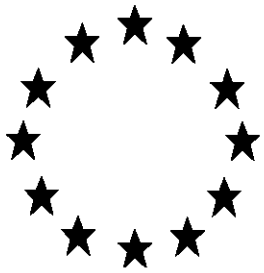
Directive 98/8/EC concerning the placing biocidal products on the market

Inclusion of active substances in Annex I to Directive 98/8/EC

Assessment Report



Propiconazole

Product-type 8
(Wood preservatives)

29 November 2007

Annex I - Finland

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 29 November 2007 in view of its inclusion in Annex I to Directive 98/8/EC

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 propiconazole as product-type 8 (wood preservatives), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with a view to the possible inclusion of this substance into Annex I to the Directive.

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 8 (wood preservatives).

Commission Regulation (EC) No 2032/2003 of 4 November 2003[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 5(2) 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 8 was the 28th of March 2004, in accordance with Annex V of Regulation (EC) No 2032/2003.

On the 26th of March 2004, Finnish competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on the 24th of September 2004.

On the 5th of April 2006, the Rapporteur Member State submitted, in accordance with the provisions of Article 10(5) and (7) of Regulation (EC) No 2032/2003, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on the 21st April 2006. The competent authority report included a recommendation for the inclusion of propiconazole in Annex I to the Directive for PT 8.

In accordance with Article 12 of Regulation (EC) No 2032/2003, the Commission made the competent authority report publicly available by electronic means on the 23rd of May 2006. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

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

2 Commission Regulation (EC) No 2032/2003 of 4 November 2003 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 and amending Regulation (EC) No 1896/2000. OJ L 307, 24.11.2003, p. 1

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

On the basis of the final competent authority report, the Commission proposed the inclusion of propiconazole in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 29 November 2007.

In accordance with Article 11(4) of Regulation (EC) No 2032/2003, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 29 November 2007.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include propiconazole in Annex I to Directive 98/8/EC for product-type 8. The aim of the assessment report is to facilitate the authorisation in Member States of individual biocidal products in product-type 8 that contain propiconazole. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website[3], shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Directive 98/8/EC, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Overall conclusion in the context of Directive 98/8/EC

The overall conclusion from the evaluation is that it may be expected that there are products containing propiconazole for the product-type 8, which will fulfil the requirements laid down in Article 10(1) and (2) of Directive 98/8/EC. This conclusion is however subject to:

i. compliance with the particular requirements in the following sections of this assessment report,

ii. the implementation of the provisions of Article 5(1) of Directive 98/8/EC, and

iii. the common principles laid down in Annex VI to Directive 98/8/EC.

Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond

3 http://ec.europa.eu/comm/environment/biocides/index.htm

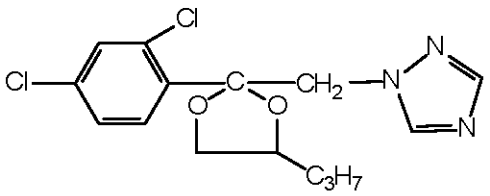
those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity

Identification of the active substance

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

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

Identification of the representative products

Trade name	WOCOSEN 12 OL	
Manufacturer's development code number(s)	BA049362	
Manufacturer of the biocidal product	Janssen Pharmaceutica N.V. Belgium	
Ingredient of preparation	Function	Content
Propiconazole	Active ingredient (fungicide)	1.5 % w/w
Permethrin	active ingredient (insecticide)	0.5 % w/w
Solvent naphtha	solvent	To 100 %
Physical state of preparation	Clear pale-yellow oily solution	
Nature of preparation	Solvent based concentrate	

Trade name	WOCOSEN 100 SL	
Manufacturer's development code number(s)	DA049362	
Manufacturer of the biocidal product	Janssen Pharmaceutica N.V. Belgium	
Ingredient of preparation	Function	Content
Propiconazole	active ingredient (fungicide)	9.67 % w/w
Physical state of preparation	Homogenous clear liquid	
Nature of preparation	Water based concentrate	

The full details of identity of the representative products are confidential and can be found in the summary dossier. None of those ingredients kept confidential is, on the basis of information currently available, of toxicological or environmental concern.

2.1.2. *Physico-Chemical Properties*

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

2.1.3. *Methods of Analysis*

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

2.1.4. *Intended Uses and Efficacy*

Propiconazole has been evaluated for its use as a wood preservative (PT8). The dossier submitted supports the use of propiconazole in wood preservatives for wood Hazard Classes 2 and 3. Therefore, risk assessment has been conducted for Hazard Classes 2 and 3 only [4].

The submitted studies have demonstrated a sufficient degree of efficacy of propiconazole against sap stain and moulds, blue stain, decay and dry rot in most of the evaluated applications. However, one of the efficacy claims is not supported with the submitted studies because there are no data on the efficacy of propiconazole against decay (Basidiomycetes) in superficial treatment of wood. The following retentions of propiconazole for wood preservation hazard classes 2 and 3 are supported on the basis of the submitted efficacy studies:

- Automated spraying or dipping at industrial sawmill for temporary protection of freshly felled wood 0.2-1.0 g a.i./m^2

- Penetrative treatments (industrial vacuum-pressure, double-vacuum and injection) 250-600 g a.i./m^3; this range is determined by the retention required against decay if a species specific label claim is given. For HC2 a retention of 430 g a.i./kg and for HC3 a retention of 600 g a.i./kg is needed to give a general label claim "against decay". However, based on the one concentration study on efficacy of propiconazole against blue stain in vacuum pressure treated wood the lower limit for efficacy seems to be 483 g a.i./m^3 if label claim against specific decay fungi species and blue stain together is given.

4 The Hazard Classes (HC) are defined as: HC1: Above ground (dry); HC2: Above ground (occasional wetting, protected from the weather); HC3: Above ground (exposed to weathering, but not in ground contact); HC4: Timber in contact with the ground or fresh water; HC5: Timber in the marine environment.

- Superficial treatment 1-3 g a.i./m^2 (brushing, dipping and spraying), even up to 10 g a.i./m^2 against *Serpula lacrimans* onto mortar to protect adjacent wood.

According to the participant *Serpula lacrimans* (dry rot) can grow from one window frame to another one via the brick/mortar wall. Therefore walls can be treated indoors to avoid that the fungus grows from one piece of wood to another one. Although the product is applied on the brick/mortar wall, the participant says that it is not to protect the brick/mortar as the fungus does not attack this substrate but wood. The Finnish CAs support the participant's view of PT8 and the Technical Meeting (TMI07) has also accepted this approach. However, although this use falls into PT8 a relevant leaching study on mortar will be needed in order to grant the product authorization to such a use outdoors in PT8. Furthermore, if the product is applied on mortar to protect some other construction material but wood it should also fall into PT10.

In February 2006 the applicant has indicated not to support so high retentions any longer due to the fact that propiconazole is normally used in mixture with other fungicides. Therefore, the applicant moves to support the retentions of 4.0-40 g a.i./m^3 for dipping, 150-200 g a.i./m^3 for vacuum-pressure treatment, double vacuum treatment and injection and 0.1-1 g a.i./m^2 for spraying and brushing. However, there is no data supporting the efficacy of propiconazole with the retention of 150-200 g a.i./m^3 against decay or blue stain fungi submitted. Furthermore, in superficial treatments with lower retentions than 0.7 g a.i./m^2 (=28 g a.i./m^3 for dipping) against blue stain fungi and 0.2 g a.i./m^2 against moulds in temporary protection of freshly cut wood is not proved by the submitted data. However, sufficient data for lower propiconazole retentions may be submitted in connection with product authorization applications.

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.5. Resistance

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

2.1.6. Classification and Labelling

Propiconazole is classified as follows:

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

*) For preparations sold to general public

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Human health hazard assessment with critical endpoints

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

Liver toxicity is the most critical effect of propiconazole. 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 which included mainly adenomas but not carcinomas 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.

2.2.1.2. Toxicological reference doses (AOELs)

Two reference doses for the systemic toxicity of propiconazole can be defined, with relevance to the assessment of risks associated with exposure to a wood preservative. 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. In this evaluation, the use patterns of products containing propiconazole products did not include long-term uses (most part of the year and major part of the life-time). 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 (eg. oral, dermal and pulmonary absorption) should therefore be considered at risk assessment. Toxicokinetic studies in rat show that 86% is absorbed within 48h after oral administration. Correction for bioavailability is therefore not considered necessary.

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

Toxicological reference doses

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

2.2.1.3. Health hazards of the products

The representative products are Wocosen 100 SL (water based) and Wocosen 12 OL (solvent based). Based on the studies submitted Wocosen 100 SL is not acutely hazardous by the oral, dermal or inhalation routes of exposure. Wocosen 100 SL is not classified as irritating to eyes or skin and it is not a skin sensitiser according to the studies.

Based on the studies submitted Wocosen 12 OL is not acutely hazardous by the oral, dermal or inhalation routes of exposure. Wocosen 12 OL showed skin irritation and has to be classified as a skin irritant with Xi; R38: Irritating to skin. It is not an eye irritant or a skin sensitiser according to the studies. The product is classified as harmful with R65 (Harmful: may cause lung damage if swallowed.) based on the viscosity value of the product.

2.2.1.4. Exposure and risk from use of the representative products

The exposure to humans is estimated for the intended uses of wood preservatives containing propiconazole. Manufacturing of the active substance is not further addressed as propiconazole is manufactured outside the EU (Switzerland). No specific data on the exposure during formulation of the products is provided, but the medical surveillance data indicate that protective measures are adequate. The exposure is divided to primary exposure including industrial/professional and non-professional use and to secondary exposure.

Calculations were performed according to the recommendations of the TNsG – Human exposure to Biocidal Product (2002) and the User Guidance (2002). The detailed calculations are presented in the document IIB. For risk characterization the exposure calculated with the 75 percentile values of the models are selected except in two scenarios (small-scale dipping and non-professional outdoor spraying) where maximum values are used instead because the uncertainty of those models was considered high. A default level of acceptability, a MOE of 100, is based on factors of 10 to allow for both inter- and intra-species variability. Industrial/professional worker is assumed to wear personal protective equipment including protective clothing, gloves and footwear.

Dermal route is the main exposure route. Exposure by inhalation and oral routes is considered in some scenarios. Dermal absorption values used in the calculations are 1% for the undiluted water based product (10 % a.s., Wocosen 100 SL), and 2% for the dilution (1% a.s.) and the solvent-based product (app. 1.4% a.s., Wocosen 12 OL). The bodyweight values used are 60 kg for adults to include also females, 15 kg for children and 10 kg for infants.

Primary exposure

Industrial/Professional exposure

For industrial and professional exposure, the scenarios of double vacuum impregnation, industrial and small-scale dipping, mixing and loading, *in situ* spraying, and product painting indoor and outdoor were considered. Exposure was compared to the NOAEL-value of 8 mg/kg bw/day of the 2-generations study in rat.

