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

Imidacloprid

Product-type 18 (Insecticides, Acaricides and Products to control other Arthropods)

18th February 2011(revised version: July 2015)

Annex I - Germany

Imidacloprid (PT 18)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 18th February 2011 in view of its inclusion in Annex I to Directive 98/8/EC, revisions with regard to $PNEC_{water}$ agree at the 11th Biocidal Products Committee in June 2015

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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 imidacloprid as product-type 18 (insecticides, acaricides and products to control other arthropods), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market*, with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Imidacloprid (CAS No. 138261-41-3) was notified as an existing active substance, by Bayer Environmental Science, hereafter referred to as the applicant, in product-type18.

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

In accordance with the provisions of Article 7(1) of that Regulation, Germany was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for imidacloprid as an active substance in Product Type 18 was 30 April 2006, in accordance with Article 9 of Regulation (EC) No 1451/2007.

On 26 April 2006, the German competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 26. October 2006.

On 15 September 2008, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 10 November 2008. The competent authority report included a recommendation for the inclusion of imidacloprid in Annex I to the Directive for product-type 18.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 10 November 2008.This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

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

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* 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

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

On the basis of the final competent authority report, the Commission proposed the inclusion of imidacloprid in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 18th February 2011.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 18th February 2011.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include imidacloprid in Annex I to Directive 98/8/EC for product-type **18**. The aim of the assessment report is to facilitate the authorisation in Member States of individual biocidal products in product-type **18** that contain imidacloprid. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website*, 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 imidacloprid for the product-type **18**, which will fulfil the requirements laid down in Article 5 of Directive 98/8/EC. This conclusion is however subject to:

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

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

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

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.

* 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

Identity of the a.s.

Analysis of five technical grade batches which are representative of the current manufacturing process demonstrated a mean purity of 98.0 % w/w. Imidacloprid technical does not contain additives and all impurities above the level of 1 g/kg have been fully identified and corresponding methods of analysis developed.

Imidacloprid is marketed by Bayer Environmental Science as a sugar based granule (GR) for rural hygiene fly control in livestock buildings and as a gel (GL) for residential and commercial indoor cockroach control.

Physico-chemical properties of the a.s.

Purified imidacloprid (99.9 %) is a colourless crystalline solid with a melting point of 144 °C. It is readily soluble in dichloromethane, acetone, acetonitrile, dimethylformamide and dimethylsulfoxide, but only slightly soluble in toluene and 2-propanol and almost insoluble in *n*-hexane. In demineralised water imidacloprid is somewhat soluble with no dependence on the pH. The $\log P_{OW}$ is 0.57, indicating a low risk of bioaccumulation. The vapour pressure and the Henry´s law constant at 20 °C are calculated to 4×10^{-10} Pa and 1.675×10^{-10} Pa m^3 mol^{-1}, respectively. The technical material is not explosive or highly flammable, does not spontaneously combust and is not an oxidizer. Imidacloprid is stable in the presence of the selected packaging materials.

Analytical Methods of the a.s.

Residue analytical methods are available for the active substance in soil, air, drinking and surface water. The analytical method for the determination of residues in surface water is also validated for the metabolites guanidine, olefinic compound and urea compound.

Validated confirmatory methods for soil, drinking and surface water were presented. An analytical method for the determination of residues in air using a column of different selectivity was presented. Although the method is not validated in the necessary extent, it is considered to be appropriate for confirmatory purposes.

According to the residue definition and the intended uses for the Annex I inclusion no analytical methods for residues in body fluids and tissues, plants and animal matrices are necessary.

Identity, Physico-chemical Properties and Method of Analysis of Imidacloprid GR 0.5∗

Imidacloprid GR 0.5 is a granule (GR) containing 5 g/Kg of imidacloprid. The preparation is not highly flammable and not explosive. It does not show oxidizing properties. Its pH lies within the range which naturally occurs e.g. in soils.

Its stability under accelerated storage stability allows extrapolation for storage for at least 2 years under practical and commercial temperate conditions. It will not degrade nor react with its container. This has since been confirmed by a 2 year storage stability study under ambient conditions.

If the application of the biocidal product corresponds to the label recommendation, no further analytical methods for the determination of the residues of the product in/on treated food or feeding stuff is necessary.

Identity, Physico-chemical Properties and Method of Analysis of Imidacloprid GL 2.15

Imidacloprid GL 2.15 is a gel (GL) containing 21.5 g/Kg of imidacloprid. The preparation is not highly flammable and not explosive. It does not show oxidizing properties. Its pH lies within the range which naturally occurs e.g. in soils.

A 5 year storage stability study under ambient conditions demonstrates that the formulation is stable under practical and commercial temperate conditions, and will not degrade nor react with its container.

If the application of the biocidal product corresponds to the label recommendation, no further analytical methods for the determination of the residues of the product in/on treated food or feeding stuff is necessary.

2.1.2. Intended Uses and Efficacy

Products containing imidacloprid are intended for professional (e.g. by pest control operators, farmers) use in bait formulations controlling insects such as house flies and cockroaches.

Imidacloprid is a neonicotinoid insecticide which acts on organisms by contact and ingestion. It has residual activity. Like other neonicotinoids and nicotine, it acts on the insects central nervous system as an agonist of the postsynaptic nicotinic acetyl-choline receptors (nAChRs).

The applicant has provided several studies on the efficacy of the active ingredient against flies and cockroaches. A detailed evaluation of the laboratory and field studies is given in Doc II, Chapters 2 and 7.

Resistance and cross-resistance against neonicotinoids (chloronicotinyls like imidacloprid, thiamethoxam and acetamiprid), a group of insecticides acting agonistically on insect nicotinic acetylcholine receptors (nAChRs), can occur in relevant susceptible pests in Europe.

[redacted]

The biochemical mechanisms conferring resistance to neonicotinoids have not yet been elucidated in detail, but synergist studies suggested a possible involvement of microsomal monooxygenases. In general, precautions should be taken to reduce the possibility of insects developing resistance to neonicotinoid insecticides.

For the intended uses as a biocidal product Imidacloprid GL 2.15 should only be used against adults and nymphs of cockroaches and is not applicable against other generations (eggs). The application as a spot (or thin ribbons equivalent to a spot, paste formulation) takes place above the lethal level. Therefore it is expected that development of resistance in target insects does not occur.

For the intended uses as a biocidal product Imidacloprid GR 0.5 as PT 18 should only be used against adult insects (e.g. *Musca domestica*) and is not applicable for other generations (e.g. eggs, larvae and pupae). The application as a granule or paint bait takes place above the lethal level. Therefore it is expected that development of resistance in target insects does not occur.

Overall, it is concluded that the data demonstrated the effectiveness of the products containing imidacloprid (GL 2.15 and GR 0.5) to a sufficient degree for inclusion of the a.i. onto Annex I to be recommended.

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

The participant's proposal from September 2007 for the active substance imidacloprid is equivalent to the EU Directive 67/548/EEC (incl. 31st ATP). The proposed classification is consistent with the EU Directive 67/548/EEC (incl. 31st ATP), however S 57 is not required.

According to annex VI, table 3.1 of the regulation (EC) No. 1272/2008 classification (and labelling) of imidacloprid for human health and environment would be as follows:

- Acute Tox. 4; H302 (Harmful if swallowed)
- Aquatic Acute 1; H400 (Very toxic to aquatic life)
- Aquatic Chronic 1, H410 (Very toxic to aquatic life with long lasting effects)

Concerning labelling the following precautionary statements are proposed:

- P264: "Wash thoroughly after handling"
- P270: "Do not eat, drink or smoke when using this product"
- P273: "Avoid release to the environment"
- P301 + P312: "If swallowed: call a poison center or doctor/ physian if you feel unwell"
- P330: "Rinse mouth"
- P391: "Collect spillage"
- P501: "Dispose of contents/container to …".

Table 2-1 Proposed classification of imidacloprid

Classification		
Indication of danger	Xn N	Harmful Dangerous for the Environment
R phrases	R 22 R 50 R 53	Harmful if swallowed Very toxic to aquatic organisms May cause long term effects in the aquatic environment
S phrases	S (2) S 22 S 60 S 61	Keep out of the reach of children Do not breathe dust The material and its container must be disposed of as hazardous waste. Avoid release to the environment and refer to special. instructions/safety data sheet

Remark:

The current classification of imidacloprid is a result of the toxicological hazard assessment done by the participant and evaluated by the competent authority. The proposed classification is based upon the acute oral toxicity studies in rats.∗

Classification and Labelling of "Imidacloprid GL 2.15" and "Imidacloprid GR 0.5"

Table 2-2 Proposed classification of "Imidacloprid GL 2.15" and "Imidacloprid GR 0.5"

Classification according Directive 1999/45/EC		
Indication of danger	N	Dangerous for the Environment.
R phrases	R 51 R 53	Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.
S phrases	S 2 S 13 S 29 S 60 S 61	Keep out of the reach of children. Keep away from food, drink and animal feeding stuffs. Do not empty into drains. This material and its container must be disposed of as hazardous waste. Avoid release to the environment. Refer to special instructions/safety data sheet.

∗ The question of whether the LD_{50} in mice (which would result in a more severe classification, i. e. R25) should be used for C & L regarding acute toxicity has been discussed at TMII09. In the view of the RMS, a uniform basis should be selected when classifying/labelling chemical substances, i.e. acute toxicity should always be classified/labelled based on rat studies, when available. While no consensus between MS could be reached, it was nevertheless decided by TMII09, that both LD_{50} values should be given, but the question of C & L of imidacloprid for acute toxicity should be left to the RAC at EChA.

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

Absorption, Distribution, Excretion, and Metabolism

Absorption - oral route

The biokinetic studies in rats showed that imidacloprid is rapidly and almost completely absorbed from the intestinal lumen (> 90 % based on urinary (56 %) and biliary (35 %) excretion).

Absorption - dermal route

The dermal absorption of imidacloprid contained in three different concentrations in the formulation Confidor 200 OD was studied in vitro on human and rat skin. In a well-performed 24-hour study on human skin with an 8-hour exposure period, dermal absorption rates of < 1 % for the concentrate and 6 % or 8 % for the diluted formulations were obtained. For risk assessment purposes, values of < 1 % and 8 % should be used. Permeability of rat skin membranes was much higher especially for the concentrate reaching a ratio as high as 22:1 whereas for the formulations penetration through rat skin was 2 or 4 times higher than through human skin.

Distribution

Peak plasma concentrations are reached within approximately 1-2 hours. The radioactivity is rapidly distributed to the peripheral tissues and organs. At 48 h after dose application, remaining radioactivity levels in the tissues are very low. Levels above average were only observed in the contents of the gastrointestinal tract, liver, kidney, adrenals, thyroid, connective tissues and the vascular walls of the aorta. The extent of penetration of the blood-brain barrier is very limited.

Metabolism

The metabolisation rate of imidacloprid in the rat was high and somewhat more pronounced in male than in female animals. The amount of unchanged parent compound in excreta varied between 10 and 16 % of the given dose. The main renally excreted metabolites are 6-chloronicotinic acid (M14) and its glycine conjugate (M15) as well as the two corresponding imidazolidine ring-containing biotrans¬formation products M26 and M27. In addition, the two monohydroxylated metabolites imidacloprid-5-hydroxy (M01) and -4-hydroxy (M02) as well as imidacloprid-olefine (M06) are detected in the urine. The latter is also excreted with the faeces together with imidacloprid-6-CNA (M14) and imidacloprid-6-CNA-glycine (M15).

Two major routes of metabolism responsible for the degradation of imidacloprid can be derived. The first involves an oxidative cleavage yielding nitroiminoimidazoline (M26) and 6-chloronicotinic acid (M14) which is conjugated with glycine to form M15. These metabolites were found only in the urine and were excreted very quickly. They constitute the major part of the identified metabolites, representing ca. 30 % of the recovered radioactivity. Only of minor importance in terms of quantity is the dechlorination of the pyridinyl moiety

leading to the 6-hydroxy-nicotinic acid (M18) and its methylmercapto derivative (M20), probably as a degradation product of a glutathione conjugate. Possibly, glutathione can also react directly with 6-chloronicotinic acid (M14) to form the same metabolite. Levels of 6-(methylmercapto)nicotinic acid conjugate with glycine (M19) amounted to 5.6 % of the recovered radioactivity.

Excretion

Elimination from the organism is fast and complete (> 95 % within 48 h), there is no indication of any bioaccumulation potential of the parent compound and/or its metabolites. In studies using methylene group-labelled test substance, on average at least three quarters of the administered radioactivity were excreted with the urine, while the remainder was found in the faeces. Most of the faecal radioactivity originated from biliary excretion. In the study with imidazolidine ring-labelled imidacloprid, excretion with urine exceeded 90 % of dose, while only ca. 8 % were excreted with the faeces.

Further studies

Studies on the relative biokinetic and metabolic behaviour of imidacloprid and its metabolite imidacloprid-nitrosimine (M07) in male rats in general yielded comparable data for absorption, distribution and elimination. However, imidacloprid-nitrosimine was eliminated somewhat more rapidly, and the radioactivity levels in the organs were lower as compared to imidacloprid. M07 was not detected in the urine or faeces following administration of single oral doses of 1 and 150 mg imidacloprid/kg bw, respectively, to male rats. After high doses of imidacloprid had been given to rats and mice in the diet over a one-year period, imidacloprid-nitrosimine was found in the urine at levels of 90 mg/L (rat) and 15 mg/L (mouse), respectively. Reduction of the nitro group of imidacloprid as required for the formation of the nitrosimine metabolite apparently only takes place in chronic exposure situations with high imidacloprid concentrations, which are likely to saturate the enzyme systems catalysing other possible degradation reactions.

Acute Toxicity

In rats, imidacloprid displayed moderate acute toxicity after oral administration, with LD_{50} values ranging from 380-650 mg/kg bw. Mice were more sensitive with LD_{50} values of ca. 130/170 mg/kg bw for males/females, respectively. Imidacloprid is non-toxic after acute dermal or inhalatory exposure, not irritant to skin or eyes, and not sensitising via skin.

Repeated Dose Toxicity

Reduced body weight gain was the most sensitive parameter in rats and dogs following oral and inhalative repeated dose administration of imidacloprid. The liver has been found to be the main target organ after repeated administration of imidacloprid to rats and dogs: at lower dose levels, adaptation processes, such as induction of hepatic microsomal enzymes (elevated activities of the mixed-function oxidases, particularly cytochrome P-450) and increased liver weights were observed, which were of limited extent and, in the absence of relevant histopathological findings, were not considered adverse. Higher doses affected hepatic function with dysregulation of the lipid and protein metabolism, as manifested by changes in blood levels of cholesterol, triglyceride, protein, and albumin. Occasional increases in blood coagulation time, elevated total serum bilirubin levels, and elevated activities of the enzymes ALT, AP, and GLDH in the blood were also seen as indicative for a disturbance of hepatic

function. Histopathologically, liver cell necrosis was observed in high dose males in the 90-d rat study.

Studies with chronic administration to rodents were submitted in the form of a combined chronic carcinogenicity study in rats and a carcinogenicity study in mice. The main target organ in the 24-mo study in the rat was the thyroid. An increased incidence of mineralisation in the colloid of the thyroid gland follicles was the most sensitive parameter observed in male (LOAEL 17 mg/kg bw/d) and female (LOAEL 73 mg/kg bw/d) rats. The increased incidence of this involution of isolated thyroid follicles is considered a treatment-related premature aging of the thyroid. An effect on thyroid function can be excluded, since the plasma levels of thyreotropin, triiodothyronine, and thyroxine remained unchanged. However, at higher dose levels, additional effects on the thyroid (increased parafollicular hyperplasia and reduced colloid aggregation) were observed. In females of the highest dose group, absolute and relative liver weights were decreased and the body weight was markedly reduced.

In mice, treatment-related effects were evident in the highest dose group. Mice in this dose group displayed behavioural abnormalities (increased vocalisation) and an increase in mortality due to an increased sensitivity to ether anaesthesia for blood withdrawal or tattooing. Reduced body weight gain in males (-25 %) and females (-21 %) and decreased absolute and relative liver weight in females were also observed in the highest dose group.

In dogs, an inconsistency between the four different study reports available was observed with regard to the critical finding off tremor/trembling:

No trembling or tremor were observed in a 14-d pilot experiment, in which the impact of mashed vs. pelleted diet containing Imidacloprid at a level of 1200 ppm (mg/kg feed) was explored. Feed intake was slightly higher in animals receiving mashed feed in this study.

In a supplementary 28-d range-finding study, tremor was observed at 5000, but not at 1000 ppm (pelleted feed). On closer inspection of the data, it was found that food intake was highly variable between days, in particular for animals from the high-dose groups. While on first glance, a clear dose-response relationship appeared to be lacking, a correlation with peak substance intake reported on ± 1 d around the reported day of tremor could be established, which can be explained by varying relative time-points of the determination of food consumption and inspection for clinical signs, respectively. In addition, slight histopathological changes were observed at dose levels at and above ca. 30 mg/kg bw/d (group average: 31.5 mg/kg bw/d) in mid- and high-dose animals, but these findings were not considered relevant for risk assessment as they were not confirmed in two other dog repeat-dose studies of longer duration. At the highest dose level, all 4 dogs (2 M + 2 F) died prematurely.

In the 90-d dog study (mashed food), all animals of the mid-dose group (600 ppm or nominal 23.5 mg/kg bw/d) displayed “trembling” on one (5/8 animals) or two (3/8) occasions during wk 1, but not later in the study. Unfortunately, the exact day of these observations has not been documented. Moreover, feed intake, too, was only reported weekly, but might be assumed to have varied in a similar fashion observed in the 28-d experiment. Animals of the top-dose group (1800 ppm during wks 1-4) showed “severe tremor” at least once, but up to five times during week 1 (one animal also once in wk 3). From wk 1 up to wk 5 all high-dose group animals showed “trembling” or “slight trembling” on one or several occasions (up to six times/wk). As a consequence of the symptoms displayed by the top-dose group, the

dietary concentration was lowered from 1800 down to 1200 ppm from wk 5 on. Starting in wk 6, tremor and/or trembling were no longer observed until the end of the study. When averaged over the whole study period of 90 days, the top level feed concentration of 1800/1200 ppm corresponded to a mean group dose level of 45.4 mg/kg bw/d. (Severe) tremor in this group, however, was only described during wk 1 and trembling occurred only up to wk 5, but did not continue to be observed when feed concentration had been lowered to 1200 ppm. In summary, as regards the 90-d study, the following conclusions are drawn:

- In the mid-dose group at 600 ppm, only single or double transient incidences of trembling were observed, presumably on one of the first days of dosing.
- The wording of "trembling" vs. "(severe) tremor" suggests a mild intensity. Furthermore, after week 1 some sort of adaptation/tolerance seems to have developed, as trembling was not reported for this group during weeks 2-13.
- Tremor or trembling in the high-dose group were only observed at dose levels believed to be clearly above the 90-d group mean dose level of 45.4 mg/kg bw/d.
- (Slight, transient) trembling was observed in the 90-d study at and above 600 ppm, severe tremor was seen in this study at 1800 ppm (mashed feed)
- No trembling or tremor were observed in the 1-yr study at dose levels up to and including 2500 ppm (pelleted feed)

Finally, in the 1-yr dog study, trembling/tremor were not observed at dose levels of 200, 500, or 1250/2500 mg imidacloprid / kg (pelleted) feed, equivalent to group mean doses of 6.1, 15, and 41/72 mg/kg bw/d. The dose level of the high-dose group was raised from 1250 to 2500 ppm from wk 17 on. Perhaps because enzyme induction had taken place by that time-point, subsequent plasma peak levels might have been lower than would be expected if 2500 ppm had been administered right from the start. Treatment with 1250 ppm was associated with a slight (below or in the order of 10 %) and transient fall in food consumption in males (week 1) and females (weeks 1 and 2). A similar transient effect was seen when the dietary concentration was increased in week 17, the effects being seen in males in weeks 17-18 and in females in weeks 17-20. Overall body weight gain was not affected in a dose-related fashion.

Based on this synopsis, the finding of transient trembling at 600 ppm in the 90-d study was in contradiction with the results of three other (14-d, 28-d and 52-wk) dog studies, where it was not reproducible at the same or even higher dose levels. It is concluded that peak doses of > 50 mg/kg bw/d were required to cause slight, transient tremor in the 28-d dog study and that, in order to elicit moderate to severe tremor in dogs, doses of ca. 80 mg/kg bw/d appear to be required.

The NOAEL for repeated oral exposure was 61 mg/kg bw/d in the 90-d, and 6 mg/kg bw/d in the 2-yr study in rats. In the dog, based on liver toxicity and decreased body weight gain observed in the oral 90-d study, a NOAEL of 23.5 mg/kg bw/d was established.

The NOAEC in the 28-d inhalation study in rats was 30.5 mg/m^3 (equivalent to a systemic dose level of ca. 8.2 mg/kg bw/d, if 100 % inhalative absorption are assumed), based on liver effects and reduced body weight gain. No local or systemic signs of toxicity were observed in rabbits exposed dermally to 1000 mg imidacloprid/kg bw/d.

Genotoxicity

In vitro tests for point-mutation effects (Salmonella/microsome reverse-mutation and CHO-HGPRT tests) and for DNA-damaging properties (yeast mitotic recombination assay, rat hepatocyte UDS test) gave negative results. A weak indication of sister chromatid exchange (SCE) induction in CHO cells was found in one of two in vitro tests. In the cytogenetic study with human lymphocyte cultures, a slight, reproducible increase in the aberration rate was observed in the cytotoxic concentration range without metabolic activation; an equivocal result was obtained with metabolic activation.

All in vivo tests for chromosome damage (micronucleus test, bone marrow cytogenetics, sister chromatid exchange, and spermatogonia cytogenetics) were negative, so that a clastogenic potential of imidacloprid in vivo can be excluded. The overall conclusion is that imidacloprid exhibits no genotoxic potential.

Carcinogenicity

No evidence of an oncogenic potential of imidacloprid was found in either the rat or the mouse long-term/carcinogenicity feeding studies.

Reproduction Toxicity

The reproductive toxicity of imidacloprid was investigated in a two-generation study in rats, as well as in developmental toxicity studies in rats and rabbits.

In the rat developmental toxicity study, appearance, behaviour, and mortality of the dams were unchanged up to and including 100 mg/kg bw/d. The NOAEL for maternal toxicity at 30 mg/kg bw/d is based on initial body weight loss, reduced food consumption, and decreased body weight gain at 100 mg/kg bw/d. No treatment-related changes were observed at necropsy. At the highest dose tested, no treatment-related changes were observed in the reproduction parameters. No treatment-related changes were determined from external and visceral examination of the foetuses. In the skeletal examination, an increased incidence of wavy ribs was observed at 100 mg/kg bw/day. Wavy ribs constitute a slight, transient alteration, which is fully reversed if pups are raised to age. This opinion is supported by a number of articles from the published literature (Khera 1981, Nishimura et al. 1982, Kast 1994). As a consequence, the occurrence of wavy ribs is not rated as an adverse effect, and the developmental NOAEL in the rat teratogenicity study in rats is set at 100 mg/kg bw/d.

In rabbits, body weight loss from the start of treatment until day 20 p.c., decreased food consumption during the treatment period, and mortality were observed at 72 mg/kg bw/d; one female from this group aborted on day 26 post coitum, and two females showed total litter resorption at terminal necropsy. The body weights of the foetuses were slightly reduced and the incidence of foetuses with retarded ossification increased at 72 mg/kg bw/d. Because of the reduced litter size in this group, which would have resulted in increased foetal weights had there not been foetal toxicity, the reduced foetal weights and the skeletal changes are regarded as signs of foetal retardation and may have resulted from the severe maternal toxicity. No treatment-related malformations were observed. Both, the maternal and developmental NOAEL is set at 24 mg/kg bw/d.

Overall, the data show that imidacloprid has no primary teratogenic potential.

In the 2-generation reproduction study, body weight gain and food consumption were reduced in the parents at a dose of 50 mg/kg bw/d. No gross pathological, organogravimetric, or histopathological alterations were apparent in the examined parents or pups. No treatment-related effects were observed on reproduction parameters. Reduced body weight gain (F_1 + F_{2A}) was the most sensitive parameter in pups. No teratogenic effect was observed by external examination of the pups in any group of either generation.

The data show that imidacloprid has no primary reproductive toxicity.

Neurotoxicity

In acute, subchronic, and developmental screening studies in rats, specific neurotoxicological parameters were investigated by functional observation battery, automated motor activity measure-ments, and special neurohistopathology. Behavioural changes in the acute experiment and, to a much lesser extent, in the developmental study were the only signs that could be indicative of primary neurotoxic effects. Most clinical signs appeared to be related to acute receptor-mediated cholinergic toxicity of this chloronicotinyl compound.

In the acute neurotoxicity study in rats, the NOAEL was 42 mg/kg bw, based on tremor and decreased motor/locomotor activity at 151 mg/kg bw/d. No specific neurotoxic effects were observed in the 13-wk neurotoxicity study in rats. In the developmental neurotoxicity study in rats, direct (but no developmental) neurotoxic effects on the pups were noted at maternal dose levels of 80.4 mg/kg bw/d and higher, the NOAEL being 45.4 mg/kg bw/d.

Studies on Metabolites

Imidacloprid-urea

Imidacloprid-urea is of low toxicity with LD_{50} values of 4080 mg/kg bw in male rats and 1820 mg/kg bw in female rats. No genotoxic potential of this metabolite was observed in the Ames test.

Imidacloprid-nitrosimine

In the rat, imidacloprid-nitrosimine is of low toxicity with LD_{50} values of 1980 mg/kg bw in male and 3560 mg/kg bw in female rats. Mice were more sensitive with an LD_{50} of 200/300 mg/kg bw (M/F). A subchronic 12-week study in the rat revealed haematology (increased lymphocyte count and a decreased number of polymorphonuclear cells) and clinical chemistry findings (decreased sodium) with a NOAEL of 13 mg/kg bw/d. In several *in vitro* and *in vivo* genotoxicity tests, imidacloprid-nitrosimine was negative.

Imidacloprid-olefine

Imidacloprid-olefine is of low to moderate toxicity in the rat with an LD_{50} of 3500 mg/kg bw in males and 1100 mg/kg bw in females. Regarding genotoxicity, this metabolite was negative in the Ames test.

Imidacloprid-desnitro

In the rat, imidacloprid-desnitro is of moderate toxicity with an LD_{50} of 300/280 mg/kg/bw (M/F). No genotoxic potential of this metabolite was seen in the Ames test.

In summary, none of the examined metabolites displayed a more toxic profile with regard to acute toxicity or genotoxicity than the parent compound.

Medical Data

Based on data from periodical occupational examinations, no adverse health effects have been reported for employees handling imidacloprid during the production of active ingredient and formulations. No epidemiological studies on the general population are available. One case of accidental ingestion of 200 mg imidacloprid by a four year old child did not result in signs of poisoning or adverse health effects. On the other hand, a report of two fatal intoxications with imidacloprid is available, but information on both clinical progress and actually ingested amount of substance is lacking.

Information on symptoms or clinical signs in humans is therefore not available. Based on agonistic effects of this class of compounds on the mammalian nicotinergic acetylcholine receptor, nicotine-like action may occur in severe intoxications. Complete recovery of non-fatal cases is expected within a few days. The analytical demonstration of parent compound or metabolites in blood, urine or gastrointestinal contents is required for an exact diagnosis of poisoning. A specific antidote is not known. In case of oral uptake, first aid measures should consist of removal of ingested compound by gastric lavage or induction of vomiting and symptomatic treatment. Contaminated skin should be washed immediately with plenty of water. Administration of activated charcoal was found to be effective under experimental conditions in laboratory rodents.

