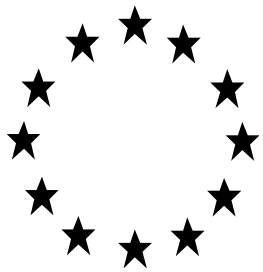
Directive 98/8/EC concerning the placing of biocidal products on the market

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

Assessment Report



Fenoxycarb

Product-type 8
(Wood preservative)

24.09.2010

RMS: DE

Fenoxycarb (PT 8)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 24.09.2010 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 Fenoxycarb 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.

Fenoxycarb (CAS no. 72490-01-8) was notified as an existing active substance, by Janssen Pharmaceutica BV. During the evaluation the applicant was changed to Syngenta Ltd UK, hereafter referred to as the applicant, in product-type 8.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[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 7(1) of that Regulation, Germany was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant.

The dossier was submitted at 27th of February 2006 on the basis of the provisions laid down in Article 9 of Commission Regulation (EC) No 1451/2007 and Article 4b of Commission Regulation (EC) No. 1048/2005 as modified by Article 3c of Commission Regulation (EC) No. 1451/2007. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 8th of August 2006.

On 12th of September 2008, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 29th of September 2008. The competent authority report included a recommendation for the inclusion of Fenoxycarb in Annex I to the Directive for product-type 8.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 5th of November 2008. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

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

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

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

On the basis of the final competent authority report, the Commission proposed the inclusion of Fenoxycarb in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 24.09.2010.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 24.09.2010.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include Fenoxycarb 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 Fenoxycarb. 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[3], 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 Fenoxycarb for the product-type **8**, which will fulfil the requirements laid down in Article 5 of Directive 98/8/EC. This conclusion is however subject to:

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

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

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

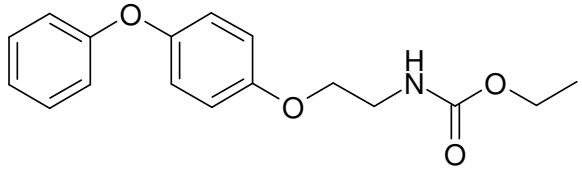
3 http://ec.europa.eu/comm/environment/biocides/index.htm

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

CAS-No.	72490-01-8
EINECS-No.	276-696-7
Other No. (CIPAC, ELINCS)	CIPAC No.: 425
IUPAC Name	Ethyl [2-(4-phenoxyphenoxy)ethyl]carbamate
CAS Name	Carbamic acid, [2-(4-phenoxyphenoxy)ethyl]-, ethyl ester
Common name, synonyma	Fenoxycarb
Molecular formula	$C_{17}H_{19}NO_4$
Structural formula	
Molecular weight (g/mol)	301.4 g/mol
Typical concentration or concentration range (% w/w)	98.3 % ,

Fenoxycarb belongs to the chemical class of carbamic acid esters. It is a colourless solid substance with a melting point of 54,6°C. Its vapour pressure (8.67 x 10^{-7} Pa at 25 °C) and volatility (Henry's law constant: 3.3 · 10^{-5} Pa · m³ / mol at 25 °C) are very low. Fenoxycarb does not dissociate in water, so the solubility in water is very low (7,09 mg/l at 20°C). The solubility in organic solvents at 25 °C (e.g. acetone, ethyl acetate, toluene) is > 500 g/L, the log Pow at 25 °C is 4.07. Thermal decomposition starts at 180 °C.

Residue analytical methods are available for determination of fenoxycarb residues in soil, air, drinking and surface water. No validated confirmatory methods are supplied by the applicant, but from open literature a confirmatory method for drinking water is available. The limit of quantification (based on final extracts) is at least ten times lower than required for soil and air.

2.1.2. Intended Uses and Efficacy

Fenoxycarb has been evaluated for its use as a wood preservative belonging to product type 8. The target organisms are beetles on wood in service.The intended use is dipping treatment (preventive use; use classes 1-3) only for industrial and professional application.

Data on the active substance fenoxycarb in methanol and on a water-based formulation (containing 0.025% w/w fenoxycarb), have demonstrated sufficient efficacy against wood-destroying insects. Preventive efficacy has been shown for the active substance fenoxycarb and for the representative product on freshly hatched larvae of the target organism House Longhorn Beetle (*Hylotrupes bajulus*). Additionally, eradicant efficacy has been demonstrated for the active substance on larvae of the Brown Powderpost Beetle (*Lyctus brunneus*) and Furniture Beetle (*Anobium punctatum*). In the frame of product evaluation, additional data

have to be provided if they are necessary to support the complete requested label claim of the product.

Mode of action:

Fenoxycarb is a non-neurotoxic insect growth regulator (IGR) with contact and stomach action. It exhibits a strong juvenile hormone activity, inhibiting metamorphosis to the adult stage and interfering with the moulting of early instar larvae.

Occurrence of Resistance

For industrial wood preservation using fenoxycarb resistance is not an issue. Industrial wood preservatives are usually applied only once and there is no evidence to suggest resistance. No resistances were noted up to now, after usage of fenoxycarb in the impregnation of wood for several years in Europe. During the last six years since the representative product is on the market, no resistance of the target organisms has been observed. Therefore, no recommendations concerning the avoidance of the continuous use of the product in order to prevent the development of resistant strains are given.

In conclusion, the assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organisms 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

Proposed classification and labelling based on Directive 67/548/EEC

Classification	Proposed	
Indication of danger	N Xn	Dangerous for the environment Harmful
R phrases	R40 R50/53	Limited evidence of a carcinogenic effect Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
S phrases	S22 S36/37 S60 S61	Do not breathe dust Wear suitable protective clothing and gloves This material and its container must be disposed of as hazardous waste. Avoid release to the environment. Refer to special instructions/Safety data sheets

Remark:

The current classification of fenoxycarb according to Annex I of Council Directive 67/548/EEC is N (dangerous for the environment), R 50/53. The proposed additional

classification of fenoxycarb with Xn (harmful), R 40 (Limited evidence of a carcinogenic effect) is based on the results observed in the long-term carcinogenicity studies in mice.

Proposed classification based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	
Hazard statements	H351 H400 H410	Suspected of causing cancer Very toxic to aquatic life Very toxic to aquatic life with long lasting effects

Proposed labelling based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	GHS08 GHS09	
Signal Word	Warning	
Hazard statements	H351 H410	Suspected of causing cancer Very toxic to aquatic life with long lasting effects
Precautionary statements	(P102) P260 P273 P281 P308 + P313 P363 P391 P405 P501	(Keep out of reach of children) Do not breathe dust Avoid release to the environment Use personal protective equipment as required If exposed or concerned: Get medical advice/ attention Wash contaminated clothing before reuse Collect spillage Store locked up Dispose of contents/container to …

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

Absorption, Distribution, Excretion, and Metabolism

In rats, fenoxycarb was rapidly and almost completely (≥ 90 % of total recovery) absorbed from the gastrointestinal tract. The systemically absorbed dose was extensively metabolised and the metabolites were almost quantitatively excreted via faeces (70-80 %) and urine (15-20

%). Residues after 7 d were low; tissue distributions at this time-point as well as observations in other toxicological studies suggest wide distribution, including liver, kidney, lung and fat. No evidence of accumulation was provided.

At least 19 metabolites were observed and the structures of 9 major compounds could be elucidated, whereas 10-30 % of excreted radioactivity was not identified. Although not explored further *in vivo*, a metabolite of toxicological concern, urethane or O-ethyl carbamate, is formed as an intermediate. The same holds true for 1,4-dihydroxybenzene and its oxidation product 1,4-benzoquinone, respectively. Two supplementary *in vitro* metabolism studies were performed in liver and lung microsomes derived from different species incl. man. Based on the overall evidence available, urethane and 1,4-benzoquinone are formed in human microsomes and thus are regarded as toxicologically relevant metabolites of fenoxycarb in humans.

The dermal absorption of fenoxycarb (formulated as INSEGAR® 25 WG) was investigated in a comparative *in vitro* test using rat and human split-thickness skin membranes, and in an *in vivo* test in rats. Both, the biocidal product Basilit FP and INSEGAR® 25 WG contain emulsifiers that have the tendency to increase dermal absorption. The presence of such formulants in Basilit FP is therefore accounted for by employing INSEGAR® 25 WG as a test substance. By combining the results from theses studies, the following equation was used to determine the dermal absorption for humans *in vivo*:

$$\%\ \text{absorption [human } \textit{in vivo}\text{]} = \frac{\%\ \text{absorption [human } \textit{in vitro}\text{]}}{\%\ \text{absorption [rat } \textit{in vitro}\text{]}} \times \%\ \text{absorption [rat } \textit{in vivo}\text{]}$$

Absorption rates of approximately 25, 5, and 0.2 % were established for concentrations of 0.05, 0.75, and 61 mg/L (0.005-0.075-6.1 % (w/v)), respectively.

2.2.1.2. Effects assessment

Acute Toxicity

Fenoxycarb is not acutely toxic when administered orally, dermally, or by inhalation. It is neither irritating to the skin nor to the eyes of rabbits. Fenoxycarb is not a skin sensitiser.

Short-term Toxicity

In rats, the main target organ following repeated oral administration of fenoxycarb was the liver as indicated by increased liver weight, hepatocellular hypertrophy and eosinophilia, increased liver enzyme levels and increased cholesterol levels. Hepatomegaly was reversible after a 4-week recovery period. Histopathological findings on the liver without changes in clinical chemistry were also observed after dermal and inhalation exposure. Follicular hypertrophy/hyperplasia of the thyroid was noted after oral exposure to high doses. The inhalation study revealed a reversible increase of the lung weights. In dogs, oral exposure resulted in a reduction in body weight gain, increased liver and kidney weights and a decrease of inorganic phosphorus in plasma.

The oral NOAEL in rats was 10 mg/kg bw/d based on liver effects (increased liver weight, hepatocellular hypertrophy and increased cholesterol levels) at 45 mg/kg bw/d in the 90-d study. The dermal NOAEL in rats was 200 mg/kg bw/d, based on the results of the 21-d study. The inhalative NOAEL in rats was 0.1 mg/L air based on liver and lung weight increase at 1.0 mg/L air in the 21-d study. The oral NOAEL in dogs was 25 mg/kg bw/d based on decreased plasma levels of inorganic phosphorus at 80 mg/kg bw/d in male dogs at week 52.

Genotoxicity

In vitro and *in vivo* tests provided no evidence for a genotoxic potential of fenoxycarb.

Chronic Toxicity/ Carcinogenicity

The non-neoplastic NOAEL in rats was 8 mg/kg bw/d, based on liver lesions at 25 mg/kg bw/d in the 104-week study. No increased rate of neoplastic lesions was observed up to and including 74 mg/kg bw/d. The NOAEL in mice was 6 mg/kg bw/d based on lung and liver tumours in males at 57 mg/kg bw/d in the 78-week study.

Based on evidence obtained in the genotoxicity tests and additional *in vitro* studies, the oncogenic potential of fenoxycarb in the liver of mice might be related to peroxisome proliferation, which is likely to be not relevant for carcinogenesis in man.

The incidence of pulmonary neoplasia in mice was increased in males at 57 mg/kg bw/d and in both sexes at 225 mg/kg bw/d and was considered to be treatment-related. The relevance of the observed lung tumours for humans cannot be ruled out. It is proposed to classify/label fenoxycarb as Xn; R40.

Reproduction Toxicity

In the developmental toxicity studies, no effects of fenoxycarb on the conceptus were observed at dose levels which were already slightly toxic to the mothers. The maternal NOAEL was 50 mg/kg bw/d in rats, based on increased nervousness of the females during the second half of the treatment period at 150 mg/kg bw/d. In rabbits, it was 100 mg/kg bw/d, based on a slight decrease in body weight gain at 300 mg/kg bw/d. No relevant embryotoxicity, including teratogenicity, was observed in either species. The embryo-/foetotoxic NOAELs were 500 mg/kg bw/d and 300 mg/kg bw/d in rats and rabbits, respectively.

In a rat two-generation study, effects on the parental generations included slightly reduced body weight gain during the pre-mating period and liver toxicity at a dose level of 1800 ppm, corresponding to a dose of approximately 100 mg/kg bw/d in males and 130 mg/kg bw/d in females. No impairment of fertility or fecundity was observed. For parental toxicity, the NOAEL was set at 35 mg/kg bw/d, based on a reduction in body weight gain and liver toxicity. The reproductive NOAEL was set at 100 mg/kg bw/d, the highest dose tested. For offspring toxicity, the NOAEL was set at 13 mg/kg bw/d, based on a slight reduction in body weight gain.

Neurotoxicity

Clinical signs of CNS effects potentially caused by fenoxycarb were only observed at dose levels far beyond the limit dose in acute toxicity studies (sedation, spasms, and tremor at ≥ 3000 mg/kg bw) or after repeated administration of fairly high amounts of fenoxycarb to pregnant rats (increased nervousness after oral doses of ≥ 150 mg/kg bw/d). Therefore submission of a generic (acute or repeat-dose) neurotoxicity study with fenoxycarb was not deemed necessary. Investigation of plasma cholinesterase (ChE) activity demonstrated the absence of plasma ChE inhibition by fenoxycarb.

Mechanistic studies

Fenoxycarb strongly induces hepatic xenobiotic metabolising enzymes in mice and can be classified as a peroxisome proliferator type inducer, but does not show inductive properties on pulmonary xenobiotic metabolising enzymes *in vitro*.

Following *in vitro* incubation of liver microsomes from rat, mouse, marmoset, and man with fenoxycarb, formation of two potential carcinogens, O-ethyl carbamate (urethane) and benzoquinone/hydroquinone was observed and monitored via HPLC and GC-MS.

When compared with mice and rats, human liver microsomes showed on average at least ten-fold lower formation rates of ethyl carbamate and benzoquinone/hydroquinone. However, large inter-individual variation was noted with the human samples and it remained unsettled, to which extent those samples (from only 3 individual donors of unknown age or gender) could be seen as generally representative. Based on the results from these mechanistic studies, the formation of O-ethyl carbamate (urethane) was regarded as relevant for humans *in vivo*.

In vivo data suggest that fenoxycarb in contrast to other carbamates does not act as an inhibitor of plasma acetylcholine esterase. However, in the published literature evidence is representative that it may directly inhibit rat nicotinic acetylcholine receptors, subtypes $\alpha 3$, $\alpha 4$, $\beta 2$ and $\beta 4$.

After exposure to 440 mg/kg bw fenoxycarb no urethane-type DNA adducts were observed in mice whereas 38 % of the radioactivity associated with liver DNA from animals treated with 20 mg/kg bw urethane were detectable as adducts.

Medical Data

No adverse effects were observed with fenoxycarb during medical surveillance of manufacturing personnel. No cases of poisoning have been reported to the applicant. No reports of poisoning cases from the open medical literature are on record. An epidemiological study has not been performed by the applicant and no other available sources of epidemiological data on fenoxycarb are known.

Biocidal Product

No studies were submitted for the representative biocidal product with regard to acute toxicity (oral, dermal, inhalation), skin and eye irritation and skin sensitisation.

Justifications for non-submission were accepted, since the purpose of this dossier is Annex I inclusion of fenoxycarb according to Directive 98/8/EC and not the authorisation of a biocidal product.

Furthermore, the active substance and similar biocidal products are in use for more than 15 years. Up to now no acute oral, dermal and inhalation intoxications have been reported. The active substance has neither shown to be acute toxic nor to have corrosive, skin- and eye-irritating or skin-sensitising properties. Irritating and sensitising effects, which have been observed for other components of the biocidal product, have been taken into account for classification and labelling.

It has to be pointed out that for national authorisation further studies are most likely required.

Summary and conclusion

In the absence of any relevant acute effects, the NOAEL of 500 mg/kg bw (the highest dose tested) from the developmental toxicity study in the rat is regarded the relevant starting point for setting a systemic reference dose for acute exposure. By using a default assessment factor of 100, a **systemic acute Acceptable Exposure Level (AEL_{acute}) of 5 mg/kg bw/d** is proposed for acute exposure towards fenoxycarb.

The NOAELs for repeat-dose toxicity after oral administration ranged from 6-10 mg/kg bw/d. The NOAEL of 10 mg/kg bw/d from the 13-week study in rats which is based on functional and morphological changes in the liver is regarded as the relevant starting point for setting a systemic reference dose for medium-term exposure.

By applying a default assessment factor of 100, a systemic **medium-term Acceptable Exposure Level** ($AEL_{medium\text{-}term}$) of

0.1 mg/kg bw/d

is proposed for medium-term exposure (2 days – 6 months) to fenoxycarb.

The NOAEL of 6 mg/kg bw/d from the 78-week study in mice which is based on lung and liver tumours in males is regarded as the relevant starting point for setting a systemic reference dose for long-term exposure.

By applying a default assessment factor of 100, a systemic **long-term Acceptable Exposure Level** ($AEL_{long\text{-}term}$) of

0.06 mg/kg bw/d

is proposed for long-term exposure (> 6 months) to fenoxycarb. This AELlong-term is considered to provide a sufficient safety margin in terms of the tumours observed in the life-span study in mice.

2.2.1.3. Exposure assessment and risk characterisation

Exposure of Professionals

Fenoxycarb is produced in the EU as a white solid. The formulated biocidal product is an emulsifiable concentrate with a concentration of 0.025 % fenoxycarb. The biocidal product is applied in preventive treatment of wood in dipping processes. The following intended uses are assessed by the rapporteur:

- Automated Dipping (preventive treatment, scenario 2)
- Secondary exposure - Mechanical processing of treated wood (scenario 3)

For theautomated dipping process the product is diluted with water to a maximum concentration of 0.0038 % active substance. The tasks of exposure are: Dilution of concentrates: connecting transfer lines (*mixing & loading phase,* duration: 10 min, daily), dipping of wood and handling of treated wet wood (*application phase* duration: 30 min/cycle, daily), cleaning of the dipping tank (*post-application phase,* duration: 360 min, once a year). According to HEEG discussion 4 cycles per day are reasonable for automated dipping processes.

The inhalation exposure is assessed as negligible for all phases of the dipping process due to the low vapour pressure of the active substance (vapour pressure of 8.67×10^{-07} Pa at 25 °C). A formation of aerosols during dipping is not expected. The dermal exposure (mixture of potential body and actual hand exposure) for all phases is based on Model 1 (Handling) of the *TNsG Human Exposure to Biocidal Products*. The resulting level of potential dermal exposure for *mixing & loading* and *application phase* is estimated as 1.77 mg a.s./person/day (daily exposure). The exposure for the *post-application phase* (exposure once a year) is estimated as 0.37 mg/person/day (for details please see Appendix I- list of endpoints acceptable exposure scenarios). A secondary exposure due to mechanical processing of treated wood cannot be excluded. Therefore the inhalation exposure to wood dust and dermal exposure during wiping are estimated. The assessment of inhalation exposure is based on the occupational exposure level (in Germany) of 5 mg/m^3 for wood dust. The resulting exposure level is 0.000013 mg/m^3 which is assessed as negligible. The estimation of the potential dermal exposure is based on the deposition of 40 g b.p./m^2 skin, which is the assumed application rate of the biocidal product.. It is assumed that the palms of both hands are exposed. The resulting potential dermal exposure is 0.06 mg a.s./person/day.

Exposure and Risk assessment for Non-Professionals

Primary exposure to fenoxycarb of non-professional users

Non professional use of the biocidal product was not considered in the CA report because the intended use of the product is professional and industrial use only. Thus non-professional primary exposure and risk assessment is not required.

