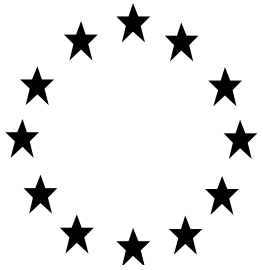
Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Tebuconazole

Product-type 7
(Film preservative)

September 2013

Denmark

Tebuconazole (PT 7)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 27 September 2013

CONTENTS

I:1 STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1 PRINCIPLE OF EVALUATION

This assessment report has been established as a result of the evaluation of tebuconazole as product-type 7 (film preservative), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with the original view to the possible inclusion of this substance into Annex I or IA to that Directive.

The evaluation has therefore been conducted in the view to determine whether it may be expected, in light of the common principles laid down in Annex VI to Directive 98/8/EC, that there are products in product-type 7 containing of tebuconazole that will fulfil the requirements laid down in Article 5(1) b), c) and d) of that Directive.

1.2 PURPOSE OF THE ASSESSMENT

The aim of the assessment report is to support a decision on the approval of tebuconazole for product-type 7 (film preservative), and should it be approved, to facilitate the authorisation of individual biocidal products in product-type 7 that contain tebuconazole. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

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

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

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

1.3 PROCEDURE FOLLOWED

This report has been established as a result of the evaluation of tebuconazole as product-type 7 (film preservative), carried out in the context of the work programme for the review of existing active

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

substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[2], 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, hereafter referred to as the applicant, in product-type 7.

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

In accordance with the provisions of Article 7(1) of that Regulation, 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 7 was 31 October 2008, in accordance with Annex V of Regulation (EC) No 1451/2007.

On 31st of October 2008, the competent authorities of Denmark received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 4th of May 2009.

On 16th of April 2012, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 3rd of May 2012. The competent authority report included a recommendation for the inclusion of tebuconazole in Annex I to the Directive for product-type 7.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 5th of March 2013. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

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

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 27 September 2013.

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

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

I:2 OVERALL SUMMARY AND CONCLUSIONS

2.1 IDENTITY, INTENDED USES, EFFICACY AND CLASSIFICATION OF THE ACTIVE SUBSTANCE

2.1.1 Identity & Analysis

The main identification characteristics and the physico-chemical properties of tebuconazole are given in Appendix I (list of endpoints). The identity of impurities in the active substance as manufactured is confidential. This information is provided separately in the confidential part of the dossier. None of the manufacturing impurities is considered to be of potential concern.

The methods of analysis for the active substance as manufactured, and for the determination of impurities, have been validated. The methods for analysis in environmental matrices, as appropriate for the areas of use assessed, have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

2.1.2 Intended uses

The biocidal products produced for film preservation have concentrations of 10-40% tebuconazole. As a worst case a product of 40% is used as the representative product. In end-use products, tebuconazole is contained at a concentration of 0.52%. In PT7, the end-use product is used indoors to seal joints (shower cabins, bathtubs, kitchen sinks, etc.) against the intrusion of moisture and to prevent fungal infestation.

The b.p. is intended for use in an industrial process and the end-use product is intended for use by professional users and by amateurs as well.

2.1.3 Efficacy

Tebuconazole is a fungicide added to the end-products to prevent fungal infestation.

Tebuconazole is particularly effective against several material destruents of practical relevance, as for example: *Penicillium brevicaule, chaetomium globosum, aspergillus niger, aureobasidium pullulans, aspergillus ustus, stachybotrys chartarum, aspergillus flavus Link, gloeophyllum trabeum, poria placenta, coriolus versicolor.*

The efficacy results show that Preventol A8 (tebuconazole) has an excellent activity, destroying the Basidiomycota tested and inhibits also all examined Ascomycota and Deuteromycota.

2.1.4 Classification

2.1.4.1 Classification of the active substance

The classification of tebuconazole according to Directive 67/548/EEC and Regulation (EC) No 1272/2008 is shown in Table **2.1-1**.

Table 2.1-1: Classification for tebuconazole

Classification	As in Directive 67/548/EEC
Class of danger	Xn: Harmful Repr. Cat. 3 N: Dangerous for the environment
R phrases	R22: Harmful if swallowed, R63: Possible risk of harm to the unborn child R51/R53: 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 S36/37: Wear suitable protective clothing and gloves S61: Avoid release to the environment

Classification	As in regulation (EC) No 1272/2008 and No 286/2011 (2nd ATP)
Classification	Repr.2, Acute Tox 4, Aquatic Chronic 2 (Aquatic Chronic 1)*
GHS Pictograms	GHS08, GHS07, GHS09
Signal Word	Warning
Hazard Statement	H361d: Suspected of damaging the unborn child H302: Harmful if swallowed H411: Toxic to aquatic life with long lasting effects (H410: Very toxic to aquatic life with long lasting effects)*
Environmental M-factor	10*

* According to No 286/2011 (2nd ATP)

Precautionary statements according to Regulation (EC) No 1272/2008 have not been assigned.

2.1.4.2 Current classification of the product(s)

The current classification and labelling of the biocidal product (40%) according to Council Directive 99/45/EEC and Regulation (EC) No. 1272/2008 is shown in Table 2.1-2.

Table 2.1-2: Current classification and labelling of the biocidal product

According to Directive 99/45/EEC

Class of danger	Xn: Repr. Cat. 3 N:	Harmful Dangerous for the environment
Risk phrases:	R22: R63: R51/R53:	Harmful if swallowed Possible risk of harm to the unborn child Toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment
Safety phrases:	S2: S24: S36/37: S46: S51:	Keep out of the reach of children Avoid contact with skin Wear suitable protective clothing and gloves If swallowed, seek medical advice immediately and show this container or label Use only in well ventilated areas
Other phrases:	Contains N-(3-(trimethoxysilyl)propyl)ethylenediamine. May produce an allergic reaction	

According to Regulation 1272/2008[4]

Classification	**As in regulation (EC) No 1272/2008 and No 286/2011 (2nd ATP)**
Classification	Repr.2, Acute Tox 4, Aquatic Chronic 2 (Aquatic Chronic 1)*
GHS Pictograms	GHS08, GHS07, GHS09
Signal Word	Warning
Hazard Statement	H361d: Suspected of damaging the unborn child H302: Harmful if swallowed H411: Toxic to aquatic life with long lasting effects (H410: Very toxic to aquatic life with long lasting effects)*

* According to No 286/2011 (2nd ATP)

No changes in classification / labelling of the biocidal product are proposed.

