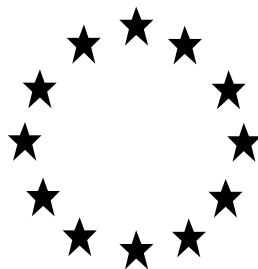


Directive 98/8/EC concerning the placing of biocidal products on the market

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

Assessment Report



Tebuconazole
Product-type PT 8
Wood Preservative

29 November 2007

Annex I - Denmark

Tebuconazole (PT8)**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	4
1.1. Procedure followed.....	4
1.2. Purpose of the assessment report.....	5
1.3. Overall conclusion in the context of Directive 98/8/EC	5
2. OVERALL SUMMARY AND CONCLUSIONS	6
2.1. Presentation of the Active Substance	6
2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis.....	6
2.1.1.1. Identity	6
2.1.1.2. Physical and chemical properties	6
2.1.1.3. Analytical methods.....	7
2.1.2. Intended Uses and Efficacy	7
2.1.3. Classification and Labelling	8
2.2. Summary of the Risk Assessment.....	8
2.2.1. Human Health Risk Assessment.....	8
2.2.1.1. Hazard identification	8
2.2.1.2. Effects assessment.....	8
2.2.1.3. Exposure assessment.....	10
2.2.1.4. Risk characterisation	11
2.2.2. Environmental Risk Assessment.....	11
2.2.2.1. Fate and distribution in the environment.....	11
2.2.2.2. Effects assessment.....	12
2.2.2.3. PBT assessment.....	13
2.2.2.4. Exposure assessment.....	13
2.2.2.5. Risk characterisation	18
2.2.3. List of endpoints	19
3. DECISION.....	20
3.1. Background to the Decision.....	20

3.2. Decision regarding Inclusion in Annex I	20
3.3. Elements to be taken into account by Member States when authorising products	21
Requirement for further information	22
3.4. Updating this Assessment Report	22
APPENDIX I: LIST OF ENDPOINTS	23
Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling	23
Chapter 2: Methods of Analysis	26
Chapter 3: Impact on Human Health	27
Chapter 4: Fate and Behaviour in the Environment	31
Chapter 5: Effects on Non-target Species	34
Chapter 6: Other End Points	36
APPENDIX II: LIST OF INTENDED USES	37
APPENDIX III: LIST OF STUDIES	38

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of tebuconazole 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 market¹, with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Tebuconazole (CAS no. 107534-96-3) was notified as an existing active substance, by LANXESS Deutschland GmbH, formerly part of Bayer Chemicals AG, hereafter referred to as the applicant, in product-type 8.

Commission Regulation (EC) No 2032/2003 of 4 November 2003² 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, Denmark 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 tebuconazole as an active substance in product-type 8 was 28 March 2004, in accordance with Annex V of Regulation (EC) No 2032/2003.

On 26 March 2004, the Danish competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 28 September 2004.

On 22 December 2005, 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 11 January 2006. The competent authority report included a recommendation for the inclusion of tebuconazole in Annex I to the Directive for product-type 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 7 February 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.

1 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of 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 tebuconazole 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 tebuconazole 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 tebuconazole. 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 website³, 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 tebuconazole for the product-type 8, which will fulfil the requirements laid down in Article 5 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.

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

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 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, Physico-Chemical Properties & Methods of Analysis

2.1.1.1. Identity

Tebuconazole, CAS No. 107534-96-3, is a fungicide produced by Bayer Corp., Agriculture Division site in Kansas City (USA).

Analysis of five technical grade batches which are representative of the current manufacturing process demonstrated a mean purity of 950 g/kg in compliance with LANXESS GmbH specifications. All impurities above the level of 1 g/kg have been fully identified and the corresponding methods of analysis have been developed. The main identification characteristics are given in the Confidential Annex document. The active substance must be technically equivalent to the specifications given. The evaluation has established that for the active substance notified by Bayer Chemicals AG/LANXESS Deutschland GmbH none of the manufacturing impurities are considered to be of potential concern.

2.1.1.2. Physical and chemical properties

Tebuconazole technical is a white to beige crystalline powder with a weak characteristic odour. The pure tebuconazole is a colourless powder with no characteristic odour- and a melting point of 105°C. Its density is 1.25 at 26°C.

The vapour pressure is found to be 1.7E-06 Pa at 20°C (extrapolated). The water solubility of tebuconazole technical is 0.029 g/l at 20°C and is independent of pH.

Tebuconazole is very soluble in organic solvents. Its octanol/water partition coefficient is 3.5 at 10°C, 20°C and 30°C.

The exothermal decomposition of the technical grade starts at 165°C where weight loss is observed by TGA, while DTA shows an exothermal reaction above 350°C. Tebuconazole is not highly flammable. It has no pyrophoric property, does not evolve any flammable gases in contact with water or humid air and has no self ignition at temperatures up to melting point (105°C). Tebuconazole is not explosive and not oxidizing.

The recommended container materials for tebuconazole are glass, C-4 clean phenolic coated steel, brass, stainless steel, aluminium, kraft paper and polyethylene. It should be noted that kraft paper is not used for the direct contact to tebuconazole, but it is used for the cardboard box (corrugated folding box). Tebuconazole is not compatible with plain tinplate and plain steel.

2.1.1.3. Analytical methods

The identification and quantification of tebuconazole as manufactured is performed using the capillary gas chromatography using flame ionisation detector. Methods of analysis for residues are gas chromatography or on gas chromatography using mass selective detection (GC-MSD).

The methods developed to analyse residues in soil and water with the respective limits of quantification of 10 µg/kg of soil and 0.05 µg/l of water. Residues in air were analysed with a GC_MSD method with a limit of quantification of 0.001 mg/m³ of air.

An analytical method for the determination of residues of tebuconazole in/on food or feedstuffs is not required because the active substance is not used in a manner that may cause contact with food or feedstuffs.

2.1.2. Intended Uses and Efficacy

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

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](#).

2.1.3. Classification and Labelling

Proposed classification/labelling for the active substance, tebuconazole, following evaluation

Classification/Labelling	as in Directive 67/548/EEC	
Class of danger	Xn	Harmful
	Repr. Cat. 3	
	N	Dangerous for the environment
R phrases	R 22:	Harmful is swallowed
	R 63:	Possible risk of harm to unborn child.
	R 51/53:	Toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.
S phrases	S 2:	Keep out of the reach of children.
	S 22:	Do not breathe dust.
	S 36/37:	Wear suitable protective clothing and gloves.
	S 61:	Avoid release to the environment. Refer to special instructions in safety data sheets.

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

Tebuconazole is of low acute toxicity by the oral, dermal and inhalative route. It is not irritating to skin and eyes and is not a skin sensitizer. In the short term studies the liver and adrenals was the target organ and in dog opacities of the lenses was seen as well. Tebuconazole is neither carcinogenic nor genotoxic. It is not toxic to reproduction but have embryotoxic and teratogenic effects.

2.2.1.2. Effects assessment

The **ADME**- studies show that oral administration of tebuconazole is followed by a rapid and extensive absorption in the rat. Thus no correction for incomplete oral absorption is necessary in the risk assessment. The substance is quickly distributed throughout the body tissues with the highest level found in the liver. The majority of the administered dose is excreted in the

faeces and enterohepatic circulation is expected. There are no indications of accumulation in any tissue. The metabolic study revealed sex differences for example in the excretion of the toxicologically relevant metabolite 1H-1,2,4-triazole amounting 5% in the urine of the male and 1.5% in that of the female. There are no toxicokinetic studies available in other animal species used in the toxicological studies, that is dogs, cats, mice, guinea pigs and rabbits nor studies using the dermal route of exposure.

In a dermal absorption study in the rat around 50% of the test substance was absorbed within 8 hours.

In **acute toxicity studies**, tebuconazole was found to be of rather low toxicity by the oral route and of low toxicity by inhalation and dermal application when the rat is used as the test species.

Tebuconazole has no potential for **skin or eye irritation** and is not **sensitising** to the skin in the Magnusson-Kligmann maximisation test or in the Buehler Patch test.

Several **short-term and long-term tests** were submitted and the dog was again found to be the most sensitive animal tested and the only species showing potential for opacities of the eye lenses. Other effects observed in both rats and dogs were minor effects in the liver in the form of slightly increased weights, enzyme induction and decreased plasma glyceride levels as well as vacuolisation of the *zona fasciculata* cells of the adrenals.

No evidence for **genotoxic** potential as no indication of gene mutations, chromosome anomalies or increases in DNA-repair activity were noted in an adequate battery of *in-vitro* and *in-vivo* assays with various endpoints including both prokaryotes and eukaryotes.

Two 21-months combined chronic toxicity/carcinogenicity studies were conducted in mice. At the highest dose, pronounced liver toxicity and an increased incidence of liver tumours were seen. This tumorigenic potential is not considered relevant to humans as it is only found in a sensitive mouse strain and at very high dose levels above the maximum tolerated dose.

In a two-year combined chronic toxicity/carcinogenicity study in rats there was no evidence for carcinogenicity with relevance to humans.

In the **developmental toxicity studies** foetotoxic effects were revealed in all three animal species tested. The developmental toxicity occurred at doses that are associated with some maternal toxicity, however, the toxicity to the dams could not in all cases be categorised in severity to a degree that would influence the development of the offspring via non-specific secondary mechanisms to effects such as malformations (e.g. peromelia in rabbits).

This conclusion of the evaluation is in agreement with the decision taken by the Specialised Experts-group at their meeting in December 2001. Here it was resolved that, according to the EU classification criteria, the evidence was not sufficient to place tebuconazole in Category Rep2, but tebuconazole should be regarded as a substance that causes concern for humans owing to possible developmental toxic effects and should therefore be allocated to Category Rep3 for developmental toxicity with the risk phrase R63: Possible risk of harm to the unborn child. The decision appears in Commission Directive 2004/73/EC of 29 April 2004 adapting to the technical progress for the twenty-ninth time Council Directive 67/548/EEC on the

approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

Impaired spatial cognitive learning was observed during development but no corresponding neuropathology could be found in a developmental neurotoxicity study in rats.

The AOEL was derived from the one-year study in dogs where unspecific effects like histopathological alterations in the adrenal cortex were found. The NOAEL for this effect was 3 mg/kg bw/day. An uncertainty factor of 100 will be applied to the NOAEL for these non-specific toxicological effects.

Therefore the values that will be used as basis for the risk characterisation is:

NOAEL = 3 mg/kg bw/day and AOEL = 0.03 mg/kg bw/day

2.2.1.3. Exposure assessment

The exposure to humans is estimated for the majority of the intended uses of wood preservatives containing tebuconazole. The tasks foreseen in primary exposure are for Industrial users: double-vacuum impregnation and vacuum-pressure impregnation, for Professional users: mechanical dipping, brush painting and manual spraying and for Non-professional users: only brush painting.

All the estimations of the primary exposure are based on the assumption that the content of tebuconazole in the products used for the application phase is maximum 0.6% w/w, while the concentration of a.i. in the products used for mixing and loading is maximum 6% w/w.

The potential exposure is calculated, where relevant, for both the use of a water-based and a solvent-based formulation. The differences seen between the estimated internal exposure from the two guide recipes originates in big differences observed in dermal penetration between a water-based and a solvent-based product (3.3% and 14.4% respectively).

The potential secondary exposure is addressed especially in the following scenarios: for adults sanding treated wood posts by the inhalation route, for infants chewing wood off-cut, children playing on playground structure outdoors and infants playing on weathered (playground) structure and mouthing (dermal and ingestion).

All calculations were performed according to the recommendations of the TNsG – Human Exposure to Biocidal Products (2002). In the model calculation, it is assumed that the 75th percentile from the measured data given in the TNsG represents a reasonable scenario for risk assessment purposes. To estimate dermal exposure, a clothing penetration of 11% and 50% was assumed for professionals and amateurs, respectively. The default value for body weight of an exposed person is assumed to be 60 kg.

The estimation of exposure of the personnel in an industrial vacuum pressure impregnation plant is based on measurement made at plants in the United Kingdom. However, it is shown that an almost identical value for the estimated internal exposure to the plant personnel could be calculated from a model developed by investigations of Danish wood impregnation plants. It

might thus be assumed that the working procedures – consisting of several tasks – in this kind of plants are similar within the European Community.

2.2.1.4. Risk characterisation

In **the risk characterisation procedure** the highest potential for primary human exposure was seen in individuals, which apply by brushing a solvent-based product that contains 0.6% w/w tebuconazole.

However, even for a realistic worst-case estimation (non-professionals, no gloves) the margin of safety is acceptable as MOE = 230 and the ratio: Exposure/AOEL= 0.43.

It is noted that this result is in compliance with the statement in Annex VI, No.73 of Dir. 98/8/EC that it should not a prerequisite for the potential exposure to non-professional users to be acceptable that they wear personal protective equipment during the application.

The highest potential for secondary exposure was both in the acute and the chronic exposure scenario calculated to be in infants (10 kg body weight). However even in the realistic worst case scenario where an infant is supposed to chew impregnated wood the MOE was estimated to be 150.

The risk assessment is in general based on the assumption that the products are used according to the conditions for normal use. It is furthermore assumed that the recommended personal protective equipment (PPE) will always be worn by industrial users but this assumption was not found to be a prerequisite for the exposure to be toxicologically acceptable.

A table of acceptable exposure scenarios is enclosed in Appendix 1 – Listing of endpoints.

2.2.2. *Environmental Risk Assessment*

2.2.2.1. Fate and distribution in the environment

Tebuconazole is stable to hydrolysis. Direct photodegradation of tebuconazole in water is low and the substance may be considered photolysis stable in both water and on soil. However, indirect photolysis of tebuconazole may occur in water.

Air will not be an environmental compartment of concern for tebuconazole used in wood preservatives because of the very low vapour pressure of this compound. It should however, be noted that the calculated DT50 of tebuconazole in air is more than 2 days.

Tebuconazole is not readily biodegradable and the biodegradation half life in surface water is estimated to about 198 days. However, tebuconazole will be adsorbed to the sediment and therefore a dissipation half-life in surface water is estimated to be 43 days based on a water/sediment study. Tebuconazole is not metabolised rapidly in soil in laboratory experiments, the half-life for primary degradation is greater than one year. In field studies the dissipation half lives are 77 days. An accumulation of Tebuconazole in soil is not anticipated when tebuconazole is used as a wood preservative.

Tebuconazole has a low mobility potential.

The bioaccumulation factor BCF for fish varies from 31 to 93. However, the higher value includes the metabolites as well. For the risk assessment, a BCF of 78 is used since this value seems to be the highest reliable value found.

1,2,4-Triazole is the primary metabolite from the degradation of tebuconazole (max 9%). The dissipation half-life of this metabolite in aerobic soil is estimated to be about 10 days.

2.2.2.2. Effects assessment

The toxicity to aquatic organisms is documented by acute and long-term studies. Long-term NOEC values are available for all three trophic levels in the aquatic compartment: The lowest NOEC from the 21-day daphnia study of 0.01 mg/l was taken as the basis for the PNEC derivation in water.

From the dose-related test on *Chironomus riparius* the NOEC (= EC₁₀) of 2.45 mg/l is used for the PNEC derivation in sediment. Calculation of a related concentration of tebuconazole in suspended sediment gave a NOEC of 54.5 mg a.s. /kg suspended sediment.

The toxicity to terrestrial organisms is documented by acute and long term studies. Test are available for test on earthworm reproduction, terrestrial micro-organisms and terrestrial plants. The 56 days NOEC of 5.7 mg a.i./kg dry weight soil from the earthworm reproduction test was taken as the basis for the terrestrial PNEC.

The following PNEC values are used in the risk assessment:

$$\text{PNEC}_{\text{water}} = 0.01 \text{ mg/l}/10 = 0.001 \text{ mg/l}$$

$$\text{PNEC}_{\text{susp.sed}} = 54.5 \text{ mg / kg suspended sediment} / 100 = 0.55 \text{ mg / kg suspended sediment}$$

$$\text{PNEC}_{\text{stp}} = 32 \text{ mg/l} / 100 = 0.32 \text{ mg/l}$$

$$\text{PNEC}_{\text{soil}} = 5.7 \text{ mg/kg dry soil}/50 = 0.114 \text{ mg/kg dry soil (0.1 mg/ kg wet soil)}$$

The ecotoxicity of the metabolite is significantly lower than than found for tebuconazole for both the aquatic and terrestrial environment and therefore the metabolite will not be considered further.

Comparison between the ecotoxicity of tebuconazole and the metabolite 1,2,4-Triazole

TEST	RESULTS	
	Tebuconazole	1,2,4-Triazole
Acute toxicity for fish	LC ₅₀ = 4.4 mg/L	LC ₅₀ = 498.0 mg/L

Acute toxicity for invertebrates	EC ₅₀ = 2.79 mg/L	EC ₅₀ > 100.0 mg/L
Growth inhibition on algae	E _r C ₅₀ = 5.3 mg/L	E _r C ₅₀ > 31.0 mg/L
Acute toxicity to earthworms	LC ₅₀ = 470 mg/kg dw	LC ₅₀ > 1000 mg/kg dw

2.2.2.3. PBT assessment

Tebuconazole does not fulfil the PBT or vPvB criteria.

2.2.2.4. Exposure assessment

The OECD ESD guidance available is limited to local exposure calculations for wood preservative life-cycle stages of product application and wood in-service only. Therefore the assessment has primarily determined local concentrations for these life-cycle stages. The risk from a normal landfill site is assumed to be lower than that described for the house scenario for wood in service because the emission from impregnated wood per m² soil is assumed to be smaller. However, if impregnated wood is collected specifically and disposed in special areas of a landfill it is assumed that special precaution has been taken for this part of the landfill.

PEC in surface water and sediment

According to the OECD models for tebuconazole used in wood preservation, PECs in water are calculated for different scenarios and applications:

Industrial application and storage

For the application stage (e.g. vacuum pressure treatment, or flow coating) it is assumed that - depending on the physical-chemical properties of the compound a certain amount of the applied active substance will enter the surface water via a waste water treatment plant. In the application scenarios concentrations in the inflow water to the STP between 1.8 µg/l and 18 µg/l are calculated from the models. In the application scenarios concentrations in surface water are between 0.14 µg/l and 1.42 µg/l. For the storage stage it is assumed in the OECD models that emissions from the storage place directly reach a small creek. Calculated tebuconazole concentrations in surface water were between 0.002 and 0.25 µg/l.

