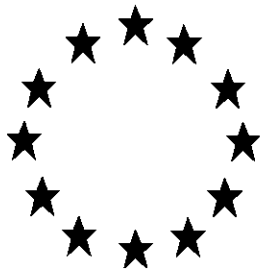
Directive 98/8/EC concerning the placing biocidal products on the market

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

Assessment Report



Deltamethrin

Product-type 18 (Insecticides)

May 2011

Annex I - Sweden

Deltamethrin (PT18)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 6 May 2011 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 Deltamethrin as product-type 18 (insecticides, acaricides and products to control other arthropods), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Deltamethrin (CAS no. 52918-63-5) was notified as an existing active substance, by Bayer S.A.S Bayer Environmental Science (former named Bayer Environmental Science SAS), 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Regulation (EC) No 1451/2007 of 4 December 2007,[2] which has repealed and replaced Commission Regulation (EC) No 2032/2003 of 4 November 2003,[3] lays down the detailed rules for the evaluation of dossiers and for the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,, Sweden 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 Deltamethrin as an active substance in Product Type 18 was 30 April 2006, in accordance with Annex V of Regulation (EC) No 2032/2003.

On 28 April 2006, SE competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 28 August 2006.

---

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

On 27 June 2008, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 2 July 2008. The competent authority report included a recommendation for the inclusion of Deltamethrin 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 July 2008. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

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

On the basis of the final competent authority report, the Commission proposed the inclusion of Deltamethrin in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 6 May 2011.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 6 May 2011.

1.2. Purpose of the assessment report

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

---

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

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 Deltamethrin 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:

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.

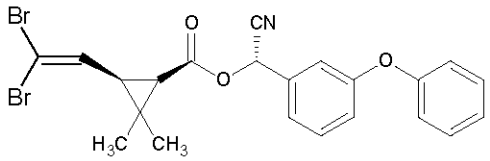
Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions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

Identity

CAS-No.	52918-63-5
EINECS-No.	258-256-6
Other No. (CIPAC, ELINCS)	CIPAC: 333
IUPAC Name	(S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate
CA Name	Cyclopropanecarboxylic acid, 3-(2,2-dibromoethenyl)-2,2-dimethyl-, (S)-cyano(3-phenoxyphenyl)methyl ester, (1R,3R)-
Common name, synonyms	ISO common name: Deltamethrin
Structural formula	
Molecular formula	$C_{22}H_{19}Br_2NO_3$
Molecular weight (g/mol)	505.2
Purity of a.s.	98.5 %w/w Minimum purity is in compliance with the approved WHO/FAO specification for deltamethrin (WHO/FAO specification 333/TC). The proposed minimum purity has been confirmed to be acceptable by an enantioselective 5-batch analysis provided in December 2010
Impurities	None of the impurities present in technical deltamethrin are considered relevant. The information on impurities are found in the Confidential Annex to the CAR.
Additives	No additives
Representative biocidal products	K-Othrine DP 0.05 (a dustable powder formulation containing 0.5 g/kg deltamethrin). K-Othrine SC 7.5 and SC 25 (suspension concentrate formulations containing 7.5 g/l and 26.25 g/l deltamethrin respectively). K-Othrine WG 250 (a water dispersible granule formulation containing 250 g/kg deltamethrin).

Physico-Chemical Properties

Purified deltamethrin is an off-white powder that has none to slight musty odour. Technical deltamethrin (purity 98.9-99.3%w/w) melts at 98.1-99.4 °C and decomposes before boiling (245-320 °C). The density is 1.5 g/cm^3 at 20°C and the solubility in water is < 5µg/l at pH 6.2 and 20 °C (based on the LOQ of the HPLC-method used for quantification). Deltamethrin is not considered to be able to dissociate within the environmentally relevant pH range due to the lack of functional groups with acidic or alkaline properties. The vapour pressure is 1.24 x 10^{-8} Pa at 25 °C and the Henry's law constant of 1.252 x 10^{-3} Pa.m^3.mol^{-1} indicates that volatilisation is not expected to significantly contribute to the dissipation of deltamethrin in the environment. The Log Pow is 4.6 in distilled water (pH not stated) which indicates that deltamethrin may bioaccumulate. The following solvent solubilities were determined for deltamethrin (g/l): 300-600 (acetone), 60-75 (acetonitrile), >600 (1,2-dichloroethane), 200-300 (DMSO and ethyl actetate), 2.47 (n-heptane), 8.15 (methanol) and 150-200 (p-xylene). Deltamethrin is not highly flammable, auto-flammable, explosive or oxidizing and does not react with the packaging material (black plastic pouches).

Analytical methods

Acceptable analytical methods, with respect to validation data, were provided for all required matrices.

The content of deltamethrin in the technical material is determined by HPLC-UV using external calibration. As deltamethrin is defined as a pure enantiomer a validated chiral HPLC-UV method is available which together with the HPLC-UV method above, are sufficient to establish the purity of the technical material.

The analytical method for determining the content of impurities in the technical material is acceptable and is presented in the Confidential Annex to the CAR. The content of deltamethrin in the representative formulations are determined by HPLC-UV, with external calibration.

Deltamethrin is considered the only relevant residue for monitoring in the various matrices. The residues in soil are determined by LC-MS/MS using 1 transition, with a LOQ of 0.1 µg/kg. The residues in air are quantified by means of GC-ECD with GC-MS for confirmation and a LOQ of 0.27 µg/m^3, which is considered acceptable with respect to the systemic AEL of 0.0075 mg/kg bw/day (i.e. a LOQ of 2.25 µg/m^3 is required). Three acceptable methods are available for deltamethrin in drinking water with LOQs of 5.9 ng/l (LC-MS/MS with 1 transition), 0.05 µg/l (GC-ECD for quantification and confirmation) and 3 ng/l (GC-ECD and GC-MS/MS for quantification and confirmation respectively). The latter method is also considered acceptable for analysis of surface water as the LOQ is lower than the relevant NOEC of 4.8 ng/l determined from a mesocosm study. The residues in human and animal body fluids and tissues are determined either by GC-ECD (tissues) or GC-MS (whole blood; two methods) with LOQs of 0.02 mg/kg and 20 ng/l for the method for tissues and the most sensitive method for whole blood, respectively.

It has been agreed (TM I 2010) that no monitoring method is required for deltamethrin in food and feeding stuffs as the intended use will not result in significant residues in those matrices when the label instruction is followed. However, two methods were provided (GC-ECD and

LC-MS/MS) for various matrices which could be useful in case of suspected contamination. The LOQs of 0.02 mg/kg and 0.01 mg/kg for the GC-ECD method and LC-MS/MS-methods respectively are acceptable with respect to the available Maximum Residue Levels (MRLs) for deltamethrin (as set by Regulation (EC) No 396/2005 of the European Parliament and of the Council).

2.1.2. Intended Uses and Efficacy

Deltamethrin is a pyrethroid insecticide which acts on harmful organisms by contact and ingestion. It expresses a strong knock-down effect. The intended uses of deltamethrin based products are to control crawling and flying insects (e.g. cockroaches, flies and stored products pests) indoor and for the control of ants outdoors.

The assessment of the biocidal activity of the active substance demonstrates that deltamethrin display effectiveness against most of the organisms to be controlled. Deltamethrin at a low dose was effective against the specified strains of flies and stored-product pests with exception of *Fannia canicularis* (fly) and *Acarus siro* (flour mite). The activity against *Ctenocephalides felis* (flea) and earwigs was not investigated. However, good control against *Ctenocephalides felis* (flea) is expected since another strain of flea *Xenopsylla cheopis* showed effectiveness of deltamethrin, and earwigs are not expected to be less sensitive to residual pyrethroids than cockroaches. The deltamethrin resistance of target organisms may not be fully investigated since the experimental data packet on effectiveness of the active substance deltamethrin contains quite old studies. Efficacy of products will be assessed thoroughly at the stage of product authorisation.

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

2.1.3. Classification and Labelling

The following classification and labelling for deltamethrin was proposed by the RMS on the basis of the available data and according to Directive 67/548/EEC.

Classification	As in Directive 67/548/EEC	
Category of danger	T N	Toxic Dangerous for the environment
R phrases	R23/25 R50/53	Toxic by inhalation and if swallowed* Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment*
S phrases	S 1/2 S24 S28 S36/37/39 S38 S45 S60 S61	Keep locked up and out of reach of children. Avoid contact with skin. After contact with skin, wash immediately with plenty of soap and water. Wear suitable protective clothing, gloves and eye/face protection. In case of insufficient ventilation, wear suitable respiratory equipment. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). This material and its container must be disposed of as hazardous waste. Avoid release to the environment. Refer to special instructions/safety data sheets.
Specific concentration limits and M-factor		M-factor = 1000 000, based on acute toxicity of 0.0000001-0.000001 mg/l

* Classification according to the new Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP): Acute tox 3, H331/H301. Aquatic Chronic H400/410.

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification and effects assessment

Absorption, distribution, metabolism and excretion

The rate of oral absorption of deltamethrin was approximately 75%, this based on urinary and biliary excretion data in rats. Deltamethrin was rapidly absorbed when orally administered to rats (the majority of the radioactivity was eliminated within 24 hrs after dosing, 19-47% with the urine; 32-55% in faeces) and distributed to most tissues. Residues in tissues and carcass were low. The highest residues were found in fat. There was no indication of accumulation, although the residue of deltamethrin in adipose tissue eliminated with a half-life of >24 hrs. Deltamethrin was rapidly excreted in both urine and faeces. 7 days postdose, 31% to 56% of the oral dose was excreted with the urine and 36% to 59% in faeces. No $^{14}CO_2$ was formed according to data from the open literature. Deltamethrin was rapidly and extensively metabolised in rats. The main route of metabolism was via cleavage of the ester bond with or without hydroxylation at the 4' position of the alcohol moiety. The acid moiety and alcohol

moiety were further transformed and excreted in urine in free forms and as conjugated metabolites. Unchanged deltamethrin was the major compound in faeces.

No studies were located regarding absorption rate following inhalation exposure to animals. Consequently a default absorption value by inhalation was considered in the risk assessment.

Dermal absorption

Dermal penetration studies have been conducted *in vitro* in rats with deltamethrin as an oil/water emulsion (EW) and as an emulsifiable concentrate (EC) in rat and human skin and in an *in vivo* study in rats. The results of these studies indicated that dermal absorption was somewhat lower for the EW 15 than for the EC 25. The Decis EC 25 formulation may be considered to be a worst case with regard to K-Othrine formulations. The main difference which is relevant to skin absorption is the solvent (water in K-Othrine SC formulations versus light aromatic solvent in Decis EC 25). The content of aromatic solvent is expected to enhance the degree of dermal absorption in comparison with K-Othrine formulations. For the solid formulations of deltamethrin a lower dermal absorption is expected since water and certain solvents favour.

Using data obtained in the dermal absorption studies on Decis EC 25 formulation, the dermal absorption of deltamethrin in man was estimated to 1.19% for the concentrate and 1.89% for the a.s. when diluted in the spray solution. The value of 2% (maximum dermal absorption) was used in the risk assessment.

Acute toxicity, irritation and corrosivity, sensitisation

Deltamethrin was considered of high acute toxicity by the oral and inhalation route (LD_{50} rat: 87 mg/kg bw; LC_{50} rat: 0.6 mg/L), while the acute dermal toxicity of deltamethrin was low (LD_{50} rat: >2000 mg/kg bw).

Clinical signs of systemic toxicity, poor condition and neurotoxicity were observed in rats after oral and inhalation administration. Skin and eye irritation and pathological changes (enlarged inguinal and mandibular lymph nodes, and pulmonary congestion) were noted in addition after administration via the inhalation route. No clinical signs were noted in rats after dermal application.

The vehicle has a great influence on the LD_{50}. Sesame oil as vehicle shows less toxicity than polyethylene glycol. Aqueous suspensions are significantly less toxic than formulations in oils.

Deltamethrin was not irritating according to skin- and eye irritation studies in rabbits, and no sensitising potential was found in tests according to GPMT (Guinea Pig Maximisation Test) or Buehler.

Repeated dose toxicity (short-term toxicity)

The short-term oral toxicity of deltamethrin was investigated in rats (90-day studies) and dogs (90-day studies; one-year study). In both species, the nervous system was the main target organ. Reduced bodyweight gain was also noted in both species.

The lowest relevant NOAEL for short-term toxicity was 1 mg/kg bw/day obtained in the 90-day (gelatine capsules, vehicle: PEG 200) and 1-year oral (gelatine capsules, vehicle: none) toxicity studies in dogs based on clinical signs of neurotoxicity noted in both sexes at the dose level of ≥ 2.5 mg/kg bw/day.

In addition, the repeated dose toxicity was investigated in rats after dermal exposure (21-day toxicity study in rats) where dermal irritation was noted, and inhalation exposure (14-day toxicity study in rats) where clinical signs (irritative and neurotoxic) and reduced bodyweight gain were noted. Scratching was noted in all treated groups in the inhalation toxicity study. This effect was considered to be related to the irritant nature of deltamethrin but may also be due to the neurotoxic nature of the substance (an indirect consequence of parasthesia).

Genotoxicity

The genotoxic potential of deltamethrin was investigated in a battery of tests *in vitro* (assays for gene mutations, chromosomal aberrations and DNA effects). All tests were negative.

Based on the weight of evidence from this full *in vitro* package and the results of the carcinogenicity studies, it was concluded that deltamethrin is not mutagenic.

Chronic toxicity (long-term toxicity) and carcinogenicity

The long term toxicity of deltamethrin was studied in rats and mice. No evidence of carcinogenic potential of deltamethrin was found in the rat or the mouse. In both species the nervous system was the target organ. The liver was another target organ in the rat.

Lowest relevant NOAEL for long-term toxicity was 1 mg/kg bw/day obtained in the 2-year chronic toxicity/carcinogenicity (feeding) study in the rat based on liver effects (histopathological changes) noted at the dose level of 5 mg/kg bw/day and above. In addition clinical signs of neurotoxicity were noted at higher doses.

Reproductive toxicity

Reproductive toxicity of deltamethrin was investigated in a two-generation study in rats. Developmental toxicity was investigated in rats, mice and rabbits. The mouse study was considered acceptable but of restricted quality due to low number of pregnant animals used in each test groups.

No effect on mating performance or fertility was noted in the rat two-generation (feeding) study. Clinical signs (indicating neurotoxic effects), reduced body growth and histopathological changes (gastric erosions) were noted in adult rats. In offsprings reduced pup body weights, increased pup deaths (F1 generation) and reduced lactation index (F1 generation) were noted at maternal toxic doses.

No developmental toxicity was noted in rats or rabbits at maternal toxic doses. Increased incidence of supernumerary ribs was noted in the offspring of mouse at doses with maternal toxicity.

Lowest relevant developmental LOAEL was 3 mg/kg bw/day based on a statistically significant increase in the occurrence of supernumerary ribs noted in mice at ≥ 3 mg/kg bw/day.

Neurotoxicity

The neurotoxicity of deltamethrin was investigated in standard toxicity studies with the rat (acute neurotoxicity study; subchronic neurotoxicity study; developmental neurotoxicity (DNT) study) and in experimental (non GLP) studies in rats and mice. No studies on acute delayed neurotoxicity were submitted (not required).

The NOAEL for acute neurotoxicity in adult CD-rats was 5 mg/kg bw, while the NOAEL for subchronic neurotoxicity in adult CD rats was 4 mg/kg bw/day. In both studies the NOAEL was based on signs of neurotoxicity noted at 15 mg/kg bw/day and above, and mortalities and reduced bodyweight gain noted at higher dose levels.

The NOAEL for developmental neurotoxicity in Wistar rats was 6.78 mg/kg bw/day based on reduced bodyweight gain, increased incidence of vocalizations with handling (males only) and delayed balanopreputial separation noted in offsprings at a dose with maternal toxicity (16.1 mg/kg bw/day).

The DNT study follows the OECD guideline no. 426 in that way that some exposure to the pups was demonstrated in the pilot study. However, the view of RMS is that there might be some uncertainty in the DNT study protocol in those cases where direct dosing of pups has not been considered and the exposure level in offspring is not clear. No blood analyses were taken and the offspring dose level might be very low. The effects noted in the pups of the high dose group (decreased body weight and body weight gain, delayed sexual maturation in males) are not sufficient evidence to support exposure to the pups during the brain growth spurt period since these effects in the offspring could be due to maternal toxicity or exposure *in utero*.

Furthermore, there is a concern for the lack of data for the most sensitive strain. Comparing data from standard neurotoxicity studies the Wistar rat used in the DNT study seems to be a less sensitive strain with regard to neurotoxicity of deltamethrin. There were no clinical signs of neurotoxicity reported for adult Wistar rats administered deltamethrin via the diet at doses up to 16.1 mg/kg bw/day (noted in the DNT study), whereas clinical signs of neurotoxicity were evident in the CD rat at a dose level of 14 mg/kg bw/day (noted in the 13-week neurotoxicity study). The choice of strain used in the deltamethrin DNT study might therefore be questioned.

Due to the uncertainties mentioned above the RMS originally proposed (draft CAR) to use an extra safety factor of 3 in the risk assessment of deltamethrin. The Technical Meeting I in 2010 reached an agreement that where uncertainties are perceived by the RMS of a pyrethroid on the DNT studies (especially negative studies), these uncertainties should be formally expressed in the CAR. The TM also agreed that the currently available evidence does not support the use of an extra assessment factor to cover for the perceived uncertainties on DNT in the dossier of deltamethrin.

During the Technical Meeting II in 2010, it was decided to use the document on survey of DNT studies for pyrethroids prepared by the Netherlands as basis for the assessment of this category of substances. The conclusions of this survey were:

- Possible DNT effects induced by pyrethroids are covered by the AELs set on neurotoxicity in the acute neurotoxicity and medium-term studies since DNT effects from acceptable OECD TG 426 performed studies are taking place at higher LOAELs than other neurotoxicological effects.

- The DNT effects are also covered by the AELs set for long-term exposure (based on neurotoxic or other critical endpoints).

- As neurotoxic effects are critical effects after acute or medium-term exposure and the available data indicate that DNT effects are induced at higher LOAELs, it is unlikely that, in the absence of DNT studies, the potential DNT effects are not covered by AELs set on neurotoxic effects observed in acute and medium-term studies. It was concluded that additional DNT studies according to OECD TG 426, if such a study is not present, is not necessary.

The RMS respects the decision of TM although the view of RMS is still that there might be some uncertainty in the DNT study protocol and the most sensitive strain has not been used in the DNT study.

Medical data

Medical data from manufacturing, formulating and packaging plants indicate that transitory skin sensations were the most prevalent finding (paraesthesia, transient local burning, tingling, pickling sensations, itching, numbness of the facial skin – erythema in some cases). Cases of intoxications (mostly occupational due to inappropriate handling of products) have been reported. Two cases of occupational acute deltamethrin poisoning died of convulsions and another died of pulmonary oedema. No late sequeala of pyrethroid poisoning have been described in the scientific literature. There is no specific antidote for pyrethroids. Any treatment can only be symptomatic.

Other test(s) related to the exposure of humans

The trans-deltamethrin isomer has been tested for oral acute toxicity and mutagenicity (Ames test). The results of these studies showed that the acute oral toxicity of the trans-deltamethrin does not exceed the acute oral toxicity of the parent compound cis deltamethrin and no genotoxicity potential was found according to the Ames test.

In a study where food commodities (covered and uncovered) were exposed to an environment in which a deltamethrin based product was applied as a general surface treatment showed that the use of deltamethrin products will not contaminate food stuffs when spray is applied downwards. Spraying overhead or direct transfer of residues from treated spaces was not investigated in this study. However, no exposure of food stuffs is expected during and after crack and crevice treatment of food handling areas with the deltamethrin product when label instructions are followed.

Biocidal products

The acute toxicity of K-Othrine SC 26.25, SC 7.5 and DP 0.05 by oral, dermal and inhalation exposure is low. The acute toxicity of K-Othrine WG 250 by oral and dermal route is low, whereas the acute toxicity by inhalation route is moderately; therefore K-Othrine WG 250

should be classified as "Harmful" and assigned the risk phrase R20 ("Harmful by inhalation"). The products are not irritating to skin or eyes, and are not sensitising to skin.

Tolerable exposure

The reference values, (acute/medium term and long term AELs) derived for deltamethrin were obtained from studies in dogs since the data submitted demonstrated that the dog was the most sensitive species to the toxicity of deltamethrin. In addition a safety factor of 100 was applied taking into account a factor for inter- and intraspecies differences of 100 (10 x 10).

