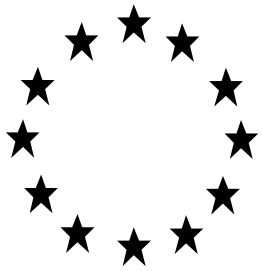
Directive 98/8/EC concerning the placing biocidal products on the market

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

Assessment Report[i]



Chlorfenapyr

Product-type 8 (Wood preservatives)

14 December 2012

Annex I - Portugal

Chlorfenapyr (PT 8)

Assessment Report

Finalised in the Standing Committee on Biocidal Products at its meeting on …. 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 chlorfenapyr as product-type 8 (wood preservatives), 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.

Chlorfenapyr (CAS no.122453-73-0) was notified as an existing active substance, by BASF, Agro B.V., hereafter referred to as the applicant, in product-type 8.

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

In accordance with the provisions of Article 5(2) of that Regulation, Portugal 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 chlorfenapyr in Product Type 8 was 28 March 2004, in accordance with Annex V of Regulation (EC) No 2032/2003.

On 28 March 2004, the Portuguese competent authority received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 28 June 2004.

On 8 August 2006 , the Rapporteur Member State submitted, in accordance with the provisions of Article 10(5) and (7) of Regulation (EC) No 2032/2003, 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 28 August 2006. The competent authority report included a recommendation for the inclusion of chlorfenapyr in Annex I to the Directive for PT 8.

In accordance with Article 12 of Regulation (EC) No 2032/2003, the Commission made the competent authority report publicly available by electronic means on 28 August 2006. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Commission.

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

2 Commission Regulation (EC) No 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,

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 Chlorfenapyr in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 14 December 2012.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007[3], the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 14 December 2012.

1.2. Purpose of the assessment report

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

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website[4], shall be taken into account.

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

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

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

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

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

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

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3 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

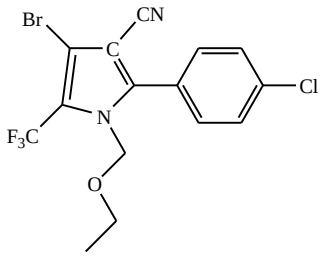
4 http://ec.europa.eu/comm/environment/biocides/index.htm

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

Active substance (ISO Common Name)	Chlorfenapyr
Function (*e.g.* fungicide)	Insecticide
Chemical name (IUPAC)	4-bromo-2-(4-chlorophenyl)-1-ethoxymethyl-5-trifluoromethylpyrrole-3-carbonitrile
Chemical name (CA)	Pyrrole-3-carbonitrile, 4-bromo-2-(p-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-
CAS No	122453-73-0
EC No	Not allocated
Other substance No.	BAS 306 I, AC 303630, AC 303,630, CL 303630, CL 303,630, MK-242, PIRATE technical, BASF Regno: 4084563
Minimum purity of the active substance as manufactured (g/kg or g/l)	940 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None
Molecular formula	$C_{15}H_{11}BrClF_3N_2O$
Molecular mass	407.6
Structural formula	
Representative biocidal product(s)	Meganium 20 SL (please note that the name Meganium 2000 is used in a number of reports and refers to the same formulation). No development code numbers Product used for read-across : MYTHIC®, Also known as: MYTHIC® termites, MYTHIC 240 SC, MYTHIC 2SC, PHANTOM Termiticide-Insecticide, PYLON Miticide-Insecticide, ALERT SC BAS 306 02I, AC 303630 240 G/L SC, AC 303630 2 SC, AC303630 240 G/L SC, AC303630 2 SC, AC 303,630 240 G/L SC, AC 303,630 2 SC, AC303,630 240 G/L SC, AC303,630 2 SC, AC 303,630 24 SC, AC 303-630, chlorfenapyr termiticide-insecticide

Physical and chemical properties

Chlorfenapyr is a solid with a low vapour pressure and practically insoluble in water without pH dependence. It is soluble in organic solvents. Its partition coefficient n-octanol/water indicates that chlorfenapyr has possibility to bioaccumulate. It is not explosive, oxidising nor flammable and after two year storage it was found to be stable in its packaging.

Analytical methods

GC-FID validated methods were submitted for the determination of chlorfenapyr and significant impurities in active substance as manufactured, except for impurity which was determined by a HPLC-UV validated method. Water and non sulphated ash were determined by international accepted methods.

For monitoring purposes validated methods were submitted for the determination of chlorfenapyr residues in relevant environmental media (soil and water) as well as in body fluids and tissues. For the matrix air more validation should be carried out at 35 ºC and 80% humidity. Methods for food/feed of plant origin are not required. Chlorfenapyr is considered the only relevant analyte for the residues analysis and the LOQ's of the methods are appropriate with respect to the toxicological, ecotoxicological and environmental endpoints of this active substance.

2.1.2. Intended Uses and Efficacy

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

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

2.1.3. Classification and Labelling

None with regard to physical/chemical data.

Classification as recommended by ECB Ispra, 25-27 April 2010

Classification chlorfenapyr: T, N

Risk phrases: R22, R23, R50/53

Safety phrases: S1/2, S13, S36/37, S45, S60, S61

Proposed labelling for the technical a.s.:

Classification: T, N

Risk phrases: R22, R23, R48/22, R50/53

Hazard phrases: H302, H331,H373, H410

Safety phrases: S1/2, S13, S23, S36/37, S38, S45, S60, S61, S63

Precaution phrases: P102, P210, P261, P264, P270, P271,P273, P281, P282, P301+P310, P301+P312, P304+P340, P311, P314, P321, P330, P391, P403+P233, P405, P501

Classification Meganium 20 SL: T, N

Risk phrases: R22, R48/22, R51/53

Hazard phrases: H302, H373, H411

Safety phrases: S2, S13, S23, S36/37, S46, S60, S61

Precaution phrases: P102, P210, P264, P270, P273, P281, P282, P301+P312, P314, P330, P391, P501

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

2.2.1.1.1 Toxicokinetics and metabolism

Pharmacokinetic and pharmacodynamic studies have been conducted with chlorfenapyr in rats. Chlorfenapyr was rapidly excreted into the faeces and urine, with more than 90% of the administered dose excreted by 168 hr. The principal route of elimination was via faeces (80.1 to 106% of administered dose in 7 days), mainly as unchanged chlorfenapyr plus minor N-dealkylated, debrominated, and hydroxylated oxidation products. Faecal excretion included both the unabsorbed portion of the oral dose and the biliary fraction. Biliary excretion represented the main route of excretion after absorption from the digestive tract. Excretion via the urine was minor (only 5.3 to 11.2% of the administered dose during 7 days) and there was no evidence of elimination of chlorfenapyr-related radiocarbons via respiration (IIIA6.2/01). There were no substantial carbon-14 label-related differences in the absorption, elimination, and distribution of radioactivity in the rat, and the bond between the phenyl and pyrrole ring apparently remained intact. In general, the higher concentration of radiocarbon in the tissues and organs was obtained from the high dose treatment. Blood and tissue radiocarbon concentrations appeared higher in the female rat than the male rat. The absorbed residue was metabolized via N-dealkylation, dehalogenation, hydroxylation and conjugation. The unchanged and the less polar metabolites were found in tissues such as fat and liver while more polar metabolites and conjugates were present in the urine and in the highly perfused tissues such as kidney and liver.(IIIA6.2/01). The mean residual percent of administered radioactivity in blood, carcass and tissues at 7 days post dose ranged from <0.01% to 3.37%, the higher concentrations being found in fat and liver and to a lesser extent in the kidneys, muscle and blood; brain showed the lowest concentrations of residual radioactivity. No potential for accumulation was observed for chlorfenapyr; during the first 24 hours following administration approximately 70% of the dose was excreted and about 88% was excreted within 48 hours .(IIIA6.2/01).

A biliary excretion study was presented to estimate the oral absorption value. Based on toxicokinetic results (urine excretion around 4-5%, bile excretion around 18-20% and tissues residues of 25-37% at 24 hours post dosing), oral absorption value could be determined to be at least about 60% of the administered low dose of 2 mg/kg bw/day (IIIA6.2/04).

An in vivo dermal penetration study in rats conducted with the biocidal preparation “Mythic” resulted in about 3.5% dermal absorption when handling the concentrate preparation and about 15% dermal absorption when handling the in-use spray dilution (IIIA6.2/03).

According to the applicant: A dermal study was conducted with the chlorfenapyr formulation Mythic 2C. Application of a 1/100 (w/w) aqueous dilution of the product resulted in a dermal absorption value of approximately 15% of the dosing, following an 8h exposure and sacrifice after 120h. As typically found, the relative dermal penetration for the formulation concentrate was much lower compared to that of the diluted product (approximately 3%).

A dermal penetration has not been conducted with the chlorfenapyr formulation Meganium 20 SL due to the fact that the formulation needs to be reworked to remove the NPE component,.

2.2.1.1.2 Acute toxicity

Acute oral toxicity of chlorfenapyr technical was investigated in rats and mice. Mice appeared to be much more sensitive to a.s. than rats, but according to generally accepted criteria, rats is the specie of reference to classify the a.s. by the oral route. So with a LD_{50} of 441 mg/kg bw in male rats and 1152 mg/kg bw in females, chlorfenapyr is classified as harmful if swallowed – R22. When administered dermally to rabbits up to 2000 mg/kg bw, no signs of toxicity were noted. In a whole body 4-hour inhalation exposure of chlorfenapyr in rats, males appeared to be much more sensitive to chlorfenapyr technical compared to females. So based on the value of LC_{50} of 0.83 mg/l air obtained in males alone, chlorfenapyr is classified as R23: toxic by inhalation.

Chlorfenapyr technical was not irritating to the rabbit's skin and was moderately irritating to the eyes, with fully reversible effects; a.s. does not require classification as a skin or eye irritant according to EU criteria.

Chlorfenapyr technical did not cause skin sensitisation in the guinea pig maximisation test

2.2.1.1.3 Short-term toxicity

Results from the repeated-dose oral studies in rats, mice and dogs showed several toxicological findings, including decreased food consumption and body weight gains in all three species. Increased liver weights, correlating with increased incidences of hepatocellular hypertrophy, and vacuolation in the brain and spinal cord were noted in rats and mice. Additionally, rats exhibited increases in spleen weights associated with decreases in haematological parameters. The lowest NOAEL was found in the dog's studies with a NOAEL of 120 ppm in both the 90-day and 1-year toxicity studies [corresponding to 3.9 (males) and 4.5 (females) mg/kg bw/day in both studies] based on the body weight effects at 200 ppm and above; no other findings were noted in this species. The NOAEL from the short-term dermal toxicity study in rabbits was 100 mg/kg bw/day, based on decreases in erythrocyte counts and increases in serum cholesterol as well as increases in liver weights and an increased incidence of cytoplasmic vacuolation in the liver at 400 mg/kg bw/day. Results observed following long-term dietary administration of chlorfenapyr technical to rats and mice were similar to those noted following short-term oral administration. The NOAELs for both species were in the same range: 60 ppm in rats [2.9 (males) and 3.6 (females) mg/kg bw/day] and 20 ppm in mice [2.8 (males) and 3.7 (females) mg/kg bw/day, see below, point 3.7: carcinogenicity].

2.2.1.1.4 Genotoxicity

Results from a battery of in vitro and in vivo genotoxicity studies showed no indication of a genotoxic potential

2.2.1.1.5 Long-term toxicity and carcinogenicity

Carcinogenicity was investigated in rats and mice; no oncogenic effect was attributed to treatment in either species.

2.2.1.1.6 Reproduction toxicity

In 2 developmental toxicity studies in rats and rabbits chlorfenapyr technical did not evidence potential for developmental toxicity or teratogenicity. The NOAELs for developmental toxicity were the highest doses tested in the respective studies, when tested up to maternally toxic doses (30 and 225 mg/kg bw/day for rabbits and rats, respectively). The NOAELs for maternal toxicity were 5 and 25 mg/kg bw/day for rabbits and rats, respectively, based on reduced body weight gains and reduced food consumption at the higher dose levels of 15 and 75 mg/kg bw/day respectively. Results from a 2-generation reproductive toxicity study in rats showed that Chlorfenapyr technical is not selectively toxic to the fertility or the developing offspring. Reductions in pup body weights (at the 300 ppm and 600 ppm) were observed at dietary concentrations that were also toxic to adults (i.e., both 300 and 600 ppm elicited reduced bodyweight gains during gestation and/or during the premating period). The NOAEL for general maternal toxicity and toxicity to the offspring was 60 ppm (equivalent to approximately 5 mg/kg bw). There was no effect on the fertility or reproduction up to the highest dose tested of 600 ppm corresponding to approximately 44 mg/kg bw/day.

2.2.1.1.7 Neurotoxicity

An acute neurotoxicity study in rats showed mortality and transient changes in posture (laying either on one side or flattened in the cage) at the top dose of 180 mg/kg bw/day. The 2 highest dose levels of 180 and 90 mg/kg bw/day presented unusual gait, impaired locomotion, decreased arousal and lethargy on the day of treatment only. The NOAEL was the lowest dose tested of 45 mg/kg bw.

Results from a one-year neurotoxicity study in rats showed in males at 600 ppm dose level myelin sheath swelling in the spinal nerve roots after 13 weeks of treatment. A more generalized myelinopathic process consisting of vacuolar myelinopathy, vacuolation and/or myelin sheath swelling of the brain and spinal cord was present in males after 52 weeks of treatment at doses of 300 and 600 ppm. The NOAEL was 60 ppm (2.6 and 3.4 mg/kg bw/day for males and females, respectively). The findings were consistent with the neuropathological findings observed in the short-term rodent and long-term mouse studies. The effects were reversible following a 4-month recovery period in a subsequent treated group. The microscopic appearance of vacuolar myelinopathy was that of intramyelinic vacuolation without evidence of associated myelin or axon degeneration and was not associated with clinical behavioural effects (as evidenced by negative findings in the functional observation battery and motor activity tests). However, taking in consideration the low level at which these effects occur (LOAEL of 13.6 mg/kg bw/day), its consistency in rodent species over repeated dose toxicity studies, and the fact that the mechanism of action is unknown, RMS has the opinion that R-phrase R48/22, “Harmful: danger of serious damage to health by prolonged exposure if swallowed”, is required.

2.2.1.1.8 Medical data

Chlorfenapyr technical has been produced since 1994 . During this period there have been no unusual or abnormal health effects observed among the personnel working in the plant. BASF policy mandates periodic medical monitoring of all production personnel, typically either annually or bi-annually. There are no medical tests specific to handling or exposure to chlorfenapyr.

2.2.1.1.9 Acceptable daily intake (ADI) and acute reference dose (ARfD)

$$\text{ADI} = \frac{\text{overall long-term NOAEL}}{\text{Safety Factor}} = \frac{2.8 \text{ mg/kg bw/day}}{100} = 0.028 \text{ mg/kg bw/day}$$

2.2.1.1.1.10 Acceptable Operator Exposure level (AOEL)

Acute AOEL = acute NOAEL /Safety Factor X oral absorption = 45 mg/kg bw/day / 100 X 0.60 = 0.27 mg/kg bw/day

$$\text{Chronic AOEL} = \frac{\text{overall NOAEL}}{\text{Safety Factor}} \text{ x oral absorption factor} =$$

$$\frac{2.8 \text{ mg/kg b.w./day}}{100} \text{ x } 0.60 = 0.017 \text{ mg/kg bw/day}$$

2.2.1.2. Effects assessment

Based on toxicokinetic data, oral absorption of chlorfenapyr was estimated to be about 60%. No potential for accumulation was observed. An *in vivo* dermal penetration study in rats conducted with the biocidal preparation "Mythic" resulted in about 3.5% Dermal absorption when handling the concentrate preparation and about 15% dermal absorption when handling the in-use spray dilution.