Industrial dipping was found with the highest potential of exposure. The margin of exposure value (MOE) was estimated as 145. In professional *in situ* spraying the MOE was 177. Product painting indoor showed exposure with the MOE of 185. Also the other exposure scenarios had the MOEs higher than 100. It is concluded that industrial/professional use of these products does not result in unacceptable health risk. However, workers using these products must wear suitable protective clothing, including gloves and footwear. **Non-professional exposure**

For non-professional exposure, the scenarios of brushing and spraying indoor and outdoor were considered. Exposure was compared to the NOAEL-value of 8 mg/kg bw/day of the 2-

generations study in rat. The exposure was found highest in indoor brushing with the MOE under 100. This is however considered as an overestimation by the model as all painting is not overhead painting exclusively. In other non-professional scenarios, brushing outdoors and spraying indoors and outdoors, the health risk is acceptable.

Secondary exposure

Secondary exposure may occur soon after application of a product with a short exposure period (acute phase) or exposure may be long term and repeated (chronic phase). Secondary exposure may result from professional and non-professional use. Exposure is mainly by dermal contact, but it could happen by inhalation and oral routes, too. For acute phase, scenarios of sanding treated wood (adult), touching wet wood after spraying (child) and chewing treated wood off-cuts (infant) were considered. In these scenarios the exposure was compared to the NOAEL of 30 mg/kg bw/day of the teratogenicity study in rat. For chronic phase the scenarios were inhalation of volatilised residues indoors (adult and infant), professional sanding, playing on playground structure (child), playing on weathered playground structure and making hand-to-mouth contact (infant) and cleaning work wear at home (adult). In these scenarios the exposure was compared to the NOAEL of 8 mg/kg bw/day of the 2-generations study in rat.

Secondary exposure was found highest for infants chewing wood off-cuts treated by dipping (acute phase) and adults cleaning work ware (chronic phase) with the MOEs of 750 and 520, respectively. For child touching wet wood after spraying (acute phase) the MOE is 880. As a conclusion, the health risk is acceptable in secondary exposure.

Combined exposure

Adults may have exposure by both primary and secondary (indirect) contact to propiconazole. Since the secondary exposure adds only negligible doses to the primary exposure, no additional concern arises from the combination of all pathways.

2.2.2. Environmental Risk Assessment

2.2.2.1. Environmental hazard assessment

Propiconazole is not readily biodegradable. Propiconazole is hydrolytically and photolytically stable. Propiconazole adsorbs to soil and sediment (arithmetic mean K_{oc} of 944 from 9 soils). The dissipation half-life of propiconazole is around 6.4 days in water and degradation half-life 636 days in the whole water-sediment system at 20 °C ± 2 °C. The degradation half-life of 636 days in the water/sediment system at 20 °C corresponds to 1206 days at 12 °C which is the default temperature according to the Technical Guidance Document for Risk Assessment (TGD). 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 has not been determined.

In the soil laboratory studies the longest DT_{50} of propiconazole was determined to be 72 days at 20 °C (DT_{50} (12 °C) = 137 days and DT_{50} (10 °C) = 160 days). From the field studies the longest dissipation half-life of 129 days for the first phase has been determined after re-analysis of the data from old studies using First Order Multi Compartmental (FOMC) kinetics. In the soil accumulation studies of the plant protection product use carried out in France and Switzerland it was found that the repeated use of propiconazole did not show any significant accumulation of propiconazole or its degradation products in Central European conditions. However, the soil accumulation studies in Canada, where the winter climate conditions were similar to Northern Europe, were not long enough to prove that there would be no accumulation in soil during several years. In addition, there are soil accumulation studies on the plant protection product use of propiconazole conducted under Finnish field conditions from 2000 to 2003 available. However, accumulation in soil under Northern European conditions can not be excluded based on these studies. Furthermore, accumulation studies of plant protection product use are not directly applicable to wood preservative use.

In the soil laboratory studies there were two degradation products of propiconazole accounting more than 10% of the active substance in the laboratory studies (CGA 118 245 and 1,2,4-triazole). Both are degraded in soil faster than the parent substance CGA 118 245 having DT_{50} of around 1 day and 1,2,4-triazole having DT_{50} of around 9.3 days at 20 °C. Both degradation products are also more mobile in soil than propiconazole CGA 118 245 having the arithmetic mean K_{oc} of 129 from 3 soils and 1,2,4-triazole having the arithmetic mean K_{oc} of 69 from 10 soils.
Propiconazole is very toxic to algae and aquatic invertebrates and toxic to fish. Predicted No-Effect Concentration (PNEC) in surface water is 1.6 µg a.i./l based on the NOEC (No Observed Effect Concentration) from algae. $PNEC_{sediment}$ = 0.054 mg a.i./kg wet sediment is based on the NOEC from chironomus. PNEC in sewage treatment plant is 1 mg a.i./l.

Toxicity to terrestrial species was studied in micro organisms, 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 0.02 mg a.i./kg wet soil.

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.

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. However, the analysis of sex ratio of F0 generation in a fish life-cycle test from the submitted dossier showed that propiconazole did not have any effect on the sex ratio of fish.

Propiconazole does not fulfil the PBT criteria given in the TGD, part II (2003), although it can be considered persistent.

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.

The submitted literature search is considered sufficient and the findings of it support the conclusions of this evaluation.

2.2.2.2. Evaluation of emission due to leaching from treated wood

The leaching values used in the calculation of Predicted Environmental Concentrations (PEC) are derived from a semi-field study of 343 days conducted in Denmark. The study provides information about the leaching of propiconazole from HC3 wood due to exposure to natural rainfall. There are results from different application methods and different orientations of wood in service reported in the study. The leaching values were corrected for the PEC calculations in terms of retention and the default of the TGD about the annual cumulative rainfall. Further details are described in Doc IIB and Doc IIIB7.1.

2.2.2.3. Risk characterization for the environment

The OECD Emission Scenarios used in the evaluation provide estimation of the local environmental concentration based on the use of a wood preservative. Concerning PEC from production and formulation, and regional PECs the RMS has made the following conclusions. Because the active substance propiconazole is manufactured outside the EU (Switzerland) the exposure from manufacturing process does not need to be evaluated. Furthermore, only very local if any environmental exposure is expected from formulation processes of biocidal products containing it. Also otherwise contribution to the regional background concentrations of the active substance can be regarded as insignificant due to the anticipated very local emission patterns of the use of the biocidal product with soil as the main receiving compartment. Thus, all regional PECs may be considered to be negligible and quantitative estimates of these are not relevant for the risk assessment. The following risk characterizations apply in local scale.

Propiconazole is adsorbed to some extent from the wastewater to the activated sludge in a sewage treatment plant (STP). The risk characterisation for the environment shows that the use of propiconazole in wood preservation does not pose unacceptable risk to STPs. In most scenarios with the maximum intended retention of propiconazole in wood there is unacceptable risk to the aquatic environment (surface water and sediment) from propiconazole coming from the application plants via the STP if propiconazole containing application solutions are not re-cycled at the application plant. There is no unacceptable risk from storages of propiconazole

application plant. There is no unacceptable risk from storages of propiconazole treated wood directly to surface water or sediment or to agricultural soil and grassland via application of STP sludge even if the maximum retention of propiconazole in wood is assumed.

Releases from the in-situ treatment of wooden structures and wood in service for HC3 with the maximum intended retentions of propiconazole pose unacceptable risk to the aquatic environment in most cases. In surface water the PEC/PNEC ratio ranges from 0.4 to 21. There is also unacceptable risk to sediment from the in-situ treatment of wood and wood in service with the maximum retentions of propiconazole, the PEC/PNEC ratios ranging from 2 to 253. However, it should be noted that PECs in sediment have been calculated on the basis of the degradation half-life of 1206 days in the whole water-sediment system. The PEC/PNEC ratios in the aquatic environment related to the in-situ treatment of wood for HC2 are of less concern than the PEC/PNEC ratios of HC3 because releases are mainly related to the application stage.

The PEC/PNEC ratios for soil in "treated wood in storage after industrial treatment" scenarios range from 27 to 78 indicating unacceptable risk when maximum a.i. retentions are assumed. The OECD ESD for wood in service assumes 10 cm horizontal and vertical distance in soil. However, in the EU biocides work it has been decided by the 23rd Competent Authority Meeting to consider soil volumes representing 50 cm horizontal and vertical distances in the risk assessment. The PEC/PNEC ratios of propiconazole in soil from the in-situ treatment of wood and wood in service for HC 3 show unacceptable risk in soil in most cases, the PEC/PNEC ratios ranging from 0.6 to 31 for the maximum a.i. retentions. There is also unacceptable risk to soil from the in-situ treatment of wood for HC2 although the releases from HC2 wood in service to the environment are considered negligible. Concerning the in-situ treatment of wood and storage of wood after industrial treatment and before shipment reasonable risk mitigation measures are available (see sections 3.2 and 3.3 below).

Two main degradation products of propiconazole in soil are biodegraded in soil faster than propiconazole. The concentrations of these two compounds are not assumed to exceed the one of propiconazole in soil. Therefore, concentrations of propiconazole in soil can be used as the worst case assumption in the risk assessment of these degradation products. Furthermore, both degradation products are found to be less toxic to earthworms than propiconazole.

Any number of re-application would increase the PECs and PEC/PNEC ratios of propiconazole derived from the intended uses of Wocosen 100 SL and Wocosen 12 OL products. The effects of possible re-applications on risk need to be evaluated at product authorisation stage.

2.2.2.4. Risk characterization for groundwater used as drinking water

The groundwater concentrations of propiconazole were calculated using FOCUS-PEARL 3.3.3 simulation in nine different FOCUS scenarios with the assumption of 35 houses of treated wood per hectare. None of these concentrations exceeded the maximum permissible concentration of 0.1 µg/l given for groundwater in Directive 80/778/EEC (amended by 98/83/EC). In addition, reasonable risk mitigation measures to protect groundwater are available for storages of treated wood after application and before shipment (see section 3.2 below).

2.2.2.5. Atmosphere

Propiconazole is very slightly volatile. With the estimated half-life less than 2 days in troposphere propiconazole is not regarded as a persistent contaminant in the air. Propiconazole is not expected to have long-range atmospheric transport or contribute to global warming, ozone depletion or acidification on the basis of the physical and chemical properties.

2.2.2.6. Risk of secondary poisoning

Although propiconazole shows a slight potential for bioaccumulate it is not classified with very toxic (T+), toxic (T) or harmful (Xn) with at least one of the risk phrases R48 "Danger of serious damage to health by prolonged exposure", R60 "May impair fertility", R61 "May cause harm to the unborn child", R62 " Possible risk of impaired fertility", R63 "Possible risk of harm to the unborn child", R64 "May cause harm to breastfed babies" or if there are other indications (e.g.) endocrine disruption. Therefore, there is no need to perform an assessment of secondary poisoning for propiconazole.

