of propiconazole toxicity. Increased liver weights and slight histopathological changes in the liver were seen already in short term studies. Mice were more sensitive than rats to the liver toxicity elicited by propiconazole; male mice were particularly susceptible to hepatotoxicity. Long-term feeding studies in mice, including re-examination of tissue samples of the original study and additional testing in male mice only, showed neoplastic changes of the liver in male mice.

Mechanistic studies, including liver enzyme induction and hepatic cell proliferation properties, indicate that propiconazole is only to a certain degree comparable to phenobarbital as a hepatotoxic substance. Propiconazole is a strong inducer of xenobiotic metabolism and a tumour promoter in rodents which probably explains the induction of tumours in male mice. It may be presumed that rodents are more susceptible than humans to the hepatotoxicity of propiconazole. The overall chronic NOAEL in mice, based on hepatoxicity, was 10 mg/kg bw/day. The NOEL for hepatotoxicity in the 2-year rat study was 18 mg/kg bw/day, and the NOAEL was 3.6 mg/kg bw/day, based on changes in body weight and food conversion, changes in hematology and blood glucose, and adrenal weight changes. The overall NOAEL for chronic effects, 3.6 mg/kg bw/day in the 2-year rat study, covers liver toxicity in both rats and mice.

Propiconazole was not genotoxic *in vitro* or *in vivo* in the supplied tests.

A slight increase in the incidence of cleft palate was observed in rat teratogenicity studies. The low incidences of this rare malformation were not clearly treatment-related and occurred at dose levels causing marked maternal toxicity. It was therefore concluded that the effect seen in rats is probably occasional. The lowest relevant NOAEL for developmental effects was 30 mg/kg bw/day in rats, based on a slight increase in cleft palate and increased visceral and skeletal variations in a teratology study in rat.

Results of a two-generation study in rats included, in addition to hepatotoxicity in parental animals at low dose levels, slight reproductive effects at a high dose (reduced litter sizes and pup weights, reductions in testes/epididymides weights). The lowest relevant NOAEL in the 2-generation study was 8 mg/kg bw/day, based on liver toxicity in parental animals.

Acceptable Exposure Level (AEL)

Three reference doses for the systemic toxicity of propiconazole can be defined, with relevance to the assessment of risks associated with exposure to a preservative for polymerized materials. The risks are related to the length of exposure and take into account the most relevant adverse health effects expected on the basis of animal studies.

The reference values are applicable both to primary (direct) exposure in professional and non-professional use, as well as secondary (indirect) exposure with intentional or unintentional exposure to the treated products. The reference values are based on systemic NOAELs from oral dosage studies in experimental animals; factors contributing to the determination of the systemic dose at different exposure routes (e.g. oral, dermal and pulmonary absorption) should therefore be

considered at risk assessment. Toxicokinetic studies in rat show that 86% is absorbed within 48 h after oral administration. Correction for bioavailability is therefore not considered necessary.

The reference doses and the relevant NOAEL-values from which they are derived are summarised in the following table.

Toxicological reference doses

Reference dose	**Value (mg/kg bw/day)**	**Study**	**NOAEL (mg/kg bw/day)**	**Uncertainty Factor**	**Relevance for risk assessment**
Long-term AEL	0.04	2-year rat study	3.6	100	long-term exposure
Medium-term AEL	0.08	2-generation rat study	8	100	repeated exposure (few weeks per year or frequent exposure)
Short-term AEL	0.3	developmental toxicity study in rat	30	100	acute exposure (single dose or a few days of exposure)

ADI and ARfD determination

Acceptable Daily Intake (ADI) is required to perform a dietary risk assessment for human consumers from residues from food origin. ADI is given for possible later need with product authorisation. ADI is based on 2-year rat study NOAEL value 3.6 mg/kg bw/day and the assessment factor of 100. Thus ADI is 0.04 mg/kg bw/day.

Acute Reference Dose (ARfD) is based on the NOAEL-value 30 mg/kg bw/day from the developmental toxicity study in rat. ARfD is 0.3 mg/kg bw/day with the assessment factor of 100.

2.2.1.2 SUMMARY OF THE HUMAN EXPOSURE ESTIMATIONS

Primary exposure

Table 2.2.1.2-1 summarises the results of the exposure assessment for professional/industrial users. The detailed assessments can be found in Doc. II-B, Section 3.2.2.

Table 2.2.1.2-1: Exposure during professional use of propiconazole in PT 9.3

Intended use (PT)	Exposure scenario	PPE	Systemic exposure [mg/kg bw/day]
PT 9.3 Polymerised material preservative	Connecting/Disconnecting transfer lines	none	**0.0429**
		gloves and coverall	**0.00438**
	Maintenance of production machines	none	**0.14**
		gloves and coverall	**0.019**

Secondary exposure - installation of flooring

Amateurs (DIY) and professional workers are exposed to propiconazole in PVC flooring they are installing.

For a 60-kg individual, the maximum systemic dose (2% dermal absorption) is

I = 588 mg/day × 2% × 15% ÷ 60 kg = **0.0294 mg/kg bw/day**

Secondary exposure - infants playing on floor

The relevant exposure route is dermal (palmar surface of the hands). Occasionally, oral exposure might also occur, e.g. in case a playing child puts its hand into the mouth.

Inhalation exposure is considered to be negligible due to the low vapour pressure of propiconazole.

The external dose on the skin is

E = 1.26 mg/kg bw/day

This dose on skin can either penetrate through skin or being ingested following hand-to-mouth contact. It is assumed that 10% of the amount of the product that ends up on the skin of a child is ingested ($\mathbf{I_{Oral}}$ **= 0.126 mg/kg bw/day**.

The systemic dose via skin is then $\mathbf{I_{Dermal}}$ = 1.26 mg/kg/day × 2% = **0.0252 mg/kg bw/day.**

The sum of both routes of exposure is **I = 0.1512 mg/kg bw/day.**

Using more realistic transfer efficient value of 3% (assumed from Schoknecht et al. 2003 study) the oral exposure of children playing on the PVC floor would be 0.0252 mg/kg bw/day and total systemic exposure 0.03 mg/kg bw/day.

Chronic inhalation exposure

Chronic inhalation exposure of general public may occur from volatilisation of propiconazole from covered PVC floors. According to the Tier-1 screening test this is not relevant.

2.2.1.3 SUMMARY OF RISK CHARACTERISATION FOR HUMANS

Exposure of workers using gloves and cotton coverall involved in the production of PVC flooring preserved with propiconazole and workers installing PVC flooring does not reach or exceed the long-term AEL (Table 2.2.1.3-1).

Exposure of the general population installing PVC flooring leaves >1000 margin of exposure to the short-term AEL. MOE for children playing on PVC floor is 24 (long-term exposure). Using more realistic transfer efficiency of 3%, the exposure of child playing on the PVC floor would be 0.03 mg/kg bw/day (MOE 120).

Propiconazole incorporated in PVC-flooring is an example of the use in treated articles. Generally, dermal exposure to a.s. may occur when consumers or professionals come in contact with treated articles. Release of propiconazole from the PVC-floor is considered to be limited (the content of a.s. in PVC-flooring is 0.1% and the transfer coefficient of 3% from PVC-floor was estimated realistic in exposure assessment). Despite the moderate sensitizing property of propiconazole itself, based on the risk assessment no specific concern is identified from similar type of applications of propiconazole in treated articles.

Table 2.2.1.3-1: Risk assessment for exposure to propiconazole during or after use in PT 9.3

Exposure scenario	Systemic exposure [mg/kg/day]	AEL [mg/kg/day]	% AEL covered	NOAEL [mg/kg/day]	Margin of Exposure
Connecting/Disconnecting transfer lines (no PPE)	0.0429	0.04	107	3.6	84
Connecting/Disconnecting transfer lines (with gloves and cotton coverall)	0.00438	0.04	11	3.6	822
Maintenance of production machines (no PPE)	0.14	0.04	350	3.6	26
Maintenance of production machines (with gloves and cotton coverall)	0.019	0.04	48	3.6	189
Installing PVC flooring 100 m^2/day (non-professionals, acute)	0.0294	0.3	10	30	1020
Installing PVC flooring 100 m^2/day (professionals, long-term)	0.0294	0.04	74	3.6	122
Playing on floor + hand-to-mouth contact (transfer efficiency 15%)	0.1512	0.04	378	3.6	24
Playing on floor + hand-to-mouth contact (transfer efficiency 3%)	0.03	0.04	75	3.6	120

2.2.2 ENVIRONMENT

2.2.2.1 FATE AND DISTRIBUTION IN THE ENVIRONMENT

2.2.2.1.1 Degradation in the aquatic compartment

Propiconazole is not readily biodegradable. Propiconazole is hydrolytically and photolytically stable. The dissipation half-life of propiconazole is around 6.4 days in water and degradation half-life 636 days in the whole water-sediment system at 20 °C ± 2 °C. The degradation half-life of 636 days in the water/sediment system at 20 °C corresponds to 1206 days at 12 °C which is the default temperature according to the Technical Guidance Document for Risk Assessment (TGD, EC, 2003). There is no simulation test of the biodegradation of propiconazole in surface water without sediment available and due to adsorption onto sediment in the water-sediment study the biodegradation half-life of propiconazole in water is not determined.

2.2.2.1.2. Degradation in soil

Based on the soil laboratory studies the geometric mean DT_{50} of propiconazole was determined to be 43 days at 20 °C (DT_{50} (12 °C) = 82 days and DT_{50} (10 °C) = 96 days). From the field studies the geometric mean dissipation half-life of 49 days was calculated after re-analysis of the data from old studies using First Order Multi Compartmental (FOMC) kinetics. In the soil accumulation studies of the plant protection product use carried out in France and Switzerland it was found that the repeated use of propiconazole did not show any significant accumulation of propiconazole or its degradation products in Central European conditions. However, the soil accumulation studies in Canada, where the winter climate conditions were similar to Northern Europe, were not long enough to prove that there would be no accumulation in soil during several years. In addition, there are soil accumulation studies on the plant protection product use of propiconazole conducted under Finnish field conditions from 2000 to 2003 available. However, accumulation in soil under Northern European conditions can not be excluded based on these studies. Furthermore, accumulation studies of plant protection product use are not directly applicable to the use of preservatives in plastics.

In the soil laboratory studies there were two degradation products of propiconazole accounting for more than 10% of the active substance (CGA 118 245 and 1,2,4-triazole). Both are degraded in soil faster than the parent substance, CGA 118 245 having DT_{50} of around 1 day and 1,2,4-triazole having DT_{50} of around 9.2 days at 20 °C. Both degradation products are also more mobile in soil than propiconazole, CGA 118 245 having the arithmetic mean K_{oc} of 129 ml/g from 3 soils and 1,2,4-triazole having the arithmetic mean K_{oc} of 69 ml/g from 10 soils.

2.2.2.1.3 Mobility in soil

Propiconazole adsorbs to soil and sediment (arithmetic mean K_{oc} of 944 ml/g from 9 soils) and is therefore of limited mobility.

2.2.2.1.4 Degradation in air

The estimated half-life of propiconazole in troposphere is between 10.2 and 42 hours assuming the OH-concentration ($5*10^5$) given in the Technical Guidance Document on Risk Assessment (TGD) and a 24-hour day.

