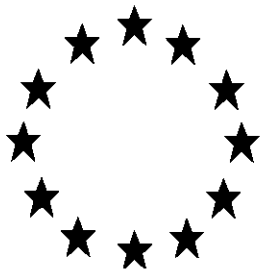
Directive 98/8/EC concerning the placing biocidal products on the market

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

Assessment Report[i]



Thiamethoxam

Product-type 18 (Insecticides, acaricides and products to control other arthropods)

21 September 2012

Annex I - SPAIN

Thiamethoxam (PT 18)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 21 September 2012 in view of its inclusion in Annex I to Directive 98/8/EC

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of **Thiamethoxam** as product-type 18 (insecticide, acaricide and product 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[1], with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Thiamethoxam (CAS no. 153719-23-4) was notified as an existing active substance, by Novartis Animal Health UK Ltd. & Syngenta European Regional Centre, hereafter referred to as the applicant, in product-type **18**.

Regulation (EC) No 1451/2007 of 4 December 2007,[2] which has repealed and replaced Commission Regulation (EC) No 2032/2003 of 4 November 2003,[3] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 5(2) of Regulation (EC) No 2032/2003, Spain was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for **Thiamethoxam** as an active substance in Product Type 18 was 30 April 2006, in accordance with Article 9(2) Regulation (EC) No 1451/2007.

On 30 March 2006, Spanish competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 30 October 2006.

On 3 February 2009, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 25 February

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

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

3 Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market and amending Regulation (EC) No 1896/2000. OJ L 307, 24.11.2003, p. 1

2009. The competent authority report included a recommendation for the inclusion of **Thiamethoxam** in Annex I to the Directive for PT **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 2 March 2009. 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.

On the basis of the final competent authority report, the Commission proposed the inclusion of **Thiamethoxam** in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 21 September 2012.

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 21 September 2012.

1.2. Purpose of the assessment report

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

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website[4], 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 **Thiamethoxam** for the product-type **18**, which will fulfil the requirements laid down in Article 10(1) and (2) of Directive 98/8/EC. This conclusion is however subject to:

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

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

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

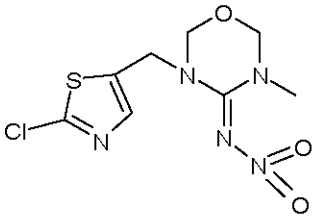
iii. the common principles laid down in Annex VI to Directive 98/8/EC.

Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

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

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

Thiamethoxam is a slightly cream fine crystalline powder at room temperature. Its vapour pressure is low and hence its Henry's Law Constant indicates that volatilisation is not expected to significantly contribute to the dissipation of thiamethoxam in the environment. Thiamethoxam is not considered highly flammable or explosive or oxidizing.

The methods of analysis of active substance as manufactured have been validated and shown to be sufficiently specific, linear, accurate and precise, and the methods for analysis in environmental matrices, as appropriate for the assessed uses, have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

The identity, physico-chemical properties and analytical methods are listed in Appendix I of this assessment report. Moreover, a detailed description and discussion of these is presented in the Competent Authority Report.

The active ingredient thiamethoxam has been already evaluated under the Directive 98/8/EC for use as Wood Preservative (PT-8). The active substance has been included in Annex I by Directive 2008/77/EC for this product type.

Regarding the Environmental Risk Assessment, studies from the dossier as PT-8 had been reconsidered in light of the PT-18 scenarios. Toxicity data for the environmental compartments had not been reevaluated in DocIIIA "Evaluation by Competent Authority-boxes" excepting the

microcosms test IIIA 7.4.3.1 (01). Nevertheless, interpretation of the data according to the current scenario had been performed in DocII. This applies especially for the aquatic toxicity assessment, for which test IIIA 7.4.3.1 (01) has been considered and evaluated.

Secondary poisoning assessment has been assessed (included as an annex to this CAR to be consulted at product authorization) for which the efficacy data from study IIIB5.10 (01) has been studied, together with one new study information entitled *Sugar Consumption of Musca domestica*. The latter is not codified as it was not submitted initially in the dossier but the summary was included in the CAR annexed to DocIIIA. This study had been used to estimate the feeding rate of *Musca domestica* and perform the secondary poisoning assessment.

Regarding the Environmental Risk Assessment for the insecticide products, given that PT-18 dossier includes three products different to those in PT-8, DocIIIB (namely, IIIB1. IIIB2 and IIIB3) contain new information not in the former PT-8 dossier.

2.1.2. Intended Uses and Efficacy

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against crawling insects such as ants, cockroaches and has a sufficient level of efficacy against house flies and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

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

Product B1

Product B1 is supplied for application by professional users, e.g. employees of private contract companies, who are trained operators used to handling various products on a daily basis. They have access to safety information and can be expected to wear personal protective equipment (PPE) when handling Product B1. The product is mixed with water and sprayed inside buildings as a crack and crevice treatment. Applications are made for the control of ants, cockroaches and other insects.

Table 2.1.2-1: Summary table of data on the method of application including description of system used

Substance(s) used for dilution	Concentration of dilutant(s)	Application technique
Water	8 g product in 1 L water (equivalent to 2 g a.s./L)	User category: Professional only. Application aim: Control. Method: Manual application by knapsack sprayer. Type of formulation: Water dispersible granule, WG (250 g a.s./kg).

Table 2.1.2-2: Summary table of data on the number and timing of applications, information relating to geographical variations and necessary waiting periods to protect man and animals

Application type	Number and timing of application	Waiting periods	Information on recommended variations of the application rate in different locations
Manual (low pressure spray to cracks and crevices where insects congregate)	Applications may be done with a minimum interval of 6 weeks.	No specified waiting or re-entry periods for personnel or animals.	None.

Table 2.1.2-3: Summary table of data on the number and timing of applications, information relating to geographical variations and necessary waiting periods to protect man and animals

Field of use envisaged	Method of application	Concentration and application rates
Application to cracks and crevices	Low pressure spray application to areas where insects congregate within buildings, and into cracks and crevices.	Concentration: 8 g product/L water (2 g thiamethoxam/L water). Maximum application rate: 0.2 g product/m^2 (0.05 g a.s./m^2) Water volumes: up to 25 mL water/m^2 equivalent to 25 L/1000m^2.

Product B1 is used for the control of ants, cockroaches and other insects in buildings. The efficacy data are:

- Update for Product B1: Technical assessment of soil applied termiticide use pattern. Second year assessments in the United States Forest Service Trials: Thiamethoxam was applied in field studies at application rates from 500 to 1000 ppm. The results from US Forest Service trials show that performance was maintained sufficiently at 750 and 1000 mg Product B1/kg rates, however, at 500 mg Product B1 /kg performance of the product was marginal. In other application, the results from testing Product B1 in structures with active infestations of termites were successful. Of 49 structures treated in 2002, five had termites present in inspections after treatment (requiring re-treatment) all of which were associated with inadequacies in the original treatment. 5 structures in 2000 and 23 structures in 2003 were treated successfully.

Product B2

Product B2 is supplied as a ready-to use formulation and is applied as a scatter bait or 'hang-up'. Applications are typically made to open poultry houses, pig farms and cattle houses used only by professional users. Farmers can be considered as professional users, which means that they are trained operators and can be expected to wear personal protective equipment (PPE).

(1) As a scatter bait. Product B2 is scattered lightly onto surfaces frequented by flies (such as windowsills and pen partitions) in animal houses. Where it is not appropriate to scatter the bait directly onto the surface, the product should be spread in a suitable container (such as a shallow plate) and placed in the desired location.

(2) As a hang-up. Product B2 is scattered lightly and evenly onto moistened cardboard sheets. The cardboard sheets are then hung up inside animal houses at appropriate points – typically suspended from ceilings. The product granules will remain attached after the cardboard has dried. Attractivity of product B2 is increased if the surface of the cardboard is moistened with lemonade, milk or beaten eggs before the product has been applied. It is considered that the application of the product should be every 6 weeks minimum, considering the minimum duration of efficacy in animal housing. It should be taken into account that dust plays an important factor which may impair efficacy. As the treated surfaces in animal housing may get dusted over, efficacy may decrease over time. This effect is obviously not related to the fact that the active ingredient is less efficacious, but rather due to the fact that less active ingredient is taken up by the fly per meal. Under artificial clean laboratory conditions, both products remain efficacious for more than 16 weeks.

Table 2.1.2-4: Summary table of data on the method of application including description of system used

Substance(s) used for dilution	Concentration of dilutant(s)	Application technique
Not applicable; product is a ready-to use formulation	Not applicable.	User category: Professional (farmer) only. Method: Manual application (200 g product/100 m^2), use indoors only. Application aim: Control. Type of formulation: Granular bait, GB (10 g a.s./kg). Applications made as a scatter bait to surfaces in animal houses or applied as a 'hang-up' (applied to moistened cardboard) and hung inside animal houses.

Table 2.1.2-5: Summary table of data on the number and timing of applications, and particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals

Application type	Number and timing of application	Waiting periods	Information on recommended variations of the application rate in different locations
Manual scatter bait or hang-up boards	Application at 200 g product/100 m^2 (0.02 g a.s./m^2). Minimum interval of 6 weeks.	No specified waiting or re-entry periods for personnel or animals.	Not applicable. Applications made to animal houses in areas where flies frequent.

Table 2.1.2-6: Field of use and method and concentration of application

Field of use envisaged	Method of application	Concentration and application rates
As a ready to use scatter bait inside animal houses	Loosely scattered by hand on surfaces where flies gather.	Application at 200 g product/100 m^2 (0.02 g a.s./m^2). Minimum interval of 6 weeks.
	Decanted into shallow dishes	10 bait stations per 100 m^2 each containing 20g product
	Loosely scattered over moistened cardboard or glued to hang-boards	Circa 20g product glued to each of 10 hang-boards prepared for use within a 100 m^2 of surface area

Product B2 is used for the control of house flies (*Musca domestica*) in animal housing. Product B2 was tested to investigate its efficacy in several tests:

- Laboratory evaluation of CGA 293343 paint-on-bait for control of the housefly *Musca domestica.* The efficacy of three thiamethoxam paint-on-bait formulations, WP 10, WP 5 and GB 1 containing 10%, 5% and 1% active ingredient respectively, was evaluated for control of houseflies, although the product of interest was the 1 % active ingredient. Adult flies of *Musca domestica* were allowed to feed on bait during 48 hours after the release into a large test chamber, in which they had access to a plywood board treated with the test formulation. Efficacy was compared in two exposure scenarios, i.e. flies were provided with water and bait only (non-choice test) or in addition with milk powder and sugar (choice test). All three formulations containing thiamethoxam showed an excellent efficacy against standard strain of *Musca domestica*. Mortality ranged from 96% to 100% after 48 hours of exposure. There were no statistical differences between the three thiamethoxam formulations and they were at least fully as effective as the two reference baits.

- A positive-controlled filed study to compare the efficacy of a new insecticide scatter bait product containing thiamethoxam (CGA 293343 1GB) with SNIP® a commercial insecticide product containing azamethiphos against *Musca domestica* in animal farm houses. The study was performed in three commercial pig farms in Spain where the efficacy of the test product and positive controls were calculated over 24 hour periods by measuring dead fly counts and adult (live) fly counts under realistic conditions. Each 24 hour period evaluation was repeated three times in each farm. Measurement of dead fly counts was carried out by counting dead flies at predefined timepoints (1, 1.5, 2, 3, 4 and 24 hours). In each trial, 10 g Product B2 was spread evenly on a tray which was placed on a cardboard sheet of about 1 m2. One treated tray was laid out at each of 3-4 bait stations in different locations per house. 20%-36% of the flies were killed within the first 4 hours of exposure and 36%-72% within the first 8 hours of exposure.

- A placebo-controlled field study to confirm insecticide efficacy in fly control of a scatter bait containing thiamethoxam (CGA 293343 1GB) in poultry houses. Product B2 has been tested under field conditions at 2 layer farms in republic of South Africa. In each trial, 10g Product B2 laid out on trays (Ø 20 to 30 cm) each placed on cardboard sheets of about Ø 80cm^2 to 1m^2. The test was performed on 3 occasions. Trays containing baits were laid out at 3 different locations per house. Mortality was assessed at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5.5 and 24 hours. It was shown, that about 30 to 40% of the total flies were killed within the first 4 hours.

Product B3

The product is supplied as a formulation designed to be mixed in water and applied as a 'paint-on' to walls and ceilings. Applications are typically made to open poultry houses, pig farms and cattle houses. The appropriate quantity is evenly mixed with lukewarm water until a brushable mixture is obtained. A minimum of 20 'spots' (approx. 10 x 30 cm) are applied per 100 m^2. Alternatively, the paint may be applied to strips of cardboard, wood or light board which are hung from the ceiling. It is considered that the application of the product should be every 6 weeks minimum, considering the minimum duration of efficacy in animal housing. It should be taken into account that dust plays an important factor which may impair efficacy. As the treated surfaces in animal housing may get dusted over, efficacy may decrease over time. This effect is obviously not related to the fact that the active ingredient is less efficacious, but rather due to the fact that less active ingredient is taken up by the fly per meal. Under artificial clean laboratory conditions, both products remain efficacious for more than 16 weeks.

Product B3 is used only by professional users. Farmers can be considered professional users,which means that they are trained operators and can be expected to wear personal protective equipment (PPE).

Table 2.1.2-7: Field of use and method and concentration of application

Field of use envisaged	Method of application	Concentration and application rates
As a paint-on inside animal houses.	Applied as a paste/paint to spots (10 x 30 cm) on indoor surfaces where flies rest/gather.	Concentration: 125 g product/100 m^2 walls and ceiling surface Maximum application rate: 100 g product mixed with 65 mL water to form paint or mixture (equivalent to 0.154 g a.s./mL) to be applied to 80 to 120 m^2 of ceiling/wall area Maximum of 6-8 applications per annum, between April and October, minimum interval between treatments – 4 to 6 weeks.
Application to hang boards.	Diluted product applied to cardboard, wood or light board sheets which are hung from the ceiling.	100 g product mixed with 65 mL water (equivalent to 0.154 g a.s./mL) to form mixture for application to hang-boards. Circa 10-15 boards used per 100 m^2 of area. Maximum of 6-8 applications per annum, between April and October, minimum interval between treatments – 4 to 6 weeks.

Product B3 is used for the control of house flies (*Musca domestica*) in animal housing by professional users. Product B3 was tested to investigate its efficacy in several tests:

- Activity of Product B3 deposits on hardboard panels, applied in different dilution rates and stored under two temperature/humidity conditions, against *Musca domestica.* Product B3 was applied in three dilution rates of 100 g in 80, 65 or 50 ml onto hardboard panels stored vertically at 25ºC/80% or 40ºC/75% relative humidity. The deposits were tested for biological effectiveness after 0, 1, 2, 4, 8 and 16 weeks storage against adult house flies of mixed sex. Product B3 was very effective against *Musca domestica* when applied on boards and even when stored for up to 16 weeks in extreme temperature and humidity conditions. Close to 100% of the tested flies were either dead or severely damaged after 24 hours exposure to the deposits. The suspension containing 100g Product B3 in 65 ml water proved to be optimal for the application onto the hardboard surface.

- Laboratory evaluation of CGA 293343 paint-on-bait for control of the housefly *Musca domestica.* The efficacy of three thiamethoxam paint-on-bait formulations, WP 10, WP 5 and GB 1 containing 10%, 5% and 1% active ingredient respectively, for control of houseflies was evaluated during 48 hours, although the product of interest was the 10 % active ingredient. Efficacy was compared in two exposure scenarios, i.e. flies were provided with water and bait only (non-choice test) or in addition with milk powder and sugar (choice test). All three formulations containing thiamethoxam showed an excellent efficacy against standard strain of *Musca domestica* (mortality ranged from 96% to 100%).

- Efficacy of product B3 against the housefly *Musca domestica* when applied under field conditions as paint-on bait. The efficacy was investigated on 5 cattle farms in Denmark. A mixture with an amount of 250g product and 75-100 ml water was used and paint-on bait was applied in narrow. In all the treated units, large number of flies was killed by the product. In 6 of the 9 treated units the applied bait resulted in infestation levels below the nuisance level (DPLI Index 3 = 13-25 flies on livestock and its surroundings). In 2 units, that had high number of flies before application and very intensive fly production, the bait was effective, but could not reduce the number of flies below the nuisance level. One unit showed very low fly infestation which would probably not have exceeded the nuisance level even without treatment. The efficacy of the paint-on bait was demonstrated on all four farms.

- Efficacy of Agita and QuickBayt adulticides for controlling summer populations of the house fly (*Musca domestica*) in a commercial pig farm in Catalonia (Spain). The formulations (Agita 10WG with TMX 10% and QuickBayt 10WG with imidacloprid 10%) were to be tested under farm conditions. The house fly population was severely reduced after spraying in all treated areas. The effect was visible all around the corridors as there were plenty of dead flies.

- Field evaluation of Agita 10WG compared to QuickBayt 10WG when applied as paint-on bait for control of the housefly *Musca domestica.* The aim trail was compare the efficacy and residual performance of the paint-on baits Agita 10WG and QuickBayt. The trials were conducted in commercial livestock houses, and the two different baits were placed simultaneously in the same fly-infested animal units. The baits were applied on small plywood boards. The fly control efficacy of the individual baits was evaluated by counting the number of flies knocked down close to the boards treated with paint-on bait. The number of flies knocked down was recorded weekly for a period of eight weeks. From the trials it can be concluded that the efficacy of Agita 10WG and QuickBayt was unchanged until five weeks after application and placement in the livestock houses. From the sixth week there was a small decrease in efficacy when compared to the newly applied Agita-control and this decline was statistically

significant for QuickBayt but not for Agita. The higher resistance level to imidacloprid than to thiamethoxam on one of the three trial locations may have caused this small difference in the residual performance of the paint-on baits.

- Comparative field trial to assess the efficacy of Agita WG10 and two competitor products against the house fly *Musca domestica* in a piggery in Australia. The objective of the trial is to confirm the efficacy of Agita 10WG in fly control on animal farms under field conditions. All products (Agita 10WG, Product X with imidacloprid and tricosene and Product Y with cyfluthrin) were diluted in water according to label directions and sprayed using a handheld pump spray. The treatment with Agita 10 WG was significantly more effective than any other treatment (after 1 and 24 hours post-treatment).

Thiamethoxam was tested to assess its susceptibility/resistance in field populations of houseflies and to evaluate its potential for cross-resistance to traditional insecticides (methomyl, azamethiphos, dimethoate and bioresmethrin). The results indicate that thiamethoxam is highly effective against all strains of flies as indicated by very low concentrations leading to 95% mortality. There was no indication of cross-resistance between thiamethoxam and any of the other insecticides tested.

2.1.3. Classification and Labelling

2.1.3.1. Proposal for the classification and labelling of the active substance

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

Classification according to the Regulation (EC) No 1272/2008 of the European Parliament and of the Council and the Globally Harmonised System of Classification and Labelling of Chemicals (hereinafter referred to as "the GHS").

GHS Pictograms	 GHS07	 GHS09
Signal Word	Warning	Hazardous to the aquatic environment
Classification for human health	Hazard class and category: Hazard statement	Acute Tox. 4 H302: Harmful if swallowed

Classification for the Environment	Hazard class and category Hazard statement	Aquatic acute 1 Aquatic chronic 1 H400 H410
Response precautionary statements	P301 + P312: IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell	

Justification for the proposal

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

The classification is based on toxicological studies summarised in III-A section 6 which indicates that thiamethoxam is harmful when swallowed.

Because of the high toxicity of the substance, setting specific lower concentration limits for the substance should be considered for both environmental effects when the substance is under discussion for inclusion on Annex VI of Regulation (EC) No 1272/2008.

2.1.3.2. Proposal for the classification and labelling of the preparations

Product B1

Hazard symbol:	N	Dangerous for the Environment
Risk phrases	R50/53	Very toxic to aquatic organism/may cause long-term adverse effects in the aquatic environment
Safety phrases	S60 S61	This material and its container must be disposed of as hazardous waste Avoid release in the environment. Refer to special instructions/safety data sheet

Classification according to the Regulation (EC) No 1272/2008 of the European Parliament and of the Council and the Globally Harmonised System of Classification and Labelling of Chemicals (hereinafter referred to as "the GHS").

GHS Pictograms	 GHS09	
Signal Word	Hazardous to the aquatic environment	
Classification for the Environment	Hazard class and category Hazard statement	Aquatic acute 1 Aquatic chronic 1 H400 H410
Response precautionary		

statements	

Justification for the proposal

The proposal is based on study results presented in the dossier

Product B2

Hazard symbol:	N	Dangerous for the Environment
Risk phrases	R51/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Safety phrases	S2 S46 S60 S61	Keep out of the reach of children If swallowed, seek medical advice immediately and show this container or label This material and its container must be disposed of as hazardous waste Avoid release to the environment. Refer to special instructions/safety data sheet

Classification according to the Regulation (EC) No 1272/2008 of the European Parliament and of the Council and the Globally Harmonised System of Classification and Labelling of Chemicals (hereinafter referred to as "the GHS").

GHS Pictograms	 GHS09	
Signal Word	Hazardous to the aquatic environment	
Classification for the Environment	Hazard class and category Hazard statement	Aquatic chronic 2 H411
Response precautionary statements	P102: Keep out of reach of children. P301 + P312: IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell	

Justification for the proposal

The proposal is based on study results presented in the dossier

Product B3

Hazard symbol:	N	Dangerous for the Environment
Risk phrases	R50/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Safety phrases	S2 S46 S60 S61	Keep out of the reach of children If swallowed, seek medical advice immediately and show this container or label This material and its container must be disposed of as hazardous waste Avoid release to the environment. Refer to special instructions/safety data sheet

Classification according to the Regulation (EC) No 1272/2008 of the European Parliament and of the Council and the Globally Harmonised System of Classification and Labelling of Chemicals (hereinafter referred to as "the GHS").

GHS Pictograms	 GHS09	
Signal Word	Hazardous to the aquatic environment	
Classification for the Environment	Hazard class and category Hazard statement	Aquatic acute 1 Aquatic chronic 1 H400 H410
Response precautionary statements	P102: Keep out of reach of children. P301 + P312: IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell	

Justification for the proposal:

The proposal is based on study results presented in the dossier.

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

Metabolism

In rat, thiamethoxam is rapidly and completely absorbed following oral administration from the gastrointestinal tract into systemic circulation. The metabolites and unchanged thiamethoxam were eliminated very rapidly (84 - 95% of the dose via urine and about 3 - 6% with the faeces, in 24 hours), 70 - 80% as unchanged thiamethoxam and 20 - 30% was biotransformed. In rat, 22 metabolites were isolated from excreta and identified. In mouse, metabolic degradation proceeds via the same pathway but 30 - 60% was excreted as metabolites. Overall, the metabolic pathways are independent of the route of administration, the dose level, pre-treatment, and the sex of the animals. CGA 322'704, one of the major metabolite of thiamethoxam in rodents, is known as the active substance Clothianidin.

An oral absorption of 100 % will be considered for risk assessment.

As no inhalation study is available, the default value of 100% absorption will be used for risk characterization.

Two studies to measure dermal absorption of thiamethoxam were completed. One investigated dermal penetration in rats *in vivo* and the other was a comparative study in vitro using rat and human skin membranes (See Doc III B1 6.4-01 and 02), using procedures OCDE-427 and OCDE-428.

In the **in vivo dermal study in rat**, 3 level of dose were applied using a product containing 25% active substance: 2.5 (low), 25.3 (middle) and 242 (high) ug/cm^2, dosing 10 ul/cm^2 equivalent dose of 2.42, 0.25 and 0.025 ug/cm^2 and studied for 6, 14 and 48 hours. Systemic dermal absorption for 48 hours (measured by total excretion) is estimated to be 1.31, 2.87 and 0.76 %. Skin treated showed 18.21, 20.92 and 3.76 % of applied dose. Therefore total absorption (systemic and skin) is considered to be **19.52, 23.79 and 4.52 %** for low, middle and high dose, respectively.

In the **in vitro** study dermal penetration for 48 hours was 25.6, 9.6 and 2.6 % for human, and 30.8, 39.6, 44.2 for rat. Therefore the ratio rat:/human was 1.2, 4.13, 17.0 for low, middle and high dose, respectively.

If the rat/human ratio is applied to the in vivo total absorption in rat, the extrapolated estimation for human total dermal absorption is 16.31, 5.77 and 0.27, rounded to **16, 6 and 0.3 %** for low, middle and high applied dose, respectively. For risk assessment, in each scenario the absorption for the dose nearer to the concentration of the actual handled material will be considered for risk assessment.

Acute toxicity

Thiamethoxam is of low acute oral toxicity to both male and female rodents; the mouse is slightly more sensitive than the rat (LD_{50} as average between male and females results are: rat LD_{50} = 1563mg/kg, mouse LD_{50} = 871mg/kg). Signs of acute thiamethoxam intoxication in these species are tonic or clonic convulsions and ptosis, requiring classification as "R22 harmful if swallowed". No classification for dermal toxicity is required (LD_{50} >2000mg/kg in the rat). No serious signs of toxicity occurred following a 4-hour inhalation exposure to 3.72 g/m^3 respirable particles of thiamethoxam (the highest technically feasible concentration in the respirable range); therefore, no classification is required for inhalation.

Thiamethoxam is not irritant to skin and eyes since the mean irritation scores 24, 48 and 72 hours after application are below the thresholds defined in Commission Directive 93/21/EEC. Thus, classification of thiamethoxam for skin and eye irritating properties is not required.An adjuvant-assisted contact sensitisation study gave an overall net response rate of 5%, below the threshold for classification as a sensitiser.