Acute toxicity studies resulted in classification of chlorfenapyr technical as toxic by inhalation (T; R23) and harmful if swallowed (Xn; R22) as is recommended by the 29th ATP of Directive 67/548/EEC.

The NOAEL from the short-term dermal toxicity study in rabbits was 100 mg/kg bw/day, based on increased serum cholesterol concentrations, increased absolute and/or relative liver weights, discolouration and cytoplasmic vacuolation in the liver at 400 mg/kg bw/day and above.

An acute neurotoxicity study in rats showed mortality and transient changes in posture (laying either on one side or flattened in the cage) at the top dose of 180 mg/ kg bw/day. The 2 highest dose levels of 180 and 90 mg/kg bw/day presented unusual gait, impaired locomotion,

decreased arousal and lethargy on the day of treatment only. The NOAEL was the lowest dose tested of 45 mg/kg bw.

For short-term oral exposure, the lowest relevant NOAEL was found in dogs, with a similar NOAELs in the 90-day and 1-year studies of 120 ppm (3.9 and 4.0 mg/kg bw/day respectively) based on the severe body weight effects above 200 ppm (90-day study the dose of 5.8/6.0 mg/kg bw/day had to be reduced due to poor conditions of animals).

Long-term dietary administration of chlorfenapyr technical to rats and mice resulted in similar NOAELs for both species, with NOAEL of 60 ppm in rats [2.9 (male) and 3.6 (female) mg/kg bw/day] and 20 ppm in mice [2.8 (male) and 3.7 (female) mg/kg bw/day]. In rats 300 ppm caused decreases in mean body weight and body weight gain, decreases in albumin/globulin ratios, increases in mean total cholesterol and increased liver weight associated with hepatocellular enlargement at 300 ppm for both sexes. In mice 120 ppm caused reduced body weight gain and vacuolation of the white matter of the brain. The results were confirmed in a one-year neurotoxicity study in rats, in which vacuolar myelinopathy was prominent within many of the white matter tracts of the brain, in spinal cord, and as myelin sheath swelling within the sciatic nerve.

A summary of most relevant NOAEL and LOAEL of toxicity studies with chlorfenapyr technical is presented in the following table:

A summary of most relevant NOAEL and LOAEL of toxicity studies with chlorfenapyr technical is presented in the following table:

Test type	**Specie**	**NOAEL mg/kg bw/day**	**LOAEL mg/kg bw/day**	**Reliability**
28-day, dermal	Rabbit	100	400	1
acute, oral, neurotoxicity	rat	45	90	1
Developmental toxicity	Rabbit	5	15	1
2-generations	Rat	5	25	1
90-day, oral	Rat	10.9	22.0	1
90-day, oral	Mouse	< 7.1	7.1	2
90-day, oral	Dog	3.9	4.4-7.3	1
1-year, oral	Dog	4.0	8.7	1
1-year, oral, neurotoxicity	Rat	2.6	13.6	1
2-year, oral, long-term/carcinogenicity	Rat	2.9	15.0	1
18-month, oral, carcinogenicity	Mouse	2.8	16.6	1

Chlorfenapyr did not present genotoxic or carcinogenic properties and it did not show a potential for reproductive toxicity (developmental toxicity or fertility impairment).

The critical effect observed in rodent species was vacuolation in the brain and spinal cord. This effect was not accompanied by degenerative damage to myelin or axons and was not associated

with clinical behavioural effect. The effect was reversible after a 4-week recovery period, but due to low dose level and consistency of effect among rats and mice, RMS proposes the classification with R48/22, "harmful: danger of serious damage to health by prolonged exposure if swallowed".

2.2.1.3. Exposure assessment

Toxicological Reference Doses

Three reference doses for the systemic toxicity of chlorfenapyr, which might be of a certain relevance when assessing the risk associated with exposure to a wood preservative. They are summarised in the following table:

Reference Dose	Value (mg/kg bw/day)	Study	Uncertainty Factor	Relevance for risk assessment
Acceptable daily intake (**ADI**)	**0.028**	Chronic/carcinogenicity mouse	100	long-term exposure (most days per year)
Acceptable operator exposure level (**AOEL**)	**0.27 (acute/short term exposure)**	acute oral neurotoxicity, rat and 60% oral absorption	100	Short term exposure (a few times per year)
	0.017 (chronic exposure)	1-year neurotoxicity rat 1-year mice 2-year rat and 60% oral absorption	100	long-term exposure (most days per year)
Acute reference dose (**ARfD**)	**Not allocated**	Not necessary as there is no dietary exposure	-	-

Meganium

Evaluation was based on the formulation Mythic 2C and therefore specific data must be request for other formulations.

According to the applicant: A dermal study was conducted with the chlorfenapyr formulation Mythic 2C. Application of a 1/100 (w/w) aqueous dilution of the product resulted in a dermal absorption value of approximately 15% of the dosing, following an 8h exposure and sacrifice after 120h. As typically found, the relative dermal penetration for the formulation concentrate was much lower compared to that of the diluted product (approximately 3%).

General Remarks

Two user types are considered to address Human Exposure Assessment for Meganium:

- Professional Users

Tier 1 Approach is not considered, as protective equipment is part of good practice. Unless otherwise specified, a default penetration value of 10% for gloves and clothing was assumed, which is in accordance with the proposal of the TNsG on Human Exposure to Biocidal Products
Tier 2 Approach is presented hereafter as personal protective equipment is assumed to be worn for any of the following professional scenarios.

- Non-Professional Users

Where exposure is calculated based on empirical data (database models provided in the TNsG on Human Exposure to Biocidal Products), these data are applied in agreement with the recommendations given by the TNsG on Human Exposure to Biocidal Products A reasonable worst case (Tier 1) is calculated by using the 95%-ile of the data. In case of continuous (chronic) exposure scenarios the typical exposure (Tier 2) is calculated based on the 75%-ile of the data. To follow a precautionary, conservative approach, for scenarios of rarely occurring (acute) exposure the 95%-ile is considered to represent the typical case. Where 95%-iles are not given, the maximum values are used instead. Additionally, exposure estimates based on the 50%-ile values can be found in the respective tables of Appendix I.

Identification of main paths of human exposure towards active substance from its use in biocidal product

Handling and application of wood preservatives in an industrial, professional or amateur environment can result in direct exposure via skin contact or via inhalation. Contamination by ingestion should not occur under usual working practices as long as a minimum of hygiene standards are observed. The oral route is therefore not included as a potential direct route for exposure during the use of wood preservatives. Exposure via the environment is another potential route, which is however rather an indirect than a direct one.
The procedures relevant for the handling and application of chlorfenapyr containing wood preservatives are described hereafter considering only direct exposure identified.

Industrial procedures

There are two application techniques for industrial wood preservation procedures relevant for chlorfenapyr containing products: double-vacuum process and dipping. These two processes are assessed hereafter.

- Industrial procedures: double-vacuum impregnation of timber

This procedure can be subdivided into several activities with and without exposure potential as described below.

Mixing/loading

Mixing/loading is a fully automated process in a closed system. Mixing occurs in large tanks to which the product and water are automatically supplied in the required quantities via hoses. There is no manual interaction needed. Loading/unloading of the impregnation chamber from and back to the mixing tank also occurs in an automated, closed system, without any need for manual interaction by the operator. Treating solutions are recycled. The concentration of a.i. may be checked from time to time and adjusted by additional supply of product, all within the same automated, closed system.
The **process of mixing/loading** in a double-vacuum impregnation system is **not associated with significant exposure** of the operator, neither by inhalation nor via dermal contact. No exposure calculation is provided for this activity.

Application

The application process itself occurs in the vacuum/pressure impregnation chamber, which is part of the closed system. There is no manual interaction possible. Product which may evaporate during the final evacuation is trapped in a condenser and fed back to the system.
The **application process** in a double-vacuum impregnation system is **not associated with significant exposure** of the operator, neither by inhalation nor via dermal contact. No separate exposure calculation is provided for this activity. However, the model applied for post-application handling as described below may partly also cover potential exposure during the treatment process itself. This model may be best described as "intermittent contact with wet objects".

Post-application

There are two activities which may potentially lead to exposure to the product. These are opening of the impregnation chamber and handling of treated wood. Theoretically, while opening the impregnation chamber product containing vapour may become released. However, the active ingredient chlorfenapyr is of very low volatility (vapour pressure = 6.52×10^{-12} Pa), the double-vacuum process occurs at ambient temperature and the chamber is evacuated before it can be opened. Therefore, the risk of exposure via the release of vapour is considered to be negligible. No exposure calculation is provided for this activity.

Timber to be treated is generally stacked to large batches which are transported mechanically by fork lift trucks. For the actual impregnation process timber stacks are loaded onto trollies. After treatment, they may remain on the trollies for a certain while (initial drying), before they are transferred to a storage place by a fork lift truck for final drying and fixation of the impregnation. Usually, there should be no manual contact with treated wood until the product has completely dried. However, under certain circumstances (e.g. time pressure), it might occasionally happen that wet timber needs to be handled manually. For this scenario the TNG

on Human Exposure to Biocidal Products provides a model to estimate dermal and inhalation exposure (Handling, Model 1).

Maintenance/Cleaning

Any sort of maintenance/repair work on the system (hoses, valves etc.) may potentially lead to exposure. However, such activities are of short duration (few minutes to few hours) and occur only occasionally (once to a few times a year or even less). Potential contamination is expected to be limited to hands.

Another potential source for contamination with residual product is cleaning the inner surface of the impregnation chamber. In some impregnation plants cleaning is done once a year, in others they never clean. The cleaning process lasts for a few hours and may be described as scraping off the dried residues which have accumulated during many impregnation runs from the inner wall of the chamber. The potential for contamination is considered to be high, both by dermal contact and by inhalation. Therefore an extensive personal protection is needed.

Cleaning is considered to represent the worst case among the possible maintenance activities with regard to the potential level of exposure but cleaning is not well described by the available models.

- Industrial procedures: dipping of timber

This procedure can be subdivided into several activities with or without exposure as described below.

Mixing/loading

Mixing/loading is a fully automated process in a closed system. Mixing occurs in large tanks to which the product and water are automatically supplied in the required quantities via hoses. There is no manual interaction needed. Loading of the dipping tank from the mixing tank also occurs in an automated, closed system, without any need for manual interaction by the operator. The concentration of a.i. may be checked from time to time and adjusted by additional supply of product, all within the same automated, closed system.

The **process of mixing/loading** for dipping of wood in industrial premises is **not associated with significant exposure** of the operator, neither by inhalation nor via dermal contact. No exposure calculation is provided for this activity.

Application

The application process itself occurs in a large tank which is opened during loading with wood but closed during treatment. Loading and unloading with wood occurs mechanically by fork lift trucks. For the actual dipping process timber stacks are loaded onto a fork lift integrated in the dipping system. Before removing treated wood from the dipping system, excessive treatment solution is allowed to drain off above the tank. Afterwards it is transported mechanically to the storage place. There is no manual interaction needed during the entire process.

Another potential source of exposure might be via evaporation of the active substance from the open dipping tank theoretically, while the dipping tank is open, product-containing vapour may become released. However, the active ingredient chlorfenapyr is of very low volatility (vapour pressure = 6.52×10^{-12}Pa) and the dipping process occurs at ambient temperature. Therefore, the risk of exposure via the release of vapour is considered to be negligible.

The **application process** during dipping of wood in industrial premises is **not associated with significant exposure** of the operator, neither by inhalation nor via dermal contact. No separate exposure calculation is provided for this activity. However, the model applied for post-application handling as described below may partly also cover potential exposure during the treatment process itself. This model may be best described as "intermittent contact with wet objects".

Post-application

Post-application exposure to the product may occur during manual contact during handling of treated (wet) wood. Timber to be treated is generally stacked to large batches which are transported mechanically by fork lift trucks. After treatment, they remain on the fork lift above the tank for a certain while (initial drying), before they are transferred to a storage place by a fork lift truck for final drying and fixation of the impregnation. Usually, there should be no manual contact with treated wood until the product has completely dried. However, under certain circumstances (e.g. time pressure), it might occasionally happen that wet timber needs to be handled manually. For this scenario the TNG on Human Exposure to Biocidal Products provides a model to estimate dermal and inhalation exposure (Handling, Model 1).

Maintenance/Cleaning

Any sort of maintenance/repair work on the system (hoses, valves etc.) may potentially lead to exposure. However, such activities are of short duration (few minutes to few hours) and occur only occasionally (once to a few times a year or even less). Potential contamination is expected to be limited to hands.

Another potential source for contamination with residual product is cleaning the inner surface of the dipping tank. This task is done once a year at maximum. The cleaning process lasts for a few hours. Whenever cleaning is done, the potential for contamination is high, both by dermal contact and by inhalation. Therefore an extensive personal protection is needed.

Cleaning is considered to represent the worst case among the possible maintenance activities with regard to the potential level of exposure but cleaning is not well described by the available models.

Summary of Main Paths of direct Human Exposures during Industrial Procedures

Exposure path	**Industrial use : double-vacuum impregnation process**				Via the environment
	Mixing/loading	Application	Post application	Maintenance/ cleaning	
Inhalation	No exposure	No significant exposure (exposure calculation covered by post application)	Potential exposure when intermittent contacts with wet timbers (TNG on human exposure, Handling, model 1)	(TNG on human exposure, Handling, model 1 modified)	No direct exposure
Dermal	No exposure	No significant exposure (exposure calculation covered by post application)	Potential exposure when intermittent contacts with wet timbers (TNG on human exposure, Handling, model 1)	(TNG on human exposure, Handling, model 1 modified)	No direct exposure
Oral	No exposure	No exposure	No exposure	No exposure	No direct exposure

Exposure path	**Industrial use : dipping**				Via the environment
	Mixing/loading	Application	Post application	Maintenance/ cleaning	
Inhalation	No exposure	No significant exposure (exposure calculation covered by post application)	Potential exposure when intermittent contacts with wet timbers (TNG on human exposure, Handling, model 1)	(TNG on human exposure, Handling, model 1 modified)	No direct exposure
Dermal	No exposure	No significant exposure (exposure calculation covered by post application)	Potential exposure when intermittent contacts with wet timbers (TNG on human exposure, Handling, model 1)	(TNG on human exposure, Handling, model 1 modified)	No direct exposure
Oral	No exposure	No exposure	No exposure	No exposure	No direct exposure

Professional procedures

There are several application techniques for indoor (*in situ*) remedial wood preservation by professionals. These are mainly spraying, brushing and injection. Out of these scenarios, spraying is considered to represent the worst case. The following exposure estimates for professional *in situ* treatment is therefore limited to the spraying technique.
Additionally, chlorfenapyr containing formulations may be used for small-scale dipping of wood in use (e.g. fences, windows).
These procedures can be subdivided into several activities with or without exposure as described below.

- Professional procedures: *in situ* spraying wooden structures

Medium pressure spraying with electric powered spray equipment.

Mixing/loading

A tank of appropriate size is filled once a day with spraying solution either by pumping from a larger reservoir (ready to use formulation) or by mixing appropriate amounts of formulation and water. This activity is considered to potentially result in contamination by dermal contact (mainly hands) and by inhalation. Several models are provided by the TNG on Human Exposure to Biocidal Products to estimate exposure levels (Mixing and loading, e.g. Models 4, 5). Further, the spraying model mentioned below (Model 2) does include exposure during mixing/loading.

Application

Spray application indoor is associated with significant exposure. Professionals may spray all over the year, 5 days a week. The average daily duration is about 40 min. The TNG on Human

Exposure to Biocidal Products provides a model to estimate exposure levels during medium pressure spray application (Spraying, Model 2). The model data include exposure during mixing/loading and application.

