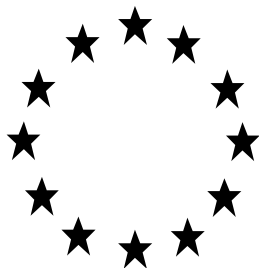
Directive 98/8/EC concerning the placing of biocidal products on the market

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

Assessment Report



THIACLOPRID

Product-type 8
(Wood Preservative)

30 May 2008

Annex I - UK

Thiacloprid (PT 8)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 30th May 2008 in view of its inclusion in Annex I to Directive 98/8/EC

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1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of Thiacloprid as product-type 8 (Wood Preservatives) in accordance with Article 11 of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with a view to the possible inclusion of this substance into Annex I to the Directive.

Thiacloprid (CAS no. 443096-59-1) is a new biocidal active substance, marketed by Lanxess Deutschland GmbH, hereafter referred to as the applicant, for product-type 8.

In accordance with Directive 98/8/EC concerning the placing of biocidal products on the market, the United Kingdom as Rapporteur Member State carried out the assessment on the basis of the dossier submitted by the applicant.

On 20 February 2006, the UK Competent Authority as Rapporteur Member State received a dossier from the applicant and subsequently accepted the dossier as complete for the purpose of the evaluation on 26 June 2006.

On 3rd July 2007, the Rapporteur Member State submitted to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 9 July 2007. The competent authority report included a recommendation for the inclusion of thiacloprid in Annex I to the Directive for product-type 8.

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

On the basis of the final competent authority report, the Commission proposed the inclusion of thiacloprid in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 30 May 2008.

The present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 30 May 2008.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include thiacloprid 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 thiacloprid. 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.

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

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[2], 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 thiacloprid 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.

2 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

The main identification characteristics and the physico-chemical properties of Thiacloprid are given in Appendix I. The active substance must be technically equivalent to the specification given.

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

2.1.2. Intended Uses and Efficacy

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

Data so far from published studies has indicated that thiacloprid is of low risk to induce resistance in insects. However, recent evidence has shown that thiacloprid resistance may be a problem in moths. The Applicant will have to provide regular updates on the status of thiacloprid resistance in the target species.

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

As thiacloprid is a new active substance to the EU, there is no current classification assigned according to Annex I of Council Directive 67/548/EEC. Based upon a review of the data submitted, proposals are presented in Table 2.1.

The observation of dystocia in rats in a multi-generation study indicates that classification for this effect may be required. Dystocia may be considered to be a manifestation of reproductive toxicity taken in its widest sense, as it indicates an adverse effect on parturition that can potentially result in adverse effects in the offspring. It is noted that the current EU classification criteria do not explicitly cover dystocia and therefore, there is uncertainty about how to classify for this effect under the existing system.

However, the criteria of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS) (Annex 1, paragraph 3.7.2.1.1) seem to allow for the classification for effects on parturition.

Consequently, this novel issue should be discussed at the Technical Committee for Classification and Labelling before making a firm proposal regarding the classification of this effect.

Table 2.1 Proposed classification for thiacloprid

Classification	Xn: Harmful. N: Dangerous for the environment.
R-phrases	R20: Harmful by inhalation. R22: Harmful if swallowed. R40 (Carc. Cat 3): Limited evidence of a carcinogenic effect. R50/53: Very toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard assessment

The potential of thiacloprid to cause adverse health effects has been investigated in studies in animals. The properties of thiacloprid and the co-formulants in the biocidal products have been used to predict effects on human health. There are no data on the adverse health effects in humans for either thiacloprid or the biocidal products.

Thiacloprid is of moderate acute toxicity via both the oral route and as an aerosol, via the inhalation route. These data indicate that classification of thiacloprid as harmful by the inhalation and oral routes (Xn: R20/R22) is appropriate. Data indicate that thiacloprid is not acutely toxic by the dermal route and no classification is considered appropriate. Studies show that two proposed environmental metabolites of thiacloprid, M02 and M30, were not acutely toxic via the oral route.

Given the data available on the health hazards of thiacloprid and the co-formulants and their concentrations in the three formulations, no classification for toxicity following single oral, dermal and inhalation exposures is predicted for any of the three example products. The surface tension of the solvent-based product at 25 ºC (24.61 nM/m) and the kinematic viscosity (2.275 mm^2/s) meet the classification and labelling criteria for aspiration hazard and therefore classification with Xn: R65 is proposed.

Data from standard studies show that thiacloprid is not a skin or eye irritant and does not require EU classification for these endpoints. Data from single and repeat inhalation exposure studies show that thiacloprid is not a respiratory tract irritant. Thiacloprid showed no skin sensitisation potential in a standard skin sensitisation test and does not require EU classification. Based on these data and the known properties of co-formulants used in thiacloprid containing products, it is not predicted that either the emulsifiable concentrate (JJT 3947) or aqueous dilution of the emulsifiable concentrate would be irritating to the skin eyes or respiratory tract and would not be skin sensitisers. These endpoints will therefore not be taken

forward for the risk characterisation for either thiacloprid or the emulsifiable concentrate and its aqueous dilution.

JJT 3968 (Solvent-based product) is co-formulated with white spirit that is classified with R66 (*repeated exposure may cause skin dryness or cracking)*. As this consitutes 89 % of the product, the solvent based product also requires similar classification. Therefore, this will be considered in the risk characterisation.

There is insufficient information to determine whether or not thiacloprid can cause occupational asthma. However, in the absence of structural alerts for thiacloprid, it is concluded that thiacloprid is unlikely to have the potential to cause occupational asthma. Based on the known properties of co-formulants used in thiacloprid containing products, it is not predicted that the biocidal products containing thiacloprid will cause occupational asthma.

The effects of repeated exposure to thiacloprid have been investigated by the oral route in rats and mice (14 days to 2 years) and in dogs (70 days to 1 year). In addition, the repeat dose toxicity has been investigated in rats after dermal exposure (28 days) and inhalation exposure (5 to 28 days). Mortality in repeat exposure studies was generally low and there were few clinical signs of toxicity. The most common sign of general toxicity were reductions in body weights that occurred particularly in rats, however, toxicologically significant reductions were noted in rats in the oral studies of 14 days to 2 years, and in the inhalation studies of 5 - 28 days. Mice and dogs were much less sensitive to body weight reductions than rats.

The most prominent findings from repeat dose toxicity studies were hepatotoxicity and thyroid toxicity particularly in rats. Enzyme induction was the most sensitive marker of hepatotoxicity and was observed in both short and long-term exposure studies primarily in rats and to a lesser extent in mice and dogs after dietary treatment with thiacloprid. For certain enzymes such as UDGPT, induction was markedly higher than in controls. Enzyme induction was often associated with changes indicative of an adaptive response within the liver such as toxicologically significant increases in liver weight, hepatocyte hypertrophy and cytoplasmic changes. There is evidence that these effects may also occur after dermal and inhalation exposures in rats. A long-term NOAEL based upon enzyme induction can be set at 1.2 mg/kg/day based on a 2 year study in rats.

More severe signs of hepatotoxicity were noted at the highest doses after chronic exposures. For example, eosinophilic / clear cell foci were noted in male rats in a 2 year dietary study, and liver degeneration and necrosis were observed in mice in a 2 year dietary study. Dose related changes in clinical chemistry indicative of liver toxicity were also noted in some studies. Dogs appeared less sensitive to the hepatotoxicity, although this may have occurred with longer exposure periods.

Histopathological changes were noted in the thyroids of rats but not in dogs or mice. The most common thyroid finding in rats was a dose related increase in the incidence of hypertrophy or increased mitotic index within the follicular epithelium. Males appeared more sensitive to this effect than females although the reason for this is not known. These effects occurred at a lowest dose of 2.5 mg/kg/day and above in male rats treated with thiacloprid in the diet over 2 years. There were inconsistent effects reported on rat thyroid weights, with increases observed in a dietary study and decreases reported in an inhalation study.

There is evidence that follicular epithelial hypertrophy also occurs after inhalation and dermal exposures, where in the latter this effect was reversible in females but not males after the cessation of exposure.

Changes in the thyroid hormones T3 and T4 were noted inconsistently in some studies, with both increases and decreases being reported. More consistently, increases in TSH were noted, occurring in both a 14 day and a 90 day dietary study in rats.

Hypertrophy of the thyroid follicular epithelium may be a result of hepatic enzyme induction, however, no causal link between these events is considered to have been established. Hepatic enzyme induction may lead to an increased rate of conjugation and excretion of thyroid hormones, which in turn leads to compensatory hyperplasia in the thyroid. It is known that thiacloprid leads to an increased incidence of thyroid tumours in rats during chronic studies. Because of the uncertainty regarding the mechanism by which the thyroid tumours arise, a long-term NOAEL is set at 1.2 mg/kg/day based on liver enzyme induction that occurs in rats at 2.5 mg/kg/day in a 2 year study and this will be taken forward for the risk assessment.

As the main health concern following hepatic enzyme induction is the development of thyroid tumours which only occur following prolonged exposures, an increase in hepatic enzyme induction is not considered a suitable endpoint on which to base the short-term NOAEL. Instead, this will be based on reductions in body weight gain. The most appropriate study is considered to be a rabbit developmental study in which a NOAEL of 2 mg/kg/day was derived based on toxicologically significant decreased body weight gain at the next highest dose of 10 mg/kg/day.

Effects in organs other than the liver and thyroid were occasionally noted after repeated oral exposures to thiacloprid. These effects were histopathological changes in the ovaries and adrenals of mice and in the prostate gland of dogs. Although these effects are considered treatment-related, they occur at dose levels above the NOAELs for both long and short-term exposure and therefore should be protected against.

Overall, the data indicate that no classification for repeat dose toxicity is appropriate for thiacloprid. Similarly, none of the co-formulants in the biocidal products are classified for repeat dose toxicity. Therefore, no classification for repeat dose toxicity is considered appropriate for any of the biocidal products.

Data indicate that thiacloprid is not mutagenic *in vitro*. In addition, a negative result was obtained in a standard *in vivo* micronucleus test. Three environmental metabolites of thiacloprid, M02, M30 and M34, also tested negative in standard *in vitro* studies. Therefore, EU classification for mutagenicity is not required. As neither of the co-formulants in the biocidal products are mutagenic, it is not predicted that any of the biocidal products will pose a mutagenic hazard.

The potential carcinogenicity of thiacloprid has been investigated in both rats and mice in 2 year dietary exposure studies. The data show that thiacloprid causes an increase in malignant uterine adenocarcinomas and thyroid adenomas in rats and ovarian luteomas in mice. These tumours occur against a background of hepatic enzyme induction. It has been suggested by the Applicant that thyroid tumours in rats occur as a consequence of increased conjugation and

clearance of thyroid hormones by the liver and compensatory thyroid follicular epithelial hyperplasia. However, there is no direct evidence in the studies available to causally link liver enzyme induction to thyroid tumours.

It has also been speculated by the Applicant that uterine tumours in rats and ovarian tumours in mice are the consequence of hepatic enzyme induction, specifically the induction of aromatase. Induction of this enzyme could lead to an increase in serum oestradiol concentrations and persistent stimulation of oestrogen responsive tissues. Increased serum oestradiol concentrations have occasionally been seen in rats after treatment with thiacloprid, however, there is no direct evidence to inform on whether this was causal.

Overall, the mechanism of carcinogenicity is not known for either thyroid or reproductive tract tumours but is not considered to involve genotoxicity and may be related to the liver enzyme induction caused by thiacloprid. Based on the T25 estimate of carcinogenic potency, thiacloprid is considered within the EU as a 'medium potency' carcinogen (1 mg/kg/day < T25 value ≤ 100 mg/kg/day). It is considered that classification as a category 3 carcinogen is the most appropriate for thiacloprid. Therefore, carcinogenicity will be considered in the risk characterisation; the NOAELs identified for long-term exposures will also be appropriate for this endpoint.

None of the co-formulants in either of the biocidal products are classified for carcinogenicity. As the concentrations of thiacloprid in all the biocidal products are below 1 %, no EU classification for carcinogenicity is required for any of the biocidal products.

The potential for thiacloprid to affect development has been investigated in standard studies in rats and rabbits. No evidence of developmental toxicity was observed in rats at doses of up to 50 mg/kg/day, or in rabbits at doses of up to 45 mg/kg/day. No classification for developmental toxicity is considered appropriate. None of the co-formulants are classified as developmental toxicants and therefore, no classification for this endpoint is considered necessary for all of the biocidal products.

The potential for thiacloprid to cause adverse effects on fertility has been investigated in a standard 2-generation study in rats. No treatment-related adverse effects on fertility were observed at doses of up to 43 mg/kg/day, the highest dose tested. Therefore, no classification for effects on fertility is considered appropriate. None of the co-formulants are classified as toxic to fertility and therefore, no classification for this endpoint is considered necessary for all of the biocidal products.

In a 2-generation study in rats, supported by findings a supplemental investigation also in rats, it was shown that treatment with thiacloprid may cause dystocia. A NOAEL for dystocia can be set at 3.7 mg/kg/day based on findings in a 2-generation study in rats. It is considered that dystocia is of sufficient concern to necessitate communication of this hazard. However, dystocia as a specific hazard does not appear to be covered directly in the current classification and labeling criteria for reproductive toxicity. Consequently, this novel issue should be discussed at the Technical Committee for Classification and Labelling before making a firm proposal regarding the classification of this effect (see also section 2.1.3).

The potential neurotoxicity of thiacloprid has been investigated in two acute and one 13 week repeat dose study. Signs of neurotoxicity, primarily decreased motor and locomotor activity, were noticed in rats after a single oral gavage but not in rats after dietary administration over 13 weeks. The NOAEL for acute neurotoxicity is 3.1 mg/kg based on effects seen in females at 11 mg/kg. Consequently these effects should be protected against by the short-term NOAEL of 2 mg/kg.

CRITICAL ENDPOINTS

For risk characterisation of long-term repeated exposure, the critical effects identified were tumours of the thyroid and uterus (by a non-genotoxic mechanism), and dystocia in rats and ovarian tumours in mice (by a non-genotoxic mechanism).

The NOAEL for the onset of tumours in the rat was 2.5 mg/kg/day, based on tumours in the uteri and thyroids of rats at the next highest dose. However, tumours in the thyroid are likely to be due to enzyme induction leading to histopathogical change in the liver and thyroid. The NOAEL to protect against these tumours has therefore been set at 1.2 mg/kg/day based on liver enzyme induction and histopathological changes that occured in the liver and thyroid at 2.5 mg/kg/day and above in a two-year dietary administration study in rats. For effects in the liver and thyroid, there are data to suggest that rats are the most sensitive species followed by mice and then dogs. It is unknown whether or not humans will be more succeptable than rodents or dogs. Therefore, these effects following oral exposure are considered relevant to human health. The NOAEL for ovarian tumours in mice was identified as 11 mg/kg/day. The NOAEL for dystocia was identified as 3.7 mg/kg/day. Consequently, the NOAEL of 1.2 mg/kg/day will be used for long-term exposure scenarios in the risk characterisation.

In terms of short/medium-term exposures, the most relevant toxicological effects are considered to be reductions in bodyweight gain and food consumption. Toxicologically significant reductions in bodyweight gain and food consumption occurred at 10 and 45 mg/kg/day in a developmental toxicity study in rabbits. Food consumption and bodyweight gain was not affected at 2 mg/kg/day. There is evidence to suggest that rabbits are the most sensitive species and it is unknown whether or not humans will be more susceptible. Therefore, these effects following oral exposure are considered relevent to human health following short-term exposures.

Consequently, a NOAEL of 2 mg/kg/day will be used for short/medium-term exposure scenarios in the risk characterisation. (It is noted that effects on the liver and thyroid have not been used to set the short/medium-term NOAEL as they are only considered toxicologically significant here in the context of the development of tumours).

UNCERTAINTIES

Dermal Absorption Values Used in the Risk Assessment

No data are available on the dermal absorption of JJT 3947 the emulsifiable concentrate. However, data are available from a toxicokinetics study in monkeys to show that the dermal absorption of an aqueous suspension of thiacloprid is 10 %. As a consequence, it is considered that a dermal absorption value of 10 % is appropriate for the emulsifiable concentrate in the absence of data to show otherwise.

The ability of [thiazolidine-4,5-^{14}C] thiacloprid to penetrate human skin was examined *in vitro* with solvent-based and aqueous dilutions of the emulsifiable concentrate (JJT 3947) containing 0.02 % and 0.05 % thiacloprid, respectively. A dermal absorption value of 17 % was obtained for the solvent-based formulation JJT 3968 and this value will be taken forward to the risk characterisation. A dermal absorption value of 7 % was obtained for the aqueous formulation and this value will be taken forward to the risk characterisation.

Inter- and Intra-species Variability

Following oral exposure to thiacloprid, thyroid and uterine tumours and dystocia were seen in the rat, and ovarian tumours were seen in the mice. There is no definitive information available to identify the relative sensitivities of humans compared to experimental animals in relation to these effects. Similarly, there are no data to reliably inform on the potential inter-individual variability in susceptibility to these effects. Given these uncertainties, standard default factors of 10 to account for potential inter-species (human to rodent) and 10 to account for intra-species variability (human to human) will be included in the risk characterisation. Therefore, an assessment factor of 100 will be applied to both the occupational and consumer exposure scenarios.

Route to Route Extrapolation

From the toxicokinetics studies there appears to be no significant first-pass metabolism. Therefore, one would expect similar toxicokinetic and toxicodynamic profiles for thiacloprid following both oral, dermal and inhalation exposures. Hence, oral to inhalation or dermal extrapolation is considered valid for the risk characterisation for systemic effects following short-term, medium-term or long-term exposures. Although inhalation and dermal data are available for repeated exposures of up to 28-days, the NOAEL for short-term exposures is being based on the most sensitive effect observed which were bodyweight gain reductions seen after oral exposure in a developmental toxicity study.

Dose-response/severity for key health effects

There are two key studies that will be used in the risk assessment, a developmental toxicity study in rabbits for short/medium-term exposures and a 2-year rat study for long-term oral exposure. The dose-response characteristics of each study are briefly described below. In addition, it is considered that dystocia observed in a rat 2-generation study is a key health effect and this will also be considered below.

In a 2-year study in rats, a dose-related increase in the incidence of uterine tumours (malignant adenocarcinoma), and thyroid tumours was reported. The tumours arise by a non-genotoxic mechanism and therefore, it is possible to identify a threshold for their onset. In the uterus, malignant adenocarcinoma was observed in 12, 6, 6, 28 and 36 % of animals at 0, 1.6, 3.3, 33.5 and 69.1 mg/kg/day, respectively, statistically significant at the top two doses; benign adenoma in 0, 0, 2, 2 and 4 % of animals, respectively; and malignant adenosquamous carcinoma in 0, 0, 0, 2 and 4 % of animals, respectively. In the thyroid follicular cell adenomas were reported in 0, 0, 2, 10 and 16 % of males at 0, 1.2, 2.5, 25.2 and 51.7 mg/kg/day, respectively, statistically significant at the top two doses; while a lower incidence was reported in females, 0, 2, 2, 2 and 4 % at 0, 1.6, 3.3, 33.5 and 69.1 mg/kg/day, respectively. Although not proven, it is likely that thyroid tumours are due to hepatic enzyme induction that in turn affects the thyroid. The NOAEL for these effects will therefore be based on liver and thyroid effects seen in the same 2-year study.

The long-term NOAEL of 1.2 mg/kg/day was based on histopathological changes noted in the liver and thyroid and hepatic enzyme induction at 2.5 mg/kg/day and above. Statistically significant increases in the incidences of histopathological changes in the liver were reported in males at 2.5 mg/kg/day and above and in females at 33.5 mg/kg/day and above. Histopathological changes observed in the liver included centrilobular hypertrophy (m: 0, 0, 24, 88 and 98 % of animals at 0, 1.2, 2.5, 25.2 and 51.7 mg/kg/day, respectively; f: 0, 2, 0, 60 and 72 % of animals at 1.6, 3.3, 33.5 and 69.1 mg/kg/day, respectively), cytoplasmic changes in the hepatocytes (eosinophilic cytoplasm with basophilic strands) (m: 0, 0, 16, 82 and 94 % of animals, respectively; f: 0, 2, 0, 60 and 68 % of animals, respectively) and eosinophilic/clear cell foci (m: 2, 4, 10, 30 and 44 % of animals, respectively; f: 4, 2, 6, 12 and 20 % of animals, respectively).

Follicular epithelial hypertrophy was observed in the thyroid (m: 24, 20, 44, 54 and 68 % of animals, respectively; f: 12, 4, 12, 32 and 46 % of animals, respectively).

Hepatic enzyme induction was reported in males at 2.5 mg/kg/day and above and at 33.5 mg/kg/day and above in females. In addition, increases in liver weights of 20 % were observed in males at the top dose of 51.7 mg/kg/day.

A 2-year study in mice has shown that thiacloprid leads to ovarian luteomas at 475 and 872 mg/kg/day at an incidence of 10 % at both dose levels, compared to 0 % in controls. In addition, adrenal x-zone vacuolation was noted also in mice, and prostate enlargement was noted in three studies in dogs. As these effects occur at relatively high doses they will be protected against by the long term NOAEL of 1.2 mg/kg/day.