Secondary exposure to fenoxycarb of the general public

If the fenoxycarb containing product is applied in accordance with the intended use (wood protection) no residues of fenoxycarb are to be expected in food of plant or animal origin. The estimation of the potential and actual exposure of fenoxycarb through diet following the proper use of the representative product is therefore not considered to be required.

The general public (adults, children, infants) can be exposed via treated wood in houses or outside (e.g. on playgrounds). House attics are often constructed to provide additional living space. The uptake may occur by inhalation (sanding, volatility), dermally (uncovered roof beams are touched for cleaning, playing), and orally (infants licking contaminated hands or mouthing wood pieces).

All the following reasonable exposure scenarios were estimated by Tier 1 approaches. That means that the maximum theoretically possible exposures were calculated. These worst case scenarios are not essentially realistic. Tier 2 approaches have not been regarded since estimations resulting from Tier 1 approaches were sufficiently low. Risk assessment was performed comparing acute and chronic exposure estimates to the respective AEL.

- Acute oral exposure of infants chewing wood pieces:
  Infants: 4.80×10^{-3} mg/kg bw (0.1% of AEL_{acute})

- Acute inhalation exposure by non-professional sanding:
  Adults: 3.49×10^{-7} mg/kg bw (7.0×10^{-6}% of AEL_{acute})

- Acute dermal exposure by non-professional sanding:
  Adults: 1.06×10^{-4} mg/kg bw (0.002% of AEL_{acute})

- Chronic inhalation exposure indoors:
  Infants: 4.82×10^{-5} mg/kg bw/d (0.08% of $AEL_{long\text{-}term}$)

  Adults: 5.36×10^{-5} mg/kg bw/d (0.09% of $AEL_{long\text{-}term}$)

- Chronic dermal exposure indoors:
  Infants: 1.00×10^{-3} mg/kg bw/d (1.7% of $AEL_{long\text{-}term}$)

  Adults: 0.70×10^{-3} mg/kg bw/d (1.2% of $AEL_{long\text{-}term}$)

- Chronic dermal and oral exposure of infants outdoors, e.g. on playgrounds:
  Infants: 4.00×10^{-3} mg/kg bw/d (6.7% of $AEL_{long\text{-}term}$)

It can be concluded that secondary exposure to fenoxycarb of the general public (adults and infants including children) is considered acceptable.

Chronic indirect exposure of the general public as a result of use - Secondary Exposure (fenoxycarb)

Exposure Scenario (indicate duration)		**Estimated Internal Exposure** [1]				**Relevant NOAEL/ LOAEL** [mg/kg b.w./day] & Reference Value e.g.: AEL (acute or medium or chronic)	**AF** MOE_{ref}	**MOE**	**Exposure /AEL**
		estimated oral uptake [mg/kg b.w./day]	**estimated inhalation uptake** [mg/kg b.w./day]	**estimated dermal uptake** [mg/kg b.w./day]	**estimated total uptake** [mg/kg b.w./day]				
Tier 1 (Worst case) **Chronic Scenarios**	Indoors, contact to treated wood					NOAEL = 6 mg/kg b.w/day			
	Infants		4.82×10^{-5}	1.00×10^{-3}	1.05×10^{-3}			5720	0.017
	Adults		5.36×10^{-5}	0.70×10^{-3}	0.75×10^{-3}		100	7960	0.013
	Outdoors, e.g. infants on play-grounds	4.00×10^{-3}	-	Covered by oral uptake	4.00×10^{-3}	$AEL\text{-}S_{long\ term}$ = 0.06 mg/kg b.w/day		1500	0.067
Tier 2 (Refinement - Specify) Chronic Scenarios	Tier 2 is not required.								

Acute indirect exposure of the general public as a result of use - Secondary Exposure (fenoxycarb)

Exposure Scenario (indicate duration)		Estimated Internal Exposure (1)				Relevant NOAEL/ LOAEL [mg/kg b.w./day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated oral uptake [mg/kg b.w.]	estimated inhalation uptake [mg/kg b.w.]	estimated dermal uptake [mg/kg b.w.]	estimated total uptake [mg/kg b.w.]				
Tier 1 (Worst case) Acute Scenarios	Infants, chewing wood	4.80×10^{-3}	-	-	4.80×10^{-3}	NOAEL = 500 mg/kg b.w/day		104000	0.0001
	Adults, sanding treated wood	-	3.49×10^{-7}	1.42×10^{-4}	1.42×10^{-4}	$AEL\text{-}S_{acute}$ = 5 mg/kg b.w	100	3510000	0.00003
Tier 2 (Refinement - Specify) Acute Scenarios	Tier 2 is not required.								

Risk Assessment for Professionals

For professional exposure it cannot be excluded that repeated contact at the workplace may have a long-term characteristic. In a first step (Tier 1) occupational risk assessment is based on the internal reference dose (AEL-$S_{long\text{-}term}$) of 0.06 mg/kg/day. A comparison with exposure values (in this special case a mixed calculation of potential exposure of the body and actual exposure of hands) gives a rough but cautious assessment to decide on concern. Under the specific conditions described there is no concern for the scenarios evaluated in this report.

The following two tables summarise the risk characterisation outcome:

Professional Users – Primary Exposure (fenoxycarb)

Exposure Scenario (indicate duration)		**Estimated Internal Exposure** [1]				**Relevant NOAEL/ LOAEL** [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	**AF MOE$_{ref}$**	**MOE**	**Exposure /AEL**
		estimated oral uptake [mg/kg b.w/day]	**estimated inhalation uptake** [mg/kg b.w/day]	**estimated dermal uptake** [mg/kg b.w/day]	**estimated total uptake** [mg/kg b.w/day]				
Tier 1 (no PPE)	Application of biocidal product								
	a) Mixing& loading[2] 10 min/daily	-	negligible	0.001	0.001	NOAEL = 6 mg/kg b.w/day AEL-S long term = 0.06 mg/kg b.w/day	100	6000	0.02
	b) Application[2] 150 min/daily	-	negligible	0.006	0.006			1000	0.1
	total a) + b)	-	negligible	0.007	0.007			857	0.12
	c) Post-application[3] 360 min/once a year	-	negligible	0.0015	0.0015			4000	0.025
Tier 2 (Refinement, PPE or other risk mitigation measures – Specify)	Tier 2 is not required								

[1] based on the assumption of 25% systemic availability after dermal exposure

[2] Conc. biocidal product 0.025 %, the biocidal product is diluted for application to an aqueous solution containing 0.0038 % of the active substance, duration: 5 cycles per day, frequency: daily

[3] Cleaning of the dipping tank, form of exposure: liquid (0.0038 % a.s.), duration: 360 min., frequency: once a year

Indirect Exposure as a result of use - Secondary Exposure (fenoxycarb)

Exposure Scenario (indicate duration)		**Estimated Internal Exposure** [1]				**Relevant NOAEL/ LOAEL** [mg/kg b.w/day] & **Reference Value** e.g: AEL (acute or medium or chronic)	**AF** MOE_{ref}	**MOE**	**Exposure /AEL**
		estimated oral uptake [mg/kg b.w/day]	**estimated inhalation uptake** [mg/kg b.w/day]	**estimated dermal uptake** [mg/kg b.w/day]	**estimated total uptake** [mg/kg b.w/day]				
Tier 1 (Worst case)	mechanical processing of treated wood 8h/day					NOAEL = 6 mg/kg b.w/day			
Chronic Scenario		-	negligible	0.0003	0.0003	AEL-S $_{long\ term}$ = 0.06 mg/kg b.w/day	100	20000	0.005
Tier 2 (Refinement - Specify)	Tier 2 is not required								
Chronic Scenario									

[1] based on the assumption of 25% systemic availability after dermal exposure

Safety Measures for Professionals

The general legislation on occupational safety and health is sufficient to control the risks in the described exposure scenarios. Additional occupational safety measures are not necessary.

Conclusion:

The occupational risk assessment for fenoxycarb is based upon the AEL approach and the estimate of a mixed calculation of potential dermal exposure of the body and actual dermal exposure of the hands. The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of Annex I inclusion of fenoxycarb.

For all exposure scenarios specified the risk assessment does not lead to concern. It is essential to recognize that this conclusion only applies to the active substance (fenoxycarb) in

the biocidal product. From the point of view of occupational safety and health there is no risk-related reason for conditioning the requested Annex I inclusion for fenoxycarb.

2.2.2. Environmental Risk Assessment

2.2.2.1. Fate and distribution in the environment

Biodegradation

Aquatic system

Fenoxycarb is considered to be not readily biodegradable. The dissipation behaviour of fenoxycarb in aquatic system was studied in two Swiss water/sediment systems (river and pond) resulting in primary degradation half-lives of 14.0 days (river) and 5.0 days (pond) for the water phase as well as 12.0 days (river) and 8.0 days (pond) for the entire system at an average EU outdoor temperature of 12°C. For modelling purposes the recalculated half-lives of the entire systems are 12.0 and 18.0 days. Mineralisation of fenoxycarb to carbon dioxide reached maximum amounts of 40.4 % and 36.3 % of the applied radioactivity (AR) after 119 days in the river and pond test system, respectively. Organic volatilisation is negligible. The non-extractable residues in sediment achieved a maximum of 56.2 % AR (river) and 54.9% AR (pond) after 29 and 14 days, respectively and stayed on a high plateau of 50 and 52% AR by the end of the study.

Soil

In an aerobic laboratory study with Swiss silt loam soil fenoxycarb rapidly degraded with a mean DT_{50} of 2.17 d (pF 2, 12 °C). Degradation process in North American sandy loam soils followed biphasic first order kinetics characterised by a rapid initial decline (phase 1: DT_{50} = 6.7 h and 7.4 d) and a slow secondary phase (DT_{50} = 237 d and 144 d), only concerning a small fraction of a.s. (< 10 % AR). The observed slow secondary phase of degradation might result from both, tight binding of the components to soil and incorporation of the radiolabelled material into the carbon cycles of soil microorganisms Recalculation with ModelMaker 4.0 resulted in half-lives of 16.4 d and 21.7 d (FOMC kinetics, pF 2, 12 °C). Geometric mean DT_{50} of all laboratory studies was 9.19 days (pF 2, 12 °C). Bound residues reached a high plateau of 41-60 % AR at end of the studies. Mineralisation rates (CO_2) increased continously accounting for maxima of 46 % AR (silt loam, after 100 d) and 38.3 % AR (sandy loam, after 365 d). Formation of other volatiles is negligible.

In comparison to the aerobic tests, the degradation process was slower under anaerobic conditions. A lower production of ^{14}C-carbon dioxide was observed under anaerobic conditions (22-25 % AR after 90 days, 26-32 % after 365 days). The amount of non-extractable residues was 51 and 52 % AR after 90 days, reached a maximum of 67 % after 180 days and stayed on a high level up to study end (58-60 % after 12 months). No metabolites > 10 % AR were observed in soil under anaerobic conditions.

Field dissipation studies were performed to provide a more adapted assessment of the degradation kinetics. The DT_{50} value (12 °C) ranged between 7.5 - 15.6 days. The geometric mean half life (dissipation) for five European soils was 9.84 days at 12 °**C**. The results are

suitable for exposure modelling in the terrestrial compartment (PEC_{soil}), since the volatilisation of fenoxycarb or metabolites was negligible (with exception of mineralisation to CO_2) and significant leaching in the course of field dissipation studies was not observed.

Neither in aquatic system nor in soil (aerobic as well as anaerobic conditions) metabolites exceeding 10 % of AR were found.

Abiotic Degradation

Fenoxycarb was stable to hydrolysis in sterile buffer solutions at pH 5, 7, and 9. Therefore hydrolytic processes do not represent a major degradation pathway for fenoxycarb under environmental pH and temperature conditions. In sterile phosphate buffer solutions (pH 7) fenoxycarb degraded photolytically with half-lives between 18 to 23 d following (pseudo) first order kinetics. Several metabolites were observed and some also identified, but only phenol and CGA 294847 were found at >10 % AR. In all submitted studies artificial sunlight was used. The higher irradiation intensities applied can be an explanation of higher degradation rates in aqueous solution. Based on the half life (5.9 h) and chemical lifetime (8.51 h) of fenoxycarb in the atmosphere, accumulation in the air is not to be expected.

Phenol may volatise from dry soil, but because of the rapid rate of phenol degradation, volatility of phenol is considered negligible. Volatility from water is not expected due to its sufficiently high water solubility and rapid degradation. Thus, phenol is not considered to be a relevant metabolite in water or air.Moreover, photolytic transformation of the a.s. in a static or running water will take place solely in the upper centimetres of the water body. Therefore, metabolites formed via phototransformation are not considered to be relevant for the environmental exposure assessment.

Distribution and Mobility

The adsorption and desorption laboratory studies on fenoxycarb indicate that fenoxycarb is expected not to reach the groundwater. According to the results of the soil field dissipation and water/sediment studies, the metabolites phenol and CGA 294847 are not considered as being relevant in any environmental compartment. It is very unlikely that one of the two metabolites could reach the groundwater table or exceed a concentration of 0.1 µg/L in the groundwater.

Bioaccumulation

In a study according to OECD 305 a bioconcentration factor for the aquatic compartment of BCF_{fish} = 569 was measured for fenoxycarb. The bioconcentration factors for the terrestrial compartment ($BCF_{earthworm}$ = 141.82) was estimated on basis of log K_{ow} = 4.07. Both values indicate that fenoxycarb has a potential for bioaccumulation via terrestrial and aquatic food chain.

2.2.2.2. Effects assessment

Aquatic Compartment

Fenoxycarb is of high acute toxicity to fish (96h-LC_{50} = 0.66 mg a.s./L), daphnids (48h-EC_{50} = 0.6 mg a.s./L) and green algae (96h-EbC50 = 0.54 mg/L). In long-term studies, *Daphnia magna* was the most sensitive aquatic species with a 21 d-NOEC of 0.0016 µg a.i./L based on mean measured concentrations. This NOEC is by orders lower than the NOECs from the fish early life stage test (NOEC = 48 µg a.s./L). Also for *Chironomus riparius* a high toxicity of fenoxycarb was found with a nominal 25 d-EC_{10} of 0.18 µg a.s./L. For green algae no valid NOEC is available. However, in a mesocosm study, no effects on phytoplankton community were observed at concentrations that have significant effects on invertebrates. The high sensitivity of *Daphnia* and *Chironomus* in long-term tests can be explained by the mode of action of fenoxycarb (inhibiting metamorphosis to the adult stage and interfering with the moulting of early instar larvae by exhibiting juvenile hormone activity). A $PNEC_{water}$ of 0.16 ng/L was derived from the available data using an assessment factor of 10.

The available effect data for the metabolites CGA 294847 and CGA 294850 indicate that the metabolites are by orders of magnitude less toxic than the parent substance fenoxycarb. For the metabolite CGA 294847 acute tests with fish, daphnids and algae are available. The lowest effect value (48h-EC_{50} of 61 mg/L) was found for *D. magna*. A PNEC water of 61 µg/L was derived for this metabolite with an assessment factor of 1000.

For the metabolite CGA 294850 there is only one acute toxicity test with *D. magna* available in which a 48h- EC_{50} of 8.5 mg/L was found. A $PNEC_{water}$ of 8.5 µg/L was derived for this metabolite using an assessment factor of 1000.

Sediment

There are no tests with benthic organisms available in which the test substance was applied to sediment. Therefore, the $PNEC_{sediment}$ is derived from the $PNEC_{water}$ using the equilibrium partitioning method according to the TGD, resulting in a $PNEC_{sediment}$ of 0.006 µg/kg ww.

Terrestrial Compartment

Short-term tests with earthworms (LC_{50} = 850 mg a.s./kg dw), plants (EC_{50} = 88.2 mg a.s./kg dw) and a soil microorganism study (NOEC carbon transformation = 3 mg a.s/kg dw, NOEC nitrogen transformation = 0.3 mg a.s./kg dw) are available for fenoxycarb. All effect values are based on nominal concentrations as no analytical monitoring was performed. Due to the degradation in soil, the nominal effect values may underestimate the toxicity of fenoxycarb. Therefore, a mean effective concentration for the lowest effect value (0.3 mg/kg dw) is calculated using the time-weight average approach. This results in a NOEC of 0.105 mg/kg

dw. From this value a $PNEC_{soil*}$ of 1.05 µg/kg dw equivalent to 0.92 µg/kg ww was derived using an assessment factor of 100.

For the metabolite CGA294850 a short term test with earthworm (LC_{50} = 843 mg/kg dw) was carried out. This effect values is nearly identical with the effect value found in the earthworm test with fenoxycarb and supports the assumption that in this test not the toxicity of fenoxycarb but rather the toxicity of the degradation product(s) was determined.

Inhibition of microbial activity (aquatic)

In the study on inhibition of microbial activity (aquatic) an EC_{50} of ≥5.66 mg a.s./L was found. The NOEC was determined being ≥1.81 mg/L. Both values are based on nominal concentrations. A $PNEC_{microorganism}$ of 0.181 mg/L was derived using an assessment factor of 10.

Non Compartment specific Effects relevant to the Food Chain (Secondary Poisoning)

A dietary study for birds (*Colinus virginianus*) results in a 5d-LC_{50} > 5620 mg a.s./kg food. From this value a $PNEC_{oral,bird}$ of > 1.87 mg/kg food was derived using an assessment factor of 3000.

The relevant effect value for the derivation of a $PNEC_{oral}$ for mammals is the NOAEL of 6 mg/kg bw/d determined in a 78 week chronic study with mice. The NOAEL of 6 mg/kg bw/d corresponds to a food concentration of 50 mg/kg food. A $PNEC_{oral,mammal}$ of 1.7 mg/kg food was derived using an assessment factor of 30.

2.2.2.3. PBT-, vPvB-assessment

In two water/sediment systems half-lives for the water phase of a river and a pond system are 14.0 and 5.0 days, respectively at an average EU outdoor temperature of 12 °C. For the whole system, DT_{50} values of 12.0 and 8.0 days were determined at 12 °C. All values are below the trigger value. Therefore, fenoxycarb does not fulfil the **P criterion** for freshwater.

From three aerobic laboratory degradation studies in soil half-lives between 2.17 and 21.4 days were derived, normalised to 12 °C and pF2 (SFO kinetics). Field studies on aerobic degradation in soil resulted in DT_{50} values from 7.5 to 22.6 days (n=6) at 12°C. Thus, the **P-criterion** for soil is not fulfilled.

∗ The $PNEC_{soil}$ of 0.92 µg/kg ww depends on a NOEC of ≥0.3 mg a.s./kg dw which was derived regarding to formed quantity of nitrogen as prescribed for non-agrochemicals by OECD test guideline 216. The NOEC derived on nitrate rates would be ≥0.6 mg a.s./kg dw. In case PECsoil/PNECsoil ≥1 arise during authorisation of new products, a NOEC of ≥0.6 mg a.s./kg dw should be used for risk assessment (see Doc III A 7.5.1.1).

In fish a bioconcentration factor of 569 (whole fish) and 959 (viscera) was measured, the calculated BCF_{fish} amounts to 575. For earthworm a BCF of 142 was estimated. Therefore, the **B criterion** is not fulfilled.

Fenoxycarb is considered as toxic (21d-NOEC for *Daphnia magna* is 1.6 ng/L). The **T criterion** is fulfilled.