Biocidal Products

Imidacloprid GL 2.15:

No in vivo as well as in vitro data for dermal absorption of the product Imidacloprid GL 2.15 were submitted by the participant. But the applicant has submitted test results with an oil formulation for the assessment of imidacloprid as pesticide for the inclusion in Annex I of Directive 91/414/EEC.

Imidacloprid Cockroach Gel was tested for oral and dermal acute toxicity. The LD_{50} for both were > 5000 mg/kg bodyweight. Imidacloprid Cockroach Gel is not irritating to the skin and to the eyes. The biocidal product used in acute toxicity testing contains another antifoaming agent than the biocidal product in this dossier. Due to the low concentration and the toxicological properties of this component this change is considered to have no effect on study results. The biocidal product was not tested for inhalation toxicity. Due to the physico-chemical properties of the product and the mode of application non-submission was accepted. The sensitisation study submitted by the applicant suggests that the biocidal product is not sensitising.

Summarising the study results and all considerations above Imidacloprid GL 2.15 does not require classification/labelling according to Directive 1999/45/EC but the following S-phrases. Since contact of the general public to the biocidal product cannot excluded and for preventive health care the biocidal product should be labelled as:

S2 Keep out of reach of children.

S13 Keep away from food, drink and animal feeding stuffs.

Imdacloprid GR 0.5:

No in vivo as well as in vitro data for dermal absorption of the product Imidacloprid GR 0.5 were submitted by the participant. But the applicant has submitted test results with an oil formulation for the assessment of imidacloprid as pesticide for the inclusion in Annex I of Directive 91/414/EEC.

Imidacloprid Fly Bait, as used in acute toxicity studies, in eye and skin irritation studies and in the skin sensitisation study is considered identical to Imidacloprid GR 0.5 - biocidal product of this dossier. No effects of acute oral or dermal toxicity were observed after administration of 2000 mg/kg bw. LD_{50} are >2500 mg/kg bw and 2000 mg/kg bw, respectively. No skin irritating and no skin-sensitising effects and only very slight eye irritating effects of the biocidal product were observed in the study.

Summarising the study results and all considerations above Imidacloprid GR 0.5 does not require classification/labelling according to Directive 1999/45/EC but the following S-phrases. Since contact of the general public to the biocidal product cannot excluded and for preventive health care the biocidal product should be labelled as:

S2 Keep out of reach of children.

S13 Keep away from food, drink and animal feeding stuffs.

2.2.1.2. Effects assessment

The biokinetic studies in rats showed that imidacloprid is rapidly and almost completely absorbed from the intestinal lumen. Elimination from the organism is fast and complete, there is no indication of any bioaccumulation potential of the parent compound and/or its metabolites. Both absorption and elimination progress independently of the route of administration. Depending on the position of the radioactive label, 75 - 90 % of radioactivity are excreted via the urine, and the remainder via faeces. Evidence was found for an enterohepatic circulation.

The metabolisation rate of imidacloprid in the rat was high and somewhat more pronounced in male than in female animals. A variety of metabolites was generated, the amount of unchanged parent compound in excreta varied between 10 and 16 % of the given dose.

Imidacloprid is of moderate acute toxicity with an LD_{50} in rats in the order of 500 mg/kg bw. Mice were more sensitive with an LD_{50} of 131/168 mg/kg bw (M/F). No toxic effects were observed after dermal application of a single dose of 5 g imidacloprid/kg bw. When acutely exposed to aerosol concentrations of up to 0.069 g aerosol/m^3 (max. attainable conc.) or 5.3 g/m^3 dust, respectively, rats did not display any signs of toxicity.

With regard to acute local effects, imidacloprid is neither irritant to skin nor eyes. It also did not demonstrate a sensitizing potential.

No evidence was found for a genotoxic or carcinogenic potential of imidacloprid. In repeat-dose studies, liver and thyroid were identified as toxicological targets. No substance-related fertility or developmental impairment was noted in the reproduction toxicity studies.

For acute, medium-term, and long-term exposure to imidacloprid, the following systemic Acceptable Exposure Levels (AEL) were derived:

- an **AEL_{acute} = 0.4 mg/kg bw/d**, based on the NOAEL of ca. 40 mg/kg bw from the acute neurotoxicity study in rats and supported by the results from the 28-d oral toxicity study in dogs,

- an **$AEL_{medium\text{-}term}$ = 0.2 mg/kg bw/d**, based on the overall NOAEL of ca. 20 mg/kg bw/d established for the rat multigeneration study and supported by the dog 90-d and rabbit developmental studies,

- an **$AEL_{long\text{-}term}$ = 0.06 mg/kg bw/d**, based on the NOAEL of ca. 6 mg/kg bw/d obtained in the 2-yr study in rats.

In all cases, standard assessment factors of 100 were applied. An ARfD and an ADI have not been derived for imidacloprid used in biocidal products (PT 18), since no residues in food or feed are expected. However it should be noted that these values have been set analogously to the acute and long-term AELs above by the WHO JMPR in 2001 and, recently, have been confirmed by the RMS during the preparation of the Draft Assessment Report for inclusion of imidacloprid in Annex I of Dir 91/414/EEC.

2.2.1.3. Exposure assessment

Exposure of Professionals

Imidacloprid is produced within the EU. Two different biocidal products are on the market: Imidacloprid GR 0.5 is a granule bait formulation insecticide which contains 0.5 % w/w active substance and Imidacloprid GL 2.15 is a 2.15 % w/w ready for use imidacloprid gel. For the assessment of inhalation exposure, the main focus is set on the exposure to dusts and droplet aerosols. Due to the low vapour pressure (vapour pressure of 9×10^{-10} Pa, 25 °C) inhalation exposure to vapour is of minor relevance. The following scenarios are covered by the exposure assessment in this report:

- Application of Imidacloprid granules (scenario 1)
- Brushing of diluted Imidacloprid granules (scenario 2)
- Application of Imidacloprid gel (scenario 3)
- Secondary exposure to Imidacloprid granules (scenario 4)

The biocidal product Imidacloprid GR 0.5 granules is a ready for use product and is foreseen to be placed in dishes or suitable proprietary fly bait stations on dry level surfaces (ledges, windowsills etc) as 5 g baiting points (scenario 1). Handling the granules during all phases of application inhalation and dermal exposure to dust of the granules is expected. The assessment of the inhalation exposure is based on a suitable model of the *TNsG Human Exposure to Biocidal Products* (Part 2) determining the inhalation exposure as inhaled amount of 0.0006 mg/person/day. The air concentration in mg/m^3 is not covered by this model and cannot be calculated because essential parameters, such as sampling time etc are missing. The amount in mg/person/day is therefore taken forward for the risk assessment (see Table 2-3 below). Based on the same model the potential dermal exposure is assessed to dust of the granules in use. The resulting potential dermal exposure for all phases of application is 0.049 mg/person/day. This low level of exposure is reasonable since the dustiness of the granules is expected to be low.

The second use (scenario 2) is brushing of a bait paste with a concentration of 0.33 % active substance prepared as an aqueous solution from Imidacloprid GR 0.5 granules. During the mixing and loading phase the inhalation and dermal exposure to dust of the granules is estimated. Since the formation of aerosols is considered to be unlikely only potential dermal exposure is expected for the brushing (application) and cleaning procedure of the brush (post-application). The brushing use pattern (mixing and loading, application and post-application) is the use with the highest level of potential dermal exposure with 11.1 mg/person/day compared with the other scenarios (for details please see Table 2-3 below).

When assessing dermal exposure to Imidacloprid GL 2.15 (scenario 3) the special application pattern of the product – spot application using a suitable gel applicator – has to be taken into account. The spot application together with the gel formulation avoids dermal exposure to the operator via splashes or drift during application. However there might be a risk for hand exposure when opening and /or sealing the end cap of the cartridge. The assessment of dermal exposure during 5 opening and 5 sealing operations is based on the estimation that a string of 0.5 cm gel per opening or sealing will be transferred to the hand. Despite the high concentration of the gel (2.15 % gel vs. 0.33 % bait paste) the resulting level of potential dermal exposure is ten times lower than it is estimated for the brushing scenario for Imidacloprid GR 0.5. This is reasonable against the background of a product design which significantly reduces the dermal exposure to the active substance (for details please see Table 2-3 below).

A detailed list of the exposure determinants and the models used is listed in Appendix I.

Non-occupational Exposure

Since primary exposure to non-professionals is not expected a risk characterisation is not required. Secondary exposure from the use of the biocidal products Imidacloprid GL 2.15 and Imidacloprid GR 0.5 is acceptable in relation to human health.

2.2.1.4. Risk characterisation

Risk Assessment for Professionals

Potential exposure and default assumptions on dermal and inhalative absorption are used for estimates of total internal body burden without PPE (see Table 2-3). The risk characterisation is performed with the AEL approach. As reference dose the long-term AEL is taken because repeated exposure at the workplace with a long-term characteristic cannot be excluded for the use of imidacloprid for the control of insecticides. If the total internal body burden is lower than the reference dose health risks leading to concern are not anticipated.

As can be seen from table 2-3, for all the professional exposure scenarios the total internal body burden (caused by potential exposure of the active substance imidacloprid) is significantly below the long-term AEL. The assessment of inhalation toxicity based on the results from oral toxicity studies combined with the assumption of a 100 % absorption by inhalation is consistent with the results of the experimental inhalation studies. There are several precautionary elements in the risk characterisation (tier 1): professional exposure is estimated without accounting for possible personal protective measures. The long-term AEL is used for the assessment of dermal exposure scenarios with an assumed frequency of exposure of 90 days per year. Concerning dermal toxicity, the 8 % dermal absorption used for risk assessment is considered to be a conservative assumption. Overall, the occupational risk

characterisation performed in tier 1 does not result in concern. Based on this analysis, there is no need for further refinement of this risk assessment (e.g. to assess the actual exposure instead of the potential exposure used).

Table 2-3 Risk characterisation for professionals using Tier 1

Exposure scenario		Specific conditions	potential exposure (external values)		Total internal body burden (mg/kg/d) (1)	Total internal body burden divided by AEL(2)
			inhalation (mg/kg/d)	dermal (mg/kg/d)		
1	**Application of Imidacloprid granules**	Placing 2 kg b.p. (dust 0.5 % a.s.) in dishes in a 1000 m^2 stable floor. Post-application: collection of 1 kg b.p. (dust 0.5 % a.s.)	0.007×10^{-3} 0.003×10^{-3}	0.55×10^{-3} 0.27×10^{-3}	0.075×10^{-3}	0.001
2	**Brushing of diluted Imidacloprid granules**	Preparation of bait paste, filling and stirring (dust 0.5 % a.s.) Brushing of bait paste (liquid 0.33 % a.s.), duration: 120 min. Cleaning of application equipment (liquid 0.33 % a.s.)	0.007×10^{-3} negligible negligible	0.55×10^{-3} 150×10^{-3} 35×10^{-3}	14.8×10^{-3}	0.25
3	**Application of Imidacloprid gel**	Spot application using a suitable gel applicator, 5 opening and 5 sealing of cartridge, gel (2.15 % a.s.) Handling of empty cartridge gel (2.15 % a.s.)	negligible negligible	17×10^{-3} 1.7×10^{-3}	1.45×10^{-3}	0.024
4	**Secondary exposure to Imidacloprid granules**	Typical work in animal housing (e.g. cleaning) Active substance stick to dust	negligible	7×10^{-3}	0.56×10^{-3}	0.009

(1) based on the assumption of 8 % systemic availability after dermal exposure and 100 % inhalative absorption
(2) 0.06 mg/kg/day (long-term AEL) x 60 kg/person

Safety Measures for Professionals

Risk reduction measures for exposure to biocidal products Imidacloprid GR 0.5 and Imidacloprid GL 2.15 are not necessary regarding the active substance imidacloprid (up to 2.15 % w/w) since no concern was deduced in any of the assessed in occupational exposure scenarios.

Conclusion:

The occupational risk assessment for imidacloprid is based upon the AEL approach and the estimate of potential occupational exposure. The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of Annex I inclusion of imidacloprid.

For all exposure scenarios specified the risk assessment does not lead to concern. It is essential to recognize that this conclusion only applies to the active substance (imidacloprid) in the biocidal product. From the point of view of occupational safety and health there is no risk-related reason for conditioning the requested Annex I inclusion for imidacloprid.

Risk Assessment for Non-Professionals

Primary exposure is not expected since the biocidal products Imidacloprid GL 2.15 and Imidacloprid GR 0.5 are not used by non-professionals.

Secondary exposure of non-professionals to Imidacloprid GL 2.15 is unlikely due to the nature of the product and the mode of action. However acute dermal or oral exposure might be possible if non-professionals remove old bait spots or if dried bait spots are ingested orally by infants. Acute secondary exposure is considered acceptable.

Chronic secondary exposure is not expected.

Secondary acute exposure of non-professionals to Imidacloprid GR 0.5 cannot be excluded if these subjects re-enter animal housings after treatment. Although the general public normally has no access to animal housings re-entry cannot be generally excluded, e.g. for horse stables, kennels. Secondary exposure may occur if persons get in touch with treated walls. Acute secondary exposure is considered acceptable if all instruction of use are followed.

Chronic secondary exposure is not expected for the general public.

Safety Measures for Non-Professionals

Specific safety measures are not considered necessary for non-professionals. However, to prevent health particularly of infants to imidacloprid by use of the biocidal product Imidacloprid GL 2.15 it should be clearly labeled that the biocidal product is restricted to professional user, the gel spots has to be placed inaccessible for children and the PCO has to be urged on the technical leaflet to inform parents and other supervising persons accordingly.

To prevent exposure particularly of children to imidacloprid by use of the biocidal product Imidacloprid GR 0.5 it should be placed in small baiting points on dry surfaces. It should not be used on pathways or manures. If necessary the bait should be placed in trays inaccessible to (food producing) animals, pets (and children), and where foodstuffs will not be contaminated. The use of aversive agents is recommended.

2.2.2. Environmental Risk Assessment

2.2.2.1. Fate and distribution in the environment

Biodegradation

Higher tier studies in water/sediment and soil systems show that imidacloprid is neither readily nor inherently biodegradable. In open aquatic systems the a.s. disappears very slowly whereas its disappearance time is significantly shorter when exposed to light. A geometric mean DT_{50} of 185.4 d for the whole water/sediment-system was determined from three water/sediment-studies at 12 °C. In the water phase of two Dutch systems the half-lives amount to 31.6 and 242 days at a temperature of 12 °C. Primary biodegradation of imidacloprid under aerobic conditions in the dark is considered to be slow to negligible.

Mineralisation of imidacloprid is negligible (maximum of 2 % CO_2). Regarding the three relevant parameters - primary and ultimate degradation together with the extent of bound residues (up to 66.3 % after 92 days) in the sediment - imidacloprid must be considered to be persistent in the aquatic systems.

From laboratory studies in soil it can be concluded that imidacloprid is very slowly degraded under aerobic conditions (geometric mean DT_{50} = 295 days at 12 °C). No main metabolites > 10 % have been identified in laboratory soil studies. Imidacloprid shows limited mineralisation rate (maximum 20.3 % after 126 days) and increasing bound residues up to 39.5 % after 366 days (26.9 % after 100 days). Taking into account the inherent difficulty in maintaining the desired optimal microbial activity of soil under laboratory conditions over a longer time period, field studies were performed to provide a more adapted assessment of the degradation kinetics of compounds having relatively long laboratory half-lives. The results are considered suitable for the calculation of the dissipation half-lives. A geometric mean DT_{50} of 135.1 d at 12 °C for the soil compartment was determined from the field studies. Translocation into deeper soil layers was not observed in the long term field studies. The half-life determined under anaerobic conditions lies within the range observed under aerobic conditions.

Abiotic Degradation

Imidacloprid is stable at pH 5 and 7 and shows slight hydrolysis degradation at pH 9. Not any significant hydrolysis products were determined. In conclusion, hydrolysis is not considered to be a significant degradation route for imidacloprid at environmentally relevant temperature and pH.

In pure water imidacloprid is rapidly photolytically degraded with half-lives <1 day in spring and summer. In dependence on degree of latitude and seasonal conditions half-lives between 0.15 and 6.12 days were estimated. However, indirect photodegradation should also contribute to degradation processes in the environment. Five degradation products were quantitatively identified. The degradation process is suggested as stepwise photodegradation with oxygen.

In air imidacloprid will be degraded immediately by indirect photodegradation.

Mobility

Based on the adsorption/desorption studies, imidacloprid could be classified as being moderately mobile in soil. The arithmetic mean of K_{aOC} is 230 mL/g. The value for arithmetic mean of K_{dOC} is 277 mL/g. Imidacloprid was stated to be stable during the adsorption/desorption study. Hence, not any relevant degradation products/metabolites (> 10 % of a.s.) were detected in these studies.

Bioconcentration

Bioconcentration factors for the aquatic (BCF_{fish} = 0.61) and the terrestrial compartment ($BCF_{earthworm}$ = 0.88) were estimated on basis of log P_{ow} = 0.57. The values indicate that imidacloprid has low potential to bioaccumulate in organisms.

2.2.2.2. Effects assessment

Aquatic Compartment

Imidacloprid is of low acute toxicity to fish (96h-LC_{50} = 211 mg/L), daphnids (48h-EC_{50} = 85 mg/L) and green algae (72h-ErC_{50} > 100 mg/L). However, due to the mode of action, the toxicity to aquatic insects is high. In an acute study with the midge *Chironomus riparius*, a 24h-EC_{50} of 0.055 mg/L was found. A long-term laboratory study with *Chironomus riparius* resulted in a 28d-EC_{10} of 0.87 µg/L. Also in a mesocosm study freshwater insects were found to be highly affected by the substance (NOEC = 0.6 µg/L). A $PNEC_{water}$ of 0.174 µg/L was derived from the available studies applying an assessment factor of 5 on the EC10 from the *Chironomus* study.

This PNEC was used for risk assessment during the active substance approval process.

Since approval of the active substance new information on the effect of imidacloprid to mayfly nymphs became available in 2013 (Roessink et al.): The lowest long-term effect values reported in this study are a factor of about 30 below the lowest available effect value in the CAR of 0.87 µg/L (*Chironomus riparius*) and even lower than the $PNEC_{water}$ derived in the CAR (0.174 µg/L, see above). That means that the PNEC derived in the CAR may underestimate the risk caused by imidacloprid. At TM III/2013 it was agreed to derive a new $PNEC_{water}$ under consideration of the new effect data. A proposal for a new $PNEC_{water}$ was prepared by the evaluating competent authority Germany. This new proposal was discussed and agreed at the BPC-WG-ENV IV in September 2014. In the 11th Biocidal Product Committee Meeting, the new $PNEC_{water}$ of 4.8 ng/L was endorsed.

New effect data taken into account for PNEC revision in 2015:

Table 2-4 Acute toxicity to invertebrates

Method / Guide-line	Species	Endpoint / Type of test	Exposure		Results [µg a.i./L]		Remarks	Reference
			design	duration	E/LC_{10}	E/LC_{50}		
No guideline study	*Cloeon dipterum*	immobili-sation	static	96 h	0.1	1.02	Results based on nominal conc. Confirmed by analytical monitoring	Roessink et al. (2013)
No guideline study	*Caenis horaria*	immobili-sation	static	96 h	0.325	1.77	Results based on nominal conc. Confirmed by analytical monitoring	Roessink et al. (2013)
No guideline study	Asellus aquaticus	immobili-sation	static	96 h	24.7	119	Results based on nominal conc. Confirmed by analytical	Roessink et al. (2013)

Method / Guide-line	Species	Endpoint / Type of test	Exposure		Results [ug a.i./L]		Remarks	Reference
			design	duration	E/LC_{10}	E/LC_{50}		
							monitoring	
No guideline study	*Gammarus pulex*	immobili-sation	static	96 h	3.63	18.3	Results based on nominal conc. Confirmed by analytical monitoring, control mortality > 10 %, RI 3	Roessink et al. (2013)
No guideline study	*Chaoborus obscuripes*	immobili-sation	static	96 h	223	284	Results based on nominal conc. Confirmed by analytical monitoring	Roessink et al. (2013)
No guideline study	*Sialis lutaria*	immobili-sation	static	96 h	15.7	50.6	Results based on nominal conc. Confirmed by analytical monitoring	Roessink et al. (2013)
No guideline study	*Plea minutissima*	immobili-sation	static	96 h	30.4	35.9	Results based on nominal conc. Confirmed by analytical monitoring	Roessink et al. (2013)
No guideline study	*Notonecta* spp.	immobili-sation	static	96 h	3.00	18.2	Results based on nominal conc. Confirmed by analytical monitoring	Roessink et al. (2013)
No guideline study	*Micronecta* spp.	immobili-sation	static	96 h	9.41	10.8	Results based on nominal conc. Confirmed by analytical monitoring, control mortality > 10 %, RI 3	Roessink et al. (2013)
No guideline study	Limnephilidae	immobili-sation	static	96 h	0.532	1.79	Results based on nominal conc. Confirmed by analytical	Roessink et al. (2013)

Method / Guide-line	Species	Endpoint / Type of test	Exposure		Results [ug a i./L]		Remarks	Reference
			design	duration	E/LC_{10}	E/LC_{50}		
							monitoring	

Table 2-5 Long-term toxicity to invertebrates

Guideline /Test method	Species	Endpoint / Type of test	Exposure		Results [ug a.i./L]		Remarks	Reference
			design	duration	EC_{10}	EC_{50}		
No guideline study	*Cloeon dipterum*	immobili-sation	semi-static	28 d	0.033	0.123	Results based on nominal concentration confirmed by analytical monitoring	Roessink et al. (2013)
No guideline study	*Caenis horaria*	immobili-sation	semi-static	28 d	0.024	0.126	Results based on nominal concentration confirmed by analytical monitoring	Roessink et al. (2013)
No guideline study	*Asellus aquaticus*	immobili-sation	semi-static	28 d	1.71	11.9	Results based on nominal concentration confirmed by analytical monitoring	Roessink et al. (2013)
No guideline study	*Gammarus pulex*	immobili-sation	semi-static	28 d	2.95	15.4	Results based on nominal concentration confirmed by analytical monitoring	Roessink et al. (2013)
No guideline study	*Chaoborus obscuripes*	immobili-sation	semi-static	28 d	4.57	11.8	Results based on nominal concentration confirmed by analytical monitoring	Roessink et al. (2013)
No guideline study	*Sialis lutaria*	immobili-sation	semi-static	28 d	1.28	3.46	Results based on nominal concentration confirmed by analytical monitoring	Roessink et al. (2013)

No guideline study	*Plea minutissima*	immobili-sation	semi-static	28 d	2.03	6.45	Results based on nominal concentration confirmed by analytical monitoring	Roessink et al. (2013)

Short and long-term toxicity tests were performed with 10 (short-term) and 7 (long-term) aquatic invertebrate species from different taxonomic groups. Test organisms were collected from an uncontaminated aquatic ecosystem. Early larval insect instars were used for the tests. The test organisms were acclimated for at least 3 days to laboratory conditions (18 +/- 2 °C, 12:12 hours light: dark). In the acute tests 5 concentrations and a control were tested using 2-3 replicates with each 10 test animals. Exposure period was 96 h. Endpoints were immobilisation and mortality. In the long-term tests also 5 concentrations and a control were tested using 3 replicates with each 10 test animals. Exposure period was 28 d. Endpoints were immobilisation and mortality. Every week test solution was renewed and the living animals were transferred to the new test vessels. Analytical monitoring was performed for the control and the highest test concentration. Samples were collected at the end of each test week. Samples were analysed by liquid chromatography – tandem mass spectrometry. Measured concentrations were in the range of 84.9 – 97 %, thus proving the test substance to be stable during the exposure phase.

In the acute tests 96h-EC_{50} values for the 10 test species range from 1.02 - 119 µg/L for the endpoint immobilisation. Most sensitive species were *Cloeon dipterum* (1.02 µg/L), *Caenis horaria* (1.77 µg/L) and Limnephilidae (1.79 µg/L). Least sensitive were *Chaoborus obscuripes* (284 µg/L) and *Asellus aquaticus* (119 µg/L). In the long-term tests 28d-EC_{10} values (immobilisation) for the 7 tested species were in the range of 0.024 – 4.57 µg/L. Again the mayflies *Cloeon dipterum* (28d-EC10 = 0.033 µg/L) and *Caenis horaria* (28d-EC10 = 0.024 µg/L) were most sensitive.

Outdoor pond study

Furthermore, an outdoor pond study (Colombo et al, 2013) became available in 2013. In the study imidacloprid was applied 3 times at 0.6 to 40 µg/L. Ephemeroptera were found to be the most sensitive taxa with clear effects at 3.2 µg/L (nominal concentration). As imidacloprid rapidly disappeared from the water phase (DT 50 = 28 h) this study can only be used as supporting information on the sensitivity of different species to imidacloprid.

Derivation of $PNEC_{water}$

The following long-term effect data are available:

Species	**Test duration**	**Effect value**	**Reference**
Oncorhynchus mykiss	91 d	NOEC = 9.02 mg/L	Gries T. 2002
Daphnia magna	21 d	NOEC = 1.8 mg/L	Young B., Blakemore, G.C. 1990

Selenastrum capricornutum	72 h	NOEC < 100 mg/L	Dorgerloh, M. 2000
Chironomus riparius	28 d	EC10 = 0.87 µg/L	Dorgerloh, M., Sommer, H. 2001
Cloeon dipterum	28 d	EC10 = 0.033 µg/L	Roessink et al. 2013
Caenis horaria	**28 d**	**EC10 = 0.024 µg/L**	**Roessink et al. 2013**
Plea minutissima	28 d	EC10 = 2.03 µg/L	Roessink et al. 2013
Sialis lutaria	28 d	EC10 = 1.28 µg/L	Roessink et al. 2013
Chaoborus obscuripes	28 d	LC10 = 1.99 µg/L	Roessink et al. 2013
Gammarus pulex	28 d	EC10 = 2.95 µg/L	Roessink et al. 2013
Asellus aquaticus	28 d	EC10 = 1.71 µg/L	Roessink et al. 2013

The lowest effect value was obtained for the mayfly *Caenis horaria* (28d-EC_{10} = 0.024 µg/L).

Normally, an assessment factor of 10 has to be applied, as long-term tests with species from 3 trophic levels are available. This would result in a $PNEC_{water}$ of 0.0024 µg/L = **2.4 ng/L.**

However, for the derivation of the previous $PNEC_{water}$ an assessment factor of 5 was used justified by the availability of a mesocosm study (Ratte et al., 2003) that shows that Chironomids were among the most sensitive species to imidacloprid. Although no statistical evaluation for Ephemeroptera could be performed in this study, it seems not appropriate to increase the assessment factor to 10 while the effect value for the PNEC derivation is significantly lower than the former effect value. Therefore, an assessment factor of 5 seems sufficiently conservative for the risk assessment. In addition there is an outdoor pond study availabe that show that Ephemeroptera are among the most sensitive taxa (Colombo et al, 2013).

Thus, a reduction of the assessment factor to 5 would be possible as the uncertainty whether the most sensitive species/group is considered for the effects assessment is reduced.

Therefore, it is proposed to apply an assessment factor of 5 on the lowest effect value found for *Caenis horaria*, resulting in a $PNEC_{water}$ of 0.0048 µg/L **= 4.8 ng/L.**

A further possibility would be the derivation of the $PNEC_{water}$ using SSD, as there are 11 long-term effect values available. The exclusion of the data for green algae, as it is an unbound value, results in 10 available long-term effect values. According to the TGD, at least 10 NOECs for different species covering at least 8 taxonomic groups are required to perform a SSD.

SSD considering the above mentioned effect values (except for *Selenastrum* as it is an unbound value, see above) results in a HC_5 of 3.28 ng/L. However the range of the lower and the higher estimate is very high (0.023 ng/L- 54 ng/L) and the resulting curve does not fit the data points appropriately.