The short/medium-term NOAEL of 2 mg/kg/day has been based on reductions in bodyweight and food consumption. In the two-year dietary study in rats, toxicologically significant reductions in terminal bodyweight were observed at doses of 25.2 mg/kg/day and above. However, toxicologically significant reductions in bodyweight gain and food consumption (up to 28 % decrease) occurred at 10 and 45 mg/kg/day in a developmental toxicity study in rabbits. In this study food consumption and bodyweight gain was not affected at 2 mg/kg/day.

In a fertility study, dystocia occurred in 4/30 animals at 22 mg/kg/day and in 3/30 at 43 mg/kg/day in P0 females. Although this effect was not seen in F1 generation animals in this

study, signs of dystocia were seen in a supplemental study but at higher doses. The NOAEL for dystocia was set at 3.7 mg/kg/day, and therefore these effects should be protected against by the long and short/medium-term NOAELs of 1.2 and 2 mg/kg/day, respectively.

2.2.1.2. Exposure assessment

The modelling of exposure and risk assessment/risk characterisation during production and formulation of thiacloprid should be addressed under other EU legislation (eg Directive 98/24/EC) and not repeated under Directive 98/8/EC (as agreed at Biocides Technical Meeting TMI06).

When considering the manufacture of thiacloprid and the formulation of products, Directive 98/24/EC on the *Protection of the health and safety of workers from the risks related to chemical agents at work* was taken into consideration.

It is considered that as a minimum, the control approach used should be that of containment (enclosure of the process). In addition, e.g. if production volume is increased, it may occasionally be necessary to seek expert advice from a competent occupational hygienist to ensure that the control measures used remain appropriate.

RISKS FROM PRIMARY EXPOSURE

Exposure assessments have been carried out for a solvent-based product (JJT 3968), an emulsifiable concentrate (JJT 3947) and a water-based ready-for-use product (derived from aqueous dilution of JJT 3947).

Industrial/Professional Application of Products

It is considered that it is possible for industrial/professional workers in the relevant industries to be working with products containing thiacloprid on most workdays and a long-term NOAEL/AOEL is most appropriate for use in the risk characterisation. Exposure assessments have been carried out for a solvent-based product (JJT 3968), an emulsifiable concentrate (JJT 3947) and a water-based ready-for-use product (derived from aqueous dilution of JJT 3947).

The primary exposure scenarios for the industrial/professional use of these products are:

JJT 3968

- Double vacuum impregnation
- Vacuum pressure impregnation with supercritical carbon dioxide
- Automated spraying
- Dipping
- Handling treated wet wood
- Cleaning out the dipping tank

JJT 3947

- Vacuum pressure impregnation
- Double vacuum impregnation
- Automated spraying
- Flow coating
- Dipping
- Handling treated wet wood
- Cleaning out the dipping tank

The NOAEL/AOEL has been compared with the relevant primary exposure in Tables 2.8 and 2.9, for industrial and professional users respectively.

Table 2.2 Summary of primary combined dermal and inhalation exposure risk characterisation for industrial users.

Exposure Scenario	NOAEL [mg/kg/d]	AOEL [mg/kg/day]	Systemic dose [mg/kg/day]	MOE	$\frac{\text{Exposure}}{\text{AOEL}}$
Vacuum pressure impregnation Water-based product (JJT 3947) Cycle calculation	1.2	0.01	9.51×10^{-5}	12618	0.010
Double-vacuum impregnation Water-based product (JJT 3947) Cycle calculation			3.22×10^{-3}	373	0.322
Double-vacuum impregnation Solvent-based product (JJT 3968) Cycle calculation			4.45×10^{-4}	2697	0.045
Automated spraying Water-based product (JJT 3947)			6.30×10^{-4}	1905	0.063
Automated spraying Solvent-based product (JJT 3968)			5.94×10^{-4}	2020	0.059
Flow coating Water-based product (JJT 3947)			1.86×10^{-3}	645	0.183
Vacuum pressure impregnation with hypercritical carbon dioxide (JJT 3968) Cycle calculation			1.11×10^{-4}	10909	0.011
Dipping Water-based product (JJT 3947)			4.77×10^{-4}	2516	0.048
Dipping Solvent-based product (JJT 3968)			4.45×10^{-4}	2697	0.045
Handling of treated wet wood Water-based product (JJT 3947)			6.78×10^{-4}	1770	0.068
Handling of treated wet wood Solvent-based product (JJT 3968)			9.38×10^{-5}	12793	0.009
Cleaning out dipping tank (Without RPE) Water-based product (JJT 3947)			5.34×10^{-4}	2247	0.053
Cleaning out dipping tank (With RPE) Water-based product (JJT 3947)			5.02×10^{-4}	2390	0.050
Cleaning out dipping tank (Without RPE) Solvent-based product (JJT 3968)			6.67×10^{-5}	17991	0.007
Cleaning out dipping tank (With RPE) Solvent-based product (JJT 3968)			6.33×10^{-5}	18957	0.006

The highest systemic dose expected for industrial users of the water-based formulation (JJT 3947) occurs during the double vacuum impregnation application. With the assumption that the obligatory PPE is used, a sufficient margin of exposure, MOE = 373, is nevertheless maintained.

The highest systemic dose expected for industrial users of the solvent-based formulation (JJT 3968) also occurs during the double vacuum impregnation application. With the assumption that the obligatory PPE is used, a sufficient margin of exposure, MOE = 2697, is nevertheless maintained. However, as the proposed classification for this product includes Xn: R66 (Repeated exposure may cause skin drying or cracking), it is recommended that the product label includes the requirement to wear suitable protective gloves. In addition, the proposed classification also includes Xn: R65 (Harmful: May cause lung damage if swallowed). To mitigate this risk, it is recommended that the product label that the product label includes the requirement to keep it out of the reach of children and to not induce vomiting if swallowed but seek medical advice immediately.

For all of the primary exposure scenarios detailed within Table 2.2 above, the calculated MOEs are > 100 and the ratio of Exposure / AEOL is < 1, therefore it is considered that the risks to the industrial users from use of the proposed products, under the specified conditions, are acceptable.

Table 2.3 Summary of primary combined dermal and inhalation exposure risk characterisation for professional users.

Exposure Scenario	NOAEL [mg/kg/day]	AOEL [mg/kg/day]	Systemic dose [mg/kg/day]	MOE	$\frac{\text{Exposure}}{\text{AOEL}}$
Painting wearing gloves Water-based product (JJT 3947)	1.2	0.01	2.17×10^{-4}	5530	0.022
Painting without wearing gloves Water-based product (JJT 3947)			7.07×10^{-4}	1697	0.071
Painting wearing gloves Solvent-based product (JJT 3968)			1.49×10^{-4}	8054	0.015
Painting without wearing gloves Solvent-based product (JJT 3968)			5.30×10^{-4}	2264	0.053
Dipping of wooden articles Water-based product (JJT 3947)			4.77×10^{-4}	2516	0.048
Dipping of wooden articles Solvent-based product (JJT 3968)			4.45×10^{-4}	2697	0.045
Handling of treated wet wood Water-based product (JJT 3947)			6.78×10^{-4}	1770	0.068
Handling of treated wet wood Solvent-based product (JJT 3968)			9.38×10^{-5}	12793	0.009

The highest exposure expected during application of the water-based formulation (JJT 3947) by professionals is during application by brush (painting) without gloves, but even for this scenario, a MOE of 1697 was calculated.

The highest exposure expected during application of the solvent-based formulation (JJT 3968) is during application by brush painting (without gloves), but even for this scenario, a MOE of 2264 was calculated. However, as the proposed classification for this product includes Xn:

R66 (Repeated exposure may cause skin drying or cracking), it is recommended that the product label includes the requirement to wear suitable protective gloves. In addition, the proposed classification for JJT 3968 includes Xn: R65 (Harmful: May cause lung damage if swallowed), therefore to mitigate against this risk, it is recommended that the product label includes the requirement to keep it out of the reach of children and to not induce vomiting if swallowed but seek medical advice immediately.

For all of the primary exposure scenarios detailed within Table 2.3 above, the calculated MOEs are > 100 and the ratio of Exposure / AEOL < 1, therefore it is considered that the risks to the professional users from use of the proposed products under the specified conditions, including using the obligatory PPE, are acceptable.

Amateur Application of Products

The primary exposure scenarios for amateur (non-professional) use are considered to be short-term and are:

JJT 3947 (aqueous dilution ready for use)

- Painting

JJT 3968 (solvent-based ready for use)

- Painting

Using the MOE approach, the risk characterisation for primary exposure by amateur users is summarised in Table 2.4.

Table 2.4 Summary of risk characterisation (primary combined dermal and inhalation exposure) for amateur users.

Scenario	NOAEL [mg/kg/day]	Systemic dose [mg/kg/day]	MOE
Painting (without gloves) water-based product (produced by the aqueous dilution of an JJT 3947)	2	1.3×10^{-3}	1538
Painting (with gloves) water-based product (produced by the aqueous dilution of an JJT 3947)		8.08×10^{-4}	2457
Painting (without gloves) Solvent-based product (JJT 3968)		9.90×10^{-4}	2020
Painting (with gloves) Solvent-based product (JJT 3968)		6.09×10^{-4}	3284

The highest exposure expected during application of the water-based formulation (JJT 3947) is during application by brush (painting) without gloves, but even for this scenario, a MOE of 1538 was calculated.

The highest exposure expected during application of the solvent-based formulation (JJT 3968) is during application by brush painting (no gloves), but even for this scenario, a MOE of 2020 was calculated. The potential for the product to cause dryness and cracking of the skin on repeated exposure (R66) (due to the solvents) is not believed to be a concern for amateur users since they are unlikely to use the product frequently enough. In addition, the proposed classification for JJT 3968 includes Xn: R65 (Harmful: May cause lung damage if swallowed), therefore to mitigate against this risk, it is recommended that the product label includes the requirement to keep it out of the reach of children and to not induce vomiting if swallowed but seek medical advice immediately. Member States may need to consider appropriate warning labels and, as necessary, child-resistant closures, when they evaluate genuine products for authorisation.

Even without making the assumption that gloves are worn, MOE's are significantly greater than 100, indicating that the risks posed to amateurs by applying thiacloprid-based products under the conditions specified are acceptable.

RISKS FROM SECONDARY EXPOSURE

The following scenarios and assumptions have been considered:

- An adult (non-professional) sands the surface of treated wood posts (short- term and also 6 h daily)
- An infant chews a wood chip (short-term)
- An adult, child and infant inhale volatilised residues indoors (short- or long- term)
- An adult launders a working garment contaminated with thiacloprid at home once weekly.
- A child plays on outdoor playground structure daily
- An infant plays on outdoor playground structure daily and there is hand-to-mouth contact

The relevant NOAEL/AOEL has been compared with the relevant primary exposure in Table 2.5.

For all of the secondary short-term and long-term exposure scenarios detailed, the calculated MOEs are significantly greater than 100. Even after the short-term scenario where an infant chews treated wood and experiences the highest potential exposure of all the scenarios, the MOE is 962. Likewise, for the worst-case exposure scenario where infants are exposed whilst playing on treated wooden structures, an MOE of 1079 is obtained.

Therefore it is considered that the use risks to bystanders from short-term and long-term exposure to wood treated with the thiacloprid-based products discussed are acceptable.

Table 2.5 Summary of risk characterisation - secondary exposure.

Secondary exposure scenario	Calculated exposure to thiacloprid	NOAEL [mg/kg/day]	MOE
Short-term	Adult (amateur) sanding treated wood: 4.04×10^{-5} mg kg(bw)$^{-1}$ event^{-1} (inhalation + dermal)	2.0	49505
	Infant chewing treated wood: 2.08×10^{-3} mg kg(bw)$^{-1}$ event^{-1} (ingestion)		962
	Adult inhaling volatilised residues from treated timber indoors during construction work: 0.036 x 10^{-8} mg kg(bw)$^{-1}$.d^{-1} (inhalation)		5.6 x 10^{9}
	Child inhaling volatilised residues from treated timber indoors: 0.0249 x 10^{-8} mg kg(bw)$^{-1}$.d^{-1} (inhalation)		8.0 x 10^{9}
	Infant inhaling volatilised residues from treated timber indoors: 0.0275 x 10^{-8} mg kg(bw)$^{-1}$.d^{-1} (inhalation)		7.3 x 10^{9}
Long-term	Adult cleaning work clothes at home: 4.12×10^{-4} mg kg(bw)$^{-1}$ w^{-1} (dermal)	1.2	2913
	Adult (professional) sanding treated wood: 5.67×10^{-5} mg kg(bw)$^{-1}$ d^{-1} (inhalation + dermal)		21693
	Child playing on treated wood structures: 6.9×10^{-5} mg kg(bw)$^{-1}$d^{-1} (dermal)		17826
	Infant playing on treated wood structures and mouthing hands: 1.14×10^{-3} mg kg(bw)$^{-1}$ d^{-1} (ingestion + dermal)		1079
	Adult inhaling volatilised residues from treated timber indoors: 0.036 x 10^{-8} mg kg(bw)$^{-1}$.d^{-1} (inhalation)		3.3 x 10^{9}
	Child inhaling volatilised residues from treated timber indoors: 0.0249 x 10^{-8} mg kg(bw)$^{-1}$.d^{-1} (inhalation)		4.8 x 10^{9}
	Infant inhaling volatilised residues from treated timber indoors: 0.0275 x 10^{-8} mg kg(bw)$^{-1}$.d^{-1} (inhalation)		4.3 x 10^{9}

RISKS FROM COMBINED EXPOSURE

It is considered in industrial/professional treatment plants that painting of timber with the product would be extremely limited and any subsequent handling of treated wet wood would be primarily by mechanical means (e.g. using a fork-lift truck). For treatment plants where painting is the main means of applying the product some limited manual handling of treated wet wood may occur. In this scenario, the total systemic dose for an adult is set out in Table 2.6, for both products, with and without the use of gloves.

It can be considered that dipping of timber would not occur on the day the dipping tank was scheduled for cleaning. It is highly unlikely that an operator involved in dipping, handling wet treated wood, painting or cleaning dipping tanks would be involved in the professional sanding of treated wood. Sanding/preparation of treated wood is usually undertaken by a different workforce, often in different factories.

It is considered unlikely that an industrial/professional operator, having spent a working day dipping, handling wet treated timber, painting wood, cleaning dipping tanks or sanding treated timber would then – in the same day – undertake sanding of treated timber at home. It is also unlikely that operators would wash work clothing on a workday but would leave this task until a weekend or rest day. Also, it is possible that a person not involved in the use of the wood preservative would undertake the cleaning of the clothing, either at home or at the wood treatment plant.

For amateur users, there should be no additive effects of exposure from the secondary exposure scenarios. The possibility of an infant chewing a piece of treated wood and then playing on a wooden structure containing the same wood preservative active ingredient is considered to be an extremely rare event.

It can be considered that none of the primary and secondary exposure scenarios described, other than the possible professional painting and handling of treated wet timber realistically warrant combination to provide a combined dose of thiacloprid.

Table 2.6 Summary of risk characterisation for professional users during combined painting+handling scenarios.

Exposure Scenario	NOAEL [mg/kg/day]	AOEL [mg/kg/day]	Systemic dose [mg/kg/day]	Combined dose [mg/kg/day]	MOE	$\frac{\text{Exposure}}{\text{AOEL}}$
Painting (with gloves) JJT 3947	1.2	0.01	2.17×10^{-4}	8.95×10^{-4}	1341	0.090
Handling treated wood JJT 3947			6.78×10^{-4}			
Painting (without gloves) JJT 3947			7.07×10^{-4}	1.39×10^{-3}	863	0.139
Handling treated wood JJT 3947			6.78×10^{-4}			
Painting (with gloves) JJT 3968			1.49×10^{-4}	2.43×10^{-4}	4938	0.024
Handling treated wood JJT 3968			9.38×10^{-5}			
Painting (without gloves) JJT 3968			5.30×10^{-4}	6.24×10^{-4}	1923	0.062
Handling treated wood JJT 3968			9.38×10^{-5}			

For all of the exposure scenarios combining painting and handling treated wood, as detailed within Table 2.6, the calculated MOEs are > 100 and the ratio of Exposure / AEOL < 1. Therefore it is considered that the risks to the professional users from use of the proposed products are acceptable.

2.2.1.3. Risk characterisation

The risks for industrial, professional and amateur users from combined dermal and inhalation exposure during the application of the solvent-based product (JJT 3968), the emulsifiable concentrate (JJT 3947) or the water-based ready-for-use product (derived from aqueous dilution of JJT 3947) are considered low and of no concern as the calculated MOEs are ≥ 100 and the ratios of Exposure/AEOL are ≤ 1 Combined exposure to those painting and then handling treated wood are also considered acceptable.

As the proposed classification for JJT 3968 includes Xn: R66 (Repeated exposure may cause skin drying or cracking), it is recommended that the product label includes the requirement that industrial and professional users wear suitable protective gloves. In addition, the proposed classification for JJT 3968 includes Xn: R65 (Harmful: May cause lung damage if swallowed), therefore to mitigate against this risk, it is recommended that the product label includes the requirement to keep it out of the reach of children and to not induce vomiting if swallowed but seek medical advice immediately.

For all of the secondary exposure scenarios summarised here, the risks to bystanders arising from the use of material treated with either the solvent-based product (JJT 3968), the

emulsifiable concentrate (JJT 3947) or the water-based ready-for-use product (derived from aqueous dilution of JJT 3947) are considered low and of no concern as the calculated MOEs are > 100.

Therefore it is considered that the risks to industrial, professional and amateur users applying the proposed products under the specified conditions; and to bystanders from short-term and long-term exposure to wood treated with the thiacloprid-based products, are acceptable.

2.2.2. Environmental Risk Assessment

The majority of available fate and effects data were performed using thiacloprid (also referred to as YRC 2894) or the agricultural formulation YRC 2894 SC 480 (~ 40 % w/w thiacloprid), which has been accepted as sufficiently representative of the active substance (a.s.). It should be noted that many of the endpoints presented in support of thiacloprid, for use in water-based (JJT 3947) and solvent-based (JJT 3968) wood preservative products, have already been assessed (and accepted) as part of a review under Directive 91/414/EEC on Plant Protection Products.

2.2.2.1. Fate and distribution in the environment

FATE IN THE AQUATIC COMPARTMENT

From abiotic aquatic degradation data, it was concluded that thiacloprid was both hydrolytically and photolytically stable under environmentally relevant conditions with respective DT_{50}s of > 1 year and > 1000 d reported. Under biotic conditions; whilst thiacloprid cannot be classified as readily biodegradable, data from both laboratory and field (microcosm) studies have shown that thiacloprid was quickly dissipated from the water compartments through adsorption to the sediment compartment, where the majority of degradation then took place. In the laboratory study, thiacloprid has been shown to degrade (DT_{50} 20.3 – 52.9d at 12 °C) in natural water/sediment systems via M02 to M30, with the potential for formation of CO_2 and bound residues from all 3 compounds. However, the microcosm study has been accepted as more relevant for use in the risk assessment, which is also in agreement with decisions made for the Plant Protection Products Directive (PPPD). This study included repeated exposure and was maintained outdoors and so can be considered as a more realistic worst-case scenario when compared to the available laboratory studies. Therefore, the DT_{50} of 31 d derived for water from the microcosm study is considered as the appropriate endpoint for use in the risk assessment for the refinement of predicted environmental concentrations in the aquatic compartment.

No major metabolites were identified in the water compartment of the microcosm study, which suggests that in the field the known metabolites M02 and M30 would not be of concern in the water phase. However, as M02 was found at significant levels in the water phase under laboratory conditions, it was considered that exposure to this metabolite cannot be dismissed. In the study the levels of M02 reached a peak on day 35 giving a mean peak concentrations of 39.25 % applied parent, which has been used in the risk assessment calculations for this metabolite in the aquatic phase. For M30, maximum levels of 5.3 % and 9.5 % AR were recorded for the water phase of the pond and lake waters respectively by the end of 100 d. Therefore, it is possible that greater levels (i.e. > 10 %) could have been reached at the elevated

laboratory temperature of 20 °C. However, it was considered that in the field this metabolite would not be of concern.

Both the laboratory and microcosm studies suggested that thiacloprid was predominantly found in the sediment phase and the DT_{50} value of 62 d in sediment (from the microcosm study) has been used in the risk assessment. This was considered to be an appropriate realistic worst-case estimate for use in the risk assessment as the study was carried out under natural environmental conditions and the test material was added on 2 separate occasions. The laboratory study showed that the major metabolite in sediment was M02, which was supported by sediment analysis in the microcosm study and a mean of 47.58 % applied parent has been used to predict the initial concentrations of M02 in sediment for the purpose of risk assessment. M30 was not found in the sediment compartment at levels > 10 % and is not considered to be of concern.

