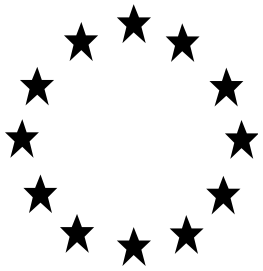
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Propiconazole

Product-type 7
(Film preservatives)

January 2015

Finland

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of the active substance propiconazole as product-type 7 (film preservatives), carried out in the context of the work programme for the review of existing active substances provided for in Article 89 of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

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-type 7 (film preservatives), 8 (wood preservatives) and 9 (fibre, leather, rubber and polymerised materials preservatives).

Commission Regulation (EC) No 1451/2007 of 4 December 2007[1] lays down the detailed rules for the evaluation of dossiers and for the decision-making process.

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 7 was 31 October 2008, in accordance with Annex V of Regulation (EC) No 1451/2007.

On 30 October 2008, Finland 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 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 7) was transferred to Lanxess Deutschland GmbH as of 6th 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.

On 6 November 2013, the Rapporteur Member State submitted to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report.

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 Agency. Revisions agreed upon were presented at the Biocidal Products Committee and its Working Groups meetings and the competent authority report was amended accordingly.

1.2. Purpose of the assessment report

The aim of the assessment report is to support the opinion of the Biocidal Products Committee and a decision on the approval of propiconazole for product-type 7, and, should it be approved, to facilitate the authorisation of individual biocidal products. 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.

[1] 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

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available from the Agency web-site shall be taken into account.

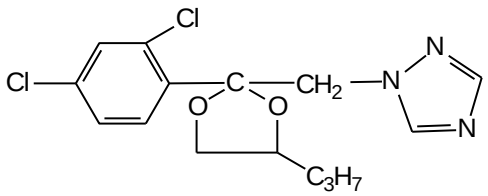
However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data for that purpose has been granted to that applicant.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Identity of the active substance

CAS-No.	60207-90-1
EINECS-No.	262-104-4
Other No. (CIPAC, ELINCS)	CIPAC number 408
IUPAC Name	(2RS,4RS;2RS,4SR)-1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole
Common name, synonyms	CGA 64250 - Propiconazole
Molecular formula	$CR_{15}RHR_{17}RClR_2RNR_3ROR_2$
Structural formula	
Molecular weight (g/mol)	342.2
Minimum purity	96% w/w

The active substance consists of four isomers which all have biocidal activity. The applicant has submitted reports on the field performance of these isomers in Plant Protection Product uses. Obviously, there is no specific information of biocidal use 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. In the new specification the minimum purity of propiconazole is 96.0 % (by weight). The ratios on isomers fit within the earlier data where the ratios of cis/trans isomers are 1.25-1.60.

Identity of the representative product

Trade name	The biocidal product is a theoretical product. A trade name is thus not available.	
Ingredient of preparation	Function	Content
Propiconazole	active ingredient (fungicide)	10 % w/v
IPBC	active ingredient (fungicide)	10 % w/v
Physical state of preparation	liquid	
Nature of preparation	solvent containing technical concentrate	

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 $x10^{-5}$ Pa (at 25 °C) and Henry's law constant of 9.2 $x10^{-5}$ $Paxm^3/mol$. 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.

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.

2.1.2. Intended Uses and Efficacy

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s) and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

This product is used in paints and adhesives, where it protects the paint or adhesive film against fungal infestation. In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

Propiconazole showed antifungal activity in *in vitro* assays and was most active against *Penicillium citrinum*, *Chaetomium globosum*, *Cladosporium cladosporioides* and to less extent against *Alternaria tenuissima*, *Aspergillus niger* and *Aureobasidium pullulans*. In the microtiter test the innate efficacy of propiconazole for certain fungal species was demonstrated with the likely concentration at which the active substance will be used (= 0.3 %) but this concentration was supported in the specific efficacy tests with paint coatings for one test species (*Aureobasidium pullulans*) only. In the efficacy tests with paint coatings submitted in the dossier efficacy against most test species was only demonstrated with higher concentrations (0.5-1.0 % w/w) than the likely concentration at which the active substance will be used in paint films (0.1 % w/w and 0.3 % w/w). In addition, there was one exterior

efficacy test on wood submitted in the dossier but it did not show sufficient efficacy at the likely concentration of 0.3 %.

The specific test with paint coatings was made on filter paper applied on agar and there was neither wooden nor mineral surface present, and therefore, it was considered to be applied for both surface materials. Efficacy data on tile glues was not submitted in the dossier. Efficacy of treated articles was not assessed in this report because the dossier was submitted and the evaluation by eCA carried out in the time of BPD when requirements on treated articles did not exist and guidance for dossier preparation and evaluation presumed at least one safe use to be included. However, the applicant anticipates that the concentration range of 0.1-0.3% propiconazole is representative for treated articles.

As other triazole fungicides propiconazole inhibits the C14 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 (demethylation inhibitor) 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. It is therefore 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.

Propiconazole is a triazole substance and triazoles are also used as medicines. Resistance of a human pathogen *Aspergillus fumigatus* to triazoles used for medical purposes has been found (e.g. casualties due to treatment failure reported in the Netherlands) and a concern about the use of triazoles in biocides and other chemicals has been raised. However, the source of the resistance is not yet clear and may also lie in agricultural or animal health use of triazoles and, therefore, no specific precautionary measurements with respect to biocide use have to be taken at this moment. Further information about the concern of cross-resistance can be found in the following publication by European Centre for Disease Prevention and Control (ECDC): http://www.ecdc.europa.eu/en/publications/publications/risk-assessment-impact-environmental-usage-of-triazoles-on-aspergillus-spp-resistance-to-medical-triazoles.pdf

2.1.3. Classification and Labelling

A harmonised classification for propiconazole is available and the active substance is listed in Annex VI of the Regulation (EC) No 1272/2008. The re-evaluation of the active substance under PPP process is currently on-going. If new data gives evidence for the update of classification, a CLH dossier will be prepared by the Finnish CA for CLP Regulation, and will be submitted to ECHA by June 2015 in alignment with the PPP process. 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:

Classification according to CLP regulation	
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.

Classification according to Annex I of Directive 67/548/EEC		
Class of danger	**R phrases**	**S phrases**
Xn	R22 R43	(S2)* S36/37 S46
N	R50/53	S60 S61

*) For preparations sold to general public

Proposed classification according to CLP regulation of theoretical product based on IPBC (9.9 %) and Propiconazole (10%) content:	
Hazard class and hazard category	Acute Tox. 4 STOT RE 2 Skin Sens. 1 Eye Dam. 1 [Aquatic Aqute 1] Aquatic Chronic 1
Proposed labelling	
Pictogram(s)	GHS07; GHS09
Signal word:	Danger
Hazard (H) statements:	H332: Harmful if inhaled. H373: May cause damage to larynx through prolonged or repeated exposure. H317: May cause an allergic skin reaction. H318: Causes serious eye damage. [H400 Very toxic to aquatic life.] H410 Very toxic to aquatic life with long lasting effects.
Precautionary (P) statements:	P260: Do not breath dust/fume/gas/mist/vapous/spray. P271: Use only outdoors or in well-ventilated area. P272: Contaminated work clothing should not be allowed out of the workplace. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. P312: Call a POISON CENTER or a doctor/physican if you feel unwell.P363: Wash contaminated clothing before reuse. P391: Collect spillage. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P333+P313: If skin irritation or rash occurs: Get medical advice/attention. P337+P313: If eye irritation persists: Get medical advice/attention P501:Dispose of contents/container to …

The classification and labelling of the product is deduced from the classification of its ingredients propiconazole and IPBC.

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. **Hazard identification and effects assessment**

Propiconazole is moderately toxic with an oral acute LD_{50} of 1500 mg/kg bw/day and it is a 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.

Propiconazole interferences with steroid hormone synthesis. The relevance of this mechanism of action (MoA) has to be analysed in the light of observed endocrine effects. At this stage, the causal association between the MoA and the observed endocrine effects is not clearly seen and the significance of weak potency of propiconazole to interfere with steroid hormone receptors remains unclear. Therefore, more data on endocrine effects of propiconazole should be gained, and classification of propiconazole as an identified ED substance should be re-considered if new data is published.

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 preservatives in paints and adhesives. 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 Table 2. 1.

Table 2.1 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.