2.2.2.2 EFFECTS ON ENVIRONMENTAL ORGANISMS

2.2.2.2.1 Aquatic compartment (including STP)

Propiconazole is very toxic to aquatic invertebrates and toxic to algae and fish. Predicted No-Effect Concentration (PNEC) in surface water is 6.8 µg a.i./l based on the NOEC (No Observed Effect Concentration) from marine fish. $PNEC_{sediment}$ = 0.054 mg a.i./kg wet sediment based on the NOEC from chironomus. PNEC in sewage treatment plant is 100 mg a.i./l.

2.2.2.2.2 Terrestrial compartment

Toxicity to terrestrial species was studied in three trophic levels (microorganisms, plants and earthworms). Based on the evaluation of the dossier, the long-term study on earthworms resulted in the lowest effect values. $PNEC_{soil}$ is 0.1 mg a.i./kg wet soil.

2.2.2.2.3 Non-compartment specific effects relevant to the food chain (secondary poisoning)

In the bioaccumulation study the mean steady-state BCF of propiconazole was 180 and depuration half-life 0.4 days for the whole fish. The estimated BCF of propiconazole for bioconcentration to soil dwelling species is 64.

For mammals, a NOAEC of 100 mg a.i./kg feed (lowest average intake 8.0 mg/kg bw/day) was obtained from a two generation reproduction study with rats. The $PNEC_{oral}$ of 3.33 mg a.i./kg food is derived by dividing the NOAEC by an assessment factor, which is 30 in case of a chronic study with mammals.

The $PNEC_{oral}$ of 3.33 mg a.i./kg feed is used for the risk characterisation.

2.2.2.2.4 PBT

Propiconazole fulfills the P-criterion in the water-sediment as well as in the soil compartment. For P-assessment, the DT_{50} values at 12 °C have to be considered and field studies are not to be taken into account (as agreed in the TM II 2009). The DT_{50} value for the water compartment is a dissipation half-life which cannot be used for assessing the P-criterion in the water phase but DT_{50} in the whole water/sediment system has to be compared with the P trigger value for water. Propiconazole does not fulfill other preliminary PBT and vPvB criteria proposed in the TGD.

In conclusion, propiconazole is considered as Persistent, but not Bioaccumulative and not Toxic.

2.2.2.2.5 Endocrine effects

Propiconazole is listed in the document of EU Commission on endocrine disrupting chemicals (COMMISSION STAFF WORKING DOCUMENT on implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706)) in Table 4: Substances classified as HPV and/or persistent and/or exposure expected in humans and wildlife, with insufficient data. The listing was done due to lack of information.

The dossier evaluated for this assessment report does not warrant conclusion of endocrine disruption potential for propiconazole. In the toxicity tests with mammals there were no effects in test animals which could be related to possible endocrine disruption. The analysis of sex ratio of F0 generation in a fish life-cycle test from the submitted dossier showed that propiconazole did not have any effect on the sex ratio of fish.

2.2.2.3 CALCULATION OF PECS

The environmental risk assessment for propiconazole used as preservative in vinyl floors (PT 9.3) is based on the ESD for plastic additives provided by the OECD (2004). For the assessment of predicted environmental concentrations of propiconazole in the different environmental compartments the manufacturing step, as well as the final end-use of the vinyl floor are considered. The treated vinyl contains 0.1% (w/w) of propiconazole for preservation of the plastic product against biodeterioration. The pathway for propiconazole residues emitted by either the production process or the in-service life of the product is by waste water emission to the drain with sewage treatment plants being the primary residues receiving environmental compartment. Soils and ground as well as surface water are only understood as indirect targets for emissions. The Predicted Environmental Concentrations (PECs) in different environmental compartments are reported in Document IIB of the Competent Authority Report.

2.2.2.4 RISK CHARACTERISATION FOR THE ENVIRONMENT

The following PEC/PNEC ratios have been calculated for the aquatic and terrestrial compartments. The risk is considered acceptable if PEC is less than PNEC (PEC/PNEC < 1).

2.2.2.4.1 PEC/PNEC for sewage treatment plants

The derived risk quotient is clearly < 1, showing that manufacturing and in-service of vinyl floors does not pose any unacceptable risk to microorganisms in a STP even when emissions from both life-cycle stages are considered to enter the same waste water treatment plant.

Table 2.2.2.4-1: PEC/PNEC ratio for sewage treatment plant

Compartment	PEC_{STP} [µg/L]	$PNEC_{microorganisms}$ [µg/L]	PEC / PNEC
Sewage treatment plant	27.052	100 000*	**0.0003**

* water solubility of the active substance without any assessment factor

2.2.2.4.2 PEC/PNEC for surface water

The PEC/PNEC value is below the trigger value of 1. No unacceptable risk is posed to aquatic organisms by the use of propiconazole as preservative agent in vinyl floors.

Table 2.2.2.4-2: PEC/PNEC ratio for propiconazole in surface water

Compartment	$PEC_{surface\ water}$ [µg/L]	$PNEC_{surface\ water}$ [µg/L]	PEC / PNEC
Surface water	2.70	6.80	**0.4**

2.2.2.4.3 PEC/PNEC for sediment

The sediment compartment can only be affected due to emissions to surface water. The PEC/PNEC ratio for sediment dwelling organisms is slightly above the trigger value of 1, indicating that sediment dwelling organisms would be at unacceptable risk by the intended use of propiconazole as biocidal product for Product Type 9.3.

Table 2.2.2.4-3: PEC/PNEC ratio concerning exposure of the sediment compartment

Compartment	$PEC_{sediment}$ [µg/kg]	$PNEC_{sediment}$ [µg/kg]	PEC / PNEC
Sediment	57.5	54	**1.065**

However, taking into account the further comments by the applicant (see Doc IIB) after the TM discussion on the CAR concerning the quantities of vinyl produced and the type of manufacturing process (closed or partially open) the PEC/PNEC ratios for sediment would be clearly below 1.

2.2.2.4.4 PEC/PNEC for soil

The calculations revealed a PEC/PNEC ratio of < 1 for year one and year ten after consecutive sludge applications on agricultural soil. Therefore, no unacceptable risk for soil organisms due to the use of propiconazole as preservative agent in vinyl floors is indicated.

Table 2.2.2.4-4: PEC/PNEC ratio concerning exposure of the soil compartment

Compartment	PEC_{soil} [µg/kg soil]	$PNEC_{soil}$ [µg/kg soil]	$\frac{PEC}{PNEC}$
Soil after 1 sludge application	12.45	100	**0.12**
Soil after 10 sludge applications	13.05		**0.13**

2.2.2.4.5 Groundwater

In the risk assessment for propiconazole used as wood preservative (PT 8, already evaluated by the Finnish CA and endorsed at the EU level), FOCUS-PEARL-3.3.3 groundwater modelling was carried out. The modelling was made for the parent compound and the main degradation product in soil 1,2,4-triazole. In one soil study another degradation product (CGA 118 245) has been identified and quantified >10% of the initial radioactivity. However, CGA 118 245 degrading more rapidly and being slightly less mobile than 1,2,4-triazole the modelling results of the latter are considered sufficient. The calculations were performed for a total applied amount of 4375 g a.i. per ha over 5 years, resulting in an annual application rate of 875 g a.i. per ha and year. If the data for the annual application of propiconazole-containing sludge (5000 kg/ha/year) is multiplied with the a.i. concentration of the sludge (Csludge = 7.133 mg/kg) a 24-fold lower annual application of propiconazole (35.66 g a.i./ha) is to be expected to soil by the use of the compound as biocide in PT 9.3 (vinyl floors) compared to PT 8.

For the use of propiconazole as wood preservative (PT 8) the PECs for the parent compound itself and its main degradation product in soil (1,2,4-triazole) in groundwater, represented by the 80th percentile leachate concentration at 1 m soil depth, was lower than 0.001 µg/l in all FOCUS-PEARL scenarios. Thus, in the present risk assessment groundwater concentrations far below 0.001 µg/l are expected due to a much lower total application amount of 35.66 g/ha for the use of propiconazole within Product Type 9.3 (vinyl flooring).

2.2.2.4.6 Air

According to the vapour pressure and the Henry's law constant of propiconazole a volatilisation of the compound or transfer from the liquid phase into the air is not indicated.

Although the ESD for plastic additives (OECD, 2004, Table 6.1) foresees the calculation of releases to air during the compounding and conversion section of plastic manufacturing, this calculation was not deemed reasonable in this assessment since the active substance is not stable in the atmosphere. The calculations of the chemical lifetime in the troposphere resulted in a half-life between 10.2 and

42 hours. Therefore, propiconazole when entering the air compartment is rapidly degraded by photochemical processes. Accumulation in the air or transport over longer distances is not to be expected. In summary, the atmosphere is not a compartment of concern for propiconazole.

2.2.2.4.7 PEC/PNEC for biota

The PEC/PNEC ratio for vertebrates is clearly < 1, indicating that the use of propiconazole in preservatives for polymerized materials as vinyl floors would not pose an unacceptable risk to top predators in the aquatic food chain.

Table 2.2.2.4-2: PEC/PNEC ratio concerning accumulation in the food chain

Compartment	PECoral, predator (µg/kg)	PNECoral (µg/kg)	PEC/PNEC
Biota	497	3330	**0.15**

2.2.3 LIST OF END POINTS

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the most important endpoints as identified during the evaluation process are listed in "List of endpoints" in Appendix I.

2.3 OVERALL CONCLUSIONS OF THE EVALUATION

With regard to human health, propiconazole is a skin sensitizer. Despite the moderate sensitizing property of propiconazole, based on the risk assessment no specific concern is identified due to use of treated articles intentionally incorporating propiconazole. Therefore, there is no need to set restrictions or specific conditions for use of propiconazole in similar type of applications as evaluated in this CAR. It is stressed that propiconazole is free of carcinogenic or mutagenic effects and adverse effects on reproduction and development. The results of the risk assessment indicate that users will not be exposed to unacceptable levels of propiconazole during production and in-life phase of preserved polymers. The overall conclusion from the evaluation of propiconazole, for use in Product Type 9.3, is that the active substance will not present an unacceptable risk to humans during normal use when instructions for use on the label of the product are followed.

The environmental risk assessment for propiconazole used as preservative in plastics (PT 9) is based on the emission scenario of its use in vinyl floor manufacturing and during service-lifetime. The ESD for plastic additives (OECD, 2004) assumes that the process of product application generates emissions to the drain with sewage treatment plants being the primary environmental compartment receiving residues. Further emissions assumed to enter the same STP are caused due to cleaning operations of the vinyl floor in service. Since propiconazole is slightly volatile it remains on the surface of the floor and probably will primarily be removed by cleaning activities. Surface water bodies (water and sediment) and soils are indirect targets via STP effluents or the application of sewage sludge to agricultural fields. Due to the physical and chemical properties of propiconazole, groundwater and the air are no compartments of concern. Concentrations for the affected compartments are calculated taking the model assumptions for the distribution of propiconazole in a STP from the SimpleTreat model integrated in EUSES (10% going into the sludge and 90% staying in the water phase).

Propiconazole is very toxic to aquatic organisms and due to its persistency may cause long-term adverse effects in the environment. However, the PEC/PNEC relations for all environmental compartments are < 1, even though emissions from manufacturing and in-service use of the product are assumed to be discharged in the same STP. No unacceptable risk can be seen for organisms due to potential emissions arising from the use of propiconazole within a PT 9 product.

According to the applicant propiconazole has a broad efficacy against potentially harmful fungi, and thus, bio-spoilage during the in-service life of manufactured plastic products as vinyl floors can be avoided by the addition of propiconazole as preservative in plastics. However, on the basis of the efficacy test submitted in the dossier, likely concentration at which the active substance will be used (1000 ppm = 1 g/kg plastic) cannot be fully justified because there was no difference observed in the efficacy for 500 ppm compared with the higher concentrations.