FATE IN AIR

The air compartment was not considered to be a major compartment of concern for this active substance, based on its very low vapour pressure (8×10^{-10} Pa at 25 °C, extrapolated). This is supported by data showing the low potential for volatilisation of thiacloprid from plants and soil (mean 15 % in the field). In addition the chemical lifetime of thiacloprid in the air, was predicted to be significantly less than one-day.

FATE IN SOIL

In soil, thiacloprid was thoroughly metabolised and rapidly degraded to CO_2 under aerobic conditions. A total of 0.6 to 2.0 % of the unchanged parent compound was detected in the extracts after an incubation period of 100 d. Based on the available data the mean DT_{50} of thiacloprid in soil at 12 °C was 4.4 d. The results according to 1st order kinetics were accepted (as these were used in the PPPD assessment) as they represent the worse-case scenario based on the available data i.e. visually these data suggest shorter half-lives than those suggested. However, whilst results obtained from dissipation studies, carried out under European field conditions, demonstrated that thiacloprid was well degradable in soil the mean DT_{50} value was higher than that from the laboratory studies at 15.25 d. Therefore, this value has been used in the risk assessment.

Two major metabolites; M02 and M30, were identified in both laboratory and field soil dissipation studies. However, under field conditions, too few samples were available in which the metabolite M30 could be quantified. Therefore, the mean DT_{50}s derived from the laboratory data of M02 and M30 (131.8 d and 71.5 d at 12 °C respectively) was adopted to ensure a consistent approach for the risk assessment.

Based on the mean estimated K_{oc} values from laboratory studies, the mobility of the parent compound and its 2 major metabolites can be given as; M30 (mean K_{oc} 20.0) > M02 (mean K_{oc} 229.0) > thiacloprid (mean K_{oc} 615.0). In a 30 d aged column leaching study, thiacloprid was shown to be largely degraded or non-mobile making up only 1.1 % of the applied radioactivity. Only one of the major soil metabolites of thiacloprid, M30 plus the secondary metabolite M34, was found at significant levels in the leachate, with annual concentrations exceeding 0.1 $\mu g\ l^{-1}$ leachate on more than one occasion for M30.

In addition, data from a 3 year lysimeter study showed that the predominant fraction of radioactivity was located in the upper 20 cm of soil. At the end of the experiment thiacloprid was not found and both M02 and M30 were classed only as minor metabolites (< 10 %) with a mean of 33.7 % applied radioactivity identified as bound residues. The remaining radioactivity was assumed to be lost via mineralisation of thiacloprid in soil. These results are further supported by the field soil dissipation studies, which showed that residues were largely associated with the top 10 cm soil layer. Translocation of thiacloprid, M02 or M30 into deeper soil layers of 20 - 30 cm was excluded down to a concentration of 2 µg kg^{-1}, corresponding to less than 1 % of the initial concentration applied.

Thiacloprid has measured log K_{ow} values of < 3 (0.73 and 1.26 determined with the OECD 113 and OECD 103, respectively), which suggests that there is no trigger for an assessment of the bioaccumulation potential of this a.s. in aquatic organisms.

2.2.2.2. Effects assessment

AQUATIC TOXICITY

In the aquatic environment, toxicity against thiacloprid and its major aquatic metabolite M02 has been investigated where appropriate. For STP microorganisms it has been assumed that exposure would be mainly to the a.s. and a 30 min respiration inhibition test reported an EC_{50} of 6330 mg l^{-1}. Data on short and long-term toxicity of thiacloprid to aquatic organisms are available with the most sensitive endpoint reported to be the 28 d NOEC of 0.0005 mg l^{-1} against Chironomus. The Chironomus study was included for the pelagic assessment because overlying spike used and exposure was likely to have been via the water column, which was the approach accepted for the assessment of the main metabolite of dichlofluanid considered at TMI06. The PNEC for thiacloprid was derived using an assessment factor (AF) of 10 to give 0.05 µg l^{-1}. For M02, reported as a major metabolite in water-sediment studies under laboratory conditions, acute and chronic data has shown this to be less toxic than thiacloprid with the lowest reported endpoint a NOEC of 0.0826 mg l^{-1} taken from a 28 d study with *Chironomus riparius*. As there were both acute and chronic endpoints for the most sensitive organisms, an AF of 100 was applied to the NOEC to define a PNEC of 0.826 µg l^{-1}.

No robust sediment toxicity data was available for thiacloprid or M02. Therefore, an effects endpoint for the risk assessment (predicted no effect concentration or $PNEC_{sediment}$) was determined to be 0.0069 and 0.006 mg kg^{-1} respectively using the Equilibrium Partition Method (EPM), which uses the available aquatic endpoints (TGD, equation 70).

TERRESTRIAL TOXICITY

In the soil compartment, endpoints are available thiacloprid against earthworms and terrestrial microorganisms. The long-term NOEC of 0.15 mg kg^{-1} from the field study against soil invertebrates is considered to be the most appropriate endpoint for the risk assessment. Whilst, earthworms have been shown to be the most sensitive species when tested in the laboratory, the field test investigated the impact on natural populations and allows for a more realistic endpoint to be derived. Extensive discussions at the TMV07 decided that this study can be used to derive a $PNEC_{long\text{-}term}$ because;

i) it uses repeated applications
ii) with a maximum application rate representing a total of 50 % of the expected losses to soil over 15 years in the wooden house scenario, and
iii) there are metabolite studies available against soil insects (thiacloprid is an insecticide) that show effect concentrations are greater than a magnitude higher than those tested in the field.

The TGD allows for the assessment factors applied to field studies to be considered on a case-by-case basis and values < 10 can be used. However, although a repeated exposure scenario was tested (2 applications) this was still less than can be expected from wood preservatives used in the field. Therefore, a $PNEC_{soil}$ of 0.015 mg a.s. kg^{-1} dwt based on the NOEC of 0.15 mg kg^{-1} was adopted but a precautionary assessment factor of 10 was used because of the limitations within the available soil toxicity methods (i.e. not directly applicable to the exposure pattern expected from wood preservatives).

Metabolite (M02 and M30) acute and chronic endpoints were provided for the effects assessment of the soil compartment, which suggest that these have lower toxicity to the soil compartment than the parent compound. For M02 and M30 the most sensitive endpoint available was that for the soil arthropod, *Folsomia candida* with reported 28 d NOECs of 10 and 316 mg kg^{-1} respectively from which PNECs of 0.1 and 3.16 mg kg^{-1} were derived using AFs of 100.

2.2.2.3. PBT assessment

According to the TGD, 'The Persistent, Bioaccumulative and Toxic (PBT) assessment is considered to be different from the local and regional assessments approaches, as it seeks to protect ecosystems where risks are more difficult to estimate'. Under the Biocidal Products Directive (BPD), a PBT assessment is needed to demonstrate that a substance does not fulfil selection under the United Nations Environment Programme – Persistent Organic Pollutants convention (UNEP-POPs) to limit emissions to the environment of those chemicals with high potential for persistence, bioaccumulation, long-range transport and adverse effects to human health and the environment. Any substance which is found to be either a PBT or very Persistent very Bioaccumulative (vPvB) substance shall not be allowed on Annex I unless releases to the environment can be effectively prevented.

PERSISTENCE: Data have been presented, which shows that thiacloprid did degrade reasonably rapidly in the aquatic environment with DT_{50} values of 31 and 62 d derived from an outdoor microcosm for the water and sediment compartments respectively. Therefore, the a.s. does not fulfil the criteria for a persistent compound according to the TGD (> 40 d in freshwater and/or > 120 d in freshwater sediment).

BIOACCUMULATION: A substance is considered to have the potential to fulfil the criterion of bioaccumulation when the log Kow exceeds 4.5, but as a mean log Kow of 0.995 has been derived for thiacloprid there is no trigger for an assessment of the bioaccumulation potential of this a.s in aquatic organisms. Therefore, the bioaccumulation criterion is not fulfilled.

TOXIC: According to the available data, the most sensitive chronic endpoint for thiacloprid is that derived for a 28 d Chironomus study (NOEC of 0.0005 mg l^{-1}). This means that the trigger of < 0.01 mg l^{-1} given in the TGD is exceeded and thiacloprid fulfils the toxic criterion.

No data on the effects against birds have been submitted (or is considered necessary) for this assessment.

As thiacloprid has only fulfilled one criterion (T) out of the 3 considered, it can be accepted that it is not a PBT substance.

2.2.2.4. Exposure assessment

The exposure assessment was based on all available guidance presented in the Organisation for Economic Co-operation and Development (OECD) Emission Scenario Document (ESD) on wood preservatives (OECD, 2003) and TGD on risk assessment.

The OECD ESD guidance is limited to local exposure calculations for the wood preservative life-cycle stages of 'product application' and 'wood in-service' only. Production of the active substance (a.s.), formulation of the wood preservative product, waste treatment, recovery (out-of-service use) and contamination of treatment sites have not been addressed for thiacloprid. The local scale exposure assessments presented in this document are considered worst-case in terms of environmental concentrations for this product type and substance. Where a particular Member State concern exists, it is recommended that a detailed consideration of this should be possible at the product authorisation stage.

Thiacloprid is to be used as a wood preservative, in both water and solvent-based products, for use up to hazard class 4a as defined in OECD ESD (wood in contact with ground permanently exposed to wetting). These wood preservative products are intended for use by:

- Amateur / Professional users
    - brushing/painting

- Industrial application methods, which includes;
    - vacuum pressure,
    - double vacuum pressure,
    - vacuum treatment with hypercritical CO_2,
    - automated spraying,
    - flow-coating and
    - dipping of wooden articles.

Industrial applications of thiacloprid can also be expected in joineries, where treated wooden articles like fences and window frames will be further processed.

Emissions to the environment have been considered to occur during industrial scale application and subsequent storage, during *in situ* treatment and leaching during the in-service life-stage of treated wooden articles (fence, house, bridge and noise barrier).

It should be noted that the air compartment is unlikely to be exposed because thiacloprid has a very low vapour pressure (8×10^{-10} Pa at 25 °C), which suggests that the a.s. is not volatile and the air compartment is unlikely to be of concern. This was supported by a study that investigated the volatilisation potential of thiacloprid, when used as a plant protection product, which showed that up to 15 % of the applied product was lost from the plant surface.

2.2.2.5. Risk characterisation

The following environmental risk characterisation sections address the risks posed from thiacloprid and its major metabolites M02 and M30 (where appropriate) for the environmental compartments of concern based on the proposed patterns of use.

AQUATIC COMPARTMENT

It is considered that losses via drains would result in exposure of sewage treatment plants (STP) to the parent compound only, as a DT_{50} of 31 d (under field conditions) suggests that significant amounts of the major metabolite M02 will not be formed until after the effluent stage. The risk to the STP (microorganisms) has been assessed following releases during industrial applications and in-service leaching from a noise barrier and in all scenarios the risk quotient (PEC:PNEC) was acceptable (< 1).

Emissions to surface waters from industrial treatment processes (application [via STP] + run-off from on-site stored timber) was shown to be acceptable in terms of risk from thiacloprid exposure, with the exception of automated spray (large plant) and dipping facilities using either water or solvent-based products. For the major metabolite, initial exposure levels have been predicted to be unacceptable for the same processes as the parent compound but only when using the proposed water-based product. The removal of the parent to the sediment compartment and degradation to M02 has been shown to pose an unacceptable risk in some of the industrial scenarios tested. The impact of degradation in the sediment compartment was not investigated, as the risks identified for the surface waters would remain. Therefore, mitigation measures are proposed, which would restrict the use of thiacloprid wood preservative products to industrial wood treatment sites that can comply with the following requirements, intended to prevent losses of treatment solution and leachate to the aquatic environment:

- Application processes must be carried out within a contained area;
    - Situated on impermeable hard standing,
    - With bunding to prevent run-off and
    - A recovery system in place (e.g. sump).
- Storage of treated wood must be either;
    - Undercover with a recovery system in place (e.g. sump) or
    - On impermeable hard standing and bunded to prevent run-off with a recovery system in place (e.g. sump).

These measures are considered a reasonable requirement for all industrial wood treatment sites to prevent unnecessary contamination of the environment. They are common to best available practice (BAP) throughout much of the existing industry in many Member States.

The risk to surface waters and sediment from thiacloprid resulting from the use of wood preservatives *in situ* and subsequent in-service leaching has been considered for the bridge over a pond and noise barrier scenarios. The bridge scenario resulted in unacceptable risk (PEC:PNEC > 1) for thiacloprid after either of the proposed products were applied *in situ* by

brush or if timber pre-treated by dipping using vacuum treatment processes. The exposure of the sediment compartment to thiacloprid was also unacceptable for all treatment scenarios, as was risks from the metabolite M02 to both water and sediment compartments.

The bridge scenario was not considered representative of a common use pattern for wood preservatives and as restrictions for end-use of pre-treated timber are not practical (beyond those already associated with the hazard classification scheme for treated wood - HC 1-5) no restrictions are recommended. However, the *in situ* use of these products by amateurs and professionals can be controlled through labelling. Therefore, it was recommended that the *in situ* use of thiacloprid wood preservative products should be restricted to prevent use on wooden structures over water and/or where direct losses and leaching to water from freshly treated timber may occur.

For the noise barrier scenario, long-term aquatic exposure (including sediment) to thiacloprid or its major metabolite (M02) from timber pre-treated by automated spray, dipping or vacuum treatment using either product was shown to be acceptable. Furthermore the noise barrier scenario can also be used to indicate that the long-term risks of direct losses of thiacloprid to water are acceptable. This is because if the PECs were recalculated to allow for 100 % (and not 70 %) of the leachate passing directly to water [i.e. no removal at STP] the PEC:PNEC values for the long-term assessments of thiacloprid would still be less than 1. This suggests that at product authorisation stage, Member States may wish to consider an alternative option (to the bridge scenario) for the assessment of direct losses to water, provided the use patterns in their respective countries support such a departure from the OECD ESD. Overall, no risk mitigation for end-use of timber products with respect to the aquatic environment is considered necessary.

TERRESTRIAL COMPARTMENT

The use of both water and solvent-based products in all industrial scenarios has been shown to present an unacceptable risk (PEC:PNEC > 1) to the soil compartment, from thiacloprid and its major metabolites, after long-term use. Whilst this reflects the lack of degradation within the scenario, continuous losses to soil should not be permitted. Therefore, to minimise this risk, all timber treated with thiacloprid-based products should be stored on bunded, impermeable ground and any waste collected for re-cycling or waste disposal. This requirement is identical as that for preventing losses from industrial processes to the aquatic environment (see aquatic compartment, page 30) and is considered to reinforce current BAP throughout the industry.

Unacceptable risks to the soil compartment from either thiacloprid or its major metabolite M02 (M30 acceptable for all scenarios) have only been identified following the short-term assessments for some of the *in situ* use or in-service leaching scenarios for HC3 (outdoors, out-of-ground contact) use scenarios. However, no unacceptable risks for the soil compartment were identified for the long-term scenarios of HC3 or any HC4 (outdoors, in-of-ground contact) scenario tested. Therefore, no additional risk mitigation measures are considered necessary for the *in situ* use or in-service use scenarios.

A groundwater assessment showed that there was no potential for thiacloprid or M02 to reach groundwater at levels > 0.1 µg l^{-1} (drinking water limit) based on gross assumptions of 100 % application of thiacloprid containing wood preservative to houses. However, there was potential for M30 to reach unacceptable levels using the same gross assumption but that these

levels were seen to reduce significantly (< 0.1 µg l^{-1} in ≥ 30 % of available FOCUS scenarios) if the assumed market share/usage levels were reduced to 25 % or less. In addition, data available for M30 with respect to mammalian toxicology showed that this metabolite was not toxic to rats (LD_{50} > 2000 mg kg^{-1}) with all clinical signs (4-hour post treatment diarrhoea and lack of faeces) resolved within 2 days of treatment. Further standard *in vitro* studies; bacterial gene mutation, mammalian cell gene mutation and chromosome aberration, showed that a number of environmental metabolites of thiacloprid (M02, M30, M34) tested negative. Therefore, the metabolite M30, does not appear to be a substance of toxicological concern.

BIOTA

No data or concerns have been addressed due to the low potential for bioaccumulation (see Section 2.2.2.3).

2.2.3. List of endpoints

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

3. DECISION

3.1. Background to the Decision

Based on the assessment of the data on the active substance and the representative products (JJT 3947 and JT 3968), the human health risk assessment indicates that the risks for the users of the biocidal products for all of the exposure scenarios are acceptable. Principles of good working practice should be applied and label instructions and recommendations on the products respected.

As this chemical is a new biocidal active substance, the products assessed as part of this evaluation are not yet on the EU market. This means that the composition of products intended to be placed on the EU market may vary. It will be part of the product authorisation process for Member States to evaluate the risks to humans, animals and the environment for 'real' biocidal products to be placed on the EU market.

The environmental risk assessment presented indicates that for the majority of scenarios investigated, the proposed products (water-based; JJT 3947, 0.5 % w/w a.s. or solvent-based; JJT 3968, 0.02 % w/w a.s.) would not result in unacceptable exposure of the aquatic or terrestrial compartment from thiacloprid or its major metabolites (M02 and M30). However, in order to address the concerns highlighted for the aquatic and soil compartments, risk mitigation measures are required as a condition of use to remove these concerns:

1. For the aquatic environment (industrial use):
    - Application processes must be carried out within a contained area;
        - situated on impermeable hard standing,
        - with bunding to prevent run-off and
        - a recovery system in place (e.g. sump).

    - Storage of treated wood must be either;
        - undercover with a recovery system in place (e.g. sump) or
        - on impermeable hard standing and bunded to prevent run-off with a recovery system in place (e.g. sump).

2. For the aquatic environment (*in situ* use):
    - Applications by brush should not be permitted where direct losses to water cannot be prevented.

3. For the terrestrial environment (industrial use):
    - Storage of treated wood must be either;
        - undercover with a recovery system in place (e.g. sump) or
        - on impermeable hard standing and bunded to prevent run-off with a recovery system in place (e.g. sump).

The data on the active substance and the wood preservative products have demonstrated sufficient efficacy for inclusion into Annex I to be recommended. However, further efficacy data will be required on specific products to support product authorisation at the Member State

level.

The physico-chemical properties of the active substance and biocidal products have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal products.

3.2. Decision regarding Inclusion in Annex I

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

Purity of the Active Substance

The active substance thiacloprid, as manufactured, shall have a minimum purity of 975 % g/kg.

Proposed Product Type

Product Type 8 - Wood Preservative

Proposal for Conditions on Particular Uses

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 wooden structures near water, where direct losses to the aquatic compartment cannot be prevented, or for wood that will be in contact with surface water, 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

1. Products must be labelled appropriately to ensure safe storage, handling, use and disposal in accordance with national arrangements.

2. Use of thiacloprid-based products should be undertaken using the obligatory PPE detailed within the human health risk assessment.

3. The proposed classification for JJT 3968 includes Xn: R66 (Repeated exposure may cause skin drying or cracking), it is therefore recommended that if authorisation is sought for this product then the label should include the requirement for professional users to wear suitable protective gloves. The potential for the product to cause dryness and cracking of the skin on repeated exposure (due to the solvents) is not believed to be a concern for amateur users since they are unlikely to use the product frequently enough.

4. Given that thiacloprid is a non-genotoxic carcinogen of medium potency, products containing ≥ 1 % thiacloprid should therefore be classified as Carcinogenic Category 3 (Xn: R40) in accordance with the Dangerous Substances Directive (76/548/EEC).

5. The proposed classification for JJT 3968 includes Xn: R65 (Harmful: May cause lung damage if swallowed), therefore to mitigate against this risk, it is therefore recommended that if authorisation is granted for this product then the label should include the requirement to not induce vomiting if swallowed and to seek medical advice immediately. The product should also be labelled with a warning to keep it out of reach of children. Member States may need to consider appropriate warning labels and, as necessary, child-resistant closures, when they evaluate genuine products for authorisation.

6. The likelihood of Hazard Class 3 timbers being used to construct structures near to water (as there is a potential risk to the aquatic environment) should be considered as part of each Member State's product authorisation process.

7. Losses during industrial/professional application by the dipping and automated enclosed spraying processes, as well as during tank cleaning, must be contained (no drain connections to storm drains or STPs) and recycled; or collected and treated as waste in accordance with the national regulations of the Member State authorising individual products;

8. The need to address any specific national conditions and/or undertake regional assessments should be considered, as only local environmental risk assessments have been carried out in this evaluation.

9. The need for a risk assessment for bats should be determined at a national level.

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 thiacloprid on to Annex I of the Directive 98/8/EC. The conditions and restrictions proposed are considered reasonable, and no further information is required. However, the following additional information will need to be submitted:

1. Further efficacy data in line with the requirements set out in EN 599-1 will be required at the product authorisation stage to support all thiacloprid based products for preventative treatments by both superficial and penetrative application methods.

2. This assessment has only considered preventative treatment. As such, the inclusion of remedial treatment methods for thiacloprid-based products should be assessed at the product authorisation stage.

