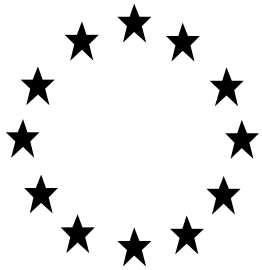
Directive 98/8/EC concerning the placing of biocidal products on the market

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

Assessment Report



Thiamethoxam

Product-type 8
(Wood preservative)

22 February 2008

Annex I - Spain

Thiamethoxam (PT 8)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 22 February 2008 in view of its inclusion in Annex I to Directive 98/8/EC

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of Thiamethoxam as product-type 8 (wood 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 a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Thiamethoxam (CAS no. 153719-23-4) was notified as an existing active substance, by Syngenta European Center, hereafter referred to as the applicant, in product-type 8.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 7(1) of that Regulation, Spain 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 Thiamethoxam as an active substance in product-type 8 was 28 March 2004, in accordance with Article 9(2) of Regulation (EC) No 1451/2007.

On 11 March 2004 Spain 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 June 2004.

On 5 July 2006 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 25 July 2006. The competent authority report included a recommendation for the inclusion of Thiamethoxam in Annex I to the Directive for product-type 8.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 19 December 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.

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.

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

2 Commission Regulation (EC) No 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

On the basis of the final competent authority report, the Commission proposed the inclusion of thiamethoxam in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 22 February 2008.

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 22 February 2008.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include thiamethoxam 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 thiamethoxam. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

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

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

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

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

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

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

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

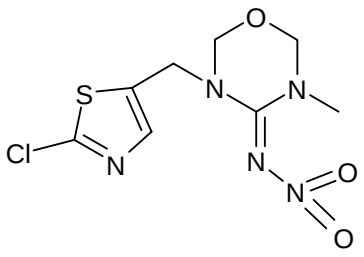
Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions 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.

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

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

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

CAS-No.	153719-23-4
EINECS-No.	428-650-4
Other No. (CIPAC, ELINCS)	CIPAC No. 637
IUPAC Name	3-(2-chloro-thiazol-5-ylmethyl)-5-methyl-[1,3,5] oxadiazinan-4-yllidine-N-nitroamine
Common name, synonym	Thiamethoxam
Molecular formula	$C_8H_{10}ClN_5O_3S$
Structural formula	
Molecular weight (g/mol)	291.7
Purity:	min 98% (w/w)

Thiamethoxam, is a slightly cream fine crystalline powder at room temperature with a melting point of 139.1ºC. Its relative density, $D^{20}_{4,}$ is 1.57 at 20 ºC. Thiamethoxam is a solid that thermally decomposes at about 147ºC. Its vapour pressure is low (6.6 x 10^{-9} Pa at 25ºC) and hence its Henry's Law Constant indicates that volatilisation is not expected to significantly contribute to the dissipation of Thiamethoxam in the environment. The solubility in pure water was determined to be 4.1 g/l at 25°C (pH 7). Thiamethoxam is not considered highly flammable or explosive or oxidizing. Full details of these properties are given in the Annex I Listing of End Points at the end of this document.

The methods of analysis of active substance as manufactured and for determination of impurities of toxicological, ecotoxicological or environmental concern or which are present at quantities > 0.1 g/kg in the active substance as manufactured have been validated and shown to be sufficiently specific, linear, accurate and precise, and the methods for analysis in environmental matrices, as appropriate for the assessed uses have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

2.1.2. Intended Uses and Efficacy

Thiamethoxam is an insecticide to be used as a wood preservative (main group 02, product type 8). It is used to control termites (*R. flavipis, R. hegani, R. santonensis)* and the house longhorn beetle (*H. bajulus)*.

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

Hazard symbol(s)	N, Xn	
Indication of danger	Harmful.	
Risk phrases	R22	Harmful if swallowed.
	R50/53	Very toxic to aquatic organisms/may cause long-term adverse effects in the aquatic environment
Safety phrases	S46	If swallowed, seek medical advice immediately and show this container or label.
	S60	This material and its container must be disposed of as hazardous waste.
	S61	Avoid release in the environment. Refer to special instructions/safety data sheet

Justification for the proposal

Thiamethoxam is a solid and not classified as flammable. It is not explosive nor does it have oxidising properties. There is no record that it has reacted with any storage container during many years of industrial production. Therefore, there are no physical chemistry related hazards associated with normal use of the active substance.

The safety phrases proposed are based on the classification and risk phrases. The classification is based on toxicological studies, which indicate that thiamethoxam is harmful when swallowed.

Because of the high toxicity of the substance, setting specific lower concentration limits for the substance should be considered for both environmental effects when the substance is under discussion for inclusion on Annex I of Directive 67/548/EEC.

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification and effect assessment

Thiamethoxam is classified structurally as a member of the neonicotinoid chemical class. The biological effects of this chemical class in the target animals are mediated primarily by an interaction with nicotinic acetylcholine receptor sites. Delayed neurotoxicity studies according to OECD Guideline 418 were not performed because the structure and chemistry of Thiamethoxam does not resemble chemical structures known to induce delayed neurotoxicity.

Metabolism

In rat, thiamethoxam is rapidly and completely absorbed following oral administration. Compound is absorbed, from the gastrointestinal tract into systemic circulation. The metabolites and unchanged thiamethoxam were eliminated very rapidly and almost completely via urine. Within 24 hours about 84-95% of the dose was excreted via kidneys and about 3-6% of the dose with the faeces. Metabolism studies in rats with thiamethoxam showed that it is rapidly absorbed and partially degraded following oral administration, with a short plasma half-life (2-6 hours). In total, about 70-80% of the dose test substance was eliminated as unchanged thiamethoxam. Only 20-30% of the dosed test substance was biotransformed. In rat, 22 metabolites were isolated from excreta and identified.

In mouse, metabolic degradation of thiamethoxam proceeds via the same pathway as in the rat. About 30-60% of the administered thiamethoxam was excreted as metabolites. All major and almost all minor metabolites found in rat excreta were also detected in mouse excreta.

Overall, the metabolic pathways are independent of the route of administration, the dose level, pre-treatment, and the sex of the animals.

Regarding dermal absorption, a comparative *in vitro* study in rat and human skin demonstrated very low dermal absorption from the formulated product. Human dermal absorption was approximately 4.8-5.8 times lower than rat dermal absorption. This data can be used to produce a prediction for human in vivo dermal absorption of 0.02% of applied dose for the concentrate, and 1.25% of applied dose for the in-use dilution.

Dermal Absorption

A comparative *in vitro* dermal absorption study in rat and human skin demonstrated very low dermal absorption from the formulated product. Human dermal absorption was approximately 4.8-5.8 times lower than rat dermal absorption.

This data can be used to produce a prediction for human in vivo dermal absorption of 0.02% of applied dose for the concentrate, and 1.25% of applied dose for the in-use dilution.

Acute toxicity

Thiamethoxam is of low acute oral toxicity to both male and female rodents; the mouse is slightly more sensitive than the rat (LD_{50} as average between male and females results are: rat LD_{50} = 1563mg/kg, mouse LD_{50} = 871mg/kg). Signs of acute thiamethoxam intoxication in these species are tonic or clonic convulsions and ptosis. According to Commission Directive 93/21/EEC it would require a label of "harmful if swallowed" (R22).

Thiamethoxam is of low percutaneous toxicity in the rat (LD_{50} >2000mg/kg). No classification for dermal toxicity is required according to Commission Directive 93/21/EEC.

No serious signs of toxicity occurred following a 4-hour inhalation exposure to 3.72 g/m^3 respirable particles of thiamethoxam. Since this was the highest technically feasible concentration in the respirable range, no classification is required for inhalation hazard according to Commission Directive 93/21/EEC.

Thiamethoxam is not irritant to skin and eyes since the mean irritation scores 24, 48 and 72 hours after application are below the thresholds defined in Commission Directive 93/21/EEC. Thus, classification of thiamethoxam for skin and eye irritating properties is not required.

An adjuvant-assisted contact sensitisation study gave an overall net response rate of 5%. According to Commission Directive 93/21/EEC, this result is below the threshold for classification as a sensitiser.

Repeated toxicity

The liver and kidneys were identified as target organs. Treatment for 13 weeks induces liver hypertrophy, inflammatory cell infiltration and pigmentation of Kupffer cells in both rodent species. In mice, single cell necrosis occurs in parallel with these alterations. Dogs were generally refractory to hepatotoxicity, but at high dosage, minimal pigmentation of Kupffer cells occurred.

Effects on the kidneys occur in rats only. Both sexes are affected, but there is a clear difference between the sexes in both morphology and sensitivity. In the male, nephrotoxicity is characterised by tubular epithelial hyaline droplet accumulation, acute and chronic tubular lesions, basophilic proliferation and cast formation. In the female, morphological alterations are confined to chronic tubular lesions and enhanced nephrocalcinosis.

Other target organs and alterations, occurring in one species only, were fatty changes in the adrenal cortex, enhanced hemosiderosis or extramedullary hematopoiesis in the spleen, and follicular epithelial hypertrophy in the thyroid gland of rats. The latter alteration is likely to reflect activation of liver metabolising activity concomitant with observed liver hypertrophy. Thymic and splenic atrophy in the dog, and alterations suggestive of delayed maturation of the gonads in dogs and female mice, occurred at dosages causing substantial growth retardation

Genotoxicity

None of the studies revealed any genotoxic effects of thiamethoxam at the DNA level, the gene level or the chromosome level of organization, either with or without metabolic activation (standard or from thiamethoxam induced mice).

The test was designed to evaluate *in vivo* clastogenic potential in somatic cells. Thiamethoxam was not clastogenic or aneugenic.

Carcinogenicity

Two long-term toxicity and carcinogenicity studies were performed in mice and rats. The main target organs were the liver in mice and female rats and the kidneys in male rats. Minor and morphologically different changes occurred in the spleen of both rats and mice.

The lowest NOEL for toxicity determined in these studies, in the male rat, was 1.29mg/kg bw/day (30 ppm) based on the presence of an increased incidence of renal tubular regenerative lesions (at 500 ppm). These lesions are considered to represent the sequelae of alpha-2μ-globulin mediated nephropathy, observed in a previous 13-week study in the rat. Since it is widely acknowledged that this condition is unique to sexually mature male rats, and is not indicative of a human health hazard, a NOAEL in the male rat can be established at >63.0mg/kg bw/day.

Therefore, the lowest NO(A)EL established in this group of studies, occurring in the male mouse, is 2.63mg/kg bw/day, based on the occurrence of neoplastic and non-neoplastic alterations in the liver. A neoplastic response was unique to the mouse liver and only occurred simultaneously with hepatotoxicity (necrosis). Therefore, the MTD was achieved or exceeded at all dose levels at which neoplasia occurred. Subsequent investigative studies have provided evidence indicating the neoplastic outcome of prolonged administration of thiamethoxam is mediated by sustained regenerative cell proliferation in response to cytotoxicity, and by liver enzyme induction. Since a clear threshold level for non-neoplastic hepatotoxicity was established and given the absence of genotoxicity in all *in vitro* and *in vivo* mutagenicity studies, it is concluded that the neoplastic effect in mouse liver is a non-genotoxic event with a definable threshold. A carcinogenic response did not occur in rats.

Reproductive toxicity

Teratogenicity

The potential for thiamethoxam to affect the mammalian reproductive process specifically, embryogenesis and foetal development was assessed in embryotoxicity studies in the rat and rabbit.

In both studies was observed reduced fetal weight, delayed ossification and increased post-implantation loss (rabbit only) at maternal toxic doses.

Fertility

The potential for thiamethoxam to affect the mammalian reproductive process including gonadal function and, specifically, embryogenesis, foetal and post-natal development was assessed in two multigeneration study in the rat. There was an effect on testicular histopathology (germ cell loss/disorganisation +/- Sertoli cell vacuolation) in F1 animals. So, a NOAEL of 1000 ppm (62 mg/kg bw/day) in males was established for parental reproduction based on this effect. This histological change did not affect reproductive function.

Was observed a parental systemic toxicity based on the kidney findings in male of both generations at higher levels. They were consistent with ά-2μ globulin nephropathy, specific for male rats and therefore was not considered in risk assessment

Neurotoxicity

Thiamethoxam is classified structurally as a member of the neonicotinoid chemical class. The biological effects of this chemical class in the target animals are mediated primarily by an interaction with nicotinic acetylcholine receptor sites. Delayed neurotoxicity studies, according to OECD Guideline 418, were not performed because the structure and chemistry of thiamethoxam does not resemble chemical structures known to induce delayed neurotoxicity.

Medical data

Manufacturing employees in Switzerland are medically examined in Occupational Health Surveillance Programs by a company physician at the beginning of their employment and then routinely once a year according to the criteria of the Swiss Accident Insurance Institution (SUVA). It has been reported that no adverse health effects that could be related to thiamethoxam.

Data and safety factors used for deducing AOEL

The AOEL is a health-based exposure limit and is established on the basis of the toxicological properties of the active substance.

For long duration exposure (industrial /professional users) the AOEL used is based on the basis of changes to liver morphology and increased incidences of non-neoplastic alterations in the liver (hypertrophy, pigment deposition, mitotic activity, kupffer cells hyperplasia and single cell necrosis) derived from the combined chronic toxicity/carcinogenicity study performed in mice, the relevant NOAEL value is considered to be 2.63 mg/kg bw/day. Uncertainly factors of 10 for both inter and intra species were considered adequated. This results in a systemic AOEL value of 0.0263 mg/kg bw/day.

The use of short-term studies of up to 13 weeks duration is used in the case of short duration exposure (non-professional users). In this case, the lowest NO(A)EL is seen the 90 day mouse study. A NOEL value of 1.41 mg/kg bw/day was derived on the basis of histological findings in liver. Nonetheless, a very large interval was used; the gap between LOAEL and NOEL is at least 10-fold (LOAEL 14.3 mg/kg bw/day). This reason together with the NOEL for the mouse is very conservative and driven by the large dose different selected for the mouse studies (hypertophy was an isolated finding and seems to be related to enzyme induction which can be

considered and adaptative effect). So, the semi-chronic AOEL is established on the NOAEL of 8.2 mg/k bw/day (250 ppm) found in the 90day study with dog, based on prolonged thromboplastin times, slightly reduced plasma Ca^{2+} and minimal adaptative changes in blood chemistry at ≥ 1000 ppm (32mg/kg bw/day). Hence, a safety factor of 100 was considered adequated, and AOEL value of 0.08 mg/kg bw/day for short duration exposures for non professional users.

An acute AOEL has been established based on the NOAEL of rabbit developmental toxicity study. The NOAEL in this study was of 50 mg/kg bw/day for dams (based on the findings of minimally reduced weight gain and food consumption) and for offsprings (based on reduced foetal weight, delayed ossification and increased post-implantation loss at maternal toxic doses at 150 mg/kg bw/day). The corresponding acute AOEL is 0.5 mg/kg bw/day applying a safety factor of 100.

2.2.1.2. Exposure assessment and risk characterisation

Human health risk for professional users

The application of thiamethoxam as wood preservative (PT8) in an industrial and a professional environment can result in direct exposure via skin contact or via inhalation, but the oral ingestion is not considered as a potential direct route for exposure during the use of wood preservatives. As there are not measurements of human exposure, exposure has been estimated with the models provided in the TNsG.

The most relevant exposure path associated to the **industrial procedures** is dermal and it potentially might happen during the post application task, in dipping, double-vacuum and pressure impregnation of timber. Although inhalation is considered to be no significant, it has been assessed as well, and the estimated total exposure, considering that used gloves are worn but there is not respiratory protective equipment (RPE).

Regarding the **professional procedures**, the task with potential exposure while in situ spraying is the application of the wood preservative, and the most important route in this case is the inhalation. In the brushing procedure the inhalation route has been considered the most relevant as well, though in both cases the dermal route of exposure has been assessed for the application task too.

Summary of risk assessment for industrial/professional use

Scenario			Systemic dose (75%-ile/95%-ile) mg/kg/day	MOE
Industrial/Professional	Double-vacuum (with gloves but without RPE)		0.00104616	2514
			0.00292443	899
	Pressure impregnation (with gloves but without RPE)		0.0001247	21091
			0.00025335	10381
	Dipping (with used gloves but without RPE)		0.00314992	835
			0.00620575	424
Professional	Small scale dipping (with used gloves but without RPE)		0.01515208	174
			0.02205023	119
	In situ spraying (indoors) (without RPE neither gloves)		0.00212975	1235
			0.01839151	143
	Brushing (without protection)	Indoor	0.00250067	1052
			0.00411137*	640
		Outdoor	0.00042477	6192
			0.00177886*	1478

All MOE calculated are above 100. This default cut-off value of 100 is based on the use of inter and intra-species variability factors, each of 10. Therefore, the exposure for industrial/professional users is considered to be within the acceptable range.

Human health risk for non professional users

Only product containing 0.04% in ready-to-use mixtures are available to non-professional users, therefore mixing and loading is no a relevant task for this group. The total systemic exposure has been estimated for the application of the wood preservative and the cleaning of the equipment, and the exposure routes assessed for both brushing and spraying techniques are dermal and inhalation.

Summary of risk assessment for non-professional use

Scenario Non-Professional		Systemic dose (75%-ile/maximum) mg/kg/day	MOE
Brushing (without personal protective equipment)	indoor	0.00250067	3279
		0.00411137	1994
	outdoor	0.00042477	19305
		0.00177886	4610
Spraying (without personal protective equipment)	indoor	0.0027492	2983
		0.003459467	2370
	outdoor	0.000777226	10550
		0.00156385	5243

Margins of exposure above 100 were calculated. Therefore, the exposure for non-professional users is considered to be within the acceptable range.

Other effects: Products applied by non-professionals are water based ready to use formulations and its application not more than one or twice a year (since they are unlikely to use the product sufficiently frequently). It is considered that its use for non-professional users will not be of concern.

Human health risk from indirect exposure as a result of use

Secondary exposure scenarios has been assessed to represent worst cases for all of the relevant exposure routes: dermal (manual handling of wet wood; cleaning work wear at home; children playing on preserved wood), oral (infants chewing preserved timber off-cuts) and inhalation (processing of treated wood).

The handling and processing of treated wood can be performed by professionals as well as by amateurs. The dermal contact while handling wet wood represents the highest exposure. On the other hand, the processing of dry treated wood, especially when it generates large amounts of dust, is considered to be the worst case for exposure by inhalation. Another secondary scenario for adults is the washing of contaminated work clothing and the relevant route for this task is also the dermal mainly to hands.

Children and infants are a group of risk through secondary exposure because the may contact surfaces treated with wood preservatives. When playing on preserved timber, the relevant exposure is dermal; oral exposure might occur when children put their hands into the mouth, but this is assumed to result in lower exposure than estimated in the scenario of chewing preserved timber off-cuts. This second scenario is then considered to represent the worst case for oral exposure.

Summary of risk assessment from indirect exposure as a result of use

Secondary exposure Scenario	Calculated exposure (mg a.i./kg bw/day)		MOE
Intended secondary exposure	Handling of wet wood treated by double vacuum impregnation	Professionals: 0.0003284	8009
		Amaeturs: 0.0003284	152253
	Handling of wet wood treated by dipping	Professionals: 0.0021896	1201
		Amaeturs: 0.0021896	22835
	Processing of treated wood	Professionals: 0.0000682	38563
		Amaeturs: 0.0000085	5882353
Unintended secondary exposure	Cleaning work wear	(Adult): 0.000054	48704
	Playing on preserved timber	Children: 0.000001	2630000
		Infants : 0.000002	1315000
	Chewing preserved timber off-cuts	Pressure or double vacuum: 0.0024	20833
		Surface treatments (Spraying or brushing): 0.0006	83333

Chronic secondary exposure is relevant for adults who handling of treated wet wood or wash contaminated clothing. The calculated exposure of adults is very low and this results in large MOEs that are considered to be acceptable.

Children may have repeated contact with thiamethoxam- treated wood, eg. on playgrounds. For infants, dermal contact and oral absorption after hand-to-mouth contact are possible routes of exposure.

Margins of exposure above 100 were calculated. Therefore, they are considered to be acceptable.

Human health risk for combined exposure

The potential for combined exposure for the different groups of risk has been calculated adding the indirect exposure to each user. Only the 75^{th} –ile has been considered, because in some scenarios there is no 95^{th} –ile, and always the worst case has been selected.

For an **industrial user**, the estimated worst total systemic exposure corresponds to double vacuum impregnation technique. As an amateur, he or she can apply the thiamethoxam by spraying indoor, which is the worst case among the non-professional techniques. Moreover, it has to be considered the potential secondary exposure after the contact to the residues in air or in surfaces in places where the wood preservative has been used. Finally, the cleaning of work wear is a task that may be carried out by the same person. Adding up all these figures, it gives a **MOE of 1447**.

Regarding the **professional user**, the worst case between the application techniques is the in situ spraying indoors. If this user is supposed to carry out a non-professional application and he also handles treated wood and washes contaminated clothes, a **MOE of 1207** is obtained.

The last scenario for combined exposure is for a **non-professional user**, who applies the product by spraying indoor as a worst case. Secondarily, this user may be exposed after handling treated wood and cleaning work wear, giving a MOE of 10979**.** These exposures are considered acceptable.

Summary of risk assessment for combined exposure

User	Combined exposure (mg a.i./kg bw/day)	MOE
Industrial	0.03078176	85
Professional	0.0510331	52
Non-professional	0.0297356	276

2.2.2. Environmental Risk Assessment

Thiamethoxam [3-(2-chloro-thiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-ylidene-N-nitroamine] is a novel broad spectrum insecticide currently under development by Syngenta Crop Protection AG and Xamox TK10 is the formulated product. The active ingredient has insecticidal (not acharicidal) activity and is a neonicotinoid compound. Thiamethoxam is intended to be used in mixtures for wood treatment for control various wood pests. The submission was initially for industrial use (application techniques are double-vacuum process and pressure impregnation), *in situ*, remedial wood preservation by professionals and non-professionals by brushing and spraying and indoors. Later, the submission was redefined for industrial preventive treatments (vacuum-pressure and surface automated treatments by spraying and dipping) and in situ remedial wood preservation by professionals and non-professionals by brushing. The wood hazard classes were initially 1, 2, 3 and 4a but later the applicant retired the application for class 4a.

The in situ spraying use was not evaluated in this report. There was no scenario to calculate PEC for this use at the time this report was prepared. Then, it was agreed in the TMII07 that the use would be evaluated at the product authorization stage.

The information submitted in the dossier was evaluated and interpreted in the light of the OECD series on Emission Scenario Documents for Wood Preservatives (OECD-ESD) and ECB Technical Guidance Document on Risk Assessment (TGD), together with the knowledge from experts in the Technical Meetings held ad hoc. Risk scenarios for in situ application were calculated for brushing (house, bridge) and industrial treatments considered were vacuum-pressure, dipping and automated spraying. Risk for wood in service scenarios were calculated for class 3 woods.

Consequently, from the dossier presented by the applicant to comply the requirements of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, it has been elaborated the present report.

Thiamethoxam is released to the environment due to application processes, storage of the treated wood and service life of the treated item in the proposed scenarios for each hazard class.

One of the more relevant metabolites from Thiamethoxam is formed in soil, and was named in this dossier CGA 322704. This molecule is equivalent to the active ingredient Clothianidin.