Dermal absorption values used in the risk assessment

For exposure assessment purposes a dermal absorption value of 9% is used for both handling of undiluted formulation (propiconazole concentration 10%) and for exposure to ready-to use products (paints or adhesives containing 0.3% propiconazole). This represents a worst-case value extrapolated from the available *in vivo* and *in vitro* studies conducted with the plant protection product (see details in Doc IIA and IIB).

Dermal absorption studies or data or scientifically justified statements on possible read-across are necessary for each product on authorisation stage in case of default values according to EFSA guidance on dermal absorption (2012) are not applicable.

2.2.1.2. **Exposure assessment**

Local effects

Propiconazole is classified as skin sensitizer according to the Regulation (EC) No 1272/2008. Qualitative local risk characterization was performed for local dermal effects.

Primary exposure

Table 2.2 summarises the results of the exposure assessment for professional/industrial and amateur users. The detailed assessments can be found in Doc. II-B, Sections 3.2.2 and 3.2.3

Table 2.2 Exposure during industrial, professional and amateur use of propiconazole in PT 7

Exposure scenario	Exposed population	Total Systemic exposure [mg/kg bw/day]
Connecting/Disconnecting transfer lines	Professional, no PPE	0.207
	Professional, gloves	0.00207
Maintenance of production machines	Professional, no PPE	0.00695
Brush painting including cleaning of brush, 0.3% propiconazole in paint, **indoors**	Amateur	0.126
	Professional, no PPE	0.175
	Professional, gloves, coated coverall	0.0317
Brush painting including cleaning of brush, 0.3% propiconazole in paint, **outdoors**	Amateur	0.0163
Spraying including cleaning of equipment, 0.3% propiconazole in paint	Amateur	0.0648
	Professional, no PPE	0.598
	Professional, gloves, double coverall, RPE	0.0217
Applying ready-to-use tile glue, 0.3% propiconazole	Amateur or Professional, no PPE	0.0648
	Professionals, gloves	0.00648

Secondary exposure

Table 2.3 shows an overview of all secondary exposure scenarios that were assessed.

Table 2.3 Risk assessment for secondary exposure to propiconazole in coatings.

Scenario	Exposed population	Total Systemic exposure (mg/kg bw/day)
Acute phase	Adult (non-professional) - Removal of a coating by sanding	0.00058
	Infant - Ingestion of paint chips containing biocide residues	0.012
	Toddler – dermal contact with wet paint	0.031
	Infant- dermal contact with wet paint and mouthing	0.070
Chronic phase	Adult - Cleaning work clothes at home	0.0047
	Adult (professionals) - Removal of a coating by sanding, no PPE	0.0021
	Infant - playing on weathered (playground) structure (dermal contact) and mouthing	0.0011
	Child - Chronic inhalation exposure to volatilised residues	negligible

2.2.1.3. **Risk characterisation**

Propiconazole is classified as skin sensitizer according to the Regulation (EC) No 1272/2008. Qualitative local risk characterisation was done to the dermal effects. Worker dermal exposure during industrial production of end-use products, maintenance of production machines, painting with brush or spraying equipment and applying ready-to-use tile glue is mostly excluded by the use of protective gloves and suitable coveralls. The use of gloves is obligatory in all scenarios, in addition to coveralls during brushing and spraying and RPE during spraying. The use of gloves is also required due to sensitizing property of propiconazole. Non-professionals will be exposed during painting and applying ready-to-use tile glue for propiconazole concentration below the threshold for classification of the product as sensitizing according to the Regulation (EC) No 1272/2008. Secondary exposure may occur also to the propiconazole concentration below the threshold for classification of the product as sensitizing.

The comparison of the estimated exposure with the relevant limit values demonstrates that addition of propiconazole into coating formulations as film preservative is safe for industrial workers with appropriate personal equipment (Table 24).

The use of propiconazole as film preservative in an industrial application does not involve non-professional users. The exposure to the a.s. in an industrial setting is typically chronic and the long-term AEL of 0.04 mg/kg bw/day is used to characterise the risk associated with this exposure.

The vast majority of propiconazole (95%) is excreted within 48 hours after exposure, so that there is no potential for accumulation of the compound in exposed individuals.

Table 2.4 Risk assessment for primary exposure to propiconazole in PT 7, industrial use

Exposure scenario	PPE	Systemic exposure [mg/kg/ day]	AEL [mg/kg/ day]	% AEL covered	NOAEL [mg/kg/ day]	MOE
Connecting/ Disconnecting transfer lines	–	0.207	0.04	520	3.6	17
	gloves	0.00207	0.04	5	3.6	1700
Maintenance of production machines	-	0.00695	0.3	2	30	4300

Primary professional or amateur use of propiconazole containing coatings and adhesives do not pose a risk (Table 2.5).

Amateur exposures from application of propiconazole-containing coatings and adhesives are considered short-term exposures that are thought to occur only once every few years. The short-term AEL of 0.3 mg/kg bw/day is used for risk characterization. The same use made by professionals is chronic exposure due to frequent and long (many years) use and the long-term AEL is appropriate reference value for risk assessment.

Secondary (indirect) exposure may occur by coating removal by sanding, ingestion of coating chips or dermal contact with wet paint and mouthing. Coating removal by amateur is short-term exposure and by professionals chronic exposure. Propiconazole concentration in the paint after solvents have been dried is 0.6% (solvent rich paints contains 40-50% solvents, thus the a.s. concentration is doubled in the paint film after drying the solvent). Cleaning of coveralls made by professionals is chronic exposure to propiconazole. Chronic inhalation exposure to evaporated residues of propiconazole is negligible. Infant chronic dermal and oral exposure when playing on weathered (playground) structure is smaller than acute scenario dermal contact with paint and mouthing. All other secondary exposures are short-term. Consequently, the short-term AEL (0.3 mg/kg bw/day) is used to characterise the risk associated with these exposures. The secondary exposure to propiconazole in coatings does not pose a risk to amateurs or professionals (Table 2.6).

Table 2.5 Risk assessment for primary exposure to propiconazole in PT 7, professional and amateur use

Exposure scenario	Exposed population	Use of PPE	Systemic exposure [mg/kg/ day]	AEL [mg/kg/ day]	% AEL covered	NOAEL [mg/kg/ day]	MOE
Brush/roller painting including cleaning of brush, 0.3% propiconazole in paint, **indoors**	Amateur	No	0.126	0.3	42	30	240
	Professional	No	0.175	0.04	440	3.6	21
	Professional	gloves, coated coveralls	0.0317	0.04	79	3.6	110
Brush/roller painting including cleaning of brush, 0.3% propiconazole in paint, **outdoors**	Amateur	No	0.0163	0.3	5	30	1800
Spraying including cleaning of equipment, 0.3% propiconazole in paint	Amateur	No	0.0648	0.3	22	30	460
	Professional	No	0.598	0.04	1500	3.6	6
	Professional	gloves, double coveralls , RPE	0.0217	0.04	54	3.6	170
Applying ready-to-use tile glue, 0.3% propiconazole	Amateur	No	0.0648	0.3	22	30	460
	Professional	No	0.0648	0.04	160	3.6	56
	Professional	gloves	0.00648	0.04	16	3.6	560

Yellow colour means unacceptable risk.

Table 2.6 Risk assessment for secondary exposure to propiconazole in coatings

Exposure Scenario	PPE use	Total Systemic Exposure [mg/kg bw/day]	AEL [mg/kg/ day]	% AEL covered	NOAEL [mg/kg/ day]	MOE
Adult (non-professional) Removal of a coating by sanding	-	0.00058	0.3	<1	30	52000
Infant Ingestion of paint chips containing biocide residues	-	0.012	0.3	4	30	2500
Toddler Dermal contact with wet paint	-	0.031	0.3	10	30	970
Infant Dermal contact with wet paint and mouthing	-	0.070	0.3	23	30	430
Adult Cleaning work clothes at home	No	0.0047	0.04	12	3.6	770
Adult (professionals) Removal of a coating by sanding	No	0.0021	0.04	5	3.6	1700
Infant - playing on weathered (playground) structure (dermal contact) and mouthing	No	0.0011	0.04	3	3.6	330
Child - Chronic inhalation exposure to evaporated residues	-	negligible	0.04	-	3.6	-

Yellow colour means unacceptable risk.

Combined exposure is the total exposure arising from individual tasks through different phases of use with a single product. Combined exposure to propiconazole at different stages of its service life is very unlikely and is not considered relevant.