3.5. Updating this Assessment Report

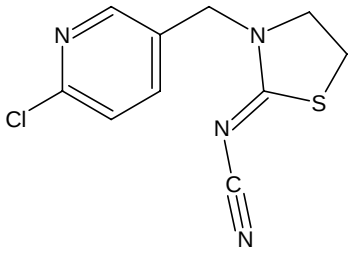
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of thiacloprid 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)	Thiacloprid
Product-type	PT 8 – Wood Preservatives

Identity

Chemical name (IUPAC)	(Z)-3-(6-chloro-3-pyridylmethyl)-1,3-thiazolidin-2-ylidenecyanamide
Chemical name (CA)	Cyanamide, Z-[3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene
CAS No	443096-59-1
EC No	Not Available (New active)
Other substance No.	Not Available (New active)
Minimum purity of the active substance as manufactured (g/kg or g/l)	≥ 975 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	No substances of concern have been identified.
Molecular formula	$C_{10}H_9ClN_4S$
Molecular mass	252.73
Structural formula	

Physical and chemical properties

Melting point (state purity)	136 °C (purity: ≥ 97.5%)
Boiling point (state purity)	Not measurable, substance decomposes.
Temperature of decomposition	270 °C. Thiacloprid can be considered stable at room temperature
Appearance (state purity)	At 20 °C and 101.3 kPa: Physical state: Powdered solid Colour: Yellowish to slight brown Odour: weak characteristic odour
Relative density (state purity)	1.46 at 20 °C
Surface tension	69.7 mN/m
Vapour pressure (in Pa, state temperature)	3.49×10^{-10} Pa at 20 °C
Henry's law constant (Pa m^3 mol^{-1})	5×10^{-10} Pa m^3 mol^{-1} at 20 °C
Solubility in water (g/l or mg/l, state temperature)	Results at 20 °C : 186 mg/L at pH 4 184 mg/L at pH 5.5-7 (Unbuffered water) 185 mg/L at pH 7 185 mg/L at pH 9
Solubility in organic solvents (in g/l or mg/l, state temperature)	Results at 20 ºC: n-Heptane <0.1 g/l Xylene 0.30 g/l Dichloromethane 160 g/l 1-Octanol 1.4 g/l 2-propanol 3.0 g/l Acetone 64 g/l Ethyl acetate 9.4 g/l Polyethylene glycol 42 g/l Acetonitrile 52 g/l Dimethyl sulfoxide 150 g/l
Stability in organic solvents used in biocidal products including relevant breakdown products	Thiacloprid as manufactured does not include an organic solvent. Therefore a study regarding stability in organic solvents is not applicable for thiacloprid.
Partition coefficient (log P_{OW}) (state temperature)	Log P_{ow} = 1.26 at 20 ºC
Hydrolytic stability (DT_{50}) (state pH and temperature)	Stable to hydrolysis at pH 5-9 at 25 °C. Estimated hydrolytic half-life value: > 1 year
Dissociation constant	No pKa was observed, as the substance does not ionise.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Spectra confirms the chemical structure
Photostability (DT_{50}) (aqueous, sunlight, state pH)	pH 7: DT_{50} = 79.7 d.
Quantum yield of direct phototransformation in water at Σ > 290 nm	As the absorption of thiacloprid in the range above 290 nm is very limited, direct photodegradation in water is assumed to be negligible.
Flammability	Thiacloprid is not highly flammable according to EC Test Method A.10.
Explosive properties	Thiacloprid is non-explosive

Classification and proposed labelling

with regard to physical/chemical data	Not Classified
with regard to toxicological data	R20: Harmful by inhalation. R22: Harmful if swallowed. R40 (Carc. Cat 3): Limited evidence of a carcinogenic effect.
with regard to fate and behaviour data	R53: May cause long-term adverse effects in the aquatic environment.
with regard to ecotoxicological data	R50: Very toxic to aquatic organisms.

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	High Performance Liquid Chromatography using UV detection for the analysis of thiacloprid and impurities in the active substance and formulated product. The method was suitably validated.
Impurities in technical active substance (principle of method)	

Analytical methods for residues

Soil (principle of method and LOQ)	High Performance Liquid Chromatography using UV detection for the analysis of thiacloprid and metabolite residues in soil. The method was suitably validated. Limit of quantification (LOQ): 10 µg /kg
Air (principle of method and LOQ)	High Performance Liquid Chromatography using UV detection for the analysis of thiacloprid and metabolite residues in soil. The method was suitably validated. Limit of quantification: 0.0018 mg as /m^3
Water (principle of method and LOQ)	High Performance Liquid Chromatography using UV detection for the analysis of thiacloprid residues in drinking and surface water. The method was suitably validated. Limit of quantification (LOQ): 0.05 µg/l
Body fluids and tissues (principle of method and LOQ)	Relevant when an active substance is classified as toxic or highly toxic. Thiacloprid is classified as harmful (Xn) and so no analytical methods need to be submitted.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	The toxicokinetics of thiacloprid have been investigated in three studies in rats after oral gavage and intravenous administration. Overall, these data indicate that both single and repeated administration of thiacloprid results in oral absorption values of 100 %.
Rate and extent of dermal absorption:	The dermal penetration of thiacloprid has been investigated *in vivo* in monkeys. Thiacloprid is poorly absorbed across the skin of monkeys and an overall, worst-case dermal absorption value of 10 % is derived.
Rate and extent of inhalational absorption	There are no toxicokinetic studies by the inhalation route, but as thiacloprid is well-absorbed from the GI tract, it is predicted that it will be well-absorbed from the respiratory tract. This is supported by single exposure toxicodynamic studies that provide evidence for systemic effects. Therefore, following inhalation exposure to thiacloprid, 100 % absorption is considered to occur.
Distribution:	Single and repeat oral dosing studies in rats show that following absorption, radiolabel was widely distributed throughout the body. The highest concentrations of residual radiolabel were found in the liver with evidence of minimal distribution of the radiolabel to the bone marrow, brain, testis and uterus.
Potential for accumulation:	Thiacloprid has relatively limited potential for bioaccumulation.
Rate and extent of excretion:	Elimination was rapid via both the urine and faeces.
Toxicologically significant metabolite(s)	The acute toxicity of two proposed environmental metabolites of thiacloprid, M02 and M30, has been studied via the oral route. The LD_{50} for both metabolites was >2000 mg/kg. The mutagenicity of a number of environmental metabolites of thiacloprid (M02, M30, M34) also tested negative in standard *in vitro* bacterial gene mutation, mammalian cell gene mutation and chromosome aberration studies.

Acute toxicity

Rat LD_{50} oral	Thiacloprid is of moderate toxicity in female rats (LD_{50} 444 mg/kg). Males less sensitive (LD_{50} 836 mg/kg). Clinical signs of toxicity occurred at ≥ 100 mg/kg, within 25 min to 6 h of dosing and lasted up to 5 d (males) or 8 d (females).
Rat LD_{50} dermal	No deaths occurred in rats after the dermal application of 2000 mg/kg thiacloprid (limit test). There were no clinical signs of toxicity or local skin reactions.
Rat LC_{50} inhalation	> 2.535 mg/l (male) 1.223 mg/l (female)
Skin irritation	Not Classified
Eye irritation	Not Classified
Skin sensitization (test method used and result)	Negative in a Magnusson and Kilgman guinea pig maximisation test.

Repeated dose toxicity

Species/ target / critical effect	Repeat dose studies with thiacloprid show that the liver is a target organ for toxicity. Hepatic enzyme induction and histopathological changes are the most sensitive effects. The rat seems to be more sensitive to most effects than the mouse or the dog; the dog appearing the least sensitive. Signs of adverse effects in the thyroid after treatment with thiacloprid occurred primarily in rats.
Lowest relevant oral NOAEL / LOAEL	NOAEL: 1.2 mg/kg/day (2 year study in rats)
Lowest relevant dermal NOAEL / LOAEL	NOAEL: 100 mg/kg/day (28 day study in rats)
Lowest relevant inhalation NOAEL / LOAEL	NOAEL: 18-19 mg/m^3 (5 and 28 day study in rats)

Genotoxicity	Data indicate that thiacloprid is not mutagenic *in vitro* or *in vivo* and does not meet the EU criteria for classification as a mutagen.

Carcinogenicity

Species/type of tumour	Increase in malignant uterine adenocarcinomas and thyroid adenomas in rats and ovarian luteomas in mice. Tumours occur by a non-genotoxic mechanism and a threshold can be identified for the onset of tumours. The carcinogenic potential of thiacloprid will be protected against using the long term AEL value. Based on the T25 estimate of carcinogenic potency, thiacloprid is considered to be of medium potency within the EU. Classified as Carc Cat 3. (R40)
lowest dose with tumours	Mice: 1250 ppm (475 mg/kg/day). Rats: 500 ppm (25 mg/kg/day).

Reproductive toxicity

Species/ Reproduction target / critical effect	Absence of effects on fertility demonstrated in a 1 and 2-generation study. In two standard developmental toxicity studies, no treatment related effects of concern were observed. Treatment with thiacloprid causes dystocia.
Lowest relevant reproductive NOAEL / LOAEL	2 mg/kg/day 3.7 mg/kg/day (dystocia)
Species/Developmental target / critical effect	Thiacloprid caused reduced body weight, body weight gain and food consumption in maternal rabbits. Decreased foetal weight, increased incidence of arthrogyposis and skeletal retardations were considered secondary non-specific consequences of maternal toxicity.
Lowest relevant developmental NOAEL / LOAEL	2 mg/kg/day

Neurotoxicity / Delayed neurotoxicity

Acute neurotoxicity study in rats	No compound related clinical signs of toxicity were noted at either 3.1 or 11 mg/kg. Decreased activity was seen in females treated with 11 mg/kg and consequently the NOAEL was set at 3.1 mg/kg.
13-weeks neurotoxicity study in rats	Signs of neurotoxicity not observed in rats after dietary administration over 13 weeks.
12-month chronic neurotoxicity study in rats	No signs of neurotoxicity were observed in a chronic carcinogenicity study in rats after dietary administration.

Other toxicological studies

.....	None

Medical data

.....	None

Summary	Value	Study	Safety factor
ADI (if residues in food or feed)	Not Required	N/A	N/A
AEL (acute)	0.02 mg/kg	Rabbit Development Study	100
AEL (medium-term)	0.02 mg/kg	Rabbit Development Study	100
AEL (long-term)	0.012 mg/kg	2-year Rat Study	100
Drinking water limit	Not Required	N/A	N/A
ARfD (acute reference dose)	Not Required	N/A	N/A

Acceptable exposure scenarios (including method of calculation)

Primary Exposure (Amateur Use)

Exposure Route Combined dermal/inhalation

Method of Calculation MOE

Scenario	Value used in the assessment
Painting (without gloves) water-based product (produced by the aqueous dilution of JJT 3947)	1538
Painting (with gloves) water-based product (produced by the aqueous dilution of JJT 3947)	2457
Painting (without gloves) Solvent-based product (JJT 3968)	2020
Painting (with gloves) Solvent-based product (JJT 3968)	3284

Primary Exposure (Professional Use)

Exposure Route Combined dermal/inhalation

Method of Calculation MOE

Exposure Scenario	Value used in the assessment
Painting wearing gloves Water-based product (JJT 3947)	5530
Painting without wearing gloves Water-based product (JJT 3947)	1697
Painting wearing gloves Solvent-based product (JJT 3968)	8054
Painting without wearing gloves Solvent-based product (JJT 3968)	2264
Dipping of wooden articles Water-based product (JJT 3947)	2516
Dipping of wooden articles Solvent-based product (JJT 3968)	2697
Handling of treated wet wood Water-based product (JJT 3947)	1770
Handling of treated wet wood Solvent-based product (JJT 3968)	12793

Primary Exposure (Industrial Use)

Exposure Route: Combined dermal/inhalation

Method of Calculation: MOE

Exposure Scenario	Value used in the assessment
Vacuum pressure impregnation Water-based product (JJT 3947) Cycle calculation	12618
Double-vacuum impregnation Water-based product (JJT 3947) Cycle calculation	373
Double-vacuum impregnation Solvent-based product (JJT 3968) Cycle calculation	2697
Automated spraying Water-based product (JJT 3947)	1905
Automated spraying Solvent-based product (JJT 3968)	2020
Flow coating Water-based product (JJT 3947)	645
Vacuum pressure impregnation with supercritical carbon dioxide Cycle calculation	10909
Dipping Water-based product (JJT 3947)	2516
Dipping Solvent-based product (JJT 3968)	2697
Handling of treated wet wood Water-based product (JJT 3947)	1770
Handling of treated wet wood Solvent-based product (JJT 3968)	12793
Cleaning out dipping tank (Without RPE) Water-based product (JJT 3947)	2247
Cleaning out dipping tank (With RPE) Water-based product (JJT 3947)	2390
Cleaning out dipping tank (Without RPE) Solvent-based product (JJT 3968)	17991
Cleaning out dipping tank (With RPE) Solvent-based product (JJT 3968)	18957

Secondary Exposure

Method of Calculation MOE

Exposure	Scenario	Value used in the assessment
Short-term	Adult (amateur) sanding treated wood (inhalation + dermal)	49505
	Infant chewing treated wood (ingestion)	962
	Adult inhaling volatilised residues from treated timber indoors during construction work: (inhalation)	5.6×10^9
	Child inhaling volatilised residues from treated timber indoors: (inhalation)	8.0×10^9
	Infant inhaling volatilised residues from treated timber indoors: (inhalation)	7.3×10^9
Long-term	Adult cleaning work clothes at home: (dermal)	2913
	Adult (professional) sanding treated wood: (inhalation + dermal)	21693
	Child playing on treated wood structures: (dermal)	17826
	Infant playing on treated wood structures and mouthing hands: (ingestion + dermal)	1079
	Adult inhaling volatilised residues from treated timber indoors: (inhalation)	3.3×10^9
	Child inhaling volatilised residues from treated timber indoors: (inhalation)	4.8×10^9
	Infant inhaling volatilised residues from treated timber indoors: (inhalation)	4.3×10^9

Combined Exposure

Exposure Route: Combined dermal/inhalation

Method of Calculation: MOE

Exposure Scenario	**Value used in the assessment**
Painting (with gloves) and handling treated wood (JJT 3947)	1341
Painting (without gloves) and handling treated wood (JJT 3947)	863
Painting (with gloves) and handling treated wood (JJT 3968)	4938
Painting (without gloves) and handling treated wood (JJT 3968)	1923

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)	Stable to hydrolysis at pH 5-9 at 25 °C. Estimated hydrolytic half-life value: > 1 year
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	DIRECT PHOTODEGRADATION: As the absorption of thiacloprid in the range above 290 nm is very limited, direct photodegradation in water is assumed to be negligible. INDIRECT PHOTODEGRADATION in aqueous solution (artificial radiation equated to summer days of Phoenix, Arizona, 40 °N): $t_{1/2}$ = 324 summer days. No major (> 10 %) metabolites formed.
Readily biodegradable (yes/no)	not readily biodegradable
Biodegradation in seawater	No data provided, not required for the currently requested uses
Distribution in water / sediment systems (active substance)	AEROBIC DT_{50} whole system = 10.7 - 27.9 days at 20 °C DT_{50} water = 2.9 - 10.8 days at 20 °C Maximum of 10 – 50 %AR in sediment after 1 - 3 days ANAEROBIC DT_{50} whole system >> 1 year at 20 °C MICROCOSM STUDY [MEAN TEMP 17.6 ± 3.7 °C] DT_{50} water = 31 days (mean value) Max. = 79.7 and 95.3 % at day 2 and 74.4 and 85 % at day 16 (two days after the second application). The majority of concentrations were of the nominal (as calculated by summing the individual nominal concentrations from a single application). DT_{50} sediment = 62 days (n = 1) Max. = 141 % (sum of 2 applications) in sediment 28 days after 2nd application.
Distribution in water / sediment systems (metabolites)	AEROBIC M02 max., water = 17 - 62 % AR after 35 days M02 max., sediment = 7 - 36 % AR after 35 - 62 days M30 (no peak), water = 5.3 - 9.5 % AR at the end of the study (100 days) M30 (no peak), sediment = 0.3 - 1.2 % AR at the end of the study (100 days) ANAEROBIC M02 max., whole system = 21 % AR at day 360 MICROCOSM STUDY In water no analysis for metabolites carried out In sediment only M02 analysed. M02 max., sediment = 62 - 89 % of the nominal initial water concentrations 98 days after the second application (study end)
Mineralisation	4 % AR (AT 100 DAYS, N = 2)
Non-extractable residues	17 – 22 % AR (AT 100 DAYS, N = 2)

Route and rate of degradation in soil

Mineralization (aerobic)	6.5 - 34 % after 100 days (n = 4)
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20 °C, aerobic): (12 °C, aerobic): parent 0.7 - 4.7 days (n = 4) 1.3 – 8.9 days M02 32 - 142 days (n = 4) 60.7 – 269.3 days

	M30 16 - 79 days (n = 3) 30.3 – 149.8 days
Field studies (state location, range or median with number of measurements)	$DT_{50field}$, parent: Northern Europe: 9 - 27 days (n = 6) Southern Europe: 10 - 16 days (n = 2) $DT_{50field}$, M02: Northern Europe: 46 - 314 days (n = 6) Southern Europe: 68 - 107 days (n = 2)
Anaerobic degradation	No data provided, not required
Soil photolysis	Negligible (dissipation rate in irradiated sample comparable to dark controls)
Non-extractable residues	22 - 30 % after 100 days (n = 4)
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	Major metabolites (> 10 % AR): M02[1] max. = 60 – 74 % after 3 - 30 days (n = 4) M30[2] max. = 4.5 – 20 % after 14 - 100 days (n = 4)
Soil accumulation and plateau concentration	No testing is required if DT_{90} of the total residue is < 1 year.

[1]M02: (Z)-[3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene]urea)
[2]M30: 2[1-(6-chloropyridine-3-ylmethyl)-3-carbamoyl-ureido]-ethane sulfonic acid sodium salt

Adsorption/desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	Koc, thiacloprid = 393 – 870 (geo. mean 595.8, n = 6) Koc, M02 = 166 – 438 (geo. mean 274, n = 5) Koc, M30 = 11.9 – 26.2 (geo. mean 18.8, n = 5) No evidence that changes in soil pH influences the sorption of parent or metabolites.

Fate and behaviour in air

Direct photolysis in air	DIRECT PHOTODEGRADATION: Not expected (as UV-absorption is below 290 nm)
Quantum yield of direct photolysis	0.00035
Photo-oxidative degradation in air	INDIRECT PHOTODEGRADATION: DT_{50} = 4.313 hours in the presence of hydroxyl radicals. This corresponds to a chemical life-time of 6.2 hours
Volatilization	FIELD STUDY: overall volatilisation from plants and soil = 15 % AR over 24 days (volatiles not trapped)

Monitoring data, if available

Soil (indicate location and type of study)	New substance. Not available, not required.
Surface water (indicate location and type of study)	New substance. Not available, not required.
Ground water (indicate location and type of study)	New substance. Not available, not required.
Air (indicate location and type of study)	New substance. Not available, not required.

Chapter 5: Effects on Non-target Species

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

Species	Time-scale	Endpoint	Toxicity
Fish			
Lepomis macrochirus	96 hours	Mortality	LC_{50} = 25.2 mg l^{-1} (m)
Oncorhynchus mykiss	96 hours	Mortality	LC_{50} = > 79.4 mg l^{-1} (M02) LC_{50} = > 90.1 mg l^{-1} (M30)
Oncorhynchus mykiss	97 days (ELS)	Mortality and other symptoms, e.g. hatching success	NOEC = 0.24 mg l^{-1} (m) LC_{50} > 3.91 mg l^{-1} (m)
Aquatic Invertebrates			
Daphnia magna	48 hours	Immobility	EC_{50} = > 85.1 mg l^{-1} (m)
Daphnia magna	48 hours	Immobility	EC_{50} = > 100 mg l^{-1}
Hyalella azteca	96 hours	Immobility	EC_{50} = 0.0407 mg l^{-1} (m)
Hyalella azteca	96 hours	Immobility	EC_{50} = > 47 mg l^{-1}
Asellus aquaticus	48 hours	Mortality combined with immobility	EC_{50} = 0.0758 mg l^{-1} (n)
Gammarus pulex	48 hours	Mortality combined with immobility	EC_{50} = 0.027 mg l^{-1} (n)
Ecydonurus sp	48 hours	Immobility	EC_{50} = 0.0077 mg l^{-1} (m)
Daphnia magna	21 days	Survival, reproduction and growth	NOEC = 0.58 mg l^{-1} (m)
Algae			
Scenedesmus subspicatus	72 hours	Growth inhibition	$NOEC_r$ = 32 mg l^{-1} (n) E_bC_{50} = 44.7 mg l^{-1} (n) E_rC_{50} = 96.7 mg l^{-1} (n)
Pseudokirchneriella subcapitata	72 hours	Growth inhibition	$NOEC_r$ = 100 mg l^{-1} (M02 / M30)
Aquatic plants			
Lemna gibba	15 days	Reduced frond number	EC_{50} > 95.4 mg l^{-1} (m)
Sediment dwelling organisms			
Chironomus riparius	28 days	Number and time of emergence Emergence rate Development	NOEC = 0.0005 mg l^{-1} (p) EC_{50} = 0.00218 mg l^{-1} (n) EC_{50} = > 0.0018 mg l^{-1} (n)
Chironomus riparius	28 days	Number and time of emergence	NOEC = 0.0826 mg l^{-1} (M02) NOEC = > 74.8 mg l^{-1} (M30)
Microcosm study (most sensitive species)			
Outdoor microcosm study: insects, sediment dwellers, zooplankton, phytoplankton. Most sensitive group: Ceratopogonidae (insects)	98 days	Treatment related effects, e.g. increase of number of species	EAC* = 1.6 µg l^{-1} (m)
Microorganisms			
Activated sludge	30 min	Inhibition of respiratory rate	EC_{50} = 6330 mg l^{-1} (n)

n = nominal concentration
m = measured concentration
p = predicted from mean measured concentrations
*EAC = Ecologically Acceptable Concentration. Based on the EAC, appropriate risk mitigation measures should be considered at Member State level.

Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworms (Annex IIIA, point XIII.3.2)	*Eisenia foetida andrei*: 14d LC50 = 51 mg kg-1 a.s. dw (n) (study with YRC 2894 SC 480)
Acute toxicity to earthworms (Annex IIIA, point XIII.3.2) Metabolites M02/M30	*Eisenia foetida andrei*: 14d LC50 = > 1000 mg kg-1 a.s. dw
Acute toxicity to terrestrial plants (Annex IIIA, point XIII.3.2)	*Brassica napus*: 21d NOEC = 10.2 mg kg-1 dw soil (n) 21d LOEC = 25.6 mg kg-1 soil dw soil (n) 21d EC50 = 27.67 mg kg-1 soil dw soil (n) *Avena sativa*: 21d NOEC < 32.6 mg kg-1 soil dw soil (n) 21d LOEC = 32.6 mg kg-1 soil dw soil (n) 21d EC50 = 51.30 mg kg-1 soil dw soil (n) *Glycine max*: 21d NOEC = 25.6 mg kg-1 soil dw soil (n) 21d LOEC = 64.0 mg kg-1 soil dw soil (n) 21d EC50 = 83.34 mg kg-1 soil dw soil (n)
Reproductive toxicity to non-target organisms (Annex IIIA, point XIII.3.2)	No reproduction test with thiacloprid technical was carried out. A long-term field study to natural earthworm fauna with the plant protection product YRC 2894 SC 480 following two applications at 250 g a.s. ha-1 was undertaken. No effects on the earthworm population. NOEC > 250 g a.s. ha-1 ≅ 0.15 mg a.s. kg-1 dw

Effects on soil micro-organisms

Nitrogen mineralization Carbon mineralization	28 d-EC_0 > 2.57 mg a.s. kg^{-1} dw soil (n)

Effects on terrestrial vertebrates

Acute toxicity to mammals (Annex IIIA, point XIII.3.3)	See acute toxicity towards mammals (lower result: LD_{50} = 444 mg kg^{-1} bw)
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	*Coturnix coturnix japonica* LD_{50} = 49 mg kg^{-1} bw (14 days, nominal) non-GLP [*Colinus virginianus* LD_{50} = 2716 mg kg^{-1} bw (14 days, nominal) GLP]
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	*Coturnix coturnix japonica* short-term dietary toxicity, LC_{50} = 2500 mg kg^{-1} bw (5 days, nominal)
Reproductive toxicity to birds (Annex IIIA, point XIII.1.3)	*Anas platyrhynchos* reproductive toxicity, No treatment related effects. LOEC > 418 mg kg^{-1} feed (20 weeks, measured)

Effects on honeybees

Acute oral toxicity	LD_{50} = 17.32 µg/bee (n)
Acute contact toxicity	LD_{50} = 38.82 µg/bee (n)

Effects on other beneficial arthropods

Acute oral toxicity	Not Applicable
Acute contact toxicity	Not Applicable
Acute toxicity to ……..	Not Applicable

Bioconcentration (Annex IIA, point 7.5)

Bioconcentration factor (BCF)	Low potential for bioconcentration. Mean measured log Pow = 1.26. Therefore study not required as the log Pow ≤ 3. A calculated BCF for thiacloprid is 2.35 using equation 74 of the TGD.
Depuration time (DT_{50}) (DT_{90})	Not Applicable
Level of metabolites (%) in organisms accounting for > 10% of residues	Not Applicable

Chapter 6: Other End Points

No other end points.

Appendix II: List of Intended Uses

Field of use envisaged	Likely concentration (% w/w) at which the a.s. will be used*	Effective retention in wood in a.s./m² or a.s./m³	Hazard class (use class)
Vacuum pressure treatment (industrial)	JJT 3947: 0.002% JJT 3968: N/A	JJT 3947: 0.010 kg/m³ JJT 3968: N/A	1-4a
Dilute 0.4% JJT 3947 in water. Apply 500 kg dilution per m^3 wood by vacuum pressure treatment.			
Double vacuum treatment including Vacuumat (industrial)	JJT 3947: 0.04% JJT 3968: 0.02%	JJT 3947: 0.010 kg/m³ JJT 3968: 0.005 kg/m³	1-3
Dilute 8% JJT 3947 in water. Apply 25 kg dilution per m^3 wood by double vacuum treatment. Apply 25 kg JJT 3968 per m^3 wood by double vacuum treatment.			
Automated spraying (industrial)	JJT 3947: 0.04% JJT 3968: 0.02%	JJT 3947: 0.06 g/m² JJT 3968: 0.03 g/m²	1-3
Dilute 8% JJT 3947 in water. Apply 150 g dilution per m^2 wood by spraying. Apply 150 g JJT 3968 per m^2 wood by spraying.			
Flow coating (industrial)	JJT 3947: 0.03% JJT 3968: N/A	JJT 3947: 0.06 g/m² JJT 3968: N/A	1-3
Dilute 6% JJT 3947 in water. Apply 200 g dilution per m^2 wood by flow coating.			
Vacuum pressure with Hypercritical CO_2 (industrial)	SC CO_2: 0.005%	0.010 kg/m³	1-4
To achieve a loading of 0.10 kg thiacloprid per m^3 wood, a concentration of 0.005% thiacloprid is required in the gas phase. The deposition of thiacloprid happens during a thermodynamic process, which is (in a model calculation) similar to a retention of 200 kg supercritical CO_2 per m^3 wood.			
Dipping of wooden articles (industrial and professional)	JJT 3947: 0.03% JJT 3968: 0.015%	JJT 3947: 0.09 g/m² JJT 3968: 0.05 g/m²)	1-3
Dilute 6% JJT 3947 in water. Apply 300 g dilution per m^2 wood by approximately 3 hours dip treatment. (The necessary dipping time is dependent on the kind of wood, its water content, surface properties etc.) Dilute 75% JJT 3968 with Shellsol D 60. Apply 333 g dilution per m^2 wood by approx. 2 h dipping. (The necessary dipping time is dependent on the kind of wood, its water content, surface properties etc.)			
Painting by brushing (professionals)	JJT 3947: 0.05% JJT 3968: 0.02%	JJT 3947: 0.10 g/m² JJT 3968: 0.04 g/m²	1-3
Dilute 10% JJT 3947 in water. Apply 200 g dilution per m^2 wood by brushing. Apply 200 g JJT 3968 per m^2 wood.			
Painting by brushing (amateurs)	JJT 3947: 0.05% JJT 3968: 0.02%	JJT 3947: 0.10 g/m² JJT 3968: 0.04 g/m²	1-3
Dilute 10% JJT 3947 in water. Apply 200 g dilution per m^2 wood by brushing. Dilute 10% JJT 3947 in water. Apply 200 g dilution per m^2 wood by brushing.			

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.

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
A2.6 IIA, II.2.6 /01 Also filed in: A2.7 IIA, II.2.7 /01 A2.8 IIA, II.2.8 /01	Anonymous	2003	Data submitted by Bayer CropScience AG. In: PPP-Monograph to thiacloprid, Annex IIa	–	–	–	No	Yes -Confid.-	BCS
A2.7 IIA, II.2.7 /01 Also filed in: A2.6 IIA, II.2.6 /01 A2.8 IIA, II.2.8 /01	Anonymous	2003	Data submitted by Bayer CropScience AG. In: PPP-Monograph to thiacloprid, Annex IIa	–	–	–	No	Yes -Confid.-	BCS
A2.7 IIA, II 2.7 /02 Also filed in: A2.8 IIA, II 2.8/02	Reubke, K. J.	2001	Material Accountability of Thiacloprid (YRC 2894) (including Amendment 1). Date: 2001-07-02, amended: 2002-09-04	Bayer AG	159202148	Yes	No	Yes -Confid.-	BCS
A2.8 IIA, II.2.8 /01 Also filed in: A2.6 IIA, II.2.6 /01 A2.7 IIA, II.2.7 /01	Anonymous	2003	Data submitted by Bayer CropScience AG. In: PPP-Monograph to thiacloprid, Annex IIa	–	–	–	No	Yes -Confid.-	BCS
A2.8 IIA, II 2.8/02 Also filed in: A2.7 IIA, II 2.7 /02	Reubke, K. J.	2001	Material Accountability of Thiacloprid (YRC 2894) (including Amendment 1). Date: 2001-07-02, amended: 2002-09-04	Bayer AG	159202148	Yes	No	Yes -Confid.-	BCS

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
A2.8.1 IIA, II 2.8/01	Göhrt, A.	1995	Crystal Structure Analysis of YRC 2894. Date: 1995-01-24	Bayer AG	PC1935	No	No	No	BCS
A2.8.1 IIA, II.2.8 /02	Reubke, K. J.	1998 [Mon: 1998a]	Analytical Notice – YRC 2894 E/Z-Configuration. Date: 1998-07-09	Bayer AG	PC1972	No	No	Yes -Confid.-	BCS
A3.1.1 IIA, III.3.1 /01 Also filed in: A3.1.2 IIA, III.3.1 /01 A3.1.3 IIA, III.3.1 /01 A3.2 IIA, III.3.2 /01 A3.3 IIA, III.3.3 /01 A3.5 IIA, III.3.5 /01 A3.6 – /01 A3.7 IIIA, III.1 /01 A3.9 IIA, III3.6 /01 A3.10 IIA, III.3.7 /01 A3.13 IIA, III.3.10 /01	Krohn, J.	1996	Physical and chemical properties of YRC 2894. Date: 1996-07-09	Bayer AG	PC1418	Yes	No	Yes	BCS

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
A3.1.2 IIA, III.3.1 /01 Also filed in: A3.1.1 IIA, III.3.1 /01 A3.1.3 IIA, III.3.1 /01 A3.2 IIA, III.3.2 /01 A3.3 IIA, III.3.3 /01 A3.5 IIA, III.3.5 /01 A3.6 – /01 A3.7 IIIA, III.1 /01 A3.9 IIA, III3.6 /01 A3.10 IIA, III.3.7 /01 A3.13 IIA, III.3.10 /01	Krohn, J.	1996	Physical and chemical properties of YRC 2894. Date: 1996-07-09	Bayer AG	PC1418	Yes	No	Yes	BCS
A3.1.3 IIA, III.3.1 /01 Also filed in: A3.1.1 IIA, III.3.1 /01 A3.1.2 IIA, III.3.1 /01 A3.2 IIA, III.3.2 /01 A3.3 IIA, III.3.3 /01 A3.5 IIA, III.3.5 /01 A3.6 – /01 A3.7 IIIA, III.1 /01 A3.9 IIA, III3.6 /01 A3.10 IIA, III.3.7 /01 A3.13 IIA, III.3.10 /01	Krohn, J.	1996	Physical and chemical properties of YRC 2894. Date: 1996-07-09	Bayer AG	PC1418	Yes	No	Yes	BCS

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
A3.1.3 IIA, III.3.1 /02	Bogdoll, B.	2005	Bulk density (Pour/Tap) of thiacloprid according to CIPAC MT 186. Date: 2005-12-22	Bayer Crop Science AG	AF05/106	No	No	Yes	BCS
A3.2 IIA, III.3.2 /01 Also filed in: A3.1.1 IIA, III.3.1 /01 A3.1.2 IIA, III.3.1 /01 A3.1.3 IIA, III.3.1 /01 A3.3 IIA, III.3.3 /01 A3.5 IIA, III.3.5 /01 A3.6 – /01 A3.7 IIIA, III.1 /01 A3.9 IIA, III3.6 /01 A3.10 IIA, III.3.7 /01 A3.13 IIA, III.3.10 /01	Krohn, J.	1996	Physical and chemical properties of YRC 2894. Date: 1996-07-09	Bayer AG	PC1418	Yes	No	Yes	BCS

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
A3.3 IIA, III.3.3 /01 Also filed in: A3.1.1 IIA, III.3.1 /01 A3.1.2 IIA, III.3.1 /01 A3.1.3 IIA, III.3.1 /01 A3.2 IIA, III.3.2 /01 A3.5 IIA, III.3.5 /01 A3.6 – /01 A3.7 IIIA, III.1 /01 A3.9 IIA, III3.6 /01 A3.10 IIA, III.3.7 /01 A3.13 IIA, III.3.10 /01	Krohn, J.	1996	Physical and chemical properties of YRC 2894. Date: 1996-07-09	Bayer AG	PC1418	Yes	No	Yes	BCS
A3.3 IIA, III.3.3 /02	Wanner, B.	2006	Thiacloprid technical – Appearance. Date: 2006-01-09	Bayer Crop Science AG	--	No	No	Yes	BCS
A3.4 IIA, III.3.4 /01	Stupp, H. P.	1995	Spectra of YRC 2894 - UV Spectrum. Date: 1995-12-06	Bayer AG	PC1360	No	No	Yes	BCS
A3.4 IIA, III.3.4 /02	Grohs, R	1995	Spectra of YRC 2894 - Infrared Spectrum. Date: 1995-12-06	Bayer AG	PC1361	No	No	Yes	BCS
A3.4 IIA, III.3.4 /03	Etzel, W.	1995	Spectra of YRC 2894 – NMR Spectrum. Date: 1995-11-30	Bayer AG	PC 1362	No	No	Yes	BCS

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
A3.4 IIA, III.3.4 /04	Thielking, G.	1995	Spectra of YRC 2894 - Mass Spectrum. Date: 1995-11-29	Bayer AG	PC1363	No	No	Yes	BCS
A3.4 IIA, III.3.4 /05	Etzel, W.	1999	Spectral data set of YRC 2894. Date: 1999-03-17	Bayer AG	156002090	Yes	No	Yes	BCS
A3.5 IIA, III.3.5 /01 Also filed in: A3.1.1 IIA, III.3.1 /01 A3.1.2 IIA, III.3.1 /01 A3.1.3 IIA, III.3.1 /01 A3.2 IIA, III.3.2 /01 A3.3 IIA, III.3.3 /01 A3.6 – /01 A3.7 IIIA, III.1 /01 A3.9 IIA, III3.6 /01 A3.10 IIA, III.3.7 /01 A3.13 IIA, III.3.10 /01	Krohn, J.	1996	Physical and chemical properties of YRC 2894, date: 1996-07-09.	Bayer AG	PC1418	Yes	No	Yes	BCS

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
A3.6 – /01 Also filed in: A3.1.1 IIA, III.3.1 /01 A3.1.2 IIA, III.3.1 /01 A3.1.3 IIA, III.3.1 /01 A3.2 IIA, III.3.2 /01 A3.3 IIA, III.3.3 /01 A3.5 IIA, III.3.5 /01 A3.7 IIIA, III.1 /01 A3.9 IIA, III3.6 /01 A3.10 IIA, III.3.7 /01 A3.13 IIA, III.3.10 /01	Krohn, J.	1996	Physical and chemical properties of YRC 2894. Date: 1996-07-09.	Bayer AG	PC1418	Yes	No	Yes	BCS
A3.7 IIIA, III.1 /01 Also filed in: A3.1.1 IIA, III.3.1 /01 A3.1.2 IIA, III.3.1 /01 A3.1.3 IIA, III.3.1 /01 A3.2 IIA, III.3.2 /01 A3.3 IIA, III.3.3 /01 A3.5 IIA, III.3.5 /01 A3.6 – /01 A3.9 IIA, III3.6 /01 A3.10 IIA, III.3.7 /01 A3.13 IIA, III.3.10 /01	Krohn, J.	1996	Physical and chemical properties of YRC 2894. Date: 1996-07-09.	Bayer AG	PC1418	Yes	No	Yes	BCS

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
A3.9 IIA, III3.6 /01 Also filed in: A3.1.1 IIA, III.3.1 /01 A3.1.2 IIA, III.3.1 /01 A3.1.3 IIA, III.3.1 /01 A3.2 IIA, III.3.2 /01 A3.3 IIA, III.3.3 /01 A3.5 IIA, III.3.5 /01 A3.6 – /01 A3.7 IIIA, III.1 /01 A3.10 IIA, III.3.7 /01 A3.13 IIA, III.3.10 /01	Krohn, J.	1996	Physical and chemical properties of YRC 2894. Date: 1996-07-09	Bayer AG	PC1418	Yes	No	Yes	BCS
A3.9 IIA, III.3.6 /02	Gruener, R.	2001	Partition Coefficient in Octanol-Water of YRC 2894-amide. Date: 2001-11-23	Bayer AG	MO-01-021878	Yes	No	Yes	BCS
A3.10 IIA, III.3.7 /01 Also filed in: A3.1.1 IIA, III.3.1 /01 A3.1.2 IIA, III.3.1 /01 A3.1.3 IIA, III.3.1 /01 A3.2 IIA, III.3.2 /01 A3.3 IIA, III.3.3 /01 A3.5 IIA, III.3.5 /01 A3.6 – /01 A3.7 IIIA, III.1 /01 A3.9 IIA, III3.6 /01 A3.13 IIA, III.3.10 /01	Krohn, J.	1996	Physical and chemical properties of YRC 2894. Date: 1996-07-09	Bayer AG	PC1418	Yes	No	Yes	BCS

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
A3.11 IIA, III.3.8 /01 Also filed in: A3.12 IIA, III.3.9 /01 A3.15 IIA, III.3.11 /01 A3.16 IIA, III.3.12 /01	Mix, K.H.	1995	Final GLP report - determination of safety-relevant parameters of YRC 2894 Mischpt 290894 97,5 %. Date: 1995-10-30	Bayer AG	PC1103	Yes	No	Yes	BCS
A3.12 IIA, III.3.9 /01 Also filed in: A3.11 IIA, III.3.8 /01 A3.15 IIA, III.3.11 /01 A3.16 IIA, III.3.12 /01	Mix, K.H.	1995	Final GLP report - determination of safety-relevant parameters of YRC 2894 Mischpt 290894 97,5 %. Date: 1995-10-30	Bayer AG	PC1103	Yes	No	Yes	BCS
A3.13 IIA, III 3.13/02	Bogdoll, B	2007	Surface tension of thiacloprid (YRC 2894) technical substance	Bayer Crop Science AG	PA07/084	Yes	No	Yes	BCS
A3.13 IIA, III.3.10 /01 Also filed in: A3.1.1 IIA, III.3.1 /01 A3.1.2 IIA, III.3.1 /01 A3.1.3 IIA, III.3.1 /01 A3.2 IIA, III.3.2 /01 A3.3 IIA, III.3.3 /01 A3.5 IIA, III.3.5 /01 A3.6 – /01 A3.7 IIIA, III.1 /01 A3.9 IIA, III3.6 /01 A3.10 IIA, III.3.7 /01	Krohn, J.	1996	Physical and chemical properties of YRC 2894. Date: 1996-07-09	Bayer AG	PC1418	Yes	No	Yes	BCS

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
A3.15 IIA, III.3.11 /01 Also filed in: A3.11 IIA, III.3.8 /01 A3.12 IIA, III.3.9 /01 A3.16 IIA, III.3.12 /01	Mix, K.H.	1995	Final GLP report - determination of safety-relevant parameters of YRC 2894 Mischpt 290894 97,5 %. Date: 1995-10-30	Bayer AG	PC1103	Yes	No	Yes	BCS
A3.16 IIA, III.3.12 /01 Also filed in: A3.11 IIA, III.3.8 /01 A3.12 IIA, III.3.9 /01 A3.15 IIA, III.3.11 /01	Mix, K.H.	1995	Final GLP report - determination of safety-relevant parameters of YRC 2894 Mischpt 290894 97,5 %. Date: 1995-10-30	Bayer AG	PC1103	Yes	No	Yes	BCS
A3.17 IIA, III.3.13 /01 Also filed in: A8.1 IIA, VIII.8.1/02	Swan, J.L.	1997	Corrosion evaluation of BAY YRC 2894 technical. Date: 1997-10-16	Bayer Corporation, Agricultural Division	107899	Yes	No	Yes	BCS
A3.17 IIA, III.3.13 /02 Also filed in: A8.1 IIA, VIII.8.1/03	Wittmann, O.	2006	Thiacloprid technical Preventol ® TX – Packaging material. Date: 2006-01-12	LANXESS Deutschland GmbH	--	No	No	Yes	LAN
A4.1 IIA, IV.4.1 /01	Reubke, K. J.	1997 [Mon: 1997a]	YRC 2894 Assay of technical grade active ingredient. Date: 1997-09-25	Bayer AG	2005-0006201-97	No	No	Yes -Confid.-	BCS