Post-application/Maintenance/Cleaning
Freshly treated, wet wood is assumed not to be touched. If nevertheless accidental contact occurs, it will be of very short duration and to a small skin area only. It is assumed that it will in any case cause much lower contamination than during application. Exposure through accidental contact with wet wood is not calculated. Contamination of residents by contact with treated, wet wood is considered to be secondary or indirect exposure and is treated separately bellow.
Repair activities might be necessary from time to time and may potentially lead to some exposure of the hands. It will be a rare event and of short duration only. Contamination with spray solution would be most likely to the bare skin of hands.
Another relevant post-application task which may lead to some degree of exposure is the cleaning of the spray equipment. Cleaning of the equipment is assumed to be done once a day and lasts for about 15 min. It might result in some skin exposure. The cleaning phase is not covered by any of the proposed TNG on human exposure to biocidal products. Therefore, an internal calculation has been developed.

- Professional procedures: small-scale dipping of timber

Mixing/loading
A small-scale dipping tank is filled at maximum once a day with treating solution either by pumping from a larger reservoir (ready to use formulation) or by mixing appropriate amounts of formulation and water. This activity is considered to potentially result in contamination by dermal contact (mainly hands) and by inhalation. Several models are provided by the TNG on Human Exposure to Biocidal Products to estimate exposure levels (e.g.: Mixing/loading, Model 7).

Application
Dipping is typically performed outdoor (protected with a roof) and maybe associated with some, mainly dermal, exposure. Professionals may apply this technique during most part of the year. The average daily duration is about 30 min. The TNG on Human Exposure to Biocidal Products provides a model to estimate exposure levels during dipping of wooden articles (Dipping, Model 1).

Post-application
Treated wood should normally be stored for complete drying and fixation of the preservative before further handling. Nevertheless, manual contact with wet wood may occasionally occur. Exposure appears to be a function of wetness. The later a treated piece of treated wood is handled the less exposure will occur. Therefore, it is assumed that handling of the wooden articles during the dipping process itself reflects the worst case situation. No separate exposure estimate is performed for post-application handling by the operator. Contamination of customers or residents by contact with treated, wet wood is considered to be secondary or indirect exposure and is treated separately in Section 8.2.4.

Maintenance/Cleaning

There is no technical equipment which might require maintenance work. The dipping tank may be cleaned occasionally - possibly once a year or less. Cleaning may last for a relatively short

time (e.g. 1 hour or less). There is a certain potential for contamination mainly due to dermal contact. However, compared to an industrial dipping tank the expected contamination during cleaning should be lower, due to the lower size of the tank and consequently the lower time need. Therefore, the exposure during this activity is not specifically assessed. As a worst case scenario it can be referred to the cleaning of industrial dipping tanks.

Summary of Main Paths of direct Human Exposures during PROFESSIONAL Procedures

Exposure path	**Professional use : *in situ* spraying wooden structures**				Via the environment
	Mixing/loading	Application	Post application	Maintenance/ cleaning	
Inhalation	Exposure (TNG on human exposure, spraying, model 2)	Significant exposure (TNG on human exposure, spraying, model 2)	No exposure	No exposure	No direct exposure
Dermal	Exposure, mainly hands (TNG on human exposure, spraying, model 2)	Significant Exposure (TNG on human exposure, spraying, model 2)	Very limited exposure compared to application No exposure calculation	Exposure when cleaning (internal calculation of the exposure)	No direct exposure
Oral	No exposure	No exposure	No exposure	No exposure	No direct exposure

Exposure path	**Professional use : small-scale dipping of timber**				Via the environment
	Mixing/loading	Application	Post application	Maintenance/ cleaning	
Inhalation	Exposure (TNG on human exposure, several models, e.g. mixing/loading Model 7)	No exposure	No exposure	No exposure	No direct exposure
Dermal	Exposure, mainly hands (TNG on human exposure, several models, e.g. mixing/loading Model 7)	Exposure (TNG on human exposure, dipping, model 1)	Very limited exposure compared to application no exposure calculation	Exposure when cleaning (assessment covered by cleaning of industrial dipping tanks)	No direct exposure
Oral	No exposure	No exposure	No exposure	No exposure	No direct exposure

Non-professional (Do-it-yourself *in situ*) applications

The relevant application technique for do-it-yourself *in situ* treatment of wood are brushing and spraying, both indoor and outdoor.
These procedures can be subdivided into several activities with or without exposure as described below

- Non-professional applications: brushing indoor and outdoor

Mixing/loading

Products in the do-it-yourself market are sold as ready to use products. Mixing/loading is therefore not a relevant activity for this user group and therefore not assessed.

Application
Brushing indoor or outdoor may be associated with some exposure, mainly by skin contact. Amateurs apply wood preservatives very rarely, not more than once or twice a year. The

average daily duration of the task is 155 min. The TNG on Human Exposure to Biocidal Products provides several models to estimate exposure levels during brush painting which are considered to be suitable for this scenario:

- for overhead indoor brush painting (Consumer product painting, Model 1)
- for outdoor painting of sheds and fences (Consumer product painting, Model 3).

Model 1 gives separate data for water based and solvent based products but contains no data for inhalation. Dermal data are only provided as potential exposure.
Model 3 contains data for inhalation exposure and for hand and feet exposure inside gloves and shoes.

Post-application/Maintenance/Cleaning

Freshly treated, wet wood is assumed not to be touched. If nevertheless accidental contact by the operator occurs, it will be of very short duration and to a small skin area only. It is assumed that it will in any case cause much lower contamination than during application and/or cleaning. Exposure through accidental contact with wet wood is not calculated. Contamination of other residents by contact with treated, wet wood is considered to be secondary or indirect exposure and is treated separately.
The only other relevant post-application task which may lead to some degree of exposure is the cleaning of the brush. In accordance to above description of brushing, cleaning of the equipment (brush) by amateurs is done once to twice a year at maximum and lasts for no more than 15 min. It might result in some exposure to hands. The exposure during cleaning is not covered by any of the proposed TNG models; therefore an internal calculation is provided.

Summary of Main Paths of direct Human Exposures during NON PROFESSIONAL (Do-it-yourself *in situ*) applications

Exposure path	**Non-Professional use : Do-it-yourself *in situ* applications Brushing indoor and outdoor**				Via the environment
	Mixing/loading	Application	Post application	Maintenance/ Cleaning	
Inhalation	No exposure	Exposure (TNG on human exposure, consumer product painting, outdoor, model 3)	No exposure	No exposure	No direct exposure
Dermal	No exposure	Significant Exposure (TNG on human exposure, consumer product painting outdoor model 3)	Very limited exposure compared to application no exposure calculation	Exposure when cleaning (internal calculation)	No direct exposure
Oral	No exposure	No exposure	No exposure	No exposure	No direct exposure

2.2.1.4. Risk characterisation

Risk characterisation for product type 8

Meganium – Primary exposure

Primary Exposure covers industrial, professional and non-professional users.
Models and assumptions were taken from the Technical Notes for Guidance (TNsG) – Human Exposure to Biocidal Products (2002). These models are mainly based on the HSE databases.

Comparison of estimated exposure with AOEL or NOAEL
(For details assumption and models refer to revised Doc IIB Meganium)
The comparison of the exposure and the toxicity is represented by the margin of exposure (MOE) approach. The MOE is calculated as: MOE = NOAEL (mg/kg bw/day) / Exposure (mg/kg bw/day) and in the AOEL concept the exposure estimates should be compared with the determined systemic AOEL. The following default assumptions are applied if the MOE $\geq$ 100 or the ratio: Exposure / AOEL $\leq$ 1, then the risk for the operator under the circumstances specified above is acceptable.

The basis for the risk characterization is in all scenarios the references doses derived from the toxicological data: a NOAEL of 2.8 mg/kg bw/day (chronic NOAEL) and a Systemic Chronic AOEL of 0.017 mg/kg bw/day, or for example tasks that are made once a year, a short-term NOAEL of 45 mg/kg bw/day and a Systemic Short Term AOEL of 0.27 mg/kg bw/day.

Summary of Risk Assessment for Industrial/Professional users (Meganium)

Scenario	NOAEL (mg/kg bw/day)	AOEL (mg/kg bw/day)	Systemic exposure (mg/kg bw/day) 75%-ile/ 95%-ile/or Maximum	MOE	Exposure /AOEL
Industrial Double-vacuum impregnation, water-based	2.8	0.017	0.0346	80.92	2.0
			0.085	32.94	5
Industrial Double-vacuum impregnation, solvent-based	2.8	0.017	0.0377	74.3	2.2
			0.085	32.94	5
Industrial Dipping, water-based	2.8	0.017	0.0346	80.92	2.0
			0.085	32.94	5
Industrial Dipping, solvent based	2.8	0.017	0.0377	74.3	2.2
			0.085	32.94	5
Professional In Situ spraying solvent-based	2.8	0.017	0.0010826	2586.3	0.0636
			0.007055	396.88	0.415
Professional small-scale dipping – pouring liquids	2.8	0.017	0.0005313	5270	0.0313
			0.0010571	2648.7	0.062
Professional small scale dipping-pumping liquids	2.8	0.017	0.0005391	5193.8	0.0317
			0.0010896	2569.7	0.064

Conclusion:

For Industrial workers using water-based and solvent-based clorfenapyr formulations (Meganium) in double-vacuum impregnation and dipping applications, MOE is bellow 100. However, it must be highlighted that the total exposure obtained, represent a worst case situation, as it is assuming that all activities including cleaning are done by one and the same person at one day.

Although this may occasionally happen, it certainly does not occur every working day. Application is assumed to be done every day, whereas cleaning might be done a few times a year only, with the assumption that the obligatory PPE is used

For Professional workers involved in wood treatment by spraying or small-scalle dipping wooden articles does not represent a risk, a sufficient margin of exposure (MOE above 100) was reach with the assumption that they use the obligatory PPE.

The evaluation was based on the formulation Mythic 2C and therefore specific data must be requested for other formulations.

According to the applicant: A dermal study was conducted with the chlorfenapyr formulation Mythic 2C. Application of a 1/100 (w/w) aqueous dilution of the product resulted in a dermal absorption value of approximately 15% of the dosing, following an 8h exposure and sacrifice after 120h. As typically found, the relative dermal penetration for the formulation concentrate was much lower compared to that of the diluted product (approximately 3%).

All the assessment was therefore carried out with the worst case assumptions, and so we can conclude that the risk is acceptable.

NON-PROFESSIONAL USERS

This chapter assesses the primary exposure in case of non-professional applications, Do-it-yourself in situ (brushing indoor and outdoor). The biocidal product Meganium 20SL is not suitable for do-it-yourself use as the concentration of the active substance in the product is not at use concentration. Concentration of chlorfenapyr in an end use product would be 0.02% (solvent based) and 0.005% (water based).

Meganium

Risk characterization for the product:

Summary of Risk Assessment for Non-professional users

Scenario	NOAEL (mg/kg bw/day)	AOEL (mg/kg bw/day)	Systemic exposure (mg/kg bw/day) 75%-ile/ 95%-ile/or Maximum	MOE	Exposure/ AOEL
Brushing, indoor	2.8	0.017	0.0144325	194.0	0.848
			0.0228874	122.33	1.346
Brushing, outdoor, water based formulations, model 2	2.8	0.017	0.0001554	18018.0	0.009
			0.00039	7179.4	0.0229
Brushing, outdoor, solvent based formulations, model 2	2.8	0.017	0.0017515	1598.6	0.103
			0.00780	358.97	0.458
Brushing, outdoor, Model 3	2.8	0.017	0.0006454	4338.4	0.0379
			0.0019068	1468.42	0.1121

Conclusion:

Brush painting indoors and outdoors is the only application envisaged for non-professional users. The highest exposure is expected when the product is applied indoors. The use of clorfenapyr in biocidal products (Meganium) by amateurs would be safe with the use of gloves. As products are normally not authorized for non-professional users if they have to wear PPE, this use should not be authorized, unless data are submitted at the product authorization stage to demonstrate that risks can be reduced to acceptable levels by other means.

No safe uses for non-professionals can therefore be derived for the biocidal product Meganium.

Indirect exposure as a result of use

Meganium

Intended exposure due to secondary contact with treated wood

Using preserved timber in construction

Persons at risk are adults, either professionals or amateurs. The relevant exposure routes are dermal and inhalation. Exposure duration is either acute (amateurs) or chronic (professionals). The dermal contact while handling wet wood represents the highest exposure. On the other hand, the processing of dried treated wood, especially when it generates large amounts of dust, is considered to be the worst case of exposure by inhalation.

Children and infants are a group of risk through secondary exposure because they may contact surfaces treated with wood preservatives. When playing on preserved timber, the relevant exposure is dermal; oral exposure might occur when children put their hands into the mouth, but is assumed to result in lower exposure than estimated in the scenario of chewing preserved

timber off-cuts. This second scenario is then considered to represent the worst case of oral exposure.

RISK CHARACTERISATION FOR THE PRODUCT

The comparison of the exposure and the toxicity is represented by the margin of exposure (MOE) approach. The MOE is calculated as: MOE = NOAEL (mg/kg bw/day) / Exposure (mg/kg bw/day) and in the AOEL concept the exposure estimates should be compared with the determined systemic AOEL. The following default assumptions are applied if the MOE $\geq$ 100 or the ratio: Exposure / AOEL $\leq$ 1, then the risk for the operator under the circunstances specified above is acceptable.

The basis for the risk characterization is in all scenarios the references doses derived from the toxicological data: a NOAEL of 2.8 mg/kg bw/day (chronic NOAEL) and a Systemic Chronic AOEL of 0.017 mg/kg bw/day, or for example tasks that are made once a year, a short-term NOAEL of 45 mg/kg bw/day and a Systemic Short Term AOEL of 0.27 mg/kg bw/day.

(For details assumptions and models refer to revised Doc IIB Meganium)

Summary of Risk Assessment for secondary exposure

Secondary exposure Scenario		Calculated exposure	NOAEL (mg/kg bw/day)	MOE
Intended secondary exposure	Handling of treated wet wood (acute exposure)	Water based formulations: (75%ile) 0.0003262	45 (acute NOAEL)	137952.2
		(95%ile) 0.0008469		531349.90
		Solvent based formulations: (75%ile) 0.0000156	45 (acute NOAEL)	2884615.3
		(95%ile) 0.00004468		1008968.6
	Processing of treated wood (chronic exposure)	Professionals: 0.00069	2.8 (chronic NOAEL)	4057.9
		Amateurs 0.00022	45 (acute NOAEL)	204545.45
Unintended secondary exposure	Playing on preserved timber (chronic exposure)	Childs (15 kg bw): 0.0000341	2.8 (chronic NOAEL)	82111.4
		Infants (10 kgbw): 0.0005632		4971.59
	Chewing preserved timber off-cuts (acute exposure)	Double vacuum impregnation timber: 0.00006	2.8 (chronic NOAEL)	46666.6
		Dipping: 0.00192	2.8 (chronic NOAEL)	1458.3

Conclusion:

An acute secondary exposure to clorfenapyr (Meganium) can be anticipated for adults who work with treated wood (handling or processing treated wood) and for infants who may have oral contact with treated wood (e.g. chewing on a chip of treated wood). The calculated exposure for adults in this acute scenario is extremely low (MOE above 100 and very high).
Children are not at risk for acute secondary exposure to wood preservatives, MOE is above 100 and very high.
Chronic secondary exposure is relevant for adults who cut or sand treated wood as part of their occupation (e.g. carpenters) Children may have repeated contact to clorfenapyr treated wood, e.g. on playgrounds.
.

For infants, dermal contact and oral absorption after hand-to-mouth contact are possible routes of exposure; MOE is above 100, and very high, no risk is expected.
In conclusion, dermal exposure of children playing on preserved timber does not represent a risk, when the wood is treated by dipping for childs and infants, (MOE above 100 and very high).

For adults professionals or amateurs no risk is expected when processing treated wood with clorfenapyr, MOE is very high.

