Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report

Alpha-cypermethrin

Product-type 18 (insecticide)

DATE SCB

Belgium

Alpha-cypermethrin (PT18)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on date SCB

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1 STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1 Procedure Followed

This assessment report has been established as a result of the evaluation of the active substance alpha-cypermethrin as product-type 18 (insecticide), carried out in the context of the work programme for the review of existing active substances provided for in Article 89 of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

Alpha-cypermethrin (CAS no. 67375-30-8) was notified as an existing active substance, by BASF, hereafter referred to as the applicant, in product-type 18.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[1] lays down the detailed rules for the evaluation of dossiers and for the decision-making process.

In accordance with the provisions of Article 7(1) of that Regulation, Belgium was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for alpha-cypermethrin as an active substance in Product Type 18 was 30/04/2006, in accordance with Annex V of Regulation (EC) No 1451/2007.

On 28/04/2006, Belgian competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 28/07/2006.

On 17/11/2011, the Rapporteur Member State submitted to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report.

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 Agency. Revisions agreed upon were presented at the Biocidal Products Committee and its Working Groups meetings and the competent authority report was amended accordingly.

1.2 Purpose of the assessment

The aim of the assessment report is to support the opinion of the Biocidal Products Committee and a decision on the approval of alpha-cypermethrin for product-type 18, and, should it be approved, to facilitate the authorisation of individual biocidal products. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be

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

applied, in particular the provisions of Chapter IV, 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 from the Agency web-site shall be taken into account.

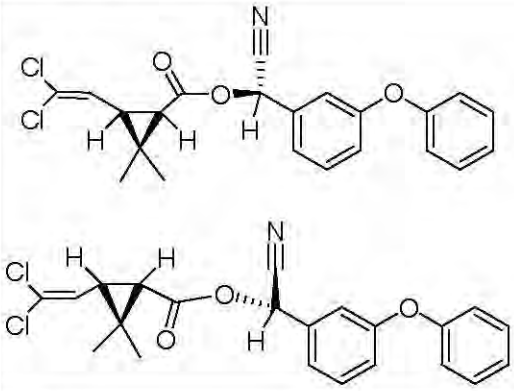
However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data for that purpose has been granted to that applicant.

2 OVERALL SUMMARY AND CONCLUSIONS

2.1 Presentation of the Active Substance

2.1.1 Identity, Physico-Chemical Properties & Methods of Analysis

2.1.1.1 Identity

CAS-No.	67375-30-8
EINECS-No.	Not allocated
Other No. (CIPAC, ELINCS)	CIPAC: 454
IUPAC Name	1:1 mixture (racemate) of the pair of enantiomers (S)-α-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(1S,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
Common name, synonyms	Alpha-cypermethrin
Molecular formula	$C_{22}H_{19}Cl_2NO_3$
Structural formula	
Molecular mass [g/mol]	416.3

2.1.1.2 Physico-chemical properties

Purified alpha-cypermethrin (> 99 %) is a white, fine crystalline powder without detectable characteristic odour. The melting point was determined at 82.3 °C.

Alpha-cypermethrin technical is a creamy white fine powder exhibiting a slight chemical odour. Its relative density (D_4^{20}) is 1.33. Alpha-cypermethrin is not volatile and its vapour pressure is low (2.5×10^{-7} Pa at 20 °C, 5.6×10^{-7} Pa at 25 °C, extrapolated).

The substance is almost insoluble in water at 20 °C (4.59–7.87 µg/l, depending on pH). It is soluble in most organic solvents (≥ 5.3 g/L for toluene, methanol, ethyl acetate, n-hexane, and 2-propanol, acetone and dichloromethane). The log P_{ow} was determined to be 5.5, without pH dependence due to absence of dissociating groups.

Alpha-cypermethrin is hydrolytically stable at pH 4: At 50 °C hydrolytic degradation was so slow that at 25 °C a half-life above 1 year can safely be assumed. At neutral and basic pH hydrolysis rates increase with increasing pH: By extrapolation, the half-lives at 20 °C are 101 days at pH 7 and 7.3 days at pH 9. 3-phenoxybenzaldehyde was identified as the major transformation product, whereas an additional metabolite amounted to less than 10 % at any sampling time and therefore needed not be identified.

Alpha-cypermethrin undergoes photolytic degradation in water. Three major metabolites were identified and the degradation pathway established as presented in chapter 4.1.1.1.2. below. The DT_{50} under natural sunlight conditions was calculated to range between 3.4 and 6.3 days.