Propiconazole is considered as Persistent, but not Bioaccumulative and not Toxic.

There is no evidence of endocrine effects of propiconazole in the dossier evaluated for this assessment report. However, propiconazole is listed in the document of EU Commission on endocrine disrupting chemicals due to lack of information.

3. PROPOSED DECISION

3.1 BACKGROUND TO THE PROPOSED DECISION

The minimum purity of 93% w/w is a guaranteed minimum content given by the applicant, which means that no batch is released in production if it does not meet this minimum purity, whereas the 5-batch analysis shows slightly higher purities (> 94.5% w/w). The toxicological and ecotoxicological studies were conducted with purities of 92 to 93% in most cases and always at least 88%.

With regard to human health, propiconazole is a skin sensitizer. It is stressed that propiconazole is free of carcinogenic or mutagenic effects and adverse effects on reproduction and development. The results of the risk assessment indicate that users will not be exposed to unacceptable levels of propiconazole during production and in-life phase of preserved polymers. The overall conclusion from the evaluation of propiconazole, for use in Product Type 9.3, is that the active substance will not present an unacceptable risk to humans during normal use when instructions for use on the label of the product are followed.

The environmental risk assessment for propiconazole used as preservative in plastics (PT 9) is based on the emission scenario of its use in vinyl floor manufacturing and during service-lifetime. The ESD for plastic additives (OECD, 2004) assumes that the process of product application generates emissions to the drain with sewage treatment plants being the primary environmental compartment receiving residues. Further emissions assumed to enter the same STP are caused due to cleaning operations of the vinyl floor in service. Since propiconazole is slightly volatile it remains on the surface of the floor and probably will primarily be removed by cleaning activities. Surface water bodies (water and sediment) and soils are indirect targets via STP effluents or the application of sewage sludge to agricultural fields. Due to the physical and chemical properties of propiconazole, groundwater and the air are no compartments of concern. Concentrations for the affected compartments are calculated taking the model assumptions for the distribution of propiconazole in a STP from the SimpleTreat model integrated in EUSES (10% going into the sludge and 90% staying in the water phase).

Propiconazole is very toxic to aquatic organisms and due to its persistency may cause long-term adverse effects in the environment. However, the PEC/PNEC relations for all environmental compartments are < 1, even though emissions from manufacturing and in-service use of the product are assumed to be discharged in the same STP. No unacceptable risk can be seen for organisms due to potential emissions arising from the use of propiconazole within a PT 9 product.

According to the applicant propiconazole has a broad efficacy against potentially harmful fungi, and thus, bio-spoilage during the in-service life of manufactured plastic products as vinyl floors can be avoided by the addition of propiconazole as preservative in plastics. However, on the basis of the efficacy test submitted in the dossier, likely concentration at which the active substance will be used (1000 ppm = 1 g/kg plastic) cannot be fully justified because there was no difference observed in the efficacy for 500 ppm compared with the higher concentrations.

Propiconazole is considered as Persistent, but not Bioaccumulative and not Toxic.

There is no evidence of endocrine effects of propiconazole in the dossier evaluated for this assessment report. However, propiconazole is listed in the document of EU Commission on endocrine disrupting chemicals due to lack of information.

3.2 PROPOSED DECISION

The overall conclusion from the evaluation of propiconazole for use in product-type 9 (fibre, leather, rubber and polymerised materials preservatives), is that it may be possible to issue authorisations of products containing that substance in accordance with the conditions laid down in Article 5(1) b), c) and d) of Dir. 98/8/EC.

It is therefore proposed to approve propiconazole for use in product-type 9 (fibre, leather, rubber and polymerised materials preservatives), subject to the following specific conditions:

The minimum purity of 93% w/w for the approval is a guaranteed minimum content given by the applicant, which means that no batch is released in production if it does not meet this minimum purity, whereas the 5-batch analysis shows slightly higher purities (> 94.5% w/w). The toxicological and ecotoxicological studies were conducted with purities of 92 to 93% in most cases and always at least 88%. In order to respect the development of the manufacturing processes a minimum purity of 93% w/w can be taken although some of the older effect studies refer to slightly lower purities.

The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.

Where a treated article has been treated with or intentionally incorporates propiconazole, and where necessary due to the possibility of skin contact as well as the release of propiconazole under normal conditions of use, the person responsible for placing the treated article on the market shall ensure that the label provides information on the risk of skin sensitisation, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012

3.3 ELEMENTS TO BE TAKEN INTO ACCOUNT WHEN AUTHORISING PRODUCTS

1. In the dossier submitted for the review program the minimum purity of 93 % w/w was supported.

2. Complete data package on the identity and physico-chemical properties of products should be submitted at the product authorisation stage.

3. The efficacy of the individual products shall be demonstrated prior to product authorisation at the Member State level.

4. Dermal absorption values used in the applications for product authorisation should be justified, if available by the submission of specific dermal absorption data on the product, or by read-across to existing data if scientifically justified, or by using default values.

5. Migration of the a.s. from the treated article to skin should be minimized when considered relevant due to skin sensitizing property of a.s.

6. It is recommended that at the product authorisation stage an aerobic water-sediment simulation test with ^{14}C-phenyl labelled propiconazole should be required.

7. Based on the directive 1999/45/EEC preparations not classified as sensitising but containing at least one sensitising substance in a concentration ≥0.1% must bear the inscription 'Contains (name of sensitising substance). May produce an allergic reaction.'

8. Based on suspected properties of the azole group and insufficient data propiconazole is listed in the Annexes of the EU Commission document on implementation of the Community Strategy for Endocrine Disruptors as a substance which may have the potential to cause endocrine disruption in both humans and animals. With this in mind, further information may be required to assess the potential for endocrine disruption of propiconazole when EU harmonised guidelines are established for test methods and risk assessment. However, in the submitted studies there were no effects in the test animals which could be related to possible endocrine disruption.

   It has been agreed that propiconazole should be further assessed with regards to its potential endocrine disruptor properties once further guidance is available and preferably before the product authorisation stage. The conclusion of that assessment might lead to review the active substance approval.

3.4 REQUIREMENT FOR FURTHER INFORMATION

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the approval of propiconazole in accordance with Article 9 of Regulation (EU) No 528/2012.

3.5 UPDATING THIS ASSESSMENT REPORT

This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information submitted in relation with Regulation (EU) No 528/2012. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the approval of propiconazole.

Appendix I: List of end points

Appendix II: List of intended uses

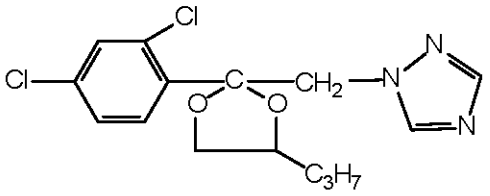
Appendix III: List of studies

Appendix I: List of Endpoints

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Common Name)	propiconazole
Function (*e.g.* fungicide)	fungicide
Rapporteur Member State	Finland

Identity (Annex IIA, point II.)

Chemical name (IUPAC)	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
Chemical name (CA)	1H-1,2,4-Triazole, 1-[[2-(2,4-dichloro phenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-
CAS No	60207-90-1
EC No	EINECS : 262-104-4
Other substance No.	CIPAC no: 408
Minimum purity of the active substance as manufactured (g/kg or g/l)	Min 930 g/kg (Syngenta)
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None
Molecular formula	$C_{15}H_{17}Cl_2N_3O_2$
Molecular mass	342.2
Structural formula	

Physical and chemical properties (Annex IIA, point III., unless otherwise indicated)

Freezing point (state purity)	-23°C (98.8%)
Boiling point (state purity)	> 250°C at 101.325 kPa (The highest temperature in the test was 270 °C.) 120°C at 1.9 Pa (92.2%) (decomposition begins around 355°C)
Temperature of decomposition	355°C (92.2%)
Appearance (state purity)	Clear, viscous liquid (purified 98.8%), yellowish (technical 92.2%)

Relative density (state purity)	1.289 at 20°C (92.2%)
Surface tension	filtrates of 10.0 g / l suspensions : σ = 46.6 - 48.4 mN / m filtrates of 1.0 g / l suspensions : σ = 55.8 - 62.3 mN / m (at 20°C). The results are based on too concentrated samples compared to the guideline. When this and the molecular structure are taken into account, propiconazole is not regarded as a surface-active substance.
Vapour pressure (in Pa, state temperature)	5.6×10^{-5} Pa at 25°C (99.1%)
Henry's law constant (Pa m^3 mol^{-1})	9.2×10^{-5} Pa m^3 mol^{-1}
Solubility in water (g/l or mg/l, state temperature)	pH 6.9 : 100 mg/l at 20°C (99.1%) There are no measurements on pH dependency of the solubility in water. However, based on the dissociation constant (pKa =1.09) it can be assumed that there is no marked pH dependency over a wide range of pH values.
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	n-hexane : 47 g / l Completely miscible in solvents: toluene, dichloromethane, ethanol, n-octanol, acetone and ethyl acetate (25°C) (92.2% and 92.4%)
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	Not available
Partition coefficient (log K_{OW}) (state temperature)	3.72 at 25°C , pH 6.6 (99.1%)
Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	pH 1, 5, 7, 9 and 13: no remarkable hydrolysis at 70 °C in 28 days
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	pKa = 1.09 at 20°C (99.1%)
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	λ_{max} : 220.4 nm, ε_{max} : 11666 M^{-1} cm^{-1} No absorption between 290 and 750 nm. (98.8%)
Photostability (DT_{50}) (aqueous, sunlight, state pH) (point VII.7.6.2.2)	pH 7: no remarkable photolysis at 25 ±1°C in 30 days
Quantum yield of direct phototransformation in water at Σ > 290 nm (point VII.7.6.2.2)	No absorption > 290 nm
Flammability	There was no self-ignition of propiconazole up to the start of decomposition (355 °C). (Self-ignition temperature of the decomposition products: 430°C) Not flammable, not highly flammable, not extremely flammable (92.4%)
Explosive properties	Not explosive (92.4%)
Oxidizing properties	Not oxidizing (92.4%)

Classification and proposed labelling (Annex IIA, point IX.)

with regard to physical/chemical data	No classification
with regard to toxicological data	Xn R22 R43; S(2), S36/37, S46
with regard to fate and behaviour data	
with regard to ecotoxicological data	N R50/53; S60, S61

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	GC-FID packed column, internal standardization
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	Refer to Confidential Annex

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	GLC-NPD; LOQ : 0.02 mg/kg (parent compound) GLC-ECD; LOQ : 0.05 mg/kg (total; 2,4-DCBA) HPLC-UV; LOQ : 0.01 mg/kg as 1,2,4-triazole (total; 1,2,4-triazole) LC-LC-ESI/MS/MS; LOQ : 0.005 mg/kg (CGA 118 244) HPLC-MS/MS; LOQ: 0.005 mg/kg as parent compound and its degradation products CGA 21795, CGA 91305, CGA 118244, CGA 118245, CGA 136735 and CGA 71019 (1,2,4-triazole)
Air (principle of method and LOQ) (Annex IIA, point 4.2)	GLC-NPD; LOQ : 10 µg/m^3 (parent compound) GC-MS; LOQ : 10 µg/m^3 (parent compound)
Water (principle of method and LOQ) (Annex IIA, point 4.2)	GLC-ECD; LOQ : 0.05 µg/l (parent compound in potable water) GC-MS : 0.05 µg/l (parent compound in potable water and surface water) *Sediment* HPLC-LC/MS/MS: 0.010 mg/kg (parent compound and its degradation products CGA 217495, CGA 91305 and CGA 136735)
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	Not applicable (not toxic or very toxic substance)
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not applicable
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not applicable