2.2.2.7. Waste disposal stage

It is most unlikely that propiconazole containing biocidal product wastes will result in unacceptable environmental risk during incineration under controlled conditions required in waste legislation. The propiconazole emissions from a landfill site due to disposal of propiconazole containing wood are evaluated to be significantly less than that described for the house scenario for wood in service during the period up to 20 years because the amount of treated wood per m^2 soil is assumed to be less. Therefore, it is unlikely that propiconazole treated timber wastes will result in unacceptable environmental risk from a normal landfill site. If treated wood is collected and disposed in special areas of a landfill it is assumed that special precaution has been taken for this part of the landfill.

2.2.3. List of endpoints

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

3. DECISION

3.1. Background to the Decision

Based on the assessment of data on the active substance and the representative products, Wocosen 100 SL and Wocosen 12 OL, health risks for the users of the biocidal product are at an acceptable level if principles of good working practice are applied and use instructions and recommendations on the label of the product are respected. In addition, the criteria for approval given in Article 5(1) of Directive 98/8/EC concerning efficacy, physical and chemical properties and analytical methods are fulfilled.

The RMS considered to recommend Annex I inclusion to HC 2 only due to unacceptable risk to soil, surface water and sediment from treated wood in HC 3. On the other hand, the RMS is unaware if at present there is a sufficient number of alternative active substances for same use

aware if at present there is a sufficient number of alternative active substances for same use purposes for HC 3 with significantly lower risk and without unacceptable effects. Therefore, the RMS does not find a restriction in terms of Hazard Class necessary. However, several other conditions and restrictions are considered necessary for the authorisation of propiconazole containing wood preservative products at the Member State level. The detailed justifications for the proposed risk mitigation measures are described in section 2.2.

The minimum purity of 93% w/w for Annex I listing in section 3.2 is a guaranteed minimum content given by the applicant, which means that no batch is released in production if it does not meet this minimum purity, whereas the 5-batch analysis shows slightly higher purities (> 94.5% w/w). The toxicological and ecotoxicological studies were conducted with purities of 92 to 93% in most cases and always at least 88%. In order to respect the development of the manufacturing processes a minimum purity of 93% w/w can be adopted into Annex I although some of the older effect studies refer to slightly lower purities.

3.2. Decision regarding Inclusion in Annex I

The substance propiconazole shall be included in Annex I to Directive 98/8/EC as an active substance for use in product-type 8 (Wood preservatives), subject to the following specific provisions:

Minimum purity of the active substance in the biocidal product as placed on the market 930 g/kg.

Member States shall ensure that authorisations are subject to the following conditions:

(1) In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means.

(2) In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.[5]

In addition, products cannot be authorised for the *in situ* treatment of wood outdoors or for wood that will be exposed to weathering unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

5 These requirements may actually be determined in detail in the environmental permits of the application plants on the basis of the Council Directive 96/61/EC on Integrated Pollution Prevention and Control (IPPC) but should be listed in the instructions for use of a biocidal product.

3.3. Elements to be taken into account by Member States when authorising products

1. In the review program propiconazole has been evaluated as a fungicide in wood preservatives (Product Type 8) for wood above ground exposed to occasional wetting and above ground not covered (Hazard Class 2 and 3). Extension of the use pattern beyond those reviewed will require a re-evaluation of the acceptance of propiconazole in order to establish whether the proposed extensions of use can satisfy the requirements of Article 10(1) and 5(1).

2. In the dossier submitted for the review program the minimum purity of 93 % w/w was supported. The FAO specification (AGP: CP/330, 1995) is min. 88 % w/w.

3. Products containing propiconazole may be used in the preventive treatment of wood by vacuum-pressure, double-vacuum, spraying, brushing and industrial dipping for constructions outdoors. Wood indoors may be treated by brushing, spraying and professional injection.

4. Protective clothing, gloves and footwear are required in industrial/professional use.

5. According to the EU waste legislation waste from wood preservative products and application solutions are considered hazardous waste. Therefore, application solutions must be collected and reused or disposed of as hazardous waste and they must not be released to soil, surface water or any kind of sewer[6].

6. Soil in the vicinity of the object to be treated in-situ has to be mechanically protected during the treatment (e.g. with a tarpaulin or plastic sheeting) and subsequent waste management has to be sorted out in an appropriate way.

7. In-situ application by brush or spray in the vicinity of water courses must not be conducted where direct losses to the aquatic compartment cannot be prevented.

8. Member States shall ensure that authorisations of propiconazole containing products are subject to the restrictions and conditions specified by number 5., 6. and 7. above. These requirements shall be given in labels/accompanying leaflets integral to the packaging and safety-data sheets of products authorised.

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

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

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6 These requirements may actually be determined in detail in the environmental permits of the application plants on the basis of the Council Directive 96/61/EC on Integrated Pollution Prevention and Control (IPPC) but should be listed in the instructions for use of a biocidal product.

11. Specific dermal absorption data of the products and information on the duration of exposure shall be demonstrated at the product authorisation stage.

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

13. If indoor use for non-professionals is intended in the product authorisation applications, it has to be demonstrated that the exposure is acceptable.

14. When Member States are authorising products containing propiconazole the potential of propiconazole to cause endocrine disruption must be considered. This is because propiconazole may have the potential to cause endocrine disruption based on suspected properties for the azole group and that there is not sufficient data. However, in the submitted studies there were no effects in the test animals which could be related to possible endocrine disruption.

15. The effects of possible re-applications on risk need to be evaluated at product authorisation stage. Re-applications in-situ (remedial treatment) are only possible according to conditions to be set in the product authorisation procedure.

16. In the product authorisation applications it has to be demonstrated that treated wood in service does not pose unacceptable risk to the environment. This is because in the dossier submitted for the review program environmentally safe use of propiconazole as a wood preservative in wood for Hazard Class 3 as required in Article 5(1)(b)(iv) of Directive 98/8/EC has not been demonstrated. E.g. additional treatment with a propiconazole-free coating or fixative may be considered to reduce the leaching of propiconazole from treated wood in wood Hazard Class 3.

17. In the evaluation of the active substance in the review program it was not possible to confirm the data protection claims of individual studies in accordance with Article 12.1(c) (i) or (ii) of Directive 98/8/EC.

3.4. Requirement for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the inclusion of propiconazole in Annex I to Directive 98/8/EC.

3.5. Updating this Assessment Report

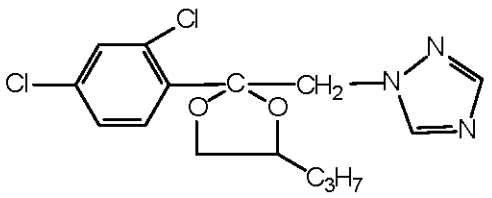
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of propiconazole in Annex I to the Directive.

Appendix I: List of End Points

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

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

Identity (Annex IIA, point II.)

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

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

Freezing point (state purity)	-23°C (98.8%)
Boiling point (state purity)	> 250°C at 101.325 kPa (The highest temperature in the test was 270 °C.) 120°C at 1.9 Pa (92.2%) (decomposition begins around 355°C)
Temperature of decomposition	355°C (92.2%)
Appearance (state purity)	Clear, viscous liquid (purified 98.8%), yellowish (technical 92.2%)
Relative density (state purity)	1.289 at 20°C (92.2%)
Surface tension	filtrates of 10.0 g / l suspensions : σ = 46.6 - 48.4 mN / m filtrates of 1.0 g / l suspensions : σ = 55.8 - 62.3 mN / m (at 20°C). The results are based on too concentrated samples compared to the guideline. When this and the molecular structure are taken into account, propiconazole is not regarded as a surface-active substance.
Vapour pressure (in Pa, state temperature)	5.6×10^{-5} Pa at 25°C (99.1%)
Henry's law constant (Pa m^3 mol^{-1})	9.2×10^{-5} Pa m^3 mol^{-1}
Solubility in water (g/l or mg/l, state temperature)	pH 6.9 : 100 mg/l at 20°C (99.1%) There are no measurements on pH dependency of the solubility in water. However, based on the dissociation constant (pKa =1.09) it can be assumed that there is no marked pH dependency over a wide range of pH values.
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	n-hexane : 47 g / l Completely miscible in solvents: toluene, dichloromethane, ethanol, n-octanol, acetone and ethyl acetate (25°C) (92.2% and 92.4%)
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	Propiconazole, in a representative solvent-based wood preservative, is stable for 8 weeks at 40°C .
Partition coefficient (log K_{ow}) (state temperature)	3.72 at 25°C , pH 6.6 (99.1%)

Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	pH 1, 5, 7, 9 and 13: no remarkable hydrolysis at 70 °C in 28 days
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	pKa = 1.09 at 20°C (99.1%)
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	λ_{max} : 220.4 nm, ε_{max} : 11666 M^{-1} cm^{-1} No absorption between 290 and 750 nm. (98.8%)
Photostability (DT_{50}) (aqueous, sunlight, state pH) (point VII.7.6.2.2)	pH 7: no remarkable photolysis at 25 ±1°C in 30 days
Quantum yield of direct phototransformation in water at Σ > 290 nm (point VII.7.6.2.2)	No absorption > 290 nm
Flammability	There was no self-ignition of propiconazole up to the start of decomposition (355 °C). (Self-ignition temperature of the decomposition products: 430°C) Not flammable, not highly flammable, not extremely flammable (92.4%)
Explosive properties	Not explosive (92.4%)
Oxidizing properties	Not oxidizing (92.4%)

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

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

Chapter 2: Methods Of Analysis

Analytical methods for the active substance

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

of method) (Annex IIA, point 4.1)	

Analytical methods for residues

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

Chapter 3: Impact on Human Health

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

Rate and extent of oral absorption:	86% within 48 h
Rate and extent of dermal absorption:	The estimated dermal absorption in humans is 1% for the Wocosen 100 SL product (10% propiconazole) and 2% for the 1% Wocosen 100 SL dilution and the Wocosen 12 OL product, based on an in vivo study in rat and a comparative in vitro dermal penetration study using rat and human skin
Distribution:	Widely distributed; highest residues in liver and kidneys
Potential for accumulation:	No evidence of accumulation
Rate and extent of excretion:	95% in 48 h, in about equal amounts in urine and feces (enterohepatic re-circulation)
Toxicologically significant compounds:	Parent compound and metabolites (animals). Triazolyl alanine and triazolyl acetic acid formed only in plants; not toxicologically significant
Metabolism in animals:	Extensively metabolised (>20 metabolites identified in rat urine)

Acute toxicity (Annex IIA, point 6.1)

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

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

Species/ target / critical effect:	Liver toxicity

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

Genotoxicity (Annex IIA, point 6.6)	No genotoxic effects

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

Target / critical effect:	Liver in rats and mice
Lowest relevant NOAEL / LOAEL:	NOAEL: 100 ppm (3.6 mg/kg bw/day; 2 year, rat)
Carcinogenicity:	Liver tumors in male mice. The lowest dose with tumors (mainly hepatocellular adenomas) was 2500 ppm (344.3 mg/kg bw/day)

Reproductive toxicity (Annex IIA, point 6.8)

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

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

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

Other toxicological studies (Annex IIIA, VI/XI)

	Triazolyl alanine and triazolyl acetic acid (formed only in plants) were studied for toxicokinetics, acute toxicity, short-term toxicity and genotoxicity (also reproductive

.....	toxicity of triazolyl alanine). No adverse effects were observed. Studies on tumor promotion and induction of drug metabolising enzymes showed that propiconazole is a promoter of proliferative changes and causes induction of hepatic enzymes.