COMBINED EXPOSURE

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

For an industrial worker, the estimated worst total systemic exposure corresponding to industrial double-vacuum impregnation, solvent based is 0.0346 mg a.i./kg bw/day. If as an amateur he or she applies chlorfenapyr, by brushing indoor, which is the worst case among the non-professionals techniques, a total systemic exposure of 0.0144325 mg a.i./kg bw/day is to be added. Then it has to be considered the potential secondary exposure as a result of the contact to the residues in air or in surfaces in places where the wood preservative has been used, this amounts to 0.00069 mg a.i./kg bw/day, corresponding to the processing of treated wood by professionals, considered the worst case among all the intended secondary exposure scenarios for adults.

Adding up all these figures a combined exposure of **0.0511225 m**g a.i./kg bw/day is obtained for an industrial user, giving a MOE of 55, so these exposures are not considered safe. However, as it is not envisaged that the same worker will also use chlorfenapyr based products as an amateur, via a non-professional use, the risk can be considered acceptable.

Regarding the professional user, the worst case between the applications techniques is the in situ spraying, solvent based, that supposes a total systemic exposure of 0.0010826 mg a.i./kg bw/day. If this user is supposed to fulfill a non-professional application as well as the handling of treated wood, the total combined exposure amounts to 0.0162051, giving a MOE of 172. This exposure is considered acceptable.

The last scenario for combined exposure is for non-professional user, who applies the product by brushing indoor, and has a total systemic exposure of 0.0144325 mg a.i./kg bw/day. Secondarily, this user may be exposed after handling treated wood, and therefore the combined exposure experienced is 0.0151225 mg a.i./kg bw/day, giving a MOE of 185. This exposure is considered acceptable. However, as products are normally not authorized for non-professional users if they have to wear PPE, this use should not be authorized, unless data are submitted at the product authorization stage to demonstrate that risks can be reduced to acceptable levels by other means.

Estimated total systemic combined exposure

User	Total Systemic Exposure (mg a.i./kg bw/day)				
	Industrial application	Professional application	Non-professional application	Secondary	Combined
				Handling	
Industrial	0.0346	-	0.0144325	0.00069	0.0511225
Professional	-	0.0010826	0.0144325	0.00069	0.0162051
Non-professional	-	-	0.0144325	0.00069	0.0151225

Comparison of NOAELS and combined exposure

User	Total systemic exposure mg a.i./kg bw/day	NOAEL	MOE
Industrial	0.0511225	2.8	55
Professional	0.0162051	2.8	172
Non-professional	0.0151225	2.8	185

Conclusion :

The combined exposure assessment shows unacceptable risks for industrial workers. Nevertheless, the risks for industrial workers is considered as acceptable, as an industrial worker will not be exposed to a non-professional use of product, because products won't be authorized for non-professional users as indicated above.

2.2.2. Environmental Risk Assessment

Summary of intended uses evaluated

MEGANIUM	
Industrial	*Dipping surface*
	Double vaccum-low pressure
Wood in Service	*Fence*
	Noise barrier
	House
	Fence post
	Transmission pole

Professional	Brushing	*Fence*
		House
	Injection	*Transmission pole*
Amateur	Brushing	*Fence*
		House

2.2.2.1. Fate and distribution in the environment

Chlorfenapyr is a solid with a low vapour pressure (2.37×10^{-6} Pa at 20ºC), therefore air has not been considered as a compartment of concern.
Considering the water compartment chlorfenapyr is practically insoluble in water without pH dependence. It is soluble in organic solvents. Its partition coefficient n-octanol/water indicates that chlorfenapyr has possibility to bioaccumulate.
Chlorfenapyr is considered hydrolytically stable. Chlorfenapyr is rapidly degraded by photolysis in aqueous systems. Studies conducted following the OECD 301C Ready Biodegradability, demonstrated that chlorfenapyr is not readily biodegradable. Microbes are very important in the degradation of chlorfenapyr in aquatic systems. In conclusion, chlorfenapyr is microbially degraded.
Finally, considering the soil compartment chlorfenapyr is slowly degraded under aerobic conditions. There was only one metabolite (CL 312094), which was present in the soil at concentrations greater than 0.01 ppm. This metabolite accounted for a maximum of 8% of the dose (approximately 0.08 ppm). The adsorption and desorption of chlorfenapyr was studied by the batch equilibrium method in four soils. The K_{OC} values for chlorfenapyr ranged from 10000 to 14762 with an average of 11960 L/kg, indicating that chlorfenapyr is strongly adsorbed by soil.
Chlorfenapyr can reach the soil from direct application and deposition from atmosphere. Consequently the adverse effects have to be assessed regarding those considerations.

2.2.2.2. Effects assessment

The aquatic acute toxicity tests show that the substance is very toxic to aquatic organisms, and aquatic invertebrates represent the most sensitive taxonomic group, with EC50 of 0.002 and 0.0061 mg/l, respectively for *Mysidopsis bahia* and *Daphnia.* Reproduction and growth rate tests preformed with *D .magna* and *M.bahis* indicated that the a.s. is highly toxicity to aquatic invertebrates, since a NOEC of 0.0036 mg/l and 0.00017 mg/l were determinate.

The acute toxicity of CL 312094, has investigated in *Americamysis bahia* and the 96-hr LC_{50} value estimated by binominal probability was 0.28 mg/L, with 95% confidence intervals of 0.15 to 0.49 mg/L.

A Lyfe cycle toxicity test with the metabolite CL 312094 has been performed with *Americamysis bahia.* The MATC value determined based on the most sensitive statistically

significant endpoint, F1-mysid length, was 44.4 µg/L (NOEC = 31.2 µg/L and LOEC = 63.3 µg/L).

The results of the acute toxicity tests conducted with the biocidal product MYTHIC to the standard aquatic organisms (fish, D. magna and algae) are similar to the results of the active substance, indicating that the biocide product is very toxic to aquatic organisms. However, no aquatic exposition will be predicted from the uses of MYTHIC and regarding that no risk could be identified.
No ecotoxicological studies were presented with the product MEGANIUM.20 SL

For assessment of the effects of chlorfenapyr on aquatic organisms eight acute studies were preformed with different species of the standard organisms: fish, aquatic invertebrates and algae. Seven chronic tests were preformed, two with fish, two with aquatic invertebrates and three with sediment- dwelling organism. According to the TGD (EC, 2003) an assessment factor of 10 can be applied to derive a $PNEC_{water}$ if Long-therm NOECs from at least three tropic levels are available and the $PNEC_{water}$ should be calculated from the lowest available NOEC.

Considering an assessment factor of 10 and the lowest NOEC for aquatic organisms, NOEC of 0.17µg/l for *Mysidopsis bahia*, is possible to estimate a $PNEC_{water}$ of 0.017 µg/l (0.000017 mg/l).

According to the TGD (EC, 2003) the $PNEC_{sediment}$ should be derived from the lowest available NOEC/EC10 obtained in long-term tests by application of an assessment factor of 10 if three long-term tests with species representing different living and feeding conditions are available.

As result of the application of chlorfenapyr to water it was considered a NOEC of 0.0188 mg/l (*C. riparius*), so applying assessment factor of 10 is possible to estimate a $PNEC_{sediment}$ of 0.00188 mg/l (eq. 0.49 mg/kg)

A respiration inhibition test was conducted with active sludge, where was estimated an EC50 value of 0.6 mg/l. In agreement with the TGD (EC, 2003) an assessment factor of 100 can be applied. A $PNEC_{microrganisms}$ value of 0.006 mg/l can be estimated for STP.

Regarding effects on terrestrial organisms, the acute toxicity tests show that the substance is toxic to them, with LD50, LC50 and NOECrep values for the most sencitive birds of 10.3 mg/kg, 8.6 ppm and 0.5 ppm, respectively. Chlorfenapyr was also acutely toxic to bees with LD50oral value of 1.0 µg/bee and LD50 contact value of 0.33 µg/bee and to earthworms with EC50 value of 23 mg/kg.

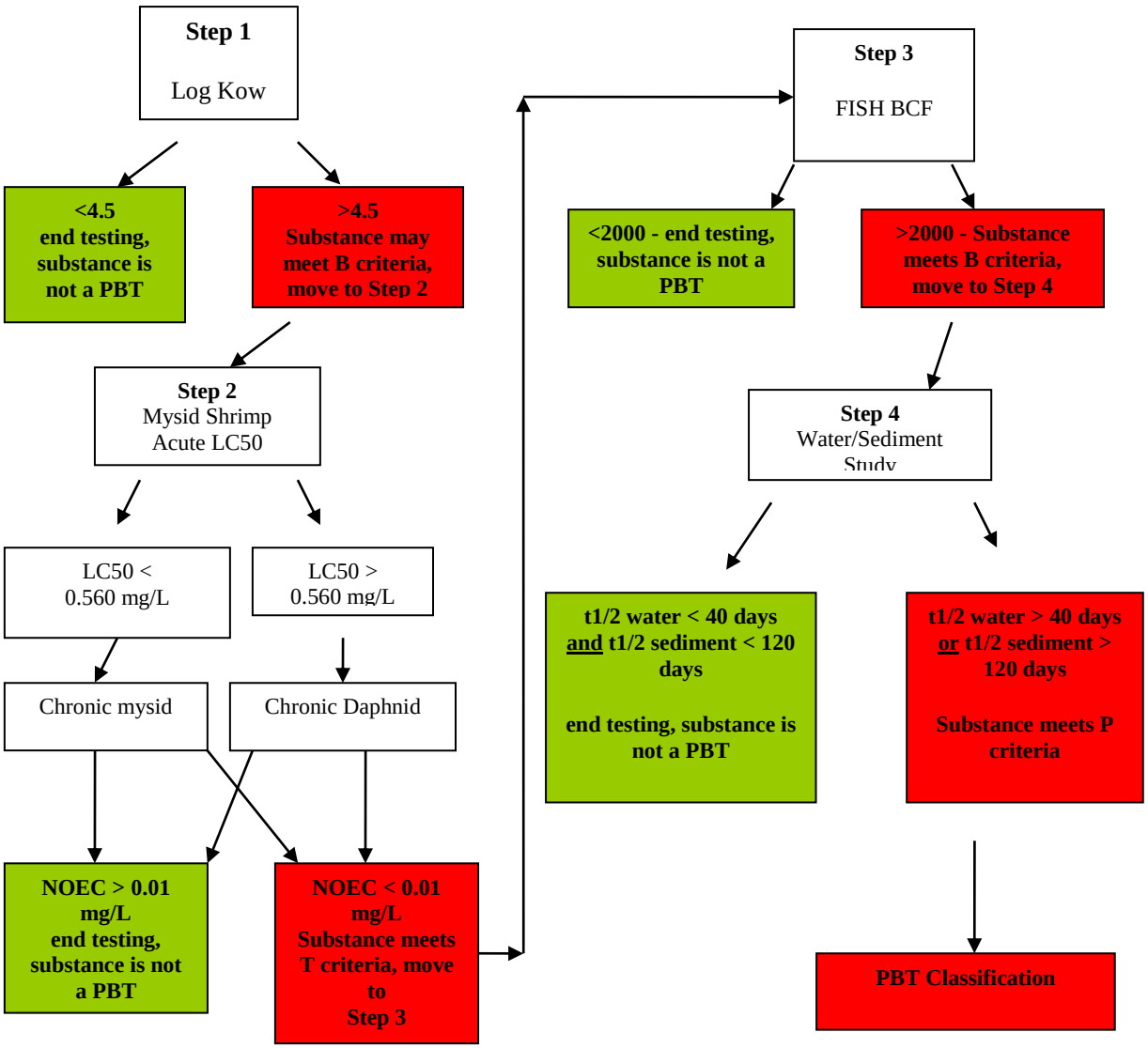
Five studies were conducted to terrestrial organisms, two with terrestrial microorganisms, two with earthworms and one with terrestrial plants. According to the TGD (EC, 2003) an assessment factor of 10 can be applied if long-term studies with three different tropic levels were conducted. A $PNEC_{soil}$ value of 0.14 mg/kg dry weigth soil was estimated, based on chronic effects on earthworms (normalized NOEC to 3.5% OM is 1.4 mg/kg dry weight).

2.2.2.3. PBT assessment

An assessment is provided to evaluate whether the biocidal active substance chlorfenapyr and the major soil and fish metabolite CL 312094, merit consideration to be classified as Persistent, Bioaccumulative and Toxic (PBT). After a thorough evaluation of the chlorfenapyr database, it has been considered that the active substance chlorfenapyr does not merit consideration for PBT classification because it does not meet the criteria for a bioaccumulative compound as outlined in the Technical Guidance Document (TGD) in support of Directive 98/8/EC. Since the database for CL 312094 was incomplete, the RMS and BASF requested the opinion of the Technical Committee Sub-group on PBT and vPvB substances regarding a proposed four-step testing program, which was endorsed by the Sub-group.

The main features of the program are that the testing would terminate once it was determined that any one of the three PBT criteria was not met, and the program delayed additional vertebrate testing until it was absolutely necessary to evaluate a criteria. The testing program, which was endorsed by the Technical Committee Sub-group on PBT and vPvB substances is summarized below.

Proposed PBT Testing Program for CL 312094



An octanol/water partition coefficient study with CL 312094 has been conducted [redacted] and resulted in an experimental Log K_{ow} of 4.56, which is slightly higher than the trigger value of 4.5. Therefore, Step 2 of the program has been conducted.

An acute toxicity study with the saltwater mysid has been conducted [redacted] and resulted in an acute LC50 (96h) of 0.28 mg/L. This value is lower than the acute toxicity value for *Daphnia magna* (EC50 (48h) = 0.56 mg/L, [redacted]. Therefore, a mysid chronic toxicity study was conducted.

Regarding that the mysid chronic toxicity study with CL 312094 [redacted] was conducted. The 28-day study evaluated effects on adult survival, reproduction, adult growth (body lengths), offspring survival and offspring growth (body lengths). The evaluation of offspring body lengths is a new endpoint in the draft guidelines. The NOEC values for the various endpoints, as well as the overall study endpoint are as follows:

NOEC for adult survival = 130 µg/L

NOEC for reproduction = 63.3 µg/L

NOEC for adult body lengths = 63.3 µg/L

NOEC for offspring survival = 130 µg/L

NOEC for offspring lengths = 31.2 µg/L

Maximum Acceptable Toxicant Concentration (MATC) = 44.4 µg/L

Although a significant reduction was detected in the 15.6 µg/L treatment level this was not typical for a concentration-response curve and considering that at the test concentration of 31.2 µg/L no effects were observed, the NOEC from the study has been established as 31.2 µg/L.

Based on this information, the proposed MATC from the study is 44.4 µg/L. Since both of these values are > 10 µg/L, RMS considered that the "**T" criteria is not met** and the testing program can be terminated.

There is no definitive data on the persistence of CL 312094 in water or in soil. However, in the guideline aerobic soil metabolism studies that were conducted with chlorfenapyr [redacted] the concentrations of CL 312094 in soil generally increased throughout the study period, indicating that the compound was being formed more rapidly than it was being degraded. Therefore, circumstantial evidence indicates that the **persistence (P) criterion for CL 312094 may be fulfilled**.

The experimental Log K_{ow} for CL 312094 was 4.56, which is marginally higher than the trigger value of 4.5. A fish bioaccumulation study with CL 312094 has not been conducted. However, the results from the bluegill sunfish bioaccumulation study chlorfenapyr demonstrated rapid elimination of radioactive residues from the fish during the depuration phase, with a calculated t1/2 for clearance of 3-4 days. Since > 89% of the radioactive residues in the fish was CL 312094, the results indicate rapid elimination of CL 312094 from fish. In addition, CL 312094 is far more water soluble than chlorfenapyr (369 µg/L as opposed to 140 µg/L for chlorfenapyr) [redacted] confirming its lower lipophilicity.

Although an experimental fish BCF for CL 312094 has not been determined, Quantitative Structure Activity Relationship (QSAR) programs can be used to estimate the bioaccumulation potential of this molecule, and to evaluate whether the results meet the bioaccumulation trigger for PBT classification. In the absence of experimental data, QSAR-based assessments are recommended in the Technical Guidance Document (TGD) for PBT evaluations of biocides and will also be applied under REACH.