Acceptable daily intake (ADI)

Setting of an ADI is not considered necessary since no exposure of foodstuffs should occur during and after treatment of food handling areas with deltamethrin when product label instructions are followed.

Acute reference dose (ARfD)

Setting of an ARfD is not considered necessary since no exposure of foodstuffs should occur when product label instructions are followed, and risk of contamination of drinking water is not considered.

Acceptable exposure levels (AELs)

AEL (acute): An AEL of **0.0075 mg/kg bw/day** was derived based on the NOAEL (1 mg/kg bw/day) obtained in a 13-week dog study after taking an oral absorption of 75% and a safety factor of 100 into account. In the study neurotoxic effects occurred early after dosing.

AEL (medium-term): An AEL of **0.0075 mg/kg bw/day** was derived based on the NOAEL (1 mg/kg bw/day) obtained in the 13-week and 1-year dog studies after taking an oral absorption of 75% and a safety factor of 100 into account.

AEL (long-term): An AEL of **0.0075 mg/kg bw/day** was derived based on the NOAEL (1 mg/kg bw/day) obtained in the 1-year dog study after taking an oral absorption of 75% and a safety factor of 100 into account.

Maximum acceptable concentration in drinking water

According to Council Directive 98/83/EC relating to the quality of water intended for human consumption, the maximum admissible concentration for pesticides in drinking water is 0.1µg/l for substances considered separately.

2.2.1.2. Exposure and risk characterisation

Intended uses

K-Othrine WG250, K-Othrine SC26.25 and K-Othrine SC7.5

In the case of indoor applications of K-Othrine WG 250, K-Othrine SC 26.25 and K-Othrine SC 7.5, the quantity of spray solution applied will be variable; depending upon factors including the target pest, the location of the infestation and the size of the affected area. The products will be applied by professionals. Treatment of a single premise might consist of a combination of band, surface, crack and crevice and spot treatments. The maximum use rate for any of these products is 0.0125 g/m^2.

K-Othrine DP0.05

Outdoors, the product may be applied by consumers (i.e. non-trained members of the public) to control ants (e.g. the black ant, *Lasius niger*). The product is applied directly to the exposed entrances of ant nests by using the measuring device included with the packaging. The product label states that 0.5 g of powder should be applied to each ant nest entrance, giving a total dose rate of 1 mg of active substance per nest (assuming four entrances).

Professional uses

Production and formulation of the active substance

Deltamethrin is not manufactured in the EU, unlike the products K-Othrine WG 250, K-Othrine SC 26.25, K-Othrine 7.5 and K-Othrine DP 0.05. Therefore, only exposures to the formulations are evaluated.

Formulation of deltamethrin occurs on just a few occasions per year. Formulators may be exposed to deltamethrin via dermal and inhalation routes. Exposures may occur during the formulation and packaging steps to the active ingredient and the final product.

Due to the automated closed system for formulation and packaging; the effective personal protective measures worn by production workers (self breathing hood, protective gloves and chemical resistant suit) and the ventilation semi-open system, neither inhalation nor dermal exposure is expected for the people involved in the production/re-packaging of deltamethrin products. No oral exposure is anticipated. Therefore, there is no unacceptable risk anticipated for production workers during the formulation and repackaging of these products.

Application of biocidal products

Primary exposure

Professional operators may be exposed to deltamethrin when mixing, loading and applying deltamethrin formulations (K-Othrine WG 250, K-Othrine SC 26.25 and K-Othrine SC 7.5) indoors via spray application. Post-application exposure can occur during the cleaning of spray equipment. However, the cleaning practice would not give rise to exposure higher than already anticipated for the application of the in-use diluted product. The dermal and inhalation routes were considered to be key in operator risk assessment.

The following table provides a comparison of the estimates with the corresponding proposed systemic AEL (in terms of percentage of the AEL) as well as margins of exposure (MOE)

Active Substance	**PPE**	**Exposure estimates** [mg/kg bw/day]	**% of AEL** [0.0075 mg/kg bw/day]*	**MOE** [0.75 mg/kg bw/day]**
Deltamethrin	no PPE	0.0039	52	192
	with PPE	0.00137	18	547

* proposed systemic AEL= 0.0075 mg/kg bw/day (based on a NOAEL of 1 mg/kg bw/day corrected for oral absorption of 75%, and a safety factor of 100).
** systemic NOAEL=NOAEL of 1 mg/kg bw/day corrected for oral absorption of 75%= 0.75 mg/kg bw/day

Conclusion:

The estimated primary exposure for the intended use of K-Othrine WG 250, K-Othrine SC 26.25 and K-Othrine 7.5 is below the proposed systemic AEL with or without PPE. Based on these results there is no unacceptable risk for the operator anticipated with the intended use of these deltamethrin formulations.

Secondary exposure

Scenario 1: Secondary exposure to a toddler after spot type- or surface treatment application indoors

Persons (adults and/or children) may be secondarily exposed to deltamethrin professional products when re-entering rooms where the product has been applied. Inhalation exposure (secondary) as a result of use of deltamethrin in the biocidal product is considered to be low since operator exposures are limited to professional pest control operators only and there are no relevant acute phase scenarios for adults or infants in professional applications where

bystanders are kept out of the treatment areas until spray aerosols have dispersed or dust have settled. Further, vapour pressure of deltamethrin is low (1.24 x 10^{-8} Pa; 25°C, according to Council Directive 1999/13/EC, it is considered a substance should be considered volatile at a vapour pressure of >0.01 kPa at 20°C). Thus it is reasonable to conclude that re-entry exposure is predominantly via the dermal route (transfer of surface bound residues to the skin). Oral exposure could also occur following transfer from skin to mouth. Re-entry by a toddler (10 kg) is considered as being worse case for the purpose of secondary exposure risk assessment.

The following table provides a comparison of the estimates with the systemic AEL (in terms of percentage of the AEL) and margins of safety to the relevant systemic NOAEL for toddlers exposed to formulations applied by professionals indoors.

The following table provides a comparison of the estimates with the systemic AEL (in terms of percentage of the AEL) and margins of safety to the relevant systemic NOAEL for toddlers exposed to formulations applied by professionals indoors.

Exposure scenario	**Exposure estimates** [mg/kg bw/day]	**% of AEL** [0.0075 mg/kg bw/day]*	**MOE** [0.75 mg/kg bw/day]**
Spot type application	0.0007125	9	1053
Full surface treatment	0.0017765	24	422

* proposed systemic AEL=0.0075 mg/kg bw/day (based on a NOAEL of 1 mg/kg bw/day corrected for oral absorption of 75%, and a safety factor of 100).
** systemic NOAEL=NOAEL of 1 mg/kg bw/day corrected for oral absorption of 75%= 0.75 mg/kg bw/day

Conclusion:

The result of the calculations shows that the estimated systemic exposure of the toddler is below the proposed systemic AEL. Based on these calculations there is no unacceptable risk anticipated for persons being secondary exposed to the specified deltamethrin products after spot type- or surface treatment application indoors.

Scenario 2: Secondary inhalation exposure to deltamethrin residues dislodged from treated carpet during and after vacuuming of the carpet

With respect to secondary inhalation exposure to deltamethrine residues dislodged from treated carpet during and after vacuuming of the carpet the approach proposed by UK-HSE during its evaluation of bendiocarb under the Biocidal Products Directive 98/8/EC was considered.

With vacuuming of a treated carpet it is reasonable to conclude that the amount of active substance present on the carpet is the main factor which determines airborne residue concentrations during and shortly after vacuuming. Based on this consideration it is justified to use the data generically (= corrected for the relevant application rate) when assessing inhalation exposure of persons occupying a room during and soon after vacuuming of a carpet treated with K-Othrine WG 250. Corresponding exposure calculations consider the same very conservative approach as proposed by UK-HSE:

- Highest mean values determined during and shortly after vacuuming will be considered
- An overall exposure duration of 24 hours will be taken into account

The following table provides a comparison of the exposure estimates with the proposed AEL (in % AEL) and margins of exposure (MOE) to the relevant systemic NOAEL

Scenario	**Person**	**Estimated exposure** [mg/kg bw/day]	**% AEL#**	**MOE#**
Inhalation exposure during and after vacuuming of a treated carpet	Infant	0.00021	2.8	3570
	Child	0.00019	2.5	3950
	Adult	0.00012	1.6	6250

#: AEL = 0.0075 mg/kg bw/day, systemic NOAEL = 0.75 mg/kg bw/day

The estimated secondary inhalation exposure of the infant, child and adult accounts for 2.8, 2.5 and 1.6% of the systemic AEL (systemic AEL=0.0075 mg/kg bw/day), respectively. Based on these calculations there is no unacceptable risk anticipated for persons being secondary exposed to K-Othrine WG 250 by inhalation during and after vacuuming of a treated carpet.

Scenario 3: Secondary dermal exposure from sleeping on a treated mattress

With respect to exposure of persons sleeping on a treated mattress the approach proposed by UK-HSE during its evaluation of bendiocarb under the Biocidal Products Directive 98/8/EC. With the tier 1 approach the following assumptions/considerations are made:

The total body surface areas of an infant, child and adult are 6400 cm^2, 11900 cm^2 and 20600 cm^2 respectively (ECETOC, 2001) and the body weights are 10, 34.4 and 60 kg, respectively. It is proposed that 9% of the surface residue is transferred to the skin from the mattress (data from TNsG, Part 2 for dried fluid on a carpet) and that people have 100% skin contact with the treated mattress, with no protective cover sheet. The maxium recommended application rate for

the products (K-Othrine WG 250, K-Othrine SC 26.25, K-Othrine SC 7.5) is 12.5 mg/m^2 (0.00125 mg/cm^2), and dermal absorption rate is 2%.

The following table provides a comparison of the exposure estimates with the proposed AEL (in % AEL) and margins of exposure (MOE) to the relevant systemic NOAEL

Estimated exposure	**Person**	**Estimated exposure** [mg/kg bw/day]	**% AEL#**	**MOE#**
Person sleeping on a treated mattress	Infant	0.0014	19	536
	Child	0.0008	11	938
	Adult	0.0008	11	938

AEL= 0.0075 mg/kg bw/day, systemic NOAEL=0.75 mg/kg bw/day

Conclusion:

The estimated secondary dermal exposure of the infant, child and adult accounts for 19, 11 and 11% of the proposed systemic AEL (systemic AEL=0.0075 mg/kg bw/day), respectively. Based on these calculations there is no unacceptable risk anticipated for persons being secondary dermal exposed to K-Othrine WG 250 from sleeping on a treated mattress.

Scenario 4: Secondary exposure to persons laundering contaminated work clothing

With respect to exposure of persons laundering contaminated work clothing the approach proposed by UK-HSE during its evaluation of bendiocarb under the Biocidal Products Directive 98/8/EC was considered.

In general this approach assumes that the laundering is undertaken in a domestic, automatic washing machine. Therefore, exposure will be by the dermal route, via the hands, from handling the contaminated clothing prior to and during introduction of the clothing into the washing machine. It is considered that laundering is undertaken after a five day work week: hence the total amount of active substance present on the work clothing is assumed to be five times the amount of one work day.

For the products K-Othrine WG 250, K-Othrine SC 26.25 and K-Othrine SC 7.5 this amounts to 55200 µL in use product (= 5 x 11040 µL in use product/day). Taking into account the in use concentration of 0.00025 mg deltamethrin/µL this corresponds to 13.8 mg deltamethrin present on the work clothing. Furthermore UK-HSE considers that the area of a medium-sized coverall is 22700 cm^2. Therefore, expressed as mg deltamethrin/cm^2, the accumulated residues over 5 days would be 0.000608 mg deltamethrin/cm^2.

The total area of the palms and backs of both hands for an adult is 840 cm^2, the transfer coefficient for contamination (of dried fluid) from cotton or knitwear to wet hands is 30% (Technical notes for guidance; Human exposure risk assessment to biocidal products, Guidance on exposure estimation, June 2002") and using the dermal penetration figure of 2%, the systemic dose for a 60 kg adult can be calculated as:

$$\frac{\text{a.s. residues on coverall x surface area of both hands x transfer coefficient x dermal absorption}}{\text{body weight}}$$

$$= \frac{0.000608 \times 840 \times 30/100 \times 2/100}{60}$$

The systemic dermal dose from laundering the contaminated work clothing is 0.00005 mg technical deltamethrin/kg bw (= 0.7% of AEL (0.0075 mg/kg bw/day); MOE = 15000).

Conclusion:

The estimated secondary exposure of persons laundering contaminated work clothing accounts for 0.7% of the proposed systemic AEL (proposed systemic AEL=0.0075 mg/kg bw/day). Based on these calculations there is no unacceptable risk anticipated for persons laundering contaminated work clothing.

Combined exposure

Combined exposure is most relevant for a pest control operator who applies the product (representing the highest application rate of deltamethrin) and then returns to a home that has also been treated with deltamethrin. In this respect, a comparison of potential exposure is made to the systemic AEL of 0.0075 mg/kg bw/day. The worst-case potential exposure during application (without PPE), has been used for the calculation of professional exposure. For the calculation of secondary exposure worst case exposure (full surface treatment) calculated for an adult has been used.

The following table provides a comparison of the exposure estimates with the proposed AEL (in % AEL) and margins of exposure (MOE) to the relevant systemic NOAEL

Exposure scenario	**Exposure estimates** [mg/kg bw/day]	**% of AEL** [0.0075 mg/kg bw/day]*	**MOE** [0.75 mg/kg bw/day]**
Professional exposure (no PPE)	0.0039	-	-
Secondary Exposure (full surface treatment)	0.000435***	-	-
Total exposure	0.0043	58	174

* proposed systemic AEL= 0.0075 mg/kg bw/day (based on a NOAEL of 1 mg/kg bw/day corrected for oral absorption of 75%, and a safety factor of 100).
** systemic NOAEL=NOAEL of 1 mg/kg bw/day corrected for oral absorption of 75%= 0.75 mg/kg bw/day
*** for calculations of the secondary exposure in adults see Doc II B.1 point 8.2.5.1

Conclusion:

The results of the calculations show that the combined exposure to deltamethrin will be below the proposed systemic AEL (58% of AEL) when secondary exposure is calculated for an adult. Based on this result a professional applicator will not be at unacceptable risk from combined exposure.

Non-Professional uses

Application of K-Othrine DP 0.05

Primary exposure

K-Othrine DP 0.05 is formulated as a ready-to-use dry powder. Therefore, no mixing/loading is required. In addition no disposal of the applied powder is performed. Therefore, primary exposure is confined to the application phase of the product.

The following table provides a comparison of the estimates with the AEL (in terms of percentage of the AEL) and margins of safety to the relevant systemic NOAEL

Exposure scenario	**Exposure estimates** [mg/kg bw/day]	**% of AEL** [0.0075 mg/kg bw/day]*	**MOE** [0.75 mg/kg bw/day]**
Application of the neat product	0.000001142	0.02	6.6×10^5

* proposed systemic AEL= 0.0075 mg/kg bw/day (based on a NOAEL of 1 mg/kg bw/day (corrected for oral absorption of 75%, and a safety factor of 100).
** systemic NOAEL=NOAEL of 1 mg/kg bw/day corrected for oral absorption of 75%= 0.75 mg/kg bw/day

Conclusion:

The calculations above show that primary exposure will not give rise to unacceptable risk in the use of deltamethrin product by amateur users.

Secondary exposure

K-Othrine DP 0.05 is applied around ant nest entrance. Thus, with the intended use of the product it can be assumed to be accessible for persons (children/adults) re-entering the treated terrace. A calculation of secondary exposure was performed considering the worst case scenario of a child re-entering a treated terrace.

The following table provides a comparison of the estimates with the AEL (in terms of percentage of the AEL) and margins of safety to the relevant systemic NOAEL for toddlers exposed to formulations applied by amateurs outdoors.

Exposure scenario	**Exposure estimates** [mg/kg bw/day]	**% of AEL** [0.0075 mg/kg bw/day]*	**MOE** [0.75 mg/kg bw/day]**
Child re-enters the treated terrace with bare feet	0.000171	2	4386

* proposed systemic AEL= 0.0075 mg/kg bw/day (based on a NOAEL of 1 mg/kg bw/day (corrected for oral absorption of 75%, and a safety factor of 100).
** systemic NOAEL=NOAEL of 1 mg/kg bw/day corrected for oral absorption of 75%= 0.75 mg/kg bw/day

Conclusion:

The calculations above show that secondary exposure will not give rise to unacceptable risk in the use of deltamethrin product by amateur users.

2.2.2. Environmental Risk Assessment

2.2.2.1. Fate and distribution in the environment

Abiotic degradation

The hydrolysis of deltamethrin was shown to be insignificant at pH 5 and 7. At pH 9, however, the hydrolysis was significant with a half-life of 2.5 days (25°C), normalised to 7 days (12°C). At pH 8, half-life was 31 days (23°C), normalised to 75 days (12°C). Direct photochemical reactions do not occur at a rate that makes this a significant route of degradation of deltamethrin under natural conditions in water. In soil, direct and indirect photochemical reactions may contribute to the degradation of deltamethrin, but other routes of transformation account for the major loss of parent compound.

Biodegradation

Deltamethrin was not readily biodegradable in laboratory tests. In aquatic environments, deltamethrin will very rapidly partition to the sediment, to suspended organic matter and to biota. In the laboratory about 60% of the applied radioactivity was found in the sediments immediately after application. In water/sediment systems, the degradation DT_{50} was estimated to 45 and 141 days in two different systems at 20°C (85 and 267 days as normalised to 12°C) and the dissipation DT_{50} in sediment to 55 and 133 days at 20°C (104 and 253 days as normalised to 12°C). The pH of the aqueous phase of these systems were 8.0-9.1 and hydrolysis may have contributed to the degradation observed. pH of the sediments were lower (7.1/7.5). The difference in degradation rate between the two systems probably reflects difference in amount of fine-textured material and amount of organic matter.

In soil, first order DT_{50} values for deltamethrin were 11-27 days and short-lived metabolites were formed. When normalised to 12°C, the DT_{50} was 31-74 days, with a geometric mean of 48 days. The pH of the four soils used were 5.8, 5.9, 7.5 and 8.1 and hydrolysis was probably an insignificant route of degradation in the soils. The DT_{50}s of the major metabolite of deltamethrin, Br_2CA, has been calculated to 0.7-11.6 days in three soils with a geometric mean of 2.0 days (normalised to 25°C and field capacity). When normalised to 12°C and field capacity the DT_{50}s for Br_2CA were 2.1-32.3 days, geometric mean 5.6 days.

Distribution

Deltamethrin is very strongly adsorbed to soil and other organic matter, with a K_{oc} value ranging from 204 000 to 577 000 L/kg. The arithmetic mean K_{oc} value was 408 250 L/kg. The metabolites are more mobile with a arithmetic mean K_{oc} of 25.6 L/kg for Br_2CA and 115 L/kg for mPBacid. Due to its low vapour pressure, deltamethrin is not expected to volatilise to air from plants and soil at significant levels, which was confirmed in a wind tunnel study. However, the calculated Henry's law constant is 1.252×10^{-3} $Pa \cdot m^3 \cdot mole^{-1}$, indicating that

deltamethrin has a tendency to volatilise from water. If present in air, the data on indirect photo-oxidation indicate a rapid degradation when reacting with hydroxyl radicals.

Accumulation

The bioaccumulation of ^{14}C-deltamethrin was investigated in bluegill sunfish (*Lepomis macrochirus*). The BCF values obtained were 310, 2800 and 1400 for edible, non-edible and whole body tissue, respectively. After the 14-day depuration period 70, 75 and 76% of the ^{14}C-residues had been eliminated from the edible, non-edible and whole body tissue, respectively. The biological half-life was 4.3 days for whole body tissue.

The potential for bioconcentration of deltamethrin in earthworms was estimated by modelling the hydrophobic partitioning between soil pore water and the phases inside the organism, in accordance with equation 82d in the TGD. Using the Kow of 40 200 for deltamethrin, the $BCF_{earthworm}$ was 483.

Assessments of the potential for secondary poisoning via terrestrial and aquatic food chain indicate that there is no unacceptable risk for earthworm- and fish-eating birds and small mammals.