Medical data (Annex IIA, point 6.9)

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

Summary (Annex IIA, point 6.10)	Value	Study	Safety factor
AOEL:	0.08 mg/kg bw/day	2-generation rat study	100
Acute AOEL:	0.3 mg/kg bw/day	Developmental study in rat	100
Drinking water limit:	0.1 µg/l	As set by EU Drinking Water Directive (98/83/EC)	Not relevant

Acceptable exposure scenarios (including method of calculation)

Professional users:	Vacuum-pressure / Double-vacuum impregnation	MOE 296 (water-based form.) MOE 1630 (solvent-based formulation)

Acceptable exposure scenarios (including method of calculation)

	Industrial dipping	MOE 145
	Small scale dipping	MOE 1600
	Mixing and loading	MOE 13000 (pouring) MOE 1780 (pumping)
	Cleaning of impregnation/dipping tank	MOE 1600
	Spraying	MOE 177
	Brushing (including cleaning of a brush)	MOE 185 (indoor) MOE 708 (outdoor)
	Suitable protective clothing, gloves and footwear required.	
	Models and parameters – see document IIB	
Non-professional users:	Brushing (outdoor) (including cleaning of a brush)	MOE 800 (water-based form.) MOE 620 (solvent-based formulation)
	Spraying	MOE 110 (indoor) MOE 235 (outdoor)
	Models and parameters – see document IIB	
Indirect exposure as a result of use:	Adult – sanding treated wood posts	MOE 300000
Acute phase	Child – touching wet wood after spraying	MOE 880
	Infant – chewing wood off-cut (double vacuum impregnated wood)	MOE 3800
	Infant – chewing wood off-cut (treatment by dipping)	MOE 750

Acceptable exposure scenarios (including method of calculation)

Chronic phase	Adult – inhalation of volatilised residues indoors	MOE 320000
	Infant – inhalation of volatilised residues indoors	MOE 250000
	Adult – professional sanding	MOE 40000
	Child – playing on playground structure outdoors	MOE 73000
	Infant – playing on weathered (playground) structure and mouthing (modified)	MOE 1900
	Adult – cleaning work wear at home	MOE 520
	Models and parameters – see document IIB	

Chapter 4: Fate and Behaviour in the Environment

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 1, 5, 7, 9 and 13: no remarkable hydrolysis at 70 °C in 28 days major metabolites : not relevant
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	pH 7: no remarkable photolysis at 25 ±1°C in 30 days major metabolites : not relevant
Readily biodegradable (yes/no)	No
Biodegradation in seawater	Not applicable
Non-extractable residues	No
Distribution in water / sediment systems (active substance)	Expressed as parent compound 96.5 – 98.1 % of applied radioactivity in water at the beginning of the study and 0.9 – 2.0 % of applied radioactivity in water at the end of the study (175 days), respective amounts in the sediment were 2.0 and 76.8 – 81.7 % of applied radioactivity (175 days); non-extractable residues were found at the end of the study 7.6 –9.1 %; mineralisation 0.4 % of applied radioactivity (1 Rhine water and 1 pond water)

	Dissipation half-life in water 5.5 - 6.4 days, 6.4 days used in the risk assessment Total degradation half-life in the whole system 485 – 636 days, 636 days used in the risk assessment
Distribution in water / sediment systems (metabolites)	Eight metabolites were found CGA 217 495 2.8 – 2.9 %; CGA 91305 3.1 – 5.0 %; M3 (unknown) 3.1 – 4.4 %; 1,2,4-triazole 2.1 – 2.3 % after 90 to 175 days. Others were found at concentrations below 1.3 % (1 Rhine water and 1 pond water), all metabolites amounting < 10% of the applied radioactivity, no further evaluation needed

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

Mineralization (aerobic)	Propiconazole: -CO_2 evolved < 5% of applied radioactivity (triazole labelled a.i.) in 120 days and 29 - 35 % (phenylring labelled a.i. 1 soil) of applied radioactivity in 168 days -1,2,4-triazole (was used as a starting substance): CO_2 evolved 1.6 – 32.2 % of applied radioactivity (120 d) -CGA 118 245 CO_2 0.1 –0.2 % of applied radioactivity (3 soils, 5 d)
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): Propiconazole: DT_{50lab} (20 – 25 °C, aerobic): 29 - 72 days (n = 8), 128 days (n=1) at 13.5°C 1,2,4-triazole: DT_{50lab} 6 – 12 days (20 °C) (n = 3) CGA 118 245: DT_{50lab} around 1 day (20 °C) (n = 3)
	DT_{50lab} (20°C, anaerobic): not determined

	degradation in the saturated zone: not available
Field studies (state location, range or median with number of measurements)	DT_{50f}: Propiconazole: DT_{50f}: Switzerland, 16 days (n = 1) Switzerland, 121 - 129 days (n =2) Germany, 24 - 73 days (n = 3) Maximum 129 d from FOMC kinetics used in the risk assessment. DT_{50f} longer than three months cannot be excluded.
	DT_{90f}: Propiconazole: DT_{90f}: > 380 - > 665 days (n = 4) DT_{90f} longer than one year cannot be excluded.
Anaerobic degradation	Not applicable
Soil photolysis	Not applicable
Non-extractable residues	In the laboratory studies after 100 days at 20-25 °C : Propiconazole: -triazole labelled 14.1 - 15.5 % of applied radioactivity (84 d), 47.3 % of applied radioactivity (120 d) -phenylring labelled 23.3 - 27.3 % of applied radioactivity (84 d) -triazole labelled 3.4 – 24.6 % of applied radioactivity (105 days) in different conditions -1,2,4-triazole (was used as a starting substance): 41.8 – 66.2 % of applied radioactivity (3 soils, 120 d) -CGA 118 245 non-extractables 9.8 – 12.3 % of applied radioactivity (3 soils, 5 d)

Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	1,2,4-triazole (CGA 71019) 24 % - 43 % of applied radioactivity

	-CGA 118 245 (U3) 22 % of applied radioactivity
Soil accumulation and plateau concentration	- France: maximum residues of propiconazole were < 0.02 – 0.12 mg/kg and 1,2,4-triazole < 0.01 mg/kg within 6 – 7 years of annual 2 x 125 g a.i./ha use - Switzerland: maximum residues of propiconazole were < 0.02 – 0.06 mg/kg and 1,2,4-triazole < 0.01 – 0.05 mg/kg within 10 years of annual 2 – 3 x 125 g a.i./ha - Canada: maximum residues of propiconazole were 0.03 mg/kg - 0.1 mg/kg (250 g a.i./ha/year) and 0.03 – 0.17 mg/kg (500 g a.i./ha/year) within two years; 1,2,4-triazole was not found above detection limit of 0.1 ppm - Canada: maximum residues of propiconazole were 0.03 mg/kg - 0.09 mg/kg (cumulative use rate 250 – 375 g a.i./ha within two years) and 0.04 – 0.18 mg/kg (cumulative use rate 500 – 750 g a.i./ha) within three years; 1,2,4-triazole was found at trace amounts in higher use rate plots Finland: the residues of propiconazole were 0.01 – 0.06 mg/kg (0- 20 cm, 7 fields) except one residue of 0.26 after many years use

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

Ka , Kd Ka_{oc} , Kd_{oc}	Propiconazole: Ka_{oc} 382 – 1789 (9 soils) 1,2,4-triazole: Ka_{oc} 13 – 202 (10 soils) CGA 118 245: Ka_{oc} 101 – 166 (3 soils) Propiconazole: Kd_{oc} 455 – 2279 (9 soils)

pH dependence (yes / no) (if yes type of dependence)	No

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

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

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

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

Chapter 5: Effects on Non-target Species

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

Species	Time-scale	Endpoint	Toxicity
Fish			
Rainbow trout *Oncorhynhus mykiss* Fathead minnow, *Pimephales promelas*	Acute 96 h Chronic 35 d	LC_{50} NOEC	4.3 mg ai/L 0.43 mg ai/L
Aquatic invertebrates			
Daphnia magna	Acute 48 h Chronic 21 d	LC_{50} NOEC	10.2 mg ai/L 0.31 mg ai/L
Algae			
Green algae *Scenedesmus subspicatus*	72 h	ECr_{50} NOEC	0.058 mg ai/L 0.016 mg ai/L
Sediment organisms			
Chironomus riparius (propiconazole)	28 d	Emergence, NOEC Development, NOEC	8.0 mg ai/L(water) 25.0 mg ai/kg dw (sed.) = 5.4 mg ai/kg ww (dividing by a conversion factor of 4.6) 4.0 mg ai/L (water) 50.0 mg ai/kg dw (sed.) = 10.8 mg ai/kg ww (dividing by a conversion factor of 4.6)
Microorganisms			
Activated sludge from STP	3 h	Respiration inhibition EC_{50}	> 100 mg ai/L

Effects on earthworms or other soil non-target organisms

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

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

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

Effects on terrestrial plants (Annex IIIA, point 3.4)

Propiconazole: EC_{50} = 4.32 mg ai/kg ww (at 3.4% organic matter)

Effects on terrestrial vertebrates

Not applicable

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

Not applicable

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

Not applicable

Bioconcentration (Annex IIA, point 7.5)

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

Chapter 6: Other End Points

Appendix II: List of Intended Uses

Summary of data on intended uses and the method of application

Object and/or situation	Member State or Country	Product name Examples	Organisms controlled Applicant's proposal revised by the RMS based on the submitted efficacy studies	Formulation		Application * Proposal by applicant for number and interval			Applied amount per treatment Applicant's proposal revised by the RMS based on the submitted efficacy studies			Remarks: (related emission scenario)
				Type	Conc. of a.i.	method kind	number min max *	interval between applications min *	g as/L min max	water L/m² min max	g as/m² min max	
Temporary protection of freshly felled wood industrial use	**EU**	**Wocosen 100 SL**	**Sap stain fungi**	**SL**	**100 g/l**	**Surface application (spray/ dip)**	**1**	**na**	**Depending on the treatment procedure, the degree of protection, the climatic circumstances different dilutions can be used, but uptake of active ingredient should be situated between 0.2 and 1.0 g active ingredient per square meter. Using the default of 40 for wood area/wood volume ratio 1 g/m² = 40 g/m³ for dipping.**			**automated spraying or dipping, industrial sawmill**
Preventive protection against wood rot and discolouring industrial use	**EU**	**Wocosen 100 SL**	**Decay fungi and blue stain fungi**	**SL**	**100 g/l**	**impregnation**	**1**	**na**	**Depending on the treatment cycle different dilution rates can be used, but the uptake of active ingredient should be 600 g active ingredient per cubic meter of wood in order to be able to give a**			**Industrial vacuum pressure**