Using the program BCFWIN (Meylan *et al*., 1996), a model estimate value for a fish QSAR BCF for CL 312094 was determined to be 720.

Since it is clear that CL 312094 is less lipophilic than chlorfenapyr (based on both log K_{ow} and water solubility), and chlorfenapyr does not meet the PBT bioaccumulation trigger based on experimental data, it can be safely assumed that CL 312094 will not meet the bioaccumulation trigger for PBT classification. Therefore, there is no need to conduct a fish bioaccumulation study with CL 312094.

There is definitive toxicity data for CL 312094 and the compound does not meet the PBT trigger value for toxicity (T). The LC/EC50 values for bluegill sunfish [redacted] *Daphnia magna* [redacted] and green algae (*Selenastrum capricornutum*) [redacted] and saltwater mysid [redacted] were > 0.928, 0.56, 0.60, and 0.28 mg/L, respectively. These values are all higher than the acute toxicity trigger value recommended in the TGD (LC / EC50 < 0.1 mg/L). The chronic toxicity values for the most sensitive species, the saltwater mysid [redacted] (NOEC = 0.0312 mg/L; MATC = 0.0444 mg/L) were higher than the chronic toxicity trigger value recommended in the TGD (i.e., 0.01 mg/L).

CL 312094 is also practically non-toxic to mammals (rat oral LD50 > 5000 mg/Kg bw; [redacted] and slightly toxic to birds (Northern bobwhite and Mallard duck LD50 values of 1687 and > 2400 mg/kg, respectively; [redacted]

In all instances, the metabolite is less toxic than parent chlorfenapyr.

Based on experimental toxicity results in aquatic organisms, CL 312094 does not meet the toxic "T" criteria for PBT classification. In addition, circumstantial evidence and the results from QSAR modeling indicate a low potential to bioaccumulate in fish. Considering that RMS concluded that the metabolite does not meet the bioaccumulative "B" criteria for PBT classification.

In conclusion, it is considered that:

- chlorfenapyr :
  - meets the criteria to be considered as "T"
  - may meet the criteria to be considered as "P"
  - does not meet the criteria to be considered as "B"
- CL 312094 :
  - does not meet the criteria to be considered a "T"
  - may meet the criteria to be considered as "P"
  - does not meet the criteria to be considered as "B"

As a consequence, it is considered that neither chlorfenapyr nor CL 312094 merit classification as PBT compounds.

However, it has been agreed that both compounds should be further assessed by the ECHA PBT working group, in order to have a formal conclusion on those properties.

2.2.2.4. Exposure assessment

The estimated PEC's on air of Meganium for industrial treatments range between 1.9 E^{-09} mg/m^3 and 2.8 E^{-08} mg/m^3, the risk could be considered negligible.

The product MEGANIUM 20 SL was proposed for industrial, professional and amateur wood treatments. As result of industrial preventive treatment, emissions of chlorfenapyr could occur directly to waste water by direct discharge into facility drain. During storage, emissions could occur indirectly to ground water by leaching of the substance from the soil. Surface water can be also indirectly exposed by run-off from the storage site.
For professional and amateur indoor and outdoor treatments no emissions to the aquatic environment will occur.
The estimated PEC's on surface water of MEGANIUM 20 SL for industrial treatments range between 4.82 E^{-02} mg/L and 7.25 E^{-02} mg/L.
The estimated PEC's on sediment of MEGANIUM 20 SL for industrial treatments range between 0.25 mg/L (10.83E^{-11} mg/kg) and 1.67 mg/L (16.28E^{-11} mg/kg).

No models were used to estimate the PECgroundwater for MEGANIUM 20 SL intended uses.

However, as mentioned before, chlorfenapyr is classified as immobile in soil and presents low potential to leach to groundwater. Therefore, a negligible risk of contamination of groundwater is expected.

During storage, emissions of the product MEGANIUM 20 SL could occur directly to soil by leaching from treated wood via rainfall. Although the Applicant did not present clear information on intended uses classes of treated wood in service, it was considered for evaluation the Use Classes 1, 2, 3 and 4a. For Use classes 3 and 4a, outdoor classes, in which treated wood is exposed to weather conditions, rainfall will be the major emission tool. Soil will be the mainly exposed compartment.
From professional and amateur outdoors treatments soil will the mainly exposed compartment.
The PEC soil values for MEGANIUM 20 SL ranged between 3.1 and 91.9 mg/kg for different exposure scenarios.

2.2.2.5. Risk characterisation

The PEC/PNEC ratio of MEGANIUM 20 SL show unacceptable risk for aquatic environment for industrial treatments, dipping and double vacuum, with this biocidal product (b.p).
However, this assessment represent a worst case situation because 100% wood leaching was considered (as first tier approach) and the scenario considered that treated wood will be exposed to environmental conditions, in particular rainfall, during the storage period. If during the storage period the treated wood were placed under paved ground and below some covering structure, exposure to rainfall will be avoid and no emission to surface water, by run-off, will occur. So, aquatic compartment won't be at risk.

Regarding sediment risk assessment the PEC/PNEC ratio show acceptable risk for sediment dwelling organisms.

For all the intended uses of b.p MEGANIUM 20 SL the PEC/PNEC ratio was higher than one, i.e. unacceptable risk for terrestrial compartment was identified for all uses. Even for the double vacuum pressure, the process with highest impregnation level (lowest emission potential) the estimated risk to terrestrial compartment is very high. Note that the assessment represents a worst case situation because 100% wood leaching and treated wood exposure during storage were considered for industrial scenario. However, for industrial scenario, emissions to soil can be avoided if the treated wood were placed above paved ground. Therefore no exposition of soil compartment will occur, so no risk for terrestrial organisms will be expected.
An unacceptable risk was identified for treated wood in service scenarios, considering a worst case situation with 100% wood leaching. Moreover, no reasonable measures to avoid emissions from treated wood in service to soil for Use Classes 3 and 4a can be applied, since treated wood is continually exposed to environmental conditions. Therefore, **the treated wood should only be used for use Classes 1 and 2,** in which no exposure to environmental conditions is predicted, since they will be indoor uses. For those classes, C1 and C2, no terrestrial exposure will occur, so no risk to terrestrial compartment will be predicted.
Regarding professional and amateur outdoors treatments, it was possible to conclude that unacceptable risk was identified for terrestrial compartment, for the worst case scenario evaluated, with 100% wood leaching. For those treatments there are no reasonable measures to risk reduction, as well as there are no reasonable measures to avoid the emission of the product to soil. For those reasons **only the indoor professional or amateur treatments present no risk** to terrestrial compartment, since in those conditions environmental exposure will not be expected.
The assessment of secondary poisoning of birds and mammals has not been considered, since treated wood is now only proposed for indoor use. However during product authorisation the secondary poisoning of birds and mammals should be assessed if exposure is expected, for example for outdoor use.

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

On the basis of the proposed and supported uses and the evaluation conducted as summarised in the tables appended at the end of this document, it can be concluded that chlorfenapyr fulfils under the conditions listed in 3.2 the requirements laid down in Article 5(1) (b), (c), and (d) of Directive 98/8/EC.
Article 10 of the Biocides Directive 98/8/EC addresses the inclusion of an active substance in the Annexes I, IA or IB. For the decision of inclusion or non-inclusion, it has to be examined if the criteria of article 10 (1) are fulfilled.
For Annex I inclusion toxicological evaluation was based on the formulation Mythic 2C (dermal absorption value), as the formulation MEGANIUM 20 SL needs to be reworked to remove the NPE component.

Insufficient data exists to address the Phys-chem properties and no ecotoxicity data are available for the product MEGANIUM 20L.

The physico-chemical properties of chlorfenapyr and MYTHIC are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

With regard to efficacy, sufficient experimental data have showed that chlorfenapyr is efficacious as a wood preservative. Organisms to be controlled are the wood boring beetles, *Hylotrupes bajulus* (Longhorn beetle), *Anobium punctatum* (common furniture beetle) and *Lyctus brunneus* (powderpost beetle) and subterranean termites (*Reticulitermes* sp). Laboratory studies have demonstrated efficacy of the chlorfenapyr as an insecticide in use classes 1, 2, 3 and 4 however when included in a formulated wood preservative complementary aging tests (evaporation EN73 and leaching EN84) and/or field tests with termites (EN252) will have to be performed to confirm this claims at national level. Additional tests for superficial application should also be performed to demonstrate the efficacy of the product when applied by superficial application methods.

With regard to human health exposure and effects, acute toxicity studies resulted in classification of chlorfenapyr technical as toxic by inhalation (T; R23) and harmful if swallowed (Xn; R22). Chlorfenapyr did not present genotoxic or carcinogenic properties and it did not show a potential for reproductive toxicity (developmental toxicity or fertility impairment). RMS proposes the classification with R48/22, "harmful: danger of serious damage to health by prolonged exposure if swallowed".

For MEGANIUM, for industrial workers using water-based and solvent-based chlorfenapyr formulations in double-vacuum impregnation and dipping applications, MOE is bellow 100. It must be indicate that the total exposure obtained, represent a worst case situation, assuming that (combined exposure) all activities including cleaning are done by one and the same person at one day. Although this may occasionally happen it certainly does not occur every working day. Application is assumed to be done every day, whereas cleaning might be done a few times a year only, with the assumption that the obligatory PPE is used.

For professional workers involved in wood treatment by spraying or small-scale dipping wooden articles does not represent risk, a sufficient margin of exposure (MOE above 100) was reach with the assumption that they use the obligatory PPE.

Brush painting indoors and outdoors is the only application envisage for non-professional users. The highest exposure is expected when the product is applied indoors. The use of chlorfenapyr in biocidal products (MEGANIUM) by amateurs is deemed safe with the use of gloves. As products are normally not authorized for non-professional users if they have to wear PPE, this use should not be authorised, unless data are submitted at the product authorization stage to demonstrate that risks can be reduced to acceptable levels by other means.

An acute secondary exposure to MEGANIUM can be anticipated for adults who work with treated wood (handling or processing treated wood) and for infants who may have oral contact with treated wood (e.g. chewing on a chip of treated wood). The calculated exposure for adults in this acute scenario is extremely low (MOE above 100 and very high). Children are not at risk for acute secondary exposure to wood preservatives MOE is above 100 and very high.

Chronic secondary exposure to MEGANIUM is relevant for adults who cut or send treated wood as part of there occupation (e.g. carpenters). Children may have repeated contact to MEGANIUM treated wood, e.g. on playgrounds. For infants, dermal contact and oral absorption after hound-mouth contact are possible routes of exposure MOE is above 100, and very high, no risk is expected.

In conclusion, dermal exposure of children playing on preserved timber does not represent a risk when the wood is treated by dipping for childs and infants (MOE abve 100 and very high).

For adult professional or amateurs no risk is expected when processing treated wood with MEGANIUM., MOE is very high.

With regard to environmental exposure and effects, Chlorfenapyr is considered hydrolytically stable but photo labile in aqueous systems. Chlorfenapyr is of high persistence but immobile in soil. Chlorfenapyr has a very limited potential for reaching the atmosphere in significant amounts. Therefore, both short- and long-range transport of chlorfenapyr in the atmosphere are expected to be negligible.

Based on the information available the RMS considers that chlorfenapyr and CL 312094 do not merit classification as PBT compounds.

However, both compounds should be further assessed by the ECHA PBT working group.

Chlorfenapyr is of high acute and chronic toxicity to aquatic organisms. The major metabolite CL 312094 is less toxic than the active substance. The product MYTHIC is of comparable toxicity to the active substance, on an a.s. basis. No ecotoxicological data have been presented for the product MEGANIUM.

Chlorfenapyr was shown to be highly toxic to birds from acute, short and long term exposure. It also shows high acute toxicity to mammals. The metabolite CL 312094 is of lower acute toxicity to birds than the active substance. The active substance is also acutely toxic to earthworms Testing has not been carried out with the metabolite, but it is expected to be less

toxic than the active substance. Chlorfenapyr was also concluded as toxic to honey bees. Testing of effects of the a.s. on soil microorganisms showed that there was no significant effect on carbon fixation but nitrogen fixation was affected in more than a 25% after 91-days.

Although a complete database exists for the potential effects of chlorfenapyr on numerous terrestrial organisms, the application method for chlorfenapyr, coupled with the locations where it is applied, have low relevance to any significant exposure of birds, small mammals, and beneficial insects. Earthworms and soil organisms will be exposed within the small treated area associated with houses. In general, high populations of earthworms are not expected to be present in the bare area immediately adjacent to a house. Concentrations in the treated soil are quite high, and outright earthworm mortality can be expected in the treated area. In laboratory studies, chlorfenapyr did not cause intoxicated earthworms to surface, so there will be minimal exposure to birds.

Therefore, **the treated wood should only be used for use Classes 1 and 2,** in which no exposure to environmental conditions is predicted, since they will be indoor uses. For those classes, C1 and C2, no terrestrial exposure will occur, so no risk to terrestrial compartment will be predicted. **The indoor professional or amateur treatments present no risk** to terrestrial compartment, since in those conditions environmental exposure will not be expected.

3.2. Decision regarding Inclusion in Annex I

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

The active substance chlorfenapyr as manufactures shall have a minimum purity of 940g/kg

The identity and the maximum content of impurities have to comply with the confidential Annex III A document.

The Union level risk assessment did not address all potential uses and exposure scenarios. 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, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment.

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

(1) for industrial or professional users safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means;

(2) products shall not be authorised for non-professional users, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level;

(3) labels and, where provided, safety data sheets of products authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment on impermeable hard standing to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal;

(4) products shall not be authorised for treatment of wood that will be used outdoors, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate mitigation measures.

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

For Annex I inclusion the toxicological evaluation was based on the formulation Mythic 2C (dermal absorption value), as the formulation MEGANIUM 20 SL needs to be reworked to remove the NPE component, and therefore; specific data must be request for other formulations, namely “Dermal absorption studies” at MS level.

The use of chlorfenapyr in biocidal products (Meganium) by amateurs would be safe with the use of gloves. As products are normally not authorized for non-professional users if they have to wear PPE, this use should not be authorized, unless data are submitted at the product

authorization stage to demonstrate that risks can be reduced to acceptable levels by other means.

Additionally, Member states should pay particular attention to the combined exposure for industrial workers and ensure that risks for those users can be reduced to acceptable levels if it is demonstrated that risk for non-professional use is acceptable,

No ecotoxicity data are available for the product MEGANIUM 20L Specific ecotoxicity data should be requested at National level if exposure is expected, for example by outdoor use.

During product authorization the secondary poisoning of birds and mammals should be assessed.

Therefore, **the treated wood should only be used for use Classes 1 and 2,** in which no exposure to environmental conditions is predicted, since they will be indoor uses. For those classes, C1 and C2, no terrestrial exposure will occur, so no risk to terrestrial compartment will be predicted.
Regarding professional and amateur outdoors treatments, it was possible to conclude that unacceptable risk was identified for terrestrial compartment, for the worst case scenario evaluated, with 100% wood leaching. For those treatments there are no reasonable measures to risk reduction, as well as there are no reasonable measures to avoid the emission of the product to soil. For those reasons **only the indoor professional or amateur treatments present no risk** to terrestrial compartment, since in those conditions environmental exposure will not be expected.

When assessing applications for product authorisation, Member states should consider the fact that it is considered that:

- chlorfenapyr :
    - meets the criteria to be considered as “T”
    - may meet the criteria to be considered as “P”
    - does not meet the criteria to be considered as “B”
- CL 312094 :
    - does not meet the criteria to be considered a “T”
    - may meet the criteria to be considered as “P”
    - does not meet the criteria to be considered as “B”

It has been agreed that both compounds should be further assessed by the ECHA PBT working group, in order to have a formal conclusion on those properties. Those conclusions should be taken into consideration at the stage of product authorisation.