Aggregated exposure covers exposure to a single chemical from multiple sources i.e. through primary exposure, secondary exposure and exposure to the same chemical in different products and matrices through various routes of uptake. Propiconazole is used in biocidal products for product types 8 (wood preservatives) and 9 (preservatives for polymerised materials) in addition to product type 7. However, primary exposures for professionals and non-professionals to these products are rare to occur for all product types. For product type 7 it is not known whether consumer may use several paints and glues containing products with propiconazole. To evaluate the aggregated exposure a very conservative approach where acute scenarios are compared with the long term AEL-value was chosen. By this way the repetitive cumulative nature of consumer exposure to propiconazole containing products was assessed. For consumer scenarios, outdoor brush painting is the only acceptable scenario. All other scenarios including indoor brush painting, painting with spray and application ready-to-use tile glue are unacceptable. However, amateur exposure in these tasks is assumed to occur only once every few years and it is not probable wether these products contain propiconazole or other active substance. Thus the aggregated exposure evaluation is very conservative and it can be concluded that there is no concern.

2.2.2. Environmental Risk Assessment

2.2.3. Fate and distribution in the environment

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 $\pm$ 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. Due to a concern about the fate of dichlorobenzyl moiety in the active substance molecule it was decided that an aerobic water-sediment simulation test with 14C-phenyl labelled propiconazole should be required.

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 cannot be excluded based on these studies. Furthermore, accumulation studies of plant protection product use are not

directly applicable to the use of preservatives in paint coatings.

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). CGA 118 245 is degraded in soil faster than the parent substance, CGA 118 245 having DT_{50} of around 1 day at 20 °C. In the trilateral discussions on CA report of propiconazole in PT7 it was raised that the UK RMS made a PPPD review on propiconazole in January 2014 indicating that the DT_{50} of a relevant metabolite in soil (1,2,4-triazole) should be 60.5 days at 20 °C. Due to the metabolite's bi-phasic behaviour in soils (fast and slow degradation phases) the DT_{50} is 1.68 d for the fast fraction (48.9%) and 60.5 days for the slow fraction (51.1%). BPC Working Group on environmental issues decided that instead of the previous value of 12 days the DT_{50} of 60.5 days from the slow fraction, being the worst-case, should be used in PEC soil calculations. For groundwater assessment a bi-phasic approach including a fast phase as well as a slow phase degradation should be employed according to FOCUS guidance.

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.

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.

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.

2.2.4. Effects assessment

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. $PNEC_{sediment}$ is 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.

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.

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.

2.2.5. PBT and POP assessment

In the assessment of biocides the PBT and vPvB criteria according to Annex XIII of REACH Regulation are considered. Propiconazole fulfils the criterion for persistence (P) in the water-sediment system with the worst-case degradation half-life of 1206 days at 12 °C as well as in the soil compartment with the worst-case degradation half-life of 137 days in soil at 12 °C (but not with the geometric mean half-life of 82 days in soil at 12 °C). Furthermore, it fulfils the vP criterion in the water-sediment but not 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 fulfil other PBT criteria (B or T) with the BCF of 180 for fish and NOEC of 0.068 mg/l for fish and because it does not meet the criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), toxic for reproduction (category 1A, 1B or 2) or specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to Regulation 1272/2008. Reproductive toxicity in mammals will be further evaluated in the upcoming re-evaluation of propiconazole under Plant Protection Product Regulation.

With the degradation half-life of 115 days at 12 °C (= 60.5 d at 20 °C) in soil the main metabolite of propiconazole (1,2,4-triazole) would not fulfil P criteria. According to EPI Suite 4.00 modelling 1,2,4-triazole would not fulfil the screening criteria for B (log Kow). With respect to the consideration of T criteria there is no aquatic NOEC for 1,2,4-triazole in the evaluated data of this report. However, 1,2,4-triazole has the harmonised classification as toxic for reproduction, category 2, and thus fulfils T criteria.

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

Propiconazole is not expected to have long-range transport potential because the estimated half-life in air is between 10.2 and 42 hours, i.e. below the criterion of 2 days given for persistent organic pollutants (POP) as defined in the Annex D of the Stockholm Convention 2001.

2.2.6. Exposure assessment

The environmental risk assessment for propiconazole used as preservative in coatings (PT 7) for wooden surfaces is based on the OECD scenarios of wood preservatives (PT 8) and for mineral surfaces on the City Scenario. The emissions through sewage treatment plant (STP) to surface water and sediment and via STP sludge application to soil were evaluated according to Technical Guidance Document on Risk Assessment (TGD Part II, 2003). The applied dosage of propiconazole as preservative in coatings (PT 7) containing 0.1% (w/w) propiconazole corresponds to a final amount of 151 mg a.i./m² surface of wood and 0.3 % (w/w) propiconazole to 447 mg a.i./m².

For a detailed presentation of all PEC values Document IIB can be consulted. In Document IIC risk ratios (PEC/PNEC values) for different environmental compartments are determined. If the PEC/PNEC value is below 1, this is interpreted as an acceptable risk to the environment.

Propiconazole is used, both alone and in combination with other active substances in coatings on wood (BPD product-type 7, film preservatives) and in minor extent on mineral surfaces. Emissions to the environment can occur during application and subsequent storage, due to *in*

situ treatment and in service leaching of treated wooden articles (fence, house, bridge, noise barrier) and from façades of houses in cities (mineral surfaces). For the envisaged fields of use for propiconazole products two main scenarios have been addressed:

1) Amateur / Professional users
- brushing/painting

2) Industrial application methods, which includes
- automated spraying
- dipping of wooden articles

With respect to aquatic exposure via STP aggregated exposure is relevant within one product type and between different product types. In the evaluated dossier, however, use in paint coatings was only described and therefore there is not much data to use in the aggregated risk assessment within PT7. Propiconazole was previously approved in PT9 (preservatives for polymerised materials) where emission to STP is likely, but as well, the risk assessment only covered one use of all possible uses in that product type (use in PVC floorings). Thus, results from the aggregated evaluation on the basis of the submitted dossier would not reflect the idea of aggregated risk assessment.

Within PT7, propiconazole is also used to preserve adhesives as tile glues for indoor-use. Tile glues have higher viscosity than coatings and therefore no splashing or dripping takes place during application. Since the active substance incorporated in the solidified tile glue will be located in a sealed compartment between wall (or floor) and tile after application, no potential for environmental release is given. Thus no environmental risk assessment is required for the use of propiconazole in adhesives as tile glues.

2.2.7. Risk characterisation

Risk characterisation for use of propiconazole containing coatings on wooden surfaces are presented for different compartments below in tables 2.7 to 2.11. Table 2.12 gives the risk ratios (PEC/PNEC) in all environmental compartments for a calculation example of propiconazole containing coatings on mineral surfaces (emission via STP in 5 years' service-life of the paint on façades of houses in a city).

Aquatic compartment (STP, surface water, sediment)
For a sewage treatment plant (STP) very low risk quotients (« 1) were determined for the industrial application of propiconazole and the noise barrier scenario, indicating that there is no risk for the micro-organisms in a STP (Table 2.7).

Table 2.7 Propiconazole PEC/PNEC-ratios resulting from industrial application and in-service leaching emissions to a local sewage treatment plant (STP).

SCENARIO		PEC_{stp} (µg/L)		$PNEC_{stp}$ (mg/L)	PEC/PNEC	
		0.1%[1]	0.3%[1]		0.1%[1]	0.3%[1]
Dipping		8.15	24.14	100	0.0001	0.0002
Automated spraying	Small plant	4.08	12.07		<0.0001	0.0001
	Large plant	40.77	120.69		0.0004	0.0012
Noise Barrier	30 days	0.0227	0.0869		<0.0001	<0.0001
	15 years	0.0010	0.0034		<0.0001	<0.0001

[1] Propiconazole concentration within the coating

With regard to surface water (Table 2.8) no unacceptable risk (PEC/PNEC < 1) was calculated for industrial use (application and storage) of propiconazole except for automated spraying plant of large size using the coating with 0.3% propiconazole. The conclusion remains the same if the PECs from the application and storage scenarios are summed up assuming that the releases from application via STP and from storage enter the same small creek at the same time which is, however, rather unusual. With regard to the industrial application scenarios it should be considered that emissions to sewage water and further to surface water during the applications process are not likely to occur, because residues and waste solvent will be treated as hazardous waste and not allowed to enter the STP.