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

2.2.2.4. Exposure assessment

For environmental exposure estimation data on the representative biocidal product (b.p.) are provided by the applicant. The representative b.p. contains two active substances - fenoxycarb as insecticidal wood preservative and propiconazole as fungicidal substance - as well as solvent (water), co-solvent and emulsifier. During national authorisation of biocidal products, containing fenoxycarb as active substance, a re-evaluation of all ingredients in the final product will be required.

Predicted environmental concentrations (PECs) have been estimated for the life cycle stages “industrial use” (industrial application of the b.p. via dipping/immersion including the post-treatment conditioning, industrial storage of the treated wood prior to shipment) and “service life” of industrially treated wood in use class 3. The dipping / immersion process has been considered as application technique. For estimation of emissions from on-site storage of treated timber direct losses to the environment were postulated, suggesting that one half of the leachate directly runs to surface water, where the other half completely seeps into the soil of the storage site.

For “service life” the emission scenarios “fence”, “noise barrier”, “house”, and “bridge over pond” were estimated. For PEC estimations a receiving soil volume of 50 cm in distance and 50 cm in depth to the treated wooden structures were considered to be relevant for the final risk assessment. Two different time windows were regarded. Time 1 reflects the initial assessment period and covers a period of 30 days. The longer time span (time 2) for wood during storage and for service life (after application process dipping/immersion) was set to 15 years. A standard sewage treatment plant (STP) was applied as waste treatment technique in the life cycle stages “industrial use” and “service life”. Waste disposal to landfill sites is not expected to contribute significantly to the overall exposure so that this route of exposure is not considered.

For the life cycle stage “production of the a.s.” no exposure assessment was performed as the applicant did not provide any information. For the life cycle stage “formulation of the b.p.” no exposure assessment was carried out as the applicant stated no emissions to the environment during formulating the biocidal product. Applicant’s statement is deemed to be plausible during active substance evaluation. No exposure estimation was performed for the life cycle stages “professional use of the b.p.” and “private use of the b.p.” as both uses are not intended by the applicant.

The emissions for industrial use and the service life were estimated using the guidance given in the OECD Emission Scenario Document for Wood Preservatives (2003) and the EU

Technical Guidance Document on Risk Assessment (2003). The estimation of the local PECs for the aquatic compartment includes sewage treatment plant (STP), surface water, and sediment. The estimation of the local PECs for the terrestrial compartment comprises soil and groundwater. Due to the bioaccumulation potential of fenoxycarb PECs for the assessment of secondary poisoning are estimated for all scenarios.

2.2.2.5. Risk characterisation

Aquatic Compartment

There is no risk to sewage treatment plants from industrial application and wood in service (scenario noise barrier).

A risk for surface water and sediment dwelling organisms was identified for industrial application by dipping (surface water: PEC/PNEC = 29, sediment: 28) and storage of pre-treated timber after dipping (surface water: 662, sediment: 638).

For wood in service the noise barrier and the bridge over pond scenario are considered for the risk characterisation for surface water and sediment. For the noise barrier scenario the identified risk in short term assessment is removed in the long-term assessment (time 2) for both compartments. Following the conclusions drawn at various Technical Meetings the risk identified for time 1 should be considered as acceptable.

The PEC/PNEC ratios for the bridge over pond scenario exceed the trigger value by orders of magnitude for the surface water (time 1: 11000, time 2: 147) and the sediment (time 1: 10600, time 2: 142). Thus, the risk from the use of timber pre-treated with fenoxycarb for outdoor constructions near or above water bodies is considered as unacceptable.

As a risk refinement is not possible, it is recommended appropriate risk reduction measures to prevent risk for surface water and sediment during application, storage of pre-treated timber and wood in service:

- During application of the representative product via dipping all losses have to be recycled (and shall not enter the facility drain). If recycling will not be possible all losses have to be disposed of as hazardous waste.
- To prevent a risk for surface water and sediment via run-off the pre-treated timber has to be stored on hard standing plus storage under roof.

During service life constructive timber treated with fenoxycarb containing products shall not be used in conjunction to water bodies as long as no feasible risk mitigation measures are available. The discussed alternative risk mitigation measure “top coating” is only appropriate if the wooden structure does not significantly change its dimensions due to swelling and shrinking processes during permanent weathering. These processes inevitably lead to the formation of cracks in the coating resulting in an unfeasible risk reduction measure. As the penetration of wood preservatives strongly depends on the application procedure, leaching of fenoxycarb could be reduced in case of selecting other application methods than dipping. Before risk reduction measures or changes in application process are applied, it may also be checked whether more realistic environmental exposure can be assessed with a higher Tier assessment for flux estimation of fenoxycarb, e.g. a (semi)-field leaching study, than with the results obtained by laboratory testing. It is stated that measures to reduce the emissions of

fenoxycarb to surface water and sediment will have to be proven at the stage of product authorisation.

Terrestrial Compartment including Groundwater

The industrial application resulted in PEC/PNEC ratios lower than 1 for soil and groundwater. Thus industrial application by dipping poses no risk to the terrestrial compartment.

For treated timber held in storage, the estimated PEC/PNEC ratios for soil and groundwater indicate a risk (72 and 15) via run-off from storage place.

For soil (50 x 50 cm) during service life the calculated PEC/PNEC values exceed the trigger value only for time 1. These identified risks for soil resulting from leaching processes during service-life (noise barrier, house, fence) are removed in the long-term assessment (time 2) and should be considered as acceptable based on decisions made at the several Technical Meetings. For groundwater, a risk was only identified in a first tier approach ($PEC_{groundwater}$ = $PEC_{porewater}$). Fenoxycarb is expected not to pose a risk to groundwater at storage site and during service life due to its K_{OC} and degradation half-life in soil (qualitative second tier approach). In summary, the risk assessment for all relevant scenarios for service life (noise barrier, house, and fence) does not indicate a risk for the terrestrial compartment.

For the storage of pre-treated timber the risk reduction measure stated above to protect surface water and sediment will also be effective to prevent risks for soil at storage sites.

Non Compartment specific Effects relevant to the Food Chain (Secondary Poisoning)

Although values for BCF_{fish} and $BCF_{earthworm}$ indicate that fenoxycarb has a potential for bioaccumulation via terrestrial and aquatic food chain an assessment for secondary poisoning in both the aquatic and terrestrial food chain indicate no risk from application, storage and service life.

2.2.3. List of endpoints

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

3. DECISION

3.1. Background to the Decision

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

The representative biocidal product, which contains the active substance fenoxycarb, is placed on the market as a wood preservative for more than 15 years. The physico-chemical properties of fenoxycarb are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. The available data on analytical methods for determination of residues are considered sufficient to support an Annex I inclusion of fenoxycarb. Concerning analytical methods all studies required by Directive 98/8/EC are available.

It was demonstrated, that fenoxycarb and a fenoxycarb containing formulation have shown efficacy against wood-destroying insects, and therefore the inclusion into Annex I of Directive 98/8/EC can be recommended.

The representative biocidal product is intended for use as a wood preservative only by industrial and professional application. Risk assessment for professionals in this dossier only refers to the active substance fenoxycarb and its content in the referred products. Coformulants have not been considered. Only those applications included by the applicant were evaluated (automated dipping). A Tier 1 approach, which did not take account of mitigation measures, was sufficient for occupational risk assessment. There was no need to go into further detail because the estimated risks seemed acceptable at all potential exposure scenarios evaluated.

The effects on human health have been assessed, in accordance with the provisions of Article 10(1) of Directive 98/8/EC, for the uses proposed by the applicant. The available data on mammalian toxicology, mutagenicity and animal metabolism are considered to adequately support the risk evaluation of fenoxycarb in humans. Concerning toxicology and metabolism the studies required by Directive 98/8/EC are available or statements for non submission have been accepted. If the representative fenoxycarb containing product is applied in accordance with the intended use no residues of fenoxycarb are to be expected in food of plant or animal origin. According to the performed human health risk assessment of fenoxycarb, it can be concluded that secondary exposure to fenoxycarb of the general public (adults and infants including children) is considered acceptable.

Based on the results observed in the long-term and carcinogenicity studies in mice, fenoxycarb was classified as Xn (harmful), R 40 (Limited evidence of a carcinogenic effect). In accordance with the provisions of Article 10(1) therefore the inclusion into Annex IA of Directive 98/8/EC as proposed by the participant can not be recommended.

Based on the available data for the representative product and the results of the risk characterisation the following risks for the environment were identified:

- during application process: risk for surface water and sediment,
- during storage of pre-treated timber: risk for surface water, sediment, and soil,
- during life cycle stage: risk for surface water and sediment (scenario bridge over pond).

Furthermore, fenoxycarb is classified as very toxic to aquatic organisms, but not as persistent or bioaccumulating according to PBT criteria. A risk for surface water and sediment was identified regarding the service life of pre-treated timber in construction near water bodies. Without appropriate risk reduction measures which effectiveness has to be shown at product

authorisation stage, a use of timber treated with fenoxycarb containing products near water bodies is not allowed. In compliance with the environmental criteria for approval of active substance according to Annex VI of Directive 98/8/EC further explained in Technical Notes for Guidance on Annex I Inclusion, chapter 5.3, fenoxycarb does not fulfills the criteria for exclusion from Annex I for surface water, groundwater and soil.

Nevertheless the inclusion of fenoxycarb in Annex I Directive 98/8/EC is proposed on condition that during application all losses have to be recycled or collected and disposed of as hazardous waste and shall not enter the facility drain. Pre-treated timber has to be stored on impermeable ground under roof. Fenoxycarb treated timber shall not be used near water bodies during service life. Risks to the environment will be contained by these risk mitigation measures.

3.2. Decision regarding Inclusion in Annex I

The Fenoxycarb shall 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:

1. The active substance fenoxycarb, as manufactured, shall have a minimum purity of 960 g/kg.
2. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to environmental compartments and populations that have not been representatively addressed in the Union level risk assessment.
3. Member States shall ensure that authorisations are subject to the following conditions:

   - Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular, labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing under roof or both, 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.

   - Products shall not be authorised for treatment of wood that will be used in outdoor constructions near or above water, unless data is submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

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

During national authorisation of biocidal products containing fenoxycarb as active substance, a consideration of all ingredients in the final product will be required.

In the frame of product evaluation, additional data have to be provided if they are necessary to support the complete requested label claim of the product.

It is stated that appropriate risk reduction measures should be specified at the stage of product authorisation to reduce the emissions of fenoxycarb to surface water, sediment, soil, and groundwater (life cycle stage application, storage and service life).

The PNECsoil was derived from tests with earthworms, plants and soil microorganisms. Tests with terrestrial arthropods are no data requirement for PT 8. However, due to the specific insecticidal mode of action of fenoxycarb, it should be considered, if necessary, to require a long-term test with terrestrial arthropods for the product authorization.

3.4. Requirement for further information

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

3.5. Updating this Assessment Report

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

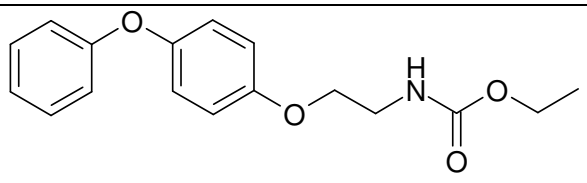
Appendix I: List of endpoints

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

Active substance (ISO Common Name)	Fenoxycarb
Function (*e.g.* fungicide)	Wood preservative

Rapporteur Member State	Germany

Identity

Chemical name (IUPAC)	Ethyl (2-(4-phenoxyphenoxy)ethyl)carbamate
Chemical name (CA)	Carbamic acid, (2-(4-phenoxyphenoxy)ethyl)-, ethyl ester
CAS-No	72490-01-8 Old CAS-No: 79127-80-3
EC No	276-696-7
Other substance No	CIPAC-No. 425
Minimum purity of the active substance as manufactured (g/kg or g/l)	The minimum purity of the active substance is confidential. This information is provided in the confidential part of the dossier.
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	The identity of impurities and additives of the active substance is confidential. This information is provided in the confidential part of the dossier.
Molecular formula	$C_{17}H_{19}NO_4$
Molecular mass	301.4
Structural formula	

Physical and chemical properties

Melting point (state purity)	54.6 °C (purity 99.5 %)
Boiling point (state purity)	no boiling until decomposition (> 180 °C) (purity 99.5 %)
Temperature of decomposition	> 180 °C (purity 99.5 %)
Appearance (state purity)	Pure active substance: Odourless white solid (flakes) (purity: 99.2%). Technical active substance: Odourless and colourless to white solidified melt (97.6%).
Relative density (state purity)	1.23 (T = 22 °C) (purity: 99.2 %)
Surface tension	62.7 mN/m (20 °C) (purity: 97.6 %)
Vapour pressure (in Pa, state temperature)	$8.67 \cdot 10^{-7}$ Pa (25 °C), extrapolated
Henry's law constant (Pa m^3 mol^{-1})	$3.3 \cdot 10^{-5}$ Pa · m³ / mol (25 °C)
Solubility in water (g/l or mg/l, state temperature)	4.45 mg/L at 10°C, 7.09 mg/L at 20°C, 11.05 mg/L at 30°C (purity: 99.5 %)
	Fenoxycarb has no dissociation constant, so the pH has no effect on the water solubility of the compound in the pH range 4-10
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	Acetone, Methanol, Dichloromethane, Ethyl acetate, Toluene > 500 g / L at 25 °C (purity: 97.6 %)
	Octanol 110 g / L at 25 °C; Hexane 4.6 g / L at 25 °C (purity: 97.6 %)
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)	log P_{ow}: 4.07 at 25 °C (purity: 99.2 %) As fenoxycarb does not dissociate in water it is assumed that the values for the partition coefficient are independent of pH within the range 5-9.

Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	No hydrolysis was observed during 30 days at 25 °C in the pH range 5 to 9
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	Fenoxycarb has no dissociation constant in an accessible pH-range
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Extinction coefficients: 228 nm (15219 l / mol · cm) 278 nm (2453 l / mol · cm), 300 nm (745 l / mol · cm), neutral solution
Photostability (DT_{50}) (aqueous, sunlight, state pH) (point VII.7.6.2.2)	Photolytic DT_{50} between 18 and 23 days (sterile aqueous buffered solution (pH 7), 25°C, using Xenon arc light, 12 h light followed by 12 h dark intervals; in dark control experiments negligible degradation of a.s., total recovery: 92.4-100% AR) Two photolytic products > 10%: Phenol (max. 17.9%) CGA 294847(max. 16.9%)
Quantum yield of direct phototransformation in water at Σ > 290 nm (point VII.7.6.2.2)	$\Phi = 6.5 \times 10^{-2}$
Flammability	No flammability
Explosive properties	No explosive properties

Classification and proposed labelling

with regard to physical/chemical data	-
with regard to toxicological data	Xn, R 40
with regard to fate and behaviour data	-
with regard to ecotoxicological data	N, R50, R53

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	HPLC on a reversed phase C-18 column using isocratic elution and UV detection at 275 nm. Quantification is done by internal standard method.
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	The analytical methods for the determination of impurities in the active substance as manufactured are confidential. This information is provided in the confidential part of the dossier.

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	residue definition: fenoxycarb LC-MS/MS LOQ = 0.01 mg/kg
Air (principle of method and LOQ) (Annex IIA, point 4.2)	residue definition: fenoxycarb LC-MS/MS LOQ = 2.8 µg/m³
Water (principle of method and LOQ) (Annex IIA, point 4.2)	residue definition: fenoxycarb LC-MS/MS LOQ = 0.1 µg/L (drinking and surface water)
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	not required
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	not required
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	not required

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	≥ 90 % based on faecal (70-80 %) and urinary (15-20 %) excretion within 48 h
Rate and extent of dermal absorption:	25, 5, and 0.2 % at concentrations of 0.05, 0.75, and 61 mg/L (corresponding to applied dosages of 0.5, 7.5, and 612 µg/cm^2), based on rat/human *in vitro* and rat *in vivo* studies with product INSEGAR© 25 WG
Distribution:	Widely distributed; tissue residues (72 h): 0.5 %, highest residues in fat, liver, kidney, lung, ovaries, bones
Potential for accumulation:	No evidence of accumulation
Rate and extent of excretion:	≥ 90 % within 48 h, mainly via faeces (70-80 %)
Toxicologically significant metabolite	Metabolites: Extensively and quantitatively metabolised, > 19 metabolites, 9 major compounds. Little or no unchanged fenoxycarb found in urine or faeces, major metabolic pathway: hydroxylation of the terminal phenyl ring followed by stepwise oxidation and conjugation with sulphate; N-dealkylation at the carbamate moiety to an acid and alkyl oxidation followed by conjugation with sulphate; formation of hydroquinone/benzoquinone Toxicologically significant metabolite: Urethane (O-ethyl carbamate, Carc. Cat. 2), 1,4-benzoquinone (T) /1,4-hydroquinone (Xn, Carc Cat. 3 Muta Cat. 3)

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral	> 10000 mg/kg bw
Rat LD_{50} dermal	> 2000 mg/kg bw
Rat LC_{50} inhalation	> 4,4 mg/L (4-h exposure, nose-only)
Skin irritation	Non-irritant
Eye irritation	Non-irritant
Skin sensitization (test method used and result)	Non-sensitiser (M&K)

Repeated dose toxicity

Species/ target / critical effect	Rat: Hepatotoxicity, thyroid (follicular hypertrophy/ hyperplasia), decreased Hb and RBC (2-yr), increased lung weight (inhalation study) Dog: Hepatotoxicity, increased kidney weight Mouse: Decreased body weight gain, increased liver and spleen weight
Lowest relevant oral NOAEL / LOAEL	90-d rat: 10 mg/kg bw/d 1-yr dog: 25 mg/kg bw/d 18-mo mouse: 6 mg/kg bw/d 2-yr rat: 8 mg/kg bw/d
Lowest relevant dermal NOAEL / LOAEL	21-d rat: 200 mg/kg bw/d
Lowest relevant inhalation NOAEL / LOAEL	21-d rat: 0.1 mg/L, 6 h/d

Genotoxicity	Fenoxycarb is unlikely to be genotoxic

Carcinogenicity

Species/type of tumour	Mouse: Lung (adenomata and carcinomata) **R40** Liver (benign hepatomata, carcinomata, species-specific, not relevant for human beings)
lowest dose with tumours	18-mo oral mouse: 57 mg/kg bw/d
Relevant carcinogenic NOAELs (rat, mouse)	18-mo oral mouse: 6 mg/kg bw/d 2-yr oral rat: 74 mg/kg bw/d

Reproductive toxicity

Species/ Reproduction target / critical effect	Parents: Hepatotoxicity Reproduction: No adverse effects observed Offspring: Decreased body weight gain

Relevant parental NOAEL	35 mg/kg bw/d
Relevant reproductive NOAEL	100 mg/kg bw/d
Relevant offspring NOAEL	13 mg/kg bw/d

Developmental toxicity

Species/Developmental target / critical effect	Rat - Dams: Increased nervousness Fetuses: No effect Rabbit - Dams: Decrease in body weight gain Fetuses: No effect
Relevant maternal NOAEL	Rat: 50 mg/kg bw/d Rabbit: 100 mg/kg bw/d
Relevant developmental NOAEL	Rat: 500 mg/kg bw/d Rabbit: 300 mg/kg bw/d