In-situ treatment

During outdoors in situ treatment an initial PEC can be calculated. The OECD model covers a wooden bridge over a small pond. Initial PECs for the guide recipe containing 0.6% tebuconazole are calculated. The initial PECs in water resulting from the models were 18 µg/l for professionals and 30 µg/l for amateurs. These initial concentrations in water could be reduced after 30 days by taking into account a transfer to sediment (using dissipation DT50 of 43 days). Thus after 30 days the PEC water was 11.1 and 18.5 µg/l for professionals and amateurs, respectively.

Outdoor service life - In-situ treatment

The OECD model “bridge over a small pond” calculates the realistic worst case concentrations after brushing in pond water 30 days and 5 years after application. Applying this scenario and taking into account the amount from application (amateurs) for the 30 days situation the concentrations in water is between 342 µg/l (312.2 + 30) and 270 µg/l (239.9 +30) for a water and solvent based formulation, respectively (without taken adsorption to the sediment into consideration). The corresponding values taken adsorption into consideration were 281 µg/l (262 + 18.5) and 220 µg/l (201 + 18.5) for water and solvent based formulation, respectively.

Applying the same scenario for the 5 years situation the concentrations in water is between 73.8 µg/l and 73.5 µg/l for water and solvent based formulation, respectively (without taken adsorption to the sediment into consideration). The corresponding values taken adsorption into consideration were 17 µg/l and 17 µg/l for water and solvent based formulation, respectively.

The corresponding values for the sediment are for the 30 days situation between 6 mg/kg and 7.6 or 1.6 and 1.6 mg/kg after 5 years.

Outdoor service life - HC 3 and HC 4 treatment excluding In- situ treatment (brushing)

The OECD model “bridge over a small pond” calculates concentrations in pond water after 30 days and a longer relevant time period after application. Applying this scenario and taking into account a half-life of 198 or 43 days in the surface water, concentrations in water after 30 days was between 0.3 µg/l and 32 µg/l (without taken adsorption to the sediment into consideration). The corresponding values were between 0.26 and 27 µg/l (taken adsorption to the sediment into consideration).

The corresponding values were between 0.16 and 4.56 µg/l (without taken adsorption to the sediment into consideration) and between 0.4 and 1.05 µg/l (taken adsorption to the sediment into consideration) after a relevant longer time period depending on the application specific emission rates.

The OECD model “noise barrier” assumes that one third of the emissions from wood will reach the sewage and – via STP - the surface water. Depending on the application specific emission rates from wood for this scenario, concentrations of tebuconazole in surface water after the first 30 days were calculated to be between 0.002 and 0.187 µg tebuconazole/l. After the longer time period the corresponding values were 0.001–0.003 µg/l) taking into account 21% adsorption of the active on the sludge in the sewage treatment plant. Depending on the application specific emission rates from wood for this scenario, concentrations of tebuconazole in the influent to the STP after the first 30 days were calculated between 0.02 and 23.1 µg tebuconazole/l. After the longer time period the corresponding values were <0.01–0.6 µg/l)

The OECD models for wood in permanent contact with water (Hazard Class 4b)⁴ cover a jetty in the lake scenario and a sheet piling in a waterway. These scenarios only apply for vacuum pressure treatment.

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.

In the “jetty in lake scenario”, concentrations in water of about 0.3 µg/l were calculated for 30 days after application. For the longer time period the corresponding values was 0.1 and 0.4 µg/l, taking into account a half life of 43 or 198 days for the water phase, respectively.

In the sheet piling scenario, water concentrations of 85 µg/l after 30 days and 11 µg/l after the longer time period.

The transferred tebuconazole concentration in suspended sediment was calculated from µg a.i./l (water) to mg a.i./kg suspended sediment using formula 50 from the TGD (2003). These calculated PEC sediment was used for the sediment risk assessment. During outdoor service life an initial PEC can be calculated according to the respective models for wood in hazard class 3 and 4. Applying these scenario the concentration in the sediment is between 0.001 and 7 mg a.i./kg after 30 days and between < 0.001 and 1.65 mg/kg after a longer time period, respectively.

PEC in air

Not relevant due to the low vapour pressure of the active substance.

PEC in soil

Industrial application and storage

Emissions into soil are assumed to occur during outdoor storage of the treated wood. It is assumed in the OECD models, that emissions from the storage place reach the soil directly. Calculated tebuconazole concentrations in the soil of the storage places were between 0.02 and 1.9 mg tebuconazole/kg wet soil after 30 days and 0.08 and 8.1 mg tebuconazole/kg wet soil after 20 years, taking into account degradation in soil and depending on the application-specific emissions rates.

In-situ treatment

During outdoors in-situ treatment, an initial PEC can be calculated according to the OECD models. The OECD models cover outdoor brushing of a fence and a timber house. Assuming a 3% (professionals) or 5% (amateurs) emission of the applied product into soil, initial PECs for the guide recipe containing 0.6% tebuconazole were calculated. These initial (after 30 days) PECs in soil resulting from the fence scenario model were 3.24 and 5.39 mg tebuconazole/kg wet soil for professionals and amateurs, respectively. For the timber house 4.04 and 6.73 mg tebuconazole/kg wet soil were calculated for professionals and amateurs, respectively. After 5 years the concentration of tebuconazole in the soil was less than 1 nanno gram / kg wet soil.

Outdoor service life - HC 3

For use (hazard) class 3 the service life of the OECD models “fence“, “timber house” and “noise barrier” was applied. Soil concentrations were calculated for 30 days and a relevant long service time after application taking into account a half-life of tebuconazole in soil of 77 days.

The highest soil concentrations were reached in the timber house scenario (0.08–85.1 mg tebuconazole/kg wet soil after 30 days and 0.02–9.0 mg /kg wet soil after a relevant longer time

period, taking into account degradation of tebuconazole in soil and depending on the application-specific emission rates). The highest concentration was found in the timber house scenarios related to brushing.

For the brushing scenario the PEC after 30 days should also include the amount from the application, taken into account degradation of tebuconazole in the soil. Thus the PEC (worst case) after 30 days can be estimated to 89.14 (4.04+85.1) and 91.83 mg/kg wet soil (6.73 + 85.1) for professional and amateurs, respectively.

The OECD model “noise barrier” assumes that 2/3 of the emissions from wood will reach the soil. The calculated PECs are considerably lower than in the fence or the timber house scenario.

Outdoor service life - HC 4a

The OECD models for wood in permanent contact with ground the OECD models “transmission pole” and “fence post” was applied. These scenarios only apply for vacuum pressure treatment.

In the “transmission pole” scenario a concentration in soil of about 3.7 mg tebuconazole/kg wet soil were calculated for 30 days and 1.1 mg tebuconazole /kg wet soil after 20 years after the application, taking into account a half life of 77 days in soil.

In the “fence post” scenario, concentrations in soil of 2.1 and 0.46 mg tebuconazole/kg wet soil were calculated for 30 days and 20 years after the application, respectively, taking into account a half life of 77 days in soil.

Direct PEC determination from a field test show much lower concentrations of tebuconazole in the soil. Thus after 30 days a concentration of 0.005 mg /kg was found and after two years a concentration of 0.16 mg tebuconazole / kg soil was found. After about 6 years a concentration of 0.06 mg tebuconazole / kg dry wet soil was found.

Receiving soil volume

In all model calculations the receiving soil compartment was based on default compartment assuming 10 cm distance and depth from the treated wood. This very small receiving volume is not scientifically based but a political decision, which results in a relatively high soil concentration in immediate vicinity of the treated wood.

Therefore for a refined assessment an enlarging of the receiving soil volume was done. Increasing the distance from the treated wood both with respect to the horizontal and lateral distance enlarged the receiving soil compartment. The calculations were done for 20, 30, 40 and 50 cm distance and depth resulting in an enlargement of the receiving soil volume by a factor of 4 (20 cm), 9 (30 cm), 16 (40 cm) and 25 (50 cm). Bases are the PEC values, which include the degradation of tebuconazole in soil. The results revealed that with a distance of 50 cm the concentration in the soil varied between < 0.1 to 3.4 mg tebuconazole/kg soils (wet weight) after 30 days. At TIME 2 the concentrations varied between < 0.01 and 0.23 mg tebuconazole / kg soils (wet weight), depending on the formulation and the application rate.

1,2,4-Triazole as a relevant metabolite

1,2,4-triazole was identified as a relevant metabolite of tebuconazole in soil, because it was found in soil degradation studies at concentrations up to 9%, which is close to the limit value of 10%. Due to the considerably shorter half-life of 1,2,4-triazole in soil compared to that of tebuconazole, 1,2,4-triazole can be regarded as a transient metabolite.

PEC_{groundwater}

The fate and behaviour for tebuconazole suggest that it is not expected to reach groundwater since this compound has been shown to be having a low mobility in soil. For the service life of the wood the leaching potential was evaluated using the leaching model PEARL 3.3.3. The results show that tebuconazole is not expected to leach to groundwater in unacceptable amounts.

For the industrial treatment plants (storage sties) no tebuconazole is expected in the ground water during the first year. However, after a few years tebuconazole and 1,2,4 triazole concentrations in the ground water may be above 0.1 ug/l.

2.2.2.5. Risk characterisation

Aquatic Compartment

For industrial application the PEC:PNEC values for surface water was only unacceptable (> 1) for large plants with Automated spraying. A risk mitigation measure is proposed to prevent losses to drains (connected to STP) during application (e.g. no drain connections to storm drains or STPs and recycled; or collected and treated the wastewater).

For *in situ* applications, the risk was evaluated for brushing of a bridge over a small pond. The risk was unacceptable for both professionals and amateurs after 30 days. The the Applicant's proposal of labelling against applications where direct losses to water are possible, therefore preventing use in these situations was endorsed.

For in-service life, it was agreed to accept the small risk identified for the noise barrier scenario after 30 days because it is expected to be for a short period of time. As there was identified an unacceptable risk where direct losses to water are possible wood which is installed over small ponds should normally be protected with a topcoat or other risk reduction measurements to avoid leaching into water.

For Hazard Class 4b tebuconazole has been evaluated for vacuum pressure impregnation with a copper-containing product during the service phase. No unacceptable risk was seen in the lake scenario but a risk based on aquatic toxicity was identified in the sheet piling in a water way scenario. Consequently appropriate risk mitigation measures must be taken at the product evaluation stage for treated timber with a formulation of tebuconazole which shows a PEC:PNEC ratio of more than 1.

The risk quotients are more favourable for sediment than for the water phase and therefore, this PEC: PNEC values were not considered further.

Terrestrial Compartment

The risk posed to the local soil compartment within industrial wood treatment sites is not acceptable. Therefore, it was agreed that this risk is mitigated by restricting the storage of industrial treated timber to hard standing (preventing the direct losses to soil) and collecting rain water from the storage area or make other risk reductions measurements. This is currently considered good practice in many member states.

The PEC:PNECs produced for the *in situ* application scenarios for wood out of ground contact range from 32 to 67. However covering the ground surrounding the object to be treated with protective foil can drastically reduce the emissions during *in situ* treatment. Therefore it was agreed that a labelling which stresses that a sufficient covering of the ground surrounding the object must be don for *in situ* application.

When the risk assessment for in-service life is performed according to the present OECD environmental emission scenario the risk to soil was unacceptable for all the applications in HC 3 with the exemption of vacuum pressure impregnation with a formulation also containing copper. For a metal containing formulation the risk to soil was acceptable both for HC 3 and for wood in contact to soil (HC 4a), when the leaching data for wood in contact to soil is based

on a field study. Consequently the wood which is treated with tebuconazole for HC 3 and have a PEC:PNEC ratio of more than 1 an appropriate risk mitigation measures must be taken to protect the soil compartment. This could for example be that the treated wood should be protected with a topcoat to avoid leaching into soil. However, based on the agreed position of only focusing on TIME 2 and increase the soil compartment to 50 cm. this means that for all the scenario evaluated the risk to the soil compartment was acceptable with the exception of brushing.

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

The overall conclusion from the evaluation of tebuconazole for use in product-type 8 (Wood preservatives), is that it may be possible for Member States to issue authorisations of products containing tebuconazole in accordance with the conditions laid down in Article 5(1) (b), (c) and (d) of Directive 98/8/EC.

Assessed from the documentation for the active substance, tebuconazole, and the representative biocidal products containing 0.6% w/w tebuconazole, the proposed manner and areas of use of products intended to control wood- rotting fungi may be sufficient effective for these uses and without unacceptable risk neither to human health nor to the environment. Furthermore the evaluation of the risks for humans and the environment originating in exposure for tebuconazole from impregnated wood resulted in the overall conclusion that the manner and areas of the proposed uses were acceptable.

The manner and areas of use listed were proposed and supported by data submitted by the Applicant and the maximum effective retention of tebuconazole that were acceptable from an environmental point of view were identified within the framework of the risk assessment:

- Vacuum pressure; metal free product; maximum retention: 0.10 kg/m³
- Vacuum pressure; copper containing product; maximum retention: 0.05 kg/m³
- Double vacuum; maximum retention: 0.1 kg/m³
- Automated spraying; maximum retention: 0.15 g/m²
- Flow coating; maximum retention: 0.60 g/m²
- Dipping and spraying; maximum retention: 1.00 g/m²
- *In situ* outdoors brush painting; maximum retention: 1.00 g/m²

However, certain mitigation measures are required as a condition of use of wood preservatives containing tebuconazole in order to remove those concerns that have been identified in the risk assessment for the environment.

This overall conclusion relies on the fact that users of the biocidal product will be applying the basic principles of good practice and respect the conditions for the normal use recommended on the label of the product.

3.2. Decision regarding Inclusion in Annex I

The tebuconazole 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:

- a) The active substance tebuconazole, as manufactured, shall have a minimum purity of 950 g/kg
- b) 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 indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil and that any losses must be collected for reuse or disposal.

In addition, products cannot be authorised for the *in situ* treatment of wood outdoors or for wood that will be in continuous contact with water unless data are 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.

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

Products containing tebuconazole have been evaluated for the used to control wood-rotting fungi by impregnation of wood for use up to HC3 for all application methods and up to HC4 for vacuum pressure impregnation with a copper-containing product.

- When Member States are authorising products, both the application methods and the nature of the product including concentrations of the active components and of the non-active components within the product must be considered, since these factors could affect e.g. the leaching rate of these substances from the treated wood, the (eco)toxicity and the overall classification of the product.
- No *in situ* application by brush (professional or amateur) to wooden structures should be permitted where direct losses to the environmental compartment cannot be prevented.
- The efficacy of individual products must be demonstrated prior to product authorisation at the Member State level.
- Losses during industrial/professional application, as well as during tank cleaning, must be contained and recycled; or collected and treated as waste in accordance with the national regulations of the Member State authorising individual products. It is most unlikely that tebuconazole from treated timber will result in an environmental risk during incineration under controlled conditions; however other active substance in a formulation may result in an environmental risk during incineration of treated timber. Therefore special focus on this life-cycle stage has been deferred to the Member State assessment at the product authorisation stage.

In the treatment of wood, Member States shall ensure that:

- Where direct losses to water are possible products showing a PEC:PNEC ratio of more than 1 appropriate risk mitigation measures are taken to protect the water compartment.

- Appropriate risk mitigation measures are taken when treated timber with a formulation of tebuconazole shows a PEC/PNEC ratio of more than 1.

Impregnated wood must not come in contact with food or feedstuffs.

When Member States are authorising products containing Tebuconazole the potential of Tebuconazole to cause endocrine disruption must be considered. This is because Tebuconazole may have the potential to cause endocrine disruption based on suspected properties for the azole group and that there is not sufficient data.

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 tebuconazole in Annex I to Directive 98/8/EC.

3.4. 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 tebuconazole in Annex I to the Directive.

Appendix I: List of endpoints

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

Active substance (ISO Common Name)

Tebuconazole

Product-type

Fungicide

Identity

Chemical name (IUPAC)

(RS)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol. Ratio (1:1)

Chemical name (CA)

1H-1,2,4-triazole-1-ethanol,.Alpha. -[2-(4-chlorophenyl)ethyl]-.alpha.-(1,1-dimethylethyl)-,(.+-.) Ratio (1:1)

CAS No

107534-96-3

EC No

403-640-2 (ELINCS)

Other substance No.

CIPAC No. 494

Minimum purity of the active substance as manufactured (g/kg or g/l)

950 g/kg

Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)

No (Eco)toxicological relevant impurities present.

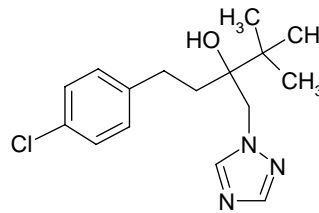
Molecular formula

C₁₆ H₂₂ Cl N₃ O

Molecular mass

307.8

Structural formula



Physical and chemical properties

Melting point (state purity)	105°C (99.9% pure)
Boiling point (state purity)	Not measurable, decomposes
Temperature of decomposition	TGA: Weight loss above 165°C DSC: exothermic reaction above 350°C
Appearance (state purity)	99.5% Physical state: Crystalline powder, Colour: Colourless, Odour: no characteristic odour Tech. Physical state: powder, Colour: white to beige, Odour: slight characteristic odour
Relative density (state purity)	1.25 g/cm ³ at 26°C (99.5% pure) – (density).
Surface tension	64.26 mN/m at 20°C (saturated aq. soln.)
Vapour pressure (in Pa, state temperature)	1.7 × 10 ⁻⁶ Pa at 20°C
Henry's law constant (Pa m ³ mol ⁻¹)	1 × 10 ⁻⁵ Pa m ³ /mol
Solubility in water (g/l or mg/l, state temperature)	pH_5____: 0.027 g/l at 20°C ----- pH_7____: 0.029 g/l at 20°C ----- pH_9____: 0.032 g/l at 20°C
Solubility in organic solvents (in g/l or mg/l, state temperature)	temperature: 10 °C 2-Propanol: 89.3 g/l, Toluene:46.9 g/l, n-Hexane: 0.543 g/l, Acetone: 222 g/l, Acetonitrile: 61.9 g/l, 1,2-dichloroethane: 205 g/l, Octanol:95.5 g/l, temperature: 20 °C n-Hexane: 0.841 g/l, Octanol: 98.1 g/l, temperature: 30 °C 2-Propanol: 140 g/l, Toluene:107 g/l, n-Hexane: 1.36 g/l, Acetone: 403 g/l, Acetonitrile: 172 g/l, 1,2-dichloroethane: 322 g/l, Octanol: 126 g/l,

Stability in organic solvents used in biocidal products including relevant breakdown products	Not applicable (the active substance as manufactured didn't include any organic solvent)
Partition coefficient (log P _{OW}) (state temperature)	3.53 at 10°C
	3.49 at 20°C
	3.47 at 30°C
	The effect of different pHs was not investigated because there is no much influence of pH on the water solubility.
Hydrolytic stability (DT ₅₀) (state pH and temperature)	pH__5__: Stable at 25°C
	pH__7__: Stable at 25°C
	pH__9__: Stable at 25°C
Dissociation constant	no pKa value in water
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	221.4 nm; Molar absorptivity [1000 cm ² /mol] = 38.92
Photostability (DT ₅₀) (aqueous, sunlight, state pH)	Tebuconazole was stable at pH 7. Under the experimental conditions formation of photolysis products was not observed after 30 days of irradiation. Considering the photolytic stability determined under environmental pH and temperature conditions it is not expected that photolytic processes in aqueous solutions will contribute to the degradation of tebuconazole in the environment.
Quantum yield of direct phototransformation in water at Σ > 290 nm	The UV absorption data showed that aqueous solutions of tebuconazole do not absorb any light at wavelengths above 290 nm. In agreement with the Draft Test Guideline "Phototransformation of Chemicals in Water", UBA, Nov. 1989, determination of quantum yield in order to estimate the environmental half-life makes no sense in this case, because no contribution of direct photodegradation to the overall elimination of tebuconazole in the environment is expected.
Flammability	Tebuconazole is not highly flammable. It has no pyrophoric property. It does not evolve any flammable gases in contact with water or humid air and has no self ignition at temperatures up to melting point (105°C).
Explosive properties	Tebuconazole is not explosive
Oxidising properties	From structural reasons the test substance has not oxidising properties.