Repeated toxicity (short and medium term exposure)

The liver and kidneys were identified as target organs. Treatment for 13 weeks induces liver hypertrophy, inflammatory cell infiltration and pigmentation of Kupffer cells in both rodent

species. In mice, single cell necrosis occurs in parallel with these alterations. Dogs were generally refractory to hepatotoxicity, but at high dosage, minimal pigmentation of Kupffer cells occurred.

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

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

Genotoxicity

The mutagenic potential of thiamethoxam was investigated in five in vitro test systems representing 3 fundamental organization levels: Gene mutation in bacteria (S. Typhimurium, E Coli), mammalian gene mutation assay in Chinese hamster V79 cells, Mammalian cytogenetic test (Chromosome aberrations) in CHO cells, all with and without metabolic activation with S9, and Unscheduled DNA repair in rat and in mouse hepatocytes. In vivo was tested in a micronucleous test in mouse somatic cells. None of the in vitro studies revealed any genotoxic effects of thiamethoxam at the DNA level, the gene level or the chromosome level of organization, either with or without metabolic activation (standard or from thiamethoxam induced mice). Thiamethoxam was not clastogenic or aneugenic in in vivo micronucleus test.

The mutagenic potential of metabolites (CGA 322´704 and NOA 407´475) was also investigated in a gene mutation test in bacteria with and without metabolic activation with negative results.

Carcinogenicity and long term toxicity

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

The lowest NOEL for toxicity determined in these studies, in the male rat, was 1.29 mg/kg bw/day based on increased incidence of renal tubular regenerative lesions. These lesions are considered to represent the sequelae of alpha-2μ-globulin mediated nephropathy, also observed in the 13-week study in the rat. Since it is widely acknowledged that this condition is unique to sexually mature male rats, and is not indicative of a human health hazard it was not considered for risk characterization.

The lowest NO(A)EL established in this group of studies, occurring in the male mouse, is 2.63 mg/kg bw/day, based on neoplastic and non-neoplastic alterations in the liver. A neoplastic

response was unique to the mouse liver and only occurred simultaneously with hepatotoxicity (necrosis). Therefore, the MTD was achieved or exceeded at all dose levels at which neoplasia occurred. Subsequent investigative studies have provided evidence indicating the neoplastic outcome of prolonged administration of thiamethoxam is mediated by sustained regenerative cell proliferation in response to cytotoxicity, and by liver enzyme induction and is a non-genotoxic event with a definable threshold. A carcinogenic response did not occur in rats.

Reproductive toxicity

Teratogenicity

In embryotoxicity studies in the rat and rabbit, reduced fetal weight, delayed ossification and increased post-implantation loss (rabbit only) was observed at maternal toxic doses. The systemic NOAEL in rabbit was 50 mg/kg bw/day for dams (based on the findings of minimally reduced weight gain and food consumption) and for offsprings (based on reduced foetal weight, delayed ossification and increased post-implantation loss at maternal toxic doses at 150 mg/kg bw/day).

Fertility

In two multigeneration studies in the rat, an effect on testicular histopathology (germ cell loss/disorganisation +/- Sertoli cell vacuolation) in F1 animals was observed. A NOAEL of 1000 ppm (62 mg/kg bw/day) in males was established for parental reproduction. This histological change did not affect reproductive function. Parental systemic toxicity, based on the kidney findings in male of both generations at higher levels, were consistent with ά-2μ globulin nephropathy, specific for male rats and therefore it was not considered in risk assessment.

Neurotoxicity

Since thiamethoxam does not belong to a chemical class which is suspected to cause delayed neurotoxic effects (organophosphates, carbamates) and above described investigations indicate no neurotoxic potential, specific studies on delayed neurotoxicity were not deemed to be necessary.

Thiamethoxam is classified structurally as a member of the neonicotinoid chemical class. The biological effects of this chemical class in the target animals are mediated primarily by an interaction with nicotinic acetylcholine receptor sites. Ptosis (drooping eye lid due to nerve damage) was observed in the acute toxicity studies. Two neurotoxic studies were evaluated under PPP, an acute and a 13-week neurotoxicity studies in rats [Minnema, 1997, 1998]. No indication for a neurotoxic effect was obtained.

Medical data

Manufacturing employees in Switzerland are medically examined in Occupational Health Surveillance Programs by a company physician at the beginning of their employment and then

routinely once a year according to the criteria of the Swiss Accident Insurance Institution (SUVA). No adverse health effects related to thiamethoxam had been reported.

2.2.1.2. Effects assessment

The critical toxicity data considered for risk characterization were as follows:

Long term exposure

The liver was considered as a target organ for long term exposure. According to the NOAEL values obtained in experimental animal studies, mice were more sensitive to thiamethoxam toxicity. Thus, the relevant **NOAEL value is considered to be 2.63 mg/kg bw/day** on the basis of changes to liver morphology and increased incidences of non-neoplastic alterations in the liver (hypertrophy, pigment deposition, mitotic activity, kupffer cells hyperplasia and single cell necrosis) derived from the combined chronic toxicity/carcinogenicity study performed in mice. Assessment factor of 100 were considered adequate. This results in a **systemic AOEL value of 0.0263 mg/kg bw/day**.

Medium term exposure.

The NOAEL of 4.05 **mg/kg bw/day** for medium term exposure has been deduced from the 1 year dog oral study, based on decrease body weight and food consumption histological findings in testes and increased plasma creatinine and urea. Assessment factor **of 100** was considered adequate and an **AOEL value of 0.0405 mg/kg bw/day is established**.

Acute-single exposure

The acute toxicity studies were not considered adequate in order to identify a critical N/LOAEL. An acute **NOAEL of 15 mg/kg bw/day** has been established based on the rabbit developmental toxicity study, based on the findings of minimally reduced weight gain and food consumption of dams. **AOEL is 0.15 mg/kg bw/day** applying an assessment factor of 100.

2.2.1.3. Exposure assessment

Professional users

Product B1

Total systemic exposure to thiamethoxam of professional operators applying product B1 to cracks and crevices inside buildings with a sprayer and cleaning the spray equipment after use is estimated at **0.06052267 mg/kg bw/day** if gloves are not worn, and **0.0160507 mg/kg bw/day** with gloves.

Product B2

Total systemic exposure to thiamethoxam of professional operators applying product B2 inside animal houses by scattering on surfaces, into containers and onto adhesive hang-boards is estimated at **0.1565 mg/kg bw/day** if gloves are not worn, and **0.0169 mg/kg bw/day** with gloves.

Product B3

Total systemic exposure to thiamethoxam of professional operators mixing and loading and applying product B3 inside animal houses by brush painting on spots around walls, floors and other surfaces or onto hang-boards is estimated at **0.1803030 mg/kg bw/day**, if gloves are not worn, and **0.0510907 mg/kg bw/day** with gloves.

Non professional users

None of the three products is intended for use by non-professionals. From the exposure scenarios there is no anticipated human health risk for non-professionals.

Indirect exposure as a result of use

Product B1

Adults or children are unlikely to be present during application of product B1 or immediately after application when surfaces inside buildings may be wet. They are not expected to come into contact with wet product B1 following application into cracks and crevices, due to physical restrictions. Dermal exposure to dried residues of thiamethoxam can be considered to be negligible, as well as inhalation exposure, because thiamethoxam is non-volatile. Nevertheless, and as a worst case, it can be considered that bystanders may contact the treated surface with the hands and subsequently have hand-to-mouth contact, especially children. Oral exposure through hand-to-mouth contact will only be described for children. Apart from these two acute scenarios, the risk of chronic exposure to all non-users can be considered to be unlikely.

The following total systemic dose has been calculated for adults, children and infants

Table 2.2.1.3-1: Total systemic exposure to product B1 for adults, children and infants

Route of exposure	Exposure (mg/kg bw/day)		
	Adult	Children	Infants
Dermal	0.0001512	0.000108	0.000216
Oral	-	-	0.00036000
Total	**0.0001512**	**0.000108**	**0.000576**

Product B2

Adults or children are unlikely to be present during application of product B2. Children or adult workers may enter animal houses after scattering of the bait but inhalation exposure of is likely to be minimal because thiamethoxam is non-volatile. Dermal exposure is also likely to be

minimal, as non-users will be wearing shoes or rubber boots. Nevertheless, the dermal and oral exposure can not be totally excluded for children and a possible acute oral exposure of children after an incidental ingestion can be assessed, as the worst route of exposure. Apart from this acute scenario, the risk of chronic exposure to all non-users can be considered to be unlikely.

The oral exposure calculated for a child exposed to a granular formulation of product B2 is 0.01 mg a.i / kg bw. In addition, a reverse scenario to assess the amount of product that a child would need to ingest to achieve the AEL concludes that he would need to eat 150 mg of product. Even if this is a small quantity, a child would need to have access to this product, which is a highly unlikely situation, if dish or hang-board of granules are placed as required in the label.

Product B3

Adults or children are unlikely to be present during application of product B3 or immediately after application when surfaces inside animal houses may be wet. Children and adults are not expected to come into contact with suspended hang-boards during use, and the dermal exposure to dried residues of thiamethoxam at "paint-on spots" on surface can also be considered negligible. Thiamethoxam is non-volatile therefore inhalation exposure of children and adults to dried residues of thiamethoxam is considered to be negligible. Nevertheless, and as a worst case, it can be considered that bystanders can contact the treated surface with the hands and subsequently have hand-to-mouth contact, especially children.

The following total systemic dose has been calculated for adults, children and infants:

Table 2.2.1.3-2: Total systemic exposure to productB3 for adults, children and infants

Route of exposure	Exposure (mg/kg bw/day)		
	Adult	Children	Infants
Dermal	0.0000189	0.0000135	0.000027
Oral	-	-	0.0009
Total	0.0000189	0.0000135	**0.000927**

2.2.1.4. Risk characterisation

Human health risk for professional users

Product B1

The margin of exposure for professional operators applying Product B1 on a regular basis compared with the chronic systemic **NOAEL of 2.63 mg/kg bw/day/** was **164,** based on exposure calculations in which minimum protective clothing was included. It is reasonable to expect professionals to regularly use more protective clothing as routine safety wear.

Product B1 may be used by professionals also for single or occasional applications. Compared to the short/medium term **NOAEL of 4.05 mg/kg bw/day**, the margin of exposure was **252** when a minimum protection (gloves) was used.

Product B2

High margins of safety exist for professional operators (farmers) applying product B2 on a single or infrequent basis. Compared to the short/medium term **NOAEL of 4.05 mg/kg bw/day**, the margin of exposure is **2807** for scattering bait on surfaces, in dishes or on hang-boards in animal houses wearing gloves.

Product B3

The margin of safety for professional operators (farmers) applying product B3 on a single or infrequent basis was derived by comparison to the short/medium term **NOAEL of 4.05 mg/kg bw/day**. The margin of exposure was **79.3** (when applied as paint on to surfaces in animal houses wearing only protective gloves) lower than 100. Nevertheless, the exposure has been estimated using EU default values from a model for consumers (Consumer Product painting - Brush painting 'Model 1) and the NOAEL/AEL used for medium term exposure based on the 1 year study in dog is also very conservative.

The results of the human health risk assessment for professional users are summarised in the following tables:

Table 2.2.1.4-1 Estimated chronic internal exposure and summary of risk assessment for professional users for product B1

Exposure Scenario		Estimated Internal Exposure [mg/kg bw/day]				Relevant NOAEL/ LOAEL [mg/kg bw/day]&Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		Oral uptake	Inhalation uptake	Dermal uptake	Estimated total uptake				
Tier 1 (no PPE)	Product B1 Spray application to cracks and crevices without gloves	-	0.00866667	0.051856	0.06052267	2.63	100	43	2.3
Tier 2 (Refinement, PPE or other risk mitigation measures)	Product B1 Spray application to cracks and crevices with gloves	-	0.00866667	0.007384	0.0160507	2.63	100	164	0.6

Table 2.2.1.4-2 Estimated acute and medium term internal exposure and summary of risk assessment for professional users for products B1, B2 and B3.

Exposure Scenario		Estimated Internal Exposure [mg/kg bw/day]				Relevant NOAEL/ LOAEL [mg/kg bw/day]&Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		Oral uptake	**Inhalation uptake**	**Dermal uptake**	**Estimated total uptake**				
Tier 1 (no PPE)	Product B1: Spray application to cracks and crevices without gloves and cleaning the spraying equipment	-	0.00866667	0.051856	0.06052267	4.05	100	**67**	**1.49**
Tier 2 (Refinement, PPE or other risk mitigation measures)	Product B1: Spray application to cracks and crevices with gloves and cleaning the spraying equipment	-	0.00866667	0.007384	0.0160507	4.05	100	252	0.40
Tier 1 (no PPE)	Product B2: Scatter bait on surfaces, in dishes or on hang-boards without gloves	-	0.00114774	0.002912651	0.004060391	4.05	100	997	0.10
Tier 2 (Refinement, PPE or other risk mitigation measures)	Product B2: Scatter bait on surfaces, in dishes or on hang-boards with gloves	-	0.00114774	0.000295071	0.001442811	4.05	100	2807	0.04
Tier 1 (no PPE)	Product B3: Brush painted onto surfaces in animal houses without gloves	-	0.020240387	0.160062660	0.1803030	4.05	100	**22.5**	**4.45**
Tier 2 (Refinement, PPE or other risk mitigation measures)	Product B3: Brush painted onto surfaces in animal houses with gloves	-	0.020240387	0.030850326	0.0510907	4.05	100	**79.3**	**1.26**

Human health risk for non professional users

None of the three products is intended for use by non-professionals. From the exposure scenarios there is no anticipated human health risk for non-professionals.

Human health risk from indirect exposure as a result of use

Product B1

Adults or children are unlikely to be present during application of product B1 or immediately after application when surfaces inside buildings may be wet. The risk of acute or chronic exposure to all non-users can be considered to be negligible. Nevertheless, a worst case has been considered regarding bystanders contacting the treated surface with the hands and subsequently having hand-to-mouth contact, especially children. High MOE is deduced.

Product B2

Adults or children are unlikely to be present during application of product B2. Children or adult workers may enter animal houses after scattering of the bait but inhalation exposure of is likely to be minimal because thiamethoxam is non-volatile. Dermal exposure is also likely to be minimal, as non-users will be wearing shoes or rubber boots. The risk of chronic exposure to all non-users can be considered to be unlikely. Nevertheless, the dermal and oral exposure can not be totally excluded for children and a possible acute oral exposure of children after an incidental ingestion has been assessed, as the worst route of exposure. High MOE is deduced.

Product B3

Adults or children are unlikely to be present during application of product B3 or immediately after application when surfaces inside animal houses may be wet. Thiamethoxam is non-volatile therefore inhalation exposure of children and adults to dried residues of thiamethoxam is considered to be negligible. Children and adults are not expected to come into contact with suspended hang-boards during use, and the dermal exposure to dried residues of thiamethoxam at “paint-on spots” on surface can also be considered negligible. Nevertheless, and as a worst case, it has been considered that bystanders can contact the treated surface with the hands and subsequently have hand-to-mouth contact, especially children. Apart from these acute scenarios, the risk of chronic exposure to all non-users can be considered to be negligible. High MOE is deduced.

The MOE deduced is very high in all cases. The results of the human health risk assessment from indirect exposure are summarised in the following table:

Table 2.2.1.4-3: Summary of risk assessment for non-users for products B1, B2 and B3..

Exposure Scenario (indicate duration)				Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg bw/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
				Estimated inhalation uptake [mg/kg bw/day]	Estimated dermal uptake [mg/kg bw/day]	Estimated oral uptake [mg/kg bw/day]	Estimated total uptake [mg/kg bw/day]				
Tier 1 (Worst Case)	**Acute Scenario**	Product B1	Adult	-	0.0001512	-	0.0001512	15	100	99206	-
			Children	-	0.000108	-	0.000108	15	100	138889	-
			Infant		0.000216	0.00036	0.000576	15	100	26042	-
		Product B2	Infant	-	-	0.01	0.01	15	100	1500	-
		Product B3	Adult	-	0.0000189	-	0.0000189	15	100	793651	-
			Children	-	0.0000135	-	0.0000135	15	100	1111111	-
			Infant		0.000027	0.0009	0.000927	15	100	16181	-

Human health risk from indirect exposure through food and feedingstuffs

Regarding product B1, no direct contact with food should normally occur if precautionary measures are observed during the application of the product to surfaces and cracks and crevices inside buildings. Furthermore, it will only be applied by professional, and they are supposed not to use the product in presence of food.

Considering product B2 and product B3, it is very unlikely that livestock can have access to these biocidal products, because they are sprayed, scattered or painted in locations out of reach of animals. Nevertheless, a worst case scenario has been described to estimate the number of dead flies needed to achieve the MRL established for thiamethoxam, and a high value is obtained (161 flies). Therefore, the associated risk can be considered negligible, both for the livestock and the human population.

2.2.2. Environmental Risk Assessment

The information submitted in the dossier was evaluated and interpreted in the light of the OECD series on Emission Scenario Documents for Insecticides for Stables and Manure Storage systems for the product B2 and product B3 products and the Emission Scenario Document for Insecticides, acaricides and products to control other arthropods (PT-18) for household and professional uses for the product B1 product, and ECB Technical Guidance Document on Risk Assessment (TGD), together with the knowledge from experts in the Technical Meetings held ad hoc.

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

PRODUCT B1

Product B1 is an insecticide (containing 25% w/w active substance thiamethoxam) which is used to control ants, cockroaches and other insects. The product is indicated for use inside buildings as crack and crevice treatment. The formulation is WG (water dispersible granule), applications are only made by professionals using a knapsack sprayer. The product is intended to be dissolved in water and to be sprayed in areas where ants and cockroaches congregate as a crack and crevice treatment only.

The indicated use proceeds by this preparation: 40 g of product are mixed in 5 L water (equivalent to 8 g product/L, 2 g a.s./L). This is directed to be applied to 200 m^2 (equivalent to 25 mL diluted product/m^2, 0.05 g a.s./m^2 equivalent to 500 g a.s./ha). Applications are repeated as necessary, the minimum application interval is 6 weeks.

PRODUCT B3

Product B3 is an insecticide (containing 10% w/w active substance thiamethoxam) which is used to control house flies. The product is indicated for use inside animal houses. The formulation is WG (water dispersible granule) and is used as paint-on. According to section B5 (Intended uses and efficacy), the product is intended to be dissolved in water and to be applied to walls, ceilings and *areas likely to be frequented by flies, e.g. warm wall areas, pen partitions, posts, windowsills, milk pipes, outside of feeding throughs etc* of open poultry houses, pig farms and cattle houses. The product is not broadcast by spraying or sprinkling. The appropriate quantity is evenly mixed with lukewarm water until a brushable mixture is obtained. A minimum of 20 "spots" (approx. 10 x 30 cm) are applied per 100 m^2 surfaces. Alternatively, the paint may be applied to strips of cardboard, wood or light board which are hung from the ceiling.

Where an insufficient surface is available, the product is applied to cardboard which is then hung from the ceiling. The product contains attractant (0.05% w/w).

Treatments are not made to manure, however during the service life of the product, it is assumed that indirectly the active substance can come into contact with manure which is subsequently collected and stored. Where applicable, baits are collected and safely disposed following use.

The indicated use proceeds by this preparation: a maximum of 100 g of product are mixed in 65 ml of water to result in approx. 125 mL end volume (at 0.8 g a.s/mL and paste concentration of 0.154 g/ml). This is directed to 80-120 m^2 of surface (i.e.: 0.125 g a.s./m^2). The minimum interval of application is 6 weeks. This dossier does not evaluate the use in floors.

PRODUCT B2

Product B2 is an insecticide (containing 1% active substance thiamethoxam) which is used to control house flies. The product is only used inside animal houses. The product is available in three forms, a ready to used bait station, a ready to use scatter bait granule and a ready to use hang board bait. The products effectively apply the active substance at 2 g a.s. /100 m^2 to the area being treated. Treatments are only done by professionals.

The ready to use bait stations are placed around the treatment area (10 bait stations, each containing 20 g bait per 100 m^2), the scattered bait granules are placed around the treatment area (200 g per 100 m^2) in areas likely to be frequented by flies (windowsills, pen partitions etc.). The product is not to be scattered directly on the floor, thus, devices such as shallow plates or containers are used and hang-board bait that consists of moistened cardboard with the product granules attached (25 cardboards each containing 8 g per 100 m^2) which are hung at the area being treated. The product contains an attractant (0.1% w/w).

Treatments are not made to manure, however during the service life of the product, it is assumed that indirectly the active substance can come into contact with manure which is subsequently collected and stored. Where applicable, baits are collected and safely disposed following use.

2.2.2.1. Fate and distribution in the environment

The type of formulation and inert substances used in product B1, product B3 and product B2 are not expected to affect the properties of the active substance in soil or aquatic systems. The data generated with the unformulated active substance can therefore be used to extrapolate to this formulation.

PRODUCT B1

Based on the type of use, emission is only considered to affect the aquatic compartment.

Product B1 would be only used indoors. The following release pathways to the environment exist after indoor spray applications:

Table 2.2.2.1-1

Step	"Intermediate" receiving compartments	"Final" receiving compartments
Mixing loading step	Indoor air Floor Applicator	Outdoor air STP (surface water) (agricultural soil/ground water)
Application step	Indoor air Floor Applicator	Outdoor air STP (surface water) (agricultural soil/ground water)
Cleaning step	Indoor air Waste water Wastes	Outdoor air STP (surface water) (agricultural soil/ground water)

Emission to waste water following the cleaning of treated surface areas is the most relevant release pathway for transport to the environment after indoor use of **product B1**.

Metabolite CGA322704 is formed in soil. Therefore, it is not studied within product B1 risk assessment, as its risk for the environment is not of concern for this product. The metabolite CGA 322704 is neither formed on wall surfaces, in sewage treatment plants or in aquatic water bodies, therefore no environmental exposure to CGA 322704 has to be expected after application of Thiamethoxam as **Product B1.** Analogously, metabolite NOA 407475 was not assessed as it is only formed in anaerobic conditions which are not present at this scenario.

PRODUCT B3 and PRODUCT B2

Manure is the vector for emission of the active ingredient to the environment. The first receiving compartment is the soil compartment (arable lands or grassland) where the manure is applied. From soil, the compound and its metabolites are distributed to groundwater and surface water and sediment.

Arable lands and grassland were considered for material (manure and slurry) application. Four manure land applications per year for Grassland and one land application for Arable lands were foreseen.

The product should be protected from water. Furthermore, in general it is not assumed the discharge to STP of the product upon application as it has been considered that, in the case of field application of the manure, the liquid waste is applied evenly on all fields together with the manure, as is the case with wet storage (slurry pits, where manure and waste water are collected together) according to the ESD point 4.2.5. Also in general it has been assumed the prohibition to discharge waste water containing manure to the public (municipal) sewer according to point 4.1.1 of ESD. In addition, emission as liquid wastes (cleaning operations from horizontal surfaces and other places such as walls, ceilings, window sills, ledges and others) has been considered as kept in a separate waste water slurry tank and not discharged to the sewer. The liquid waste is considered to be spread together with the manure from the dry storage (point 4.2 of the ESD). In some MS direct emission to STP of liquid wastes is allowed. In this case Liquid wastes could be emitted to STP (not applied to land).. Arable or Grassland scenarios are not relevant in these calculations because the emissions to the STP are the same regardless where the manure is applied.The fraction of the biocide reaching the manure storage system will depend on the animal species and category considering (i.e. the type of housing and manure collection system), the way of application and the way of action of the biocide.

Two metabolites were relevant in the risk assessment: CGA 322704 formed by aerobic degradation in soil up to 35.6% and metabolite NOA 407475 found after anaerobic degradation up to 62.3%. Thus, upon manure storage, anaerobic degradation yields mainly NOA 407475 and upon land application, thiamethoxam yields mainly CGA 322704.

2.2.2.1.1. Fate and distribution in air

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

2.2.2.1.2. Fate and distribution in water/sediment systems

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

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

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

The most ecotoxicologically relevant metabolite, CGA 322704, which is in fact other active substance (Clothianidin), is not formed as degradation product in water sediment studies but is stable in water at any pH or temperature. In water/sediment systems it may attach to sediment and be degraded via de-nitrification to some extent more data may be available from the LOEP list corresponding to its dossier.

Relevant data can be summarized as follows, from studies 7.1.2.2.2/01 (guanidyl radiolabel) and /02 (thiazollyl radiolabel): for water/sediment systems in river, no valid water phase or sediment phase DT50 was obtained, and the total system half live were, recalculated at 12ºC, 68.8 and 66.9. Regarding pond, DT50 water was 46.5 at 12ºC and for the total system was 48.7 and 53.9. Regarding paddy soils, DT50 in water was 9.3 and 9.6; DT50 for sediment was 131.8 and 1109 d and for the total system 146 and 146.5 respectively. Regarding NER and other information related with the degradation, the data are summarized in the following table.