Deleting the effect values for *Oncorhynchus mykiss* and *Daphnia magna* from the calculation as these species are by orders less sensitive results in a HC_5 of 21.9 ng/L with a lower estimate 1.29 ng/L and higher estimate 95.3 ng/L. Again the estimation is not very good.

In addition, deleting these 2 values results in only 8 available NOEC values instead of the minimum of 10.

Further literature data are referenced in Smit (2014), from which a HC_5 value of 25 ng/L was derived. This value is in the same order as the lowest available effect value for *Caenis horaria*. An assessment factor of 3 was proposed resulting in an EQS of 8.3 ng/L.

However it was concluded at the BPC-ENV-WG IV/2014 not to follow this approach because not all the referenced data could be reproduced and for some species different effect values were used. In addition, the available data sets do not meet the TGD requirements for performing an SSD, because several taxa are missing.

Furthermore, the use of the lowest effect value of 24 ng/L instead of the HC5 is more conservative and thus more protective.

Conclusion:

A new $PNEC_{water}$ was derived from the lowest available long-term effect value of *Caenis horaria* applying an assessment factor of 5 resulting in:

$PNEC_{water}$ = 0.024 µg/L / 5 = 0.0048 µg/L = 4.8 ng/L

The environmental risk assessment included in the assessment report has not been revised and does therefore not reflect the changes following the revision of the $PNEC_{water}$.

For the metabolite Imidacloprid-desnitro a 28d-EC_{10} of 9.45 mg/L was found in a long-term study with *Chironomus riparius*. This indicates that the metabolite is by orders of magnitude less toxic than the parent substance imidacloprid. Therefore, the derivation of a $PNEC_{water}$ for this metabolite is not required.

Sediment

There are no tests with benthic organisms available in which the test substance was applied to sediment. Therefore, the $PNEC_{sediment}$ is derived from the $PNEC_{water}$ using the equilibrium partitioning method according to the TGD resulting in a $PNEC_{sediment}$ of 0.02695 µg/kg ww.

Inhibition of microbial activity

In a standard activated sludge respiration inhibition test with sludge from domestic sewage treatment plant a NOEC of 5,600 mg/L and a EC_{50} > 10,000 mg/L were determined. From these data a $PNEC_{microorganism}$ of 100 mg/L was derived.

Atmosphere

Imidacloprid is not considered to be used as fumigant. The vapour pressure of imidacloprid is 4.0×10^{-10} Pa indicating that the substance is non-volatile. The Henry's constant is 1.677×10^{-10} Pa × m^3 mol^{-1} at 20 °C, therefore imidacloprid has a low potential of volatilizing from water. The half-life of imidacloprid in the troposphere was estimated to be 2.54 hours considering a global 24-hours mean OH-radical concentration. Based on these results, accumulation of imidacloprid in the air is not to be expected.

Terrestrial Compartment

Tests with earthworms, collembolans, mites, plants and soil microorganisms have been provided. The lowest effect value was obtained in an earthworm reproduction study (56d-NOEC (reproduction) ≥ 0.178 mg/kg dw). A $PNEC_{soil}$ of 15.75 µg/kg ww was derived from the available data by application of an assessment factor of 10.

Imidacloprid was shown to be highly toxic to bees both by oral and contact exposure. The 48 hour LD_{50} for oral toxicity was 0.0037 µg/bee. For contact toxicity a LD_{50} of 0.081 µg/bee was found.

Primary/ Secondary Poisoning

Several studies on the toxicity of imidacloprid to birds were provided. In a reproductive toxicity study the NOEC for the reproductive performance of bobwhite quails exposed to imidacloprid was 126 mg/kg food, equivalent to 9.3 mg/kg bw/d. In a 2 generation study with rats a NOAEL of 20 mg/ kg bw /d equivalent to a NOEC of 250 mg/kg food was obtained.

A $PNEC_{oral,bird}$ of 4.2 mg/kg food and a $PNEC_{oral,mammal}$ of 8.33 mg/kg food was derived. For the assessment of primary poisoning the $PNEC_{oral}$ related to dose are 0.31 mg/kg bw/d for birds and 0.66 mg/kg bw/d for mammals.

2.2.2.3. PBT, vPvB assessment

P-/vP-Criterion:

In an aquatic laboratory study under aerobic conditions a DT_{50} of 331 days (20 °C, in the dark) was measured for imidacloprid. Converted to 12 °C average EU outdoor temperature the half-life amounts to 628 days. For the water phase in two water/sediment systems DT_{50} values of 31.6 and 242 days at 12 °C (corresponding to 14.2 and 108.7 days at 22 °C) were determined. The geometric mean DT_{50} for total system of all water/sediment-studies amounts to 185.4 d at 12 °C (n=3). From four aerobic laboratory degradation studies in soil a geometric mean DT_{50}-value of 295 days at 12 °C (corresponding to 156 days at 20 °C) was derived. Although field studies are in principle not appropriate for assessment of persistency criteria, the results of fourteen field studies in soil representative for northern as well as southern Europe resulted in an averaged DT_{50}-value of 135 days at 12 °C average EU outdoor temperature and 100% field capacity (n=14) and reached maximum half-lives of 184.5 and

337.9 days thus confirming the high persistency of imidacloprid. From these data imidacloprid can definitely be considered to fulfil the P- as well as the vP-criterion.

B-/vB-Criterion:

The calculated bioconcentration factor in fish is 0.61 and the estimation on terrestrial bioconcentration leads to a value of 0.88 for earthworm. Therefore, neither the B- nor the vB-criterion is fulfilled.

T-Criterion:

EC_{10} (equivalent to NOEC) for chironomids (*Chironomus riparius*)~~, the most sensitive aquatic species,~~ is 0.00087 mg/L after 28 days. For the most sensitive species *Caenis horaria* the 28d-NOEC is 0.024 µg/L. Therefore the T criterion is complied.

Even though the P- and the T-criteria are fulfilled, the active substance imidacloprid is neither PBT - nor vP/vB - candidate as the B-criterion is not fulfilled.

2.2.2.4. Exposure assessment

For environmental exposure estimation data about two pilot biocidal products are provided by the applicant. For the life cycle stages "production" and "formulation" no exposure assessment has been performed as the applicant stated no emissions to the environment during production of the a.s. or formulation of both biocidal products. Applicant's statement is deemed to be plausible during active substance evaluation. For the life cycle stage "professional use" different environmental exposure assessments for the two pilot products have been performed regarding the particular intended uses and applications.

The environmental exposures are assessed applying the EU Technical Guidance Document (TGD) on Risk Assessment (2003) and the OECD Emission Scenario Document Number 14 for Insecticides for Stables and Manure Storage Systems (January 2006) for pilot product GR 0.5 as well as the OECD 4th draft Emission Scenario Document of Insecticides, acaricides and products to control other arthropods (PT 18) for household and professional uses (July 2007) for pilot product GL 2.15. Different modelling inputs describing the emission scenarios in currently available ESDs were questioned and finally discussed at the TM I 2010. Based on the facts that firstly not any risk could be ascertained for the b.p. GL 2.15 during environmental exposure assessment applying the OECD 4th draft ESD (2007) and secondly all PECs will significantly decrease by the new estimations, it was decided to renounce a renewed calculation of the PECs. During national product authorisation of biocidal products containing imidacloprid, which will be used to control insecticides, acaricides and other arthropods in households and professional uses, the environmental exposure assessment shall be carried out on the basis of the updated emission scenarios for PT 18.

Imidacloprid GR 0.5:

An exposure estimation has been performed for the life cycle stage "professional use" of the biocidal product indoors in commercial animal housings. The two different application modes are direct granule bait application and paint application.

The product contains the a.s at a concentration of 0.5 % w/w. The application rate of the product for the two recommended ways of application is 1g a.s per 100 m² floor area with a

frequency limited to a maximum of 8 applications per year from April to October with an interval of 21 to 56 days.

Predicted environmental concentrations (PECs) have been estimated for the terrestrial compartment including soil and groundwater and for the aquatic compartment including sewage treatment plant (STP), surface water, and sediment. The estimation of PECs is based on two emission models:

- soil, due to manure applications carried out according to maximum nitrogen or phosphorus immission limits (Europe), afterwards to ground water and surface water and

- waste water, which is subsequently treated by a sewage treatment plant, leading to releases to soil (via sludge deposition), surface water, sediment, and ground (pore) water.

The calculations of the releases of imidacloprid during manure and slurry applications have been accomplished for all animal categories and subcategories according to OECD ESD No. 14. A detailed description for the emission scenario for insecticidal application in animal housings including also the input and output values is given in chapter II-8 (GR 0.5). For the soil compartment the calculation of PEC assumes application of manure/slurry onto agricultural soils (arable land and grassland). Different approaches have been calculated:

- An unrealistic worst case situation without consideration of degradation of a.s. in soil;

- A more realistic situation, taking into account the degradation of a.s. in soil and carry over of a.s. residues due to successive manure application;

- Calculation of time-weighted average concentrations in soil.

The result of the time-weighted average approach is a time depending curve for the worst-case estimates of soil exposure. Although this approach is favoured by the applicant, it is concluded to chose the more realistic approach of taking into account the degradation of a.s. in soil during subsequent manure applications on agricultural soil. The PEC soil values calculated with this approach were used for further calculations of PEC groundwater and surface water in consideration of both Nitrogen and Phosphate limited immission.∗ Concerning releases via manure to soil, the maximum PEC values in arable and grassland soil for Nitrogen limited immission are associated with slurry application from veal calves. In the case of Phosphate limited immission maximum values are observed by slurry application of dairy cattle (in grazing season). For both, PEC groundwater and surface water estimation, a refinement step of the first approach (pore water calculation model according to EU TGD (2003)) was accomplished using EU FOCUS scenarios based transport and fate simulation

∗ The maximum N immission standards used for PEC estimation amount to 280 kg N per ha and year in case of grassland and 250 kg N per ha and year in case of arable land. As the environmental assessment of the a.s. has already been finalised the decisions made at the Technical Meeting I / 2008 to use the lower N immission limits according to the EU Nitrate Directive (91/676/EC) could not be taken into account. As no risks for the environment were identified for the related entry pathway via manure application when using the higher N immission limits a re-calculation did not seem to be necessary.

tools. The predicted concentrations in groundwater were significantly below the threshold criteria of 0.1 μg.L^{-1} for all scenarios and for both grassland and arable situations. Indirect release to surface water via the pathway manure/slurry – agricultural soil is also acceptable. Emission to air is negligible.

Particularly during the cleaning procedure of poultry housing systems with high-pressure cleaning equipment a fraction of the applied biocidal product can be released to waste water that is discharged to a STP. These release fractions to waste water were calculated according to recommendations in the OECD ESD No. 14. Hence, the PECs for the environmental compartments were carried out, assuming that only one farm releases liquid wastes into the sewer at one day. The PEC estimation is based on the worst case assumption, that untreated waste water is released to STP and that the influent concentration of the a.s. is representative for the PEC for microorganisms. PEC_{STP}, $PEC_{surface\ water,}$ and $PEC_{sediment}$ were calculated for the animal categories-subcategories 8, 11, 17, and 18 according to equation 48 and 50, EU TGD (2003).

For the terrestrial compartment the PECs for soil and groundwater were calculated according to equation 66 and 68, EU TGD (2003) after sewage sludge application.

Imidacloprid GL 2.15:

The estimation of releases of the a.s. in the life cycle stage "professional use" of the biocidal product GL 2.15 comprises the exposure estimation for the application steps by professional operators indoor and cleaning steps of the product GL 2.15.

The application of the b.p. as ready-to-use insecticidal gel bait is envisaged for the control of cockroach adults and nymphs for public hygiene, nuisance control, and food storage practice. Due to the proposed professional indoor use of the product the application mode is described by dispensing spots to surfaces in target areas in private houses and larger buildings. For the particular application it is further divided in:

- Domestic households (kitchen and bathroom for private houses)

- Commercial facilities and public facilities for larger buildings

Regarding the cleaning step, taking place at the same day as the application the cleaning methods wet and dry cleaning with emission to waste water or wastes are supposed.

It is not expected that residues of the product could be removed by dry cleaning methods. Thus, the exposure pathway of solid waste to municipal landfill is negligible.

The wet room cleaning process is relevant for the environmental risk assessment. Due to the fact and according to the frame label, that the b.p. is placed in areas difficult to access, the cleaning efficacy is low. The emission rates to waste water for severe treatments (not for normal treatment), taking into account the fate and behaviour of the a.s., were selected as the worst-case for the exposure assessment.

Assuming that residues of the a.s. removed through wet cleaning may be emitted to waste water, the STP is considered as the primary receiving compartment for the a.s. (OECD 4th draft ESD). Hence, PECs have been estimated for the terrestrial compartment including soil

and groundwater and for the aquatic compartment including STP, surface water, and sediment.

Regarding the environmental compartments, the water releases from households, larger buildings and hospital were summed up to perform a cumulative assessment.

2.2.2.5. Risk characterisation

For imidacloprid the applicant provided data for two pilot products used in different application areas and with different application rates. For the production and the formulation process no environmental exposure assessment and thus no risk characterisation was carried out. Within the scope of the product authorisation it has to be checked again whether the production and formulation processes as described by the applicant still apply.

Aquatic Compartment*

Two different emission pathways were identified regarding the aquatic compartment:

- Emission via wastewater to STP and subsequently to surface water and sediment (indoor application in animal housings / indoor application in domestic, commercial, and industrial areas with wet cleaning of treated surfaces)

- Emission via manure application to soil leading to releases to surface water and sediment (indoor application in animal housings)

Regarding the emission pathway via waste water to STP and subsequently to surface water and sediment a risk for surface water and sediment was identified from the use of Imidacloprid in poultry stables with a wastewater discharge to sewage treatment plants (product for indoor application in animal housings). After consultation with the applicant it was decided to include a label restriction that prevents the use of products containing imidacloprid in animal housings where emission to a STP cannot be prevented. Consequently, direct releases from animal housings to surface water have to be avoided as well.

Considering the use of imidacloprid in domestic, commercial, and industrial areas with wet cleaning of treated surfaces no risk for the aquatic compartment including the STP was identified.

In summary, there is no risk for the aquatic compartment related to the use of imidacloprid when implementing the necessary restriction for poultry stables as mentioned above.

Terrestrial Compartment including Groundwater

Two different emission pathways were identified regarding the terrestrial compartment:

- Emission via wastewater to STP leading to releases to soil via sewage sludge deposition and subsequently, to groundwater (indoor application in animal housings / indoor

* The here presented risk assessment for the aquatic compartment has not been revised as consequence of the new PNECwater derived in 2015.

application in domestic, commercial, and industrial areas with wet cleaning of treated surfaces)

- Emission via manure application leading to releases to soil and subsequently, to groundwater (indoor application in animal housings)

From the use of imidacloprid for both applications (in animal housings as well as in domestic, commercial, and industrial areas) with releases to soil from sewage sludge application no risks for the terrestrial compartment including groundwater were identified. For the main entry pathway into the terrestrial environment via manure application, a refined risk estimation leads to PEC/PNEC ratios below the trigger value of 1 for soil and groundwater, respectively.

In summary, no risk for the terrestrial compartment including groundwater is identified for the use of imidacloprid in animal housings and domestic, commercial, and industrial areas.

Primary/ Secondary Poisoning

Direct exposure of birds and mammals to Imidacloprid GR 0.5 can be supposed when the b.p. is applied as direct granule baits, whereat the product is placed in dishes or fly bait stations. Both a qualitative acute and a quantitative long-term risk assessment for birds and mammals were performed, Both scenarios show that a risk to birds and mammals cannot totally be excluded. As the assessment was highly conservative a re-evaluation on the basis of new proper information is recommended during national product authorisation. A further acceptance/avoidance study on a relevant species of small birds could be performed with exposure similar to the proposed use (i.e. granule bait application) and may indicate whether the proposed use may lead to adverse effects on birds and mammals (pets). Thereafter appropriate mitigation measures should be proposed. If these informations are not delivered, the following methods should be taken to minimize the risk:

Upon treatment, the stables should as much as possible be made inaccessible to birds, by closing doors and windows, or by using nettings or similar devices to keep birds outside.

Granules should preferably be placed using specifically designed bait boxes, inaccessible to birds

It is assumed that the precautionary measures as formulated above for birds are also sufficient to protect mammals (pets) as well.

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

Article 10 of the Biocides Directive 98/8/EC addresses the inclusion of an active substance in the Annexes I, IA or IB. For the decision of inclusion or non-inclusion, it has to be examined if the criteria of article 10 (1) are fulfilled.

The available data on analytical methods for determination of residues are considered sufficient to support an Annex I inclusion of imidacloprid. Concerning analytical methods all studies required by Directive 98/8/EC are available. Measurable residues in food or feed from the use of imidacloprid in PT 18 biocidal products are not expected. No MRLs specific to biocidal product uses are necessary.

The data on the active substance and the products have demonstrated sufficient efficacy of imidacloprid against insects (house flies, cockroaches) for inclusion onto Annex I to be recommended.

Even though no resistance against this type of insecticides has occurred as yet, resistance is recognized as a potential problem and the applicant has proposed an adequate resistance management strategy. The German Competent Authority therefore suggests that the issue should be further addressed at product authorisation stage.

The effects on human health have been assessed, in accordance with the provisions of Article 10(1) of Directive 98/8/EC, for the uses proposed by the applicant.

Imidacloprid is of moderate acute toxicity. With regard to acute local effects, imidacloprid is neither irritant to skin nor eyes. The evaluation of the active substance has indicated that imidacloprid has no carcinogenic and genotoxic potential and is not sensitising. No substance-related fertility or developmental impairment was noted in the reproduction toxicity studies.

Acceptable exposure levels for acute, medium- and long-term exposure could be derived for imidacloprid. Therefore, no risk to human health could be anticipated for the active substance. All studies required by Directive 98/8/EC are available or statements for non submission have been accepted.

The biocidal product Imidacloprid GL 2.15 contains 2.15 % imidacloprid and Imidacloprid GR 0.5 contains 0.5 % of the active substance and beside the proposal for classification of imidacloprid with Xn, R 22 (Harmful if swallowed), no further hazards with regard to human health could be identified and no further classification and labelling of the products according to Directive 1999/45/EC are required with regard to toxicity data. Since contact of the general public to the biocidal products cannot be excluded and for preventive health care the biocidal products should be labelled with the following S-phrases:

S2 Keep out of reach of children.

S13 Keep away from food, drink and animal feeding stuffs.

Based on the available data for the two pilot products and the results of the risk characterisation no risks for the environment were identified (with the exception of animal housings with discharges to sewer or direct releases to surface water).

3.2. Decision regarding Inclusion in Annex I

The active substance imidacloprid shall be included in Annex I to Directive 98/8/EC as an active substance for use in product-type 18 (Insecticides, Acaricides and Products to control other Arthropods), subject to the following specific provisions:

1. The active substance imidacloprid, as manufactured, shall have a minimum purity of 97 % w/w.

2. Only the E-isomer is present in the active substance imidacloprid, with the associated CAS 138261-41-3.

3. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to environmental compartments and populations that have not been representatively addressed in the Union level risk assessment.

4. Products may not be authorised for uses in animal housings where emission to a STP or direct emission to surface water cannot be prevented, unless information has 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.

5. Authorisations shall be subject to appropriate risk mitigation measures. In particular, preventive appropriate risk mitigation measures shall be taken for infants and children."

6. For products containing imidacloprid that may lead to residues in food or feed, Member States shall verify the need to set new and/or amended existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 and/or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.

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

So far no environmental exposure assessment and no risk characterisation were carried out for the life cycle stages production of the a.s. and the formulation of the b.p. Within the scope of the product authorisation it has to be checked whether the production and formulation processes as described by the applicant still apply.

It has to be checked during product authorisation if the products additionally contain active substances used as attractants.

During national product authorisation of biocidal products containing imidacloprid, which will be used to control insecticides, acaricides and other arthropods in households and professional uses, the environmental exposure assessment shall be carried out on the basis of the updated emission scenarios for PT 18 considering the modified modelling inputs finally discussed on the TM I 2010.

Toxicity to bees might require labelling of products for outdoor use.

The harmonisation of application of FOCUS groundwater model PEARL is still under discussion at TM level. The results of the discussion concerning the FOCUS groundwater models and input parameters should be considered during product authorisation of imidacloprid containing products, if necessary.

In view of the potential for the development of resistance against imidacloprid it is suggested that the issue should be further addressed at product authorisation stage.

To minimize the risk of primary poisoning to birds and mammals, the following precautionary measurements should be applied for the application of fly bait granules:

- Upon treatment, the stables should as much as possible be made inaccessible to birds, by closing doors and windows, or by using nettings or similar devices to keep birds outside.

- Granules should preferably be placed using specifically designed bait boxes, inaccessible to birds

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

Currently, no test about the elimination of the a.s. in sewage treatment plants (STP) is available. The environmental exposure assessment was performed without considering elimination in STP. Thus, a risk for surface water and sediment from the use of imidacloprid containing products in poultry stables with a wastewater discharge to sewage treatment plants was identified. Consequently, imidacloprid must not be applied in animal housings with an effluent to a sewer system or a direct release to surface water.

Products may not be authorised for uses in animal housings where emission to a STP or direct emission to surface water cannot be prevented, unless information 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.

To refine the environmental exposure assessment, i.e. to demonstrate a potential elimination of imidacloprid in the STP, it is suggested to perform the following study at the stage of product authorisation:

- Aerobic sewage treatment plant simulation study (OECD 303 A).

The following tests under GLP are required for the stage of product authorisation referring to the Physical and Chemical Properties of the biocidal product Imidacloprid GL 2.15:

-3.5 Acidity/Alkalinity

The submitted test is not acceptable. A new test conducted under GLP conditions is required for the stage of product authorisation.

Results: participant gave a range of pH 4.4 – 5.0. The correct value is pH 4.6.

- 3.6 Relative density
  The submitted test is not acceptable. A new test conducted under GLP conditions is required for the stage of product authorisation. If the test is technical not feasible a scientific justification has to be submitted.
  The technical feasibility of such a test for this product will be addressed for national re-registration.

- 3.7 Storage stability – stability and shelf life (Reactivity towards container material)
  Demand for detailed information on suitable packaging materials for the stage of product authorisation.

- 3.8 Technical characteristics
  No test is available because the product is a Gel. A test conducted under GLP conditions is required for the stage of product authorisation.

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 imidacloprid in Annex I to the Directive.

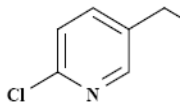
Appendix I: List of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Further Information, and Proposed Classification and Labelling

Active substance (ISO Common Name)	Imidacloprid
Function (*e.g.* fungicide)	Insecticide

Rapporteur Member State	Germany

Identity (Annex IIA, point II.)

Chemical name (IUPAC)	(2*E*)-1-[(6-chloropyridin-3-yl)methyl]-N-nitroimidazolidin-2-imine
Chemical name (CA)	2-imidazolidinimine, 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-, (2*E*)-
CAS-No	138261-41-3
EC No	ELINCS: 428-040-8
Other substance No	CIPAC: 582 Manufacturer's development code number NTN 33893
Minimum purity of the active substance as manufactured (g/kg or g/l)	970 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	See confidential data and information folder under Doc IIIA for impurities
Molecular formula	$C_9H_{10}ClN_5O_2$
Molecular mass	255.7 g/mol
Structural formula	 only E-isomer

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

Melting point (state purity)	144 °C (99.9 %)
Boiling point (state purity)	not applicable (decomposition)
Temperature of decomposition	>200 °C
Appearance (state purity)	Colorless crystal (99.8 %) to cream colored powder (98.5 %)
Relative density (state purity)	$D^{23}_4 = 1.54$
Surface tension	72.20 mN/m at 20 °C (c = 458.91 mg/L)
Vapour pressure (in Pa, state temperature)	4×10^{-10} Pa at 20 °C 9×10^{-10} Pa at 25 °C
Henry's law constant (Pa m^3 mol^{-1})	1.7×10^{-10} Pa m^3 mol^{-1} (20 °C)
Solubility in water (g/l or mg/l, state temperature)	pH5: independent of pH
	pH9: independent of pH
	pH7: 613 mg/L in demineralised water at 20 °C
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	at 20 °C **Solvent** **Solubility** *n*-Hexane < 100 mg/L Toluene 690 mg/L Dichloromethane 67000 mg/L 2-Propanol 2300 mg/L Acetone 50000 mg/L Ethylacetate 6700 mg/L Acetonitrile 50000 mg/L DMSO >200000 mg/L DMF >200000 mg/L
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	no solvents used in biocidal products
Partition coefficient (log P_{OW}) (state temperature)	pH 5:independent of pH
	pH 9:independent of pH
	pH 7: log $P_{O/W}$ = 0.57 (demin. water) at 21 °C
Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	pH 5: stable at 25 °C
	pH 7: stable at 25 °C
	pH 9: DT50 approx. 1 year at 25 °C DT50 2.75 years (calculation to EU outdoor Temperature at 12 °C)
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	It is not possible to specify a pK value of the test substance in pure aqueous system.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	**λ_{max} [nm]** **ε** 212 13346 270 22054
Photostability (DT_{50}) (aqueous, sunlight, state pH) (point VII.7.6.2.2)	pH 7: 30 - 50° latitude (calculation) DT50 experimental: 57 min, DT50 calculated: 0.2 - 1.6 days (spring, summer) 1.4 - 16 days (fall, winter)
Quantum yield of direct phototransformation in water at Σ > 290 nm (point VII.7.6.2.2)	Φ = 0.0142 (highly pure water, 25 °C)

Flammability	Not highly flammable
Explosive properties	Not explosive

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

with regard to physical/chemical data	none
with regard to toxicological data	Xn, R22*
with regard to fate and behaviour data	none
with regard to ecotoxicological data	N, R50, R53

* The question of whether the LD_{50} in mice (which would result in a more severe classification, i. e. R25) should be used for C & L regarding acute toxicity has been discussed at TMII09. In the view of the RMS, a uniform basis should be selected when classifying/labelling chemical substances, i.e. acute toxicity should always be classified/labelled based on rat studies, when available. While no consensus between MS could be reached, it was nevertheless decided by TMII09, that both LD_{50} values should be given, but the question of C & L of Imidacloprid for acute toxicity should be left to the RAC at EChA.