The main receiving compartments are the aquatic and the soil compartment.

2.2.2.1. Fate and distribution in the environment

Fate and behaviour in air

The substance is not volatile and quickly oxidized by hydroxyl radicals in the atmosphere. It is more likely to be dispersed in air as aerosol than as vapour. Then, PEC for this compartment was not calculated as risk was considered not of concern for this compartment.

Fate and behaviour in water/sediment systems

In water thiamethoxam is hydrolyzed in neutral to alkaline pH in a temperature dependent manner. The chemical is photosensitive and binds to the sediment, and it is substrate for biota although is not readily biodegradable. The degradation of thiamethoxam in water seems to occur primarily by biological and then some photolytic processes.

Dissipation in water/sediment systems seems to occur because thiamethoxam binds to sediment and then is either degraded or builds up non extractable residues.

In anaerobic conditions degradation takes place and thiamethoxam is mostly transformed into metabolites. The main was formed by reduction and is NOA 407475 (de-nitro derivative formed up to 63% of initial thiamethoxam), which has potential to bind to sediment.

The most ecotoxicologically relevant metabolite, CGA 322704, is not formed as degradation product in water sediment studies but is stable in water at any pH or temperature. In water/sediment systems it may attach to sediment and be degraded via de-nitrification to some extent.

Fate and behaviour in soil compartment

Thiamethoxam is degraded in soil and can be even mineralized, but its half life depends mainly on the nature and biota of the soil. The anaerobic metabolism is very effective. Photodegradation contributes to superficially located substance. In aerobic soil, thiamethoxam yields several metabolites, including CGA 322704, which can reach up to 35.6%. The metabolite CGA 322704 is stable in water over a wide pH and temperature ranges and is found mainly in soils as thiamethoxam derived product The field soil dissipation and accumulation studies suggest the tendency of metabolite CGA 322704 to increase with time in deeper soil layers.

The submitted adsorption-desorption studies indicated that adsorption of thiamethoxam is not a single step process, but continues with time. Thiamethoxam binds weakly to soil and so does its metabolite (see Koc in endpoint listing). Therefore, Thiamethoxam and its metabolite CGA 322704 have potential to leach.

2.2.2.2. *Effects assessment*

Effects on aquatic organisms

Toxicity of Thiamethoxam to aquatic organisms

Type of Organisms	Species	Study Type	LC_{50} or EC_{50} or LOEC[a] [mg/L]	LC_0 (acute)or NOEC (chronic) [mg/L]
Fish	Rainbow trout	96-h acute	> 125	125
	Rainbow trout	96-h acute	> 100	100
	Bluegill sunfish	96-h acute	> 114	114
	Rainbow trout	28-d chronic	> 100[a]	100
	Rainbow trout	88-d chronic	> 20[a]	20
Crustaceans	*Daphnia magna*	48-h acute	> 100	32
	Gammarus Sp.	48-h acute	2.8	< 1.6
	Daphnia pulex Leydig	24-h acute	> 100	6.3
	Thamnocephalus platyurus	24-h acute	> 100	100
	Ostracoda	48-h acute	0.18	0.063
	Daphnia magna	21-d chronic	> 100[a]	100
Molluscs	*Lymnea stagnalis*	48-h acute	> 100	100
	Radix peregra	48-h acute	> 100	100
Insects	*Cloeon* Sp. (Ephemeroptera)	48-h acute	0.014	0.0063
	Chaoborus Sp.	48-h acute	5.5	3.1
	Chironomus riparius	48-h acute	0.035[d]	0.013[d]
	Chironomus riparius larvae	30-d chronic / water applic.	0.0114	0.01
	Chironomus riparius larvae	30-d chronic / sediment appl.	0.11[e]	0.1[e]
Rotifer	*Brachionus calyciflorus*	24-h acute	> 100	100
Aquatic plants	Green algae *Selenastrum capric.*	72-h acute	> 81.8[b]	81.8
	Green algae *Selenastrum capric.*	96-h acute	> 100[b]	100
	Duckweed *Lemna gibba*	7-d subchronic	> 90.2	90.2

[a] LOEC , [b] E_rC_{50} based on growth rate, [c] pH equilibrated (pH not equilibrated), [d] derived from spiking the water phase, [e] in mg /kg sed., [f] based on emergence rate

For the aquatic compartment, insects were the most sensitive taxa with a distance of two orders of magnitude with the rest of taxa tested. This is as consequence of the mechanism of action of the active substance, a broad spectrum insecticide designed to control suckling and chewing insects.

Aquatic PNEC value for thiamethoxam (and as no data was submitted for the formulated product, is assumed to be extensive to it) was estimated **in 0.00014 mg a.i./l**. PNEC was derived from lowest toxicity data (i.e the toxicity data for the most sensitive taxa data, EC50 for Cloeon of 0.014 mg a.i./l) using an assessment factor of 100 instead of the TGD recommended 1000 because this taxa was regarded with high probability the most sensitive and a further long-term NOEC from different taxonomic group would not be lower than the data already available. Therefore, the endpoint was derived to cover both long and short term effects in the most sensitive taxa

Toxicity of Thiamethoxam metabolite CGA 322704 to aquatic organisms

CGA 322704				
Type of Organisms	**Species**	**Study Type**	**LC_{50}/EC_{50} or LOEC[a] [mg/L]**	**LC_0 (acute) NOEC (chronic) [mg/L]**
Fish	Rainbow trout,	96-h acute	> 100	100
Crustaceans	*Daphnia magna*	48-h acute	> 100	100

CGA 322704				
Type of Organisms	Species	Study Type	LC_{50}/EC_{50} or LOEC[a] [mg/L]	LC_0 (acute) NOEC (chronic) [mg/L]
Algae	Green algae *Selenastrum capric.*	72-h acute	> 100	100
Insects	*Chironomus riparius larvae*	30-d chronic / sediment appl.	0.025 [e]	0.015 [e]
	Chironomus riparius (Larvae development rate)	30-d chronic / sediment appl.	0.0529	0.015
	Chironomus riparius	28-d chronic water spiked		0.00067

Aquatic PNEC for metabolite CGA 322704 was obtained from the most sensitive taxa in a long term test performed in Chironomids, NOEC was 0.67 µg/l and an assessment factor of 10 was applied following TGD, as the taxa tested is with high probability the most sensitive and a further long-term NOEC from different taxonomic group would not be lower than the data already available. Then **aquatic PNEC for CGA 322704 is 0.067 µg/l.**

Sediment PNEC of thiamethoxam was estimated in 0.01 mg/kg and was derived from the lowest chronic toxicity to chironomids (NOEC of 0.10 mg a.i./kg sediment) applying an assessment factor of 10 as there is enough data from the aquatic compartment and the test was performed in the most sensitive taxa.

Sediment PNEC for metabolite CGA 322704 was based on a NOEC for chironomids of 0.015 mg/kg sediment and applying an assessment factor of 100 as this was the only toxicity data for this metabolite, and resulted in a value of **0.00015 mg /kg.**

The output of the Chironomid tests was based on nominal concentrations, which for some opinions might underestimate the risk. Measured concentrations could not be obtained due to technical reasons and an estimation could not be applied since the available parameter DT50 was not appropriate for it.

PNEC for sewage organisms was estimated to be higher than 1 mg/l based on a EC50 value obtained from the respiration inhibition test (>100 mg/l) applying a safety factor of 100 as directed by the TGD.

Effects on terrestrial organisms

Thiamethoxam and its metabolites had no significant effects on soil micro-organisms as indicated by respiration and nitrification studies. The studies with arthropods presented in the dossier are not relevant for assessing the risk for Thiamethoxam used as wood preservative biocide, as all the studies were presented exposing the animals to treated seeds, which is not comparable to the exposition route expected for a wood preservative biocide proposed scenarios.

From the data available, earthworms are the most sensitive group. These organisms are sensitive to both thiamethoxam and to metabolite CGA 322704. Tests presented within the Biocide Dossier together with data from PPP monograph proposed by the applicant were used for the risk evaluation. A field study of toxicity of thiamethoxam, evaluated for the PPP monograph, was used although adapted to the Biocides scenarios to obtain an endpoint and

calculate a PNEC applying an AF = 2 to the NOEC of the test. Regarding the metabolite CGA 322704, also field data were submitted and used for PNEC calculations, and an AF = 2 was applied to the NOEC of the study.

Toxicity data used to calculate Thiamethoxam terrestrial PNEC value

Testing	Species	Test duration	Measurement	Result
Acute toxicity earthworm	*Eisenia foetida*	14 days	LC_{50}	>1000 mg a.i./kg
Chronic toxicity earthworm	*Eisenia foetida*	8 weeks	NOEC	**0.68 mg a.i./kg** Data from the PPP monography, page 795, 10.6.1.2/01: 4616 g formulation (Actara WG 25)/ha, then 1154 g a.i./ha and assuming 1 ha as 1700000 kg wet soil in a biocide scenario.
Earthworm field study	Various species	337 d	NOEC	200 g a.i./ha. This is equivalent to **0.133 mg a.i./kg** wet soil. Field study found in the PPP monograph Ecotox addenda (Jan 2004).
Nitrification – Carbon transformation	Soil microorganisms	28 days	NOEC	2.67 mg a.i./kg

PNEC for thiamethoxam was estimated from the earthworm toxicity field study lasting 337 d (evaluated in one of the PPP monograph addenda). Applying a factor of 2 for a field study, the PNEC for thiamethoxam in soil results in 0.0665 mg a.i./kg soil.

Toxicity data for thiamethoxam metabolite CGA 322704 used to calculate a terrestrial PNEC value

CGA 322704				
Testing	**Species**	**Test duration**	**Measurement**	**Result**
Acute toxicity earthworm	*Eisenia foetida*	14 days	LC_{50}	5.93 mg a.i./kg
Acute toxicity earthworm	*Eisenia foetida*	14 days	NOEC	2.5 mg a.i./kg
Chronic toxicity earthworm	*Eisenia foetida*		NOEC	0.06 mg a.i./kg
Earthworm field study	Various species	337 d	NOEC	**0.016 mg a.i./kg**
Nitrification – Carbon transformation	Soil microorganisms	28 days	NOEC	0.5 mg a.i./kg

Regarding CGA 322704 soil ecotoxicity the endpoint of 0.016 mg a.i./kg soil was considered to estimate the PNEC for this compound. This concentration produced effects in the numbers of ‘epilobous juvenile’ and ‘total juvenile’ the first sampling date, however the effects were overcome at the end of the test. Considering that the data comes from a field study on the most sensitive taxonomic group, and that effects are recovered at the end of the test, covering as well intertaxa variability, then PNEC after AF=2 for CGA 322704 in soil is 0.008 mg a.i./kg of soil.

Secondary poisoning

Thiamethoxam (log K_{ow} = - 0.13 at 25 ˚C) has a low potential to accumulate in environmental compartments. With limited exposure under practical use pattern, the potential for biomagnification of thiamethoxam in the food chain is negligible. Thus, birds are not considered to be exposed to hazard by these means.

2.2.2.3. PBT assessment

PBT assessment

Following the TGD directions as in part II page 164.

P criterium: Half life > 40 d freshwater or >120 d in freshwater sediment.

From data of hydrolysis:
- Half life is 640-572 d at pH7
- Half life is 4.2-15.6 d at pH9
- Thiamethoxam is considered stable at pH5

From data of photolysis:
- Half life is 2.3-3.1 d

From the submitted studies there are data of half life of thiamethoxam in sediment. However, the calculated DT50 provided for water and for sediment were not validated due to the method of calculation. There is data from the total system as well. In all cases, DT50 is under 120 d.

Consequently, at pH 7 the substance complies with the P criterium.

B criterium: BCF > 2000.

Given the low K_{ow} of thiamethoxam (log K_{ow}= - 0.13 at 25ºC) it suggests a low potential to accumulate in environmental compartments the substance has not potential to bioaccumulate.

Then the B criterium is not complied.

T criterium: Chronic NOEC < 0.01 mg/l or CMR or endocrine disrupting effects.

NOEC for chironomids 0.01 mg/l (is the most sensitive NOEC). The T criterium is not complied.

vP-vB assessment

vP criterium : DT50 in aquatic sediment is >180 d and DT50 in water is >60 d.

Consequently, in water the vP criterium it is complied at pH 7. In sediment it is not complied.

vB: BCF > 5000.

As it was discussed above, given the log K_{ow} of thiamethoxam (log K_{ow}= - 0.13 at 25ºC) it suggests a low potential to accumulate in environmental compartments the substance has not potential to bioaccumulate.

The vB criterium is not complied.

2.2.2.4. Exposure assessment

PEC values in the different compartments were calculated according to the proposed OECD scenarios for industrial preventive processes and or wood in service according to the wood hazard classes, "OECD series on emission scenario documents, Number 2. Emission scenario document for wood preservatives". Environment Directorate. Joint Meeting of the chemicals committee and the working party on chemicals, pesticides and biotechnology.

OECD emission scenarios for industrial preventive processes were: Automated Spraying, Dipping and Vacuum Pressure. Dipping-immersion scenario was used in first instance in the assessment provided by the applicant instead of double vacuum impregnation assuming that dipping has lower uptake and higher leaching potential (is worse scenario than double vacuum). When the leaching tests were submitted, the Vacuum-Pressure scenario was included. Automated spraying was not claimed for preventive use of thiamethoxam in first instance. However, as it was provided by the applicant, it was re-calculated by the rapporteur.

In addition, in situ spraying was being considered by the applicant at the time of the discussion of this report (TMII07). The industry is pending on confirmation of this use to be included in the assessment. Also, at the date in which this assessment was elaborated, no scenario was developed to calculate PEC from in situ spraying. Further calculation in case the in situ spraying is confirmed as applied use in the registration proccess will be postponed until the scenario is ready and will be applied to the product evaluation stage.

For application rate the reported uses were industrial, professional and amateur, by double vacuum (10-15 g/m^3), pressure impregnation (at 10-15 g/m^3) and brushing and spraying each at 0.04%. Then new data rectifiying was submitted (see above) after the leaching tests were available for the rapporteur.

The more reasonable assimilation of the provided information to the rapporteur was carried out by using the following scenarios: For treated wood in service the scenarios used: house (use class 3), fence (use class 3), bridge (use class 3), noise barrier (use class 3). At first instance, before the leaching from treated woods data were available for the assessment, the scenarios of fence post (use class 4a), and transmission pole (use class 4a) were calculated as well, but are not included in the present report as the applicant notified the intention of claiming only for use 3.

For *in situ* outdoors treatments, the scenarios applied were brushing outdoors house and fence by amateurs and professionals. Input data from the treatment rate indicated in the second submission, was 100 mg a.i./m^2. The measured uptake for surface treatment was 108 mg a.i./m^2 from the leaching test. Leaching input data were from the leaching test.

For preventive industrial surface treatments, the scenarios applied were automated spraying and industrial dipping. Input data was from the second treatment rate data submission in point IIB 3.3.2. Then the industrial surface treatment rate was 100 mg a.i. per m^2 and the wood retained it all.

$FLUX_{storage}$ and $Q_{leach,\ storage,\ time1}$ were obtained using data from the brushing leaching test at time 3d for automated spraying, as wood is renewed in storage places every 3th day, and at time 14 d for dipping. The percentage of leaching at these times was applied to the assumed retention in the industrial treatments, i.e.: 100 mg/m^2 instead of 108 mg/m^2.

For preventively treated wood in service, $Q^*_{leach,time}$ was as for brushed items but using TIME1=30 days and applying percentage of leaching in brushing to the retained in wood, that for spraying and dipping were assumed to be the same, as informed by the applicant: 100 mg a.i./m^2. TIME2 for item service life was used to further refine the risk.

For the items treated by vacuum preasure, treatment rate was according to data in the leaching test: application rate of 15 g/m^3 wood and 7.8 g a.i./m^3 absorbed. Leaching data ($FLUX_{storage,\ vac\text{-}pres}$ and $Q^*_{leach,\ time}$) were calculated directly from the test for the industrial treatment and for the treated items. As the absorbed was c.a the half (1/1.92) of the expressed in the intended uses, linear extrapolation was applied to the leaching rate of the vaccuum treated items.

In adition, AFs were applied to the calculations, according to TMII07.

Thus, AF=5 and linear extrapolation from dose (15/7.8= 1.92) were applied to the leaching rate from vacuum treated wood, and calculations were corrected with a factor of 9.6, and AF=5 was applied to the leaching rate of surface treated wood.

This correction affects to PEC_{soil}, $PEC_{groundwater}$, $PEC_{surface\ water}$ and $PEC_{sediment}$. PECs were corrected according to the AFs. For PECsoil and groundwater the result is directly affected by the AFs. To ease the calculation, they were applied to the final PEC result.

PEC in surface water

For industrial scenarios, $PEClocal_{water}$ is contributed by the emission to adjacent waters plus the emission from the STP of the facility. Emission to adjacent waters depends on the leaching rate (equation 4.17 in OECD ESD for PT-8). The emission to surface waters from the STP does not depend on the leaching rate (equation 4.11 in OECD ESD for PT-8). Consequently, the mentioned factors only affect to the Clocalsurfacewater contributed by the Emissions to adjacent waters.

For the wood in service class 3 that have emissions to water, in the case of the Noise barrier scenario, PEClocalwater is contributed by the emissions to the STP. This depends on the leaching rate (equations 5.8 in OECD ESD for PT-8). In the case of the bridge scenario, the emission to water also depends on the leaching rate (eq. 6.12 in the OECD ESD for PT-8).

The AFs do not apply to the brushing in situ application scenarios, since no leaching rate is implicated in the calculations.

Preventive surface treatments yield the same results as the input data (a.s. dose and retention) is the same for both cases, as indicated by the applicant.

Consequently, the following values of PEC for TIME1 were obtained:

PEC surface water for Thiamethoxam

Scenario			PEC (Local concentration in water [ug*l-1])
Industrial preventive processes (TOTAL)	Vacuum-Pres		7.155
	Spraying		0.516
	Dipping-immersion		2.154
Industrial preventive processes (only emission from facility STP)	Vacuum-Pres		0.675
	Spraying		0.300
	Dipping-immersion		1.500
Vacuum-Press treated wood in service	House		
	Fence post		
	Noise barrier		0.745
	Bridge		106.560
Spray Treated wood in service	House		
	Fence post		
	Noise barrier		0.263
	Bridge		37.639
In-situ treatment ESD p. 93: Clocal,total,time1=Clocal,applic+Clocal,leach,time1(5)	Brushing house outdoor-application	amateur	
		prof	
	Brushing fence outdoor application	amateur	
		prf	
	Brushing bridge outdoor-application	amateur	40.650
		prf	40.650

PEC in ground water

Estimation of concentration of thiamethoxam and metabolite CGA 322704 in ground water were performed using two approaches: a theoretical approach based on the TGD and a data supported approach based on the adaptation of the PPP lysimeter study to the biocide use scenarios. For both approaches, the PEC for the surface water compartment receiving ground or pore water was calculated. Risk mitigation measures to prevent direct losses to soil on-site are proposed since the initial levels predicted in soil for this scenario were deemed unacceptable. Therefore no assessment of the levels in ground water for industrial treatment is needed. Risk mitigation measures for soil on site storage of wood consideres: *restricting the storage of industrial trated timber to hard standing (preventing the direct losses to soil and to drains).*

In order to estimate the potential of groundwater to reach surface waters, it was considered as a reasonable assumption that the unit contributing to one groundwater *source* is at least 10 ha and the minimum time period to monitor groundwaters bodies one year. Then there is a groundwater concentration of the active substance just underneath the storage soil (industrial

facilities) or the receiving soil (wood in service scenarios). These soils correspond to a determined surface area according to each scenario and will contribute accordingly to the ground water source unit, where the pollutant will be diluted with the pore water pore water of adjacent sites. Such dilution (N times or 1/N) has been calculated for each scenario.

Groundwater or soil run off water sources may reach surface waters. In case of the present risk assessment this is important as Thiamethoxam and its metabolite are very toxic for aquatic organisms. A dilution of 10 times has been considered to calculate the final concentration in surface water contributed by the substance from the ground water source.

PEC groundwater calculated using lysimeter studies. The applicant included in its submission references to a PPP soil lysimeter studies although they were not submitted or referenced in the present dossier to support the estimation of ground water concentration of Thiamethoxam and metabolite CGA 322704 to be under 0.05 µg/l.

Two lysimeter were summarized in the Thiamethoxam PPP monograph and addenda. First was a soil lysimeter study where thiamethoxam was applied as a foliar treatment on potatoes grown on loamy sand with low organic content in Germany. Second was a lysimeter study using treated seeds. These treatments are not a realistic case for thiamethoxam used as a Biocide for wood protection.

Nevertheless, the rapporteur used the cited information to obtain a PECgroundwater estimation by comparing the leaching measured from a field study in the PPP monograph with the case of Thiamethoxam used as wood preservative in the wood in service scenarios. That estimation is explained below.

The lysimeter study evaluated in the PPP monograph indicated that CGA 322704 has potential of leaching contaminating groundwater. The existence of preferential flow to deeper soil layers shortly after application in the lysimeter core cannot be discarded as in a realistic situation. Average concentrations of thiamethoxam in relation to the total volume leachate sampled in each year were not higher than 0.1 µg/l, but individual samples were collected in which peak concentrations were observed for thiamethoxam (0.39 µg/l and 0.23 µg/l in lysimeter nº 13 and 0.14 µg/l in nº 14). However, for metabolite CGA 322704 concentration increased with time, and ranged from 0.03 to 0.3 µg/l, being the highest value 0.74 µg/l. The field, a loamy sand with low organic content, was subject to foliar treatment with 200 g a.i./yr/ha in conditions of 800 mm of rain. A percentage of 33% of the substance reached the surface of the soil. Thus, as worst case it can be estimated that 0.3 x 200 = 60 g ai/ha/yr was the source for subsequent leaching as described above. This is for PPP use and application of thiamethoxam.

The PPP monograph addenda contains an evaluation on a second lysimeter study, using treated seeds sowed for two years in a loamy sand soil subject to a rainfall of c.a. 1000 $mm/m^2/yr$. In these conditions leachates were analyzed for this period and including the following year. In this test, the leaching of CGA 322404, though it was under 0.05 µg/l in the leachates (maximum value on the third year of 0.041 µg/l) still shows the tendency of rising with time. In this same study other metabolites were analyzed but did not show that trend.

The second lysimeter study was very difficult to assimilate to the PT-8 use of Thiamethoxam, which is the subject of the present report.

Treated wood in service. Data from the first lysimeter study was used to estimate PEC groundwater instead of using models as PELMO or PEARL. There was the need to adapt real data from the PPP use to the Biocide scenario. The adaptation first presented by the rapporteur was one scenario assuming a given density of wood per area of soil based in a treated fence sourronding 1 ha of field.

After the report was written, it was agreed at TM III06 a different wood density corresponding to 35 houses per ha, that is conceptually analogous to that described before the TMIII06, as in both cases density of wood per soil surface unit was alluded.

To use the data from the lysimeter in the wood preservative use assessment, an equivalence between the study presented as PPP and the biocide use was needed. For this aim a wood density of 35 houses per ha (or 4375 m^2 treated wood per ha according to the house OECD scenario) was assumed by the rapporteur.