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
A4.1 IIA, IV.4.1 /02	Reubke, K. J.	1999a [Mon: 1999b, e, i]	YRC 2894 ; By-products - HPLC - external standard. Date: 1999-09-14	Bayer AG	2005-0009501-99E	No	No	Yes -Confid.-	BCS
A4.1 IIA, IV.4.1 /03	Reubke, K. J.	1999b [Mon: 1999g]	Determination of 1-Butanol; Assay - GLC - external standard (Headspace). Date: 1999-11-30	Bayer AG	2005-0010201-99E	No	No	Yes -Confid.-	BCS
A4.1 IIA, IV.4.1 /04	Reubke, K. J.	1999c [Mon: 1999a]	Validation report VB2-2005-0006201E, edition Number: MO-99-015114. Date: 1999-09-07	Bayer AG	VB2-2005-0006201 E	No	No	Yes -Confid.-	BCS
A4.1 IIA, IV.4.1 /05	Reubke, K. J.	1999d	Validation report V01.01-2005-0010201E ; 1-Butanol in active ingredient agrochemicals, Headspace GC. Bayer AG, Leverkusen, Germany. Bayer CropScience AG, Report No. V01.01-2005-0010201, Edition Number: MO-99-019568. Date: 1999-12-02	Bayer AG	V01.01-2005-0010201	No	No	Yes -Confid.-	BCS

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
A4.1 IIA, IV.4.1 /06	Reubke, K. J.	2000	Validation report; Method 2005-0009501-99; YRC 2894 - By-products - HPLC - external standard. Date: 2000-08-03	Bayer AG	V01.02-2005-0009501	No	No	Yes -Confid.-	BCS
A4.1 IIA, IV.4.1 /07	Schroeder, S.	2002a	Validation report VB1-2005-0000703-00E; Argentometric determination of ionogenic chlorine. Date: 2000-05-09	Bayer AG	VB1-2005-0000703	No	No	Yes -Confid.-	BCS
A4.1 IIA, IV.4.1 /08	Schroeder, S.	2002b	Validation report VB1-2005-0009701-99 ; Karl Fischer water determination: MO-00-007238. Date: 2000-04-20	Bayer AG	VB1-2005-0009701-99	No	No	Yes -Confid.-	BCS
A4.1 IIA, IV.4.1 /09	Schroeder, S.	2002c	Validation report VB1-2005-0000602-99; Sulfated Ash, Edition Number: MO-00-001761. Date: 2000-01-18	Bayer AG	VB1-2005-0000602	No	No	Yes -Confid.-	BCS
A4.1 IIA, IV.4.1 /10	Wanner, B.	1999a	Analytical procedure for the Karl Fischer water determination. Date: 1999-11-04	Bayer AG	2005-0009701-99	No	No	Yes -Confid.-	BCS
A4.1 IIA, IV.4.1 /11	Wanner, B.	1999b	Analytical procedure for the determination of sulphated ash. Date: 1999-10-29	Bayer AG	2005-0000602-99	No	No	Yes -Confid.-	BCS

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A4.1 IIA, IV.4.1 /12	Wanner, B.	2000	Analytical procedure for the argentometric determination of ionogenic chlorine. Date: 2000-05-11	Bayer AG	2005-0000703-00	No	No	Yes -Confid.-	BCS
A4.2 IIA, IV.4.2 /01	Sommer, H.	1998a	Method 0532 for liquid chromatographic determination of YRC 2894 and the metabolite YRC 2894-amide in soil. Date: 1998-07-29	Bayer AG	MR-535/98	Yes	No	Yes	BCS
A4.2 IIA, IV.4.2 /02	Sommer, H.	1995	Validation of the method 00389 (MR-235/95) for liquid chromatographic determination of YRC 2894 and the metabolites YRC 2894-amide and YRC-sulfonic acid in soil. Date: 1995-06-09	Bayer AG	MR-235/95	Yes	No	Yes	BCS
A4.2 IIA, IV.4.2 /03	Sommer, H.	1997a	Method 00440 (MR-368/96) for liquid chromatographic determination of YRC 2894 and the metabolites YRC 2894-amide and YRC 2894-sulfonic acid in soil. Date: 1997-01-20	Bayer AG	MR-368/96	Yes	No	Yes	BCS

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A4.2 IIA, IV.4.2 /04	Sommer, H.	1997b	Method 00440, M001 (MR-21/97) for liquid chromatographic determination of YRC 2894 and the metabolites YRC 2894-amide and YRC 2894-sulfonic acid in soil. Date: 1997-11-07	Bayer AG	MR-21/97	Yes	No	Yes	BCS
A4.2 IIA, IV.4.2 /05	König, Th.; Sommer, H.	1995	Method for determination of YRC 2894 in drinking water by HPLC with on-line solid phase (Method 00383). Date: 1995-01-31, amendment report dated: 1999-03-03	Bayer AG	MR-109/95 (Amendment Report No.: MR-122/99 (MOA 610))	Yes	No	Yes	BCS
A4.2 IIA, IV.4.2 /06	Sommer, H.	1999	Enforcement and Confirmatory Method for Determination of YRC 2894 in Drinking Water and Surface Water by HPLC. Date: 1999-10-25	Bayer AG	MR-384/99	Yes	No	Yes	BCS
A4.2 IIA, IV.4.2 /07	Sommer, H.	1997c	Method 00467, (MR-873/96) for liquid chromatographic determination of YRC 2894. in sediment. Date: 1997-01-29	Bayer AG	MR-873/96	Yes	No	Yes	BCS

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A4.2 IIA, IV.4.2 /08	Riegner, K.; Hellpointner, E.	1996	Method for the determination of YRC 2894 in air (including the confirmatory Method), Method 00436. Date: 1996-04-25, amendment report by Hellpointner, E., dated: 1999-02-26	Bayer AG	MR-326/96 Amendment Report No.: MR-111/99 (MOA 607)	Yes	No	Yes	BCS
A5 IIA, V5.3/01	Schumacher, P.; Fennert, E-M.	1999a	Bestimmung der Giftwerte von LP OU 28430 gegenüber Larven von *Hylotrupes bajulus* L. gemäß DIN EN 47 – (08/90). Date: 1999-11-10	Materialprüfungsamt des Landes Brandenburg, Germany	3.2/7693/3	No	No	Yes	LAN
A5 IIA, V5.3/02	Schumacher, P.; Fennert, E-M.	1999b	Bestimmung der Grenze der Wirksamkeit von LP OU 28430 gegenüber Termiten (*Reticulitermis santonesis* De Feytaud) – gemäß DIN EN 117 – (08/90). Date: 1999-12-16	Materialprüfungsamt des Landes Brandenburg, Germany	3.2/7693/1	No	No	Yes	LAN
A5 IIA, V5.3/03	Schumacher, P.; Fennert, E-M.	1999c	Bestimmung der Grenze der Wirksamkeit von LP OU 28430 gegenüber Termiten (*Reticulitermis santonesis* De Feytaud) – gemäß DIN EN 117 – (08/90). Kombiniert mit einer Auswaschbeanspruchung – gemäß EN 84 – (05/97). Date: 1999-12-16	Materialprüfungsamt des Landes Brandenburg, Germany	3.2/7693/2	No	No	Yes	LAN

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A5 IIA, V5.3/04	Schumacher, P.; Fennert, E-M.	2001a	Determination of the toxic values of LP OU 28430 against larvae of *Hylotrupes bajulus* (L.) according to EN 47 (08/90) after leaching procedure according to EN 84 (05/97). Date: 2001-05-15	Materialprüfungsamt des Landes Brandenburg, Germany	3.2/00/8105/03	No	No	Yes	LAN
A5 IIA, V5.3/05	Schumacher, P.; Fennert, E-M.	2001b	Determination of the toxic values of LP OU 28430 against *Reticulitermes santonesis* De Feytaud according to EN 117 (08/90) after evaporative ageing procedure according to EN 73 (04/90). Date: 2001-06-18	Materialprüfungsamt des Landes Brandenburg, Germany	3.2/00/8105/01	No	No	Yes	LAN
A5 IIA, V5.3/06	Schumacher, P.; Fennert, E-M.	2001c	Determination of the toxic values of LP OU 28430 against larvae of *Hylotrupes bajulus* (L) according to EN 47 (08/90) after evaporative ageing procedure according to EN 73 (04/90). Date: 2001-07-03	Materialprüfungsamt des Landes Brandenburg, Germany	3.2/00/8105/02	No	No	Yes	LAN

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A5 IIA, V5.3/07	Schumacher, P.; Fennert, E-M.	2002c	Determination of the protective effectiveness of LP OU 28430 against *Anobium punctatum* (de Geer) by egg-laying and larval survival according to EN 49 part 2 – Application by impregnation treatment after leaching procedure according to EN 84 (05/97). Date: 2002-06-11	Materialprüfungsamt des Landes Brandenburg, Germany	3.2/01/8160/01	No	No	Yes	LAN
A5 IIA, V5.4/01	Thornton, H.M.	1999	BIOLOGICAL OVERVIEW (EFFICACY) - A summary of information supporting the claims made for YRC 2894 SC 480 an SC formulation containing 480 g/l YRC 2894 for the control of aphids in apples [Revised]. Date: 2000-01-31	Bayer AG	RD. 113/2	No	No	Yes	BCS
A5 IIA, V5.4/02	IRAC	2005	Online available classification scheme on mode of action of insecticides, v4.2.1.	–	–	–	–	Yes	–
A6.1.1 IIA, VI.6.1.1/02 Also filed in: A6.3.1 IIA, VI.6.3/01	Krötlinger, F.	1995a	YRC 2894 - Pilot toxicity study on rats. Date: 1995-03-22	Bayer AG	23861	No	No	Yes	BCS

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A6.1.1 IIA, VI.6.1.1/01	Krötlinger, F.	1996a	YRC 2894 - Study of acute oral toxicity in rats. Date: 1996-08-27	Bayer AG	25376	Yes	No	Yes	BCS
A6.1.1 IIA, VI.6.1.5/03	Krötlinger, F.	1995b	KKO 2254 - Study for acute oral toxicity in rats. Date: 1995-12-01	Bayer AG	24553	Yes	No	Yes	BCS
A6.1.1 IIA, VI.6.1/04	Krötlinger, F.	1996d	WAK 6999 - (YRC 2894 metabolite) - Study for acute oral toxicity in rats. Date: 1996-02-15	Bayer AG	24794	Yes	No	Yes	BCS
A6.1.2 IIA, VI.6.1.2/01	Krötlinger, F.	1996b	YRC 2894 - Study for acute dermal toxicity in rats. Date: 1996-03-11	Bayer AG	24879	Yes	No	Yes	BCS
A6.1.3 IIA, VI.6.1.3/01	Pauluhn, J.	1996	YRC 2894 - Study on acute inhalation toxicity in rats according to OECD No. 403. Date: 1996-02-09	Bayer AG	24775	Yes	No	Yes	BCS
A6.1.4 IIA, VI.6.1.4/01	Krötlinger, F.	1995b	YRC 2894 - Study for skin and eye irritation / corrosion in rabbits. Date: 1995-08-01, amendment report dated: 1998-06-18	Bayer AG	24217 Amendment Report No.: 24217A	Yes	No	Yes	BCS

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A6.1.5 IIA, VI.6.1.5/01	Stropp, G.	1996	YRC 2894 - Skin-sensitization effect in guinea pigs (Guinea pig Maximization test method according to Magnusson and Kligman). Date: 1996-01-16, amendment report dated 1996-02-07	Bayer AG	24641 Amendment report No.: 24641A	Yes	No	Yes	BCS
A6.2 IIA, VI.6.2/01	Wicke, H.	2002	Application for approval for the use of YRC 2894 Calypso on various crops. Bayer CropScience AG, Monheim, Germany. Date: 2002-10-21	Bayer AG	MR-439/02	Yes	No	Yes	BCS
A6.2 IIA, VI.6.2/02	Klein, O.	1996	YRC 2894: general rat metabolism study. Part A: distribution of the total radioactivity in the rat determined by conventional whole-body autoradiography and radioluminography. Date: 1996-06-26	Bayer AG	PF4145	Yes	No	Yes	BCS
A6.2 IIA, VI.6.2/03 Also filed in: A6.2 IIA, VI.6.2/05	Klein, O.; Bornatsch, W	1998	[Methylene-14C] YRC 2894: general rat metabolism study Part B: toxicokinetics and metabolism in the rat. Date: 1998-02-05	Bayer AG	PF4331	Yes	No	Yes	BCS

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A6.2 IIA, VI.6.2/04 Also filed in: A6.2 IIA, VI.6.2/06	Printz, H.; Bornatsch, W.	1997	[Thiazolidine-4,5-14C]YRC 2894: absorption, distribution, excretion and metabolism in the rat. Date: 1997-12-08, 1. revision 1998-03-05, 2. revision 1998-06-29	Bayer AG	PF4299	Yes	No	Yes	BCS
A6.2 IIA, VI.6.2/05 Also filed in: A6.2 IIA, VI.6.2/03	Klein, O.; Bornatsch, W	1998	[Methylene-14C] YRC 2894: general rat metabolism study Part B: toxicokinetics and metabolism in the rat. Date: 1998-02-05	Bayer AG	PF4331	Yes	No	Yes	BCS
A6.2 IIA, VI.6.2/06 Also filed in: A6.2 IIA, VI.6.2/04	Printz, H.; Bornatsch, W.	1997	[Thiazolidine-4,5-14C]YRC 2894: absorption, distribution, excretion and metabolism in the rat. Date: 1997-12-08, 1. revision 1998-03-05, 2.revision 1998-06-29	Bayer AG	PF4299	Yes	No	Yes	BCS
A6.3.1 IIA, VI.6.3/01 Also filed in: A6.1.1 IIA, VI.6.1.1/02	Krötlinger, F.	1995a	YRC 2894 - Pilot toxicity study on rats. Date: 1995-03-22	Bayer AG	23861	No	No	Yes	BCS
A6.3.1 IIA, VI.6.3/02	Krötlinger, F.	1996c	YRC 2894 - Study for subacute oral toxicity in rats (Feeding study over 2 weeks). Date: 1996-12-09, amendment report dated: 1999-02-22	Bayer AG	25720 Amendment report No.: 25720A	Yes	No	Yes	BCS

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A6.3.1 IIA, VI.6.3/03	Wirnitzer, U.	1994	YRC 2894 - Pilot study on subacute toxicity in B6C3F1 mice (Administration in feed over 3 weeks). Date: 1994-11-04	Bayer AG	23450	No	No	Yes	BCS
A6.3.1 IIA, VI.6.3/04	Krötlinger, F.	1997a	YRC 2894 - Study for subacute oral toxicity in mice (Feeding study over 2 weeks). Date: 1997-02-25	Bayer AG	26017	Yes	No	Yes	BCS
A6.3.2 IIA, VI.6.3/01	Krötlinger, F.	1997b	YRC 2894 - Study for subacute dermal toxicity in rats (four-week treatment and two-week recovery period). Date: 1997-02-07	Bayer AG	25959	Yes	No	Yes	BCS
A6.3.3 IIA, VI.6.3/01	Pauluhn, J.	1995	YRC 2894 - Pilot study on subacute inhalation toxicity in rats (Exposure: 5 x 6 hours). Date: 1995-08-21	Bayer AG	24248	Yes	No	Yes	BCS
A6.3.3 IIA, VI.6.3/02	Pauluhn, J.	1998	YRC 2894 - Subacute inhalation toxicity on rats (Exposure 5 x 6 hour/week for 4 weeks). Date: 1998-07-20	Bayer AG	27689	Yes	No	Yes	BCS

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A6.4.1 IIA, VI.6.4/01	Krötlinger, F.; Geiß, V.	1997	YRC 2894 -Subchronic toxicity study in Wistar rats (Feeding study over 12 weeks with a subsequent recovery period over 5 weeks). Date: 1997-05-06	Bayer AG	26239	Yes	No	Yes	BCS
A6.4.1 IIA, VI.6.4/02	Wirnitzer, U.; Rühl-Fehlert, C.	1995	YRC 2894 - Subchronic range-finding study for a two-year study in B6C3F1 mice (Administration in feed over about 14 weeks). Date: 1995-03-14, amendment report dated: 1998-08-26	Bayer AG	23834 Amendment report No.: 23834A	Yes	No	Yes	BCS
A6.4.1 IIA, VI.6.4/03	Wetzig, H.; Geiß, V.	1998a	YRC 2894 - Subacute toxicity in Beagle dogs (Dose range finding study by feed admixture over at least 10 weeks). Date: 1998-02-05, revised 1999-02-11	Bayer AG	27177	Yes	No	Yes	BCS
A6.4.1 IIA, VI.6.4/04	Wetzig, H.; Rinke, M.	1998	YRC 2894 -Subchronic toxicity study in Beagle dogs (Feeding study for about 15 weeks). Date: 1998-05-08	Bayer AG	27464	Yes	No	Yes	BCS

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A6.5 IIA, VI.6.5/01	Wetzig, H.; Geiß, V.	1998b	YRC 2894 - Chronic toxicity study in Beagle dogs (52 week feeding study). Date: 1998-06-22	Bayer AG	27563	Yes	No	Yes	BCS
A6.5 IIA, VI.6.5/02 Also filed in: A6.7 IIA, VI.6.7/01	Bomhard, E.M.; Popp, A.; Rühl-Fehlert, C.	1998	YRC 2894 - Combined chronic toxicity/carcinogenicity study in wistar rats - Dietary administration over 2 years. Date: 1998-05-14	Bayer AG	27480	Yes	No	Yes	BCS
A6.6.1 IIA, VI.6.6.1/01	Herbold, B.	1995a	YRC 2894 - Salmonella/microsome test plate incorporation and preincubation method. Date: 1995-02-21	Bayer AG	23781	Yes	No	Yes	BCS
A6.6.1 IIA, VI.6.6.1/02	Otha, K.	1995	YRC 2894 - Reverse mutation assay (*Salmonella typhimurium* and *Escherichia coli*). Date: 1995-08-24	Nihon Bayer Agrochem K.K.	RA95011	Yes	No	Yes	BCS
A6.6.2 IIA, VI.6.6.2/02	Brendler-Schwaab, S.	1996a	YRC 2894 - Test on unscheduled DNA synthesis in rat liver primary cell cultures in vitro. Date: 1996-09-16	Bayer AG	25429	Yes	No	Yes	BCS

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A6.6.3 IIA, VI.6.6.3/01	Brendler-Schwaab, S.	1996b	YRC 2894 - Mutagenicity study for the detection of induced forward mutations in the V79-HPRT assay in vitro. Date: 1996-06-13	Bayer AG	25163	Yes	No	Yes	BCS
A6.6.4 IIA, VI.6.6.4/01	Herbold, B.	1995b	YRC 2894 - Micronucleus test on the mouse. Date: 1995-11-24	Bayer AG	24515	Yes	No	Yes	BCS
A6.7 IIA, VI.6.7/01 Also filed in: A6.5 IIA, VI.6.5/02	Bomhard, E.M.; Popp, A.; Rühl-Fehlert, C.	1998	YRC 2894 - Combined chronic toxicity/carcinogenicity study in wistar rats - Dietary administration over 2 years. Date: 1998-05-14	Bayer AG	27480	Yes	No	Yes	BCS
A6.7 IIA, VI.6.7/02	Wirnitzer, U.; Geiss, V.	1998	YRC 2894 - Oncogenicity study in B6C3F1-mice. Administration in the food over 2 years. Date: 1998-03-05, amendment report dated: 1998-08-26	Bayer AG	27247 Amendment report No.: 27247A (Tox 3216),	Yes	No	Yes	BCS
A6.8.1 IIA, VI.6.8.1/01a	Stahl, B.	1997	YRC 2894 - Developmental toxicity study in rats after oral administration.	Bayer AG	26132	No	No	Yes	BCS

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A6.8.1 IIA, VI.6.8.1/01b	Bomann, W.; Klaus A.M.	2000	YRC 2894 (thiacloprid) Toxicological Comments (staining/Renal Pelvis Dilation). Date: 2000-07-27 *Amendment to Stahl, B. (1997)*	Bayer AG	TOX 3233	No	No	Yes	BCS
A6.8.1 IIA, VI.6.8.1/02	Holzum, B.	1996	YRC 2894 - Developmental toxicity in rabbits after oral administration. Date: 1996-01-26	Bayer AG	24709	Yes	No	Yes	BCS
A6.8.2 IIA, VI.6.8.2/01	Eigenberg, D.A.; Hamilton, B.F.	1997	A two-generation dietary reproduction study in rats using technical YRC 2894. Date: 1997-12-08	Bayer Corporation	8385	Yes	No	Yes	BCS
A6.8.2 IIA, VI.6.8.2/02	Porter, M.C.; Jasty, V.; Grosso, D.S.; Hartnagel, R.E.	1995	A two-generation reproduction range-finding study with YRC 2894. Date: 1995-06-02	Miles Incorporation	24084	Yes	No	Yes	BCS
A6.9 IIIA, VI.1/01	Sheets, L.P.; Gilmore, R.G.	1997	An acute oral neurotoxicity screening study with technical grade YRC 2894 in Fischer 344 rats. Date: 1997-05-12	Bayer Corporation	8158	Yes	No	Yes	BCS