Table 2.2.2.1.2-1 Degradation data in water/sediment systems

Thiamethoxam	**label***		**Rhine River (water/sediment)**	**Pond (water/sediment)**		**Paddy soil**	
		Max NER (%)	Max. Mineralizat (%)	Max NER	Max. Mineralizat	Max NER	Max. Mineralizat
total system	thiazolyl	13.8 (day 100)	6.34 (day 100)	25.3 (day 80)	9.28 (day 100)	61.9 (day 363)	3.57 (day 363)
total system	guanid	22.2 (day 80)	7.22% (day 100)	23.9 (day 100)	7.18 (day 80)	62.8 (day 363)	2.15 (day 363)

2.2.2.1.3. Fate and distribution in soil compartment included groundwater.

Thiamethoxam is degraded in soil and can be even mineralized, but its half life depends mainly on the nature and biota of the soil. The anaerobic metabolism is very effective; thiamethoxam can dissipate in anaerobic conditions at 365 yielding up to 62.3% of metabolite NOA 407475 at 120d. Photodegradation contributes to superficially located substance. In aerobic soil, thiamethoxam yields several metabolites, including CGA 322704, which can reach up to 35.6%. The metabolite CGA 322704 is stable in water over a wide pH and temperature ranges and is found mainly in soils as thiamethoxam derived product. The field soil dissipation and accumulation studies (ref. studies: 7.2.2.2/01 and 02) suggest the tendency of metabolite CGA 322704 to increase with time in deeper soil layers The endpoint included in the LOEP for DT50 soil was from a field study at 9.9ºC (average over one year) and was 72d from the key study 7.2.2.2/02,. It was compared to the outcome of PPP data cited by the applicant and the result was consistent. Data on laboratory tests were also available, but not relevant for this risk assessment. It can be summarized as follows: the aerobic DT50 lab at 20°C and FC moisture of 40-60% ranged from 34d (k = 0,0202) to 219d (k = 0.00316) (studies 7.2.2.1/01 and 02 corresponding to radiolabel of guanidyl moiety and thiazollyl moiety of the molecule respectively). The DT_{50lab} at 10°C, aerobic was 233 days (studies 7.2.2.1/01). NERs were ranging from 8.4 to 16.8 at 360 d (7.2.2.1/01) and from 7.6 to 16.6 at 181 d (7.2.2.1/02).

The submitted adsorption-desorption studies indicated that adsorption of thiamethoxam is not a single step process, but continues with time. Thiamethoxam binds weakly to soil and so does its

metabolite (see Koc in endpoint listing). Therefore, Thiamethoxam and its metabolite CGA 322704 have potential to leach. Metabolite NOA 407475 binds stronger to sediment and once adsorbed to soil is less likely to be removed into the aqueous phase.

2.2.2.2. Effects assessment

2.2.2.2.1. Aquatic compartment

Thiamethoxam. The following table summarizes the toxicity of thiamethoxam to aquatic organisms. To facilitate the identification, the results of **chronic** tests are highlighted in grey.

Table 2.2.2.2.1-1. Toxicity of Thiamethoxam to the aquatic organisms.

Type of Organisms	Species	Study Type	LC_{50} or EC_{50} or LOEC[a] [mg/L]	LC_0 (acute)or NOEC (chronic) [mg/L]	Reference
Thiamethoxam					
Fish	Rainbow trout	96-h acute	>125	125	A7.4.1.1/01
	Rainbow trout	96-h acute	>100	100	A7.4.1.1/02
	Bluegill sunfish	96-h acute	>114	114	A7.4.1.1/03
	Rainbow trout	28-d chronic	>100[a]	100	A7.4.3.1
	Rainbow trout	88-d chronic	>20[a]	20	A7.4.3.2
Crustaceans	*Daphnia magna*	48-h acute	>100	32	A7.4.1.2/01
	Gammarus Sp.	48-h acute	2.8	<1.6	A7.4.1.2/02
	Daphnia pulex Leydig	24-h acute	>100	6.3	A7.4.1.2/03
	Thamnocephalus platyurus	24-h acute	>100	100	A7.4.1.2/03
	Ostracoda	48-h acute	0.18	0.063	A7.4.1.2/04
	Daphnia magna	21-d chronic	>100[a]	100	A7.4.3.4
Molluscs	*Lymnea stagnalis*	48-h acute	>100	100	A7.4.1.2/04
	Radix peregra	48-h acute	>100	100	A7.4.1.2/04
Insects	*Cloeon* Sp. (Ephemeroptera)	48-h acute	0.014	0.0063	A7.4.1.2/09
	Chaoborus Sp.	48-h acute	5.5	3.1	A7.4.1.2/04
	Chironomus riparius	48-h acute	0.035[d]	0.013[d]	A7.4.1.2/10
	Chironomus riparius larvae	30-d chronic / water applic.	0.0114	0.01	A7.4.3.5.1/01
	Chironomus riparius larvae	30-d chronic / sediment appl.	0.11[e]	0.1[e]	A7.4.3.5.1/01
Rotifer	*Brachionus calyciflorus*	24-h acute	>100	100	A7.4.1.2/03
Aquatic plants	Green algae *Selenastrum capric.*	72-h acute	>81.8[b]	81.8	A7.4.1.1/01
	Green algae *Selenastrum capric.*	96-h acute	>100[b]	100	A7.4.1.1/02
	Duckweed *Lemna gibba*	7-d subchronic	>90.2	90.2	A7.4.3.5.2

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

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

Derivation of aquatic PNEC.

Aquatic PNEC value for thiamethoxam was estimated **in 0.00014 mg a.i./l** (see section 4.7.1 of Doc IIA for more details). PNEC was derived from lowest toxicity data (i.e. the toxicity data for the most sensitive taxa data, EC50 for Cloeon of 0.014 mg a.i./l) using an assessment factor of 100 instead of the TGD recommended 1000 because this taxa was regarded with high probability the most sensitive and a further long-term NOEC from different taxonomic group would not be lower than the data already available. Therefore, the endpoint was derived to cover both long and short term effects in the most sensitive taxa.

Metabolite CGA 322704

Table 2.2.2.2.1-2. Toxicity of Thiamethoxam metabolite CGA 322704 to aquatic organisms

CGA 322704					
Type of Organisms	**Species**	**Study Type**	**LC_{50} /EC_{50} or LOEC[a]** [mg/L]	**LC_0 (acute) NOEC (chronic)** [mg/L]	**Reference**
Fish	Rainbow trout,	96-h acute	> 100	100	A7.4.1.1/04
Crustaceans	*Daphnia magna*	48-h acute	> 100	100	A7.4.1.2/05
Algae	Green algae *Selenastrum capric.*	72-h acute	> 100	100	A7.4.1.3/03
Insects	*Chironomus riparius larvae*	30-d chronic / **sediment appl.**	0.025 [e]	0.015 [e]	A7.4.3.5.1/02
	Chironomus riparius (Larvae development rate)	30-d chronic / **sediment appl.**	0.0529	0.015	A7.4.3.5.1/02
	Chironomus riparius	28-d chronic **water spiked**		0.00067	A7.4.3.5.1/05

Aquatic PNEC for metabolite CGA 322704 was obtained from the most sensitive taxa in a long term test performed in Chironomids (Section 4.7.1 Document IIA), NOEC was 0.67 µg/l and an assessment factor of 10 was applied following TGD, as the taxa tested is with high probability the most sensitive and a further long-term NOEC from different taxonomic group would not be lower than the data already available. Then **aquatic PNEC for CGA 322704 is 0.067 µg/l.**

Metabolite NOA 407475.

Table 2.2.2.2.1-3. Toxicity of metabolite NOA407475 to aquatic organisms.

NOA 407475

Type of Organisms	Species	Study Type	LC_{50} /EC_{50} or LOEC[a] [mg/L]	LC_0 (acute) NOEC (chronic) [mg/L]	Reference
Fish	*Onchorynchusmykiss*	96-h acute	> 100		A7.4.1.1/06
Crustaceans	*Daphnia magna*	48-h acute	82.9		A7.4.1.2/07
Algae	Green algae *Scenedesmus subspicatus*	72-h acute	ECb50=14 ECr50=33.8	NOECb and NOECr= 4.6	A7.4.1.3/05

Acute data was available for three trophic levels of the base set (fish, Daphnia and algae) and consequently, and according to the TGD for calculation of PNEC using assessment factors, an assessment factor of 1000 is applied to the lowest L(E)C50 of the three trophic levels (to ECr50 in algae as this is less dependent on test conditions) resulting in **aquatic PNEC for NOA 407475 = 0.0338 mg/l**

2.2.2.2.2. Sediment

Thiamethoxam. Sediment PNEC was estimated in 0.01 mg/kg for product B1 and was derived from the lowest chronic toxicity to chironomids (NOEC of 0.10 mg a.i./kg sediment) applying an assessment factor of 10 as there is enough data from the aquatic compartment and the test was performed in the most sensitive taxa (Document IIA section 4.7.2).

Metabolite CGA 322704. **Sediment PNEC** for product B3, product B2 and product B1 products was based on a NOEC for chironomids of 0.015 mg/kg sediment and applying an assessment factor of 100 as this was the only toxicity data for this metabolite, and resulted in a value of **0.00015 mg /kg** (Document IIA section 4.7.2).

The output of the Chironomid tests were based on nominal concentrations, which for some opinions might underestimate the risk. Measured concentrations could not be obtained due to technical reasons and estimation could not be applied since the available parameter DT50 was not appropriate to it (DocIIA section 4.5.1.7)

Metabolite NOA 407475. Sediment PNEC. To calculate a PNEC for sediment valid for the three products, an assessment factor of 100 according to the TGD, part II section 3.5.4 was applied to the NOEC of 1 mg/kg sed from the 30d test performed following OECD guidelines on Chironomus riparius monitorizing larvae development and midge emergence. In the test, the substance was mixed with sediment. Consequently, NOA 407475 **PNECsed=0.01 mg/kg**

2.2.2.2.3. Sewage

PNEC for sewage organisms was estimated to be 1 mg/l based on a EC50 value obtained from the respiration inhibition test (>100 mg/l) applying a safety factor of 100 as directed by the TGD (Document IIA section 4.7.3).

2.2.2.2.4. Terrestrial compartment.

Thiamethoxam and its metabolites had no significant effects on soil micro-organisms as indicated by respiration and nitrification studies. The studies with arthropods presented in the dossier are not relevant for assessing the risk for Thiamethoxam used as the formulations of insecticide here presented, as all the studies were presented exposing the animals to treated seeds, which is not comparable to the exposition route expected for a indoors insecticide scenario. In addition, information on laboratory tests with bees was available as contact and oral toxicity in the dossier (listing of endpoints) but when this report was elaborated there were no harmonized approach to evaluate risk for bees with this data. Further data on field studies with arthropods can be found in the PPP dossier, but were not submitted by the applicant.

From the data available, earthworms are the most sensitive group. These organisms are sensitive to both thiamethoxam and to metabolite CGA 322704. Tests presented within the Biocide Dossier together with data from PPP monograph proposed by the applicant were used for the risk evaluation. A field study of toxicity of thiamethoxam, evaluated for the PPP monograph, was used although adapted to the Biocides scenarios to obtain an endpoint and calculate a PNEC applying an AF=2 to the NOEC of the test. Regarding the metabolite CGA 322704, also field data were submitted and used for PNEC calculations and an AF=2 were applied to the NOEC of the study.

Table 2.2.2.2.4-1 Toxicity data used to calculate Thiamethoxam terrestrial PNEC value

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

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

Table 2.2.2.2.4-2 Toxicity data for thiamethoxam metabolite CGA 322704 used to calculate a terrestrial PNEC value

CGA 322704					
Testing	**Species**	**Test duration**	**Measurement**	**Result**	**Remarks**
Acute toxicity earthworm	*Eisenia foetida*	14 days	LC_{50}	5.93 mg a.i./kg	7.5.1.2/05
Acute toxicity earthworm	*Eisenia foetida*	14 days	NOEC	2.5 mg a.i./kg	7.5.1.2/05 (This is from an acute test and was considered as chronic by the applicant. Data is considered as chronic in the PPP monography addendum Ecotox pag 10)
Chronic toxicity earthworm	*Eisenia foetida*		NOEC	0.06 mg a.i./kg	A. 7.5.2.1_01 report 773976. This was not submitted in the original dossier. A summary was submitted by request of the rapporteur.
Earthworm field study	Various species	337 d	NOEC	**0.016 mg a.i./kg**	7.5.2.1_02. Report ER-04-KCB 196 (Syngenta project No. 2033604)
Nitrification – Carbon transformation	Soil microorganisms	28 days	NOEC	0.5 mg a.i./kg	7.5.1.1/02

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

Table 2.2.2.2.4-3 Toxicity data for thiamethoxam metabolite NOA 407475 used to calculate a terrestrial PNEC value

NOA 407475					
Testing	**Species**	**Test duration**	**Measurement**	**Result**	**Remarks**
Chronic toxicity earthworm	*Eisenia foetida*	14d	LC50	>1000 mg ai/kg	A7.5.2.1_02

In addition a test entitled "Biological activity of metabolites of Thiamethoxam CGA293343 on insects and mites" 7.5.4.1/08 was presented. The test was not presenting information on GLPs and guidelines but was informative as additional data. In the test, metabolite NOA 407475 was lacking of effects of mortality in arthropods at 100 ppm, while other metabolites tested did present effects.

PNEC for NOA 407475 for soil was calculated applying assessment factor of 1000 as indicated in the TGD section 3.6.2.2. Thus, **PNEC >1mg/kg soil.**

Thiamethoxam and CGA 322704 have shown to be highly toxic to bees both by oral and contact exposure. The 48-hour LD_{50} for oral toxicity was 0.005 µg/bee for Thiamethoxam and 0.0168 µg/bee for CGA 322704. The 48-hour LD_{50} for contact toxicity was 0.024 µg/bee for Thiamethoxam and 0.0275 µg/bee for CGA 322704. The applicant submitted only acute test.

The data from the oral exposure test was transformed to mg a.s./kg $_{nectar/pollen}$ using the volume of test solution consumed by each individual and the density of the syrup (data present in the test reports). Therefore, the threshold exposition (absence of non desirable effects) was 0.314 mg a.s/kg $_{nectar/pollen}$ for Thiamethoxam and 0.7 mg a.s/kg $_{nectar/pollen}$ for CGA 322704.

To calculate PNEC values, since the toxicity data was obtained from a mortality 48-hour test of adult bees, an assessment factor of 10 was applied to the threshold values. This factor of 10 is supported by data reported in guidelines used for PPP assessment (EPPO, 2010[5]).

Table 2.2.2.2.4-4 Toxicity data for Thiamethoxam and metabolite CGA 322704 used to calculate a $PNEC_{bees}$ value.

	LD_{50} mg a.s/kg $_{nectar/pollen}$	**$PNEC_{bees}$ mg a.s/kg $_{nectar/pollen}$**
Thiamethoxam	0.314	0,0314
CGA 322704	0.7	0,07

[5] European and Mediterranean Plant Protection Organization. Environmental risk assessment scheme for plant protection products, Chapter 10: honeybees. *Bulletin OEPP/EPPO* **40**, 323–331 (2010).

2.2.2.2.5. Secondary poisoning

At the time this report was elaborated there was no agreed scenario for secondary poisoning considering the use of insecticides inside animal houses and farms. The RMS ES launched an electronic consultation in 2008 to recover the opinion of the MS regarding the inclusion of such scenario, and no unfavourable opinion was received. The scenario proposed by the RMS ES was discussed at the TM I 2010 and no consensus opinion was achieved and it was left to the RMS to decide the inclusion of the scenario within the CAR. There were controversial issues regarding the scenario. The main ones were the percentage of poisoned insects in the diet of the insectivorous farm surrounding fauna and the residue of the a.i. in the poisoned insects. The scenario is included as an annex to this CAR to be consulted at product authorization for site specific assessment and diagnosis purposes.

2.2.2.3. PBT assessment

PBT assessment for Thiamethoxam

Following the TGD directions as in part II page 164 and REACH guidance (information requirements r_11).

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

Data on DT50 water (hydrolysis) are

- Half life is 640-572 d at pH7
- Half life is 4.2-15.6 d at pH9

Thiamethoxam is considered stable at pH5

From data of photolysis:

(1) Half life is 2.3-3.1 d

This qualifies the substance for further study for the Persistence criterium.

Thiamethoxam does not pass the ready biodegradation test. It is very soluble (c.a 4g/l) and its partition coefficient is Pow: 0.73 (25ºC)

However, further data on water or sediment compartments are not definitive.

Data on DT50 water/sediment biodegradation in river and pond is only valid for the total system.

DT50 total:

-river: 36.6d/35.3d at 20 ºC (68.8d/66.9d at 12ºC)

-pond: 25.7d/28.4d at 20 ºC (48.7d/53.9d at 12ºC)

DT50 for sediment was not accepted because it was not possible to establish a good pattern of degradation of the substance in the compartment, and DT50 for water was not accepted either

because it was calculated following a model of two compartments. There was a re-calculation made by the PPP expert in the monography presented for the AnexI entry of the PPP directive where DT50 for the water compartment in Pond was estimated to be 24.5d at 25ºC (46.5d at 12ºC).

Data on DT50 water/sediment biodegradation in paddy soil for the total system is:
Total: 51.6d/51.8d at 25ºC (146d/146.5d at 12ºC).

Thiamethoxam seems to bind to the sediment matrix and it is in part transformed into the de-nitro metabolite NOA 407475, for which no valid DT50 was provided. Thiamethoxam DT50 in soil (aerobic) is 72d (10ºC), being the main metabolite CGA322704 (Clothianidin). DT50 for Clothianidin in soil is 178d (20ºC) or 337.95d (12ºC).

Taking this altogether Thiamethoxam might be exonerated from the P classification. But considering that the main aerobic metabolite of thiamethoxam (clothianidin) is persistent, **the parent substance should be considered persistent.**

B criterium: BCF > 2000.

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

Then the B criterium is not complied.

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

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

<u>vP-vB assessment</u>

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

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

vB: BCF > 5000.

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

The vB criterium is not complied.

Endocrine disruption.

In addition, Thiamethoxam does not accomplish the criteria for CMR substances. The RMS performed a search in the list included in the web link http://ec.europa.eu/environment/docum/01262_en.htm, (December 2010) which contains the Commission of a Communication to Council and European Parliament on a Community Strategy for Endocrine Disrupters in December 1999 (COM(1999)706), and the substance was not found in the list. Analogously, the RMS performed a search in the PubMed (http://www.ncbi.nlm.nih.gov/sites/entrez in 23/07/2009) with the terms: "Thiamethoxam hormonal disrupting" and "Thiamethoxam disrupting activity" and no result related to endocrine disruption or hormone synthesis was found.

2.2.2.4. Exposure assessment

2.2.2.4.1. Aquatic compartment **product B1**

The current version of the ESD ad hoc for household and professional uses by the OECD was applied: "Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses". Estimates of potential exposures resulting from STPs are carried out according to the standard calculation frameworks presented in the Technical Guidance Document (E.C. 2003).

From the time the assessment was prepared to the time this AR was presented, there have been amendments in the scenario that were not incorporated. The relevant amendments is regarding to the Area treated (subject to wet cleaning). The current assessment presented here assumed 3.85 m2 for household and 97.1 m2 for large buildings and the accepted amendments (TM II 2010) are: 2m2 (household) and 9.3 m2 (large building).

Therefore, the PEC values presented here cover largely the current harmonized scenario.
To obtain PECs values according to the Area treated (subject to wet cleaning) of 2m2 (household) and 9.3 m2 (large building) a multiplication of the here presented PEC values by factor of 2/3.85= 0.519 (household) and by a factor of 9.4/97.1=0.097 (large building) can be applied where pertinent.

The most relevant release pathway for transport to the environment after indoors use of product B1 is the cleaning step.

Three cases were envisaged, according to the ESD for insecticides, acaricides and products to control other arthropods (PT-18) for household and professional uses:

- CASE A: cleaning events result only in emissions to solid wastes (100% of the surfaces are cleaned by vacuum/broom and the clothes of the applicator are disposable)

- CASE B: cleaning events result only in emissions to wastewater: 100% of the surfaces are washable and the clothes of the applicator are washed (counting with cleaning efficiency factors proposed by the ESD).

- Case C: All releases are directed waste water during cleaning excepting those emitted by the applicator during application.

Relevant emission to water was from cases B and C.

Table 2.2.2.4.1-1 Local emission to water calculated for case B (washable coveralls, 100% treated surfaces wet cleaned)

Variable/parameter	Symbol	Unit	large building	private House
Washable coveralls, 100% wet cleaning	Elocalwater	kg.d-1	0.00317566	0.00164748
Concentration in untreated wastewater as TGD eq 32 (washable coveralls, 100% wet cleaning)	Clocal,inf	mg.l-1	0.00159	0.00082
Concentration of substance in the STP effluent as TGD eq 33 (washable coveralls, 100% wet cleaning)	Clocal,eff	mg.l-1	0.00159	0.00082
Local concentration in surface water during emission episode as TGD eq 45 (washable coveralls, 100% wet cleaning)	Clocal,water	mg.l-1	**0.00016**	**0.00008**

Table 2.2.2.4.1-2 Local emission to water calculated for case C (disposable coveralls, 100% treated surfaces wet cleaned)

Variable/parameter	Symbol	Unit	large building	private House
Disposable coveralls, 100% wet cleaning	Elocalwater	kg.d-1	0.002938224	0.001521954
concentration in untreated wastewater as TGD eq 32 (disposable coveralls, 100% wet cleaning)	Clocal,inf	mg.l-1	0.00147	0.00076
Concentration of substance in the STP effluent as TGD eq 33 (disposable coveralls, 100% wet cleaning)	Clocal,eff	mg.l-1	0.00147	0.00076
Local concentration in surface water during emission episode as TGD eq 45 (disposable coveralls, 100% wet cleaning)	Clocal,water	mg.l-1	**0.00015**	**0.00008**

PEC in sediment

This was calculated for the cases where emission to water happens (cases B and C) following equation #50 in TGD. Defaults were set as in TGD, using values for Koc 33.1 mL /g and values for PEClocal water and RHOsusp =1150 kg.m-3

Table 2.2.2.4.1-3 PEC sediment for case B (washable coveralls, 100% wet cleaning)

	crack and crevice at large building	Crack and crevice at House
PEC local sed (washable coveralls, 100% wet cleaning) according to TGD eq [50] mg/kg	0.00024	0.00012

Table 2.2.2.4.1-4 PEC sediment for case C (disposable coveralls, 100% wet cleaning)

	crack and crevice at large building	Crack and crevice at House
PEC local sed (disposable coveralls, 100% wet cleaning) according to TGD eq [50] mg/kg	0.00022	0.00011

2.2.2.4.2. Aquatic compartment **product B2**

PEC values in the different compartments were calculated according to the proposed OECD scenarios and the applicant claims.

The RMS performed this environmental risk assessment having into account the conclusions and agreements of TM I 2010. The TIER 1 results obtained from direct application of the corresponding Emission Scenario Document for PT-18 for Insecticides for Stables and Manure Storage systems (OECD) were refined using data from degradation of Thiamethoxam in anaerobic conditions and in some cases, further application of FOCUS models. Other possibility to show safe uses for Thiamethoxam as insecticide was explored by the NL Competent Authority and consisted to apply FOCUS for groundwater and surface water directly to TIER 1 results. This approach confirmed the safe use of Thiamethoxam.

According to ESD, and in lack of other data from the applicant, emission as liquid wastes (cleaning operations from horizontal surfaces and other places such as walls, ceilings, window sills, ledges and others) has been considered as kept in a separate waste water slurry tank and not discharged to the sewer. The liquid waste is considered to be spread together with the manure from the dry storage (point 4.2).

Regarding manure storage systems, it has been considered that, in the case of field application of the manure, the liquid waste is applied evenly on all fields together with the manure, as is the case with wet storage (slurry pits, where manure and waste water are collected together) according to the ESD point 4.2.5. Also it has been assumed the prohibition to discharge waste water containing manure to the public (municipal) sewer according to point 4.1.1 of ESD.

Regarding type of insecticide for the modelling, type 1 (Insecticides, adulticides, specifically against flies) has been used (point 4.3 of ESD).

Thus, basic steering parameters considered in this modelling have been, according to ESD point 5.1:

Table 2.2.2.4.2-1

index	Variable subscript name	Parameter description	Considered for product B2
i1	cat-subcat	animal subcategories and manure storage type	1,2,3,4,5,6,7,9,10,11,12,13,14,15,16,17,18
i2	bioctype	biocide type	1
i3	appway	the way the insecticide is applied	4 (sprinkling, as worst case as indicated by the applicant)
i4	stream	the stream(s) where the biocide is emitted to	1 (manure), 2 (waste water), 3 (slurry)

Product B2 is used inside animal houses and therefore direct application to soil is not expected, however potential exposure to soil is anticipated via land application of stored manure (see section 3.3.2), subsequent leaching from affected areas could then result in loadings to ground water.

Groundwater.

Using a first tier approach, PEC in ground water (PEC_{gw}) was calculated by estimation of pore water concentration. PEC soil input was from first tier calculation. Equations were from the ESD and according to the TGD (Technical Guidance Notes) on Risk assessment, to estimate the ***theoretical maximum concentration*** in groundwater.

To refine the emissions, PEC soil used as input were those that considered thiamethoxam degradation in manure prior land application and carry over of substances after application (for the grassland scenario). For Thiamethoxam, refined PEC_{grw} was calculated as a PECporewater. using refined PEC_{soil}. Refined PECsoil considered anaerobic degradation in manure occurring during the storage period. The rapporteur used K_{oc} for thiamethoxam as 33.1 mL/g, worst case value (study 7.2.3.1/01). Accumulation in soil was calculated using aerobic DT50 (72 d) at 10ºC. Then, PECgw was calculated from the maximal emission to soil that considered the carry over of the compound. Thiamethoxam is stable in water.

When applied to land, manure contains also metabolites, mainly NOA 407475. This may pass to porewater as well. In addition, metabolite CGA 322704 is formed in soil upon aerobic degradation of thiamethoxam and it accumulates from one application to the following in the grassland scenario due to its DT50 of 178.2 d at 20ºC. Those can be eventually transferred to porewater (groundwater). Metabolite CGA 322704 is stable in water.