Houses (worst class 3 scenario) may be treated by vacuum, industrial surface preventive treatment (spraying or dipping) or by in situ brushing. After the application of AFs agreed in TMII07, the leaching rates for 35 houses in one ha for these cases are a total of 932400 mg a.i. leached in 30 days for vacuum treated houses, 329328.125 for preventive dipping or spraying and 355687.5 for in situ brushed houses, using the $Q^*_{leach,time1}$ values estimated.

Considering this as a worst case leaching from wood to soil in a PPP equivalent scenario, this amount of a.i. entering soil can be compared to the amount of a.i. that reaches the soil in the PPP study and think about this quantity as the starting point from which leaching in soil to ground water will occur.

The leaching behaviour could be expected to behave according to that figures in the absence of any other data (linear relation between starting amount to be leached and substance recovered in leachates is suposed).

Houses Treatment	a i. entering soil g/ha	Times more a i. than in PPP per ha
Vacuum-Pressure	932.400	14.127
Preventive surface	329.328	4.990
In situ Brushing	355.687	5.389

Comparing agricultural field treated with Thiamethoxam and 1 ha of soil holding 35 houses and receiving Thiamethoxam leaching from treated wood

Houses treated by	Times more a.i. than in PPP use per soil surface unit in the storage soil	Estimated concentration of substances in leachate (1) in µg/l PECgw underneath receiving soil	Estimated conc. of substances in ground water (2) in µg/l PECgw in the aquifer	Estimated conc. of substances in surface water (3) in µg/l
Vacuum-Pressure	14.127	1.41272727	0.14127273	0.01412727
Preventive surface	4.990	0.498982008	0.049898201	0.00498982
In situ Brushing	5.389	0.53892045	0.05389205	0.0053892

(1) assuming Thiamethoxam and CGA 322704 in leachates c.a. 0.1 µg/l when agricultural soil was treated with 200 g a.i./ha and year in the lysimeter PPP test and assuming linear relation between substance in soil/substance in leachate

(2) from comparison to lysimeter and considering N times dilution of the income substance in the aquifer unit (see above pore water approach: 10ha for one water source) with adjacent ground water bodies.

(3) considering 10 times dilution when ground water emissions reach surface water

Thus, by this approach, 35 treated houses are estimated to leach to groundwater just beneath one ha more than tenfold over the cut off value of 0.1 µg/l, being the worst case when vacuum treated.

When dilution of these waters with the whole aquifer is considered, then the values are above (but close) to the 0.1 µg/l for both metabolite and thiamethoxam for the vacuum treatment. For the other treatments values are below 0.1µg/l.

For the metabolite, that leached increasingly with time and that, according to the mentioned lysimeter test, could overpass in individual measures the 0.2 µg/l for the PPP treatment, this means that values over 0.1 µg/l could not be discarded in the whole aquifer.

PEC in sediment

PEC in sediment was calculated according to the TGD eq. 50 from estimated PEC values in the aquatic compartment.

Thiamethoxam PEC for different exposure situations concerning SEDIMENT

Scenario			PEC (Local conc. in sediment) [ug*Kgww-1]
Industrial preventive processes	Vacuum-pressure		10.732
	Spraying		0.774 2
	Dipping-immersion		3.231
Vacuum-pressure treated wood in service	House		
	Fence post		
	Noise barrier		0.118
	Bridge		159.84
Spray Treated wood in service	House		
	Fence post		
	Noise barrier		0.395
	Bridge		56.458
In-situ treatment ESD p. 93: Clocal.total.time1=Clocal.applic+Clocal. leach.time1(5)	Brushing house outdoor-application	amateur	
		prof	
	Brushing fence outdoor	amateur	

Scenario			PEC (Local conc. in sediment) [ug*Kgww-1]
	application	prf	
	Brushing bridge outdoor-application	amateur	60.975
		prf	60.975

PEC in air

PEC in air was calculated only for industrial preventive processes according to the OECD. Bearing in mind the low volatility of thiamethoxam, PEC for thiamethoxam in air is not relevant.

PEC in soil

To estimate PEC in soil the proposed OECD were used for all the considered scenarios.

Metabolite CGA 322704 formed in soil from Thiamethoxam was calculated based in the 90 percentile of the validated field studies, corrected by the molecular weigth, what means 24% of active ingredient being transformed into the metabolite.

The concentrations were estimated considering different soil receiving compartments.

AFs were applied to the calculations, according to TMII07.

Thus, AFs were AF= 1.92*5= 9.6, as explained in the beginning of this section, applied to the leaching rate from vacuum treated wood, and AF=5 was applied to the surface treated wood. This result in PEC values increased proportionally in the AF. In situ application does not depend on the leaching rate, thus it is not incremented. Leaching from in situ treated wood does depend on the leaching rate.

Thiamethoxam (TMX) and its metabolite CGA 322704 estimated PEC values in soil for TIME 1 assessment

distance soil recieving compartment	Scenario	TMX PEC (Local conc. in soil [mg*Kgww-1])	Metabolilte CGA 322704 PEC (Local conc. in soil [mg*Kgww-1])
0.1 m	**Vacuum-pressure**	5.9101	1.3942
0.2 m		2.9202	0.6889
0.3 m		1.9241	0.4539
0.4 m		1.4263	0.3365
0.5 m		1.1280	0.2661
0.1 m	**Automated spraying**	12.4918	2.9468
0.2 m		6.1068	1.4406
0.3 m		3.9815	0.9392
0.4 m		2.9211	0.6891
0.5 m		2.2865	0.5394
0.1 m	**Dipping-immersion**	4.2752	1.0085
0.2 m		2.1134	0.4986
0.3 m		1.3931	0.3286
0.4 m		1.0332	0.2437
0.5 m		0.8175	0.1928
0.1 m	**Fence-Vacuum press treated**	25.0729	5.9147
0.2 m		6.2682	1.4787
0.3 m		2.7859	0.6572
0.4 m		1.5671	0.3697
0.5 m		1.0029	0.2366
0.1 m	**Fence-Sprayed**	8.8562	2.0892
0.2 m		2.2141	0.5223
0.3 m		0.9840	0.2321
0.4 m		0.5535	0.1306

distance soil recieving compartment	Scenario	TMX PEC (Local conc. in soil [mg*Kgww-1])	Metabolilte CGA 322704 PEC (Local conc. in soil [mg*Kgww-1])
0.5 m		0.3542	0.0836
0.1 m	**Fence-in situ brushed**	9.5647	2.2563
0.2 m		2.3912	0.5641
0.3 m		1.0627	0.2507
0.4 m		0.5978	0.1410
0.5 m		0.3826	0.0903
0.1 m	**Noise barrier Vacuum treated**	11.2828	2.6616
0.2 m		2.8207	0.6654
0.3 m		1.2536	0.2957
0.4 m		0.7052	0.1664
0.5 m		0.4513	0.1065
0.1 m	**Noise barrier Sprayed**	3.9853	0.9401
0.2 m		0.9963	0.2350
0.3 m		0.4428	0.1045
0.4 m		0.2491	0.0588
0.5 m		0.1594	0.0376
0.1 m	**House-vacuum treated**	31.0924	7.3347
0.2 m		7.7119	1.8192
0.3 m		3.4007	0.8022
0.4 m		1.8981	0.4478
0.5 m		1.2054	0.2844
0.1 m	**House-Sprayed**	10.9824	2.5907
0.2 m		2.7240	0.6426
0.3 m		1.2012	0.2834
0.4 m		0.6704	0.1582
0.5 m		0.4258	0.1004
0.1 m	**House-in situ Brushed**	11.8610	2.7980
0.2 m		2.9419	0.6940
0.3 m		1.2973	0.3060
0.4 m		0.7241	0.1708
0.5 m		0.4598	0.1085
0.1 m	**Brushing house outdoor (amateur)**	0.7295	0.1721
0.2 m		0.1824	0.0430
0.3 m		0.0811	0.0191
0.4 m		0.0456	0.0108
0.5 m		0.0292	0.0069
0.1 m	**Brushing house outdoor (professional)**	0.4377	0.1032
0.2 m		0.1094	0.0258
0.3 m		0.0486	0.0115
0.4 m		0.0274	0.0065
0.5 m		0.0175	0.0041
0.1 m	**Brushing fence outdoor (amateur application)**	0.5882	0.1388
0.2 m		0.1471	0.0347
0.3 m		0.0654	0.0154
0.4 m		0.0368	0.0087
0.5 m		0.0235	0.0056
0.1 m	**Brushing fence outdoor (prof application)**	0.3529	0.0833
0.2 m		0.0882	0.0208
0.3 m		0.0392	0.0093
0.4 m		0.0221	0.0052
0.5 m		0.0141	0.0033

PEC in non compartment specific exposure relevant to the food chain (secondary poisoning)

The active ingredient has low potential for bioaccumulation as it is a hydrophilic compound with a negative n-octanol/water partition coefficient of log K_{ow} = - 0.13. With limited exposure under practical use pattern, the pontential for bimagnification of thiamethoxam in the food chain is negligible.

2.2.2.5. Risk characterisation

Surface waters

Industrial scenarios. The risk characterized as PEC/PNEC ratio for the aquatic compartment is not acceptable for the proposed industrial preventive treatments (see the table below). The risk is mainly originated in the emissions from the facility STP. PEC values for processes of preventive industrial treatment were calculated as directed in the OECD ESD. The applicant provided the data of fraction of the emission to the effluent=1 in the facility STP. This assumes that 100 % of the inflow will go to the effluent. The applicant probably has derived it from the low Koc of Thiamethoxam which involves negligible retention in sewage of the substance. Specific risk mitigation measures are needed to recommend the use of Thiamethoxam with an acceptable risk in preventive industrial treatments.

Risk mitigation measures *applied to the facility STP avoiding water emission to surface water bodies and disposal of the sludges should be applied to recommend industrial uses and lower potential risk to the aquatic compartment.*

Preventively treated wood in service. From the studied 'class use 3' scenarios, only noise barrier and bridge produce emissions to water. From both of them, none has acceptable risk for this compartment. Wood treated used nearby water, like in bridges, is a non recommended use from the point of view of potential risk for the aquatic compartment. In addition, wood that produce direct emissions to water or to the STP, as noise barriers, are not recommended uses, unless risk mitigation measures are applied as preventing direct emissions to the STP.

In situ treatments and in situ treated wood in service. The risk is not acceptable for in situ treatment of woods that produce direct emission to water.

Extending this to any wood near of water bodies, then it is proposed by the applicant the following **risk mitigation measure** that the rapporteur accepted *for in situ treatment by brush (professional or amateur), wood preservative products must not be used to treat wooden structures located where direct losses to water cannot be prevented.* No in situ treatment is applied to the noise barrier, following the OECD scenario.

PEC/PNEC ratios for Thiamethoxam for different exposure situations concerning WATER

Thiamethoxam	Scenario		PEC (Local concentration in water) [µg.l-1]	PNEC [µg.l-1]	PEC/PNEC
Industrial preventive processes (TOTAL)	Vacuum-Pres		7.155	0.14	51.11
	Spraying		0.516	0.14	3.68
	Dipping-immersion		1.716	0.14	12.26
Industrial preventive processes	Vacuum-Pres		0.675	0.14	4.8

Thiamethoxam	Scenario		PEC (Local concentration in water) [µg.l-1]	PNEC [µg.l-1]	PEC/PNEC
(only emission from facility STP)	Spraying		0.3	0.14	2.15
	Dipping-immersion		1.5	0.14	10.7
Vacuum-Press treated wood in service	House				
	Fence post				
	Noise barrier		0.746	0.14	5.33
	Bridge		106.560	0.14	761.14
Spray Treated wood in service	House				
	Fence post				
	Noise barrier		0.263	0.14	1.88
	Bridge		37.639	0.14	268.85
In-situ treatment ESD p. 93: Clocal,total,time1=Clocal,applic+Clocal,leach,time1(5)	Brushing house outdoor-application	amateur			
		prof			
	Brushing fence outdoor application	amateur			
		prf			
	Brushing bridge outdoor-application	amateur	40.650	0.14	290.36
		prf	40.650	0.14	290.36

STP

PEC/PNEC ratios for Thiamethoxam for different exposure situations concerning facility STP sewage

Scenario	PEC [µg/kg]	PNEC [µg/l]	PEC/PNEC
Spraying	1.000	1000	0.001
Dipping	3.000		0.003
Noise Barrier Spray treated	15.000		0.015

There is no risk for microorganisms in sewage treatment plants (STP) when thiamethoxam is applied as wood preservative according to the calculated ratio PEC/PNEC.

Sediment

There is potential risk for the bridge scenario regarding thiamethoxam according to the calculated ratio PEC/PNEC.

Regarding the metabolite CGA 322704, it may reach the sediment compartment only from leaching or run off from soils as it is not formed by hydrolysis of thiamethoxam. The metabolite can reach surface waters. The calculated PNEC for sediment is 1.5 µg/kg wws. It is 10 fold more toxic than the thiamethoxam itself for the sediment compartment. Considering the calculated $PEC_{surfacewater}$ from the substance originated in soil for Thiamethoxam, that can be considered similar to that of metabolite (assuming Thiamethoxam and CGA 322704 in leachates c.a. 0.1 µg/l when agricultural soil was treated with 200 g a.i./ha and year in the lysimeter PPP test and assuming linear relation between substance in soil/substance in leachate) then the potential risk posed by the metabolite can be considered not of concern.

PEC/PNEC ratios for Thiamethoxam for different exposure situations concerning SEDIMENT

Thiamethoxam	Scenario		PEC (Local conc. in sediment) [ug*Kgww-1]	PNEC [ug*kgww-1]	PEC/PNEC
Industrial preventive processes	Vacuum-pressure		10.732	10	**1.07**

Thiamethoxam	Scenario		PEC (Local conc. in sediment) [ug*Kgww-1]	PNEC [ug*kgww-1]	PEC/PNEC
	Spraying		0.774	10	**0.08**
	Dipping-immersion		2.574	10	**0.26**
Vacuum-pressure treated wood in service	House				
	Fence post				
	Noise barrier		1.119	10	**0.11**
	Bridge		159.84	10	15.98
Spray Treated wood in service	House				
	Fence post				
	Noise barrier		0.395	10	**0.04**
	Bridge		56.458	10	5.65
In-situ treatment ESD p. 93: Clocal.total.time1=Clocal.applic+Clocal.leach.time1(5)	Brushing house outdoor-application	amateur			
		prof			
	Brushing fence outdoor application	amateur			
		prf			
	Brushing bridge outdoor-application	amateur	60.975	10	6.10
		prf	60.975	10	6.10

Ground waters

Two approaches were considered to calculate thiamethoxam and metabolite CGA 322704 PEC values for ground water. First, following the TGD (part II, section 2.3.8.6, eq. 68) where $PEC_{localgwr} = PEC_{local\ agr.soil,\ porew}$ and second, other more realistic approach that used data from a field lysimeter submitted within the PPP evaluation of Thiamethoxam. The rapporteur preferred the second approach for a more realistic prediction.

It was considered that the soil unit contributing to one groundwater *source* is at least 10 ha and the minimum time period to monitor ground waters bodies one year. Then there is a groundwater concentration of the active substance just underneath the storage soil (industrial facilities) or the receiving soil (wood in service scenarios). These soils correspond to a determined surface area according to each scenario and will contribute accordingly to the ground water source unit, where the pollutant will be diluted with the ground water of adjacent sites.

Industrial scenarios. The estimated concentration of thiamethoxam (and metabolite CGA 322704) in soil leachates was over 0.1 µg/l for the three treatments considered: vacuum-preassure, automated spraying and dipping. This is the estimated concentration of the substances in groundwater just underneath the storage area. Considering the dilution of the substances in the ground water unit, PECgw for thiamethoxam were calculated and were over 0.1 µg/l for the vacuum-pressure treatment. PECgw for the metabolite could not be completely discarded to be over 0.1µg/l for every treatment.

In addition, there was risk for the on site storage soil for industrial treated wood. Risk mitigation measures were proposed for the soil compartment that prevents also risk for ground water.

Treated wood in service. For vacuum-pressure treated wood, and following an analogous reasoning, it was estimated that ground waters in the aquifer unit could not be discarded to reach thiamethoxam and metabolite CGA 322704 concentrations over 0.1 µg/l. For preventive surface treatments and in situ brushing, thiamethoxam was expected below 0.1 µg/l but the

metabolite could not be discarded to reach concentrations over 0.1 µg/l. In summary, risk of thiamethoxam treated wood in service is of concern for groundwater.

Thus, risk mitigation measures are needed to recommend this use, and they should eliminate risk of concern of thiamethoxam treated wood in service for groundwater.

The terrestrial compartment

The PEC/PNEC ratios were calculated for both Thiamethoxam and its metabolite CGA 322704. The calculations included different soil compartments, having into account the recommendations on the ad hoc Technical Meetings on Biocide Evaluation under directive 98/8. Soil compartment was first considered as described in the ESD as a standard 10 cm deep and in its case, 10 cm horizontal for woods in service soil scenarios. Tables enclosed included 20, 30, 40 and 50 cm distances.

In addition, for wood in service scenarios, two time intervals were had into account, TIME1 of 30 days not considering removal processes and TIME2 of service life and having the removal process into consideration, according to equations in the ESD. This refinement was applied to industrial preventive treatments but is not shown in the enclosed text as the predictions do not ameliorate, due to the high values of DT50 for both thiamethoxam and its metabolite CGA 322704 and the continuous renewal of wood in the storage areas. The following conclusions were obtained.

ASSESSMENT FOR THIAMETHOXAM

Preventive industrial treatments. No preventive industrial treatment can be recommended even when receiving soil compartment is considered at least 50 cm deep, as they will pose risk for the soil compartment, considered as PEC/PNEC ratio, higher than 1 (see the table below).

Risk mitigation measures as proposed by the applicant and mentioned earlier are needed in order to use Thiamethoxam in preventive industrial treatments: *Loses during industrial/professional application by the dipping and automated enclosed spraying processes, as well as during tank cleaning, must be contained. It is proposed that this risk is mitigated by restricting the storage of industrial treated timber to hard standing (preventing the direct losses to soil and to drains)*

Preventively treated wood in service by industrial means. The studied scenarios do pose potential risk even provided that receiving soil compartments are at least 50 cm long and wide for TIME1=30 days assessment. For the service life assessment and considering the removal process, then vacuum-pressure and spraying (dipping) fence and house can be used without risk of concern.

Curatively treated wood in service (by brushing). For TIME 1=30 d the in situ treated items pose unacceptable risk for the service life.

For TIME2=service life assessment and for thiamethoxam the studied scenarios do not pose potential risk provided that receiving soil compartments are considered up to at least 50 cm long and wide.

In situ application of thiamethoxam by brushing. Brushing by professionals does not pose potential risk to soil provided that receiving soil compartments are at considered up to 50 cm long and wide. Similarly, brushing by amateurs does not pose potential risk to soil that receiving soil compartments provided.

ASSESSMENT FOR METABOLITE CGA 322702

A risk assessment for thiamethoxam metabolite CGA 322704 was performed separately as the risk posed by the metabolite is not covered by the risk of the parent substance. This is as consequence of the persistence of the metabolite, the ecotoxicity and the amount of metabolite formed from thiamethoxam in soil.

Preventive industrial treatments. No preventive industrial treatment is recommended, as potential risk for the soil compartment posed by CGA 322704 is not acceptable. This prediction is even less favorable when applying formulas that have removal process into consideration, as they incorporate DT50 (*k*) and this is hig**her** for the metabolite. Then risk mitigation measures are needed in order to recommend the preventive industrial use of thiamethoxam as wood preservative. Risk mitigation measures proposed by the applicant were:

Loses during industrial/professional application by the dipping and automated enclosed spraying processes, as well as during tank cleaning, must be contained. It is proposed that this risk is mitigated by restricting the storage of industrial treated timber to hard standing (preventing the direct losses to soil and to drains).

Preventively treated wood in service. Estimations for TIME1=30 d yielded risk of concern for every scenario considered. When longer assessment time was considered, TIME2= service life plus removal processes, then wood treated by vacuum-pressure and automated spraying or dipping are uses that can be recommended as they do not pose risk of concern for soil considering compartments up to 50 cm wide and deep, from the calculated PEC/PNEC ratios.

Thus, taking the risk assessment for thiamethoxam and metabolite CGA 322704 together, the uses of preventively treated wood, either by vacuum-pressure or by surface treatments as spraying or dipping are not recommended unless appropriate risk mitigation measures are applied.

Risk mitigation measures proposed by the NL in Technical meeting I 06 that would be welcome are as follows:

Treated timber with a formulation of thiamethoxam that shows a PEC/PNEC ratio of more than 1 must be protected with a topcoat to prevent leaching into the soil. Regarding the topcoat, scientific evidence (through testing) showing that such a coating will prevent the wood preservative from leaching through the coating, also in the long term. This evidence should be presented as well for preventive as curative treatment of the wood. Also, evidence that the proposed risk reduction measure is feasible for the practical use of the product in combination with a coating is needed. The consumer/user/purchaser should be aware that the wood is treated with a product making it obligatory the wood has to be coated before use. The coating should not be damaged or processed further, and the risk mitigation measure should be assessed for its feasibility.

And other risk mitigation measures that could be proposed by the applicant and show their effectiveness to lower the risk down to turn it not of concern.

Curatively treated wood in service (by brushing). Fence and House treated by in situ brushing are not recommended uses as associated potential risk is not acceptable at any of the soil distances and time intervals considered, unless appropriate risk mitigation measures are applied.

In situ application of thiamethoxam by brushing. Application itself performed either by professionals or amateurs to Fence or House do not pose potential risk for the soil. Consequently this use can be recommended. However, it does not make sense to recommend the application if the wood treated is a non recommended use.