There was no unacceptable risk (PEC/PNEC < 1) to aquatic organisms from the leaching in service within the noise barrier and bridge over pond scenarios or the *in situ* treatment within the bridge over pond scenario. .

Table 2.8 Propiconazole PEC/PNEC ratios for surface water.

SCENARIO				PEC surface water (µg/L)		PNEC surface water (µg/L)	PEC/ PNEC	
				0.1%[1]	0.3%[1]		0.1%[1]	0.3%[1]
Dipping	Application via STP			0.815	2.414	6.80	0.12	0.36
	Storage			0.0018	0.0068		0.0003	0.001
Automated spraying	Application via STP	Small plant		0.408	1.207		0.06	0.18
		Large plant		4.077	12.07		0.60	1.77
	Storage	Small plant		0.0002	0.0008		0.00003	0.0001
		Large plant		0.002	0.0077		0.0003	0.001
Noise Barrier	Leaching in-service via STP after dipping or automated spraying		30 days	0.0023	0.009		0.0003	0.001
			15 years	0.0001	0.0004		0.00002	0.00006
Bridge over pond (Vwater = 1000m³)	Application *in situ*	Professional	1 day	0.0453	0.1341		0.007	0.020
		Amateur	1 day	0.0755	0.2235		0.011	0.033
	Application *in situ* + leaching in service	Professional	30 days	0.048	0.147		0.007	0.02
			5 years	0.041	0.128		0.006	0.02
		Amateur	30 days	0.078	0.235		0.011	0.03
			5 years	0.060	0.184		0.009	0.03
	Leaching in service after brushing		30 days	0.0036	0.014		0.0005	0.002
			5 years	0.0133	0.045		0.002	0.007
	Leaching in service after dipping or spraying		30 days	0.0036	0.014		0.0005	0.002
			15 years	0.0154	0.053		0.002	0.008

[1] Propiconazole concentration within the coating

For the sediment (Table 2.9) no unacceptable risk (PEC/PNEC < 1) was determined for the industrial use (application and storage) of propiconazole except for automated spraying plant of large size. With regard to the industrial application scenarios it should be considered that emissions to sewage water and further to surface water and sediment during the applications process are not likely to occur, because residues and waste solvent will be treated as hazardous waste and not allowed to enter the STP.

There was no unacceptable risk (PEC/PNEC < 1) to aquatic organisms from the leaching in service within the noise barrier and bridge over pond scenarios or the *in situ* treatment within the bridge over pond scenario.

Table 2.9 Propiconazole PEC/PNEC ratios for the sediment.

SCENARIO				$PEC_{sed.}$ (mg/kg wwt)		$PNEC_{sed}$ (mg/kg wwt)	PEC/ PNEC	
				0.1%[1]	0.3%[1]		0.1%[1]	0.3%[1]
Dipping	Application + storage			0.01741	0.05157	0.054	0.32	0.96
Automated spraying	Application + storage	Small plant		0.00869	0.02573		0.16	0.48
		Large plant		0.08690	0.25729		1.61	4.76
Noise Barrier	Leaching in-service via STP after dipping or automated spraying		30 days	<0.0001	0.0002		0.0009	0.0034
			15 years	<0.0001	<0.0001		<0.0001	0.0002
Bridge over pond (Vwater = 1000m³)	Application *in situ*	Professional	1 day	0.0010	0.0029		0.02	0.05
		Amateur	1 day	0.0016	0.0048		0.03	0.09
	Application *in situ* + leaching in service	Professional	30 days	0.0010	0.0031		0.02	0.06
			5 years	0.0010	0.0027		0.02	0.05
		Amateur	30 days	0.0017	0.0050		0.03	0.09
			5 years	0.0013	0.0039		0.02	0.07
	Leaching in service after brushing		30 days	0.0001	0.0003		0.001	0.01
			5 years	0.0003	0.0010		0.01	0.02
	Leaching in service after dipping or spraying		30 days	0.0001	0.0003		0.001	0.01
			15 years	0.0003	0.0011		0.01	0.02

[1] Propiconazole concentration within the coating

Terrestrial compartment

The use of the coating with 0.1% propiconazole does not pose any unacceptable risk (PEC/PNEC < 1) to soil organisms (Table 2.10). The calculated PEC/PNEC ratios for all scenarios are below the trigger value of 1.

Unacceptable risk (PEC/PNEC > 1) was identified for *in situ* treatment in amateur use up to 30 days from the treatment with the coating containing 0.3% propiconazole. However, to prevent unacceptable risk to soil organisms risk mitigation is possible during *in situ* treatment by covering the soil with protective sheeting.

There is no unacceptable risk (PEC/PNEC < 1) to soil organisms due to the application of STP sludge containing propiconazole derived from the application plants. However, it should be considered that emissions to sewage water during the applications process are not likely to occur, because residues and waste solvent will be treated as hazardous waste and not allowed to enter the STP.

Table 2.10 Propiconazole PEC/PNEC ratios for soil.

SCENARIO				PEC_{soil} (mg/kg wwt)		PNEC soil (mg/kg wwt)	PEC/ PNEC	
				0.1%[1]	0.3%[1]		0.1%[1]	0.3%[1]
Dipping	Storage		30 days	0.0021	0.0082	0.100	0.02	0.08
			15 years	0.0180	0.0689		0.18	0.69
Automated spraying	Storage		30 days	0.0021	0.0082		0.02	0.08
			15 years	0.0180	0.0689		0.18	0.69
Fence	Application *in situ*	Professional	1 day	0.0213	0.0631		0.21	0.63
		Amateur	1 day	0.0355	0.1052		0.36	1.05
	Application *in situ* + leaching in service	Professional	30 days	0.0204	0.0617		0.20	0.62
			5 years	0.0024	0.0076		0.02	0.08
		Amateur	30 days	0.0330	0.0989		0.33	0.99
			5 years	0.0033	0.0103		0.03	0.10
	Leaching in service after brushing		30 days	0.0016	0.0060		0.02	0.06
			5 years	0.0010	0.0035		0.02	0.04
	Leaching in service after dipping or spraying		30 days	0.0016	0.0060		0.02	0.06
			15 years	0.0007	0.0024		0.01	0.02
House	Application *in situ*	Professional	1 day	0.0256	0.0758		0.26	0.76
		Amateur	1 day	0.0427	0.1264		0.43	1.26
	Application *in situ* + leaching in service	Professional	30 days	0.0245	0.0742		0.25	0.74
			5 years	0.0029	0.0092		0.03	0.09
		Amateur	30 days	0.0396	0.1188		0.40	1.19
			5 years	0.0040	0.0124		0.04	0.12
	Leaching in service after brushing		30 days	0.0019	0.0072		0.02	0.07
			5 years	0.0013	0.0042		0.01	0.04
	Leaching in service after dipping or spraying		30 days	0.0019	0.0072		0.02	0.07
			15 years	0.0008	0.0028		0.01	0.03
Noise	Leaching in		30	0.0002	0.0008		0.002	0.008

SCENARIO				PEC_{soil} (mg/kg wwt)		PNEC soil (mg/kg wwt)	PEC/ PNEC	
				0.1%[1]	0.3%[1]		0.1%[1]	0.3%[1]
Barrier	service after dipping or spraying		days					
			15 years	0.0001	0.0003		0.001	0.003
STP sludge application to soil	Dipping		1 time	0.004	0.011		0.04	0.11
			10 times	0.0042	0.012		0.042	0.12
	Automated spraying, small		1 time	0.002	0.006		0.02	0.06
			10 times	0.0021	0.0063		0.021	0.063
STP sludge application to soil	Automated spraying, large		1 time	0.019	0.056		0.19	0.56
			10 times	0.020	0.059		0.20	0.59

[1] Propiconazole concentration within the coating

1,2,4-triazole

For the soil metabolite of propiconazole (1,2,4-triazole) a calculation example for the worst case exposure situation of soil according to the following assumptions was provided:

Scenario	House, brushing application *in situ* by amateur + subsequent leaching
Amount of active substance	0.3% of propiconazole within the coating
Fraction of 1,2,4-triazole formed from propiconazole (using molecular weights)	MW: 69.07/342.2= 0.2 Fraction to convert emission of propiconazole to 1,2,4-triazole: 0.2
Rate constant for degradation of 1,2,4-triazole in soil in the slow phase of biphasic degradation at 12 °C	k = 0.006 (DT_{50} = 115.5 d)

The calculation of example for the soil metabolite 1,2,4-triazole in the worst-case scenario gives the following risk ratios in soil:

	PEC/PNEC
Initial	2.53
Time 1 (30 days)	2.46
Time 2 (5 years)	0.33

The risk ratios of 1,2,4-triazole in soil indicating unacceptable risk support the conclusion of the risk management measures needed on the basis of the risk assessment of the parent substance. There is a need for guidance to protect the soil environment close to the object to be painted for the time of application with temporary sheeting. This can be achieved by giving the necessary information in the labels and/or instructions for use to the user. The information should be transmitted from the supplier of the active substance of the biocidal product in PT7 through the production chain to the manufacturer of the coating (paint), which is not a biocidal product as such but which is treated with a film preservative product. The manufacturer of the coating product should receive this information in order to be able to reflect it in the labelling of his product.