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A6.9 IIIA, VI.1/02	Sheets, L.P.	1998	A special acute oral neurotoxicity study to establish a no-observed-effect level with technical grade YRC 2894 in Fischer 344 rats. Date: 1998-05-04	Bayer Corporation	8158	Yes	No	Yes	BCS
A6.9 IIIA, VI.1/03	Sheets, L.P.	1997	A subchronic dietary neurotoxicity screening study with technical grade YRC 2894 in Fischer 344 rats. Date: 1997-06-03	Bayer Corporation	8162	Yes	No	Yes	BCS
A6.9 IIIA, VI.1/03	Hoberman, A.M.	2001	Oral (diet) developmental neurotoxicity study of YRC 2894 in CRL:CD (SD)IGS VAF/PLUS	Argus Research Laboratories	110834	Yes	No	Yes	BCS
A6.10 IIIA, VI.7/01	Freyberger, A.	1994	Studies on the inhibition of thyroid peroxidase-catalysed reactions by YRC 2894 and its metabolites in vitro. Date: 1994-11-24, revised 1999-01-28	Bayer AG	23495A	No	No	Yes	BCS
A6.10 IIIA, VI.7/02	Andrews, P.; Bomann, W.; Krötlinger, F.; Schmidt, U.	1998a	YRC 2894 - Mechanistic studies on aromatase induction and toxicokinetics in rats (4 week feeding studies). Date: 1998-07-27, date: 1998-09-07	Bayer AG	27717 (Amendment report No.: 27717B)	Yes	No	Yes	BCS

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A6.10 IIIA, VI.7/03	Schmidt, U.	1998a	Investigation of the inhibition of Cytochrome P450 dependent monoxygenases in liver microsomes (in vitro). Date: 1998-07-27	Bayer AG	27719	No	No	Yes	BCS
A6.10 IIIA, VI.7/04	Eigenberg, D.A.	1998a	A one-generation dietary reproduction study in rats using technical grade YRC 2894 to evaluate the reproducibility of dystocia and an increase in stillbirths in the P generation of a two-generation dietary reproduction study in rats. Date: 1998-05-12	Bayer Corporation	8489	Yes	No	Yes	BCS
A6.10 IIIA, VI.7/05	Eigenberg, D.A.	1998b	An experimetal study to investigate the cause of dystocia and stillbirths in rats treated with technical grade YRC 2894. Date: 1998-09-02	Bayer Corporation	8605	Yes	No	Yes	BCS
A6.10 IIIA, VI.7/06	Eigenberg, D.A.	1998c	A reproduction study in rats to determine if administration of technical YRC 2894 from gestation days 18 to 21 will cause dystocia (study number II). Date: 1998-05-04	Bayer Corporation	8481	Yes	No	Yes	BCS

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A6.10 IIIA, VI.7/07a	Christenson, R.	1998	Further examination of the increased occurrence of dystocia and stillbirths observed in a reproductive bioassay with an experimental cyanamide (YRC 2894). Date: 1998-08-31	Bayer Corporation	108360	Yes	No	Yes	BCS
A6.10 IIIA, VI.7/07b	Schmidt, U.	1998b	YRC 2894 - Determination of aromatase activity in ovary tissue of a modified 1-generation study in Sprague Dawley rats. Date: 1998-07-27 *Related to Christenson, R (1998)*	Bayer AG	27718	No	No	Yes	BCS
A6.10 IIIA, VI.7/08	Andrews, P.; Schmidt, U.	1998	YRC 2894 - Special study for subacute oral toxicity in rats (toxicokinetics in pregnant and non-pregnant rats). Date: 1998-07-14	Bayer AG	27657	No	No	Yes	BCS
A6.10 IIIA, VI.7/09	Krötlinger, F.; Freyberger, A.; Schmidt, U.	2003	YRC 2894, YRC 2894-sulfonic acid amide and YRC 2894-sulfonic acid sodium salt: Determination of Liver Effects in Female Rats after a 7 Day Administration in the Diet. Date: 2003-11-26	Bayer AG	T1073146	Yes	No	Yes	BCS

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A6.10 IIIA, VI.7/10	Andrews, P.; Bomann, W.; Rühl-Fehlert, C.; Schmidt, U.	1998b	Mechanistic study on aromatase induction in mice (feeding study for 13 weeks). Date: 1998-07-27	Bayer AG	27716	Yes	No	Yes	BCS
A7.1.1.1.1 IIA, VII.7.6.2.1/01	Brumhard, B.	1998a	Hydrolysis of YRC 2894 in sterile aqueous buffer solutions, date: 1998-02-16.	Bayer AG	PF4338	Yes	No	Yes	BCS
A7.1.1.1.2 IIA, VII.7.6.2.2/01	Henneböle, J.; Bornatsch, W.	1998	Photolysis of YRC 2894 in aqueous buffer solution. Date: 1998-02-18	Bayer AG	PF4330	Yes	No	Yes	BCS
A7.1.1.1.2 IIA, VII.7.6.2.2/02	Hellpointner, E.	1995a	Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation of YRC 2894 in water. Date: 1995-03-01	Bayer AG	PF4083	Yes	No	Yes	BCS
A7.1.1.2.1 IIA, VII.7.6.1.1/01	Reis, K-H.	2005	Ready biodegradability of Thiacloprid in a Manometric Respirometry Test. Sponsored by LANXESS Deutschland GmbH. Date: 2005-07-18	IBACON GmbH	23252160	Yes	No	Yes	LAN

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A7.1.2.2.2 IIIA, XII.2.1/01	Riegner, K.	1997	Aerobic aquatic degradation and metabolism of YRC 2894 in the water-sediment system. Date: 1997-12-09	Bayer AG	PF4273 (MR-622/97)	Yes	No	Yes	BCS
A7.1.2.2.2 IIIA, XII.2.1/02	Fritz, R.	1998	Anaerobic aquatic metabolism of the active ingredient YRC 2894. Date: 1998-03-23	Bayer AG	F4352	Yes	No	Yes	BCS
A7.1.2.2.2 IIIA, XII.2.1/03 Also filed in: A7.4.3 IIIA, XIII.2/01a	Heimbach, F.	1997a	Biological effects and fate of YRC 2894 SC 480 in outdoor microcosm ponds. Date: 1997-03-21	Bayer AG	HBF/Bt 01	Yes	No	Yes	BCS
A7.2.1 IIIA, XII.1.1/01	Fritz, R.; Bornatsch, W.	1998	Degradation and metabolism of [14C]YRC 2894 in soils under aerobic conditions. Date: 1998-03-17	Bayer AG	PF4332 (MR-544/97)	Yes	No	Yes	BCS
A7.2.2.1 IIIA, XII.1.1/01	Schäfer, H.	1998	Calculation of DT-50 values of YRC 2894 metabolite KKO 2254 in soil under aerobic conditions. Date: 1998-03-02	Bayer AG	MR-241/98	No	No	Yes	BCS

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A7.2.2.1 IIIA, XII.1.1/02a	Hellpointner, E.	1998a	Degradation of [methylene-14C]WAK 6999 in three soils. Date: 1998-02-11	Bayer AG	PF4334	Yes	No	Yes	BCS
A7.2.2.1 IIIA, XII.1.1/02b	Schad, T.	2002	Calculation of DT50 values of the YRC 2894 metabolite YRC 2894-sulfonic acid amid (M34) based on aerobic soil degradation studies. Date: 2002-02-28 *Related to Hellpointner, E.(1998a)*	Bayer AG	MR-084/02	No	No	Yes	BCS
A7.2.2.2 IIIA, XII.1.1/02	Sommer, H.	1998b	Dissipation of YRC 2894 (480 SC) in soil under field conditions (France and Spain). Date: 1998-01-22	Bayer AG	RA-2077/95 (R502898, R502928)	Yes	No	Yes	BCS
A7.2.2.4 IIIA, XII.1.1/01	Hellpointner, E.	1998b	Photolysis of [14C]YRC 2894 on soil surface. Date: 1998-02-26	Bayer AG	PF4333	Yes	No	Yes	BCS
A7.2.3.1 IIIA, XII.1.2/01a	Henneböle, J.	1994	Adsorption/desorption of YRC 2894 on soils. Date: 1994-06-09, 1. revision 1995-12-05 and revision 1999-10-20	Bayer AG	PF3980 (also MS 930)	Yes	No	Yes	BCS

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A7.2.3.1 IIIA, XII.1.2/02	Graney, R.	1995	Adsorption/desorption of KKO 2254 on soils. Date: 1995-06-26	Bayer AG	PF4062	Yes	No	Yes	BCS
A7.2.3.1 IIIA, XII.1.2/03	Brumhard, B.	1998b	Adsorption/desorption of WAK 6999 on different soils. Date: 1998-03-11	Bayer AG	PF4339	Yes	No	Yes	BCS
A7.2.3.1 IIIA, XII.1.2/04	Stupp, H. P.	2002a	Adsorption and desorption of YRC2894-sulfonic acid amide in soils. Date: 2002-03-08	Bayer AG	MR-102/02	Yes	No	Yes	BCS
A7.2.3.2 IIIA, XII.1.3/01	Henneböle, J.	1995	Leaching behaviour of the crop protection compound YRC 2894 with previous ageing in soil. Date: 1995-10-31, revised 1995-12-22	Bayer AG	PF4099	No	No	Yes	BCS
A7.2.3.2 IIIA, XII.1.3/02a	Brumhard, B.	1998c	Lysimeter study for testing the leaching behaviour of YRC 2894 in case of repeated application on grass. Date: 1998-07-02	Bayer AG	PF4342	No	No	Yes	BCS

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A7.2.3.2 IIIA, XII.1.3/02b	Schaefer, H.	2002	Expected concentrations of thiacloprid metabolite Z5 in percolate water considering intended application rates and plant interception. Date: 2002-02-27 *Related to Brumhard, B. (1998c)*	Bayer AG	MR-093/02	No	No	Yes	BCS
A7.2.3.2 IIIA, XII.1.3/02c	Stupp, H. P.	2002b	Formation and identification of metabolites of YRC2894 (e.g. Z5) in lysimeter soil. Date: 2002-09-12 *Related to Brumhard, B. (1998c)*	Bayer AG	MR-340/02	No	No	Yes	BCS
A7.3.1 IIIA, VII.5/01	Fàbregas, E.	2005	Calculation of indirect photodegradation of thiacloprid. Dr. Knoell Consult.	_	_	No	No	Yes	LAN
A7.4.1.1 IIA, VII.7.1/01	Dorgerloh, M.	1995a	YRC 2894 techn.: acute toxicity (96 hours) to rainbow trout (*Oncorhynchus mykiss*) in a static test. Date: 1995-04-11, revised 1998-09-25	Bayer AG	DOM 95004	Yes	No	Yes	BCS

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A7.4.1.1 IIA, VII.7.1/02	Dorgerloh, M.	1995b	YRC 2894 techn.: acute toxicity (96 hours) to bluegill (*Lepomis macrochirus*) in a static test. Date: 1995-08-20	Bayer AG	DOM 95003	Yes	No	Yes	BCS
A7.4.1.1 IIA, VII.7.1/03	Lam, C.V.	1997	Acute toxicity of KKO 2254 to the rainbow trout (*Oncorhynchus mykiss*) under static conditions. Date: 1998-01-08	Bayer AG	107943	Yes	No	Yes	BCS
A7.4.1.1 IIA, VII.7.1/04	Bowers, L.M.	1997a	Acute toxicity of KKO 2254 to the bluegill (*Lepomis macrochirus*) under static conditions. Date: 1997-06-30	Bayer AG	107746	Yes	No	Yes	BCS
A7.4.1.1 IIA, VII.7.1/05	Dorgerloh, M.	1995c	YRC 2894 - sulfonic acid - acute toxicity (96 hours) to rainbow trout (*Oncorhynchus mykiss*) in a static test. Date: 1995-09-26	Bayer AG	DOM 95051	Yes	No	Yes	BCS
A7.4.1.2 IIA, VII.7.2/01	Heimbach, F.	1995a	Acute toxicity of YRC 2894 (techn.) to water fleas (*Daphnia magna*). Date: 1995-05-16	Bayer AG	HBF/Dm 141	Yes	No	Yes	BCS

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A7.4.1.2 IIA, VII.7.2/02	Bowers, L.	1996	Acute toxicity of YRC 2894 to *Hyalella azteca* under static conditions. Date: 1996-06-24	Bayer AG	107336	Yes	No	Yes	BCS
A7.4.1.2 IIA, VII.7.2/03	Bowers, L.M.	1997b	Acute toxicity of KKO 2254 to *Hyalella azteca* under static conditions. Date: 1997-06-18	Bayer AG	107719	Yes	No	Yes	BCS
A7.4.1.2 IIA, VII.7.2/04	Heimbach, F.	1995b	Acute toxicity of YRC 2894 – sulfonic acid to waterfleas (*Daphnia magna*). Date: 1995-02-16	Bayer AG	HBF/Dm 152	Yes	No	Yes	BCS
A7.4.1.2 IIA, VII.7.2/05	Manson, P.S.	2002a	Thiacloprid: Acute toxicity to Asellus aquaticus. COVANCE Ltd., North Yorkshire, England. Date: 2002-09-24	Bayer AG	262/141	Yes	No	Yes	BCS
A7.4.1.2 IIA, VII.7.2/06	Manson, P.S.	2002b	Thiacloprid: Acute toxicity to larvae of Sericostoma personatum (caddis fly). COVANCE Ltd., North Yorkshire, England. Date: 2002-09-24	Bayer AG	262/140	Yes	No	Yes	BCS

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A7.4.1.2 IIA, VII.7.2/07	Manson, P.S.	2002c	Thiacloprid: Acute toxicity to Gammarus pulex. COVANCE Ltd., North Yorkshire, England, date: 2002-09-24.	Bayer AG	262/142	Yes	No	Yes	BCS
A7.4.1.3 IIA, VII.7.3/01	Anderson, J.P.E.	1995a	Influence of YRC 2894 on the growth of the green alga, *Selenastrum capricornutum*. Date: 1995-07-06	Bayer AG	AJO/129495	Yes	No	Yes	BCS
A7.4.1.3 IIA, VII.7.3/02	Anderson, J.P.E.	1995b	Influence of YRC 2894 on the growth of the green alga, *Scenedesmus subspicatus*. Date: 1995-09-04	Bayer AG	AJO/132695	Yes	No	Yes	BCS
A7.4.1.3 IIA, VII.7.3/03	Dorgerloh, M.	1998	KKO 2254 - Influence on the growth of the green alga, *Pseudokirchneriella subcapitata*. Date: 1998-08-24	Bayer AG	DOM 98055	Yes	No	Yes	BCS
A7.4.1.3 IIA, VII.7.3/04	Anderson, J.P.E.	1996	Influence of YRC 2894-sulfonic acid on the growth of the green alga, *Scenedesmus subspicatus*. Date: 1996-02-27	Bayer AG	AJO/130495	Yes	No	Yes	BCS
A7.4.1.4 IIA, VII.7.4/01	Müller, G.	1995	Studies on the ecological behaviour of YRC 2894. Date: 1995-09-21	Bayer AG	544A/95	Yes	No	Yes	BCS

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A7.4.3 IIIA, XIII.2/01a Also filed in: A7.1.2.2.2 IIIA, XII.2.1/03	Heimbach, F.	1997a	Biological effects and fate of YRC 2894 SC 480 in outdoor microcosm ponds. Date: 1997-03-21	Bayer AG	HBF/Bt 01	Yes	No	Yes	BCS
A7.4.3 IIIA, XIII.2/01b	Heimbach, F.	1999	Letter Response (dated 13 December 1999): COP 98/01202 – YRC 2894 (proposed name thiaclopid) Committee Stream Application. PSD-reference YPP 53/ASY 191. Technical report No. ECO.040. Date: 1999-12-13	–	–	–	No	Yes	BCS
A7.4.3 IIIA, XIII.2/01c	Heimbach, F.	2000	Letter Response (dated 31 January 2000): Additional comments: Interpretation of the Ceratopogonidae data. Date: 2000-01-31	–	–	–	No	Yes	BCS
A7.4.3.2 IIIA, XIII.2.2/01	Dorgerloh, M.	1997	YRC 2894 technical- early life stage toxicity to rainbow trout (*Oncorhynchus mykiss*) under flow-through conditions. Date: 1997-08-05	Bayer AG	DOM 95018	Yes	No	Yes	BCS

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A7.4.3.4 IIIA, XIII.2.4/01	Heimbach, F.	1996a	Influence of YRC 2894 (techn.) on the reproduction rate of water fleas (*Daphnia magna*). Date: 1996-01-05	Bayer AG	HBF/RDM 54	Yes	No	Yes	BCS
A7.4.3.5.1 IIIA, XIII.3.4/05	Manson, P.S.	2002d	Thiacloprid: Acute toxicity to mayfly larvae. COVANCE Ltd., North Yorkshire, England. Date: 2002-09-24	Bayer AG	262/144	Yes	No	Yes	BCS
A7.4.3.5.1 IIIA, XIII.3.4/01	Heimbach, F.	1996b	Influence of YRC 2894 (techn.) on development and emergence of larvae of *Chironomus riparius* in a water-sediment syste. Date: 1996-04-03	Bayer AG	HBF/Ch 09	Yes	No	Yes	BCS
A7.4.3.5.1 IIIA, XIII.3.4/02	Heimbach, F.	1997b	Influence of KKO 2254 on development and emergence of larvae of *Chironomus riparius* in a water-sediment system. Date: 1997-02-26	Bayer AG	HBF/Ch 12	Yes	No	Yes	BCS
A7.4.3.5.1 IIIA, XIII.3.4/03	Dorgerloh, M.; Sommer, H.	2002	Influence of thiacloprid-sulfonic acid Na-salt on development and emergence of larvae of *Chironomus riparius* in a water-sediment system. Date: 2002-03-20	Bayer AG	DOM 22022	Yes	No	Yes	BCS

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A7.4.3.5.1 IIIA, XIII.3.4/04	Heimbach, F.	1997c	Acute toxicity of leachate water samples of lysimeter studies on YRC 2894 to larvae of *Chironomus riparius*. Date: 1997-02-26	Bayer AG	HBF/CH 15	Yes	No	Yes	BCS
A7.4.3.5.2 IIIA, XIII.3.4/01	Dorgerloh, M.	1996	YRC 2894 - toxicity (15 days) to *Lemna gibba* G3. Date: 1996-03-01	Bayer AG	DOM 95085	Yes	No	Yes	BCS
A7.5.1.1 IIIA, XIII.3.3/01	Anderson, J.P.E.	1995c	Influence of YRC 2894 on glucose stimulated respiration in soils. Date: 1995-09-15, revised 1999-02-09	Bayer AG	AJO/135795	Yes	No	Yes	BCS
A7.5.1.1 IIIA, XIII.3.3/02	Anderson, J.P.E.	1995d	Influence of YRC 2894 on microbial mineralization of nitrogen in soils. Date: 1995-09-14, revised 1999-02-10	Bayer AG	AJO/135895	Yes	No	Yes	BCS
A7.5.1.2 IIIA, XIII.3.2/01	Heimbach, F.	1994	Toxicity of YRC 2894 (techn.) to earthworms (*Eisenia fetida*). Date: 1994-11-28	Bayer AG	HBF/Rg 193	Yes	No	Yes	BCS
A7.5.1.2 IIIA, XIII.3.2/02	Heimbach, F.	1995c	Toxicity of YRC 2894 SC 480 to earthworms (*Eisenia fetida*). Date: 1995-07-04	Bayer AG	HBF/Rg 214	Yes	No	Yes	BCS

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A7.5.1.2 IIIA, XIII.3.2/03	Heimbach, F.	1998	Acute toxicity of KKO 2254 (YRC 2894-Metabolite) to earthworms (*Eisenia fetida*). Date: 1998-07-158	Bayer AG	HBF/RG 276	Yes	No	Yes	BCS
A7.5.1.2 IIIA, XIII.3.2/04	Lechelt-Kunze, C.	2002	Acute toxicity of thiacloprid-sulfonic acid Na-salt to earthworms (*Eisenia fetida*). Date: 2002-02-27	Bayer AG	LKC/Rg 397/02	Yes	No	Yes	BCS
A7.5.1.3 IIIA, XIII.3.4/01	Großmann, A.; Meinerling M.	2005	Effects of thiacloprid on terrestrial (non-target) plants: Seedling Emergence and Seedling Growth Test (Dose Response Test). Sponsored by LANXESS Deutschland GmbH. Date: 2005-07-20	IBACON GmbH	23251084	Yes	No	Yes	LAN
A7.5.2.1 IIIA, XIII.3.2/01	Heimbach, F.	1997d	Effects of YRC SC 480 on the earthworm fauna of a grassland area. Date: 1997-05-13	Bayer AG	HBF/RgF 40	Yes	No	Yes	BCS
A7.5.2.1 IIIA, XIII.3.2/02	Heimbach, F.	1995e	Influence of YRC 2894 SC 480 on the reproduction of earthworms (*Eisenia fetida*). Date: 1995-04-06	Bayer AG	HBF/Rg 212	Yes	No	Yes	BCS