Alpha-cypermethrin is not highly flammable and no relative self-ignition temperature could be observed up to its melting point and the substance does not exhibit oxidising or explosive properties. Any reactivity to container materials has not been observed (polyethylene has been established as a suitable packaging material).

2.1.1.3 Identification of the products

Trade name	Tenopa	
Manufacturer's development code number(s)	BAS 308 04 I	
Ingredient of preparation	Function	Content [g/l]
Alpha-cypermethrin	Active ingredient	30
The identity of all other ingredients is confidential. This information is provided separately in the confidential part of the dossier.		
Physical state of preparation	White, opaque, viscous, free-flowing liquid, free from foreign matter. Slight odour.	
Nature of preparation	SC formulation (suspension concentrate)	

The detailed composition of the biocidal product Tenopa is confidential. This information is provided separately in the confidential part of the dossier.

2.1.1.4 Methods of analysis

2.1.1.4.1 Analysis of active substance as manufactured

Analytical methods for the detection and identification of the active substance (alpha-cypermethrin) and its impurities in technical grade material are presented and validated in references A4.1/01 to /03 and are summarised in detail in the confidential file (Appendix 1 to Document III-A). HRGC-FID and HPLC-UV methods are available for the determination of the content of active substance and impurities and the isomeric composition in technical material. The analytical techniques were validated and were generally found to be linear, with adequate repeatability and reproducibility (RSDs generally in the acceptable range).

2.1.1.4.2 Formulation analysis

Analytical methods for the formulation analysis are presented and validated in reference B4.1 and are summarised in the confidential file (Appendix 1 to Document III-B). HPLC-UV method is available for the determination of the concentration of the actives substances alpha-cypermethrine and flufenoxuron. The analytical techniques were validated and were generally found to be linear, with adequate repeatability and reproducibility (RSDs generally in the acceptable range).

2.1.1.4.3 Residue analysis

Suitable methods (GC-ECD, GC-MS, GC-NPD, and LC)MS/MS) for the detection and identification of alpha-cypermethrin in soil, air, water, human and animal body fluids and tissues are summarised in Table 1.4-1 in Document II-A.

A method for the determination of alpha-cypermethrin in air is normally not required due to low volatility and the intended uses (low-pressure spraying, not resulting in the formation of aerosols) but is nevertheless available.

Validation of the confirmatory method for residues in water are still required.

The applicant agreed to provide these methods as soon as possible and at the latest 6 months before the product authorisation stage.

2.1.1.4.4 Conclusions for analytical methods

The methods of analysis of active substance as manufactured (technical grade active ingredient) and for determination of identified impurities present in pure active ingredient at quantities ≥ 0.05 % w/w have been validated and shown to be sufficiently specific, linear, accurate and precise.

The methods of analysis of alpha-cypermethrin in environmental matrices, as appropriate, have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

2.1.2 Intended Uses and Efficacy

2.1.2.1 Field of use envisaged / Function

Product Type 18: Insecticide

2.1.2.2 Organism(s) to be controlled and products, organisms or objects to be protected

Alpha-cypermethrin is an insecticide intended to be used indoor by professionals to control a broad range of insects for hard surfaces, crack and crevice treatments, areas behind furnishings and equipment by low-pressure spraying.

In the context of the dossier for Annex I inclusion, the applicant submitted efficacy tests performed on surfaces against cockroaches (*Blatella germanica* and *Periplaneta Americana*) and against cat fleas (*Ctenocephalides felis* - only for environmental control, not on animals especially cats) as examples of target organisms.

Use in industrial processes and by the general public is not envisaged.

Use of biocidal products containing alpha-cypermethrin and used in a sensitive area (hospital, kitchens, restaurants, food-processing and storage areas) may lead to residues in foods. Therefore it was agreed during TM I 2013 that a label restriction for such products used in sensitive areas is required (e.g. "Do not contaminate foodstuffs, eating utensils or food contact surfaces"; "Keep away from food, drink and animal feeding stuffs"). Additionally for such products, a dietary risk assessment (DRA) will be required at product authorisation stage.

2.1.2.3 Effects on target organisms

Alpha-cypermethrin is a synthetic pyrethroid and as such does not depend on conversion or degradation to an active form in order to exert its insecticidal activity. It acts by preventing transmission of impulses along nerves on adult insects. This effect is brought about by blocking the passage of positive sodium ions through sodium channels in nerve membranes, thus preventing action potentials passing down axons. Typically, this intoxication results in a rapid "knockdown" and resultant mortality. The affected insect shows uncoordinated movements and finally dies.