PEC/PNEC ratios for different exposure situations concerning soil for different size of receiving soil

Substance	Thiamethoxam				CGA 322704		
Distance soil recieving compartment	Scenario	PEC (Local concentration in soil) [mg*Kgww-1]	PNEC [mg*kgww-1]	PEC/PNEC	PEC (Local concentration in soil) [mg*Kgww-1]	PNEC [mg*kgww-1]	PEC/PNEC
0.1 m	Vacuum-pressure	5.9101	0.0665	88.87	1.3942	0.008	174.27
0.2 m		2.9202		43.91	0.6889		86.11
0.3 m		1.9241		28.93	0.4539		56.74
0.4 m		1.4263		21.45	0.3365		42.06
0.5 m		1.1280		16.96	0.2661		33.26
0.1 m	Automated spraying	12.4918		187.85	2.9468		368.35
0.2 m		6.1068		91.83	1.4406		180.07
0.3 m		3.9815		59.87	0.9392		117.40
0.4 m		2.9211		43.93	0.6891		86.13
0.5 m		2.2865		34.38	0.5394		67.42
0.1 m	Dipping-immersion	4.2752		64.29	1.0085		126.06
0.2 m		2.1134		31.78	0.4986		62.32
0.3 m		1.3931		20.95	0.3286		41.08
0.4 m		1.0332		15.54	0.2437		30.47
0.5 m		0.8175		12.29	0.1928		24.11
0.1 m	Fence-Vacuum press treated	25.0729		377.04	5.9147		739.34
0.2 m		6.2682		94.26	1.4787		184.83
0.3 m		2.7859		41.89	0.6572		82.15
0.4 m		1.5671		23.56	0.3697		46.21
0.5 m		1.0029		15.08	0.2366		29.57
0.1 m	Fence-Sprayed	8.8562		133.18	2.0892		261.15
0.2 m		2.2141		33.29	0.5223		65.29
0.3 m		0.9840		14.80	0.2321		29.02
0.4 m		0.5535		8.32	0.1306		16.32
0.5 m		0.3542		5.33	0.0836		10.45
0.1 m	Fence-in situ brushed	9.5647		143.83	2.2563		282.04
0.2 m		2.3912		35.96	0.5641		70.51
0.3 m		1.0627		15.98	0.2507		31.34
0.4 m		0.5978		8.99	0.1410		17.63
0.5 m		0.3826		5.75	0.0903		11.28
0.1 m	Noise barrier (Use Class 3) Vacuum treated	11.2828		169.67	2.6616		332.70
0.2 m		2.8207		42.42	0.6654		83.18
0.3 m		1.2536		18.85	0.2957		36.97
0.4 m		0.7052		10.60	0.1664		20.79
0.5 m		0.4513		6.79	0.1065		13.31
0.1 m	Noise barrier	3.9853		59.93	0.9401		117.52

Substance	Thiamethoxam				CGA 322704		
Distance soil recieving compartment	**Scenario**	**PEC (Local concentration in soil) [mg*Kgww-1]**	**PNEC [mg*kgww-1]**	**PEC/PNEC**	**PEC (Local concentration in soil) [mg*Kgww-1]**	**PNEC [mg*kgww-1]**	**PEC/PNEC**
0.2 m	**(Use Class 3) Sprayed**	0.9963		14.98	0.2350		29.38
0.3 m		0.4428		6.66	0.1045		13.06
0.4 m		0.2491		3.75	0.0588		7.34
0.5 m		0.1594		2.40	0.0376		4.70
0.1 m	**House-vacuum treated**	31.0924		467.56	7.3347		916.83
0.2 m		7.7119		115.97	1.8192		227.40
0.3 m		3.4007		51.14	0.8022		100.28
0.4 m		1.8981		28.54	0.4478		55.97
0.5 m		1.2054		18.13	0.2844		35.54
0.1 m	**House-Sprayed**	10.9824		165.15	2.5907		323.84
0.2 m		2.7240		40.96	0.6426		80.32
0.3 m		1.2012		18.06	0.2834		35.42
0.4 m		0.6704		10.08	0.1582		19.77
0.5 m		0.4258		6.40	0.1004		12.56
0.1 m	**House-in situ Brushed**	11.8610		178.36	2.7980		349.75
0.2 m		2.9419		44.24	0.6940		86.75
0.3 m		1.2973		19.51	0.3060		38.25
0.4 m		0.7241		10.89	0.1708		21.35
0.5 m		0.4598		6.91	0.1085		13.56
0.1 m	**Brushing house outdoor (amateur)**	0.7295		10.97	0.1721		21.51
0.2 m		0.1824		2.72	0.0430		5.34
0.3 m		0.0811		1.20	0.0191		2.35
0.4 m		0.0456		**0.67**	0.0108		1.31
0.5 m		0.0292		**0.43**	0.0069		**0.83**
0.1 m	**Brushing house outdoor (professional)**	0.4377		6.58	0.1032		12.91
0.2 m		0.1094		1.65	0.0258		3.23
0.3 m		0.0486		**0.73**	0.0115		1.43
0.4 m		0.0274		**0.41**	0.0065		**0.81**
0.5 m		0.0175		**0.26**	0.0041		**0.52**
0.1 m	**Brushing fence outdoor (amateur application)**	0.5882		8.85	0.1388		17.35
0.2 m		0.1471		2.21	0.0347		4.34
0.3 m		0.0654		**0.98**	0.0154		1.93
0.4 m		0.0368		**0.55**	0.0087		1.08
0.5 m		0.0235		**0.35**	0.0056		**0.69**
0.1 m	**Brushing fence outdoor (prof. application)**	0.3529		5.31	0.0833		10.41
0.2 m		0.0882		1.33	0.0208		2.60
0.3 m		0.0392		**0.59**	0.0093		1.16
0.4 m		0.0221		**0.33**	0.0052		**0.65**
0.5 m		0.0141		**0.21**	0.0033		**0.42**
distance soil recieving compartment	**PEC/PNEC ratios for *in situ* treatment plus service of items concerning SOIL**						
0.1 m	**House. professional**			184.94			362.66
0.2 m				45.88			89.98
0.3 m				20.24			39.69
0.4 m				11.30			22.16
0.5 m				7.18			14.08
0.1 m	**House. amateur**			189.33			371.26
0.2 m				46.96			92.08
0.3 m				20.71			40.61
0.4 m				11.56			22.66
0.5 m				7.34			14.39
0.1 m	**Fence. professional**			149.14			292.45
0.2 m				37.28			73.11
0.3 m				16.57			32.49
0.4 m				9.32			18.28

Substance	Thiamethoxam				CGA 322704		
Distance soil recieving compartment	Scenario	PEC (Local concentration in soil) [mg*Kgww-1]	PNEC [mg*kgww-1]	PEC/PNEC	PEC (Local concentration in soil) [mg*Kgww-1]	PNEC [mg*kgww-1]	PEC/PNEC
0.5 m				5.97			11.70
0.1 m	Fence. amateur			152.68			299.38
0.2 m				38.17			74.85
0.3 m				16.96			33.26
0.4 m				9.54			18.71
0.5 m				6.11			11.98

PEC/PNEC calculations for thiamethoxam and metabolite CGA 322704 for TIME2=service life having the removal process into consideration

Thiamethoxam					CGA 322704		
distance soil recieving compartment	Scenario	PEC (Local concentration in soil) [mg*Kgww-1]	PNEC [mg*kgww-1]	PEC/PNEC	PEC (Local concentration in soil) [mg*Kgww-1]	PNEC [mg*kgww-1]	PEC/PNEC
0.1 m	Fence-Vacuum press treated	0 1650		2.48	0.0973		12.16
0.2 m		0.0413		**0.62**	0.0243		3.04
0.3 m		0.0183		**0.28**	0.0108		1 35
0.4 m		0.0103		**0.16**	0.0061		**0.76**
0.5 m		0.0066		**0.10**	0.0039		**0.49**
0.1 m	Fence-Sprayed	0 2190		3.29	0.1262		15.78
0.2 m		0.0547		**0.82**	0.0316		3 94
0.3 m		0.0243		**0.37**	0.0140		1.75
0.4 m		0.0137		**0.21**	0.0079		**0.99**
0.5 m		0.0088		**0.13**	0.0050		**0.63**
0.1 m	Fence-in situ brushed	0.6538		9.83	0.3570		44.63
0.2 m		0 1635		2.46	0.0893		11.16
0.3 m		0.0726		1.09	0.0397		4 96
0.4 m		0.0409		**0.61**	0.0223		2.79
0.5 m		0.0262		**0.39**	0.0143		1.79
0.1 m	House-vacuum treated	0 2046		3.08	0.1188		14.85
0.2 m		0.0512		**0.77**	0.0297		3.71
0.3 m		0.0227		**0.34**	0.0132		1.65
0.4 m		0.0128		**0.19**	0.0074		**0.93**
0.5 m		0.0082		**0.12**	0.0048		**0.59**
0.1 m	House-Sprayed	0 2715		4.08	0.1565		19.57
0.2 m		0.0679		1.02	0.0391		4.89
0.3 m		0.0302		**0.45**	0.0174		2 17
0.4 m		0.0170		**0.26**	0.0098		1 22
0.5 m		0.0109		**0.16**	0.0063		**0.78**
0.1 m	House-in situ Brushed	0.7693		11.57	0.4181		52.26
0.2 m		0 1923		2.89	0.1045		13.07
0.3 m		0.0855		1.29	0.0465		5.81
0.4 m		0.0481	0.0665	**0.72**	0.0261	0.0080	3 27
0.5 m		0.0308		**0.46**	0.0167		2.09

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 risk assessment for Thiamethoxam and its formulated product Xamox 10 TK (10% Thiamethoxam w/w) used as wood preservative has been performed following the directions from Directive 98/8/EC and extended in the TGD and ESD documents and agreed decisions in Technical Meetings on Biocide Evaluation.

The overall conclusion from the human health evaluation of thiamethoxam for use in product type 8 (wood preservatives) is that when applied as concentrated up to 10% w/w solutions in industrial timber treatment and used by professionals and non professionals, in ready to use formulations with other wood preservatives, at concentrations not exceeding 1% w/w, thiamethoxam will not present an unacceptable risk to humans during the proposed normal use. This conclusion relies on the fact that industrial/professional uses will be applying the basic principles of good practice and using appropriate and obligatory PPE.

The results of risk assessment for non-professional users demonstrate that the use has no unacceptable health risk when it is used by brushing and spraying, both indoor and outdoor.

The results of the secondary exposure risk assessment demonstrate that adult, children and infants will not be exposed to unacceptable levels of thiamethoxam during the realistic worst-case scenarios presented.

From the environmental point of view the more relevant receiving compartments are soil and water:

Aquatic environment is sensitive due to the toxicity of thiamethoxam to insects, not only in water but in sediment. Risk is of concern for the formulation in preventive industrial treatments (Vacuum-pressure applying 15 g a.i./m^3 wood, and surface treatments as spraying or dipping applying 100 mg a.i. /m^2) and these uses cannot be recommended unless risk mitigation measures are applied and shown to be effective.

For example all losses must be contained (no drain connections to storm drains or STPs) and recycled /disposed of appropriately.

In addition, wood treated used nearby water or that cause emission to water or directly to STP is a non recommended use. Regarding In situ treatments, the risk mitigation measure proposed by the applicant is agreed by the rapporteur, such *treatments must not be done where direct losses to water cannot be prevented.* In addition, direct emissions to STP should be prevented from treated wood by effective risk mitigation measures.

Regarding **groundwaters** from soil just underneath industrial scenarios it cannot be discarded that thiamethoxam is over 0.1 µg/l for proposed wood retentions of a.i. (vacuum-treated 15 g/m^3 as in the leaching test used for calculations and surface treatments with 100 mg/m^2) . When dilution within a greater groundwater source unit is considered then this value is not probable to overpass 0.1 µg/l according to the present assessment for preventive surface treatments. However, risk is of concern for preventive vacuum-pressure. Risk for spraying is of concern considering the metabolite CGA 322704 assessment.

For treated wood, the presence of thiamethoxam may cause risk of concern for the vacuum treated wood. The metabolite CGA 322704 was estimated to be in groundwaters. The risk of concentrations over the cut off value of 0.1 µg/l is of concern for all the treatments

Consequently, risk mitigation measures regarding storage areas are needed, as those proposed by the applicant or other like *restricting the storage of industrial treated timber to hard standing (preventing the direct losses to soil and to drains).*

Soil is a very sensitive compartment due to the referred toxicity to earthworms. In addition, metabolite CGA 322704, formed in soil as major metabolite from thiamethoxam, is toxic to earthworms and very stable in soil. The rapporteur has considered the exposition and toxicity of the metabolite CGA 322704 to perform a risk evaluation for soil organisms as this risk is not covered by the risk of thiamethoxam since the metabolite is more toxic and stable than the parent substance. As a result of the assessment, the risk was calculated using the PEC/PNEC ratios for each soil scenario.

Risk originated by thiamethoxam, when using the formulation, is not acceptable for any of the preventive automated treatments.

PEC of CGA 322704 was estimated from degradation of thiamethoxam in soil in field studies and from PEC data of parent substance in each scenario not using worst case, but a 90 percentile of accepted studies (c.a. 24 % of thiamethoxam converted into the metabolite). PNEC was estimated from a field study of toxicity in the most sensitive taxa, earthworms. The metabolite is more toxic to earthworms than thiamethoxam itself. This fact together with the expected percentage of metabolite formed in soil and is long DT50 leads to a calculation of PEC/PNEC ratios that indicate non acceptable risk for the proposed uses of the formulation in any of the proposed preventive industrial facilities that consequently are not recommended as long as adequate and effective risk mitigation measures are applied (hard standing storage areas to prevent direct losses to soil for example).

Regarding treated wood in service, if service life and removal are considered, the studied scenarios pose acceptable risk when receiving soil is at least 50 cm deep and wide and the treatment received was preventive. Risk is of concern for the in situ treated items (brushing) and it is due to the PEC/PNEC ratios for the metabolite CGA 322704.

Fence and House treated by in situ brushing are uses not recommended as associated potential risk is of concernwhile the process of in situ treatment itself has not risk of concern.

Risk mitigation measures proposed by the applicant are:

To prevent non acceptable risk for the aquatic compartment:

For **industrial** preventive treatments: *Loses during industrial/professional application by the dipping and automated enclosed spraying processes, as well as during tank cleaning, must be contained. All loses must be contained (no drain connections to storm drains or STPs) and recycled/disposed of appropriately.*

In situ: *treatment by brush (professional or amateur), wood preservative products must not be used to treat wooden structures located where direct losses to water cannot be prevented.*

The rapporteur suggests also including a risk mitigation measure to avoid direct release of leachates to STP from treated items such as noise barriers. For example, leachates should be collected and disposed/treated correctly.

To prevent non acceptable risk for the soil compartment:

For **industrial** preventive treatments*: It is proposed that this risk is mitigated by restricting the storage of industrial treated timber to hard standing (preventing the direct losses to soil and to drains).*

For **treated wood in service** risk mitigation measures were not proposed by the applicant. This or other effective measure could be considered:

Treated timber with a formulation of thiamethoxam that shows a PEC/PNEC ratio of more than 1 must be protected with a topcoat to prevent leaching into the soil. Regarding the topcoat, scientific evidence (through testing) showing that such a coating will prevent the wood preservative from leaching through the coating, also in the long term. This evidence should be presented as well for preventive as curative treatment of the wood. Also, evidence that the proposed risk reduction measure is feasible for the practical use of the product in combination with a coating is needed. The consumer/user/purchaser should be aware that the wood is treated with a product making it obligatory the wood has to be coated before use. The coating should not be damaged or processed further, and the risk mitigation measure should be assessed for its feasibility.

3.2. Decision regarding Inclusion in Annex I

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

The active substance thiamethoxam, as manufactured, shall have a minimum purity of 980 g/kg.

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

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

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

(3) Products shall not be authorised for the *in situ* treatment of wood outdoors or for wood that will be exposed to weathering, unless data have been 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 thiamethoxam may be used in the pre-treatment of wood by:

- double-vacuum process, pressure impregnation and dipping for industrial wood preservation.

- remedial wood preservation by mainly small scale dipping, spraying in situ and also brushing indoor and outdoor for professionals

- brushing and spraying, indoor and outdoor, for do-it-yourself treatment of wood for non-professionals

Thiamethoxam has shown efficacy against wood pests as demonstrated for termites (*R. flavipis, R. hegani, R. santonensis)* and the house longhorn beetle (*H. bajulus)* in a number of experimental laboratory studies.

Further efficacy data will be required to support authorisation of products with thiamethoxam at the Member State level.

Application solutions and losses during industrial/professional application by vacuum-pressure, dipping and automated spraying 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. Effluents from facility STP must be avoided to produce emissions to the aquatic compartment unless it can be demonstrated in the application for product authorisation that risks to aquatic compartment can be reduced to an acceptable level. Analogously from the treated items that produce direct emissions to STP.

Specially, risk mitigation measures for treated wood in service should be applied that prevent leaching of the active ingredient to soil. Only when this is guaranteed, thiamethoxam and its formulated product the formulation can be recommended for entry in Annex I for the proposed uses.

For use class 3 in those treated wood in service where risk is of concern effective risk mitigation measures as proposed above cited hereby:

- *Treated timber with a formulation of thiamethoxam that shows a PEC/PNEC ratio of more than 1 must be protected with a topcoat to prevent leaching into the soil. Regarding the topcoat, scientific evidence (through testing) showing that such a coating will prevent the wood preservative from leaching through the coating, also in the long term. This evidence should be presented as well for preventive as curative treatment of the wood. Also, evidence that the proposed risk reduction measure is feasible for the practical use of the product in combination with a coating is needed. The consumer/user/purchaser should be aware that the wood is treated with a product making it obligatory the wood has to be coated before use. The coating should not be damaged or processed further, and the risk mitigation measure should be assessed for its feasibility.*

Or other proposed by the applicant should be shown they lead to a safe use of the formulation for the environment.

The in situ spraying use was not evaluated in this report. There was no scenario to calculate PEC for this use at the time this report was prepared. Then, it was agreed in the TMII07 that the use would be evaluated at the product authorization stage.

3.4. Requirement for further information

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

However, the following information should be submitted at the latest when applying authorization of the biocidal product for the first time after Annex I Inclusion of thiamethoxam:

- The surface tension of the formulation.

- A fully validated analytical method for the determination of the content of active substance in the formulation.

- The in situ spraying use was not evaluated in this report regarding environmental exposure. There was no scenario to calculate PEC for this use at the time this report was prepared. Then, it was agreed in the TMII07 that the use would be evaluated at the product authorization stage.

3.5. Updating this Assessment Report

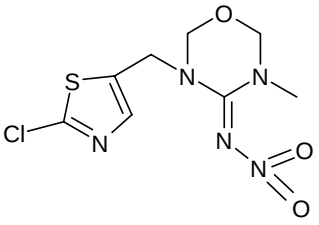
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of thiamethoxam 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)	Thiamethoxam
Product-type	Insecticide to be used as a wood preservative (PT 8)

Identity

Chemical name (IUPAC)	3-(2-chloro-thiazol-5-ylmethyl)-5-methyl[1,3,5]oxadiazinan-4-ylidene-Nnitroamine
Chemical name (CA)	3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4H-1,3,5-oxadiazin-4 imine
CAS No	153719-23-4
EC No	428-650-4
Other substance No.	637 (CIPAC No.)
Minimum purity of the active substance as manufactured (g/kg or g/l)	980 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	All impurities and by-products < 0.1 % each
Molecular formula	$C_8H_{10}ClN_5O_3S$
Molecular mass	291.7
Structural formula	

Physical and chemical properties

Melting point (state purity)	139.1°C (= 412.3 K) (purity: 99.7%)
Boiling point (state purity)	Thermal decomposition starts at about 147°C (i.e. before the boiling point is reached) (purity: 99.3%)
Temperature of decomposition	Thermal decomposition starts at about 147°C. No exothermic peak between room temperature and the me point of the substance is observed.
Appearance (state purity)	Slightly cream fine crystalline powder (purity: 99.7%)
Relative density (state purity)	$1.57 \cdot 10^3$ kg / m³ at 20°C corresponding to a relative dens 1.57. (purity: 99.7%)
Surface tension	σ = 71.7 mN / m (1.0 g / l aqueous solution). Thiamethoxam has not to be regarded as a surface active substance because the surface tension is not lower than 60 mN /m.
Vapour pressure (in Pa, state temperature)	ln P [Pa] = - 15400.447 / T [K] + 32.81766 from fit of measurements between 90.5 and 121.0°C vapour pressure 25°C : $6.6 \cdot 10^{-9}$ Pa (extrapolated).
Henry's law constant (Pa m^3 mol^{-1})	$4.7 \cdot 10^{-10}$ Pa · m³ / mol at 25°C
Solubility in water (g/l or mg/l, state temperature)	PH 7: 4.1 g / l at 25°C Thiamethoxam has no dissociation within the range pH 2 to pH 12, that means the pH has no effect to the water solubility of the compound in the pH range 4 to 10.
Solubility in organic solvents (in g/l or mg/l, state temperature)	acetone: 48 g / l ethyl acetate 7.0 g / l dichloromethane 110 g / l hexane < 1 mg / l toluene 680 mg / l methanol 13 g / l n-octanol 620 mg / l
Stability in organic solvents used in biocidal products including relevant breakdown products	stable in organic solvents
Partition coefficient (log P_{OW}) (state temperature)	P_{OW}: 0.73 ± (0.0029) at 25°C log P_{OW}: -0.13 ± (0.0017) at 25°C

Hydrolytic stability (DT_{50}) (state pH and temperature)

pH	**k (s^{-1})**		**DT_{50} (days**	
	Thia	Guan	Thia	Guan
5	No degradation		N.A.	No degradation
7	$1.27\ 10^{-8}$	$1.39\ 10^{-8}$	$1.27\ 10^{-8}$	$1.39\ 10^{-8}$
9	$9.53\ 10^{-7}$	$1.94\ 10^{-6}$	$9.53\ 10^{-7}$	$1.94\ 10^{-6}$

Dissociation constant	Thiamethoxam does not have a dissociation constant within the range 2 to 12.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	255 nm the ε = 16800 l / mol · cm in neutral solution. No absorption maximum between 290 nm and 750 nm was observed.
Photostability (DT_{50}) (aqueous, sunlight, state pH)	2.3 to 3.1 days (25°C; sterile conditions in aqueous buffer solutions at pH 5; 10 mg/l, sunlight (Xenon arc light) at 12 hours light/dark cycles over a total period of 30 days)
Quantum yield of direct phototransformation in water at Σ > 290 nm	$\Phi = 0.013 \pm 0.002$
Flammability	not highly flammable
Explosive properties	not explosive

Classification and proposed labelling

with regard to physical/chemical data	No classification is required
with regard to toxicological data	Xn – Harmful R22 – Harmful if swallowed S 46 – If swallowed, seek medical advice immediately and show this container or label.
with regard to ecotoxicological data	N, R50/53 - may cause long-term adverse effects in the aquatic environment S60 - This material and its container must be disposed of as hazardous waste S61 - Avoid release in the environment. Refer to special instructions/safety data sheet

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	HPLC. RP column. UV detection at 254 nm. Quantification external standard of CGA-293343.
Impurities in technical active substance (principle of method)	**Nitrosamines.** Thermal cleavage after HPLC separation and chemiluninescence detection of the formed NO. Quantification by comparison of peak area with that of standard N-nitrosopiperidine.

Analytical methods for residues

Soil (principle of method and LOQ)	REM 179.03. Soil samples are extracted by shaking with water / methanol (10 ml, 1 + 1; vol. + vol.) for 1h at 250 r.p.m. Purified with phenyl solid-phase cartridge. Thaimethoxam and for CGA 322704 are determined by HPLC two column switching system with UV-detector (Column 1: 125 mm x 2 mm Nucleosil C18 5 µm and Column 2: 125 mm x 2 mm Nucleosil 100 Phenyl 7µm, 255 nm or 270 nm for CGA 322704 and for CGA 293343 respectively. Mobile phase 1: water/methanol (85:15) and Mobile phase 2: water/acetonitrile (8:2). LOQ = 0.002 mg a.i. / kg soil
Air (principle of method and LOQ)	REM 179.04. Thiamethoxam is sorbed from air in XAD-2 sorbent tubes. Is extracted with methanol (2 x 15 ml) Thiamethoxam is determined by HPLC using UV detection (Column Sphersorb PC 18.5 µm, UV 255 nm. Mobile phase: methanol water (3 +7; vol + vol). LOQ = 0.05 µg / l.
Water (principle of method and LOQ)	REM 179.05. Samples of potable water (200 ml) are extracted by solid phase extraction on a Lichrolut EN solid-phase extraction cartridge. For surface water samples an additional cleanup step using phenyl and EN cartridges is necessary. thiamethoxam and CGA 322704 is determined by HPLC using UV detection. (Column 125 mm x 2 mm Nucleosil C18-5µm. Mobile phase: water acetonitrile (85 + 15; vol + vol) at 0.25 ml/min.