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	HPLC
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	HPLC

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	residue definition: imidacloprid LC-MS/MS LOQ: 0.005 mg/kg HPLC-UV [redacted] LOQ: 0.01 mg/kg
Air (principle of method and LOQ) (Annex IIA, point 4.2)	residue definition: imidacloprid HPLC-UV confirmation by [redacted] LOQ: 5 µg/m³
Water (principle of method and LOQ) (Annex IIA, point 4.2)	residue definition: imidacloprid HPLC-UV [redacted] LOQ: 0.03 µg/L (for drinking and surface water) LC-MS/MS LOQ: 0.1 µg/L (for surface water) HPLC-UV [redacted] LOQ: 0.05 µg/L (for drinking water)
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	not necessary
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	not necessary
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	not necessary

Chapter 3: Impact on Human Health

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

Rate and extent of oral absorption:	Rapid and extensive: > 90 % based on urinary (56 %) and biliary (35 %) excretion
Rate and extent of dermal absorption:	0.3 % for concentrate and ca. 8 % in dilution, based on human *in vitro* study with a formulation of imidacloprid in oil
Distribution:	Widely distributed, sum of residues in tissue after 48 h < 1 % of dose, highest in liver, kidney, lung, and skin
Potential for accumulation:	No potential for accumulation
Rate and extent of excretion:	> 95 % within 48 h, mainly via urine
Metabolism	Extensively metabolised (at least 16 different metabolites), ca. 10-15 % parent excreted unchanged *Major metabolic pathways*: oxidative cleavage between methylene group and imidazolidine moiety; hydroxylation of imidazolidine ring in position 4 or 5 and subsequent elimination to yield a C-C double bond
Toxicologically significant metabolite	No specific concern, but information given only for some metabolites (cf. "Other Studies" section)

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral	380-650 mg/kg bw **R22***
Mouse LD_{50} oral	131/168 mg/kg bw (M/F)
Rat LD_{50} dermal	> 5000 mg/kg bw
Rat LC_{50} inhalation	Aerosol > 0.069 mg/L, Dust > 5.323 mg/L (4 h, nose-only, max. attainable concentrations.)
Skin irritation	Non-irritant
Eye irritation	Non-irritant
Skin sensitization (test method used and result)	Non-sensitising (M+K)

Repeated dose toxicity (Annex IIA, point 6.3)

Species/target/critical effect	Rat: Decreased body weight gain; hepatotoxicity, thyroid mineralisation (long-term) Dog: Decreased body weight gain; tremor (at higher doses) Mouse: Hepatotoxicity, decreased body weight gain
Relevant medium-term oral NOAEL	90-d neurotoxicity rat: 9.3 mg/kg bw/d 90-d dog: 23.5 mg/kg bw/d

* The question of whether the LD_{50} in mice (which would result in a more severe classification, i. e. R25) should be used for C & L regarding acute toxicity has been discussed at TMII09. In the view of the RMS, a uniform basis should be selected when classifying/labelling chemical substances, i.e. acute toxicity should always be classified/labelled based on rat studies, when available. While no consensus between MS could be reached, it was nevertheless decided by TMII09, that both LD_{50} values should be given, but the question of C & L of Imidacloprid for acute toxicity should be left to the RAC at EChA.

Relevant long-term oral NOAEL	2-yr rat: 5.7 mg/kg bw/d 1-yr dog: 41 mg/kg bw/d 2-yr mouse: 208 mg/kg bw/d
Relevant dermal NOAEL	21-d rabbit: 1000 mg/kg bw/d
Relevant inhalation NOAEL	28-d rat: 0.03 mg/L air (8.2 mg/kg bw/d)

Genotoxicity (Annex IIA, point 6.6)	Imidacloprid is unlikely to be genotoxic in humans

Carcinogenicity (Annex IIA, point 6.4)

Species/type of tumour	None
lowest dose with tumours	Not applicable

Reproductive toxicity (Annex IIA, point 6.8)

Species/ Reproduction target/critical effect	<u>Parental</u> Decreased food consumption and body weight gain <u>Reproduction</u> No effect <u>Offspring</u> Decreased body weight gain and birth weight
Relevant parental NOAEL	20 mg/kg bw/d
Relevant reproductive NOAEL	50 mg/kg bw/d
Relevant offspring NOAEL	20 mg/kg bw/d

Developmental toxicity (Annex IIA, point 6.8)

Species/ Developmental target / critical effect	<u>Maternal</u> Decreased body weight gain, reduced food consumption (rat) <u>Foetuses</u> Rat: No adverse effects up to highest dose tested Rabbit: Decreased body weight, ret. ossification
Relevant maternal NOAEL	Rat: 30 mg/kg bw/d Rabbit: 24 mg/kg bw/d
Relevant developmental NOAEL	Rat: 100 mg/kg bw/d Rabbit: 24 mg/kg bw/d

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

Species/ target/critical effect	Tremor, decreased motor/locomotor activity No evidence of developmental neurotoxicity
Relevant NOAEL for neurotoxicity	Acute, rat: 42 mg/kg bw/d 13-wk, rat: 196 mg/kg bw/d (highest dose level tested) Dev., rat: 30 mg/kg bw/d
Relevant developmental NOAEL	Not applicable

Other toxicological studies (Annex IIIA, VI/XI)

Studies on metabolites:	<u>Imidacloprid-nitrosimine</u> LD_{50} (rat) = 1980/3560 mg/kg bw (M/F), LD_{50}(mouse) = 200-300 mg/kg bw 12-wk rat: NOAEL = 13 mg/kg bw/d based on haematology/clinical chemistry findings Standard battery of in vitro and in vivo genotoxicity tests: unlikely to be genotoxic <u>Imidacloprid-urea</u> LD_{50} = 4080/1820 mg/kg bw (M/F), neg. in the Ames test <u>Imidacloprid-desnitro</u> LD_{50} = 300/280 mg/kg/bw (M/F), neg. in the Ames test <u>Imidacloprid-olefine</u> LD_{50} = 3500/1100 mg/kg bw (M/F), neg. in the Ames test

Medical data (Annex IIA, point 6.9)

Medical surveillance data on manufacturing plant personnel	No adverse health effects reported.
Intoxication case reports	Ingestion of 200 mg in 4-yr old child without adverse effects; two suicidal fatalities reported in a second case report

Summary (Annex IIA, point 6.10)	Value	Study	Safety factor
AEL_{acute}*	0.4 mg/kg bw	Rat, acute neurotoxicity, supported by dog, 28-d (acute effects)	100
$AEL_{medium-term}$*	0.2 mg/kg bw/d	Rat, 2-gen., supported by dog, 90-d and rabbit, develop-mental)	100
$AEL_{long-term}$*	0.06 mg/kg bw/d	Rat, 2-yr	100
Drinking water limit	Not allocated		

* AEL: Systemic (= Internal) Acceptable Exposure Level

Acceptable exposure scenarios (including method of calculation)

Professional users		
Production of active substance:	Not assessed by the rapporteur under the requirements of the BPD	
Formulation of biocidal product	Not assessed by the rapporteur under the requirements of the BPD	
Intended uses: Application of Imidacloprid granules	Ready for use granules with 0.5 % active substance	
Mixing & loading: No mixing & loading, ready for use product **Application:** Placing 2 kg b.p. in dishes in a 1000 m^2 stable floor. Form of exposure: dust of granules (0.5 % a.s.) Duration: 120 min Frequency: 8 days per year (farmer), 90 days per year (pest control operator) Model: TNsG Human Exposure Model 5 Mixing & loading (Part 2, p.137) **Post-application:** collection of 1 kg b.p. Form of exposure: dust of granules (0.5 % a.s.) Duration: 120 min. Frequency: 8 days per year (farmer), 90 days per year (pest control operator) Model: TNsG Human Exposure Model 5 Mixing & loading (Part 2, p.137)	Potential inhalation exposure (all phases): Potential dermal exposure (all phases):	0.0006 mg/person/day The respective air concentration (mg/m^3) is not given and cannot be calculated because essential parameters, such as sampling time etc are missing. The resulting value in mg/person/day is therefore taken forward for risk assessment concerning inhalation. 0.049 mg/person/day
Intended uses: Brushing of diluted Imidacloprid granules	Granules with 0.5 % active substance diluted with water to 0.33 % a.s. bait paste	

Mixing & loading: Preparation of bait paste, filling of granules and dilution with water, stirring Form of exposure: dust of granules (0.5 % a.s.) Duration: 15 min Frequency: 8 days per year (farmer), 90 days per year (pest control operator) Model: TNsG Human Exposure Model 5 Mixing & loading (Part 2, p.137) **Application:** Brushing of bait paste Form of exposure: liquid (0.33 % a.s.) Duration: 120 min Frequency: 8 days per year (farmer), 90 days per year (pest control operator) Model: Model 3 (Consumer product painting) TNsG Human Exposure (Part 2, p. 202) **Post-application:** Cleaning of application equipment Form of exposure: liquid (0.33 % a.s.) Duration: 5 min. Frequency: 8 days per year (farmer), 90 days per year (pest control operator) Model: Cleaning of a brush is not covered by any of the proposed models in the TNsG Human Exposure. Calculations are based on an approach by the Competent Authority of Finland used in the CA Report for Tolylfluanid (PT 8).	Potential inhalation exposure (all phases) Potential dermal exposure (all phases)	0.0004 mg/person/day 11.1 mg/person/day
Intended uses: Application of Imidacloprid gel	Ready for use gel with 2.15 % active substance	
Mixing & loading: No mixing & loading, ready for use product **Application:** Spot application using a suitable gel applicator Form of exposure: liquid (2.15 % a.s.) Duration: 30 min per site, 5 sites per day Frequency: 5 opening and 5 sealing operations of cartridge per day Model (dermal): Expert judgment assuming the transfer of 0.5 cm gel string to the hand per opening or sealing **Post-application:** Handling of empty cartridge Form of exposure: liquid (2.15 % a.s.) Duration: 5 min. Frequency: 1 event per day Model (dermal): Expert judgment assuming the transfer of 0.5 cm gel string to the hand per event	Potential inhalation exposure (all phases) Potential dermal exposure (all phases)	Negligible 1.1 mg/person/day
Secondary exposure	Typical work in animal housing (e.g cleaning)	
Typical work in animal housing Form of exposure: Active substance stick to dust Model (dermal): Expert judgment based on the	Potential inhalation exposure Potential dermal	Negligible 0.42 mg/person/day

calculation that 10 mg a.s./m^2 is used and that the palms of both hands (420 cm^2) are exposed	exposure	
Non-professional users	Non-professional use is not intended.	
Indirect exposure as a result of use	<u>Imidacloprid GL 2.15:</u> Acute exposure (dermal absorption 8%) to adults removing old baits, basing on simplified assumptions: 0.0086 mg/kg bw (2.2% of AEL-S_{acute}) Acute exposure (oral, dermal) exposure to children by uptake of dried baits, basing on simplified worst case assumptions: oral: 0.215 mg/kg bw (54% of AEL-S_{acute}) <u>Imidacloprid GR 0.5:</u> Acute exposure (dermal absorption: 8%) to adults by contact to treated walls, basing on simplified assumptions: 0.000224 mg/kg bw/d (0.1% of AEL-S_{acute}) Acute exposure (dermal, oral) to children by contact to treated walls, basing on simplified worst case assumptions: oral: 0.005333 mg imidacloprid/kg bw (1.3% of AEL-S_{acute}) dermal: 0.000427 mg imidacloprid/kg bw (0.1% of AEL-S_{acute}) total: 0.00576 mg imidacloprid/kg bw (1.4% of AEL-S_{acute})	

Chapter 4: Fate and Behaviour in the Environment

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 5 (298 K): stable
	pH 7 (298 K): stable
	pH 9 (298 K): DT50: 355 days (285 K): DT50: 2.75 years (calculation to EU outdoor temperature)
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Half-life: 57 min (experimental) GC-solar: 0.15 to 0.32 d (spring and summer); 0.25 - 6.12 d (fall and winter) as function of latitude Frank&Kloeppfer: 0.2 - 1.6 d (spring and summer); 1.4 - 16 d (fall) Metabolites (results are an aggregate of 3 studies): - 17.2 % imidacloprid guanidine eq. NTN33893-desnitro eq. NTN38014; - 9.8 % 1-[(6-chloro-3-pyridinyl)methyl]-2-imidazolidone eq. NTN33893-urea eq. NTN33519 - 12.6 % NTN33893-desnitro-olefine - 15 % 6-chloropicolyl-guanidine eq. NTN 33893-ring-open guanidine and 6-chloro-nicotinic acid
Readily biodegradable (yes/no)	no
Biodegradation in seawater	Not relevant for intended use
Non-extractable residues	Aerobic at 22 ± 1°C in the dark, 30 d: 8.2 % after 30 days, max. 9.7 % (day 21) Aerobic at 22 ± 1°C in the dark, 92 d, two systems: a) 66.3 % after 92 days (max.) b) 15.4 % after 92 days (max.) Anaerobic at 22 ± 1°C in the dark, 358 d: 16.0 % after 120 days, max. 22.6 % (day 358)
Distribution in water / sediment systems (active substance)	Aerobic at 22 ± 1°C in the dark, 30 d, silty clay : Water: max. 90.7 % (day 0); decline to 64 % (day 30) Sediment: max. 23.5 % (day 7); 20.4 % after 30 days DT_{50} (dissipation) = > 30 d (water) DT_{50} = 129 d (entire system) Converted to average EU outdoor temperature of 12°C: DT_{50} (dissipation, 12°C) = > 67 d (water) DT_{50} (12°C) = 287 d (entire system) Mineralisation: 0.7 % after 30d (max.) Aerobic at 22 ± 1°C in the dark, 92 d, two systems (a, loamy silt, b loamy sand): Distribution Water: a) max. 78.5 % (day 0); decline to 5.1 % (day 92)

	b) max. 90.3 % (day 0); decline to 52.8 % (day 92) Sediment: a) max. 31.9 % (day 14); 6.6 % after 92 days b) max. 10.3 % (day 60); 8.9 % after 92 days DT_{50} a) DT_{50} (dissipation) = 14.2 d (water) DT_{50} (dissipation) = 35.7 d (sediment) DT_{50} = 30 d (entire system) b) DT_{50} (dissipation) = 108.7 d (water) DT_{50} = 149.7 d (entire system) Converted to average EU outdoor temperature of 12°C: a) DT_{50} (dissipation, 12°C) = > 31.6 d (water) DT_{50} (dissipation, 12°C) = 79.4 d (sediment) DT_{50} (12°C) = 66.8 d (entire system) b) DT_{50} (dissipation, 12°C) = 242 d (water) DT_{50} (12°C) = 333.2 d (entire system) Mineralisation: a) 1.4 % after 92 days (max.) b) 2.0 % after 92 days (max.) **Geometric mean DT_{50} (n=3):** **entire system** = **83.3 days** at 22°C, corresponding to 185.4 days at 12°C average EU outdoor temperature <u>Anaerobic at 22 ± 1°C in the dark, 358 d:, silt loam</u> Distribution Water: max. 93.4 % (day 0); decline to 3 % (day 120); 0.1 % after 358 days Sediment: max. 18.7 % (day 14); 1.7 % after 120 days; 0.1 % after 358 days DT_{50} DT_{50} (dissipation) = not determined in water DT_{50} = 36 d (entire system) Converted to average EU outdoor temperature of 12°C: DT_{50} (12°C) = 80 d (entire system) Mineralisation < 0.1 % after 120 days; max. 0.2 % after 358 days <u>Aerobic at 20°C in the dark, 366 d, open water system:</u> Water: max. 97 % (day 0); decline to 65.4 and 47.8 % (days 91 and 366) DT_{50} (dissipation) = 331 d (water) Converted to average EU outdoor temperature of 12°C: DT_{50} (dissipation, 12°C) = 628 d (water) Mineralisation: 0.7 % and 1.0 % after 92 days, max. 4.3 % after 366 days
Distribution in water / sediment systems (metabolites)	<u>Aerobic at 22 ± 1°C in the dark, 30 d:</u> No metabolites > 10 % detected, four minor metabolites (< 3 %) identified <u>Aerobic at 22 ± 1°C in the dark, 92 d, two systems (a, b):</u>

	a) NTN33893-desnitro: 12.3% total system (water 6.0% and sediment 6.3%) after 92 days b) No metabolites > 10 % detected, three minor metabolites identified Anaerobic at 22 ± 1°C in the dark, 358 d: NTN33893-desnitro in water and sediment phase Water: max. 20% after 60 days Sediment: max. 51.5% after 249 days Total system: max. 66% after 249 days Aerobic at 20°C in the dark, 366 d, open water system: NTN33893-desnitro in water phase Water: 14.8 % after 92 days, max. 26.4 % after 274 days, 19.2 % after 366 days

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

Mineralization (aerobic)	After 100 days: sandy loam (a): 2.7% Silt soil: 6.4% loamy sand 10.0% sandy loam (b): 16.6% after 91 days, 20.3% after 126 days, sandy loam (a): 4.9% after 366 days
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): 106 – 193 days (n=4) Geometric mean: 156 days (n=4) Soil type DT_{50} kinetic Loamy sand 154 1st oder silt soil 193 1st oder sandy loam 186 1st oder sandy loam 106 1st oder **Standardised to FOCUS kinetics (20ºC, 100% FC): geo, mean: 117.7 days (n=4)** Converted to average EU outdoor temperature of **12ºC:** **DT_{50}: 201-366 days, geo. mean: 295 days (n=4)** DT_{90lab} (20°C, aerobic): n/a DT_{50lab} (10°C, aerobic): 233-425 days (n=4) Geometric mean: 343 days (n=4)
	DT_{50lab} (20°C, anaerobic): not determined
	degradation in the saturated zone: n/a
Field studies (state location, range or median with number of measurements)	DT_{50f}: Northern Europe

	Kirchlauter Worms Worms Laacher Hof Laacher Hof median (d) Range: 104-228 d (n=10) Geometric mean: 174 d (n=10) <u>Southern Europe</u> Investigated: Cor s France s Italy s Italy l Spain s geometric mean square root 1st o square root 1.5st o Range: 40-288 d (n=4) Geometric mean: 110 d Total geometric mean for Europe: 153 d (n=14) Normalised to FOCUS reference conditions (20°C, 100% FC): Kirchlauter-Pettst Swisstal-Hohn Höfchen Worms-Heppenhe Laacher Hof Kirchlauter-Pettst Swisstal-Hohn Höfchen Worms-Heppenhe Laacher Hof Bagnolo di Nogar St. Etienne du Gr Ca Degli Oppi, It <u>Castellarnau</u> median geometric mean Range: 27.1-179.8 d (n=14) Converted to average EU outdoor temperature of 12°C: DT_{50}: range 50.9-337.9 days (n=14); **geometric mean: 135.1 days (n=14; 12°C, 100%**

	FC)
	DT_{90f}: s s s l l s s geometric mean
Anaerobic degradation	n/a
Soil photolysis	n/a
Non-extractable residues	Laboratory soil degradation studies 16.6% (sandy loam) – 25% (sandy loam) after 100 days (n=4) sandy loam: 26.9% after 91 days, 28.1% after 126 days, sandy loam: 23% after 366 days sandy loam: 39.5% after 366 days
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	No metabolites > 10% In total nine minor metabolites were found. Maximum fraction: NTN33893-olefine (1.8 % TAR after 100 d), NTN33893-ring-open-nitroguanidine (max. 3.4 % TAR after 77 d) NTN33893-desnitro (4,3 % TAR after 201 d).
Soil accumulation and plateau concentration	Not required

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

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	Arithmetic mean: 2.32 mL/g, 3.18 mL/g 230 mL/g, 277 mL/g no pH-dependence

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

Direct photolysis in air	-
Quantum yield of direct photolysis	-
Photo-oxidative degradation in air	Theoretical estimation according to Atkinson, using US EPA AOPWIN, version 1.87. DT_{50}: 2.54 h 24-hours-mean concentration: 5×10^5 OH radicals/cm³
Volatilization	No data supplied, not required

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

Soil (indicate location and type of study)	None available
Surface water (indicate location and type of study)	None available
Ground water (indicate location and type of study)	Germany, groundv Data from 4 Feder total 2000 9 2001 23 2002 279 total 627
Air (indicate location and type of study)	None available

Chapter 5: Effects on Non-target Species

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

Species	Time-scale	Endpoint	Toxicity
Fish			
Oncorhynchus mykiss	96 h	mortality	LC_{50} = 211 mg/l
Oncorhynchus mykiss	91 d	time to hatch	NOEC = 9.02 mg/l
Invertebrates			
Daphnia magna	48 h	immobility	EC_{50} = 85 mg/l
Chironomus riparius	24 h	mortality	LC_{50} = 0.055 mg/l
Cloeon dipterum	96 h	immobility	EC_{50} = 1.02 µg/L
Caenis horaria	96 h	immobility	EC_{50} = 1.77 µg/L
Daphnia magna	21 d	reproduction	NOEC =1.8 mg/l
Chironomus riparius	28d	development, emergence	EC_{10} = 2.09 µg/l (nominal conc.) EC_{10} = 0.87 µg/l (mean measured conc.); this value was used for the effects assessment
Cloeon dipterum	28 d	immobility	EC_{10} = 0.033 µg/L
Caenis horaria	28 d	immobility	EC_{10} = 0.024 µg/L
Metabolite Imidacloprid, desnitro: *Hyalella azteca*	96 h	mortality	LC_{50} = 51.8 mg/l
Metabolite Imidacloprid, desnitro: *Chironomus riparius*	28 d	development, emergence	EC_{10} = 27 mg/l (nominal conc.) EC_{10} = 9.45 mg/l (mean measured conc.)
Algae			
Selenastrum capricornutum	72 h	Growth rate inhibition	E_rC_{50} > 100 mg/l NOEC < 100 mg/l
Microorganisms			

Activated sludge from sewage treatment plant (treating predominantly domestic sewage)	3 h stat.	respiration inhibition	EC_{50} > 10000 mg/L (nominal) NOEC = 5600 mg/L (nominal)
Freshwater species community			
Sediment dwelling organisms, phytoplankton and zooplankton	26 weeks	mesocosm	NOEC = 0.6 µg/l

Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworms (Annex IIIA, point XIII.3.2)	*Eisenia fetida*: LC_{50} (14 d) = 10.7 mg/kg dw
Reproductive toxicity to earthworms (Annex IIIA, point XIII.3.2)	*Eisenia fetida*: NOEC (56 d) ≥ 0.178 mg/kg dw
Long-term toxicity to other soil non-target macroorganisms	*Folsomia candida*: NOEC (28 d) = 0.3 mg/kg dw (mortality) NOEC (28 d) = 1.25 mg/kg dw (reproduction) *Hypoaspis aculeifer* : NOEC (14-23 d) ≥ 2.66 mg/kg dw* (mortality and reproduction)

*assuming a soil depth of 3 mm and a soil density of 1500 kg/m³ for dry soil

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

Nitrogen mineralization	NOEC = 2.7 mg/ kg dw
Carbon mineralization	NOEC = 2.67 mg/ kg dw

Effects on terrestrial vertebrates

Acute toxicity to mammals (Annex IIIA, point XIII.3.3)	See chapter 3 (LOEP)
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	*Coturnix japonica*: LD_{50} = 31 mg/kg bw
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	*Coturnix japonica:* LC_{50} (5d) = 392 mg/kg food
Reproductive toxicity to birds (Annex IIIA, point XIII.1.3)	*Colinus virginianus :* NOEC (20 week) = 126 mg/kg food

Effects on terrestrial plants

Acute toxicity to plants (3 species)	EC_{50} (14 d) > 100 mg/kg dw (emergence, growth) NOEC (14 d) = 10 mg/kg dw (emergence, growth)

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

Acute oral toxicity	LD_{50} (48 h) = 0.0037 µg/bee
Acute contact toxicity	LD_{50} (48 h) = 0.081 µg/bee

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

Acute oral toxicity	Not relevant to biocidal product
Acute contact toxicity	Not relevant to biocidal product
Acute toxicity to ……..	Not relevant to biocidal product

Bioconcentration (Annex IIA, point 7.5)

Bioconcentration factor (BCF)	estimated on basis of log P_{ow} = 0.57 according to TGD: BCF_{fish} = 0.61 (equation 74) $BCF_{earthworm}$ = 0.88 (equation 82d)
Depuration time(DT_{50}) (DT_{90})	n/a
Level of metabolites (%) in organisms accounting for > 10 % of residues	n/a

Appendix II: List of Intended Uses

Summary of intended uses

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Re-marks:
(a)			(c)	Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	number min max (k)	interval between applications (min)	g a.s./L min max	water L/m^2 min max	g a.s./m^2 min max	(m)
Fly control indoors, hygiene in animal houses or other agricultural buidlings		Quick Bayt GR	Musca domestica	GR	5 g/kg	Granule) placed in ≈ 5 g baiting points free, in small vessels or bait stations on dry level surfaces Paint (200g of product in 150 ml H_2O treats 1m²): treat where flies rest, with a total of 1m² per 100m² floor area"	Up to 8 times per year	21 to 56 days			1 g a.s./100 m^2 floor area	
Cockroach control indoors		Max-force® White IC, Premise Gel, Blattene x Gel	Cockroaches	GL	21.5 g/kg	Place spots in areas where cock-roaches congre-gate (cracks & crevices, corners, wall voids, behind stoves, under sinks, etc.) and low access to children	One application when insects appear. At high infestations and/or if infesta-tion persists, re-applications should be made	When gel is no longer in evidence, depends upon level of infestation			One to 3 0.1g spots per m2 (2.15 – 6.45 mg a.s / m^2)	

(a) e.g. biting and suckling insects, fungi, molds; (b) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(c) GCPF Codes - GIFAP Technical Monograph No 2, 1989 ISBN 3-8263-3152-4); (d) All abbreviations used must be explained

(e) g/kg or g/l;(f) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench;

(g) Kind, e.g. overall, broadcast, aerial spraying, row, bait, crack and crevice equipment used must be indicated;

(h) Indicate the minimum and maximum number of application possible under practical conditions of use;

(i) Remarks may include: Extent of use/economic importance/restrictions

Appendix III: Human Health Tables for Risk Characterisation

Table 1: Professional Users – Primary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure [1]				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated oral uptake [mg/kg b.w/day]	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (no PPE) GR 0.5	application and brushing of diluted Imidacloprid GR 0.5 duration: 380 min	-	0.02×10^{-3}	14.87×10^{-3}	14.89×10^{-3}	NOAEL = 6 mg/kg b.w/day AEL $_{long\ term}$ = 0.06 mg/kg b.w/day	100	403	0.25
Tier 1 (no PPE) GL 2.15	application of Imidacloprid GL 2.15 duration: 155 min	-	negligible	1.46×10^{-3}	1.46×10^{-3}	NOAEL = 6 mg/kg b.w/day AEL $_{long\ term}$ = 0.06 mg/kg b.w/day	100	4110	0.025
Tier 2 (Refinement, PPE or other risk mitigation measures – Specify)	Tier 2 is not required.								

[1] body weight professional 60 kg

Table 2: Non Professional Users – Primary Exposure

Exposure Scenario (indicate duration)	Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
	estimated oral uptake [mg/kg b.w/day]	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (no PPE)	Primary exposure is not expected since the biocidal product is for professional use only.							
Tier 2 Refinement or other risk mitigation measures – Specify)								

Table 3: Indirect Exposure as a result of use – Secondary Exposure
Product: Imidacloprid GR 0.5

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (Worst Case) Short term Scenario	Adults, touching treated walls, acute	-	0.000224	-	0.000224	40 0.4	100	179000	0.001
	Infants, contact to granules, acute	-	0.000267	0.003333	0.003600	40 0.4	100	11100	0.01
	Professionals, working in animal housing(1)	-	negligible	0.56×10^{-3}	0.56×10^{-3}	NOAEL = 6 mg/kg b.w/day $AEL_{long\ term}$ = 0.06 mg/kg b.w/day	100	10714	0.009
Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 2 (Refinement - Specify) Short Term Scenario	Tier 2 is not required.								

(1) Estimated Internal Exposure: Based on the assumption of 100 % absorption by inhalation and 8 % dermal absorption and a body weight for professionals of 60 kg

Table 3a: Indirect Exposure as a result of use – Secondary Exposure
Product: Imidacloprid GL 2.15

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (Worst Case) Short term Scenario	Adults, removing old baits, acute	-	0.0086	-	0.0086	40 0.4	100	4650	0.02
	Infants, uptake of baits, acute	-	c f. oral exposure	0.215	0.215	40 0.4	100	186	0.54
Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 2 (Refinement - Specify) Short Term Scenario	Tier 2 is not required.								

Table 4: Indirect Exposure as a result of use – Secondary Exposure

Exposure Scenario (indicate duration)	Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (Worst Case) Chronic Scenario	Chronic secondary exposure of the general public is not expected.							
Exposure Scenario (indicate duration)	Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 2 (Refinement- Specify) Chronic Scenario	Chronic secondary exposure of the general public is not expected.							

Appendix IV: 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.