2.2.2.2. Effects assessment

Aquatic

The acute toxicity of deltamethrin to fish was high, with a 96-hour LC_{50} of 0.26 µg/l (m). The major metabolite (Br_2CA) had a low toxicity to fish, with a 96-hour LC_{50} estimated to be 10.4 mg/l. Deltamethrin is very acutely toxic to aquatic invertebrates and the LC50 for the most sensitive organism, *Gammarus fasciatus*, was 0.3 ng/l (m). The major metabolite (Br_2CA) shows a lower toxicity to aquatic invertebrates than the parent compound, with an EC_{50} (48h) of 84.9 mg/l. Deltamethrin did not have any acute toxic effects to algae after 96 hours exposure, and the EC_{50} was >0.47 mg/l. There was no inhibiting effects of deltamethrin on microbial respiration in activated sludge either, and the EC_{50} was >0.3 mg/l. Using this value and an assessment factor of 10, the $PNEC_{STP}$ was set to 30 µg/l.

The chronic toxicity of deltamethrin to fish was high, with a NOEC of 17 ng/l (m), based on effects on growth in a 260 day full life cycle test. In a 21 day test with *Daphnia magna*, the NOEC was 4.1 ng/l (m), based on inhibition of growth. For sediment dwelling organisms (*Chironomus riparius*), the chronic toxicity was also high and the 28 day NOEC for emergence was 3.5 ng/l, based on estimated actual exposure concentrations. In a higher tier study, a comprehensive 119 day mesocosm study with about 50 test organisms and three applications at five test concentrations, a NOEC was determined to be < 4.8 ng/l (n), based on decreased abundances of the phantom midge *Chaoborus crystallinus* at this concentration. The abundance of Copepod Nauplii was decreased at the next higher test concentration of 10.5 ng/l, but no other organisms showed any direct effects at this concentration. Thus, a NOEC of 4.8 ng/l was considered sufficient, considering that *C. crystallinus* was the only organism affected at this concentration, and that this effect was only temporarily, with full recovery observed within

seven weeks after the last application. In a bioassay with the organism that was identified as the most sensitive in the laboratory studies; Gammarus pulex, a $NOEC_{mortality}$ of 9 ng/l based on mean measured concentrations was determined.

At TM I 2010 (first technical discussion), it was decided that due to the observed effects at the lowest test concentrations in the mesocosm, and also due to uncertainties regarding the exposure pattern in this higher tier study compared to biocidal use of deltamethrin, the risk assessment should be based on laboratory data. It was also agreed that the possible potential for recovery observed in the mesocosm and bioassays should not be taken into account in the PNEC calculation. Due to the large number of species tested, however, it was agreed that the available data support a lower assessment factor.

Using the lowest chronic laboratory NOEC value (3.5 ng/l, from *Chironomus*) and an assessment factor of 5 (considering that the test organism had been identified as the most sensitive) the $PNEC_{water}$ is 0.7 ng/l. The corresponding $PNEC_{sediment}$, calculated from $PNEC_{water}$ and using the Equilibrium Partitioning Method with the mean Koc for deltamethrin of 408 250, is 6.2 µg/kg ww sediment.

Terrestrial

The acute toxicity of deltamethrin to adult earthworms (*Eisenia fetida*) was low, with a 14-day LC_{50} of >1290 mg/kg dw soil. A study with the predatory mite, *Hypoaspis aculeifer*, and the major metabolite of deltamethrin in the environment, Br_2CA, gave a $NOEC_{mortality}$ of 10 mg test item/kg dw soil, based on nominal concentrations. Considering the use pattern of the biocidal products, no exposure of deltamethrin to terrestrial plants is anticipated. On the contrary, deltamethrin is an insecticide used/registered for crop protection and no phytotoxic effects are expected. Therefore, studies on toxicity to terrestrial plants were waived by the applicant, which was accepted by the RMS. The effects on soil microorganisms were observed to be negligible, and the NOEC was accordingly determined to be >375 g/ha, which is equivalent to >0.50 mg/kg dw soil. However, the RMS considered that neither this test organism nor earthworms are probably the most sensitive organism to an insecticide like deltamethrin. Therefore, the notifier has submitted further studies on soil dwelling organisms. From these data, the chronic toxicity of deltamethrin was estimated to a NOEC of 1.25 mg/kg dw soil (0.75 mg/kg ww standard soil), based on reduction of reproduction in springtails or alternatively 0.43 mg/kg ww standard soil based on effects on earthworms (note that no effects were observed at the highest test concentrations in the study).

Due to the lack of effects in the tests on micro-organisms and chronic toxicity to earthworms, the PNEC is based on the NOEC from the reproduction test on springtails. Using an assessment factor of 10, the resulting PNEC is 0.075 mg/kg ww standard soil. This value will be used in the risk assessment.

Several studies were performed to assess the acute and long-term effects of deltamethrin to birds. Deltamethrin showed low toxicity to birds at short as well as long term exposure, and the NOEL was >55 mg/kg bw/d.

Based on the use pattern of the deltamethrin biocidal product used outdoors for ant control (K-Othrine DP 0.05), there will be no application to plants and flower beds. Furthermore, the

treated areas (entrances of ant nests) are not visited by honey bees. Exposure (if any) to honey bees and other beneficial arthropods would be limited to the immediate vicinity of the treated areas. Consequently, on population level, no significant risk to honey bees and other beneficial arthropods is anticipated. Thus, studies on bees and other beneficial arthropods were not deemed necessary. This is also in line with the outcome of an e-consultation between member states in July 2007, and a decision taken at the Technical Meeting in March 2008.

2.2.2.3. PBT assessment

The PBT/vPvB assessment was done in relation to criteria set out in Annex XIII to the REACH Regulation.

There was no simulation study on biodegradation in water available.

One simulation test on two different water/sediment systems was available. From the results, DT50s representing degradation in the whole water/sediment systems were calculated. Since deltamethrin very rapidly partitions to sediment the RMS believes the most appropriate approach is to compare these values with the P-criteria for the sediment compartment (i.e., P-criterion >120 days; vP-criterion >180 days). The degradation half-lives of deltamethrin in the two different systems were 45 and 141 days, respectively, at 20°C (based on sum of deltamethrin and insecticidally inactive alpha-R-isomer). Normalised to a temperature of 12°C these values correspond to 85 and 267 days, respectively. It can be concluded that in one system the DT50 normalised to 12°C exceeds the P- and the vP-criteria for freshwater sediment – while in the other system the DT50 normalised to 12°C does not exceed any of these criteria. Both systems are considered as representative. The slow degradation was observed in the more coarse-textured system with less organic carbon, while the more rapid degradation was observed in the more fine-textured and carbon-rich sediment system. The difference in degradation rate between the two systems can probably be attributed to differences in biological activity. It was not a simple effect of increased adsorption. The pH of the aqueous phase of both systems was high enough for hydrolysis to occur so it cannot be excluded that the rate of degradation would be slower in more acidic/neutral systems. However, the pH of the sediments was low enough not to present hydrolysis as a significant factor to the degradation.

Laboratory data from four different soils were available; the DT50s ranged from 11 to 27 days (20°C), or when normalised to 12°C from 31 to 74 days. Hence, none of the half-lives for degradation in soil exceeds the P-criterion for soil (i.e. > 120 days). All four soils are considered as representative. It is not considered likely that hydrolysis contributed to the degradation observed in the soils. It is concluded that deltamethrin cannot be classified as persistent in the soil compartment.

Both environmental compartments for which there is adequate data available (i.e., sediment and soil) are considered to represent relevant environmental compartments since emissions may occur to both systems, via release from STP or application of sludge.

The BCF of deltamethrin in fish (whole body tissue) was 1400. The clearance time was 4.3 days. In soil, the estimated BCFearthworm, calculated based on the Kow of 40 200, was 483. Therefore, deltamethrin does not fulfil the criterion for bioaccumulation.

Deltamethrin has a high chronic toxicity to aquatic organisms with a NOEC of 4.8 ng/l, which is clearly below the T criterion. Hence the criterion for toxicity is fulfilled.

Conclusion: The P criterion is not fulfilled for soil, and not fulfilled for freshwater sediment using the lower of the two DT50 values derived of the water/sediment studies, but is fulfilled using the higher DT50 value derived of the water/sediment studies. The B criterion is not fulfilled. The T criterion is fulfilled. Therefore, deltamethrin is not a PBT substance.

2.2.2.4. Exposure assessment

The environmental exposure assessment of deltamethrin has been performed following the general guidance in the OECD Emission Scenario Document (ESD) for Insecticides, acaricides and products to control other arthropods (PT18) for household and professional uses and the Technical Guidance Document on Risk Assessment (TGD). The exposure assessment of deltamethrin includes the estimation of local emissions to various receiving environmental compartments from application of products indoors to control crawling and flying insects and spot application outdoors to control ants. The only exposure pathway for deltamethrin to surface waters and sediment is via STP outlet, following emissions from application indoors and entering a local STP after a cleaning event. Similarly, the only major exposure of deltamethrin to soil is indirectly via sludge application.

Aditionally, a "back-calculation" of the tonnage put on the market based on the default assumptions of the ESD No 18, as well as EUSES modelling based on actual tonnage put on the market was submitted by the applicant. These assessments, especially the "back-calculation", demonstrated the conservative nature of the approach of the ESD No 18. The results from the "back-calculation" and the EUSES modelling were however not used for risk assessment.

2.2.2.5. Risk characterisation

<u>Aquatic compartment</u>

Sewage Treatment Plant (STP)
There is no risk posed to micro-organisms in a sewage treatment plant (STP) resulting from losses occurring during product mixing/loading, product application and service life in any of the treatment scenarios for insecticide products containing deltamethrin. The PEC/PNEC ratios

ranged between 0.00008 and 0.002 and thus do not indicate unacceptable concentrations of the active substance deltamethrin in local STPs

Surface water
The PEC/PNEC ratios indicate that there is no risk for aquatic organisms following use in crack and crevice treatments in domestic houses and larger buildings (ratio 0.57 and 0.20, respectively), and outdoor spot treatment (no exposure). However, there is a risk posed to these organisms following barrier treatment in domestic houses and larger buildings, with PEC/PNEC ratios of 5.1 and 1.86, respectively.

Sediment
The PEC/PNEC ratios indicate that there is no risk for sediment dwelling organisms following use in crack and crevice treatments in domestic houses and larger buildings (ratio 0.57 and 0.20, respectively) and outdoor spot treatment (no exposure). However, there is a risk posed to these organisms following barrier treatment in domestic houses and larger buildings with PEC/PNEC ratios of 5.1 and 1.86, respectively.

Terrestrial compartment

Soil
The PEC/PNEC ratios indicate that there is no risk for soil dwelling organisms following application of sludge after use in crack and crevice treatments, barrier treatments and outdoor spot treatment (ratios 0.00095 – 0.056).

Groundwater
A higher-tier assessment of the potential for groundwater contamination associated with soil appli-cations of deltamethrin was carried out using the simulation model FOCUS-PEARL 2.2.2. The concentration of deltamethrin in soil was calculated on the basis of the maximum default application rate for sewage sludge specified in the TGD (EC, 2003). The calculated PECgw values of deltamethrin and its metabolites were several orders of magnitude below the groundwater trigger value of 0.1 µg/l in all scenarios. It was therefore concluded that neither deltamethrin nor Br_2CA represent a risk to groundwater following the application of sewage sludge to land.

The RMS has also considered the properties of deltamethrin in relation to the additional environmental criteria for exclusion from Annexes I, IA and/or IB as presented in the TNsG on Annex I inclusion (April, 2002); impact on air quality, persistence in soil or sediments (including formation of non-extractable residues); contamination of surface water intended for abstraction of drinking water; potential for bioaccumulation and secondary poisoning of predators. The RMS concludes that there are no reasons for concern in addition to those identified in the risk assessment as shown by the PEC/PNEC ratios above.

Summary of risk characterisation for the application scenarios

Table 2.2.2.5-1 Summary of the results of the environmental risk characterisation for deltamethrin for the application scenarios assessed. Degradation processes were not assumed for STP, sediment or water.

	PEC/PNEC >1, Yes / No			
Scenario	**STP**	**Surface water**	**Sediment**	**Soil**
Domestic house (Crack and crevice)	No	No	No	No
Domestic house (Barrier)	No	**Yes**	**Yes**	No
Larger building (Crack and crevice)	No	No	No	No
Larger building (Barrier)	No	**Yes**	**Yes**	No
Added emissions: Crack and crevice (domestic houses + larger buildings)*	No	No	No	No
Added emissions: Barrier treatments (domestic houses + larger buildings)*	No	**Yes**	**Yes**	No
Added emissions (crack and crevice + barrier treatments; domestic houses + larger buildings)*	No	**Yes**	**Yes**	No
Outdoor spot application**	-	-	-	No

* See Doc II-B1, II-B2, and II-B4, section 8.3.2.
**According to the ESD No 18, Point 4.3.4.1, the only relevant receiving compartment for this use scenario is soil

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

Deltamethrin is classified as T; R23/25, and N; R50/53.

The assessment has been performed based on the documentation for the active substance and the representative biocidal products, K-Othrine SC 26.25, SC 7.5 and WG 250 that are intended for indoor use for the control of crawling and flying insects by professional operators only and K-Othrine DP 0.05 which is intended for ant control (outdoor use) by non-professionals.

In the original dossier, the intended uses of the products for indoor use were wider than those on which the final risk assessment was based. More restricted usage was described by the applicant during the peer-review process.

Deltamethrin is a fast-acting, broad spectrum insecticide which complements the use of more specific pest control products, such as baits, that target specific insects (ants or cockroaches) in circumstances where a range of other public health insect species are present (eg. flies, silverfish, bedbugs, fleas) and residual performance is required to prevent re-infestation. Deltamethrin is a pyrethroid insecticide, and deltamethrin-containing products used as general insect sprays provide a valuable tool in resistance management for cockroaches, in particular, where bait products are based upon entirely different classes of insecticide (eg. chloronicotinyl, fiprole). The data on the active substance and the insecticide products have demonstrated sufficient efficacy against insects (e.g. cockroaches and ants) for inclusion into Annex I to be recommended. However, further efficacy data may be required on specific products to support product authorisation at Member State level, and the potential for resistance should be taken into account for the regional situation.

The risk characterisation for human health indicates that there is no unacceptable risk anticipated for the operator or the non-professional user with the intended uses of the biocidal products, nor for persons being secondary exposed.

In the risk characterisation for the environment, no risks were found for application of products applied indoors as crack and crevice treatment in domestic houses and larger buildings. Additionally, no risks were identified for spot application outdoors to control ants. Risks were identified for aquatic and sediment-dwelling organisms following barrier treatment in domestic houses and larger buildings, with PEC/PNEC ratios of 5.1 and 1.9, respectively. For soil dwelling organisms, no risks were identified in any of the uses evaluated. This was also the case for secondary poisoning in the aquatic and terrestrial food chains.

There was no risk identified for contamination of groundwater at levels of 0.1 µg/L or above from the use of the products assessed. Deltamethrin is also not characterised as a PBT substance since only the criterion for toxicity (T) is clearly fulfilled.

Hence it can be concluded that among the intended uses considered in the exposure assessments no risks were identified from the human health perspective. From the environmental perspective no risks were identified for crack and crevice treatment indoors and spot treatment outdoors to control ants.

Initial work carried out under the EU Strategy for Endocrine Disruptors identified and included Deltamethrin in Group III of a list of 553 candidate priority substances with the potential to act as endocrine disruptors in both humans and animals5.

In a follow-up to the first prioritising exercise, further information was gathered and presented for chemicals not previously prioritised6. Substances were categorized specifically in relation to human health and wildlife. Overall, deltamethrin was identified as Category 1.

As part of the evaluation of the application for the inclusion of Deltamethrin in Annex I of the Biocidal Products Directive (98/8/EC) toxicology and ecotoxicology data have been assessed. It is concluded that there was no evidence of endocrine disruption effects from these studies. However, it should be noted that due to limitations in the test guidelines available at the time, the potential for endocrine effects may not have been fully investigated.

The RMS recommends that the potential for endocrine disruption of deltamethrin is reconsidered when EU harmonised guidance is established based on the work and final conclusions of the EC work on defining criteria to identify endocrine disrupting substances.

3.2. Decision regarding Inclusion in Annex I

The active substance Deltamethrin 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:

- The active substance, deltamethrin, as manufactured, shall have a minimum purity of

≥ 98.5 % w/w

- In view of the risks identified for aquatic ecosystems for the indoor barrier treatments in domestic/larger buildings (resulting in emissions to STP), products shall not be authorised for this use unless it can be demonstrated that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of risk mitigation measures.

---

5 Okkerman, P.C. and Groshart, Ch., 2000, Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption – preparation of a candidate list of substances as a basis for priority setting. BKH, The Netherlands.

6 Okkerman, P.C. and van der Putte, I., 2002, Endocrine disrupters: Study on gathering information on 435 substances with insufficient data. RPS BKH, The Netherlands.

- When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, the populations and environmental compartments that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Union level risk assessment.

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

Only the products K-Othrine WG 250, K-Othrine SC 26.25 and K-Othrine 7.5 containing deltamethrin that are intended for indoor use for the control of crawling and flying insects by professional operators, and the product K-Othrine DP 0.05 which is intended for ant control outdoors by non-professionals have been evaluated. The risk assessments performed are based on the maximum application rate of 12.5 mg a.s./m^2 for intended uses of K-Othrine WG 250, K-Othrine SC 26.25 and K-Othrine 7.5, and the application rate of 2 g deltamethrin DP 0.05/nest for intended use of K-Othrine DP 0.05. For higher application rates, new risk assessments are needed.

In view of the risks identified to the environment, emissions within an STP catchment need to be taken into particular consideration. The environmental exposure assessment for the products used indoor was based on default areas treated for crack and crevice and barrier treatments in domestic houses and larger buildings. The default removal by wet cleaning was refined to 15% for the cracks and crevices treatment since a band width of spraying 0.1 m was prescribed. It was assumed that 0.81% of houses/buildings within an STP catchment are treated on the same day.

Risks to aquatic systems were identified for some scenarios and these need to be considered when products are authorised at MS level.

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

When evaluating products containing deltamethrin MS should take into account cumulative exposure from biocidal uses of deltamethrin using agreed EU guidance where possible. Further efficacy data may be required on specific products.

Further data on resistance may be required. The resistance situation should be taken into account for the regional situation.

Risk assessment to companion animals (pets) has not been carried out in this evaluation but should be considered, at the product authorisation stage.

Multiple exposures of infants may occur in case an infant is exposed during contact with treated areas first at general buildings such as day-care centres and hospitals and then in domestic properties. Due to some uncertainties with regard to developmental neurotoxicity (no data for the most sensitive strain) precautions should be taken regarding exposure of children and

pregnant users during the last trimester. The exposure level for children should be carefully considered in order to protect children during the sensitive period of brain development, and Member States may consider attaching conditions on use area, application method, type of formulation etc when granting authorisation of a product.

For the products that are used indoors (K-Othrine WG 250, K-Othrine SC 26.25, K-Othrine SC 7.5) following precautionary phrases on the product label are recommended: "Do not apply directly to surfaces on which food or feed is stored, prepared or eaten", "Cover food, food preparing equipment and eating utensils before application", "Cover water storage tanks before application".

Considering normal use conditions no unacceptable risk is anticipated for persons being exposed to K-Othrine DP 0.05 via secondary routes of exposure. However, to minimise accidental exposure to children by the oral route bittering agents (Bitrex) should be considered according to the applicant.

Should applications be made for authorisation of products containing deltamethrin 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.