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals (Annex IIA, point 6.2)

Rate and extent of oral absorption:	86% within 48 h
Rate and extent of dermal absorption:	1% for the concentrated b.p. at 25% a.i. 2% for dilute solutions and residues from treated articles considering 0.1% a.i.
Distribution:	Widely distributed; highest residues in liver and kidneys
Potential for accumulation:	No evidence of accumulation
Rate and extent of excretion:	95% in 48 h, in about equal amounts in urine and feces (enterohepatic re-circulation)
Toxicologically significant compounds:	Parent compound and metabolites (animals). Triazolyl alanine and triazolyl acetic acid formed only in plants; not toxicologically significant
Metabolism in animals:	Extensively metabolised (>20 metabolites identified in rat urine)

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral:	Appr. 1500 mg/kg bw; R22
Rat LD_{50} dermal:	>4000 mg/kg bw
Rat LC_{50} inhalation:	>5.8 mg/l/4 h, nose-only
Skin irritation:	Not irritating
Eye irritation:	Not irritating
Skin sensitization (test method used and result):	Skin sensitizer (Maximisation test); R43

Repeated dose toxicity (Short term toxicity) (Annex IIA, point 6.3)

Species/ target / critical effect:	I:1 Liver toxicity
Lowest relevant oral NOAEL / LOAEL:	NOAEL: 20 ppm (2.7 mg/kg bw/day; 17 week, mice)
Lowest relevant dermal NOAEL / LOAEL:	NOAEL: 100 mg/kg bw/day (28 day, rat)
Lowest relevant inhalation NOAEL / LOAEL:	NOAEC: 21 mg/m^3 (90 days rat; 6 h head-only/day)

Genotoxicity (Annex IIA, point 6.6)	No genotoxic effects

Long term toxicity and carcinogenicity (Annex IIA, point 6.4)

Target / critical effect:	Liver in rats and mice
Lowest relevant NOAEL / LOAEL:	NOAEL: 100 ppm (3.6 mg/kg bw/day; 2 year, rat)

Carcinogenicity:	Liver tumors in male mice. The lowest dose with tumors (mainly hepatocellular adenomas) was 2500 ppm (344.3 mg/kg bw/day)

Reproductive toxicity (Annex IIA, point 6.8)

Species/ Reproduction target / critical effect:	Reduced litter size, pup weight and viability. Effects at dose levels causing parental toxicity
Lowest relevant reproductive NOAEL / LOAEL:	NOAEL: 100 ppm (8 mg/kg bw/day; 2-generation, rat)
Species/Developmental target / critical effect:	Slight increase in cleft palate in rat, also increased visceral and skeletal variations at dose levels causing marked maternal toxicity
Lowest relevant developmental NOAEL / LOAEL:	NOAEL: 30 mg/kg bw/day (rat)

Neurotoxicity / Delayed neurotoxicity (Annex IIIA, point VI.1)

Species/ target/critical effect:	No further data required
Lowest relevant NOAEL / LOAEL:	

Other toxicological studies (Annex IIIA, VI/XI)

.....	Triazolyl alanine and triazolyl acetic acid (formed only in plants) were studied for toxicokinetics, acute toxicity, short-term toxicity and genotoxicity (also reproductive toxicity of triazolyl alanine). No adverse effects were observed. Studies on tumor promotion and induction of drug metabolising enzymes showed that propiconazole is a promoter of proliferative changes and causes induction of hepatic enzymes.

Medical data (Annex IIA, point 6.9)

.....	Surveillance of manufacturing plant personnel reports four cases of compound related adverse effects (skin reactions, allergenic in one case) during handling of plant protection product (PPP) formulations. Dermal testing of 20 human volunteers with epicutaneous doses up to 1% caused no dermal reactions in any of the test subjects. Three occupational exposure cases involving Tilt (PPP) are reported. The occupationally exposed showed no sensitisation reactions, but chest pain and local skin reactions were observed. A literature search for publications between 1975 and 2000 has been performed using 32 different data bases. No studies indicating possible health effects in humans attributable to the use of propiconazole was found in this search. Later, a study from 2004 has shown one case of sensitisation (confirmed by patch test) to propiconazole among banana plantation workers exposed to pesticides.

Summary (Annex IIA, point 6.10)

	Value	Study	Safety factor
Short-term AEL:	0.3 mg/kg bw/day	Developmental study in rat	100
Medium-term AEL:	0.08 mg/kg bw/day	2-generation rat study	100
Long-term AEL:	0.04 mg/kg bw/day	2-year rat study	100
ADI	0.04 mg/kg bw/day	2-year rat study	100
ARfD	0.3 mg/kg bw/day	Developmental study in rat	100
Drinking water limit:	0.1 µg/l	As set by EU Drinking Water Directive (98/83/EC)	Not relevant

Acceptable exposure scenarios (including method of calculation)

	Systemic exposure / Margin of Exposure
PT 9.3:	
Connecting/disconnecting transfer lines RISKOFDERM	0.0429 mg/kg bw/day (no PPE) 0.00438 mg/kg bw/day (with PPE) MOE = 84 (no PPE) MOE = 822 (with PPE)
Maintenance of production machines BEAT	0.14 mg/kg bw/day (no PPE) 0.019 mg/kg bw/day (with PPE) MOE = 26 (no PPE) MOE = 189 (with PPE)
Amateur/professional, installing PVC flooring (100 m^2/day)	0.0294 mg/kg bw/day MOE = 1020 (amateur) MOE = 122 (professional)
Infant, playing on floor + hand-to-mouth contact	0.1512 mg/kg bw/day (transfer efficient 15%) 0.03 mg/kg bw/day (transfer efficient 3%) MOE = 24 (transfer efficient 15%) MOE = 120 (transfer efficient 3%)

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water (Annex IIA, point 7.6, IIIA, point XII.2.1, 2.2)

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 1, 5, 7, 9 and 13: no remarkable hydrolysis at 70 °C in 28 days major metabolites : not relevant
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	pH 7: no remarkable photolysis at 25 ±1°C in 30 days major metabolites : not relevant
Readily biodegradable (yes/no)	No
Biodegradation in seawater	Not applicable
Non-extractable residues	No
Distribution in water / sediment systems (active substance)	Expressed as parent compound 96.5 – 98.1 % of applied radioactivity in water at the beginning of the study and 0.9 – 2.0 % of applied radioactivity in water at the end of the study (175 days), respective amounts in the sediment were 2.0 and 76.8 – 81.7 % of applied radioactivity (175 days); non-extractable residues were found at the end of the study 7.6 –9.1 %; mineralisation 0.4 % of applied radioactivity (1 Rhine water and 1 pond water) Dissipation half-life in water 5.5 - 6.4 days Total degradation half-life in the whole system 485 – 636 days, 636 days used in the risk assessment
Distribution in water / sediment systems (metabolites)	Eight metabolites were found CGA 217 495 2.8 – 2.9 %; CGA 91305 3.1 – 5.0 %; M3 (unknown) 3.1 – 4.4 %; 1,2,4-triazole 2.1 – 2.3 % after 90 to 175 days. Others were found at concentrations below 1.3 % (1 Rhine water and 1 pond water), all metabolites amounting < 10% of the applied radioactivity, no further evaluation needed

Route and rate of degradation in soil (Annex IIIA, point VII.4, XII.1.1, XII.1.4; Annex VI, para. 85)

Mineralization (aerobic)	Propiconazole: -CO_2 evolved < 5% of applied radioactivity (triazole labelled a.i.) in 120 days and 29 - 35 % (phenylring labelled a.i. 1 soil) of applied radioactivity in 168 days -1,2,4-triazole (was used as a starting substance): CO_2 evolved 1.6 – 32.2 % of applied radioactivity (120 d) -CGA 118 245 CO_2 0.1 –0.2 % of applied radioactivity (3 soils, 5 d)
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): Propiconazole: DT_{50lab} (20 – 25 °C, aerobic): 29 - 72 days (n = 8, geometric mean 43 days), 128 days (n=1) at 13.5°C

	1,2,4-triazole: DT_{50lab} 6 – 12 days (20 °C) (n = 3) CGA 118 245: DT_{50lab} around 1 day (20 °C) (n = 3)
	DT_{50lab} (20°C, anaerobic): not determined
	degradation in the saturated zone: not available
Field studies (state location, range or median with number of measurements)	DT_{50f}: Propiconazole: DT_{50f}: Switzerland, 16 days (n = 1) Switzerland, 121 - 129 days (n =2) I:2 Germany, 24 - 73 days (n = 3) I:3 Maximum 129 d from FOMC kinetics used in the risk assessment. DT_{50f} longer than three months cannot be excluded.
	DT_{90f}: Propiconazole: DT_{90f}: > 380 - > 665 days (n = 4) DT_{90f} longer than one year cannot be excluded.
Anaerobic degradation	Not applicable
Soil photolysis	Not applicable
Non-extractable residues	In the laboratory studies after 100 days at 20-25 °C : Propiconazole: -triazole labelled 14.1 - 15.5 % of applied radioactivity (84 d), 47.3 % of applied radioactivity (120 d) -phenylring labelled 23.3 - 27.3 % of applied radioactivity (84 d) -triazole labelled 3.4 – 24.6 % of applied radioactivity (105 days) in different conditions -1,2,4-triazole (was used as a starting substance): 41.8 – 66.2 % of applied radioactivity (3 soils, 120 d) -CGA 118 245 non-extractables 9.8 – 12.3 % of applied radioactivity (3 soils, 5 d)
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	1,2,4-triazole (CGA 71019) 24 % - 43 % of applied radioactivity -CGA 118 245 (U3) 22 % of applied radioactivity
Soil accumulation and plateau concentration	France: maximum residues of propiconazole were < 0.02 – 0.12 mg/kg and 1,2,4-triazole < 0.01 mg/kg within 6 – 7 years of annual 2 x 125 g a.i./ha use Switzerland: maximum residues of propiconazole were < 0.02 – 0.06 mg/kg and 1,2,4-triazole < 0.01 – 0.05 mg/kg within 10 years of annual 2 – 3 x 125 g a.i./ha Canada: maximum residues of propiconazole were 0.03 mg/kg - 0.1 mg/kg (250 g a.i./ha/year) and 0.03 – 0.17 mg/kg (500 g a.i./ha/year) within two years; 1,2,4-triazole was not found above detection limit of 0.1 ppm Canada: maximum residues of propiconazole were 0.03 mg/kg - 0.09 mg/kg (cumulative use rate 250

	– 375 g a.i./ha within two years) and 0.04 – 0.18 mg/kg (cumulative use rate 500 – 750 g a.i./ha) within three years; 1,2,4-triazole was found at trace amounts in higher use rate plots Finland: the residues of propiconazole were 0.01 – 0.06 mg/kg (0- 20 cm, 7 fields) except one residue of 0.26 after many years use

Adsorption/desorption (Annex IIA, point XII.7.7; Annex IIIA, point XII.1.2)

Ka , Kd Ka_{oc} , Kd_{oc}	Propiconazole: Ka_{oc} 382 – 1789 ml/g (9 soils) 1,2,4-triazole: Ka_{oc} 13 – 202 ml/g (10 soils) CGA 118 245: Ka_{oc} 101 – 166 ml/g (3 soils) Propiconazole: Kd_{oc} 455 – 2279 ml/g (9 soils)
pH dependence (yes / no) (if yes type of dependence)	No