Efficacy has only been validated on wood boring beetles (*Hylotrupes bajulus*) and Termites (*Reticulitermes spp*.) at the annex I inclusion stage. Member States should pay attention to assess the efficacy on the other target organisms if claimed in the applications for product authorisation. Efficacy should be assessed on a case by case basis, regarding the use class and the claims at product authorisation.

3.4. Requirement for further information

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

However additional validation of the methods of analysis for air, soil and sediment are considered necessary. Those data should preferably be submitted to the original Rapporteur Member State (Portugal) at the latest 6 months before the date of inclusion of the active substance into Annex I.

3.5. Updating this Assessment Report

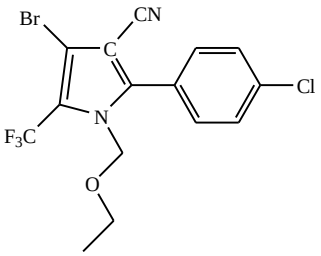
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any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

Identity

Chemical name (IUPAC)	4-bromo-2-(4-chlorophenyl)-1-ethoxymethyl-5-trifluoromethylpyrrole-3-carbonitrile
Chemical name (CA)	Pyrrole-3-carbonitrile, 4-bromo-2-(p-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-
CAS No	122453-73-0
EC No	Not allocated
Other substance No.	BAS 306 I, AC 303630, AC 303,630, CL 303630, CL 303,630, MK-242, PIRATE technical, BASF Regno: 4084563
Minimum purity of the active substance as manufactured (g/kg or g/l)	940 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None
Molecular formula	$C_{15}H_{11}BrClF_3N_2O$
Molecular mass	407.6
Structural formula	

Physical and chemical properties

Melting point (state purity)	101.4 – 102.3 °C (99.0% purity)
Boiling point (state purity)	Decomposes (93.8% purity)
Temperature of decomposition	183 °C, onset of decomposition
Appearance (state purity)	Solid powder, white with pale yellow tint (98.9% purity) Solid powder, light tan to light yellow (93.8% purity)
Relative density (state purity)	0.543 g/mL (bulk density, 93.8% purity)
Surface tension	Not required as solubility in water is less than 1mg/L
Vapour pressure (in Pa, state temperature)	2.37×10^{-6} Pa @ 20 °C 5.40×10^{-6} Pa @ 25 °C
Henry's law constant (Pa m^3 mol^{-1})	6.91×10^{-3} $Pa \cdot m^3 \cdot mol^{-1}$ (20 °C, unbuffered/deionized water)
Solubility in water (g/l or mg/l, state temperature)	pH__5__: 0.11 mg/L, 20°C
	pH__9__: 0.14 mg/L, 20°C
	pH__7___: 0.11mg/L, 20 °C
	unbuffered/deionized water: 0.14 mg/L, 20 °C
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	For PAI 99.0% purity, 20 °C
	Hexane: 6.85 g/L
	Methanol: 50.6 g/L
	Acetonitrile: 394 g/L
	Toluene: 490 g/L
	Acetone: 697 g/L
	Dichloromethane 744 g/L
	Ethyl Acetate: 514 g/L
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	Not applicable. The active substance, as manufactured, does not include an organic solvent
Partition coefficient (log P_{OW}) (state temperature)	pH__5__: log P_{OW} = 5.28, 20°C
	pH__9__: log P_{OW} = 5.24, 20°C
	pH__7__: log P_{OW} = 5.21, 20°C
	Deionized water: log P_{OW} = 5.28, 20°C
Hydrolytic stability (DT_{50}) (state pH and temperature)	Stable at pH 4, 7 and 9 at 50ºC
Dissociation constant	Not measurable. There are no ionizable groups in the molecule.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	260nm (ε = 11062 M^{-1} cm^{-1}) no λ max above 290 nm
Photostability (DT_{50}) (aqueous, sunlight, state pH)	Environmental half-lives as simulated for a small lake

	($100m^2$, 3 m deep) in Central Europe (52º N) were 2.3 hours for June and 1.0 day for December
Quantum yield of direct phototransformation in water at $\Sigma > 290$ nm	Quantum Yield, $\Phi_x - 1 \times 10^{-2} \pm 0.2 \times 10^{-2}$
Flammability	Non-flammable.
Explosive properties	Not explosive.

Classification and proposed labelling

with regard to physical/chemical data	None
with regard to toxicological data	T, R23; Xn, R22; Xn, R48/22
with regard to fate and behaviour data	R53
with regard to ecotoxicological data	N, R50
Existing classification and labelling according to Annex I of Council Directive 67/548/EEC	**Classification as recommended by ECB Ispra, 25-27 April 2010** Classification: T, N Risk phrases: R22, R23, R50/53 Safety phrases: S1/2, S13, S36/37, S45, S60, S61 **Proposed labelling for the technical a.s.:** Classification: T, N Risk phrases: R22, R23, R48/22, R50/53 Safety phrases: S1/2, S13, S23, S36/37, S38, S45, S60, S61, S63 **Classification Meganium 20 SL**: T, N Risk phrases: R22, R48/22, R51/53 Safety phrases: S2, S13, S23, S36/37, S46, S60, S61

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	Capillary GC-FID
Impurities in technical active substance (principle of method)	Capillary GLC-FID (organic impurities) HPLC-UV (impurity) CIPAC MT 30 (water) Gravimetric method (non-sulphated ash)

Analytical methods for residues

Soil (principle of method and LOQ)	GC-ECD: LOQ = 10ppb (0.1 mg/kg) GC-MS/MS: LOQ = 1ppb (0.1 mg/kg)
Air (principle of method and LOQ)	GC-MS/MS: LOQ = 0.5 ng/l (0.5 µg/m3)
Water (principle of method and LOQ)	Surface and drinking water: GC-MS/MS: LOQ = 0.1 ppb (0.1 µg/L) Sediment: GC-ECD: LOQ = 10 ppb(0.1 mg/kg) HPLC-MS/MS: LOQ = 10ppb (0.1 mg/kg)
Body fluids and tissues (principle of method and LOQ)	GC-ECD: LOQ = 50 ppb (skin/fat, liver, gastrointestinal track, blood) HPLC-MS/MS: LOQ = 50 ppb (0.5 mg/L) (blood)
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	About 60% . .
Rate and extent of dermal absorption:	3.5% when handling the concentrate preparation; 15 % when handling the in use spray dilution (in vivo study conducted whit "Mythic 2C")
Distribution:	Higher concentrations found in fat and liver, and to a lesser extent in kidneys, muscle and blood, brain had the lowest concentration of residual radioactivity.
Potential for accumulation:	No evidence of accumulation
Rate and extent of excretion:	80%-100% within 7 days via faeces, only about 10% via urine
Toxicologically significant metabolite(s)	None

Acute toxicity

Rat LD_{50} oral	441 ♂ and 1152 ♀ mg/kg bw; **Xn; R22**
Mice LD50 oral	55 mg/kg bw/day for both male and female; **Xn;T25**
Rabbit LD_{50} dermal	> 2000 mg/kg bw; no lethal effect at maximal dose
Rat LC_{50} inhalation	0.83 ♂ and > 2.7 ♀ mg/l/4h, dust, whole body; **T; R23** (based on ♂ only)
Skin irritation	Non-irritant
Eye irritation	Non-irritant
Skin sensitization (test method used and result)	Non-sensitiser (M&K, 0%)

Repeated dose toxicity

Species/ target / critical effect	Rodents: liver, vacuolation of the brain & spinal cord, **Xn; R48/22**
Lowest relevant oral NOAEL / LOAEL	1y & 90d dog: 4.0 mg/kg bw/d
Lowest relevant dermal NOAEL / LOAEL	18m mouse: 2.8 mg/kg bw/d
Lowest relevant inhalation NOAEL / LOAEL	28d rabbit: 100 mg/kg bw/d

Genotoxicity	No genotoxic potential

Carcinogenicity

Species/type of tumour	No carcinogenic potential (rat and mouse)
lowest dose with tumours	No oncogenic effect up to 30.8 mg/kg bw/d in rats and up to 34.5 mg/kg bw/d in mouse

Reproductive toxicity

Species/ Reproduction target / critical effect	Reduction in pup body weights at parental toxic dose, no effect on fertility or reproductive function (rat)
Lowest relevant reproductive NOAEL / LOAEL	Reproductive: 44 mg/kg bw/d General toxicity: 5 mg/kg bw/d
Species/Developmental target / critical effect	No developmental toxicity or teratogenicity (rat and rabbit)
Developmental toxicity	
Lowest relevant developmental NOAEL / LOAEL	Developmental : 30 mg/kg bw/d (rabbit) Maternal - 5 mg/kg bw/d (rabbit)

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	Rodents : vacuolation and/or myelin sheath swelling of the brain and spinal cord
Lowest relevant developmental NOAEL / LOAEL.	2.6 mg/kg bw/d

Other toxicological studies

.....	none

Medical data

.....	Chlorfenapyr has been formulated in a plant in the US since 1994. During this time no unusual or abnormal health effects have been observed among operators or other employees involved in the formulation process.

Summary	Value	Study	Safety factor
Non-professional user			
ADI (acceptable daily intake, external long-term reference dose)	0.028mg/kg bw/d	18m mouse	100
AOEL (Operator Exposure)	0.27 mg/kg bw/d (acute exposure) 0.017 mg/kg bw/day (chronic exposure)	acute oral neurotoxicity, rat 1y neurotoxicity rats 1 y mice 2 y rat	100 / 60% oral absorption
ARfD (acute reference dose)	Not applicable		
Professional user	0.27 mg/kg bw/d (acute/short term exposure)	Acute oral neurotoxicity, rat. 1y neurotoxicity rats 1 y mice	100 / 60% oral absorption

	0.017 mg/kg bw/day (chronic exposure)	2 y rat	
Reference value for inhalation (proposed OEL)	Not applicable		
Reference value for dermal absorption	3.5% when handling the concentrate preparation 15% when handling the in-use spray dilution.	*In vivo* dermal absorption study with **"Mythic"**	

Acceptable exposure scenarios (including method of calculation)

Professional users **(Meganium 20 SL)**		
	Double vacuum impregnation: Application/post-application Water based formulations	
	75%-ile 11.58% of AOEL (with PPE)	95%-ile 2.29% of AOEL (with PPE)
	Solvent based formulations	
	75%-ile 30.09% of AOEL (with PPE)	95%-ile 7.14% of AOEL (with PPE)
	Cleaning: Water based Formulations 75%-ile 13.6% of AOEL (more PPE is needed) 95%-ile 35.3% of AOEL (more PPE is needed)	
	Industrial dipping: Application/post-application Water based formulations	
	75%-ile 11.58% of AOEL (with PPE)	95%-ile 2.29% of AOEL (with PPE)
	Solvent based formulations	
	75%-ile 30.09% of AOEL (with PPE)	95%-ile 7.14% of AOEL (with PPE)

	Cleaning: Water based Formulations 75%-ile 13.6% of AOEL (more PPE is needed) 95%-ile 35.3% of AOEL (more PPE is needed) **Professional spraying (indoors):** 75%-ile 6.368% of AOEL 95%-ile 41.5% of AOEL **Professional small-scale dipping**: 75%-ile 3.17% of AOEL 95%-ile 6.41% of AOEL	
Production of active substance:	Not applicable	
Formulation of biocidal product	Not applicable	
Intended uses (Meganium)	Wood preservative, Industrial pre-construction treatment and Post-construction remedial treatment, in the concentration of chlorfenapyr : 10 - 25 g a.s/m^3 for impregnation and 0.01 – 0.05 g/m^2 for superficial treatment	
Secondary exposure **(Meganium 20SL)**	**Playing on preserved timber:** 0.20% (Childs) – 3.3% (Infants) of AOEL **Chewing preserved timber off-cuts:** 0.214 – .6.86% of ADI for double vacuum impregnated timber and for surface treated timber (dipping) respectively, for infants(worst case)	
Non-professional users **(Meganium 20SL)**	**Brushing indoor:** 75%-ile 84.89% of AOEL **Brushing outdoor:** water based formulations 75%-ile 0.914% of AOEL Solvent based formulations 75%-ile 10.30% of AOEL Safe uses only derived with the use of gloves	
Indirect exposure as a result of use **(Meganium 20SL)**	**Manual handling of treated, wet wood:** Water based formulations	
	75%-ile 0.12% of acute AOEL	95%-ile 0.3136% of acute AOEL
	Solvent based formulations	
	75%-ile 0.0056% of acute AOEL	95%-ile 0.0165% of acute AOEL

	Processing treated wood: 2.3% of ADI for professionals 0.092% of AOEL for amateurs

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)	pH4 : Stable for 5 days at 50ºC
	pH 7: Stable for 5 days at 50ºC
	pH 9: Stable for 5 days at 50ºC
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Conditions simulating a summer day in Princeton NJ: k^c_p $t_{1/2}$ PH 5 0.1333 day $^{-1}$ 5.2 days PH 7 0.0924 days^{-1} 7.5 days PH 9 0.1140 days^{-1} 4.8 days CL 357806 accounted for 62 to 68% of the dose. Quantum Yield, Φ_x – 1 x 10^{-2} ± 0.2 x 10^{-2} Environmental half-lives as simulated for a small lake (100m^2, 3 m deep) in Central Europe (52º N) were 2.3 hours for June and 1.0 day for December
Readily biodegradable (yes/no)	No
Biodegradation in seawater	Waiver
Non-extractable residues	
Distribution in water / sediment systems (active substance)	Chlorfenapyr moves rapidly to sediments in aquatic systems, Whole system DT_{50} values were 218 to 418 days under aerobic conditions and 177 days for anaerobic conditions. The DT_{50} values for water were 97 to 114 days and for sediment vary between 222 and 402 days under aerobic conditions. Under anaerobic conditions the DT_{50} value for sediment was 214 days. CL 312094 was the only significant metabolite, accounting for up to 20% of the applied radiocarbon in the aerobic studies, and 60% in the anaerobic study.
Distribution in water / sediment systems (metabolites)	Waiver

Route and rate of degradation in soil

Mineralization (aerobic)	< 1% after 1 year at 25 or 28ºC

Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): 1370 days (1 soil; US EPA 162-1)
	DT_{90lab} (20°C, aerobic):
	DT_{50lab} (10°C, aerobic):): not determined
	DT_{50lab} (20°C, anaerobic):
	degradation in the saturated zone:
Field studies (state location, range or median with number of measurements)	DT_{50f}: 157days - loamy sand , WA 177 days - sand , FL 266 days - loam, WA 275 days - sandy loam, NC
	DT_{90f}: 522 to 914 days (4 locations)
Anaerobic degradation	DT_{50lab} (25°C, anaerobic): 663 to 667 days (1 soil, 2 labels).
Soil photolysis	
Non-extractable residues	Non-extractable residues were ≤ 20% of the applied a.i. and were not further characterized.
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	CL 312094 was the predominant metabolite in laboratory soil studies under aerobic conditions, reaching 12% of the applied a.i. at 28ºC and 8% at 25ºC. This metabolite was not identified at 20ºC. Under anaerobic conditions CL 312094 reaches 7% at 25ºC.
Soil accumulation and plateau concentration	

Adsorption/desorption

Ka , Kd		Ka	Kd	Ka_{oc}	Kd_{oc}	Avg of n soils
Ka_{oc} , Kd_{oc}	CL 303630	106	248	11960	27279	4
pH dependence (yes / no) (if yes type of dependence)	CL 312094	24	53	3055	6362	4
	CL 325195	2.4	3.7	139	222	5
	Mean Koc = 11959.5 L/kg					
	No pH dependence					

Fate and behaviour in air

Direct photolysis in air	Waiver
Quantum yield of direct photolysis	Waiver
Photo-oxidative degradation in air	Latitude: ..... Season: ..... DT_{50} .....
Volatilization	Waiver

Monitoring data, if available

Soil (indicate location and type of study)	None
Surface water (indicate location and type of study)	None
Ground water (indicate location and type of study)	None
Air (indicate location and type of study)	Occupant exposure in termiticide treated homes. Air conc. <0.5ng/L, <1.8µg/hr for a male doing heavy work.