Classification and proposed labelling

with regard to physical/chemical data

None

with regard to toxicological data

Xn; Repr. Cat.3

R63: Possible risk of harm to the unborn child

R22: Harmful if swallowed

with regard to fate and behaviour data

Symbol N (in connection with R51)

R53: May cause long term adverse effects in the aquatic environment

with regard to ecotoxicological data

Symbol N (in connection with R53)
R51: Toxic to aquatic organisms**Chapter 2: Methods of Analysis****Analytical methods for the active substance**

Technical active substance (principle of method)

The method to determine the assay of Folicur (tebuconazole) in industrial active component is based on capillary gas chromatography using flame ionisation detector. The quantitative evaluation is carried out according to the method of the internal standard (Di-(2-ethylhexyl)phthalate (DIOP))

Impurities in technical active substance (principle of method)

The method to determine the assay of the by-products in technical active substance (Folicur, techn., tebuconazole) in the range 0.05 to 5% is based on capillary gas chromatography using flame ionisation detector. The quantitative evaluation is carried out according to the method of the internal standard (Dimethylphthalate)

Analytical methods for residues

Soil (principle of method and LOQ)

The DFG Method S 19 describes the analytical procedures for the determination of tebuconazole in soil. The extraction from soil is performed with acetone followed by the clean-up procedures of gel permeation chromatography (GPC) on Bio Beads S-X3 polystyrene gel. Tebuconazole is analysed by gas chromatography on fused silica gel with a nitrogen/phosphorus detector or mass specific detector. Evaluation is carried out with external standard.

Limit of quantification (LOQ): 0.01mg/kg

Air (principle of method and LOQ)

Air is sucked through Tenax or XAD-2 adsorption tubes at a rate of 2 l/min during a period of 6 hours. The adsorbed active ingredient is extracted with ethyl acetate and determined after gas chromatographic separation by means of a nitrogen and phosphorous selective detector (GC-NPD).

A confirmatory procedure is based on gas chromatography using mass selective detection (GC-MSD). No deviation from the described Tenax sampling and extraction technique is necessary. The same crude extracts could be investigated by both different GC methods. Evaluation is carried out with external

Water (principle of method and LOQ)	<p>standard.</p> <p>Limit of quantification (LOQ): 0.001 mg a.i./ m³ air</p> <p>Determination for tebuconazole in surfacewater is performed according to DFG Method W 5. Water samples are analysed by means of gas chromatography on fused silica gel after extraction with dichloromethane and clean up by gel permeation chromatography on Bio Beads S-X3 polystyrene gel. For detection a mass selective detector (MSD) is used. Evaluation is carried out with external standard. Limit of quantification (LOQ) surface- ground- and drinking water: 0.05 µg/l</p>
Body fluids and tissues (principle of method and LOQ)	Relevant only for toxic substances.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not relevant
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not relevant

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	<p>> 98% (based on urinary (7.4%) and biliary (90.9%) excretion within 48 hours) Peak plasma levels approximately 1 to 2 hours after administration</p>
Rate and extent of dermal absorption:	<p>The active substance:</p> <p>Rapid (peak 0.5-4h) and 50% of the dose within 8 hours in the rat. The vehicle was ethanol</p> <p>The guide recipes: the ability of tebuconazole to penetrate the skin was examined in-vitro with the solvent-based and water-based guide formulations containing approx. 0.63-0.65% [¹⁴C]-tebuconazole. The dermal absorption was studied on dermatomed human skin according to the OECD draft Guideline 428.</p> <p>After 24 hours with 8 hours of exposure to the solvent-based preparation, the total amount of radioactive material absorbed and residues found in stratum corneum strip 6-20 was 14.4%</p> <p>After 24 hours with 8 hours of exposure to the water-based preparation, the absorbed dose and residues found in stratum corneum strip 6-20 was 3.3%</p>
Distribution:	Widely distributed, highest concentrations in kidney and liver
Potential for accumulation:	No evidence for accumulation
Rate and extent of excretion:	Rapid and extensively as: 72 hours after administration: between 86.5 and 98.4 % of the administered dose (approx. 99 % of the recovered dose) was excreted with the urine and faeces.

Toxicologically significant metabolite(s)

1H-1.2.4.-triazole (5% (m); 1.5% (f))

Acute toxicityRat LD₅₀ oral

1700 (f) and 4000 (m) mg/kg bw

Rat LD₅₀ dermal

> 2000 mg/kg bw

Rat LC₅₀ inhalationExposure: 1 x 4 hours (head/nose only)
> 371 mg/m³ (aerosol) > 5093 mg/m³ (dust)

Skin irritation

None

Eye irritation

None

Skin sensitization (test method used and result)

No skin sensitisation in Magnusson-Kligman or Buehler Patch Test

Repeated dose toxicity

Species/ target / critical effect

Dog/adrenals/hypertrophy of *zona fasciculata* cells

Lowest relevant oral NOAEL / LOAEL

Approx. 3.0/4.4 mg/kg bw/day (dog, 1 year)

Lowest relevant dermal NOAEL / LOAEL

1000 mg/kg bw/day (rabbit, systemic/local)

Lowest relevant inhalation NOAEL / LOAEL

10.6 mg/m³ (rat)**Genotoxicity**

No evidence for genotoxic potential was observed in an adequate battery of in-vitro tests with various endpoints including both prokaryotes and eukaryotes

Carcinogenicity

Species/type of tumour

Mouse/liver tumours Not relevant for humans. Only found in a sensitive mouse strain and at very high dose levels above the maximum tolerated dose

Rat/spontaneous tumours typically for old rats: C-cell tumours of the thyroid in males and endometrial adenocarcinomas in females. No relevance for humans

lowest dose with tumours

1500 ppm equal to 280 mg/kg bw/day (mouse)

Reproductive toxicity

Species/ Reproduction target / critical effect

Rat/Decreased body weight gain and effects on the liver

Lowest relevant reproductive NOAEL / LOAEL

Rat/2-generation study: NOAEL in parental as well as F1 and F2 generation:
300 ppm equal to 27/34 mg/kg bw/day (m/f)

Species/Developmental target / critical effect

Rat/rabbit/mice/Embryotoxic and teratogenic effects

Developmental toxicity

Lowest relevant developmental NOAEL / LOAEL

Mice: dams: 10/30 mg/kg w/day
fetuses: 10/30 mg/kg bw/day

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect

Lowest relevant developmental NOAEL / LOAEL.

Rats
No signs of neurotoxicity have been observed after acute and subchronic oral treatment.
50/100 mg/kg bw/day (acute neurotoxicity)
29.2/107 mg/kg bw/day (subchronic neurotoxicity)
20/60 mg/kg bw/day (developmental neurotoxicity)

Other toxicological studies

.....

None of the metabolites except for 1H-1,2,4-triazole show effects of concern related to toxicity. 1H-1,2,4-triazole is classified as Xn; R63
--

Medical data

.....

No negative effects on the health of the workers engaged in the production of tebuconazole were determined during routine medical monitoring from 1998 till now.
--

Summary (Annex IIA, point 6.10)

ADI (if residues in food or feed)

AOEL (Operator/Worker Exposure)

Drinking water limit

ARfD (acute reference dose)

Value	Study	Uncertainty factor
n/a	n/a	n/a
0.03 mg/kg bw/day	1 year / dog	100
Limit for pesticides in the Drinking Water Directive is <u>0.1 µg/L</u> , no other value will be calculated.		
Not relevant		

Acceptable exposure scenarios (Methods of calculation from the Technical Notes for Guidance - Human Exposure to Biocidal Products (2002))

Industrial users

Dipping,
water-based

Dipping,
solvent-based

Double-vacuum impregnation,
water-based

MOE = 428 Exposure ÷ AOEL = 0.233
MOE = 250 Exposure ÷ AOEL = 0.4
MOE = 1000 Exposure ÷ AOEL = 0.1

Acceptable exposure scenarios (Methods of calculation from the Technical Notes for Guidance - Human Exposure to Biocidal Products (2002))

Double-vacuum impregnation,
solvent-based

MOE = 400
Exposure ÷ AOEL = 0.25

Vacuum pressure impregnation,
water-based

MOE = 3000
Exposure ÷ AOEL = 0.033

Professional Users

Painting,
water-based

MOE = 500
Exposure ÷ AOEL = 0.2

Painting,
solvent-based

MOE = 250
Exposure ÷ AOEL = 0.4

Manual spraying,
water-based

MOE = 1111 Exposure ÷ AOEL = 0.09

Manual-spraying,
solvent-based

MOE = 967
Exposure ÷ AOEL = 0.103

Non-Professional Users

Painting,
water-based, with gloves

MOE = 500
Exposure ÷ AOEL = 0.2

Painting,
water-based, no gloves

MOE = 333
Exposure ÷ AOEL = 0.3

Painting,
solvent-based, with gloves

MOE = 375 Exposure ÷ AOEL = 0.27

Painting,
solvent-based, no gloves

MOE = 230
Exposure ÷ AOEL = 0.43

Secondary exposure

Acute phase

MOE:
Adult: 4347
Child: not relevant
Infant: 150

Chronic phase

MOE:
Adult: 3896
Child: 1579
Infant: 313

Chapter 4: Fate and Behaviour in the Environment**Route and rate of degradation in water**

Hydrolysis of active substance and relevant metabolites (DT₅₀) (state pH and temperature)

Tebuconazole is stable at pH 5, 7 and 9, at 25 °C after 28 days

pH_____:

pH_____:

Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites

No significant photolytic degradation: Aqueous solution of tebuconazole do not show an absorbance of UV-light at wavelengths above 290 nm

Readily biodegradable (yes/no)

No

Biodegradation in surface water

Degradation in aquatic systems
DegT50 water layer: 198 days
(according to first order kinetics).

no data on seawater

Biodegradation in seawater

Non-extractable residues

For the sediment the non-extractable amount increased to a maximum of 19% of the applied amount after 1 year in a laboratory experiment. The mineralization rate measured as CO₂ evolved constitute 21% after 1 year.

Distribution in water / sediment systems (active substance)

The average dissipation DT50 for total water/sediment system is 54 days (SFO calculation). A refined calculation resulted in a DT50 for the total system of 46 days (may be used for modelling purposes). The dissipation DT50 for the water phase is 43 days and one year (or default) for the sediment (outdoor microcosm study).

Distribution in water / sediment systems (metabolites)

No major metabolites were found in water/sediment systems.

Route and rate of degradation in soil

Mineralization (aerobic)

Mineralization after 100 days at 20 °C :

The mineralisation is very low (0-0.3% after 12 month).

Laboratory studies (range or median, with number of measurements, with regression coefficient)

Not determinable under laboratory conditions

DT_{50lab} (20 °C, aerobic): > 1 year

The percentage of bound residues varies a great deal, from 7.2 to 64.9%.

DT_{90lab} (20°C, aerobic):

DT_{50lab} (10°C, aerobic):

DT_{50lab} (20°C, anaerobic):

degradation in the saturated zone:

Field studies (state location, range or median with number of measurements)	DT50 _{field} : 77 days In field studies the dissipation half lives (including other dissipation rates than degradation) were below one year. In the 4 northern European sites, the dissipation half-lives range from 36 to 77 days. The single DT50-values were 76.9, 56.6, 36.3 and 57.8 days. In the 2 southern European sites, the single DT50-values were 20 and 34 days. A realistic worst case dissipation half-lives is considered to be 77 days.
Anaerobic degradation	No new metabolite not already occurring under aerobic degradation.
Soil photolysis	Tebuconazole is photolytically stable on soil
Non-extractable residues	Non-extractable residues after 100 days at 20 °C
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	1,2,4-triazole was the major metabolite formed with a maximum of 9.0% of applied radioactivity(10 - 12.5 months). (aerobic degradation)
Soil accumulation and plateau concentration	Accumulation in soil may be anticipated in soil with intermediate releases.

Adsorption/desorption

K _a , K _d	K _a : arithmetic mean value: 12.7
K _{aoc} , K _{doc}	K _{oc} : arithmetic mean value: 992
pH dependence (yes / no) (if yes type of dependence)	Depending on organic carbon content no influence of inorganic soil components known
	K _{ocads} : Adsorption: 992 mL/g (n = 6)
	K _{ocdes} : Desorption: 1300 mL/g (n = 6)
	No pH dependence

Fate and behaviour in air

Direct photolysis in air	Tebuconazole is stable to direct photolysis.
Quantum yield of direct photolysis	
Photo-oxidative degradation in air	Latitude: Season: DT ₅₀ estimated: Chemical lifetime is 3.8 days in the troposphere, acc. calculation model by Atkinson
Volatilization	Insignificant Low vapour pressure and Henry law constant exclude direct volatilisation, from water.

Monitoring data, if available

Soil (indicate location and type of study)

Surface water (indicate location and type of study)

Ground water (indicate location and type of study)

Air (indicate location and type of study)

Outdoor pond studies available

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity
Fish			
Rainbow trout	96 hours, flow-through	LC ₅₀	4.4 mg/l
Rainbow trout	83d ELS, flow-through	NOEC	0.012 mg/l
	21d,chronics emi-static	NOEC	0.010 mg/l
Invertebrates			
<i>Daphnia magna</i>	48h,,flow-through.	EC ₅₀ (mortality) EC ₅₀	4.2 mg/l 2.8 mg/l
<i>Daphnia magna</i>	21 d, semi-static	NOEC	0.01 mg/l
Algae			
<i>Scenedesmus subspicatus</i> <i>Scenedesmus subspicatus</i>	chronic, 72 h, static	E _r C ₅₀	5.30 mg/l
		NOEC	0.56 mg/l
		E _b C ₅₀	1.96 mg/l
<i>Selenastrum capricornutum</i> (<i>Pseudokirchneriella subcapitata</i>)	chronic, 72 h, static chronic, 96 h, static	E _r C ₅₀	3.80 mg/l
		NOEC	1.19 mg/l
		E _b C ₅₀	2.83 mg/l
Microorganisms			
Activated sludge	30 min.	EC ₅₀ (resp. inhib.)	EC ₅₀ above water sol. (32 mg/L)
Sediment-dwelling organisms			
<i>Chironomus riparius</i>	chronic, 28d, static, spiked water	EC ₁₀	2.45 mg/l
		NOEC (sediment)	54.5 mg/kg suspended sediment

Effects on earthworms or other soil non-target organisms

Acute toxicity to	<i>Eisenia fetida</i> LC ₅₀ (14 d): 470 mg/kg dry weight soil
Reproductive toxicity to	<i>Eisenia fetida</i> NOEC: 5.7 mg/kg dry weight soil. (56 d) (after conversion to the TGD standard organic matter.)

Effects on Plants

Acute toxicity to plants.

Cress (<i>Lepidium sativum</i>)
OECD 208 study with tebuconazole a.s. (14 days, a s incorporated in the soil)
LC50 (emergence): ≥ 100 mg a.s./kg dry soil
EC50 (growth): 24 mg/kg dry soil (shoot fresh weight) after conversion to the TGD standard organic matter
EC ₀ (growth 1.7 mg/kg dry soil (shoot fresh weight) after conversion to the TGD standard organic matter.

Effects on soil micro-organisms

Nitrogen mineralization

EC ₅₀ (28d):	>8.3 mg a.s./kg dw
NOEC:	8.3 mg a.s./kg dw

Carbon mineralization

EC ₅₀ (28 d):	>8.3 mg a.s./kg dw
NOEC:	8.3 mg a.s. /kg dw

Effects on terrestrial vertebrates

Acute toxicity to mammals

Rats LD ₅₀ :1700 (f) and 4000 (m) mg/kg bw

Acute toxicity to birds

Bobwhite quail, LD ₅₀ 1988 mg/kg bw
--

Dietary toxicity to birds

Bobwhite quail, LC ₅₀ (5 day): >5000 mg a.s./kg feed
Mallard duck, LC ₅₀ (5 day): >4816 mg a.s./kg feed

Reproductive toxicity to birds

--

Effects on honeybees

Acute oral toxicity

--

Acute contact toxicity

--

Effects on other beneficial arthropods

Acute oral toxicity

--

Acute contact toxicity

--

Acute toxicity to

Soil mite EC ₀ = 50 mg a.s. / kg soil dw.
--

Chronic toxicity to

Collembola (28 days), NOEC = 250 mg a.s. / kg soil dw.
--

Bioconcentration

Bioconcentration factor (BCF)

78 for bluegill sunfish (<i>Lepomis macrochirus</i>)
The BCF for earthworm is estimated according to TGD to 28.

Depuration time (DT₅₀)(DT₉₀)

0.44 days for fish

Level of metabolites (%) in organisms accounting
for > 10 % of residues**Chapter 6: Other End Points**

Appendix II: List of Intended Uses

Tebuconazole has been evaluated for its use in wood preservation (Product Type 8 of the Biocidal Products Directive) up to Hazard Class 4a and 5b. It is applied in both solvent- and water based formulations and can be applied by industrial as well as professional and amateur user.

Products can be used for:

- The pre-treatment of timber (dipping, automated spraying, double vacuum and vacuum pressure by industrial/professional users); and
- The protective treatment of wood *in situ* by brush application (both professional and amateur users)

Tebuconazole is not recommended for treatment of wood inside housing areas (with the exception of window frames and external doors, which will usually be treated on or before installation) or for spraying manually in open systems.