Object and/or situation	Member State or Country	Product name Examples	Organisms controlled Applicant's proposal revised by the RMS based on the submitted efficacy studies	Formulation		Application * Proposal by applicant for number and interval			Applied amount per treatment Applicant's proposal revised by the RMS based on the submitted efficacy studies			Remarks: (related emission scenario)
				Type	Conc. of a.i.	method kind	number min max *	interval between applications min *	g as/L min max	water L/m^2 min max	g as/m^2 min max	
Preventive protection against wood rot and discolouring industrial use	**EU**	**Wocosen 12 OL**	**Decay fungi and blue stain fungi**	**OL**	**12 g/l**	**impregnation**	**1**	**na**	**general label claim against decay without specifying individual species. In practice, lower uptake rates in the range of 150 to 200 g active substance per cubic meter of wood will be applicable because combination with other fungicides are used in many cases.**			**Double vacuum, industrial joinery**
Preventive protection against wood discolouring industrial use	**EU**	**Wocosen 100SL**	**Blue stain fungi**	**SL**	**100 g/l**	**superficial application**	**1**	**na**	**Depending on the application active ingredient uptake should be situated between 1 and 3 g a.i. per square meter. Using the default of 40 for wood area/wood volume ratio 3 g/m^2 = 120 g/m^3 for dipping. In practice, the lower uptake rate of 1 g active substance per square meter of wood will be applicable because combination with other fungicides are used in many cases.**			**Manual or mechanized dipping (large scale joinery)**

Object and/or situation	Member State or Country	Product name Examples	Organisms controlled Applicant's proposal revised by the RMS based on the submitted efficacy studies	Formulation		Application * Proposal by applicant for number and interval			Applied amount per treatment Applicant's proposal revised by the RMS based on the submitted efficacy studies			Remarks: (related emission scenario)
				Type	Conc. of a.i.	method kind	number min max *	interval between applications min *	g as/L min max	water L/m² min max	g as/m² min max	
Preventive and curative protection against wood rot and discolouring professionol use	**EU**	**Wocosen 100SL**	**Blue stain fungi and dry rot fungi**	**SL**	**100 g/l**	**superficial**	**1 to 5**	**1 year**	**Depending on the application active ingredient uptake should be situated between 1 and 3 g a.i. per square meter . Using the default of 40 for wood area/wood volume ratio 3 g/m² = 120 g/m³ for dipping.** **Curative up to 10 g a.i./m² of mortar against *Serpula lacrimans*, indoors use only.** **In practice, the lower uptake rate of 1 g active substance per square meter of wood will be applicable because combination with other fungicides are used in many cases.**			**Dipping (small scale joinery)** **Brushing (indoors), professionals** **Brushing (outdoors), professionals** **Spraying (indoors and outdoors) professionals and amateurs**

Object and/or situation	Member State or Country	Product name Examples	Organisms controlled Applicant's proposal revised by the RMS based on the submitted efficacy studies	Formulation		Application * Proposal by applicant for number and interval			Applied amount per treatment Applicant's proposal revised by the RMS based on the submitted efficacy studies			Remarks: (related emission scenario)
				Type	Conc. of a.i.	method kind	number min max *	interval between applications min *	g as/L min max	water L/m^2 min max	g as/m^2 min max	
Preventive and curative protection against wood rot and discolouring professionol use	**EU**	**Wocosen 100SL**	**Decay fungi and blue stain fungi**	**SL**	**100 g/l**	**injection**	**1 to 2**	**1 year**	**Depending on the treatment cycle different dilution rates can be used, but the uptake of active ingredient should be 600 g active ingredient per cubic meter of wood in order to be able to give a general label claim against decay without specifying individual species.** **In practice, lower uptake rates in the range of 150 to 200 g active substance per cubic meter of wood will be applicable because combination with other fungicides are used in many cases.**			**Injection (indoors) professionals**
Preventive and curative protection against wood rot and discolouring public use	**EU**	**Wocosen 100SL**	**Blue stain fungi**	**SL**	**100 g/l**	**superficial**	**1 to 5**	**1 year**	**Depending on the application active ingredient uptake should be situated between 1 and 3 g a.i. per square meter.** **In practice, the lower uptake rate of 1 g active substance per square meter of wood will be applicable because combination with other fungicides are used in many cases.**			**Brushing (indoors), amateurs** **Brushing (outdoors), amateur**

Object and/or situation	Member State or Country	Product name Examples	Organisms controlled Applicant's proposal revised by the RMS based on the submitted efficacy studies	Formulation		Application * Proposal by applicant for number and interval			Applied amount per treatment Applicant's proposal revised by the RMS based on the submitted efficacy studies			Remarks: (related emission scenario)
				Type	Conc. of a.i.	method kind	number min max *	interval between applications min *	g as/L min max	water L/m^2 min max	g as/m^2 min max	
Preventive and curative protection against wood rot and discolouring public use	EU	**Wocosen 12 OL**	**Blue stain fungi**	**OL**	**12 g/l**	**superficial**	**1 to 5**	**1 year**	**Depending on the application active ingredient uptake should be situated between 1 and 3 g a.i. per square meter.** **In practice, the lower uptake rate of 1 g active substance per square meter of wood will be applicable because combination with other fungicides are used in many cases.**			**Brushing (indoors), amateurs** **Brushing (outdoors), amateur**

Appendix III: List of studies

On request by the applicant the names of authors, companies and organisations related to unpublished studies have been blanked out in the tables below. Data protection is claimed 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. During the evaluation of the active substance propiconazole in the review program it was not possible to confirm the data protection claims with respect to Article 12.1(c) (i) or (ii) of Council Directive 98/8/EC. 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.

Active substance propiconazole (CGA 64250)

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

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
2.8/03	Kreuzer A., Report on chemical composition (nitrosamines) Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 30011, 15.02.1995 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG CONFIDENTIAL INFORMATION	yes	No Y
2.8/04	Friedrich K., Determination of 2,3,7,8 - TCDD and 2,3,7,8 - TCDF in CGA 64250, Syngenta Crop Protection AG, Basle Project Report, 09.10.1987 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG CONFIDENTIAL INFORMATION	no	No Y
2.8/05	Burkhard N., Analytical certificates of technical propiconazole used for the determination of physico-chemical properties Syngenta Crop Protection AG, Basle, 20.02.1995 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG CONFIDENTIAL INFORMATION	yes	no Y
2.8/06	Maier W., Purity of test material used in toxicity tests Syngenta Crop Protection AG, Basle, 12.01.1995 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG CONFIDENTIAL INFORMATION	no	no Y
3.1.1	Geoffroy A., Report on freezing temperature, Syngenta Crop Protection AG, Basle, Rep N° PP-94/37P.MPR, 29.09.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.1.2	Das R., Report on boiling point/boiling range, Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep N° 16313, 08.11.1993 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
3.1.3	Das R., Report on density, Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep N° 16314, 08.11.1993 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.2.1/01	Rordorf B.F., Report on vapor pressure curve, Syngenta Crop Protection AG, Basle, Rep.N° AG-88-02P, 15.06.1988 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.2.1/02	Burkhard N., Henry's Law Constant, Syngenta Crop Protection AG, Basle, Data Sheet, 12.09.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	no	No Y
3.3/01	Das R., Report on general physico-chemical properties (pure active ingredient), Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep N° 20751, 22.03.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.3/02	Das R., Report on general physico-chemical properties (technical grade active ingredient), Ciba-Geigy Muenchwilen AG, Muenchwilen Rep N° 16311, 08.11.1993 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.4	Käser W., Report on spectra, Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep.N° 28042, 20.12.1994, Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	no Y
3.5	Jäkel K., Report on water solubility, Syngenta Crop Protection AG, Basle, Rep.N° AG-87-22P, 19.11.1987 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
3.6/01	Jäkel K., Report on dissociation constant in water, Syngenta Crop Protection AG, Basle, Rep.N° EA-133549, 08.08.1990 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.6/02	Stulz J., Propiconazole - Dissociation constant, Ciba-Geigy Muenchwilen AG, Muenchwilen, Statement, 26.10.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG		No Y
3.7	Stulz J., Report on solubility in organic solvents, Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep N° 20752, 15.03.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	no Y
3.9	Jäkel K., Report on partition coefficient, Syngenta Crop Protection AG, Basle, Rep.N° AG-87-22P, 20.11.1987 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.10	Schürch H., Report on thermal stability and stability in air, Syngenta Crop Protection AG, Basle, Rep N° 20753, 18.04.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.11	Schürch H., Report on auto-flammability of liquids, Syngenta Crop Protection AG, Basle, Rep N° PP-94/10T.AFG, 18.04.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y
3.12	Schürch H., Report on determination of flash-point, Syngenta Crop Protection AG, Basle, Rep. N° PP-94/10T.FLP, 18.04.1994 Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	yes	No Y

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

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

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
4.2 / 06	Formica, G., 1992. CGA 64250, Determination of free 1,2,4-triazole by high performance liquid chromatography, soil, Syngenta Crop Protection AG., Basel, Rep.No. REM-130-04, 09.04.1992 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	no	No Y
4.2 / 08	Tribolet, R., 2001. Determination of Metabolite CGA 118245 by LC-LC-MS/MS Syngenta Crop Protection AG, Basel, Switzerland REM 130.10, 23.10.2001 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	yes	No Y
4.2 / 09	Formica, G.; 1986. CGA 64250, Determination of residues of parent compound by gas liquid chromatography, potable water, Syngenta Crop Protection AG., Basel, Rep.No. REM-10-86, 30.07.1986 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	no	No Y
4.2 /10B	Pointurier R. – Duchêne P., 2000, Propiconazole in Drinking and Surface Water Validation of Method REM 10/86 with GC/MS, 28.12.2000 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	yes	No Yes
4.2 / 11	Tribolet, R., 1992, Sampling of air and determination of residues of parent compound by high performance liquid chromatography incl. validation, Syngenta Crop Protection AG., Basel, Rep. Nr. REM-130-07, 14.12.1992 Owned by: Syngenta Crop Protection AG. Submitted by: Syngenta Crop Protection AG.	yes	No Y
4.2 /11B	Pointurier R. – Duchêne P., 2000, Propiconazole in Air : Development of a Confirmatory Technique with GC/MS 28.12.2000 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	yes	No Yes