2.1.2.4 Efficacy of alpha-cypermethrin and product Tenopa.

At the time the dossier was submitted to the RMS, several laboratory and field tests were submitted with the representative product Tenopa [water-based suspension concentrate containing 30 g/L of each a.s. (alpha-cypermethrin and flufenoxuron) in combination with 7.5 mg of each a.s./m2 on surfaces].

Tenopa was shown to be efficacious against cockroaches (*Blatella germanica, Periplaneta americana, Blatta orientalis*) and cat fleas (*Ctenocephalides felis*). However, as this product is

the combination of two active substances, the relative activity of alpha-cypermethrin could not be deduced.

Only two laboratory tests were performed on surfaces with a representative product (Fendona, containing 60 g/L of alpha-cypermethrin with 15 mg/m² on surfaces) containing the active ingredient alone and were submitted to support the efficacy of alpha-cypermethrin. These tests were considered acceptable and showed that at 15 mg/m², alpha-cypermethrin is efficacious against cockroaches and cat fleas. No lower application rates were tested. There was only a very small evidence of the efficacy of alpha-cypermethrin used at 7.5 mg/m² on surfaces in the Jung study (2006). To conclude on the efficacy of alpha-cypermethrin alone at 7.5 mg/m², the Applicant submitted a last efficacy study in 2012.

This new lab study investigated the residual efficacy of Fendona 6 SC (used at 7.5 and 15 mg/m²) against *Blattella germanica* (German cockroach), *Ctenocephalides felis* (cat flea) and *Cimex lectularius* (bed bugs) on porous (carpet) and non-porous (glazed tiles) surfaces. The new data demonstrated the effectiveness of the alpha-cypermethrin-based product (Fendona 6SC) used at an application rate 7.5 mg a.i./m² against the 3 target organisms (cockroaches, bed bugs and fleas) to a sufficient degree.

In conclusion, even if only one study per application was submitted, it is sufficient to demonstrate a basic efficacy against the claimed target organisms and sufficient for the Annex I inclusion. However, at the Product Authorisation Stage, new efficacy tests should be performed on cockroaches taking in account development stage, sex and species of the target organisms (due to the possible variability of susceptibility towards pyrethroids).

There is no information available on the activity or efficacy of the different individual enantiomers of alpha-cypermethrin.

2.1.2.5 Development of resistance.

Development of resistance against alpha-cypermethrin is in principle possible in a wide range of insect taxa. Due to the common mode of action of pyrethroids cross-resistance may be of importance. However, actual resistance (including cross-resistance) has to date only been observed in agricultural pest insects, which are the targets of large-scale applications of insecticides, thus increasing the likelihood of resistance development. Biocidal treatments, in contrast, are typically targeted on relatively small populations of pest insects forming more or less closed populations. Good treatment practice will most likely results in high control levels which in turn reduces the likelihood of resistance development.

In the literature search, *Blattella germanica* is identified as susceptible to alpha-cypermethrin, with no indications of resistance (p. 70 of the literature search).

Any records related to *Periplaneta americana* or to fleas (*Siphonaptera*) were not identified by the literature search. This suggests that both the American cockroach and the whole order of fleas (*Siphonaptera*) resistance has to date not been detected.

In conclusion, resistance against alpha-cypermethrin has to date not been observed in the organisms to be controlled (cockroaches, fleas.

Whilst resistance has occurred and is a real problem in agricultural use, its expression is by no means uniform. The continued threat of resistance must be managed in order to prevent its manifestation in species where it has already developed and in order to minimize the risk of resistance developing in species which have not yet developed resistance to the synthetic pyrethroids. For this reason, strategies such as alteration of insecticides with different modes of action, mixtures of insecticides with different modes of action and avoidance of frequent and repeated use are standard practice.