[4] Precautionary statements have not been assigned.

2.2 SUMMARY OF THE RISK ASSESSMENT

2.2.1 Human Health

2.2.1.1 Summary of mammalian toxicity studies (incl. AEL)

Oral administration of tebuconazole is followed by a rapid and extensive absorption in the rat. The substance is quickly distributed throughout the body tissues with the highest level in the liver. The majority of the administered dose is excreted in the faeces (65-80%) 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 1H-1,2,4-triazole amounting 5% in the urine of the male and 1,5% in that of the female.

Percutaneus absorption was investigated *in vitro* in human skin with a solvent based and a water based wood preservative containing 0.6% Tebuconazole. The study was performed according to OECD Guideline 428. The dermal absorption for the water-based product was found to be 4.1% when including stratum corneum except the amount found in tape strip 1-2.

In acute toxicity studies, tebuconazole was found to be of low to moderate toxicity by the oral route and of low toxicity by inhalation and dermal application when the rat is used as the test species. LD_{50} was found to be 1700 mg/kg bw. in female rats after oral administration. The dermal LD_{50} was above 5000 mg/kg bw and LC_{50} above 371 mg/m^3 (aerosol) and above 5093 mg/m^3 (dust) when rats were exposed 4 hours nose-only. There were no deaths and no clinical symptoms at these maximal attainable concentrations.

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

Several short-term and long-term tests were submitted and the dog was found to be the most sensitive animal tested and the only species showing potential for opacities of the 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. The lowest relevant NOAEL was 3 mg/kg bw/day and was found as an overall NOAEL from two 1 year dog studies. This value was used for the derivation of medium and long term AEL.

No evidence for genotoxic potential was observed in an adequate battery of in-vitro and in-vivo tests with various end-points 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.

In a two-generation study in rats the only observations were reduced body weight gain in the parental generation and corresponding adverse effects on litters, mainly reduced pup weight at the highest dose.

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 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). In agreement with this tebuconazole is classified with Repr.2 (CLP). Lowest

relevant NOAEL was found in the rabbit and was 10 mg/kg bw/day for foetuses and 30 mg/kg bw/day for dams. This value is used for the derivation of acute AEL.

There is no evidence that exposure to tebuconazole during developmental produces neuropathology at any dose level after oral administration to rats.

The AEL for medium and long term was derived from the one-year study in dogs where histopathological alterations in the adrenal cortex were found. The NOAEL for this effect was 3 mg/kg bw/day. An assessment factor of 100 is applied.

Therefore the proposed **AEL medium and long term is 0.03 mg/kg bw/day**.

The acute AEL is derived from the developmental study in mice where a NOAEL of 10 mg/kg bw/day was found. An additional AF of 3 was added due to the severe foetotoxic effects of the substance.

Therefore the proposed **AEL acute is 0.03 mg/kg bw/day.**

2.2.1.2 Summary of the human exposure estimations

Human exposure during the formulation of the sealant end-use-product was estimated using RISKOFDERM (loading liquids, automated or semi-automatic). Inhalation exposure is not relevant in this scenario.

Human exposure during application of the joint sealant end-use-product was estimated using a default scenario from ConsExpo 4.1.

The primary exposure is summarised in Table 2.2-1.

Table 2.2-1**: Risk assessment for primary exposure to tebuconazole in PT7**

Intended use (PT)	**Exposure scenario**	**PPE**	**Systemic exposure [mg/kg bw/day]**
PT 7 Film preservative	Connecting/Disconnecting transfer lines	Gloves and coverall	Dermal: 0.0029
	Applying joint sealant, spreading with fingertip	None	Dermal: 0.0053 Inhalation: 8.3×10^{6} **Total: 0.0053**

2.2.1.3 Summary of risk characterisation for humans

The risk assessment for primary exposure is summarised in Table 2.2.-2.

Table 2.2-2:Risk assessment for primary exposure to tebuconazole in PT7

Exposure scenario	User	Systemic exposure [mg/kg/day]	AEL [mg/kg/day]	% AEL covered	NOAEL [mg/kg/day]	Margin of Exposure
Connecting/discon-necting transfer lines	Industrial	0.0029	0.03	96.6	3.0	103
Applying joint sealant, spreading with fingertip	Professional	0.0053	0.03	17.7	3.0	566
	Amateur	0.0053	0.03	17.7	3.0	566

Industrial users

The Risk Assessment for industrial users is summarised in Table 2.2-2. Exposure is acceptable for the industrial users if PPE is worn.

Professional Users

The Risk Assessment for professional users is summarised in Table 2.2-2. Professional users of tebuconazole-containing joint sealants are unlikely to be exposed to critical doses of tebuconazole.

Even though no PPE is used and direct skin contact is established, a sufficient margin of exposure is maintained.

Non-Professional Users

The risk assessment for amateur users is summarised in Table 2.2-2**Error! Reference source not found.**. Amateur users of tebuconazole-containing joint sealants are unlikely to be exposed to critical doses of tebuconazole.

Indirect exposure as a result of use

The risk assessment for worst case secondary exposure to infants playing in a preserved shower is summarised in Table 2.2-3. The exposure of infants is acceptable.

Table 2.2-3 Risk assessment for secondary exposure to tebuconazole in PT7

Exposure scenario	User	Systemic exposure [mg/kg/day]	AEL [mg/kg/day]	% AEL covered	NOAEL [mg/kg/day]	Margin of Exposure
Accidental exposure via dermal contact and ingestion	Infant	0.027	0.03	90	10.0	370

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 photolytically 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 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

Based on the modified MITI test, tebuconazole is concluded to be not ready biodegradable.

Tebuconazole is not readily biodegradable and the biodegradation half -life in surface water is estimated to about 198 days. The active substance will be adsorbed to the sediment and therefore a dissipation half-life in surface water is estimated to be 43 days, indicated by 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-life period is 77 days. An accumulation of Tebuconazole in soil is not anticipated.