Groundwater

In the risk assessment for propiconazole used as wood preservative (PT8, 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) was 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 an application rate of 1000 mg/mP^{2}P wood and using a worst case scenario of 35 wooden houses per hectare.

For the use of propiconazole as wood preservative (PT8) the PECs for the parent compound 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. For the use of propiconazole in coatings on wooden surfaces the application rates (151 mg/m^2 for the 0.1% coating and 447 mg/m^2 for the 0.3% coating) are lower than for the use in wood preservatives. Therefore, groundwater concentrations below 0.001 µg/l can also be assumed for the present risk assessment for PT7. The evaluated groundwater concentrations are considerably below the legal drinking water limit of 0.1 µg/l.

As a result of discussion in BPC Working Group on environmental issues a revised FOCUS PEARL groundwater calculation for the soil metabolite of propiconazole (1,2,4-triazole) was requested because new half-life values of the metabolite in soil became available on the bi-phasic basis giving DT50 of 1.68 d for the fast fraction (48.9%) and 60.5 days for the slow fraction (51.1%).

The modelling was carried out with FOCUS PEARL 4.4.4 for three different scenarios of PT7 use and leaching data (Scenario 1 and 2a and 2b described in Document IIB). In the modelling the house number of 16 and the fraction of house surface exposed to weather (0.5) were applied according to the revised OECD ESD for wood preservatives (2013). The evaluated groundwater concentrations of 1,2,4-triazole based on the available field-leaching data are considerably below the legal drinking water limit of 0.1 µg/l.

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.

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.

Biota

No unacceptable risk (PEC/PNEC < 1) of secondary poisoning through the aquatic food chain could be determined (Table 2.11). The calculated PEC/PNEC ratios for all scenarios are below the trigger value of 1. With respect to secondary poisoning in the terrestrial environment there is no concern as calculation of $C_{earthworm}$ with the equation 82c of TGD from the highest PEC_{soil} of 0.1315 mg a.i./kg wwt gives 0.10 mg a.i./kg wet earthworm while $PNEC_{oral}$ is 3.33 mg a.i./kg feed.

Table 2.11 Summary of propiconazole PEC/PNEC ratios for biota

SCENARIO				PEC oral, predator (µg/kg)		PNEC oral (µg/kg)	PEC/ PNEC	
				0.1%[1]	0.3%[1]		0.1%[1]	0.3%[1]
Dipping	Application + storage			150.36	445.39	3330	0.05	0.13
Automated spraying	Application + storage	Small plant		75.05	222.22		0.02	0.07
		Large plant		750.54	2222.11		0.23	0.67
Noise Barrier	Leaching in-service via STP after dipping or automated spraying		30 days	0.42	1.60		0.0001	0.0005
			15 years	0.02	0.06		<0.0001	<0.0001
Bridge over pond (Vwater = 1000m³)	Application *in situ*	Professional	1 day	416.76	1233.72		0.13	0.37
		Amateur	1 day	694.60	2056.20		0.21	0.62
	Application *in situ* + leaching in service	Professional	30 days	446.14	1349.47		0.13	0.41
			5 years	362.88	1115.02		0.11	0.33
		Amateur	30 days	721.63	2164.96		0.22	0.65
			5 years	535.61	1626.88		0.16	0.49
	Leaching in service after brushing		30 days	32.94	126.24		0.01	0.04
			5 years	103.83	348.11		0.03	0.10
	Leaching in service after dipping or spraying		30 days	32.94	126.24		0.01	0.04
			15 years	123.17	403.07		0.04	0.12

[1] Propiconazole concentration within the coating

Emission via STP in urban areas

The calculation example for 5 years' service-life of paints for mineral surfaces shows unacceptable risk (PEC/PNEC > 1) to sediment (Table 2.12). For surface water the risk ratio is very close to 1 while risk ratios for STP and soil (via STP sludge application) are well below 1 indicating no unacceptable risk. Emission to STP from the application phase of the paint was calculated to correspond to approximately the same amount per day as daily leaching during 5 years of service-life so the risk ratios would also be corresponding. Leaching during the first 30 days of service-life according to the assumptions of the City Scenario would mean much higher risk ratios. These conclusions substantiate the need for leaching tests on mineral surfaces with the relevant products for the product authorisation stage and the guidance to protect the surroundings of the façade to be treated for the time of application with temporary sheeting.

Table 2.12 Summary of PEC/PNEC ratios for different compartments from paint use on mineral surfaces in urban areas (emission via STP, service-life 5 years).

Compartment	PEC	PNEC	PEC/PNEC
STP	0.0645 mg/l	100 mg/l	0.000645
Surface water	0.00644 mg/l	0.0068 mg/l	0.947
Sediment	0.137 mg/kg wwt	0.054 mg/kg wwt	2.54
Soil	0.0259 mg/kg wwt (30 days)	0.1 mg/kg wwt	0.259

2.2.8. Assessment of endocrine disruptor properties

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 literature review on endocrine disrupting mechanism of action (MoA) of propiconazole revealed that propiconazole has an endocrine MoA by interference of steroid hormone synthesis, however, the relevance of this remains unclear in the light of observed endocrine effects (See also 2.2.1.1.). The analysis of sex ratio of F0 generation in the fish life-cycle test from the submitted dossier showed that propiconazole did not have any effect on the sex ratio of fish.

2.3. Overall conclusions

The outcome of the assessment for propiconazole in product-type 7 is specified in the BPC opinion following discussions at the 8th meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2.4. List of endpoints

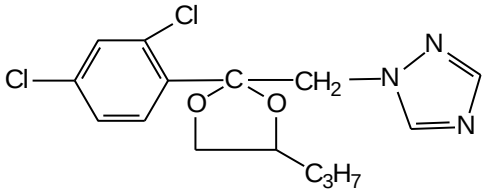
The most important endpoints, as identified during the evaluation process, are listed in Appendix I.

Appendix I: List of endpoints

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

Active substance (ISO Name)	propiconazole
Product-type	PT7 (Film preservatives)

Identity

Chemical name (IUPAC)	(2RS,4RS;2RS,4SR)-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 960 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	
	The range of the ratios of cis/trans isomers is 1.25-1.60. See the Confidential Annex for new production data.

Physical and chemical properties

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)
Thermal stability / 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 (state temperature and concentration of the test solution)	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 $x10^{-5}$ Pa at 25°C (99.1%)
Henry's law constant (Pa m^3 mol^{-1})	9.2 $x10^{-5}$ PPa m^3 mol^{-1}
Solubility in water (g/l or mg/l, state temperature)	pH 6.9 at 20^0C: 100 mg/l (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)	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	Not available
Partition coefficient (log P_{OW}) (state temperature)	pH 6.6 at 25^0C: 3.72 (99.1%)
Dissociation constant	pKa = 1.09 at 20°C (99.1%)
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	λR_{max}: 220.4 nm, $\varepsilon R_{max}R$: 11666 M^{-1} cm^{-1} No absorption between 290 and 750 nm. (98.8%)
Flammability or flash point	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%)
Oxidising properties	Not oxidizing (92.4%)

Classification and proposed labelling

with regard to physical hazards	No classification

with regard to human health hazards	Acute Tox 4, Skin Sens. 1: H302, H317 (Harmonised classification, 1272/2008) Xn; R22 R43; S(2), S36/37, S46 (67/548/EEC)
with regard to environmental hazards	Aquatic Acute 1, Aquatic Chronic 1: H400, H410 (Harmonised classification, 1272/2008) N; R50/53; S60, S61 (67/548/EEC)