Fate and behaviour in air (Annex IIIA, point VII.3, VII.5)

Direct photolysis in air	No photolysis
Quantum yield of direct photolysis	Not relevant
Photo-oxidative degradation in air	The estimated half-life of propiconazole in troposphere is between 10.2 and 42 hours assuming the OH-concentration ($5*10^5$) given in the TGD (formula 28) and a 24-hour day
Volatilization	Very slightly volatile

Monitoring data, if available (Annex VI, para. 44)

Soil (indicate location and type of study)	Not available
Surface water (indicate location and type of study)	Available data related to plant protection product use, biocide related data not available
Ground water (indicate location and type of study)	Available data related to plant protection product use, biocide related data not available
Air (indicate location and type of study)	Available data related to plant protection product use, biocide related data not available

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)
(Annex IIA, point 8.2, Annex IIIA, point 10.2)

Species	Time-scale	Endpoint	Toxicity
Fish			
Spot *Leiostomus xanthurus* (marine species)	Acute 96 h	LC_{50}	2.6 mg ai/L
Sheepshead minnow *Cyprinodon variegates* (marine species)	Chronic 100 d	NOEC	0.068 mg ai/L
Aquatic invertebrates			
Mysid shrimp *Mysidopsis bahia* (marine species)	Acute 96 h Chronic 28 d	LC_{50} NOEC	0.51 mg ai/L 0.11 mg ai/L
Algae			
Green algae *Pseudokirchneriella subcapitata*	72 h	ECr_{50} NOEC	9.0 mg ai/l 0.46 mg ai/l
Sediment organisms			
Chironomus riparius	28 d	Emergence, NOEC Development, NOEC	8.0 mg ai/L(water) 25.0 mg ai/kg dw (sed.) = 5.4 mg ai/kg ww (dividing by a conversion factor of 4.6) 4.0 mg ai/L (water) 50.0 mg ai/kg dw (sed.) = 10.8 mg ai/kg ww (dividing by a conversion factor of 4.6)
Microorganisms			
Activated sludge from STP	3 h	Respiration inhibition EC_{50}	> 100 mg ai/L

Effects on earthworms or other soil non-target organisms

Acute toxicity to **earthworms** ……. (Annex IIIA, point XIII.3.2)	-Propiconazole : LC_{50} 686 mg ai/kg dw = 205 mg ai/kg ww (at 3.4% organic matter and using a conversion factor of 0.88 from dw to ww) - 1,2,4-triazole: LC_{50} > 1000mg/kg dw = 299 mg/kg ww (at 3.4% organic matter and using a conversion factor of 0.88 from dw to ww) - CGA 118 245 LC_{50} > 1000 mg/kg dw = 299 mg/kg ww (at 3.4% organic matter and using a conversion factor of 0.88 from dw to ww)
Reproductive toxicity to **earthworms** … (Annex IIIA, point XIII.3.2)	- Propiconazole: NOEC = 0.998 mg ai/kg ww (at 3.4% organic matter)

Effects on soil micro-organisms (Annex IIIA, point 3.3)

Nitrogen mineralization	- Propiconazole: EC_{50} > 1.67 mg ai/kg dw = 2.16 mg ai/kg ww (at 3.4% organic matter and using a conversion factor of 0.88 from dw to ww) NOEC = 1.67 mg ai/kg dw = 2.16 mg ai/kg ww (at 3.4% organic matter and using a conversion factor of 0.88 from dw to ww) - 1,2,4-triazole: EC_{50} > 0.33 mg/kg dw = 0.82 mg/kg ww (at 3.4% organic matter and using a conversion factor of 0.88 from dw to ww) NOEC = 0.33 mg/kg dw = 0.82 mg/kg ww (at 3.4% organic matter and using a conversion factor of 0.88 from dw to ww)
Carbon mineralization	Not available

Effects on terrestrial plants (Annex IIIA, point 3.4)

Propiconazole Seedling emergency and survival EC_{50} = 4.32 mg ai/kg ww (at 3.4% organic matter) Reproduction NOEC 0.96 mg propiconazole/kg dw soil = 1.69 mg ai/kg wet soil (at 3.4% organic matter)

Effects on terrestrial vertebrates

Not applicable

Effects on honeybees (Annex IIIA, point XIII.3.1)

Not applicable

Effects on other beneficial arthropods (Annex IIIA, point XIII.3.1)

Not applicable

Bioconcentration (Annex IIA, point 7.5)

Bioconcentration factor fish (BCF)	180 (bluegill)
Depuration time(DT_{50}) (DT_{90})	99 % of propiconazole was eliminated during 3-day depuration period Depuration time for the whole fish (DT_{50}) = 0.29 d (0.064 mg/l) and 0.48 d (0.0064 mg/l)
Level of metabolites (%) in organisms accounting for > 10 % of residues	Not relevant
Estimated BCF for earthworms	64 (TGD formula 82d)

Chapter 6: Other End Points

Appendix II: List of intended uses

Summary of intended uses

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks
			(a)	Type (b-d)	Conc. of as (g)	method kind (d-f)	number min max (h)	interval between applications (min)	g as/kg min max	water L/m^2 min max	g as/m^2 min max	(i)
Polymer preservative PT 9.3	All	Mystox IP	Fungi	SL soluble concentrate	250 g/L	addition	1	–	1 g/kg	–	–	–

(a) *e.g.* biting and suckling insects, fungi, molds;
(b) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR);
(c) GCPF Codes - GIFAP Technical Monograph No 2, 1989 ISBN 3-8263-3152-4)
(d) All abbreviations used must be explained
(e) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench;
(f) Kind, *e.g.* overall, broadcast, aerial spraying, row, bait, crack and crevice equipment used must be indicated;
(g) g/kg or g/l
(h) Indicate the minimum and maximum number of application possible under practical conditions of use;
(i) Remarks may include: Extent of use/economic importance/restrictions

Appendix III: List of studies

On request by the applicant the names of authors, companies and organisations related to unpublished studies have been blanked out in the tables below. Data protection is claimed by the applicant under Article 12.1(c) (ii) of Council Directive 98/8/EC for all study reports marked "Y" in the "Data Protection Claimed" column of the tables below. These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

Most studies listed below were already submitted for Annex I listing of propiconazole as PT 8 (wood preservative). The studies/information first submitted for the evaluation of propiconazole in PT 9 have been flagged with * in the first column of the tables below.

Active substance propiconazole (CGA 64250)

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
2.6	Burkhard N., Manufacturing process - CGA 64250 Syngenta Crop Protection AG, Basle, Process Description, 15.02.1995 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG CONFIDENTIAL INFORMATION	no	No Y
2.7	Burkhard N., Purity and by-products of techn. A.I. , Syngenta Crop Protection AG, Basle, Data Sheet, 06.02.1995 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG CONFIDENTIAL INFORMATION	no	No Y
2.8/01	Käser W., List of by-products (codes, names, formulae), Ciba-Geigy Muenchwilen AG, Muenchwilen, Overview, 21.02.1995 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG CONFIDENTIAL INFORMATION	no	No Y
2.8/02	Käser W., Report on chemical composition (5 batches) Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 30040, 15.02.1995 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG CONFIDENTIAL INFORMATION	yes	No Y
2.8/03	Kreuzer A., Report on chemical composition (nitrosamines) Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 30011, 15.02.1995 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG CONFIDENTIAL INFORMATION	yes	No Y

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
2.8/04	Friedrich K., Determination of 2,3,7,8 - TCDD and 2,3,7,8 - TCDF in CGA 64250, Syngenta Crop Protection AG, Basle Project Report, 09.10.1987 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG CONFIDENTIAL INFORMATION	no	No Y
2.8/05	Burkhard N., Analytical certificates of technical propiconazole used for the determination of physico-chemical properties Syngenta Crop Protection AG, Basle, 20.02.1995 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG CONFIDENTIAL INFORMATION	yes	no Y
2.8/06	Maier W., Purity of test material used in toxicity tests Syngenta Crop Protection AG, Basle, 12.01.1995 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG CONFIDENTIAL INFORMATION	no	no Y
3.1.1	Geoffroy A., Report on freezing temperature, Syngenta Crop Protection AG, Basle, Rep N° PP-94/37P.MPR, 29.09.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.1.2	Das R., Report on boiling point/boiling range, Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep N° 16313, 08.11.1993 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.1.3	Das R., Report on density, Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep N° 16314, 08.11.1993 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.2.1/01	Rordorf B.F., Report on vapor pressure curve, Syngenta Crop Protection AG, Basle, Rep.N° AG-88-02P, 15.06.1988 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.2.1/02	Burkhard N., Henry's Law Constant, Syngenta Crop Protection AG, Basle, Data Sheet, 12.09.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	no	No Y

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
3.3/01	Das R., Report on general physico-chemical properties (pure active ingredient), Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep N° 20751, 22.03.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.3/02	Das R., Report on general physico-chemical properties (technical grade active ingredient), Ciba-Geigy Muenchwilen AG, Muenchwilen Rep N° 16311, 08.11.1993 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.4	Käser W., Report on spectra, Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep.N° 28042, 20.12.1994, Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	no Y
3.5	Jäkel K., Report on water solubility, Syngenta Crop Protection AG, Basle, Rep.N° AG-87-22P, 19.11.1987 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.6/01	Jäkel K., Report on dissociation constant in water, Syngenta Crop Protection AG, Basle, Rep.N° EA-133549, 08.08.1990 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.6/02	Stulz J., Propiconazole - Dissociation constant, Ciba-Geigy Muenchwilen AG, Muenchwilen, Statement, 26.10.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG		No Y
3.7	Stulz J., Report on solubility in organic solvents, Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep N° 20752, 15.03.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	no Y
3.9	Jäkel K., Report on partition coefficient, Syngenta Crop Protection AG, Basle, Rep.N° AG-87-22P, 20.11.1987 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.10	Schürch H., Report on thermal stability and stability in air, Syngenta Crop Protection AG, Basle, Rep N° 20753, 18.04.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
3.11	Schürch H., Report on auto-flammability of liquids, Syngenta Crop Protection AG, Basle, Rep N° PP-94/10T.AFG, 18.04.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.12	Schürch H., Report on determination of flash-point, Syngenta Crop Protection AG, Basle, Rep. N° PP-94/10T.FLP, 18.04.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.13	Ryser M., Report on surface tension of aqueous solutions, Syngenta Crop Protection AG, Basle, Rep N° PP-94/21T.SUR, 19.09.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	no Y
3.14	Ryser M., Report on viscosity of liquids, Syngenta Crop Protection AG, Basle, Rep N° PP-96/32T.VIL, 24.06.96 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.15	Schürch H., Report on explosive properties, Syngenta Crop Protection AG, Basle, Rep N° PP-94/10T.EXP, 18.04.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	no Y
3.16	Angly, H., Oxidizing properties (liquids) of CGA 64250 tech.. Institute of Safety and Security, Testing Laboratory, Basle, Switzerland Project 81905, 31.03.2000. Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
4.1 / 01	Heizler W., Analytical Method CGA 64250; Syngenta Crop Protection AG., Basel, Met. N° AW-88/4, 28.04.1982 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	no	No Y
4.1 / 02	Käser W., Method Validation for technical active substance Syngenta Crop Protection AG., Basel, Met. N° AW-88/4, 05.03.1987 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	yes	No Y
4.1 / 03	Heizler W., Appendix to Analytical Method CGA 64250 Syngenta Crop Protection AG., Basel, Met. N° AW-88/4 + A 1, 28.04.1982 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG. CONFIDENTIAL INFORMATION	no	No Y