Body fluids and tissues (principle of method and LOQ)	Not required
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	**Cow (fat, kidney, liver), goat (meat), milk and eggs.** AG-675. Samples are extracted twice by homogenisation in acetonitrile / water (8 + 2 vol. + vol.). Liquid samples such as milk and eggs, are extracted by shaking for 20 minutes in acetonitrile / water (8 + 2 vol. + vol.). Liquid-liquid partition using toluene and hexane. Sample is purified with reverse-phase solid-phase extraction (SPE), normal phase SPE amino and alumina cardtridges), content of thiamethoxam and metabolite CGA-322704 are determined by normal phase HPLC/UV (Waters Spherisorb S5 NH_2 (250 mm x 4.6 mm I.D.), with a mobile phase of hexane:ethyl acetate: isopropanol methanol (11 + 3 + 1 + 1; vol. + vol. + vol. + vol.).). LOQ = 0.01 mg/kg. For milk LOQ = 0.005 mg/kg.

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Rapid and complete absorption in the rat within 24 hours, based on urinary and biliary excretion. In the mouse, about 75%, based on urinary excretion.
Rate and extent of dermal absorption:	1.25%
Distribution:	Widely distributed. Highest residues in the liver.
Potential for accumulation:	No evidence of accumulation
Rate and extent of excretion:	Rat: 95 % in urine and 5 % in feces within 168 hours. (about 90% via kidney and about 4% with faeces and biliary excretion was negligible accounting for 4%).
Toxicologically significant metabolite(s)	Parent compounds and metabolites: CGA 322´704 (10% of dose) (clothianidine) and CGA 265´307 (1% of dose). All the other metabolites were below 1% of dose

Acute toxicity

Rat LD_{50} oral	1563 mg/kg bw (Xn- R22)
Mice LD_{50} oral	871 mg/kg
Rat LD_{50} dermal	>2000 mg/kg bw
Rat LC_{50} inhalation	> 3.72 mg/l (4 hours exposure, nose-only)
Skin irritation	Non-irritant
Eye irritation	Non-irritant
Skin sensitization (test method used and result)	Not-sensitiser (Maximization Method)

Repeated dose toxicity

Species/ target / critical effect	Liver hypertrophy and inflammation in rodents, histopathological findings in kidneys (male rat: α-2-microglobulin nephropathy). This effect is not relevant to humans. Histopathological findings in testes (dog).
Lowest relevant oral NOAEL	NOEL=10 ppm (1.41 mg/kg bw/day) 90-day male mice NOAEL=150 ppm (4.05 and 4.49 mg/kg bw/day in males and females respectively) 1 year dog NOAEL=250 ppm (8.23 and 9.27 mg/kg bw/day in males and females respectively) 90-day dog
Lowest relevant dermal NO(A)EL	NOEL=60 mg/kgbw/day; 28-day female rats
Lowest relevant inhalation NOAEL / LOAEL	Data not required

Genotoxicity	No genotoxic potential

Carcinogenicity

Target / critical effect	Liver (hypertrophy, inflammation, necrosis) in mice Kidney (male rat α-2-μ-globulin nephropathy)
Lowest relevant NOAEL/NOEL	2.63 – 3.68 mg/kg bw/day in male and female mice respectively, based on the occurrence of neoplastic and non-neoplastic alterations in the liver.
	Increased incidence of liver cell adenoma and adenocarcinoma in mice at 500 ppm (64 mg/kg bw/day)and above (LOAEL), as effect secondary to liver enzyme induction

Reproductive toxicity

Target / critical effect reproduction	germ cell loss/disorganization Sertoli cell vacuolation
Lowest relevant reproductive NOAEL / NOEL	NOAEL= 1000 ppm (62mg/kg bw/day) 2-generation reproduction toxicity study in rats
Species/Developmental target / critical effect	Reduced fetal weight, delayed ossification and increased post-implantation loss (rabbit only) at maternal toxic doses.
Developmental toxicity	
Lowest relevant developmental NOAEL / LOAEL	NOAEL=50 mg/kg bw/day (rabbit developmental study)

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	There are no studies of neurotoxicity available although there are signs of acute neurotoxicity from the acute tox studies
Lowest relevant developmental NOAEL / LOAEL.	Data not required. Available data on neurotoxicity on the EPA website indicate that there is no concern for long term neurotoxicity

Other toxicological studies

Mechanistic	-No cytotoxicity on rat and mouse hepatocytes *in vitro*. -No effects on hepatocyte proliferation in rats *in vivo*. -Induction of liver enzymes (phenobartbital-type) in mouse liver. -Induction of hepatocyte proliferation in mouse *in vivo*. -CNS depression at high doses. -Evidence for α-2-microglobulin nephropathy in male rats confirmed by immunohistochemistry. regenerative cell proliferation and enzyme induction are the etiology of the specific liver tumour formation in mice
Acute toxicity of metabolites	CGA 322704 tech. LD_{50} >2000 mg/kg bw. (m, f) NOA 407475 tech LD_{50} >500 rng/kg bw. <1000 mg/kg bw (m, f)

Genotoxicity testing of metabolites	CGA 322704 and NOA 407475 were not mutagenic to bacterial systems

Medical data

Limited, new compound No detrimental effects on health in manufacturing plant personnel reported

Summary	Value	Study	Safety factor
Non-professional user	0.08 mg/kg bw/day	90-day oral study in dog	100
ADI (acceptable daily intake, external long-term reference dose)	-	-	-
AOEL-S (Operator Exposure)	0.0263 mg/kg bw/day	18 month study mice	100
ARfD (acute reference dose)	-	-	-
AOEL (acute)	0.5 mg/kg bw/day	Rabbit developmental toxicity study	100
Professional user			
Reference value for inhalation (proposed OEL)			
Reference value for dermal absorption			

Acceptable exposure scenarios (including method of calculation)

Professional users	For industrial wood preservation the application techniques are double-vacuum process, pressure impregnation and dipping. Models used are Mixing and loading 7 and Handling 1. For indoor and outdoor remedial wood preservation by professionals, the application techniques are small scale dipping (Mixing and loading 7, Dipping model 1 and Handling model 1), spraying (Spraying model 2) and brushing (Consumer product painting, indoor model 1 and outdoor, model 3).
Non-professional users	For do-it-yourself *in* situ treatment of wood (non-professional) the application techniques are brushing (Consumer product painting, indoor model 1 and outdoor, model 3) and spraying, indoor and outdoor (consumer product spraying & dusting, model 3)
Indirect exposure as a result of use	Intended exposure due to secondary contact with treated wood: Using preserved timber in construction, manual handling of treated wet wood, and processing of treated wood. Unintended exposure due to secondary contact with treated wood: Cleaning work ware at home, children playing on preserved timber, and infants chewing preserved timber off-cuts

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 1: Stable (20 ºC)
	pH 5: Stable (20 ºC)

pH	k (s^{-1})		DT_{50} (days)	
	Thia.	Guan	Thia.	Guan
7	$1.27\ 10^{-8}$	$1.39\ 10^{-8}$	640 (25 C) 1114(20 C)	572(25 C) 1253(20 C)
9	$9.53\ 10^{-7}$	$1.94\ 10^{-6}$	8.4 (25 C) 15.6 (20 C)	4.2 (25 C) 7.3 (20 C)

	Metabolites detected by hydrolysis (not half life reported): CGA 355190 (max at pH 9, 25ºC, 30 d: 59.5%) NOA 404617 (max at pH 9, 25ºC, 30 d: 33.28%) CGA 309335 (max at pH 9, 25ºC, 30 d: 9%) CGA 322704 (max: 1%). Stable at 20ºC and pH range 4-9
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	2.3 to 3.1 days (25ºC, sterile conditions in aqueous buffer solutions at pH 5; 10 mg/l, sunlight (Xenon ar light) at 12 h light/dark cycles over a total period of 30 d. Metabolites: Volatiles (56 % AR) identified as carbonyl sulphide (the most part) and isocyanic acid. CGA 353042 (65.8%) CGA 355190 (10%) CGA 322704, CGA 353968, NOA 407475, methyl urea less than 5%.
Readily biodegradable (yes/no)	No
Biodegradation in seawater	Not relevant
Non-extractable residues	13.8 % to 25.3% (100 and 80 days respectively) (7.1.2.2.2/01 and 02)
Distribution in water / sediment systems (active substance)	Maximum percentage of parent compound in sediment: 36.6% at 8 days. (7.1.2.2.2/01)
Distribution in water / sediment systems (metabolites)	Water: CGA355190 4.5% max at day 100 Sediment: CGA 355190 4.7% max at day 100 NOA407475 47.4% max at day 42 (at day 100 in other study)

Route and rate of degradation in soil

Mineralization (aerobic)	44% to 17 % 7.2.2.1/01 in 363 d (key study): 5 to 21% in 90 days
Method of calculation	First order kinetics
Thiamethoxam	

Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): 34d (*k* = 0,0202) to 219d (*k* = 0.00316) (studies 7.2.2.1/01 and 02).
	DT_{90lab} (20°C, aerobic): 114 to 727 days (studies 7.2.2.1/01 and 02). MEDIAN –DT50 at 20ºC 135.5 MEDIAN –DT90 at 20ºC 475
	DT_{50lab} (10°C, aerobic): 233 days (studies 7.2.2.1/01 and 02).
	DT_{50lab} (20°C, anaerobic): 23.5 to 24.2 days (study 7.1.2.1.2/01 and 02) MEDIAN –DT50 anaerobic: 23.85 (only 2 values)
	DT_{50lab} (20°C, aerobic): 34d (*k* = 0,0202) to 219d (*k* = 0.00316) (studies 7.2.2.1/01 and 02).
Metabolites	
Laboratory studies (range or median, with number of measurements, with regression coefficient)	Not validated DT50 for metabolites has been provided, except for CGA322704: DT50 (20 ºC, aerobic): 178.2 d (k=0.00389 ± 0.00019) study 7.2.2.1/06 DT90 (20ºC, aerobic): 592 d NOA 459602: DT50 (20 ºC, aerobic): 28.3 to 172 d (study 7.2.2.1/07) DT90 (20 ºC, aerobic): 94 to 571
	Degradation in the saturated zone: *no data.*
Field studies (state location, range or median with number of measurements)	DT_{50f}: 72 days (r2= 0.85) German soil
	DT_{90f}: 238 days
Anaerobic degradation	The main metabolite formed in anaerobic degradation was NOA 407475 (63.4% at 180 days). CGA 355190 reached 10 % of AR.
Soil photolysis	This route is considered of low relevance, Only small increases in the dissipation rate between irradiated and non-irradiated soils were observed.
Non-extractable residues	5.8 at 20 ºC (7.2.2.1/01) to 20 % at 90 days (from PPP monograph endpoint listing) 3.2% to 10.9% at 90 days (from 7.2.2.1/01)
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	CGA 322704: 35.6% at 90 days (7.2.2.1/01) and CGA 355190: 23.1% at 180 days (7.2.2.1/05)
Soil accumulation and plateau concentration	Due to DT90 value below one year, the rapporteur does not considers necessary to estimate a plateau PCE for continuous annual application

Adsorption/desorption

K_{oc} pH dependence (yes / no) (if yes type of dependence)	Parent: 33 to 176.7 (study 7.2.3.1/01) CGA 322704: 63 (study 7.2.3.1/08) to 77 (7.2.3.1/07) 7.2.3.1/06 ranging from 93,1 (silt loam) to 382,5 (sandy loam) CGA 355190: 37.6 to 187.5 (study 7.2.3.1/10) NOA 407475: 433 to 1555 (study 7.2.3.1/12) CGA 353042: 198 to1425 (study7.2.3.1/09) NOA 404617: 16.3 to 72.5 (7.2.3.1/11) No pH dependence was observed.

Fate and behaviour in air

Direct photolysis in air	Not relevant as the substance is not volatile and is quickly oxidized by hydroxy radicals in the athmosphere.
Quantum yield of direct photolysis	1.2 to 1.6 days
Photo-oxidative degradation in air	DT50 (Atkinson calculation) 0.5 to 2.5 hours
Volatilization	from soil: < 2.1% in 24 hours

Monitoring data, if available

Soil (indicate location and type of study)	Not available
Surface water (indicate location and type of study)	Not available
Groundwater (indicate location and type of study)	Not available
Air (indicate location and type of study)	Not available

Chapter 5: Effects on Non-target Species

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

Species	Time-scale	Endpoint	Toxicity
Fish			
	Acute	96 h LC50	>125 mg/l
	Chronic	88 days NOEC	20 mg/l
Invertebrates			
Ostracoda	Acute	48h static EC50	0.18 mg/l
Gammarus Sp.	Acute	48h static EC50	2.8 mg/l
Daphnia magna (waterflea)	Chronic	21 days NOEC	100 mg/l
Lymnea stagnalis (mollusc)	Acute	48 h static EC50	100 mg/l
Cloeon Sp. (Ephemeroptera)	Acute	48h static EC50	0.014 mg/l
Chironomus riparius	Chronic	30 days NOEC	0.01 mg/l

Algae			
Selenastrum capricornutum		72 h NOEC	81.8 mg/l
Selenastrum capricornutum		72 h ERC	> 81.8 mg/l
Aquatic plants			
Lemna Gibba G3	subchronic	7 d EC50	> 90.2 mg/l
Microorganisms			
Inhibition of activated sludge from Reinach (Switzerland) STP		3 h EC50	>100 mg/l

Metabolites

Species	Test substance	Time-scale	Endpoint	Toxicity
Fish				
Onchorynchus mykiss	CGA 322704	Acute	96 h LC50	>100 mg/l (7.4.1.1/04)
Onchorynchus mykiss	CGA 355190	Acute	96 h LC50	>100 mg/l (7.4.1.1/05)
Onchorynchus mykiss	NOA 407475	Acute	96 h LC50	>100 mg/l (7.4.1.1/06)
Onchorynchus mykiss	NOA 459602	Acute	96 h LC50	>120 mg/l (7.4.1.1/07)
Invertebrates				
Daphnia magna (waterflea)	CGA 322704	Acute	48 h EC50	>100 mg/l (7.4.1.2/06)
Daphnia magna (waterflea)	CGA 355190	Acute	48 h EC50	>100 mg/l (7.4.1.2/06)
Daphnia magna (waterflea)	NOA 407475	Acute	48 h EC50	>82.9 mg/l (7.4.1.2/07)
Daphnia magna (waterflea)	NOA 459602	Acute	48 h EC50	>120 mg/l (7.4.1.2/08)
Chironomus riparius	CGA 322704	Chronic (run off event)	28 d EC50 (emergency rate) NOEC	0.025 mg/kg sediment (dry) 0.015 mg/kg sediment (dry)
Chironomus riparius	CGA 322704	Chronic (spiked water)	NOEC	0.00067mg/kg sediment (7.4.3.5.1)

Species	Test substance	Time-scale	Endpoint	Toxicity
Chironomus riparius	NOA 407475	Chronic (run off event)	28 d EC50 (emergency rate) NOEC	1 mg /Kg dry sediment 1.0 mg/Kg dry sediment
Chironomus riparius	NOA 459602	Chronic (spray drift ev	24 d EC50 (emerg rate) NOEC	56 mg /l 50 mg/l
Algae				
Selenastrum capricornutum	CGA 322704	Acute	72 h EC50 NOEC	>100 mg/l 50 mg/l (7.4.1.3/03)
Scenedesmus subspicatum	CGA 355190	Acute	72 h EC50 NOEC	>100 mg/l 100 mg/l (7.4.1.3/04)
Scenedesmus subspicatum	NOA 407475	Acute	72 h EC50 NOEC	14 mg/l 4.6 mg/l (7.4.1.3/05)
Selenastrum capricornutum	NOA 459602	Acute	96 h EC50 NOEC	>120 mg/l 60 mg/l (7.4.1.3/06)

Effects on earthworms or other soil non-target organisms

Acute toxicity to	**Thiamethoxam technical** 14 d LC50 >1000 mg ai/kg soil **NOA 407475** 14d LC 50 >1000 mg ai/kg soil **CGA 355190** 14 d LC 50: 753 mg ai/kg soil **CGA 322704** 14 d LC50: 5.93 mg ai/kg soil **NOA 459602** 14 d LC50>1000 mg ai/kg soil
Reproductive toxicity to various Earthworm species	Thiamethoxam technical NOEC 4616 g formulation/ha equivalent to 1154 g a.i./ha or **0.68 mg/kg** soil in the biocide scenario, soil surface spraying, 8 weeks. (Ruffli, 1997 IIIA, 10.6.1.2/01 in PPP monograph pag. 795) Thiamethoxam applied as the test item A 9584 at a dose of 50, 100 and 200 g a.s./ha (equivalent to 0.066, 0.133 and 0.266 mg/kg of soil respectively) from a 361 d test accepted in the PPP monograph Ecotox_addenda (Jan 2004) by Forster, A., 2003. Effects were observed along a year and showed that at these concentrations, Thiamethoxam did not significantly reduce total number or biomass of any earthworm group (adult or juvenile) or specie on any of

the six post treatment occasions.
CGA 322704 NOEC 0.06 mg ai /kg dry soil or 0.004 mg ai/kg wet soil (Bätscher, R. 2000 'Effects of CGA 322704 on survival, growth and reproduction of the earthworm Eisenia fetida') Test A7.5.2.1_01 or A7.5.1.2 (applicant).

*CGA 322704 NOEC **0.016 mg/kg wet soil**. Field study by Pease and Webster, 2004, study A7.5.2.1_02 or A7.4.3.5/01 (applicant) Earthworm species, including Apporectodea longa, and Aporrectodea caliginosa, epilobous juveniles were the dominant groups in terms of numbers and biomass. Also adults of Lumbricus terrestris and Allolobophora chlorotica. Few occurrences of epigeic species such as Lumbricus festivus and L. castaneus. The treatments were as follows: Control (water), 37.5 g CGA 322704/ha, 75 g CGA 322704/ha, 150 g CGA 322704/ha.* The lowest rate of 37.5 g/ha nominal was measured as 23.05 g/ha (mean) and translated to the biocide scenario, 0.016 mg/kg soil. Duration of test: 386 d

Thiamethoxam NOEC 0.133 mg/kg wet soil (field study).

CGA 322704 NOEC 0.016 mg/kg wet soil (field study).

Effects on soil micro-organisms

Nitrogen mineralization	**Thiamethoxam Technical** No relevant effects at 2.67 mg ai/kg dry soil (equivalent to 10 x the maximum application rate of 200 g ai/ha as PPP) Note: 200 g ai/ha is equivalent to 0.13 mg ai/kg wet soil assuming RHO =1500 Kg/m3 and 0,1 m deep receiving compartment. RHO= 1700 Kb/m3 in biocide scenarios, but data is not much affected by this (0,12 mg ai/kg) **CGA 322704** No relevant effects at 0.5 mg metabolite/kg dry soil **CGA 355190** No relevant effects at 0.5 metabolite/kg dry soil.
Carbon mineralization	**Thiamethoxam Technical** No relevant effects at 2.67 mg ai/kg dry soil (equivalent to 10 x the maximum application rate of 200 g ai/ha) **CGA 322704** No relevant effects at 0.5 mg metabolite/kg dry soil **CGA 355190** No relevant effects at 0.5 metabolite/kg dry soil

Effects on terrestrial vertebrates

Acute toxicity to mammals	
Acute toxicity to birds	**Thiamethoxam technical** Mallard duck-LD50:576 mg /kg bw Quail-LD50: 1552 mg/kg bw **CGA 322704** Quail LD50>2000 mg/kg bw
Dietary toxicity to birds	**Thiamethoxam** Bobtail Quail and Mallard duck LC50>5200 ppm (Quail: LC50 >1929 g /kg bw/day duck: LC50 >1175 g ai/kg bw/day)
Reproductive toxicity to birds	Mallard duck NOEC 300 ppm

Effects on honeybees

Acute oral toxicity	LD50 oral = 0.005 µg/bee **CGA 322704** LD50 oral=0.0168 ug/bee
Acute contact toxicity	LD50 contact = 0.024 µg/bee **CGA 322704** LD50 contact=0.0275 ug/bee.

Effects on other beneficial arthropods

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect
Laboratory Tests					
Poecilus cupreus L	Larvae	Formulation (35%)	3750	Mortality	100
Semi-field Tests					
Poecilus cupreus L	Adults	Formulation (70%)	0.140	Mortality	18.9% corrected mortality
Aleochara bilineata	Adults	Formulation (25%)	0.140	Parasitisation of fly pupae	66.6% reduction in parasitisation

Bioconcentration

Bioconcentration factor (BCF)	No bioconcentration
Depration time (DT_{50}) (DT_{90})	
Level of metabolites (%) in organisms accounting for > 10 % of residues	

Chapter 6: Other End Points

Not applicable

Appendix II: List of Intended Uses

Thiamethoxam has been evaluated for its use as wood preservative (product type 8). According to the foreseen intended uses of thiamethoxam and the information given by the applicant, the formulations used for the risk assessment have been the followings:

- industrial wood preservation. **The application techniques are pressure impregnation, double-vacuum impregnation and dipping. Thiamethoxam containing products for industrial use are solvent based, 10% formulations that are diluted to** an in treatment solution with a content of a.i. of **0.005% for pressure impregnation, 0.15% for double vacuum impregnation and 1% for dipping**.
- Professional procedures. **These are mainly small scale dipping** (content of a.i. in treatment solution of 1%) **and spraying indoor and brushing indoor and outdoor** (content of a.i. in treatment solution is 0.04%).
- Non-professional applications: **Do-it-yourself** ***(*****brushing and spraying indoor and outdoor).** Products applied by non-professionals are water based ready-to-use formulations (content of a.i. in treatment solution is 0.04%).

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.