Chapter 2:Methods of Analysis

Analytical methods for the active substance

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

Analytical methods for residues

Soil (principle of method and LOQ)	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)	GLC-NPD; LOQ : 10 μg/m^3 (parent compound) GC-MS; LOQ : 10 μg/m^3 (parent compound)
Water (principle of method and LOQ)	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)	Not applicable (not toxic or very toxic substance)
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not applicable

Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not applicable

Chapter 3:Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	86% within 48 h (based on urine and biliary excretion)
Rate and extent of dermal absorption*:	9% for the concentrated b.p. at 10% a.i. 9% for dilute solutions and residues from treated articles considering 0.3% 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 metabolite(s)	Parent compound and metabolites (animals). Triazolyl alanine and triazolyl acetic acid formed only in plants; not toxicologically significant. Extensively metabolised (>20 metabolites identified in rat urine)

* the dermal absorption value is applicable for the active substance and might not be usable in product authorization

Acute toxicity

Rat LD_{50} oral	Appr. 1500 mg/kg bw; H302
Rat LD_{50} dermal	>4000 mg/kg bw
Rat LC_{50} inhalation	>5.8 mg/l/4 h, nose-only
Skin corrosion/irritation	Not corrosive / irritating
Eye irritation	Not irritating
Skin sensitisation (test method used and result)	Skin sensitizer (Maximisation test); H317

Repeated dose toxicity

Species / target / critical effect	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	No genotoxic effects

Carcinogenicity

Species/type of tumour	Liver tumors in male mice.
Relevant NOAEL/LOAEL	2500 ppm (344.3 mg/kg bw/day)

Reproductive toxicity

Developmental toxicity

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

Neurotoxicity

Species/ target/critical effect	No further data required.

Developmental Neurotoxicity

Species/ target/critical effect	No further data required.

Immunotoxicity

Species/ target/critical effect	No further data required.

Developmental Immunotoxicity

Species/ target/critical effect	No further data required.

Other toxicological studies

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

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

	Value	Study	Safety factor
$AEL_{long\text{-}term}$	0.3 mg/kg bw/day	Developmental study in rat	100
$AEL_{medium\text{-}term}$	0.08 mg/kg bw/day	2-generation rat study	100
$AEL_{short\text{-}term}$	0.04 mg/kg bw/day	2-year rat study	100
ADI[2]	0.04 mg/kg bw/day	2-year rat study	100
ARfD	0.3 mg/kg bw/day	Developmental study in rat	100

Reference value for groundwater

According to BPR Annex VI, point 68	0.1 µg/l as set by EU Drinking Water Directive (98/83/EC)

Acceptable exposure scenarios (including method of calculation) PT7

	Systemic exposure/ Margin of Exposure
Industrial Production of End-Use Products Mixing and Laoding model 7, TNsG	0.00207 mg/kg bw/day (with PPE) % AEL = 5 (with PPE) MOE = 1700 (with PPE)
Maintenance of production machines (industrial) US-EPA Exposure Factors Handbook (2011)	0.00695 mg/kg bw/day (no PPE) % AEL = 17 (no PPE) MOE = 520 (no PPE)
Brush painting including brush cleaning, indoors TNsG 2007, Brush model 1 - amateurs BEAT - professionals	0.126 mg/kg/day (amateurs, no PPE) % AEL= 42 (no PPE) MOE = 240 (no PPE) 0.0317 mg/kg bw/day (professionals, with PPE)

[2] If residues in food or feed.

	% AEL = 79 MOE = 110 (professionals, with PPE)
Brush painting including brush cleaning, outdoors TNsG 2007, Model 2 brushing sheds and fences - amateurs	0.0163 mg/kg/day % AEL= 4 (no PPE) MOE = 2800 (no PPE)
Spraying including cleaning of equipment TNsG 2007, Consumer model spraying and dusting, model 3 BEAT - professionals	0.0.0648 mg/kg/day (amateurs) % AEL = 22 (no PPE) MOE = 460 (no PPE) 0.0217 mg/kg bw/day (professionals, with PPE) % AEL = 54 (professionals, with PPE) MOE = 170 (professionals, with PPE)
Applying ready-to-use tile glue ConsExpo	0.0648 mg/kg bw/day (amateurs) % AEL = 22 (no PPE) MOE = 460 (no PPE) 0.00648 mg/kg bw/day (professionals, with PPE) % AEL = 16 (professionals, with PPE) MOE = 560 (professionals, with PPE)
Secondary exposure: Removal of a coating by sanding (non-professional), TNsG	0.00058 mg/kg bw/day (no PPE) % AEL =<1 MOE = 52000
Ingestion of paint chips (Infant), TNsG	0.012 mg/kg bw/day % AEL =4 MOE = 2500
Dermal contact with wet paint (toddler), TNsG	0.031 mg/kg bw/day % AEL =10 MOE = 97+
Dermal contact with wet paint and mouthing (infant), TNsG	0.036 mg/kg bw/day % AEL =12 MOE = 830
Cleaning of contaminated coverall, TNsG	0.0047 mg/kg bw/day % AEL = 12 MOE = 770

Removal of a coating by sanding (professional), TNsG	0.0021 mg/kg bw/day % AEL = 5 MOE = 1700
Infant - playing on weathered (playground) structure (dermal contact) and mouthing	0.0011 mg/kg bw/day % AEL = 3 MOE = 330
Chronic inhalation exposure to volatilised residues (child), HEEG opinion	negligible

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	
pH 5	no remarkable hydrolysis at 70 °C in 28 days
pH 9	no remarkable hydrolysis at 70 °C in 28 days
Other pH: *[indicate the value]*	pH 1, 7, 13: no remarkable hydrolysis at 70 °C in 28 days
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	
Mineralization (aerobic)	Propiconazole: -COR_2R 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): COR_2R evolved 1.6 – 32.2 % of applied radioactivity (120 d) -CGA 118 245 COR_2R 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: 29 - 72 days (n = 8, geometric mean 43 days), 128 days (n=1) at 13.5°C 1,2,4-triazole: 25-126 days (20 P°PC) (n = 4, geometric mean 60.5 days) CGA 118 245: DTR_{50lab} Raround 1 day (20 P°PC) (n = 3)
DT_{90lab} (20°C, aerobic):	
DT_{50lab} (10°C, aerobic):	
DT_{50lab} (20°C, anaerobic):	not determined
degradation in the saturated zone:	
Field studies (state location, range or median with number of measurements)	
DT_{50f}:	Switzerland, 16 days (n = 1) Switzerland, 121 - 129 days (n =2) Germany, 24 - 73 days (n = 3)
DT_{90f}:	DTR_{90f}R: > 380 - > 665 days (n = 4) DTR_{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

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	Propiconazole: $KaR_{oc}R$ 382 – 1789 ml/g (9 soils) 1,2,4-triazole: $KaR_{oc}R$ 13 – 202 ml/g (10 soils) CGA 118 245: $KaR_{oc}R$ 101 – 166 ml/g (3 soils) Propiconazole: $KdR_{oc}R$ 455 – 2279 ml/g (9 soils) Not pH dependent.

Fate and behaviour in air

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 x10P^{5}P) given in the TGD (formula 28) and a 24-hour day
Volatilization	Very slightly volatile

Monitoring data, if available

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)

Species	Time-scale	Endpoint	Toxicity
Fish			

Spot *Leiostomus xanthurus* (marine species) Sheepshead minnow *Cyprinodon variegates* (marine species)	Acute 96 h Chronic 100 d	LC_{50} NOEC	2.6 mg ai/L 0.068 mg ai/L
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	EC_{50} NOEC	9.0 mg ai/l 0.46 mg ai/l
Microorganisms			
Activated sludge from STP	3 h	Respiration inhibition EC_{50}	> 100 mg ai/L

Acute toxicity to *Chironomus riparius*	28 d: Emergence, 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)
Reproductive toxicity to *Chironomus riparius*	Development, NOEC 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)

Effects on soil micro-organisms

Nitrogen mineralization	<u>Propiconazole:</u> 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) <u>1,2,4-triazole</u>: 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 vertebrates

Acute toxicity to mammals	Not applicable
Acute toxicity to birds	Not applicable
Dietary toxicity to birds	Not applicable
Reproductive toxicity to birds	Not applicable

Effects on honeybees

Acute oral toxicity	Not applicable
Acute contact toxicity	Not applicable

Effects on other beneficial arthropods

Acute oral toxicity	Not applicable
Acute contact toxicity	Not applicable

Bioconcentration

Bioconcentration factor (BCF)	180 (bluegill)
Depration time (DT_{50})	99 % of propiconazole was eliminated during 3-day depuration period
Depration time (DT_{90})	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

Chapter 6: Other End Points

Appendix II: List of Intended Uses

Summary of intended uses

Object and/or situation	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks:
			Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	number min max	interval between applications (min)	g a.s./L min max [g/kg]	water L/m^2 min max	g a.s./m^2 min max [g/m²]	
Film preservative PT 7	Theoretical product	Fungi	SL soluble concentrate	100 g/L	addition	1	–	1 3	–	0.151 0.447	–

(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

Data protection is claimed by the applicant in accordance with Article 60 of Regulation (EU) No 528/2012.