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
4.2 /17A	Vargo J.D., 1997, Analytical Method for the determination of Propiconazole (CGA-64250) and its Degradates CGA21795, CGA91305, CGA118244, CGA118245, CGA136735 and CGA71019 in soil and Water by high performance liquid chromatography with mass spectrometric detection including method validation data. 30.10.1997 Owned by : Syngenta Crop Protection AG.	yes	No Yes
4.2 /17B	Cassidy S.L., 2004, Independent Laboratory Validation - Syngenta Residue Analytical Method No. AG-677 and Modified Method AG-677 for Water, with a 0.02 ppb Limit of Quantitation - "Analytical Method for the Determination of Propiconazole (CGA-64250) and its Degradates CGA-217495, CGA-91305, CGA-118244, CGA-118245, CGA-136735, and CGA-71019 in Soil and Water by High Performance Liquid Chromatography with Mass Spectrometric Detection Including Method Validation Data" 4.5.2004 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	yes	No Yes
4.2/18	Vargo J.D., 1994, Analytical Method for the determination of propiconazole (CGA-64250) and its metabolites CGA-217495, CGA-91305, and CGA-136735 in water and sediment by high performance liquid chromatography with mass spectrometric and ultraviolet absorbance detection including validation data. 20.12.1994 Owned by : Syngenta Crop Protection AG. Submitted by : Syngenta Crop Protection AG.	yes	No Yes
6.1.1 / 01	[redacted] (1978a), Acute oral LD_{50} in the rat of technical CGA 64250, [redacted] 07.12.1978 [redacted]	no	No Y

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6.1.1 / 02	[redacted] (1979), Acute oral LD_{50} in the mouse of technical CGA 64250, [redacted] 07.05.1979 [redacted]	no	No Y
6.1.2 / 01	[redacted] (1978b), Acute dermal LD_{50} in the rat of technical CGA 64250, [redacted] 22.01.1979 [redacted]	no	No Y
6.1.2 / 02	[redacted] (1979a), Acute dermal LD_{50} 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

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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

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6.2 / 03	[redacted] (1992), Biliary excretion, absorption, and distribution kinetics of [U-^{14}C]phenyl CGA 64250 in the rat after oral administration., [redacted], 14.01.1992 [redacted]	yes	No Y
6.2 / 04	[redacted] (1983), Dermal absorption of triazole ^{14}C-CGA 64250 by rats., [redacted], 11.05.1983 [redacted]	no	No Y
6.2 / 05	[redacted] (1986), Dermal absorptiopn of ^{14}C-propiconazole in rats after a ten hour exposure period., [redacted] 08.04.1986 [redacted]	no	No Y
6.2 / 06	[redacted] (1986), The metabolism of [U-^{14}C]-phenyl-CGA 64250 in mice after pretreatment with unlabelled CGA 64250., [redacted] 20.05.1986 [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

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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-^{14}C]-Propiconazole in a lactating goat, [redacted] 29.07.1980 [redacted]	no	No Y
6.2 / 12	[redacted] (1980) Balance and metabolism of triazole-^{14}C-CGA 64250 in a lactating goat, [redacted] 18.09.1980 [redacted]	no	No Y

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6.2 / 13	[redacted] (1981) Characterization of metabolites in urine, milk and liver of a goat treated with triazole-^{14}C-CGA 64250, [redacted] 27.03.1981 [redacted]	no	No Y
6.2 / 14	[redacted] (1989) Biological report for the metabolism of Phenyl-^{14}C-Propiconazole in a lactating goat, [redacted] 30.11.1989 [redacted]	no	No Y
6.2 / 15	[redacted] (1990a) Metabolism of phenyl ^{14}C-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 ^{14}C-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

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6.2 / 18	[redacted] (1990) Biological report for the metabolism of ^{14}C-Propiconazole in laying hens, [redacted] 05.01.1990 [redacted]	yes	No Y
6.2 / 19	[redacted] (1990b) Metabolism of [phenyl ^{14}C]-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

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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

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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

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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

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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

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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] 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

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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	Dr. med. B. Jaquet (1991) Industrial Health Record CGA 64'250 Propiconazole, Medical Surveillance, Monthey, Switzerland, October 1991 Owned by Syngenta Crop Protection AG. Basle, Switzerland Submitted by Syngenta Crop Protection AG. Basle, Switzerland	not applic.	No Y
6.12.1/02	Maier, W-M.. Medical Data Ciba-Geigy Ltd., Basel, Switzerland 16.10.1995 Owned by Syngenta Crop Protection AG. Basle, Switzerland Submitted by Syngenta Crop Protection AG. Basle, Switzerland	Not applicable	No Y
6.12.1/03	Schulze-Rosario C., Hertner T. 2000. Medical Data - Overview/summary data of: 1) Medical surveilance on manufacturing plant personnel 2) Direct observations, e.g. clinical cases and poisoning incidents 3) Diagnosis of poisoning First aid measures 14.09.2000 Owned by Syngenta Crop Protection AG. Basle, Switzerland Submitted by Syngenta Crop Protection AG. Basle, Switzerland	No	No Y

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

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7.1.1.2.1	Bader, U. 1990. Report on the test for ready biodegradability in the modified Sturm test of CGA 64250. CIBA-GEIGY LTD., Basle, Test No.: 901111. 24/04/90. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.1.2.2.1	Keller, A. 1983 b. Degradation of Propiconazole (TILT) in aquatic systems. Ciba-Geigy Ltd., Basle, Project Report 03/83, March, 30.1983. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.1.2.2.2/03	Das, Y.T. 1987. Anaerobic aquatic soil metabolism of CGA-64250 (Propiconazole). Biospherics Incorporated, 4928 Wyaconda Road, Rockville, Maryland 20852; Biospherics 85E468AM-Anaerobic; June 12, 1987. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.1.2.2.2/04	Das, Y.T. 1992. Metabolism of (Phenyl(U)-^{14}C)Propiconazole under anaerobic aquatic soil conditions. Innovative Scientific Services, Inc. (ISSI), 515 Blue Ridge Avenue, Piscataway, N.J. 08854. ISSI-No. 90072, CIBA-GEIGY Protocol Number 87-90. July 20, 1992. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.1.2.2.2/05	Reischmann, F.J. 1999. Metabolism of 14C-triazole labelled CGA 64250 in two aerobic aquatic systems under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland Study Report No. 98RF03, 02.11.1999 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Y	No Y
7.2.1/01	Keller, A. 1980. Degradation of CGA 64250 (TILT) in Soil under aerobic, aerobic/anaerobic and sterile/aerobic conditions. Ciba-Geigy Ltd., Basle, Project Report 22/80, 24. 06.1980. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y

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7.2.1/02	Keller, A. 1982 b. Degradation of CGA 64250 (Tilt) in aerobic soil. Isolation and identification of the major, polar soil metabolite. Ciba-Geigy Ltd., Basle, Project Report 45/82, addendum to Project Report 08/82, 15.09.1982. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.1/03	Keller, A. 1982 a. Degradation of ^{14}C-dioxalane- and ^{14}C-phenyl-ring labelled CGA 64250 (Tilt) in aerobic soil. Ciba-Geigy Ltd., Basle, Project Report 08/82, 08. 04.1982. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.1/04	Keller, A. 1981 b. Distribution and Degradation of CGA 64250 (TILT) in a field soil. Ciba-Geigy Ltd., Basle, Project Report 10/81, 24.03.1981. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.2.1	Timme, G. and Frehse, H. 1980. Zur statistischen Interpretation und graphischen Darstellung des Abbauverhaltens von Pflanzenbehandlungsmitteln I. Pflanzenschutz-Nachrichten Bayer 33/1980,1, p. 47 - 60. Submitted by: Syngenta Crop Protection AG	No	Yes N
7.2.2.1	Timme, G., Frehse, H. and Laska, V. (1986). Zur statistischen Interpretation und graphischen Darstellung des Abbauverhaltens von Pflanzenbehandlungsmitteln II. Pflanzenschutz-Nachrichten Bayer 39/1986,2, p. 188 - 204 Submitted by: Syngenta Crop Protection AG.	No	Yes N
7.2.2.1/03	Müller-Kallert, H.-M. 1992. Degradation of ^{14}C-CGA 64250 in one soil incubated under various experimental conditions. RCC Project 255971; RCC Umweltchemie AG, CH-4452 Itingen/BL.; 22.04.1992. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y

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7.2.2.1/05	Keller, A. 1981 a. Verhalten der Pflanzenschutzmittel im Boden: CGA 64250. Ciba-Geigy Ltd., Basle, Project Report 04/81, 19.02.1981. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.2.1/08	Adam, D. 2001. Metabolism of 14C-triazolering labelled CGA 64250 under aerobic and aerobic/anaerobic laboratory conditions in one soil at 20 °C. Report 00DA06. Syngenta Crop Protection AG, Basel, CH. 4.04.2001 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Y	No Y
7.2.2.1/09	Adam, D. 2000. Rate of degradation of C-triazole labelled CGA 118 245 in various soil under aerobic conditions at °20 C.Report 00DA04. Novartis Crop Protection AG, Basel, CH. 26.09.2000 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Y	No Y
7.2.2.1/10	Slangen, P.J. 2000. Degradation of 1,2,4-triazole in three soils under aerobic conditions .Notox Project 278336, 26.05.2000 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Y	No Y
7.2.2.2/07	Büttler, B. 1982 a. CGA 64250: Dissipation and leaching of TILT EC 250 under field conditions (St. Aubin). Ciba-Geigy Ltd., Basle, Project Report 20/82, May 27, 1982. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.2.2/08	Büttler, B. 1982 b. CGA 64250: Dissipation and leaching of TILT EC 250 under field conditions (Les Barges). Ciba-Geigy Ltd., Basle, Project Report 22/82, May 28, 1982. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y

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7.2.2.2/09	Resseler, H. 1991 a. Field dissipation of Propiconazole. Test-report - field experiment. CGD Experiment No.: 32-89 B; corresponding RCC-project: 170515; CIBA-GEIGY GmbH, Liebigstraße 51-53, D-60323 Frankfurt/M.; January 21, 1991. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
	including:		
	Offizorz, P. 1990 a. Dissipation rate determination of Propiconazole - field soil. RCC Project 170515; RCC, In den Leppsteinwiesen 19, D-6101 Roßdorf. 03.12.1990. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.2.2/12	Resseler, H. 1991 d. Field dissipation of Propiconazole. Test-report - field experiment. CGD Experiment No.: 90-04 B; corresponding RCC-project: 214413; CIBA-GEIGY GmbH, Liebigstraße 51-53, D-60323 Frankfurt/M.; March 23, 1991. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
	including:		
	Offizorz, P. 1991 a. Dissipation rate determination of Propiconazole - field soil. RCC Project 214413; RCC, In den Leppsteinwiesen 19, D-6101 Roßdorf. 27.03.1991. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.2.2.2/14	Resseler, H. 1991 f. Field dissipation of Propiconazole. Test-report - field experiment. CGD Experiment No.: 57-90 B; corresponding RCC-project: 214457; CIBA-GEIGY GmbH, Liebigstraße 51-53, D-60323 Frankfurt/M.; April 2, 1991. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
	including:		
	Offizorz, P. 1991 c. Dissipation rate determination of Propiconazole - field soil. RCC Project 214457; RCC, In den Leppsteinwiesen 19, D-6101 Roßdorf. 27.03.1991. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y