2.1.3 Classification and Labelling

2.1.3.1 Classification and Labelling of the active substance

Classification	**as proposed by the BE CA according to Regulation EC 1272/2008 CLP**
Hazard Class and Category Codes Hazard statement Code(s)	Acute Tox. 3 H301 Acute Tox. 4 H332 STOT SE 3 H335 STOT RE 2 H373 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
Labelling	
Pictograms	 GHS06 GHS08 GHS09
Signal Word	Danger
Hazard Statement Codes	H301: Toxic if swallowed H332: Harmful if inhaled H373: May cause damage to the Central Nervous System (CNS) through prolonged or repeated exposure H335: May cause respiratory irritation H410: Very toxic to aquatic life with long lasting effects
Specific Concentration Limits, M-factors	Acute 1: M = 1000, based on 48h EC_{50} of 0.0003 mg/L for *Daphnia magna* Chronic 1: M = 1000, based on a long term NOEC of 0.00003 mg/L for both fish and crustacean.

Justification for the proposal

Alpha-cypermethrin is included in Annex I of Regulation 67/548/EEC, containing the list of harmonised classifications and labelling for substances which are legally binding within the EU. It is proposed to maintain the current classification, but to extend this by "R20" (harmful by inhalation), and "R38" (irritating to skin), based on recent experimental data in rats and rabbits (see chapter 3.2 and 3.3 Doc-II-A).

In addition, alpha-cypermethrin is listed in Annex VI table 3.1 of Regulation (EC) No 1272/2008, which is also understood to be legally binding. It is proposed to maintain this current classification, but to extend this by "Acute tox. 4" and "H332" (harmful if inhaled) based on the result of recent inhalation toxicity studies.

2.1.3.2 Classification and Labelling of the representative product

Classification and labelling	**as proposed by the BE CA according to Directive 1999/45/EC**	
Classification	N; R50/53	
Indication of Danger	 N	
R-phrases	R64:	May cause harm to breastfed babies
	R50/53:	Very toxic to aquatic organisms; may cause long term adverse effects in the aquatic environment.
S-phrases:	S2:	Keep out of the reach of children.
	S13:	Keep away from food, drink and animal feeding stuffs.
	S20/21:	When using do not eat, drink or smoke.
	S24:	Avoid contact with skin.
	S35:	This material and its container must be disposed of in a safe way.
	S57:	Use appropriate container to avoid environmental contamination.

Classification	**as proposed by the BE CA according to Regulation EC 1272/2008 CLP**	
Hazard Class and Category Codes Hazard Statement Code(s)	Aquatic Acute 1 Aquatic Chronic 1 Lact.	H400 H410 H362
Labelling		
Pictograms	 GHS09	
Signal Word	Warning	
Hazard Statement Codes	H362: H410:	May cause harm to breast-fed children Very toxic to aquatic life with long lasting effects
Precautionary Statement Codes	P102: P263: P270: P273: P280: P308+P313:	Keep out of reach of children Avoid contact during preygnancy/while nursing Do not eat, drink or smoke when using this product Avoid release to the environment Wear protective gloves/protective clothing/eye protection/face protection If exposed or concerned, get medical advice/attention.

Justification for the proposal

No classification results from the physico-chemical properties.

For toxicological properties, only Lact H362/ R64 is also applied for the product Tenopa as this product contains 3% of active ingredient flufenoxuron (proposed classification R64): the limit of classification for Lact H362 is 0.3% and for R64 it is 1%.

The product contains: Alpha-cypermethrin. In common with other synthetic pyrethroids it may cause paraesthesia. Therefore the safety phrase S24 (Avoid contact with skin) is recommended.

Tenopa has not been tested regarding ecotoxicological/environmental properties. The classification proposal is derived from data collected from the active ingredients (alpha-cypermethrin and flufenoxuron) and based on Directives 1999/45/EC and 2006/8/EC:

A.S.	$P_{N, R50/53}$	$L_{N, R50/53}$
Flufenoxuron	0.0025	3
Alpha-cypermethrin	0.025	3

Classification as N, R50/53 is required.