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
4.1 / 04	Käser W., Analytical Method CGA 64250 (propiconazole) by-products Ciba-Geigy Muenchwilen AG, Muenchwilen, Met. N° AK-88/6, 13.02.1995 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG. CONFIDENTIAL INFORMATION	no	No Y
4.1 / 05	Käser W., Method validation for impurities in technical active substances Ciba-Geigy Muenchwilen AG, Muenchwilen, Met. N° AK-88/6, 13.02.1995 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG. CONFIDENTIAL INFORMATION	yes	No Y
4.2 / 01	Forrer, K., 1991. CGA 64250, Gas chromatographic determination of residues of parent compound, Plant material and Soil, Syngenta Crop Protection AG., Basel, Rep.No. REM-130-02, 09.07.1991 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	no	No Y
4.2 / 02	Anonymous, 1986. CGA 64250 - Gas chromatographic determination of residues in soil, RCC, Itingen, Switzerland Rep.No.RUE8-86; **NOT ISSUED** Owned by: RCC Submitted by :not submitted; not issued	no	No Y
4.2 / 04	Perez, R., 1985. Determination of total residues of CGA 64250 in soil as 2,4-dichlorobenzoic acid by capillary gas chromatography, Ciba-Geigy Corp., USA, Rep.No. AG-465, 14.05.1985 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	no	No Y
4.2 / 05	Formica, G., 1991. CGA 64250, Determination of free 1,2,4-triazole by high performance liquid chromatography, soil, Syngenta Crop Protection AG., Basel, Rep.No. REM-130-03, 13.09.1991 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	no	No Y
4.2 / 06	Formica, G., 1992. CGA 64250, Determination of free 1,2,4-triazole by high performance liquid chromatography, soil, Syngenta Crop Protection AG., Basel, Rep.No. REM-130-04, 09.04.1992 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	no	No Y
4.2 / 08	Tribolet, R., 2001. Determination of Metabolite CGA 118245 by LC-LC-MS/MS Syngenta Crop Protection AG, Basel, Switzerland REM 130.10, 23.10.2001 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	yes	No Y
4.2 / 09	Formica, G.; 1986. CGA 64250, Determination of residues of parent compound by gas liquid chromatography, potable water, Syngenta Crop Protection AG., Basel, Rep.No. REM-10-86, 30.07.1986 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	no	No Y

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
4.2 /10B	Pointurier R. – Duchêne P., 2000, Propiconazole in Drinking and Surface Water Validation of Method REM 10/86 with GC/MS, 28.12.2000 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	yes	No Yes
4.2 / 11	Tribolet, R., 1992, Sampling of air and determination of residues of parent compound by high performance liquid chromatography incl. validation, Syngenta Crop Protection AG., Basel, Rep. Nr. REM-130-07, 14.12.1992 Owned by: Syngenta Crop Protection AG. Submitted by: Syngenta Crop Protection AG.	yes	No Y
4.2 /11B	Pointurier R. – Duchêne P., 2000, Propiconazole in Air : Development of a Confirmatory Technique with GC/MS 28.12.2000 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	yes	No Yes
4.2 /17A	Vargo J.D., 1997, Analytical Method for the determination of Propiconazole (CGA-64250) and its Degradates CGA21795, CGA91305, CGA118244, CGA118245, CGA136735 and CGA71019 in soil and Water by high performance liquid chromatography with mass spectrometric detection including method validation data. 30.10.1997 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	yes	No Yes
4.2 /17B	Cassidy P., 2004, Independent Laboratory Validation - Syngenta Residue Analytical Method No. AG-677 and Modified Method AG-677 for Water, with a 0.02 ppb Limit of Quantitation - "Analytical Method for the Determination of Propiconazole (CGA-64250) and its Degradates CGA-217495, CGA-91305, CGA-118244, CGA-118245, CGA-136735, and CGA-71019 in Soil and Water by High Performance Liquid Chromatography with Mass Spectrometric Detection Including Method Validation Data" 4.5.2004 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	yes	No Yes
4.2/18	Vargo J.P., 1994 Analytical method for the determination of propiconazole (CGA-64250) and its metabolites CGA-217495, CGA-91305, and CGA-136735 in water and sediment by high performance liquid chromatography with mass spectrometric and ultraviolet absorbance detection including validation data. 20.12.1994 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	yes	No Yes
6.1.1 / 01	[redacted] (1978a), Acute oral LD_{50} in the rat of technical CGA 64250, [redacted] 07.12.1978 [redacted]	no	No Y
6.1.1 / 02	[redacted] (1979), Acute oral LD_{50} in the mouse of technical CGA 64250, [redacted] 07.05.1979 [redacted]	no	No Y

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
6.1.2 / 01	[redacted] (1978b), Acute dermal LD_{50} in the rat of technical CGA 64250, [redacted] 22.01.1979	no	No Y
6.1.2 / 02	[redacted] (1979a), Acute dermal LD_{50} in the rabbit of technical CGA 64250, [redacted] 02.07.1979	no	No Y
6.1.3	[redacted] (1988), Acute aerosol inhalation toxicity in the rat, [redacted] 14.01.1988	yes	No Y
6.1.4 / 01	[redacted] (1978a), Skin irritation in the rabbit after single application of technical CGA 64250, [redacted] 26.10.1978	no	No Y
6.1.4 / 02	[redacted] (1978b), Eye irritation in the rabbit after single application of technical CGA 64250, [redacted] 26.10.1978	no	No Y
6.1.5 / 01	[redacted] (1979b), Skin sensitization (contact allergenic) effect in Guinea pigs of technical CGA 64250, [redacted] 08.02.1979	no	No Y
6.1.5 / 02	[redacted] 1999. CGA 64250 tech. - Skin sensitization in the Guinea Pig (Maximization test) [redacted] 07.09.1999	Yes	No Y
6.2 / 01	[redacted] (1979), Distribution, degradation and excretion of CGA 64250 in the rat, [redacted] 18.07.1979	no	No Y
6.2 / 02	[redacted] (1989), Absorption, distribution, metabolism and excretion in the rat., [redacted] 08.06.1989	yes	No Y

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
6.2 / 03	[redacted] (1992), Biliary excretion, absorption, and distribution kinetics of [U-^{14}C]phenyl CGA 64250 in the rat after oral administration., [redacted], 14.01.1992	yes	No Y
6.2 / 04	[redacted] (1983), Dermal absorption of triazole ^{14}C-CGA 64250 by rats., [redacted], 11.05.1983	no	No Y
6.2 / 05	[redacted] (1986), Dermal absorptiopn of ^{14}C-propiconazole in rats after a ten hour exposure period., [redacted] 08.04.1986	no	No Y
6.2 / 06	[redacted] (1986), The metabolism of [U-^{14}C]-phenyl-CGA 64250 in mice after pretreatment with unlabelled CGA 64250., [redacted] 20.05.1986	no	No Y
6.2 / 07	[redacted]2000a . Dermal absorbtion of [Phenyl-U-14C] CGA 64250 formulated as Tilt 250 EC (A-6097 K) in the rat [redacted] 09.02.2000	yes	No Y
6.2 / 08	[redacted]2000b. The in vitro percutaneous absorption of [Phenyl-U-14] CGA 64250 formulated as TILT 250 EC (A-6097 K) through rat and human epidermis. [redacted] 04.01.2000	yes	No Y
6.2 / 09	[redacted] (1979), Characterization of urinary and faecal metabolites of rats after oral application of CGA 64250., [redacted] 31.08.1979	no	No Y
6.2 / 10	[redacted] (1983), The metabolism of CGA 64250 in the rat., [redacted] 01.09.1983	no	No Y

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
6.2 / 11	[redacted] (1980) Biological report for the metabolism of [triazole-^{14}C]-Propiconazole in a lactating goat, [redacted] 29.07.1980	no	No Y
6.2 / 12	[redacted] (1980) Balance and metabolism of triazole-^{14}C-CGA 64250 in a lactating goat, [redacted] 18.09.1980	no	No Y
6.2 / 13	[redacted] (1981) Characterization of metabolites in urine, milk and liver of a goat treated with triazole-^{14}C-CGA 64250, [redacted] 27.03.1981	no	No Y
6.2 / 14	[redacted] (1989) Biological report for the metabolism of Phenyl-^{14}C-Propiconazole in a lactating goat, [redacted] 30.11.1989	no	No Y
6.2 / 15	[redacted] (1990a) Metabolism of phenyl ^{14}C-propiconazole in goats., [redacted] 31.07.1990	no	No Y
6.2 / 16	[redacted] (1984), Biological report for the metabolism of phenyl and triazole ^{14}C-labelled CGA 64250 in laying hens, [redacted] 06.01.1984	no	No Y
6.2 / 17	[redacted] (1985) Distribution, extraction and partitioning characteristics of phenyl and triazole labeled propiconazole in chickens., [redacted] 25.06.1985	no	No Y
6.2 / 18	[redacted] (1990) Biological report for the metabolism of ^{14}C-Propiconazole in laying hens, [redacted] 05.01.1990	yes	No Y

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6.2 / 19	[redacted] (1990b) Metabolism of [phenyl ^{14}C]-propiconazole in chickens., [redacted] 14.06.1990	yes	No Y
6.3.1	[redacted] (1980), 28-day cumulative toxicity study on rats of CGA 64250 technical, [redacted] 11.11.1980	no	No Y
6.3.2/01	[redacted] (1980a), 21-day percutaneous toxicity study in rabbits technical CGA 64250, [redacted] 30.05.1980	no	No Y
6.3.2/02	[redacted] (2001), CGA 64250 tech. - 28-Day repeated dose dermal toxicity study in rats [redacted] 20.03.2001	yes	No Y
6.4.1 / 01	[redacted] (1979), Three months toxicity study on rats of CGA 64250 technical, [redacted] 30.08.1979	no	No Y
6.4.1 / 02	[redacted] (1979), Three months toxicity study on dogs of CGA 64250 technical, [redacted] 09.08.1979	no	No Y
6.4.1 / 03	[redacted] (1991a), Subchronic dietary toxicity study with CGA 64250 in mice, [redacted] 30.04.1991	yes	No Y
6.4.1 / 04	[redacted] (1991b), 13-week dietary toxicity study with CGA 64250 in male mice, [redacted] 30.04.1991	yes	No Y

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6.4.3	[redacted] (1980b), 90-days aerosol inhalation toxicity study in rats of technical CGA 64250, [redacted] 10.09.1980 [redacted]	no	No Y
6.6.1	[redacted] (1983), Salmonella/mammalian-microsome mutagenicity test (induction of liver enzyme activity with Aroclor or with the test substance), [redacted] 27.06.1983 [redacted]	no	No Y
6.6.3 / 01	[redacted] (1982a), L5178Y/TK+/-mouse lymphoma mutagenicity test CGA 64250 (in vitro test for mutagenic properties of chemical substances in mammalian cells)., [redacted] 10.08.1982 [redacted]	no	No Y
6.6.3 / 02	[redacted] (1982b), BALB/3T3 cell transformation assay CGA 64250 (in vitro test for transformation-inducing properties in mammalian fibroblasts)., [redacted] 10.08.1982 [redacted]	no	No Y
6.6.2	[redacted] (1984), Chromosome studies on human lymphocytes in vitro, [redacted] 10.05.1984 [redacted]	no	No Y
6.6.4 / 01	[redacted] (1987), Micronucleus test (Chinese Hamster), [redacted] 14.12.1987 [redacted]	no	No Y
6.6.4 / 02	[redacted] 1999. CGA 64250 tech. - Micronucleus test, mouse [redacted] 14.12.1999 [redacted]	yes	No Y
6.6.5	[redacted] (1982), Autoradiographic DNA repair test on rat hepatocytes (in vitro test for DNA-damaging properties), [redacted] 12.08.1982 [redacted]	no	No Y