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7.2.2.2	Tummon O.J. 2004. Determination of residues of propiconazole and free triazole in soil samples from Finland during 2003. 2.7.2004 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.3/01	Burkhard, N. 1980 c. Adsorption and desorption of CGA-64250 in various soil types. CIBA-GEIGY Ltd., Basle, Project Report 26/80; August 14, 1980. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.3/02	Saxena, A. M. 1988. The adsorption and desorption of ^{14}C-Propiconazole on representative agricultural soils. Halzleton Laboratories America Inc., 3301 Kinsman Boulevard, Madison, Wisconsin 53704; HLA 6117-140; July 27, 1988. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.2.3/03	Keller, A. 1983 a. Adsorption and Desorption of 1,2,4-Triazole in various soil types. Ciba-Geigy Ltd., Basle, Project Report 31/83, 05.10.1983. Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.2.3/04	Hawkins, D.R. 1988. Soil adsorption and desorption of 1,2,4-Triazole. Rohm and Haas Company, 727 Norriston Road, Spring House, PA, 19477; Nov. 03, 1988. Originated by: Rohm and Haas Co-owned by: Syngenta Crop Protection AG Company Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.2.3.1	Adam, D. 2000. Adsorption/Desorption of CGA 118245 in various soils. Novartis Crop Protection AG, Basel, Switzerland Study Report No. 99DA09, 11.05.2000 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
-	Rainbird, P. 2007. Propiconazole. A Leaching Assessment for Parent and Soil Metabolite CGA 71019 using the FOCUS-PEARL 3.3.3 Groundwater Scenarios Following Application as a Wood Preservative. Modeling study. Report Series RAJ0541B. Syngenta Research Center UK. 26.04.2007		
7.3.1	Stamm, E. 1994. Rate estimation of the hydroxyl radical oxidation of propiconazole CGA 64250, 31.05.1994 Submitted by: Syngenta Crop Protection AG	No	Yes N
7.4.1.1/09	1999. Acute toxicity test of CGA 64250 techn. to Rainbow Trout (Oncorhynchus mykiss) under static conditions 09.08.1999	Yes	No Y
7.4.1.2 / 05	LeBlanc, G.A. and Mastone, J.D. 1981a. Acute toxicity of CGA-64250 to crayfish (Procambarus sp.), EG&G, Bionomics, Aquatic Toxicology Laboratory, Wareham, Massachusetts, US, Rep. N° BW-81-10-1035, 10.1981 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.4.1.2. /07	Grade, R. 1999. Acute toxicity test of CGA 64250 techn. to the Cladoceran Daphnia magna Straus in the static system Syngenta Crop Protection AG, Basel, Switzerland Study Report No. 983985, 21.07.1999 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	yes	No Y
7.4.1.3/08	Thun, S. 1993c. Algae growth inhibition test, Test Article: "Desmel A 6097 G", IBR Forschungs GmbH, Bioanalytisches Zentrum, Hannover, FRG, Rep. N° 80-91-2310-01-93, 07.06.1993 Owned by: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited	yes	No Y

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
7.4.1.3/09	Grade R., 1999, Growth inhibition test of CGA 64250 EC 250 (A-6097 K) to green algae (Selenastrum capricornutum) under static conditions Novartis Crop Protection AG, Basel, Switzerland 983998, 26.11.1999 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	yes	No Y
7.4.1.4 / 01	Bader, U. 1990. Report on the test for inhibitory concentration on aerobic bacteria CGA 64250, Syngenta Crop Protection AG, Basel, CH, Rep. N° 901112, 28.03.1990 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.4.1.4 / 02	Spare, W.C. 1980. CGA-64250 activated sludge metabolism, Biospherics Incorporated, Rep. N° 80PL-98-SL, 22.08.1980 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.4.3.2 / 01	[redacted]1987. The toxicity of CGA-64250 (Propiconazole) to fathead minnow (Pimephales promelas) embryos and larvae, [redacted] 10.11.1987 [redacted]	Yes	No Y
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

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
7.4.3.3.1 / 03	[redacted] (2000). Accumulation and Elimination of [Triazole-(U)-^{14}C] CGA64250 by Bluegill Sunfish (*Lepomis macrochirus*) in a Flow-Through System. [redacted]	Yes	No Y
7.4.3.4 / 01	LeBlanc, G.A. and Mastone, J.D. 1981b. The chronic toxicitity of CGA-64250 to the water flea (Daphnia magna), EG&G, Bionomics, Aquatic Toxicology Laboratory, Wareham, Massachusetts, US, Rep. N° BW-81-11-1043, 11.1981 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.4.3.5.1	Grade, R. 1999. Toxicity test of CGA 64250 tech. on sediment-dwelling Chironomus riparius under static conditions Syngenta Crop Protection AG, Basel, Switzerland Study Report No. 983985, 07.05.1999 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	yes	No Y
7.5.1.1 / 05	Völkel, W. 2000. The effects of CGA 71019 on soil respiration and nitrification. Novartis Crop Protection Study Number: 2003502, 16.05.2000 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection A	Yes	No Y
7.5.1.1/06	Lang, B. 1993b. Effects on the activity of soil microflora according to BBA Guideline VI, 1-1 (1990) - Desmel / A 6097 G, BioChem GmbH, Labor Cunnersdorf, Cunnersdorf, FRG, Rep. N° 931049003, 30.04.1993 Owned by: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited	Yes	No Y
7.5.1.2 / 02	Lang, B. 1993. Acute toxicity earthworm test - Eisenia foetida: Desmel/A 6097 G, BioChem GmbH, Labor Cunnersdorf, Cunnersdorf, FRG, Rep. N° 931049004, 30.04.1993 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
7.5.1.2 / 03	Heimbach, F. 1986. Acute toxicity of 1,2,4-triazole (technical) to earthworms, Bayer AG, Leverkusen, FRG, Rep. N° HBF/rg 59, 24.02.1986 Originated by: Bayer AG Co-owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.5.1.2 / 04	Bätscher, R. 2000. Acute toxicity of CGA 118245 (metabolite of CGA 64250) to the earthworm (Eisenia foetida) in a 14 day test RCC AG, Itingen, Switzerland Study Report No. 747088, 13.04.2000 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.5.1.2 / 05	Nienstedt, K.M. 1999. A 14-day acute toxicity test with the Earthworm (Eisenia fetida) Springborn Lab., Horn, Switzerland Study Report No. 1047.070.630, 09.12.1999 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.5.1.3/01	Ruess, W. 1987. Effect of CGA-64250 (propiconazole) against various crops and weeds, Syngenta Crop Protection AG, Basel, CH, 26.05.1987 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	No	No Y
7.5.1.3/02	Maggio, R.M.,Tier 2 seedling emergence nontarget phytotoxicity study using propiconazole Pan-Agricultural Labs. Inc, Madera, United States LR90-420, 04.10.1990 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.5.1.3/03	Maggio, R.M., Tier 2 vegetative vigor nontarget phytotoxicity study using propiconazole Pan-Agricultural Labs. Inc, Madera, United States LR90-418, 04.10.1990 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y

Annex point / reference number Doc IIIA	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	GLP GEP	Published (Yes/No) Data Protection Claimed (Y/N)
7.5.2.1/ 01	Nienstedt, K.M. 1999. A chronic Toxicity and reproduction test exposing the Earthworm Eisenia fetida to CGA 64250 EC 250 (A-6097 K) in OECD artificial soil Springborn Lab., Horn, Switzerland Study Report No. 1047.071.630, 07.12.1999 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
7.5.2.1 / 03	Friedrich, S. 2003. Propiconazole (CGA64250): Sublethal toxicity of a 155.87 g/L EC formulation (A6780D) to the earthworm Eisenia fetida BioChem agrar, Gerichshain, Germany 03 10 48 087, 05.11.2003 Owned by: Syngenta Crop Protection AG Submitted by: Syngenta Crop Protection AG	Yes	No Y
8.3	Käser W., CGA 64250 - Statement on emergency measures in case of an accident, Ciba-Geigy Muenchwilen AG, Muenchwilen, Statement, 18.01.1995, Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	no	No N
8.4	Käser W., CGA 64250 - Statement on procedures for destruction or decontamination, Ciba-Geigy Muenchwilen AG, Muenchwilen, Statement, 18.01.1995, Owned by : Syngenta Crop Protection AG Submitted by : Syngenta Crop Protection AG	no	No N

Biocidal product Wocosen 100 SL

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
B2.2/01	Kempen, T.	2003	- Product Composition Report for WOCOSEN 100 SL - Janssen Pharmaceutica N.V. - Report No. PCR-03-02 (160703) - Not GLP, Unpublished	Y	Janssen
B2.2/02	Not specified	2004	- Safety Data Sheet WOCOSEN Technical - Janssen Pharmaceutica N.V.Report No.: not applicable - GLP: not applicable Unpublished	N	Janssen
B2.2/03	Not specified	2000	- Safety Data Sheet ALKAMULS BR - Rhodia Geronazzo S.p.A. Report No.: not applicable - GLP: not applicable Unpublished	N	Rhodia
B2.2/04	Not specified	1999	- Safety Data Sheet DOWANOL DPM - Dow Europe SA Report No.: not applicable - GLP: not applicable Unpublished	N	Dow
B2.2/05	Not specified	2003	- Safety Data Sheet WOCOSEN 100 SL - Janssen Pharmaceutica N.V. Report No.: not applicable - GLP: not applicable Unpublished	N	Janssen
B3.1	Ligtvoet, Th.	1993	- Physical and Chemical Properties of Wocosen 100 SL - Janssen Pharmaceutica N.V. Report No. 69 - GLP, Unpublished	Y (Exist./First)	Janssen
B3.5	Verbeeck, G.	1999	- Determination of the pH of the aqueous dilution (1 % and 10 % v/v in tap water) of Wocosen 100	Y	Janssen