The test results revealed a low mobility character of tebuconazole in soils. Tebuconazole is partly reversibly adsorbed to the soil. However, organic carbon adsorption coefficients of 800-1250 L/kg indicate a moderate to high adsorption of tebuconazole to soil and thus a low mobility potential in soil. In the risk assessment, an adsorption coefficient K_a arithmetic mean value of 12.7 L/kg and a K_{aOC} of 992 L/kg (arithmetic mean) are used. The triazole metabolite has a high mobility potential, the K_{aOC} values are on average 89 L/kg.

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

2.2.2.2 Effect assessment

In an activated respiration inhibition test, an EC_{50} of 32 mg a.i./L was obtained for activated sludge (based on the solubility of tebuconazole). According to the TGD for Risk Assessment (EC, 2003) for such tests an assessment factor of 100 should be applied to the available EC_{50}, resulting in a $PNEC_{microorganisms}$ of 320 µg a.i./L.

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 ($PNEC_{water}$ = 1 µg a.i./L).

From the dose-related test on *Chironomus riparius* the NOEC (= EC_{10}) 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.i./kg suspended sediment ($PNEC_{sed}$ = 550 µg a.i./kg suspended sediment).

The toxicity to terrestrial organisms is documented by acute and long term studies. Tests 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 ($PNEC_{soil}$ = 100 µg a.i./kg wet weight soil).

The ecotoxicity of the metabolite 1,2,4-triazole is significantly lower than found for the tebuconazole for both the aquatic and terrestrial environment and therefore the metabolite will not be considered further as concluded for the tebuconazole evaluation in PT8.

2.2.2.3 PBT assessment

Considering tebuconazoles physico-chemical properties and degradation pathways, tebuconazole is not expected, according to the REACH guidance on PBT assessment to be a PBT or a vPvB substance.

Persistence criteria (P, vP)

Tebuconazole is not readily biodegradable and the biodegradation half- life in surface water is estimated to about 198 days ($T_{½}$ > 40 days in freshwater). The half-life of tebuconacole in an outdoor microcosm study is 43 days for the water phase (dissipation) ($T_{½}$ > 40 days in freshwater) and one year for the sediment phase ($T_{½}$ > 120 and 180 days in freshwater sediment). In field studies a worst case dissipation half-live of 77 days ($T_{½}$ < 120 days in soil) is found.

Considering these results, tebuconazole is considered as persistent (P), and based on the slow degradation in freshwater sediment also as very persistent (vP).

Bioaccumulation criteria (B, vB)

The experimentally derived BCFfish value considered in the risk assessment is 78 L/kg. A substance is considered to fulfil the B criteria when the bioconcentration factor exceeds a value of 2000 L/kg. Tebuconazole is therefore not considered as bioaccumulative (B) or very bioaccumulative (vB).

Toxicity criteria (T)

Based on the lowest ecotoxicology data on Daphnia magna, NOEC (21 days, reproduction) = 0.01 mg/L, tebuconazole does not fulfil the toxic (T) criteria. However, tebuconazole meets the criteria for classification as toxic for reproduction, category 2 according to the CLP Regulation. Tebuconazole is therefore considered as toxic (T).

2.2.2.4 Endocrine disruption assessment

Tebuconazole is an azole fungicide developed to inhibit sterol biosynthesis in fungi. Tebuconazole or the metabolite 1,2,4 triazole are not included in the EU list of substances with evidence (Catefory 1) or potential endocrine disruption (Category 2) (COM (1999) 706). However, tebuconazole is included in table 4 (substances classified as HPV and/or persistent and/or exposure expected in humans and wildlife, with insufficient data). A number of studies investigating the endocrine effects of tebuconazole and other triazoles have been performed recently, e.g. Kjaerstad et al. (2010), Cericato et al. (2008), Sancho et al. (2010) showing some potential endocrine disrupting properties of tebuconazole and a number of other triazoles. However the interpretation of the results from these studies has not been fully agreed on but the results from these studies will be considered when criteria for endocrine disrupting substance are developed.

2.2.2.5 Exposure assessment

For the environmental exposure assessment of tebuconazole as ingredient in silicone sealant mass its application patterns are of major importance. The tebuconazole containing end-product is used to seal joints indoor in buildings on small interfacial areas in e.g. bathrooms and kitchens. The environmental risk assessment for tebuconazole is based on the emission scenario developed for the use of biocides in film preservatives (PT7).

For the exposure assessment, two approaches have been used, i.e. a consumption and a tonnage based approach. For the consumption based approach market shares of 1 and 0.5 have been applied to uses

where there is a direct emission to the STP. Using a market share of 0.5 is a refinement that is performed as several substances are notified within PT7 and as tonnage data are submitted by the applicant which is a requirement for lowering the market share. For the consumption based approach emissions from the formulation of the end-products are considered negligible as the process of film preservation is highly automated in a semi-automatic process. The exposure assessment therefore covers the service life of the end product.

For the consumption based approach, emissions are calculated for a house scenario discharging directly to the facility drain (city scenario).

The applied dosage of tebuconazole containing 0.52% tebuconazole (w/w) corresponds to a final amount of 0.0052 kg a.i./kg sealant mass surface. Considering the consumption per m^2, a quantity of 0.03057 kg/m^2 was used. In order to estimate a consumption of the compound, the surface area covered by joints was set to 0.2 m^2 for the indoor use[5].

For the risk assessment of the consumption based approach, a consecutive leaching of 100% of the initial tebuconazole amount was assumed during the service life (10 years) induced by regularly wetting triggered by indoor wetting/cleaning operations. Leaching studies were however submitted late in the evaluation period, these are not considered as study summaries were not provided. It is assumed that there is no loss of the active substance to the environment during application since no spray drift, dripping or rinsing occurs.

For the tonnage based approach different calculations have been performed considering the formulation, the application and the service life of the end-product. One approach considers that 3% (application phase) of the amount used is emitted to the STP (following ESD PT7) while a worst case approach considers that 100% is emitted to the STP.

A risk assessment for the atmosphere is not considered necessary; based on the Henry's Law constant, no significant volatilisation of tebuconazole is to be expected and air is therefore not a compartment of concern.

Tebuconazole showed a low bioconcentration potential in aquatic and terrestrial organisms ($BCF_{fish} < 100$) and it did not undergo biomagnification through the food chain. No exposure of wild birds to the formulated product was expected for the specific use applications. Tebuconazole and its formulated end product did not represent a real risk to birds due to the low toxicity of the active ingredient. Therefore it is not considered necessary to calculate a PEC for food chain risk assessment.