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

3.5. Updating this Assessment Report

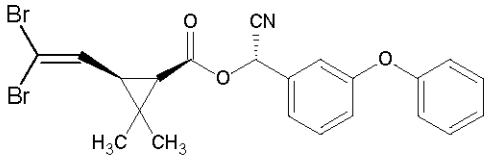
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of deltamethrin 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)	deltamethrin
Product-type	PT 18

Identity

Chemical name (IUPAC)	(S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate
Chemical name (CA)	Cyclopropanecarboxylic acid, 3-(2,2-dibromoethenyl)-2,2-dimethyl-, (S)-cyano(3-phenoxyphenyl)methyl ester, (1R,3R)-
CAS No	52918-63-5
EC No	258-256-6
Other substance No.	CIPAC: 333
Minimum purity of the active substance as manufactured (g/kg or g/l)	985 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None of the impurities in technical deltamethrin are considered relevant
Molecular formula	$C_{22}H_{19}Br_2NO_3$
Molecular mass	505.2 g/mol
Structural formula	

Physical and chemical properties

Melting point (state purity)	98.1-99.4 °C (98.9-99.3%w/w)
Boiling point (state purity)	None. Decomposition (99.3%w/w)
Temperature of decomposition	245-320°C (99.3%w/w)
Appearance (state purity)	Off-white solid powder with no to slight musty odour (99.7%w/w).
Relative density (state purity)	Density: 1.5 g/cm^3 at 20°C (98.9%w/w)
Surface tension	Not applicable as the solubility in water is below 1 mg/l
Vapour pressure (in Pa, state temperature)	99.7%w/w: 1.24 x 10^{-8} Pa at 25°C 4.13 x 10^{-8} Pa at 35°C 1.98 x 10^{-7} Pa at 45°C
Henry's law constant (Pa m^3 mol $^{-1}$)	1.252 x 10^{-3} Pa.m^3/mol
Solubility in water (g/l or mg/l, state temperature)	99.6%w/w: pH 6.2: < 5 µg/l at 20°C (based on the LOQ of the HPLC-method used for quantification) No pH effect anticipated as deltamethrin cannot dissociate under environ-mentally relevant pH
Solubility in organic solvents (in g/l or mg/l, state temperature)	At 20°C (98.6%w/w): 300-600 g/l in acetone 60-75 g/l in acetonitrile >600 g/l in 1,2-dichloroethane 200-300 g/l in DMSO 200-300 g/l in ethyl acetate 2.47 g/l in n-heptane 8.15 g/l in methanol 150-200 g/l in p-xylene
Stability in organic solvents used in biocidal products including relevant breakdown products	Not applicable because the active substance as manufactured does not include an organic solvent and the active substance is mainly not formulated in organic solution in the biocidal product. The stabilities of the representative formulations are addressed in document II-B to the CAR.
Partition coefficient (log P_{OW}) (state temperature)	99.3%w/w: Log P_{ow}= 4.6 at 25°C (in distilled water with no pH control) No pH effect anticipated as deltamethrin cannot dissociate under environ-mentally relevant pH
Hydrolytic stability (DT_{50}) (state pH and temperature)	See chapter 4 below pH_____:

Dissociation constant	Not relevant as deltamethrin does not contain any functional groups that may dissociate within the environmentally relevant pH range.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	In hexane (99.5%w/w): λ_{max} [nm] ε ($l.mol^{-1}.cm^{-1}$) 267.5 2300 271 2300 278 2400 Very low to no absorption by deltamethrin above 295-300 nm.
Photostability (DT_{50}) (aqueous, sunlight, state pH)	See chapter 4 below
Quantum yield of direct phototransformation in water at Σ > 290 nm	See chapter 4 below
Flammability	Flammability Not highly flammable (100.2%w/w) Auto-flammability Not auto-flammable (100.2%w/w)
Explosive properties	Not explosive

Classification and proposed labelling

with regard to physical/chemical data	None
with regard to toxicological data	T; R23/25
with regard to fate and behaviour data	None
with regard to ecotoxicological data	N; R50/53

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	HPLC-UV and chiral HPLC-UV
Impurities in technical active substance (principle of method)	See Confidential Annex to CAR

Analytical methods for residues

Soil (principle of method and LOQ)	LC-MS/MS using 1 transition (LOQ 0.1 µg/kg)
Air (principle of method and LOQ)	GC-ECD for quantification and GC-MS for confirmation (LOQ 0.27 µg/m^3)
Water (principle of method and LOQ)	<u>Drinking water</u> GC-ECD for quantification and confirmation (LOQ 0.05 µg/l) LC-MS/MS using 1 transition (LOQ 5.9 ng/l) GC-ECD for quantification and GC-MS/MS for confirmation (LOQ 3 ng/l) <u>Surface water</u> GC-ECD for quantification and GC-MS/MS for confirmation (LOQ 3 ng/l)
Body fluids and tissues (principle of method and LOQ)	<u>Tissues</u> GC-ECD for quantification and confirmation (LOQ 0.02 mg/kg for milk, eggs, meat, fat, liver and kidney) <u>Fluids</u> GC-MS for quantification and confirmation (LOQ 200 µg/l for whole blood) GC-MS multi-method for pyrethroids for quantification (LOQ 20 ng/l for whole blood)
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required as the intended uses will not result in significant residues when the label instruction is followed. However two methods are provided which can be used in case of suspected contamination: GC-ECD for quantification (LOQ 0.02 mg/kg for rice, flour, bread, meat, candy, butter, banana cream pie and

	lettuce) LC-MS/MS (LOQ 0.01 mg/kg for edible materials and 0.05 mg/kg for non-edible materials for barley, broccoli, corn, melon, lettuce, olive, pepper, sugar beet, tobacco, tomato, wheat and zucchini)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required as the intended uses will not result in significant residues when the label instruction is followed. However the method presented for body tissues above could be used for this purpose (to some extent also the method presented for food and feeding stuffs of plant origin).

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Fairly rapid but limited to approximately 75% (based on urinary and biliary excretion in a low oral dose and an i.v. dose study in rat).
Rate and extent of dermal absorption:	Concentrate: 1.19%; Spray dilution: 1.89% (based on *in vivo* (rat) and *in vitro* (rat and human) data). The value of 2% (maximum dermal absorption) was used in the risk assessment.
Distribution:	Widely distributed (highest levels found in fat after 7 days).
Potential for accumulation:	No evidence of accumulation, although t½ >24 h in fat.
Rate and extent of excretion:	Fairly rapid (19-47% with urine, 32-55% in faeces within 24 hrs). 7 days post-dose, 31-56% of the oral dose was excreted with the urine and 36-59% in faeces.
Toxicologically significant metabolite(s)	Parent compound and metabolites (Br_2CA and mPBacid: 3-phenoxy-benzoic acid).
Metabolism in animals	Moderately metabolised. Cleavage of ester bound, hydroxylation and conjugation.

Acute toxicity

Rat LD_{50} oral	87 mg/kg bw (females); 95 mg/kg bw (males)	R25
Rat LD_{50} dermal	>2000 mg/kg bw (both sexes)	-
Rat LC_{50} inhalation	0.6 mg/L (6 hrs, whole body, dust) (males and females combined)	R23
Skin irritation	Not irritating	-
Eye irritation	Not irritating	-
Skin sensitization (test method used and result)	Not sensitising (M&K and Buehler)	-

Repeated dose toxicity

Species/ target / critical effect	Target organ: nervous system (clinical signs of neurotoxicity in rats and dogs). Reduced bw gain at higher doses (rat, dog).
Lowest relevant oral NOAEL / LOAEL	1 mg/kg bw/day (13-week and 1-year oral studies, dog).
Lowest relevant dermal NOAEL / LOAEL	NOAEL systemic: 1000 mg/kg bw/day (21-day dermal study, rat). LOAEL local: 100 mg/kg bw/day (21-day dermal study, rat).
Lowest relevant inhalation NOAEL / LOAEL	LOAEL: 3 mg/m^3 (14-day inhalation study, rat).

Genotoxicity	No genotoxic potential (based on *in vitro* tests).
Carcinogenicity	
Species/type of tumour	No evidence of carcinogenicity in rats or mice.
lowest dose with tumours	NOEL for carcinogenicity in rats >36 mg/kg bw/day NOEL for carcinogenicity in mice >315 mg/kg bw/day.
Reproductive toxicity	
Species/ Reproduction target / critical effect	Increased pup mortality, reduced lactation index and reduced pup weight at parental toxic dose levels (rat).
Lowest relevant reproductive NOAEL / LOAEL	Parental NOAEL: 4.2 mg/kg bw/day (2-gen study, rat). Reproductive NOAEL: >18.3 mg/kg bw/day (2-gen study, rat). Offspring NOAEL: 4.2 mg/kg bw/day (2-gen study, rat).
Species/Developmental target / critical effect	Rats; No developmental toxicity at maternal toxic doses. Mice; Increased incidence of supernumerary ribs at maternal toxic doses. Rabbits; No developmental toxicity at maternal toxic doses.
Lowest relevant developmental NOAEL / LOAEL	Rat: Maternal NOAEL: 2.5 mg/kg bw/day. DevelopmentalNOAEL: >5 mg/kg bw/day. Mouse: Maternal LOAEL: 3 mg/kg bw/day. Developmental LOAEL: 3 mg/kg bw/day. Rabbit: Maternal NOAEL: 32 mg/kg bw/day. Developmental NOAEL: >32 mg/kg bw/day.
Neurotoxicity / Delayed neurotoxicity	
Species/ target/critical effect	Delayed neurotoxicity: No data- not required. Acute neurotoxicity (CD rat): neurotoxic effects (clinical signs and functional alterations noted in FOB), Mortalities and reduced bw gain at highest dose. NOAEL acute neurotoxicity (rat): 5 mg/kg bw/day Subchronic neurotoxicity (CD rat): neurotoxic effects (clinical signs and functional alterations noted in FOB). Mortalities and reduced bw at highest dose. NOAEL subchronic neurotoxicity (CD rat): 4 mg/kg bw/day

	DNT (Wistar rat): reduced pup weight, increased incidence of vocalizations in male pups and delayed onset of balanopreputial separation at maternal toxic dose.
Lowest relevant developmental NOAEL / LOAEL.	Rat: NOAEL developmental neurotoxicity in Wistar rat: 6.78 mg/kg bw/day.

Other toxicological studies

.....	The trans-deltamethrin isomer was tested for oral acute toxicity and mutagenicity (Ames test). The results of these studies showed that the acute oral toxicity of the trans-deltamethrin does not exceed the acute oral toxicity of the parent compound cis deltamethrin and no genotoxicity potential was found according to the Ames test. In a study where food commodities (covered and uncovered) were exposed to an environment in which a deltamethrin based product was applied as a general surface treatment at the dose rates of 24 and 100 mg a.s./m^2, results showed that the use of deltamethrin products will not contaminate food stuffs when spray is applied downwards.

Medical data

.....	Medical data from manufacturing, formulating and packaging plants indicate that transitory skin sensations were the most prevalent finding (paraesthesia, transient local burning, tingling, pickling sensations, itching, numbness of the facial skin – erythema in some cases). Cases of intoxications (mostly occupational due to inappropriate handling of products) have been reported. Two cases of occupational acute deltamethrin poisoning died of convulsions and another died of pulmonary oedema. No late sequeala of pyrethroid poisoning have been described in the scientific literature. There is no specific antidote for pyrethroids. Any treatment can only be symptomatic.

Summary	Value	Study	Safety factor
ADI (Acceptable daily intake)	Not required since no exposure of foodstuffs should occur during and after treatment of food handling areas with deltamethrin when product label instructions are followed.		
ARfD (Acute reference dose)	Not required since no exposure of foodstuffs should occur when product label instructions are followed, and		

	risk of contamination of drinking water is not considered.		
AEL acute (Acceptable exposure)	AEL systemic: 0.0075 mg/kg bw/day*	13-week dog study	100
AEL medium-term (Acceptable exposure)	AEL systemic: 0.0075 mg/kg bw/day*	13-week and 1-year dog studies	100
AEL long-term (Acceptable exposure)	AEL systemic: 0.0075 mg/kg bw/day*	1-year dog study	100
Drinking water limit	Not required since no exposure of foodstuffs should occur when product label instructions are followed, and risk of contamination of drinking water is not considered.		

* based on NOAEL of 1 mg/kg bw/day (corrected for oral absorption of 75%, and a safety factor of 100)

Acceptable exposure scenarios (including method of calculation)	
Professional users	Acceptable (modelling conducted according to the TNsG, Spray Model 1 "Low pressure insecticide application. Professional operators mixing and loading liquids and powders in compression applicators, and applying at 1 or 3 bar pressure as a coarse or medium spray, indoors and outdoors, overhead and downwards"). Exposure without the use of PPE represented 52% of systemic AEL and MOE was192.
Production of active substance:	No unacceptable risk anticipated due to automated closed system.
Formulation of biocidal product	No unacceptable risk anticipated due to automated closed system/ventilation semi-open system and the use of personal protective equipment.
Non-professional users	Acceptable (modelling conducted according to the TNsG consumer product spraying and dusting: model 2, Hand – held dusting applicator pack for crack and crevice). Exposure represented 0.02% of systemic AEL and MOE was 6.6×10^5.
Intended uses	Acceptable.

Secondary exposure (professional products and amateur uses)	Professional products: Acceptable Scenario 1: Calculations for a toddler re-entering a room with treated carpet. Exposure (full surface treatment) represented 24% of systemic AEL and MOE was 422. Scenario 2: Calculations for persons being exposed by inhalation during and after vacuuming of a treated carpet. Exposure of the infant, child and adult accounts for 2.8%, 2.5% and 1.6% of the systemic AEL, and MOE was 3570, 3950 and 6250, respectively. Scenario 3: Calculations for persons sleeping on a treated mattress. Exposure of the infant, child and adult accounts for 19%, 11% and 11% of the systemic AEL, and MOE was 536, 938 and 938, respectively. Scenario 4: Calculations for persons secondary exposed by laundering contaminated work clothing. Exposure represented 0.7% of systemic AEL, and MOE was 15000. Amateur uses: Acceptable (calculations for a toddler re-entering a treated terrace with bare feet). Exposure represented 2% of systemic AEL and MOE was 4386
Combined exposure	Acceptable (calculated for a pest control operator who applies the product and then returns to a home that has also been treated). Exposure represented 58% of systemic AEL and MOE was 174.
Indirect exposure (from the environment)	Low predicted exposure potential since groundwater and surface water used for drinking water are predicted to contain negligible levels of deltamethrin from its use in biocidal products.

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 5: Insignificant degradation (25°C)
	pH 7: Insignificant degradation (25°C)
	pH 8: DT_{50} = 31 days (23°C) (75 days at 12°) Metabolite: mPBaldehyde (3-phenoxybenzaldehyde)
	pH 9: DT_{50} = 2.5 days (25°C) (7 days at 12°) Metabolite: mPBaldehyde (main) and Br_2CA (trace)
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Direct (non-sensitised): $DT_{50} \geq 48$ days Indirect (sensitised): DT_{50} = 4 days, main metabolite mPBacid
Readily biodegradable (yes/no)	No
Biodegradation in seawater	Not applicable based on use pattern
Non-extractable residues	8-20 % after 84 days in water/sediment system
Distribution in water / sediment systems (active substance)	Two water/sediment systems: 22-23% (water) / 60-62% (sediment) day 0; 4-10% (water) / 84% (sediment) day 4; 0% (water) / 39-70% (sediment) day 28. Degradation DT_{50} in whole systems = 45/141 days (20°C) (corresponding to 85/267 at 12°C), (2 systems, pH water 8.0-9.1 and hence hydrolysis may have contributed to degradation observed in both systems, pH sediment 7.1/7.5). Median DT_{50} = 92 days, geomean 79 days (20°C), 151 d (12°C). Degradation DT_{90} in whole systems = 151/469 days. Dissipation DT_{50} in sediment = 55/133 days (20°C) (corresponding to 104/253 at 12°C) . All DT_{50}s above based on sum of α-S-isomer (deltamethrin) and α-R-isomer (inactive). In a higher tier mesocosm study (pH 8-9 at start, 9-10 by the end): - mean DT_{50} in water = 22.4 hours - mean DT_{50} in whole system = 31.6 hours.
Distribution in water / sediment systems (metabolites)	Two water/sediment systems: total radioactivity 37-38% (water) / 60-63% (sediment) day 0; 10-20% (water) / 75-89% (sediment) day 4; 0-0.25% (water) / 65-82% (sediment) day 28. α-R-deltamethrin (insecticidally inactive) max. 21-24% after 1-2 weeks, no other products > 10%; Br_2CA not possible to detect due to position of ^{14}C-labelling. Identification of metabolites in a microcosm study (non-key study), in water: Br_2CA as max. 13.3% of the total applied rate of deltamethrin, 7 days after the last treatment; α-R-deltamethrin (insecticidally inactive) max. 37% of

	nominal applied 180 ng/l deltamethrin, immediately after the first treatment, then decline rapidly; trans-deltamethrin (transient metabolite formed by photochemical processes) max. 14% of nominal applied 56 ng/l deltamethrin, 24 hours after the first treatment, then declined rapidly.

Route and rate of degradation in soil

Mineralization (aerobic)	64-d: 50-69% (vinyl-^{14}C), 53-65% (benzyl-^{14}C) 64-d: 62% (cyano-^{14}C), 60% (vinyl-^{14}C) 90-d: 52% (benzyl-^{14}C), 36% (gem-^{14}C) 123/128-d: 62-69% (cyano-^{14}C), 52-58% (phenoxy-^{14}C)
Non-extractable residues (aerobic)	64-d: 16-26% (vinyl-^{14}C), 18-20% (benzyl-^{14}C) 64-d: 20% (cyano-^{14}C), 21% (vinyl-^{14}C) 90-d: 18% (benzyl-^{14}C), 48% (gem-^{14}C) 123/128-d: 10-17% (cyano-^{14}C), 24-31% (phenoxy-^{14}C)
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} deltamethrin: Range: 11-27 days; geomean 17 days (4 soils, normalised to 25°C and field capacity, first order rate equation) Range: 31-74 days; geomean 48 days (4 soils, normalised to 12°C and field capacity, first order rate equation) DT_{50lab} Br_2CA: Range: 0.7-11.6 days days; geomean 2.0 days (normalised to 25°C and field capacity) Range: 2.1-32.3 days, geomean 5.6 days (normalised to 12°C and field capacity) (intrinsic degradation rate of Br_2CA alone, calculated by compartmental analysis using first-order kinetic equation using data from studies on deltamethrin on three soils and at different temperatures)
	DT_{90lab} deltamethrin (25°C, aerobic): Range: 36-88 days; geomean 57 days (4 soils)
	Major metabolite: Br_2CA max. 23% (14-d), nd day 120
	DT_{50lab} (10°C, aerobic): not required
	DT_{50lab} (20°C, anaerobic): not required
	degradation in the saturated zone: not required
Field studies (state location, range or median with number of measurements)	not required
Anaerobic degradation	not required
Soil photolysis	DT_{50} = 9 days (DT_{50} ≤ 14 days in dark control).
Non-extractable residues	16-44% (8-9 weeks), 10-44% (4-6 months)
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	Br_2CA: 36% after 30 days (but 54% in dark control)

Soil accumulation and plateau concentration	not required

Adsorption/desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	Deltamethrin: K_a: 960; 3 000; 3 790; 4 750 L/kg K_{aoc}: 204 000; 392 000; 460 000; 577 000 L/kg arithmetic mean 408 250 L/kg (n = 4) No pH dependence Br_2CA: K_a: 0.27; 0.36; 0.59 L/kg K_{aoc}: 10.10; 23.00; 43.73 L/kg, arithmetic mean 25.6 L/kg (n = 3) K_d: 0.40; 1.91; 2.51 L/kg K_{doc}: 15.16; 98.36; 234.97 L/kg No pH dependence

Fate and behaviour in air

Direct photolysis in air	Not likely to occur (absorption max. at 270 and 280 nm, very little/no absorption above 290/300 nm)
Quantum yield of direct photolysis	not required
Photo-oxidative degradation in air	DT_{50}: 16 hours (Atkinson, AOPWIN-model)
Volatilization	Wind-tunnel study: negligible volatilization from soil

Monitoring data, if available

Soil (indicate location and type of study)	not required
Surface water (indicate location and type of study)	not required
Ground water (indicate location and type of study)	not required
Air (indicate location and type of study)	not required

Chapter 5: Effects on Non-target Species

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

Species	Time-scale	Endpoint	Toxicity
Fish			
Oncorhynchus mykiss (Rainbow trout)	96-h	LC_{50}	0.26 µg/l (m)
Pimephales promelas (Fathead minnow)	260-day	NOEC	0.017 µg/l (m)

Invertebrates			
Gammarus fasciatus (freshwater amphipod)	96-h	LC_{50}	0.0003 µg/l (m)
Daphnia magna (water flea)	21-d	NOEC	0.0041 µg/l (m)
Chironomus riparius (midge)	28-d	NOEC	0.0035 µg/l (m)
Algae			
Chlorella vulgaris	96-h	E_rC_{50}	> 0.47mg/l
Microorganisms			
Activated sludge	3-h	EC_{50}	> 300 µg/l
Higher tier studies (mesocosm study + bioassay)			
Zooplankton, phytoplankton, macro-invertebrates, including sediment dwelling organisms	Long-term	NOEC	0.0048 µg/l (n)
Gammarus pulex (freshwater amphipod)	21-d	$NOEC_{mortality}$	0.009 µg/l (m)

Effects on earthworms or other soil non-target organisms

Acute toxicity to *Eisenia fetida*	LC_{50} (14-d) > 1290 mg/kg soil (dry weight)
Reproductive toxicity to *Hypoaspis aculeifer*	Br_2CA: $NOEC_{mortality}$ 10 mg/kg soil (dry weight); $NOEC_{Reproduction}$ > 1000 mg/kg soil (dry weight)

Effects on soil micro-organisms

Nitrogen mineralization	at 0.5 mg/kg dw soil, none or only slight deviations from controls
Carbon mineralization	at 0.5 mg/kg dw soil, none or only slight deviations from controls

Effects on terrestrial vertebrates

Acute toxicity to mammals	See Section 3 on the toxicology of deltamethrin in laboratory animals
Acute toxicity to birds	LD_{50} > 2250 mg/kg bw (*Colinus virginianus*) LD_{50} > 4640 mg/kg bw (*Anas platyrhynchos*)
Dietary toxicity to birds	LC_{50} > 5620 ppm (*C. virginianus*)

	LC_{50} 8039 ppm (*A. platyrhynchos*)
Reproductive toxicity to birds	NOEC > 450 ppm/> 55 mg/kg bw/d (*C. virginianus* and *A. platyrhynchos*)

Effects on honeybees

Acute oral toxicity Acute contact toxicity	No data, the exposure of deltamethrin to honeybees is expected to be very limited.