Chapter 5: Effects on Non-target Species

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

Species	Time-scale	Endpoint	Toxicity
Fish			
Rainbow Trout (1992/7001128)	96-hours	LC_{50}	7.4 µg/l
Rainbow Trout (1993/7001103)	Early Life Stage (94-days)	NOEC	3.68 µg/l
Invertebrates			
Daphnid (1992/7001127)	96-hours	LC_{50}	6.1 µg/l
Mysids CL 312094 (2008/7019241)	96-hours	LC_{50}	0.28 mg/l
Daphnid (1994/7000840)	Full Life Cycle (21-days)	NOEC	3.57 µg/l
Mysids CL 312094 (2010/7012682)	Life-Cycle	NOEC MATC	31.2 µg/l 44.4 µg/l
Hyallela (1997/7000878)	10-days	EC_{50} NOEC	20.6 mg/kg (mean measured conc.) 10.9 mg/kg (mean measured conc.)
Leptocheirus (1998/7000835)	10-days	EC_{50} NOEC	0.18 mg/kg (mean measured conc.) 0.0863 mg/kg (mean measured conc.)
Chirinomus (1997/7000799)	28-days	$EC_{50\ (10\text{-}day)}$ NOEC MATC	49.5 µg/l 16.8 µg/l 26.5 µg/l
Algae			
Selenastrum capricornutum (1995/7000716)	72-hours	EC_{50} NOEC	132 µg/l 20 µg/l
Microorganisms			
Activated Sludge (2002/5003775)	3-hours	EC_{50}	>0.6 ppm

Effects on earthworms or other soil non-target organisms

Acute toxicity to ……..	*Eisenia* (1994/7000855) EC_{50} = 23 mg/kg soil

	(normalized EC50 to 3.5% OM is 7.8 mg/kg dry weight
Reproductive toxicity to ……	*Eisenia* (1994/7000765) NOEC > 4.2 mg/kg normalized NOEC to 3.5% OM is 1.4 mg/kg dry weight

Effects on soil micro-organisms

Nitrogen mineralization	Negligible effect at 300 g a.i./ha. However in soil II micro-organisms were significantly affected throughout the test even when prolonged above the standard 28 days. (49.5% effect observed after 91 days at 4 mg/kg soil dw).
Carbon mineralization	Negligible effect at 4.0 mg/kg soil dw.

Effects on terrestrial vertebrates

Acute toxicity to mammals	See Chapter 3, Annex IIA, 6.1 NOAL = 2.8 mg/kg bw/d.
Acute toxicity to birds	Mallard (1993/7001095) LD_{50} = 10.3 mg/kg body weight
Dietary toxicity to birds	Mallard (1993/7001158) LC_{50} = 8.6 ppm
Reproductive toxicity to birds	Mallard (1994/7000889) NOEC = 0.5 ppm

Effects on honeybees

Acute oral toxicity	Honey Bee (1995/7001534) LD_{50} = 1.0 µg/bee
Acute contact toxicity	Honey Bee (1995/7001534) LD_{50} = 0.33 µg/bee

Effects on other beneficial arthropods

Acute oral toxicity	None
Acute contact toxicity	None
Acute toxicity to ……..	None

Bioconcentration

Bioconcentration factor (BCF)	Bluegill (1994/7000786) BCF = 2080 to 2140 based on total radioactivity and 66-74 based on parent

Chapter 6: Other End Points

Depration time (DT_{50}) (DT_{90})	DT_{50} = 4 days
Level of metabolites (%) in organisms accounting for > 10 % of residues	CL 312,094

Appendix II: List of Intended Uses

Summary of intended uses[5]

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks:
				Type	Conc. of as	method kind	number min max	interval between applications (min)	g as/L min max	water L/m^2 min max	g as/m^2 * or g as/m3** min max	
Wood destroying insects	–	**20 MEGNIUM SL**	Wood boring beetles:Hylotrupes bajulus, Anobium puntactum, Lyctus bruneus Termites: Reticulitermes spp.	Solution for direct application	20% w/w <> 211.2g/L	(Double) Vacuum pressure impregnation	1	n.a.	211.2	0.047-0.118	10-25 **	The product is recommended as a wood preservative for use in Hazard Class 1, 2, 3 and 4.
						Brushing	1 - 5	n.a.	211.2	0.47-0.24	0.01-0.05 *	
						Spraying	1 - 5	n.a.	211.2	0.47-0.24	0.01-0.05 *	
						Dipping	1 - 5	n.a.	211.2	0.47-0.24	0.01-0.05 *	

5 Efficacy should be assessed on a case by case basis, regarding the use class and the claims at product authorisation

Appendix III: List of studies

Section 1: Applicant

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 1	[redacted].	2004	Applicant Information Document Covering A 1.1 and A 1.2 Filename: A1.doc	No	BASF

Section 2: Identity

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 2.6/1	[redacted]	2001	Process comparison and chemical equivalency information for Chlorfenapyr. [redacted] No Unpublished [redacted]	Yes (Exist./First)	BASF
A 2.7/1	[redacted]	2003	Chlorfenapyr Technical Insecticide. [redacted] No Unpublished [redacted]	Yes (Exist./First)	BASF
A 2.7/2	[redacted]	2001	Compositional analysis of chlorfenapyr (AC 303,630, BAS 306 I) technical grade active ingredient [redacted] No Unpublished [redacted]	Yes (Exist./First)	BASF
A 2.8/1	[redacted]	2001	Compositional analysis of chlorfenapyr (AC 303,630, BAS 306 I) technical grade active ingredient [redacted] No Unpublished [redacted]	Yes (Exist./First)	BASF
A 2.8/2	[redacted]	1995	Identification of the Impurities in AC 303,630 Technical Grade Active Ingredient (TGAI). [redacted] No Unpublished. [redacted]	Yes (Exist./First)	BASF
A 2.9/1			Waiver		BASF
A 2.10	[redacted]	2004	Exposure Data Document Filename: A2_10.doc	No	BASF

Section 3: Physical and chemical properties

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 3.1.1/1	[redacted]	1994	AC 303,360: The determination of the melting point. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 3.1.2/1			Waiver		BASF
A 3.1.3/1	[redacted]	1993	Pirate technical (AC 303,360) - Color, physical state, odor, bulk density, pH, oxidizing/reducing properties. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 3.2/1	[redacted]	1997	AC 303630: Determination of the vapor pressure. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 3.2.1/1	[redacted]	2003	BAS 306 I (Chlorfenapyr): Henry's law constant. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 3.3.2/1	[redacted]	1993	Product chemistry determinations for CL 303,630 purified (color, physical state, odor, density). [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 3.3.2/2	[redacted]	1993	Pirate technical (AC 303,360) - Color, physical state, odor, bulk density, pH, oxidizing/reducing properties. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 3.3.3/1	[redacted]	1993	Product chemistry determinations for CL 303,630 purified (color, physical state, odor, density) [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 3.3.3/2	[redacted]	1993	Pirate technical (AC 303,360) - Color, physical state, odor, bulk density, pH, oxidizing/reducing properties [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 3.4/1	[redacted]	1994	CL 303,630 spectral database. [redacted] No Unpublished [redacted]	Yes (Exist./First)	BASF

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 3.5/1	[redacted]	1994	AC 303,360: The determination of the solubility. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 3.5/2	[redacted]	1994	AC 312,094: The determination of water solubility. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 3.6/1	[redacted]	1994	The dissociation constant of AC 303,360. [redacted] No Unpublished [redacted]	Yes (Exist./First)	BASF
A 3.6/2			Waiver		BASF
A 3.7/1	[redacted]	1994	AC 303,360: The determination of the solubility. [redacted] Yes Unpublished BASF Archive #'s: CK-311-001; 1994/7000775	Yes (Exist./First)	BASF
A 3.9/1	[redacted]	1995	AC 303,630: n-octanol/water partition. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 3.10/1	[redacted]	1994	Pirate technical (AC 303,360) - Storage stability, corrosion characteristics, and stability at normal and elevated temperatures [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 3.10/2	[redacted]	1993	Pirate technical (AC 303,360) - Explodability. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 3.11/1	[redacted]	1995	CL303,630 flammability and autoflammability determinations. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 3.11/2			Waiver		BASF
A 3.12/1			Waiver		BASF
A 3.13/1*	[redacted]	2003	Surface tension of Chlorfenapyr (TC). [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 3.15/1	[redacted]	1993	Pirate technical (AC 303,360) - Explodability. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 3.16/1	[redacted]	2004	BAS 306 I (Chlorfenapyr): Oxidizing properties. [redacted] No Unpublished [redacted]	Yes (Exist./First)	BASF
A 3.17/1	[redacted]	1994	Pirate technical (AC 303,360) - Storage stability, corrosion characteristics, and stability at normal and elevated temperatures [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF

Section 4: Analytical methods.

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 4.1/1	[redacted]	1993	Validation of the High Resolution Gas Chromatographic Method M-2006.1 to Assay for CL 303,630 in PIRATE Technical Grade Active Ingredient (TGAI) [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.1/2	[redacted]	1994	Validation of High Resolution GC (HRGC) Method M-2272.03 to Assay for Impurities in CL303630 Technical Grade Active Ingredient. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.1/2b	[redacted]	1995	Identification of the Impurities in AC 303,630 Technical Grade Active Ingredient (TGAI). [redacted] No Unpublished. [redacted]	Yes (Exist./First)	BASF
A 4.1/3	[redacted]	1994	Validation of the High Performance Liquid Chromatographic Method M-2066.02 to Assay for … in CL 303630 TGAI, [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.1/4*	[redacted]	1994	Validation of Gas Chromatographic Method M-2368 for the Analysis of Residual ….. in CL 303630 Technical Grade Active Ingredient. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 4.1/5	[redacted]	1997	Residue on Ignition Method for Determining Percent Non-Sulfated Ash, [redacted] No Unpublished. [redacted]	No	BASF
A 4.1/6	[redacted]	1993	Karl Fischer Determination for Water in PIRATE Technical Grade of the Active Ingredient (TGAI), [redacted] No Unpublished. [redacted]	No	BASF
A 4.2/1	[redacted]	1993	Validation of GC Method M 2201 for the Determination of the CL 303630 Residues in Soil [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/2*	[redacted]	1996	Extractability and accountability of CL 303,630 Residues in Soil for GC Method M 2201. [redacted]. Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/3	[redacted]	1995	Freezer Stability of Residues of CL 303,630 in Soil. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/4*	Chiu S.	1995	Validation of Gas Chromatographic Method M 2471 for the Determination of CL 303,630 Residues in Air. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/5	[redacted]	1999	Independent Laboratory Validation of GC-MS Method for the Determination of the CL 303630 Residues in Surface Water, [redacted] Yes Unpublished B[redacted]	Yes (Exist./First)	BASF
A 4.2/6*	[redacted]	1994	Independent Laboratory Validation of GC Methods M 2398 and M 2405 for the Determination of the CL 303630 Residues in Cattle Fat, Muscle, Liver and Kidney [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/7*	[redacted]	1994	Independent Laboratory Validation of GC Method M 2395.01 for the Determination of the CL 303630 Residues in Cow's Milk [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/8*	[redacted]	1994	Extractability and Accountability of CL 303,630 Residues in Milk, Liver, Muscle and Fat for GC Methods M 2395.01(Milk), M 2398 (Muscle and Fat) and M 2405 (Liver). , [redacted]. Yes Unpublished [redacted]	Yes (Exist./First)	BASF

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 4.2/9	[redacted]	1999	Independent Laboratory Validation of Gas Chromatography (GC) Determinative and GC-MS Confirmatory Method for the Determination of CL 303630 and Metabolite CL 312094 Residues in Soil. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/10*	[redacted]	1994	Validation of GC Method M 2316 for the Determination of the CL 312094 Residues in Water. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/11	[redacted]	1994	Freezer Storage Stability of CL 312094 in Soil. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/12*	[redacted]	1998	Independent Laboratory Validation of LC-MS Determinative Method M3065 for Residues of theCL 303630 Degradates CL 303267 and CL 325195 in Soil. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/13	[redacted]	1992	Validation of GC Method M 2201 for the Determination of the CL 303630 Residues in Soil, [redacted] Yes (unpublished) [redacted]	Yes (Exist./First)	BASF
A 4.2/14*	[redacted]	1994	Validation of GC Method M 2201 for the Determination of the CL 303630 Residues in Soil, [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/15*	[redacted]	1996	Validation of GC Method M 2201 for the Determination of the CL 303630 Residues in Soil, [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/16	[redacted]	2000	Determination of Indoor Air Concentrations of Chlorfenapyr After Application of Chlorfenapyr 2 SC Termiticide-Insecticide Applied as a Termiticide to Basement and Crawl Space Construction Housing, [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/17*	[redacted]	1995	Gas Chromatographic Determinative and GC/MS Confirmatory Method M 2424 for the Determination of the CL 303630 Residues in Drinking Water, [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/18	[redacted]	1994	Validation of GC Method M 2201 for the Determination of the CL 303630 Residues Pond Sediment, [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 4.2/18 a (A 7.4.3.5.1/2)	[redacted]	1998	Evaluation of the acute toxicity of whole sediment-associated AC 303630 (Chlorfenapyr) to the saltwater amphipod, Leptocheirus plumulosus, under static test conditions. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/18 b (A 7.4.3.5.1/3)	[redacted]	1997	Evaluation of the toxicity of AC 303,630 to the sediment dwelling larvae of the midge, Chironomus riparius. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/19*	[redacted]	1994	Validation of GC Method M 2398 for the Determination and GC/MS Confirmation of CL 303,630 Residues in Cattle Muscle and Fat and Method M 2405 for the GC Determination and GC/MS Confirmation of CL 303,630 Residues in Cattle Liver and Kidney, [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/20*	[redacted]	1994	Validation of Method M 2395 for the GC Determination and GC/MS Confirmation of CL 303630 Residues in Cow's Milk, [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/21*	[redacted]	1995	Validation of GC Method M 2405 for the Determination of CL 303,630 Residues in Avian Blood, [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/22	[redacted]	2000	Independent Laboratory Validation of GC/MS Determinativeand GC/MSMS Confirmatory Method for the Determination of CL 303630 and Metabolite CL312094 Residues in Soil., [redacted] Yes Unpublished. [redacted]	Yes (Exist./First)	BASF
A 4.2/23	[redacted]	1999	Feeding and tissue residue study using AC 303630 in Northern Bobwhite (colinus virginianus) [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/23 a	[redacted]	1997	Pages 200-386, Appendix E, Feeding and tissue residue study using AC 303630 technical in Northern Bobwhite (colinus virginianus), [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 4.2/24	[redacted]	2006	Validation of Method M 2405 for the Determination of Chlorfenapyr (CL303,630) Residues in Avian Blood Using LC/MS/MS as Confirmatory Technique [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 4.2/25	[redacted]	2006	Validation of Method M 2201 for the Determination of Chlorfenapyr (CL303,630) Residues in Pond Sediment Using LC/MS/MS as Confirmatory Technique [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF

*Reference not relied on

Section 5: Effectiveness against target organisms and intended uses

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 5.3.1/1	[redacted]	1997	Chlorfenapyr termiticide-insecticide: Summary of termite control efficacy. [redacted] No Unpublished [redacted]	Yes (Exist./First)	BASF
A 5.3.1/2	[redacted]	1999	Efficacy of AC 303630 formulations vs. secondary urban pests. [redacted] No Unpublished [redacted]	Yes (Exist./First)	BASF