2.2.2.6 Risk characterisation

Based on the PEC and PNEC values, the following PEC/PNEC ratios have been calculated for the consumption based approach (*cf.* Table 2.2-3). Calculated PEC/PNEC values for the tonnage based approach are found in the confidential part of the CAR.

[5] At TMIV 2012 it was agreed using this value for the exposure calculation based on new information from the applicant.

Table 2.2-3: PEC/PNEC ratios of tebuconazole for the consumption based approach

Compartment	PEC value (PT 7)		PNEC value	PEC/PNEC (PT 7)	
	F_{market} = 1	F_{market} = 0.5		F_{market} = 1	F_{market} = 0.5
Sewage treatment plant [µg/L]	2.99	1.49	320	9.33×10^{-3}	4.66×10^{-3}
Surface water [µg/L]	0.298	0.149	1	0.298	0.149
Sediment [µg/L]	6.66	3.33	550	0.0121	7.56×10^{-3}
$PEC_{soil\ 1}$ [µg /kg wet weight] *	1.51	0.756	100	0.0151	7.56×10^{-3}
$PEC_{soil\ 30d}$ [µg /kg wet weight] *	1.38	0.689	100	0.0131	6.89×10^{-3}
$PEC_{groundwater}$ [µg/L]	0.0781	0.0390			
PEC_{air} [µg/m^3]	Not relevant				
PEC_{biota} [µg/kg$_{wet\ fish}$]	Not relevant				

* indirect soil contamination via sludge application

In the risk characterisation performed for the STP and the following environmental compartments several different approaches have been used, i.e. a consumption based approach with market penetration factors of 1 and 0.5 and a tonnage based approach considering formulation, application and service life of the end-product.

For the consumption based approach no unacceptable risk is identified for any of the environmental compartments when considering market penetration factors of 1 and 0.5. For the tonnage based approach also no unacceptable risk is identified for all environmental compartments even when considering the formulation where only one formulation plant in EU is considered.

According to Directive 80/778/EEC the maximum permissible concentration in groundwater is 0.1 µg/L for biocides. The calculated pore water concentrations are below this value for the consumption based approach while values are above this value for the tonnage based approach. Groundwater calculations are therefore performed in FOCUS-PEARL 4.4.4. These results show that groundwater levels below 0.1 µg/L are expected for the considered use.

2.2.3 List of endpoints

In order to facilitate Member States, in granting or reviewing authorisations, the most important endpoints as identified during the evaluation process are listed in Appendix I.

The list of endpoints is identical to the one displayed for tebuconazole in PT8.

I:3 PROPOSED DECISION

3.1 BACKGROUND TO THE PROPOSED DECISION

Tebuconazole is classified as Repr. 2, Acute Tox 4, Aquatic Chronic 1 with H361d, H302 and H410 (Rept. Cat. 3, Xn; R22-63, N; 51/53).

The assessment has been performed based on the documentation for the active substance and the representative biocidal product containing 40% tebuconazole as active ingredient. The biocidal product is intended to control fungi and yeast and is for industrial film preservation. The concentration of tebuconazole in the end product is 0.52%. The end product, a silicone sealant is for use by professional users but may be used by amateurs as well.

The efficacy results show that tebuconazole has an excellent activity, destroying the Basidiomycota tested and inhibits also all examined Ascomycota and Deuteromycota.

The risk characterisation for human health indicates that there is no unacceptable risk anticipated for the industrial worker formulating the sealants or use of preserved sealant by professional and non-professional users. Also no unacceptable risk is found for secondary exposure to infants playing in a preserved shower.

In the risk characterisation for the environment, no unacceptable risk was found for the intended use. Further, there was no risk identified for contamination of groundwater at levels of 0.1 µg/L or above from the use of the product assessed. Tebuconazole is also not characterised as a PBT substance since only the criterion for very persistent (vP) and toxic (T) is fulfilled.

Tebuconazole or the metabolite 1,2,4 triazole are not included in the EU list of substances with evidence (Catefory 1) or potential endocrine disruption (Category 2) (COM (1999) 706). However, tebuconazole is included in table 4 (substances classified as HPV and/or persistent and/or exposure expected in humans and wildlife, with insufficient data). A number of studies investigating the endocrine effects of tebuconazole and other triazoles have been performed recently, e.g. Kjaerstad et al. (2010), Cericato et al. (2008), Sancho et al. (2010) showing some potential endocrine disrupting properties of tebuconazole and a number of other triazoles. However the interpretation of the results from these studies has not been fully agreed on but the results from these studies will be considered when criteria for endocrine disrupting substance are developed.

Assessed from the documentation for the active substance, tebuconazole, and the representative biocidal product containing tebuconazole, the proposed manner and area of use of products intended to control fungi and yeast may be sufficiently effective for these uses and without unacceptable risk either to human health or to the environment.

This overall conclusion relies on the fact that users of the biocidal product and the end-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 PROPOSED DECISION

The overall conclusion from the evaluation of tebuconazole for use in Product Type 7 (film preservatives), is that it may be possible to issue authorisations of products containing tebuconazole in accordance with the conditions laid down in Article 5(1) b), c) and d) of Dir. 98/8/EC.

It also appears from the report that the characteristics of tebuconazole render it very persistent (vP) and toxic (T) in accordance with the criteria laid down in Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council[6]. The period of approval should be 10 years in consistency with the current practice under Directive 98/8/EC, since the conditions of Article 90(2) of Regulation (EU) No 528/2012 are not met. However, for the purpose of authorising products in accordance with Article 23 of Regulation (EU) No 528/2012, tebuconazole shall be considered as a candidate for substitution pursuant to Article 10(1)(d) of that Regulation.

It is therefore appropriate to approve tebuconazole for use in biocidal products for product-type 7, and subject to the following specific provisions:

Tebuconazole is considered a candidate for substitution in accordance with article 10(1)(d) of Regulation (EU) No 528/2012.

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

Authorisations are subject to the following condition:

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

3.3 ELEMENTS TO BE TAKEN INTO ACCOUNT WHEN AUTHORISING PRODUCTS

For the purpose of authorising products in accordance with Article 23 of Regulation (EU) No 528/2012, tebuconazole shall be considered as a candidate for substitution pursuant to Article 10(1)(d) of that Regulation.