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 the evaluation of propiconazole as PT 8 (wood preservative). The studies/information first submitted for the evaluation of propiconazole in PT 7 (/PT 9) have been flagged with * in the first column of the tables below.

Active substance propiconazole (CGA 64250)

Annex point / reference number[3] **Doc IIIA**	**Year**	**Author[4], title[5], 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	1995	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	1995	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	1995	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	1995	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	1995	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
2.8/04	1987	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	1995	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	1995	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	1994	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	1993	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	1993	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	1988	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	1994	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
3.3/01	1994	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	1993	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	1994	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	1987	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	1990	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	1994	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	1994	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	1987	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	1994	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
3.11	1994	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	1994	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	1994	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	1996	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	1994	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	2000	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	1982	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	1987	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	1982	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
4.1 / 04	1995	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	1995	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	1991	Forrer, K. 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	1986	Anonymous. 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	1985	Perez, R. 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	1991	Formica, G. 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	1992	Formica, G. 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	2001	Tribolet, R. 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	1986	Formica, G. 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
4.2 /10B	2000	Pointurier R. – Duchêne P. 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	1992	Tribolet, R. 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	2000	Pointurier R. – Duchêne P. 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	1997	Vargo J.D. 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	2004	Cassidy P. 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	1994	Vargo J.P. 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 LDR_{50}R in the rat of technical CGA 64250, [redacted] 07.12.1978 [redacted]	no	No Y
6.1.1 / 02		[redacted] (1979), Acute oral LDR_{50}R in the mouse of technical CGA 64250, [redacted] 07.05.1979 [redacted]	no	No Y
6.1.2 / 01		[redacted] (1978b), Acute dermal LDR_{50}R in the rat of technical CGA 64250, [redacted] 22.01.1979 [redacted]	no	No Y
6.1.2 / 02		[redacted] (1979a), Acute dermal LDR_{50}R in the rabbit of technical CGA 64250, [redacted] 02.07.1979 [redacted]	no	No Y
6.1.3		[redacted] (1988), Acute aerosol inhalation toxicity in the rat, [redacted] 14.01.1988 [redacted]	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 [redacted]	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 [redacted]	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 [redacted]	no	No Y
6.1.5 / 02	[redacted]1999. CGA 64250 tech. - Skin sensitization in the Guinea Pig (Maximization test) [redacted] 07.09.1999 [redacted]	Yes	No Y
6.2 / 01	[redacted] (1979), Distribution, degradation and excretion of CGA 64250 in the rat, [redacted] 18.07.1979 [redacted]	no	No Y
6.2 / 02	[redacted] (1989), Absorption, distribution, metabolism and excretion in the rat., [redacted] 08.06.1989 [redacted]	yes	No Y
6.2 / 03	[redacted] (1992), Biliary excretion, absorption, and distribution kinetics of [U-P^{14}PC]phenyl CGA 64250 in the rat after oral administration., [redacted], 14.01.1992 [redacted]	yes	No Y

6.2 / 04	[redacted] (1983), Dermal absorption of triazole P^{14}PC-CGA 64250 by rats., [redacted], 11.05.1983 [redacted]	no	No Y
6.2 / 05	[redacted] (1986), Dermal absorptiopn of P^{14}PC-propiconazole in rats after a ten hour exposure period., [redacted] 08.04.1986 [redacted]	no	No Y
6.2 / 06	[redacted] (1986), The metabolism of [U-P^{14}PC]-phenyl-CGA 64250 in mice after pretreatment with unlabelled CGA 64250., [redacted] 20.05.1986 [redacted]	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 [redacted]	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 [redacted]	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 [redacted]	no	No Y

6.2 / 10	[redacted] (1983), The metabolism of CGA 64250 in the rat., [redacted] 01.09.1983 [redacted]	no	No Y
6.2 / 11	[redacted] (1980) Biological report for the metabolism of [triazole-P^{14}PC]-Propiconazole in a lactating goat, [redacted] 29.07.1980 [redacted]	no	No Y
6.2 / 12	[redacted] (1980) Balance and metabolism of triazole-P^{14}PC-CGA 64250 in a lactating goat, [redacted] 18.09.1980 [redacted]	no	No Y
6.2 / 13	[redacted] (1981) Characterization of metabolites in urine, milk and liver of a goat treated with triazole-P^{14}PC-CGA 64250, [redacted] 27.03.1981 [redacted]	no	No Y
6.2 / 14	[redacted] (1989) Biological report for the metabolism of Phenyl-P^{14}PC-Propiconazole in a lactating goat, [redacted] 30.11.1989 [redacted]	no	No Y
6.2 / 15	[redacted] (1990a) Metabolism of phenyl P^{14}PC-propiconazole in goats., [redacted] 31.07.1990 [redacted]	no	No Y
6.2 / 16	[redacted] (1984), Biological report for the metabolism of phenyl and triazole P^{14}PC-labelled CGA 64250 in laying hens, [redacted] 06.01.1984 [redacted]	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 [redacted]	no	No Y
6.2 / 18	[redacted] (1990) Biological report for the metabolism of $P^{14}PC$-Propiconazole in laying hens, [redacted] 05.01.1990 [redacted]	yes	No Y
6.2 / 19	[redacted] (1990b) Metabolism of [phenyl $P^{14}PC$]-propiconazole in chickens., [redacted] 14.06.1990 [redacted]	yes	No Y
6.3.1	[redacted] (1980), 28-day cumulative toxicity study on rats of CGA 64250 technical, [redacted] 11.11.1980 [redacted]	no	No Y
6.3.2/01	[redacted] (1980a), 21-day percutaneous toxicity study in rabbits technical CGA 64250, [redacted] 30.05.1980 [redacted]	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 [redacted]	yes	No Y
6.4.1 / 01	[redacted] (1979), Three months toxicity study on rats of CGA 64250 technical, [redacted] 30.08.1979 [redacted]	no	No Y

6.4.1 / 02	[redacted] (1979), Three months toxicity study on dogs of CGA 64250 technical, [redacted] 09.08.1979 [redacted]	no	No Y
6.4.1 / 03	[redacted] (1991a), Subchronic dietary toxicity study with CGA 64250 in mice, [redacted] 30.04.1991 [redacted]	yes	No Y
6.4.1 / 04	[redacted] (1991b), 13-week dietary toxicity study with CGA 64250 in male mice, [redacted] 30.04.1991 [redacted]	yes	No Y
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
6.6.6	[redacted] (1979), Dominant lethal study mouse (test for cytotoxic or mutagenic effects on male germinal cells), [redacted] 31.10.1979 [redacted]	no	No Y
6.7 / 01	[redacted] (1985), CGA 64250 tech - 1-year subchronic oral toxicity study in Beagle dogs., [redacted] 28.05.1985 [redacted]	yes	No Y

6.7 / 02	[redacted] (1982), Potential tumorigenic and toxic effects in prolonged dietary administration to rats., [redacted] 30.09.1982 [redacted]	yes	No Y
6.7 / 03	[redacted] (1982), Long-term feeding study in mice., [redacted] 26.10.1982 [redacted]	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 [redacted]	yes	No Y
6.7 / 05	[redacted]199918-Months oncogenicity study in mice. [redacted] 26.03.1997 [redacted]	yes	No Y
6.8.1 / 01	[redacted] (1987), Teratology (Segment II) study in rats, [redacted] 28.01.1987 [redacted]	yes	No Y
6.8.1 / 02	[redacted] (1987), A modified teratology (Segment II) study in albino rats, [redacted] 06.02.1987 [redacted]	yes	No Y
6.8.1 / 03	[redacted] (1986), A teratology study (Segment II) in New Zealand white rabbits, [redacted] 01.08.1986 [redacted]	yes	No Y