2.2 Summary of the Risk Assessment

2.2.1 Human health risk assessment

2.2.1.1 Hazard identification

2.2.1.1.1 Hazard identification of the active substance alpha-cypermethrin

Alpha-cypermethrin is related to cypermethrin in the following way: Cypermethrin has three chiral centres, one at cyclopropyl C1, a second at cyclopropyl C3, and a third at the benzylic alpha-carbon atom. This pyrethroid therefore consists of a mixture of eight isomers (four diastereoisomeric pairs). The cis- and trans-isomers of cypermethrin each consist of two diastereoisomeric pairs in which the C1 carboxyl group and the C3 dichlororvinyl group are on the same, or opposite, sides of the cyclopropane ring, respectively. The following nomenclature is commonly used: 1R,S describes the configuration of the C1 carboxyl group and alpha-R,S is used to describe the configuration at the CN-bearing alpha-carbon atom. The 1S and alpha-R-isomers are inactive; the active components of cypermethrin are 1R cis alpha-S and 1R trans alpha-S. Alpha-cypermethrin is the name given to the compound consisting of two of the four cis-isomers of cypermethrin: 1R cis alpha-S and 1S cis alpha-R, present each at 12.5 % in cypermethrin. Consequently, the acute oral and inhalation toxicity of alpha-cypermethrin is approximately 2–4 times greater than that of cypermethrin (based on acute toxicity data derived from the EC review report for cypermethrin SANCO/4333/2000final, 15.02.2005). There was little or no isomerisation of alpha-cypermethrin in the animal.

Data on distribution, metabolism and excretion showed that following a single oral application, approximately 43% of the dose is absorbed and eliminated within 24 hours via urinary excretion. Distribution and elimination from tissues is rapid, for example the half-life in liver and kidney is ca. 2 days.

Studies on the metabolism of cypermethrin in animals were conducted using ^{14}C label in both the acid and alcohol portions of the molecule (^{14}C-cyclopropyl and ^{14}C-benzyl, respectively. Some studies were conducted with cypermethrin (1:1 cis/trans mixture) and others with the separate cis- and trans-isomers. The latter were carried out to assess the effect of stereochemistry on metabolism. Although cis-cypermethrin is hydrolysed more slowly than the trans-isomer, the difference in overall metabolic fate was found to be minimal . Metabolism studies in rats conducted with alpha-cypermethrin confirmed that the metabolic pathway is comparable for both compounds.

Alpha-cypermethrin is extensively metabolised by ester cleavage and subsequent elimination of the cyclopropanecarboxylic acid moiety largely as its glucuronic acid conjugate. In faeces, mainly the unchanged parent compound was found (20% of the administered dose).

Repeated dose toxicity studies showed that the main target organ of alpha-cypermethrin is the CNS (Central Nervous System). Based on this similarity to cypermethrin and the similar metabolic pathway of both compounds, it is unlikely that alpha-cypermethrin, a component of cypermethrin, would cause effects on reproduction or would elicit carcinogenic potential

in contrast to cypermethrin. This finding was supported by the lack of genotoxic potential of alpha-cypermethrin, as determined in *in-vitro* and *in-vivo* genotoxicity tests. In addition, no carcinogenic potential was found in a carcinogenicity study with alpha-cypermethrin in mice.

Overall, since alpha-cypermethrin is a component of cypermethrin, there is no indication that it would have different toxicological effects. Thus, read-across to alpha-cypermethrin from studies performed with cypermethrin is not considered to be restricted in any way.

Acute toxicity

Alpha-cypermethrin is acutely toxic via ingestion when administered in corn oil (LD_{50} = 57 mg/kg bw). However, when administered in more polar solvents (aqueous suspension, carboxymethylcellulose), no signs of toxicity were observed in rats up to the limit dose of 2000 mg/kg bw, indicating a strong dependence of bioavailability on the polarity of the vehicle.

The active substance was revealed as harmful by inhalation when administered with Aerosil®200 or Aerosil®R972 and therefore requires classification with the symbol "Xn" and with R20 "harmful by inhalation" according to the DSD (LC_{50}, inhalation, rat, for particles: 1 < LC_{50} ≤ 5 mg/l/4h). According to CLP, classification as Acute tox. 4 with the accompanying H332-phrase "harmful if inhaled" is required (LC_{50} inhalation rat for dusts and mists: 1 < LC_{50} < 5).

Experimental studies on the rats showed no significant toxicity of alpha-cypermethrin when administered topically.

Irritation and sensitation

Alpha-cypermethrin was found to be irritating to the skin in animal tests. Therefore, according to the DSD, classification with the symbol "Xi" and with R38 "irritating to skin" is required. Because the corresponding scores for skin irritation are invariably below 2.3 for any test parameter classification according to the CLP regulation is not necessary.

No significant eye irritating properties were observed.

There is no evidence of skin sensitisation of alpha-cypermethrin.

Medium-term toxicity

Medium-term toxicity was studied in dogs (most sensitive species), which were Beagles, receiving 30, 90 and 270 ppm up to 13 weeks. A dose of up to 90 ppm alpha-cypermethrin in food (equivalent to 3.5 mg/kg bw/d, based on body weights and feed consumption) for 90 days did not give rise to any clinical, haematological, biochemical or pathological findings indicative of any toxic effects. Highest dose induced body tremor, head nodding, ataxia and agitation. Thus, the no-observed-adverse-effect-level for short-term repeated-dose toxicity could be established at NOAEL = 3.5 mg/kg bw/d, which forms the basis for the occupational risk assessment.