NOA 407475 PECgw was calculated using maximal PECsoil NOA 407475. No data on water stability of this compound was available. In Arable lands, where there is one application per year, maximal NOA 407475 in soil was calculated from thiamethoxam accumulated in manure during storage (62.3% of thiamethoxam converted to metabolite). In Grassland, as no data on stability

was available, NOA 407475 in groundwater was calculated from its maximal concentration in soil considered as the sum of NOA 407475 concentration in each land application.

To calculate CGA 322704 PECgw, metabolite maximal emission to soil was used as input. In addition, CGA 322704 is stable in water. In Arable lands, maximal CGA 322704 in soil was calculated from the worst case percentage of thiamethoxam transformation (35.6%). This percentage was applied to the thiamethoxam estimated in manure after the anaerobic transformation. Then it was corrected by molecular weight. In Grassland scenario, maximal CGA322704 was calculated from the worst case percentage of thiamethoxam transformation (35.6%) and correcting by molecular weight for each application and then considering the carry over between applications.

Thus, from these calculations, PECgw for product B2 was obtained for Arable and Grassland.

The maximum PECgw (refined) were for i1=11 corresponding to Laying hens in free ranges with litter floor (partly litter floor, partly slatted).

Table 2.2.2.4.2-2

Maximum PECgroundwater (mg a.i./l) Arable lands PRODUCT B2			
	Thiamethoxam	CGA 322704	NOA 407475
I1=11	0.000121	2.116E-05	0.0001187

Table 2.2.2.4.2-3

Maximum PECgroundwater (mg a.i./l) Grassland PRODUCT B2			
	Thiamethoxam	CGA 322704	NOA 407475
I1=11	0.002062	0.000565	0.00038

FOCUS REFINEMENT.

FOCUS groundwater for pesticides was applied to further refine the risk for groundwater. The input for the model was from the worst case of animal subcategory (i1= i1=11 corresponding to Laying hens in free ranges with litter floor (partly litter floor, partly slatted). and calculated as kg of substance per year and ha from the equation (Qai-grass*QN,grassland)/(Qnitrog-grass* Nlapp-grass) as example. More details are in text in Document II and in the annexed calculations

The assumptions for modelling were: (a).Arable land. Single land application each year, default 1st September and Grassland. 4 x land applications each year with 53 days spacing (dates 1st February, 26th March, 18th May, 10th July) (b). Freundlich exponents assumed as 0.9, 0.81, 0.84 for TMX, CGA 322704 and NOA 407475, respectively. Derived from the study summaries (c) Crop uptake factor of 0 (d). Simulation period 20 years (e). Exposure pathway: for arable land applications sugar beet crop scenario was used as surrogate. For grassland applications grass scenario was chosen.

Table 2.2.2.4.2-4 FOCUS/PEARL input values were the following, in kg a.i./ha per application:

	TMX	CGA 322704	NOA 407475
Product $B2_{grassland}$	5.65E-04	As metabolite from TMX	6.36E-04

Then, considering TMX parent substance and aerobic metabolite CGA 322704 (35.6% transformation) + NOA 40747 (independently)

Table 2.2.2.4.2-5 PRODUCT B2

PEARL SCENARIO	**Annual average concentration (µg/l)**		
GRASSLAND	**TMX**	**CGA 322704**	**NOA 40747**
(Grass)	80^{th} perc	80^{th} perc.	80^{th} perc. 5
	Nitrogen standard		
Châteaudun	0.000687	0.000379	0
Hamburg	0.001415	0.001927	0
Joikionen	0.002632	0.002463	0
Kremsmünster	0.005405	0.005542	0
Okehampton	0.000007	0.000001	0
Piacenza	0.003109	0.003344	0.000604
Porto	0.002339	0.002316	0
Seville	0.000491	0.000292	0
Thiva	0.000588	0.001208	0

Surface water.

Use of **product B2** is not carried out near surface water bodies. However, following use of the formulated product in animal houses and subsequent land application of manure, exposure of the active substance to surface water could potentially occur as a result of run-off from areas treated with manure, according to the ESD.

First tier calculations for PEC in surface water (PECw) assumed that the potential concentration of the active substance in surface water is given by the equation

$$PEC_w = \frac{PEC_{local\ soil,porew}}{DILUTION_{run\text{-}off}}$$

with $DILUTION_{run\text{-}off}$ as a factor of 10.

According to this, first tier PECw was calculated for thiamethoxam from first tier PECsoil. No aerobic or anaerobic degradation is considered prior to the run off event as a worst case. Refined PECw were obtained using as input refined PECgroundwater. Refined PECw was obtained considering anaerobic degradation of Thiamethoxam during manure storage. Run off event was considered immediately after the maximal PECgw.

PECwater in Arable Land for Thiamethoxam and metabolites CGA 322704 and NOA407475.

The maximum PECw (refined) were for i1=11 corresponding to Laying hens in free ranges with litter floor (partly litter floor, partly slatted). The values were:

Table 2.2.2.4.2-6

Maximum PECwater (mg a.i./l) Arable lands PRODUCT B2			
	Thiamethoxam	CGA 322704	NOA 407475
I1=11	0.0000121	2.116E-06	0.00001187

PECwater in Grassland for Thiamethoxam and metabolites CGA 322704 and NOA407475.

The maximum PECw (refined) were for i1=11 corresponding to Laying hens in free ranges with litter floor (partly litter floor, partly slatted). The values were:

Table 2.2.2.4.2-7

Maximum PECwater (mg a.i./l) Grassland PRODUCT B2			
	Thiamethoxam	CGA 322704	NOA 407475
I1=11	0.000206	0.0000565	0.000038

PECwater for Thiamethoxam were further refined using the FOCUS surface water software by the applicant. The step 3 of FOCUS surface water was applied. The surrogate D4, stream, was the highest for the Global Maximum PEC of 0.016 ug/l.

PECstp and PECsurface water in case of emission to STP allowed.

Liquid wastes could be emitted to STP separately from solids and slurry and therefore, not applied to land, in some MS. This scenario has been calculated for the surrogates where this case can occur according to the ESD for PT-18: OECD Series on Emission Scenario Documents Number 14, Emission Scenario Document for Insecticides for Stables and Manure Storage Systems, Table 5.4 *Estimates for the fraction of active ingredient released to the relevant streams.*

Arable or Grassland scenarios are not relevant in these calculations because the emissions to the STP are the same regardless where the manure is applied.

Surface waters are receiving emission from both STP and from drift, run off and drainage from soil. Considering that both contributions would not happen in the same point and that PEC local values are calculated, emissions were not summed up and considered separately. PECsoil (and further emission to water from soil) was not recalculated as the risk is cover by the surrogate where liquid and solid contributions from animal houses are considered to be applied in land. Only PEC for Thiamethoxam was calculated as the main metabolites will not be formed (CGA 322704 is formed in soil and NOA 407475 is formed in anaerobic conditions).

Calculations were done assuming that discharge of liquid waste **was** made to STP and PECstp and values ranged from 0.00111 for i1=12 Broilers in free range with litter floor to **0.00333 i=16**

Turkeys in free range with litter floor and PECwater ranged from 0.000111 for i1=12 Broilers in free range with litter floor to **0.000333 i=16.** For detailed calculations please refer to the annexes entitled CALCULATIONS.

PEC in sediment for Product B2.

PEC in sediment was calculated according to the TGD eq. 50 from estimated PEC values in the aquatic compartment (using refined values). The details of calculations are shown in the accompanying excel worksheets in the Annexed Calculations.

Inputs used for calculation were for Thiamethoxam RHOsusp (bulk density of suspended matter in kg/m3) of 1150 and Ksusp-water (suspended matter-water partitioning coefficient in m3/m3) of 1.73 using the Koc parameter of 33 l/kg for Thiamethoxam and for CGA 322704 of 63 l/kg. For metabolite NOA 407475 Koc was estimated as 433 l/kg (study 7.2.3.1/12).

PECsediment in Arable Land for Thiamethoxam and metabolites CGA 322704 and NOA407475.

The maximum PECsediment (refined) were for i1= corresponding to Laying hens in free ranges with litter floor (partly litter floor, partly slatted). The values were:

Table 2.2.2.4.2-8

Maximum PECsediment (mg a.i./kg) Arable lands Product B2			
	Thiamethoxam	CGA 322704	NOA 407475
I1=11	1.827E-05	4.564E-06	0.000121

PECsediment in Grassland for Thiamethoxam and metabolites CGA 322704 and NOA407475.

The maximum PECsediment (refined) were for i1=11 corresponding to Laying hens in free ranges with litter floor (partly litter floor, partly slatted). The values were:

Table 2.2.2.4.2-9

Maximum PECsediment (mg a.i./kg) Grassland Product B2			
	Thiamethoxam	CGA 322704	NOA 407475
I1=11	0.000310	0.000122	0.000387

2.2.2.4.3. Aquatic compartment **product B3**

Product B3 is used inside animal houses and therefore direct application to soil is not expected, however potential exposure to soil is anticipated via land application of stored manure (see

section 3.3.2), subsequent leaching from affected areas could then result in loadings to ground water.

For the aquatic exposure assessment of product B3, the same considerations as for product B2 were applied (see point 2.2.2.4.2)

Table 2.2.2.4.3-1 Basic steering parameters considered in this modelling have been, according to ESD point 5.1:

index	Variable subscript name	Parameter description	Considered for Product B3
i1	cat-subcat	animal subcategories and manure storage type	1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18
i2	bioctype	biocide type	1
i3	appway	the way the insecticide is applied	3 smearing (brushing)
i4	stream	the stream(s) where the biocide is emitted to	1 (manure), 2 (waste water), 3 (slurry)

Ground water

Product B3 is used inside animal houses and therefore direct application to soil is not expected, however potential exposure to soil is anticipated via land application of stored manure (see section 3.3.2), subsequent leaching from affected areas could then result in loadings to ground water. The maximum PECgw (refined) were for i1=11 corresponding to Laying hens in free ranges with litter floor (partly litter floor, partly slatted). **PECgroundwater in Arable Land for Thiamethoxam and metabolites CGA 322704 and NOA407475.**

Table 2.2.2.4.3-2. The maximum PECgw (refined) were for i1=3 Veal (calves). The values were:

Maximum PECgroundwater (mg a.i./l) Arable lands PRODUCT B3			
	Thiamethoxam	CGA 322704	NOA 407475
I1=3	0.000648	0.000112	0.000634

PECgroundwater in Grassland for Thiamethoxam and metabolites CGA 322704 and NOA407475.

Table 2.2.2.4.3-3. The maximum PECgw (refined) were for i1=3 Veal (calves). The values were:

Maximum PECgroundwater (mg a.i./l) Grassland PRODUCT B3			
	Thiamethoxam	CGA 322704	NOA 407475
I1=3	0.011078	0.003035	0.002058

FOCUS REFINEMENT (PEARL).

FOCUS groundwater for pesticides was applied to further refine the risk for groundwater. The input for the model was from the worst case of animal subcategory (i1= i1=11 corresponding to Laying hens in free ranges with litter floor (partly litter floor, partly slatted). and calculated as kg of substance per year and ha from the equation (Qai-grass*QN,grassland)/(Qnitrog-grass* Nlapp-grass) as example. More details are in text in Document II and in the annexed calculations

The assumptions for modelling were: (a).Arable land. Single land application each year, default 1st September and Grassland. 4 x land applications each year with 53 days spacing (dates 15th February, 9th April, 2nd June, 25th July) (b). Freundlich exponents assumed as 0.9, 0.81, 0.84 for TMX, CGA 322704 and NOA 407475, respectively. Derived from the study summaries (c) Crop uptake factor of 0 (d). Simulation period 20 years (e). Exposure pathway: for arable land applications winter cereals crop scenario was used as surrogate. For grassland applications grass scenario was chosen.

TMX parent substance and aerobic metabolite CGA 322704 (35.6% transformation) + NOA 40747 (independently)

Table 2.2.2.4.3-4. Product B3. PECgw concentrations of Product N3 using FOCUS PEARL for the Arable land scenarios.

PEARL SCENARIO	**Annual average concentration (µg/l)**		
ARABLE	**TMX**	**CGA 322704**	**NOA 40747**
Winter cereals	80th perc	80th perc.	80th perc. 5
	Nitrogen standard		
Châteaudun	0.007633	0.009841	0.000010
Hamburg	0.002929	0.002572	0.029825
Joikionen	0.005534	0.008500	0.000000
Kremsmünster	0.001821	0.003646	0.015479
Okehampton	0.009756	0.010668	0.054187
Piacenza	0.012973	0.015274	0.101530
Porto	0.000035	0.000016	0.000000
Seville	0.000132	0.000077	0.000000
Thiva	0.001123	0.004270	0.000124

Table 2.2.2.4.3-5 Product B3. PECgw concentrations of Product N3 using FOCUS PEARL for the Grassland scenarios.

PEARL SCENARIO	**Annual average concentration (µg/l)**		
GRASSLAND	**TMX**	**CGA 322704**	**NOA 40747**
(Grass)	80th perc	80th perc.	80th perc.
	Nitrogen standard		
Châteaudun	0.010254	0.024546	0.000000
Hamburg	0.022590	0.035262	0.000304
Joikionen	0.014424	0.016141	0.000000
Kremsmünster	0.012441	0.024114	0.000000

Okehampton	0.021858	0.028982	0.000337
Piacenza	0.041356	0.049102	0.014747
Porto	0.000196	0.000140	0.000000
Seville	0.005163	0.006667	0.000000
Thiva	0.006091	0.020527	0.000041

Surface water.

Use of **product B3** is not carried out near surface water bodies. However, following use of the formulated product in animal houses and subsequent land application of manure, exposure of the active substance to surface water could potentially occur as a result of run-off from areas treated with manure, according to the ESD.

First tier calculations for PEC in surface water (PECw) assumed that the potential concentration of the active substance in surface water is given by the equation

$$PEC_w = \frac{PEC_{local\ soil,porew}}{DILUTION_{run\text{-}off}}$$

with $DILUTION_{run\text{-}off}$ as a factor of 10.

According to this, first tier PECw was calculated for thiamethoxam from first tier PECsoil. Refined PECw values were obtained using as input refined PECgroundwater. Refined PECw was obtained considering anaerobic degradation of Thiamethoxam during manure storage. Run off event was considered immediately after the maximal PECgw. FOCUS surface water modelling was applied to further refine the emission values. Complete explanations and calculations are in document IIB and the Calculation annex.In some scenarios the release to STP of liquid wastes is allowed. For such cases, calculation has been included to be considered in the product authorization stage because the direct emission to STP might be allowed in several MS. The details can be followed in the calculation annex.

PECwater in Arable Land for Thiamethoxam and metabolites CGA 322704 and NOA407475.

Table 2.2.2.4.3-6. The maximum PECw (refined) were for i1=3 corresponding to Veal (calves). The values were:

Maximum PECwater (mg a.i./l) Arable lands PRODUCT B3			
	Thiamethoxam	CGA 322704	NOA 407475
I1=3	6.48434E-05	1.12976E-05	6.33624E-05

PECwater in Grassland for Thiamethoxam and metabolites CGA 322704 and NOA407475

Table 2.2.2.4.3-7. The maximum PECw (refined) were for i1=3 corresponding to Veal (calves). The values were:

Maximum PECwater (mg a.i./l) Grassland PRODUCT B3			
	Thiamethoxam	CGA 322704	NOA 407475
I1=3	0.001108	0.000303	0.000206

FOCUS surface water.

This approach was followed to further refine PECwater in Grassland for PECs calculated before accounted for risk to the aquatic compartment for Thiamethoxam and CGA 322704 (see DocIIC). The step 3 of FOCUS surface water was applied with the following parameters: Software: FOCUS_SWASH_3.1, FOCUS_MACRO_4.4.2, FOCUS_PRZM_SW_1.1.1 and FOCUS_TOXSWA_3.3.1.Crop: Grass/alfalfa.Scenarios modelled: D1, D2, D3, D4, D5, R2 and R3.

Applications in soil. Four applications at time intervals of 53d starting 1st February. Input in soil from the surrogate i1=3 (Veal Calves) Thiamethoxam: 0.00303 kg/ha, CGA322704 as metabolite reaching up to 35.6% from the parent in soil.

For the parameters to be entered in the program, they have been collected from the endpoint list and are detailed in the annexed calculations and in DocIIB3.

Table 2.2.2.4.3-8. Actual concentration of Thiamethoxam in water layer µg/l (Global Maximum) for Product B3 in the different FOCUS surface water scenarios.

Substance	Scenario	Water body	Actual concentration in water layer µg/l Global Maximum
Thiamethoxam	D1	ditch	0.000119
	D1	stream	0.000074
	D2	ditch	0.000851
	D2	stream	0.000549
	D3	ditch	0.0024
	D4	stream	0.014
	D4	pond	0.00671
	D5	stream	0.00566
	D5	pond	0.00446
	R2	Stream	0.0191
	R3	stream	0.0226

Table 2.2.2.4.3-9. Actual concentration of CGA322704 in water layer µg/l (Global Maximum) for Product B3 in the different FOCUS surface water scenarios.

Substance	Scenario	Water body	Actual concentration in water layer µg/l Global Maximum

CGA 322704	D1	ditch	0.000036
	D1	stream	0.000024
	D2	ditch	0.000538
	D2	stream	0.000337
	D3	ditch	0.00385
	D4	stream	0.0107
	D4	pond	0.00423
	D5	stream	0.00416
	D5	pond	0.00296
	R2	stream	0.00124
	R3	stream	0.00412

PECstp and PECsurfacewater in case of emission to STP allowed.

Liquid wastes could be emitted to STP (not applied to land) in some MS. This has been calculated for the surrogates indicated in the ESD for PT-18: OECD Series on Emission Scenario Documents Number 14, Emission Scenario Document for Insecticides for Stables and Manure Storage Systems, Table 5.4 *Estimates for the fraction of active ingredient released to the relevant streams.*

Arable or Grassland scenarios are not relevant in these calculations because the emissions to the STP are the same regardless where the manure is applied.

Surface waters are receiving emission from both STP and from drift, run off and drainage from soil. Considering that both contributions would not happen in the same point and that PEC local values are calculated, emissions were not summed up and considered separatedly. PECsoil (and further emission to water from soil) was not recalculated as the risk is cover by the surrogate where liquid and solid contributions from animal houses are considered to be applied in land. Only risk for Thiamethoxam was calculated as the main metabolites will not be formed (CGA 322704 is formed in soil and NOA 407475 is formed in anaerobic conditions).

Calculations were done assuming that discharge of liquid waste **is** made to STP (and not kept to be released together with slurries or solid wastes) and PECstp values (mg/l) ranged from 0.0101 for i1=12 Broilers in free range with litter floor to 0.0294 i=16 Turkeys in free range with litter floor and PECwater (mg/l) ranged from 0.00101 for i1=12 Broilers in free range with litter floor to 0.00294 i=16 Turkeys in free range with litter floor**.** For detailed calculations please refer to the annexes entitled CALCULATIONS.**PEC in sediment**

PEC in sediment was calculated according to the TGD eq. 50 from estimated PEC values in the aquatic compartment (using refined values). Inputs used for calculation were for Thiamethoxam RHOsusp (bulk density of suspended matter in kg/m^3) of 1150 and Ksusp-water (suspended matter-water partitioning coefficient in m3/m3) of 1.73 using the Koc parameter of 33 l/kg for Thiamethoxam and for CGA 322704 of 63 l/kg. For metabolite NOA 407475 Koc was estimated as 433 l/kg in loam (study 7.2.3.1/12).

PECsediment in Arable Land for Thiamethoxam and metabolites CGA 322704 and NOA407475 for Product B3.

The maximum PECsediment (refined) were for i1=3 corresponding to Veal (calves). The values were:

Table 2.2.2.4.3-10.

Maximum PECsediment (mg a.i./kg) Arable lands Product B3			
	Thiamethoxam	CGA 322704	NOA 407475
I1=3	0.000098	0.000024	0.000646

PECsediment in Grassland for Thiamethoxam and metabolites CGA 322704 and NOA407475 for Product B3.

The maximum PECsediment (refined) were for i1=3 corresponding to Veal (calves). The values were:

Table 2.2.2.4.3-11

Maximum PECsediment (mg a.i./kg) Grassland PRODUCT B3			
	Thiamethoxam	CGA 322704	NOA 407475
I1=3	0.001662	0.000653	0.002099

2.2.2.4.4. Terrestrial compartment **product B1**

Based on the type of use, emission is only considered to affect the aquatic compartment. Application of sewage sludge in agriculture and dry and wet deposition from the atmosphere was not considered as Thiamethoxam is not retained in sludge. Fstp was set to 1 due to the high solubility (c.a 4 g/l) and low Koc (33.1 l.kg-1), and this results in negligible amount of a.i. associated in the sludge of the STP, when using the default values from the TGD and following equation #45.

2.2.2.4.5. Terrestrial compartment **product B2**

Arable lands and grassland were considered for material (manure and slurry) application. For Grassland four land applications were considered and an annual PEC was calculated in a Tier1. For Arable lands one land application was considered.

For calculations in the first tier, tables in section 5 of the ESD were used, together with data supplied in the dossier and defaults from the ESD. When further refinement was required, then it was carried out assuming degradation of the active ingredient in manure (anaerobic) prior land application.

The RMS performed this environmental risk assessment having into account the conclusions and agreements of TM I 2010. The TIER 1 results obtained from direct application of the corresponding Emission Scenario Document for PT-18 for Insecticides for Stables and Manure Storage systems (OECD) were refined using data from degradation of Thiamethoxam in anaerobic conditions and in some cases, further application of FOCUS models. Other possibility

to show safe uses for Thiamethoxam as insecticide was explored by the NL Competent Authority and consisted to apply FOCUS for groundwater and surface water directly to TIER 1 results. This approach confirmed the safe use of Thiamethoxam.

The a.i. in manure after the storage period (anaerobic degradation in manure) was calculated considering half of the interval between applications according to table 5.8 of ESD, as a reasonable approach as did the applicant. Then for Arable land it was 106 d and for grassland 26.5 d. First order kinetics was assumed using the corresponding degradation constant $Kd_{anaerobic}$.$Qai_{anaerobic}$ = Initial Qai. $e^{(-t.Kd)}$

ARABLE LAND	GRASSLAND
t =106 days	t =26.5 days
$DT50_{anaerobic}$ = 24.2d (according to tests 7.1.2.1.2/01 and 02).	

For grassland 4 manure applications were considered.Annual PEC in land after four applications considering carry over was calculated using Qai anaerobic as input. Disotiation constant Kd was $Kd_{aerobic}$

- Qai max in soil= $Qai_{anaerobic}$ $(1-e^{-nKd.t})/(1-e^{-Kd.t})$

ARABLE LAND	GRASSLAND
t =212 days	t =53 days
$DT50_{aerobic}$ = 72 d (according to endpoint list).	

Metabolites. The anaerobic degradation of thiamethoxam renders metabolite NOA 407475 up to 62.3 % (worst case) at day 120 (studies 7.1.2.1.2/01 and 02). Similarly, metabolite CGA 322704 (which is itself a biocide called clothianidin) is formed as consequence of thiamethoxam aerobic degradation up to 35.6% at day 90 (worst case, study 7.2.2.1/01). The amount of these metabolites formed as consequence of anaerobic and aerobic degradation of Thiamethoxam in manure was calculated accordingly.

- Metabolite CGA 322704 was estimated applying worst case assumption, considering 35.6% of thiamethoxam converted to metabolite in aerobic conditions in soil and molar correction.

The input to calculate metabolite CGA 322704 was the initial concentration of thiamethoxam in soil after thiamethoxam anaerobic degradation in manure.

PIECsoil for one individual application was considered (calculating 35.6% of PIECinitial,anaerobic,thiamethoxam after anaerobic degradation during storage period) and CGA 322704 aerobic DT50 was used to calculate carry-over between applications. Aerobic CGA 322704 DT50 used was 178.2 d (study 7.2.2.1/06)

- Metabolite NOA 407475 was estimated applying worst case assumption, considering 62.3% of thiamethoxam converted to metabolite. The input was Thiamethoxam PIECinitial prior anaerobic degradation in manure. For four manure applications (grassland) the maximal (annual) NOA 407475 PECsoil was obtained by summing four applications as no data on DT50 was provided for this metabolite.

The following results for PEC were obtained:

PECsoil in Arable Land for Thiamethoxam and metabolites CGA 322704 and NOA407475.

The maximum PEC assuming a Nitrogen standard immission of 170 kg.ha-1.yr-1 and anaerobic degradation of Thiamethoxam, together with the default and constants as above explained were for i1=11 corresponding to Laying hens in free ranges with litter floor (partly litter floor, partly slatted). Details can be followed in Annex I to Doc IIB2.

Table 2.2.2.4.5-1

Maximum PECsoil (mg a.i./kg) Arable lands PRODUCT B2			
	Thiamethoxam	CGA 322704	NOA 407475
I1=11	8.52E-05	8.85E-05	0.000935

PECsoil in Grassland for Thiamethoxam and metabolites CGA 322704 and NOA407475.

The maximum PEC assuming a Nitrogen standard immission of 170 kg.ha-1.yr-1 and anaerobic degradation of Thiamethoxam, and aerobic degradation plus carry over of substances when applied to land together with the default and constants as above explained were for i1=11 corresponding to Laying hens in free ranges with litter floor (partly litter floor, partly slatted). Details can be followed in Annex I to Doc IIB2.