Reference list of studies on the active substance

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A 2.6. /01	[redacted]	2002	Synthesis of Imidacloprid [redacted] Report No.: MO-02-018639, Edition Number: M-073725-01-1 Date: 18.11.2002 Non GLP, unpublished confidential	Yes	BCS
A 2.7. /01	Volkmann, T.	2003	Composition Statement - CONFIDOR techn. Bayer CropScience AG, Report No.: MO-03-001628, Edition Number: M-039228-02-1 Date: 11.02.2003 Non GLP, unpublished confidential	Yes	BCS
A 2.8. /01	[redacted]	2003	Material Accountability of Confidor T [redacted] Report No.: MO-03-004124, Edition Number: M-087652-01-1 Date: 16.01.2003 GLP, unpublished confidential	Yes	BCS
A 2.8. /02	[redacted]	2003	NTN 33893 - Reanalyzes of the analytical profile of the TOX-batches.- [redacted] Edition Number: M-088099-01-1 Date: 28.03.2003 Non GLP, unpublished confidential	Yes	BCS
A 2.8. /03	Sporenberg, W.	2003	Determination of volatile Nitrosamines Bayer Industry Services, Leverkusen, Gemany Bayer CropScience AG, Report No.: MO-03-006004, Edition Number: M-090994-01-1 Date: 09.05.2003 Non GLP, unpublished confidential	Yes	BCS
A 2.8. /04	Schindler, M.	2006	Results Concerning the Molecular Geometry of Imidacloprid Based on Quantum Chemical Calculations Bayer CropScience AG, Edition Number: M-277468-01-1 Date: 14.09.2006 Non GLP, unpublished confidential	Yes	BCS

Reference list of studies on the active substance

A 2.8. /05	Schindler, M.	2006	Results Concerning the Molecular Geometry of Imidacloprid Based on Crystal Structure Analysis Bayer CropScience AG, Edition Number: M-277469-01-1 Date: 14.09.2006 Non GLP, unpublished confidential	Yes	BCS
A 3.1.1 /01	Krohn, J.	1993	Melting Point of Imidacloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC312, Edition Number: M-004037-01-1 Date: 19.05.1993 GLP, unpublished	Yes	BCS
A 3.1.2 /01	Krohn, J.	1996	Boiling Point of Imidacloprid (NTN 33893) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC1437, Edition Number: M-004039-01-1 Date: 25.09.1996 Non GLP, unpublished	Yes	BCS
A 3.1.2 /02	Mix, K. H.; Berg, G.	1988	Thermal stability of the active ingredient NTN 33893 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC339, Edition Number: M-004178-01-2 Date: 28.06.1988 Non GLP, unpublished also filed: A 3.10. /01	Yes	BCS
A 3.1.3 /01	Weber	1987	Density of NTN 33893 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC333, Edition Number: M-004041-01-1 Date: 31.07.1987 Non GLP, unpublished	Yes	BCS
A 3.1.3 /02	Krohn, J.	1995	Density of Imidacloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC713, Edition Number: M-004040-01-1 Date: 08.02.1995 GLP, unpublished	Yes	BCS
A 3.2. /01	Krohn, J.	1993	Vapour Pressure Curve of Imidacloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC313, Edition Number: M-004042-01-1 Date: 30.09.1993 GLP, unpublished	Yes	BCS

Reference list of studies on the active substance

A 3.2.1 /01	Krohn, J.	1993	Calculation of the Henry Law Constant of Imidacloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC315, Edition Number: M-004047-01-1 Date: 08.10.1993 Non GLP, unpublished	Yes	BCS
A 3.3.1 /01	Stoecker, R. H.	2001	Appearance of the substance Imidiacloprid Technical Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: SKD APP 05/2001, Edition Number: M-041457-01-1 Date: 22.08.2001 Non GLP, unpublished also filed: A 3.3.2 /01 also filed: A 3.3.3 /01	Yes	BCS
A 3.3.2 /01	Stoecker, R. H.	2001	Appearance of the substance Imidiacloprid Technical Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: SKD APP 05/2001, Edition Number: M-041457-01-1 Date: 22.08.2001 Non GLP, unpublished also filed: A 3.3.1 /01 also filed: A 3.3.3 /01	Yes	BCS
A 3.3.3 /01	Stoecker, R. H.	2001	Appearance of the substance Imidiacloprid Technical Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: SKD APP 05/2001, Edition Number: M-041457-01-1 Date: 22.08.2001 Non GLP, unpublished also filed: A 3.3.1 /01 also filed: A 3.3.2 /01	Yes	BCS
A 3.4.1 /01	Kaussmann, M.	2001	Spectral Data Set of Imidachloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 156002172, Edition Number: M-032373-01-1 Date: 04.12.2001 GLP, unpublished also filed: A 3.4.2 /01 also filed: A 3.4.3 /01 also filed: A 3.4.4 /01	Yes	BCS

Reference list of studies on the active substance

A 3.4.2 /01	Kaussmann, M.	2001	Spectral Data Set of Imidachloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 156002172, Edition Number: M-032373-01-1 Date: 04.12.2001 GLP, unpublished also filed: A 3.4.1 /01 also filed: A 3.4.3 /01 also filed: A 3.4.4 /01	Yes	BCS
A 3.4.3 /01	Kaussmann, M.	2001	Spectral Data Set of Imidachloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 156002172, Edition Number: M-032373-01-1 Date: 04.12.2001 GLP, unpublished also filed: A 3.4.1 /01 also filed: A 3.4.2 /01 also filed: A 3.4.4 /01	Yes	BCS
A 3.4.4 /01	Kaussmann, M.	2001	Spectral Data Set of Imidachloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 156002172, Edition Number: M-032373-01-1 Date: 04.12.2001 GLP, unpublished also filed: A 3.4.1 /01 also filed: A 3.4.2 /01 also filed: A 3.4.3 /01	Yes	BCS
A 3.5. /01	Krohn, J.	1993	Water solubility of Imidacloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC320, Edition Number: M-004109-01-1 Date: 03.03.1993 GLP, unpublished	Yes	BCS
A 3.6. /01	Rosenfeldt, F.	1990	Dissociation constant of NTN 33893 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC317, Edition Number: M-004052-02-1 Date: 12.09.1990, Amended: 30.01.1992 Non GLP, unpublished	Yes	BCS
A 3.7. /01	Krohn, J.	1993	Solubility of Imidacloprid in representative organic solvents Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC323, Edition Number: M-004130-01-1 Date: 22.06.1993 Non GLP, unpublished	Yes	BCS

Reference list of studies on the active substance

A 3.9. /01	Krohn, J.	1989	Octanol/Water partition coefficient of NTN 33893 Bayer AG, Wuppertal, Germany Bayer CropScience AG, Report No.: PC337, Edition Number: M-004153-02-1 Date: 15.06.1989, Amended: 30.01.1992 GLP, unpublished	Yes	BCS
A 3.9. /02	Kaußmann, , E.	2003	Determination of the log POW of NTN 33893 - metabolites by HPLC (Analytical note) Bayer CropScience AG, Report No.: MO-03-004358, Edition Number: M-088171-01-1 Date: 31.03.2003 Non GLP, unpublished	Yes	BCS
A 3.10. /01	Mix, K. H.; Berg, G.	1988	Thermal stability of the active ingredient NTN 33893 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC339, Edition Number: M-004178-01-2 Date: 28.06.1988 Non GLP, unpublished also filed: A 3.1.2 /02	Yes	BCS
A 3.11	Bogdoll, B.	2009	NTN 33893 - Statements on the Articles A.12. and A.13., Council Directive 67/548/EEC, Annex V Flammability (substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities), A.12. Flammability (solids and liquids) / Pyrophoric properties, A.13. Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: AF09/040, Edition Number: M-347798-01-1 Date: 25.05.2009 Non GLP, unpublished	Yes	BCS
A 3.11. /01	Mix, K. H.	1993	Investigation of safety-relevant parameters of Confidor techn. Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC635, Edition Number: M-004182-01-2 Date: 29.10.1993 GLP, unpublished also filed: A 3.15. /01	Yes	BCS

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A 3.13. /01	Imre, L.	1993	NTN 33893 - Surface tension Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC319, Edition Number: M-004100-02-1 Date: 03.06.1993 GLP, unpublished	Yes	BCS
A 3.15. /01	Mix, K. H.	1993	Investigation of safety-relevant parameters of Confidor techn. Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC635, Edition Number: M-004182-01-2 Date: 29.10.1993 GLP, unpublished also filed: A 3.11. /01	Yes	BCS
A 3.16. /01	Smeykal, H.	2005	Confidor, imidacloprid; NTN 33893 (AE F106464) - Oxidizing properties A.17. Siemens AG, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: 20050628.01, Edition Number: M-255230-01-1 Date: 28.07.2005 GLP, unpublished	Yes	BCS
A 3.17. /01	Cichy, M.; Merheim, P.	2005	Stability of Imidacloprid (NTN 33893/ AE F106464) to normal and elevatedtemperature, metals and metal ions and corrosion characteristics Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: PA05/059, Edition Number: M-255320-01-1 Date: 29.07.2005 GLP, unpublished	Yes	BCS
A 4.1. /01	Werner, T.	1993	Confidor; Assay - HPLC, External Standard Bayer AG, Dormagen, Germany Bayer CropScience AG, Report No.: 2201-0260401-93, Edition Number: M-005637-01-2 Date: 17.06.1993 Non GLP, unpublished	Yes	BCS
A 4.1. /02	[redacted]	2003	Validation of HPLC-method 2201-0260401-93 -Determination of the assay in Confidor (Imidacloprid) techn. grade active ingredient- [redacted] Report No.: VB2-2201-0260401, Edition Number: M-090267-03-1 Date: 25.04.2003 Non GLP, unpublished	Yes	BCS

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A 4.1. /03	Anon.	1997	Imidacloprid 582 CIPAC Bayer CropScience AG, Report No.: CIPAC 582, Edition Number: M-032649-01-1 Date: 01.01.1997 Non GLP, unpublished	Yes	BCS
A 4.1. /04	[redacted]	1998	NTN 33893 ; By-products - Linear Synthesis ; HPLC, External Standard [redacted] Report No.: 2201-0308702-98, Edition Number: M-007778-02-2 Date: 04.06.1998 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /05	[redacted]	2003	Validation of HPLC-method 2201-0308702-98 -Determination of the by-products in Confidor (Imidacloprid) techn. grade active ingredient- [redacted] Report No.: VB2-2201-0308702, Edition Number: M-090284-02-1 Date: 28.04.2003 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /06	Cichy, M. ; Gau, W.	2005	WAK in NTN 33893 AMP W ; Assay - HPLC-external standard Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 2005-0002002-92, Edition Number: M-007788-02-3 Date: 24.01.2005 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /07	Haustein, M.	2001	Validation of HPLC-method 2005-0002002-92 -Determination of WAK 3839 in Confidor (Imidacloprid) techn. grade a.i.- Bayer AG, Dormagen, Germany Bayer CropScience AG, Report No.: VB2-2005-0002002, Edition Number: M-046369-02-1 Date: 14.03.2001 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /08	Wanner, B.	2000	[redacted]	Yes	BCS

Reference list of studies on the active substance

A 4.1. /09	Schroeder, S.	2000	[redacted]	Yes	BCS
A 4.1. /10	Wanner, B.	1999	Analytical procedure for the Karl Fischer water determination Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 2005-0009701-99, Edition Number: M-021975-01-2 Date: 04.11.1999 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /11	Schroeder, S.	2000	Validation report VB1-2005-0009701-99 ; Karl Fischer water determination Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: VB1-2005-0009701-99, Edition Number: M-031907-01-1 Date: 20.04.2000 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /12	Dobrat W.; Martijn A.	1995	CIPAC Handbook Volume F Physico-chemical methods for technical and formulated pesticides MT 30 Water 30.1 Karl Fischer method Publisher:Collab. Int. Pest. Anal. Council Ltd., Journal:CIPAC Handbook, Volume:F, Pages:91;93, Year:1995, Report No.: C042873, Edition Number: M-233461-01-1 Date: 01.01.1995 Non GLP, published confidential	No	
A 4.1. /13	Sporenberg, W.	2003	[redacted] Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, Report No.: 2011-0600201-03, Edition Number: M-091031-01-1 Date: 08.05.2003 Non GLP, unpublished confidential	Yes	BCS

Reference list of studies on the active substance

A 4.1. /14	Sporenberg, W.	2003	[redacted] Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, Report No.: 2011-0600401-03, Edition Number: M-091023-01-1 Date: 08.05.2003 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /15	Sporenberg, W.	2003	[redacted] Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, Report No.: VD-2011-0600201-03, Edition Number: M-091218-01-1 Date: 12.05.2003 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /16	Sporenberg, W.	2003	[redacted] Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, Report No.: VD-2011-0600401-03, Edition Number: M-091221-01-1 Date: 12.05.2003 Non GLP, unpublished confidential	Yes	BCS
A 4.2.1. /01	Schramel, O.	2001	Method 00680 (MR-090/01) for the determination of imidacloprid in soil by HPLC-MS/MS Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00680, Edition Number: M-082263-01-1 Method Report No.: MR-090/01 Date: 29.10.2001 GLP, unpublished	Yes	BCS
A 4.2.1. /02	Bachlechner, G.	1992	Method for high performance liquid chromatographic determination of residues of the insecticide imidacloprid in soil using a laboratory robotic system Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00270, Edition Number: M-006708-02-1 Method Report No.: RA-139/92 Date: 11.03.1992 Non GLP, unpublished	Yes	BCS

Reference list of studies on the active substance

A 4.2.1. /03	Schramel, O.	1999	Enforcement-/confirmatiory method 00577 (MR-172/99) for liquid chromatographic determination of imidacloprid in soil Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00577, Edition Number: M-012349-01-1 Method Report No.: MR-172/99 Date: 30.04.1999 GLP, unpublished	Yes	BCS
A 4.2.2. /01	Riegner, K.	1993	Method for the determination of imidacloprid in air Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00326, Edition Number: M-011427-02-1 Method Report No.: RA-357/93 Date: 22.06.1993 GLP, unpublished	Yes	BCS
A 4.2.2. /02	Riegner, K.	1993	Modification of the method 00326 (RA-357/93) for the determination of imidacloprid in air Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00326/M001, Edition Number: M-006843-03-1 Method Report No.: RA-631/93 Date: 22.10.1993 GLP, unpublished	Yes	BCS
A4.2.2/03	Hellpointner, E.	1999	Confirmatory method for the determination of imidacloprid in air *Bayer AG report no. MR-335/99, method no. 00326-M001, study no. P 625 9 6000* unpublished	Yes	BCS
A 4.2.3. /01	Sommer, H.	1999	Enforcement and confirmatory method for determination of imidacloprid in drinking water and surface water by HPLC Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00576, Edition Number: M-013524-01-1 Method Report No.: MR-173/99 Date: 18.06.1999 GLP, unpublished	Yes	BCS

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A 4.2.3. /02	Billesbach, K. S.; Leimkuehler, W. M.; Widmer, S. L.	1996	Analytical method for the determination of imidacloprid and the guanidine, olefinic guanidine, and urea metabolites in groundwater by high-performance liquid chromatography tandem mass spectrometry (LC-MS/MS) Bayer Corporation, Kansas City, MO, USA Bayer CropScience AG, Report No.: 107352, Edition Number: M-012941-01-1 Date: 11.06.1996 GLP, unpublished	Yes	BCS
A 4.2.3. /03	Koenig, T.	1996	Method for the determination of imidacloprid in drinking water by HPLC with on-line solid phase extraction Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00406, Edition Number: M-006837-02-1 Method Report No.: MR-831/95 Date: 09.01.1996 Non GLP, unpublished	Yes	BCS
A 5.3.1. /01	Nentwig	1993	Efficacy of NTN 33893 after oral application against flies (Musca domestica, Stomoxys calcitrans) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 930, Edition Number: M-114195-01-1 Date: 24.06.1993 Non GLP, unpublished	Yes	BCS
A 5.3.1. /02	Smith, G.	1994	Efficacy of Imidacloprid over a range of doses as a sugar granule fly bait against flies in a piggery Bayer Ltd., Sydney Australia Bayer CropScience AG, Report No.: MO-03-009113, Edition Number: M-116541-01-1 Date: 11.08.1994 Non GLP, unpublished	Yes	BCS
A 5.3.1. /03	Mrusek, K.	1997	Biological efficacy of imidacloprid versus the internal standards cyfluthrin and propoxur against flying and crawling insects Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: BES-EH-Mo 1442, Edition Number: M-267636-01-1 Date: 21.05.1997 Non GLP, unpublished	Yes	BCS

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A 5.3.1. /04	Nentwig, G.	2000	Efficacy of different concentrations of imidacloprid after oral application against the American cockroach (Periplaneta americana) and the German cockroach (Blattella germanica) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: BES-EH-MO 01444, Edition Number: M-267714-01-1 Date: 20.09.2000 Non GLP, unpublished	Yes	BCS
A 5.3.1. /05	Nentwig, G.	2000	Efficacy of different concentrations of imidacloprid after oral application against the American cockroach (Periplaneta americana), the German cockroach (Blattella germanica) and the housefly (Musca domestica) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: BES-EH-MO 01443, Edition Number: M-267717-01-1 Date: 09.08.2000 Non GLP, unpublished	Yes	BCS
A 5.4. /01	Tomizawa, M.; Casida, J. E.	2002	Selective toxicity of neonicotinoids attributable to specificity of insect and mammalian nicotinic receptors Publisher:Annual Reviews, Journal:Annual Review of Entomology, Volume:48, Pages:339 - 364, Year:2003, Report No.: MO-05-004254, Edition Number: M-245942-01-1 Non GLP, published	No	
A 5.7.1. /01	Nauen, R.; Ebbinghaus-Kintscher, U.; Elbert, A.; Jeschke, P.; Tietjen, K.	2001	Acetylcholine receptors as sites for developing neonicotinoid insecticides Publisher:Springer-Verlag Berlin, Location:Heidelberg, Journal:Biochemical Sites of Insecticide Action and Resistance, Pages:77-105, Year:2001, Report No.: MO-01-005653, Edition Number: M-047708-01-1 Non GLP, published	No	

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A 5.7.1. /02	Nauen, R., Denholm, I.	2005	Resistance of insect pests to neonicotinoid insecticides: current status and future prospects Publisher:Wiley InterScience, Location:Wiley-Liss, Inc., Journal:Archives of Insect Biochemistry and Physiology, Volume:58, Issue:2005, Pages:200-215, Year:2005, Report No.: MO-05-007838, Edition Number: M-250577-01-1 Non GLP, published	No	
A 5.7.2. /01	Elbert, A.; Bailo-Schleiermacher, I.; Brueggen, K.U.; Nauen, R.; Rogers, D.; Steffens, R.; Denholm, I.	2005	Pflanzenschutz-Nachrichten Bayer 58 - Special edition - Bayer CropScience Guidelines on Resistance Management for Neonicotinoids Publisher:Bayer CropScience, Location:Germany, Journal:Pflanzenschutz Nachrichten Bayer, Volume:58, Issue:76, Pages:1 - 32, Year:2005, Report No.: MO-05-008987, Edition Number: M-252077-01-1 Non GLP, published	No	
A 6.1.1. /01*	[redacted]	1989	NTN 33893 - Study for acute oral toxicity to rats [redacted] Report No.: 18594, Edition Number: M-025996-01-1 Date: 15.12.1989 GLP, unpublished	Yes	BCS
A 6.1.1. /02*	[redacted]	1991	NTN 33893 AMP (proposed c.n.: Imidacloprid) - Study for acute oral toxicity to rats [redacted] Report No.: 20591, Edition Number: M-028854-01-1 Date: 19.08.1991 GLP, unpublished	Yes	BCS
A 6.1.1. /03*	[redacted]	1991	NTN 33893 CNS (c n.: Imidacloprid (proposed) - Study for acute oral toxicity in rats [redacted] Report No.: 20637, Edition Number: M-028901-01-1 Date: 03.09.1991 GLP, unpublished	Yes	BCS

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A 6.1.1. /04*	[redacted]	1989	NTN 33893 - Study for acute oral toxicity to mice [redacted] Report No.: 18593, Edition Number: M-007509-01-1 Date: 15.12.1989 GLP, unpublished	Yes	BCS
A 6.1.2 /01*	[redacted]	1989	NTN 33893 (c n. imidacloprid (proposed) - Study for acute dermal toxicity to rats [redacted] Report No.: 18532, Edition Number: M-025697-01-1 Date: 15.11.1989 GLP, unpublished	Yes	BCS
A 6.1.3. /01	[redacted]	1988	NTN 33893 - Study for acute inhalation toxicity in the rat in accordance with OECD guideline no. 403 [redacted] Report No.: 16777, Edition Number: M-027586-01-1 Date: 06.06.1988 GLP, unpublished	Yes	BCS
A 6.1.4. /01*	[redacted]	1988	NTN 33893 - Study for irritant/corrosive potential on the skin (rabbit) according to OECD guideline no. 404 [redacted] Report No.: 16455, Edition Number: M-028272-01-1 Date: 25.02.1988 GLP, unpublished	Yes	BCS
A 6.1.4. /02*	[redacted]	1988	NTN 33893 - Study for irritant/corrosive potential on the eye (rabbit) according to OECD guideline no. 405 [redacted] Report No.: 16456, Edition Number: M-028278-01-1 Date: 25.02.1988 GLP, unpublished	Yes	BCS
A 6.1.5. /01*	[redacted]	1988	NTN 33893 technical - Study for skin sensitising effect on guinea pigs (maximisation test) [redacted] Report No.: 16533, Edition Number: M-027579-01-1 Date: 15.03.1988 GLP, unpublished	Yes	BCS

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A 6.2. /01*	[redacted]	1987	(14C)-NTN 33893: Biokinetic part of the 'General metabolism study' in the rat [redacted] Report No.: PF2889, Edition Number: M-024189-01-1 Date: 09.11.1987 GLP, unpublished	Yes	BCS
A 6.2. /02*	[redacted]	1991	Imidazolidine-4,5-14C-Imidacloprid: Investigation of the biokinetic behaviour and metabolism in the rat [redacted] Report No.: PF3629, Edition Number: M-024167-01-1 Date: 11.01.1991 GLP, unpublished also filed: A 6.2 /05	Yes	BCS
A 6.2. /03*	[redacted]	1990	Methylene-(14C)-Imidacloprid: Metabolism part of the general metabolism study in the rat [redacted] Report No.: PF3316, Edition Number: M-024182-01-1 Date: 30.01.1990 GLP, unpublished	Yes	BCS
A 6.2. /04*	[redacted]	1992	(Pyridinyl-14C-methyl)Imidacloprid: Distribution of the metabolites in some organs at different times following single oral administration to rats [redacted] Report No.: PF3635, Edition Number: M-024164-01-1 Date: 12.03.1992 GLP, unpublished	Yes	BCS
A 6.2. /05*	[redacted]	1991	Imidazolidine-4,5-14C-Imidacloprid: Investigation of the biokinetic behaviour and metabolism in the rat [redacted] Report No.: PF3629, Edition Number: M-024167-01-1 Date: 11.01.1991 GLP, unpublished also filed: A 6.2 /02 (Not included in Caddy, as already filed as A6.2/02)	Yes	BCS

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A 6.2. /06*	[redacted]	1990	[redacted] Comparison of biokinetic behaviour and metabolism in the rat following single oral dosage and investigation of the metabolism after chronic feeding of imidacloprid to rats and mice [redacted] Report No.: PF3432, Edition Number: M-024174-01-1 Date: 17.07.1990 GLP, unpublished	Yes	BCS
A 6.2. /08*	[redacted]	2005	Confidor OD 200 ([14C]-imidacloprid): Comparative in vitro dermal absorption study using human and rat skin. [redacted] Study no. SA 04242, Report amendmend no. 1, Edition Number: M-251756-02-1 Date: 21.02.2005 GLP, unpublished	Yes	BCS
A 6.3.1 *	[redacted]	1987	28-day oral range-finding toxicity (feeding) study with NTN 33893 tech. in the dog, [redacted] Bayer project T 6025018 No GLP, Unpublished	Yes	BCS
A 6.3.2 /01*	[redacted]	1990	NTN 33893 techn. - Study for subacute dermal toxicity in the rabbit [redacted] Report No.: 19152, Edition Number: M-025976-01-1 Date: 11.06.1990 GLP, unpublished	Yes	BCS
A 6.3.3 /01*	[redacted]	1989	NTN 33893 (proposed common name: Imidacloprid) - Subacute inhalation toxicity study on the rat according to OECD guideline no. 412 [redacted] Report No.: 18199, Edition Number: M-026004-01-1 Date: 18.07.1989 GLP, unpublished	Yes	BCS
A 6.4.1.1. /01*	[redacted]	1989	NTN 33893 - Subchronic toxicity study on wistar rats (administration in the feed for 96 days) [redacted] Report No.: 18187, Edition Number: M-007967-01-1 Date: 14.07.1989 GLP, unpublished	Yes	BCS

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A 6.4.1.2. /01*	[redacted]	1990	NTN 33893 technical - Subchronic toxicity study on dogs in oral administration (thirteen-week feeding study) [redacted] Report No.: 18732, Edition Number: M-026540-01-1 Date: 02.02.1990 GLP, unpublished	Yes	BCS
A 6.4.1.2. /02*	[redacted]	1989	52-week oral toxicity (feeding) study with NTN 33893 technical in the dog [redacted] Edition Number: M-027093-02-1 Date: 19.10.1989, Amended: 03.03.1992 GLP, unpublished	Yes	BCS
A 6.5. /01*	[redacted]	1991	NTN 33893 (proposed c n.: Imidacloprid) - Chronic toxicity and cancerogenicity studies on Wistar rats (administration in food over 24 months) [redacted] Report No.: 19925, Edition Number: M-027741-02-1 Date: 25.01.1991 GLP, unpublished also filed: A 6.7. /01	Yes	BCS
A 6.5. /02*	[redacted]	1991	NTN 33893 (proposed common name: Imidacloprid) - Chronic toxicity and cancerogenicity studies on Wistar rats (administration in food over 24 months) - supplementary MTD study for two-year study T1025699 [redacted] Report No.: 20541, Edition Number: M-027135-01-1 Date: 19.08.1991 GLP, unpublished also filed: A 6.7. /02	Yes	BCS
A 6.5. /03*	[redacted]	1991	NTN 33893 (proposed common name Imidacloprid) - Carcinogenicity study on B6C3F1 mice (administration in the food for 24 months) [redacted] Report No.: 19931, Edition Number: M-026310-01-1 Date: 28.01.1991 GLP, unpublished also filed: A 6.7. /03	Yes	BCS

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A 6.5. /04*	[redacted]	1991	NTN 33893 (proposed common name: Imidacloprid) - Carcinogenicity study in B6C3F1 mice (supplementary MTD testing for study T5025710 with administration in diet over a 24-month period) [redacted] Report No.: 20769, Edition Number: M-026038-01-1 Date: 24.10.1991 GLP, unpublished also filed: A 6.7. /04	Yes	BCS
A 6.6.1. /01*	[redacted]	1989	NTN 33893 - Salmonella/microsome test to evaluate for point mutagenic effects [redacted] Report No.: 17577, Edition Number: M-027611-01-1 Date: 06.01.1989 GLP, unpublished	Yes	BCS
A 6.6.1. /02*	[redacted]	1991	NTN 33893 AMP - Salmonella/microsome test [redacted] Report No.: 20090, Edition Number: M-025825-01-1 Date: 22.03.1991 GLP, unpublished	Yes	BCS
A 6.6.1. /03*	[redacted]	1992	NTN 33893 AMP W - Salmonella/microsome test [redacted] Report No.: 21775, Edition Number: M-029085-01-1 Date: 19.10.1992 GLP, unpublished	Yes	BCS
A 6.6.1. /04*	[redacted]	1991	NTN 33893 - Reverse mutation assay (Salmonella typhimurium and Escherichia coli) [redacted] Report No.: RA91002, Edition Number: M-028670-01-1 Date: 17.01.1991 GLP, unpublished	Yes	BCS