Products containing tebuconazole have been evaluated for the use to control fungi as a film preservative.

The following manner and area of use of products containing tebuconazole have been evaluated with the following specified maximum concentration of tebuconazole:

Product type	**Field of use envisaged for film preservation in:**	**Concentration at which tebuconazole has been evaluated in % (w/w)**

[6] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

PT 7 Film preservative	Joint sealants Industrial film preservation process Professional and non-professional use of end-products	Biocidal product: 10-40% End-product: 0.52%

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

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

3.4 REQUIREMENT FOR FURTHER INFORMATION

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

3.5 UPDATING THIS ASSESSMENT REPORT

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

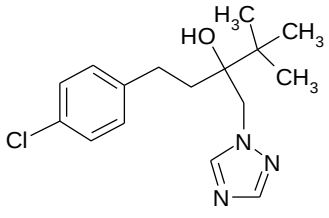
APPENDIX 1: Listing of Endpoints

CHAPTER 1: IDENTITY, PHYSICAL AND CHEMICAL PROPERTIES, DETAILS OF USES, FURTHER INFORMATION, AND PROPOSED CLASSIFICATION AND LABELLING

Active substance (ISO Common Name)	Tebuconazole
Function (*e.g.* fungicide)	Fungicide

Rapporteur Member State	Denmark

Identity (Annex IIA, point II.)

Chemical name (IUPAC)	(RS)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1*H*-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	C_{16} H_{22} Cl N_3 O
Molecular mass	307.8
Structural formula	

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

Melting point (state purity)	105ºC (99.9% pure)
Boiling point (state purity)	Not measurable, decomposes
Temperature of decomposition	TGA: Weight loss above 165ºC DSC: exothermic reaction above 350 ºC
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 26ºC (99.5% pure)
Surface tension	64.26 mN/m at 20ºC (saturated aq. soln.)
Vapour pressure (in Pa, state temperature)	1.7×10^{-6} Pa at 20ºC
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 20ºC
	pH__7____: 0.029 g/l at 20ºC
	pH__9____: 0.032 g/l at 20ºC
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	**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 (IIIA, point III.2)	Not applicable (the active substance as manufactured didn't include any organic solvent)
Partition coefficient (log P_{OW}) (state temperature)	3.53 at 10ºC
	3.49 at 20ºC

	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) (point VII.7.6.2.1)	pH___5___: Stable at 25ºC
	pH___7___: Stable at 25ºC
	pH___9___: Stable at 25ºC
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	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) (point VII.7.6.2.2)	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 (point VII.7.6.2.2)	The UV absorption data showed that aqueous solutions of tebuconazole do not absorb any light at wavelenghts 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	Tebuconazole has no oxidising properties.

Proposed classification and labelling (Annex IIA, point IX.)

with regard to physical/chemical data	None
with regard to toxicological data	According to Regulation (EC) No 1272/2008

	Repr. 2 Acute Tox 4 H361: Suspected of damaging the unborn child H302: Harmful if swallowed According to Directive 67/548/EEC 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	According to Regulation (EC) No 1272/2008 and No 286/2011 (2nd ATP) Aquatic Chronic 2 (Aquatic Chronic 1)* H411: Toxic to aquatic life with long lasting effects (H410: Very toxic to aquatic life with long lasting effects)* According to Directive 67/548/EEC Symbol N (in connection with R53) R51: Toxic to aquatic organisms

* According to No 286/2011 (2nd ATP)

CHAPTER 2: METHODS OF ANALYSIS

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	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) (Annex IIA, point 4.1)	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) (Annex IIA, point 4.2)	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) (Annex IIA, point 4.2)	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 standard. Limit of quantification (LOQ): 0.001 mg a.i./ m^3 air

Analytical methods for residues (continued)

Water (principle of method and LOQ) (Annex IIA, point 4.2)	Determination for tebuconazole in water 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
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	Relevant only for toxic substances.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not relevant
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not relevant

CHAPTER 3: IMPACT ON HUMAN HEALTH

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

Rate and extent of oral absorption:	Rapid and complete absorption, peak plasma levels approx. 1 to 2 hours after administration
Rate and extent of dermal absorption:	The active substance: Rapid (peak 0.5-4h) and 50% of the dose within 8 hours in the rat. The vehicle was ethanol 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% [^{14}C]-tebuconazole. The dermal absorption was studied on dermatomed human skin according to the OECD draft Guideline 428. 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 3-20 was 15.7% After 24 hours with 8 hours of exposure to the **water-based preparation**, the absorbed dose and residues found in stratum corneum strip 3-20 was 4.1%
Distribution:	Widely distributed, highest concentrations in kidney and liver
Potential for accumulation:	None
Rate and extent of excretion:	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	1H-1.2.4.-triazole (5% (m); 1.5% (f)

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral	1700 (f) and 4000 (m) mg/kg bw
Rat LD_{50} dermal	> 5000 mg/kg bw
Rat LC_{50} inhalation	Exposure: 1 x 4 hours > 371 mg/m^3 (aerosol) > 5093 mg/m^3 (dust)
Skin irritation	None

Eye irritation	None
Skin sensitization (test method used and result)	No skin sensitization in Magnusson-Kligman or Buehler Patch Test

Repeated dose toxicity (Annex IIA, point 6.3)

Species/ target / critical effect	Dog / adrenals / hypertrophy of *zona fasciculata* cells
Lowest relevant oral NOAEL / LOAEL	approx. 3 / 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 (Annex IIA, point 6.6)	No evidence for genotoxic potential was observed in an adequate battery of in-vitro tests with various endpoints including both prokaryotes and eukaryotes

Carcinogenicity (Annex IIA, point 6.4)

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

Reproductive toxicity (Annex IIA, point 6.8)

Species/ Reproduction target / critical effect	Rat/Decreased body weight gain and effects on the liver
Lowest relevant reproductive NOAEL / LOAEL	Rat, 2-generation Parental 300 ppm (21.6 mg/kg bw/day)/1000 ppm (72.3 mg/kg bw/dag) Reproductive 1000 ppm (72.3 mg/ kg bw/day)/- Offspring 300 ppm (21.6 mg/kg bw/day)/1000 ppm (72.3 mg/kg bw/day)
Species/Developmental target / critical effect	mice/rats/rabbits: foetotoxicity/malformations
Lowest relevant developmental NOAEL / LOAEL	Rats Dams: 10/30 mg/kg bw/day Foetuses: 30/100 mg/ kg bw/day Rabbits: Dams: 30/100 mg/kg bw/day Foetuses: 10/30 mg/kg bw/day Mice: Dams: 10/30 mg/kg bw./day Foetuses: 10/30 mg/kg bw/day