Section 6: Toxicological / metabolism studies on the active substance

Section No / Reference No.	Author(s)	Year	Title Source (where different from the company) Company, Report No. BASF Archive #s GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.1.1/01	[redacted]	1993	Oral LD50 study in albino rats with AC 303,630 technical. .[redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.1.1/02	[redacted]	1994a	Oral LD50 study in albino mice with AC 303,630 technical. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.1.1/03	[redacted]	1994b	Oral LD50 study in albino rats with AC 312,094 technical. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.1.2	[redacted]	1992	Dermal LD50 study in albino rabbits with AC 303,630 technical. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.1.3	[redacted]	1993	Acute inhalation toxicity study with AC 303,630 in rats. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.1.4/01	[redacted]	1993a	Skin irritation study in albino rabbits with AC 303,630 technical. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF

Section No / Reference No.	Author(s)	Year	Title Source (where different from the company) Company, Report No. BASF Archive #s GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.1.4/02	[redacted]	1993b	Eye irritation study in albino rabbits with AC 303,630 technical. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.1.5	[redacted]	1995	Dermal Sensitization Study of Chlorfenapyr Technical in Guinea Pigs (Maximization Test). [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.2/01	[redacted]	1994	CL 303,630 Metabolism of Carbon-14 Labeled CL 303,630 in the Rat. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.2/02	[redacted]	2005	Study on the Dermal Penetration of ^{14}C-BAS 306 I in BAS 306 02 I in Rats GLP, Unpublished	Yes (Exist./First)	BASF
A6.2/03	[redacted]	1994	Biological fate of MK-242 absorption, distribution and Excretion in Rats [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.3.1/01	[redacted]	1991a	AC 303,630: A 28-day rat feeding study. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.3.1/02	[redacted]	1991b	AC 303,630: A 28-day mouse feeding study. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.3.2	[redacted]	1993	A 28-day dermal toxicity study with AC 303,630 in rabbits. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.4.1/01	[redacted]	1993	90-day dietary toxicity study with AC 303,630 in purebred Beagle dogs. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.4.1/02	[redacted]	1993	AC 303,630: A 13-week dietary toxicity study in the albino rat. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.4.1/03	[redacted]	1994	AC 303,630: A 13-week dietary toxicity study in the albino mouse. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.4.1/04	[redacted]	1994	One year dietary toxicity study with AC 303,630 in purebred Beagle dogs. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.5 (and A6.7/01)	[redacted]	1994	A chronic dietary toxicity and oncogenicity study with AC 303,630 in rats. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.6.1/01	[redacted]	1994a	Evaluation of CL 303,630 in a bacterial/microsome mutagenicity assay. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.6.1/02	[redacted]	1994b	Microbial mutagenicity plate incorporation assay of CL 312,094. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF

Section No / Reference No.	Author(s)	Year	Title Source (where different from the company) Company, Report No. BASF Archive #s GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.6.2/01	[redacted]	1994	MK-242 technical: Analysis of metaphase chromosomes obtained from CHL cells cultured in vitro. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.6.2/02	[redacted]	1994	Evaluation of CL 303,630 in the in vitro Chromosome Aberration Assay in Chinese Hamster Ovary (CHO) Cells. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.6.3/01	[redacted]	1993	Unscheduled DNA synthesis in rat primary hepatocytes with AC 303,630. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.6.3/02	[redacted]	1994	Evaluation of CL 303,630 in the in mammalian cell CHO/HGPRT mutagenicity assay: [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.6.4	[redacted]	1994	Evaluation of CL 303,630 in the in vivo micronucleus assay in mouse bone marrow cells: [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.7/01 (see A6.5)	[redacted]	1994	A chronic dietary toxicity and oncogenicity study with AC 303,630 in rats. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.7/02	[redacted]	1994	A chronic dietary toxicity and oncogenicity study with AC 303,630 in mice. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.8.1/01	[redacted]	1993	An oral developmental toxicity (embryo-fetal toxicity / teratogenicity) definitive study with AC 303,630 in rats. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.8.1/02	[redacted]	1993	An Oral Developmental Toxicity (Embryo-Fetal toxicity/ Teratogenicity) Definitive Study with AC 303,630 in Rabbits. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.8.2	[redacted]	1994	A two-generation (one-litter) reproduction study with AC 303,630 in rats. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.9/01	[redacted]	1994	An acute neurotoxicity study with AC 303,630 in rats. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF
A6.9/02	[redacted]	1994	A one-year dietary neurotoxicity study with AC 303,630 in rats. [redacted] GLP, Unpublished	Yes (Exist./First)	BASF

Section 7: Ecotoxicological profile including environmental fate and behaviour

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 7.1.1.1.1/1	[redacted]	1995	Hydrolysis of AC 303,630. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.1.1.1.2/1	[redacted]	1995	Determination of the Quantum Yield of AC 303,630 in Water. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	
A 7.1.1.1.2/2	[redacted]	1994	AC 303,630: Photodegradation in Water. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.1.1.2.1/1	[redacted]	1994	CO_2 Evolution Test (Modified Sturm Test) for Aerobic Biodegradation of AC 303,630. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.1.1.2.1/2	[redacted]	2000	Ready biodegradability test of AC303,630. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.1.1.2.2/1			Waiver		BASF
A 7.1.1.2.3/1			Waiver		BASF
A 7.1.2/1	[redacted]	1995	Degradation of 14c-pyrrole-ring labelled AC 303,630 in water/sediment systems. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.1.2/2	[redacted]	1995	Degradation of 14C-phenyl-ring labelled AC 303,630 in water sediment systems. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.1.2.2.1/1			Waiver		BASF
A 7.1.2.2.2/1	[redacted]	1995	Degradation of 14c-pyrrole-ring labelled AC 303,630 in water/sediment systems. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.1.2.2.2/2	[redacted]	1995	Degradation of 14C-phenyl-ring labelled AC 303,630 in water sediment systems. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 7.1.2.2.2/3	[redacted]	1999	Chlorfenapyr (AC 303630): Biotransformation under anaerobic aquatic conditions [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.1.3/1			Waiver		BASF
A 7.2.1/1	[redacted]	1993	CL 303,630: Aerobic soil metabolism. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.2.2.1/1	[redacted]	1994	Study on the biological fate of MK-242 metabolism in soil. [redacted] No Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.2.2.1/2	[redacted]	1997	AC 303630: Aerobic soil metabolism. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.2.2.1/3	[redacted]	1995	Rate of degradation of 14C-AC 303,630 in three soils [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.2.2.2/1	[redacted]	1998	CL 303630 (Chlorfenapyr): AC 303630 residues in a sand soil after treatment with Alert insecticide-miticide applied to bare ground in 3 sequential applications to conduct a soil rate of dissipation study. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.2.2.2/2	[redacted]	1998	CL 303630 (Chlorfenapyr) soil dissipation study: Chlorfenapyr residues in soil after multiple applications of Alert 2SC insecticide-miticide (WA; 1993). [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.2.2.2/3	[redacted]	1997	CL 303630: The fate of carbon-14 CL 303630 (Chlorfenapyr) in outdoor cotton field soil. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.2.2.2/4	[redacted]	2000	CL 303630 (Chlorfenapyr): Soil rate of dissipation study: CL 303630 residues in soil after treatment with AC303630 2SC insecticide-miticide applied in bareground between rows of tomatoes in 5 sequential applications (GA; 1994) [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 7.2.2.2/5	[redacted]	2000	CL 303630 (Chlorfenapyr): Soil dissipation study: Chlorfenapyr residues in soil after multiple applications of Alert 2SC insecticide-miticide [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.2.2.3	[redacted]	2004	Summary of Extent and Nature of Bound Residues Filename: A7_2_2_3.doc	No	BASF
A 7.2.2.4/1	[redacted]	1994	AC 303,630: Anaerobic soil metabolism. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.2.3.1/1	[redacted]	1994d	AC 303,630: Adsorption/desorption on soils. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.2.3.1/2	[redacted]	1994	AC 312,094: Adsorption/desorption. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.2.3.1/3	[redacted]	1999	Chlorfenapyr (AC303630) metabolites, CL 303267 and CL 325195: Adsorption/desorption on soils. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.2.3.2/1	[redacted]	2004	Chlorfenapyr (BAS 306 I): Environmental exposure assessment following soil treatment with MYTHIC 2SC. [redacted] Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.2.3.2/2	[redacted]	1999	CL 312094: Determination of the DT50 in soil and the prediction of potential concentrations in groundwater using PELMO. [redacted] No Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.3.1/1			Waiver		BASF
A 7.3.2/1			Waiver		BASF
A 7.4.1.1/1	[redacted]	1992	Acute toxicity of AC 303,630 to bluegill sunfish (Lepomis macrochirus) under flow-through test conditions. Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.1.1/2	[redacted]	1992	Acute toxicity of AC 303,630 to rainbow trout (Oncorhynchus mykiss) under flow-through test conditions. Yes Unpublished [redacted]	Yes (Exist./First)	BASF

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 7.4.1.1/3	[redacted]	1996	Acute toxicity of AC 303,630 to the channel catfish (Ictalurus punctatus) under flow-through test conditions. Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.1.1/4	[redacted]	1993	Acute toxicity of AC 303,630 to the sheepshead minnow (Cyprinodon variegatus) under flow-through test conditions. Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.1.1/5	[redacted]	1994	Acute toxicity of CL 312,094 to the bluegill sunfish (Lepomis macrochirus) under flow-through test conditions. Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.1.2/1	[redacted]	1992	Acute toxicity of AC 303,630 to Daphnia magna under flow-through test conditions. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.1.2/2	[redacted]	1994	Acute toxicity of AC 303,630 to the Mysid (Mysidopsis bahia) under flow-through conditions. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.1.2/3	[redacted]	1993	Effect of AC 303,630 on new shell growth in the eastern oyster (Crassostrea virginica) under flow-through test conditions. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.1.2/4	[redacted]	1997	Acute toxicity of CL 312094 to Daphnia magna under static test conditions. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.1.2/5	[redacted]	2008	CL 312094 – Acute Toxicity to Mysids (*Americamysis bahia*), Under Static Conditions, Following OPPTS Guideline 850.1035 [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.1.2/06	[redacted]	2010	Amended - CL 312094: Life-Cycle Toxicity Test of the Saltwater Mysid, *Americamysis bahia*, Conducted Under Flow-Through Conditions [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.1.3/1	[redacted]	1995	Effect of AC 303,630 on the growth of Selenastrum capricornutum. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 7.4.1.3/2	[redacted]	1997	Effects of CL 312094 on the growth of the green algae, Selenastrum capricornutum. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.1.4/1	[redacted]	2002	BAS 306 I (Chlorfenapyr): Activated sludge, respiration inhibition test. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.1.4/2a	[redacted]	1993	Assessment of the acute toxicity of AC 303,630 technical for Spirillum volutans [redacted] No Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.1.4/2b	[redacted]	1993	Assessment of the acute toxicity of AC 303,630 technical for Spirillum volutans. [redacted] No Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.2/1	[redacted]	1994	CL 303 630: Uptake, depuration, bioconcentration and metabolism of carbon-14 CL 303,630 in bluegill sunfish (Lepomis macrochirus) under flow-through test conditions. Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.2/2	[redacted]	2000	Fish Bioconcentration Study on AC 303,630, [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.3.1/1	[redacted]	1993	Toxicity of AC 303,630 in rainbow trout (Oncorhynchus mykiss) after 28 days of exposure under flow-through test conditions. Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.3.2/1	[redacted]	1993	Early life-stage toxicity of AC 303,630 in rainbow trout (Oncorhynchus mykiss). Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.3.3.1/1	[redacted]	1994	CL 303 630: Uptake, depuration, bioconcentration and metabolism of carbon-14 CL 303,630 in bluegill sunfish (Lepomis macrochirus) under flow-through test conditions. Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.3.3.2/1			Waiver		BASF
A 7.4.3.3.2/2	[redacted]	2009	Assessment of Persistence, Bioaccumulative and Toxic (PBT) Properties of chlorfenapyr and the desbromo metabolite CL 312094. BASF	Yes (Exist./First)	BASF

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 7.4.3.4/1	[redacted]	1994	Chronic toxicity of 14C-AC 303,630 during the complete life-cycle of Daphnia magna under flow-through test conditions. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.3.4/2	[redacted]	1994	Chronic toxicity of AC 303,630 to the mysid (Mysidopsis bahia) under flow-through test conditions. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.3.4/3	[redacted]	2009	CL 312094: Life-Cycle Toxicity Test of the Saltwater Mysid, *Americamysis bahia*, Conducted Under Flow-Through Conditions [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.3.5.1/1	[redacted]	1997	Evaluation of the acute toxicity of whole sediment-associated AC 303630 to the freshwater amphipod, Hyallela azteca, under flow-through conditions. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.3.5.1/2	[redacted]	1998	Evaluation of the acute toxicity of whole sediment-associated AC 303630 (Chlorfenapyr) to the saltwater amphipod, Leptocheirus plumulosus, under static test conditions. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.3.5.1/3	[redacted]	1997	Evaluation of the toxicity of AC 303,630 to the sediment dwelling larvae of the midge, Chironomus riparius. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.4.3.5.2/1			Waiver		BASF
A 7.5.1.1/1	[redacted]	1995	The effects of AC 303,630 on the respiration and nitrification of soil microflora. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.5.1.2/1	[redacted]	1994	14-day acute toxicity study with AC 303,630 in the earthworm (Eisenia foetida). [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.5.1.3/1	[redacted]	1989, 1991, 1992	Evaluation of CL 303630 (Chlorfenapyr) for herbicidal activity. [redacted] No Unpublished [redacted]	Yes (Exist./First)	BASF

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 7.5.2.1/1	[redacted]	1995	Determination of the effects of sublethal concentrations of AC 303,630 active ingredient on earthworm (Eisenia fetida) growth and reproduction. [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.5.2.2/1			Waiver		BASF
A 7.5.3.1.1/1	[redacted]	1993	21-day acute toxicity test with AC 303,630 technical in the mallard duck (Anas platyrhlynchos). Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.5.3.1.1/2	[redacted]	1993	21-day acute toxicity test with AC 303,630 technical in the northern bobwhite (Colinus virginianus). Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.5.3.1.1/3	[redacted]	1995	14-day acute toxicity test with AC 312,094 technical in northern bobwhite (Colinus virginianus). [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.5.3.1.1/4	[redacted]	1995	14-day acute toxicity test with AC 312,094 technical in mallard ducks (Anas platyrhynchos) Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.5.3.1.2/1	[redacted]	1993	8-day acute dietary LC50 test with AC 303,630 in the mallard duck (Anas platyrhynchos). Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.5.3.1.2/2	[redacted]	1993	8-day acute dietary LC50 test with AC 303,630 in the northern bobwhite (Colinus virginianus). Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.5.3.1.3/1	[redacted]	1994	Reproduction study with AC 303,630 technical in the northern bobwhite (Collinus virginianus). Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.5.3.1.3/2	[redacted]	1994	Reproduction study with AC 303,630 technical in the mallard duck (Anas platyrhynchos). Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.5.4.1/1	[redacted]	1993	An acute contact and oral toxicity study with AC 303,630 on the honey bee (Apis mellifera L.) [redacted] Yes Unpublished [redacted]	Yes (Exist./First)	BASF
A 7.5.4.1/2			Waiver		BASF
A 7.5.5.1/1			Waiver		BASF
A 7.5.6/1			Waiver		BASF
A 7.5.7.1.1/1			Waiver		BASF
A 7.5.7.1.2/1			Waiver		BASF
A 7.5.7.1.3/1			Waiver		BASF

Section No. / Reference No.	Author(s)	Year	Title Source (where different from the company) Company Report No. GLP (where relevant) (Un)Published BASF Archive #s	Data Protection Claimed (Yes/No)	Owner
A 7.6	[redacted]	2004	Summary of Ecotoxicological Effects and Fate of Behaviour in the Environment Filename: A7_6.doc	No	BASF