Guide recipes for two representative biocidal products (a water-based and a solvent-based formulation) were submitted by the Applicant – both containing 0.6% w/w tebuconazole.

The maximum effective retention in wood in kilogram or g a.s./m² or a.s./m³ for the field of use envisaged:

– Vacuum pressure, metal free product	0.10 kg/m ³
– Vacuum pressure, copper containing product	0.05 kg/m ³
– Double vacuum	0.10 kg/m ³
– Automated spraying	0.15 g/m ²
– Flow coating	0.60 g/m ²
– Dipping, spraying and brushing	1.00 g/m ²

These values have been used in the environmental risk assessment.

5 The Hazard Classes (HC) are defined as: HC1: Above ground (dry); HC2: Above ground (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.

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked “Y” in the “Data Protection Claimed” column of the table below. For studies marked Yes(i) data protection is claimed under Article 12.1(c) (i), for studies marked Yes(ii) data protection is claimed under Article 12.1(c) (ii). These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIA, 2.6 /01	-	Stroech, K.	1994	Preventol A 8 - Synthesis. Bayer AG Non-GLP, unpublished <i>A8_PC_synthesis_SXX_1994</i> - CONFIDENTIAL -	Yes	LANXESS Deutschland GmbH
IIA, 2.6 /02	IIA, 1	Anon.	2003	Tebuconazole - Dossier According to Directive 91/414/EEC - Annex IIA, Point 1- Summary Documentation - Tier 2 - Section 1, Identity of the active substance. Bayer AG unpublished <i>A8_PC_Annex</i> <i>IIA_CropScience_conf_2003</i> - CONFIDENTIAL -	Yes	Bayer CropScience AG
IIA, 2.7 /01	IIA, 1	Anon.	2003	Tebuconazole - Dossier According to Directive 91/414/EEC - Annex IIA, Point 1- Summary Documentation - Tier 2 - Section 1, Identity of the active substance. Bayer AG unpublished <i>A8_PC_Annex</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company), Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				<i>IIA_CropScience_conf_2003</i> - CONFIDENTIAL - see also IIA, II.2.6 /02		
IIA, 2.7 /02	-	Anon.	2001	Preventol A 8 - Certificate of Analysis, 5 Batches Analysis. Bayer AG, Report Non-GLP, unpublished <i>A8_PC_production_5Batch_2001</i> - CONFIDENTIAL -	Yes	LANXESS Deutschland GmbH
IIA, 2.7 /03	IIA, 1.11 /03	Baird J. W. and Otis, G. E.	1992	The composition of technical FOLICUR. Miles Inc. Agriculture division research and development. Report No. 101393. Non-GLP, Unpublished - CONFIDENTIAL -	Yes	Bayer CropScience AG
IIA, 2.7 /04		Haack, K.J.	2005	Statement Regarding the Specification Limits for Components in Tebuconazole Technical Grade Active Substance. Code: HWG 1608. Report M-257445-01-1 Non-GLP, Unpublished - CONFIDENTIAL -	Yes	LANXESS Deutschland GmbH
IIA, 2.8 /01		Allmendinger, H.	1988	Composition of Folicur (material accountability). Bayer AG, PC 463 GLP, unpublished <i>A8_PC_impurities_material account_PC463_1988</i> - CONFIDENTIAL -	Yes	Bayer CropScience AG
IIA, 2.8 /02	IIA, 1	Anon.	2003	Tebuconazole - Dossier According to Directive 91/414/EEC - Annex IIA, Point 1- Summary Documentation - Tier 2	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				- Section 1, Identity of the active substance. Bayer AG unpublished <i>A8_PC_Annex IIA_CropScience_conf_2003</i> - CONFIDENTIAL - see also IIA, II.2.6 /02		
IIA, 2.8/03	IIA, 1.11 /03	Baird J. W. and Otis, G. E.	1992	The composition of technical FOLICUR. Miles Inc. Agriculture division research and development. Report No. 101393. Non-GLP, Unpublished - CONFIDENTIAL -	Yes	Bayer CropScience AG
IIA, 2.8 /04		Haack, K.J.	2005	Statement Regarding the Specification Limits for Components in Tebuconazole Technical Grade Active Substance. Code: HWG 1608. Report M-257445-01-1 Non-GLP, Unpublished - CONFIDENTIAL -	Yes	LANXESS Deutschland GmbH
IIA, 3.1 /01	IIA, 2.2 /01	Weber, R.	1987	Density of Tebuconazole (HWG 1608). Bayer AG, PC 438 Non-GLP, unpublished <i>A8_PC_density_PC438_1987</i>	Yes	Bayer CropScience AG
IIA, 3.1 /02	IIA, 2.1.2 /01 2.1.3 /01	Mix, K.H.; Berg, G.	1988	Thermal stability of the Agrochemical Active Ingredient Tebuconazole. Bayer AG, PC 412 GLP, unpublished <i>A8_PC_stability_DTA_PC412_19 88_=88 10012</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company), Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIA, 3.1 /03	IIA, 2.1.1 /01	Krohn, J.	1993	Melting point of Tebuconazole. Bayer AG, PC 424 GLP, unpublished <i>A8_PC_mp_PC424_1993</i>	Yes	Bayer CropScience AG
IIA, 3.1 /04	-	Anon.	2003	Material Safety Data Sheet "Preventol A 8", No. 327445/27 Bayer AG Non-GLP, unpublished <i>A8_MSDS_327445 27_2003_English</i>	-	LANXESS Deutschland GmbH
IIA, 3.2 /01	IIA, 2.3.2 /01	Krohn, J.	1988	Henry law constant of tebuconazole (HWG 1608). Bayer AG, PC 432 GLP, unpublished <i>A8_PC_henry_PC432_1988</i>	Yes	Bayer CropScience AG
IIA, 3.2 /02	IIA, 2.3.1 /02	Krohn, J.	1993	Vapour pressure curve of Tebuconazole. Bayer AG, PC 423 GLP, unpublished <i>A8_PC_vapour_PC423_1993</i>	Yes	Bayer CropScience AG
IIA, 3.2 /03	IIA, 2.3.1 /02	Weber, R.	1988a	Vapour pressure curve of tebuconazole (HWG 1608). Bayer AG, . 681594 Non-GLP, unpublished	Yes	Bayer CropScience AG
IIA, 3.3 /01	-	Schneider, K.	2005a	Apperance of tebuconazole technical (UVP No.:04069382. Bayer CropScience AG, Non-GLP, unpublished	Yes	Bayer CropScience AG
IIA, 3.3 /02	-	Schneider, K.	2005b	Odour of tebuconazole technical (UVP No.:04069382. Bayer CropScience AG Non-GLP, unpublished	Yes	Bayer CropScience AG
IIA, 3.4	IIA, 2.5.1 /01	Krohn, J.	1988b	Spectra of the active ingredient Tebuconazole (HWG 1608). Bayer AG, PC 430 GLP, unpublished <i>A8_PC_spectra_PC 430_1988</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company), Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIA, 3.5 /01	IIA, 2.6 /01	Krohn, J.	1995	Water solubility of Tebuconazole. Bayer AG, PC 664 (14 040 0839) GLP, unpublished <i>A8_PC_solubility_water_PC664_ 1995</i>	Yes	Bayer CropScience AG
IIA, 3.5 /02	IIA, 2.6 /01	Erstling, K.	2002	Determination of the water solubility (Flask method) of Tebuconazole. Bayer AG, G02/0104/01LEV GLP, unpublished <i>A8_PC_solubility_water_G 02 0104 01 LEV_2002</i>	Yes	LANXESS Deutschland GmbH
IIA, 3.6	IIA, 2.8 /01	Placke, F.J.	1987	Dissociation Constant of HWG 1608. Bayer AG, 03/87-2 Non-GLP, unpublished	Yes	Bayer CropScience AG
IIA, 3.7/01	IIA, 2.7/01	Jungheim, R.	2005a	Solubility of Tebuconazole in organic solvents at different temperatures. Bayer Industry Services, Germany, 2005/0093/02 GLP, unpublished	Yes	Bayer CropScience AG
IIA, 3.7/02	IIA, 2.7/01	Jungheim, R.	2005b	Solubility of Tebuconazole in 1- octanol at 10 C, 20 C and 30 C and calculation of the partition Coefficient (1-octanol/Water) with water solubility of Tebuconazole determined under study number G 02/0104/01 LEV. Bayer Industry Services, Germany, 2005/0093/03 GLP, unpublished	Yes	Bayer CropScience AG
IIA, 3.9/01	IIA, 2.7/01	Jungheim, R.	2005b	Solubility of Tebuconazole in 1- octanol at 10 C, 20 C and 30 C and calculation of the partition Coefficient (1-octanol/Water) with water solubility of Tebuconazole determined under study number G 02/0104/01 LEV. Bayer Industry Services, Germany, 2005/0093/03 GLP, unpublished	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				see also IIA, III.3.7 /02		
IIA, 3.10	IIA, 2.1.2 /01 2.1.3 /01	Mix, K.H.; Berg, G.	1988	Thermal stability of the Agrochemical Active Ingredient Tebuconazole. Bayer AG, PC 412 GLP, unpublished <i>A8_PC_stability_DTA_PC412_19 88_=88 10012</i> see also IIA, III.3.1 /02	Yes	Bayer CropScience AG
IIA, 3.11	IIA, 2.11.1 /01 2.11.2 /01 2.15 /01	Mueller, M.	1991	Investigation of safety-relevant parameters of Preventol A 8 (identification No. 91/04164). Bayer AG, PC 755 GLP, unpublished <i>A8_PC_safety relevant parameter_PC755_1991</i>	Yes	LANXESS Deutschland GmbH
IIA, 3.13	IIA, 2.14 /01	Imre, L.	1989	Preventol VPOC 3047 (Tebuconazole) surface tension. Bayer AG, PC 754 GLP, unpublished <i>A8_PC_surfaceTension_PC754_1 989</i>	Yes	LANXESS Deutschland GmbH
IIA, 3.15	IIA, 2.13 /01	Eberz, A.	1999	Determination of safety-relevant data of Folicur. Bayer AG, 99/00455 GLP, unpublished <i>A8_PC_safety relevant data_99 00455_1999</i>	Yes	Bayer CropScience AG
IIA, 3.15	-	Heinz, U.	2005	Determination of safety-relevant data of tebuconazole. Bayer Industry Services, Germany, 05/01054 GLP, unpublished	Yes	LANXESS Deutschland GmbH
IIA, 3.17	-	Talbott, T.D.	1988	Product Chemistry of FOLICUR Technical. Mobay Corp., USA Bayer AG, BR1614 GLP, unpublished	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				<i>A8_PC_corros_BR 1614_1988</i>		
IIA, 4.1 /01	IIA, 4.1.1 /01	Kulinna, G.	1994	Folicur, Industrial Active Component; Assay - Capillary Gas Chromatography. Bayer AG, 2201-0274001-94 Non-GLP, unpublished <i>A8_METH_assay_2201-0274001- 94E_1994</i>	Yes	Bayer CropScience AG
IIA, 4.1 /02	IIA, 4.1.3 /01	Nonn, E.	2001	Validation of GLC-method 2201- 0274001-94 - Determination of Tebuconazole (Folicur), Industrial -. Bayer AG, VB1-2201-0274001 Non GLP, unpublished <i>A8_METH_assay_VB1-2201- 0274001_2001_Validation</i>	Yes	Bayer CropScience AG
IIA, 4.1 /03	IIA, 4.1.2 /01	Nonn, E.	2002	Folicur techn. ; Nebenkomponenten - Kapillargaschromatographie. Bayer AG, 2201-0237204-02 Non GLP, unpublished <i>A8_METH_byproducts_2201- 0237204-02E_2002</i>	Yes	Bayer CropScience AG
IIA, 4.1 /04	IIA, 4.1.3 /03	Bissinger, H.	2002	Validation of GLC-method 2201- 0237204-02 - Determination of By products in Tebuconazole (Folicur), Industrial- Bayer AG, VB1-2201-0237204 Non GLP, unpublished <i>A8_METH_byproducts_VB1- 2201-0237204_2002_validation</i>	Yes	Bayer CropScience AG
IIA, 4.1 /05	II 4.1.3 /04	A, Bowen, T.	2005	First addendum to the Analytical Method AM2201-0237204-02E: "Validation of the Analytical Method for Determination of By products in Tebuconazol (Folicur)". Validation of the Analytical Method AM2201- 0237204-02E Regarding the impurities AE 2093300 and AE 1944672. Bayer AG, AF 05/027	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				Non-GLP, unpublished		
IIA, IV.4.2 /02	IIA, 4.2.4 /01	Riegner, K.	1992	Method for determination of tebuconazole in air. Bayer AG, 00278 (RA-605/92) Non GLP, unpublished <i>A8_METH_air_RA-605 92_1992_=00278</i>	Yes	Bayer CropScience AG
IIA, IV.4.2 /06	IIA, 4.2.2 /06	Weeren, R. D.; Pelz, S.	2000	Supplement E054 to method 00086: Validation of DFG method S 19 (extended revision) for the determination of residues of tebuconazole in soil. Dr. Specht & Partner, Chemische Laboratorien GmbH, Germany Bayer AG, 00086/E054 (Az.G00- 0032, BAY-0004V) GLP, unpublished <i>A8_METH_soil_BAY- 0004V_2000_validation_of_DFG S19</i>	Yes	Bayer CropScience AG
IIA, IV.4.2 /07	II 4.2.4 /02	A, Hellpointner, E.	2000	Confirmatory method for the determination of tebuconazole in air (confirmed method: 00278). Bayer AG, 00278C (MR-470/00) GLP, unpublished <i>A8_METH_air_MR470 00_2000_=00278_confirmatory</i>	Yes	Bayer CropScience AG
IIA, IV.4.2 /08	II 4.2.3 /01	A, Weeren, R. D.; Pelz, S.	2000	Validation of an analytical method (analogous to DFG method W5) for the determination of residues of tebuconazole in surface water. Dr. Specht & Partner, Chemische Laboratorien GmbH, Germany Bayer AG, 00054/M003 (Az.T3303/99) GLP, unpublished <i>A8_METH_water_00054 M003_2000_validation</i>	Yes	Bayer CropScience AG
IIA, V.5.3	-	Kugler, M.	2003	Test Report: Determination of the antimicrobial effects of Preventol A8 against fungi.	Yes	LANXESS Deutschland