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A 6.6.2. /01*	[redacted]	1988	Clastogenic evaluation of NTN 33893 in an in vitro cytogenetic assay measuring sister chromatid exchange in chinese hamster ovary (CHO) cells [redacted] Report No.: R4407, Edition Number: M-026488-01-1 Date: 21.04.1988 GLP, unpublished	Yes	BCS
A 6.6.2. /02*	[redacted]	1989	BAY NTN 33893 - Sister chromatid exchange assay in chinese hamster ovary cells [redacted] Report No.: BC1149, Edition Number: M-025499-01-1 Date: 12.09.1989 GLP, unpublished	Yes	BCS
A 6.6.2. /03*	[redacted]	1989	NTN 33893 - In vitro cytogenetic study with human lymphocytes for the detection of induced clastogenic effects [redacted] Report No.: 18092, Edition Number: M-028377-02-1 Date: 16.06.1989, Amended: 24.08.1989 GLP, unpublished	Yes	BCS
A 6.6.3. /01*	[redacted]	1989	NTN 33893 - Mutagenicity study for the detection of induced forward mutations in the CHO-HGPRT assay in vitro [redacted] Report No.: 17578, Edition Number: M-027630-01-1 Date: 06.01.1989 GLP, unpublished	Yes	BCS
A 6.6.3. /02*	[redacted]	1988	NTN 33893 - Test on S. cerevisiae D7 to evaluate for induction of mitotic recombination [redacted] Report No.: 16832, Edition Number: M-027595-01-1 Date: 27.06.1988 GLP, unpublished	Yes	BCS

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A 6.6.3. /03*	[redacted]	1988	Mutagenicity test on NTN 33893 in the rat primary hepatocyte unscheduled DNA synthesis assay [redacted] Report No.: R4631, Edition Number: M-026493-01-1 Date: 21.12.1988 GLP, unpublished	Yes	BCS
A 6.6.4. /01*	[redacted]	1989	NTN 33893 - In vivo cytogenetic study of the bone marrow in chinese hamster to evaluate for induced clastogenic effects [redacted] Report No.: 18557, Edition Number: M-025903-01-1 Date: 24.11.1989 GLP, unpublished	Yes	BCS
A 6.6.4. /02*	[redacted]	1989	NTN 33893 - Sister chromatid exchange in bone marrow of chinese hamsters in vivo [redacted] Report No.: 18093, Edition Number: M-028379-02-1 Date: 16.06.1989, Amended: 23.11.1993 GLP, unpublished	Yes	BCS
A 6.6.5. /01*	[redacted]	1988	NTN 33893 - Micronucleus-test on the mouse to evaluate for clastogenic effects [redacted] Report No.: 16837, Edition Number: M-027591-01-1 Date: 27.06.1988 GLP, unpublished	Yes	BCS
A 6.6.6. /01*	[redacted]	1990	Mouse germ-cell cytogenetic assay with NTN 33893 [redacted] Report No.: R5063, Edition Number: M-026551-01-1 Date: 22.05.1990 GLP, unpublished	Yes	BCS
A 6.7. /01*	[redacted]	1991	NTN 33893 (proposed c n.: Imidacloprid) - Chronic toxicity and cancerogenicity studies on Wistar rats (administration in food over 24 months) [redacted] Report No.: 19925, Edition Number: M-027741-02-1 Date: 25.01.1991 GLP, unpublished also filed: A 6.5. /01	Yes	BCS

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A 6.7. /02*	[redacted]	1991	NTN 33893 (proposed common name: Imidacloprid) - Chronic toxicity and cancerogenicity studies on Wistar rats (administration in food over 24 months) - supplementary MTD study for two-year study T1025699 [redacted] Report No.: 20541, Edition Number: M-027135-01-1 Date: 19.08.1991 GLP, unpublished also filed: A 6.5. /02	Yes	BCS
A 6.7. /03*	[redacted]	1991	NTN 33893 (proposed common name Imidacloprid) - Carcinogenicity study on B6C3F1 mice (administration in the food for 24 months) [redacted] Report No.: 19931, Edition Number: M-026310-01-1 Date: 28.01.1991 GLP, unpublished also filed: A 6.5. /03	Yes	BCS
A 6.7. /04*	[redacted]	1991	NTN 33893 (proposed common name: Imidacloprid) - Carcinogenicity study in B6C3F1 mice (supplementary MTD testing for study T5025710 with administration in diet over a 24-month period) [redacted] Report No.: 20769, Edition Number: M-026038-01-1 Date: 24.10.1991 GLP, unpublished also filed: A 6.5. /04	Yes	BCS
A 6.8.1. /01*	[redacted]	[redacted]	Embryotoxicity study (including teratogenicity) with NTN 33893 technical in the rat [redacted] Report No.: R5442, Edition Number: M-027900-04-1 Date: 24.11.1988, Amended: 03.03.1992 GLP, unpublished	Yes	BCS
A 6.8.1. /01*	Khera, K.S.	1981	Common fetal aberrations and their teratologic significance: A review Fund. Appl. Toxicol. 1: 13-18	No	Public

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A 6.8.1. /01*	Nishimura, M., Iizuka, M., Iwaki, S., & Kast, A.	1982	Repairability of drug-induced "wavy ribs" in rat offspring Arzneim.-Forsch./Drug Res. 32 (II), No. 12: 1518-1522	No	Public
A 6.8.1. /01*	Kast, A.	1994	"Wavy ribs". A reversible pathologic finding in rat fetuses Exp. Toxic. Pathol. 46: 203-210 Published	No	Public
A 6.8.1. /02*	[redacted]	1988	Embryotoxicity study (including teratogenicity) with NTN 33893 technical in the rabbit [redacted] Report No.: R5443, Edition Number: M-027920-04-1 Date: 24.11.1988, Amended: 03.03.1992 GLP, unpublished	Yes	BCS
A 6.8.2. /01*	[redacted]	1990	Multiple generation reproduction study with NTN 33893 technical in rats [redacted] Report No.: R5097, Edition Number: M-027300-03-1 Date: 21.06.1990, Amended: 03.03.1992 GLP, unpublished	Yes	BCS
A 6.9. /01*	[redacted]	1994	An acute oral neurotoxicity screening study with technical grade imidacloprid (NTN 33893) in rats [redacted] Report No.: BC7221, Edition Number: M-028815-02-1 Date: 16.02.1994, Amended: 07.06.1994 GLP, unpublished	Yes	BCS
A 6.9. /02*	[redacted]	1994	A subchronic dietary neurotoxicity screening study with technical grade Imidacloprid (NTN 33893) in Fischer 344 rats [redacted] Report No.: BC7331, Edition Number: M-027944-01-1 Date: 13.06.1994 GLP, unpublished	Yes	BCS

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A 6.9. /03*	[redacted]	2001	A developmental neurotoxicity screening study with technical grade Imidacloprid in Wistar rats [redacted] Report No.: 110245, Edition Number: M-084646-01-1 Date: 14.09.2001 GLP, unpublished	Yes	BCS
A 6.12.1. /01	Kehrig, B.; Steffens, W.	2004	Occupational medical experiences with Imidacloprid Bayer Industry Services, Dormagen, Germany Bayer CropScience AG, Report No.: MO-05-004265, Edition Number: M-245951-01-1 Date: 05.11.2004 Non GLP, unpublished	Yes	BCS
A 6.12.1. /02	Becker, M.	2006	Occupational, medical experience with imidacloprid gel 2,15 percent Pharma + Veterinaer Produkte, Kiel, Germany Bayer CropScience AG, Report No.: M-267506-01-1, Edition Number: M-267506-01-1 Date: 06.03.2006 Non GLP, unpublished	Yes	BCS
A 6.12.2. /01	Steffens, W.	2000	Final report on the poisoning incident "Lizetan Kombistäbchen, 30.5.00" Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: MO-00-014602, Edition Number: M-023399-01-1 Date: 26.10.2000 Non GLP, unpublished	Yes	BCS
A 6.12.5. /01	Proenca, P.; Teixeira, H.; Castanheira, F.; Pinheiro, J.; Monsanto, P.V.; Marques, E.P.; Vieira, D.N.	2005	Two fatal intoxication cases with imidacloprid: LC/MS analysis Publisher:Elsevier Ireland Ltd., Location:Anon., Journal:Forensic Science International, Volume:153, Pages:75-80, Year:2005, Report No.: M-256901-01-1, Edition Number: M-256901-01-1 Non GLP, published	No	
A 6.14. /01*	[redacted]	1991	WAK 3839 - Acute oral toxicity study on rats [redacted] Report No.: RA91017, Edition Number: M-028685-01-1 Date: 11.03.1991 GLP, unpublished	Yes	BCS

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A 6.14. /02*	[redacted]	1988	NTN 37571 - Acute toxicity study on mice [redacted] Report No.: RS88038, Edition Number: M-028572-01-1 Date: 19.10.1988 Non GLP, unpublished	Yes	BCS
A 6.14. /03*	[redacted]	1990	WAK 3839 - Reverse mutation assay (Salmonella tyhimurium and Escherichia coli) [redacted] Report No.: RA90035, Edition Number: M-028631-01-1 Date: 26.11.1990 GLP, unpublished	Yes	BCS
A 6.14. /[redacted]	[redacted]	1989	WAK 3839 - Mutagenicity study for the detection of induced forward mutations in the CHO-HGPRT assay in vitro [redacted] Report No.: 17757, Edition Number: M-027645-01-1 Date: 22.02.1989 GLP, unpublished	Yes	BCS
A 6.14. /05*	[redacted]	1989	[redacted] Mutagenicity study for the detection of induced forward mutations in the V79-HGPRT assay in vitro [redacted] Report No.: 18281, Edition Number: M-025757-01-1 Date: 15.08.1989 GLP, unpublished	Yes	BCS
A 6.14. /06	[redacted]	1991	[redacted] Rec-assay with spores in the bacterial system [redacted] Report No.: RA91015, Edition Number: M-028680-01-1 Date: 01.03.1991 GLP, unpublished	Yes	BCS
A 6.14. /07*	[redacted]	1989	Unscheduled DNA synthesis in primary hepatocytes of male rats in vitro with [redacted] Report No.: R4746, Edition Number: M-026532-01-1 Date: 24.04.1989 GLP, unpublished	Yes	BCS

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A 6.14. /08*	[redacted]	1989	Chromosome aberration assay in chinese hamster V79 cells in vitro [redacted] Report No.: R4849, Edition Number: M-026528-01-1 Date: 27.09.1989 GLP, unpublished	Yes	BCS
A 6.14. /09*	[redacted]	1989	[redacted] Micronucleus test on the mouse after oral application [redacted] Report No.: 18406, Edition Number: M-025775-01-1 Date: 03.10.1989 GLP, unpublished	Yes	BCS
A 6.14. /10*	[redacted]	1989	[redacted] Micronucleus test on the mouse after intraperitoneal injection [redacted] Report No.: 18407, Edition Number: M-025706-01-1 Date: 03.10.1989 GLP, unpublished	Yes	BCS
A 6.14. /11*	[redacted]	1992	WAK 3839 - Subchronic toxicological study on rats (twelve-week administration on drinking water) [redacted] Report No.: 21140, Edition Number: M-029731-01-1 Date: 02.03.1992 GLP, unpublished	Yes	BCS
A 6.14. /12*	[redacted]	1991	NTN 38014 - Acute oral toxicity study on rats [redacted] Report No.: RA91018, Edition Number: M-028687-01-1 Date: 18.03.1991 GLP, unpublished	Yes	BCS
A 6.14. /13*	[redacted]	1991	NTN 38014 - Reverse mutation assay (Salmonella typhimurium and Escherichia coli) [redacted] Report No.: RA91019, Edition Number: M-028689-02-1 Date: 29.03.1991 GLP, unpublished	Yes	BCS

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A 6.14. /14*	[redacted]	1991	NTN 35884 - Acute oral toxicity study on rats [redacted] Report No.: RA91039, Edition Number: M-028777-01-1 Date: 29.11.1991 GLP, unpublished	Yes	BCS
A 6.14. /15*	[redacted]	1991	NTN 35884 - Reverse mutation assay (Salmonella typhimurium and Escherichia coli) [redacted] Report No.: RA91040, Edition Number: M-028781-01-1 Date: 29.11.1991 GLP, unpublished	Yes	BCS
A 6.14./16*	[redacted]	1991	NTN 33519 – Acute oral toxicity study on rats. [redacted] Report No.: RA91023, Edition Number: M-028693-01-1 Date: May 31, 1991 GLP, unpublished	Yes	BCS
A 6.14/[redacted]	[redacted]	1991	NTN 33519 – Reverse mutation assay (Salmonella typhimurium and Escherichia coli). [redacted] Report No.: RA91024, Edition Number: M-028770-01-1 Date: July 22, 1991 GLP, unpublished	Yes	BCS
A 6.15.3. /01	[redacted]	1991	(Pyridinyl-14C-methylene) imidacloprid: Absorption, distribution, excretion and metabolism in a lactating goat [redacted] Report No.: PF3731, Report includes Trial Nos.: KNO43 KWN63 WBZ144 Edition Number: M-024212-01-1 Date: 18.12.1991 GLP, unpublished	Yes	BCS

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A 6.15.3. /02	[redacted]	1992	[Methylene-14C] Imidacloprid: absorption, distribution, excretion, and metabolism in the liver and kidney of a lactating goat - Amendment to report no. PF3731 [redacted] Report No.: PF3760, Report includes Trial Nos.: KNO56 Edition Number: M-024202-01-1 Date: 11.10.1992 GLP, unpublished	Yes	BCS
A 6.15.3. /03	[redacted]	1990	(Methylene-14C) imidacloprid - Absorption, distribution, excretion and metabolism in laying hens [redacted] Report No.: PF3558, Report includes Trial Nos.: BNA45 KNO30 Edition Number: M-024187-01-1 Date: 17.09.1990 GLP, unpublished	Yes	BCS
A 6.15.3. /04	[redacted]	1992	[Methylene-14C] Imidacloprid: Absorption, distribution, excretion, and metabolism in laying hens - Amendment to report no. PF3558 [redacted] Report No.: PF3759, Edition Number: M-024216-01-1 Date: 16.09.1992 GLP, unpublished	Yes	BCS
A 6.15.3. /05	Vogeler, K.; Linke-Ritzer, P.; Brauner, A.	1992	[Pyridinyl-14C-methyl] NTN 33893 residues in rotational crops Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3674, Edition Number: M-024386-01-1 Date: 10.08.1992 GLP, unpublished	Yes	BCS
A 7.1.1.1.1. /01	Yoshida, H.	1989	Hydrolysis of NTN 33893 Nihon Tokushu Noyaku Seizo K. K., Ibraki, Japan Bayer CropScience AG, Report No.: NR1276, Edition Number: M-024064-01-1 Date: 06.09.1989 GLP, unpublished	Yes	BCS

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A 7.1.1.1.2. /01	Anderson, C.; Bornatsch, W.; Brauner, A.	1991	Photodegradation of NTN 33893 in water Nitokuno, Ibaraki, Japan Bayer CropScience AG, Report No.: PF3517, Edition Number: M-024286-01-1 Date: 18.07.1988, revised May 14, 1991 GLP, unpublished	Yes	BCS
A 7.1.1.1.2. /02	Hellpointner, E.	1990	Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation of imidacloprid in water Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3422, Edition Number: M-024014-01-2 Date: 06.11.1990 GLP, unpublished	Yes	BCS
A 7.1.2.2.1. /01	Stevens, J.; Halarnkar, P. P.; Leimkuehler, W. M.; Davis, J. S.	1997	Characterization of three degradates of imidacloprid from aerobic aquatic biotransformation study ABC Laboratories, Inc., Columbia, MO, USA Bayer CropScience AG, Report No.: BR107547, Edition Number: M-024427-02-1 Date: 04.12.1996, Amended: 25.09.1997 GLP, unpublished	Yes	BCS
A 7.1.2.2.2. /01	Spiteller, M.	1993	Aerobic metabolism of imidacloprid, 14C-NTN 33893, in an aquatic model ecosystem Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3950, Edition Number: M-024398-01-1 Date: 20.10.1993 GLP, unpublished	Yes	BCS
A 7.1.2.2.2. /02	Wilmes, R.	1990	Aerobic aquatic metabolism of NTN 33893 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3466, Edition Number: M-024098-02-1 Date: 04.12.1990 GLP, unpublished	Yes	BCS
A 7.1.2.2.2. /03	Henneboele, J.	1998	Aerobic metabolism of imidacloprid, 14C-NTN 33893, in an aquatic model ecosystem Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF4337, Edition Number: M-032538-01-1 Date: 25.02.1998 GLP, unpublished	Yes	BCS

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A 7.1.2.2.2. /04	Fritz, R.; Hellpointner, E.	1991	Degradation of pesticides under anaerobic conditions in the system water/sediment: Imidacloprid, NTN 33893 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3524, Edition Number: M-024093-01-1 Date: 04.06.1991 GLP, unpublished	Yes	BCS
A 7.1.2.2.2. /05	Heim, D.; Yan, Z.; Halarnkar, P. P.	1996	Anaerobic aquatic biotransformation of [Pyridinyl-14C-methyl] imidacloprid at 5 °C ABC Laboratories, Inc., Columbia, MO, USA Bayer CropScience AG, Report No.: BR107546, Edition Number: M-024068-01-1 Date: 17.12.1996 GLP, unpublished	Yes	BCS
A 7.1.2.2.2. /06	Ratte, H.T.; Memmert, U.	2003	Biological effects and fate of imidacloprid SL 200 in outdoor microcosm ponds RCC Ltd., Itingen, Switzerland Bayer CropScience AG, Report No.: 811776, Edition Number: M-084035-01-1 Date: 26.02.2003 GLP, unpublished also filed: A 7.4.3.5. /01	Yes	BCS
A 7.1.2.2.2/07	Hardy, I.A.J., Patel, M.	2007	Imidacloprid: Kinetic modelling analysis of data from a water sediment study and a microcosm study Batelle UK Ltd, Essex, UK, Bayer CropScience AG, Report No.: CX/06/041, Edition Number: M-284318-01-1, Date: 21.02.2007 non GLP, unpublished	Yes	BCS
A 7.1.3./01	Fritz, R.	1988	Adsorption/desorption of NTN33893 on soils Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3128, Edition Number: M-023859-01-1 Date: 11.11.1988 GLP, unpublished	Yes	BCS
A 7.1.3. /02	Williams, M. D.; Berghaus, L.; Dyer, D.	1992	Soil/sediment adsorption-desorption of [14C] imidacloprid ABC Laboratories, Inc., Columbia, MO, USA Bayer CropScience AG, Report No.: MR103816, Edition Number: M-023828-01-1 Date: 14.09.1992 GLP, unpublished	Yes	BCS

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A 7.1.3. /03	Fritz, R.	1993	Adsorption/desorption of imidacloprid on lysimeter soils originated from "Borstel" and "Laacher Hof" Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3978, Edition Number: M-023822-02-2 Date: 24.02.1993, Amended: 01.06.2001 GLP, unpublished	Yes	BCS
A 7.1.3. /04	Fritz, R.	1998	Adsorption/desorption of imidacloprid (NTN 33893) on two light soils at different rates of application Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: MR-319/98, Edition Number: M-023808-01-1 Date: 24.04.1998 GLP, unpublished	Yes	BCS
A 7.2.2.1. /01	Anderson, C.; Fritz, R.; Brauner, A.	1990a	Metabolism of (pyridinyl-14C-methylene) NTN 33893 in loamy soil BBA 2.2 under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3321, Edition Number: M-006742-02-1 Date: 15.01.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.4 /04 also filed: A 7.2.2.4 /10	Yes	BCS
A 7.2.2.1. /02	Anderson, C.; Fritz, R.; Brauner, A.	1990b	Metabolism of (pyridinyl-14C-methylene) NTN 33893 in sandy loam under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3433, Edition Number: M-023514-01-1 Date: 14.11.1990 GLP, unpublished also filed: A 7.2.2.4 /05 also filed: A 7.2.2.4 /11	Yes	BCS
A 7.2.2.1. /03	Anderson, C.; Fritz, R.	1990a	Degradation of [pyridinyl-14C-methylene] NTN 33893 in silt soil Hoefchen under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3322, Edition Number: M-006740-02-1 Date: 19.01.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.4 /03 also filed: A 7.2.2.4 /09	Yes	BCS

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A 7.2.2.1. /04	Anderson, C.; Fritz, R.	1990b	Degradation of [pyridinyl-14C-methylene] NTN 33893 in sandy loam Monheim 1 under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3434, Edition Number: M-006728-02-1 Date: 07.12.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.4 /02 also filed: A 7.2.2.4 /08	Yes	BCS
A 7.2.2.1. /05	Hellpointner, E.	1999a	Degradation of imidacloprid in lysimeter soil Laacher Hof AXXa Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: MR-389/99, Edition Number: M-010737-01-1 Date: 02.08.1999 GLP, unpublished also filed: A 7.2.2.4 /07	Yes	BCS
A 7.2.2.2. /01	Bachlechner, G.	1993b	Dissipation of imidacloprid in soil under field conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: RA-2130/91, Report includes Trial Nos.: 10359/4 10360/8 10361/6 10362/4 10363/2 10364/0 Edition Number: M-006700-01-1 Date: 11.03.1993 GLP, unpublished	Yes	BCS
A 7.2.2.2. /02	Bachlechner, G.	1992	Dissipation of Imidacloprid in soil under field conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: RA-2082/91, Edition Number: M-006704-01-1 Date: 04.11.1992 GLP, unpublished	Yes	BCS
A 7.2.2.2. /03	Fahl, U.; Leicht, W.	1999	Recalculation of imidacloprid half-lives in bare soil (field trials) according to 1st order statistics Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: M10166, Edition Number: M-021684-01-1 Date: 10.11.1999 Non GLP, unpublished also filed: A 7.2.2.2 /06	Yes	BCS

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A 7.2.2.2. /04	Sommer, H.	1998a	Dissipation of Confidor 200 SL in soil under field conditions (Italy and Spain) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: RA-2107/96, Edition Number: M-021151-02-1 Date: 24.09.1998, Amended: 29.10.1998 GLP, unpublished	Yes	BCS
A 7.2.2.2. /05	Sommer, H.	1998b	Dissipation of Confidor 200 SL in soil under field conditions (France and Italy) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: RA-2084/95, Report includes Trial Nos.: R506230 R506249 Edition Number: M-021135-02-1 Date: 02.07.1998, Amended: 10.11.1999 GLP, unpublished	Yes	BCS
A 7.2.2.2. /06	Fahl, U.; Leicht, W.	1999	Recalculation of imidacloprid half-lives in bare soil (field trials) according to 1st order statistics Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: M10166, Edition Number: M-021684-01-1 Date: 10.11.1999 Non GLP, unpublished also filed: A 7.2.2.2 /03 (Not included in Caddy, as already filed as A7.2.2.2/03)	Yes	BCS
A 7.2.2.2. /07	Schad, T.	2001	Calculation of temperature referenced first order DT50 of Imidacloprid based on field dissipation studies conducted in Europe Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: MR-387/01, Edition Number: M-069290-01-1 Date: 20.08.2001 Non GLP, unpublished	Yes	BCS
A 7.2.2.2. /08	Schad, T.; Zerbe, P.	2005	Kinetic evaluation of the dissipation of imidacloprid under european field conditions Bayer CropScience AG, Report No.: MEF-05/077, Edition Number: M-245946-01-1 Date: 23.02.2005 Non GLP, unpublished	Yes	BCS

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A 7.2.2.4 /01	Scholz, K.	1992	Degradation of NTN 33893 in soil with groundcover Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3438, Edition Number: M-006712-02-1 Date: 20.02.1991, Amended: 21.02.1992 GLP, unpublished	Yes	BCS
A 7.2.2.4 /02	Anderson, C.; Fritz, R.	1990	Degradation of [pyridinyl-14C-methylene] NTN 33893 in sandy loam Monheim 1 under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3434, Edition Number: M-006728-02-1 Date: 07.12.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.1 /04 also filed: A 7.2.2.4 /08 (Not included in Caddy, as already filed as A7.2.2.1/04)	Yes	BCS
A 7.2.2.4 /03	Anderson, C.; Fritz, R.	1990	Degradation of [pyridinyl-14C-methylene] NTN 33893 in silt soil Hoefchen under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3322, Edition Number: M-006740-02-1 Date: 19.01.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.1 /03 also filed: A 7.2.2.4 /09 (Not included in Caddy, as already filed as A7.2.2.1/03)	Yes	BCS
A 7.2.2.4 /04	Anderson, C.; Fritz, R.; Brauner, A.	1990	Metabolism of (pyridinyl-14C-methylene) NTN 33893 in loamy soil BBA 2.2 under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3321, Edition Number: M-006742-02-1 Date: 15.01.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.1/01 also filed: A 7.2.2.4 /10 (Not included in Caddy, as already filed as A7.2.2.1/01)	Yes	BCS

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A 7.2.2.4 /05	Anderson, C.; Fritz, R.; Brauner, A.	1990	Metabolism of (pyridinyl-14C-methylene) NTN 33893 in sandy loam under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3433, Edition Number: M-023514-01-1 Date: 14.11.1990 GLP, unpublished also filed: A 7.2.2.1 /02 also filed: A 7.2.2.4 /11 (Not included in Caddy, as already filed as A7.2.2.1/02)	Yes	BCS
A 7.2.2.4 /06	Fahl, U.; Leicht, W.	2001	Recalculation of imidacloprid half-life in soil (laboratory trials) according to 1st order statistics Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: M10150, Edition Number: M-010575-03-1 Date: 19.04.2001 Non GLP, unpublished	Yes	BCS
A 7.2.2.4 /07	Hellpointner, E.	1999	Degradation of imidacloprid in lysimeter soil Laacher Hof AXXa Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: MR-389/99, Edition Number: M-010737-01-1 Date: 02.08.1999 GLP, unpublished also filed: A 7.2.2.1 /05 (Not included in Caddy, as already filed as A7.2.2.1/05)	Yes	BCS
A 7.2.2.4 /08	Anderson, C.; Fritz, R.	1990	Degradation of [pyridinyl-14C-methylene] NTN 33893 in sandy loam Monheim 1 under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3434, Edition Number: M-006728-02-1 Date: 07.12.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.1 /04 also filed: A 7.2.2.4 /02 (Not included in Caddy, as already filed as A7.2.2.1/04)	Yes	BCS

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A 7.2.2.4 /09	Anderson, C.; Fritz, R.	1990	Degradation of [pyridinyl-14C-methylene] NTN 33893 in silt soil Hoefchen under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3322, Edition Number: M-006740-02-1 Date: 19.01.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.1 /03 also filed: A 7.2.2.4 /03 (Not included in Caddy, as already filed as A7.2.2.1/03)	Yes	BCS
A 7.2.2.4 /10	Anderson, C.; Fritz, R.; Brauner, A.	1990	Metabolism of (pyridinyl-14C-methylene) NTN 33893 in loamy soil BBA 2.2 under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3321, Edition Number: M-006742-02-1 Date: 15.01.1990, Amended: 01.10.1992 GLP, unpublished also filed: A 7.2.2.1/01 also filed: A 7.2.2.4 /04 (Not included in Caddy, as already filed as A7.2.2.1/01)	Yes	BCS
A 7.2.2.4 /11	Anderson, C.; Fritz, R.; Brauner, A.	1990	Metabolism of (pyridinyl-14C-methylene) NTN 33893 in sandy loam under aerobic conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3433, Edition Number: M-023514-01-1 Date: 14.11.1990 GLP, unpublished also filed: A 7.2.2.1 /02 also filed: A 7.2.2.4 /05 (Not included in Caddy, as already filed as A7.2.2.1/02)	Yes	BCS
A 7.3.1. /01	Hellpointner, E.	1999	Calculation of the chemical lifetime of imidacloprid in the troposphere Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: MR-088/99, Edition Number: M-007805-01-1 Date: 18.02.1999 Non GLP, unpublished	Yes	BCS