The values were:

Table 2.2.2.4.5-2

Maximum PECsoil (mg a.i./kg) Grassland PRODUCT B2			
	Thiamethoxam	CGA 322704	NOA 407475
I1=11	1.45E-03	0.000695	0.00299

2.2.2.4.6. Terrestrial compartment **product B3**

Calculations were performed as for product B2 (see section 2.2.2.4.4).

PECsoil in Arable Land for Thiamethoxam and metabolites CGA 322704 and NOA407475.

The maximum PEC assuming a Nitrogen standard immission of 170 kg.ha-1.yr-1 and anaerobic degradation of Thiamethoxam, together with the default and constants as above explained were for i1=3 corresponding to Veals (calves). Details of the calculations are in the Annex I to DocIIB3.

The values were:

Table 2.2.2.4.6-1

Maximum PECsoil (mg a.i./kg) Arable lands PRODUCT B3			
	Thiamethoxam	CGA 322704	NOA 407475
I1=3	0.000455	0.000139	0.00499

PECsoil in Grassland for Thiamethoxam and metabolites CGA 322704 and NOA407475.

The maximum PEC assuming a Nitrogen standard immission of 170 kg.ha-1.yr-1 and anaerobic degradation of Thiamethoxam, and aerobic degradation plus carry over of substances when applied to land together with the default and constants as above explained were for i1=3 corresponding to Veals (calves). Details of the calculations are in the Annex I to DocIIB3.

The values were:

Table 2.2.2.4.6-2

Maximum PECsoil (mg a.i./kg) Grassland PRODUCT B3			
	Thiamethoxam	CGA 322704	NOA 407475
I1=3	0.007774	0.003731	0.015970

2.2.2.4.7. Non compartment specific exposure relevant to the food chain (secondary poisoning) for product B1, product B2 and product B3

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

This is valid for the three products evaluated **product B1**, **product B2** and **product B3.**

Products B2 and B3. At the time this report was elaborated there was no scenario for secondary poisoning considering the use of insecticides inside animal houses and farms. The RMS ES launched an electronic consultation in 2008 to recover the opinion of the MS regarding the inclusion of such scenario, and no unfavourable opinion was received. The scenario proposed by the RMS ES was discussed at the TM I 2010 and no consensus opinion was achieved and it was left to the RMS to decide the inclusion of the scenario within the CAR. There were controversial issues regarding the scenario. The main ones were the percentage of poisoned insects in the diet of the insectivorous farm surrounding fauna and the residue of the a.i. in the poisoned insects.

The scenario is included as an annex to this CAR to be consulted at product authorization for site specific assessment and diagnosis purposes.

2.2.2.5. Risk characterisation

2.2.2.5.1. Risk characterization for **product B1**

Aquatic compartment.

Surface water

PEC/PNEC ratio was calculated for the aquatic compartment of surface waters.

- For **CASE A**, where cleaning events result only in emissions to solid wastes (100% of the surfaces are cleaned by vacuum/broom and the clothes of the applicator are disposable) **no emission is envisaged and consequently the use of B1 does not have risk of concern and its use as described in this report can be recommended.** For CASES B (releases to waste water. All releases are directed waste water during cleaning including those emitted by the applicator) and C (releases are to waste water from surface cleaning and to solid wastes from disposable coveralls. All releases are directed waste water during cleaning excepting those emitted by the applicator during application.) PEC/PNEC ratios were calculated for the aquatic compartment of surface waters

Table 2.2.2.5.1-1

PEC/PNEC ratios for surface water	**large building)**			**private House**
PNEC for surface water mg/l	0.00014			
PEC for washable coveralls (CASE TWO or B) mg.l-1	0.00016			0.00008
PEC/PNEC ratio for washable coveralls (CASE TWO or B)	**1.13**			0.59
PEC for disposable coveralls (CASE THREE or C) mg.l-1	0.00015			0.00008
PEC/PNEC ratio for disposable coveralls (CASE THREE or C)	**1.05**			0.54

Regarding potential risks for surface water characterized as PEC/PNEC ratio, and specially considering that the PEC calculations for large buildings were performed using the Area treated (wet cleaning) for large buildings 97.1/9.4=10.33 times bigger than the final harmonized scenario and the PEC calculations for the private household was considering the parameter Area treated (wet cleaning) 3.85/2= 1.92 times bigger than the final harmonized scenario (see point 2.2.2.4.1) it can be said safely that **there is no risk of concern** when the product is used as assessed in this dossier.

Sewage.

The risk expressed as PEC/PNEC quotient for sewage was calculated.

Table 2.2.2.5.1-2

PEC/PNEC ratios for sewage	large building			private House
PNEC STP TMX (rapporteur)mg.l-1	1.00			
PEC for washable coveralls (case 2 or B)	0.00159			0.00082
PEC/PNEC ratio for washable coveralls (case 2 or B)	0.0016			0.0008
PEC for disposable coveralls (case 3 or C)	0.00147			0.00076
PEC/PNEC ratio for disposable coveralls (case 3 or C)	**0.0015**			**0.0008**

Therefore, risk is not of concern for the sewage compartment when the product B1 is used as studied in this evaluation.

Sediment.

Table 2.2.2.5.1-3 PEC/PNEC sediment for case B (washable coveralls, 100% wet cleaning)

	crack and crevice at large building			Crack and crevice at House
PNEC sediment for thiamethoxam [mg/kg]	0.01			
PEC (washable coveralls, 100% wet cleaning) case two	0.00024			0.00012
PEC/PNEC (washable coveralls, 100% wet cleaning) , case two, according to TGD eq [50] mg/kg	0.02			0.01

Table 2.2.2.5.1-4 PEC/PNEC sediment for case C (disposable coveralls, 100% wet cleaning)

	crack and crevice at large building			Crack and crevice at House
PNEC sediment for thiamethoxam [mg/kg]	0.01			
PEC (disposable coveralls, 100% wet cleaning), case three	0.00022			0.00011
PEC/PNEC (disposable coveralls, 100% wet cleaning) , case three, according to TGD eq [50] mg/kg	0.02			0.01

Consequently, risk is not of concern for sediment as PEC/PNEC ratio is less than 1 and for the considered potentially exposed scenarios.

Air compartment

Product B1 is applied to hard surfaces using a knapsack sprayer. This type of low pressure applicator does not lead to small particle size droplets which may potentially persist in air.

The active substance thiamethoxam has a very low vapour pressure (6.6×10^{-9} Pa) and Henry´s law constant (4.7×10^{-10} Pa m^3/mol). Consequently, volatilisation of the active substance from the baits or any treated surfaces to air is expected to be not of concern.

Terrestrial compartment

Product B1 is used as a spray inside buildings. Emission are expected to air, floor and to applicator for mixing loading and application steps. For cleaning step receiving compartments are Municipal wastes and waste waters. Thiamethoxam is not retained in sludge at STP. Thus, no terrestrial assessment has been presented, as it was not needed.

Accordingly, no PECgroundwater was calculated as no PECsoil was derived. Thus, no emission are expected to the groundwater compartment as no emission to soil is expected either.

Non compartment specific effects relevant to the food chain (secondary poisoning)

Due to its low logPow (-0.13 at 25ºC), thiamethoxam has a low potential to accumulate in environmental compartments. With limited exposure under practical use of Product B1 (only indoors use), the potential for biomagnification of the active substance in the food chain is considered not of concern.

2.2.2.5.2. Risk characterization for **product B2**

Aquatic compartment.

Groundwater.

Refined PECs were considered for the risk assessment using Thiamethoxam concentration in manure after anaerobic degradation during storage to calculate risk. Exchange with porewater as the route of entry in the aquatic compartment and further run off when maximum PIECsoil (then maximum PIECgw) were considered. In addition, FOCUS groundwater was applied to refine the risk for grassland.

The risk of product B2 for the aquatic compartment in the arable land scenarios was calculated. They were considered the risks of the active ingredient thiamethoxam and its metabolites CGA 322704 and NOA 407475 for the aquatic compartment, and calculated as a PEC/PNEC quotient. Maximum values were always for i1=11 for the N immission standard of 170 kg.ha-1.yr-1(Laying hens in free ranges with litter floor (partly litter floor, partly slatted.

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Thiamethoxam. In the following table only the scenarios with PECporewater values over 0.0001 mg/l are shown. The risk is not far from 1. Having into account that PECporewater is an overprotective approach to consider PECgroundwater, the risk can be considered not of concern for all the scenarios.

Table 2.2.2.5.2-1 Risk of Thiamethoxam from Product B2 for the groundwater in the Arable land scenarios

index (i1)	Category	Subcatergory	PNECgoundwater [mg/l]	Refined TMX PECgw for Nitrogen Standard (mg a.i. mg/l)	PEC/PNEC

index (i1)	Category	Subcatergory	PNECgoundwater [mg/l]	Refined TMX PECgw for Nitrogen Standard (mg a.i. mg/l)	PEC/PNEC
1	Cattle	Dairy cattle (outdoors during grazing season	0.0001	0.00011871	**1.19**
5		Sows in groups		0.000109947	**1.10**
11		Laying hens in free ranges with litter floor (partly litter floor, partly slatted)		0.000121469	**1.21**
16		Turkeys in free range wiht litter floor		0.000100351	**1.00**
17		Ducks in free range wiht litter floor		0.000106024	**1.06**

Metabolite CGA 322704. In all the scenarios, PECporewater values were under 0.00001 mg/l. Consequently, the risk from metabolite CGA322704 to groundwater is not of concern.

Metabolite NOA 407475. In the following table only the scenarios with PECporewater values over 0.0001 mg/l are shown. The risk is not far from 1. Having into account that PECporewater is an overprotective approach to consider PECgroundwater the risk can be safely considered not of concern for all the scenarios.

Table 2.2.2.5.2-2 Risk of metabolite NOA407475 derived from Product B2 for the groundwater in the Arable land scenarios

index (i1)	Category	Subcatergory	PNECwater [mg/l]	Refined TMX PECgw for Nitrogen Standard (mg a.i. mg/l)	PEC/PNEC
1	Cattle	Dairy cattle (outdoors during grazing season	0.0001	0.000115999	**1.16**
5		Sows in groups		0.000107436	**1.07**
11		Laying hens in free ranges with litter floor (partly litter floor, partly slatted)		0.000118694	**1.19**
17		Ducks in free range wiht litter floor		0.000103602	**1.04**

Taken all together, as PEC(µg/l)/0.1(µg/l) ratios are not far from 1, and considering that PECgroundwater has been calculated as PECporewater, which is very worst case, and that Product B3, that is applied at higher dose, was refined by FOCUS PEARL and the risk was not of concern to all the FOCUS PEARL surrogates but one, **the risk for groundwater derived from PRODUCT B2 application in arable land is not of concern for the groundwater.**

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Thiamethoxam. There was risk of concern for all the scenarios ranging from PEC/PNEC = 1.89 for i1=8 Laying hens in battery with treatment (belt drying) to PEC/PNEC= 20.62 for i1=11 Laying hens in free ranges with litter floor (partly litter floor, partly slatted).

Therefore, refining the risk was the approach to obtain more realistic PEC/PNECs. FOCUS groundwater scenarios were applied (please see below).

Metabolite CGA 322704. There were scenarios with risk not of concern where PEC were under the cut off value of 0.0001 mg/l. Those were i1= 2, Beef cattle (housed during grazing season) and i1=8 Laying hens in battery with treatment (belt drying).

For the rest of scenarios there was risk of concern, quantified by the PEC/0.0001 ratio and ranging from PEC/PNEC = 1.18 for i1=9 Laying hens in battery cages with forced drying (deep pit, high rise) to PEC/PNEC= 5.65 for i1=11 Laying hens in free ranges with litter floor (partly litter floor, partly slatted).

Therefore, refining the risk was the approach to obtain more realistic PEC/PNECs. FOCUS PEARL groundwater scenarios were applied (please see below).

Metabolite NOA 407475. There are some scenarios for which there is no risk. Those are i1=2; Beef cattle (housed during grazing season); i1=7; Laying hens in battery without treatment (aeration); i1= 8 Laying hens in battery with treatment (belt drying); i1= 9 Laying hens in battery cages with forced drying (deep pit, high rise), I1= 10 Laying hens in compact battery cages and i1= 14 Parent broilers in free range with grating floor.

The rest of scenarios had risk of concern, quantified by the PEC/0.0001as PNEC ratio and ranging from PEC/PNEC= **1.05** for Beef cattle (outdoors during grazing season) to **3.80** for i1=11 Laying hens in free ranges with litter floor (partly litter floor, partly slatted).

Therefore, refining the risk was the approach to obtain more realistic PEC/PNECs. FOCUS PEARL groundwater scenarios were applied (please see below).

PEARL / FOCUS

PEARL (PEARL model © RIVM/Alterra, FOCUS v. 3.2.2, PEARL model v. 1.5.8-F2) was used to generate concentrations of thiamethoxam and metabolites in groundwater for the 9 standard pesticide FOCUS scenarios starting from the worst case PECsoil. The aplication rate (kg a.i./yr.ha) worst case was from treatment i1=11, Laying hens in free ranges with litter floor (partly litter floor, partly slatted) to calculate the application rates used in this analysis. A dose in kg a.i./ha (applied four times a year, starting Feb 1st and spaced 53 days) was obtained to be used as input in the PEARL FOCUS software. For TMX: 5.65E-04, CGA 322704 as metabolite from TMX and NOA 407475: 6.36E-04. Crop uptake was set to 0. The simulation period was 20 yr. The details of the calculation are shown in Doc IIB2 and in the Annexed calculations.

PRODUCT B2

Table 2.2.2.5.2-3. Annual average concentration of TMX and degradation products in groundwater.

PEARL	Annual average concentration (µg/l)

SCENARIO			
GRASSLAND	**TMX**	**CGA 322704**	**NOA 40747**
(Grass)	80th perc	80th perc.	80th perc.
	Nitrogen standard		
Châteaudun	0.000687	0.000379	0
Hamburg	0.001415	0.001927	0
Joikionen	0.002632	0.002463	0
Kremsmünster	0.005405	0.005542	0
Okehampton	0.000007	0.000001	0
Piacenza	0.003109	0.003344	0.000604
Porto	0.002339	0.002316	0
Seville	0.000491	0.000292	0
Thiva	0.000588	0.001208	0

Worst case for manure application has been used to calculate risk for groundwater. Thiamethoxam and metabolites concentration are below 0.1 µg/l in all surrogates. Therefore, **risk for groundwater of PRODUCT B2 is acceptable. There are safe uses for PRODUCT B2 respecting groundwater.** In addition, there are lysimeter studies with thiamethoxam. Especially there is a lysimeter were the soil is receiving 66 g a.i./ha. This can be compared to the estimated inputs of thiamethoxam per ha and year for the N immission standard respectively calculated for the worst case in arable and grassland displayed in the above table. The input using PRODUCT B2 to soil is much less than in the lysimeter test, where the leaching of thiamethoxam was considered not of concern.

Surface water

ARABLE LAND.

Thiamethoxam. The risk is not of concern for any of the considered subscenarios, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC = 0.09 for i1=11, Laying hens in free ranges with litter floor (partly litter floor, partly slatted).

Metabolite CGA 322704. The risk is not of concern for the aquatic compartment for any of the considered subscenarios, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC = 0.03 for several scenarios: i1= 1b, 5, 11, 16, 17).

Metabolite NOA 407475. PEC/PNEC ratio for this metabolite is below 1 for every scenario in arable land, being the highest ratio 0.00035 for the subscenario i1=11.

The PEC/PNEC quotients for the aquatic compartment were below 1 for every scenario and for thiamethoxam and its metabolites in the Arable land. Consequently **the risk is not of concern for the surface water compartment when using PRODUCT B2 as considered in this dossier considering arable land scenario.**

GRASSLAND.

Thiamethoxam. There was risk of concern considered as PEC/PNEC ratios >1 for some scenarios. Those are shown in the following table. The rest of scenarios did not pose risk of concern, as PEC/PNEC ratios were <1.

Table 2.2.2.5.2-4 Risk for the aquatic compartment in the grassland scenario from Thiamethoxam in PRODUCT B2

index (i1)	Category	Subcatergory	PNECwater [mg/l]	Refined TMX PECw for Nitrogen Standard (mg a.i. mg/l)	PEC/PNEC
1b	Cattle	Dairy cattle (outdoors during grazing season	0.00014	0.000201554	**1.44**
4	Pigs	Sows		0.000147236	**1.05**
5		Sows in groups		0.000186675	**1.33**
11		Laying hens in free ranges with litter floor (partly litter floor, partly slatted)		0.000206237	**1.47**
16		Turkeys in free range wiht litter floor		0.000170382	**1.22**
17		Ducks in free range wiht litter floor		0.000180014	**1.29**

Being the risk close to 1, and calculated using as input the PECporewater as PECgroundwater and further dilution to get PECw, this risk can be considered still not of concern and the use of PRODUCT B2 can be considered safe for all the scenarios respecting the risk for surface water. To check the safe use of PRODUCT B2 in the Grassland scenarios, the applicant submitted a FOCUS surface water Step 3 analysis of the water thiamethoxam concentration. This can be followed in the annexed calculations to DocII and in DocIIB2. The input in soil was from the wors case surrogate i1=11 Laying hens in free ranges with litter floor (partly litter floor, partly slatted) Thiamethoxam: 0.000565 kg/ha, calculated from the maximum PIEC in soil (see calculation annex).

By this means, it was confirmed that riks for the surface water from PRODUCT B2 is not of concern because the higher risk ratio was 0.12 for the D4 (stream) surrogate.

Metabolite CGA 322704. The risk is not of concern for any of the considered subscenarios, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC = 0.84 for scenario i1=11).

Metabolite NOA 407475. The risk is not of concern for any of the considered subscenarios, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC = 0.0011 for scenario i1= 11).

The PEC/PNEC quotients were below 1 for every scenario excepting i1=1b (Cattle; Dairy cattle outdoors during grazing season) i1=4; Pigs (Sows); i1= 5 (Sows in groups); i1=11 (Laying hens in free ranges with litter floor; partly litter floor, partly slatted); i1=16 (Turkeys in free range wiht litter floor) and i1=17 (Ducks in free range with litter floor) for thiamethoxam, where they were not far from 1. Then the risk was refined by FOCUS surface water and the risk was discarded. Therefore as worst cases were always assumed, it can be concluded that **the risk is not of**

concern for the aquatic compartment when using PRODUCT B2 as described in this dossier considering the grassland scenario.

Sediment

The risk of product B2 for the sediment compartment in the arable land scenarios was calculated. They were considered the risks of the active ingredient thiamethoxam and its metabolites CGA 322704 and NOA 407475 for the sediment compartment, and calculated as a PEC/PNEC quotient. Maximum values were always for i1=11 for the N immission standard (Laying hens in free ranges with litter floor (partly litter floor, partly slatted). PNECs were calculated in DocII.

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Thiamethoxam. The risk is not of concern for any of the considered subscenarios, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC = 0.0018 for scenario i1= 11, Laying hens in free ranges with litter floor , partly litter floor, partly slatted)

Metabolite CGA 322704. The risk is not of concern for any of the considered subscenarios, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC = 0.003 for scenarios: i1= 1b and 11).

Metabolite NOA 407475. The risk is not of concern for any of the considered subscenarios, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC = 0.08 for scenario i1= 11).

GRASSLAND.

Thiamethoxam. The risk is not of concern for any of the considered subscenarios, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC = 0.03 for several scenarios: i1= 1b, 5, 11, 16, 17).

Metabolite CGA 322704. The risk is not of concern for any of the considered subscenarios, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC = 0.08 for several scenarios: i1= 1b and 11).

Metabolite NOA 407475. The risk is not of concern for any of the considered subscenarios, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC = 0.04 for several scenarios: i1= 1b, 5 and 11).

In conclusion, the risk of PRODUCT B2 for the sediment compartment was calculated. They were considered the risks of the active ingredient thiamethoxam and its metabolites CGA 322704 and NOA 407475 for the aquatic compartment, and calculated as a PEC/PNEC quotient.

The PEC/PNEC quotients were below 1 for every scenario in Grassland and Arable scenarios. Consequently it can be concluded that the risk is not of concern for the sediment compartment when using PRODUCT B2 as considered in this dossier.

Sewage.

Risk for the STP and the surface water in case of emission to STP allowed.

Liquid wastes could be emitted to STP (not applied to land) in some MS. This has been calculated for the surrogates indicated in the ESD for PT-18: OECD Series on Emission Scenario Documents Number 14, Emission Scenario Document for Insecticides for Stables and Manure Storage Systems, Table 5.4 *Estimates for the fraction of active ingredient released to the relevant streams.*

Arable or Grassland scenarios are not relevant in these calculations because the emissions to the STP are the same regardless where the manure is applied.

Surface waters are receiving emission from both STP and from drift, run off and drainage from soil. Considering that both contributions would not happen in the same point and that PEC local values are calculated, emissions were not summed up and considered separatedly. PECsoil (and further emission to water from soil) was not recalculated as the risk is cover by the surrogate where liquid and solid contributions from animal houses are considered to be applied in land. Only risk for Thiamethoxam was calculated as the main metabolites will not be formed (CGA 322704 is formed in soil and NOA 407475 is formed in anaerobic conditions).

Calculations were done assuming that discharge of liquid waste **is** made to STP. The scenarios i1=12 do not pose risk of concern. **Regarding scenarios i1=11, 16, 17 and 18, risk is of concern for the surface water compartment and therefore in these cases direct emission to STP of liquid wastes cannot be allowed.** A risk mitigation measure to reduce the risk could be a dilution of the liquid waste of at least 3 times prior the emission when feasible or to apply this waste to land together with manure or slurry in order to avoid direct release of liquid wastes to the sewage.

Table 2.2.2.5.2-5 Summary of the PEC/PNEC ratios in water and STP for relevant animal categories and subcategories

ANUAL PECs								
			TMX PECstp (mg/l)	PNEC STP(mg/l)	STP PEC/PNEC	TMX PECwater(mg/l)	PNEC water (mg/l)	WATER PEC/PNEC
index (i1)	**Cat**	**Subcatergory**						
11	poultry	Laying hens in free ranges with litter floor (partly litter floor, partly slatted)	0.00143	1	0.0014	0.00014299	0.00014	1.02
12		Broilers in free range wiht litter floor	0.00111	1	0.0011	0.00011099	0.00014	0.79
16		Turkeys in free range wiht litter floor	**0.00333**	1	**0.0033**	**0.00033298**	0.00014	**2.38**
17		Ducks in free range wiht litter floor	0.002	1	0.002	0.00019999	0.00014	1.43
18		Geese in free range with litter floor	0.0025	1	0.0025	0.00024999	0.00014	1.78

For detailed calculations please refer to the annexes entitled CALCULATIONS.

Terrestrial compartment.

The risk of product B2 for the terrestrial compartment in the arable land scenarios was calculated. They were considered the risks of the active ingredient thiamethoxam and its metabolites CGA 322704 and NOA 407475 for the terrestrial compartment, and calculated as a PEC/PNEC quotient. Maximum values were always for i1=11(Laying hens in free ranges with litter floor (partly litter floor, partly slatted). for the N immission standard of 170 kg.ha-1.yr-1

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Thiamethoxam. The risk is not of concern for any of the considered subscenarios, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC = 0.0013 for scenario i1= 11).

Metabolite CGA 322704. The risk is not of concern for any of the considered subscenarios, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC = 0.0033 for i1=11, Laying hens in free ranges with litter floor (partly litter floor, partly slatted).

Metabolite NOA 407475. The risk is not of concern for any of the considered subscenarios, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC = 0.0009 for i1=11, Laying hens in free ranges with litter floor (partly litter floor, partly slatted).

In conclusion, the risk of PRODUCT B2 for the terrestrial compartment was calculated. They were considered the risks of the active ingredient thiamethoxam and its metabolites CGA 322704 and NOA 407475 for the terrestrial compartment, and calculated as a PEC/PNEC quotient.

The PEC/PNEC quotients were below 1 for every scenario in the Arable land and consequently the risk is not of concern for the terrestrial compartment when using PRODUCT B2 as considered in this dossier.

GRASSLAND.

Thiamethoxam. The risk is not of concern for any of the considered subscenarios, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC = 0.022 for i1=11, Laying hens in free ranges with litter floor (partly litter floor, partly slatted).

Metabolite CGA 322704. The risk is not of concern for any of the considered subscenarios, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC = 0.087 for i1=11, Laying hens in free ranges with litter floor (partly litter floor, partly slatted).

Metabolite NOA 407475. The risk is not of concern for any of the considered subscenarios, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC = 0.003 for i1=11, Laying hens in free ranges with litter floor (partly litter floor, partly slatted).

In conclusion, the risk of product B2 for the terrestrial compartment was calculated. They were considered the risks of the active ingredient thiamethoxam and its metabolites CGA 322704 and NOA 407475 for the terrestrial compartment, and calculated as a PEC/PNEC quotient.

As Thiamethoxam and its metabolite **CGA 322704** have shown to be highly toxic to bees, risk has been calculated for both substances based on the $PNEC_{bees}$ (calculated in section 2.2.2.2.4) and the PEC soil. This assessment has been included in this AR due to indirect exposure from indoor uses and in the basis of no harmonized scenario. Harmonized scenario (currently being developed) must be used at product authorisation stage. Additionally, outdoor uses might need further assessment (e.g. following PPP models).

Worst-case approach has been considered assuming that the expected concentration in soil can be taken as expected residue levels in nectar and pollen, thereby assuming 100% uptake by the plant and 100% transfer to nectar and pollen.