Active substance

Annex point / reference number	Author(s)	Year	Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner (1)
A3.1.1	Das, R.	1995a	Report on melting point / melting range Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland 35441, 31.08.1995 GLP, not published Syngenta File N° CGA293343/0012	Y	SCP
A3.1.2	Das, R.	1997	Report on boiling point / boiling range Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland 35442, 18.08.1997 GLP, not published Syngenta File N° CGA293343/0295	Y	SCP
A3.1.3	Füldner, H.	1995	Report on density of solids Ciba-Geigy Ltd., Basel, Switzerland PP-95-53P-DES, 22.12.1995 GLP, not published Syngenta File N° CGA293343/0030	Y	SCP
A3.2	Geoffroy, A.	1995	Report on vapour pressure curve Ciba-Geigy Ltd., Basel, Switzerland PP-95-53P-VPC, 22.12.1995 GLP, not published Syngenta File N° CGA293343/0029	Y	SCP
A3.2.1	Burkhard, N.	1996	Henry`s law constant Novartis Crop Protection AG, Basel, Switzerland 4.9.1996 Syngenta File N° CGA293343/0086	Y	SCP
A3.3.1/01 A3.3.2/01 A3.3.3/01	Das, R.	1995b	Report on general physico-chemical properties (pure active ingredient) Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland 35446, 23.11.1995 GLP, not published Syngenta File N° CGA293343/0022	Y	SCP
A3.3.1/02 A3.3.2/02 A3.3.3/02	Das, R.	1998	Report on general physico-chemical properties (technical grade active ingredient) Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland 58210, 30.01.1998 GLP, not published Syngenta File N° CGA293343/0404	Y	SCP
A3.4.1	Birk, R.	1995	Report on spectra	Y	SCP

Annex point / reference number	Author(s)	Year	Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner (1)
A3.4.2 A3.4.3 A3.4.4/01			Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland 32388, 13.11.1995 GLP, not published Syngenta File N° CGA293343/0423		
A3.4.4/02	Birk, R.	1998	Report on 13C-NMR spectrum Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland 63934, 27.07.1998 GLP, not published Syngenta File N° CGA293343/0677	Y	SCP
A3.5	Stulz,, J.	1995a	Report on water solubility Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland 35444, 01.12.1995 GLP, not published Syngenta File N° CGA293343/0025	Y	SCP
A3.6	Stulz, J.	1995b	Report on dissociation constant in water Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland 38123, 13.12.1995 GLP, not published Syngenta File N° CGA293343/0026	Y	SCP
A3.7	Stulz, J.	1998	Report on solubility in organic solvents Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland 58212, 24.02.1998 GLP, not published Syngenta File N° CGA293343/0479	Y	SCP
A 3.9	Stulz, J.	1995c	Report on octanol/water partition coefficient Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland 36610, 23.11.1995 GLP, not published Syngenta File N° CGA293343/0021	Y	SCP
A3.10	Angly, H.	1998a	Screening test for thermal stability and stability in air Institute of Safety and Security, Basel, Switzerland 98.4009.TSA, 25.02.1998 GLP, not published Syngenta File N° CGA293343/0457	Y	SCP
A3.11/01	Angly, H.	1998b	Flammability of solids Institute of Safety and Security, Basel, Switzerland 98.4009.FLS, 25.02.1998 GLP, not published Syngenta File N° CGA293343/0458	Y	SCP
A3.11/02	Angly, H.	1998c	Relative self-ignition temperature for solids Institute of Safety and Security, Basel, Switzerland 98.4009.AFS, 25.02.1998 GLP, not published Syngenta File N° CGA293343/0460	Y	SCP
A3.13	Hörmann, A.	1998	Report on surface tension Novartis Services AG, Basel, Switzerland PP-98/21T.SUR, 20.03.1998 GLP, not published Syngenta File N° CGA293343/0504	Y	SCP
A3.15	Angly, H.	1998d	Explosive properties Institute of Safety and Security, Basel, Switzerland 98.4009.EXP, 25.02.1998 GLP, not published	Y	SCP

Annex point / reference number	Author(s)	Year	Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner (1)
			Syngenta File N° CGA293343/0459		
A3.16	Angly, H.	1998e	Oxidizing properties of solids Institute of Safety and Security, Basel, Switzerland 98.4009.OXP, 25.02.1998 GLP, not published Syngenta File N° CGA293343/0461	Y	SCP

(1) Owner: SCP = Syngenta Crop Protection AG, Basel

Annex point / reference number	Author(s)	Year	Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner (1)
A4.1 / 01	Düll, B.	2003a	Determination of content by HPLC Syngenta Crop Protection Münchwilen AG, Münchwilen, Switzerland SA-1/1, 21.02.2003 not GLP, not published Syngenta File N° CGA293343/1694	Y	SCP
A4.1 / 02	Düll, B.	2003b	Validation of analytical method SA-1/1 Syngenta Crop Protection Münchwilen AG, Münchwilen, Switzerland 110033, 24.03.2003 GLP, not published Syngenta File N° CGA293343/1709	Y	SCP
A4.2/01	Mair, P.	1998a	Determination of CGA 293343 and CGA 322704 by HPLC, Plant Material, Soil - Validated Method Novartis Crop Protection AG, Basel, Switzerland REM 179.03, 06.05.1998 GLP, not published Syngenta File N° CGA293343/0206	Y	SCP
A4.2/02	Giannone, C.	1998	Validation of Method REM 179.03 - Summary of results of fortified specimens of representative plant materials and soil analyzed according to REM 179.03 Novartis Crop Protection AG, Basel, Switzerland 503/98, 21.07.1998 GLP, not published Syngenta File N° CGA293343/0514	Y	SCP
A4.2/03	Tribolet, R.	1997a	Determination of CGA 293343 by high performance liquid chromatography, Air Novartis Crop Protection AG, Basel, Switzerland REM 179.04, 20.10.1997 GLP, not published Syngenta File N° CGA293343/0343	Y	SCP
A4.2/04	Tribolet, R.	1997b	Validation of Method REM 179.04 by Analyses of Fortified Air Sampling Tubes for CGA 293343 and Evaluation of Recoveries Novartis Crop Protection AG, Basel, Switzerland 178/97, 20.10.1997 GLP, not published	Y	SCP

Annex point / reference number	Author(s)	Year	Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner (1)
			Syngenta File N° CGA293343/0344		
A4.2/05	Mair, P.	1997a	Determination of CGA 293343 and CGA 322704 by HPLC, Potable Water Novartis Crop Protection AG, Basel, Switzerland REM 179.05, 02.12.1997 GLP, not published Syngenta File N° CGA293343/0389	Y	SCP
A4.2/06	Mair, P.	1997b	Validation of Method REM 179.05: Validation by Analysis of Fortified Specimens and Determination of Recoveries Novartis Crop Protection AG, Basel, Switzerland 181/97, 16.12.1997 GLP, not published Syngenta File N° CGA293343/0390	Y	SCP
A4.2/07	Mair, P.	1998b	Validation of Method REM 179.05 for the Use with Surface Water Novartis Crop Protection AG, Basel, Switzerland 106/98, 11.09.1998 GLP, not published Syngenta File N° CGA293343/0697	Y	SCP
A4.2/08	Campbell, D.D.	1998	Analytical method for the determination of residues of CGA 293343 and the metabolite CGA 322704 in animal and crop substrates by high performance liquid chromatography with detection by UV and mass spectrometry, including validation data Novartis Crop Protection Inc., Greensboro, United States AG-675, 18.09.1998 GLP, not published Syngenta File N° CGA293343/0820	Y	SCP
A4.2/09	Crawford, C.J.	1998	Independent Laboratory Validation of Method AG-675, for the Determination Of Residues of CGA-293343 and the Metabolite CGA-322704 in Animal and Crop Substrates Ricerca, LLC, Concord, United States 7693-98-0174-CR-001, 11.11.1998 GLP, not published Syngenta File N° CGA293343/0847	Y	SCP

(1) Owner: SCP = Syngenta Crop Protection AG, Basel

Annex point / reference number	Author(s)	Year	Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner (1)
A6.1.1/01	Oda, S.	1996a	CGA 293343 tech. - An acute oral toxicity study of CGA 293343 tech. in rats. Bozo Research Center Inc., Tokyo, Japan B-3120 / CG 942111, 23.05.1996 GLP, not published Syngenta File N° CGA293343/0054	Y	SCP
A6.1.1/02	Oda, S.	1996b	CGA 293343 tech. - An acute oral toxicity study of CGA 292343 tech. in mice. Bozo Research Center Inc., Tokyo, Japan B-3122 / CG 952058, 23.05.1996 GLP, not published Syngenta File N° CGA293343/0055	Y	SCP
A6.1.1/03	Cantoreggi, S.	1998a	CGA 322704 tech. (Metabolite of CGA 293343) - Acute oral toxicity in the rat. Novartis Crop Protection AG, Stein, Switzerland 982001, 28.04.1998 GLP, not published Syngenta File N° CGA322704/0013		SCP
A6.1.1/04	Cantoreggi, S.	1998b	NOA 407475 tech. (Metabolite of CGA 293343) - Acute oral toxicity in the rat. Novartis Crop Protection AG, Stein, Switzerland 982013, 28.04.1998 GLP, not published Syngenta File N° NOA407475/0001		SCP
A6.1.2/01	Oda, S.	1996c	CGA 293343 tech. - An acute dermal toxicity study of CGA 293343 tech. in rats. Bozo Research Center Inc., Tokyo, Japan B-3121 / CG 942112, 23.05.1996 GLP, not published Syngenta File N° CGA293343/0053	Y	SCP
A6.1.3	Shutoh, Y.	1996	CGA 293343 tech. - Acute inhalation toxicity study in rats. Institut of Environmental Toxicology, Kodaira, Tokyo, Japan IET 95-0120, 14.08.1996 GLP, not published Syngenta File N° CGA293343/0084	Y	SCP
A6.1.4/01	Shibata, R.	1996a	CGA 293343 tech. - A primary skin irritation study of CGA 293343 tech. in rabbits. Bozo Research Center Inc., Tokyo, Japan B-3124 / CG 942113, 31.05.1996 GLP, not published Syngenta File N° CGA293343/0056	Y	SCP
A6.1.4/02	Shibata, R.	1996b	CGA 293343 tech. - A primary eye irritation study of CGA 293343 tech. in rabbits.	Y	SCP

Annex point / reference number	Author(s)	Year	Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner (1)
			Bozo Research Center Inc., Tokyo, Japan B-3123 / CG 942114, 31.05.1996 GLP, not published Syngenta File N° CGA293343/0057		
A6.1.5	Winkler, G.	1995	CGA 293343 tech. - Skin sensitization test in the Guinea pig - Maximization test. Ciba-Geigy Ltd., Stein, Switzerland 942115, 21.12.1995 GLP, not published Syngenta File N° CGA293343/0027	Y	SCP
A6.2/01	Müller, T. Stampf, P.	1996	Absorption, distribution, and excretion of [Thiazol-2-14C] and [Oxadiazin-4-14C] CGA 293343 in the rat. Ciba-Geigy Ltd., Basel, Switzerland 11/96, 15.08.1996 GLP, not published Syngenta File N° CGA293343/0105	Y	SCP
A6.2/02	Löffler, A.	2002a	Dermal absorption of [Oxadiazin-4-14C] CGA 293343 formulated as CruiserR 350 FS (A-9700 B) in the rat (in vivo) Syngenta Crop Protection AG, Basel, Switzerland 027AM12, 11.04.2002 GLP, not published Syngenta File N° CGA293343/1464	Y	SCP
A6.2/03	Löffler, A:	2002b	The percutaneous penetration of [Oxadiazin-4-14C] CGA 293343 formulated as CRUISERr 350FS (A-9700 B) through rat and human split-thickness skin membranes (in vitro) Syngenta Crop Protection AG, Basel, Switzerland 027AM11, 26.04.2002 GLP, not published Syngenta File N° CGA293343/1469	Y	SCP
A6.2/04	Thanei, P. Rümbeli, R.	1998	The metabolism of [Thiazol-2-14C] and [Oxadiazin-4-14C] CGA 293343 in the rat. Novartis Crop Protection AG, Basel, Switzerland 027AM02, 18.09.1998 GLP, not published Syngenta File N° CGA293343/0717	Y	SCP
A6.2/05	Mewes, K.E.	1998b	The metabolism of [Thiazol-2-14C] CGA 293343 after multiple oral administration to mice. Novartis Crop Protection AG, Basel, Switzerland 027AM09, 03.11.1998 GLP, not published Syngenta File N° CGA293343/0800	Y	SCP
A6.2/06	Briswalter, C.	1999	The metabolism of [Thiazol-2-14C] CGA 293343 in the after multiple oral administration to mice – further identification of metabolites – Status Report Syngenta Crop Protection AG, Basel, Switzerland 027AM09, 10.11.1999	Y	SCP

Annex point / reference number	Author(s)	Year	Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner (1)
			GLP, not published Syngenta File N° CGA293343/1204		
A6.3.1/01	Altmann, B.	1996a	CGA 293343 tech. – 28-day range finding toxicity study in Beagle dogs. Ciba-Geigy Ltd., Stein, Switzerland 942106, 19.06.1996 GLP, not published Syngenta File N° CGA293343/0063	Y	SCP
A6.3.1/02	Bachmann, M.	1995	CGA 293343 tech. - 28-Days range finding study in rats (administration in food). Ciba-Geigy Ltd., Stein, Switzerland 942088, 05.05.1995 not GLP, not published Syngenta File N° CGA293343/0006	Y	SCP
A6.4.1/01	Altmann, B.	1996b	CGA 293343 tech. - 3-Month subchronic dietary toxicity study in Beagle dogs. Ciba-Geigy Ltd., Stein, Switzerland 942107, 15.10.1996 GLP, not published Syngenta File N° CGA293343/0115	Y	SCP
A6.5.	Altmann, B.	1998	CGA 293343 tech. - 12-Month chronic dietary toxicity study in Beagle dogs Novartis Crop Protection AG, Stein, Switzerland 942108, 22.07.1998 GLP, not published Syngenta File N° CGA293343/0628	Y	SCP
A6.4.1/02	Bachmann, M.	1996a	CGA 293343 tech. - 3-Month oral toxicity study in rats (administration in food). Ciba-Geigy Ltd., Stein, Switzerland 942089, 23.01.1996 GLP, not published Syngenta File N° CGA293343/0033	Y	SCP
A6.4.1/03	Bachmann, M.	1996b	CGA 293343 tech. - 3-Month range finding toxicity study in mice (administration in food). Ciba-Geigy Ltd., Stein, Switzerland 942105, 13.08.1996 GLP, not published Syngenta File N° CGA293343/0085	Y	SCP
A6.4.2/01	Gerspach, R.	1996	CGA 293343 tech. - 28-Day repeated dose dermal toxicity study in the rat. Ciba-Geigy Ltd., Stein, Switzerland 942116, 08.10.1996 GLP, not published Syngenta File N° CGA293343/0112	Y	SCP
A6.6.1/01	Hertner, Th.	1995a	CGA 293343 tech. - Salmonella and escherichia/mammalian-microsome mutagenicity test. Ciba-Geigy Ltd., Basel, Switzerland	Y	SCP

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			952014, 02.11.1995 GLP, not published Syngenta File N° CGA293343/0024		
A6.6.1/02	Deparade, E.	1999	CGA 293343 tech. - Salmonella/mammalian-microsome mutagenicity test Novartis Crop Protection AG, Basel, Switzerland 992020, 21.10.1999 GLP, not published Syngenta File N° CGA293343/1127	Y	
A6.6.1/03	Deparade, E.	1998a	CGA 322704 tech. (Metabolite of CGA 293343) - Salmonella and escherichia/mammalian-microsome mutagenicity test. Novartis Crop Protection AG, Basel, Switzerland 982002, 31.03.1998 (Amendment 1, 05.11.2003) GLP, not published Syngenta File N° CGA322704/0012 and CGA322704/0022		SCP
A6.6.1/04	Deparade, E.	1998b	NOA 407475 tech. (Metabolite of CGA 293343) - Salmonella and escherichia/mammalian-microsome mutagenicity test. Novartis Crop Protection AG, Basel, Switzerland 982014, 09.06.1998 GLP, not published Syngenta File N° NOA407475/0002		SCP
A6.6.2	Zeugin, S.	1996	CGA 293343 tech. - Cytogenetic test on Chinese hamster cells in vitro. Ciba-Geigy Basel, Genetische Toxikologie, Basel, Switzerland 952016, 18.06.1996 GLP, not published Syngenta File N° CGA293343/0062	Y	SCP
A6.6.3/01	Ogorek, B.	1996a	CGA 293343 tech. - Gene mutation test with Chinese hamster cells V79. Ciba-Geigy Ltd., Basel, Switzerland 952015, 12.01.1996 GLP, not published Syngenta File N° CGA293343/0032	Y	SCP
A6.6.3/02	Ogorek, B.	1996b	CGA 293343 tech. - Autoradiographic DNA repair test on rat hepatocytes (OECD conform) in vitro. Ciba-Geigy Basel, Genetische Toxikologie, Basel, Switzerland 952017, 29.01.1996 GLP, not published Syngenta File N° CGA293343/0038	Y	SCP
A6.6.3/03	Ogorek, B.	2000	CGA 293343 tech. - Autoradiographic DNA repair test on mouse hepatocytes (OECD conform) in vitro Novartis Crop Protection AG, Basel, Switzerland 992066, 14.04.2000	Y	SCP

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			GLP, not published Syngenta File N° CGA293343/1195		
A6.6.4	Hertner, Th.	1995b	CGA 293343 tech. - Micronucleus test, mouse. Ciba-Geigy Ltd., Basel, Switzerland 952018, 15.12.1995 GLP, not published Syngenta File N° CGA293343/0028	Y	SCP
A6.7/01	Bachmann, M.	1998a	CGA 293343 tech. - 18-Month oncogenicity study in mice. Novartis Crop Protection AG, Stein, Switzerland 942109, 02.06.1998 GLP, not published Syngenta File N° CGA293343/0538	Y	SCP
A6.7/02	Bachmann, M.	1998b	CGA 293343 tech. - 24-Month carcinogenicity and chronic toxicity study in rats." Novartis Crop Protection AG, Stein, Switzerland 942110, 27.07.1998 GLP, not published Syngenta File N° CGA293343/0652	Y	SCP
A6.8.1/01	Winkler, G.	1996a	CGA 293343 tech. - Rat oral teratogenicity. Ciba-Geigy Ltd., Stein, Switzerland 942118, 07.08.1996 GLP, not published Syngenta File N° CGA293343/0082	Y	SCP
A6.8.1/02	Winkler, G.	1996b	CGA 293343 tech. - Rabbit oral teratogenicity. Ciba-Geigy Ltd., Stein, Switzerland 942119, 13.08.1996 GLP, not published Syngenta File N° CGA293343/0083	Y	SCP
A6.8.2/01	Doubovetzky, M.	1998	CGA 293343 tech. - Rat dietary two-generation reproduction study. Novartis Crop Protection AG, Stein, Switzerland 942121, 20.07.1998 GLP, not published Syngenta File N° CGA293343/0626	Y	SCP
A6.8.2/02a,b	Doubovetzky, M.	1999	CGA 293343 tech. - Rat dietary two-generation reproduction study. Amendment 4 and 5 Novartis Crop Protection AG, Stein, Switzerland 942121, 26.07.1999 and 25.08.1999 GLP, not published Syngenta File N° CGA293343/1096 and CGA293343/1110	Y	SCP
A6.8.2/02c	Prentice, D.E.	1999	CGA 293343: Novartis Crop Protection study No. 942121 a two generation reproduction study in rats. A histopathological review of testes and expert opinion PreClinical Safety, Ettingen, Switzerland	Y	SCP

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			942121, 03.08.1999 GLP, not published Syngenta File N° CGA293343/1109		
A6.8.2/03	Weber, E.	2000	Morphometric assessment of thymic atrophy in F1 females of a two-generation reproduction study in the rat with CGA 293343 tech. Novartis Crop Protection AG, Basel, Switzerland CB 00/18, 25.02.2000 GLP, not published Syngenta File N° CGA293343/1187	Y	SCP
A6.8.2/04	Chapin, R.E. Filler, R.S. Gulati, D. et, al.	1992	Methods for assessing rat sperm motility. Reproductive Toxicology, Vol. 6 PP. 267-273 1992 01.01.1992 published Syngenta File N° CGA293343/0859	N	
A6.10/01	Persohn, E.	1995	CGA 293343 tech. - Assessment of replicative DNA synthesis in the course of a 28-days oral (feeding) toxicity study in male rats. Ciba-Geigy Ltd., Basel, Switzerland CB 94/47, 27.02.1995 GLP, not published Syngenta File N° CGA293343/0005	Y	SCP
A6.10/02	Bouis, P.	1997	The effects of CGA 293343 tech. and CGA 256084 in primary cultured rat and mouse hepatocytes. Novartis Crop Protection AG, Basel, Switzerland CB 97/36, 20.11.1997 GLP, not published Syngenta File N° CGA293343/0383	Y	SCP
A6.10/03	Trendelenburg, D.	1998	CGA 293343 tech. - Effects on biochemical parameters in the liver following administration to male and female mice. Novartis Crop Protection AG, Basel, Switzerland CB 98/11, 15.09.1998 GLP, not published Syngenta File N° CGA293343/0719	Y	SCP
A6.10/04	Weber, E.	1998	CGA 293343 tech. - Assessment of hepatic cell proliferation in mice. Novartis Crop Protection AG, Basel, Switzerland CB 98/12, 24.09.1998 GLP, not published Syngenta File N° CGA293343/0718	Y	SCP
A6.10/05	Weber, E.	1999a	Histochemical assessment of hepatic apoptosis upon treatment of male mice with CGA 293343 tech. (Thiamethoxam) for up to 9 months. Novartis Crop Protection AG, Basel, Switzerland CB 99/57, 06.12.1999 not GLP, not published	Y	SCP

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			Syngenta File N° CGA293343/1152		
A6.10/06	Weber, E.	1999b	Histopathologic evaluation of the liver of male mice upon treatment with a single high dose of CGA 293343 tech. (Thiamethoxam) Novartis Crop Protection AG, Basel, Switzerland CB 99/60, 17.12.1999 not GLP, not published Syngenta File N° CGA293343/1168	Y	SCP
A6.10/07	Weber, E.	2000a	Immunohistochemical assessment of a2U-Globulin in the rat kidney upon administration of CGA 293343 for 28 days Novartis Crop Protection AG, Basel, Switzerland CB 00/16, 03.07.2000 not GLP, not published Syngenta File N° CGA293343/1231	Y	SCP
A6.10/08	Weber, E.	2000b	Immunohistochemical assessment of a2U-Globulin in the rat kidney upon administration of CGA 293343 for 3 months Novartis Crop Protection AG, Basel, Switzerland CB 99/55, 03.07.2000 not GLP, not published Syngenta File N° CGA293343/1232	Y	SCP
A6.10/09	Weber, E.	2000c	Immunohistochemical assessment of a2U-Globulin in the rat kidney upon administration of CGA 293343 for 12 months Novartis Crop Protection AG, Basel, Switzerland CB 00/14, 03.07.2000 not GLP, not published Syngenta File N° CGA293343/1233	Y	SCP
A6.10/10	Weber, E.	2000d	Immunohistochemical assessment of a2U-Globulin in the rat kidney upon administration of CGA 293343 for 24 months Novartis Crop Protection AG, Basel, Switzerland CB 00/15, 03.07.2000 not GLP, not published Syngenta File N° CGA293343/1234	Y	SCP
A6.10/11	Butterworth, BE. Conolly, RB. Morgan, KT.	1995	A strategy for establishing mode of action of chemical carcinogens as a guide for approaches to risk assessments. Cancer Lett 93:129-146 (1995) 12.04.1995 published Syngenta File N° CGA293343/0803	N	
A6.10/12	Grasso, P. Hinton, R.H.	1990	Evidence for and possible mechanisms of non-genotoxic carcinogenesis in rodent liver. Mutation Research, 248 (1991) 271-290 25.10.1990 published	N	