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	No specific studies available, observations from other studies include increased nervousness in pregnant female rats and sedation, spasms, tremor in acute toxicity study in rats in all doses (≥ 3000 mg/kg bw)
Relevant developmental neurotoxicity NOAEL / LOAEL.	No data, not required

Other toxicological studies

Investigation of plasma cholinesterase inhibition Metabolite data	Rat: No plasma cholinesterase inhibition, NOAEL: 5000 mg/kg bw In vitro incubation with liver microsomes from mouse, rat, marmoset, man: formation of two potential carcinogens, O-ethyl carbamate (urethane) and benzoquinone/hydroquinone. Hydroquinone formation: Mouse > rat = marmoset > man (at least 10fold lower) O-ethyl carbamate: Marmoset > mouse (M) > mouse (F) > rat > man (on average 10fold lower, but high interindividual variation)
Investigation of enzyme induction	Strong inducer of hepatic xenobiotic metabolising

	enzymes, peroxisome proliferator type inducer

Medical data

Medical surveillance data on manufacturing plant personnel.	No critical effects observed

Summary

	Value	Study	Safety factor
AEL_{acute}*	5 mg/kg bw	Dev. tox. rat	100
$AEL_{medium\text{-}term}$*	0.1 mg/kg bw/d	90-d oral rat	100
$AEL_{long\text{-}term}$*	0.06 mg/kg bw/d	18-mo oral mouse	100
Drinking water limit	Not necessary, not allocated		
ADI (if residues in food or feed)	Not allocated, no residues in food or feed		
ARfD (acute reference dose)	Not allocated, no residues in food or feed, no acute toxic alerts		

Acceptable exposure scenarios (including method of calculation)

Professional users		
Production of active substance:	Not assessed by the rapporteur under the requirements of the BPD	
Formulation of biocidal product	Not assessed by the rapporteur under the requirements of the BPD	
Intended uses: Dipping	Conc. biocidal product 0.025 %, the biocidal product is diluted for application to an aqueous solution containing max. 0.0038 % of the active substance	
<u>Mixing & loading:</u> connecting transfer lines Form of exposure: liquid (0.025 % a.s.) Duration: 10 min Frequency: daily Model: TNsG Human Exposure Model 1	Potential inhalation exposure (all phases)	Calculation: 0.00001 mg/m^3 assessed as negligible
	Potential dermal exposure (mixing&loading + application)	1.77 mg/person/day

Handling <u>Application:</u> dipping of wood and handling of treated wet wood Form of exposure: liquid (0.0038 % a.s.) Duration: 4 cycles per day (120 min.) Frequency: daily Model: TNsG Human Exposure Model 1 Handling (dermal) TNsG Human Exposure Model 1 Dipping (inhalation) <u>Post-application:</u> cleaning of the dipping tank Form of exposure: liquid (0.0038 % a.s.) Duration: 360 min. Frequency: once a year Model: TNsG Human Exposure Model 1 Handling	Potential dermal exposure (post-application)	0.37 mg/person/day
Secondary exposure	Mechanical processing of treated wood (sawing, sanding, wiping)	
<u>Sawing/sanding of treated wood</u> Form of exposure: dust of treated wood Duration: shift Frequency: daily Model: expert judgement on the basis of maximum exposure of 5 mg/m^3 to wood dust	Potential inhalation exposure	Calculation: 0.000013 mg/m^3 assessed as negligible
<u>Wiping residues</u> Form of exposure: residues of a.s. Model: maximum deposition 4 mg/cm^2 skin	Potential dermal exposure	0.06 mg/person/day
Indirect exposure as a result of use	<u>Acute exposure:</u> Adults, inhalation, dermal, sanding treated wood (acc. to TNSG user guidance of human exposure to biocides, individual scenarios): 0.003% of AEL_{acute} Infants, oral, mouthing treated wood (acc. to TNSG user guidance of human exposure to biocides): 0.1% of AEL_{acute} <u>Chronic exposure:</u> Adults and infants, inhalation indoors from treated wood (estimation via saturated vapour pressure): 0.09% of $AEL_{long\text{-}term}$ (adults)	

0.08% of $AEL_{long\text{-}term}$ (infants)

Adults and infants, dermal and oral, touching and licking of treated wood indoors or on playgrounds (acc. to TNSG user guidance of human exposure to biocides):

1.3% of $AEL_{long\text{-}term}$ (adults)

8.4% of $AEL_{long\text{-}term}$ (infants)

No residues in food or feed expected.

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) Degradation (hydrolysis) in seawater	No degradation was observed during 30 days at 25 °C in the pH range 5 to 9. No data provided.
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Photolytic half-lives (experimental): 18 and 23 days, pseudo-first order kinetics Experimental conditions: sterile aqueous buffered solution (pH 7), 25°C, using Xenon arc light, 12 h light followed by 12 h dark intervals; in dark control experiments negligible degradation of fenoxycarb, total recovery: 92.4-100% AR. Two relevant photolytic products > 10%: Phenol (max. 17.9% at day 22) CGA 294847(max. 16.9% at day 30)
Readily biodegradable (yes/no)	No
Biodegradation in seawater	No data provided.
Non-extractable residues	River: max. 56.2% (day 29), 49.5% (day 119, study end) Pond: max. 54.9% (day 14), 52.1% (day 119, study end)
Mineralisation	River: 40.4% (day 119) Pond: 36.3% (day 119)
Distribution in water / sediment systems (active substance)	DT_{50} total systems (20°C, aerobic, hockey-stick model): River: 6.1 d, Pond: 4.3 d DT_{50} total systems (modelling) (20°C, aerobic, hockey-stick model): River: 6.1 d, Pond: 9.3 d DT_{50} water (20°C, aerobic, single first order): River: 7.6 d, Pond: 2.9 d DT_{50} total systems (aerobic, hockey-stick model, converted to 12°C): River: 12.0 d, Pond: 8.0 d

	DT_{50} total systems (modelling) (aerobic, hockey-stick model, converted to 12°C): **River: 12.0 d, Pond: 18.0 d** DT_{50} water (aerobic, single first order, converted to 12°C): River: 14.0 d, Pond: 5.0 d Radioactivity in the water phases: River: 95.0% (day 0), decline to 1.0% (day 119, study end) Pond:94.4% (day 0), decline to 0.6% (day 119, study end) Radioactivity in the sediment (extractable): River: max. 34.1% (day 3), decline to 5.1% (day 119, study end) Pond: max. 41.3% (day 3), decline to 5.5% (day 119, study end)
Distribution in water / sediment systems (metabolites)	River and Pond: 13 metabolites were detected, non >10% AR, one minor metabolite identified as CGA 294850 ([2-4-(Hydroxy-phenoxy)-phenoxy)-ethyl]-carbamic acid ethyl ester) Radioactivity in the water phases CGA 294850: River: max. 2.7% (day 7), thereafter not detectable Pond: max. 3.8% (day 3), thereafter not detectable Radioactivity in the sediment (extractable) CGA 294850: River: max. 2.4% (day 3), 0.3% (day 119, study end) Pond: max. 3.8% (day 7), 0.7% (day 119, study end)

Route and rate of degradation in soil

Mineralization (aerobic)	Laboratory studies Aerobic: 23.5–44.3% CO_2 after 90 days (n=6) 27.2–46.2% CO_2 after 120 days (n=4) 32–38.3% CO_2 after 365 days (n=2) Anaerobic: 22, 25.3% CO_2 after 90 days (n=2) 26, 32% CO_2 after 365 days (n=2)
Laboratory studies (range or median, with number of measurements, with regression coefficient)	**Aerobic** silt loam "Gartenacker (CH)" Single-phase first-order kinetics (parent): DT_{50lab} (20 °C, pF 2): 1.15 (n=4, R^2=0.99) converted to 12 °C average EU outdoor temperature: DT_{50lab} (12 °C, pF 2): 2.17 sandy loam "Lime Kiln, Buckeystown (USA)" Biphasic first-order kinetics (parent): a) primary (phase 1) DT_{50lab} (25 °C): 6.7 h and 7.4 days (n=2) (concerned 80% and >90%, a.s. respectively) b) secondary (phase 2) DT_{50lab} (25 °C): 80 and 237 days (n=2) Recalculation to single first order kinetics according to FOCUS kinetics (with ModelMaker 4.0): $DT_{50lab, recalculated}$ (25 °C): 5.73, 2.93, days (FOMC, (n=2) (R^2=0.87, 0.98) $DT_{50lab, recal. modelling}$ (12 °C, pF2): 21.4, 16.7 days (SFO, n=2) **Total** (all laboratory studies) $DT_{50lab, modelling}$ (12 °C, pF2) = 2,17-21.4 days (SFO, n=3) **Geometric mean $DT_{50lab, modelling}$ (12 °C, pF2): 9.19 days**
	DT90-laboratory,.first order kinetics (parent) Aerobic silt loam "Gartenacker (CH)" DT_{90lab} (20 °C): 6.83 days sandy loam "Lime Kiln, Buckeystown (USA)" Recalculation to first-order kinetics (ModelMaker

	4.0) $DT_{90lab,\ recalculated}$ (25 °C): 36.6, 28.3 days (FOMC, n=2)
Field studies (state location, range or median with number of measurements)	Dissipation **Europe** Single first-order kinetics (parent): $DT_{50field}$, Northern Europe: 7.5-9.0 days (n=3) $DT_{50field}$, Southern Europe: 4.0 and 9.1 days (n=2) **North America** ("A"- or "B"-U-^{14}C-labelled) Biphasic first-order kinetics (parent): a) primary (phase 1) $DT_{50field}$: 3.1-5.11 days (n=4) b) secondary (phase 2) $DT_{50field}$: 13.7-44.9 days (n=4) Recalculation to single first order kinetics (with ModelMaker 4.0): $DT_{50field}$ USA: 6.1-7.7 days (n = 4, FOMC, SFO) $DT_{50field,\ modelling}$ (12 °C) = 7.4-12.9 days (SFO, n=4) Geometric mean $DT_{50field,\ modelling}$ (USA, 12 °C): 8.95 days (n=4) Metabolite (CGA 294850): Single first-order kinetics): $DT_{50field}$: USA: 1.2-17.5 days (n=4) Max. 5.7% AR (day 1), decreased to 0.7% AR (day 3) **Total (parent)** all field studies $DT_{50field}$: 4.0-9.1 days (n=6, SFO) $DT_{50field,\ modelling}$: (Europe, 12 °C) = 7.5-15.6 days (SFO, n=5) **Geometric mean $DT_{50field,\ modelling}$ (Europe, 12 °C): 9.84 days** (n=5)
	DT90-field, first-order kinetics (parent): $DT_{90field}$, Northern Europe: 24.9-29.8 days (n=3) $DT_{90field}$, Southern Europe: 13.3 and 30.3 days (n=2) $DT_{90field,}$ North America: 24.7-42.7 days (n=4)

	Single first-order kinetics (metabolite: CGA 294850): $DT_{90field}$, North America: 3.9-58.1 days (n = 4)
Anaerobic degradation	**sandy loam "Lime Kiln, Buckeystown (USA)"** Biphasic first-order kinetics (parent): **25°C:** "A"-U-^{14}C-labelled, a) primary (phase 1) DT_{50lab} (25 °C, anaerobic): 16 days (n = 1) (concerned approx. 80% a.s.) b) secondary (phase 2) DT_{50lab} (25 °C, anaerobic): 255 days (n = 1) "B"-U-^{14}C-labelled: *a) primary (phase 1)* *DT_{50lab} (25 °C, aerobic): 7.4 days (n = 1)* *(concerned >90%, a.s.)* b) secondary (phase 2) DT_{50lab} (25 °C, anaerobic): 114 days (n = 1) (concerned < 3%, a.s.) **Normalised to 12°C, pF 2:** "A"-U-^{14}C-labelled a) primary (phase 1) DT_{50lab} (12 °C,anaerobic): 45.3 days (n = 1) b) secondary (phase 2) DT_{50lab} (12 °C, anaerobic): 722 days (n = 1) B"-U-^{14}C-labelled *a) primary (phase 1)* *DT_{50lab} (12 °C, aerobic): 20,9 days (n = 1)* b) secondary (phase 2) DT_{50lab} (12 °C, anaerobic): 323 days (n = 1) (concerned < 3%, a.s.)
Soil photolysis	n.a.
Non-extractable residues	Aerobic: 53.0-67.9% after 90 days (n=6) 50-0-64.3% after 120 days (n=4) 58% after 212 days (n=1) 41% after 365 days (n=1) Anaerobic:

	51, 52% after 90 days (n=2) 58, 60% afte 365 days (n=2)
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	*No relevant soil metabolites > 10%* *Laboratory studies:* *At least 11 minor metabolites were detected in the soil extract none of them reached a level of 5 % AR.* *CGA 294850 (([2-4-(Hydroxy-phenoxy)-phenoxy)-ethyl]-carbamic acid ethyl ester): maximum 4.2% after 6 h* Field study: CGA 294850: maximum of 7.4 % on day 10
Soil accumulation and plateau concentration	Not required: $DT_{90field}$ < 1 year, Non-extractable residues < 70%, CO_2 > 5% after 100 days

Mobility in soil

Aged residues leaching	Soil column study not valid.
Lysimeter/ field leaching studies	No data provided.

Adsorption/desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	Adsorption: Parent: Ka_{oc}, = 1251-2599 mL/g (arithmetic mean 1816 mL/g, n = 5) There is neither dependence on the clay content, nor on the cation exchange capacity and soil pH. CGA 294847: Ka = 0.1-31 mL/g; Ka_{oc} = 44-3175 mL/g (arithmetic mean 944 mL/g, n = 5) Desorption: Parent: Kd_{oc} = 1769-3304 mL/g (arithmetic mean 2472 mL/g, n = 5) CGA 294847 Kd = 81-520000 mL/g; Kd_{oc} = 4508-29000000 mL/g (arithmetic mean 7275161 mL/g, n = 4)

Fate and behaviour in air

Direct photolysis in air	Air will not be an environmental compartment of concern for fenoxycarb used in wood preservatives,

	as fenoxycarb has a low vapour pressure and low Henry's Law constant.
Quantum yield of direct photolysis	$\phi = 6.5 \times 10^{-2}$
Photo-oxidative degradation in air	DT_{50} = 5.9 hours (calculated with AOPWIN v1.91, ©US-EPA 2000) - corresponding to a chemical life-time in air of about 8.5 hours.
Volatilization	Insignificant due to low vapour pressure and low Henry's Law constant.

Monitoring data, if available

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

Chapter 5: Effects on Non-target Species

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

Species	Test substance	Time-scale	Endpoint	Toxicity
Fish				
Oncorhynchus mykiss	Fenoxycarb	96 hours	Mortality	LC_{50} = 0.66 mg/l (m)
Oncorhynchus mykiss	metabolite CGA 294847	96 h	mortality	LC50 = 100 mg/l (n)
Oncorhynchus mykiss	Fenoxycarb	96 days (36 days prior and 60 days post-hatch)	Hatchability, survival, growth and any abnormal, sub-lethal changes of eggs and fry	NOEC = 0.048 mg/l (m)
Aquatic Invertebrates				
Daphnia magna	Fenoxycarb	48 hours	Immobility	EC_{50} = 0.60 mg/l (m)
Mysidopsis bahia (Mysid, marine species)	Fenoxycarb	96 hours	Immobility	EC_{50} = 0.35 mg/l (m)
Crassostrea virginica (Eastern oyster, marine species)	Fenoxycarb	96 hours	Shell deposition	EC_{50} = 0.52 mg/l (m)
Daphnia magna	metabolite CGA 294847	48 hours	immobility	EC_{50} = 61 mg/l (n)
Daphnia magna	metabolite CGA 294850	48 hours	immobility	EC_{50} = 8.5 mg/l (n)
Daphnia magna	Fenoxycarb	21 days	reproduction and growth	NOEC = 0.0016 µg/l (m)
Algae				
Scenedesmus subspicatus	Fenoxycarb	96 hours	Growth inhibition	E_bC_{50} = 0.54 mg/l (m)
Pseudokirchneriella subcapitata	metabolite CGA 294847	72 h	Growth inhibition	E_bC_{50} = 17.4mg/l (n) E_rC_{50} = 67.8 mg/l (n) NOEC = 1.9 mg/l (n)
Sediment dwelling organisms				

Chironomus riparius	Fenoxycarb	25 days	Emergence and development rate	EC_{10} = 0.18 µg/l (n) EC_{50} = 1.07 µg/l (n)
Microcosm study (most sensitive species)				
Outdoor microcosm study: algae, zooplankton, phytoplankton, macroinvertebrates, crayfish, Bluegill (*Lepomis macrochirus*)	Fenoxycarb	114 days	Treatment related effects, e.g. inhibition of growth, total abundance, taxa richness	NOEC = 1.11 µg/l (n)
Microorganisms				
Activated sludge	Fenoxycarb	3 hours	Inhibition of respiratory rate	NOEC ≥ 1.81 mg/l (n)

n = nominal concentration
m = measured concentration

Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworms	*Eisenia foetida*: 14d-LC_{50} = 850 mg/kg dw (n) The metabolite CGA 294850 showed similar toxicity (14d-LC_{50} = 843 mg/kg dw (n))
Acute toxicity to terrestrial plants	*Lactuca sativa:* 21d-EC_{50} = 88.2 mg/kg dw (biomass) (n) *Brassica napus:* 21d-EC_{50} = 131 mg/kg dw (biomass)(n) *Triticum aestivum:* 21d-EC_{50} > 720 mg/kg dw (emergence, growth) (n)
Reproductive toxicity to non-target organisms	No reproduction tests with fenoxycarb were carried out.

Effects on soil micro-organisms

Nitrogen mineralization	NOEC ≥0.3 mg a.s./kg soil dw (based on quantities) NOEC ≥0.6 mg a.s./kg soil dw (based on rates)
Carbon mineralization	NOEC ≥3 mg a.s./kg soil dw

Effects on terrestrial vertebrates

Acute toxicity to mammals	See acute toxicity towards mammals
Acute toxicity to birds	*Colinus virginianus* LD_{50} > 7000 mg/kg bw (nominal) *Anas platyrhynchos* LD_{50} > 3000 mg/kg bw (nominal)
Dietary toxicity to birds	*Colinus virginianus* short-term dietary toxicity, LC_{50} > 5620 mg/kg food (5 days, nominal)
Reproductive toxicity to birds	Not required

Bioconcentration

Bioconcentration factor (BCF)	Bluegill sunfish *(Lepomis macrochirus)* Concentration 0.015 mg/l 0.0015 mg/l whole fish: 467 569 edible: 116 117 viscera: 769 959 Estimation $BCF_{fish,}$ estimated: 575 (TGD, equation 74) $BCF_{earthworm,}$ estimated: 142 (TGD, equation 82d)
Depuration time (DT_{50}) (DT_{90})	$DT_{90\ whole\ fish}$: 2 days for 0.015 mg/l 3.7 days for 0.0015 mg/l
Level of metabolites (%) in organisms accounting for > 10 % of residues	Metabolites were found mostly in non-edible tissues, and were rapidly depurated on cessation of exposure. Main metabolites : B3 (2U) max. 26.8% B9 (U-14) max. 24.7%

Chapter 6: Other End Points

None.

APPENDIX II – LIST OF INTENDED USES

The intended uses of the representative wood preservative are only for professional and industrial application. Water-based formulations containing 0.025 % fenoxycarb are proposed for dipping treatments.