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A 7.4.1.1. /01	[redacted]	1988b	The acute toxicity of NTN 33893 techn. to rainbow trout (salmo gairdneri) in a static test [redacted] Report No.: FF-210, Edition Number: M-006827-01-2 Date: 03.03.1988 GLP, unpublished	Yes	BCS
A 7.4.1.1. /02	[redacted]	1990	Acute toxicity of NTN 33893 to rainbow trout (Oncorhynchus mykiss) [redacted] Report No.: 100349, Edition Number: M-007019-01-1 Date: 12.12.1990 GLP, unpublished	Yes	BCS
A 7.4.1.1. /03	[redacted]	1990	Method validation for the analysis of NTN-33893 in aquatic test water [Tox/Ecotox method] [redacted] Report No.: 100090, Edition Number: M-015716-01-1 Method Report No.: 37859 Method Report No US: F45.001-00 Date: 13.03.1990 GLP, unpublished	Yes	BCS
A 7.4.1.1. /04	[redacted]	1987	The acute toxicity of NTN 33893 techn. to golden orfe (Leuciscus idus melanotus) in a static test [redacted] Report No.: FO-1042, Edition Number: M-006830-01-2 Date: 26.10.1987 GLP, unpublished	Yes	BCS
A 7.4.1.2. /01	Young, B. M.; Hicks, S. L.	1990	Acute toxicity of NTN 33893 to Daphnia magna Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, USA Bayer CropScience AG, Report No.: 100245, Edition Number: M-006821-01-1 Date: 12.09.1990 GLP, unpublished	Yes	BCS

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A 7.4.1.2. /02	Dorgerloh, M.; Sommer, H.	2002	Acute toxicity of imidacloprid (tech.) to larvae of Chironomus riparius Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: DOM 22031, Edition Number: M-058794-01-1 Date: 12.04.2002 GLP, unpublished	Yes	BCS
A 7.4.1.2. /03	England, D.; Bucksath, J. D.	1991	Acute toxicity of NTN 33893 to Hyalella azteca ABC Laboratories, Inc., Columbia, MO, USA Bayer CropScience AG, Report No.: 101960, Edition Number: M-007182-01-1 Date: 09.10.1991 GLP, unpublished	Yes	BCS
A 7.4.1.2. /04	Roney, D. J.; Bowers, L. M.	1996	Acute toxicity of 14C-NTN 33823 to Hyallela azteca under static conditions Bayer Corporation, Kansas City, MO, USA Bayer CropScience AG, Report No.: 107315, Edition Number: M-032758-01-1 Date: 26.02.1996 GLP, unpublished	Yes	BCS
A 7.4.1.3. /01	Heimbach, F.	1986a	Growth inhibition of green algae (Scenedesmus subspicatus) caused by NTN 33893 (technical) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: HBF/AL 27, Edition Number: M-006854-01-2 Date: 28.11.1986 GLP, unpublished	Yes	BCS
A 7.4.1.3. /02	Dorgerloh, M.	2000	Imidacloprid - Influence on the growth of green alga, Selenastrum capricornutum Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: DOM 20018, Edition Number: M-033262-01-1 Date: 23.05.2000 GLP, unpublished	Yes	BCS
A 7.4.1.4. /01	Mueller; Caspers	2001	NTN 33893 - Toxicity to bacteria Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 1058 A/00 B, Edition Number: M-036840-01-1 Date: 12.02.2001 GLP, unpublished	Yes	BCS

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A 7.4.3.2. /01	[redacted]	2002	Imidacloprid (NTN 33893): Early life-stage toxicity test with rainbow trout (Oncorhynchus mykiss) under flow-through conditions [redacted] Report No.: 1022.016.321, Edition Number: M-049894-01-1 Date: 29.08.2002 GLP, unpublished	Yes	BCS
A 7.4.3.4. /01	Young, B. M.; Blakemore, G. C.	1990	21-day chronic static renewal toxicity of NTN 33893 to Daphnia magna Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, USA Bayer CropScience AG, Report No.: 100247, Edition Number: M-006824-01-1 Date: 19.09.1990 GLP, unpublished	Yes	BCS
A 7.4.3.4. /02	Dorgerloh, M.; Sommer, H.	2001a	Influence of imidacloprid (tech.) on development and emergence of larvae of Chironomus riparius in a water-sediment system Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: DOM 21035, Edition Number: M-075819-01-1 Date: 04.10.2001 GLP, unpublished	Yes	BCS
A 7.4.3.4. /03	Dorgerloh, M.; Sommer, H.	2001b	Influence of imidacloprid-desnitro on development and emergence of larvae of Chironomus riparius in a water-sediment system Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: DOM 21039, Edition Number: M-081499-01-1 Date: 26.10.2001 GLP, unpublished	Yes	BCS
A 7.4.3.5. /01	Ratte, H.T.; Memmert, U.	2003	Biological effects and fate of imidacloprid SL 200 in outdoor microcosm ponds RCC Ltd., Itingen, Switzerland Bayer CropScience AG, Report No.: 811776, Edition Number: M-084035-01-1 Date: 26.02.2003 GLP, unpublished also filed: A 7.1.2.2.2. /06	Yes	BCS

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A 7.4.3.5. /02	Brock, T.C.M.	2005	Evaluation of the report - Biological effects and fate of imidacloprid SL 200 in outdoor microcosm ponds Alterra-Centre fo Water and Climate, Wageningen, The Netherlands Bayer CropScience AG, Report No.: MO-05-008527, Edition Number: M-251183-01-1 Date: 02.05.2005 Non GLP, unpublished	Yes	BCS
A 7.5.1.1. /01	Anderson, J. P. E.	1988	Influence of NTN 33893 on the microbial mineralization of carbon in soils Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: AJO/54088, Edition Number: M-006978-01-2 Date: 11.04.1988 Non GLP, unpublished	Yes	BCS
A 7.5.1.1. /02	Anderson, J .P. E.	1999	Influence of imidacloprid (tech.) in mineralization of (carboxyl-14C) sodium acetate to 14CO2 in a slurry of soil and water Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: AJO/196699, Edition Number: M-048331-01-1 Date: 29.07.1999 GLP, unpublished	Yes	BCS
A 7.5.1.1. /03	Blumenstock, I.	1988	Influence of NTN 33893 on the microbial mineralization of nitrogen in soils Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: BSI/54288, Edition Number: M-006964-01-2 Date: 20.07.1988 Non GLP, unpublished	Yes	BCS
A 7.5.1.2. /01	Heimbach, F.	1986b	Acute toxicity of NTN 33893 (techn.) to earth worms Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: HBF/RG 63, Edition Number: M-006863-01-2 Date: 10.11.1986 GLP, unpublished	Yes	BCS
A 7.5.1.3. /01	Seyfried, B.	1999	Terrestrial plants, growth test with imidacloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 724915, Edition Number: M-017610-01-1 Date: 11.05.1999 GLP, unpublished also filed: A 7.5.2.2. /01	Yes	BCS

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A 7.5.2.1. /01	Heimbach, F.	1999	Influence of low concentrations of imidacloprid (tech.) on the reproduction of earthworms (Eisenia fetida) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: HBF/RG 301, Edition Number: M-032798-01-1 Date: 20.05.1999 GLP, unpublished	Yes	BCS
A 7.5.2.1. /02	Wilhelmy, H.	1999	NTN 33893 - Inhibition of reproduction of collembola (Folsomia candida) Dr. U. Noack-Laboratorium fuer Angewandte Biologie, Sarstedt, Germany Bayer CropScience AG, Report No.: ICR64081, Edition Number: M-031094-01-1 Date: 26.08.1999 GLP, unpublished	Yes	BCS
A 7.5.2.1. /03	Bakker, F. M.	1999	An extended laboratory dose-response study to evaluate the effects of imidacloprid tech. on the predaceous mite Hypoaspis aculeifer Canestrini (Acari: Gamasidae) MITOX Stichting Bevordering Duurzame Plaagbestrijding, Amsterdam, Netherlands Bayer CropScience AG, Report No.: B019HAE, Edition Number: M-041284-01-1 Date: 01.04.1999 GLP, unpublished	Yes	BCS
A 7.5.2.2. /01	Seyfried, B.	1999	Terrestrial plants, growth test with imidacloprid Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 724915, Edition Number: M-017610-01-1 Date: 11.05.1999 GLP, unpublished also filed: A 7.5.1.3. /01	Yes	BCS
A 7.5.3.1.1. /01	[redacted]	1990a	Technical NTN 33893: An acute oral LD50 with Bobwhite quail [redacted] Report No.: 100059, Edition Number: M-006718-01-1 Date: 01.03.1990 GLP, unpublished	Yes	BCS
A 7.5.3.1.1. /02	[redacted]	1988a	Acute oral LD50 of NTN 33893 to japanese quail [redacted] Report No.: VW-123, Edition Number: M-006710-01-1 Date: 28.01.1988 GLP, unpublished	Yes	BCS

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A 7.5.3.1.1. /03	[redacted]	1996	NTN 33893 technical: An acute oral LD50 with mallards [redacted] Report No.: 107354, Edition Number: M-006784-01-1 Date: 20.06.1996 GLP, unpublished	Yes	BCS
A 7.5.3.1.2. /01	[redacted]	1990b	Technical NTN 33893: A subacute dietary LC50 with mallard ducks [redacted] Report No.: 100238, Edition Number: M-006721-01-1 Date: 22.08.1990 GLP, unpublished	Yes	BCS
A 7.5.3.1.2. /02	[redacted]	1996	NTN 33893 techn. 5-day-dietary LC50 to japanese quail [redacted] Report No.: GMU / VW-177, Edition Number: M-006792-02-1 Date: 14.03.1996, Amended: 22.01.2002 GLP, unpublished	Yes	BCS
A 7.5.3.1.2. /03	[redacted]	1996	Age-related five day dietary toxicity of Imidacloprid to bobwhite quail [redacted] Report No.: SXR/VB 057, Edition Number: M-006782-01-1 Date: 14.11.1996 GLP, unpublished	Yes	BCS
A 7.5.3.1.3. /01	[redacted]	1991	Technical NTN 33893: A one generation reproduction study with bobwhite quail [redacted] Report No.: 101203, Edition Number: M-006723-01-1 Date: 25.02.1991 GLP, unpublished	Yes	BCS
A 7.5.3.1.3. /02	[redacted]	1992	Technical NTN 33893: A one generation reproduction study with mallard ducks [redacted] Report No.: 103813-1, Edition Number: M-006730-02-1 Date: 03.09.1992, Amended: 03.06.1993 GLP, unpublished (Caddy complete – total pages 138; Supplement pages 1-39, First report 1-99 (40-138)).	Yes	BCS

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A 7.5.4.1. /01	Cole, J. H.	1990	The acute oral and contact toxicity to honey bees of compound NTN 33893 technical Huntingdon Research Centre Ltd., Huntingdon, Great Britain Bayer CropScience AG, Report No.: BAY 158/901384, Edition Number: M-006940-02-1 Date: 28.12.1990, Amended: 06.01.1994 GLP, unpublished	Yes	BCS
A 7.5.4.1. /02	Schmitzer, S.	1999	Laboratory testing for toxicity (acute oral LD50) of NTN 33893 on honey bees (Apis mellifera L.) (Hymenoptera, Apidae) IBACON GmbH, Rossdorf, Germany Bayer CropScience AG, Report No.: 6400036, Edition Number: M-016942-01-1 Date: 30.09.1999 GLP, unpublished	Yes	BCS
A 7.5.4.1. /03	Kemp, J. R.; Rogers, R. E. L.	2002	Imidacloprid (Admire) residue levels following in-furrow application in potato fields in Prince Edward Island and New Brunswick University Prince Edward Island, Wildwood Labs., Canada Bayer CropScience AG, Report No.: MO-02-006773, Edition Number: M-061850-01-1 Date: 02.05.2002 Non GLP, unpublished	Yes	BCS
A 7.5.4.1. /04	Schmuck, R.; Schoening, R.; Schramel, O.	1999a	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of sunflowers cultivated on soils with different imidacloprid residue levels and effects on these residues on foraging honeybees. 'Laacher Hof' 1999 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: SXR/AM 007, Edition Number: M-016827-01-1 Date: 28.09.1999 GLP, unpublished	Yes	BCS
A 7.5.4.1. /05	Schmuck, R.; Schoening, R.; Schramel, O.	1999b	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of sunflowers cultivated on soils with different imidacloprid residue levels and effects of these residues on foraging honeybees. 'Hoefchen' 1999 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: SXR/AM 006, Edition Number: M-016820-01-1 Date: 27.09.1999 GLP, unpublished	Yes	BCS

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A 7.5.4.1. /06	Schmuck, R.; Schoening, R.; Schramel, O.	1999c	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of summer rape cultivated on soils with different imidacloprid residue levels and effects of these residue on foraging honeybees. 'Hoefchen' 1999 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: SXR/AM 010, Edition Number: M-016842-01-1 Date: 28.09.1999 GLP, unpublished	Yes	BCS
A 7.5.4.1. /07	Schmuck, R.; Schoening, R.; Schramel, O.	1999d	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of summer rape cultivated on soils with different imidacloprid residue levels and effects of these residues on foraging honeybees. Laacher Hof 1999 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: SXR/AM 008, Edition Number: M-016828-01-1 Date: 28.09.1999 GLP, unpublished	Yes	BCS
A VIII. /01	Anon.	2006	Imidacloprid technical insecticide Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-246172-02-1, Edition Number: M-246172-02-1 Date: 18.01.2006 Non GLP, unpublished also filed: A IX. /01	Yes	BCS
A IX. /01	Anon.	2006	Imidacloprid technical insecticide Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-246172-02-1, Edition Number: M-246172-02-1 Date: 18.01.2006 Non GLP, unpublished also filed: A VIII. /01	Yes	BCS
AR/2.2.2.2	Rossink et al. (2013)	2013	The neonicotinoid imidacloprid shows high chronic toxicity to mayfly nymphs, Environmental Toxicology and Chemistry, 2013, Vol 32, No. 5, pp 1096-1100, published	No	

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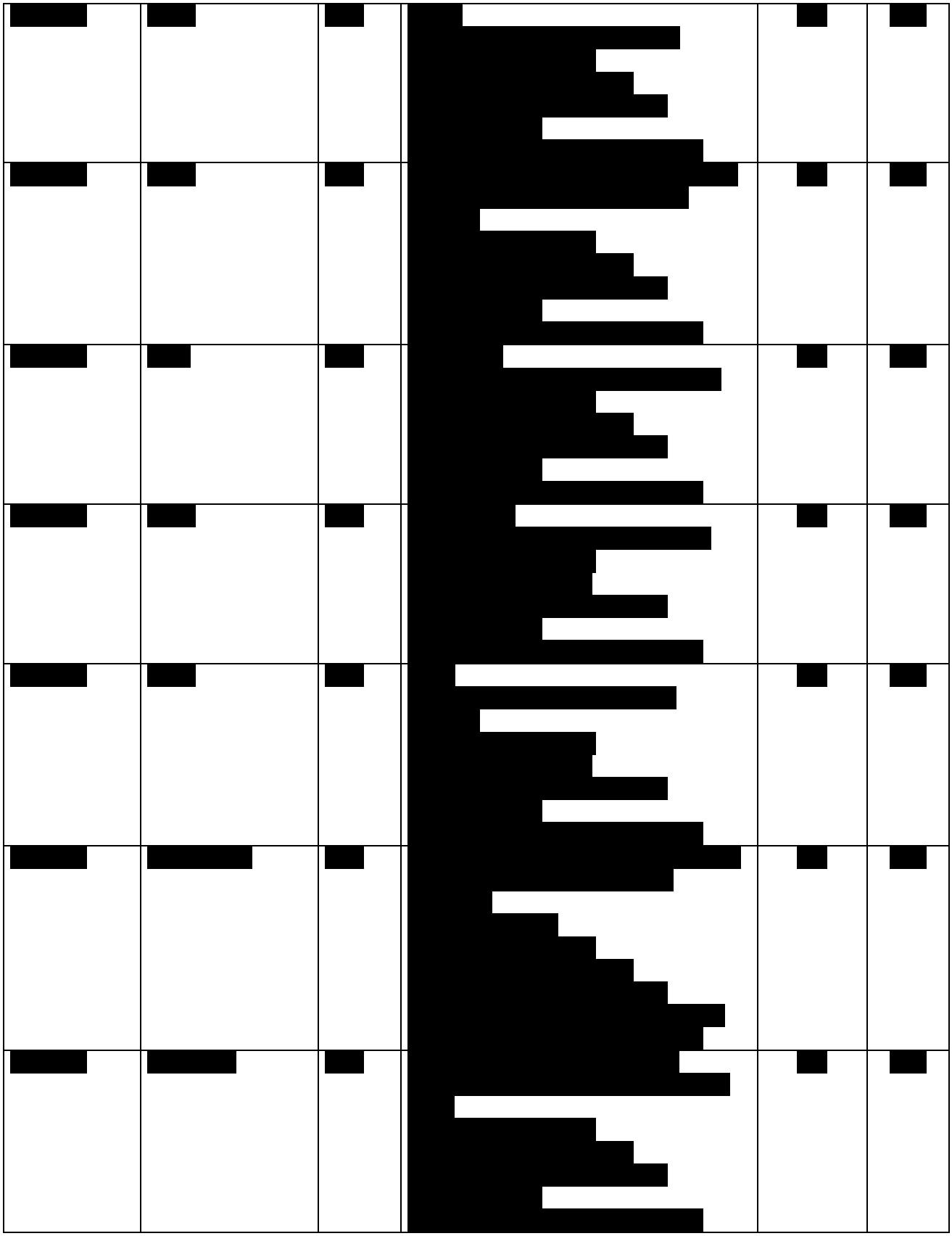
AR/2.2.2.2	Colombo V, Mohr S, Berghahn R, Pettigrove VJ.	2013	Structural changes in a macrozoobenthos assemblage after imidacloprid pulses in aquatic field-based microcosms, 2013, Arch Environ Contam Toxicol 65(4), 683-92, published	No	
AR/2.2.2.2	Ratte HT, Memmert A.	2003	Biological effects and fate of imidacloprid SL 200 in outdoor microcosm ponds. Ittingen, Switzerland. RCC Ltd., 2003, Report 811766 (WAS2003-259 in DAR), GLP, unpublished	No	
AR/2.2.2.2	Smit CE	2014	Water quality standards for imidacloprid. Proposal for an update according to the Water Framework Directive. Bilthoven, the Netherlands. Report 270006001/2014, published	No	

* key study

Reference list of studies on the biocidal product Imidacloprid GL 2.15

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Reference list of studies on the biocidal product Imidacloprid GL 2.15



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[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
B 3.1.1. /01	Stoecker, R. H.	2005	Storage stability data collected on the Bayer product imidacloprid GL 2,15 W - product No.: 005178819 - report on 5 years of storage - Bayer CropScience AG, Report No.: M-263107-01-1, Edition Number: M-263107-01-1 Date: 31.01.2005 Non GLP, unpublished also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.5. /01 also filed: B 3.7. /01	Yes	BCS
B 3.1.1. /02	Stoecker, R.	2005	Storage Stability Data Collected on the Bayer Product Imidacloprid GL 2,15 W - Product No.: 05178819 QA Statement on Certification of Involved Laboratories Bayer EnvironmentalScience AG, Monheim, Germany Bayer CropScience AG, Report No.: M-266594-01-1, Edition Number: M-266594-01-1 Date: 17.10.2005 Non GLP, unpublished also filed: B 3.10.2. /03	Yes	BCS
B 3.1.2. /01	Stoecker, R. H.	2005	Storage stability data collected on the Bayer product imidacloprid GL 2,15 W - product No.: 005178819 - report on 5 years of storage - Bayer CropScience AG, Report No.: M-263107-01-1, Edition Number: M-263107-01-1 Date: 31.01.2005 Non GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.3. /01 also filed: B 3.5. /01 also filed: B 3.7. /01	Yes	BCS

Reference list of studies on the biocidal product Imidacloprid GL 2.15

B 3.1.3. /01	Stoecker, R. H.	2005	Storage stability data collected on the Bayer product imidacloprid GL 2,15 W - product No.: 005178819 - report on 5 years of storage - Bayer CropScience AG, Report No.: M-263107-01-1, Edition Number: M-263107-01-1 Date: 31.01.2005 Non GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.5. /01 also filed: B 3.7. /01	Yes	BCS
B 3.2. /01	Heinz, U.	2002	Final GLP report; determination of safety-relevant data of Imidacloprid 2.15 percent Cockroach Gel Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 02/00436, Edition Number: M-250416-01-1 Date: 24.10.2002 GLP, unpublished also filed: B 3.4. /01 also filed: B 3.4. /02	Yes	BCS
B 3.3. /01	Heinz, U.	2006	Determination of Safety-Relevant Data of Imidacloprid Gel 2,15% - Further code name: Maxforce White IC Bayer Industry Services, Leverkusen, Germany Bayer CropScience AG, Report No.: 2006/00081, Edition Number: M-266788-01-1 Date: 24.02.2006 GLP, unpublished	Yes	BCS
B 3.4. /01	Heinz, U.	2002	Final GLP report; determination of safety-relevant data of Imidacloprid 2.15 percent Cockroach Gel Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 02/00436, Edition Number: M-250416-01-1 Date: 24.10.2002 GLP, unpublished also filed: B 3.2. /01 also filed: B 3.4. /02	Yes	BCS

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B 3.4. /02	Heinz, U.	2002	Final GLP report; determination of safety-relevant data of Imidacloprid 2.15 percent Cockroach Gel Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 02/00436, Edition Number: M-250416-01-1 Date: 24.10.2002 GLP, unpublished also filed: B 3.2. /01 also filed: B 3.4. /01	Yes	BCS
B 3.5. /01	Stoecker, R. H.	2005	Storage stability data collected on the Bayer product imidacloprid GL 2,15 W - product No.: 005178819 - report on 5 years of storage - Bayer CropScience AG, Report No.: M-263107-01-1, Edition Number: M-263107-01-1 Date: 31.01.2005 Non GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.7. /01	Yes	BCS
B 3.6. /01	Erstling, K., Jungheim, R.	2002	Imidacloprid 2,15 percent Cockroach Gel - GLP final report: physicochemical properties Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: MO-05-007646, Edition Number: M-250432-01-1 Date: 06.11.2002 GLP, unpublished	Yes	BCS
B 3.7. /01	Stoecker, R. H.	2005	Storage stability data collected on the Bayer product imidacloprid GL 2,15 W - product No.: 005178819 - report on 5 years of storage - Bayer CropScience AG, Report No.: M-263107-01-1, Edition Number: M-263107-01-1 Date: 31.01.2005 Non GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.5. /01	Yes	BCS
B 3.10.1 /01	Olf, G.	2002	Imidacloprid 2,15 percent Cockroach Gel - GLP final report: surface tension, physical-chemical properties Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 02/022/03, Edition Number: M-250438-01-1 Date: 13.11.2002 GLP, unpublished	Yes	BCS

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B 3.10.2. /01	Stoecker, R. H.	2005	Impact of temperature on the viscosity of imidacloprid GL 2.5 during storage Bayer EnvironmentalScience AG, Monheim, Germany Bayer CropScience AG, Report No.: M-263946-01-1, Edition Number: M-263946-01-1 Date: 31.07.2005 GLP, unpublished	Yes	BCS
B 3.10.2. /02	Stoecker, R.	2006	Statement on release limits specified for the viscosity of the product imidachloprid GL 2.15W Bayer Environmental Science AG, Monheim, Germany Bayer CropScience AG, Report No.: M-266592-01-1, Edition Number: M-266592-01-1 Date: 23.02.2006 Non GLP, unpublished	Yes	BCS
B 3.10.2. /03	Stoecker, R.	2005	Storage Stability Data Collected on the Bayer Product Imidacloprid GL 2,15 W - Product No.: 05178819 QA Statement on Certification of Involved Laboratories Bayer EnvironmentalScience AG, Monheim, Germany Bayer CropScience AG, Report No.: M-266594-01-1, Edition Number: M-266594-01-1 Date: 17.10.2005 Non GLP, unpublished also filed: B 3.1.1. /02	Yes	BCS
B 3.10.2. /04	Bittner, P.; Grimmig, B.	2004	Viscosity, Rotating Viscometer according to CIPAC Bayer CropScience AG, Report No.: PM001603MF2, Edition Number: M-104291-02-2 Date: 11.03.2004 Non GLP, unpublished	Yes	BCS
B 4.1. /01	Seidel, E.	1997	Determination of Imidacloprid in Formulations Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 2001-0002502-97, Edition Number: MO-99-000068 Date: 23.04.1997 Non GLP, unpublished	Yes	BCS

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B 4.1. /02	Odendahl, A.	2002	Validation of HPLC-method 2001-0002502-97 - Determination of Imidacloprid in Cockroach Gel-Bait - Bayer CropScience AG, Report No.: VS42.1-2001-0002502, Edition Number: M-074269-01-1 Date: 29.07.2002 Non GLP, unpublished	Yes	BCS
B 5.10.1. /01	Anon.	2006	BPD frame label: Imidacloprid GL 2.15 Bayer Environmental Science Bayer CropScience AG, Report No.: M-268846-01-1, Edition Number: M-268846-01-1 Date: 04.04.2006 Non GLP, unpublished	Yes	BCS
B 5.10.2. /01	Nentwig, G.	1998	Efficacy of Imidacloprid cockroach gel against the german cockroach Blattella germanica under laboratory conditions in comparison to a Hydramethylnon containing cockroach bait Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 549/36, Edition Number: M-105412-01-1 Date: 30.03.1998 Non GLP, unpublished	Yes	BCS
B 5.10.2. /02	Nentwig, G.	1998	Efficacy of imidacloprid cockroach gel against the German cockroach Blattella germanica, the brown banded cockroach Supellea longipalpa and the oriental cocokroach Blatta orientalis under laboratory conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: AH-D-ID 18807, Edition Number: M-266733-01-1 Date: 29.09.1998 Non GLP, unpublished	Yes	BCS
B 5.10.2. /03	Nentwig, G.	2004	BES0206: MF White IC and MF 124K (both with 2,15percent imidacloprid): biological efficacy against the American cockroach (Periplaneta americana) and the Oriental cockroach (Blatta orientalis) Bayer Environmental Science Bayer CropScience AG, Report No.: BES-EH-Mo 013890, Edition Number: M-265493-01-1 Date: 29.11.2004 Non GLP, unpublished	Yes	BCS

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B 5.10.2. /04	Nentwig, G.	2001	Initial efficacy of an imidacloprid containing gel in comparison to a gel with fipronil against the German cockroach Blattella germanica Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: M-266722-01-1, Edition Number: M-266722-01-1 Date: 02.07.2001 Non GLP, unpublished	Yes	BCS
B 5.10.2. /05	Nentwig, G.	2001	Efficacy of imidacloprid cockroach gel (2.15 percent imidacloprid) stored for almost three years in comparison to a fresh gel against the German cockroach Blattella germanica and the oriental cockroach Blatta orientalis Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: AH-D-ID 26869, Edition Number: M-267076-01-1 Date: 08.01.2001 Non GLP, unpublished	Yes	BCS
B 5.10.2. /06	Miller, P. F.; Peters, B.	1997	Field study to determine the efficacy of Imidacloprid cockroach gel and Hydramethylnon cockroach gel against the german cockroach University of Technology, Sydney, Australia Bayer CropScience AG, Report No.: R1266, Edition Number: M-105455-01-1 Date: 25.09.1997 Non GLP, unpublished	Yes	BCS
B 5.10.2. /07	Rashid, M. Z.; Ramli, S.	2000	Premise cockroach gel in food outlet Bayer Malaysia, Selangor, Malaysia Bayer CropScience AG, Report No.: AH-D-ID 26136, Edition Number: M-266719-01-1 Date: 05.02.2000 Non GLP, unpublished	Yes	BCS
B 5.10.2. /08	Miller, P. F.; Peters, B.	1998	Field study to determine the efficacy of Bayer Imidacloprid cockroach gel against the german cockroach University of Technology, Sydney, Australia Bayer CropScience AG, Report No.: R1284V2, Edition Number: M-105452-01-1 Date: 04.05.1998 Non GLP, unpublished	Yes	BCS