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			Syngenta File N° CGA293343/0772		
A6.10/13	Carmichael, NG. Enzmann, H. Pate, I. Waechter, F.	1997	The significance of mouse liver tumor formation for carcinogenic risk assessment: Results and conclusions form a survey of ten years of testing by the agrochemical industry. Environ Health Perspec 105:1196-1203 (1997) 01.11.1997 published Syngenta File N° CGA293343/0804	N	
A6.10/14	Purchase, I.F.H.	1994	Current knowledge of mechanisms of carcinogenicity: Genotoxins versus non-genotoxins Human & Experimental toxicology (1994), 13, 17-28 01.01.1994 published Syngenta File N° CGA293343/0774	N	
A6.10/15	Whysner, J. Ross, P.M. Williams, G.M.	1996	Phenobarbital mechanistic data and risk assessment: Enzyme induction, enhanced cell proliferation, and tumor promotion. Pharmacol. Ther. Vol 71, Nos 1/2 153-191 (1996) 01.01.1996 published Syngenta File N° CGA293343/0781	N	
A6.10/16	McConnell E., E. Popp, JA. Slaga, TJ. Ward, JM. Pitot, HC eds.	1990	Mouse liver tumors: The problem. in: Mouse liver carcinogenesis: Mechanisms and species comparisons. New York: Wiley-Liss, 1990 01.01.1990 published Syngenta File N° CGA293343/0808	N	
A6.10/17	Olin, SS. ed.	1991	Meeting summary. Third workshop on mouse liver tumors, ILSI Health and Environmental Sciences Institute. Arlington, VA, October 29-30, 1991. Washington, DC: ILSI Risk Sciences Institute, 1991. 30.10.1991 published Syngenta File N° CGA293343/0809	N	
A6.10/18	Velazquez, S.F. Schoeny, R. Rice, G.E. Cogliano, V.J.	1996	Cancer risk assessment, Historical perspectives current issues, and future directions. Drug and chemical toxicology 19(3) 161-185 (1996) 01.01.1996 published Syngenta File N° CGA293343/0860	N	
A6.10/19	Beasley, RP.	1988	Hepatitis B virus. The major etiology of hepatocellular carcinoma. Cancer 61:1942-1956 (1988) 15.05.1988 published	N	

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A6.10/20	Wright, T.L. Venook, A.P. Millward-Sadler, G.H.	1992	Hepatic Tumours. Chapter 39 11.11.1998 published Syngenta File N° CGA293343/0861	N	
A6.10/21	Mazzanti, R. Monsacchi, L. Gentilini, P.	1994	Epidemiology and natural history of hepatocellular carcinoma. Trends in Exp Clin Med 4:161-171 (1994) 01.01.1994 published Syngenta File N° CGA293343/0806	N	
A6.10/22	Okuda, K. Nakashima, T. Kojirjo, M. Kondo, Y. Wada, K.	1989	Hepatocellular carcinoma without cirrhosis in Japanese patients. Gastroenterology 1989, 97:140: 140-6 01.01.1989 published Syngenta File N° CGA293343/0863	N	
A6.10/23	Simonetti, R.G. Camma, C. Fiorello, F. et, al.	1991	Hepatocellular carcinoma - A worldwide problem and the major risk factors. Digestive Diseases and Sciences, Vol. 36, No.7 (July 1991) pp. 962-972 01.07.1991 published Syngenta File N° CGA293343/0862	N	
A6.10/24	McClain, RM. Popp, JA. Slaga, TJ. Ward, JM. Pitot, HC. eds.	1990	Mouse liver tumors and microsomal enzyme-inducing drugs: Experimental and clinical perspectives with phenobarbital. In: Mouse liver carcinogenesis: Mechanisms and species comparisons. New York: Wiley-Liss, 1990 01.01.1990 published Syngenta File N° CGA293343/0807	N	

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A7.1.1.1.1/01	Clark, A.	1998c	Hydrolysis of 2-14C-thiazolyl CGA 293343 under laboratory conditions Ciba-Geigy Corp., Greensboro, United States ABR-96106, 17.09.1998 GLP, not published Syngenta File N° CGA293343/0753	Y	SCP
A7.1.1.1.1/02	Lowery, E.	1997	Hydrolysis of 14C-Guanidine-CGA 293343 under laboratory conditions Ciba-Geigy Corp., Greensboro, United States ABR-97013, 03.11.1997 GLP, not published Syngenta File N° CGA293343/0373	Y	SCP
A7.1.1.1.1/03	Ulbrich, R.	1999	Hydrolysis of 14C-labelled CGA 322704 under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland 98UL03, 19.02.1999 GLP, not published Syngenta File N° CGA322704/0020	Y	SCP
A7.1.1.1.2/01	Zetzsch, C.	1997	Quantum yield of the Photochemical degradation of CGA 293343 in aqueous solution ITA Frauenhofer-Inst., Hannover, Germany 11G97014, 12.09.1997 GLP, not published Syngenta File N° CGA293343/0469	Y	SCP
A7.1.1.1.2/02	Rüdel, H.	1998	Quantum yield of the photochemical degradation of CGA 322704 ITA Frauenhofer-Inst., Hannover, Germany NOV-001/7-21, 10.11.1998 GLP, not published Syngenta File N° CGA322704/0018	Y	SCP
A7.1.1.1.2/03	Schwartz, B.	1998b	Photodegradation of 14C-Thiazolyl-CGA 293343 in pH 5 buffered solution under artificial light Novartis Crop Protection Inc., Greensboro, United States ABR-98091, 27.10.1998 GLP, not published Syngenta File N° CGA293343/0798	Y	SCP
A7.1.1.1.2/04	Sparrow, K.	1997c	Final report: Photodegradation of 14C-[Guanidine]-CGA 293343 in pH 5 buffered solution under artificial light Ciba-Geigy Corp., Greensboro, United States ABR-97023, 27.10.1997 GLP, not published Syngenta File N° CGA293343/0375	Y	SCP
A7.1.1.2.1	Grade, R.	1996	Report on the test for ready biodegradability of CGA 293343 tech. in the carbondioxide evolution test Ciba-Geigy Ltd., Basel, Switzerland 95G001, 08.01.1996 GLP, not published Syngenta File N° CGA293343/0031	Y	SCP
A7.1.2.2.1/0	Adam, D.	1997	Paddy soil metabolism of 14C-Thiazolring	Y	SCP

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1			labeled CGA 293343 under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland 95DA04, 15.12.1997 GLP, not published Syngenta File N° CGA293343/0452		
A7.1.2.2.1/02	Adam, D.	1998a	Paddy soil metabolism of 14C-Oxadiazinring labeled CGA 293343 under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland 95DA05, 07.01.1998 GLP, not published Syngenta File N° CGA293343/0402	Y	SCP
A7.1.2.2.2/01	Adam, D.	1998b	Degradation and metabolism of 14C-oxadiazinring labeled CGA 293343 in two aerobic aquatic systems under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland 96DA02, 04.02.1998 GLP, not published Syngenta File N° CGA293343/0436	Y	SCP
A7.1.2.2.2/02	Adam, D.	1998c	Degradation and metabolism of 14C-thiazolring labeled CGA 293343 in two aerobic aquatic systems under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland 96DA01, 09.01.1998 GLP, not published Syngenta File N° CGA293343/0401	Y	SCP
A7.2.2.1/01	Phaff, R.	1997a	Rate of degradation of CGA 293343 in soil under various conditions Ciba-Geigy Ltd., Basel, Switzerland 95RP03, 23.05.1997 GLP, not published Syngenta File N° CGA293343/0098	Y	SCP
A7.2.2.1/02	Adam, D.	1996	Degradation of 14C-Thiazolring labelled CGA 293343 in various soils under laboratory conditions Ciba-Geigy Ltd., Basel, Switzerland 95DA03, 17.12.1996 GLP, not published Syngenta File N° CGA293343/0141	Y	SCP
A7.2.2.1/02a	Ellgehausen, H.	1998	Calculation of adsorption constants of soil metabolite CGA 322704 Novartis Crop Protection AG, Basel, Switzerland 98EH04, 06.10.1998 GLP, not published Syngenta File N° CGA322704/0015	Y	SCP
A7.2.2.1/03	Dixon, B.	1998	Aerobic soil metabolism of (14C-thiazole) CGA 293343	Y	SCP

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			Novartis Crop Protection Inc., Greensboro, United States 505-95, 16.03.1998 GLP, not published Syngenta File N° CGA293343/0478		
A7.2.2.1/04	Schwartz, B.	1998	Final report: Aerobic soil metabolism of 14C-(guanidine) CGA 293343 Novartis Crop Protection Inc., Greensboro, United States 504-95, 03.03.1998 GLP, not published Syngenta File N° CGA293343/0453	Y	SCP
A7.2.2.1/05	Cruz, S.M.	1998	Metabolism of 14C-guanidine CGA 293343 in viable and sterile clay loam soil under aerobic conditions Novartis Crop Protection Inc., Greensboro, United States 148-97, 18.09.1998 GLP, not published Syngenta File N° CGA293343/0752	Y	SCP
A7.2.1/06	Adam, D.	1999b	Degradation of 14C-Thiazole labelled CGA 322704 in Schwaderloch soil under aerobic conditions at 20°C Novartis Crop Protection AG, Basel, Switzerland 99DA06, 18.11.1999 GLP, not published Syngenta File N° CGA322704/0024	Y	SCP
A7.2.2.1/07	Reischmann, F.J.	2002	Rate of degradation of [Thiazole-2-14C] labelled NOA 459602 in three soils under aerobic laboratory conditions at 20 degred C Syngenta Crop Protection AG, Basel, Switzerland 01RF03, 09.09.2002 GLP, not published Syngenta File N° NOA459602/0020	Y	SCP
A7.2.2.2/01	Pointurier, R.	1998	Residue study with CGA 293343 in or on soil in south of France ADME - Bioanalyses, Aigues-Vives, France 9731003, 30.09.1998 GLP, not published Syngenta File N° CGA293343/0746	Y	SCP
A7.2.2.2/02	Smith, J.A.	1998	Determination of residues of CGA 293343 and the metabolite CGA 322704 in soil Novartis Agro GmbH, Frankfurt, Germany GB 66197, 29.09.1998 GLP, not published Syngenta File N° CGA293343/0750	Y	SCP
A7.2.2.4/01	Sparrow, K.	1997a	Photodegradation of 14C-Thiazolyl-CGA 293343 on soil under artificial light Novartis Crop Protection Inc., Greensboro, United States ABR-97011, 07.07.1997 GLP, not published	Y	SCP

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A7.2.2.4/02	Sparrow, K.	1997b	Photodegradation of 14C-Guanidine-CGA 293343 on soil under artificial light Novartis Crop Protection Inc., Greensboro, United States ABR-97012, 07.07.1997 GLP, not published Syngenta File N° CGA293343/0376	Y	SCP
A7.2.2.4/03	Clark, A.	1998a	Anaerobic aquatic metabolism of 14C-(thiazole) CGA 293343 Novartis Crop Protection Inc., Greensboro, United States 507-95, 13.03.1998 GLP, not published Syngenta File N° CGA293343/0468	Y	SCP
A7.2.2.4/04	Clark, A.	1998b	Anaerobic aquatic metabolism of 14C-(guanidine) CGA 293343 Novartis Crop Protection Inc., Greensboro, United States 506-95, 12.03.1998 GLP, not published Syngenta File N° CGA293343/0467	Y	SCP
A7.2.3.1/01	Concha, M.	1998a	Soil adsorption / desorption of 14C-guanidine-CGA 293343 by the batch equilibrium method 612W, 02.11.1998 GLP, not published Syngenta File N° CGA293343/0835	Y	SCP
A7.2.3.1/02	Keller, A.	1996	Adsorption / desorption of CGA 293343 in various soil types Ciba-Geigy Ltd., Basel, Switzerland 95AK03, 12.06.1996 GLP, not published Syngenta File N° CGA293343/0078	Y	SCP
A7.2.3.1/03	Peters, J.	2000	Time dependent sorpion of technical and of 2SC formulated (Thiazolyl-2-14C)-labeled CGA 293343 in two different soils Novartis Crop Protection Inc., Greensboro, United States 1200-99, 28.03.2000 GLP, not published Syngenta File N° CGA293343/1214	Y	SCP
A7.2.3.1/04	Peters, J.	2001	Time Dependent Sorption of (Thiazolyl-2-14C)-Labelled CGA 293343 in Various Soils Syngenta Crop Protection, Inc., Greensboro, United States 200-00, 08.05.2001 GLP, not published Syngenta File N° CGA293343/1377	Y	SCP
A7.2.3.1/05	Hein, W. Dorn, R.	2001a	Adsorption/Desorption of [Oxidiazin-4-]-CGA 293343 on Birkenheide Soil SLFA - Neustadt, Neustadt, Germany NOV18, 01.08.2001 GLP, not published Syngenta File N° CGA293343/1380	Y	SCP

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A7.2.3.1/06	Concha, M.	1998	Adsorption / desorption of 14C-thiazole CGA 322704 by the batch equilibrium method Novartis Crop Protection Inc., Greensboro, United States 419-96, 30.11.1998 GLP, not published Syngenta File N° CGA322704/0019	Y	SCP
A7.2.3.1/07	Hein, W. Dorn, R.	2001	Adsorption/Desorption of [Thiazol-2-14C]-CGA322704 on Birkenheide Soil SLFA - Neustadt, Neustadt, Germany NOV19, 12.09.2001 GLP, not published Syngenta File N° CGA322704/0034	Y	SCP
A7.2.3.1/08	Phaff, R.	1997	Adsorption / desorption of CGA 322704 in various soil types Novartis Crop Protection AG, Basel, Switzerland 96RP06, 23.04.1997 GLP, not published Syngenta File N° CGA322704/0010	Y	SCP
A7.2.3.1/09	Scott, M.	1998	Soil adsorption and desorption of Oxadiazinyl-14C-CGA 353042 by the batch equilibrium method Novartis Crop Protection Inc., Greensboro, United States 629-98, 24.11.1998 GLP, not published Syngenta File N° CGA353042/0002	Y	SCP
A7.2.3.1/10	Concha, M. Hathcock, T.	1998	Soil adsorption / desorption of 14C-CGA 355190 by the batch equilibrium method 411-97, 30.11.1998 GLP, not published Syngenta File N° CGA355190/0005	Y	SCP
A7.2.3.1/11	Concha, M. Hathcock, T.	1998	Soil adsorption and desorption of (Thiazole-2-14C-NOA 404617 by the batch equilibrium method Novartis Crop Protection Inc., Greensboro, United States 721-97, 30.11.1998 GLP, not published Syngenta File N° NOA404617/0001	Y	SCP
A7.2.3.1/12	Peters, J.	1998	Soil adsorption and desorption of Thiazolyl-2-14C-NOA 407475 by the batch equilibrium method Novartis Crop Protection Inc., Greensboro, United States 420-98, 19.11.1998 GLP, not published Syngenta File N° NOA407475/0012	Y	SCP
A7.2.3.1/13	Nicollier, G.	2000	Adsorption / Desorption of [Thiazol-2-^{14}C]NOA 459602 in Various Soils and Time Dependent Sorption Syngenta Crop Protection AG, Basel, Switzerland	Y	SCP

Annex point / reference number	Author(s)	Year	Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner (1)
			01GN08, 3.7.2002 GLP, not published Syngenta File N° NOA459602/0015		
A7.2.3.1/14	Hein, W.	2001	Time Dependent Sorption of [Thiazol-2- 14C]-CGA322704 in Birkenheide Soil SLFA - Neustadt, Neustadt, Germany NOV21, 12.09.2001 GLP, not published Syngenta File N° CGA322704/0036	Y	SCP
A7.2.3.2	Adam, D.	1996	Leaching model study with CGA 293343 in four soils under laboratory conditions Ciba-Geigy Ltd., Basel, Switzerland 95DA02, 10.04.1996 GLP, not published Syngenta File N° CGA293343/0049	Y	SCP
A7.3.1/01	Adam, D.	1996	Volatilization of 14C-Thiazolring-Labelled CGA 293343 from soil surface under controlled laboratory conditions Ciba-Geigy Ltd., Basel, Switzerland 96DA03, 15.08.1996 GLP, not published Syngenta File N° CGA293343/0104	Y	SCP
A7.3.1/02	Stamm, E.	1998	Atmospheric oxidation of CGA 293343 by hydroxyl radicals Novartis Crop Protection AG, Basel, Switzerland 98SM10, 24.03.1998 not GLP, not published Syngenta File N° CGA293343/0477	Y	SCP
A7.4.1.1/01	Rufli, H.	1996	Acute toxicity test of CGA 293343 tech. to rainbow trout (Oncorhynchus mykiss) in the flow-through system Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland 95R002, 30.01.1996 GLP, not published Syngenta File N° CGA293343/0036	Y	SCP
A7.4.1.1/02	Rufli, H.	1997a	Acute toxicity test of CGA 293343 tech. to rainbow trout (Oncorhynchus mykiss) under flow-through conditions Novartis Crop Protection AG, Basel, Switzerland 972548, 26.11.1997 GLP, not published Syngenta File N° CGA293343/0388	Y	SCP
A7.4.1.1/03	Drottar, K.R. Swigert, J.P.	1996	CGA 293343: A 96-hour flow-through acute toxicity test with the bluegill (Lepomis macrochirus) Wildlife International Ltd., Easton, MD, United States 205-96, 14.10.1996 GLP, not published Syngenta File N° CGA293343/0145	Y	SCP
A7.4.1.1/04	Rufli, H.	1997b	Acute toxicity test of CGA 322704 (Metabolite	Y	SCP

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			of CGA 293343) to rainbow trout (Oncorhynchus mykiss) in the static system Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland 962527, 21.01.1997 GLP, not published Syngenta File N° CGA322704/0009		
A7.4.1.1/05	Böttcher, J.	1998	Acute toxicity of CGA 355190 (metabolite of CGA 293343) for Rainbow trout Novartis Services AG, Basel, Switzerland G 541 04, 29.10.1998 GLP, not published Syngenta File N° CGA355190/0002	Y	SCP
A7.4.1.1/06	Seyfried, B.	1998a	Acute toxicity of NOA 407475 (metabolite of CGA 293343) to rainbow trout (Oncorhynchus mykiss) in a 96-hour static test RCC AG, Itingen, Switzerland 688781, 14.08.1998 GLP, not published Syngenta File N° NOA407475/0010	Y	SCP
A7.4.1.1/07	Wallace, SJ	2002a	NOA459602 (Thiamethoxam metabolite): Acute toxicity to rainbow trout (Oncorhynchus mykiss) Brixham Environmental Laboratory, Brixham, United Kingdom BL7243/B, 17.04.2002 GLP, not published Syngenta File N° NOA459602/0016	Y	SCP
A7.4.1.2/01	Neumann, Ch.	1996	Acute toxicity test of CGA 293343 to the cladoceran daphnia magna straus under static conditions Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland 95G003, 25.04.1996 GLP, not published Syngenta File N° CGA293343/0043	Y	SCP
A7.4.1.2/02	Knauer, K.	2000b	Acute toxicity test of CGA 293343 tech. to the Gammarus sp. under static conditions Novartis Crop Protection AG, Basel, Switzerland 2002614, 10.07.2000 GLP, not published Syngenta File N° CGA293343/1229	Y	SCP
A7.4.1.2/03	Knauer, K.	2000c	Acute toxicity test (24h) of CGA 293343 tech. to three invertebrate species Daphnia pulex leydig, Thamnocephalus platyurus, and Brachionus calyciflorus under static conditions Novartis Crop Protection AG, Basel, Switzerland 2002612, 21.07.2000 GLP, not published Syngenta File N° CGA293343/1274	Y	SCP
A7.4.1.2/04	Knauer, K.	2000d	Acute toxicity test of CGA 293343 tech. to individual invertebrate species and molluscs	Y	SCP

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			from a natural pond assemblage under static conditions Novartis Crop Protection AG, Basel, Switzerland 2002642, 21.07.2000 GLP, not published Syngenta File N° CGA293343/1273		
A7.4.1.2/05	Neumann, Ch.	1997a	Acute toxicity test of CGA 322704 (Metabolite of CGA 293343) to the cladoceran Daphnia magna strauss under static conditions Novartis Crop Protection AG, Basel, Switzerland 962528, 31.01.1997 GLP, not published Syngenta File N° CGA322704/0008	Y	SCP
A7.4.1.2/06	Maetzler, P.	1998	Acute toxicity of CGA 355190 to Daphnia magna (Immobilisation test) Novartis Services AG, Basel, Switzerland G 541 14, 30.10.1998 GLP, not published Syngenta File N° CGA355190/0003	Y	SCP
A7.4.1.2/07	Seyfried, B.	1998b	Acute toxicity of NOA 407475 (metabolite of CGA 293343) to Daphnia magna in a 48-hour immobilization test RCC AG, Itingen, Switzerland 688803, 22.09.1998 GLP, not published Syngenta File N° NOA407475/0011	Y	SCP
A7.4.1.2/08	Wallace, SJ	2002b	NOA459602 (Thiamethoxam metabolite): Acute toxicity to Daphnia magna Brixham Environmental Laboratory, Brixham, United Kingdom BL7244/B, 17.04.2002 GLP, not published Syngenta File N° NOA459602/0017	Y	SCP
A7.4.1.2/09	Knauer, K.	2000a	Acute toxicity test of CGA 293343 tech. to the Ephemeroptera Cloeon sp. under static conditions Novartis Crop Protection AG, Basel, Switzerland 2002613, 10.07.2000 GLP, not published Syngenta File N° CGA293343/1228	Y	SCP
A7.4.1.2/10	Mank, M.A. Krueger, H.O.	1998	CGA 293343 technical: a 48-hour static acute toxicity test with the midge (Chironomus riparius) Wildlife International Ltd., Easton, MD, United States 819-98, 15.10.1998 GLP, not published Syngenta File N° CGA293343/0890	Y	SCP
A7.4.1.3/01	Grade, R.	1996a	Growth inhibition test of CGA 293343 tech. to green algae (Selenastrum capricornutum) in a static system	Y	SCP

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			Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland 95G005, 12.01.1996 GLP, not published Syngenta File N° CGA293343/0035		
A7.4.1.3/02	Grade, R.	1998a	Growth inhibition test of CGA 293343 tech. to green algae (Selenastrum capricornutum) under static conditions Novartis Crop Protection AG, Basel, Switzerland 972549, 16.06.1998 GLP, not published Syngenta File N° CGA293343/0580	Y	SCP
A7.4.1.3/03	Grade, R.	1997	Growth inhibition test of CGA 322704 (Metabolite of CGA 293343) to green algae (Selenastrum capricornutum) under static conditions Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland 962529, 09.01.1997 GLP, not published Syngenta File N° CGA322704/0007	Y	SCP
A7.4.1.3/04	Maetzler, P.	1998b	Toxicity of CGA 355190 to Green algae (Growth inhibition test) Novartis Services AG, Basel, Switzerland G 541 17, 30.10.1998 GLP, not published Syngenta File N° CGA355190/0004	Y	SCP
A7.4.1.3/05	Seyfried, B.	1998c	Toxicity of NOA 407475 (metabolite of CGA 293343) to Scenedesmus subspicatus in a 72-hour algal growth inhibition test RCC AG, Itingen, Switzerland 688825, 14.08.1998 GLP, not published Syngenta File N° NOA407475/0009	Y	SCP
A7.4.1.3/06	Wallace, SJ	2002c	NOA459602 (Thiamethoxam metabolite): Toxicity to the Green Alga Selenastrum capricornutum Brixham Environmental Laboratory, Brixham, United Kingdom BL7245/B, 17.04.2002 GLP, not published Syngenta File N° NOA459602/0018	Y	SCP
A7.4.1.4	Grade, R.	1996b	Report on the test for activated sludge respiration inhibition of CGA 293343 tech. Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland 95G002, 08.01.1996 GLP, not published Syngenta File N° CGA293343/0034	Y	SCP
A 7.4.3./01	Ashwell, J., Dark, R. Emburey, S.	2003	Thiamethoxam 25 WG (A9584C) Outdoor Microcosm Study to Assess Effects on Aquatic Organisms. Syngenta, Jealott's Hill International Research Centre, Bracknell, Berkshire, UK.	Y	SCP