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company), Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				Bayer AG GLP, unpublished <i>A8_EFF_Kugler_2003</i>		GmbH
IIA, VI.6.1.1 /01	IIA, 5.2.1 /01 5.2.2 /01 5.2.3 /01 5.2.4 /01 5.2.5 /01 5.2.7 /01	Heimann, K.G.; Pauluhn, J.; Maertins, T.	1983 (rev. 1987, 1990)	HWG 1608 - Study for acute toxicity. Bayer AG, 12168 (12168 A, 12168 B) Non-GLP, unpublished <i>A8_TOX_acSkin Inhal_12168_1983_incl amendments</i>	Yes	Bayer CropScience AG
IIA, VI.6.1.1 /02	IIA, 5.2.1 /04	Ohta, K.	1991	HWG 1608 technical - Acute oral toxicity study on mice. Nihon Bayer Agrochem K.K., Japan Bayer AG, RA 91042 GLP, unpublished <i>A8_TOX_acOral_mouse_RA9104 2_1991</i>	Yes	Bayer CropScience AG
IIA, VI.6.1.1 /03	IIA, 5.2.1 /03	Ohta, K.	1991	HWG 1608 technical - Acute oral toxicity study on rats. Nihon Bayer Agrochem K.K., Japan Bayer AG, RA 91041 GLP, unpublished <i>A8_TOX_acOral_rat_RA91041_1 991</i>	Yes	Bayer CropScience AG
IIA, VI.6.1.2 /01	IIA, 5.2.1 /01 5.2.2 /01 5.2.3 /01 5.2.4 /01 5.2.5 /01 5.2.7 /01	Heimann, K.G.; Pauluhn, J.; Maertins, T.	1983 (rev. 1987, 1990)	HWG 1608 - Study for acute toxicity. Bayer AG, 12168 (12168 A, 12168 B) Non-GLP, unpublished <i>A8_TOX_acSkin Inhal_12168_1983_incl amendments</i> see also IIA, VI.6.1.1	Yes	Bayer CropScience AG
IIA, VI.6.1.2 /02	IIA, 5.8.2 /01	Eigenberg, D.A.	1988 (rev. 1991)	Dermal absorption of 14C-HWG 1608 technical in rats. Mobay Corporation, USA Bayer AG, 4373 (97470)	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				GLP, unpublished <i>A8_TOX_derm_penetr_BC4373_1991_Revised report =97470</i>		
IIA, VI.6.1.2 /03	IIA, 5.2.2 /02	Ohta, K.	1991	HWG 1608 technical - Acute dermal toxicity study on rats. Nihon Bayer Agrochem K.K, Japan Bayer AG, RA 91029 GLP, unpublished <i>A8_TOX_acDermal_rat_RA91029_1991</i>	Yes	Bayer CropScience AG
IIA, VI.6.1.3 /01	IIA, 5.2.1 /01 5.2.2 /01 5.2.3 /01 5.2.4 /01 5.2.5 /01 5.2.7 /01	Heimann, K.G.; Pauluhn, J.; Maertins, T.	1983 (rev. 1987, 1990)	HWG 1608 - Study for acute toxicity. Bayer AG, 12168 (12168 A, 12168 B) Non-GLP, unpublished <i>A8_TOX_acSkin Inhal_12168_1983_incl amendments</i> see also IIA, VI.6.1.1	Yes	Bayer CropScience AG
IIA, VI.6.1.3 /02	IIA, 5.2.3 /02	Pauluhn, J.	1988	HWG 1608 - Study for acute inhalation toxicity to the rat to OECD-guideline no. 403. Bayer AG, 16345 GLP, unpublished <i>A8_TOX_acInhal_16345_1988</i>	Yes	Bayer CropScience AG
IIA, VI.6.1.4 /01	IIA, 5.2.1 /01 5.2.2 /01 5.2.3 /01 5.2.4 /01 5.2.5 /01 5.2.7 /01	Heimann, K.G.; Pauluhn, J.; Maertins, T.	1983 (rev. 1987, 1990)	HWG 1608 - Study for acute toxicity. Bayer AG, 12168 (12168 A, 12168 B) Non-GLP, unpublished <i>A8_TOX_acSkin Inhal_12168_1983_incl amendments</i> see also IIA, VI.6.1.1	Yes	Bayer CropScience AG
IIA, VI.6.1.4 /02	IIA, 5.2.5 /02	Eigenberg, D.A.; Sheets, L.P.	1988	Primary eye irritation of Folicur (HWG 1608) technical in albino rabbits. Mobay Corporation, USA	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company), Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				Bayer AG, BC1003 GLP, unpublished <i>A8_TOX_acEye_BC1003_1988</i>		
IIA, VI.6.1.5 /01	IIA, 5.2.6 /01	Heimann, K.G.	1983	HWG 1608 - Study for skin- sensitizing effects on guinea pigs. Bayer AG, Report No. 12024 Non-GLP, unpublished <i>A8_TOX_acSens_12024_1983</i>	Yes	Bayer CropScience AG
IIA, VI.6.1.5 /02	IIA, 5.2.6 /02	Heimann, K.G.	1987	HWG 1608 technical - Study of skin sensitization effects on guinea pigs (Buehler Patch Test). Bayer AG, 16238 GLP, unpublished <i>A8_TOX_acSens_16238_1987</i>	Yes	Bayer CropScience AG
IIA, VI.6.1.5 /03	IIA, 5.2.4 /02	Sheets, L.P.	1988	Primary dermal irritation of technical grade Folicur in rabbits. Mobay Corporation, USA Bayer AG, BC1066 GLP, unpublished <i>A8_TOX_acSkin_BC1066_1988</i>	Yes	Bayer CropScience AG
IIA, VI.6.1.5 /04	IIA, 5.2.6 /03	Sheets, L.P.	1990	Dermal sensitization study with technical grade tebuconazole (Folicur) in Guinea pigs. Mobay Corporation, USA Bayer AG, BC5052 GLP, unpublished <i>A8_TOX_acSens_BC5052_1990</i>	Yes	Bayer CropScience AG
IIA, VI.6.1.5 /05	IIA, 5.2.6 /04	Stropp, G.	1996	HWG 1608 - Study for the skin sensitization effect in guinea pigs (guinea pig maximization test according to Magnusson and Kligman). Bayer AG, 25655 GLP, unpublished <i>A8_TOX_acSens_25655_1996</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company), Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIA, VI.6.2 /01	IIA, 5.1.1 /01 6.2.1.1 /01	Weber, H.	1987	(Phenyl-U-14C) HWG 1608: Study of biokinetic behaviour in the rat. Bayer AG, PF 2859 GLP, unpublished <i>A8_TOX_metabol_PF 2859_1987</i>	Yes	Bayer CropScience AG
	-	Chopade, H.M.	1992	Addendum I - (Phenyl-U-14C) HWG 1608 - Study of biokinetic behavior in the rat, response to EPA requests and inquiries. Miles Inc., USA Bayer AG, MR 97439-1 GLP, unpublished <i>A8_TOX_metabol_97439- 1_1992_Addendum to PF 2859</i>	Yes	Bayer CropScience AG
	-	Weber, H.	1993	Addendum 2 - (Phenyl-U-14C) HWG 1608 - Study of biokinetic behavior in the rat. Raw Data and Additional Information. Bayer AG, MR 97439-2 GLP, unpublished <i>A8_TOX_metabol_97439- 2_1993_Addendum to PF 2859</i>	Yes	Bayer CropScience AG
IIA, VI.6.2 /02	IIA, 5.1.1 /02 6.2.1.1 /02	Weber, H.	1988	[Phenyl-UL-14C]) HWG 1608: Whole-body autoradiographic distribution of the radioactivity in the rat. Bayer AG, PF 2962 GLP, unpublished <i>A8_TOX_metabol_PF 2962_1988</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company), Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIA, VI.6.2 /03	II A, 5.1.2 /01 6.2.1.2 /01	Ecker, W.; Brauner, A.; Klein, O.; Weber, H.	1988	Folicur - Metabolism part of general metabolism study in the rat. Bayer AG, PF 2907 (MR 97438) GLP, unpublished <i>A8_TOX_metabol_97438_1987_ = PF 2907</i>	Yes	Bayer CropScience AG
	-	Chopade, H.M.	1991	Folicur - Metabolism part of general metabolism study in the rat. Additional Information requested by the EPA. Mobay Corp. USA Bayer AG, 97438-1 GLP, unpublished <i>A8_TOX_metabol_97438- 1_1991_Addendum to PF 2907</i>	Yes	Bayer CropScience AG
IIA, VI.6.3 /01	IIA, 5.3.3.1 /01	Heimann, K.G.; Schilde, B.	1984 (rev. 1988)	HWG 1608 - Subacute study of dermal toxicity to rabbits. Bayer AG, 12669 (12669 A) GLP, unpublished <i>A8_TOX_subacDermal_12669_1 984_incl Addendum A_1988</i>	Yes	Bayer CropScience AG
IIA, VI.6.3 /02	IIA, 5.3.1 /01	Heimann, K.G.; Kaliner, G.	1984 (rev. 1987)	HWG 1608 - Study for subacute oral toxicity to rats. Bayer AG, 13028 (13028 A) GLP, unpublished <i>A8_TOX_subacOral_13028_1984 _incl Addendum A_1987</i>	Yes	Bayer CropScience AG
IIA, VI.6.3 /03	IIA, 5.3.3.2 /01	Pauluhn, J.; Mohr, U.	1985 (rev. 1987)	HWG 1608 - Study for subacute inhalation toxicity to rat for three weeks (exposure 15 x 6 hours). Bayer AG, 13305 (13305 A) GLP, unpublished <i>A8_TOX_subacInhal_rat_13305_ 1985_incl addendum A</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company), Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIA, VI.6.3 /04	IIA, 5.3.3.2 /03	Maertins, T.	1991	HWG 1608 (c.n. Tebuconazole, proposed) - Subacute inhalation toxicity to dogs - study for cataracts. Bayer AG, 20884 GLP, unpublished <i>A8_TOX_subacInhal_dog_20884 _1991</i>	Yes	Bayer CropScience AG
IIA, VI.6.4 /01	IIA, 5.3.2.1 /01	Bomhard, E.; Schilde, B.	1986 (rev. 1987, 1991)	HWG 1608 - Subchronic toxicological study with rats - feeding for thirteen weeks. Bayer AG, 15211 (15211 A, 15211 B) GLP, unpublished <i>A8_TOX_subchrOral_rat_15211_ 1986_incl Addendum A+B_1991</i>	Yes	Bayer CropScience AG
IIA, VI.6.4 /02	IIA, 5.3.2.2 /01	von Keutz, E.; Schilde, B.	1987 (rev. 1987, 2002)	HWG 1608 - Subchronic study for toxicity to dogs with oral administration (thirteen weeks feeding study). Bayer AG, 15763 (15763 A, 15763 B) GLP, unpublished <i>A8_TOX_subchrOral_dog_15763 _1987_incl Addendum A+B_2002</i>	Yes	Bayer CropScience AG
IIA, VI.6.4 /03	-	Hockwin, O.; Wegener, A.	1989	Final Expert Opinion on the In- Vivo Examination of the Lens Using Slit-Lamp Microscope and Scheimpflug Photography and Post-Mortem Biochemistry of the Lenses from Bayer Study T 3 027 392 in Beagle Dogs. Department of Exp. Ophthalmology of the Rheinische Friedrich-Wilhelm University Bonn, Germany Non-GLP, unpublished <i>A8_TOX_dog eye_109988_1989_=BC9066</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIA, VI.6.4 /04	-	Heimann, K.G.	2004	Tebuconazole - Assessment of Eye Effects after Repeated Application in Dog. Bayer CropScience AG, Germany Bayer AG Non-GLP, unpublished <i>A8_TOX_REV_Heimann_2004_d og eye</i>	Yes	Bayer CropScience AG
IIA, VI.6.5 /01	IIA, 5.5.3 /01	von Keutz, E.; Schilde, B.	1987	HWG 1608 - Study of chronic toxicity to dogs after oral administration (twelve months feeding study). Bayer AG, 16211 GLP, unpublished <i>A8_TOX_chrOral_dog_16211_19 87</i>	Yes	Bayer CropScience AG
IIA, VI.6.5 /02	IIA, 5.5.2 /01	Bomhard, E.; Ramm, W.	1988 (rev. 1991, 1992)	HWG 1608 - Study for cancerogenicity in NMRI mice (administration in diet for up to twenty-one months). Bayer AG, 16376 GLP, unpublished <i>A8_TOX_chrOral_mouse_16376_ 1988_incl Addendum A+B_1992</i>	Yes	Bayer CropScience AG
IIA, VI.6.5 /03	IIA, 5.5.1 /01	Bomhard, E.; Ramm, W.	1988	HWG 1608 - Study for chronic toxicity and cancerogenicity in Wistar rats (administration in diet for up to two years). Bayer AG, 16375 GLP, unpublished <i>A8_TOX_chrOral_rat_16375_19 88</i>	Yes	Bayer CropScience AG
IIA, VI.6.5 /04	IIA, 5.5.3 /02	Porter, M.C.; Jasty, V.; Troup, C.M.; Hartnagel, R.E.	1989 (rev. 1993)	Safety evaluation of HWG 1608: Chronic (1 year) feeding study in dogs. Miles Inc., USA Bayer AG, R4781 (BC 4949) GLP, unpublished <i>A8_TOX_chrOral_dog_R4781_1 989</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company), Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIA, VI.6.5 /05	-	Heimann, K.G.	2004	Tebuconazole - Assessment of Eye Effects after Repeated Application in Dog. Bayer CropScience AG, Germany Bayer AG Non-GLP, unpublished <i>A8_TOX_REV_Heimann_2004_d og eye</i> see also IIA, VI.6.3 /04	Yes	Bayer CropScience AG
IIA, VI.6.6 /01	IIA, 5.4.1 /07	Cifone, M.A.	1987 (rev. 1988)	HWG 1608 - Mutagenicity test in the rat primary hepatocyte unscheduled DNS synthesis assay. Hazleton Laboratories Inc., USA Bayer AG, R 4111 A GLP, unpublished <i>A8_TOX_mut_UDS_R4111A_198 7</i>	Yes	Bayer CropScience AG
IIA, VI.6.6 /02	IIA, 5.4.1 /03	Putman, D.L.	1987	Sister chromatid exchange assay in chinese hamster ovary (CHO) cells. Microbiological Associates Inc. Bayer AG, R 953 GLP, unpublished <i>A8_TOX_mut_HPRT_BC953_19 87</i>	Yes	Bayer CropScience AG
IIA, VI.6.6.1 /02	IIA, 5.4.1 /02	Herbold, B.	1983 (rev. 1990)	HWG 1608 - Salmonella/microsome test for determination of point mutations. Bayer AG, 12086 GLP, unpublished <i>A8_TOX_mut_ames_12086_1983 _incl addendum A</i>	Yes	Bayer CropScience AG
IIA, VI.6.6.1 /02	IIA, 5.4.1 /04	Herbold, B.	1988 (rev. 1988)	HWG 1608 - Salmonella/microsome test to evaluate for point mutagenic effects. Bayer AG, 16383 (16383 A) GLP, unpublished <i>A8_TOX_mut_ames_16383_1988 _incl addendum A</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company), Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIA, VI.6.6.1 /03	IIA, 5.4.1 /08	Ohta, K.	1991	HWG 1608 - Reverse mutation assay (Salmonella typhimurium and Escherichia coli). Nihon Bayer Agrochem K.K., Japan Bayer AG, RA 91036 GLP, unpublished <i>A8_TOX_mut_RA91036_1991</i>	Yes	Bayer CropScience AG
IIA, VI.6.6.1 /04	IIA, 5.4.1 /09	Ohta, K.	1992	HWG 1608 - Rec-assay with spores in the bacterial system. Nihon Bayer Agrochem K.K., Japan Bayer AG, RA 92007 GLP, unpublished <i>A8_TOX_mut_RA92007_1992</i>	Yes	Bayer CropScience AG
IIA, VI.6.6.2	IIA, 5.4.1 /05	Herbold, B.	1988	HWG 1608 - In vitro cytogenetic study with human lymphocytes for the detection of induced clastogenic effects. Bayer AG, 16395 GLP, unpublished <i>A8_TOX_mut_lymph_16395_1988</i>	Yes	Bayer CropScience AG
IIA, VI.6.6.3	IIA, 5.4.1 /06	Lehn, H.	1988	HWG 1608 - Mutagenicity study for the detection of induced forward mutations in the CHO- HGPRT assay in vitro. Bayer AG, 16749 GLP, unpublished <i>A8_TOX_mut_HPRT_16749_1988</i>	Yes	Bayer CropScience AG
IIA, VI.6.6.4	IIA, 5.4.2 /01	Herbold, B.	1985	HWG 1608 - Micronucleus test on the mouse to evaluate for mutagenic effect. Bayer AG, 13159 GLP, unpublished <i>A8_TOX_mut_micronuc_13159_1985</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company), Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIA, VI.6.6.6	IIA, 5.4.2 /02	Herbold, B.	1986	HWG 1608 - Dominant lethal test on the male mouse to evaluate for mutagenic effect. Bayer AG, 14985 GLP, unpublished <i>A8_TOX_mut_dominant_14985_1 986</i>	Yes	Bayer CropScience AG
IIA, VI.6.6.7	IIA, 5.4.1 /01	Herbold, B.	1983	HWG 1608 - Pol Test on E. coli to evaluate for harmful effects on DANN. Bayer AG, 11902 Non-GLP, unpublished <i>A8_TOX_mut_11902_1983</i>	Yes	Bayer CropScience AG
IIA, VI.6.8.1 /01	IIA, 5.6.2.2 /01	Renhof, M.	1985	HWG 1608 - Study for embryotoxic effects on rabbits after oral administration. Bayer AG, 13287 GLP, unpublished <i>A8_TOX_tera_rabbit_13287_198 5</i>	Yes	Bayer CropScience AG
IIA, VI.6. 8.1 /02	IIA, 5.6.2.1 /01	Renhof, M.	1985	HWG 1608 - Study for embryotoxic effects on rats after oral administration. Bayer AG, 13273 GLP, unpublished <i>A8_TOX_tera_rat_oral_13273_1 985</i>	Yes	Bayer CropScience AG
IIA, VI.6. 8.1 /04	IIA, 5.6.2.3 /01	Renhof, M.	1988 (rev. 1991)	HWG 1608 - Study for embryotoxic effects on mice following oral administration. Bayer AG, 16527 GLP, unpublished <i>A8_TOX_tera_mouse_oral_1652 7_1988_=97411</i>	Yes	Bayer CropScience AG
IIA, VI.6. 8.1 /05	IIA, 5.6.2.1 /03	Renhof, M.	1988	HWG 1608 - Study for embryotoxic effects on rats after dermal administration. Bayer AG, 17089 GLP, unpublished <i>A8_TOX_tera_rat_dermal_17089</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				_1988		
IIA, VI.6.8.1 /06	IIA, 5.6.2.3 /02	Renhof, M.; Karbe, E.; Heimann, K.G.	1988 (rev. 2000)	HWG 1608 - Supplementary study for maternal toxicity on mice following oral administration. Bayer AG, 16511 GLP, unpublished <i>A8_TOX_tera_mouse_oral_1651 1_1988</i>	Yes	Bayer CropScience AG
IIA, VI.6.8.1 /07	IIA, 5.6.2.2 /02	Becker, H.; Vogel, W.; Terrier, C.	1988	Embryotoxicity study (including teratogenicity) with HWG 1608 technical in the rabbit. RCC, Switzerland Bayer AG, R 4323 GLP, unpublished <i>A8_TOX_tera_rabbit_R4323_198 8</i>	Yes	Bayer CropScience AG
IIA, VI.6.8.1 /08	IIA, 5.6.2.1 /02	Becker, H.; Vogel, W.; Terrier, C.	1988 (rev. 1991)	Embryotoxicity study (including teratogenicity) with HWG 1608 technical in the rat. RCC, Switzerland Bayer AG, R 4451 (R 4451 A) GLP, unpublished <i>A8_TOX_tera_rat_oral_R4451_1 988_incl addendum A</i>	Yes	Bayer CropScience AG
IIA, VI.6.8.1 /09	IIA, 5.6.2.3 /04	Becker, H.; Biedermann, K.; Terrier, C.; Vogel, O.; Luetkemeier, H.	1990	Embryotoxicity study (including teratogenicity) with HWG 1608 technical in the mouse (dermal application). RCC, Switzerland Bayer AG, R 5116 GLP, unpublished <i>A8_TOX_tera_mouse_dermal_R5 116_1990</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company), Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIA, VI.6.8.1 /10	IIA, 5.6.2.2 /03	Becker, H.; Biedermann, K.	1995 (rev. 2001)	Combined report of embryotoxicity study (including teratogenicity) and supplementary investigations on the maternal toxicity of HWG 1608 technical (c n. Tebuconazole) in pregnant rabbits. RCC, Switzerland Bayer AG, R 6377 (R6377 A) GLP, unpublished <i>A8_TOX_tera_rabbit_R6377_1995</i>	Yes	Bayer CropScience AG
IIA, VI.6.8.1 /11	IIA, 5.6.2.3 /03	Becker, H.; Biedermann, K.	1995	Combined report of embryotoxicity study (including teratogenicity) and supplementary embryotoxicity study (including teratogenicity) with HWG 1608 technical (c n. Tebuconazole) in the mouse. RCC, Switzerland Bayer AG, R 6378 GLP, unpublished <i>A8_TOX_tera_mouse_oral_R6378_1995</i>	Yes	Bayer CropScience AG
IIA, VI.6.8.1 /12	IIA, 5.6.2.1 /04	Becker, H.; Biedermann, K.	1995	Limit test of embryotoxicity (including teratogenicity) with HWG 1608 technical (c n. Tebuconazole) in the rat (dermal application). RCC, Switzerland Bayer AG, R 6365 GLP, unpublished <i>A8_TOX_tera_rat_dermal_R6365_1995</i>	Yes	Bayer CropScience AG
IIA, VI.6.8:2	IIA, 5.6.1 /01	Eiben, R.	1987	HWG 1608 - Two-generation study in rats. Bayer AG, 16223 GLP, unpublished <i>A8_TOX_generation_16223_1987</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company), Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIA, VI.6.9.1 /01	IIA, 5.9.1 /01	Kollert, W.	1987	HWG 1608 - Internal experiences. Bayer AG, MO-00-002131 Non-GLP, unpublished <i>A8_TOX_humans_Kollert_1987</i>	Yes	Bayer CropScience AG
IIA, VI.6.9.1 /02	IIA, 5.9.1 /02	Faul, J.; Krauthausen, E.	1995	HWG 1608 - In-company experience, Bayer AG Bayer CropScience AG, Germany Bayer AG, MO-00-002188 Non-GLP, unpublished <i>A8_TOX_humans_Faul et al_1995</i>	Yes	Bayer CropScience AG
IIA, VI.6.9.1 /03	IIA, 5.9.1 /03	Metz, T.E.; Tice, M.A.; Wey, J.M.	1996	HWG 1608 - In company experience, production employees, Bayer Corporation Bayer AG, MO-00-014783 Non-GLP, unpublished <i>A8_TOX_humans_Metz et al_1996</i>	Yes	Bayer CropScience AG
IIA, VI.6.9.1 /04	IIA, 5.9.1 /04	Wey, J.M.; Forbes, J.D.	1997	HWG 1608 - Medical certification for tebuconazole and its formulation. Bayer Corporation, USA Bayer AG, MO-00-002189 GLP, unpublished <i>A8_TOX_humans_Wey et al_1997</i>	Yes	Bayer CropScience AG
IIA, VI.6.9.7 /01	IIA, 5.9.5 /01	Reuver, I.	1987	Guidance for the physician - HWG 1608 Bayer AG, MO-00-002119 Non-GLP, unpublished <i>A8_TOX_humans_Reuver_1987</i>	Yes	Bayer CropScience AG
IIA, VI.6.9.7 /02	IIA, 5.9.5 /02	Doull, J.; Rozman, K.K.	1996	Treatment of poisoning by Folicur technical. The University of Kansas Medical Center, USA Bayer AG, BC7984 Non-GLP, unpublished <i>A8_TOX_humans_107444_1996_ =7984</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIA, VII.7.1 /01	IIA, 8.2.1 /03	Surprenant, D.C.	1987	Acute toxicity of HWG 1608 (Technical grade) to Bluegill (<i>Lepomis macrochirus</i>) under flow-through conditions. Springborn Life Sciences, Inc., USA Bayer AG, 94861 (955) GLP, unpublished <i>A8_ECO_fish_ac_94861_1987_= 955</i>	Yes	Bayer CropScience AG
IIA, VII.7.1 /02	IIA, 8.2.1 /02	Surprenant, D.C.	1987	Acute toxicity of HWG 1608 (Technical grade) to Rainbow Trout (<i>Salmo gairdneri</i>) under flow-through conditions. Springborn Life Sciences, Inc., USA Bayer AG, 94860 (954) GLP, unpublished <i>A8_ECO_fish_ac_94860_1987_= 954</i>	Yes	Bayer CropScience AG
IIA, VII.7.1 /03	IIA, 8.2.1 /01	Grau, R.	1987	Fish toxicity - HWG 1608 - Golden Orfe. Bayer AG, FO-682 A Non-GLP, unpublished <i>A8_ECO_fish_ac_FO- 682A_1987_English</i>	Yes	Bayer CropScience AG
IIA, VII.7.1 /04	IIA, 8.2.1 /04	Surprenant, D.C.	1988	Acute Toxicity of Technical Grade HWG 1608 to Sheepshead Minnow (<i>Caprinodon variegatus</i>) under Flow-Trough Conditions. Springborn Life Sciences, USA Bayer AG, 97467 GLP, unpublished <i>A8_ECO_fish_ac_97467_1988</i>	Yes	Bayer CropScience AG
IIA, VII.7.1 /05	IIA, 8.2.1 /07	Rufli, H.	1983	Report on the test for acute toxicity of CGA 98032 to rainbow trout. Ciba-Geigy, Basel (Switzerland), 821418 Non-GLP, unpublished	Yes	TDMG (triazole derivative metabolites group)
IIA,	IIA,	Forbis, A.D.	1988 (rev.	Acute Flow-Through of HWG 1608 to <i>Daphnia magna</i> .	Yes	Bayer CropScience