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			SL - Janssen Pharmaceutica N.V. Report No. 99067 - Not GLP, Unpublished		
B3.6	Not specified	1996	- Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter - American Society for Testing and Materials D4052-96 - Not GLP, Published	N	ASTM
B3.7	Paris, E.	2000	- Storage stability study of WOCOSEN 100 SL (Janssen Formula DA049362, code 054494) in high density polyethylene - Janssen Pharmaceutica N.V. Report No. AGR 118 - GLP, Unpublished	Y (Exist./First)	Janssen
B3.10.1	Verbeeck, G.	2004	- Surface tension of Wocosen 100 SL - Janssen Pharmaceutica N.V. Report No. 04103 TS - Not GLP, Unpublished	Y	Janssen
B3.10.2	Dobrat, W.	1995	- CIPAC Handbook Volume F Physico-chemical methods for Technical and Formulated Pesticides p 75-84: Viscosity - CIPAC Report no.: not applicable - Not GLP	N	CIPAC
B4.1/01	Nuyts, M.	1991	- Liquid chromatographic methods for the quantitave determination of propiconazole (R49362) in the Wocosen 100 SL-formulation and its dilutions. - Janssen Pharmaceutica N.V. Report No. 47 - Not GLP, Unpublished	Y	Janssen
B4.1/02	Nuyts, M.	1994	- Liquid chromatographic methods for the quantitave determination	Y	Janssen

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			of cypermethrine and / or propiconazole in aqueous dilutions of propiconazole based formulations. - Janssen Pharmaceutica N.V. Report No. AGR70 - GLP, Unpublished CONFIDENTIAL INFORMATION		
B4.1/03	Stockis, A.	1996	- Development and validation of a gas chromatographic assay method of propiconazole in Wocosen 100 SL - Report No.: Lab Simon, 796.516/1 - GLP, Unpublished	Y	Janssen
B5.10.1	Van der Flaas M., Willems W., De Witte	2003	- Efficacy of Wocosen 100 SL against moulds and sapstain fungi in a mini-board test. - Report No.: MB/08/2003 - GLP: not applicable, Unpublished	Y	Janssen
B5.10.2	Not specified	1993	- Fungicidal efficacy studies (submission registration file UK) - Janssen Pharmaceutica N.V. Report No. : not specified - Not GLP, Unpublished	Y	Janssen
B5.10.3	Leclerq A.	1989	- Seuils d'efficacité fongicide Wocosen 100SL-C, EN113, EN113+EN84 et EN113 +EN73 - Station de Technologie Forestière de l'Etat, Gembloux, Belgique - Report No.: not specified - Not GLP	Y	Janssen
B5.10.4	Van der Flaas M., Willems W., De Witte L., Van Gestel J.	1995	- Efficacy against blue stain in service of Wocosen 100SL. - Janssen Pharmaceutica N.V. - Report No. BS/04/95 - Not GLP	Y	Janssen
B5.10.5	Graf, E.	1993	- Determination of the Fungicide Efficacy Against the Dry Rot Fungus (Serpula Lacrimans) in Masonry.	Y	Janssen

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			- Swiss Federal laborotories for Materials Testing and Research, EMPA - Report No. :117'628 - GLP, Unpublished		
B6.1.1	[redacted]	1995	- The acute oral toxicity of Wocosen 100 SL[redacted], a formulation containing propiconazole (R49362; 100 g/l) and [redacted]) in rats - [redacted] Report No. R49362/6 - GLP, Unpublished	Y (Exist./First)	[redacted]
B6.1.2	[redacted]	1992	- The acute dermal toxicity in Albino rabbits - [redacted] Report No. 2816 - GLP, Unpublished	Y (Exist./First)	[redacted]
B6.1.3	[redacted]	1992	- Acute inhlation toxicity study for Wocosen 100 SL[redacted] in rats - [redacted] Report No. OEFZS-A--2437 - GLP, Unpublished	Y (Exist./First)	[redacted]
B6.2.1	[redacted]	1992	- Primary dermal irritation study in Albino rabbits - [redacted] Report No. 2814 - GLP, Unpublished	Y (Exist./First)	[redacted]
B6.2.2	[redacted]	1992	- Primary eye irritation study in Albino rabbits - [redacted]	Y (Ex-	[redacted]

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Report No. 2815 - GLP, Unpublished	ist./First)	
B6.3	[redacted]	1994	- Skin sensitisation study with "WOCOSEN 100 SL" (Bühler Test) [redacted] - [redacted] Report No. OEFZS-A--3154 - GLP, Unpublished	Y (Exist./First)	[redacted]
B7.1/01a	Morsing, N. and Lindegaard, B.	2003	- Development of a method for characterising: Leaching of Active Ingredients from Preservative-Treated Timber Stage 1: Field Testing - Danish Toxicological Institute - DTI project no. 1029576-01 - Not GLP, Unpublished	Y	DTI
B7.1/01b	Morsing, N. and Lindegaard, B.	2003	- Leaching of Active Ingredients from Preservative Treated Timber Ongoing Research: Status after approx. 4 months' Outdoor exposure - Danish Toxicological Institute - 183758_IRG paper - Not GLP, Unpublished	Y	DTI
B7.1/02	Not specified	1993	- A study of the leaching characteristics of British Columbia Hemfir treated with the antisapstain formulation B49362.50 SL - B.C. Research Incorporated - Janssen Pharmaceutica Project No. 2-51-626 - Not GLP, Unpublished	Y	Janssen
B9.4/01	Not specified	1997	- Technische fiche 10 L stapelbare jerrycan	N	Polimo on

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			- Polimoon N.V. Report No. not applicable - Not GLP, Unpublished		N.V.
B9.4/02	Blümel, P. and Skutnik, M.	1993	- Zulassungsschein 10-Liter Kanister - Bundesanstalt für Materialforschung- und Prüfung Report No. : 9539/3H1 - Not GLP	N	BAM

Biocidal product Wocosen 12 OL

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
B2.2/01	Kempen, T.	2003	- Product Composition Report for WOCOSEN 12 OL - Janssen Pharmaceutica N.V. Report No. PCR-03-08 (270803) - Not GLP, Unpublished	Y	Janssen
B2.2/02	Not specified	2002	- Safety Data Sheet WOCOSEN Technical - Janssen Pharmaceutica N.V. Report No.: not applicable - GLP: not applicable Unpublished	N	Janssen
B2.2/03	Not specified	1998	- Safety Data Sheet PERMETHRIN 25/75 - Hoechst Schering AgrEvo S.A. Report No.: not applicable - GLP: not applicable Unpublished	N	AgrEvo
B2.2/04	Not specified	2002	- Safety Data Sheet NECIRÈS EPX-L5 - Nevcin Polymers B.V. Report No.: not applicable - GLP: not applicable Unpublished	N	Nevcin
B2.2/05	Not specified	2002	- Safety Data Sheet SHELLSOL H	N	Caldic

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			- Caldic Belgium n.v. Report No.: not applicable - GLP: not applicable Unpublished		
B2.2/06	Not specified	2004	- Safety Data Sheet WOCOSEN 12 OL - Janssen Pharmaceutica N.V. Report No.: not applicable - GLP: not applicable Unpublished	N	Janssen
B3.1	Ligtvoet, Th.	1991	- Physico-chemische parameters van Wocosen 12 OL - Janssen Pharmaceutica N.V. Report No.: Agroform note 91084 - Not GLP, Unpublished	Y	Janssen
B3.7/01	Verbeeck, G.	2004	- Accelerated storage stability of a R049362 10 g/l a.i. OL formulation: WOCOSEN 12 OL - Janssen Pharmaceutica N.V. Report No. 04127 TS - Not GLP, Unpublished	Y	Janssen
B3.7/02	Verbeeck, G.	2004	- Low temperature stability of a WOCOSEN tech 10 g/l a.i. OL formulation: WOCOSEN 12 OL - Janssen Pharmaceutica N.V. Report No. 04138 TS - Not GLP, Unpublished	Y	Janssen
B3.10.1	Verbeeck, G.	2004	- Surface tension of Wocosen 12 OL - Janssen Pharmaceutica N.V. Report No. 04104 TS - Not GLP, Unpublished	Y	Janssen
B5.10.2	Not specified	1993	- Fungicidal efficacy studies	Y	Janssen

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			(submission registration file UK) - Janssen Pharmaceutica N.V. Report No. : not specified - Not GLP, Unpublished		
B5.10.3	Leclerq A.	1989	- Seuils d'efficacité fongicide Wocosen 100SL.., EN113, EN113+EN84 et EN113 +EN73 - Station de Technologie Forestière de l'Etat, Gembloux, Belgique - Report No.: not specified - Not GLP	Y	Janssen
B5.10.4	Van der Flaas M., Willems W., De Witte L., Van Gestel J.	1995	- Efficacy against blue stain in service of Wocosen 100SL. - Janssen Pharmaceutica N.V. - Report No. BS/04/95 - Not GLP	Y	Janssen
B6.1.1	[redacted]	1988	- The acute oral toxicity of R49362-12OL, containing 12 g/l propiconazole (R49362) and 4 g/l permethrin 25:75 - [redacted] Report No. R49362-12OL/1 - Not GLP, Unpublished	Y	[redacted]
B6.1.2	[redacted]	1989	- The acute dermal toxicity study in rabbits - [redacted] Report No. 2147 - GLP, Unpublished	Y (Exist./First)	[redacted]
B6.1.3	[redacted]	1990	- 4-hour, acute inhalation toxicity	Y	[redacted]

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			study (limit test) with Wocosen 12 OL in rats [redacted] - [redacted] Report No. 279077 - GLP, Unpublished	(Exist./First)	
B6.2.1	[redacted]	1989	- Primary dermal irritation study in rabbits - [redacted] Report No. 2135 - GLP, Unpublished	Y (Exist./First)	[redacted]
B6.2.2	[redacted]	1989	- Primary eye irritation study in rabbits - [redacted] Report No. 2134 - GLP, Unpublished	Y (Exist./First)	[redacted]
B6.3	[redacted]	1998	- Dermal Sensitisation Test - Buehler Method [redacted] - [redacted] Report No. 6382 - GLP, Unpublished	Y (Exist./First)	[redacted]
B7.1/01a	Morsing, N. and Lindegaard, B.	2003	- Development of a method for characterising: Leaching of Active Ingredients from Preservative-Treated Timber Stage 1: Field Testing - Danish Toxicological Institute - DTI project no. 1029576-01	Y	DTI

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			- Not GLP, Unpublished		
B7.1/01b	Morsing, N. and Lindegaard, B.	2003	- Leaching of Active Ingredients from Preservative Treated Timber Ongoing Research: Status after approx. 4 months' Outdoor exposure - Danish Toxicological Institute - 183758_IRG paper - Not GLP, Unpublished	Y	DTI
B7.1/02	Not specified	1993	- A study of the leaching characteristics of British Columbia Hemfir treated with the antisapstain formulation R49362 50 SL - B.C. Research Incorporated - Janssen Pharmaceutica Project No. 2-51-626 - Not GLP, Unpublished	Y	Janssen
B9.4/01	Not specified	1997	- Technische fiche 10 L stapelbare jerrycan - Polimoon N.V. Report No. not applicable - Not GLP, Unpublished	N	Polimoon N.V.
B9.4/02	Blümel, P. and Skutnik, M.	1993	- Zulassungsschein 10-Liter Kanister - Bundesanstalt für Materialforschung- und Prüfung Report No. : 9539/3H1 - Not GLP	N	BAM