The submitted studies indicate preventive action of fenoxycarb against beetles. The tests have been performed with the active substance fenoxycarb in methanol and a water-based formulation.

Summary of intended uses

Product type	**Field of use envisaged**		**Use Class**	**Concentration of a.s. in treatment solution [% w/w]**	**Application rate** representative product **[g/m² wood]**	**Concentration of** representative product **in treatment solution [% w/w]**
PT 8	**professional and industrial use only**	Protective insect control dipping, use class 1-3	1	0.0008	25	3
			2	0.0025	40	10
			3	0.0038	40	15

Appendix III: Human Health Tables for Risk Characterisation

Note: The following tables are for internal exposure. In case external reference values are set and used in the risk characterisation, these should be mentioned separately.

Table 1: Professional Users – Primary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure [1]				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated oral uptake [mg/kg b.w/day]	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (no PPE)	Application of biocidal product -								
	a) Mixing& loading[2] 10 min/daily	-	negligible	0.001	0.001	NOAEL = 6 mg/kg b.w/day AEL-S long term = 0.06 mg/kg b.w/day	100	6000	0.02
	b) Application[2] 150 min/daily	-	negligible	0.006	0.006			1000	0.1
	total a) + b)	-	negligible	0.007	0.007			857	0.12
	c) Post-application[3] 360 min/once a year	-	negligible	0.0015	0.0015			4000	0.025
Tier 2 (Refinement, PPE or other risk mitigation measures – Specify)	Tier 2 is not required								

[1] based on the assumption of 25% systemic availability after dermal exposure

[2] Conc. biocidal product 0.025 %, the biocidal product is diluted for application to an aqueous solution containing 0.0038 % of the active substance, duration: 5 cycles per day, frequency: daily

[3] Cleaning of the dipping tank, form of exposure: liquid (0.0038 % a.s.), duration: 360 min., frequency: once a year

Table 2: Non Professional Users – Primary Exposure

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

Table 3: Indirect Exposure as a result of use – Secondary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w./day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w./day]	estimated dermal uptake [mg/kg b.w./day]	estimated oral uptake [mg/kg b.w./day]	estimated total uptake [mg/kg b.w./day]				
Tier 1 (Worst Case) Short term Scenario	Acute exposure of infant chewing wood pieces	-	-	4.80×10^{-3}	4.80×10^{-3}	$NOAEL_{acute}$: 500 AEL_{acute}: 5	100	104000	0.001
	Acute dermal and inhalation exposure by non-professional sanding, adult	3.49×10^{-7}	1.42×10^{-4}	-	1.42×10^{-4}	$NOAEL_{acute}$: 500 AEL_{acute}: 5	100	3.51×10^{6}	0.00003
Tier 2 (Refinement - Specify) Short Term Scenario	Tier 2 is not required.								

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

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w./day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w./day]	estimated dermal uptake [mg/kg b.w./day]	estimated oral uptake [mg/kg b.w./day]	estimated total uptake [mg/kg b.w./day]				
Tier 1 (Worst Case) Chronic Scenario	Chronic dermal and inhalation exposure indoors, adults	5.36×10^{-5}	7.00×10^{-4}	-	7.54×10^{-4}	$NOAEL_{long\text{-}term}$: 6 $AEL_{long\text{-}term}$: 0.06	100	7960	0.013
	Chronic oral, dermal and inhalation exposure indoors, infants	4.82×10^{-5}	1.00×10^{-3}	4.00×10^{-3}	5.05×10^{-3}	$NOAEL_{long\text{-}term}$: 6 $AEL_{long\text{-}term}$: 0.06	100	1190	0.084
	Chronic dermal and oral exposure of infants on playground	-	covered by oral uptake	4.00×10^{-3} including dermal exposure	4.00×10^{-3}	$NOAEL_{long\text{-}term}$: 6 $AEL_{long\text{-}term}$: 0.06	100	1500	0.067
Tier 2 (Refinement- Specify) Chronic Scenario	Tier 2 is not required.								

Appendix IV: List of studies

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

Section No / Reference No	Author(s)	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
A3.1.1/01 A3.3/02	Rodler, M.	Fenoxycarb (pure substance)	1992a	Report on general physico-chemical properties (aspect, odour, melting point, pH). Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. EA-162180 GLP Unpublished	N	Syngenta
A3.1.1/02 A3.1.2/02	Geffroy, A.	Fenoxycarb	2007	Melting point and boiling point of Fenoxycarb Syngenta Crop Protection Münchwilen AG, Münchwilen, Switzerland Study Number L07-000500 GLP Unpublished	Y	Syngenta
A3.1.2/01 A3.10/01	Das, R.	Fenoxycarb (pure substance)	1997	Report on boiling point / boiling range. Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 55883 GLP Unpublished	N	Syngenta
A3.1.3/01	Füldner, H.	Fenoxycarb (pure substance)	1992	Report on densitiy of solids. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.VPC GLP Unpublished	N	Syngenta
A3.2/01	Rordorf, B.	Fenoxycarb (pure substance)	1992	Report on vapor pressure curve. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.VPC GLP Unpublished	N	Syngenta

A3.2/02	Burkhard, N.	No test material (Calculation)	1998	Henry`s law constant. Novartis Crop Protection AG, Basel, Switzerland Brian Christensen Companies, Inc., Minnetonka, United States Report No. N/A GLP Unpublished	N	Syngenta
A3.3/01	Das, R.	Fenoxycarb (pure and technical substance)	1999	General physico-chemical properties of CGA 114597. Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 78916 GLP Unpublished	N	Syngenta
A3.3/02 A3.1.1/01	Rodler, M.	Fenoxycarb (pure substance)	1992a	Report on general physico-chemical properties (aspect, odour, melting point, pH). Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. EA-162180 GLP Unpublished	N	Syngenta
A3.4/01	Oggenfuss, P.	Fenoxycarb (pure substance)	1999a	Spectra of CGA 114597. Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 77493 GLP Unpublished	N	Syngenta
A3.5/01	Stulz, J.	Fenoxycarb (pure substance)	1993	Report on water solubility. Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 16650 GLP Unpublished	N	Syngenta
A3.6/01	Jäkel, K.	Fenoxycarb (pure substance)	1992	Report on dissociation constant in water. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.DCW GLP Unpublished	N	Syngenta
A3.7/01	Kettner, R.	Fenoxycarb (technical substance)	2000	Solubility in organic solvents of CGA 114597. Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 78917 GLP Unpublished	N	Syngenta

A3.9/01	Rodler, M.	Fenoxycarb (pure substance)	1992b	Report on octanol/water partition coefficient. Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. EA-162180 GLP Unpublished	N	Syngenta
A3.10/01 A3.1.2/01	Das, R.	Fenoxycarb (pure substance)	1997	Report on boiling point / boiling range. Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 55883 GLP Unpublished	N	Syngenta
A3.11/01	Schürch, H.	Fenoxycarb (technical substance)	1992a	Report on flammability of solids. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.FLS GLP Unpublished	N	Syngenta
A3.11/02	Schürch, H.	Fenoxycarb (technical substance)	1992b	Report on autoflammability of solids. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.AFS GLP Unpublished	N	Syngenta
A3.13/01	Ryser, M.	Fenoxycarb (technical substance)	1992	Report on surface tension of aqueous solutions. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.SUR GLP Unpublished	N	Syngenta
A3.13/02	Martin-Keusch, Ch.	Fenoxycarb	2007	Fenoxycarb techn. Surface tension Syngenta Crop Protection Münchwilen AG, Münchwilen, Switzerland Study Number 117423 GLP Unpublished	Y	Syngenta
A3.15/01	Schürch, H.	Fenoxycarb (technical substance)	1992c	Report on explosive properties. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.EXP GLP Unpublished	N	Syngenta
A3.16/01	Schürch, H.	Fenoxycarb (technical substance)	1992d	Report on oxidizing properties. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.OXP GLP Unpublished	N	Syngenta

A3.17/01	Meyer, K.	Fenoxycarb	1991	Statement of corrosion characteristics of CGA 114 597. Ciba-Geigy AG, Packaging development Syngenta Crop Protection AG, Basel, Switzerland Report No. N/A Not GLP Unpublished	N	Syngenta
A4.1/01	Rodler, M.	Fenoxycarb	1992c	Analytical Method for CGA 114597. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AW-164/1 Not GLP Unpublished	N	Syngenta
A4.1/02	Rodler, M.	Fenoxycarb	1991	Method Validation for technical active substances. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AW-164/1 Not GLP Unpublished	N	Syngenta
A4.2/01	Robinson, N.J.	Fenoxycarb	2004	Residue analytical method for the determination of residues of fenoxycarb in soil (RAM 406/01). Syngenta Crop Protection, Jealott's Hill International Research Centre, Bracknell, Berkshire, UK Syngenta Crop Protection AG, Basel, Switzerland Report No. - GLP Unpublished	Y	Syngenta
A4.2/02	Emburey, S.N.	Fenoxycarb	2004	Validation of a residue analytical method for the determination of residues in soil. Syngenta Crop Protection, Jealott's Hill International Research Centre, Bracknell, Berkshire, UK Syngenta Crop Protection AG, Basel, Switzerland Report No. TMJ4912B GLP Unpublished	Y	Syngenta
A4.2/03	Hargreaves, S.L.	Fenoxycarb	2003a	Residue Analytical method for the Determination of Fenoxycarb Residues in Air (RAM 409/01). Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom Syngenta Crop Protection AG, Basel, Switzerland Report No. TMJ4834 GLP Unpublished	Y	Syngenta

A4.2/04	Hargreaves, S.L.	Fenoxycarb	2003b	Fenoxycarb: Validation of an Analytical Method for the Determination of Residues in Air (RAM 409/01). Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom Syngenta Crop Protection AG, Basel, Switzerland Report No. TMJ4834 GLP Unpublished	Y	Syngenta
A4.2/05	Hargreaves, S.L.	Fenoxycarb	2003c	Residue Analytical Method for the determination of Residues of Fenoxycarb in Water (RAM 408/01). Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom Syngenta Crop Protection AG, Basel, Switzerland Report No. RJ3391B GLP Unpublished	Y	Syngenta
A4.2/06	Hargreaves, S.L.	Fenoxycarb	2003d	Fenoxycarb: Validation of a Residue Analytical Method for the Determination of Residues of Fenoxycarb in Surface Water (RAM 408/01). Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom Syngenta Crop Protection AG, Basel, Switzerland Report No. RJ3391B GLP Unpublished	Y	Syngenta
A4.2/03	Greulich, K., Alder, L.		2006	Fast multi residue screening of 300 pesticides in drinking water. Federal Institute for Risk Assessment, Berlin, Germany Report No. BFR-IX-2005 GLP published: http://www.bfr.bund.de/cd/5832	No	Public
A5.3/01	Grube , Rudolph	Fenoxycarb	1998	Abschlußbericht zur Wirksamkeit von FAROX (Fenoxycarb) gegen Hylotrupes bajulus. BAM, FG IV.1, Berlin, Germany ReportNo N/A Not GLP Unpublished	Y	Syngenta
A5.3/02	Graf, E., Barkhoff, M., Hamberg, R., Büttner, H. and Pallaske, M.	Fenoxycarb	2002	The use of insect hormones as non-neurotoxic insecticides in wood preservatives. The International Research Group on Wood Preservation. Sponsored by the “Deutsche Bundestiftung Umwelt”, Projekt Nr. DBSU 08176 Report No. IRG/WP 02-30277 Not GLP Published	N	Published
A6.1.1/01	[redacted]	Fenoxycarb	1982	Acute Oral LD50 In Rats On Ro 13 5223/000. RCC Switzerland, Report No. 007402 GLP Unpublished	N	Syngenta

A6.1.2/01	[redacted]	Fenoxycarb	1981	Acute Percutaneous Toxicity to Rats of Ro 13-5223/000. Huntingdon Research Centre, UK, Report No. 80648D/HLR85/AC	N	Syngenta
A6.1.3/01	[redacted]	Fenoxycarb	1992	CGA 114597: Acute Inhalation Toxicity in the Rat. CGA 114597 tech. Ciba-Geigy Ltd., Stein, Switzerland, Report No. 911362	N	Syngenta
A6.1.4/01	[redacted]	Fenoxycarb	1992a	Primary Dermal Irritation Study of Fenoxycarb Technical in Rabbits. Hazleton Wisconsin Inc., Madison, USA, Report No. HWI 20800880	N	Syngenta
A6.1.4/02	[redacted]	Fenoxycarb	1992b	Primary Eye Irritation Study of Fenoxycarb Technical in Rabbits. Hazleton Laboratories, Madison, USA, Report No. HWI 20800882	N	Syngenta
A6.1.5/01	[redacted]	Fenoxycarb	1998	Skin Sensitization in the Guinea Pig (Maximization Test). CGA 114597 tech. Novartis Crop Protection AG, Stein, Switzerland, Report No. 972170	N	Syngenta
A6.2/01	[redacted]	[hydroquinone-U-14C]-Fenoxycarb	2003a	The Percutaneous Penetration of [Hydroquinone-U-14C] CGA 114597 Formulated as INSEGAR® 25 WG (A-8995 B) Through Rat and Human Split-Thickness Skin Membranes (in vitro). Ciba-Geigy Limited, Division Crop Protection, Basel, Switzerland, Report No. 029AM03	Y	Syngenta
A6.2/02	[redacted]	[hydroquinone-U-14C]-Fenoxycarb	2003b	Dermal Absorption of [hydroquinone-U-14C] CGA 114597 formulated as INSEGARÒ 25 WG (A 8995 B) in the rat (in vivo). Syngenta Crop Protection AG, Basel, Switzerland; Report 029AM03	Y	Syngenta
A6.2/03	[redacted]	[hydroquinone-U-14C]-Fenoxycarb	1993	Metabolism of 14C-Fenoxycarb in rats (preliminary and definitive phases). Hazleton Laboratories, Madison, Wisconsin, United States; Report No. HWI 6117-209	N	Syngenta
A6.2/04	[redacted]	phenyl-14C-(B)-Fenoxycarb	1995	Characterisation and identification of metabolites in rats administered phenyl-14C-(B)-Fenoxycarb. Ciba Crop Protection, Ciba-Geigy Corporation, Greensboro, United States; Unpublished Report No. ABR-94068	N	Syngenta
A6.3.1/01	[redacted]	Fenoxycarb	1986	28-Day Cumulative Toxicity (Gavage) Study with CGA 114597 in the Rat. RCC, Itingen, Switzerland, Report No. 056283 / 85090	N	Syngenta
A6.3.2/01	[redacted]	Fenoxycarb	1985	21 Day Dermal Toxicity Study In The Rat. Hazleton Laboratories Europe Ltd., England, Report No. 4552-161/157 (CGA 114597/0043)	N	Syngenta
A6.3.3/01	[redacted]	Fenoxycarb	1987	Subacute (28-Day) Repeated Dose Inhalation Toxicity Study In Rats. RCC, Itingen, Switzerland, Report No. RCC-085500	N	Syngenta

A6.4.1/01	[redacted]	Fenoxycarb	1993	3-Month Oral Toxicity Study In Rats (Administration In Food). CGA 114597 tech. Ciba-Geigy Ltd., Stein, Switzerland, Report No. 92211	N	Syngenta
A6.5/01	[redacted]	Fenoxycarb	1988	Chronic Toxicity Study Following Oral Administration of Ro 13 5223/000, An Insect Growth Regulator, To Dogs For A Period Of One Year. F. Hoffmann-La Roche & Co. Ltd., Basel, Switzerland, Report No. B-153778	N	Syngenta
A6.5/02 also filed as A6.7/01	[redacted]	Fenoxycarb	1992	Ro 13 5223/000:104-Week Oral (Dietary Administration) Carcinogenicity And Toxicity Study In The Rat With A 52-Week Interim Kill. Hazleton UK, England, Report No. 5191-161/123R	N	Syngenta
A6.6.1/01	[redacted]	Fenoxycarb	1988	Mutagenicity evaluation of fenoxycarb (Ro 13 5223/000) in the Ames assay. F. Hoffmann-La Roche & Co. Ltd., Basel, Switzerland, Report No. B-153'219	N	Syngenta
A6.6.2/01	[redacted]	Fenoxycarb	1998	Cytogenetic test on Chinese hamster cells in vitro. CGA 114597 tech. Genetic Toxicology, Novartis Crop Protection AG, Basel, Switzerland, Report No. 972169	Y	Syngenta
A6.6.3/01	[redacted]	Fenoxycarb	1982	Mutagenicity evaluation of the insect growth regulator Ro 13 5223/000 in Chinese hamster cells in vitro in the absence and presence of a mouse liver homogenate metabolic activation system. F. Hoffmann-La Roche & Co. Ltd., Basel, Switzerland, Report No. B-96728	N	Syngenta
A6.6.4/01	[redacted]	Fenoxycarb	1996	Micronucleus test, mouse, in vivo study. CGA 114597 tech. - (Fenoxycarb). Ciba-Geigy Limited, Genetic Toxicology, Basel, Switzerland, Report No. 962052	N	Syngenta
A6.7/01 also filed as A6.5/02	[redacted]	Fenoxycarb	1992	Ro 13 5223/000:104-Week Oral (Dietary Administration) Carcinogenicity And Toxicity Study In The Rat With A 52-Week Interim Kill. Hazleton UK, England, Report No. 5191-161/123R	N	Syngenta
A6.7/02	[redacted]	Fenoxycarb	1995	18-Month Oncogenicity Study In Mice. CGA 114597 tech. Ciba-Geigy Ltd., Stein, Switzerland, Report No. 922117	N	Syngenta
A6.8.1/01	[redacted]	Fenoxycarb	1984	Embryotoxicity Study In Rabbits With Oral Administration Of Ro 13 5223/000. Segment II – Teratological Study. F. Hoffmann-La Roche & Co., Basel, Switzerland, Report No. B-104700	N	Syngenta

A6.8.1/02	[redacted]	Fenoxycarb	1983	Embryotoxicity Study In Rats With Oral Administration Of Ro 13 5223/000. Segment II – Teratological Study With Post-Natal Evaluations. F Hoffmann-La Roche & Co., Basel, Switzerland, Report No. B-104875	N	Syngenta
A6.8.2/01	[redacted]	Fenoxycarb	1986	Ro 13-5223/000: 2 Generation Oral (Dietary Administration) Reproduction Study In The Rat. Hazleton Laboratories Europe Ltd., Report No. 4623-161/124	N	Syngenta
A6.9/01	[redacted]	Fenoxycarb	1982	Effect Of Ro 13 5223/000 (IGR) On Plasma Cholinesterase In Rats.	N	Syngenta
A6.10/01	[redacted]	Fenoxycarb	1996a	CGA 114597 tech.(Fenoxycarb) - Effects On Biochemical Liver Parameters Following Dietary Administration To Male And Female Mice. Ciba-Geigy Ltd., Basel, Switzerland, Report No. CB 95/36	N	Syngenta
A6.10/02	[redacted]	Fenoxycarb	1996b	CGA 114597 tech. (Fenoxycarb) - Effects On Biochemical Lung Parameters Following Dietary Administration To Male And Female Mice. CIBA-GEIGY Limited, Basel, Switzerland, Report No. CB 95/46	N	Syngenta
A6.10/03	[redacted]	Fenoxycarb	1996	CGA 114597 tech. - Assessment Of Replicative DNA Synthesis In The Lung And Liver Of Male Mice Treated For 7, 14 And 42 Days. Investigation Of The Reversibility In A 42-Day Treatment/28-Day Recovery Experiment. CIBA-GEIGY Limited, Basel, Switzerland, Report No. CB 95/03	N	Syngenta
A6.10/04	[redacted]	Fenoxycarb	1997	CGA 114597 (Fenoxycarb) - In Vitro Metabolism By Liver And Lung Of Mouse, Rat, Marmoset And Man. Novartis Crop Protection Inc., Toxicology/Cell Biology, Basel, Switzerland, Report No. CB 95/45	N	Syngenta
A6.10/05	[redacted]	Fenoxycarb	1998	CGA 114597 tech. (Fenoxycarb) - In Vitro Formation Of Urethane From Fenoxycarb By Liver Microsomes Of Mouse And Man. Novartis Crop Protection Inc., Toxicology/Cell Biology, Basel, Switzerland, Report No. CB 97/16	Y	Syngenta
A6.10/06	[redacted]	Fenoxycarb	1998	CGA 114597 tech. (Fenoxycarb) - Investigation Of The Formation Of Urethane-Derived DNA Adducts In Male Mice. Toxicology/Cell Biology Novartis Crop Protection AG, Basel, Switzerland, Report No. CB 96/48	Y	Syngenta
A6.10	Smulders C, Bueters T J, Van Kleef R G, Vijverberg H P	carbamate pesticides	2003	Selective effects of carbamate pesticides on rat neuronal nicotinic acetylcholine receptors and rat brain acetylcholinesterase. Toxicology and Applied Pharmacology 193 (2), 139-146.	N	Public