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6.6.6	[redacted] (1979), Dominant lethal study mouse (test for cytotoxic or mutagenic effects on male germinal cells), [redacted] 31.10.1979	no	No Y
6.7 / 01	[redacted] (1985), CGA 64250 tech - 1-year subchronic oral toxicity study in Beagle dogs., [redacted] 28.05.1985	yes	No Y
6.7 / 02	[redacted] (1982), Potential tumorigenic and toxic effects in prolonged dietary administration to rats., [redacted] 30.09.1982	yes	No Y
6.7 / 03	[redacted] (1982), Long-term feeding study in mice., [redacted] 26.10.1982	yes	No Y
6.7 / 04	[redacted] (1991), Reexamination of the liver tumor response in male and female mice (Pathology report), [redacted] 06.05.1991	yes	No Y
6.7 / 05	[redacted] 199918-Months oncogenicity study in mice. [redacted] 26.03.1997	yes	No Y
6.8.1 / 01	[redacted] (1987), Teratology (Segment II) study in rats, [redacted] 28.01.1987	yes	No Y
6.8.1 / 02	[redacted] (1987), A modified teratology (Segment II) study in albino rats, [redacted] 06.02.1987	yes	No Y
6.8.1 / 03	[redacted] (1986), A teratology study (Segment II) in New Zealand white rabbits, [redacted] 01.08.1986	yes	No Y

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6.8.2	[redacted] (1985), Two-generation reproduction study in albino rats with [redacted] 12.03.1985	yes	No Y
6.10 / 01	[redacted] 1998. CGA64250 tech. (Propiconazole). Effects on biochemical parameters in the liver following administration to male mice [redacted] 07.04.1998	yes	No Y
6.10 / 02	• [redacted] 1999. CGA 64250 (Propiconazole) - Assessment of hepatic cell proliferation in male mice [redacted] 01.09.1999	yes	No Y
6.10 / 03	[redacted] (1984), Promotion study with CGA 64250 techn., [redacted] 01.10.1984	no	No Y
6.10 / 04	[redacted] (1984), The effect of propiconazole on drug metabolizing enzymes in the livers of male rats and mice., [redacted] 01.07.1984	no	No Y
6.12.1/01	Dr. med. B. Jaquet (1991) Industrial Health Record CGA 64'250 Propiconazole, Medical Surveillance, Monthey, Switzerland, October 1991 Owned by Syngenta Crop Protection AG. Basle, Switzerland Submitted by Syngenta Crop Protection AG. Basle, Switzerland	not applic.	No Y
6.12.1/02	Maier, W-M.. Medical Data Ciba-Geigy Ltd., Basel, Switzerland 16.10.1995 Owned by Syngenta Crop Protection AG. Basle, Switzerland Submitted by Syngenta Crop Protection AG. Basle, Switzerland	Not applicable	No Y
6.12.1/03	Schulze-Rosario C., Hertner T. 2000. Medical Data - Overview/summary data of: 1) Medical surveilance on manufacturing plant personnel 2) Direct observations, e.g. clinical cases and poisoning incidents 3) Diagnosis of poisoning First aid measures 14.09.2000 Owned by Syngenta Crop Protection AG. Basle, Switzerland Submitted by Syngenta Crop Protection AG. Basle, Switzerland	No	No Y

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6.12.2	Th. Fuchs (1991) Epicutaneous Test with propiconazole in 20 human volunteers. Centre for Dermatology and Veneralogy.Hospital of the Georg-August Univerity Göttingen, Germany, August 1, 1991 Submitted by Syngenta Crop Protection AG. Basle, Switzerland	not applic.	No Y
6.12.2	Penaros, H., Ruepert, C., Partanen, T. and C. Wesseling. 2004. Pesticide patch test series for the assessment of allergic contact dermatitis among banana plantation workers in Panama. *Dermatitis*, Vol 15, No 3, pp. 137-145.	Not applicable	Yes N
7.1.1.1.1/01	Burkhard, N. 1980 a. Rate of hydrolysis of CGA 64250 under laboratory conditions. CIBA-GEIGY Ltd., Basle, Project Report 07/80; March 24, 1980. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.1.1.1.1/02	Spare, W.C. 1983. Determination of the hydrolysis rate constant of 1,2,4-H-Triazole. Biospherics Incorporated, 4928 Wyaconda Road, Rockville, Maryland 20852, USA. Project Number 83-E-074; September 20, 1983. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.1.1.1.2/03	Das, Y.T. 1990. Photodegradation of (Phenyl(U)-^{14}C)Propiconazole in aqueous solution buffered at pH 7 under artificial sunlight. Innovative Scientific Services, Inc. (ISSI), 515 Blue Ridge Avenue, Piscataway, N.J. 08854. ISSI-No. 90070, CIBA-GEIGY Protocol Number 85-90. November 26, 1990. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.1.1.1.2/05	Miller, G.C. 1983. Sunlight photolysis of 1,2,4-Triazole in distilled water and humic acid solutions. Department of Biochemistry, University of Nevada Reno, Reno, NV 89557, submitted to Dr. R.C. Honeycutt, CIBA GEIGY Corporation, P.O. Box 11422, Greensboro, N.C. 27409; 08.08.1983. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.1.1.2.1	Bader, U. 1990. Report on the test for ready biodegradability in the modified Sturm test of CGA 64250. CIBA-GEIGY LTD., Basle, Test No.: 901111. 24/04/90. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.1.2.2.1	Keller, A. 1983 b. Degradation of Propiconazole (TILT) in aquatic systems. Ciba-Geigy Ltd., Basle, Project Report 03/83, March, 30.1983. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.1.2.2.2/03	Das, Y.T. 1987. Anaerobic aquatic soil metabolism of CGA-64250 (Propiconazole). Biospherics Incorporated, 4928 Wyaconda Road, Rockville, Maryland 20852; Biospherics 85E468AM-Anaerobic; June 12, 1987. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y

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7.1.2.2.2/04	Das, Y.T. 1992. Metabolism of (Phenyl(U)-^{14}C)Propiconazole under anaerobic aquatic soil conditions. Innovative Scientific Services, Inc. (ISSI), 515 Blue Ridge Avenue, Piscataway, N.J. 08854. ISSI-No. 90072, CIBA-GEIGY Protocol Number 87-90. July 20, 1992. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.1.2.2.2/05	Reischmann, F.J. 1999. Metabolism of 14C-triazole labelled CGA 64250 in two aerobic aquatic systems under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland Study Report No. 98RF03, 02.11.1999 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Y	No Y
7.2.1/01	Keller, A. 1980. Degradation of CGA 64250 (TILT) in Soil under aerobic, aerobic/anaerobic and sterile/aerobic conditions. Ciba-Geigy Ltd., Basle, Project Report 22/80, 24. 06.1980. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.1/02	Keller, A. 1982 b. Degradation of CGA 64250 (Tilt) in aerobic soil. Isolation and identification of the major, polar soil metabolite. Ciba-Geigy Ltd., Basle, Project Report 45/82, addendum to Project Report 08/82, 15.09.1982. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.1/03	Keller, A. 1982 a. Degradation of ^{14}C-dioxalane- and ^{14}C-phenyl-ring labelled CGA 64250 (Tilt) in aerobic soil. Ciba-Geigy Ltd., Basle, Project Report 08/82, 08. 04.1982. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.1/04	Keller, A. 1981 b. Distribution and Degradation of CGA 64250 (TILT) in a field soil. Ciba-Geigy Ltd., Basle, Project Report 10/81, 24.03.1981. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.2.1	Timme, G. and Frehse, H. 1980. Zur statistischen Interpretation und graphischen Darstellung des Abbauverhaltens von Pflanzenbehandlungsmitteln **I**. Pflanzenschutz-Nachrichten Bayer 33/1980,1, p. 47 - 60. Submitted by: Syngenta Crop Protection AG	No	Yes N
7.2.2.1	Timme, G., Frehse, H. and Laska, V. (1986). Zur statistischen Interpretation und graphischen Darstellung des Abbauverhaltens von Pflanzenbehandlungsmitteln **II**. Pflanzenschutz-Nachrichten Bayer 39/1986,2, p. 188 - 204 Submitted by: Syngenta Crop Protection AG.	No	Yes N
7.2.2.1/03	Müller-Kallert, H.-M. 1992. Degradation of ^{14}C-CGA 64250 in one soil incubated under various experimental conditions. RCC Project 255971; RCC Umweltchemie AG, CH-4452 Itingen/BL.; 22.04.1992. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.2.2.1/05	Keller, A. 1981 a. Verhalten der Pflanzenschutzmittel im Boden: CGA 64250. Ciba-Geigy Ltd., Basle, Project Report 04/81, 19.02.1981. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y

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7.2.2.1/08	Adam, D. 2001. Metabolism of 14C-triazolering labelled CGA 64250 under aerobic and aerobic/anaerobic laboratory conditions in one soil at 20 °C. Report 00DA06. Syngenta Crop Protection AG, Basel, CH. 4.04.2001 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Y	No Y
7.2.2.1/09	Adam, D. 2000. Rate of degradation of C-triazole labelled CGA 118 245 in various soil under aerobic conditions at °20 C.Report 00DA04. Novartis Crop Protection AG, Basel, CH. 26.09.2000 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Y	No Y
7.2.2.1/10	Slangen, P.J. 2000. Degradation of 1,2,4-triazole in three soils under aerobic conditions .Notox Project 278336, 26.05.2000 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Y	No Y
7.2.2.2/07	Büttler, B. 1982 a. CGA 64250: Dissipation and leaching of TILT EC 250 under field conditions (St. Aubin). Ciba-Geigy Ltd., Basle, Project Report 20/82, May 27, 1982. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.2.2/08	Büttler, B. 1982 b. CGA 64250: Dissipation and leaching of TILT EC 250 under field conditions (Les Barges). Ciba-Geigy Ltd., Basle, Project Report 22/82, May 28, 1982. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.2.2/09	Resseler, H. 1991 a. Field dissipation of Propiconazole. Test-report - field experiment. CGD Experiment No.: 32-89 B; corresponding RCC-project: 170515; CIBA-GEIGY GmbH, Liebigstraße 51-53, D-60323 Frankfurt/M.; January 21, 1991. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
	including: Offizorz, P. 1990 a. Dissipation rate determination of Propiconazole - field soil. RCC Project 170515; RCC, In den Leppsteinwiesen 19, D-6101 Roßdorf. 03.12.1990. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.2.2/12	Resseler, H. 1991 d. Field dissipation of Propiconazole. Test-report - field experiment. CGD Experiment No.: 90-04 B; corresponding RCC-project: 214413; CIBA-GEIGY GmbH, Liebigstraße 51-53, D-60323 Frankfurt/M.; March 23, 1991. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
	including: Offizorz, P. 1991 a. Dissipation rate determination of Propiconazole - field soil. RCC Project 214413; RCC, In den Leppsteinwiesen 19, D-6101 Roßdorf. 27.03.1991. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y