Effects on other beneficial arthropods

Acute oral toxicity Acute contact toxicity Acute toxicity to ……..	No data, the exposure of deltamethrin to beneficial arthropods is expected to be very limited, and data is not required.

Bioconcentration

Bioconcentration factor (BCF)	310, 2800 & 1400 as total ^{14}C for edible, non-edible and whole body tissue (*Lepomis macrochirus*). Major part of ^{14}C consisted of deltamethrin. $BCF_{earthworm}$ was estimated to be 483
Depuration time (DT_{50}) (DT_{90})	Clearance time: 4.3 days for the whole body tissue. By day 14 of the depuration period 76% of the ^{14}C-residues present on the last day of exposure had been eliminated from the whole body tissue.
Level of metabolites (%) in organisms accounting for > 10 % of residues	Not measured

Chapter 6: Other End Points

Appendix II: List of Intended Uses

Summary of intended uses[7]

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks
				Type	Conc. of a.s.	Method kind	Number min - max	Application interval	g a.s./L min - max	water L/m^2 min - max	g a.s./m^2 min - max	
Crawling and flying insects	EU	K-Othrine WG 250	Indoors: black ants, bedbugs, fleas, earwigs, carpet beetles, booklice, and cockroaches, as well as spiders and woodlice. Flying insects when at rest (e.	water dispersible granule	250 g/kg	spray applications indoors for professional users only	1 - 4	1 month (low dose rate of 6.25 mg/m^2) 3 months (high dose rate of 12.5	0.0625 - 0.25g as/l based on 12.5mg/ m^2 dose at 5 L/100m^2, and 6.25mg/ m^2 in the	0.05-0.1 L/m^2	0.00625-0.0125	Data were provided and accepted to support this use

7 adapted from: EU (1998a): European Commission: Guidelines and criteria for the preparation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EC (Article 5.3 and 8,2). Document 1663/VI/94 Rev 8, 22 April 1998

			g. flies and mosquitoes)					mg/m^2)	10 L/100m^2 dilution for porous surfaces			
Crawling and flying insects	EU	K-Othrine SC 7.5, and SC 26.25	Indoors: black ants, bedbugs, fleas, earwigs, carpet beetles, booklice, and cockroaches, as well as spiders and woodlice. Flying insects when at rest (e. g. flies and mosquitoes)	suspension concentrate	7.5 and 26.25 g/L, respect-tively	Spray applications indoors for professional users only	1 - 4	1 month (low dose rate of 6.25 mg/m^2) 3 months (high dose rate of 12.5 mg/m^2)	0.0625 – 0.25	0.05 L/m^2	0.00625-0.0125	Data were provided and accepted to support this use
Crawling insects	EU	K-Othrine DP 0.05	ants outdoors	dry powder	0.5 g/kg	As neat product directly around the nest entrance, by amateurs	Up to 5 treat-ments/ property and season	Once per nest	-	-	0.001 g /nest	Data were provided and accepted to support this use

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "Y" in the "Data Protection Claimed" column of the table below. For studies marked Yes(i) data protection is claimed under Article 12.1(c) (i), for studies marked Yes(ii) data protection is claimed under Article 12.1(c) (ii). These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

Section No / Reference No	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company** **Report No.** **GLP (where relevant)** **(Un)Published**	**Data Protection Claimed** **Y/N**	**Owner**
IIIA 2.7/01	Bascou J.P.	2006	Composition Statement – Technical material Bayer CropScience AG, Germany Report No: M-270681-02-1 30 May 2006 GLP n/a. Unpublished – CONFIDENTIAL	Y	Bayer Crop-Science AG
IIIA 2.7/02 2.8/04	Cichy, M. & Junker, H	2010b	Material Accountability of technical Deltamethrin (AE F032640) – Enantiomeric Purity Bayer CropScience AG, Germany Laboratory Project ID: Study No. PA10/085 Document M-398297-01-1 22 December 2010 GLP. Unpublished - CONFIDENTIAL	Y	Bayer Crop-Science AG
IIIA 2.10.1.2/01	Leng, G.; Berger-Preiss, E.; Levsen, K.; Ranft, U.; Sugiri, D.; Hadnagy, W.; Idel, H.	2005	Pyrethroids used indoors – ambient monitoring of pyrethroids following a pest control operation Journal: International Journal of Hygiene and Environmental Health, Volume: 208, Issue: 3, Pages: 193-199, Year: 2005 Report No.: M-259585-01-1 2005 GLP n/a. Published	N	Public domain
IIIA 3.1.1/01 3.1.2/01	Smeykal H.	2002	Melting point/melting range - Deltamethrin substance technical Axiva GmbH, Frankfurt, Germany Bayer CropScience AG Report No.: C025764 14 August 2002 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 3.1.3/01	Bourgogne M.; Rexer K.	2000	Determination of the density - Deltamethrin substance, technical Aventis CropScience GmbH Bayer CropScience AG Report No.: C010328 23 October 2000 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA3.2/01	Yoder S.J.	1991a	Deltamethrin A.I. - Determination of vapour pressure Dep. Anal. Serv. Ricerca, USA Bayer CropScience AG Report No.: A47916 12 September 1991 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 3.2.1/01	Grelet D.	1995	Deltamethrin: Henry's law constant Roussel-Uclaf Bayer CropScience AG Report No.: A70747 21 March 1995 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 3.3.1/01 3.3.2/01 3.3.3/01	Thomas E.A.; Sweetapple G.G.	1990	Deltamethrin active ingredient: Determination of color, physical state, odor, density and pH Ricerca, Inc USA Bayer CropScience AG Report No.: A70752 29 March 1990 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 3.4/01	Devaux Ph.	1993	Deltamethrin: Structural analysis AgrEvo UK Ltd. Bayer CropScience AG Report No.: A70764 23 November 1993 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 3.5/01	Jordan G. and Muehlberger B.	2000a	Solubility in water at 20 degrees C – Deltamethrin substance technical Aventis Research & Technologies GmbH & Co. KG, Frankfurt, Germany Bayer CropScience AG Report No.: C009221 02 August 2000 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 3.5/02	Yoder J.S.	1990	Deltamethrin A.I. - Determination of solubility in water, n-Octanol, and Xylenes Dep. Anal. Serv. Ricerca, USA Bayer CropScience AG Report No.: A45109 04. October 1990 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 3.7/01	Jordan G. and Muehlberger B.	2000 b	Solubility in organic solvents at 20 degrees C Deltamethrin substance technical Aventis Research & Technologies GmbH, Germany Bayer CropScience AG Report No.: C009220 02 August 2000 GLP. Unpublished	Y	Bayer Crop-Science AG
(IIA 3.9)	Eriksson P.	1997	Developmental neurotoxicity of environmental agents in the neonate. NeuroToxicology 18(3): 719-726 Published.	N	Public domain
(IIA 3.9)	Eriksson P; Fredriksson A.	1991	Neurotoxic effects of two different pyrethroids, bioallethrin and deltamethrin, on immature and adult mice: Changes in behavioural and muscarinic receptor variables. Toxicol Appl Pharmacol 108: 78-85 Published.	N	Public domain
(IIA 3.9)	Eriksson P; Nordberg A.	1990	Effects of two pyrethroids, bioallethrin and deltamethrin on subpopulations of muscarinic and nicotinic receptors in the neonatal mouse brain. Toxicol Appl Pharmacol 102: 456-463. Published.	N	Public domain
(IIA 3.9)	[redacted]	2006	A pilot study to verify the exposure of offspring during lactation to technical grade deltamethrin administered via the diet to Wistar rats. [redacted] Report No.: M-276949-01-1 3 April 2006 GLP. Unpublished.	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
(IIA 3.9)	Muhammad B.Y.; Ray D.E.	1997	Report on the potential developmental neurotoxicity of pyrethroids in mice. MRC Toxicology Unit, Leicester, U.K. Doc. A74192 Non GLP. Unpublished.	N	Bayer Crop-Science AG
(IIA 3.9)	Sheets L.P; Doherty J.D.; Law M.W.; Reiter L.W.; Crofton K.M.	1994	Age-dependent differences in the susceptibility of rats to deltamethrin. Toxicol Appl Pharmacol 126: 186-190. Published.	N	Public domain
IIIA 3.9/01	Yoder S.J.	1991 b	Deltamethrin A.I. - Determination of Octanol/ Water partition coefficient Dep. Anal. Serv. Ricerca, USA Bayer CropScience AG Report No.: A47915 12 September 1991 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA3.10/01	Smeykal H.	2002	Melting point/melting range - Deltamethrin substance technical Axiva GmbH, Frankfurt, Germany Bayer CropScience AG Report No.: C025764 14 August 2002 GLP. Unpublished	Y	Bayer Crop-Science AG
(Doc. IIA 3.11 & 4.1.1.2.3)	Schanné C. et al.	2001	[14C]-Deltamethrin Formulated as Emulsifiable Concentrate (25 g/L Deltamethrin): Outdoor Aquatic Microcosm Study of the Ecological Effects and Environmental Fate Springborn Laboratories (Europe) AG, Switzerland Aventis CropScience GmbH, Germany Report No. C015510 21 September 2001 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 3.11/01	Hoffmann H.	1996a	Deltamethrin substance, technical: Flammability (solids) Hoechst AG Bayer CropScience AG Report No.: A70970 19 January 1996 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 3.11/02	Hoffmann H.	1996 b	Deltamethrin substance, technical: Auto-flammability (solids - determination of relative self-ignition temperature) Hoechst AG Bayer CropScience AG Report No.: A70971 19 January 1996 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 3.15/01	Smeykal H.	2000	Explosive properties - Deltamethrin substance, technical Axiva GmbH, Frankfurt, Germany Bayer CropScience AG Report No.: C010909 15 December 2000 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 3.16/01	Smeykal H.	2005	Oxidizing properties - Deltamethrin (AE F032640); substance, technical Siemens AG, Frankfurt, Germany Bayer CropScience AG Report No.: C047050 24 February 2005 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 3.17/01	Sanders J.M.	1991	Deltamethrin A.I.: Determination of stability Ricerca, Inc USA Bayer CropScience AG Report No.: A70762 01 October 1991 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 3.17/02	Kerestman S.G.	1991	Deltamethrin a.i.: Determination of corrosion characteristics Ricerca, Inc USA Bayer CropScience AG Report No.: A70751 04 September 1991 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 4.1/01	Feucht G.; Ruppmann G.	2003	Validation of the analytical method AL003/99-2 for the determination of AE F032640 (active ingredient) in technical AE F032640 Bayer CropScience GmbH, Germany Bayer CropScience AG Report No.: C032557 24 March 2003 GLP. Unpublished-CONFIDENTIAL	Y	Bayer Crop-Science AG
IIIA 4.1/02	Feucht G.; Michel A.	2003	Analytical method Quantification of AE F032640 (deltamethrin) in formulations (DP, EC, EG, EW, SC, TB, WDG, WP) and technical grade active ingredient by high performance liquid chromatography (HPLC) Bayer CropScience GmbH, Frankfurt, Germany Bayer CropScience AG Report No.: C033242 17 July 2003 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 4.1/03	Cichy, M. & Junker, H.	2010c	Analytical method Determination of the enantiomeric purity of AE F032640 in technical grade and pure Deltamethrin by high performance liquid chromatography (HPLC) Code AE F032640 Bayer CropScience AG, Germany Report No.: AM028810FP2 Document M-398206-01-1 Non-GLP, Unpublished-CONFIDENTIAL*	Y	Bayer Crop-Science AG
IIIA 4.1/04	Cichy, M. & Junker, H.	2010 d	Validation of the analytical method AM028810FP2 Determination of the enantiomeric purity in technical grade and pure Deltamethrin (AE F032640) by high performance liquid chromatography (HPLC) Bayer CropScience AG, Germany Laboratory Project ID: PA10/079 Document M-398212-01-1 GLP, Unpublished-CONFIDENTIAL*	Y	Bayer Crop-Science AG
IIIA 4.2.1/01	Brumhard B.	2005a	Analytical method 00877 for the determination of total residues of deltamethrin (AE F032640) in / on soil and sediment by HPLC-MS/MS Bayer CropScience AG Report No.: C047210 04 March 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 4.2.1/02	Grigor A.	1991	Analytical method for the determination of deltamethrin, trans-deltamethrin and degradates in soil by gas chromatography Chemalysis Inc., USA Bayer CropScience AG Report No.: A48622 26 July 1991 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 4.2.2/01	Class T.	1994	Validation of an analytical method for the determination of deltamethrin in air (Method and validation) PTRL Europe, Germany Bayer CropScience AG Report No.: C012850 01 March 1994 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 4.2.2/02	Class T.	2001a	Validation of an Analytical Method for the Determination of Deltamethrin in Air PTRL Europe, Germany Bayer CropScience AG Report No.: B003367 29 June 2001 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 4.2.3/01	Brumhard B.	2005 b	Analytical method 00886 for the determination of total residues of deltamethrin (AE F032640) in surface water by HPLC-MS/MS Bayer CropScience AG Report No.: C047388 04 March 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 4.2.3/02	Martens R.	1999	Enforcement method and validation for water by GC - Deltamethrin, endosulfan Hoechst Schering AgrEvo GmbH, Germany Bayer CropScience AG Report No.: C005528 05 October 1999 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 4.2.3/03	Class T.	2001 b	Analytical Method for the Determination of Deltamethrin in Surface Water PTRL Europe, Germany Bayer CropScience AG Report No.: B003535 31 October 2001 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIA 4.2.4	Lautraite S.	2006 b	Deltamethrin – Assessment of Deltamethrin (pyrethroid insecticide) in relation to endocrine disruption Bayer CropScience SA, Sophia Antipolis, France Bayer CropScience AG Report No.: M-263733-01-1 16 January 2006 GLP n/a. Unpublished	Y	Bayer Crop-Science AG
IIIA 4.2.4/01	Martens R.	2000	Validation of analytical method DGM F01/97-1 for foodstuff of animal origin (milk, eggs, meat, fat, liver, kidney) - Deltamethrin Aventis CropScience GmbH, Germany Bayer CropScience AG Report No.: C009558 06 September 2000 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 4.2.4/02	Haines B.; Tauber R.	2001	Independent Laboratory Validation for the Determination of Residues of Deltamethrin in Lettuce, Oranges, Milk and Fat and Endosulfan in Lettuce and Oranges Using Method DGM F01/97-1 Xenos Laboratories Inc. Bayer CropScience AG Report No.: B003259 29 March 2001 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 4.2.4/03	Frenzel T.; Sochor H.; Speer K.; Uihlein M.	1998	Rapid multimethod for verification and determination of toxic pesticides in whole blood by means of capillary GC-MS Hoechst Schering AgrEvo Bayer CropScience AG Report No.: A67646 12 August 1998 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 4.2.4/04	Frenzel T.; Sochor H.; Speer K.; Uihlein M.	2000	Rapid multimethod for verification and determination of toxic pesticides in whole blood by means of capillary GC-MS Journal: Journal of Analytical Toxicology, Volume: 24, Issue: 5, Pages: 365;371, Year: 2000 Report No.: C011634 July/August 2000 Non GLP. Published	N	Public domain
IIIA 4.2.4/05	Brennecke R.	1998	Independent laboratory validation of method EM F-05/98-0 "Rapid multimethod for verification and determination of toxic pesticides in whole blood by means of capillary GC-MS" according to European Guidelines Bayer CropScience AG Report No.: C002476 21 December 1998 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 4.2.4/06	Tillier C. and Supatto F.	1989	RU 22974: Assay procedure in plasma Roussel-Uclaf Bayer CropScience AG Report No.: A70887 21 December 1989 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA4.2.4/07	Ramesh A. and Ravi P.E.	2004	Negative Ion Chemical Ionization-Gas Chromatographic-Mass Spectrometric Determination of Residues of Different Pyrethroid Insecticides in Whole Blood and Serum Journal of Analytical Toxicology, Volume 28, Nov/Dec 2004, 660-666 Document No.: M-282150-01-1 November/December 2004 Non GLP. Published	N	Public domain
IIIA 4.3/01	Silvoy J.S.	1993a	Determination of residues resulting from a single application of LX1217-04 (K-Othrine SC 5.0) as a general surface, crack and crevice, and spot treatment spray in simulated food processing, service and manufacturing areas Appendix C – Analytical Final Report Bayer CropScience AG Report No.: A97690 08 April 1993 Non GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 4.3/02	Zimmer D. and Philipowski C.	2005	Residue Analytical Method 00855/M002 for the Determination of Residues of cis-deltamethrin (AE F032640) in/on pepper (fruit), zucchini (fruit), tomato (fruit), olive (fruit), melon (fruit, pulp), sugarbeet (body, leaf with root collar), tobacco (leaf green, leaf cured), lettuce (head) and broccoli (curd), wheat and barley (rest plant, ear, grain and straw) and corn (plant without root, cob without husk and kernel) by HPLC-MS/MS Bayer CropScience AG, BCS-D-ROCS - Germany Report No.: C044300 05 October 2004 Unpublished	Y	Bayer Crop-Science AG
IIIA 5.3.1/01	Behrenz, W.; Elbert, A.; Fuchs, R.	1983	Cyfluthrin (FCR 1272), a new pyrethroid with long-lasting activity for the control of public health and stored-product pests Journal: Bayer Pflanzenschutz-Nachrichten, Volume: 36, Pages: 127-176, Year: 1983 Report No.: M-075183-01-2 1983 Non GLP. Published	N	Public Domain
IIIA 5.3.1/02	Michaelides, P. M.; Adams, A.; Welsh, J. L.; Bowron, M. J. ; Lucas, J. R.; Slatter, R. S.	1993	Comparative activity of beta-Cyfluthrin (Bulldock) Roussel Uclaf Environmental Health Ltd.; France Bayer CropScience AG Report No.: M-261596-01-1 30 June 1993 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 5.3.1/03	Anon.	1982	Deltamethrin monograph - Applications of deltamethrin Bayer CropScience AG, Report No.: M-255452-01-2 18 October 1982 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 5.7/01	Anon.	1987	Insecticide/acaricide resistance: survey and recommendations by industry FRAC/IRAC Newsletter Report No.: M-001507-01-1 December 1987 GLP n/a. Published	N	Public domain
IIIA5.7/02	Anon.	1992	Vector Resistance to Pesticides Fifteenth Report of the WHO Expert Committee on Vector Biology and Control, TRS 818, 1992 Report No.: M-267730-01-1 1992 Non GLP. Published	N	Public domain
IIIA 5.7/03	Anon.	2000	Guidelines for preventing and managing insecticide resistance in the peach-potato aphid, *Myzus persicae* Insecticide Resistance Action Group Report No.: M-041872-01-1 February 2000 GLP n/a. Published	N	Public domain
IIIA 5.7/04	Staetz	2004	Insecticide Mode of Action Classification: A Key to Insecticide Resistance Management (v.3.3.2) Insecticide Resistance Action Committee (IRAC International) Report No.: M-267712-01-1 2004 GLP n/a. Published	N	Public domain