A6.10.2	Haag, M., Leusink-Muis, T., Le Bouquin, R., Nijkamp, F. P., Lugnier, A., Frossard, N., Folkerts, G., Pons, F.	toluene diisocyanate	2002	Increased expression and decreased activity of cytochrome P450 1A1 in a murine model of toluene diisocyanate-induced asthma. Arch Toxicol (2002) 76:621-627	No	Public
A6.10.2	Sapone, A., Pozzetti, L., Canistro, D., Broccoli, M., Bronzetti, G., Potenza, G., Affatato, A., Biagi, G. L., Cantelli-Forti, G., Paolini, M.	Diflubenzu-ron, acephate	2003	CYP superfamily perturbation by diflubenzuron or acephate in different tissues of CD1mice. Food Chem Toxicol (2003) 43:173-183	No	Public
A 6.12/01	anonymous		12.04. 2006	Medical surveillance data on manufacturing plant personnel		
A 6.12/02	anonymous		12.04. 2006	Health monitoring of personnel		
A 6.12/03:	anonymous		12.04. 2006	Health records, both from industry		
A 6.12/04	anonymous		12.04. 2006	Signs of poisoning		
A 6.12/05	anonymous		12.04. 2006	Diagnosis of poisoning		
A 6.12/06	anonymous		12.04. 2006	Sensitisation/allergenicity observations		
A 6.12/07	anonymous		12.04. 2006	Specific treatment in case of an accident or poisoning		
A7.1.1.1.1/01	Britt, T.	Fenoxycarb	1994	Hydrolysis of 14C-Fenoxycarb at pH 5, 7 and 9 Novartis Crop Protection AG, Basel, Switzerland Mckenzie Laboratories, Inc., Phoenix, United States, Report No RC-0001 Syngenta File N° CGA114597/0468 GLP Unpublished	N	Syngenta
A7.1.1.1.2/01	Clark, A.	Fenoxycarb	1994	Photodegradation of [14C]-Fenoxycarb (Phenyl-14C-CGA-114597) in pH 7 buffered solution under artificial sunlight Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-94071 Syngenta File N° CGA114597/0513 GLP Unpublished	N	Syngenta

A7.1.1.1.2/01	Clark, A., Phelps, L., Cruz, S.	Fenoxycarb	1995	Photodegradation of [14C]-Fenoxycarb (Phenyl-14C-CGA-114597) in pH 7 buffered solution under artificial sunlight Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-94072 Syngenta File N° CGA114597/0529 GLP Unpublished	N	Syngenta
A7.1.1.1.2/02	Sack, S.	Fenoxycarb	1991	Photodegradation studies in aquous solution Novartis Crop Protection AG, Basel, Switzerland Dr. R. Maag Ltd., Dielsdorf, Switzerland, Report No RES-MET-J58 Syngenta File N° CGA114597/0109 GLP unpublished	N	Syngenta
A7.1.1.2.1/01	Lebertz, H.	Fenoxycarb	1990	CGA 114597, Ready Biodegradability (modified Sturm test) of RO-13-5223 Novartis Crop Protection AG, Basel, Switzerland Battelle Institut, Frankfurt Germany, Germany, Report No BE-EA-25-89-01-STT-03 Syngenta File N° CGA114597/0093 GLP Unpublished	N	Syngenta
A7.1.2.2.2/01 A7.4.3/01	Kennedy, J.H., Reed, C.W., and Hosmer, A.J.	Fenoxycarb	1995	Assessment of the Potential Biological Effects of Fenoxycarb Exposures on Aquatic Ecosystems as Measured in an Outdoor Microcosm Tank System (microcosms). Water Research Field Station, University of North Texas, Denton, Texas, USA and ABC Laboratories, Columbia, Missouri, USA. Unpublished report Number. CMP3 (Syngenta No. CGA11457/0555). Experimental period: May 1993 to September 1993 GLP Unpublished	N	Syngenta
A7.1.2.2.2/02	Nicollier, G.	Fenoxycarb	2000	Degradation and metabolism of Phenyl-U-14C labelled CGA 114597 under aerobic laboratory conditions in aquatic systems Novartis Crop Protection AG, Basel, Switzerland, Report No 99GN05 Syngenta File N° CGA114597/0763 GLP Unpublished	N	Syngenta
A7.1.3/01	Spare, W. C.	Fenoxycarb	1995c	Adsorption/Desorption of 14C-Fenoxycarb by the Batch Equilibrium Method on Representative Agricultural Soils Novartis Crop Protection AG, Basel, Switzerland Agrisearch Inc., Frederick, United States, Report No 12213 Syngenta File N° CGA114597/0526 GLP Unpublished	N	Syngenta

A7.1.3/02	Pryde, A.	Fenoxycarb	1982	CGA 114597 (RO 13-5223), Freundlich adsorption and desorption constants of 14C RO 13-5223/024 in four soils Novartis Crop Protection AG, Basel, Switzerland Dr. R. Maag Ltd., Dielsdorf, Switzerland, Report No 041-2674 Syngenta File N° CGA114597/0080 non-GLP Unpublished	N	Syngenta
A7.1.3/03	Spare, W. C.	CGA 294847 (fenoxycarb metabolite)	1995d	Adsorption/Desorption of 14C-CGA-294847 by the Batch Equilibrium Method on Representative Agricultural Soils Novartis Crop Protection AG, Basel, Switzerland Agrisearch Inc., Frederick, United States, Report No 12214 Syngenta File N° CGA294847/0001 GLP Unpublished	N	Syngenta
A7.1.3/03	Spare, W. C.	CGA 294847 (fenoxycarb metabolite)	1995e	Analytical phase report: adsorption/desorption of 14C-CGA-294847 by the batch equilibrium method on representative agricultural soils Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-95044 Syngenta File N° CGA294847/0002 GLP Unpublished	N	Syngenta
A7.2.1/01	Adam, D., Nicollier, G.	Fenoxycarb	2001	Rate of Degradation of [Phenoxy-U-14C]-labelled CGA 114597 in one Soil under Various Laboratory Conditions Syngenta Crop Protection AG, Basel, Switzerland, Report No 01GN02 Syngenta File N° CGA114597/0793 GLP Unpublished	Y	Syngenta
A7.2.1/02 A7.2.2.4/01	Spare, W. C.	Fenoxycarb	1995a	Aerobic and Aerobic/Anaerobic Metabolism of "A" Label 14C-Fenoxycarb in a Sandy Loam Soil: In-Life/Balance Phase Syngenta Crop Protection AG, Basel, Switzerland Agrisearch Inc., Frederick, United States, Report No 12212 Syngenta File N° CGA114597/0873 GLP Unpublished	N	Syngenta
A7.2.1/03 A7.2.2.4/02	Spare, W. C.	Fenoxycarb	1995b	Aerobic and anaerobic metabolism of 14C-Fenoxycarb in sandy loam soil: in-life/balance phase Novartis Crop Protection AG, Basel, Switzerland Agrisearch Inc., Frederick, United States, Report No 12209 Syngenta File N° CGA114597/0525 GLP Unpublished	N	Syngenta

A7.2.1/02 A7.2.2.4/01	Thede, B.	Fenoxycarb	1995a	Aerobic and aerobic/anaerobic metabolism of "A" label 14C-Fenoxycarb in a sandy loam soil Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-95019 Syngenta File N° CGA114597/0570 GLP Unpublished	N	Syngenta
A7.2.1/03 A7.2.2.4/02	Thede, B.	Fenoxycarb	1995b	Aerobic and anaerobic metabolism of 14C-Fenoxycarb in sandy loam soil Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-95018 Syngenta File N° CGA114597/0566 GLP Unpublished	N	Syngenta
A7.2.2.2/01	McDonald, J.	Fenoxycarb	1995	Terrestrial Field Dissipation of 14C-Fenoxycarb 25WP on Bareground Soil in California Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-95022 Syngenta File N° CGA114597/0534 GLP Unpublished	N	Syngenta
A7.2.2.2/02	Dorn, R.	Fenoxycarb	2003	Calculation of degradation rates for field trials in Europe Syngenta Crop Protection AG, Basel, Switzerland, Report No Ass03RD01 Syngenta File N° CGA114597/0866 non-GLP Unpublished	Y	Syngenta
A7.2.2.2/02	Hänni, R.	Fenoxycarb	1990	CGA 114597 (Ro-5223), Dissipation of fenoxycarb in soil after application of Insegar (ACR 2907B) under outdoor conditions Novartis Crop Protection AG, Basel, Switzerland Dr. R. Maag Ltd., Dielsdorf, Switzerland, Report No 6158-88034-88039 Syngenta File N° CGA114597/0110 non-GLP Unpublished	N	Syngenta
A7.2.2.2/02	Schwager, L.	Fenoxycarb	1990	CGA 114597 (RO-13-5223), Dissipation in soil after application of Insegar (ACR 2907B) under outdoor conditions Novartis Crop Protection AG, Basel, Switzerland Dr. R. Maag Ltd., Dielsdorf, Switzerland, Report No RES-ANA-89030-38 Syngenta File N° CGA114597/0094 non-GLP Unpublished	N	Syngenta

A7.2.3.2/01	Ochsenbein, U.	Fenoxycarb	1990	CGA 114597 (RO 13-5223), Leaching characteristics of Ro-13-5223 (A its formulated end-use product insegar WP) in trhee soils Novartis Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, Report No 233346 Syngenta File N° CGA114597/0118 GLP Unpublished	N	Syngenta
A7.2.3.2/02	Galicia, H.	Fenoxycarb	1990	CGA 114597 (RO 13-5223), Leaching characteristics of aged residues in BBA soil 2.1 Novartis Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, Report No 233357 Syngenta File N° CGA114597/0083 GLP Unpublished	N	Syngenta
A7.2.3.2/03	Shepler, K.	Fenoxycarb	1995	Column leaching of [14C] Fenoxycarb in five soil types Novartis Crop Protection AG, Basel, Switzerland PTRL West, Inc., Hercules, United States, Report No 504W Syngenta File N° CGA114597/0568 GLP Unpublished	N	Syngenta
A7.3.1/01	Fàbregas, E.	No test material (Calculation)	2006	Calculation of the Indirect Photodegradation Dr. Knoell Consult, Leverkusen, Germany, 05.01.2006 not GLP Unpublished	Y	Janssen NV
A7.4.1.1/01a	.[redacted]	Fenoxycarb	1993a	Acute Flow-through Toxicity of Fenoxycarb to the Rainbow Trout (Oncorhynchus mykiss). Experimental period September 4th 1992 to September 8th 1992. T.R. Wilbury Laboratories, Inc., Marblehead, United States Report No. 14-CG (Syngenta No. CGA114597/0416) GLP Unpublished	N	Syngenta
A7.4.1.1/01b	.[redacted]	Fenoxycarb	1993b	Acute Flow-through Toxicity of Fenoxycarb to the Bluegill Sunfish (Lepomis macrochirus). Experimental period August 20th 1992 to August 24th 1992. T.R. Wilbury Laboratories, Inc., Marblehead, United States Report No. 13-CG (Syngenta No. CGA114517/0418) GLP Unpublished	N	Syngenta

A7.4.1.1/01c	[redacted]	Fenoxycarb	1993c	Acute Flow-through Toxicity of Fenoxycarb to the Carp (Cyprinus carpio). T.R. Wilbury Laboratories, Inc., Marblehead, United States, unpublished report No. 47-CG (Syngenta No. CGA114598/0421). Experimental period August 7th 1992 to August 11th 1992 GLP Unpublished	N	Syngenta
A7.4.1.1/01d	[redacted]	Fenoxycarb	1993 d	Acute Flow-through Toxicity of Fenoxycarb to the Channel Catfish (Ictalurus punctatus). T.R. Wilbury Laboratories, Inc., Marblehead, United States, unpublished report No. 48-CG (Syngenta No. CGA114598/0419). Experimental period September 25th 1992 to September 29th 1992 GLP Unpublished	N	Syngenta
A7.4.1.1/01e	[redacted]	Fenoxycarb	1993e	Acute Flow-through Toxicity of Fenoxycarb to the Sheepshead Minnow (Cyprinodon variegatus). T.R. Wilbury Laboratories, Inc., Marblehead, United States, unpublished report No. 16-CG (Syngenta No. CGA11457/0417). Experimental period August 13th 1992 to August 17th 1992 GLP Unpublished	N	Syngenta
A7.4.1.1/02	[redacted]	CGA294847 (fenoxycarb metabolite)	2002	CGA294847 (fenoxycarb metabolite): Acute toxicity to rainbow trout (Oncorhynchus mykiss). Brixham Environmental Laboratory, AstraZeneca UK Limited, Brixham, Devon TQ5 8BA. Unpublished report number 2022502 (Syngenta No. CGA294848/0003). Experimental period: September 30th 2002 to October 4th 2002 GLP Unpublished	Y	Syngenta
A7.4.1.2/01	Ward, J.T. and Boeri, R.L.	Fenoxycarb	1993f	Acute Flow-through Toxicity of Fenoxycarb to the Daphnid (Daphnia magna), T R Wilbury Laboratories, Marblehead, United States, unpublished report No. 15-CG (Syngenta No. CGA114597/0420). Experimental period: July 29th to July 31st 1992 GLP Unpublished	N	Syngenta
A7.4.1.2/02	Penwell, A. J. and Maynard, S. J	CGA 294847 (fenoxycarb metabolite)	2002	CGA 294847 (fenoxycarb metabolite): Acute toxicity to Daphnia magna. Brixham Environmental Laboratory, AstraZeneca UK Limited, Brixham, Devon TQ5 8BA. Unpublished report number 2022503 (Syngenta No. CGA294847/0004). Experimental period: October 1st 2002 to October 3rd 2002 GLP Unpublished	Y	Syngenta

A7.4.1.2/03	Bätscher, R.	CGA 294850 (fenoxycarb metabolite)	2003	Acute Toxicity of CGA 294850 (Metabolite of CGA 114597) to Daphnia magna in a 48-hour Immobilization Test. RCC Ltd, Environmental Chemistry and Pharmanalytics, CH-4452 Itingen, Switzerland. Unpublished report No.2032539. (Syngenta No. CGA 294850/0001). Experimental period September 22nd 2003 to November 3rd 2003 GLP Unpublished	Y	Syngenta
A7.4.1.2/04	Ellgehausen , H	Fenoxycarb	1982	Acute toxicity of RO 13-5223 (CGA 114597 tech.) to Daphnia magna (48 Hours EC 50). RCC AG, Itingen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No 007435 Not GLP Unpublished	N	Syngenta
A7.4.1.3/01	Ellgehausen , H	Fenoxycarb	1984	Acute toxicity of Ro 13-5223/000 to Scenedesmus subspicatus (OECD: Algae growth inhibition test). RCC Research and Consulting Company AG CH-4452, Itingen, Switzerland, unpublished report No. 025266 (Syngenta No. CGA114597/0012). Experimental period: November 7th to December 9th 1983 GLP Unpublished	N	Syngenta
A7.4.1.3/02	Maynard, S. J., Swarbrick, R.H.	CGA 294847 (fenoxycarb metabolite)	2002	CGA 294847 (fenoxycarb metabolite): Toxicity to the Green Alga, Selenastrum capricornutum. Brixham Environmental Laboratory, AstraZeneca UK Limited, Brixham, Devon TQ5 8BA. Unpublished report number 2022504 (Syngenta No. CGA294847/0005). Experimental period: September 30th 2002 to October 4th 2002 GLP Unpublished	Y	Syngenta
A7.4.1.4/01	Grade, R.	Fenoxycarb	2001	Test for Activated Sludge Respiration Inhibition of CGA 1145797 tech.. Syngenta Crop Protection AG, Ecotoxicology, CH-4002 Basel, Switzerland. Unpublished report number: 2002645 (Syngenta No. CGA 114597/0778). Experimental period October 25th 2000 to October 25th 2000 GLP Unpublished	Y	Syngenta
A7.4.2	Fàbregas, E.	Fenoxycarb	2005	Calculation of the Bioconcentration Factor (BCF) of Fenoxycarb. Dr. Knoell Consult (unpublished) Report No. KC-BCF-02/06, date: 2006-09-29.	Y	Janssen

A7.4.2/01 A7.4.3.3.1	Volz E.	Fenoxycarb	2001	Accumulation and elimination of [Hydroquinone –(U)-14C] CGA114597 by Bluegill Sunfish (Lepomis macrochirus) In a Dynamic Flow-Through System. Syngenta Crop Protection AG, Ecological Sciences, CH-4002 Basel, Switzerland Unpublished report number: 2002502 (Syngenta No.CGA114597/0779). Experimental period: October 10th 2000 to April 9th 2001 GLP Unpublished	Y	Syngenta
A7.4.3/01 A7.1.2.2.2/01	Kennedy, J.H., Reed, C.W., Hosmer, A.J.	Fenoxycarb	1995	Assessment of the Potential Biological Effects of Fenoxycarb Exposures on Aquatic Ecosystems as Measured in an Outdoor Microcosm Tank System (microcosms). Water Research Field Station, University of North Texas, Denton, Texas, USA and ABC Laboratories, Columbia, Missouri, USA. Unpublished report Number. CMP3 (Syngenta No. CGA11457/0555). Experimental period: May 1993 to September 1993 GLP Unpublished	N	Syngenta
A7.4.3.2/01	[redacted]	Fenoxycarb	1990	Early Life Stage Toxicity of Fenoxycarb technical to Rainbow Trout (Oncorhynchus mykiss) in a Flow-through System. ABC Analytical Bio-Chemistry Lab. Inc., Columbia, Missouri, United States, unpublished report No 37431 (Syngenta No. CGA114597/0024). Experimental period: August 24th 1989 to November 28th 1989 GLP Unpublished	N	Syngenta
A7.4.3.4/01	Forbis, A.D.	Fenoxycarb	1987b	Chronic Toxicity of ^{14}C-Fenoxycarb to *Daphnia magna* under flow-through test conditions. ABC Analytical Bio-Chemistry Lab. Inc., Columbia, United States, unpublished report No. 35568 (Syngenta No. CGA114597/0019). Experimental period: April 13th 1987 to May 4th 1987 GLP Unpublished	N	Syngenta
A7.4.3.4/02	Ward, T.J., Magazu, J.P., Boeri, R.L.	Fenoxycarb	1995	Chronic toxicity of fenoxycarb to the Daphnid, Daphnia magna exposed to environmentally realistic concentrations. T.R. Wilbury Laboratories, INC., 40 Doake Lane, Marblehead, Massachusetts, 01945, USA. Unpublished report No. 193-CG (Syngenta No. CGA114597/0514). Experimental period: July 21st 1994 to August 11th 1994 GLP Unpublished	N	Syngenta