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
VII.7.2 /01	8.2.4 /01		1993)	ABC, USA Bayer AG, 96791 GLP, unpublished <i>A8_ECO_daphnia_ac_96791_19 88_incl supplement</i>		AG
	IIA, 8.2.4 /01	Gagliano, G.G.	1988	Raw Data Supplemental for Acute Flow-Through of HWG 1608 to <i>Daphnia magna</i> . ABC, USA Bayer AG, 96791-1 GLP, unpublished <i>A8_ECO_daphnia_ac_96791_19 88_incl supplement</i>	Yes	Bayer CropScience AG
IIA, VII.7.2 /02	IIA, 8.2.4 /04	Bell, G.	1997	Fluquinconazole, technical material, 100.8% w/w - 1,2,4 triazole: acute toxicity to <i>Daphnia magna</i> . Huntingdon Life Sciences, Huntingdon (UK), ENVIR/95/52 GLP, unpublished	Yes	TDMG (triazole derivative metabolites group)
IIA, VII.7.3 /01	IIA, 8.2.6 /01	Heimbach, F.	1987	Growth inhibition of green algae (<i>Scenedesmus subspicatus</i>) caused by HWG 1608 (technical). Bayer AG, HBF/AL 31 GLP, unpublished <i>A8_ECO_algae_HBF Al 31_1987</i>	Yes	Bayer CropScience AG
IIA, VII.7.3 /02	IIA, 8.2.6 /02	Bowers, L.M.	1996	Toxicity of Folicur technical to the green alga <i>Selenastrum capricornutum</i> . Bayer Corp., USA Bayer AG, 107341 GLP, unpublished <i>A8_ECO_algae_107341_1996</i>	Yes	Bayer CropScience AG
IIA, VII.7.3 /03	IIA, 8.2.6 /05	Palmer S.J.; Kendall T.Z.; Krueger H.O.	2001	1,2,4-triazole: A 96 hours toxicity test with the freshwater alga (<i>Selenastrum capricornutum</i>). Wildlife International Ltd, (USA), 528A 101 GLP, unpublished	Yes	TDMG (triazole derivative metabolites group)
IIA,	IIA,	Mueller, G.	1993 (rev.	Studies on the Ecological Behaviour of Preventol A8. Bayer	Yes	LANXESS Deutschland

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
VII.7.4 /01	8.7 /01		2000)	AG, 419 A/93 GLP, unpublished <i>A8_ECO_bacteria_419 A 93_1993</i>		GmbH
IIA, VII.7.4 /02	IIA, 8.5 /02	Anderson, J.P.E.	2001	Influence of Folicur (tebuconazole) EW 250 on the microbial mineralization of nitrogen in soils. Bayer AG, AJO/217701 GLP, unpublished <i>A8_PREP_EW 250_ECO_soil_microorg_AJO 217701_2001</i>	Yes	Bayer CropScience AG
IIA, VII.7.4 /07	IIA, 8.5 /01	Anderson, J.P.E.	2001	Influence of Folicur (tebuconazole) EW 250 on glucose stimulated respiration in soils. Bayer AG, AJO/217601 GLP, unpublished <i>A8_PREP_EW 250_ECO_soil_microorg_AJO 217601_2001</i>	Yes	Bayer CropScience AG
IIA, VII.7.5 /01	IIA, 8.2.3 /01	Grau, R.; Ecker, W.; Klein, O.	1988	Bioaccumulation of HWG 1608 in Bluegill Sunfish. Bayer AG, BF-001 (PF2932) GLP, unpublished <i>A8_ECO_bioacc_fish_BF 001_1988_=PF2932</i>	Yes	Bayer CropScience AG
IIA, VII.7.5 /02	IIA, 8.2.3 /02	Surprenant, D.C.	1988	Bioconcentration and Elimination of ¹⁴ C-Residues by Bluegill (<i>Lepomis macrochirus</i>) exposed to HWG 1608. Sprinborn Life Sciences, USA Bayer AG, 98036 (M 6253) GLP, unpublished <i>A8_ECO_bioacc_fish_MR98036_ 1988</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company), Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIA, VII.7.5 /03	-	Mulford, D.J.	1988	Identification of residues from bluegill sunfish exposed to Folicur. Mobay Chemical Corporation, USA Bayer AG, MR98037 <i>A8_ECO_bioacc_fish_MR98037_1988</i>	Yes	Bayer CropScience AG
IIA, VII.7.5 /04	-	Leimkuehler, W.M.; Moore, K.S.	1992	Identification of radioactive residues of triazole-3,5-[14C] tebuconazole in the nonedible fraction of bluegill sunfish (<i>Lepomis macrochirus</i>). Miles Incorp., USA Bayer AG, MR98037-1 GLP, unpublished <i>A8_ECO_bioacc_fish_MR98037-1_1992</i>	Yes	Bayer CropScience AG
IIA, VII.7.5 /05	-	Nisikawa, A.	1992	Bioaccumulation Study of Preventol A 8 with Carp (<i>Cyprinus carpio</i>). Mitsubishi-kasei Institute of Toxicological and Environmental Sciences (MITES), Japan Bayer AG, 1 B 454 G (M7619) GLP, unpublished <i>A8_ECO_bioacc_fish_1 B 454 G_1992_=M7619</i>	Yes	LANXESS Deutschland GmbH
IIA, VII.7.6.1.1 /01	-	Kanne, R.	1989	Biodegradation of Preventol VPOC 3047. Bayer AG, 94 N/89 GLP, unpublished <i>A8_ECO_degr_94N 89_1989_English</i>	Yes	LANXESS Deutschland GmbH
IIA, VII.7.6.1.1 /02	-	Yoshida, K.	1991	Ready Biodegradability Test. Mitsubishi-kasei Institute of Toxicological and Environmental Sciences (MITES), Japan Bayer AG, 1 B 232 G GLP, unpublished <i>A8_ECO_degr_1B232G_1991</i>	Yes	LANXESS Deutschland GmbH

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIA, VII.7.6.2.1 /01	IIA, 7.2.1.1 /01 2.9.1 /01	Coffmann, M.W.; Sietsema, W.K.	1984 (rev. 1988)	Hydrolysis Study of BAY HWG 1608 in Sterile Aqueous Buffered Solutions. Mobay Corp., USA Bayer AG, MR 88726 Non-GLP, unpublished <i>A8_PC_hydrolysis_MR88726_19 84</i>	Yes	Bayer CropScience AG
IIA, VII.7.6.2.1 /02	-	Krohn, J.	1984	Behaviour of agrochemical in water: active substance HWG1608. Bayer AG, M 2618 GLP, unpublished <i>A8_PC_hydrolysis_M2618_1984 _English</i>	Yes	Bayer CropScience AG
IIA, VII.7.6.2.1 /03	II A, 7.2.1.1 /02	A, Spare, W.C.	1983	Determination of the hydrolysis rate constants of 1,2,4-triazole. Ciba-Geigy Corporation (U.S.A.), meanwhile owned by the TDMG, 83-E-074 Non-GLP, unpublished	Yes	TDMG (triazole derivative metabolites group)
IIA, VII.7.6.2.2 /01	IIA, 2.9.2 /01 7.1.1.1.2 /02 7.2.1.2 /01	Coody, P.N.	1987	Photodecomposition of Folicur in Soil and Water. Mobay Corp., USA Bayer AG, MR 94901 Non-GLP, unpublished <i>A8_ECO_degr_photo_94901_198 7</i>	Yes	Bayer CropScience AG
IIA, VII.7.6.2.2 /02	IIA, 7.2.1.2 /02 2.9.3 /01	Hellpointner, E.	1990	Determination of the quantum yield and assessment of the environmental half-life of the direct photo-degradation of Tebuconazole in water. Bayer AG, PF 3370 GLP, unpublished <i>A8_ECO_degr_water_PF- 3370_1990</i>	Yes	Bayer CropScience AG
IIA, VII.7.6.2.2 /03	IIA, 7.2.1.2 /03	Miller, G.C.	1983	Sunlight photolysis of 1,2,4 triazole in distilled water and humic acid solutions. University of Nevada Reno, USA, ordered by Ciba Geigy, now	Yes	TDMG (triazole derivative metabolites)

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				Syngenta AG, M9224 Non-GLP, unpublished		group)
IIA, VIII.8.1	-	Anon.	2003	Material Safety Data Sheet "Preventol A 8", No. 327445/27 Bayer AG Non-GLP, unpublished <i>A8_MSDS_327445 27_2003_English</i> see also IIA, III.3.1 /03	-	LANXESS Deutschland GmbH
IIA, VIII.8.2	-	Anon.	2003	Material Safety Data Sheet "Preventol A 8", No. 327445/27 Bayer AG Non-GLP, unpublished <i>A8_MSDS_327445 27_2003_English</i> see also IIA, III.3.1 /03	-	LANXESS Deutschland GmbH
IIA, VIII.8.3 /01	IIA, 5.9.5 /02	Doull, J.; Rozman, K.K.	1996	Treatment of poisoning by Folicur technical. The University of Kansas Medical Center, USA Bayer AG, BC7984 Non-GLP, unpublished <i>A8_TOX_humans_107444_1996_ =7984</i> see also IIA, VI.6.9.7	Yes	Bayer CropScience AG
IIA, VIII.8.3 /02	-	Anon.	2003	Material Safety Data Sheet "Preventol A 8", No. 327445/27 Bayer AG Non-GLP, unpublished <i>A8_MSDS_327445 27_2003_English</i> see also IIA, III.3.1 /03	-	LANXESS Deutschland GmbH
IIA, VIII.8.4	-	Anon.	2003	Material Safety Data Sheet "Preventol A 8", No. 327445/27 Bayer AG Non-GLP, unpublished <i>A8 MSDS 327445</i>	-	LANXESS Deutschland GmbH

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company), Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				<i>27_2003_English</i> see also IIA, III.3.1 /03		
IIA, VIII.8.5	-	Anon.	2003	Material Safety Data Sheet "Preventol A 8", No. 327445/27 Bayer AG Non-GLP, unpublished <i>A8_MSDS_327445</i> <i>27_2003_English</i> see also IIA, III.3.1 /03	-	LANXESS Deutschland GmbH
IIA, VIII.8.6	-	Anon.	2003	Material Safety Data Sheet "Preventol A 8", No. 327445/27 Bayer AG Non-GLP, unpublished <i>A8_MSDS_327445</i> <i>27_2003_English</i> see also IIA, III.3.1 /03	-	LANXESS Deutschland GmbH