Table 2.2.2.5.2-6 Summary of the PEC/PNEC ratios for bees for Thiamethoxam and metabolite CGA 322704 for Product B2

		PEC_{soil} mg a.s/kg	**$PNEC_{bees}$ mg a.s/kg**	**PEC/PNEC**
GRASSLAND	**Thiamethoxam**	0.0015	0.0314	0.046
	Metabolite CGA 322704	0.0007	0.07	0.009
ARABLE LAND	**Thiamethoxam**	8.52E-5	0.0314	0.0027
	Metabolite CGA 322704	8.85E-5	0.07	0.0013

Thiamethoxam. The risk is not of concern for honeybees, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC (Grassland)= 0.046

Metabolite CGA 322704. The risk is not of concern for honeybees, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC (Grassland)= 0.009

The PEC/PNEC quotients were below 1 for every scenario in the Arable and Grassland scenarios and consequently the risk is not of concern for the terrestrial compartment when using product B2 as considered in this dossier.

2.2.2.5.3. Risk characterization for **Product B3**

Aquatic compartment.

Groundwater.

The active substance and metabolites enter from use of product B3 in this compartment via pore water exchange. PEC in ground water (PEC_{gw}) was calculated (see point 2.2.2.4 Exposure assessment) from PECsoil as $PEClocal_{soilporew}$ in first tier plus a refinement where anaerobic degradation in manure during the storage period was considered in addition to substance carry over between applications. Refined calculations were considered in order to define risk for the ground water compartment and FOCUS groundwater applied where further refinement was needed.

For assessing the risk for groundwater, the cut off 0.1µg/l (Water Frame Directive) is to be considered. Therefore, PEC/0.0001 was the mean to quantify the risk.

ARABLE LAND

Thiamethoxam. Risk was of concern for all the scenarios. The fraction PEC/0.0001 ranged from 1,02 for i1=2 Beef cattle, housed, to 6.48 i1=3 Veal Calves. FOCUS/PEARL was further applied to refine the risk (see below).

Metabolite CGA 322704. PECporewater values were under the cut off of 0.0001 mg/l for all the scenarios excepting for the scenarios i1=3 Veal (Calves) where the risk was 1.13.FOCUS/PEARL was further applied to refine the risk (see below).

Metabolite NOA 407475. Risk was of concern for all the scenarios. The fraction PEC/0.0001 ranged 1.00 for i1=2 Beef cattle (housed),to 6.34 i1=3 Veal Calves. FOCUS/PEARL was further applied to refine the risk (see below).

GRASSLAND

Thiamethoxam Risk was of concern for all the scenarios. The fraction PEC/0.0001 ranged from 17.41 for i1=2 Beef cattle (housed)up to 110.78i1=3 Veal Calves. FOCUS/PEARL was further applied to refine the risk (see below).

Metabolite CGA 322704. Risk was of concern for all the scenarios. The fraction PEC/0.0001 ranged from 4.77 for i1=2 Beef cattle (housed) to 30.35for i1=3 Veal Calves. FOCUS/PEARL was further applied to refine the risk (see below).

Metabolite NOA 407475. Risk was of concern for all the scenarios. The fraction PEC/0.0001 ranged from 3.24 for i1=2 Beef cattle (housed) to 20.58 for i1=3 Veal Calves. FOCUS/PEARL was further applied to refine the risk (see below).

FOCUS /PEARL

As shown in Doc IIB3, section 8.3.1.2, PEC in ground water, the Rapporteur has used PEARL (PEARL model © RIVM/Alterra, FOCUS v. 3.2.2, PEARL model v. 1.5.8-F2) to generate concentrations of thiamethoxam and degradation products in groundwater for the 9 standard pesticide FOCUS scenarios starting from the worst case PECsoil. Aplication rate (kg a.i./yr.ha) worst case was chosen in order to cover the rest of scenarios and it was from treatment i1=3 ,

Veal Calves. This was to calculate the application rates used in this analysis. Details of the calculation are shown in Doc IIB3 and in the annexed calculations.

Product B3

Table 2.2.2.5.3-2. Annual average concentration of TMX and degradation products in groundwater frp, Product B3 from the Arable land scenario.

PEARL SCENARIO	**Annual average concentration (µg/l)**		
Sugarbeet	**TMX**	**CGA 322704**	**NOA 40747**
ARABLE	80th perc	80th perc.	80th perc.
	Nitrogen standard		
Châteaudun	0.007633	0.009841	0.000010
Hamburg	0.002929	0.002572	0.029825
Joikionen	0.005534	0.008500	0.000000
Kremsmünster	0.001821	0.003646	0.015479
Okehampton	0.009756	0.010668	0.054187
Piacenza	0.012973	0.015274	0.101530
Porto	0.000035	0.000016	0.000000
Seville	0.000132	0.000077	0.000000
Thiva	0.001123	0.004270	0.000124

Table 2.2.2.5.3-3 Annual average concentration of TMX and degradation products in groundwater frp, Product B3 from the Grassland scenario.

PEARL SCENARIO	**Annual average concentration (µg/l)**		
GRASSLAND	**TMX**	**CGA 322704**	**NOA 40747**
(Grass)	80th perc	80th perc.	80th perc.
	Nitrogen standard		
Châteaudun	0.010254	0.024546	0.000000
Hamburg	0.022590	0.035262	0.000304
Joikionen	0.014424	0.016141	0.000000
Kremsmünster	0.012441	0.024114	0.000000
Okehampton	0.021858	0.028982	0.000337
Piacenza	0.041356	0.049102	0.014747
Porto	0.000196	0.000140	0.000000
Seville	0.005163	0.006667	0.000000
Thiva	0.006091	0.020527	0.000041

ARABLE LAND. FOCUS/PEARL simulation yielded results for PEC_{gw} in arable land under the cut off value of 0.1 µg/l for scenarios excepting for the Piacenza surrogate and the metabolite NOA407475 (0.101 ug/l). Considering that the worst case (from the i1=3 Veal Calves) had been used for the calculation, **risk can be considered not of concern for the groundwater of arable land when using PRODUCT B3 as indicated in this dossier.**

GRASSLAND. FOCUS/PEARL simulation yielded results for PEC_{gw} in grassland under the cut off value of 0.1 µg/l for all the scenarios

Taking all together, **risk for groundwater is acceptable. There are safe uses for Product B3 respecting groundwater when the product is used as assessed in this dossier.**

In addition, there are lysimeter studies with thiamethoxam. Especially there is a lysimeter linked to the PPP use of thiamethoxam were the soil is receiving 66 g a.i./ha. By the calculations here presented in DocIIB3, the soil is receiving much less amount of Thiamethoxam than this by the use as insecticide.

Surface water

Refined PECs were considered for the risk assessment using Thiamethoxam concentration in manure after anaerobic degradation during storage to calculate risk. Exchange with porewater as the route of entry in the aquatic compartment and further run off when maximum PIECsoil (then maximum PIECgw) were considered. When further refinement was needed, FOCUS surface water was applied.

ARABLE LAND.

The risk of product B3 for the surface water compartment in the arable land scenarios was calculated. They were considered the risks of the active ingredient thiamethoxam and its metabolites CGA 322704 and NOA 407475 for the aquatic compartment, and calculated as a PEC/PNEC quotient. Maximum values were always for i1=3(veal calves) for the N immission standard considering 170 kg.ha-1.yr-1. **Thiamethoxam.** Risk was not of concern for all the scenarios. The fraction PEC/PNEC ranged from 0.07 for i1=2 Beef cattle (housed) to 0.46for i1=3 Veal Calves.

Metabolite CGA 322704. Risk was not of concern for all the scenarios. The fraction PEC/PNEC ranged from 0.03 for i1=2 Beef cattle (housed), to 0.17for i1=3 Veal Calves.

Metabolite NOA 407475. Risk was not of concern for all the scenarios. The fraction PEC/PNEC was under 0.00 for all the scenarios.

In conclusion, the risk of Product B3 for the surface water compartment was calculated. They were considered the risks of the active ingredient thiamethoxam and its metabolites CGA 322704 and NOA 407475 for the aquatic compartment, and calculated as a PEC/PNEC quotient.

The PEC/PNEC quotients were below 1 for every scenario consequently, the risk is not of concern for the aquatic compartment and the Arable land scenarios when using Product B3 as considered in this dossier.

GRASSLAND

Thiamethoxam. Risk was of concern for all the scenarios. The fraction PEC/PNEC ranged from 1.24 for i1=2 Beef cattle (housed), to 7.91for i1=3 Veal Calves. Further refinement of PEC values was performed using the FOCUS approach.

Metabolite CGA 322704. Risk was of concern for all the scenarios. The fraction PEC/PNEC ranged from 0.71 for i1=2 Beef cattle (housed)to 4.53for i1=3 Veal Calves. Further refinement of PEC values was performed using the FOCUS approach.

Metabolite NOA 407475. Risk was not of concern for all the scenarios. The fraction PEC/PNEC ranged from 0.001 for i1=2 Beef cattle (housed) to 0.006for i1=3 Veal Calves.

In conclusion, the risk of Product B3 for the surface water compartment was calculated. They were considered the risks of the active ingredient thiamethoxam and its metabolites CGA 322704 and NOA 407475 for the aquatic compartment, and calculated as a PEC/PNEC quotient.

The PEC/PNEC quotients for thiamethoxam and metabolite CGA 322704 were over 1 for all the scenarios in Grassland. **Further refinement for PEC calculation was performed following the FOCUS surface water approach.**

After FOCUS surface water PEC calculation, PEC/PNEC ratios were calculated for Product B3 in the Grassland scenarios being in a range between 0.00 and 0.16 for Thiamethoxam in the R3 scenario and between 0.00 and 0.08 for the metabolite CGA 322704 in the D4 (stream) scenario. The details can be followed in the annexed calculations.

Thus, all the scenarios are covered with this approach as application of manure was from the worst case PEC (i3= Veal Calves) and in the worst case surrogates (R3 and D4, stream) risk is less than 1.

Therefore, risk for the surface water in the Grassland scenarios is not of concern when using PRODUCT B3 as described in this dossier.

Sediment

The risk of product B3 for the sediment compartment in the arable land scenarios was calculated. They were considered the risks of the active ingredient thiamethoxam and its metabolites CGA 322704 and NOA 407475 for the sediment compartment, and calculated as a PEC/PNEC quotient. Maximum values were always for i1=3 (veal calves) for the N immission standard considering 170 kg.ha-1.yr-1.

ARABLE LAND.

Thiamethoxam. Risk was not of concern for all the scenarios. The fraction PEC/PNEC ranged from 0.002 for i1=2 Beef cattle (housed), to 0.010 for i1=3 Veal Calves.

Metabolite CGA 322704. Risk was not of concern for all the scenarios. The fraction PEC/PNEC ranged from 0.003 for i1=2 Beef cattle (housed), to 0.016 for i1=3 Veal Calves.

Metabolite NOA 407475. Risk was not of concern for all the scenarios. The fraction PEC/PNEC ranged from 0.010 for i1=2 Beef cattle (housed) to 0.065for i1=3 Veal Calves.

GRASSLAND.

Thiamethoxam. Risk was not of concern for all the scenarios. The fraction PEC/PNEC ranged from 0.03 for i1=2 Beef cattle (housed)) to 0.17for i1=3 Veal Calves.

Metabolite CGA 322704. Risk was not of concern for all the scenarios. The fraction PEC/PNEC ranged from 0.07 for i1=2 Beef cattle (housed) to 0.44for i1=3 Veal Calves.

Metabolite NOA 407475. Risk was not of concern for all the scenarios. The fraction PEC/PNEC ranged from 0.03 for i1=2 Beef cattle (housed) to 0.21 for i1=3 Veal Calves.

In conclusion, the risk of PRODUCT B3 for the sediment compartment was calculated. They were considered the risks of the active ingredient thiamethoxam and its metabolites CGA 322704 and NOA 407475 for the sediment compartment, and calculated as a PEC/PNEC quotient.

The PEC/PNEC quotients were below 1 for every scenario in the Arable and Grassland scenarios and consequently the risk is not of concern for the sediment compartment when using product B3 as considered in this dossier.

Sewage.

Risk for the STP and the surface water in case of emission to STP allowed.

Liquid wastes could be emitted to STP (not applied to land) in some MS. This has been calculated for the surrogates indicated in the ESD for PT-18: OECD Series on Emission Scenario Documents Number 14, Emission Scenario Document for Insecticides for Stables and Manure Storage Systems, Table 5.4 *Estimates for the fraction of active ingredient released to the relevant streams.*

Arable or Grassland scenarios are not relevant in these calculations because the emissions to the STP are the same regardless where the manure is applied.

Surface waters are receiving emission from both STP and from drift, run off and drainage from soil. Considering that both contributions would not happen in the same point and that PEC local values are calculated, emissions were not summed up and considered separatedly. PECsoil (and further emission to water from soil) was not recalculated as the risk is cover by the surrogate where liquid and solid contributions from animal houses are considered to be applied in land. Only risk for Thiamethoxam was calculated as the main metabolites will not be formed (CGA 322704 is formed in soil and NOA 407475 is formed in anaerobic conditions).

Calculations were done assuming that discharge of liquid waste **is** made to STP. **For all the scenarios risk is of concern for the surface water compartment and therefore in these cases direct emission to STP of liquid wastes cannot be allowed.** A risk mitigation measure to reduce the risk is to apply these wastes to land together with manure or slurry and avoid direct liquid releases to the STP.

Table 2.2.2.5.3-4 Summary of the PEC/PNEC in water for relevant animal categories and subcategories

index (i1)	Category	Subcatergory	TMX PECstp (mg/l)	PNEC STP(mg/l	STP PEC/PNEC	TMX PECwater (mg/l)	PNEC water (mg/l)	WATER PEC/PNEC
8	Poultry	Laying hens in battery with treatment (belt drying)	0.01537		0.01537	0.00154		10.98
11		Laying hens in free ranges with litter floor (partly litter floor, partly slatted)	0.01394		0.01394	0.00139		9.96
12		Broilers in free range wiht litter floor	0.01012	**1**	0.01012	0.00101	0.00014	7.23
16		Turkeys in free range wiht litter floor	**0.02944**		**0.02944**	0.00294		21.03
17		Ducks in free range wiht litter floor	0.018		0.018	0.00180		12.86
18		Geese in free range with litter floor	0.02225		0.02225	0.00223		15.89

Terrestrial compartment.

Refined PECs were considered for the risk assessment using Thiamethoxam concentration in manure after anaerobic degradation during storage to calculate risk. The substance enters the environment via manure land application.

ARABLE LAND.

The risk of product B3 for the terrestrial compartment in the arable land scenarios was calculated. They were considered the risks of the active ingredient thiamethoxam and its metabolites CGA 322704 and NOA 407475 for the terrestrial compartment, and calculated as a PEC/PNEC quotient. Maximum values were always for i1=3 (veal calves) for the N immission standard of 170 kg.ha-1.yr-1. **Thiamethoxam**. Risk was not of concern for all the scenarios. The fraction PEC/PNEC ranged from 0.001 for i1=2 Beef cattle (housed) to 0.007 for i1=3 Veal Calves.

Metabolite CGA 322704. Risk was not of concern for all the scenarios. The fraction PEC/PNEC ranged from 0.003 for i1=2 Beef cattle (housed) to 0.001 for i1=3 Veal Calves.

Metabolite NOA 407475. Risk for the soil compartment in the arable land scenario from metabolite NOA 407475 in Product B3 was not of concern because the worst case PEC was for i1=3 (Veal Calves) and this was for the N immission standard 0.0049 mg of substance/kg soil and the PNEC NOA 407475>1mg/kg

In conclusion, the risk of Product B3 for the terrestrial compartment was calculated. They were considered the risks of the active ingredient thiamethoxam and its metabolites CGA 322704 and NOA 407475 for the terrestrial compartment, and calculated as a PEC/PNEC quotient.

As Thiamethoxam and its metabolite **CGA 322704** have shown to be highly toxic to bees, risk has been calculated for both substances based on the $PNEC_{bees}$ (calculated in section 2.2.2.2.4) and the PEC soil. This assessment has been included in this AR due to indirect exposition from indoor uses and in the basis of no harmonized scenario. Harmonized scenario (currently being developed) must be used at product authorisation stage. Additionally, outdoor uses might need further assessment (e.g. following PPP models).

Worst-case approach has been considered assuming that the expected concentration in soil can be taken as expected residue levels in nectar and pollen, thereby assuming 100% uptake in the plant and 100% transfer to nectar and pollen.

Table 2.2.2.5.3-5 Summary of the PEC/PNEC ratios for bees for Thiamethoxam and metabolite CGA 322704 for Product B3.

		PEC_{soil} mg a.s/kg	**$PNEC_{bees}$ mg a.s/kg**	**PEC/PNEC**
GRASSLAND	**Thiamethoxam**	0.00777	0.0314	0.248
	Metabolite CGA 322704	0.00373	0.07	0.053
ARABLE LAND	**Thiamethoxam**	0.00046	0.0314	0.014
	Metabolite CGA 322704	0.00014	0.07	0.002

Thiamethoxam. The risk is not of concern for honeybees, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC (Grassland)= 0.248

Metabolite CGA 322704. The risk is not of concern for honeybees, as PEC/PNEC ratios are <1 (the higher ratio PEC/PNEC (Grassland)= 0.053

The PEC/PNEC quotients were below 1 for every scenario in the Arable land and consequently the risk is not of concern for the terrestrial compartment when using Product B3 as considered in this dossier.

GRASSLAND.

Refined PECsoil were used to calculate quotients PEC/PNEC for the soil compartment.

The risk of product B3 for the terrestrial compartment in the grassland scenarios was calculated analogously to the risk for arable land. Maximum values were always for i1=3 (veal calves) for the N immission standard of 170 kg.ha-1.yr-1. **Thiamethoxam**. Risk was not of concern for all

the scenarios. The fraction PEC/PNEC ranged from 0.02 for i1=2 Beef cattle (housed) to 0.12for i1=3 Veal Calves.

Metabolite CGA 322704. Risk was not of concern for all the scenarios. The fraction PEC/PNEC ranged from 0.07 for i1=2 Beef cattle (housed), Poultry. Laying hens in battery without treatment (aeration) to 0.47 for i1=3 Veal Calves.

Metabolite NOA 407475. Risk for the soil compartment in the grassland scenario from metabolite NOA 407475 in the Product B3 was not of concern because the worst case PEC was for i1=3 (Veal Calves) and this was for the N immission standard 0.056 mg of substance/kg soil and the PNEC NOA 407475>1mg/kg

In conclusion, the risk of Product B3 for the terrestrial compartment was calculated. They were considered the risks of the active ingredient thiamethoxam and its metabolites CGA 322704 and NOA 407475 for the terrestrial compartment, and calculated as a PEC/PNEC quotient.

The PEC/PNEC quotients were below 1 for every scenario in the Grassland and consequently the risk is not of concern for the terrestrial compartment when using Product B3 as considered in this dossier.

The PEC/PNEC quotients were below 1 for every scenario in the Arable and Grassland scenarios and consequently the risk is not of concern for the terrestrial compartment when using product B3 as considered in this dossier.

2.2.3. List of endpoints

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

3. DECISION

3.1. Background to the Decision

The risk assessment for Thiamethoxam and its formulated products product B1 (25% Thiamethoxam w/w), product B2 (1% Thiamethoxam w/w) and product B3 (10% Thiamethoxam w/w) used as insecticides, acaricides and products to control other arthropods has been performed following the directions from Directive 98/8/EC and extended in the TGD and ESD documents and agreed decisions in Technical Meetings on Biocide Evaluation.

Thiamethoxam is a broad spectrum insecticide formulated as a water dispersible granule (WG) formulation and is applied by hand-held spray equipment to control ants, cockroaches and other

insects in buildings. It is also formulated as granular bait (GB) ready to use formulation to be applied to surfaces as scatter bait inside animal houses as well as a WG formulation which is mixed with water and painted into surfaces, both to control house flies in animal housings.

Regarding **efficacy**, the active substance and the products demonstrated an excellent degree of efficacy against *Musca domestica*, ants and cockroaches in laboratory and field studies.

The overall conclusion from the **human health** evaluation of thiamethoxam used in product type 18 (insecticides) is that when applied by spraying (Product B1) and scattering (Product B2) it will not present an unacceptable risk to humans during the proposed normal use if gloves are worn. On the other hand, when thiametoxam is applied by painting onto surfaces or cardboards (Product B3), an unacceptable risk to humans has been derived even if gloves are worn. Nevertheless, the exposure to this Product 3 has been estimated using EU default values from a model for consumers (Consumer Product painting - Brush painting 'Model 1), and additionally the NOAEL/AEL considered for medium term exposure, based on the 1 year study in dog, is also very conservative.

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

From the **environmental** point of view, the risk has been estimated for the different scenarios of application and products.

Safe scenarios have been identified for every product. In such scenarios where risk is estimated of concern, risk mitigation measures, to be proposed by the applicant or already proposed in this dossier, are needed to recommend the safe use of thiamethoxam as PT-18.

As Thiamethoxam and its metabolite **CGA 322704** have shown to be highly toxic to bees, risk has been calculated for both substances based on the guideline that was available at the time of the decision. Further discussions and methodologies are expected to be available at the product authorisation stage that must be used then.

Considering the use in farms and animal houses, a use pattern specific secondary poisoning route has been investigated. At the time this report was elaborated there was no agreed scenario for secondary poisoning considering the use of insecticides inside animal houses and farms. The RMS ES launched an electronic consultation in 2008 to recover the opinion of the MS regarding the inclusion of such scenario, and no unfavourable opinion was received. The scenario proposed by the RMS ES was discussed at the TM I 2010 and no consensus opinion was achieved and it was left to the RMS to decide on the inclusion of the scenario within the CAR. There were controversial issues regarding the scenario. The main ones were the percentage of poisoned insects in the diet of the insectivorous farm surrounding fauna and the residue of the a.i. in the poisoned insects. The scenario is included as an annex to this CAR to be consulted at product authorization for site specific assessment and diagnosis purposes.

3.2. Decision regarding Inclusion in Annex I

Thiamethoxam shall be included in Annex I to Directive 98/8/EC as an active substance for use in product-type **18** (Insecticides, acaricides and products to control other arthropods), subject to the following specific provisions:

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

2. 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 human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment.

3. Products shall not be authorised for application by brushing, unless data are submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

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

5. Products applied in such a way that emission to a sewage treatment plant cannot be prevented shall not be authorised, unless data are submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

6. Products authorised for professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced to an acceptable level by other means.

7. The risk of using the product shall be acceptable for bees and the conditions of the authorisation shall include, where appropriate, an assessment for bees and risk mitigation measures to protect them.

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

When assessing the application for authorisation of a product, Member States shall assess those use/exposure scenarios and/or populations that have not been representatively addressed in the Community level risk assessment and may be exposed to the product.

Member States shall also ensure that authorisations are subject to the following conditions regarding the human health:

(a) Given the risk identified for professionals applying product B3, the exposure assessment should be refined for this kind of formulations at the product authorisation stage, for

example reducing the content of Thiamethoxam in the products without affecting the efficacy, or proposing the use of new gloves for each application, etc.

(b) Product should contain a bittering agent unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means..

(c) Additionally, the label will have to clearly indicate "**Apply always out of the reach of children and non target animals**".

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

(a) When assessing the application for authorisation of a product, Member States shall assess those use/exposure scenarios and/or populations that have not been representatively addressed in the Community level risk assessment and may be exposed to the product.

(b) During national product authorization of biocidal products containing thiamethoxam, 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.

(c) When evaluating products containing Thiamethoxam, Member States should take into account cumulative exposure from biocidal uses of Thiamethoxam (in accordance with Article 10(1) of Directive 98/8/EC) using agreed EU guidance where possible..

Additionally, when assessing the application for authorisation of a product, Member States shall take into account that thiamethoxam will degrade into clothianidin, another active substance also notified and therefore conduct the assessment of clothianidin according to the its particular Assessment Report.

3.4. Requirement for further information

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

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

Study on degradation of thiamethoxam in manure shall be submitted at the product authorisation stage, for the use in animal housing, if the refinement based on degradation in manure is needed to reach an acceptable risk.

In addition, risk mitigation measures directed to protect the environment in those cases where risk was identified of concern should be shown to be effective.

3.5. Updating this Assessment Report

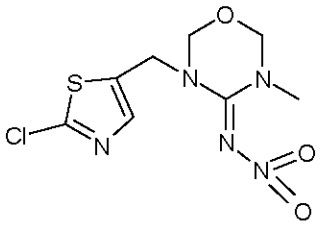
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of thiamethoxam in Annex I to the Directive.