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

Delayed neurotoxicity : Not relevant

Neurotoxicity **Species/ target/critical effect**	Rats
Neurotoxicity **Lowest relevant developmental NOAEL / LOAEL.**	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 (Annex IIIA, VI/XI)

Toxicological studies of metabolites	All metabolites except 1,2,4-triazole do not show effects of concern related to toxicity. 1,2,4-triazole is classified with Repr. 2 (CLP)

Medical data (Annex IIA, point 6.9)

Medical surveillance on manufacturing plant personnel	No negative effects on the health of the workers engaged in the production of tebuconazole were determined during routine medical monitoring from 1998.

Summary (Annex IIA, point 6.10)	Value	Study	Uncertainty factor
AEL acute	0.03 mg/kg bw/day	Developmental mice	300
AEL medium term	0.03 mg/kg bw/day	1 year / dog	100
AEL long term	0.03 mg/kg bw/day	1 year / dog	100
Drinking water limit	Limit for pesticides in the Drinking Water Directive is 0.1 µg/l, no other value will be calculated.		

Acceptable exposure scenarios (including method of calculation)

Acceptable exposure scenarios (including method of calculation)

Industrial Users	RISKOFDERM (loading liquids, automated or semi-automatic)
Connecting/Disconnecting transfer lines	MOE = 103
Professional Users	ConsExpo 4.1, default scenario
Applying joint sealant, spreading with fingertip	MOE = 566
Non-Professional Users	
Applying joint sealant, spreading with fingertip	MOE = 566

CHAPTER 4: FATE AND BEHAVIOUR IN THE ENVIRONMENT

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	Tebuconazole is stable at pH 5, 7 and 9, at 25 °C after 28 days
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).
Biodegradation in seawater	no data on 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 CO_2 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 (Annex IIIA, point VII.4, XII.1.1, XII.1.4; Annex VI, para. 85)

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 $DT50_{lab}$ (20 °C, aerobic): > 1 year
	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 rotes 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 (Annex IIA, point XII.7.7; Annex IIIA, point XII.1.2)

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	K_a : arithmetic mean value: 12.7 L/kg Koc : arithmetic mean value: 992 L/kg Depending on organic carbon content no influence of inorganic soil components known Koc_{ads}: Adsorption: 992 mL/g (n = 6) Koc_{des}: Desorption: 1300 mL/g (n = 6) No pH dependence

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

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 presssure and Henry law constant exclude direct volatilisation, from water.

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

Soil (indicate location and type of study)	

Surface water (indicate location and type of study)	Outdoor pond studies available
Ground water (indicate location and type of study)	
Air (indicate location and type of study)	

CHAPTER 5: EFFECTS ON NON-TARGET SPECIES

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

Species	Time-scale	Endpoint	Toxicity
Fish			
Rainbow trout	96 hours, flow-through	$LC_{50,}$	4.4 mg/l
Rainbow trout	83d ELS, flow-through 21d,chronic semi-static	NOEC NOEC	0.012 mg/l 0.010 mg/l
Invertebrates			
Daphnia magna	48h, flow-through	EC_{50}(mortality) EC_{50}	4.2 mg/l 2.8 mg/l
Daphnia magna	21 d, semi-static	NOEC	0.01 mg/l
Algae			
Scenedesmus subspicatus *Demodesmus subspicatus*	chronic, 72 h, static	E_rC_{50} NOEC E_bC_{50}	5.30 mg/l 0.56 mg/l 1.96 mg/l
Selenastrum capricornutum *(Pseudokirchneriella subcapitata)*	chronic, 72 h, static chronic, 96 h, static	E_rC_{50} NOEC E_bC_{50}	3.80 mg/l 1.19 mg/l 2.83 mg/l
Microorganisms			
Activated sludge	30 min	EC_{50} (resp. inhib.)	EC_{50} above water sol. (32 mg/l)

Sediment-dwelling organisms *Chironomus riparius*	chronic, 28 d, static, spiked water	EC_{10} NOEC (sediment)	2.45 mg/l 54.5 mg/kg suspended sediment

Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworms (Annex IIIA, point XIII.3.2)	*Eisenia fetida* LC_{50} (14 d): 470 mg/kg dry weight soil
Reproductive toxicity to earthworms…… (Annex IIIA, point XIII.3.2)	Eisenia fetida 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 (Annex IIIA, point XIII.3.2)	Cress (Lepidium sativum) 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 EC0 (growth): 1.7 mg/kg dry soil (shoot fresh weight) after conversion to the TGD standard organic matter

Effects on soil micro-organisms (Annex IIA, point 7.4)

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 (Annex IIIA, point XIII.3.3)	Rats LD_{50}:1700 (f) and 4000 (m) mg/kg bw
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	Bobwhite quail, LD_{50} 1988 mg/kg bw
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	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	

(Annex IIIA, point XIII.1.3)	

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

Acute oral toxicity	
Acute contact toxicity	

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

Acute oral toxicity	
Acute contact toxicity	
Acute toxicity to	Soil mite EC_o = 50 mg a.s. / kg soil dw.
Chronic toxicity to	Collembola (28 days), NOEC = 250 mg a.s. / kg soil dw.