A7.4.3.5.1/01	Pfeifle V.	Fenoxycarb	2002a	Toxicity Test of CGA 114597 tech. On Sediment-Dwelling Chironomus riparius (syn. Chironomus thummi) under Static Conditions. Solvias AG, GLP Test Facility Solvias, CH-4002 Basel, Switzerland. Unpublished report number: 2012538 (Syngenta No CGA114597/0804). Experimental period: 23rd October 2001 to 27th February 2002 GLP Unpublished	Y	Syngenta
A7.5.1.1/01	Völkel, W.	Fenoxycarb	2001	The Effects of FENOXYCARB TECH. on Soil Respiration and Nutrification. RCC AG, Itingen, Switzerland unpublished report No. 833130 (Syngenta file No. CGA114597/0794). Experimental period August 29th 2001 to October 10th 2001 GLP Unpublished	Y	Syngenta
A7.5.1.2/01	Hakin, B., Johnson, A. B.	Fenoxycarb	1990	The acute toxicity (LC50) of Ro 13-5223/000 to the earthworm (Eisenia foetida). Huntingdon Research Centre Ltd., Cambridgeshire, England, unpublished report No. HLR 183/90934 (Syngenta No. CGA114597/0011).Experimental period: May 15th to May 29th 1990 GLP Unpublished	N	Syngenta
A7.5.1.2/02	Schmidt, T.	CGA 294850 (fenoxycarb metabolite)	2003	Acute toxicity of CGA 294850 (Metabolite of CGA 114597) to the Earthworm, Eisenia foetida in a 14-day test in Artificial soil.RCC Ltd. Environmental Chemistry and Pharmanalytics, CH-4452 Itingen, Switzerland. Unpublished Report number 2032529. (Syngenta No. CGA 294850/0002). Experimental period November 24th 2003 to December 9th 2003 GLP Unpublished	Y	Syngenta
A7.5.1.3/01	Wälder L.	Fenoxycarb	2000	Herbicide profiling test to evaluate the phytotoxicity of CGA 114597 25 WG (A-8995 B) to terrestrial non-target higher plants. Novartis Crop Protection AG, Research Biology Weed Control, CH-4332 Stein, Switzerland. Unpublished report No. SMQ 00006, Report no 41 (Syngenta No. CGA 114597/0748). Experimental period March 30th 2000 to April 20th 2000 non-GLP Unpublished	N	Syngenta
A7.5.3.1.1/01	[redacted]	Fenoxycarb	1982a	The acute oral toxicity (LD50) of Ro 13-5223/000 to the Bobwhite quail, Huntingdon Research Centre Ltd., Huntingdon, England, unpublished report No. HLR 104WL/82371 (Syngenta study number CGA 114597/0026). Experimental period: March to April 1982 GLP Unpublished	N	Syngenta

A7.5.3.1.1/02	[redacted]	Fenoxycarb	1982b	The acute oral toxicity (LD50) of Ro 13-5223/000 to the Mallard Duck, Huntingdon Research Centre Ltd., Huntingdon, England, unpublished report No. HLR 103WL/82372 (Syngenta study number CGA114598/0025). Experimental period: March to April 1982 GLP Unpublished	N	Syngenta
A7.5.3.1.2/01	[redacted]	Fenoxycarb	1993	Fenoxycarb - A dietary LC50 study with the Northern bobwhite. Wildlife International Ltd., Maryland, United States, unpublished project No. 108-354 (Syngenta study number CGA114597/0424). Experimental period: October 1st to October 9th 1992 GLP Unpublished	N	Syngenta
A7.5.4.1/01	Wilde, P.	Fenoxycarb	1982	Acute oral toxicity test on RO 13-5223/000 in Honey bees, RCC Ltd. P.O. Box, CH-4452; Itingen; Switzerland. Unpublished report No. 007446 (Syngenta No. CGA114597/0031). Reported June 3rd 1982 non-GLP Unpublished	N	Syngenta
A7.5.4.1/02	Winter, P.A., Hoxter, K.A., Smith, G.J	Fenoxycarb	1992	Fenoxycarb technical - An acute contact toxicity study with the honey bee, Wildlife International Ltd. 8598 Commerce Drive, Easton, Maryland. MD 21601, USA. Unpublished report No. 294-102A (Syngenta No. CGA114597/0411). Experimental period: October 9th 1990 to October 11th 1990 GLP Unpublished	N	Syngenta
A7.5.5	Fàbregas, E.	Fenoxycarb	2007	Calculation of the Bioconcentration Factor in earthworms (BCFearthworm) of fenoxycarb. Dr. Knoell Consult, Leverkusen, Germany, Report No. KC-BCF-02/07, date: 2007-03-12 (unpublished).	Y	Janssen
A8.1/01 A8.3/01 A8.4/01 A8.5/01	Anonymous	Fenoxycarb	2002	Safety Data Sheet Farox technical (fenoxycarb). Janssen Pharmaceutica N.V., Beere, Belgium Report No N/A GLP N/A Unpublished	N	Janssen
A8.3/01 A8.1/01 A8.4/01 A8.5/01	Anonymous	Fenoxycarb	2002	Safety Data Sheet Farox technical (fenoxycarb). Janssen Pharmaceutica N.V., Beere, Belgium Report No N/A GLP N/A Unpublished	N	Janssen

A8.4/01 A8.1/01 A8.3/01 A8.5/01	Anonymous	Fenoxycarb	2002	Safety Data Sheet Farox technical (fenoxycarb). Janssen Pharmaceutica N.V., Beere, Belgium Report No N/A GLP N/A Unpublished	N	Janssen
A8.5/01 A8.1/01 A8.3/01 A8.4/01	Anonymous	Fenoxycarb	2002	Safety Data Sheet Farox technical (fenoxycarb). Janssen Pharmaceutica N.V., Beere, Belgium Report No N/A GLP N/A Unpublished	N	Janssen

Reference list of studies on the product

Section No / Reference No	Author(s)	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
B3.1/01	Beez, V.	Basilit FP	2006a	Appearance of Basilit FP. RÜTGERS Organics GmbH, Mannheim, Germany Report No. 060214-3.1 Not GLP Unpublished	Yes	RÜTGERS Organics GmbH
B3.2/01 B3.4/02	Seubert, B.J.	Basilit FP	2006	Explosion hazards of Basilit FP. RÜTGERS Organics GmbH, Mannheim, Germany Report No. N/A Not GLP Unpublished	Yes	RÜTGERS Organics GmbH
B3.3/01	Beez, V.	Basilit FP	2006b	Oxidising properties of Basilit FP. RÜTGERS Organics GmbH, Mannheim, Germany Report No. 060214-3.3 Not GLP Unpublished	Yes	RÜTGERS Organics GmbH
B3.4/01	Beez, V.	Basilit FP	2006c	Flash point, flammability or spontaneous ignition of Basilit FP. RÜTGERS Organics GmbH, Mannheim, Germany Report No. 060214-3.4 Not GLP Unpublished	Yes	RÜTGERS Organics GmbH
B3.4/02 B3.2/01	Seubert, B.J.	Basilit FP	2006	Explosion hazards of Basilit FP. RÜTGERS Organics GmbH, Mannheim, Germany Report No. N/A Not GLP Unpublished	Yes	RÜTGERS Organics GmbH

B3.5/01	Beez, V.	Basilit FP	2006d	pH-Value of Basilit FP. RÜTGERS Organics GmbH, Mannheim, Germany Report No. 060214-3.5 Not GLP Unpublished	Yes	RÜTGERS Organics GmbH
B3.6/01	Beez, V.	Basilit FP	2006e	Relative density of Basilit FP. RÜTGERS Organics GmbH, Mannheim, Germany Report No. 060214-3.6 Not GLP Unpublished	Yes	RÜTGERS Organics GmbH
B3.6/02	Billen, M.	Basilit FP	2006	Determination of the density of Baselit FP RÜTGERS Organics GmbH, Mannheim, Germany Report No. 06101201G912 GLP Unpublished	Yes	RÜTGERS Organics GmbH
B3.7/01	Jung, R.	Basilit FP	2006a	Storage stability of Basilit FP. RÜTGERS Organics GmbH, Mannheim, Germany Report No. 060214-3.7 Not GLP Unpublished	Yes	RÜTGERS Organics GmbH
B3.7/02	Jung, R.	Basilit FP	2006b	Long term storage stability of Basilit FP. RÜTGERS Organics GmbH, Mannheim, Germany Report No. 060216-3.7 Not GLP Unpublished	Yes	RÜTGERS Organics GmbH
B3.8/01	Jung, R.	Basilit FP	2006c	Persistent Foaming of Basilit FP according to CIPAC MT 47. RÜTGERS Organics GmbH, Mannheim, Germany Report No. 060220-3.8 Not GLP Unpublished	Yes	RÜTGERS Organics GmbH
B3.10/01	Hofmann, A.	Basilit FP	2006a	Surface tension of Basilit FP. LAUDA DR. R. WOBSER GMBH & CO. KG, Lauda-Königshofen, Germany Report No. N/A Not GLP Unpublished	Yes	RÜTGERS Organics GmbH
B3.10/02	Hofmann, A.	Basilit FP	2006b	Viscosity of Basilit FP. LAUDA DR. R. WOBSER GMBH & CO. KG, Lauda-Königshofen, Germany Report No. N/A Not GLP Unpublished	Yes	RÜTGERS Organics GmbH
B4.1/01	Anonymous	Basilit FP	2001	Qualitätsprüfanweisung Quantitative Bestimmung von Farox und Propiconazole in Basilit FP. RÜTGERS Organics GmbH, Mannheim, Germany Report No. QPA-MS PRÜ 480.1 Not GLP Unpublished	Yes	RÜTGERS Organics GmbH

B5.10/01	Wegner, R., Unger, W.	Basilit FP	1999	Determination of the preventive action of FE-IG 2776 (= Basilit FP) against eggs and recently hatched larvae of *Hylotrupes bajulus (L.)* according to NMP 412/09/98 (WG 24 N 14) and EN 46. Materialprüfungsamt des Landes Brandenburg, Germany RÜTGERS Organics GmbH, Mannheim, Germany Report No. 3.2/7464/30 Not GLP Unpublished	Yes	RÜTGERS Organics GmbH
B6.5/01	European Chemicals Bureau	2-(2-Butoxyethoxy) ethanol	2000	European Risk Assessment Report (2000) – 2-(2-Butoxyethoxy) ethanol, CAS No. 112-34-5, EINECS-No. 203-961-6 – Risk Assessment.	No	Published
B7.1/01	Graf, E., Barkhoff, M., Hamberg, R., Büttner, H., Pallaske, M.	Fenoxycarb	2002	The use of insect hormones as non-neurotoxic insecticides in wood preservatives. The International Research Group on Wood Preservation. Sponsored by the "Deutsche Bundestiftung Umwelt", Projekt Nr. DBSU 08176 Report No. IRG/WP 02-30277 Not GLP Published	No	Published
B7.1/02	Hertel, H., Schoknecht, U.	Basilit FP	2007	Leaching test according to the OECD guideline proposal "Estimation of Emissions from Preservative-Treated Wood to the Environment: Laboratory Method for Wood held in Storage after Treatment and for Wooden Commodities that are not covered, and are not in Contact with Ground", version from 2006-06-09. Federal Institute for Materials Research and Testing (BAM), Division IV.1 Biology in Materials Protection and Environmental Issues, test report No. Vh 4126-7	Yes	Janssen Pharma-ceutica NV
B8.1/01 B8.2/01 B8.4/01 B8.5/01 B8.6/01	Anonymous	Basilit FP	2006	Material Safety Data Sheet Basilit FP. RÜTGERS Organics GmbH, Mannheim, Germany Report No. N/A GLP N/A Unpublished	No	RÜTGERS Organics GmbH
B8.2/01 B8.1/01 B8.4/01 B8.5/01 B8.6/01	Anonymous	Basilit FP	2006	Material Safety Data Sheet Basilit FP. RÜTGERS Organics GmbH, Mannheim, Germany Report No. N/A GLP N/A Unpublished	No	RÜTGERS Organics GmbH
B8.4/01 B8.1/01 B8.2/01 B8.5/01 B8.6/01	Anonymous	Basilit FP	2006	Material Safety Data Sheet Basilit FP. RÜTGERS Organics GmbH, Mannheim, Germany Report No. N/A GLP N/A Unpublished	No	RÜTGERS Organics GmbH

B8.5/01 B8.1/01 B8.2/01 B8.4/01 B8.6/01	Anonymous	Basilit FP	2006	Material Safety Data Sheet Basilit FP. RÜTGERS Organics GmbH, Mannheim, Germany Report No. N/A GLP N/A Unpublished	No	RÜTGERS Organics GmbH
B8.6/01 B8.1/01 B8.2/01 B8.4/01 B8.5/01	Anonymous	Basilit FP	2006	Material Safety Data Sheet Basilit FP. RÜTGERS Organics GmbH, Mannheim, Germany Report No. N/A GLP N/A Unpublished	No	RÜTGERS Organics GmbH
B9/01	Anonymous	Basilit FP	not known	Data sheet Basilit®-FP - For dipping impregnation Hazard Classes 1-3. RÜTGERS Organics GmbH, Mannheim, Germany Report No. N/A GLP N/A Unpublished	No	RÜTGERS Organics GmbH

Reference list of studies mentioned in Doc II

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
Adam, D., Nicollier, G.	Doc II-A 4	Fenoxycarb	2001	Rate of Degradation of [Phenoxy-U-14C]-labelled CGA 114597 in one Soil under Various Laboratory Conditions Syngenta Crop Protection AG, Basel, Switzerland, Report No 01GN02 Syngenta File N° CGA114597/0793 GLP Unpublished	Y	Syngenta
Anonymus	Doc II-A 4		1993-2000	Model Maker User Manual, Version 4.0. Cherwell Scientific Publishing Limited. Not GLP Published	N	Public
Anonymus	Doc II-C 12		2001	International Programme on Chemical Safety (IPCS) of the World Health Organisation (2001): Guidance Document for the Use of Data in Development of Chemical-Specific Adjustment Factors (CSAFs) for Interspecies Differences and Human Variability in Dose/Concentration–Response Assessment.	N	Public
Anonymus	Doc II-B 6 Doc II-B 9		1999	Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.	N	Public
Anonymus	Doc II-B 9		1991	Council Directive 91/414/EEC concerning the placing of plant protection products on the market	N	Public

Anonymus	Doc II-B 9 Doc II-C 12		2002	European Chemicals Bureau (ECB 2002): Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market. Human Exposure to Biocidal Products, Guidance on Exposure Estimation, Part 3, Final draft.	N	Public
Bätscher, R.	Doc II-A 4	CGA 294850 (Metabolite of CGA 114597)	2003	Acute Toxicity of CGA 294850 (Metabolite of CGA 114597) to Daphnia magna in a 48-hour Immobilization Test. Experimental period September 22nd 2003 to November 3rd 2003. RCC Ltd, Environmental Chemistry and Pharmanalytics, CH-4452 Itingen, Switzerland Report No. 2032539 (Syngenta No. CGA 294850/0001) GLP Unpublished	Y	Syngenta
Britt, T.	Doc II-A 4	Fenoxycarb	1994	Hydrolysis of 14C-Fenoxycarb at pH 5, 7 and 9 Novartis Crop Protection AG, Basel, Switzerland McKenzie Laboratories, Inc., Phoenix, United States, Report No RC-0001 Syngenta File N° CGA114597/0468 GLP Unpublished	N	Syngenta
Burnett, G., Nixon, W. B.	----	Phenol	1997	Phenol - Soil Adsorption Mobility Novartis Crop Protection Inc., Greensboro, United States, Report No ABR-97051 Syngenta File N° CGA73330/0001 non-GLP Unpublished	N	Syngenta
[redacted]	Doc II-A 4	Fenoxycarb	1993	Fenoxycarb - A dietary LC_{50} study with the Northern bobwhite. Experimental period: October 1st to October 9th 1992. Wildlife International Ltd., Maryland, United States Report No. 108-354 (Syngenta study number CGA114597/0424) GLP Unpublished	N	Syngenta
Clark, A.	Doc II-A 4	Fenoxycarb	1994	Photodegradation of [14C]-Fenoxycarb (Phenyl-14C-CGA-114597) in pH 7 buffered solution under artificial sunlight Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-94071 Syngenta File N° CGA114597/0513 GLP Unpublished	N	Syngenta

Clark, A., Phelps, L. and Cruz, S.	Doc II-A 4	Fenoxycarb	1995	Photodegradation of [14C]-Fenoxycarb (Phenyl-14C-CGA-114597) in pH 7 buffered solution under artificial sunlight Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-94072 Syngenta File N° CGA114597/0529 GLP Unpublished	N	Syngenta
Curry, P.B., Iyengar, S., Maloney, P.A. and Maroni, M.	Doc II-B8		1995	Methods of Pesticide Exposure Assessment, Plenum Press, New York	N	Public
Dorn, R.	Doc II-A 4	Fenoxycarb	2003	Calculation of degradation rates for field trials in Europe Syngenta Crop Protection AG, Basel, Switzerland, Report No Ass03RD01 Syngenta File N° CGA114597/0866 non-GLP Unpublished	Y	Syngenta
EC	Doc II B 8	Fenoxycarb	2002	Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market. Human Exposure to Biocidal Products - Guidance on Exposure Estimation [„Report 2002“ http://ecb.jrc.it/biocides]	N	Public
EC	Doc II-C 13		2006	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, authorisation and restriction of chemicals (REACH) establishing an European Chemicals Agency amending Directive 1999/45/EC and repealing Concil Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Concil Directive 76/769/EEC, Commission Directives 91/155/EEC, 93/105/EC and 2000/21/EC	N	Public
Ellgehausen, H	Doc II-A 4	Fenoxycarb	1984a	Acute toxicity of Ro 13-5223/000 to Scenedesmus subspicatus (OECD: Algae growth inhibition test). Experimental period: November 7th to December 9th 1983. RCC Research and Consulting Company AG CH-4452, Itingen, Switzerland Report No. 025266 (Syngenta No. CGA114597/0012) GLP Unpublished	N	Syngenta