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
III A, III	II A, 2.9.4 /01	Placke, F.J.	1987	Dissociation constant of HWG 1608 at 20°C. Bayer AG, PC 414 Non-GLP, unpublished <i>A8_PC_dissociation_PC414_1987</i>	Yes	Bayer CropScience AG
III A, III.1	II A, 2.7 /01	Krohn, J.	1988	Solubility of tebuconazole (HWG 1608) in organic solvents. Bayer AG, PC 433 GLP, unpublished <i>A8_PC_solubility_orgSolv_PC433_1988</i>	Yes	Bayer CropScience AG
III A, VI.1 /01	II A, 5.8.3 /01	Sheets, L.P.; Gilmore, R.G.; Hamilton, B.F.	1997 (rev. 1998)	An acute oral neurotoxicity screening study with technical grade tebuconazole (Folicur) in Fischer 344 rats. Bayer Corporation, USA Bayer AG, BC8386 (107782) GLP, unpublished <i>A8_TOX_acOral_107782_1997_ =BC8386_neurotox</i>	Yes	Bayer CropScience AG
III A, VI.1 /02	II A, 5.8.4 /01	Sheets, L.P.; Gilmore, R.G.; Hamilton, B.F.	1998	A subchronic dietary neurotoxicity screening study with technical grade tebuconazole in Fischer 344 rats. Bayer Corporation, USA Bayer AG, BC8483 (108029) GLP, unpublished <i>A8_TOX_subchrOral_BC8483_1998_neurotox</i>	Yes	Bayer CropScience AG
III A, VII.5	II A, 2.10 /01 7.2.2.3 /01	Hellpointner, E.	1993	Calculation of chemical lifetime of tebuconazole in the troposphere. Bayer AG, PF 3808 Non-GLP, unpublished <i>A8_ECO_degr_troposphere_PF-3808_1993</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIIA, XII.1.1 /01	IIA, 2.9.2 /01 7.1.1.1.2 /02 7.2.1.2 /01	Coody, P.N.	1987	Photodecomposition of Folicur in Soil and Water. Mobay Corp., USA Bayer AG, MR 94901 Non-GLP, unpublished <i>A8_ECO_degr_photo_94901_19 87</i> see also IIA, VII.7.6.2.2	Yes	Bayer CropScien ce AG
IIIA, XII.1.1 /05		Werthmann, U.	1987	Leaching behaviour of pesticides - Active ingredient: Tebuconazole/Bay 12540: HWG 1608 (250 EC) Standard soil 2.1: Report No.: RR10638/86; Standard soil 2.2: Report No.: RR10639/86; Standard soil 2.3: Report No.: RR10640/86, Bayer AG GLP, unpublished <i>A8_ECO_degr_soil_RR10638 86_1987</i> <i>A8_ECO_degr_soil_RR10639 86_1987</i> <i>A8_ECO_degr_soil_RR10640 86_1987</i>	Yes	Bayer CropScien ce AG
IIIA, XII.1.1 /02	IIA, 7.1.3.2 /01	Fritz, R.	1987	Leaching behaviour of HWG 1608 Folicur (TM) aged in soil. Bayer AG, PF 2895 Non-GLP, unpublished <i>A8_ECO_leaching_soil_PF2895 _1987</i>	Yes	Bayer CropScien ce AG
IIIA, XII.1.1 /03	IIA, 7.1.1.1.1 /01 7.1.1.1.2 /01	Lee, S.G.K.; Hanna-Bey, L.A.	1987	The metabolism of Folicur (TM) in soil. Mobay Corp., USA Bayer AG, MR 94369 GLP, unpublished <i>A8_ECO_degr_soil_MR94369_1 987</i>	Yes	Bayer CropScien ce AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIIA, XII.1.1 /04	IIA, 7.1.1.1.1 /02 7.1.1.2.1 /01	Fritz, R.; Brauner, A.	1989	Supplementary experiment on the degradation of tebuconazole in soil. Bayer AG, PF 3285 Non-GLP, unpublished <i>A8_ECO_degr_soil_PF3285_1989</i>	Yes	Bayer CropScience AG
IIIA, XII.1.1 /05	IIA, 7.1.1.2.2 /21	Sommer, H.	1997	Dissipation of Tebuconazole in soils under field conditions (France, Italy). Bayer AG, RA-2086/95 GLP, unpublished <i>A8_ECO_degr_soil_RA-2086 95_1997</i>	Yes	Bayer CropScience AG
IIIA, XII.1.1 /06	IIA, 7.1.1.2.2 /28	Allmendinger, H.	1997	Five-year long-term trial for the determination of residues of Folicur (250 EC, 250 EW) in soil in the United Kingdom. Bayer AG, RA-2106/95 GLP, unpublished <i>A8_PREP_EC 250_ECO_degr_soil_RA-2106 95_1997</i>	Yes	Bayer CropScience AG
IIIA, XII.1.1 /07	IIA, 7.1.1.2.2 /22	Schramel, O.	2001	Dissipation of tebuconazole (Folicur 250 EW) in soil under field conditions (France, Germany, UK). Bayer AG, RA-2095/00 GLP, unpublished <i>A8_ECO_degr_soil_RA-2095 00_2001</i>	Yes	Bayer CropScience AG
IIIA, XII.1.1 /08	IIA, 7.1.1.2.2 /23	Schad, T.	2001	Calculation of temperature referenced first order DT50 values of tebuconazole based on field dissipation studies conducted in Europe. Bayer AG, MR-554/01 Non-GLP, unpublished <i>A8_ECO_degr_soil_MR-554 01_2001_calculation</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIIA, XII.1.1 /09	IIA, 7.1.1.2.2 /24	Schad, T.	2002	Calculation of temperature referenced first order DT50 values of Tebuconazole based on field dissipation studies conducted in Southern Europe. Bayer AG, MR-344/02 Non-GLP, unpublished <i>A8_ECO_degr_soil_MR-344_02_2002_calculation</i>	Yes	Bayer CropScience AG
IIIA, XII.1.1 /10	IIA, 7.1.1.2.1 /02	Slangen, P.J.	2000	Degradation of 1,2,4-triazole in three soils under aerobic conditions. NOTOX, s-Hertogenbosch (The Netherlands), MM 71 GLP, unpublished	Yes	TDMG (triazole derivative metabolites group)
IIIA, XII.1.2 /01	IIA, 7.1.2 /01	Fritz, R.	1988	Adsorption/desorption of Folicur (TM) (HWG 1608) on soils. Bayer AG, PF 2923 Non-GLP, unpublished <i>A8_ECO_adsDes_soil_PF2923_1988</i>	Yes	Bayer CropScience AG
IIIA, XII.1.2 /02	IIA, 7.1.2 /02	Fritz, R.	1993	Adsorption/Desorption of Tebuconazole on Lysimeter Soils Originated from "Borstel" and "Laacher Hof". Bayer AG, PF 3875 GLP, unpublished <i>A8_ECO_adsDes_soil_PF3875_1993</i>	Yes	Bayer CropScience AG
IIIA, XII.1.2 /03	IIA, 7.1.2 /03	Hawkins, D.R.	1988	Soil adsorption and desorption of 1,2,4-triazole. Rohm and Haas (USA), 34S-88-27 GLP, unpublished	Yes	TDMG (triazole derivative metabolites group)
IIIA, XII.1.3	-	Smyser, B.P.; Lenz, C.A.	1987	Leaching of Aged Residues of FOLICUR-14C. Mobay Corporation, USA Bayer AG, MR 94801 GLP, unpublished <i>A8_ECO_leaching_soil_MR94801_1987</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIIA, XII.2.1 /01	IIA, 7.2.1.3.2 /01	Fritz, R.	1987	Degradation behaviour of HWG 1608 Folicur(TM) in an aquatic model ecosystem, Part 1. Bayer AG, PF 2821 Non-GLP, unpublished <i>A8_ECO_degr_aquatic eco system_PF 2821_1987_English</i>	Yes	Bayer CropScien ce AG
IIIA, XII.2.1 /02	IIA, 7.2.1.3.2 /02	Fritz, R.	1987	Degradation behaviour of HWG 1608 Folicur(TM) in an aquatic model ecosystem, Part 2. Bayer AG, PF 2890 Non-GLP, unpublished <i>A8_ECO_degr_aquatic eco system_PF 2890_1987_English</i>	Yes	Bayer CropScien ce AG
IIIA, XII.2.1 /03	IIA, 7.2.1.3.2 /03	Fritz, R.	1988	Degradation behaviour of HWG 1608 Folicur(TM) in an aquatic model ecosystem, Part 3. Bayer AG, PF 3069 Non-GLP, unpublished <i>A8_ECO_degr_aquatic eco system_PF 3069_1988</i>	Yes	Bayer CropScien ce AG
IIIA, XII.2.1 /04	IIA, 7.2.1.3.2 /04	Fritz, R.	1988	Degradation behaviour of HWG 1608 Folicur(TM) in Rhine water. Bayer AG, PF 3070 Non-GLP, unpublished <i>A8_ECO_degr_water_PF 3070_1988</i>	Yes	Bayer CropScien ce AG
IIIA, XII.2.1 /05	IIA, 7.2.1.3.2 /08	Guenther, U.; Herrmann, R.A.	1989	Biological effects as well as distribution and fate of HWG 1608 EC 250 (Folicur) in a pond ecosystem. Ökolimna, Germany Bayer AG, F-89431 Non-GLP, unpublished <i>A8_ECO_pond_F-89431_1989</i>	Yes	Bayer CropScien ce AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIIA, XII.2.1 /06	IIA, 7.2.1.3.2 /07	Fritz, R.	1990	Balance experiments on the degradation of tebuconazole in natural water with the exposure to artificial light. Bayer AG, PF 3596 GLP, unpublished <i>A8_ECO_degr_water_PF3596_1991</i>	Yes	Bayer CropScience AG
IIIA, XII.2.1 /07	IIA, 7.2.1.3.2 /06	Fritz, R.	1990	Experiments on the degradation of tebuconazole in natural water at different rates of application and with the addition of "sensitizers" with exposure to sunlight. Bayer AG, PF 3595 GLP, unpublished <i>A8_ECO_degr_water_PF-3595_1990</i>	Yes	Bayer CropScience AG
IIIA, XII.2.1 /08	IIA, 7.2.1.3.2 /05	Fritz, R.; Brauner, A.	1990	Experiments on the environmentally relevant degradation of tebuconazole in water. Bayer AG, PF 3594 Non-GLP, unpublished <i>A8_ECO_degr_water_PF-3594_1990</i>	Yes	Bayer CropScience AG
IIIA, XII.2.1 /09	IIA, 7.2.1.3.2 /09	Heimbach, F.	2003 (rev. 2003)	Fate of Tebuconazole EW 250 in outdoor microcosms. Bayer CropScience AG, Germany Bayer AG HBF/MT 15 GLP, unpublished <i>A8_PREP_EW 250_ECO_pond_HBF MT 15_2003</i>	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIIA, XII.2.2	IIA, 7.2.1.3.2 /10	Chapple, A, K.; Hammel, K.; Schad, T.	2003	Kinetic evaluation of the dissipation of tebucoazole in a mesocosm water-sediment system by inverse modelling using the PEST program and TOXSWA model. Bayer CropScience AG, Germany Bayer AG, MEF-284/03 Non-GLP, unpublished <i>A8_ECO_pond_MEF-284 03_2003_Calculation</i>	Yes	Bayer CropScienc ce AG
IIIA, XIII.1.1	IIA, 8.1.1 /01	Stubblefield, W.A.	1987	HWG 1608 technical - Acute LD50 to bobwhite quail. Mobay Corp., USA Bayer AG, 828 GLP, unpublished <i>A8_ECO_birds_ac_quail_828_1 987</i>	Yes	Bayer CropScienc ce AG
IIIA, XIII.1.2 /01	IIA, 8.1.2 /01	Toll, P.A.	1988	HWG 1608 (FOLICUR) Subacute dietary LC 50 to bobwhite quail. Mobay Corp., USA Bayer AG, 1023 GLP, unpublished <i>A8_ECO_birds_subac_quail_102 3_1988</i>	Yes	Bayer CropScienc ce AG
IIIA, XIII.1.2 /02	IIA, 8.1.2 /02	Toll, P.A.	1988	HWG 1608 Subacute dietary LC 50 to mallard ducks. Mobay Corp., USA Bayer AG, 1024 GLP, unpublished <i>A8_ECO_birds_subac_duck_102 4_1988</i>	Yes	Bayer CropScienc ce AG
IIIA, XIII.2.1	IIA, 8.2.2.1 /01	Scheerbaum, D.	1999	HT 308 technical; fish (rainbow trout), prolonged toxicity test, 21 days (semi static). Source: Dr. U. Noack- Laboratorium Owner: Irvita Plant Protection N.V., co owned by Bayer CropScience AG, FVR60962	Yes	Irvita Plant Protection N.V. + Bayer CropScienc ce AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				GLP, unpublished <i>A8_ECO_fish_chr_FVR60692_1 999_TASK FORCE</i>		
IIIA, XIII.2.2 /01	IIA, 8.2.2.2 /01	Surprenant, D.C.	1988	The toxicity of HWG 1608 technical to rainbow trout (<i>Salmo gairdneri</i>) embryos and larvae. Springborn Life Sciences, USA Bayer AG, 96723 (including supplement No. 99628) GLP, unpublished <i>A8_ECO_fish_repro_96723_198 8_ELS_incl 99628</i>	Yes	Bayer CropScien ce AG
IIIA, XIII.2.2 /02	IIA, 8.2.2.2 /02	Ward, G.S.	1991	BAY HWG 1608, toxicity to embryos and larvae of the sheepshead minnow (<i>Cyprinodon variegatus</i>) under flow through test conditions. Mobay Corp., USA Bayer AG, 101328 GLP, unpublished <i>A8_ECO_fish_repro_101328_19 91_ELS</i>	Yes	Bayer CropScien ce AG
IIIA, XIII.2.2 /03	IIA, 8.2.2.3 /01	Wheat, J.	1993	HWG 1608 (tebuconazole): Life cycle chronic toxicity to the sheepshead minnow (<i>Cyprinodon variegatus</i>) under flow through conditions. Miles Inc., USA Bayer AG, 105169 GLP, unpublished <i>A8_ECO_fish_repro_105169_19 93_life-cycle</i>	Yes	Bayer CropScien ce AG
IIIA, XIII.2.4 /01	IIA, 8.2.5 /01	Burgess, D.	1988	Chronic toxicity of HWG-1608 to <i>Daphnia magna</i> under flow through test conditions. Mobay Corp., USA Bayer AG, 96792 (Supplemental 99627) GLP, unpublished <i>A8_ECO_daphnia_repro_96792 _1988_incl 99627</i>	Yes	Bayer CropScien ce AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIIA, XIII.2.4 /02	IIA, 8.2.5 /02	Noack, M.	1999	HT 308 technical - <i>Daphnia magna</i> reproduction test (21 d). Source: Dr. U. Noack-Laboratorium Owner: Irvita Plant Protection N.V.; co owned by Bayer CropScience AG, DRE60961 GLP, unpublished <i>A8_ECO_daphnia_repro_DRE60961_1999_TASK FORCE</i>	Yes	Irvita Plant Protection N.V. + Bayer CropScience AG
IIIA, XIII.3.1 /01	IIA, 8.3.1.1 /01	Kling, A.	2001	Assessment of side effects of tebuconazole a. i. to the honey bee, <i>Apis mellifera</i> L. in the laboratory. GAB Biotechnologie GmbH, Germany Bayer AG, 20011031/01 BLEU GLP, unpublished <i>A8_ECO_insects_bees_2001103101 BLEU_2001</i>	Yes	Bayer CropScience AG
IIIA, XIII.3.1 /02	IIA, 8.6 /07	Hoogendoorn, G.M.	1999	An extended laboratory dose-response study to evaluate the effects of HWG 1608 on the predaceous mite <i>Hypoaspis aculeifer</i> Canestrini (Acari: Gamasidae) MITOX, The Netherlands Bayer AG, B052HAE GLP, unpublished <i>A8_ECO_insects_B052HAE_1999</i>	Yes	Bayer CropScience AG
IIIA, XIII.3.1 /03	IIA, 8.6 /05	Wilhelmy, H.	1999	Inhibition of reproduction of Collembola (<i>Folsomia candida</i>) Dr.U.Noack-Laboratorium, Germany Bayer AG, ICR64011 GLP, unpublished <i>A8_ECO_soil_collembola_ICR64011_1999</i>	Yes	Bayer CropScience AG
IIIA, XIII.3.2 /01	IIA, 8.4.1 /01	Heimbach, F.	1987	Acute toxicity of HWG 1608 (tech) to earthworms. Bayer AG, HBF/Rg 82	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				GLP, unpublished <i>A8_ECO_soil_earthworm_ac_HBF RG 82_1987</i>		
III A, XIII.3.2 /02	II A, 8.4.2 /01	Baetscher R.	1999	Influence of low concentrations of tebuconazole (tech.) on reproduction of earthworms (<i>Eisenia fetida</i>). Bayer AG, 729112 GLP, unpublished <i>A8_ECO_soil_earthworm_repro_729112_1999</i>	Yes	Bayer CropScience AG
III A, XIII.3.2 /03	II A, 8.4.1 /02	Heimbach, F.	1986	Acute toxicity of 1,2,4-triazole (technical) to earthworms. Bayer AG, HBF/Rg 59 GLP, unpublished	Yes	TDMG (triazole derivative metabolites group)
III A, XIII.3.3	-	Voelkel, W.	2000	The effects of CGA71019 on soil respiration and nitrification. RCC Project 763367, Novartis Crop Protection study number: 2003502 GLP, unpublished	Yes	TDMG (triazole derivative metabolites group)
III A, XIII.3.4 /01	II A, 6.6.1 /02	Leimkuehler, W.M.; Lenz, C.A.; Valadez, S.K.; Moore, K.S.	1992	Radioactive Residues of [Phenyl-UL-14C] Tebuconazole in Rotational Crops. Bayer AG, 100126 GLP, unpublished <i>A8_ECO_plants_100126_1992</i>	Yes	Bayer CropScience AG
III A, XIII.3.4 /02	II A, 8.2.7 /01	Heimbach, F.	1996	Influence of Tebuconazole (tech.) on Development and Emergence of Larvae of <i>Chironomus riparius</i> in a Water-Sediment System. Bayer AG, HBF/Ch 10 GLP, unpublished <i>A8_ECO_chironomus_HBF CH 10_1996</i>	Yes	Bayer CropScience AG
III A, XIII.3.4 /03	II A, 8.6 /04	Seyfried, B.	1999	Terrestrial plants, growth test with tebuconazole. RCC Ltd. Bayer AG, 727907	Yes	Bayer CropScience AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				GLP, unpublished <i>A8_ECO_plants_727907_1999</i>		
III A, XIII.3.4 /04	II A, 8.6 /01	Meisner, P.	2001	Herbicidal screening data for HWG 1608. Bayer AG, DOM 99106 Non-GLP, unpublished <i>A8_ECO_plants_DOM 99106_2001</i>	Yes	Bayer CropScien ce AG
III A, XIII.3.4 /05	II A, 8.6 /03	Meisner, P.	2001	Herbicidal screening data for tebuconazole EW 250. Bayer AG, MPE NTP 25/01 GLP, unpublished <i>A8_PREP_EW 250_ECO_plants_MPE NTP 25 01_2001</i>	Yes	Bayer CropScien ce AG
III A, XIII.3.4 /06	II A, 8.6 /02	Meisner, P.	2001	Herbicidal screening data for tebuconazole EW 250. Bayer AG, MPE NTP 23/01 Non-GLP, unpublished <i>A8_PREP_EW 250_ECO_plants_MPE NTP 23 01_2001</i>	Yes	Bayer CropScien ce AG
III A, XIII.3.4 /07	II A, 8.2.7 /02	Dorgerloh, M.	2003	Influence of tebuconazole (tech.) on development and emergence of larvae of <i>Chironomus riparius</i> in a water sediment system. Bayer CropScience AG, Germany Bayer AG, DOM 22066 GLP, unpublished <i>A8_ECO_chironomus_DOM 22066_2003</i>	Yes	Bayer CropScien ce AG
III A, XIII.4	II A, 8.2.8 /01	Bowers, L.M.	1997	Toxicity of Folicur Technical to <i>Lemna gibba</i> . Bayer Corp., USA Bayer AG, 107681 GLP, unpublished <i>A8_ECO_lemna_107681_1997</i>	Yes	Bayer CropScien ce AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIB, II.2.2 /01	-	Anon.	2002	Material Safety Data Sheet "Tanalith E". Arch Timber Protection Ltd., United Kingdom published <i>A8_PREP_Tanalith E_MSDS_2002</i>	-	Arch Timber Protection Ltd.
IIB, II.2.2 /02	-	Anon.	2002	Material Safety Data Sheet "Baysilone Paint Additive OL 17". Borchers GmbH published <i>A8_PREP_JJT 3582_MSDS_Baysilone Paint Additive OL_865846 02_2002</i>	-	Borchers GmbH
IIB, II.2.2 /03	-	Anon.	2002	Material Safety Data Sheet "Octa- Soligen Calcium 10, basic". Borchers GmbH, Germany published <i>A8F_PREP_Octa-Soligen Calcium_MSDS_864173 06_2002_English</i>	-	Borchers GmbH
IIB, II.2.2 /04	-	Anon.	2003	Material Safety Data Sheet "Dowanol DPM Glycol Ether". Dow Chemical Company Ltd. published <i>A8_PREP_JJT 3582_MSDS_Dowanol DPM_Dow_2003</i>	-	Dow Chemical Company Ltd.
IIB, II.2.2 /05	-	Anon.	2003	Material Safety Data Sheet "Shellsol D60". Shell Chemicals published <i>A8_PREP_JJT 3582_MSDS_Shellsol D60_Shell_2003</i>	-	Shell Chemicals

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIB, II.2.2 /06	-	Anon.	2003	Material Safety Data Sheet "Borchi Gel WN 50 S". Borchers GmbH published <i>A8_PREP_JJT 3583_MSDS_Borchi Gel WN_865706_06_2003</i>	-	Borchers GmbH
IIB, II.2.2 /07	-	Anon.	2003	Material Safety Data Sheet "Resydrol VAL 5547w". Surface Specialties Austria GmbH, Austria published <i>A8_PREP_JJT 3583_MSDS_Resydrol VAL 5547w_2003</i>	-	Surface Specialties Austria GmbH
IIB, II.2.2 /08	-	Anon.	2003	Material Safety Data Sheet "Additol VXW 6206". Surface Specialties Austria GmbH, Austria published <i>A8_PREP_JJT 3583_MSDS_Additol VXW 6206_2003</i>	-	Surface Specialties Austria GmbH
IIB, II.2.2 /09	-	Anon.	2003	Material Safety Data Sheet "Emulsifier KS". Bayer Chemicals AG published <i>A8_PREP_JJT 3583_MSDS_Emulsifier KS_140140_06_2003</i>	-	LANXESS Deutschlan d GmbH
IIB, II.2.2 /10	-	Anon.	2003	Material Safety Data Sheet "Texanol". Eastman Chemical Company, USA published <i>A8_PREP_JJT 3583_MSDS_Texanol_2003</i>	-	Eastman Chemical Company