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B 5.10.2. /09	Miller, P. F.; Peters, B.	2000	Field study to determine the efficay of Bayer imidacloprid cockroach gel and Rhone-Pulenc Goliath cockroach gel against the German cockroach (12 month assessment) University of Technology, Sydney, Australia Bayer CropScience AG, Report No.: AH-D-ID 26185, Edition Number: M-266671-01-1 Date: 28.02.2000 Non GLP, unpublished	Yes	BCS
B 5.10.2. /10	Rao, J. V.; Kavitha, P.; Makkapati, A. K.	2006	Efficacy if imidacloprid gel (Premise) bait to control cockroach infestation in food storage godowns Bayer (India) Limited, Mumbai, India Bayer CropScience AG, Report No.: BES-EH-Mo 00274, Edition Number: M-266713-01-1 Date: 27.02.2006 Non GLP, unpublished	Yes	BCS
B 5.10.2. /11	Serrano, B.	2005	Field testing of the efficacy of gel baits to control German Cockroaches T.E.C. Laboratory, Anglet, France Bayer CropScience AG, Report No.: BES-EH-Mo 01205, Edition Number: M-265241-01-1 Date: 28.09.2005 Non GLP, unpublished	Yes	BCS
B 5.10.2. /12	Boase, C.	2004	UK Field Trials with Maxforce White IC against the Oriental Cockroach the Pest Management Consultancy, Haverhill, Suffolk, UK Bayer CropScience AG, Report No.: M-256847-01-1, Edition Number: M-256847-01-1 Date: 30.09.2004 Non GLP, unpublished	Yes	BCS
B 5.10.2. /13	Boase, C. J.	2006	UK field trial with imidacloprid gels against Oriental cockroaches Hazel Stub, Suffolk, Great Britain Bayer CropScience AG, Report No.: BES-EH-Mo 01393, Edition Number: M-265749-01-1 Date: 01.02.2006 Non GLP, unpublished	Yes	BCS

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B 5.10.2. /14	Ahmad, A. I.	1998	Field study to determine the efficacy of imidacloprid cockoroach gel and hydramethylnon cockroach gel against the american cockoroach University Sains Malaysia, Penang, Malaysia Bayer CropScience AG, Report No.: AH-D-ID 18836, Edition Number: M-266708-01-1 Date: 09.11.1998 Non GLP, unpublished	Yes	BCS
B 5.10.2. /15	Miller P.F.; Peters B.	2001	Field study to determine the efficacy of two Goliath cockroach gels and premise cockroach gel against the American and Australian cockroach (Aventis project IH00AUSP51) Aventis, Australia; Bayer CropScience AG, Report No.: C015022, Report includes Trial Nos.: IH00AUSP51 Edition Number: M-199714-01-1 Date: 02.08.2001 Non GLP, unpublished	Yes	BCS
B 5.11.2. /01	Wank, C.; Scharf, M. E.; Bennett, G. W.	2004	Behavioral and physical resistance of German cockroach to gel baits (Blattodea: Blattellidae) Publisher:Entomological Society of America, Volume:97, Issue:6, Pages:2067 -2072, Year:2004, Report No.: BES-EH-Mo 1039, Edition Number: M-268284-01-1 Non GLP, published	No	
B 6.1.1. /01	[redacted]	1998	Acute oral toxicity study with Imidacloprid Cockroach Gel in rats [redacted] Report No.: BC8457, Edition Number: M-026014-01-1 Date: 03.04.1998 GLP, unpublished	Yes	BCS
B 6.1.2 /01	[redacted]	1998	Acute dermal toxicity study with Imidacloprid Cockroach Gel in rats [redacted] Report No.: BC8461, Edition Number: M-026741-01-1 Date: 09.04.1998 GLP, unpublished	Yes	BCS

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B 6.2. /01	[redacted]	1998	Primary dermal irritation study in rabbits with Imidacloprid Cockroach Gel [redacted] Report No.: BC8460, Edition Number: M-026757-01-1 Date: 20.03.1998 GLP, unpublished	Yes	BCS
B 6.2. /02	[redacted]	1998	Primary eye irritation study in rabbits with Imidacloprid Cockroach Gel [redacted] Report No.: BC8459, Edition Number: M-026718-01-1 Date: 20.03.1998 GLP, unpublished	Yes	BCS
B 6.3. /01	[redacted]	2005	NTN 33893 2.15 GL (Project: Imidacloprid (NTN33893)) - Study for the skin sensitization effect in guinea pigs (guinea pig maximization test according to Magnusson and Kligman) [redacted] Report No.: AT02372, Edition Number: M-257484-01-1 Date: 13.09.2005 GLP, unpublished	Yes	BCS
B 6.3. /02	[redacted]	2005	Alpha Hexyl Cinnamic Aldehyde - Validation of the Magnusson-Kligman maximization test method used by the Bayer HealthCare AG, PH-PD Toxicology International, performed in guinea pigs of the strain Crl:HA [redacted] Report No.: 33759, Edition Number: M-267619-01-1 Date: 22.02.2005 GLP, unpublished	Yes	BCS
B 6.4	[redacted]	2005	Confidor OD 200 ([14C]-imidacloprid): Comparative in vitro dermal absorption study using human and rat skin. [redacted] Study no. SA 04242, Report amendmend no. 1, Date: 21.02.2005 GLP, unpublished	Yes	BCS

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B 8/01	Anon.	2006	Imidacloprid GL 2.15 Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-266764-01-1, Edition Number: M-266764-01-1 Date: 23.02.2006 Non GLP, unpublished also filed: B IX. /01	Yes	BCS
B 9/01	Anon.	2006	Imidacloprid GL 2.15 Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-266764-01-1, Edition Number: M-266764-01-1 Date: 23.02.2006 Non GLP, unpublished also filed: B VIII. /01	Yes	BCS
B 9/02	Anon.	2006	BPD frame label: Imidacloprid GL 2.15 Bayer Environmental Science Bayer CropScience AG, Report No.: M-268846-01-1, Edition Number: M-268846-01-1 Date: 04.04.2006 Non GLP, unpublished	Yes	BCS

Reference list of studies on the biocidal product Imidacloprid GR 0.5

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
B 3.1.1. /01	Gueldner, W.	2005	Storage stability at elevated temperature of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 weeks at 54°C) Bayer CropScience AG, Report No.: 1410505371, Edition Number: M-257402-01-1 Date: 06.09.2005 GLP, unpublished also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.7. /01 also filed: B 3.7. /03 also filed: B 3.8. /01 also filed: B 3.8. /03 also filed: B 3.8. /04 also filed: B 3.11. /01 also filed: B 3.11. /03	Yes	BCS

Reference list of studies on the biocidal product Imidacloprid GR 0.5

B 3.1.1. /02	Gueldner, W. Hoppe, M.	2007	Storage stability and shelf life of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 years at ambient temperature) Bayer CropScience AG, Report No.: 1410505372, Edition Number: M-293853-01-1 Date: 17.09.2007 GLP, unpublished also filed: B 3.1.2. /02 also filed: B 3.1.3. /02 also filed: B 3.5. /02 also filed: B 3.7. /02 also filed: B 3.7. /04 also filed: B 3.8. /02 also filed: B 3.8. /05 also filed: B 3.11. /02 also filed: B 3.11. /04	Yes	BCS
B 3.1.2. /01	Gueldner, W.	2005	Storage stability at elevated temperature of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 weeks at 54°C) Bayer CropScience AG, Report No.: 1410505371, Edition Number: M-257402-01-1 Date: 06.09.2005 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.3. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.7. /01 also filed: B 3.7. /03 also filed: B 3.8. /01 also filed: B 3.8. /03 also filed: B 3.8. /04 also filed: B 3.11. /01 also filed: B 3.11. /03	Yes	BCS

Reference list of studies on the biocidal product Imidacloprid GR 0.5

B 3.1.2. /02	Gueldner, W. Hoppe, M.	2007	Storage stability and shelf life of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 years at ambient temperature) Bayer CropScience AG, Report No.: 1410505372, Edition Number: M-293853-01-1 Date: 17.09.2007 GLP, unpublished also filed: B 3.1.1. /02 also filed: B 3.1.3. /02 also filed: B 3.5. /02 also filed: B 3.7. /02 also filed: B 3.7. /04 also filed: B 3.8. /02 also filed: B 3.8. /05 also filed: B 3.11. /02 also filed: B 3.11. /04	Yes	BCS
B 3.1.3. /01	Gueldner, W.	2005	Storage stability at elevated temperature of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 weeks at 54°C) Bayer CropScience AG, Report No.: 1410505371, Edition Number: M-257402-01-1 Date: 06.09.2005 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.7. /01 also filed: B 3.7. /03 also filed: B 3.8. /01 also filed: B 3.8. /03 also filed: B 3.8. /04 also filed: B 3.11. /01 also filed: B 3.11. /03	Yes	BCS

Reference list of studies on the biocidal product Imidacloprid GR 0.5

B 3.1.3. /02	Gueldner, W. Hoppe, M.	2007	Storage stability and shelf life of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 years at ambient temperature) Bayer CropScience AG, Report No.: 1410505372, Edition Number: M-293853-01-1 Date: 17.09.2007 GLP, unpublished also filed: B 3.1.1. /02 also filed: B 3.1.2. /02 also filed: B 3.5. /02 also filed: B 3.7. /02 also filed: B 3.7. /04 also filed: B 3.8. /02 also filed: B 3.8. /05 also filed: B 3.11. /02 also filed: B 3.11. /04	Yes	BCS
B 3.2. /01	Heitkamp, D.	2001	Final GLP report: Determination of safety-relevant data of imidacloprid 0,5 percent (Flybait) Bayer Industry Services GmbH & CoOHG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00/00772, Report includes Trial Nos.: 1026038/2000 Edition Number: M-255323-01-1 Date: 22.03.2001 GLP, unpublished also filed: B 3.2. /02 also filed: B 3.2. /03 also filed: B 3.3. /01 also filed: B 3.4. /01 also filed: B 3.4. /02 also filed: B 3.4. /03	Yes	BCS
B 3.2. /02	Heitkamp, D.	2001	Final GLP report: Determination of safety-relevant data of imidacloprid 0,5 percent (Flybait) Bayer Industry Services GmbH & CoOHG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00/00772, Report includes Trial Nos.: 1026038/2000 Edition Number: M-255323-01-1 Date: 22.03.2001 GLP, unpublished also filed: B 3.2. /01 also filed: B 3.2. /03 also filed: B 3.3. /01 also filed: B 3.4. /01 also filed: B 3.4. /02 also filed: B 3.4. /03	Yes	BCS

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B 3.2. /03	Heitkamp, D.	2001	Final GLP report: Determination of safety-relevant data of imidacloprid 0,5 percent (Flybait) Bayer Industry Services GmbH & CoOHG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00/00772, Report includes Trial Nos.: 1026038/2000 Edition Number: M-255323-01-1 Date: 22.03.2001 GLP, unpublished also filed: B 3.2. /01 also filed: B 3.2. /02 also filed: B 3.3. /01 also filed: B 3.4. /01 also filed: B 3.4. /02 also filed: B 3.4. /03	Yes	BCS
B 3.3. /01	Heitkamp, D.	2001	Final GLP report: Determination of safety-relevant data of imidacloprid 0,5 percent (Flybait) Bayer Industry Services GmbH & CoOHG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00/00772, Report includes Trial Nos.: 1026038/2000 Edition Number: M-255323-01-1 Date: 22.03.2001 GLP, unpublished also filed: B 3.2. /01 also filed: B 3.2. /02 also filed: B 3.2. /03 also filed: B 3.4. /01 also filed: B 3.4. /02 also filed: B 3.4. /03	Yes	BCS
B 3.4. /01	Heitkamp, D.	2001	Final GLP report: Determination of safety-relevant data of imidacloprid 0,5 percent (Flybait) Bayer Industry Services GmbH & CoOHG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00/00772, Report includes Trial Nos.: 1026038/2000 Edition Number: M-255323-01-1 Date: 22.03.2001 GLP, unpublished also filed: B 3.2. /01 also filed: B 3.2. /02 also filed: B 3.2. /03 also filed: B 3.3. /01 also filed: B 3.4. /02 also filed: B 3.4. /03	Yes	BCS

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B 3.4. /02	Heitkamp, D.	2001	Final GLP report: Determination of safety-relevant data of imidacloprid 0,5 percent (Flybait) Bayer Industry Services GmbH & CoOHG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00/00772, Report includes Trial Nos.: 1026038/2000 Edition Number: M-255323-01-1 Date: 22.03.2001 GLP, unpublished also filed: B 3.2. /01 also filed: B 3.2. /02 also filed: B 3.2. /03 also filed: B 3.3. /01 also filed: B 3.4. /01 also filed: B 3.4. /03	Yes	BCS
B 3.4. /03	Heitkamp, D.	2001	Final GLP report: Determination of safety-relevant data of imidacloprid 0,5 percent (Flybait) Bayer Industry Services GmbH & CoOHG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00/00772, Report includes Trial Nos.: 1026038/2000 Edition Number: M-255323-01-1 Date: 22.03.2001 GLP, unpublished also filed: B 3.2. /01 also filed: B 3.2. /02 also filed: B 3.2. /03 also filed: B 3.3. /01 also filed: B 3.4. /01 also filed: B 3.4. /02	Yes	BCS

Reference list of studies on the biocidal product Imidacloprid GR 0.5

B 3.5. /01	Gueldner, W.	2005	Storage stability at elevated temperature of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 weeks at 54°C) Bayer CropScience AG, Report No.: 1410505371, Edition Number: M-257402-01-1 Date: 06.09.2005 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.6. /01 also filed: B 3.7. /01 also filed: B 3.7. /03 also filed: B 3.8. /01 also filed: B 3.8. /03 also filed: B 3.8. /04 also filed: B 3.11. /01 also filed: B 3.11. /03	Yes	BCS
B 3.5. /02	Gueldner, W. Hoppe, M.	2007	Storage stability and shelf life of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 years at ambient temperature) Bayer CropScience AG, Report No.: 1410505372, Edition Number: M-293853-01-1 Date: 17.09.2007 GLP, unpublished also filed: B 3.1.1. /02 also filed: B 3.1.2. /02 also filed: B 3.1.3. /02 also filed: B 3.7. /02 also filed: B 3.7. /04 also filed: B 3.8. /02 also filed: B 3.8. /05 also filed: B 3.11. /02 also filed: B 3.11. /04	Yes	BCS

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B 3.6. /01	Gueldner, W.	2005	Storage stability at elevated temperature of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 weeks at 54°C) Bayer CropScience AG, Report No.: 1410505371, Edition Number: M-257402-01-1 Date: 06.09.2005 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.5. /01 also filed: B 3.7. /01 also filed: B 3.7. /03 also filed: B 3.8. /01 also filed: B 3.8. /03 also filed: B 3.8. /04 also filed: B 3.11. /01 also filed: B 3.11. /03	Yes	BCS
B 3.7. /01	Gueldner, W.	2005	Storage stability at elevated temperature of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 weeks at 54°C) Bayer CropScience AG, Report No.: 1410505371, Edition Number: M-257402-01-1 Date: 06.09.2005 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.7. /03 also filed: B 3.8. /01 also filed: B 3.8. /03 also filed: B 3.8. /04 also filed: B 3.11. /01 also filed: B 3.11. /03	Yes	BCS

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B 3.7. /02	Gueldner, W. Hoppe, M.	2007	Storage stability and shelf life of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 years at ambient temperature) Bayer CropScience AG, Report No.: 1410505372, Edition Number: M-293853-01-1 Date: 17.09.2007 GLP, unpublished also filed: B 3.1.1. /02 also filed: B 3.1.2. /02 also filed: B 3.1.3. /02 also filed: B 3.5. /02 also filed: B 3.7. /04 also filed: B 3.8. /02 also filed: B 3.8. /05 also filed: B 3.11. /02 also filed: B 3.11. /04	Yes	BCS
B 3.7. /03	Gueldner, W.	2005	Storage stability at elevated temperature of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 weeks at 54°C) Bayer CropScience AG, Report No.: 1410505371, Edition Number: M-257402-01-1 Date: 06.09.2005 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.7. /01 also filed: B 3.8. /01 also filed: B 3.8. /03 also filed: B 3.8. /04 also filed: B 3.11. /01 also filed: B 3.11. /03	Yes	BCS

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B 3.7. /04	Gueldner, W. Hoppe, M.	2007	Storage stability and shelf life of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 years at ambient temperature) Bayer CropScience AG, Report No.: 1410505372, Edition Number: M-293853-01-1 Date: 17.09.2007 GLP, unpublished also filed: B 3.1.1. /02 also filed: B 3.1.2. /02 also filed: B 3.1.3. /02 also filed: B 3.5. /02 also filed: B 3.7. /02 also filed: B 3.8. /02 also filed: B 3.8. /05 also filed: B 3.11. /02 also filed: B 3.11. /04	Yes	BCS
B 3.8. /01	Gueldner, W.	2005	Storage stability at elevated temperature of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 weeks at 54°C) Bayer CropScience AG, Report No.: 1410505371, Edition Number: M-257402-01-1 Date: 06.09.2005 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.7. /01 also filed: B 3.7. /03 also filed: B 3.8. /03 also filed: B 3.8. /04 also filed: B 3.11. /01 also filed: B 3.11. /03	Yes	BCS

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B 3.8. /04	Gueldner, W.	2005	Storage stability at elevated temperature of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 weeks at 54°C) Bayer CropScience AG, Report No.: 1410505371, Edition Number: M-257402-01-1 Date: 06.09.2005 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.7. /01 also filed: B 3.7. /03 also filed: B 3.8. /01 also filed: B 3.8. /03 also filed: B 3.11. /01 also filed: B 3.11. /03	Yes	BCS
B 3.8. /05	Gueldner, W. Hoppe, M.	2007	Storage stability and shelf life of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 years at ambient temperature) Bayer CropScience AG, Report No.: 1410505372, Edition Number: M-293853-01-1 Date: 17.09.2007 GLP, unpublished also filed: B 3.1.1. /02 also filed: B 3.1.2. /02 also filed: B 3.1.3. /02 also filed: B 3.5. /02 also filed: B 3.7. /02 also filed: B 3.7. /04 also filed: B 3.8. /02 also filed: B 3.11. /02 also filed: B 3.11. /04	Yes	BCS

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B 3.11. /01	Gueldner, W.	2005	Storage stability at elevated temperature of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 weeks at 54°C) Bayer CropScience AG, Report No.: 1410505371, Edition Number: M-257402-01-1 Date: 06.09.2005 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.7. /01 also filed: B 3.7. /03 also filed: B 3.8. /01 also filed: B 3.8. /03 also filed: B 3.8. /04 also filed: B 3.11. /03	Yes	BCS
B 3.11. /02	Gueldner, W. Hoppe, M.	2007	Storage stability and shelf life of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 years at ambient temperature) Bayer CropScience AG, Report No.: 1410505372, Edition Number: M-293853-01-1 Date: 17.09.2007 GLP, unpublished also filed: B 3.1.1. /02 also filed: B 3.1.2. /02 also filed: B 3.1.3. /02 also filed: B 3.5. /02 also filed: B 3.7. /02 also filed: B 3.7. /04 also filed: B 3.8. /02 also filed: B 3.8. /05 also filed: B 3.11. /04	Yes	BCS

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B 3.11. /04	Gueldner, W. Hoppe, M.	2007	Storage stability and shelf life of Imidacloprid GR 0.5 - Packaging material: HDPE - Final report (2 years at ambient temperature) Bayer CropScience AG, Report No.: 1410505372, Edition Number: M-293853-01-1 Date: 17.09.2007 GLP, unpublished also filed: B 3.1.1. /02 also filed: B 3.1.2. /02 also filed: B 3.1.3. /02 also filed: B 3.5. /02 also filed: B 3.7. /02 also filed: B 3.7. /04 also filed: B 3.8. /02 also filed: B 3.8. /05 also filed: B 3.11. /02	Yes	BCS
B 4.1. /01	Veith, M.	2003	Determination of Imidacloprid in Bait Formulations ; Assay - HPLC - External Standard Bayer Industry Services, Dormagen, Germany Bayer CropScience AG, Report No.: 2201-0322602-03, Edition Number: M-085932-02-2 Date: 28.01.2003 Non GLP, unpublished	Yes	BCS

Reference list of studies on the biocidal product Imidacloprid GR 0.5

B 4.1. /02	Guedel, F.	2005	Imidacloprid Fly Bait ; Determination of Imidacloprid ; Validation of Method 2201-0322602-03 Bayer CropScience AG, Report No.: VB1-2201-0322602, Edition Number: M-261691-01-1 Date: 29.11.2005 Non GLP, unpublished	Yes	BCS
B 5.10.1. /01	Anon.	2006	BPD frame label: Imidacloprid GR 0.5 Bayer Environmental Science Bayer CropScience AG, Report No.: M-268845-01-1, Edition Number: M-268845-01-1 Date: 04.04.2006 Non GLP, unpublished	Yes	BCS
B 5.10.2. /01	Nentwig, G.	2006	StB P208 imidacloprid GR 0.5 (quick bayt) in comparison to a methomyl containing product (trial 1: both with different applications): efficacy against the house fly (Musca domestica), susceptible strain WHO(N) Bayer CropScience AG, Report No.: BES-EH-Mo 01425, Edition Number: M-266802-01-1 Date: 09.02.2006 Non GLP, unpublished	Yes	BCS
B 5.10.2. /02	Nentwig, G.	2006	StB P208 imidacloprid GR 0.5 (quick bayt) in comparison to a methomyl containing product (trial 2: both as paint on different surfaces): efficacy against the house fly (Musca domestica), susceptible strain WHO(N) Bayer CropScience AG, Report No.: BES-EH-Mo 01426, Edition Number: M-266783-01-1 Date: 09.02.2006 Non GLP, unpublished	Yes	BCS
B 5.10.2. /03	Nentwig, G.	2006	StB P208 imidacloprid GR 0.5 (quick bayt) (trial 3: old batch versus new batch): efficacy against the house fly (Musca domestica), susceptible strain WHO(N) Bayer CropScience AG, Report No.: BES-EH-Mo 01427, Edition Number: M-266784-01-1 Date: 24.02.2006 Non GLP, unpublished	Yes	BCS
B 5.10.2. /04	Junkersdorf, J.	2000	Residual efficacy of Imidacloprid fly bait in a pig breeding unit against the house fly Musca domestica Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: MO-03-009182, Edition Number: M-116591-01-1 Date: 24.08.2000 Non GLP, unpublished	Yes	BCS

Reference list of studies on the biocidal product Imidacloprid GR 0.5

B 5.10.2. /05	Junkersdorf, J.	2000	Residual efficacy of Imidacloprid fly bait in a pig fattening stable against the house fly Musca domestica Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: JUK01-00, Edition Number: M-116595-01-1 Date: 24.08.2000 Non GLP, unpublished	Yes	BCS
B 5.10.2. /06	Fioretti, D. P.	2004	Quick bayt granulare Bayer CropScience (Year of trial 2004) Univerity of Perugia, Via S. Costanzo, Italy Bayer CropScience AG, Report No.: M-266121-01-1, Edition Number: M-266121-01-1 Date: 30.11.2004 Non GLP, unpublished	Yes	BCS
B 5.10.2. /07	Pospischil, R.; Junkersdorf, J.; Hedwig, V.	2001	Treatment of pig stables in North Germany with imidacloprid GR 0.5 against Musca domestica Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: BES-EH-Mo 01406, Edition Number: M-266189-01-1 Date: 13.12.2001 Non GLP, unpublished	Yes	BCS
B 5.10.2. /08	Pospischil, R.; Junkersdorf, J.	2003	Efficacy of imidacloprid WG 10 after pre-treatment with pyrethroid sprays against house flies (Musca domestica) in the farm Eisenach Bayer Environmental Science, Monheim, Germany Bayer CropScience AG, Report No.: BES-EH-Mo 00941, Edition Number: M-264457-01-1 Date: 20.11.2003 Non GLP, unpublished	Yes	BCS
B 5.10.2. /09	Pospischil, R.; Junkersdorf, J.	2003	Efficacy of imidacloprid GR 0.5 after application as paint-on against house flies (Musca domestica) in the farm Eisenach Bayer CropScience AG, Report No.: BES-EH-Mo 01104, Edition Number: M-266748-01-1 Date: 20.11.2003 Non GLP, unpublished	Yes	BCS

Reference list of studies on the biocidal product Imidacloprid GR 0.5

B 5.10.2. /10	Pospischil, R.; Junkersdorf, J.	2004	Treatment of the pig farm Ralingen (Bitburg, Germany) with different paint-on baits against the larger house fly musca domestica Bayer CropScience AG, Report No.: M-263694-01-1, Edition Number: M-263694-01-1 Date: 08.12.2004 Non GLP, unpublished	Yes	BCS ES
B 5.10.2. /11	Knorr, M. Kristensen,M. Jespersen, J.B.	2005	Efficacy of imidacloprid bait against the housefly Musca domestica when applied under field conditions as -gel bait- or -paint-on bait- Danish Pest Infestation Laboratory, Denmark Bayer CropScience AG, Report No.: BES-EH-Mo 01119, Edition Number: M-266736-01-1 Date: 30.06.2005 Non GLP, unpublished	Yes	BCS
B 5.10.2. /12	Pospischil, R.; Junkersdorf, J.; Hedwig, V.	2001	Treatment of a caged layer house in North Germany with imidacloprid GR 0.5 as a paint-on against Musca domestica Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: BES-EH-Mo 01405, Edition Number: M-266185-01-1 Date: 13.12.2001 Non GLP, unpublished	Yes	BCS
B 6.1.1. /01	[redacted]	[redacted]	Imidacloprid Fly Bait - Study for acute oral toxicity in rats [redacted] Report No.: 30075, Edition Number: M-086290-02-1 Date: 25.07.2000, Amended: 29.08.2001 GLP, unpublished	Yes	BCS
B 6.1.2 /01	[redacted]	2000	Imidacloprid Fly Bait - Study for acute dermal toxicity in rats [redacted] Report No.: 30074, Edition Number: M-086389-02-1 Date: 25.07.2000, Amended: 29.08.2001 GLP, unpublished	Yes	BCS
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B 7.5. /02	Schad, T.	2003	Predicted environmental concentrations of imidacloprid in ground water recharge based on calculations with FOCUS PELMO Use in apple, sugar beets and tomatoes in Europe Bayer CropScience AG, Report No.: MEF-103/03, Edition Number: M-089479-01-1 Date: 15.04.2003 Non GLP, unpublished	Yes	BCS

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B 7.8.7.2. /01	Barfknecht, R.	2000	Acceptance of Imidacloprid Fly Bait, consisting of 0.5 % imidacloprid, by chicks (Gallus gallus), tested in two possible scenarios of accidental exposure Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: BAR/ANN013, Edition Number: M-046835-01-1 Date: 21.08.2000 GLP, unpublished	Yes	BCS
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B 9/01	Anon.	2006	Safety Data Sheet Quick Bait Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-266496-01-1, Edition Number: M-266496-01-1 Date: 20.02.2006 Non GLP, unpublished also filed: B VIII. /01	Yes	BCS
B 9/02	Anon.	2006	BPD frame label: Imidacloprid GR 0.5 Bayer Environmental Science, Bayer CropScience AG Report No.: M-268845-01-1 BES Ref.: M-268845-01-1 Date: 04.04 2006 Non GLP, unpublished	Yes	BCS