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 5.7/05	Brogdon and McAllister	1998	Insecticide Resistance and Vector Control Emerging Infectious Diseases; Vol. 4 No. 4, http://www.cdc.gov/ncidod/EID/vol4no4/brogdon.htm Report No.: M-267737-01-1 December 1998 GLP n/a. Published	N	Public domain
IIIA 6.1.1/01	[redacted]	1996	Acute oral toxicity study of Deltamethrin in albino rats [redacted] Report No.: A55812 06 August 1996 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.1.2/01	[redacted]	2005	Deltamethrin technical - Acute toxicity in the rat after dermal application [redacted] Report No.: M-258954-01-1 06 October 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.1.3/01	[redacted]	1978	RU 22974 - Acute inhalation toxicity in rats. 6 hour LC 50 [redacted] Report No.: A28960 15 May 1978 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.1.3/02	[redacted]	1990	Acute inhalation toxicity evaluation of deltamethrin in rats [redacted] Report No.: A70770 09 June 1990 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.1.4/01	[redacted]	2005a	Deltamethrin technical - Acute skin irritation/corrosion on rabbits [redacted] Report No.: M-260123-01-1 27 October 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.1.4/02	[redacted]	2005 b	Deltamethrin technical - Acute eye irritation on rabbits [redacted] Report No.: M-260858-01-1 18 November 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.1.5/01	[redacted]	1977	RU22974 - decamethrine; Decis technical - Roussel Uclaf. Sensitization test in the guinea pig [redacted] Report No.: A28978 26 September 1977 Non GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 6.1.5/02	[redacted]	2005	Deltamethrin technical (Project: Deltamethrin technical) - Study for the skin sensitization effect in guinea pigs (Buehler patch test) [redacted] Report No.: M-261562-01-1 18 November 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.2.1/01	[redacted]	1990	Metabolism of 14C-deltamethrin in rats [redacted] Report No.: A70824 09 July 1990 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA6.2.1/02	[redacted]	1993	(14C-Benzyl)-deltamethrin: Distribution - Kinetics and excretion after single intravenous administration to female rats [redacted] Report No.: A51513 05 August 1993 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.2.2/01	[redacted]	2003	(14C)-Decis EW 15 - In vitro dermal penetration study using rat skin [redacted] Report No.: C037106 19 November 2003 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.2.2/02	[redacted]	2003	(14C)-Decis EC 25 - Comparative in vitro dermal penetration study using human and rat skin [redacted] Report No.: C037107 13 October 2003 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA6.2.2/03	[redacted]	2004	(14C)- Deltamethrin in vivo dermal absorption study in the male rat [redacted] Report No.: C037108 15 January 2004 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.3.2/01	[redacted]	1993	21-day dermal toxicity study in rats with deltamethrin technical. [redacted] Report No.: A50968 09 April 1993 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.3.3/01	[redacted]	1978	RU 22974 (Decis) - Inhalation toxicity study in rats; 14 x 6 hour exposures over a period of 3 weeks [redacted] Report No.: A41948 19 October 1978 Non GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 6.4.1/01	[redacted]	1977	RU 22974: Assessment of toxicity to rats by oral administration for 13 weeks (followed by a 4-week withdrawal period) [redacted] Report No.: A70872 21 March 1977 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.4.1/02	[redacted]	1991a	Deltamethrin toxicity studies in rat by dietary administration for 13 weeks with a 4-week recovery period (3 volumes) [redacted] Report No.: A70875 03 July 1991 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.4.1/03	[redacted]	1977	RU 22974 - Oral toxicity study in beagle dogs (repeated dosage for 13 weeks followed by a 20-week observation period) [redacted] Report No.: A70871 09 June 1977 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.4.1/04	[redacted]	1991 b	Deltamethrin: Oral toxicity study in beagle dogs (repeated dosage for 13 weeks with a 4-week recovery period) [redacted] Report No.: A70874 08 July 1991 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.5/01	[redacted]	1993	Deltamethrin (technical): Toxicity to dogs by repeated oral administration for 52 weeks [redacted] Report No.: A70808 21 October 1993 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.6.1/01	[redacted]	2005	Deltamethrin: reverse mutation test in bacterial system [redacted] Report No.: M-253266-01-2 20 April 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.6.2/01	[redacted]	1989	Chromosome aberration assay of deltamethrin in Chinese hamster ovary [redacted] Report No.: A98126 23 February 1989 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.6.3/01	[redacted]	1989	Unscheduled DNA synthesis of deltamethrin in rat primary hepatocytes [redacted] Report No.: A70853 13 March 1989 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 6.7/01	[redacted]	1995	Deltamethrin (technical) - Potential tumorigenic and toxic effects in prolonged dietary administration to rats [redacted] Report No.: A56161 11 December 1995 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.7/02	[redacted]	1995	Deltamethrin technical: 97-week carcinogenicity study by oral route (dietary admixture) in mice [redacted] Report No.: A70820 26 December 1995 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA6.8.1/01	Kavlock R.; Chernoff N.; Baron R.	1979	Toxicity studies with decamethrin, a synthetic pyrethroid insecticide Journal: Journal of Environmental Pathology and Toxicology, Issue: 2, Pages: 751;765, Year: 1979 Report No.: A20968 1979 Non GLP. Published	N	Public domain
IIIA 6.8.1/02	[redacted]	1990	Developmental toxicity study of deltamethrin in rats [redacted] Report No.: A70869 06 July 1990 GLP. Unpublished	Y	Bayer Crop-Science AG
A6.8.1/03	[redacted]	2001	Prenatal developmental toxicity study by oral route (gavage) in rabbits - Deltamethrin [redacted] Report No.: C017345 14 November 2001 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.8.2/01	[redacted]	1992	Reproductive effects of deltamethrin administered orally in diet to Crl: CD BR VAF/Plus rats for two generations. (Vol.1/4) [redacted] Report No.: A70863 17 January 1992 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.9.1/01	[redacted]	1998a	An acute neurotoxicity study of deltamethrin in rats [redacted] Report No.: A74318 18 March 1998 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.9.1/02	Sargent D.; Heusel R.	2001	Aventis CropScience Response to RMS Review of the Acute Neurotoxicity Study Bayer CropScience AG Report No.: B003436 30 August 2001 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.9.2/01	[redacted]	1998 b	A subchronic (13-week) neurotoxicity study of deltamethrin in rats [redacted] Report No.: A74317 19 March 1998 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 6.9.3/01	[redacted]	2006	A developmental Neurotoxicity Screening Study with Technical Grade Deltamethrin in Wistar Rats [redacted] Report No.: 201469 (M-270180-01-1) 03 Arpil 2006 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.11/01	[redacted]	1992	Acute Intravenous Toxicity Study with Deltamethrin (Preparation with PEG 300) in Rats [redacted] Report No.: A49669 15 June 1992 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.11/02	[redacted]	1976	RU22974. An acute toxicity study in the mouse and rat by the intraperitoneal route [redacted] Report No.: A95064 30 March 1976 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA6.12.1/01	He F.; Sun J.; Han K.; Wu Y.; Yao P.; Wang S.; Liu L.	1988	Effects of pyrethroid insecticides on subjects engaged in packaging pyrethroids Journal: British Journal of Industrial Medicine, Volume: 45, Pages: 548;551, Year: 1988 Report No.: A70850 1988 GLP n/a. Published	N	Public Domain
IIIA 6.12.1/02	Wang S.; Zheng Q.; Geng T.; Luo Y.	1988	Industrial hygiene survey among workers exposed to deltamethrin during packing Inst. of Occupational Medicine, Beijing, China Bayer CropScience AG Report No.: A71239 01 January 1988 GLP n/a. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.12.1/03	Boggio M.	1994	Données médicales concernant la deltamethrine Roussel-Uclaf Bayer CropScience AG Report No.: A70883 18 November 1994 GLP n/a. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.12.1/04	Hermouet C.	1994	Cutaneous subjective sensations: Pyrethroids handling in [redacted] France for 10 years. Report from occupational medical survey [redacted] Report No.: A70823 09 August 1994 GLP n/a. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.12.1/05	Steffens W.	2004a	Occupational medical experiences with Deltamethrin (K-Othrine WG 250(R)) [redacted] Report No.: C044736 06 January 2004 GLP n/a. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.12.1/06	Hamid, W. *et al.*	2005	Occupational medical experiences with deltamethrin [redacted] Report No.: M-266323-01-1 21 June 2005 GLP n/a. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 6.12.1/07	Boucaud, B.; Vaissiere	2006	Occupational medical experiences with Deltamethrine technical [redacted] Report No.: M-264800-01-1 17 January 2006 GLP n/a. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.12.2/01	Hewson R.T.; Burgess J.E.	1981	An operator study with deltamethrin including measurements of nerve conduction times Hoechst UK Bayer CropScience AG Report No.: A41943 01 November 1981 GLP n/a. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.12.2/02	Jouglard J.; Boulet O.	1987	Bilan du Decis dans l'activité du Centre anti-poisons de Marseille Centre Anti-Poisons de Marseille - France Bayer CropScience AG Report No.: A71237 01 January 1987 GLP n/a. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.12.2/03	Shujie Wang; Qinglang Zheng; Lan Yu; Bohong Xu; Yurui Li	1988	Health Survey among Farmers Exposed to Deltamethrin in the Cotton Fields Journal: Ecotoxicology and Environmental Safety, Issue: 15, Pages: 1;6, Year: 1988 Report No.: A41945 1988 GLP n/a. Published	N	Public domain
IIIA 6.12.2/04	Yao P.; Li Y.; Ding; Y.; He F.	1992	Biological monitoring of deltamethrin in sprayers by HPLC method Journal: Journal of Hygiene, Epidemiology, Microbiology and Immunology, Volume: 36, Issue: 1, Pages: 31;36, Year: 1992 Report No.: A71232 1992 GLP n/a. Published	N	Public domain
IIIA 6.12.2/05	Chataignier D.; Garnier R.	1995	Intoxications par la deltamethrine: 84 cas notifies au Centre Anti Poisons de Paris de 1988 a 1992 Centre Anti-Poisons de Paris, France Bayer CropScience AG Report No.: A72704 1995 GLP n/a. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.12.4/01	Leng, G.; Ranft, U.; Suigiri, D.; Hadnagy, W.; Berger-Preiss, E.; Idel, H.	2003	Pyrethroids used indoors - Biological monitoring of exposure to pyrethroids following an indoor pest control operation Journal: International Journal of Hygiene and Environmental Health, Volume: 206, Pages:1-8, Year: 2003 Report No.: M-258943-01-1 2003 GLP n/a. Published	N	Public domain
IIIA 6.12.4/02	Hadnagy, W.; Leng, G.; Sugiri, D.; Ranft, U.; Idel, H.	2003	Pyrethroids used indoors - Immune status of humans exposed to pyrethroids following a pest control operation - a one year follow-up study Journal: International Journal of Hygiene and Environmental Health, Volume: 206, Issue: 2, Pages: 93-102, Year: 2003 Report No.: M-259521-01-1 2003 GLP n/a. Published	N	Public domain

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 6.12.5/01	He F.; Wang S.; Liu L.; Chen S.; Zhang Z.; Sun; J.	1989	Clinical manifestations and diagnosis of acute pyrethroid poisoning Journal: Archives of Toxicology, Volume: 63, Pages: 54;58, Year: 1989 Report No.: A71235 1989 GLP n/a. Published	N	Public domain
IIIA 6.12.5/02	Steffens, W.	2004 b	Global QHSE - Intoxication treatment database - Deltamethrin Bayer CropScience AG Report No.: M-258948-01-1 07 October 2004 GLP n/a. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.12.6/01	Lisi P.	1992	Sensitization risk of pyrethroid insecticides. Journal: Contact Dermatitis, Volume: 26, Pages: 349;350, Year: 1992 Report No.: A70889 1992 GLP n/a. Published	N	Public domain
IIIA 6.12.7/01	Hermouet C.	1992	Traitement de l'intoxication aiguë a la deltaméthrine par l'atropine et/ou le diazepam. Roussel-Uclaf Bayer CropScience AG Report No.: A70988 09 December 1992 GLP n/a. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.12.7/02	Raynaud C.	1992	Lettre interne sur l´efficacité des médicaments et crèmes différentes chez des gens avec des paresthesia Roussel-Uclaf Bayer CropScience AG Report No.: A70989 21 September 1992 GLP n/a. Unpublished	Y	Bayer Crop-Science AG
IIIA6.12.7/03	Dumont C.; Laurent J.	1979	Recherche d'antagonistes des effets neurotoxiques aigus du RU 22974 Roussel-Uclaf Bayer CropScience AG Report No.: A72737 30 January 1979 GLP n/a. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.12.7/04 6.12.8/01	Steffens, W.	2004 b	Global QHSE - Intoxication treatment database - Deltamethrin Bayer CropScience AG Report No.: M-258948-01-1 07 October 2004 GLP n/a. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.14/01	Lautraite, S.	2006	Deltamethrin - Statement on alpha-R and trans-deltamethrin isomers toxicity Bayer CropScience SA, Sophia Antipolis, France Bayer CropScience AG Report No.: M-264782-01-1 25 January 2006 GLP n/a. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.14/02	[redacted]	2004	Acute toxicity in the rat after oral administration [redacted] Report No.: C039758 09 February 2004 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 6.14/03	[redacted]	2004	AE 0035073 00 1B97 0001 - Salmonella/ microsome test - Plate incorporation and preincubation method [redacted] Report No.: C040291 02 March 2004 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 6.15/01	Silvoy J.S.	1993 b	Determination of residues resulting from a single application of LX1217-04 (K-Othrine SC 5.0) as a general surface, crack and crevice, and spot treatment spray in simulated food processing, service and manufacturing areas Bayer CropScience AG Report No.: A97690 08 April 1993 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.1.1.1.1/01	Smith A.M.	1990a	Determination of aqueous hydrolysis rate constant and half-life of deltamethrin Bionomics Laboratories Bayer CropScience AG Report No.: A45079 02 July 1990 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.1.1.1.1/02	Maurer T.; Schaefer D.	2002	Additional information on hydrolysis of deltamethrin at pH8 and contribution of hydrolysis to the overall dissipation of deltamethrin from surface/natural water bodies Aventis CropScience GmbH, Germany Bayer CropScience AG Report No.: C018813 21 January 2002 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA7.1.1.1.2/01	Bowman B.; Carpenter M.	1987	Determination of photodegradation of 14C-Deltamethrin in aqueous solution Anal. Bio-Chem. Lab., USA Bayer CropScience AG Report No.: A41919 25 June 1987 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.1.1.1.2/02	Maurer T.	2000	Determination of the quantum yield of direct photolysis in aqueous solution - Deltamethrin Aventis CropScience GmbH, Germany Bayer CropScience AG Report No.: C008524 26 May 2000 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.1.1.1.2/03	Wang W.W.; Reynolds J.L	1991a	Aqueous photolysis of 14C-deltamethrin Bayer CropScience AG Report No.: A47960 18 July 1991 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.1.1.2.1/01	Wuethrich V.	1994	Ready biodegradability: "Manometric respirometry test" for deltamethrin Research & Consulting Company Ltd, Switzerland Bayer CropScience AG Report No.: A71006 01 July 1994 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 7.1.2.2.2/01	Muttzall P.I.	1993	Water / sediment biodegradation of (benzyl-14C) Deltamethrin TNO, Netherlands Bayer CropScience AG Report No.: A50953 24 May 1993 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.1.2.2.2/02	Schaefer D.; Schwedhelm S.	2005	First-tier predicted environmental concentrations of deltamethrin and its metabolite Br_2CA in surface water and sediment Bayer CropScience AG Report No.: C048212 15 April 2005 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.1.2.2.2/03	Heimbach, F.; Arnold, M.; Brumhard, B.	2005	Biological effects and fate of Deltamethrin EW 015 in outdoor mesocosm ponds Bayer CropScience AG Report No.: MO-05-004459 / M-246137-01-1 24 February 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.2.1/01	Kaufman D.D.; Kaiser A.J.; Barnett E.A.; Daniels P.W.; Russell B.A.	1978	Preliminary soil metabolism investigations with decamethrin United States Department of Agriculture Bayer CropScience AG Report No.: A12524 01 January 1978 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.2.1/02	Kaufman D.D.; Kayser A.J.; Barnett E.A.; Russell B.	1979a	Degradation of 14C-phenoxy- and 14C-cyano-decamethrin in soil United States Department of Agriculture Bayer CropScience AG Report No.: A71064 01 January 1979 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA A7.2.1/03	Kaufman D.D.; Kayser A.J.; Russell B.; Barnett E.A.	1979 b	The effect of soil temperature on the degradation of 14C-cyano-decamethrin in soil. United States Department of Agriculture Bayer CropScience AG Report No.: A71051 01 January 1979 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.2.1/04	Wang W.W.	1991a	Aerobic soil metabolism of 14C-deltamethrin. Xenobiotics Laboratories Inc Bayer CropScience AG Report No.: A47917 21 June 1991 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.2.1/05	Feyerabend M.; John B.M.	1997	Deltamethrin 14C-labelled Calculation of the half-life times of Deltamethrin and becisthemic acid in soil using TOPFIT 2.0 AgrEvo Report No.: A74227 October 1997 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.2.1/06	Schaefer D.; Mikolasch B.	2004	Kinetic evaluation of soil laboratory studies with deltamethrin and its metabolites D-COOH, Br_2CA and mPBacid to determine input parameters for model calculations Bayer CropScience AG Report No.: C044585 08 October 2004 Non GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 7.2.2.4 /01	Wang W.W.; Reynolds J.L.	1991 b	Soil photolysis of 14C-deltamethrin. Xenobiotics Laboratories Inc Bayer CropScience AG Report No.: A47919 29 July 1991 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.2.3.1/01	Smith A. M.	1990 b	Determination of the adsorption and desorption coefficients of deltamethrin Bionomics Laboratories Bayer CropScience AG Report No.: A47159 29 June 1990 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA7.2.3.1/02	Christensen, K.P.	1993	Deltamethrin - Determination of the Sorption and Desorption Properties Springborn Laboratories Inc, USA Report No: A73876 13 October 1993 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.2.3.1/03	Wang W.W.	1991 b	Adsorption and desorption of 14C-Br_2CA in five soils Xenobiotics Laboratories Inc Bayer CropScience AG Report No.: A72145 16 December 1991 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.2.3.1/03	Reynolds J.L.	1992	Adsorption and desorption of 14C-m-phenoxybenzoic acid in four soils Xenobiotics Laboratories Inc Bayer CropScience AG Report No.: A71037 18 November 1992 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.3.1/01	Meichsner C.	1999	Calculation of the indirect photolysis reaction using the incremental method of Atkinson and the Program AOPWIN, Version 1.80 - Deltamethrin Bayer CropScience AG Report No.: C002214 19 January 1999 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.3.2/01	Ruedel H.; Waymann B.	1993	Testing for volatility of 14C-deltamethrin (formulated as the product Decis fluessig EC): Volatilisation from plant surfaces volatilisation from soil Bayer CropScience AG Report No.: A53910 23 April 1993 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA7.4.1.1/01	[redacted]	1986	Acute toxicity of deltamethrin to rainbow trout *(Salmo gairdneri)* [redacted] Report No.: A70935 06 January 1986 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.1.1/02	[redacted]	1990a	(IS-002A) - Acute toxicity to rainbow trout *(Oncorhynchus mykiss)* under flow-through conditions [redacted] Report No.: A47096 21 June 1990 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 7.4.1.1/03	Grau, R.; Maus, C.	2006	Aquatic toxicity of Br_2CA, a metabolite of deltamethrin Bayer CropScience AG Report No.: M-264711-01-1 16 January 2006 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.1.2/01	Putt A.E.	1999	Acute toxicity to Daphnids *(Daphnia magna)* under flow-through conditions - Deltamethrin (14C-labelled) [redacted] Report No.: C003959 13 May 1999 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.1.2/02	Putt A.E.	2000a	Acute toxicity to gammarids *(Gammarus fasciatus)* under flow-through conditions Decis EC 25 g/L [redacted] Report No.: C006608 07 January 2000 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.1.2/03	Putt A.E.	2000 b	Acute toxicity to gammarids *(Gammarus fasciatus)* in a sediment-water system Decis EC 25 g/L [redacted] Report No.: C009363 14 August 2000 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.1.2/04	Gries T.; van der Kolk J.	2001	Acute toxicity test with fresh water isopods *(Asellus aquaticus)* under semi-static conditions (14C)-Deltamethrin formulated as emusifiable concentrate (25 g/L deltamethrin) [redacted] Report No.: C015003 30 July 2001 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.1.2/05	Grau, R.; Maus, C.	2006	Aquatic toxicity of Br_2CA, a metabolite of deltamethrin Bayer CropScience AG Report No.: M-264711-01-1 16 January 2006 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.1.3/01	Giddings Jeffrey M.; Bayne Mary C.R.; Mitchell Karen L.; Shepherd Susan P.	1990	LX165-08 (deltamethrin technical) - Toxicity to the freshwater green alga, *Selenastrum capricornutum* [redacted] Report No.: A47090 02 May 1990 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.1.3/02	Hoberg J.R.	1992	Deltamethrin technical: Toxicity to the freshwater green alga, *Chlorella vulgaris* [redacted] Report No.: A70905 09 March 1992 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 7.4.1.3/03	Grau, R.; Maus, C.	2006	Aquatic toxicity of Br_2CA, a metabolite of deltamethrin Bayer CropScience AG Report No.: M-264711-01-1 16 January 2006 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.1.4/01	Hertl J.	2001	Toxicity of AE F032640 deltamethrin, substance technical to activated sludge in a respiration test [redacted] Report No.: C012186 26 March 2001 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.1.4/02	Weyers A.	2007	Deltamethrin Techn. (AE F032640) – Toxicity to Bacteria [redacted] Document M-292974-01-1 25 September 2007 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.2/01	[redacted]	1990	(Deltamethrin) - Bioconcentration and elimination of 14C-residues by bluegill *(Lepomis macrochirus)* [redacted] Report No.: A47117 05 July 1990 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.2/02	[redacted]	1992	Supplemental information to the study: (deltamethrin): Bioconcentration and elimination of 14C-residues by Bluegill *(Lepomis macrochirus)* [redacted] Report No.: A70929 03 September 1992 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA7.4.3.1/01	[redacted]	1990 b	(LX 165-08, deltamethrin technical) - Acute (28-Day) toxicity to rainbow trout *(Oncorhynchus mykiss)* under flow-through conditions [redacted] Report No.: A47111 11 April 1990 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.3.2/01	[redacted]	1991	Deltamethrin: Toxicity test with Fathead minnow *(Pimephales promelas)* embryos and larvae [redacted] Report No.: A70931 18 July 1991 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.3.2/02	[redacted]	1993	Deltamethrin: The chronic toxicity to the fathead minnow *(Pimephales promelas)* during a full life-cycle exposure [redacted] Report No.: A70972 20 May 1993 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 7.4.3.4/01	McNamara Pauline C.	1991	(Deltamethrin) - The Chronic Toxicity To Daphnia magna Under Flow-Through Conditions [redacted] Report No.: A44479 22 May 1991 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.3.5.1/01	Heusel R.; Gildemeister H.; Gosch H.	1998	Chronic toxicity to the sediment dwelling chironomid larvae *Chironomus riparius* Deltamethrin 14C-labelled Hoechst Schering AgrEvo GmbH, Germany Bayer CropScience AG Report No.: A74315 06 April 1998 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.3.5.1/02	Grau, R.	2006	Toxicity of deltamethrin to sediment dwelling organisms Bayer CropScience AG Report No.: M-264713-01-1 18 January 2006 GLP n/a. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.3.5.3/01	Heimbach, F.; Arnold, M.; Brumhard, B.	2005	Biological effects and fate of Deltamethrin EW 015 in outdoor mesocosm ponds Bayer CropScience AG Report No.: MO-05-004459 / M-246137-01-1 24 February 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.4.3.5.3/02	Heimbach, F.; Arnold, M.	2005	Bioassay on the effects of Deltamethrin EW 015 on *Gammarus pulex* in mesocosm water Bayer CropScience AG Report No.: MO-05-004496 / M-246173-01-1 24 February 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA7.4.3.5.3/03	Verboom, J.; Baveco, J. M. H.; Brink, P. J.	2005	A simulation model for spatial population dynamics of *Asellus aquaticus* after a spray drift event of deltamethrin in aquatic ecosystems Alterra, Netherlands Bayer CropScience AG Report No.: MO-05-004734 24 February 2005 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.5.1.1/01	Frings H.; Bock K.D.	1994a	Deltamethrin; technical substance (Hoe 032640 00 ZD99 0001): Investigating the effect on the microbial activity in soil (short-term effects on aerobic soil respiration in accordance with BBA, VI, 1-1, 2nd edition) Bayer CropScience AG Report No.: A52240 18 February 1994 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.5.1.1/02	Frings H.; Bock K.D.	1994 b	Deltamethrin; technical substance (Hoe 032640 00 ZD99 0001) - Investigating the effect on the nitrogen cycle in soil (in accordance with BBA, VI, 1-1 2nd edition) Bayer CropScience AG Report No.: A52241 21 February 1994 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 7.5.1.2/01	Hoxter K.A; Smith G.J.	1993	Deltamethrin technical: An acute toxicity study with the earthworm in an artificial soil substrate. Final report [redacted] Report No.: A50956 17 May 1993 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.5.2.1/01	Moser, T.; Scheffczyk, A.	2005	Deltamethrin-Br_2CA: Effects on survival and reproduction of the predaceous mite *Hypoaspis aculeifer Canestrini* (Acari: Laelapidae) in standard soil (LUFA 2.1) Bayer CropScience AG Report No.: M-255441-01-1 Date: 01.08.2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.5.2.1/02	Luehrs, U.	2004	Deltamethrin EW15: Effects on reproduction and growth of earthworms *Eisenia fetida* in artificial soil with 5% peat. [redacted] Report No. M-085431-01-1 7.5.2.1/02 Date: 19 August 2004 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.5.2.1/03	Lechelt-Kunze, C.	2004	Deltamethrin EC 025: Influence on the reproduction of the collembola species *Folsomia candida* tested in artificial soil with 5% peat. BayerCropScience, Germany Report No.: M-233529-01-1 7.5.2.1/03 Date: 14 July 2004 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.5.2.1/04	Lechelt-Kunze, C.	2005	Deltamethrin EC25 G: Influence on mortality and reproduction of the soil mite species *Hypoaspis aculeifer* tested in artificial soil with 5% peat. Bayer CropScience, Germany Report No.: M-255821-01-1 7.5.2.1/04 Date: 11 August 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.5.3.1.1/01	[redacted]	1986	Deltamethrin - An acute oral toxicity study with the Bobwhite. Final report [redacted] Report No.: A41913 17 February 1986 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.5.3.1.1/02	[redacted]	1977	Acute Oral LD50 - Mallard Duck. Technical Decis. Final Report [redacted] Report No.: A20231 06 June 1977 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.5.3.1.2/01	[redacted]	1986a	Deltamethrin: A dietary LC50 study with the Bobwhite. Final report. [redacted] Report No.: A41915 02 May 1986 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIA 7.5.3.1.2/02	[redacted]	1986 b	Deltamethrin: A dietary LC50 study with the mallard Final report [redacted] Report No.: A41870 22 July 1986 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.5.3.1.3/01	[redacted]	1991a	Deltamethrin: A one-generation reproduction study with the Northern Bobwhite *(Colinus virginianus)* [redacted] Report No.: A97605 13 September 1991 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 7.5.3.1.3/02	[redacted]	1991 b	Deltamethrin: A one-generation reproduction study with the mallard *(Anas platyrhynchos)* [redacted] Report No.: A97604 13 September 1991 Non GLP. Unpublished	Y	Bayer Crop-Science AG
IIIA 8/01	Anon	2006	MSDS - Deltamethrin technical Bayer CropScience SA, Lyon, France Bayer CropScience AG Report No.: M-264413-01-1 17 January 2006 GLP n/a. Unpublished	Y	Bayer Crop-Science AG