Bioconcentration (Annex IIA, point 7.5)

Bioconcentration factor (BCF)	78 L/kg for bluegill sunfish (*Lepomis macrochirus*) The BCF for earthworm is estimated according to TGD to 28 L/kg
Depuration time (DT_{50}) (DT_{90})	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

Summary of intended use for tebuconazole in PT7

Object and/or situation (a)	Member State or Country	Product name	Organisms controlled (c)	Formulation		Application			Applied amount per treatment			Remarks: (m)
				Type (d-f)	Conc. of as (i)	method kind (f-h)	number min max (k)	interval between applications (min)	g as/L min max	water L/m^2 min max	g as/m^2 min max	
Film preservative	EU	n.a.	Fungi	n.a.	10-40% (w/w)	The film preservation product containing tebuconazole is added to the end product in a semi-automatic process. The end-product is a sealant with a service life of 10 years			The concentration of tebuconazole in the end-product is 0.52% (w/w)			The biocidal product is intended for industrial use. The end product can be used by professionals and non-professionals

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

Appendix III: List of studies

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	Data Protection Claimed (Yes/No)	Owner	Submitted for the PT 08 dossier (Yes/No)
IIA, 2.6 /01	-	Stroech, K.	1994	Preventol A 8 - Synthesis. Bayer AG Non-GLP, unpublished **- CONFIDENTIAL -**	Yes	LANXESS Deutschland GmbH	Yes
IIA, 2.6 /02 2.7 /01 2.8 /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 **- CONFIDENTIAL -**	Yes	Bayer CropScience AG	Yes
IIA, 2.7 /02	-	Anon.	2001	Preventol A 8 - Certificate of Analysis, 5 Batches Analysis. Bayer AG, Report Non-GLP, unpublished **- CONFIDENTIAL -**	Yes	LANXESS Deutschland GmbH	Yes
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	Yes
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	Yes

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	Data Protection Claimed (Yes/No)	Owner	Submitted for the PT 08 dossier (Yes/No)
IIA, 2.8 /01		Allmendinger, H.	1988	Composition of Folicur (material accountability). Bayer AG, PC 463 GLP, unpublished **- CONFIDENTIAL -**	Yes	Bayer CropScience AG	Yes
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	Yes
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	Yes
IIA, 3.1 /01	IIA, 2.2 /01	Weber, R.	1987	Density of Tebuconazole (HWG 1608). Bayer AG, PC 438 Non-GLP, unpublished	Yes	Bayer CropScience AG	Yes
IIA, 3.1 /02 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	Yes	Bayer CropScience AG	Yes
IIA, 3.1 /03	IIA, 2.1.1 /01	Krohn, J.	1993	Melting point of Tebuconazole. Bayer AG, PC 424 GLP, unpublished	Yes	Bayer CropScience AG	Yes

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	Data Protection Claimed (Yes/No)	Owner	Submitted for the PT 08 dossier (Yes/No)
IIA, 3.1 /04 VIII.8.3 /02 VIII.8.4 VIII.8.5 VIII.8.6	-	Anon.	2003	Material Safety Data Sheet "Preventol A 8", No. 327445/27 Bayer AG Non-GLP, unpublished	-	LANXESS Deutschland GmbH	Yes
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	Yes	Bayer CropScience AG	Yes
IIA, 3.2 /02	IIA, 2.3.1 /02	Krohn, J.	1993	Vapour pressure curve of Tebuconazole. Bayer AG, PC 423 GLP, unpublished	Yes	Bayer CropScience AG	Yes
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	Yes
IIA, 3.3 /01	-	Schneider, K.	2005a	Apperarance of tebuconazole technical (UVP No.:04069382. Bayer CropScience AG, Non-GLP, unpublished	Yes	Bayer CropScience AG	Yes
IIA, 3.3 /02	-	Schneider, K.	2005b	Odour of tebuconazole technical (UVP No.:04069382. Bayer CropScience AG Non-GLP, unpublished	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes

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	Data Protection Claimed (Yes/No)	Owner	Submitted for the PT 08 dossier (Yes/No)
IIA, 3.5 /01	IIA, 2.6 /01	Krohn, J.	1995	Water solubility of Tebuconazole. Bayer AG, PC 664 (14 040 0839) GLP, unpublished	Yes	Bayer CropScience AG	Yes
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	Yes	LANXESS Deutschland GmbH	Yes
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	Yes
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	LANXESS Deutschland GmbH	Yes
IIA, 3.7/02 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 Coeficient (1-octanol/Water) with water solubility of Tebuconazoe determined under study number G 02/0104/01 LEV. Bayer Industry Services, Germany, 2005/0093/03 GLP, unpublished	Yes	LANXESS Deutschland GmbH	Yes

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	Data Protection Claimed (Yes/No)	Owner	Submitted for the PT 08 dossier (Yes/No)
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	Yes	LANXESS Deutschland GmbH	Yes
IIA, 3.13	IIA, 2.14 /01	Imre, L.	1989	Preventol VPOC 3047 (Tebuconazole) surface tension. Bayer AG, PC 754 GLP, unpublished	Yes	LANXESS Deutschland GmbH	Yes
IIA, 3.15	IIA, 2.13 /01	Eberz, A.	1999	Determination of safety-relevant data of Folicur. Bayer AG, 99/00455 GLP, unpublished	Yes	Bayer CropScience AG	Yes
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	Yes
IIA, 3.17	-	Talbott, T.D.	1988	Product Chemistry of FOLICUR Technical. Mobay Corp., USA Bayer AG, BR1614 GLP, unpublished	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes

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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	Yes	Bayer CropScience AG	Yes
IIA, 4.1 /03	IIA, 4.1.2 /01	Nonn, E.	2002	Folicur techn. ; Nebenkomponenten - Kapillargaschromatographie. Bayer AG, 2201-0237204-02 Non GLP, unpublished	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
IIA, 4.1 /05	II A, 4.1.3 /04	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 Non-GLP, unpublished	Yes	Bayer CropScience AG	Yes

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	Data Protection Claimed (Yes/No)	Owner	Submitted for the PT 08 dossier (Yes/No)
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
IIA, IV.4.2 /07	II A, 4.2.4 /02	Hellpointner, E.	2000	Confirmatory method for the determination of tebuconazole in air (confirmed method: 00278). Bayer AG, 00278C (MR-470/00) GLP, unpublished	Yes	Bayer CropScience AG	Yes
IIA, IV.4.2 /08	II A, 4.2.3 /01	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	Yes	Bayer CropScience AG	Yes

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IIA, V.5.3	-	Kugler, M.	2003	Test Report: Determination of the antimicrobial effects of Preventol A8 against fungi. Bayer AG Non-GLP, unpublished	Yes	LANXESS Deutschland GmbH	Yes
IIA, VI.6.1.1 /01 VI.6.1.2 /01 VI.6.1.3 /01 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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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) GLP, unpublished	Yes	Bayer CropScience AG	Yes

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	Data Protection Claimed (Yes/No)	Owner	Submitted for the PT 08 dossier (Yes/No)
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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 Bayer AG, BC1003 GLP, unpublished	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes