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A7.5.2.1 IIIA, XIII.3.2/03	Luehrs, U.	2003	Thiacloprid SC 480: Effects on Reproduction and Growth of Earthworms *Eisenia fetida* in Artificial Soil. Date: 2003-05-09	IBACON	16661022	Yes	No	Yes	BCS
A7.5.2.1 IIIA, XIII.3.2/04	Nienstedt, K. M.	2001	Reproduction toxicity exposing Folsomia candida to YRC 2894-amide. Spingborn Lab., Horn, Switzerland. Date: 2001-08-21	Bayer AG	1022.019.641	Yes	No	Yes	BCS
A7.5.2.1 IIIA, XIII.3.2/05	Moser, T.; Scheffczyk, A.	2002	Thiacloprid-sulfonic acid Na-salt: Acute and reproduction to the collembolan species Folsomia candida. ECT GmbH, Floersheim, Germany. Date: 2002-03-13	Bayer AG	P38CR	Yes	No	Yes	BCS
A7.5.3.1.1 IIIA, XIII.1.1/01	Grau, R.	1995a	YRC 2894 techn. Acute oral toxicity to bobwhite quail. Date: 1995-09-07, revised 1998-09-21	Bayer AG	VB-036,	Yes	No	Yes	BCS
A7.5.3.1.1 IIIA, XIII.1.1/02	Grau, R.	1994	YRC 2894 (technical grade), acute oral toxicity to Japanese quail, range finding test. Date: 1994-03-17	Bayer AG	VW-166	No	No	Yes	BCS

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A7.5.3.1.2 IIIA, XIII.1.2/01	Schmuck, R.	1998a	Five day dietary toxicity of YRC 2894 on mallard ducklings (*Anas platyrhynchos*). Date: 1998-02-02, revised 1998-09-21	Bayer AG	SXR/VE 010	Yes	No	Yes	BCS
A7.5.3.1.2 IIIA, XIII.1.2/02	Grau, R.	1995b	YRC 2894 (techn.): 5-day dietary LC50 to bobwhite quail. Date: 1995-09-08, revised 19998-09-21	Bayer AG	VB-043	Yes	No	Yes	BCS
A7.5.3.1.2 IIIA, XIII.1.2/03	Grau, R.	1995c	5-day dietary LC50 to Japanese quail. Date: 1995-09-29	Bayer AG	VW-176	Yes	No	Yes	BCS
A7.5.3.1.3 IIIA, XIII.1.3/01	Schmuck, R.	1998b	Effects of a subchronic dietary exposure to YRC 2894 (techn.) on Japanese quail including effects on reproduction and health. Date: 1998-02-16	Bayer AG	SXR/REP 07	Yes	No	Yes	BCS
A7.5.3.1.3 IIIA, XIII.1.3/02	Schmuck, R.	1997	Effects of a subchronic dietary exposure of YRC 2894 (techn.) on bobwhite quail including effects on reproduction and health. Date: 1997-08-04	Bayer AG	SXR/REP 05	Yes	No	Yes	BCS

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A7.5.3.1.3 IIIA, XIII.1.3/03	Hancock, G.A.	1997	Effect of technical YRC 2894 on mallard reproduction. Date: 1997-12-18	Bayer Corporation	107360	Yes	No	Yes	BCS
A7.5.4.1 IIIA, XIII.3.1/01	Nengel, S.	1995	Assessment of side effects of YRC 2894 (techn.) to the honey bee, *Apis mellifera* L. in the laboratory following the EPPO Guideline No. 170. Source: GAB Biotechnologie GmbH. Date: 1995-10-13	Bayer AG	95087/ 01-BLEU	Yes	No	Yes	BCS
A8.1-A8.7 IIA, VIII.8.1-A8.7/01	Anonymous	2005	Safety Data Sheet of Preventol TX. Lanxess Deutschland GmbH, MSDS No. 161040/04. Date: 2005-02-10	_	_	_	No	No	LAN
A8.1 IIA, VIII.8.1/02 Also filed in: A3.17 IIA, III.3.13 /01	Swan, J.L.	1997	Corrosion evaluation of BAY YRC 2894 technical. Date: 1997-10-16	Bayer Corporation, Agricultural Division	107899	Yes	No	Yes	BCS
A8.1 IIA, VIII.8.1/03 Also filed in: A3.17 IIA, III.3.13 /02	Wittmann, O.	2006	Thiacloprid technical Preventol ® TX – Packaging material. Date: 2006-01-12	LANXESS Deutschland GmbH	--	No	No	Yes	LAN

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Bayer CropScience AG A7.2.2.2 IIIA, XII.1.1/01	Sommer, H.	1997d	Dissipation of YRC 2894 (480 SC) in soil under field conditions (France, Germany, Great Britain). Date: 1997-11-14	Bayer AG	RA-2076/95 (R502855,R502863,R502871, R505633,R505641, R505668),	Yes	No	Yes	BCS
B2.2 IIB, I 2.2 /01	Anonymous	2004a	Material Safety Data Sheet Shellsol D 60. Date: 2004-09-17	Shell Chemicals Europe B.V., Rotterdam, Netherlands	Version 1.3	No	No	No	Shell
B2.2 IIB, I 2.2 /02	Anonymous	2005	Safety Data Sheet Benzylalcohol. Date: 2005-01-12	LANXESS Deutschland GmbH, Leverkusen, Germany	56060719	No	No	No	LAN
B2.2 IIB, I 2.2 /03	Anonymous	2004b	Safety Data Sheet ALKYDAL F 681 TBA. Date: 2004-02-04	Bayer Material Science, Leverkusen, Germany	023918/09	No	No	No	BMS

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B2.2 IIB, I 2.2 /04	Anonymous	2004c	Safety Data Sheet Texanol. Date: 2004-03-15	LANXESS Deutschland GmbH, Leverkusen, Germany	440039/01	No	No	No	LAN
B2.2 IIB, I 2.2 /05	Anonymous	2002	Safety Data Sheet Emulsifier KS. Date: 2002-10-17	LANXESS Deutschland GmbH, Leverkusen, Germany	140140/06	No	No	No	LAN
B2.2 IIB, I 2.2 /06	Anonymous	2004d	Safety Data Sheet Emulsifier RMH 8435. Date: 2004-09-28	LANXESS Deutschland GmbH, Leverkusen, Germany	206257/03	No	No	No	LAN
B3.1 IIB, III 3.1 /01	Jaetsch, T.	2005	Product description JJT 3947 / JJT 3968. Date: 2005-04-21	LANXESS Deutschland GmbH, Uerdingen, Germany	--	No	No	No	LAN

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
B3.10 – /01 also filed: B3.4 IIB, III 3.4 /01, also filed: B3.5 IIB, III 3.5 /01, also filed: B3.6 IIB, III 3.6 /01	Heitkamp, D.; Krasemann, R.	2005a	Determination of safety relevant data of JJT 3947. Date: 2005-03-18	Bayer Industry Services, Laboratories for Safety Data and Measurements, Leverkusen, Germany	2004/12362	No	No	Yes	LAN
B3.10 – /02 also filed: B3.4 IIB, III 3.4 /02, also filed: B3.5 IIB, III 3.5 /02, also filed: B3.6 IIB, III 3.6 /02	Heitkamp, D.; Krasemann, R.	2005b	Determination of safety relevant data of JJT 3968. Date: 2005-06-28	Bayer Industry Services, Laboratories for Safety Data and Measurements, Leverkusen, Germany	2004/12391	No	No	Yes	LAN
B3.2 IIB, III 3.2 /01	Heinz, U.; Eberz, A.	2005a	Explosion hazards JJT 3580. Date: 2005-09-05	Bayer Industry Services, Leverkusen, Germany	05/01121	No	No	Yes	LAN

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
B3.2 IIB, III 3.2 /02	Heinz, U.; Eberz, A.	2005b	Explosion hazards JJT 3582. Date: 2005-09-05	Bayer Industry Services, Leverkusen, Germany	05/01122	No	No	Yes	LAN
B3.4 IIB, III 3.4 /01 also filed: B3.5 IIB, III 3.5 /01, also filed: B3.6 IIB, III 3.6 /01, also filed: B3.10 – /01	Heitkamp, D.; Krasemann, R.	2005a	Determination of safety relevant data of JJT 3947. Date: 2005-03-18	Bayer Industry Services, Laboratories for Safety Data and Measurements, Leverkusen, Germany	2004/12362	No	No	Yes	LAN
B3.4 IIB, III 3.4 /02 also filed: B3.5 IIB, III 3.5 /02, also filed: B3.6 IIB, III 3.6 /02, also filed: B3.10 – /02	Heitkamp, D.; Krasemann, R.	2005b	Determination of safety relevant data of JJT 3968. Date: 2005-06-28	Bayer Industry Services, Laboratories for Safety Data and Measurements, Leverkusen, Germany	2004/12391	No	No	Yes	LAN

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
B3.5 IIB, III 3.5 /01 also filed: B3.4 IIB, III 3.4 /01, also filed: B3.6 IIB, III 3.6 /01, also filed: B3.10 – /01	Heitkamp, D.; Krasemann, R.	2005a	Determination of safety relevant data of JJT 3947. Date: 2005-03-18	Bayer Industry Services, Laboratories for Safety Data and Measurements, Leverkusen, Germany	2004/12362	No	No	Yes	LAN
B3.5 IIB, III 3.5 /01 also filed: B3.4 IIB, III 3.4 /02, also filed: B3.6 IIB, III 3.6 /02, also filed: B3.10 – /02	Heitkamp, D.; Krasemann, R.	2005b	Determination of safety relevant data of JJT 3968. Date: 2005-06-28	Bayer Industry Services, Laboratories for Safety Data and Measurements, Leverkusen, Germany	2004/12391	No	No	Yes	LAN
B3.6 IIB, III 3.6 /01 also filed: B3.4 IIB, III 3.4 /01, also filed: B3.5 IIB, III 3.5 /01, also filed: B3.10 – /01	Heitkamp, D.; Krasemann, R.	2005a	Determination of safety relevant data of JJT 3947. Date: 2005-03-18	Bayer Industry Services, Laboratories for Safety Data and Measurements, Leverkusen, Germany	2004/12362	No	No	Yes	LAN

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
B3.6 IIB, III 3.6 /02 also filed: B3.4 IIB, III 3.4 /02, also filed: B3.5 IIB, III 3.5 /02, also filed: B3.10 – /02	Heitkamp, D.; Krasemann, R.	2005b	Determination of safety relevant data of JJT 3968. Date: 2005-06-28	Bayer Industry Services, Laboratories for Safety Data and Measurements, Leverkusen, Germany	2004/12391	No	No	Yes	LAN
B3.7 IIB, III 3.7 /01	Knopf, R.	2005a	Storage stability – JJT 3947. Date: 2005-02-23 Amended: 2005-08-02	Bayer Industry Services GmbH & Co OHG, BIS-SUA-Analytics, Leverkusen, Germany	U04/0111/00 UER	No	No	Yes	LAN
B3.7 IIB, III 3.7 /02	Knopf, R.	2005b	Storage stability – JJT 3968. Date: 2005-03-04 Amended: 2005-08-02	Bayer Industry Services GmbH & Co OHG, BIS-SUA-Analytics, Leverkusen, Germany	U04/0112/00 UER	No	No	Yes	LAN

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
B4.1 IIB, IV 4.1 /01	Schultz, C.	2005a	Thiacloprid (Preventol TX) in wood protection systems, Thiacloprid – HPLC-MS method. Date: 2005-07-14	Bayer Industry Services, Analytical Services, Krefeld, Germany	Analytical method No.: 2301-0292202-05	No	No	Yes	LAN
B4.1 IIB, IV 4.1 /02	Schultz, C.	2005b	Validation report Thiacloprid, method 2301-0292202-05; revised version of method 2301-0292201-04. Date: 2005-08-01	Bayer Industry Services, BIS ZA UER, Krefeld, Germany	Validation of method 2301-0292202-05	No	No	Yes	LAN
B5 IIB, V 5.10/01	Schumacher, P.; Fennert, E.-M.	2002a	Determination of the preventive action of JJT 3091 (water based) against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46 (04/90) after leaching procedures according to EN 84 (05/97). Date: 2002-03-08.	Materialprüfungsamt des Landes Brandenburg, Germany	3.2/01/8246 /01	No	No	Yes	LAN
B5 IIB, V 5.10/02	Schumacher, P.; Fennert, E.-M.	2002b	Determination of the preventive action of JJT 3091 (water based) against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46 (04/90) after evaporative ageing procedure according to EN 73 (04/90). Date: 2002-04-08	Materialprüfungsamt des Landes Brandenburg, Germany	3.2/01/8246 /02	No	No	Yes	LAN

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
B5 IIB, V 5.10/03	Schumacher, P.; Fennert, E.-M.	2005a	Determination of the preventive action of JJT 3968 (solvent based) against termites (Reticulitermis santonesis De Feytaud) according to EN 118 (02/91) after leaching ageing procedure according to EN 84 (05/97). Date: 2005-09-20.	Materialprüfungsamt des Landes Brandenburg, Germany	32/05/8708/01-02	No	No	Yes	LAN
B5 IIB, V 5.10/04	Schumacher, P.; Fennert, E.-M.	2005b	Determination of the preventive action of JJT 3947 (water based) against termites (Reticulitermis santonesis De Feytaud) according to EN 118 (02/91) after leaching ageing procedure according to EN 84 (05/97). Date: 2005-09-20.	Materialprüfungsamt des Landes Brandenburg, Germany	32/05/8707/01-03	No	No	Yes	LAN
B7 IIB, VII 7.1/01	Wegner , R.; Sauer, C.	2005a	Leaching test from wood for the preservative JJT 3947. Application: brushing treatment. Date: 2005-09-05	Materialprüfungsamt des Landes Brandenburg, Germany	31/05/7558/01	No	No	Yes	LAN
B7 IIB, VII 7.1/02	Wegner , R.; Sauer, C.	2005b	Leaching test from wood for the preservative JJT 3947. Application: vacuum pressure treatment. Date: 2005-09-06	Materialprüfungsamt des Landes Brandenburg, Germany	31/05/7558/02	No	No	Yes	LAN

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
B7 IIB, VII 7.1/03	Wegner , R.; Sauer, C.	2005c	Leaching test from wood for the preservative JJT 3947. Application: vacuum pressure treatment; permanent immersion assay. Date: 2005-09-06	Materialprüfungsamt des Landes Brandenburg, Germany	31/05/7558/03	No	No	Yes	LAN
B7 IIB, VII 7.1/04	Wegner , R.; Sauer, C.	2005d	Leaching test from wood for the preservative JJT 3968. Application: brushing treatment Date: 2005-09-05	Materialprüfungsamt des Landes Brandenburg, Germany	31/05/7559/01	No	No	Yes	LAN
B7 IIB, VII 7.1/05	Wegner , R.; Sauer, C.	2005e	Leaching test from wood for the preservative JJT 3968. Application: vacuum pressure treatment^ Date: 2005-09-05	Materialprüfungsamt des Landes Brandenburg, Germany	31/05/7559/02	No	No	Yes	LAN

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
B8.1 IIB, VIII 8.1 /01 also filed: B8.2 IIB, VIII 8.2 /01, also filed: B8.3 IIB, VIII 8.3 /01, also filed: B8.4 IIB, VIII 8.4 /01, also filed: B8.5 IIB, VIII 8.5 /01	Anonymous	2005a	Safety Data Sheet JJT 3947 Thiacloprid Emulsifiable Concentrate Guide Recipe. Date: 2005-06-09	LANXESS Deutschland GmbH, Leverkusen, Germany	288156/00	No	No	No	LAN
B8.1 IIB, VIII 8.1 /02 also filed: B8.2 IIB, VIII 8.2 /02, also filed: B8.3 IIB, VIII 8.3 /02, also filed: B8.4 IIB, VIII 8.4 /02, also filed: B8.5 IIB, VIII 8.5 /02	Anonymous	2005b	Safety Data Sheet JJT 3968 Thiacloprid Solvent-based Guide Recipe. Date: 2005-06-24	LANXESS Deutschland GmbH, Leverkusen, Germany	288148/01	No	No	No	LAN
B8.2 IIB, VIII 8.2 /01 also filed: B8.1 IIB, VIII 8.1 /01, also filed: B8.3 IIB, VIII 8.3 /01, also filed: B8.4 IIB, VIII 8.4 /01, also filed: B8.5 IIB, VIII 8.5 /01	Anonymous	2005a	Safety Data Sheet JJT 3947 Thiacloprid Emulsifiable Concentrate Guide Recipe. Date: 2005-06-09	LANXESS Deutschland GmbH, Leverkusen, Germany	288156/00	No	No	No	LAN

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B8.2 IIB, VIII 8.2 /02 also filed: B8.1 IIB, VIII 8.1 /02, also filed: B8.3 IIB, VIII 8.3 /02, also filed: B8.4 IIB, VIII 8.4 /02, also filed: B8.5 IIB, VIII 8.5 /02	Anonymous	2005b	Safety Data Sheet JJT 3968 Thiacloprid Solvent-based Guide Recipe. Date: 2005-06-24	LANXESS Deutschland GmbH, Leverkusen, Germany	288148/01	No	No	No	LAN
B8.3 IIB, VIII 8.3 /01 also filed: B8.1 IIB, VIII 8.1 /01, also filed: B8.2 IIB, VIII 8.2 /01, also filed: B8.4 IIB, VIII 8.4 /01, also filed: B8.5 IIB, VIII 8.5 /01	Anonymous	2005a	Safety Data Sheet JJT 3947 Thiacloprid Emulsifiable Concentrate Guide Recipe. Date: 2005-06-09	LANXESS Deutschland GmbH, Leverkusen, Germany	288156/00	No	No	No	LAN
B8.3 IIB, VIII 8.3 /02 also filed: B8.1 IIB, VIII 8.1 /02, also filed: B8.2 IIB, VIII 8.2 /02, also filed: B8.4 IIB, VIII 8.4 /02, also filed: B8.5 IIB, VIII 8.5 /02	Anonymous	2005b	Safety Data Sheet JJT 3968 Thiacloprid Solvent-based Guide Recipe. Date: 2005-06-24	LANXESS Deutschland GmbH, Leverkusen, Germany	288148/01	No	No	No	LAN

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
B8.4 IIB, VIII 8.4 /01 also filed: B8.1 IIB, VIII 8.1 /01, also filed: B8.2 IIB, VIII 8.2 /01, also filed: B8.3 IIB, VIII 8.3 /01, also filed: B8.5 IIB, VIII 8.5 /01	Anonymous	2005a	Safety Data Sheet JJT 3947 Thiacloprid Emulsifiable Concentrate Guide Recipe. Date: 2005-06-09	LANXESS Deutschland GmbH, Leverkusen, Germany	288156/00	No	No	No	LAN
B8.4 IIB, VIII 8.4 /02 also filed: B8.1 IIB, VIII 8.1 /02, also filed: B8.2 IIB, VIII 8.2 /02, also filed: B8.3 IIB, VIII 8.3 /02, also filed: B8.5 IIB, VIII 8.5 /02	Anonymous	2005b	Safety Data Sheet JJT 3968 Thiacloprid Solvent-based Guide Recipe. Date: 2005-06-24	LANXESS Deutschland GmbH, Leverkusen, Germany	288148/01	No	No	No	LAN
B8.5 IIB, VIII 8.5 /01 also filed: B8.1 IIB, VIII 8.1 /01, also filed: B8.2 IIB, VIII 8.2 /01, also filed: B8.3 IIB, VIII 8.3 /01, also filed: B8.4 IIB, VIII 8.4 /01	Anonymous	2005a	Safety Data Sheet JJT 3947 Thiacloprid Emulsifiable Concentrate Guide Recipe. Date: 2005-06-09	LANXESS Deutschland GmbH, Leverkusen, Germany	288156/00	No	No	No	LAN

(Sub)Section / Annex point	Author(s)	Year **	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Owner*
B8.5 IIB, VIII 8.5 /02 also filed: B8.1 IIB, VIII 8.1 /02, also filed: B8.2 IIB, VIII 8.2 /02, also filed: B8.3 IIB, VIII 8.3 /02, also filed: B8.4 IIB, VIII 8.4 /02	Anonymous	2005b	Safety Data Sheet JJT 3968 Thiacloprid Solvent-based Guide Recipe. Date: 2005-06-24	LANXESS Deutschland GmbH, Leverkusen, Germany	288148/01	No	No	No	LAN
	EC	2003	Technical Guidance Document (TGD) 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 active substances and Commission Directive 98/8/EC concerning the placing of biocidal products on the market. ECB, JRC, Ispra, Italy	-	-	No	Yes	No	-
	OECD (Environment Directorate, Paris)	2003	Emission scenario document for wood preservatives OECD series on emission scenario documents No. 2 (Parts 1 & 2)	-	-	No	Yes	No	-