*: These reports contain information related to the identity of isomers and impurities which should be considered confidential

K-Othrine WG 250

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB1 3.1.1/01	Emeric G.; Patzke D.	2003	Determination of the storage stability Deltamethrin water dispersible granule 250 g/kg Code: AE F032640 00 WG25 A105 Bayer CropScience GmbH, DEU;Product Technology-Analytics, Frankfurt Bayer CropScience AG, Report No.: C033503, Edition Number: M-233289-01-1 Date: 16.06.2003 GLP, unpublished also filed: B 3.1.2. /01 also filed: B 3.11. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.7. /01 also filed: B 3.8. /01	Y	Bayer Crop-Science AG
IIIB1 3.1.2/01	Emeric G.; Patzke D.	2003	Determination of the storage stability Deltamethrin water dispersible granule 250 g/kg Code: AE F032640 00 WG25 A105 Bayer CropScience GmbH, DEU;Product Technology-Analytics, Frankfurt Bayer CropScience AG, Report No.: C033503, Edition Number: M-233289-01-1 Date: 16.06.2003 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.11. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.7. /01 also filed: B 3.8. /01	Y	Bayer Crop-Science AG
IIIB1 3.1.3/01	Martinez J.; Rexer K.	1999	Determination of the odour Deltamethrin water dispersible granule 25 %-w/w Code: AE F032640 00 WG25 A105 Hoechst Schering AgrEvo GmbH;Forschung Formulierung, Frankfurt Bayer CropScience AG, Report No.: C004357, Edition Number: M-187791-01-1 Date: 22.06.1999 GLP, unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB1 3.2/01	Martinez J.; Rexer K.	1999	Determination of the explosive properties Deltamethrin water dispersible granule 25 %-w/w Code: AE F032640 00 WG25 A105 Hoechst Schering AgrEvo GmbH;Research Formulation, Frankfurt Bayer CropScience AG, Report No.: C003871, Edition Number: M-186926-01-1 Date: 19.04.1999 Non GLP, unpublished	Y	Bayer Crop-Science AG
IIIB1 3.3/01	Martinez J.; Rexer K.	1999	Determination of the oxidizing properties Deltamethrin water dispersible granule 25 %-w/w Code: AE F032640 00 WG25 A105 Hoechst Schering AgrEvo GmbH;Research Formulation, Frankfurt Bayer CropScience AG, Report No.: C003870, Edition Number: M-186924-01-1 Date: 19.04.1999 Non GLP, unpublished	Y	Bayer Crop-Science AG
IIIB1 3.4/01	Smeykal H.	1999	Auto-flammability (solids - determination of relative self-ignition temperature) Deltamethrin water dispersible granule 25 % Code: AE F032640 00 WG25 A105 Aventis Research & Technologies GmbH & Co KG,DEU; Analytical Technologies, Frankfurt Bayer CropScience AG, Report No.: C003985, Edition Number: M-187160-01-1 Date: 17.05.1999 GLP, unpublished	Y	Bayer Crop-Science AG
IIIB1 3.4/02	Smeykal H.	1999	Flammability (solids) Deltamethrin water dispersible granule 25 % Code: AE F032640 00 WG25 A105 Aventis Research & Technologies GmbH & Co KG,DEU; Analytical Technologies, Frankfurt Bayer CropScience AG, Report No.: C003984, Edition Number: M-187158-01-1 Date: 17.05.1999 GLP, unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB1 3.5/01	Emeric G.; Patzke D.	2003	Determination of the storage stability Deltamethrin water dispersible granule 250 g/kg Code: AE F032640 00 WG25 A105 Bayer CropScience GmbH, DEU;Product Technology-Analytics, Frankfurt Bayer CropScience AG, Report No.: C033503, Edition Number: M-233289-01-1 Date: 16.06.2003 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.11. /01 also filed: B 3.6. /01 also filed: B 3.7. /01 also filed: B 3.8. /01	Y	Bayer Crop-Science AG
IIIB1 3.5/02	Gueldner, W.	2006	pH-value, acidity, attrition resistance and particle size distribution of Detamethrin WG 25 W Bayer CropScience AG, Report No.: 1410505420, Edition Number: M-274201-01-1 Date: 22.06.2006 GLP, unpublished also filed: B 3.11. /02 also filed: B 3.8. /03	Y	Bayer Crop-Science AG
IIIB1 3.5/03	Noeding G.; Rexer K.	1999	Determination of the pH-value Deltamethrin water dispersible granule 25%-w/w Code: AE F032640 00 WG25 A105 Hoechst Schering AgrEvo GmbH;Research Formulation, Frankfurt Bayer CropScience AG, Report No.: C004946, Edition Number: M-188858-01-1 Date: 06.08.1999 Non GLP, unpublished	Y	Bayer Crop-Science AG
IIIB1 3.6/01	Emeric G.; Patzke D.	2003	Determination of the storage stability Deltamethrin water dispersible granule 250 g/kg Code: AE F032640 00 WG25 A105 Bayer CropScience GmbH, DEU;Product Technology-Analytics, Frankfurt Bayer CropScience AG, Report No.: C033503, Edition Number: M-233289-01-1 Date: 16.06.2003 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.11. /01 also filed: B 3.5. /01 also filed: B 3.7. /01 also filed: B 3.8. /01	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB1 3.7/01	Emeric G.; Patzke D.	2003	Determination of the storage stability Deltamethrin water dispersible granule 250 g/kg Code: AE F032640 00 WG25 A105 Bayer CropScience GmbH, DEU;Product Technology-Analytics, Frankfurt Bayer CropScience AG, Report No.: C033503, Edition Number: M-233289-01-1 Date: 16.06.2003 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.11. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.8. /01	Y	Bayer Crop-Science AG
IIIB1 3.8/01	Emeric G.; Patzke D.	2003	Determination of the storage stability Deltamethrin water dispersible granule 250 g/kg Code: AE F032640 00 WG25 A105 Bayer CropScience GmbH, DEU;Product Technology-Analytics, Frankfurt Bayer CropScience AG, Report No.: C033503, Edition Number: M-233289-01-1 Date: 16.06.2003 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.11. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.7. /01	Y	Bayer Crop-Science AG
IIIB1 3.8/02	Rexer, K.	2002	1. Amendment to determination of the attrition resistance Deltamethrin water dispersible granule 250 g/kg Bayer CropScience GmbH, DEU;Formulation Technology, Frankfurt Bayer CropScience AG, Report No.: FOR0663(51)01A1, Edition Number: M-213080-02-1 Date: 21.10.2002, Amended: 20.06.2006 Non GLP, unpublished	Y	Bayer Crop-Science AG
IIIB1 3.8/03	Gueldner, W.	2006	pH-value, acidity, attrition resistance and particle size distribution of Detamethrin WG 25 W Bayer CropScience AG, Report No.: 1410505420, Edition Number: M-274201-01-1 Date: 22.06.2006 GLP, unpublished also filed: B 3.11. /02 also filed: B 3.5. /02	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB1 3.11/01	Emeric G.; Patzke D.	2003	Determination of the storage stability Deltamethrin water dispersible granule 250 g/kg Code: AE F032640 00 WG25 A105 Bayer CropScience GmbH, DEU;Product Technology-Analytics, Frankfurt Bayer CropScience AG, Report No.: C033503, Edition Number: M-233289-01-1 Date: 16.06.2003 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.7. /01 also filed: B 3.8. /01	Y	Bayer Crop-Science AG
IIIB1 3.11/02	Gueldner, W.	2006	pH-value, acidity, attrition resistance and particle size distribution of Detamethrin WG 25 W Bayer CropScience AG, Report No.: 1410505420, Edition Number: M-274201-01-1 Date: 22.06.2006 GLP, unpublished also filed: B 3.5. /02 also filed: B 3.8. /03	Y	Bayer Crop-Science AG
IIIB1 4.1/01	Patzke, D. and Stalker, A.M.	1999	Validation of the analytical method AL003/99-0 for the determination of AE F032640 (Deltamethrin) in water dispersible granules (WDG) by liquid chromatography (HPLC) Hoechst Schering AgrEvo GmbH, Germany Report No: C004354 18 June 1999 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIB1 4.1/02	Müller, Th. and Stalker, A.	1999	The determination of Deltamethrin (AE F032640) in water dispersible granules (WDG), water dispersible tablets (TB), emulsifiable granules (EG), emulsifiable concentrates (EC) and suspension concentrates (SC) by liquid chromatography (HPLC) Hoechst Schering AgrEvo GmbH, Germany Report No: C006464 23 November 1999 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIB1 5.10.1/01	Anon		Frame label		
IIIB1 5.10.2/01	Wagenbach, M., Höbel, S. and Kunkel, S	1998	Comparative Evaluation of Deltamethrin Granules VR980007-01 (extruded granule) and VR980008-01 (spraydried granule) vs. K-Othrine SC25 on different surfaces against cockroaches Hoechst Schering AgrEvo GmbH, Germany Report No: C004100 10 June 1998. Unpublished.	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB1 5.10.2/02	Zhai, J.	1997	Evaluation of residual treatments of deltamethrin RTU, Ford's Dursban, Empire® 20, InterCept®, Sage® WP, Suspend® SC, Vikor® 26% and Vikor® RTU on concrete and floor tiles for the control of pharoh ants, fire ants and crazy ants PerformingLaboratory Report No: C004334 February 1997. Unpublished.	Y	Bayer Crop-Science AG
IIIB1 5.10.2/03	Wagenbach, M.	1998	Comparative evaluation of deltamethrin granules VR980007-01 (extruded granule) and VR980008-01 (spray dried granule) vs. K Othrine SC25 on different surfaces against various insects Hoechst Schering AgrEvo GmbH, Germany Report No: C004182 18 November 1998 Unpublished.	Y	Bayer Crop-Science AG
IIIB1 5.10.2/04	Welsh, J.L. and Invest, J.F.	1990	An Evaluation of Crackdown against *Tineola bisselliella* and *Anthrenus flavipes* Wellcome Group R & D, England Report No: A96584 15 August 1990. Unpublished.	Y	Bayer Crop-Science AG
IIIB1 5.10.2/05	Kirkland, L.R. and Andis, M.	1994	Efficacy of Deltamethrin 0.05% Dust, Deltamethrin SC and Tralomethrin 40 WP in control of ornamental pests Bio Research, USA Report No: A97575 1 August 1994. Unpublished.	Y	Bayer Crop-Science AG
IIIB1 5.10.2/06	Serrano, B. and Adams, A	1999	Field trial of residual spray treatments to control German cockroaches Hoechst Schering AgrEvo GmbH, Germany Report No: C004102 14 January 1999 Unpublished.	Y	Bayer Crop-Science AG
IIIB1 5.10.2/07	Carter, S.W., Bowron, M.J. and Taylor, R.N.	1980	Further Field Trials in the UK using BRDC 161 to Control Cockroaches Wellcome Group R & D, England Report No: A95319 29 October 1980. Unpublished.	Y	Bayer Crop-Science AG
IIIB1 5.10.2/08	Wagenbach, M. and Köhler, P	1999	Comparative evaluation of deltamethrin water-dispersible granules VR980007-01 (extruded granule) vs. K-Othrine SC25 on ceramic tiles against *Lasius spp.* AgrEvo Environmental Health Biology, Germany Report No: C004622 16 July 1999. Unpublished.	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB1 5.10.2/09	St John, S.	1999	Laboratory Performance of Three Formulations of DeltaGard and Competitor's Products as a Direct Spray against Common Sowbugs and Pillbugs AgrEvo Environmental Health, USA Report No: C004099 April 1999. Unpublished.	Y	Bayer Crop-Science AG
IIIB1 5.10.2/10	Zhai, J.	1998	Comparison of deltamethrin WDG71 and Suspend SC efficacy against cat fleas AgrEvo Environmental Health, USA Report No: C004101 August 1998. Unpublished.	Y	Bayer Crop-Science AG
IIIB1 5.10.2/11	Miller, P.F. and Peters, B	1999a	Field Study to Determine the Efficacy of Deltamethrin 25% WG and Cislin Residual Insecticide Against Common Web Spinning Spiders Sydney University of Technology, Australia Report No: C004599 23 June 1999. Unpublished.	Y	Bayer Crop-Science AG
IIIB1 5.10.2/12	Pope, A.R.J.	1982	A laboratory evaluation of deltamethrin formulated as a microcapsule and suspension concentrate against a range of flying and crawling domestic insect pests The Wellcome Foundation Ltd, South Africa Report No: A96645 15 April 1982 Unpublished.	Y	Bayer Crop-Science AG
IIIB1 5.10.2/13	Downing, F.S. and Dodd, G.D.	1989	Cooper Insecticides for Control of the Booklouse – *Liposcelis bostrychophilus* Part 2 The Wellcome Foundation Ltd, England Report No: A95518 30 June 1989 Unpublished.	Y	Bayer Crop-Science AG
IIIB1 5.10.2/14	Miller, P.F. and Peters, B.	1999b	Field Study to Determine the Efficacy of AgrEvo Cislin Residual Insecticide, Deltamethrin 25% WG, Coopex Insecticidal Dusting Powder and DeltaDust Insecticide Against the German Cockroach Sydney University of Technology, Australia Report No: C004598 23 June 1999 Unpublished.	Y	Bayer Crop-Science AG
IIIB1 6.1.1/01	[redacted]	1999a	Rat acute oral toxicity – Deltamethrin water dispersible granule: 25% [redacted] Report No: C004362 29 June 1999 GLP. Unpublished.	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB1 6.1.2/01	[redacted]	1999b	Rat acute dermal toxicity – Deltamethrin Water dispersible granule; 25% [redacted] Report No: C004361 29 June 1999 GLP. Unpublished.	Y	Bayer CropScience AG
IIIB1 6.1.3/01	[redacted]	1999	AE F032640 00 WG 25 A105: 4-hour Acute Inhalation Toxicity Study in Rats [redacted] Report No: C004951 11 August 1999. GLP. Unpublished.	Y	Bayer CropScience AG
IIIB1 6.2.1/01	[redacted]	1999c	Rabbit Skin Irritancy – Deltamethrin Water dispersible granule; 25% [redacted] Report No: C004359 25 June 1999 GLP. Unpublished.	Y	Bayer CropScience AG
IIIB1 6.2.2/01	[redacted]	1999d	Rabbit Eye Irritancy – Deltamethrin Water dispersible granule; 25% [redacted] Report No: C004360 25 June 1999. GLP. Unpublished.	Y	Bayer CropScience AG
IIIB1 6.3/01	[redacted]	1999	AE F032640 00 WG25 A105: Contact Hypersensitivity in Albino Guinea Pigs – Büehler Test [redacted] Report No: C006489 6.3/01 20 December 1999 GLP. Unpublished.	Y	Bayer CropScience AG