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	Data Protection Claimed (Yes/No)	Owner	Submitted for the PT 08 dossier (Yes/No)
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes

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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	Yes	Bayer CropScience AG	Yes
	-	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	Yes	Bayer CropScience AG	Yes
	-	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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes

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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	Yes	Bayer CropScience AG	Yes
	-	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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes

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	Data Protection Claimed (Yes/No)	Owner	Submitted for the PT 08 dossier (Yes/No)
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes

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IIA, VI.6.4 /04 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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes

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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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes

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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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes

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	Data Protection Claimed (Yes/No)	Owner	Submitted for the PT 08 dossier (Yes/No)
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes

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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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes

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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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes

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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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
IIA, VI.6.9.1 /04	IIA, 5.9.1 /04	Wey, J.M.; Forbes, J.D.	1997	HWG 1608 - Medical certification for tebuconacole and its formulation. Bayer Corporation, USA Bayer AG, MO-00-002189 GLP, unpublished	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
IIA, VI.6.9.7 /02 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	Yes	Bayer CropScience AG	Yes

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IIA, VII.7.1 /01	IIA, 8.2.1 /03	Surprenant, D.C.	1987	Acute toxicity of HWG 1608 (Technical grade) to Bluegill (*Lepomis macrochirus*) under flow-through conditions. Springborn Life Sciences, Inc., USA Bayer AG, 94861 (955) GLP, unpublished	Yes	Bayer CropScience AG	Yes
IIA, VII.7.1 /02	IIA, 8.2.1 /02	Surprenant, D.C.	1987	Acute toxicity of HWG 1608 (Technical grade) to Rainbow Trout (*Salmo gairdneri*) under flow-through conditions. Springborn Life Sciences, Inc., USA Bayer AG, 94860 (954) GLP, unpublished	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
IIA, VII.7.1 /04	IIA, 8.2.1 /04	Surprenant, D.C.	1988	Acute Toxicity of Technical Grade HWG 1608 to Sheepshead Minnow (*Caprinodon variegatus*) under Flow-Trough Conditions. Springborn Life Sciences, USA Bayer AG, 97467 GLP, unpublished	Yes	Bayer CropScience AG	Yes
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)	Yes

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IIA, VII.7.2 /01	IIA, 8.2.4 /01	Forbis, A.D.	1988 (rev. 1993)	Acute Flow-Through of HWG 1608 to *Daphnia magna*. ABC, USA Bayer AG, 96791 GLP, unpublished	Yes	Bayer CropScience AG	Yes
	IIA, 8.2.4 /01	Gagliano, G.G.	1988	Raw Data Supplemental for Acute Flow-Through of HWG 1608 to *Daphnia magna*. ABC, USA Bayer AG, 96791-1 GLP, unpublished	Yes	Bayer CropScience AG	Yes
IIA, VII.7.2 /02	IIA, 8.2.4 /04	Bell, G.	1997	Fluqinconazole, technical material, 100.8% w/w - 1,2,4 triazole: acute toxicity to *Daphnia magna*. Huntingdon Life Sciences, Huntingdon (UK), ENVIR/95/52 GLP, unpublished	Yes	TDMG (triazole derivative metabolites group)	Yes
IIA, VII.7.3 /01	IIA, 8.2.6 /01	Heimbach, F.	1987	Growth inhibition of green algae (*Scenedesmus subspicatus*) caused by HWG 1608 (technical). Bayer AG, HBF/AL 31 GLP, unpublished	Yes	Bayer CropScience AG	Yes
IIA, VII.7.3 /02	IIA, 8.2.6 /02	Bowers, L.M.	1996	Toxicity of Folicur technical to the green alga *Selenastrum capricornutum.* Bayer Corp., USA Bayer AG, 107341 GLP, unpublished	Yes	Bayer CropScience AG	Yes

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IIA, VII.7.3 /03	IIA, 8.2.6 /05	•	2001	1,2,4-triazole: A 96 hours toxicity test with the freshwater alga (*Selenastrum capricornutum*). Wildlife International Ltd, (USA), 528A 101 GLP, unpublished	Yes	TDMG (triazole derivative metabolites group)	Yes

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IIA, VII.7.4 /01	IIA, 8.7 /01	Mueller, G.	1993 (rev. 2000)	Studies on the Ecological Behaviour of Preventol A8. Bayer AG, 419 A/93 GLP, unpublished	Yes	LANXESS Deutschland GmbH	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes
IIA, VII.7.5 /02	IIA, 8.2.3 /02	Surprenant, D.C.	1988	Bioconcentration and Elimination of14C-Residues by Bluegill (*Lepomis marcochirus*) exposed to HWG 1608. Sprinborn Life Sciences, USA Bayer AG, 98036 (M 6253) GLP, unpublished	Yes	Bayer CropScience AG	Yes

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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	Yes	Bayer CropScience AG	Yes
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 (*Lepomis macrochirus*). Miles Incorp., USA Bayer AG, MR98037-1 GLP, unpublished	Yes	Bayer CropScience AG	Yes
IIA, VII.7.5 /05	-	Nisikawa, A.	1992	Bioaccumulation Study of Preventol A 8 with Carp (*Cyprinus carpio*). Mitsubishi-kasei Institute of Toxicological and Environmental Sciences (MITES), Japan Bayer AG, 1 B 454 G (M7619) GLP, unpublished	Yes	LANXESS Deutschland GmbH	Yes
IIA, VII.7.6.1.1 /01	-	Kanne, R.	1989	Biodegradation of Preventol VPOC 3047. Bayer AG, 94 N/89 GLP, unpublished	Yes	LANXESS Deutschland GmbH	Yes
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	Yes	LANXESS Deutschland GmbH	Yes

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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	Yes	Bayer CropScience AG	Yes
IIA, VII.7.6.2.1 /02	-	Krohn, J.	1984	Behaviour of agrochemical in water: active substance HWG1608. Bayer AG, M 2618 GLP, unpublished	Yes	Bayer CropScience AG	Yes
IIA, VII.7.6.2.1 /03	II A, 7.2.1.1 /02	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)	Yes
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	Yes	Bayer CropScience AG	Yes
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	Yes	Bayer CropScience AG	Yes

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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 Syngenta AG, M9224 Non-GLP, unpublished	Yes	TDMG (triazole derivative metabolites group)	Yes