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7.2.2.2/14	Resseler, H. 1991 f. Field dissipation of Propiconazole. Test-report - field experiment. CGD Experiment No.: 57-90 B; corresponding RCC-project: 214457; CIBA-GEIGY GmbH, Liebigstraße 51-53, D-60323 Frankfurt/M.; April 2, 1991. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
	including:		
	Offizorz, P. 1991 c. Dissipation rate determination of Propiconazole - field soil. RCC Project 214457; RCC, In den Leppsteinwiesen 19, D-6101 Roßdorf. 27.03.1991. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.2.2.2	Tummon O.J. 2004. Determination of residues of propiconazole and free triazole in soil samples from Finland during 2003. 2.7.2004 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.3/01	Burkhard, N. 1980 c. Adsorption and desorption of CGA-64250 in various soil types. CIBA-GEIGY Ltd., Basle, Project Report 26/80; August 14, 1980. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.3/02	Saxena, A. M. 1988. The adsorption and desorption of ^{14}C-Propiconazole on representative agricultural soils. Halzleton Laboratories America Inc., 3301 Kinsman Boulevard, Madison, Wisconsin 53704; HLA 6117-140; July 27, 1988. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.2.3/03	Keller, A. 1983 a. Adsorption and Desorption of 1,2,4-Triazole in various soil types. Ciba-Geigy Ltd., Basle, Project Report 31/83, 05.10.1983. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.3/04	Hawkins, D.R. 1988. Soil adsorption and desorption of 1,2,4-Triazole. Rohm and Haas Company, 727 Norriston Road, Spring House, PA, 19477; Nov. 03, 1988. Originated by: Rohm and Haas Co-owned by: Syngenta Crop Protection AG Company Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.2.3.1	Adam, D. 2000. Adsorption/Desorption of CGA 118245 in various soils. Novartis Crop Protection AG, Basel, Switzerland Study Report No. 99DA09, 11.05.2000 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
-	Rainbird, P. 2007. Propiconazole. A Leaching Assessment for Parent and Soil Metabolite CGA 71019 using the FOCUS-PEARL 3.3.3 Groundwater Scenarios Following Application as a Wood Preservative. Modeling study. Report Series RAJ0541B. Syngenta Research Center UK. 26.04.2007		
7.3.1	Stamm, E. 1994. Rate estimation of the hydroxyl radical oxidation of propiconazole CGA 64250, 31.05.1994 Submitted by: Syngenta Crop Protection AG	No	Yes N

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7.4.1.1/09	1999. Acute toxicity test of CGA 64250 techn. to Rainbow Trout (Oncorhynchus mykiss) under static conditions 09.08.1999	Yes	No Y
7.4.1.2 / 05	LeBlanc, G.A. and Mastone, J.D. 1981a. Acute toxicity of CGA-64250 to crayfish (Procambarus sp.), EG&G, Bionomics, Aquatic Toxicology Laboratory, Wareham, Massachusetts, US, Rep. N° BW-81-10-1035, 10.1981 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.4.1.2. /07	Grade, R. 1999. Acute toxicity test of CGA 64250 techn. to the Cladoceran Daphnia magna Straus in the static system Syngenta Crop Protection AG, Basel, Switzerland Study Report No. 983985, 21.07.1999 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.4.1.3/08	Thun, S. 1993c. Algae growth inhibition test, Test Article: "Desmel A 6097 G", IBR Forschungs GmbH, Bioanalytisches Zentrum, Hannover, FRG, Rep. N° 80-91-2310-01-93, 07.06.1993 Owned by: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited	Yes	No Y
7.4.1.3/09	Grade R., 1999, Growth inhibition test of CGA 64250 EC 250 (A-6097 K) to green algae (Selenastrum capricornutum) under static conditions Novartis Crop Protection AG, Basel, Switzerland 983998, 26.11.1999 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.4.1.3 / 10 *	Höger S., 2011. Propiconazole - Toxicity to Pseudokirchneriella subcapitata in a 96-Hour Algal Growth Inhibition, Report number D06766, 11.01.2011 Sponsor: Syngenta Ltd.	Yes	No Y
7.4.1.4 / 01	Bader, U. 1990. Report on the test for inhibitory concentration on aerobic bacteria CGA 64250, Syngenta Crop Protection AG, Basel, CH, Rep. N° 901112, 28.03.1990 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.4.1.4 / 02	Spare, W.C. 1980. CGA-64250 activated sludge metabolism, Biospherics Incorporated, Rep. N° 80PL-98-SL, 22.08.1980 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.4.3.2 / 01	[redacted]1987. The toxicity of CGA-64250 (Propiconazole) to fathead minnow (Pimephales promelas) embryos and larvae, [redacted]10.11.1987[redacted]	Yes	No Y

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7.4.3.2 / 02	[redacted] 1988. The chronic toxicity of CGA-64250 technical (Propiconazole) to sheepshead minnow (Cyprinodon variegatus), [redacted] 18.07.1988 [redacted]	Yes	No Y
7.4.3.3.1 / 03	[redacted] (2000). Accumulation and Elimination of [Triazole-(U)-^{14}C] CGA64250 by Bluegill Sunfish (*Lepomis macrochirus*) in a Flow-Through System. [redacted]	Yes	No Y
7.4.3.4 / 01	LeBlanc, G.A. and Mastone, J.D. 1981b. The chronic toxicitity of CGA-64250 to the water flea (Daphnia magna), EG&G, Bionomics, Aquatic Toxicology Laboratory, Wareham, Massachusetts, US, Rep. N° BW-81-11-1043, 11.1981 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.4.3.5.1	Grade, R. 1999. Toxicity test of CGA 64250 tech. on sediment-dwelling Chironomus riparius under static conditions Syngenta Crop Protection AG, Basel, Switzerland Study Report No. 983985, 07.05.1999 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	yes	No Y
7.5.1.1 / 05	Völkel, W. 2000. The effects of CGA 71019 on soil respiration and nitrification. Novartis Crop Protection Study Number: 2003502, 16.05.2000 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection A	Yes	No Y
7.5.1.1/06	Lang, B. 1993b. Effects on the activity of soil microflora according to BBA Guideline VI, 1-1 (1990) - Desmel / A 6097 G, BioChem GmbH, Labor Cunnersdorf, Cunnersdorf, FRG, Rep. N° 931049003, 30.04.1993 Owned by: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited	Yes	No Y
7.5.1.2 / 02	Lang, B. 1993. Acute toxicity earthworm test - Eisenia foetida: Desmel/A 6097 G, BioChem GmbH, Labor Cunnersdorf, Cunnersdorf, FRG, Rep. N° 931049004, 30.04.1993 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.5.1.2 / 03	Heimbach, F. 1986. Acute toxicity of 1,2,4-triazole (technical) to earthworms, Bayer AG, Leverkusen, FRG, Rep. N° HBF/rg 59, 24.02.1986 Originated by: Bayer AG Co-owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.5.1.2 / 04	Bätscher, R. 2000. Acute toxicity of CGA 118245 (metabolite of CGA 64250) to the earthworm (Eisenia foetida) in a 14 day test RCC AG, Itingen, Switzerland Study Report No. 747088, 13.04.2000 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y

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7.5.1.2 / 05	Nienstedt, K.M. 1999. A 14-day acute toxicity test with the Earthworm (Eisenia fetida) Springborn Lab., Horn, Switzerland Study Report No. 1047.070.630, 09.12.1999 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.5.1.3/01	Ruess, W. 1987. Effect of CGA-64250 (propiconazole) against various crops and weeds, Syngenta Crop Protection AG, Basel, CH, 26.05.1987 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.5.1.3/02	Maggio, R.M.,Tier 2 seedling emergence nontarget phytotoxicity study using propiconazole Pan-Agricultural Labs. Inc, Madera, United States LR90-420, 04.10.1990 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.5.1.3/03	Maggio, R.M., Tier 2 vegetative vigor nontarget phytotoxicity study using propiconazole Pan-Agricultural Labs. Inc, Madera, United States LR90-418, 04.10.1990 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.5.1.3/04 *	Porch, J. R; Martin K. H; Krueger H. O. Propiconazole formulation (LAg 2008 045) – Chronic toxicity in higher plants Wildlife International Ltd.; Easton, USA Study Report No. 528-284, 12.02.2009 Sponsor: Syngenta Ltd.	Yes	No Y
7.5.2.1/ 01	Nienstedt, K.M. 1999. A chronic Toxicity and reproduction test exposing the Earthworm Eisenia fetida to CGA 64250 EC 250 (A-6097 K) in OECD artificial soil Springborn Lab., Horn, Switzerland Study Report No. 1047.071.630, 07.12.1999 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.5.2.1 / 03	Friedrich, S. 2003. Propiconazole (CGA64250): Sublethal toxicity of a 155.87 g/L EC formulation (A6780D) to the earthworm Eisenia fetida BioChem agrar, Gerichshain, Germany 03 10 48 087, 05.11.2003 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
8.3	Käser W., CGA 64250 - Statement on emergency measures in case of an accident, Ciba-Geigy Muenchwilen AG, Muenchwilen, Statement, 18.01.1995, Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	No	No N
8.4	Käser W., CGA 64250 - Statement on procedures for destruction or decontamination, Ciba-Geigy Muenchwilen AG, Muenchwilen, Statement, 18.01.1995, Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	No	No N

(Sub)Section/ Annex point	Authors (s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
B3.1(01) IIB, III 3.1 also filed B3.4(01) also filed B3.6(01) also filed B8(01) *	Anonymous	2002	Safety Data Sheet Mystox IP. Date: 2002-04-01	Catomance Technologies Limited, Herts, UK	SDS Reference: CAT042	No	Yes	No	Catomance Technologies Limited
B3.4(01) IIB, III 3.4 also filed B3.1(01) also filed B3.6(01) also filed B8(01) *	Anonymous	2002	Safety Data Sheet Mystox IP. Date: 2002-04-01	Catomance Technologies Limited, Herts, UK	SDS Reference: CAT042	No	Yes	No	Catomance Technologies Limited
B3.6(01) IIB, III 3.6 also filed B3.1(01) also filed B3.4(01) also filed B8(01) *	Anonymous	2002	Safety Data Sheet Mystox IP. Date: 2002-04-01	Catomance Technologies Limited, Herts, UK	SDS Reference: CAT042	No	Yes	No	Catomance Technologies Limited
B3.7(01) IIB, III 3.7 *	European Commission (Ed.)	2006	Content of the product dossier accompanying the active substance for Annex I inclusion. Date: 2006-09-14	European Commission, Directorate-General-JRC, Institute for Health and Consumer Protection, Unit: Toxicology and Chemical Substances, European Chemicals Bureau	–	No	Yes	No	European Commission, European Chemicals Bureau
B5.10(01) IIB, V 5.10 *	Wolf, H.C.	2008	Materials Protection Review Report. Efficacy of Propiconazole to control mold growth on plastics and paint coatings. Date: 2008-08-21	Syngenta Crop Protection AG, Stein, CH	PDB 2008-PPZ-REG	No	No	Yes	Syngenta Crop Protection AG

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B8(01) IIB, VIII 8 also filed B3.1(01) also filed B3.4(01) also filed B3.6(01) *	Anonymous	2002	Safety Data Sheet Mystox IP. Date: 2002-04-01	Catomance Technologies Limited, Herts, UK	SDS Reference: CAT042	No	Yes	No	Catomance Technologies Limited
3.2.4 Doc IIB *	Schoknecht et al.	2003	Emission of biocides from treated materials test procedures for water and air, Environmental Science and Pollution Research Volume 10, Number 3 (2003), 154-161	-	-	-	Yes	No	-