K-Othrine SC 26.25

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB2 3.1.1/01 3.1.2/01 3.1.3/01	Güldner, W.	2005a	Storage Stability and cold stability of Deltamethrin SC 26.25B G Bayer CropScience AG, Germany Report No: M-257399-01-1 1 September 2005 GLP. Unpublished	Y	Bayer CropScience AG
IIIB2 3.2/01 3.4/01	Heinz, U.	2003	Determination of Safety-Relevant Data of AE F032640 00 SC03 A2 (Deltamethrin SC 25) Bayer Industry Services, Germany Report No: C034009 MO-03-006617 14 May 2003 GLP. Unpublished.	Y	Bayer CropScience AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB2 3.5/01 3.6/01	Güldner, W.	2005a	Storage Stability and cold stability of Deltamethrin SC 26.25B G Bayer CropScience AG, Germany Report No: M-257399-01-1 1 September 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIB2 3.7/01	Güldner, W.	2005b	Storage Stability and Shelf Life of AE F032640 00 SC03 A2 (Packaging Material: HDPE) Bayer CropScience AG, Germany Report No: C048463 M-251423-01-1 10 May 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIB2 3.7/02	Güldner, W.	2005a	Storage Stability and cold stability of Deltamethrin SC 26.25B G Bayer CropScience AG, Germany Report No: M-257399-01-1 1 September 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIB2 3.8/01	Güldner, W.	2005b	Storage Stability and Shelf Life of AE F032640 00 SC03 A2 (Packaging Material: HDPE) Bayer CropScience AG, Germany Report No: C048463 M-251423-01-1 10 May 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIB2 3.8/02	Güldner, W.	2005a	Storage Stability and cold stability of Deltamethrin SC 26.25B G Bayer CropScience AG, Germany Report No: M-257399-01-1 1 September 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIB2 3.10.1/01	Schneider, J.	2003	Characterization of a SC-Formulation AE F032640 00 SC03 A2 Bayer CropScience AG, Germany Report No: C032775 24 April 2003 Not GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB2 3.10.1/02	Güldner, W.	2005a	Storage Stability and cold stability of Deltamethrin SC 26.25B G Bayer CropScience AG, Germany Report No: M-257399-01-1 1 September 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIB2 3.10.2/01	Güldner, W.	2005a	Storage Stability and cold stability of Deltamethrin SC 26.25B G Bayer CropScience AG, Germany Report No: M-257399-01-1 1 September 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIB2 3.10.2/02	Güldner, W. and Hoppe, M	2007	Viscosity of Deltamethrin SC 26.25B G Bayer CropScience AG, Germany Report No: M-284165-01-1 1 February 2007 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIB2 4.1/01	Seidel E.	2003	Determination of Deltamethrin in formulations (2001-0054801-03E) Bayer CropScience, Germany Report No. MO-03-000764 17 January 2003 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB2 4.1/02	Odendahl A.	2003	Validation of HPLC-method 2001-0054801-03 – Determination of Deltamethrin in formulations, Report No. VB1-2001-0054801 (basic report) Bayer CropScience, Germany Report No MO-03-002999 19 February 2003 Unpublished	Y	Bayer Crop-Science AG
IIIB2 4.1/03	Odendahl A.	2004	Validation of HPLC method 2002-0054801-03 – Determination of Deltamethrin in Formulations Bayer CropScience, Germany Report No. MO-04-011408 19 October 2004 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIB2 4.1/04	Odendahl A.	2006	Validation of HPLC-method 2001-0054801-03 – Determination of Deltamethrin in formulations, Bayer CropScience, Germany Report No. VB3-2001-0054801 (basic report) Document 4.1/02 (M-28312-03-1) 18 December 2006 Unpublished	Y	Bayer Crop-Science AG
IIIB2 5.10.1/01	Anon	2006	Frame label – SC 26.25 M-268693-02-1	Y	Bayer Crop-Science AG
IIIB2 5.10.2/01	Zhai, J	1997	Evaluation of residual treatments of deltamethrin RTU, Ford's Dursban, Empire® 20, InterCept®, Sage® WP, Suspend® SC, Vikor® 26% and Vikor® RTU on concrete and floor tiles for the control of pharoh ants, fire ants and crazy ants Performing Laboratory Document C004334 February 1997. Unpublished.	Y	Bayer Crop-Science AG
IIIB2 5.10.2/02	Wagenbach, M	1998	Comparative evaluation of deltamethrin granules VR980007-01 (extruded granule) and VR980008-01 (spray dried granule) vs. K Othrine SC25 on different surfaces against various insects Hoechst Schering AgrEvo GmbH, Germany Document C004182 18 November 1998 Unpublished.	Y	Bayer Crop-Science AG
IIIB2 5.10.2/03	Welsh, J.L. and Invest, J.F.	1990	Welsh, J.L. and Invest, J.F. An Evaluation of Crackdown against *Tineola bisselliella* and *Anthrenus flavipes* Wellcome Group R & D, England Document A96584 15 August 1990. Unpublished.	Y	Bayer Crop-Science AG
IIIB2 5.10.2/04	Serrano, B. and Adams, A.	1999	Field trial of residual spray treatments to control German cockroaches Hoechst Schering AgrEvo GmbH, Germany Document C004102 14 January 1999 Unpublished.	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB2 5.10.2/05	Carter, S.W., Bowron, M.J. and Taylor, R.N.	1980	Further Field Trials in the UK using NRDC 161 to Control Cockroaches Wellcome Group R & D, England Document A95319 29 October 1980. Unpublished.	Y	Bayer Crop-Science AG
IIIB2 5.10.2/06	Wagenbach, M. and Köhler, P.	1999	Comparative evaluation of deltamethrin water-dispersible granules VR980007-01 (extruded granule) vs. K-Othrine SC25 on ceramic tiles against *Lasius spp.* AgrEvo Environmental Health Biology, Germany Document C004622 16 July 1999. Unpublished.	Y	Bayer Crop-Science AG
IIIB2 5.10.2/07	Zhai, J.	1998	Comparison of deltamethrin WDG71 and Suspend SC efficacy against cat fleas AgrEvo Environmental Health, USA Document C004101 August 1998. Unpublished.	Y	Bayer Crop-Science AG
IIIB2 5.10.2/08	Miller, P.F. and Peters, B	1999b	Field Study to Determine the Efficacy of AgrEvo Cislin Residual Insecticide, Deltamethrin 25% WG, Coopex Insecticidal Dusting Powder and DeltaDust Insecticide Against the German Cockroach Sydney University of Technology, Australia Document C004598 23 June 1999 Unpublished.	Y	Bayer Crop-Science AG
IIIB2 6.1.1/01	[redacted]	1986a	Decis 5 Flow – Acute Oral Toxicity Study in the Rat [redacted] Report No: A53488 12 August 1986. GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB2 6.1.2/01	[redacted]	1986b	Decis 5 Flow – Acute Dermal Toxicity Study in the Rabbit [redacted] Report No: A53489 12 August 1986 GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB2 6.1.3/01	[redacted]	1986	The Acute Toxicity of Inhaled Deltamethrin 5.0 flowable in the Albino Rat (Safety Test) [redacted] Report No: A53490 4 December 1986 GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB2 6.2.1/01	[redacted]	1986c	Decis 5 Flow – Primary Dermal Irritation Study in the Male Rabbit [redacted] Report No: A53486 12 August 1986 GLP. Unpublished.	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB2 6.2.2/01	[redacted]	1986d	Decis 5 Flow – Primary Eye Irritation Study in the Male Rabbit [redacted] Report No: A53487 12 August 1986 GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB2 6.3/01	[redacted]	2005	Deltamethrin SC 26.25B G – Local Lymph Node Assay in Mice (LLNA/IMDS) [redacted] Report No. M-256343-01-1 8 August 2005 GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB2 10.8	Anon	2005	Safety Data Sheet – SC 26.25 M-269284-01-1	Y	Bayer Crop-Science AG

K-Othrine DP 0.05

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB3 3.1.1/01 3.1.2/01 3.1.3/01 3.5/01 3.6/01 3.8/01 3.8/02 3.8/03 3.11/01	Güldner, W.	2004a	Physical, chemical and technical properties of Deltamethrin DP 0.05 Bayer CropScience AG Report No: M-237645-01-1 6 December 2004 GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB3 3.2/01 3.3/01 3.4/01 3.4/02	Heinz, U.	2004	Determination of Safety-Relevant Data of Deltamethrin DP 0.05 Bayer Industry Services GmbH & Co. OHG Report No: M-237699-01-1 16 December 2004 GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB3 3.7/01	Güldner, W.	2004b	Storage Stability of Deltamethrin DP 0.05 (Packaging material HDPE) – Interim report Bayer CropScience AG Report No: M-237411-01-1 2 December 2004 Not GLP. Unpublished.	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB3 3.7/02	Güldner, W & Hoppe, M.	2007	Storage Stability of Deltamethrin DP 0.05 (Packaging material HDPE) – Final report Bayer CropScience AG Report No: M-237411-02-1 14 May 2007 GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB3 3.8/01	Güldner, W. & Hoppe	2007	Physical, chemical and technical properties of deltamethrin DP 0.05 Amendment n°1 Bayer CropScience AG Report No: M-237645-02-1 28 November 2006 Not GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB3 4.1/01	Seidel, E.	2003	Determination of deltamethrin in formulations (2001-0054801-03E) Bayer CropScience, Germany Report No: M-075625-01-2 17 January 2003 Not GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB3 4.1/02	Odendahl, A	2004	Validation of HPLC method 2002-0054801-03 – Determination of Deltamethrin in Formulations Bayer CropScience, Germany Report No: M-092792-01-1 15 October 2004 Not GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB3 4.1/03	Odendahl A.	2003	Validation of HPLC-method 2001-0054801-03 – Determination of Deltamethrin in formulations, Report No. VB1-2001-0054801 (basic report) Bayer CropScience, Germany Report No MO-083990-01-1 19 February 2003 Unpublished	Y	Bayer Crop-Science AG
IIIB3 5.10.1/01	Anon	2006	Frame label M-268519-01-1	Y	Bayer Crop-Science AG
IIIB3 5.10.2/01	Hansen, L., Zhai, J. and Adams, A.J.	1996	Summary on efficacy tests and residual activity of deltamethrin, silafluofen and Tempo dusts in carpenter ant control AgrEvo Environmental Health Ltd, England Report No: M-179988-01-1 10 January 1996 Unpublished.	Y	Bayer Crop-Science AG
IIIB3 5.10.2/02	Serrano, B.	2004a	Laboratory Assessment of the Efficacy of Two Speciality Products to Control Garden Ants – Laboratory Trial Bayer Environmental Science, France Report No: M-268536-01-1 2 November 2004 Unpublished.	Y	Bayer Crop-Science AG
IIIB3 5.10.2/03	Dobie, L.Z.	1993	Efficacy data for deltamethrin 0.05% and permethrin 0.5% dusts against *Lasius niger* Roussel Uclaf, England Report No: M-171549-01-1 30 October 1993 Unpublished.	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB3 5.10.2/04	Serrano, B.	2004b	Laboratory Assessment of the Efficacy of Two Speciality Products to Control Garden Ants – Field Trial Bayer Environmental Science, France Report No: 961b/0804 M-268539-01-1 2 November 2004 Unpublished.	Y	Bayer Crop-Science AG
IIIB3 6.1/01	Garcin, J.C., Vinck, K.	2005	Bridging statement from toxicity of K-OTHRINE WP50, KOBIOL PP to Deltamethrin DP 0.05 Bayer CropScience SA Report No: M-255680-01-1 11 August 2005 Not GLP. Unpublished-CONFIDENTIAL*	Y	Bayer Crop-Science AG
IIIB3 6.1.1/01	[redacted]	1989a	K. Othrine WP 5 – Acute Oral Toxicity Study in the Rat [redacted] Report No: M-150515-01-1 25 September 1989 GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB3 6.1.2/01	[redacted]	1989b	K. Othrine WP 5 – Acute Dermal Toxicity Study in the Rabbit [redacted] Report No: M-150516-01-1 25 September 1989 GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB3 6.1.3/01	[redacted]	1990	Acute Inhalation Toxicity Study in Rats with Decis 5% WP. [redacted] Report No: M-150522-01-1 19 November 1990 GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB3 6.2.1/01	[redacted]	1989c	K. Othrine WP 5 – Primary Dermal Irritation Study in the Male Rabbit [redacted] Report No: M-150519-01-1 25 September 1989 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIB3 6.2.2/01	[redacted]	1989d	K. Othrine WP 5 – Primary Eye Irritation Study in the Male Rabbit [redacted] Report No: M-150517-01-1 25 September 1989 GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB3 6.3/01	[redacted]	1990	Dermal Sensitization Study in Guinea Pigs with Decis 5% WP [redacted] Report No: M-150521-01-1 14 November 1990 GLP. Unpublished.	Y	Bayer Crop-Science AG

K-Othrine SC 7.5

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB4 3.0/01	Anon	2006	Physico-chemical bridging paper, Bayer Environmental Science, M-266407-01-1 Non-GLP, unpublished - Confidential	Y	Bayer Crop-Science AG
IIIB4 3.1.1/01 3.1.2/01 3.1.3/01	Güldner, W.	2005	Storage stability at elevated temperature and cold stability of Deltamethrin SC 7.5 – Final report Bayer CropScience AG, Germany Report No: M-259703-01-1 21 September 2005. GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB4 3.2/01 3.3/01 3.4/01 3.4/02	Heinz, U.	2005	Determination of Safety-Relevant Data of Deltamethrin SC 7.5 Bayer Industry Services GmbH & Co. OHG, Germany Report No: C 046624 20 January 2005. GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB4 3.5/01 3.6/01 3.7/01 3.7/02 3.8/01 3.8/02 3.8/03 3.8/04 3.10.1/01 3.10.2/01	Güldner, W.	2005	Storage stability at elevated temperature and cold stability of Deltamethrin SC 7.5 – Final report Bayer CropScience AG, Germany Report No: M-259703-01-1 21 September 2005. GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB4 3.7/02	Güldner, W. and Hoppe, M.	2007	Storage stability and shelf-life of Deltamethrin SC 7.5 – Final report Bayer CropScience AG, Germany Report No: M-237514-02-1 27 April 2007. GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB4 4.1/01	Seidel E.	2003	Determination of Deltamethrin in formulations (2001-0054801-03E) Bayer CropScience, Germany Report No. MO-03-000764 17 January 2003 GLP. Unpublished	Y	Bayer Crop-Science AG
IIIB4 4.1/02	Odendahl A.	2003	Validation of HPLC-method 2001-0054801-03 – Determination of Deltamethrin in formulations, Report No. VB1-2001-0054801 (basic report) Bayer CropScience, Germany Report No MO-03-002999 19 February 2003 Unpublished	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB4 4.1/03	Odendahl A.	2004	Validation of HPLC-method 2001-0054201-02 Determination of Deltamethrin in Formulations Bayer CropScience, Germany Report no. M-089552-01-1 23 October 2004 Unpublished	Y	Bayer Crop-Science AG
IIIB4 4.1/04	Odendahl A.	2006	Validation of HPLC-method 2001-0054801-03 – Determination of Deltamethrin in formulations, Bayer CropScience, Germany Report No. VB2-2001-0054801 (basic report) Document 4.1/02 (M-281314-02-1) 18 December 2006 Unpublished	Y	Bayer Crop-Science AG
IIIB4 5.10.1/01	Anon	2006	INDOOR Frame label – SC 7.5 M-268688-02-1	Y	Bayer Crop-Science AG
IIIB4 5.10.2/01	Nentwig, G.	2004	StB-AI0022 (StB Phoxim) Blattanex Ameisenmittel (1.5% Phoxim), Imidacloprid 0.05 GR and K-Othrine 0.75 SC: drench test against the Black Garden Ant *(Lasius niger)* in the laboratory Bayer Environmental Science Report No: NE-LA040813 13 August 2004. GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB4 5.10.2/02	Nentwig, G.	2005a	BES0337 Ant Kill plus (pbi Home & Garden) in comparison to K-Othrine flow: immediate and residual efficacy against the Black garden ant *(Lasius niger)* Bayer Environmental Science, Germany Report No: NE-LA050726 26 July 2005 GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB4 5.10.2/03	Nentwig, G.	2005b	Field efficacy of deltamethrin SC 7.5 as drench application against *L. niger* nests in the field Bayer Environmental Science, Germany Report No: NE-LA040924-c 15 December 2004 GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB4 5.10.2/04	Wagenbach, M. and Köhler, P	1999	Comparative evaluation of deltamethrin water-dispersible granules VR980007-01 (extruded granule) vs. K-Othrine SC25 on ceramic tiles against *Lasius spp.* AgrEvo Environmental Health Biology, Germany Report No: C004622 16 July 1999. Unpublished.	Y	Bayer Crop-Science AG
IIIB4 5.10.2/05	Serrano, B. and Adams, A	1999	Field trial of residual spray treatments to control German cockroaches Hoechst Schering AgrEvo GmbH, Germany Report No: C004102 14 January 1999 Unpublished.	Y	Bayer Crop-Science AG

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed Y/N	Owner
IIIB4 5.10.2/06	Serrano, B.	2004	Laboratory Assessment of the Efficacy of Two Speciality Products to Control Garden Ants – Laboratory Trial Bayer Environmental Science, France Report No: 961b2/0804 2 November 2004 Unpublished.	Y	Bayer Crop-Science AG
IIIB4 6.1.1/01	[redacted]	1986a	Decis 5 Flow – Acute Oral Toxicity Study in the Rat [redacted] Report No: A53488 12 August 1986. GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB4 6.1.2/01	[redacted]	1986b	Decis 5 Flow – Acute Dermal Toxicity Study in the Rabbit [redacted] Report No: A53489 12 August 1986 GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB4 6.1.3/01	[redacted]	1986	The Acute Toxicity of Inhaled Deltamethrin 5.0 flowable in the Albino Rat (Safety Test) [redacted] Report No: A53490 4 December 1986 GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB4 6.2.1/01	[redacted]	1986c	Decis 5 Flow – Primary Dermal Irritation Study in the Male Rabbit [redacted] Report No: A53486 12 August 1986 GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB4 6.2.2/01	[redacted]	1986d	Decis 5 Flow – Primary Eye Irritation Study in the Male Rabbit [redacted] Report No: A53487 12 August 1986 GLP. Unpublished.	Y	Bayer Crop-Science AG
IIIB4 6.3/01	[redacted]	2005	Deltamethrin SC 26.25B G – Local Lymph Node Assay in Mice (LLNA/IMDS) [redacted] Report No. M-256343-01-1 8 August 2005 GLP. Unpublished.	Y	Bayer Crop-Science AG