6.8.2		[redacted] (1985), Two-generation reproduction study in albino rats with [redacted] 12.03.1985 [redacted]	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 [redacted]	yes	No Y
6.10 / 02	[redacted]	• [redacted] 1999. CGA 64250 (Propiconazole) - Assessment of hepatic cell proliferation in male mice [redacted] 01.09.1999 [redacted]	yes	No Y
6.10 / 03		[redacted] (1984), Promotion study with CGA 64250 techn., [redacted] 01.10.1984 [redacted]	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 [redacted]	no	No Y
6.12.1/01	1991	Dr. med. B. Jaquet. 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	1995	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	2000	Schulze-Rosario C., Hertner T. 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
6.12.2	1991	Th. Fuchs. 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	2004	Penaros, H., Ruepert, C., Partanen, T. and C. Wesseling. 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	1980a	Burkhard, N. 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	1983	Spare, W.C. 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	1990	Das, Y.T. Photodegradation of (Phenyl(U)-P^{14}PC)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	1983	Miller, G.C. 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	1990	Bader, U. 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	1983b	Keller, A. 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	1987	Das, Y.T. 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
7.1.2.2.2/04	1992	Das, Y.T. Metabolism of (Phenyl(U)-P^{14}PC)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	1999	Reischmann, F.J. 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	1980	Keller, A. 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	1982b	Keller, A. 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	1982a	Keller, A. Degradation of $P^{14}PC$-dioxalane- and $P^{14}PC$-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	1981b	Keller, A. 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	1980	Timme, G. and Frehse, H. 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	1986	Timme, G., Frehse, H. and Laska, V. 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	1992	Müller-Kallert, H.-M. Degradation of $P^{14}PC$-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	1981a	Keller, 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
7.2.2.1/08	2001	Adam, D. Metabolism of 14C-triazolering labelled CGA 64250 under aerobic and aerobic/anaerobic laboratory conditions in one soil at 20 $P^{o}PC$. 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	2000	Adam, D. Rate of degradation of C-triazole labelled CGA 118 245 in various soil under aerobic conditions at $P^{o}P20$ 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	2000	Slangen, P.J. 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	1982a	Büttler, B. 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	1982b	Büttler, 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	1991a	Resseler, H. 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:		
	1990a	Offizorz, P. 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	1991d	Resseler, H. 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:		
	1991a	Offizorz, P. 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
7.2.2.2/14	1991f	Resseler, H. 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:		
	1991c	Offizorz, P. 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	2004	Tummon O.J. 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	1980c	Burkhard, N. 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	1988	Saxena, A. M. The adsorption and desorption of P^{14}PC-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	1983a	Keller, 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	1988	Hawkins, D.R. 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	2000	Adam, D. 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
-	2007	Rainbird, P. 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	1994	Stamm, E. Rate estimation of the hydroxyl radical oxidation of propiconazole CGA 64250, 31.05.1994 Submitted by: Syngenta Crop Protection AG	No	Yes N
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	1981a	LeBlanc, G.A. and Mastone, J.D. Acute toxicity of CGA-64250 to crayfish (Procambarus sp.), EG&G, Bionomics, Aquatic Toxicology Laboratory, Wareham, Massachusetts, US, Rep. NP^{o} P 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	1999	Grade, R. 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	1993c	Thun, S. Algae growth inhibition test, Test Article: "Desmel A 6097 G", IBR Forschungs GmbH, Bioanalytisches Zentrum, Hannover, FRG, Rep. NP^{o} P 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	1999	Grade R. 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 *	2011	Höger S. 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	1990	Bader, U. Report on the test for inhibitory concentration on aerobic bacteria CGA 64250, Syngenta Crop Protection AG, Basel, CH, Rep. NP^{o} P901112, 28.03.1990 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.4.1.4 / 02	1980	Spare, W.C. CGA-64250 activated sludge metabolism, Biospherics Incorporated, Rep. NP^{o} P80PL-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
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)-P^{14}PC] CGA64250 by Bluegill Sunfish (*Lepomis macrochirus*) in a Flow-Through System. [redacted]	Yes	No Y
7.4.3.4 / 01	1981b	LeBlanc, G.A. and Mastone, J.D. The chronic toxicitity of CGA-64250 to the water flea (Daphnia magna), EG&G, Bionomics, Aquatic Toxicology Laboratory, Wareham, Massachusetts, US, Rep. NP^{o} P 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	1999	Grade, R. 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	2000	Völkel, W. 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	1993b	Lang, B. 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. NP^{o} P 931049003, 30.04.1993 Owned by: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited	Yes	No Y

7.5.1.2 / 02	1993	Lang, B. Acute toxicity earthworm test - Eisenia foetida: Desmel/A 6097 G, BioChem GmbH, Labor Cunnersdorf, Cunnersdorf, FRG, Rep. NP° P 931049004, 30.04.1993 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.5.1.2 / 03	1986	Heimbach, F. Acute toxicity of 1,2,4-triazole (technical) to earthworms, Bayer AG, Leverkusen, FRG, Rep. NP° P 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	2000	Bätscher, R. 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
7.5.1.2 / 05	1999	Nienstedt, K.M. 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	1987	Ruess, W. 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	1990	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	1990	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 *	2009	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	1999	Nienstedt, K.M. 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	2003	Friedrich, S. 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	1995	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	1995	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	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/ No)	Data Protection Claimed (Yes/No)	Data Owner
B5.10(01) IIB, V 5.10*	Wolf, HC	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	LANXESS Deutschland GmbH
B7.1*	Morsing N, Venås TM, Klamer M	2009	Propiconazole - Leaching from painted wood exposed to Outdoor Conditions (Natural Rain) Interim Report	Syngenta Ltd. UK	1235561	No	No	Yes	LANXESS Deutschland GmbH
B7.1*	Morsing N, Venås TM, Klamer M	2010	Propiconazole - Leaching from painted wood exposed to Outdoor Conditions (Natural Rain) Final Report	Syngenta Ltd. UK	1322468	No	No	Yes	LANXESS Deutschland GmbH

References in the literature review

Subsection	Year	Publication	Authors	Title
Doc IIA / 3.8	2013	EFSA Journal 11(3):3132	EFSA	EFSA Scientific Opinion on the hazard assessment of endocrine disruptors: Scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effect mediated by these substances on human health and environment.
Doc IIA / 3.8	2009	Toxicological Sciences 110(2), 449-462	Goetz AK and Dix DJ	Mode of action for reproductive and hepatic toxicity inferred from a genomic study of triazole antifungals.
Doc IIA / 3.8	2002	World Health Organisation, Geneva. 180 pp.	WHO/IPCS/EDC/02.2	Global assessment of the state-of-the-science of endocrine disruptors.
Doc IIA / 3.8	2010	Reproductive Toxicology 30, 573-58.	Kjarstad MB et al.	Endocrine disrupting effects in vitro of conazole antifungals used as pesticides and pharmaceuticals.
Doc IIA / 3.8	2013	Toxicology and Applied Pharmacology 272, 453-464.	Kjedsen LS et al.	Currently used pesticides and their mixtures affect the function of sex hormone receptors and aromatase enzyme activity.
Doc IIA / 3.11	2012	Mutagenesis, 27(5): 541-549	Ross, JA et al.	Quantitative changes in endogenous DNA adducts correlate with conazole *in vivo* mutagenicity and tumorigenicity.
Doc IIA / 3.11	2009	Mutagenesis, 24(2): 149-152	Ross, JA et al.	*In vivo* mutagenicity of conazole fungicides correlates with tumorigenicity
Doc IIA / 3.11	2010	Mutagenesis, 25(3): 231-234	Ross & Leavitt	Analysis of the mutations induced by conazole fungicides *in vivo.*
Doc IIA / 3.8	2013	Toxicological Sciences 132(2), 284-297.	Skolness S et al.	Propiconazole inhibits steroidogenesis and reproduction in the fathead minnow (*Pimephales promelas*).
Doc IIA / 3.8	2008	International Journal of Andrology, 31, 170-177.	Taxvig C et al.	Endocrine-disrupting properties *in vivo* of widely used azole fungicides.
Doc IIA / 3.8	2013	Toxicology and Applied Pharmacology 272, 757-766.	Taxvig C et al.	*In vitro - In vivo* correlations for endocrine activity of a mixture of currently used pesticides
Doc IIA / 3.8	2003	Environmental Health Perspectives 111(3), 255-261.	Zarn JA et al.	Azole fungicides affect mammalian steroidogenesis by inhibiting sterol 14α-demethylase and aromatase.