Emburey, S.N.	----	Fenoxycarb	2004b	Dissipation study with fenoxycarb (CGA114597) in or on soil in Spain Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, Report No RJ3439B Syngenta File N° CGA114597/0868 GLP Unpublished	Y	Syngenta
Emburey, S.N.	----	Fenoxycarb	2004c	Dissipation Study with Fenoxycarb (CGA114597) in or on Soil in France (South) Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, Report No RJ3440B Syngenta File N° CGA114597/0872 GLP Unpublished	Y	Syngenta
European Commission, Joint Research Center	Doc II-A 4 Doc-B 8 Doc II-C 13		2003	EU Technical Guidance Document on Risk Assessment	N	Public
European Commission, Joint Research Center	Doc II-A 4 Doc-B 8		2005	Report of the Leaching Workshop (open session), Arona, Italy, 13 and 14 June 2005, 47 pages.	N	Public
Fàbregas, E.	Doc II-A 4	No test material (Calculation)	2006	Calculation of the Indirect Photodegradation Dr. Knoell Consult, Leverkusen, Germany, 05.01.2006 not GLP Unpublished	Y	Janssen NV
FOCUS	Doc II-A 4		2006	Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pages	N	Public
Forbis, A.D.	Doc II-A 4	Fenoxycarb	1987b	Chronic Toxicity of ^{14}C-Fenoxycarb to *Daphnia magna* under flow-through test conditions. Experimental period: April 13th 1987 to May 4th 1987. ABC Analytical Bio-Chemistry Lab. Inc., Columbia, United States Report No. 35568 (Syngenta No. CGA114597/0019) GLP Unpublished	N	Syngenta
Garrod, A.N.I., Martinez M., Pearson J., Proud A., Rimmer D.A.	Doc II B 8	Fenoxycarb	1999	Exposure to preservatives used in the Industrial Pretreatment of timber, Ann. occup. Hyg. 43 No. 8, 543-555	N	Public

Gillis J, Bürgin H	IIA-3.8.1		2006	Selected Historical Control Data, Segment II Embryotoxicity Studies with Swiss Hare Rabbits; Report No. 1022886	N	Roche
Grade, R.	Doc II-A 4	Fenoxycarb	2001	Test for Activated Sludge Respiration Inhibition of CGA 1145797 tech. Experimental period October 25th 2000 to October 25th 2000. Syngenta Crop Protection AG, Ecotoxicology, CH-4002 Basel, Switzerland. Report No. 2002645 (Syngenta No. CGA 114597/0778) GLP Unpublished	Y	Syngenta
Greulich, K., Alder, L.	Doc II-A 1.4		2006	Fast multi residue screening of 300 pesticides in drinking water. Federal Institute for Risk Assessment, Berlin, Germany, Report No. BFR-IX-2005, issue date: May 2006 (published in: http://www.bfr.bund.de/cd/5832).	N	Public
Guiver R., Chambers H., Foster R., Johnson P., Rimmer D.	Doc II B 8	Fenoxycarb	1999	A report of 16 visits addressing occupational exposure arising from dipping activities with biocides and non agricultural pesticides. 3830/R51.169	N	Public
Hakin, B. and Johnson, A. B.	Doc II-A 4	Fenoxycarb	1990	The acute toxicity (LC_{50}) of Ro 13-5223/000 to the earthworm (Eisenia foetida). Experimental period: May 15th to May 29th 1990. Huntingdon Research Centre Ltd., Cambridgeshire, England Report No. HLR 183/90934 (Syngenta No. CGA114597/0011) GLP Unpublished	N	Syngenta
Hänni, R.	Doc II-A 4	Fenoxycarb	1990	CGA 114597 (Ro-5223), Dissipation of fenoxycarb in soil after application of Insegar (ACR 2907B) under outdoor conditions Novartis Crop Protection AG, Basel, Switzerland Dr. R. Maag Ltd., Dielsdorf, Switzerland, Report No 6158-88034-88039 Syngenta File N° CGA114597/0110 non-GLP Unpublished	N	Syngenta
Hertel, H. and Schoknecht, U.	Doc II-A 4		2007	Leaching test according to the OECD guideline proposal “Estimation of Emissions from Preservative-Treated Wood to the Environment: Laboratory Method for Wood held in Storage after Treatment and for Wooden Commodities that are not covered, and are not in Contact with Ground”, version from 2006-06-09. Federal Institute for Materials Research and Testing (BAM), Division IV.1 Biology in Materials Protection and Environmental Issues, test report No. Vh 4126-7	Y	Janssen Pharmaceutica NV

Inai, K., Arihiro, K., Takeshima, Y., Yonehara, S., Tachiyama, Y., Khatun, N., Nishisaka, T.	Doc II-A 3.7		1991	Quantitative risk assessment of carcinogenicity of urethane (ethyl carbamate) on the basis of long-term oral administration to $B6C3F_1$ mice. Jpn J Cancer Res (1991) 82:380-385	N	Public
Kennedy, J.H., Reed, C.W., and Hosmer, A.J.	Doc II-A 4	Fenoxycarb	1995	Assessment of the Potential Biological Effects of Fenoxycarb Exposures on Aquatic Ecosystems as Measured in an Outdoor Microcosm Tank System (microcosms). Experimental period: May 1993 to September 1993. Water Research Field Station, University of North Texas, Denton, Texas, USA and ABC Laboratories, Columbia, Missouri, USA. Report No. CMP3 (Syngenta No. CGA11457/0555) GLP Unpublished	N	Syngenta
Lebertz, H.	Doc II-A 4	Fenoxycarb	1990	CGA 114597, Ready Biodegradability (modified Sturm test) of RO-13-5223 Novartis Crop Protection AG, Basel, Switzerland Battelle Institut, Frankfurt Germany Report No BE-EA-25-89-01-STT-03 Syngenta File N° CGA114597/0093 GLP Unpublished	N	Syngenta
Manenti G, Trincucci G, Pettinicchio A, Amendola E, Scarfo M, Dragani TA	IIA-3.7		2008	Cis-acting genomic elements of the Pas1 locus control Kras mutability in lung tumors. Oncogene 27:5753-5758, Published	N	Public
Maynard, S. J. and Swarbrick, R.H.	Doc II-A 4	CGA 294847 (fenoxycarb metabolite)	2002	CGA 294847 (fenoxycarb metabolite): Toxicity to the Green Alga, Selenastrum capricornutum. Experimental period: September 30th 2002 to October 4th 2002. Brixham Environmental Laboratory, AstraZeneca UK Limited, Brixham, Devon TQ5 8BA Report No. 2022504 (Syngenta No. CGA294847/0005) GLP Unpublished	Y	Syngenta

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Mc Call et al.	Doc II-A 4		1981	Measurement of Sorption Coefficients of organic Chemicals and their use in Environmental Fate Analysis; Test protocols for Environmental Fate & Movement of Toxicants (1981); Proceedings of Symposium AOAC, 21.-22.10.1980, Washington, DC	N	Publication
[redacted]	----	Fenoxycarb	1987	Early Life Stage Toxicity of Fenoxycarb to Rainbow Trout *(Salmo gairdneri)* in a Flow-through System. Experimental period January 29th to April 13th 1987. ABC Analytical Bio-Chemistry Lab. Inc., Columbia, United States Report No. 35215 (Syngenta No. CGA114597/0023) GLP Unpublished	N	Syngenta
McDonald, J.	Doc II-A 4	Fenoxycarb	1995	Terrestrial Field Dissipation of 14C-Fenoxycarb 25WP on Bareground Soil in California Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-95022 Syngenta File N° CGA114597/0534 GLP Unpublished	N	Syngenta
McGregor, D	IIA 3.7		2007	Hydroquinone: An evaluation of the Human Risks from its Carcinogenic and Mutagenic Properties. Crit Rev Toxicol 37:887-914, Published	N	Public
Nicollier, G.	Doc II-A 4	Fenoxycarb	2000	Degradation and metabolism of Phenyl-U-14C labelled CGA 114597 under aerobic laboratory conditions in aquatic systems Novartis Crop Protection AG, Basel, Switzerland, Report No 99GN05 Syngenta File N° CGA114597/0763 GLP Unpublished	N	Syngenta
OECD	Doc-B 8 Doc II-C 13		2003	Emission Scenario Document (ESD) No. 2 for Wood Preservatives (unclassified document)	N	Publication

OECD	_ _ _		2006	OECD draft guideline, Estimation of Emissions from Preservative-Treated Wood to the Environment: Laboratory Method for Wood held in Storage after Treatment and for Wooden Commodities that are not covered, and are not in Contact with Ground", version from 2006-06-09	N	Publication
Penwell, A. J. and Maynard, S. J.	Doc II-A 4	CGA 294847 (fenoxycarb metabolite)	2002	CGA 294847 (fenoxycarb metabolite): Acute toxicity to *Daphnia magna*. Experimental period: October 1st 2002 to October 3rd 2002. Brixham Environmental Laboratory, AstraZeneca UK Limited, Brixham, Devon TQ5 8BA. Report No. 2022503 (Syngenta No. CGA294847/0004) GLP Unpublished	Y	Syngenta
Pfeifle V.	Doc II-A 4	Fenoxycarb	2002a	Toxicity Test of CGA 114597 tech. On Sediment-Dwelling Chironomus riparius (syn. Chironomus thummi) under Static Conditions. Experimental period: 23rd October 2001 to 27th February 2002. Solvias AG, GLP Test Facility Solvias, CH-4002 Basel, Switzerland. Report No.2012538 (Syngenta No CGA114597/0804) GLP Unpublished	Y	Syngenta
Porch, J. R., Martin, K. H. and Krueger, H. O.	Doc II-A 4	Fenoxycarb	2007	Fenoxycarb – A Glasshouse Toxicity Study to Determine the Effects on the Seedling Emergence and Growth of Three Species of Plants. Experimental Period: 6th June 2007 - 28 September 2007. Wildlife International, Ltd., Easton, Maryland, USA 21601. Project number: 528-243 (Syngenta study number: T001614-07) GLP Unpublished	y	Syngenta
Pryde, A.	Doc II-A 4	Fenoxycarb	1982	CGA 114597 (RO 13-5223), Freundlich adsorption and desorption constants of 14C RO 13-5223/024 in four soils Novartis Crop Protection AG, Basel, Switzerland Dr. R. Maag Ltd., Dielsdorf, Switzerland, Report No 041-2674 Syngenta File N° CGA114597/0080 non-GLP Unpublished	N	Syngenta
Renwick, AG	Doc II-C 12		1993	Renwick, AG (1993): Data-derived safety factors for the evaluation of food additives and environmental contaminants. Food Addit Contam (10), 275–305, 1993	N	Public

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Sack, S.	Doc II-A 4	Fenoxycarb	1991	Photodegradation studies in aquous solution Novartis Crop Protection AG, Basel, Switzerland Dr. R. Maag Ltd., Dielsdorf, Switzerland, Report No RES-MET-J58 Syngenta File N° CGA114597/0109 GLP unpublished	N	Syngenta
Schmaehl, D., Port, R., Wahrendorf, J.	Doc II-A 3		1977	A dose-response study on urethane carcinogenesis in rats and mice. Int J Cancer (1977) 19:77-80	N	Public
Schmidt, T.	Doc II-A 4	CGA 294850 (Metabolite of CGA 114597)	2003	Acute toxicity of CGA 294850 (Metabolite of CGA 114597) to the Earthworm, Eisenia foetida in a 14-day test in Artificial soil. Experimental period November 24th 2003 to December 9th 2003. RCC Ltd. Environmental Chemistry and Pharmanalytics, CH-4452 Itingen, Switzerland. Report No. 2032529 (Syngenta No. CGA 294850/0002) GLP Unpublished	Y	Syngenta
Schwager, L.	Doc II-A 4	Fenoxycarb	1990	CGA 114597 (RO-13-5223), Dissipation in soil after application of Insegar (ACR 2907B) under outdoor conditions Novartis Crop Protection AG, Basel, Switzerland Dr. R. Maag Ltd., Dielsdorf, Switzerland, Report No RES-ANA-89030-38 Syngenta File N° CGA114597/0094 non-GLP Unpublished	N	Syngenta

Shepler, K.	Doc II-A 4	Fenoxycarb	1995	Column leaching of [14C] Fenoxycarb in five soil types Novartis Crop Protection AG, Basel, Switzerland PTRL West, Inc., Hercules, United States, Report No 504W Syngenta File N° CGA114597/0568 GLP Unpublished	N	Syngenta
Spare, W. C.	Doc II-A 4	Fenoxycarb	1995a	Aerobic and Aerobic/Anaerobic Metabolism of "A" Label 14C-Fenoxycarb in a Sandy Loam Soil: In-Life/Balance Phase Syngenta Crop Protection AG, Basel, Switzerland Agrisearch Inc., Frederick, United States, Report No 12212 Syngenta File N° CGA114597/0873 GLP Unpublished	N	Syngenta
Spare, W. C.	Doc II-A 4	Fenoxycarb	1995b	Aerobic and anaerobic metabolism of 14C-Fenoxycarb in sandy loam soil: in-life/balance phase Novartis Crop Protection AG, Basel, Switzerland Agrisearch Inc., Frederick, United States, Report No 12209 Syngenta File N° CGA114597/0525 GLP Unpublished	N	Syngenta
Spare, W. C.	Doc II-A 4	Fenoxycarb	1995c	Adsorption/Desorption of 14C-Fenoxycarb by the Batch Equilibrium Method on Representative Agricultural Soils Novartis Crop Protection AG, Basel, Switzerland Agrisearch Inc., Frederick, United States, Report No 12213 Syngenta File N° CGA114597/0526 GLP Unpublished	N	Syngenta
Spare, W. C.	Doc II-A 4	CGA 294847 (fenoxycarb metabolite)	1995d	Adsorption/Desorption of 14C-CGA-294847 by the Batch Equilibrium Method on Representative Agricultural Soils Novartis Crop Protection AG, Basel, Switzerland Agrisearch Inc., Frederick, United States, Report No 12214 Syngenta File N° CGA294847/0001 GLP Unpublished	N	Syngenta

Spare, W. C.	Doc II-A 4	CGA 294847 (fenoxycarb metabolite)	1995e	Analytical phase report: adsorption/desorption of 14C-CGA-294847 by the batch equilibrium method on representative agricultural soils Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-95044 Syngenta File N° CGA294847/0002 GLP Unpublished	N	Syngenta
Stathopoulos G, Sherrill TP, Cheng, DS, Scoggins RM, Han W, Polosukhin VV, Connelly L, Yull FE, Fingleton B, Blackwell TS	IIA-3.7		2007	Epithelial NF-kappaB activation promotes urethane-induced lung carcinogenesis. PNAS 104(47):18514-18519, Published	N	Public
Thede, B.	Doc II-A 4	Fenoxycarb	1995a	Aerobic and aerobic/anaerobic metabolism of "A" label 14C-Fenoxycarb in a sandy loam soil Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-95019 Syngenta File N° CGA114597/0570 GLP Unpublished	N	Syngenta
Thede, B.	Doc II-A 4	Fenoxycarb	1995b	Aerobic and anaerobic metabolism of 14C-Fenoxycarb in sandy loam soil Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-95018 Syngenta File N° CGA114597/0566 GLP Unpublished	N	Syngenta
[redacted]	Doc II-A 4	Fenoxycarb	1990	Early Life Stage Toxicity of Fenoxycarb technical to Rainbow Trout (Oncorhynchus mykiss) in a Flow-through System. Experimental period: August 24th 1989 to November 28th 1989. ABC Analytical Bio-Chemistry Lab. Inc., Columbia, Missouri, United States. Report No. 37431 (Syngenta No. CGA114597/0024) GLP Unpublished	N	Syngenta
Versar, Inc.	Doc II B 8	Fenoxycarb	1984	Exposure Assessment for Retention of Chemical Liquids on Hands, Washington D.C., Exposure Evaluation Division, U.S. Environmental Protection Agency, Contract No. 68-01-6271	N	Public

Völkel, W.	Doc II-A 4	Fenoxycarb	2001	The Effects of FENOXYCARB TECH. on Soil Respiration and Nitrification. Experimental period August 29th 2001 to October 10th 2001. RCC AG, Itingen, Switzerland Report No. 833130 (Syngenta file No. CGA114597/0794) GLP Unpublished	Y	Syngenta
Volz E.	Doc II-A 4	Fenoxycarb	2001	Accumulation and elimination of [Hydroquinone –(U)-^{14}C] CGA114597 by Bluegill Sunfish (Lepomis macrochirus) In a Dynamic Flow-Through System. Experimental period: October 10th 2000 to April 9th 2001. Syngenta Crop Protection AG, Ecological Sciences, CH-4002 Basel, Switzerland. Report No. 2002502 (Syngenta No.CGA114597/0779) GLP Unpublished	Y	Syngenta
Ward, J.T. and Boeri, R.L.	----	Fenoxycarb	1993g	Acute Flow-through Toxicity of Fenoxycarb to the Mysid, *Mysidopsis bahia*). Experimental period: September 11th 1992 to September 15th 1992. T R Wilbury Laboratories, Marblehead, United States. Report No. 17-CG (Syngenta No. CGA114597/0423) GLP Unpublished	N	Syngenta
Ward, J.T. and Boeri, R.L.	----	Fenoxycarb	1993h	Acute Flow-through mollusc shell deposition test with Fenoxycarb. Experimental period: August 28th 1992 to September 1st 1992. T R Wilbury Laboratories, Marblehead, United States Report No. 18-CG (Syngenta No. CGA114597/0422) GLP Unpublished	N	Syngenta
Ward, J.T. and Boeri, R.L.	Doc II-A 4	Fenoxycarb	1993f	Acute Flow-through Toxicity of Fenoxycarb to the Daphnid (*Daphnia magna*) Experimental period: July 29th to July 31st 1992. T R Wilbury Laboratories, Marblehead, United States. Report No. 15-CG (Syngenta No. CGA114597/0420) GLP Unpublished	N	Syngenta

[redacted]	Doc II-A 4	Fenoxycarb	1993a	Acute Flow-through Toxicity of Fenoxycarb to the Rainbow Trout (*Oncorhynchus mykiss*). Experimental period September 4th 1992 to September 8th 1992. T.R. Wilbury Laboratories, Inc., Marblehead, United States Report No. 14-CG (Syngenta No. CGA114597/0416) GLP Unpublished	N	Syngenta
[redacted]	Doc II-A 4	Fenoxycarb	1993b	Acute Flow-through Toxicity of Fenoxycarb to the Bluegill Sunfish (*Lepomis macrochirus*). Experimental period August 20th 1992 to August 24th 1992. T.R. Wilbury Laboratories, Inc., Marblehead, United States Report No. 13-CG (Syngenta No. CGA114517/0418) GLP Unpublished	N	Syngenta
[redacted]	Doc II-A 4	Fenoxycarb	1993c	Acute Flow-through Toxicity of Fenoxycarb to the Carp (*Cyprinus carpio*). Experimental period August 7th 1992 to August 11th 1992. T.R. Wilbury Laboratories, Inc., Marblehead, United States. Report No. 47-CG (Syngenta No. CGA114598/0421) GLP Unpublished	N	Syngenta
[redacted]	Doc II-A 4	Fenoxycarb	1993 d	Acute Flow-through Toxicity of Fenoxycarb to the Channel Catfish (*Ictalurus punctatus*). Experimental period September 25th 1992 to T.R. Wilbury Laboratories, Inc., Marblehead, United States. September 29th 1992. Report No. 48-CG (Syngenta No. CGA114598/0419) GLP Unpublished	N	Syngenta
[redacted]	Doc II-A 4	Fenoxycarb	1993e	Acute Flow-through Toxicity of Fenoxycarb to the Sheepshead Minnow (*Cyprinodon variegatus*). Experimental period August 13th 1992 to August 17th 1992. T.R. Wilbury Laboratories, Inc., Marblehead, United States. Report No. 16-CG (Syngenta No. CGA11457/0417) GLP Unpublished	N	Syngenta