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			Unpublished Report no. RJ3379B (Syngenta File no. CGA293343/1851). Study dates. 15th April – 19th September 2002.		
A7.4.3.1	Rufli, H.	1997c	Prolonged toxicity test of CGA 293343 tech. to rainbow trout (Oncorhynchus mykiss) in the flow-through system Novartis Crop Protection AG, Basel, Switzerland 95R003, 30.07.1997 GLP, not published Syngenta File N° CGA293343/0296	Y	SCP
A7.4.3.2	Drottar, K.R. et, al.	1997	CGA 293343: an early life-stage toxicity test with the rainbow trout (Oncorhynchus mykiss) Wildlife International Ltd., Easton, MD, United States 322-96, 14.02.1997 GLP, not published Syngenta File N° CGA293343/0205	Y	SCP
A7.4.3.4	Neumann, Ch.	1997b	Daphnia magna reproduction test: effects of CGA 293343 on the reproduction of the cladoceran Daphnia magna straus in a semi-static laboratory test Novartis Crop Protection AG, Basel, Switzerland 95G004, 24.09.1997 GLP, not published Syngenta File N° CGA293343/0323	Y	SCP
A7.4.3.5.1/01	Grade, R.	1998b	Toxicity test of CGA 293343 tech. on sediment-dwelling Chironomus riparius (syn. Chironomus thummi) under static conditions Novartis Crop Protection AG, Basel, Switzerland 972552, 02.10.1998 GLP, not published Syngenta File N° CGA293343/0720	Y	SCP
A7.4.3.5.1/02	Grade, R.	1999	Toxicity test of CGA 322704 (Metabolite of CGA 293343) on sediment-dwelling Chironomus riparius (syn. Chironomus thummi) under static conditions Novartis Crop Protection AG, Basel, Switzerland 982581, 09.02.1999 GLP, not published Syngenta File N° CGA322704/0021	Y	SCP
A7.4.3.5.1/03	Grade, R.	2000	Toxicity test of NOA 407475 (Metabolite of CGA 293343) on sediment-dwelling Chironomus riparius (syn. Chironomus thummi) under static conditions Novartis Crop Protection AG, Basel, Switzerland 982580, 12.07.2000 GLP, not published Syngenta File N° NOA407475/0014	Y	SCP
A7.4.3.5.1/0	Grade, R	2002	Toxicity Test of NOA 459602 (Metabolite of	Y	SCP

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4			Thiamethoxam) on Sediment-Dwelling Chironomus riparius (syn. Chironomus thummi) under Static Conditions Syngenta Crop Protection AG, Basel, Switzerland 2012671, 04.06.2002 GLP, not published Syngenta File N° NOA459602/0009		
A7.4.3.5.1/05	Smyth, D.V., Brown, R.J., Maynard, S.J.,	2004	CGA 322704 (Thiamethoxam metabolite): Toxicity to the sediment dweller *Chironomus riparius* using spiked water. Brixham Environmental Laboratory, Brixham, Devon, England, Report No.: BL7987/B (Syngenta Project No. 2033605), 2 December 2004 (unpublished).	Y	SCP
A7.4.3.5.2	Grade, R.	1998c	Acute toxicity test of CGA 293343 tech. to the duckweed Lemna gibba G3 under semi-static conditions Novartis Crop Protection AG, Basel, Switzerland 972561, 16.06.1998 GLP, not published Syngenta File N° CGA293343/0595	Y	SCP
A7.5.1.1/01	Bader, U.	1998	The effect of CGA 293343 tech. on soil respiration and nitrification Novartis Crop Protection AG, Basel, Switzerland 972515, 24.04.1998 GLP, not published Syngenta File N° CGA293343/0532	Y	SCP
A7.5.1.1/02	Bader, U.	1999	The effect of CGA 322704 + CGA 355190 (two Metabolites of CGA 293343) on soil respiration an nitrification Novartis Crop Protection AG, Basel, Switzerland 992668, 11.11.1999 GLP, not published Syngenta File N° CGA322704/0023	Y	
A7.5.1.2/01	Candolfi, M.P.	1995	14-day acute toxicity test with the earthworm (Eisenia foetida) Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland 95-065-1008, 28.11.1995 GLP, not published Syngenta File N° CGA293343/0023	Y	SCP
A7.5.1.2/02	Bryan, R.L. et al	1999a	An Acute toxicity study with the Earthworm in an artificial soil substrate Wildlife International Ltd., Easton, MD, United States 108-417, 09.12.1999 GLP, not published Syngenta File N° NOA407475/0013	Y	SCP
A7.5.1.2/03	Bryan, R.L. et al	1999b	An Acute toxicity study with the Earthworm in an artificial soil substrate	Y	SCP

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			Wildlife International Ltd., Easton, MD, United States 108-425, 09.12.1999 GLP, not published Syngenta File N° CGA355190/0006		
A7.5.1.2/04	Pfeifle, V.	2000	Acute toxicity of CGA 355190 to the Earthworm Eisenia fetida Solvias AG, Basel, Switzerland 2002506, 16.10.2000 GLP, not published Syngenta File N° CGA355190/0007	Y	SCP
A7.5.1.2/05	Porch, J.R. et al	2000	An acute toxicity study with the Earthworm in an artificial soil substrate Wildlife International Ltd., Easton, MD, United States 108-418A, 28.03.2000 GLP, not published Syngenta File N° CGA322704/0026	Y	SCP
A7.5.1.2/06	Gillham, A M	2002	Acute toxicity (LC50) of the metabolite NOA459602 to the Earthworm (Eisenia fetida) in an artificial soil test Environmental R&D Team, York, United Kingdom JW2401, 28.02.2002 GLP, not published Syngenta File N° NOA459602/0004	Y	SCP
A. 7.5.2.1_01	Bätscher, R.	2000	Effects of CGA 322704 (metabolite of CGA 293343) on survival, growth, and reproduction of the earthworm Eisenia fetida RCC Ltd., Report No.: 773976 (Syngenta Project No. 2002615), 9 October 2000 (unpublished).	Y	SCP
7.5.2.1_ 02	Pease, G. & Webster, D.A.	2004	CGA322704 (A metabolite of CGA293343 (thiamethoxam)): A field study to investigate the forced effect and recovery of earthworm populations following application to a bare field site in Denmark Ecotox Ltd. Tavistock, Devon, England, Report No.: ER-04-KCB 196 (Syngenta Project No. 2033604), 4 November 2004 (unpublished).	Y	SCP
A7.5.3.1.1/02	Johnson, A.J.	1996b	CGA 293343 Acute oral toxicity (LD50) to the mallard duck Huntingdon Research Centre Ltd., Huntingdon, United Kingdom CBG 745/960013, 23.04.1996 GLP, not published Syngenta File N° CGA293343/0044	Y	SCP
A7.5.3.1.1/03	Heijink, E.	1998	Acute oral toxicity study in bobwhite quail with CGA 322704 242257, 07.10.1998 GLP, not published Syngenta File N° CGA322704/0017	Y	SCP
A7.5.3.1.2/01	Johnson, A.J.	1996c	CGA 293343 Subacute dietary toxicity (LC50) to the bobwhite quail	Y	SCP

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			Huntingdon Research Centre Ltd., Huntingdon, United Kingdom CBG 746/960156, 01.05.1996 GLP, not published Syngenta File N° CGA293343/0047		
A7.5.3.1.2/02	Johnson, A.J.	1996d	CGA 293343 Subacute dietary toxicity (LC50) to the mallard duck Huntingdon Research Centre Ltd., Huntingdon, United Kingdom CBG 747/960199, 23.04.1996 GLP, not published Syngenta File N° CGA293343/0045	Y	SCP
A7.5.3.1.3/01	Taliaferro, M.C. Miller, V.C.	1998	The reproductive toxicity test of CGA 293343 technical with the northern bobwhite (Colinus virginianus) EBA Inc., Snow Camp, United States 029518, 09.07.1998 GLP, not published Syngenta File N° CGA293343/0653	Y	SCP
A7.5.3.1.3/02	Brewer, L.W. Taliaferro, M.C. Miller, V.C.	1998	The reproductive toxicity test of CGA 293343 technical with the mallard duck (Anas platyrhynchos) EBA Inc., Snow Camp, United States 294-97, 09.11.1998 GLP, not published Syngenta File N° CGA293343/0889	Y	SCP
A7.5.4.1/01	Kleiner, R.	1995	Testing toxicity to Honeybee - Apis mellifera L. (laboratoy) BioChem GmbH, Cunnersdorf, Germany 95 10 48 045, 25.10.1995 GLP, not published Syngenta File N° CGA293343/0018	Y	SCP
A7.5.4.1/02	Nengel, S.	1997	Assessment of side effects of CGA 322704 to the honey bee, Apis mellifera L. in the laboratory GAB Biotechnologie GmbH, Niefern, Germany 972512, 14.07.1997 GLP, not published Syngenta File N° CGA322704/0011	Y	SCP
A7.5.4.1/03	Grimm, C.	1998a	Acute toxicity of CGA 293343 FS 350 (A 9700 B) to the predatory ground beetle Poecilus cupreus L. (Coleoptera: Carabidae) Novartis Services AG, Basel, Switzerland 983663, 02.11.1998 GLP, not published Syngenta File N° CGA293343/0876	Y	SCP
A7.5.4.1/04	Grimm, C.	1998b	Acute toxicity of CGA 293343 FS 350 (A 9700 B) to the rove beetle Aleochara bilineata Gyll. (Coleoptera, Staphylinidae) Novartis Services AG, Basel, Switzerland 983664, 03.11.1998 GLP, not published Syngenta File N° CGA293343/0877	Y	SCP
A7.5.4.1/05	Reber, B.	2000	Acute Toxicity of CGA 293343 FS 350 (A	Y	SCP

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			9700 B) to larvae of the Predatory ground beetle Poecilus cupreus L. (Coleoptera: Carabidae) Syngenta Crop Protection AG, Basel, Switzerland 2003631, 07.11.2000 GLP, not published Syngenta File N° CGA293343/1336		
A7.5.4.1/06	Candolfi., M.	1998a	Toxicity of CGA 293343 WS 70 (A-9567 B) to Poecilus cupreus L. (Coleoptera: Carabidae) under semi-field conditions Novartis Crop Protection AG, Basel, Switzerland 983772, 28.10.1998 GLP, not published Syngenta File N° CGA293343/0797	Y	SCP
A7.5.4.1/07	Candolfi., M.	1998b	Toxicity of CGA 293343 WS 70 (A-9567 B) to Aleochara bilineata Gyll. (Coleoptera, Staphylinidae) under semi-field conditions Novartis Crop Protection AG, Basel, Switzerland 983771, 17.11.1998 GLP, not published Syngenta File N° CGA293343/0842	Y	SCP
A7.5.4.1/08	Ruggle, P. Bolsinger, M.	1998	Biological activity of Metabolites of Thiamethoxam CGA 293343 on insects and mites Novartis Crop Protection AG, Basel, Switzerland 95 10 48 045, 14.10.1998 not GLP, not published Syngenta File N° CGA293343/0894	Y	SCP
A. 7.5.6	Bader, U.	2001	The effects of CGA 322704 (metabolite of thiamethoxam (CGA 293343)) on the decomposition of organic material in a field litterbag test. Syngenta Crop Protection AG, Basel, Switzerland, unpublished report No. 2002619.	Y	SCP
Not indicated	Widmer, H	1996	Vapour Pressure of CGA 322704 Ciba-Geigy Limited Crop protection Division Product Safety/Chemodyamics CH-4002 Basel, Switzerland 13.11.1996 GLP, not published Project number: 96WI28		
			References fromThiamethoxam evaluation following the PPP directive 91/414		
PPP study code IIA, 7.1.1.2.2/02	Mair, P	1996c	The report is a brief description of a determination of residues of thiamethoxam and its metabolite CGA 322704 in soil after application as WG25 (field trial).	Y	NCP
PPP study code IIA, 7.1.1.2.2/	Mair, P.	1996a	Determination of residues of CGA 293343 in potatoes and soil and CGA 322704 in soil after application as WG 25 - field trial	Y	NCP

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05a			Ciba-Geigy Ltd., Basel, Switzerland Study Report No. 1056/95, 20.09.1996, interim report 1.year GLP, not published Novartis File N° 293343- 101		
PPP study code IIA, 7.1.1.2.2/ 05b	Mair, P.	1997c	Determination of residues of CGA 293343 in potatoes and soil and CGA 322704 in soil after application as WG 25 - field trial Ciba-Geigy Ltd., Basel, Switzerland Study Report No1056/96, 08.07.1997, interim report 2.year GLP, not published Novartis File N° 293343- 101	Y	NCP
PPP study code IIA, 7.1.1.2.2/ 05c	Mair, P.	1998c	Determination of residues of CGA 293343 in potatoes and soil and CGA 322704 in soil after application as WG 25 - field trial Ciba-Geigy Ltd., Basel, Switzerland Study Report No., 1056/97, 03.04.1998, interim report 3.year GLP, not published Novartis File N° 293343- 101	Y	NCP
PPP study code IIA, 7.1.1.2.2/ 11	Pointurier, R.	1998a	Residue study with CGA 293343 in or on soil in north of France ADME Bioanalyses, Aigues-Vives, France Final report No. 9731001, 29.09.1998 GLP, not published Novartis File N° 293343- 747	Y	NCP
PPP study code IIA, 7.1.1.2.2/ 13	Pointurier, R.	1998c	Residue study with CGA 293343 in or on soil in south of France ADME Bioanalyses., Aigues-Vives, France Final report No. 9731002, 1.10.1998 GLP, not published Novartis File N° 293343- 746	Y	NCP
PPP study code 7.1.1.2.2/14	Sandmeier , P,	1997	Field dissipation of CGA 293343 after bareground application of [Thiazol-2-14C] labelled material Novartis Crop Protection AG, Basel, Switzerland Study Report No. 95PSA44PR1, 30.06.1997 GLP, not published Novartis File N° 293343- 237	Y	NCP
PPP study code IIA, 7.1.1.2.2/ 18	Smith, J.A.	1998d	Determination of residues of CGA 293343 and the metabolite CGA 322704 in soil Novartis Agro GmbH, Frankfurt, Germany Final report No. GB 67297, 04.12.1998 GLP, not published Novartis File N° 293343- 751	Y	NCP
PPP study code IIA 7.1.3.3/01	Fent,	1998	Field Lysimeter test Summary in vol III, Chapter 8 page 655		
PPP study code: IIA 8.4.2/01 IIIA	Ruffli, H	1997	"Chronic toxicity test of CGA 293343 WG 25 (A-9584) to earthworms (*Eisenia foetida foetida*)".	Y	SCP

Annex point / reference number	Author(s)	Year	Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner (1)
10.6.1.2/01					
addendum ecotox (Jan_2004), page 10 (B.5.- Effects in earthworms)	Forster, A., Salaun, F.	2003	"Field study to evaluate the effects of CGA 293343 WG (25) (A9584C) on earthworms in a grass field in Denmark. Ecotox UK LTd. Tavistcok, Den England, unpublished report No. KCB 156, Syngenta File CGA 293343/1462		
			Other references		
Not numbered.	Grimm, C	2003	Evaluation of potential side-effects of CGA 293343 WG 25 (A 9584) to plant dwelling non-target arthropods con citrus under field conditions. Lab. Study identification 2002697 Report A9584C	Y	SCP
	E. van de Plassche and K. Rasmussen Editors	2005	Leaching workshop, Arona, Italy, June 2005, document EUR 21878 EN European Chemicals Bureau-Biocides, Institute for Health and Consumer Protection, Joint Research Centre (JRC), European Comission-Directorate General JRC).		
		2003	TNsG on Dossier Preparation including preparation and evaluation of study summaries under Directive 98/8/EC		
	European Chemicals Boureau EU 20418 EN/2	2003	TGD: Technical guidance document on risk assessment in support of Commission Directive 93/67/EEC on risk assessment for new notified substances Commission regulation (EC) No 1488/94 on risk assessment for existing substances Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market.		

Biocidal product

Author(s)	Annex point / reference number	Year	Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner (1)
Tanya Cervantes, Melissa Lala		2001	A limited product chemistry analysis of the manufacturing product formulation Lag2001 135 (10% R170051) and of the end-use product formulation Lag 2000 493 (2.5% R95137 and 0.5% R170051)		Janssen Pharmaceutica N.V.
Jeff Mollica, Melissa Lala		2002	Stability study of the manufacturing product formulation Lag2001 135 (10% R170051) and of the en-use product formulation Lag2000 493 (2.5 R95137 and 0.5% R170051)		Janssen Pharmaceutica N.V.
William R. Goodwine		2003	Answer to the deficiency letter of January 14, 2003	N	Janssen Pharmacuetica N.V.
Jeff Mollica, Melissa Lala		2002	Stability study of the manufacturing product formulation Lag2001 135 (10% R170051) and of the en-use product formulation Lag2000 493 (2.5 R95137 and 0.5% R170051)		Janssen Pharmaceutica N.V.
David Helmer		2002	Product identity, composition and enforcement analytical method of XAMOX 10TK		Janssen Pharmaceutica N.V.
Xing Ping Hu	A5.3.1 / 01	2001	Initial tests on toxicity and residual effectiveness of R170051, R047133 and R214947		Janssen Pharmaceutica N.V.
D. Rudolph, S. Pantos	A5.3.1 / 02	2000	Prüfbericht im Rahmen des Entwicklungsvertrages “Termitizide”		Janssen Pharmaceutica N.V.
H. Hertel, S. Pantos	A5.3.1 / 03	2000	Zusammenfassender Bericht der Untersuchungen nach DIN EN 117 + DIN EN 84 im Rahmen des Entwicklungsvertrages „Termitizide“		Janssen Pharmaceutica N.V.
H. Hertel, C. Teuber	A5.3.1 / 04	2000	Untersuchung der vorbeugenden Wirkung von „R 170051“ gegenüber Eilarven des Hausbockkäfers gemäss EN 46 (1988) nach Auswaschbeanspruchung gemäss EN 84 (1997) Aufzubringende Schutzmittelmenge: 120 g/m^2		Janssen Pharmaceutica N.V.
Dave Helmer		2002	Testing the termite resistance of Janssen Pharmacuetica formulations		Janssen Pharmaceutica N.V.
Dave Helmer		2002	Testing the termite resistance of Janssen Pharmacuetica formulations		Janssen Pharmaceutica N.V.

Glenn M. Larkin		2002	Interim Report. Field termite test of commercial wood composites treated with Janssen experimental termiticides		Janssen Phamraceutica N.V.
David Helmer		2001	Termite response to XAMOX 30L treated wood		Janssen Pharmaceutica N.V.
H. Hertel, C. Teuber		2003	Translation of test report: Examination of the toxic threshold value of Lag 2002 254 against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 47 (1988) after an evaporative ageing procedure according to EN 73 (1990)		BAM
		2000	Testbericht im Rahmen des Entwichlungsvertrages "Termitizide" Bestimmung der vorbegenden Wirkung von "R 170051" gegenüber der Termitenart Reticulitermes santonensis gemäss EN 118.		BAM
H. Hertel, S. Pantos		2000	Prüfbericht im Rahmen des Entwichlungsvertrages „Termitizide" Bestimmung der Grenze der Wirksamkeit gegenüber Reticulitermes santonensis gem. EN 117.		BAM
H. Hertel, S. Pantos		2000	Prüfbericht im Rahmen des Entwichlungsvertrages „Termitizide" Bestimmung der vorbegenden Wirkung von "R 170051" gegenüber der Termitenart Reticulitermes santonensis gemäss EN 117.		BAM
H. Hertel, R. Mentschel		2001	Untersuchungsbericht Untersuchung der vorbeugenden Wirkung von „R 170051" gegenüber Eilarven des Hausbockkäfers gemäss EN 46 (1988)		BAM
H. Hertel, S. Pantos		2000	Zusammenfassender Bericht der Untersuchungen nach DIN EN 117 im Rahmen des Entwicklungsvertrages „Termitizide"		BAM
H. Hertel, C. Teuber		2002	Translation of Test Report: Examination of the toxic threshold value of Lag 2002 254 against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 47 (1988) after an evaporative ageing procedure according to EN 84 (1997)		BAM
R. Plarre, S. Pantos		2002	Prüfbericht im Rahmen des Entwicklungsvertrages „Termitizide" Bestimmung der Grenze der Wirksamkeit nach Verdunstungsbeanspruchung von „Lag 2002254" gegenüber Reticulitermes santonensis gem. EN 117 nach EN 84.		BAM
R. Plarre, S. Pantos		2002	Prüfbericht im Rahmen des Entwicklungsvertrages „Termitizide" Bestimmung der Grenze der Wirksamkeit nach Verdunstungsbeanspruchung von „Lag 2002254" gegenüber Reticulitermes santonensis gem. EN 117 nach EN 73.		BAM
		2002	CM-P17 (Test 237) Termite ground proximity performance (summary)		
		2002	CM-P17 (Test 238) Termite lunch box performance (summary)		

J.W. Creffield, D.K. Scown, A.G. Gosling		2003	Hazard level 2 field trial to determine the termiticidal effectiveness of R170051 when impregnated into solid Pinus radiata		
P. Schumacher, M. Doblinski		2002	Prüfbericht Nr. 3.2/02/8401/01 Bestimmung der Giftwerte gegnüber Larven von Hylotrupes bajulus L. nach MPA Screening - Test MPA E 04 (2002)		DAR
David Helmer		2002	Summary of ratings for treated and untreated pine blocks after exposure to termites		
		1997	Trus Joist Mac Millan- Termite test average decay and termite ratings[1] for timberstrand LSL – PRP/TEB/CPF and TEB/CPF[2]		
		1997	Trus Joist Mac Millan- Lap joint ratings-spring 1997 summary		
Leanne Stephens			North Qld field exposure trial to two new biocides. Ref TP 545		
George E. Moore, B.S.		2001	Acute oral toxicity study in rats – Defined LD50		Janssen Pharmaceutica N.V.
George E. Moore, B.S.		2001	Acute dermal toxicity study in rats – Limit test		Janssen Pharmaceutica N.V.
George E. Moore, B.S.		2001	Acute inhalation toxicity study in rats – Limit test		Janssen Pharmaceutica N.V.
George E. Moore, B.S.		2001	Primary skin irritation study in rabbits		Janssen Pharmaceutica N.V.
George E. Moore, B.S.		2001	Primary eye irritation study in rabbits		Janssen Pharmaceutica N.V.
George E. Moore, B.S.		2001	Dermal sensitization study in guinea pigs (Buehler Method)		Janssen Pharmaceutica N.V.
Mamouni, A.	B 7.1/01	2006	Thiamethoxam: Leaching from Wood Treated with Xamox 10 TK in Direct Contact with Water. RCC Ltd, Environmental Chemistry & Pharmanalytics, Itingen, Switzerland. Report number A31375, 2006 (unpublished).	Y	SCP