Appendix I: List of endpoints

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

Active substance (ISO Common Name)	Thiamethoxam
Product-type	Insecticides, acaricides and products to control other arthropods

Identity

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

Physical and chemical properties

Melting point (state purity)	139.1°C (= 412.3 K) (purity: 99.7%)
Boiling point (state purity)	Thermal decomposition starts at about 147°C (i.e. before the boiling point is reached) (purity: 99.3%)
Temperature of decomposition	Thermal decomposition starts at about 147°C. No exothermic peak between room temperature and the melting point of the substance is observed.
Appearance (state purity)	Slightly cream fine crystalline powder (purity: 99.7%)

Relative density (state purity)	$1.57 \cdot 10^3$ kg/m³ at 20°C corresponding to a relative density of 1.57. (purity: 99.7%)
Surface tension	σ=71.7 mN/m (1.0 g/l aqueous solution). Thiamethoxam has not to be regarded as a surface active substance because the surface tension is not lower than 60 mN /m.
Vapour pressure (in Pa, state temperature)	ln P [Pa] = - 15400.447 / T [K] + 32.81766 from fit of measurements between 90.5 and 121.0°C vapour pressure at 25°C : $6.6 \cdot 10^{-9}$ Pa (extrapolated).
Henry's law constant (Pa m^3 mol^{-1})	$4.7 \cdot 10^{-10}$ Pa · m³ / mol at 25°C
Solubility in water (g/l or mg/l, state temperature)	pH 7: 4.1 g / l at 25°C Thiamethoxam has no dissociation within the range pH 2 to pH 12 that means the pH has no effect to the water solubility of the compound in the pH range 4 to 10.
Solubility in organic solvents (in g/l or mg/l, state temperature)	acetone: 48 g/l ethyl acetate: 7.0 g/l dichloromethane: 110 g/l hexane: < 1mg / l toluene: 680 mg / l methanol: 13 g/l n-octanol: 620 mg / l
Stability in organic solvents used in biocidal products including relevant breakdown products	stable in organic solvents
Partition coefficient (log P_{OW}) (state temperature)	P_{OW}: 0.73 ± (0.0029) at 25°C log P_{ow}: -0.13 ± (0.0017) at 25°C
Hydrolytic stability (DT_{50}) (state pH and temperature)	
Dissociation constant	Thiamethoxam does not have a dissociation constant within the range 2 to 12.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	255 nm the ε = 16800 l/mol·cm in neutral solution. No absorption maximum between 290 nm and 750 nm was observed.
Photostability (DT_{50}) (aqueous, sunlight, state pH)	
Quantum yield of direct phototransformation in water at Σ > 290 nm	
Oxidising properties	not oxidising
Reactivity towards container material	Thiamethoxam is shipped in square fibre drums with inner polyethylene liner which is supposed to be inert to the active substance
Flammability	not highly flammable
Explosive properties	not explosive

Classification and proposed labelling

with regard to physical/chemical data	
with regard to toxicological data	Xn – Harmful (GHS07; Acute Tox. 4) R22 – Harmful if swallowed (H302) S 46 – If swallowed, seek medical advice immediately and show this container or label. (P301 + P312)
with regard to ecotoxicological data	N – Dangerous for the Environment (GHS09; Aquatic acute 1 and Aquatic chronic 1) R50/53 - may cause long-term adverse effects in the aquatic environment (H400, H410) S60 - This material and its container must be disposed of as hazardous waste S61 - Avoid release in the environment. Refer to special instructions/safety data sheet

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	HPLC-UV detection at 254 nm. Quantification with external standard of thiamethoxam.
Impurities in technical active substance (principle of method)	See confidential information folder

Analytical methods for residues

Soil (principle of method and LOQ)	Soil samples are extracted by shaking with water/ methanol (10 ml, 1:1; v/v) for 1h at 250 r.p.m and purified with a phenyl solid-phase cartridge. Thiamethoxam and metabolite CGA 322704 are determined by HPLC with a two column switching system with UV-detector at 255 nm and 270 nm for CGA 322704 and for CGA 293343, respectively. Mobile phase 1: water/methanol (85:15) Mobile phase 2: water/acetonitrile (8:2). LOQ = 0.002 mg a.i. / kg soil
Air (principle of method and LOQ)	Thiamethoxam is sorbed from air in XAD-2 sorbent tubes and is extracted with methanol (2x15ml). Thiamethoxam is determined by HPLC using UV detection (255 nm). Mobile phase: methanol water (3:7; v/v). LOQ = 0.05 µg / l.
Water (principle of method and LOQ)	Samples of potable water (200 ml) are extracted by solid phase extraction (SPE) on a Lichrolut EN SPE cartridge. For surface water samples an additional cleanup step using phenyl and EN cartridges is necessary. Thiamethoxam and CGA 322704 are determined by

	HPLC using UV detection. Mobile phase: water/acetonitrile (85:15) LOQ(drinking water): 0.05 µg/l LOQ(surface water): 0.5 µg/l
Body fluids and tissues (principle of method and LOQ)	Not required
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	**Cow (fat, kidney, liver), goat (meat), milk and eggs.** Samples are extracted twice by homogenisation in acetonitrile/water (8:2, v/v). Liquid samples such as milk and eggs, are extracted by shaking for 20 minutes in acetonitrile/water (8:2, v/v). Liquid-liquid partition using toluene and hexane. Sample is purified with reverse-phase SPE, normal phase SPE amino and alumina cardtridges, content of thiamethoxam and metabolite CGA-322704 are determined by normal phase HPLC/UV with a mobile phase of hexane : ethyl acetate : isopropanol : methanol (11:3:1:1; v/v/v/v)) LOQ = 0.01 mg/kg. LOQ = 0.005 mg/kg (for milk)

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Rapid and complete absorption in the rat within 24 hours, based on urinary and biliary excretion. In the mouse, about 75%, based on urinary excretion.
Rate and extent of dermal absorption:	Product B1 (P1): 6% (diluted) Product B2 (P2): 0.3% (concentrated) Product B3 (P3): 0.3% (concentrated)
Distribution:	Widely distributed. Highest residues in the liver.
Potential for accumulation:	No evidence of accumulation
Rate and extent of excretion:	Rat: 95 % in urine and 5 % in feces within 168 hours. (about 90% via kidney and about 4% with faeces and biliary excretion was negligible accounting for 4%).
Toxicologically significant metabolite(s)	Parent compounds and metabolites: CGA 322´704 (clothianidine) (10% of dose) and CGA 265´307 (1% of dose). All the other metabolites were below 1% of dose

Acute toxicity

Rat LD_{50} oral	1563 mg/kg bw (Xn- R22)

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

Short-term repeated dose toxicity

Species/ target / critical effect	prolonged thromboplastin times, slightly reduced plasma Ca^{2+} and minimal adaptative changes in blood chemistry
Oral NOAEL / LOAEL	8.2 mg/kg bw/day (90 day study in dog)
Dermal NOAEL / LOAEL	
Inhalation NOAEL / LOAEL	

Genotoxicity	No genotoxic potential

Chronic Toxicity/Carcinogenicity

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

Reproductive toxicity

Reproduction toxicity

Species/ Reproduction target / critical effect	Germ cell loss/disorganization Sertoli cell vacuolation
Parental NOAEL / LOAEL	NOAEL= 1000 ppm (62mg/kg bw/day) 2-generation reproduction toxicity study in rats
Reproductive NOAEL / LOAEL	
Offspring NOAEL / LOAEL	

Developmental toxicity

Developmental target/critical effect	Reduced fetal weight, delayed ossification and increased post-implantation loss (rabbit only) at maternal toxic doses.
Relevant maternal NOAEL	NOAEL=50 mg/kg bw/day (rabbit developmental study)
Relevant developmental NOAEL	NOAEL=150 mg/kg bw/day (rabbit developmental study)

Neurotoxicity

Acute neurotoxicity	There are signs of acute neurotoxicity from the acute tox studies. An study presented for PPP did not showed signs of neurotoxicity
Repeated neurotoxicity	Available data on neurotoxicity on the EPA website indicate that there is no concern for long term neurotoxicity. An study presented for PPP did not showed signs of neurotoxicity
Delayed neurotoxicity	Data not required.

Other studies

.....	- No cytotoxicity on rat and mouse hepatocytes *in vitro*. - No effects on hepatocyte proliferation in rats *in vivo*. - Induction of liver enzymes (phenobartbital-type) in mouse liver. - Induction of hepatocyte proliferation in mouse *in vivo*. - CNS depression at high doses. - Evidence for α-2-microglobulin nephropathy in male rats confirmed by immunohistochemistry. regenerative cell proliferation and enzyme induction are the etiology of the specific liver tumor formation in mice CGA 322704 tech. LD_{50} >2000 mg/kg bw. (m, f). However, Clothianidin a.s. is currently classified as R22; Harmful by ingestion, according to Regulation (EC) n° 1272/2008 NOA 407475 tech LD_{50} >500 mg/kg bw. <1000 mg/kg bw (m, f) CGA 322704 and NOA 407475 were not mutagenic to bacterial systems.

Medical data

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

Summary AEL values	Value	Study	Safety factor
Non-professional user			
AEL (Long term exposure))	0.0263 mg/kg bw/day	18 month study mice	100
AEL (Medium term exposure)	0.0405 mg/kg bw/day	1 year oral study in dog	100
AEL acute exposure	0.15 mg/kg bw/day	Maternal effect in rabbit developmental toxicity study	100

Acceptable exposure scenarios (including method of calculation)

Professional users

Product name		Product B1	Product B2	Product B3
Method of calculation		Spraying model 1 and cleaning the spraying equipment	US PHED Scenario 17 - Granular Bait Dispersed by hand	Mixing and Loading model + Consumer Product painting-Brush painting Model 1
Total Systemic Exposure (mg a.i./kg bw/day)	Tier 1	0.06052267	0.004060391	0.18030308
	Tier 2	0.0160507	0.001442811	0.0510907

Production of active substance:	Not relevant
Formulation of biocidal product	Not relevant
Intended uses	Insecticide, for the control of ants, cockroaches and other insects in buildings.

Secondary exposure

Route of exposure		Product B1	Product B2	Product B3
Oral exposure (mg a.i./kg bw/day)		0.00036	0.01	0.009
Dermal exposure (mg a.i./kg bw/day)	Adult	0.0001512	-	0.0000189
	Children	0.000108	-	0.0000135
	Infant	0.000216	-	0.000927

Non-professional users

None of the products (Product B1, Product B2 and Product B3) is used by non-professional users.

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)

pH 1: Stable (20 °C)

pH 5: Stable (20 °C)

DT50 were recalculated by the Arrhenius equation at 12 °C, yielding a 2646 (Thia) and 3633 (Guan) days at pH7 and analogously, 19 and 42 d at pH 9.

pH	k (s^{-1})		DT_{50} (days)	
7	Thia. 1.27 10^{-8}	Guan 1.39 10^{-8}	Thia. 640 (25°C 1114(2 0°C)	Guan 572(25 °C) 1253(2 0°C)
9	9.53 10^{-7}	1.94 10^{-6}	8.4 (25°C) 15.6 (20°C)	4.2 (25°C) 7.3 (20°C)

Metabolites detected by hydrolysis (not half life reported):

CGA 355190 (max at pH 9, 25°C, 30 d: 59.5%)

NOA 404617 (max at pH 9, 25°C, 30 d: 33.28%)

CGA 309335 (max at pH 9, 25°C, 30 d: 9%)

CGA 322704 (max: 1%). Stable at 20°C and pH range 4-9

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

2.3 to 3.1 days (25°C, sterile conditions in aqueous buffer solutions at pH 5; 10 mg/l, sunlight (Xenon ar light) at 12 h light/dark cycles over a total period of 30 d.

	Metabolites: Volatiles (56 % AR) identified as carbonyl sulphide (the most part) and isocyanic acid. CGA 353042 (65.8%) CGA 355190 (10%) CGA 322704, CGA 353968, NOA 407475, methyl urea less than 5%.
Readily biodegradable (yes/no)	No
Biodegradation in seawater	Not relevant
Non-extractable residues (bound residues)	13.8 % to 25.3% (100 and 80 days respectively) (7.1.2.2.2/01 and 02)
Distribution in water / sediment systems (active substance)	Maximum percentage of parent compound in sediment: 36.6% at 8 days. (7.1.2.2.2/01) DT50 (12ºC) range for pond and river systems (7.1.2.2.2/01 and 02) (Total system): 48.7-68.8 days DT50 (12ºC) range in days for paddy soils (7.1.2.2.1/01 and 02): Water: 9.3-9.6 d; Sediment: 131.8-110.9; Total: 146-146.5
Distribution in water / sediment systems (metabolites)	CGA 322704: DT50 range in days normalized at 12 ºC (river and pond systems, from PPP addendum *2 B8 of the monograph, point B 8.5-Fate and behaviour in water*): Water 12.4-8.3, Sediment 38.7-36, Total 82.5-45.5 CGA355190 Water: 4.5% max at day 100Sediment: 4.7% max at day 100 NOA407475 47.4% max at day 42 (at day 100 in other study)

Route and rate of degradation in soil

Mineralization (aerobic)	44% to 17 % 7.2.2.1/01 in 363 d (key study 7.2.2.1/01): 5 to 21% in 90 days
Method of calculation	First order kinetics
Thiamethoxam	
Laboratory studies (range or median, with number of measurements, with regression coefficient)	Data from studies 7.2.2.1/01 and 02:

	RANGE (not normalized): DT_{50lab} (20°C, aerobic, FC moisture of 40-60%): 34d (k = 0,0202) to 219d (k = 0.00316) DT_{50lab} (10°C, aerobic): 233 days (studies 7.2.2.1/01 and 02). DT_{90lab} (20°C, aerobic, FC moisture of 40-60%): 114 to 727 days MEDIAN –DT50 at 20ºC 135.5 MEDIAN –DT90 at 20ºC 475 RANGE DT50lab (12ºC): from 64 to 415 d MEDIAN of DT50lab (12ºC): 243 d Geometric mean DT50 lab (12ºC): 213.88 d
	DT_{50lab} (20°C, anaerobic): 23.5 to 24.2 days (study 7.1.2.1.2/01 and 02) MEDIAN –DT50 anaerobic: 23.85 (only 2 values)
Metabolites	
Laboratory studies (range or median, with number of measurements, with regression coefficient)	Not validated DT50 for metabolites has been provided, except for CGA322704: DT50 (20 ºC, aerobic): 178.2 d (k=0.00389 ± 0.00019) study 7.2.2.1/06 DT50 normalised at 12ºC: 337.95 d DT90 (20ºC, aerobic): 592 d NOA 459602: DT50 (20 ºC, aerobic): 28.3 to 172 d (study 7.2.2.1/07) DT90 (20 ºC, aerobic): 94 to 571
	Degradation in the saturated zone: *no data.*
Field studies (state location, range or median with number of measurements)	DT_{50f}: 72 days (r2= 0.85) German soil at 10ºC (key study endpoint)
	DT_{90f}: 238 days
Anaerobic degradation	DT50 of Thiamethoxam in anaerobic conditions was ranging from 14.5 to 24.2 days at 25 ºC. The main metabolite formed in anaerobic degradation was NOA 407475 (ranging from max of 58.2% at 62 days to 63.4% at 180 days). CGA 355190 reached up to 10 % of AR.(7.1.2.1.2/01 and /02)
Soil photolysis	This route is considered of low relevance, Only small

	increases in the dissipation rate between irradiated and non-irradiated soils were observed.
Non-extractable residues	5.8 at 20 °C (7.2.2.1/01) to 20 % at 90 days (from PPP monograph endpoint listing) 3.2% to 10.9% at 90 days (from 7.2.2.1/01)
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	CGA 322704: 35.6% at 90 days (7.2.2.1/01) and CGA 355190: 23.1% at 180 days (7.2.2.1/05)
Soil accumulation and plateau concentration	Due to DT90 value below one year, the rapporteur does not considers neccesary to estimate a plateau PCE for continuous annual application

Adsorption/desorption

K_{oc}	Parent: 33 to 176.7 (study 7.2.3.1/01) CGA 322704: 63 (study 7.2.3.1/08) to 77 (7.2.3.1/07) 7.2.3.1/06 ranging from 93,1 (silt loam) to 382,5 (sandy loam) CGA 355190: 37.6 to 187.5 (study 7.2.3.1/10) NOA 407475: 433 to 1555 (study 7.2.3.1/12) 441.2 ml/g in loam CGA 353042: 198 to1425 (study7.2.3.1/09) NOA 404617: 16.3 to 72.5 (7.2.3.1/11)
pH dependence (yes / no) (if yes type of dependence)	No pH dependence was observed.

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

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

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

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

Chapter 5: Effects on Non-target Species

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

Species	Time-scale	Endpoint	Toxicity
Fish			
Onchorynchus mykiss	Acute	96 h LC50	>100 mg/l (7.4.1.1/02)
Onchorynchus mykiss	Chronic	88 days NOEC	20 mg/l (7.4.3.2/01)
Invertebrates			
Ostracoda	Acute	48h static EC50	0.18 mg/l
Gammarus Sp.	Acute	48h static EC50	2.8 mg/l
Daphnia magna (waterflea)	Chronic	21 days NOEC	100 mg/l
Lymnea stagnalis (mollusc)	Acute	48 h static EC50	100 mg/l
Cloeon Sp. (Ephemeroptera)	Acute	48h static EC50	0.014 mg/l
Chironomus riparius	Chronic	30 days NOEC	0.01 mg/l
Algae			
Selenastrum capricornutum		72 h NOEC	81.8 mg/l
Selenastrum capricornutum		72 h E_rC_{50}.	> 81.8 mg/l
Aquatic plants			
Lemna Gibba G3		7 d EC50	>90.2 mg/l
Microorganisms			
Inhibition of activated sludge from Reinach (Switzerland) STP		3 h EC50	>100 mg/l

Metabolites

Species	Test substance	Time-scale	Endpoint	Toxicity
Fish				
Onchorynchus mykiss	CGA 322704	Acute	96 h LC50	>100 mg/l (7.4.1.1/04)
Onchorynchus mykiss	CGA 355190	Acute	96 h LC50	>100 mg/l (7.4.1.1/05)

Species	Test substance	Time-scale	Endpoint	Toxicity
Onchorynchus mykiss	NOA 407475	Acute	96 h LC50	>100 mg/l (7.4.1.1/06)
Onchorynchus mykiss	NOA 459602	Acute	96 h LC50	>120 mg/l (7.4.1.1/07)
Invertebrates				
Daphnia magna (waterflea)	CGA 322704	Acute	48 h EC50	>100 mg/l (7.4.1.2/06)
Daphnia magna (waterflea)	CGA 355190	Acute	48 h EC50	>100 mg/l (7.4.1.2/06)
Daphnia magna (waterflea)	NOA 407475	Acute	48 h EC50	>82.9 mg/l (7.4.1.2/07)
Daphnia magna (waterflea)	NOA 459602	Acute	48 h EC50	>120 mg/l (7.4.1.2/08)
Chironomus riparius	CGA 322704	Chronic (run off event)	28 d EC50 (emergency rate) NOEC	0.025 mg/kg sediment (dry) 0.015 mg/kg sediment (dry)
Chironomus riparius	CGA 322704	Chronic (spiked water)	NOEC	0.00067mg/kg sediment (7.4.3.5.1)
Chironomus riparius	NOA 407475	Chronic (run off event)	28 d EC50 (emergency rate) NOEC	1 mg /Kg dry sediment 1.0 mg/Kg dry sediment
Chironomus riparius	NOA 459602	Chronic (spray drift event)	24 d EC50 (emergency rate) NOEC	56 mg /l 50 mg/l
Algae				
Selenastrum capricornutum	CGA 322704	Acute	72 h EC50 NOEC	>100 mg/l 50 mg/l (7.4.1.3/03)
Scenedesmus subspicatum	CGA 355190	Acute	72 h EC50 NOEC	>100 mg/l 100 mg/l (7.4.1.3/04)

Species		Test substance	Time-scale	Endpoint	Toxicity
Scenedesmus subspicatum	NOA 407475		Acute	72 h EC50 NOEC	14 mg/l 4.6 mg/l (7.4.1.3/05)
Selenastrum capricornutum	NOA 459602		Acute	96 h EC50 NOEC	>120 mg/l 60 mg/l (7.4.1.3/06)

Effects on earthworms or other soil non-target organisms

Acute toxicity to …… (Annex IIIA, point XIII.3.2)	**Thiamethoxam technical** 14 d LC50 >1000 mg ai/kg soil **NOA 407475** 14d LC 50 >1000 mg ai/kg soil **CGA 355190** 14 d LC 50: 753 mg ai/kg soil **CGA 322704** 14 d LC50: 5.93 mg ai/kg soil **NOA 459602** 14 d LC50>1000 mg ai/kg soil
Reproductive toxicity to ……various Earthworm species…… (Annex IIIA, point XIII.3.2)	Thiamethoxam technical NOEC 4616 g formulation/ha equivalent to 1154 g a.i./ha or **0.68 mg/kg** soil in the biocide scenario, soil surface spraying, 8 weeks. (Ruffli, 1997 IIIA, 10.6.1.2/01 in PPP monograph pag. 795) Thiamethoxam applied as the test item A 9584 at a dose of 50, 100 and 200 g a.s./ha (equivalent to 0.066, 0.133 and 0.266 mg/kg of soil respectively) from a 361 d test accepted in the PPP monograph Ecotox_addenda (Jan 2004) by Forster, A., 2003. Effects were observed along a year and showed that at these concentrations, Thiamethoxam did not significantly reduce total number or biomass of any earthworm group (adult or juvenile) or specie on any of the six post treatment occasions. CGA 322704 NOEC 0.06 mg ai /kg dry soil or 0.004 mg ai/kg wet soil (Bätscher, R. 2000 'Effects of CGA 322704 on survival, growth and reproduction of the earthworm Eisenia fetida') Test A7.5.2.1_01 or A7.5.1.2 (applicant). *CGA 322704 NOEC **0.016 mg/kg wet soil.** Field study by Pease and Webster, 2004, study A7.5.2.1_02 or A7.4.3.5/01 (applicant) Earthworm species, including Apporectodea longa, and Aporrectodea caliginosa, epilobous juveniles were the dominant groups in terms of*

	numbers and biomass. Also adults of Lumbricus terrestris and Allolobophora chlorotica. Few occurrences of epigeic species such as Lumbricus festivus and L. castaneus. The treatments were as follows: Control (water), 37.5 g CGA 322704/ha, 75 g CGA 322704/ha, 150 g CGA 322704/ha. The lowest rate of 37.5 g/ha nominal was measured as 23.05 g/ha (mean) and translated to the biocide scenario, 0.016 mg/kg soil. Duration of test: 386 d **Thiamethoxam NOEC 0.133 mg/kg wet soil (field study).** **CGA 322704 NOEC 0.016 mg/kg wet soil (field study).**

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

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

Effects on terrestrial vertebrates

Acute toxicity to mammals (Annex IIIA, point XIII.3.3)	
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	**Thiamethoxam technical** Mallard duck-LD50:576 mg /kg bw Quail-LD50: 1552 mg/kg bw **CGA 322704**

	Quail LD50>2000 mg/kg bw
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	**Thiamethoxam** Bobtail Quail and Mallard duck LC50>5200 ppm (Quail: LC50 >1929 g /kg bw/day duck: LC50 >1175 g ai/kg bw/day)
Reproductive toxicity to birds (Annex IIIA, point XIII.1.3)	Mallard duck NOEC 300 ppm
Long term toxicity to mammals (Annex IIIA, point XIII, 1.3)	

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

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

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

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

Bioconcentration (Annex IIA, point 7.5)

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

Chapter 6: Other End Points

Microcosms study

$NOEC_{community.}$ = 30 µg ai/L to the aquatic biota

Appendix II: List of Intended Uses

Summary table of data on the method of application including description of system used

Product	Field of use envisaged	Method of application	Concentration and application rates
B1	Application to cracks and crevices	Low pressure spray application to areas where insects congregate within buildings, and into cracks and crevices.	Concentration: 8 g product/L water (2 g thiamethoxam/L water). Maximum application rate: 0.2 g product/m^2 (0.05 g a.s./m^2) Water volumes: up to 25 mL water/m^2 equivalent to 25 L/1000m^2
B2	As a ready to use scatter bait inside animal houses	Loosely scattered by hand on surfaces where flies gather.	Application at 200 g product/100 m^2 (0.02 g a.s./m^2). Minimum interval of 6 weeks
		Decanted into shallow dishes	10 bait stations per 100 m^2 each containing 20g product
		Loosely scattered over moistened cardboard or glued to hang-boards	Circa 20g product glued to each of 10 hang-boards prepared for use within a 100 m^2 of surface area
B3	As a paint-on inside animal houses	Applied as a paste/paint to spots (10 x 30 cm) on indoor surfaces where flies rest/gather.	Concentration: 125 g product/100 m^2 walls and ceiling surface Maximum application rate: 100 g product mixed with 65 mL water to form paint or mixture (equivalent to 0.154 g a.s./mL) to be applied to 80 to 120 m^2 of ceiling/wall area Maximum of 6-8 applications per annum, between April and October, minimum interval between treatments – 4 to 6 weeks
	Application to hang boards	Diluted product applied to cardboard, wood or light board sheets which are hung from the ceiling.	100 g product mixed with 65 mL water (equivalent to 0.154 g a.s./mL) to form mixture for application to hang-boards. Circa 10-15 boards used per 100 m^2 of area Maximum of 6-8 applications per annum, between April and October, minimum interval between treatments – 4 to 6 weeks

Appendix III: List of studies

In comparison with Thiamethoxam PT 8, only additional studies regarding sections 5 and 7 have been submitted for Thiamethoxam PT 8, and they are the following:

Section 5 reference list					
A5.10.1	Anonymous	2001	Susceptibility to thiamethoxam in Danish field populations of houseflies Musca domestica Ministry of Food, Agriculture and Fisheries, Denmark, report no. 01-2001, February 2001	Y	NAH
A5.10.2	[redacted]	2003	Efficacy of residual deposits of thiamethoxam against the pharoah ant. Syngenta Crop Protection report no. 1P/01/014, 27 February, 2003 (unpublished).	Y	SYN
A5.10.3	[redacted]	2002	Thiamethoxam: Intrinsic activity against German and American cockroaches. Syngenta Crop Protection report no. 1P/01/012, 22 October, 2002 (unpublished).	Y	NAH
A5.10.4	[redacted]	1998	Musca domestica: laboratory bioassay methodology for neonicotinoids Novartis Sanidad Health Report no. 583 unpublished	Y	NAH
A5.10.5	[redacted]	2002	Preliminary bioassays for insecticide resistance in a *Musca domestica* field strain French Novartis Sanidad Health Report no. IDL 684 unpublished	Y	NAH
A5.10.6	[redacted]	2001	Control of Argentine ants with Actar 25 WG. La Cruz Test Center of Entomology, June, 2003 Not GLP, not published	Y	SYN