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIB, II.2.2 /11	-	Anon.	2003	Texanol. International Programme on Chemical Safety (IPCS) published <i>A8_PREP_JJT 3583_REV_Texanol_IPCS 0629_2003</i>	-	IPCS + EC
IIB, II.2.2 /12	-	Anon.	2003	Material Safety Data Sheet "WhorléeThix V 800". Whorlée Chemie GmbH, Germany published <i>A8F_PREP_WhorléeThix V 800 in Isopar L_MSDS_2003_English</i>	-	Whorlée Chemie GmbH
IIB, II.2.2 /13	-	Anon.	2003	Material Safety Data Sheet "ortho-Cyclohexylphenol 88/12". Bayer Chemicals AG, 69273/02 published <i>A8F_PREP_o- Cyclohexyphenol_MSDS_692739 02_2003_English</i>	-	LANXESS Deutschlan d GmbH
IIB, II.2.2 /14	-	Anon.	2003	Material Safety Data Sheet "Isopar L". ExxonMobil Chemical Central Europe GmbH, Germany published <i>A8F_PREP_Isopar L_MSDS_2003_English_EXXON D</i>	-	ExxonMob il Chemical Central Europe GmbH
IIB, II.2.2 /15	-	Anon.	2004	Material Safety Data Sheet "Alkydal F 681 TBA". Bayer MaterialScience AG, Germany Bayer AG published <i>A8_PREP_JJT 3582_MSDS_Alkydal F 681 TBA_023918 09_2004</i>	-	Bayer Material- Science AG

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIB, III.3.1 /01	-	Anon.	2004	Material Safety Data Sheet "JJT 3582 - Tebuconazole solvent- based guide recipe". Bayer Chemicals AG, 288083/00 unpublished <i>A8_PREP_JJT 3582_MSDS_288083_00_2004</i>	-	LANXESS Deutschlan d GmbH
IIB, III.3.1 /02	-	Anon.	2004	Material Safety Data Sheet "JJT 3583 - Tebuconazole water-based guide recipe". Bayer Chemicals AG, 288091/00 unpublished <i>A8_PREP_JJT 3583_MSDS_288091_00_2004</i>	-	LANXESS Deutschlan d GmbH
IIB, 3.2/01	-	Heinz , U.; Ebers, A.	2005	Explosion Hazard. JJT 3582 Bayer Industry Services, Germany Bayer AG, 05/01122 Non-GLP, unpublished	Yes	LANXESS Deutschlan d GmbH
IIB, 3.2/02	-	Heinz, U.	2005c	Determination of Safety-Relevant Data of JJT 3583 Bayer Industry Services, Germany Bayer AG, 05/01570 GLP, unpublished	Yes	LANXESS Deutschlan d GmbH
IIB, 3.3/01	-	Heinz, U.	2005b	Determination of Safety-Relevant Data of JJT 3582 Bayer Industry Services, Germany Bayer AG, 05/01571a GLP, unpublished	Yes	LANXESS Deutschlan d GmbH
IIB, 3.3/02	-	Heinz, U.	2005c	Determination of Safety-Relevant Data of JJT 3583 Bayer Industry Services, Germany Bayer AG, 05/01570 GLP, unpublished	Yes	LANXESS Deutschlan d GmbH

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIB, 3.10 /01	-	Anon.	2003	Determination of surface tension using the du Nouy interfacial tensiometer. Bayer Technology Services, Germany Bayer AG, 2003/12214 Non-GLP, unpublished <i>A8_PREP_JJT 3582_PC_surfaceTension_2003 12214_2003_English</i>	Yes	LANXESS Deutschlan d GmbH
IIB, 3.10 /02	-	Anon.	2003	Determination of surface tension using the du Nouy interfacial tensiometer. Bayer Technology Services, Germany Bayer AG, 2003/12208 (40°C) Non-GLP, unpublished <i>A8_PREP_JJT 3583_PC_surfaceTension_40 C_2003 12208_2003_English</i>	Yes	LANXESS Deutschlan d GmbH
IIB, 3.10 /04	-	Heitkamp, D.; Krasemann, R.	2004	Determination of Safety Relevant Data of JJT 3582. Bayer Industry Services, Germany Bayer AG, 2003/12214 Non-GLP, unpublished <i>A8_PREP_JJT 3582_PC_safety relevant data_2003 12214_2004</i> see also IIB, III.3.2 /01	Yes	LANXESS Deutschlan d GmbH
IIB, 3.10 /05	-	Heitkamp, D.; Krasemann, R.	2004	Determination of Safety Relevant Data of JJT 3583. Bayer Industry Services, Germany Bayer AG, 2003/12208 Non-GLP, unpublished <i>A8_PREP_JJT 3583_PC_safety relevant data_2003 12208_2004</i> see also IIB, III.3.2 /02	Yes	LANXESS Deutschlan d GmbH

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIB, III.3.4 /01	-	Heitkamp, D.; Krasemann, R.	2004	Determination of Safety Relevant Data of JTT 3582. Bayer Industry Services, Germany Bayer AG, 2003/12214 Non-GLP, unpublished <i>A8_PREP_JTT 3582_PC_safety relevant data_2003 12214_2004</i>	Yes	LANXESS Deutschlan d GmbH
IIB, III.3.4 /01	-	Heitkamp, D.; Krasemann, R.	2004	Determination of Safety Relevant Data of JTT 3583. Bayer Industry Services, Germany Bayer AG, 2003/12208 Non-GLP, unpublished <i>A8_PREP_JTT 3583_PC_safety relevant data_2003 12208_2004</i>	Yes	LANXESS Deutschlan d GmbH
IIB, III.3.5 /01	-	Heitkamp, D.; Krasemann, R.	2004	Determination of Safety Relevant Data of JTT 3582. Bayer Industry Services, Germany Bayer AG, 2003/12214 Non-GLP, unpublished <i>A8_PREP_JTT 3582_PC_safety relevant data_2003 12214_2004</i> see also IIB, III.3.4 /01	Yes	LANXESS Deutschlan d GmbH
IIB, III.3.5 /01	-	Heitkamp, D.; Krasemann, R.	2004	Determination of Safety Relevant Data of JTT 3583. Bayer Industry Services, Germany Bayer AG, 2003/12208 Non-GLP, unpublished <i>A8_PREP_JTT 3583_PC_safety relevant data_2003 12208_2004</i> see also IIB, III.3.4 /02	Yes	LANXESS Deutschlan d GmbH
IIB, III.3.6 /01	-	Heitkamp, D.; Krasemann, R.	2004	Determination of Safety Relevant Data of JTT 3582. Bayer Industry Services, Germany Bayer AG, 2003/12214 Non-GLP, unpublished <i>A8_PREP_JTT 3582_PC_safety relevant data_2003 12214_2004</i> see also IIB, III.3.4 /01	Yes	LANXESS Deutschlan d GmbH

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIB, III.3.6 /01	-	Heitkamp, D.; Krasemann, R.	2004	Determination of Safety Relevant Data of JJT 3583. Bayer Industry Services, Germany Bayer AG, 2003/12208 Non-GLP, unpublished <i>A8_PREP_JJT 3583_PC_safety relevant data_2003 12208_2004</i> see also IIB, III.3.4 /02	Yes	LANXESS Deutschlan d GmbH
IIB, III.3.7 /01	-	Knopf, R.	2004	Storage Stability - JJT 3582 Tebuconazole Solvent-based Guide Recipe. Bayer Industry Services, Germany Bayer AG, G03/0110/00 UER Non-GLP, unpublished <i>A8_PREP_JJT 3582_PC_stability_storage_G03 0110 00 UER_2004</i>	Yes	LANXESS Deutschlan d GmbH
IIB, III.3.7 /01	-	Knopf, R.	2004	Storage Stability - JJT 3583 Tebuconazole Water-based Guide Recipe. Bayer Industry Services, Germany Bayer AG, A03/0111/00 UER Non-GLP, unpublished <i>A8_PREP_JJT 3583_PC_stability_storage_A03 0111 00 UER_2004</i>	Yes	LANXESS Deutschlan d GmbH
IIB, IV.4.1 /01	-	Schultz, C.	2003	Wood preservative formulations. Bayer Industry Services, Germany Bayer AG, 2301-0290501-03E Non-GLP, unpublished <i>A8_METH_wood formulations_2301-0290501- 03E_2003</i>	Yes	LANXESS Deutschlan d GmbH

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIB, IV.4.1 /02	-	Schultz, C.	2003	Validation Report - Tebuconazole (Preventol A8). Bayer Industry Services, Germany Bayer AG, 2301-0290501-03E Validation Non-GLP, unpublished <i>A8_METH_wood formulations_2301-0290501-03E_2003_Validation</i>	Yes	LANXESS Deutschland GmbH
IIB, V.5.7 /01	-	Rudolph, D.; Kerner, W.	1988	Test Certificate, Wood preservative EXO-87-15. Bundesanstalt fuer Materialforschung und -Prüfung (BAM), Germany. Bayer AG, 5.1/4858-A/1 Non-GLP, unpublished <i>A8_EFF_5.1 4858-A 1_1987_English</i>	Yes	LANXESS Deutschland GmbH
IIB, V.5.7 /02	-	Carey, J.K.; Hull, A.V.	1995	Evaluation of relative protective effectiveness of wood preservatives for use in surface coated timber. Building Research Establishment (BRE), United Kingdom Bayer AG, TCR/107 Non-GLP, unpublished <i>A8_EFF_B89150 2_1995</i>	Yes	LANXESS Deutschland GmbH
IIB, V.5.7 /03	-	Pfabigan, N.	2004	Biological testing of JTT 3582 in accordance with ÖNORM EN 113 (ÖNORM EN 84 and ÖNORM EN 73). Holzforschung Austria, Austria Bayer AG, 1588/2003 - HS Non-GLP, unpublished <i>A8_PREP_JTT 3582_EFF_1558 2003-HS_2004</i>	Yes	LANXESS Deutschland GmbH
IIB, V.5.7 /04	-	Pfabigan, N.	2004	Biological testing of JTT 3583 in accordance with ÖNORM EN 113 (ÖNORM EN 84 and ÖNORM EN 73). Holzforschung Austria, Austria Bayer AG, 868/2004 - HS	Yes	LANXESS Deutschland GmbH

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				Non-GLP, unpublished <i>A8_PREP_JJT 3583_EFF_868 2004 - HS_2004</i>		
IIB, VI.6.4 /01	-	Roper, C.S.; Sharatt, R.	2004	The In Vitro Percutaneous Absorption of Radiolabelled Tebuconazole in Two Wood Protection Test Products Through Human Skin. Inveresk Research, United Kingdom Bayer AG, Report No. 23271 GLP, unpublished <i>A8_TOX_derm_penetr_23271_20 04</i>	Yes	LANXESS Deutschlan d GmbH
IIB, VI.6.4 /02	-	Toner, F.	2006	The In vitro Percutaneous Absorption of Radiolabelled Tebuconazole in Two Wood Protection Formulations Through Human Skin. Charles River Laboratories, Tranent, Edinburgh (UK), 27363 GLP, unpublished	Yes	LANXESS Deutschlan d GmbH
IIB, VI.6.6	-	Buschhaus, H.U.	1994	Preventol A8 (Tebuconazole) - Migration Experiment form treated Wood to tanned Animal Skin. Bayer AG Non-GLP, unpublished <i>A8_EXP_animal skin_Buschhaus_1994</i>	Yes	LANXESS Deutschlan d GmbH
IIB, VII.7.1	-	Morsing, N.; Lindegaard, B.	2005	Test methods to evaluate the leaching of active ingredients from preservative treated wood. Phase I: Semi field testing DTI (DK), 1175742-01 Non-GLP, unpublished	Yes	Arch Chemicals + DEPA

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIIB, Pt.I.3.10 /01	-	Anon.	2003	Determination of surface tension using the du Nouy interfacial tensiometer. Bayer Technology Services, Germany Bayer AG, 2003/12214 Non-GLP, unpublished <i>A8_PREP_JJT 3582_PC_surfaceTension_2003 12214_2003_English</i>	Yes	LANXESS Deutschlan d GmbH
IIIB, Pt.I.3.10 /02	-	Anon.	2003	Determination of surface tension using the du Nouy interfacial tensiometer. Bayer Technology Services, Germany Bayer AG, 2003/12208 (40°C) Non-GLP, unpublished <i>A8_PREP_JJT 3583_PC_surfaceTension_40 C_2003 12208_2003_English</i>	Yes	LANXESS Deutschlan d GmbH
IIIB, Pt.I.3.10 /04	-	Heitkamp, D.; Krasemann, R.	2004	Determination of Safety Relevant Data of JJT 3582. Bayer Industry Services, Germany Bayer AG, 2003/12214 Non-GLP, unpublished <i>A8_PREP_JJT 3582_PC_safety relevant data_2003 12214_2004</i> see also IIB, III.3.2 /01	Yes	LANXESS Deutschlan d GmbH
IIIB, Pt.I.3.10 /05	-	Heitkamp, D.; Krasemann, R.	2004	Determination of Safety Relevant Data of JJT 3583. Bayer Industry Services, Germany Bayer AG, 2003/12208 Non-GLP, unpublished <i>A8_PREP_JJT 3583_PC_safety relevant data_2003 12208_2004</i> see also IIB, III.3.2 /02	Yes	LANXESS Deutschlan d GmbH

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
IIIB, XII.2 /01	-	Caswell, S.	2000	Determination of the emission profile from Tanalith E treated Timber. Laboratory method to simulate exposure from Tanalith E (3491) Treated timber in a water contact (Hazard Class 4) environment. Hickson Timber Products Ltd., W20/004. Non-GLP, unpublshed <i>A8_PREP_Tanalith E_EFF_W20004_2000</i>	Yes	Arch Timber Protection
IIIB, XII.2 /02	-	Caswell, S.	2001	Determination of the emission profile from Tanalith E. Interim Report - Tanalith E (3491) treated stakes exposed in ground contact for 12 months. Arch Timber Protection Ltd., W20/003c Non-GLP, unpublished <i>A8_PREP_Tanalith E_EFF_W20003c_2001</i>	Yes	Arch Timber Protection
IIIB, XII.2 /03	-	Morsing, N.	2003	Development of a Method Characterising: Leaching of Active Ingredients from Preservative Treated Timber. (a) Danish Technology Institute, Danmark (b) Swedish National Testing and Research Institute, Sweden (c) Norwegian Institute of Wood Technology and Industry Non-GLP, partly published <i>A8_ECO_leaching_1582-02_Nordtest Technical_2003</i>	Yes	sponsored by Dyrup A/S + LANXESS Deutschlan d GmbH + Troy Corporatio n + Jansen Pharmaceu tica
IIIB, XII.2 /04	-	Hughes, A.S.	2004	Determination of the emission profile from Tanalith E treated Timber. Interim Report - Tanalith E (3491) treated stakes exposed in ground contact for 24 months. Arch Timber Protection Ltd., W20/003d		Arch Timber Protection

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				Non-GLP, unpublished <i>A8_PREP_Tanalith E_EFF_W20003d_2004</i>		
IIIB, XII.2 /05	-	Partsch, S.	2006	Groundwater assessment of Tebuconazole released after the inservice use as a wood preservative. Dr. Knoell Consult GmbH (Germany), LANXESS Deutschland GmbH, 104901-3 Non-GLP, unpublished	Yes	LANXESS Deutschland GmbH

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
Literature	-	Hammerschmidt, H.	2000	Literature Search Tebuconazole - Bayer AG published <i>litrecherchetebu20000925.doc</i>	-	LANXESS Deutschland GmbH
Literature	-	Hammerschmidt, H.	2001	Literature Search Tebuconazole - Bayer AG published <i>literaturecas.doc</i>	-	LANXESS Deutschland GmbH
Literature	-	Hammerschmidt, H.	2001	Literature Search Tebuconazole - Bayer AG published <i>Litdetail.doc</i>	-	LANXESS Deutschland GmbH
Literature	-	Hammerschmidt, H.	2001	Literature Search Tebuconazole - Bayer AG	-	LANXESS Deutschland GmbH

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				published <i>Litall.doc</i>		d GmbH
Literature	-	Hammerschmidt, H.	2001	Search profile Tebuconazole - Bayer AG published <i>litsearchprofile.pdf</i>	-	LANXESS Deutschland GmbH
Literature	-	Hammerschmidt, H.	2001	Literature Search Tebuconazole - Bayer AG published <i>LiteratureSurvey.doc</i>	-	LANXESS Deutschland GmbH
Literature	-	Hammerschmidt, H.	2001	Literature Search Tebuconazole - Bayer AG published <i>recherche2000-09-25.doc</i>	-	LANXESS Deutschland GmbH
Literature	-	Hammerschmidt, H.	2003	Search profile Tebuconazole - Bayer AG published <i>tebuconazolelitsearchprofile200311update.doc</i>	-	LANXESS Deutschland GmbH
Literature	-	Hammerschmidt, H.	2003	Literature Search Tebuconazole - Bayer AG published <i>tebuconazoleupdate2003.doc</i>	-	LANXESS Deutschland GmbH
Literature	-	Hughes, A.S.; Connell, M.	1998	Occupational exposure risk assessment at a commercial treatment plant using copper azole preservatives. The International Research Group on Wood Preservation (IRG), Doc. No. IRG/WP 98-50101, Proceedings of the 4th International Symposium "The Challenge Safety and Environment in Wood Preservation", Cannes-Mandelieu, France, 1998, February 2-3, pp. 161-171. <i>Hughes et al, IRG WP (1998) pp</i>	-	-

Section No / Reference No	accord. PPP Dossier Reference No	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published <i>file name (*.pdf)</i>	Data Protection Claimed (Yes/No)	Owner
				<i>161-171</i>		
Literature	-	Laks, P.E.; Palardy, R.D.	1993	Properties and Process Considerations for Preservative- containing Waferboards. IUFRO Subgroup S.03.02 Symposium "Protection of Wood- based Composite Products", May 15, 1993, Orlando, Florida, USA. <i>Laks et al, IUFRO (1993) pp 1-13</i>	-	-
Literature	-	Wegen, H.-W.; Lucks, U.J.	1998	Ecotoxicological behaviour of leachates from superficially treated timber. The International Research Group on Wood Preservation (IRG), Document IRG/WP 98-50101, Proceedings of the 4th International Symposium "The Challenge Safety and Environment in Wood Preservation", Cannes-Mandelieu, France, February 2-3, pp. 95-112. published <i>Wegen et al, IRG WP (1998) pp 95-112</i>	-	-