Section 7 reference list					
Directive 98/8	**Author(s)**	**Year**	**Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not**	**Data Protection Claimed Y/N**	**Owner (1)**
A7.1.1.1.1/01	[redacted]	1998c	Hydrolysis of 2-14C-thiazolyl CGA 293343 under laboratory conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.1.1.1.1/02	[redacted]	1997	Hydrolysis of 14C-Guanidine-CGA 293343 under laboratory conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.1.1.1.1/03	[redacted]	1999	Hydrolysis of 14C-labelled CGA 322704 under laboratory conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.1.1.1.2/01	[redacted]	1997	Quantum yield of the Photochemical degradation of CGA 293343 in aqueous solution [redacted] GLP, not published [redacted]	Y	SCP
A7.1.1.1.2/02	[redacted]	1998	Quantum yield of the photochemical degradation of CGA 322704 [redacted] GLP, not published [redacted]	Y	SCP
A7.1.1.1.2/03	[redacted]	1998 b	Photodegradation of 14C-Thiazolyl-CGA 293343 in pH 5 buffered solution under artificial light [redacted] GLP, not published [redacted]	Y	SCP

Section 7 reference list					
Directive 98/8	**Author(s)**	**Year**	**Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not**	**Data Protection Claimed Y/N**	**Owner (1)**
A7.1.1.1.2/04	[redacted]	1997c	Final report: Photodegradation of 14C-[Guanidine]-CGA 293343 in pH 5 buffered solution under artificial light [redacted] GLP, not published [redacted]	Y	SCP
A7.1.1.2.1	[redacted]	1996	Report on the test for ready biodegradability of CGA 293343 tech. in the carbondioxide evolution test [redacted] GLP, not published [redacted]	Y	SCP
A7.1.2.2.1/01	[redacted]	1997	Paddy soil metabolism of 14C-Thiazolring labeled CGA 293343 under laboratory conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.1.2.2.1/02	[redacted]	1998a	Paddy soil metabolism of 14C-Oxadiazinring labeled CGA 293343 under laboratory conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.1.2.2.2/01	[redacted]	1998 b	Degradation and metabolism of 14C-oxadiazinring labeled CGA 293343 in two aerobic aquatic systems under laboratory conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.1.2.2.2/02	[redacted]	1998c	Degradation and metabolism of 14C-thiazolring labeled CGA 293343 in two aerobic aquatic systems under laboratory conditions [redacted] GLP, not published [redacted]	Y	SCP

Section 7 reference list					
Directive 98/8	**Author(s)**	**Year**	**Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not**	**Data Protection Claimed Y/N**	**Owner (1)**
A7.2.2.1/01	[redacted]	1997a	Rate of degradation of CGA 293343 in soil under various conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.2.2.1/02	[redacted]	1996	Degradation of 14C-Thiazolring labelled CGA 293343 in various soils under laboratory conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.2.2.1/02a	[redacted]	1998	Calculation of adsorption constants of soil metabolite CGA 322704 [redacted] GLP, not published [redacted]	Y	SCP
A7.2.2.1/03	[redacted]	1998	Aerobic soil metabolism of (14C-thiazole) CGA 293343 [redacted] GLP, not published [redacted]	Y	SCP
A7.2.2.1/04	[redacted]	1998	Final report: Aerobic soil metabolism of 14C-(guanidine) CGA 293343 [redacted] GLP, not published [redacted]	Y	SCP
A7.2.2.1/05	[redacted]	1998	Metabolism of 14C-guanidine CGA 293343 in viable and sterile clay loam soil under aerobic conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.2.1/06	[redacted]	1999 b	Degradation of 14C-Thiazole labelled CGA 322704 in Schwaderloch soil under aerobic conditions at 20°C [redacted] GLP, not published [redacted]	Y	SCP

Section 7 reference list					
Directive 98/8	**Author(s)**	**Year**	**Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not**	**Data Protection Claimed Y/N**	**Owner (1)**
A7.2.2.1/07	[redacted]	2002	Rate of degradation of [Thiazole-2-14C] labelled NOA 459602 in three soils under aerobic laboratory conditions at 20 degred C [redacted] GLP, not published [redacted]	Y	SCP
A7.2.2.2/01	[redacted]	1998	Residue study with CGA 293343 in or on soil in south of France [redacted] GLP, not published [redacted]	Y	SCP
A7.2.2.2/02	[redacted]	1998	Determination of residues of CGA 293343 and the metabolite CGA 322704 in soil [redacted] GLP, not published [redacted]	Y	SCP
A7.2.2.4/01	[redacted]	1997a	Photodegradation of 14C-Thiazolyl-CGA 293343 on soil under artificial light [redacted] GLP, not published [redacted]	Y	SCP
A7.2.2.4/02	[redacted]	1997 b	Photodegradation of 14C-Guanidine-CGA 293343 on soil under artificial light [redacted] GLP, not published [redacted]	Y	SCP
A7.2.2.4/03	[redacted]	1998a	Anaerobic aquatic metabolism of 14C-(thiazole) CGA 293343 [redacted] GLP, not published [redacted]	Y	SCP

Section 7 reference list					
Directive 98/8	**Author(s)**	**Year**	**Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not**	**Data Protection Claimed Y/N**	**Owner (1)**
A7.2.2.4/04	[redacted]	1998 b	Anaerobic aquatic metabolism of 14C-(guanidine) CGA 293343 [redacted] GLP, not published [redacted]	Y	SCP
A7.2.3.1/01	[redacted]	1998a	Soil adsorption / desorption of 14C-guanidine-CGA 293343 by the batch equilibrium method [redacted] GLP, not published [redacted]	Y	SCP
A7.2.3.1/02	[redacted]	1996	Adsorption / desorption of CGA 293343 in various soil types [redacted] GLP, not published [redacted]	Y	SCP
A7.2.3.1/03	[redacted]	2000	Time dependent sorpion of technical and of 2SC formulated (Thiazolyl-2-14C)-labeled CGA 293343 in two different soils Novartis Crop Protection Inc., Greensboro, United States 1200-99, 28.03.2000 GLP, not published [redacted]	Y	SCP
A7.2.3.1/04	[redacted]	2001	Time Dependent Sorption of (Thiazolyl-2- 14C)-Labelled CGA 293343 in Various Soils [redacted] GLP, not published [redacted]	Y	SCP
A7.2.3.1/05	[redacted]	2001a	Adsorption/Desorption of [Oxidiazin-4-]-CGA 293343 on Birkenheide Soil [redacted] GLP, not published [redacted]	Y	SCP
A7.2.3.1/06	[redacted]	1998	Adsorption / desorption of 14C-thiazole CGA 322704 by the batch equilibrium method [redacted] GLP, not published [redacted]	Y	SCP

Section 7 reference list					
Directive 98/8	**Author(s)**	**Year**	**Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not**	**Data Protection Claimed Y/N**	**Owner (1)**
A7.2.3.1/07	[redacted]	2001	Adsorption/Desorption of [Thiazol-2-14C]-CGA322704 on Birkenheide Soil [redacted] GLP, not published [redacted]	Y	SCP
A7.2.3.1/08	[redacted]	1997	Adsorption / desorption of CGA 322704 in various soil types [redacted] GLP, not published [redacted]	Y	SCP
A7.2.3.1/09	[redacted]	1998	Soil adsorption and desorption of Oxadiazinyl-14C-CGA 353042 by the batch equilibrium method [redacted] GLP, not published [redacted]	Y	SCP
A7.2.3.1/10	[redacted]	1998	Soil adsorption / desorption of 14C-CGA 355190 by the batch equilibrium method [redacted] GLP, not published [redacted]	Y	SCP
A7.2.3.1/11	[redacted]	1998	Soil adsorption and desorption of (Thiazole-2-14C-NOA 404617 by the batch equilibrium method [redacted] GLP, not published [redacted]	Y	SCP
A7.2.3.1/12	[redacted]	1998	Soil adsorption and desorption of Thiazolyl-2-14C-NOA 407475 by the batch equilibrium method [redacted] GLP, not published [redacted]	Y	SCP
A7.2.3.1/13	[redacted]	2000	Adsorption / Desorption of [Thiazol-2-^{14}C]NOA 459602 in Various Soils and Time Dependent Sorption [redacted] GLP, not published [redacted]	Y	SCP

Section 7 reference list					
Directive 98/8	**Author(s)**	**Year**	**Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not**	**Data Protection Claimed Y/N**	**Owner (1)**
A7.2.3.1/14	[redacted]	2001	Time Dependent Sorption of [Thiazol-2-14C]-CGA322704 in Birkenheide Soil [redacted] GLP, not published [redacted]	Y	SCP
A7.2.3.2	[redacted]	1996	Leaching model study with CGA 293343 in four soils under laboratory conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.3.1/01	[redacted]	1996	Volatilization of 14C-Thiazolring-Labelled CGA 293343 from soil surface under controlled laboratory conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.3.1/02	[redacted]	1998	Atmospheric oxidation of CGA 293343 by hydroxyl radicals [redacted] not GLP, not published [redacted]	Y	SCP
A7.4.1.1/01	[redacted]	1996	Acute toxicity test of CGA 293343 tech. to rainbow trout (Oncorhynchus mykiss) in the flow-through system [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.1/02	[redacted]	1997a	Acute toxicity test of CGA 293343 tech. to rainbow trout (Oncorhynchus mykiss) under flow-through conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.1/03	[redacted]	1996	CGA 293343: A 96-hour flow-through acute toxicity test with the bluegill (Lepomis macrochirus) [redacted] GLP, not published [redacted]	Y	SCP

Section 7 reference list					
Directive 98/8	**Author(s)**	**Year**	**Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not**	**Data Protection Claimed Y/N**	**Owner (1)**
A7.4.1.1/04	[redacted]	1997 b	Acute toxicity test of CGA 322704 (Metabolite of CGA 293343) to rainbow trout (Oncorhynchus mykiss) in the static system [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.1/05	[redacted]	1998	Acute toxicity of CGA 355190 (metabolite of CGA 293343) for Rainbow trout [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.1/06	[redacted]	1998a	Acute toxicity of NOA 407475 (metabolite of CGA 293343) to rainbow trout (Oncorhynchus mykiss) in a 96-hour static test [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.1/07	[redacted]	2002a	NOA459602 (Thiamethoxam metabolite): Acute toxicity to rainbow trout (Oncorhynchus mykiss) [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.2/01	[redacted]	1996	Acute toxicity test of CGA 293343 to the cladoceran daphnia magna straus under static conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.2/02	[redacted]	2000 b	Acute toxicity test of CGA 293343 tech. to the Gammarus sp. under static conditions [redacted] GLP, not published [redacted]	Y	SCP

Section 7 reference list					
Directive 98/8	**Author(s)**	**Year**	**Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not**	**Data Protection Claimed Y/N**	**Owner (1)**
A7.4.1.2/03	[redacted]	2000c	Acute toxicity test (24h) of CGA 293343 tech. to three invertebrate species Daphnia pulex leydig, Thamnocephalus platyurus, and Brachionus calyciflorus under static conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.2/04	[redacted]	2000 d	Acute toxicity test of CGA 293343 tech. to individual invertebrate species and molluscs from a natural pond assemblage under static conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.2/05	[redacted]	1997a	Acute toxicity test of CGA 322704 (Metabolite of CGA 293343) to the cladoceran Daphnia magna strauss under static conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.2/06	[redacted]	1998	Acute toxicity of CGA 355190 to Daphnia magna (Immobilisation test) [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.2/07	[redacted]	1998 b	Acute toxicity of NOA 407475 (metabolite of CGA 293343) to Daphnia magna in a 48-hour immobilization test [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.2/08	[redacted]	2002 b	NOA459602 (Thiamethoxam metabolite): Acute toxicity to Daphnia magna [redacted] GLP, not published [redacted]	Y	SCP

Section 7 reference list					
Directive 98/8	**Author(s)**	**Year**	**Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not**	**Data Protection Claimed Y/N**	**Owner (1)**
A7.4.1.2/09	[redacted]	2000a	Acute toxicity test of CGA 293343 tech. to the Ephemeroptera Cloeon sp. under static conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.2/10	[redacted]	1998	CGA 293343 technical: a 48-hour static acute toxicity test with the midge (Chironomus riparius) [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.3/01	[redacted]	1996a	Growth inhibition test of CGA 293343 tech. to green algae (Selenastrum capricornutum) in a static system [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.3/02	[redacted]	1998a	Growth inhibition test of CGA 293343 tech. to green algae (Selenastrum capricornutum) under static conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.3/03	[redacted]	1997	Growth inhibition test of CGA 322704 (Metabolite of CGA 293343) to green algae (Selenastrum capricornutum) under static conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.3/04	[redacted]	1998 b	Toxicity of CGA 355190 to Green algae (Growth inhibition test) [redacted] GLP, not published [redacted]	Y	SCP

Section 7 reference list					
Directive 98/8	**Author(s)**	**Year**	**Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not**	**Data Protection Claimed Y/N**	**Owner (1)**
A7.4.1.3/05	[redacted]	1998c	Toxicity of NOA 407475 (metabolite of CGA 293343) to Scenedesmus subspicatus in a 72-hour algal growth inhibition test [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.3/06	[redacted]	2002c	NOA459602 (Thiamethoxam metabolite): Toxicity to the Green Alga Selenastrum capricornutum [redacted] GLP, not published [redacted]	Y	SCP
A7.4.1.4	[redacted]	1996 b	Report on the test for activated sludge respiration inhibition of CGA 293343 tech. [redacted] GLP, not published [redacted]	Y	SCP
A 7.4.3./01	[redacted]	2003	Thiamethoxam 25 WG (A9584C) Outdoor Microcosm Study to Assess Effects on Aquatic Organisms. [redacted]	Y	SCP
A7.4.3.1	[redacted]	1997c	Prolonged toxicity test of CGA 293343 tech. to rainbow trout (Oncorhynchus mykiss) in the flow-through system [redacted] GLP, not published [redacted]	Y	SCP
A7.4.3.2	[redacted]	1997	CGA 293343: an early life-stage toxicity test with the rainbow trout (Oncorhynchus mykiss) [redacted] GLP, not published [redacted]	Y	SCP

Section 7 reference list					
Directive 98/8	**Author(s)**	**Year**	**Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not**	**Data Protection Claimed Y/N**	**Owner (1)**
A7.4.3.4	[redacted]	1997 b	Daphnia magna reproduction test: effects of CGA 293343 on the reproduction of the cladoceran Daphnia magna straus in a semi-static laboratory test [redacted] GLP, not published [redacted]	Y	SCP
A7.4.3.5.1/01	[redacted]	1998 b	Toxicity test of CGA 293343 tech. on sediment-dwelling Chironomus riparius (syn. Chironomus thummi) under static conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.4.3.5.1/02	[redacted]	1999	Toxicity test of CGA 322704 (Metabolite of CGA 293343) on sediment-dwelling Chironomus riparius (syn. Chironomus thummi) under static conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.4.3.5.1/03	[redacted]	2000	Toxicity test of NOA 407475 (Metabolite of CGA 293343) on sediment-dwelling Chironomus riparius (syn. Chironomus thummi) under static conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.4.3.5.1/04	[redacted]	2002	Toxicity Test of NOA 459602 (Metabolite of Thiamethoxam) on Sediment-Dwelling Chironomus riparius (syn. Chironomus thummi) under Static Conditions [redacted] GLP, not published [redacted]	Y	SCP

Section 7 reference list					
Directive 98/8	**Author(s)**	**Year**	**Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not**	**Data Protection Claimed Y/N**	**Owner (1)**
A7.4.3.5.1/05	[redacted]	2004	CGA 322704 (Thiamethoxam metabolite): Toxicity to the sediment dweller *Chironomus riparius* using spiked water. [redacted]	Y	SCP
A7.4.3.5.2	[redacted]	1998c	Acute toxicity test of CGA 293343 tech. to the duckweed Lemna gibba G3 under semi-static conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.5.1.1/01	[redacted]	1998	The effect of CGA 293343 tech. on soil respiration and nitrification [redacted] GLP, not published [redacted]	Y	SCP
A7.5.1.1/02	[redacted]	1999	The effect of CGA 322704 + CGA 355190 (two Metabolites of CGA 293343) on soil respiration an nitrification [redacted] GLP, not published [redacted]	Y	
A7.5.1.2/01	[redacted]	1995	14-day acute toxicity test with the earthworm (Eisenia foetida) [redacted]	Y	SCP
A7.5.1.2/02	[redacted]	1999a	An Acute toxicity study with the Earthworm in an artificial soil substrate [redacted] GLP, not published [redacted]	Y	SCP

Section 7 reference list					
Directive 98/8	**Author(s)**	**Year**	**Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not**	**Data Protection Claimed Y/N**	**Owner (1)**
A7.5.1.2/03	[redacted]	1999 b	An Acute toxicity study with the Earthworm in an artificial soil substrate [redacted] GLP, not published [redacted]	Y	SCP
A7.5.1.2/04	[redacted]	2000	Acute toxicity of CGA 355190 to the Earthworm Eisenia fetida [redacted] GLP, not published [redacted]	Y	SCP
A7.5.1.2/05	[redacted]	2000	An acute toxicity study with the Earthworm in an artificial soil substrate [redacted] GLP, not published [redacted]	Y	SCP
A7.5.1.2/06	[redacted]	2002	Acute toxicity (LC50) of the metabolite NOA459602 to the Earthworm (Eisenia fetida) in an artificial soil test [redacted] GLP, not published [redacted]	Y	SCP
A. 7.5.2.1_01	[redacted]	2000	Effects of CGA 322704 (metabolite of CGA 293343) on survival, growth, and reproduction of the earthworm Eisenia fetida [redacted]	Y	SCP
7.5.2.1_ 02	[redacted]	2004	CGA322704 (A metabolite of CGA293343 (thiamethoxam)): A field study to investigate the forced effect and recovery of earthworm populations following application to a bare field site in Denmark [redacted]	Y	SCP

Section 7 reference list					
Directive 98/8	**Author(s)**	**Year**	**Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not**	**Data Protection Claimed Y/N**	**Owner (1)**
A7.5.3.1.1/02	[redacted]	1996 b	CGA 293343 Acute oral toxicity (LD50) to the mallard duck [redacted] GLP, not published [redacted]	Y	SCP
A7.5.3.1.1/03	[redacted]	1998	Acute oral toxicity study in bobwhite quail with CGA 322704 [redacted] GLP, not published [redacted]	Y	SCP
A7.5.3.1.2/01	[redacted]	1996c	CGA 293343 Subacute dietary toxicity (LC50) to the bobwhite quail [redacted] GLP, not published [redacted]	Y	SCP
A7.5.3.1.2/02	[redacted]	1996 d	CGA 293343 Subacute dietary toxicity (LC50) to the mallard duck [redacted] GLP, not published [redacted]	Y	SCP
A7.5.3.1.3/01	[redacted]	1998	The reproductive toxicity test of CGA 293343 technical with the northern bobwhite (Colinus virginianus) [redacted] GLP, not published [redacted]	Y	SCP
A7.5.3.1.3/02	[redacted]	1998	The reproductive toxicity test of CGA 293343 technical with the mallard duck (Anas platyrhynchos) [redacted] GLP, not published [redacted]	Y	SCP
A7.5.4.1/01	[redacted]	1995	Testing toxicity to Honeybee - Apis mellifera L. (laboratoy) [redacted] GLP, not published [redacted]	Y	SCP

Section 7 reference list					
Directive 98/8	**Author(s)**	**Year**	**Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not**	**Data Protection Claimed Y/N**	**Owner (1)**
A7.5.4.1/02	[redacted]	1997	Assessment of side effects of CGA 322704 to the honey bee, Apis mellifera L. in the laboratory [redacted] GLP, not published [redacted]	Y	SCP
A7.5.4.1/03	[redacted]	1998a	Acute toxicity of CGA 293343 FS 350 (A 9700 B) to the predatory ground beetle Poecilus cupreus L. (Coleoptera: Carabidae) [redacted] GLP, not published [redacted]	Y	SCP
A7.5.4.1/04	[redacted]	1998 b	Acute toxicity of CGA 293343 FS 350 (A 9700 B) to the rove beetle Aleochara bilineata Gyll. (Coleoptera, Staphylinidae) [redacted] GLP, not published [redacted]	Y	SCP
A7.5.4.1/05	[redacted]	2000	Acute Toxicity of CGA 293343 FS 350 (A 9700 B) to larvae of the Predatory ground beetle Poecilus cupreus L. (Coleoptera: Carabidae) [redacted] GLP, not published [redacted]	Y	SCP
A7.5.4.1/06	[redacted]	1998a	Toxicity of CGA 293343 WS 70 (A-9567 B) to Poecilus cupreus L. (Coleoptera: Carabidae) under semi-field conditions [redacted] GLP, not published [redacted]	Y	SCP

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A7.5.4.1/07	[redacted]	1998 b	Toxicity of CGA 293343 WS 70 (A-9567 B) to Aleochara bilineata Gyll. (Coleoptera, Staphylinidae) under semi-field conditions [redacted] GLP, not published [redacted]	Y	SCP
A7.5.4.1/08	[redacted]	1998	Biological activity of Metabolites of Thiamethoxam CGA 293343 on insects and mites [redacted] not GLP, not published [redacted]	Y	SCP
A. 7.5.6	[redacted]	2001	The effects of CGA 322704 (metabolite of thiamethoxam (CGA 293343)) on the decomposition of organic material in a field litterbag test. [redacted]	Y	SCP
Not encoded	[redacted]	2001	Palatability, attractiveness and efficacy laboratory tests in *M. domestica* using a new AGITA® granular formulation (placebo -batch 709/2001) [redacted]	Y	Novartis
Not indicated	[redacted]	1996			
			References fromThiamethoxam evaluation following the PPP directive 91/414		
PPP study code IIA, 7.1.1.2.2/02	[redacted]	1996c	The report is a brief description of a determination of residues of thiamethoxam and its metabolite CGA 322704 in soil after application as WG25 (field trial).	Y	NCP
PPP study code IIA, 7.1.1.2.2/05a	[redacted]	1996a	Determination of residues of CGA 293343 in potatoes and soil and CGA 322704 in soil after application as WG 25 - field trial [redacted] GLP, not published [redacted]	Y	NCP

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PPP study code IIA, 7.1.1.2.2/ 05b	[redacted]	1997c	Determination of residues of CGA 293343 in potatoes and soil and CGA 322704 in soil after application as WG 25 - field trial [redacted] GLP, not published [redacted]	Y	NCP
PPP study code IIA, 7.1.1.2.2/ 05c	[redacted]	1998c	Determination of residues of CGA 293343 in potatoes and soil and CGA 322704 in soil after application as WG 25 - field trial [redacted] GLP, not published [redacted]	Y	NCP
PPP study code IIA, 7.1.1.2.2/ 11	[redacted]	1998a	Residue study with CGA 293343 in or on soil in north of France ADME Bioanalyses, Aigues-Vives, France [redacted] GLP, not published Novartis File N° 293343- 747	Y	NCP
PPP study code IIA, 7.1.1.2.2/ 13	[redacted]	1998c	Residue study with CGA 293343 in or on soil in south of France ADME Bioanalyses., Aigues-Vives, France [redacted] GLP, not published [redacted]	Y	NCP
PPP study code 7.1.1.2.2/14	[redacted]	1997	Field dissipation of CGA 293343 after bareground application of [Thiazol-2-14C] labelled material [redacted] GLP, not published [redacted]	Y	NCP
PPP study code IIA, 7.1.1.2.2/ 18	[redacted]	1998 d	Determination of residues of CGA 293343 and the metabolite CGA 322704 in soil [redacted] GLP, not published [redacted]	Y	NCP
PPP study code IIA 7.1.3.3/01	[redacted]	1998	Field Lysimeter test Summary in vol III, Chapter 8 page 655		

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PPP study code: IIA 8.4.2/01 IIIA 10.6.1.2/01	[redacted]	1997	"Chronic toxicity test of CGA 293343 WG 25 (A-9584) to earthworms (*Eisenia foetida foetida*)".	Y	SCP
addendum ecotox (Jan_2004), page 10 (B.5.- Effects in earthworms)	[redacted]	2003	"Field study to evaluate the effects of CGA 293343 WG (25) (A9584C) on earthworms in a grass field in Denmark. [redacted]		
			Other references		
Not numbered.	[redacted]	2003	Evaluation of potential side-effects of CGA 293343 WG 25 (A 9584) to plant dwelling non-target arthropods con citrus under field conditions. [redacted]	Y	SCP
	E. van de Plassche and K. Rasmussen Editors	2005	Leaching workshop, Arona, Italy, June 2005, document EUR 21878 EN European Chemicals Bureau-Biocides, Institute for Health and Consumer Protection, Joint Research Centre (JRC), European Comission-Directorate General JRC).		
		2003	TNsG on Dossier Preparation including preparation and evaluation of study summaries under Directive 98/8/EC		
	European Chemicals Boureau EU 20418 EN/2	2003	TGD: Technical guidance document on risk assessment in support of Commission Directive 93/67/EEC on risk assessment for new notified substances Commission regulation (EC) No 1488/94 on risk assessment for existing substances Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market.		
	Scientific Opinion of the Panel on Plant protection products and their residues on a request from the EFSA PRAPeR Unit on risk assessment for birds and mammals.	2008	The EFSA Journal (2008) 734, 1-181		