Long-term toxicity

The dog was also the most sensitive species in chronic toxicity testing. Thus, in a 1-year study in dogs (Beagles), chronic exposure at doses of up to 60 ppm alpha-cypermethrin in food (equivalent to 2.0 mg/kg bw/d, based on body weights and feed consumption) did not give rise to any clinical, haematological, biochemical or pathological findings indicative of any toxic effects. Highest doses (120 or 240 ppm) induced skin irritation. Thus, the no-observed-adverse-effect-level for chronic toxicity by oral administration could be established at NOAEL = 2.0 mg/kg bw/d, which forms the basis for the chronic risk assessment (secondary exposure of the general public).

Carcinogenicity

Two studies were conducted, one with male and female rates exposed to 1000 ppm cypermethrin and another one with mice exposed to chronic oral administration of alpha-cypermethrin..

Tumours or other signs of carcinogenicity were not observed upon chronic oral administration of alpha-cypermethrin to mice.

Genotoxicity

Concerning genotoxicity, the results of four independent in vitro assays (gene mutation study in bacteria, gene mutation study in yeast, cytogenicity study in mammalian cells and gene mutation study in mammalian cells) were all negative. In addition, in vivo micronucleus, mammalian chromosome aberration and alkaline elution-rat hepatocyte assay were also unequivocally negative, even if some deviations were noticed comparing to guidelines (e.g. duration of exposure and number of tested cells). In consequence, it is concluded that there is no evidence for any genotoxic potential of alpha-cypermethrin.

Reproductive and developmental toxicity

Teratogenic or embryotoxic effects were not observed either in rats or in rabbits. Therefore, it was concluded that there is no evidence for a teratogenic potential of alpha-cypermethrin. Likewise, there were no adverse effects on reproductive performance or fertility of rats in a three-generation study on cypermethrin. By way of read-across, it is thus concluded that any potential for reproductive effects of alpha-cypermethrin can be excluded.

Neurotoxicity

Repeated dose toxicity studies showed that the main target organ of alpha-cypermethrin is the nervous system (CNS and peripheral motor nerves). Signs of acute toxicity in rats following oral administration included clonic convulsions, salivation, ataxia, lethargy, piloerection and diarrhoea. Alpha-cypermethrin was found to have a low magnitude of toxicity by dermal and inhalation routes of exposure. In repeated-dose studies, symptoms of toxicity were described as hypersensitivity to external stimuli, ataxia, nervousness, hyperactivity, tremors and splayed gait. Again, this was confirmed in an acute oral

neurotoxicity study in rats. A 4-week neurotoxicity study aiming at the identification of the toxic mechanism showed that the effects of alpha-cypermethrin are likely due to a pharmacological effect rather than the consequence of structural damage, despite sporadic incidences of slight degeneration of the sciatic nerve.

In view of neurotoxicity being the mechanism of toxicity, the NOAEL from an acute neurotoxicity study in rats was selected as the relevant endpoint for the acute human health risk assessment. The no-observed-adverse-effect-level for acute neurotoxic effects could be established at 4.0 mg/kg bw/d. An acute reference dose (ARfD) may derived from this value by applying an assessment factor of 100, resulting in ARfD = 0.04 mg/kg bw.

2.2.1.1.2 Hazard identification of the formulation TENOPA

Percutaneous absorption

Dermal penetration of Flufenoxuron formulated as BAS 308 04H is low and amounted to 1.74 % for the formulation concentrate and 4.78 % for the spray dilution. Dermal absorption values for alpha-cypermethrin of 1.9 % and 14.2 % were determined for undiluted and diluted Tenopa, respectively. (doc IIIB.6.4)

Acute toxicity

The oral LD_{50} for rats is 4478 mg/kg bw for both sexes.

The dermal LD_{50} for Tenopa was > 2000 mg/kg bw for both sexes.

The 4-h LC_{50} is greater than 2.37 mg/L, which was the maximum attainable concentration.

According to the criteria of Directive 67/548/EEC, Tenopa is not classified as acute toxic neither by oral and dermal ways nor by inhalation.

Irritation and corrosivity

According to the criteria of Directive 67/548/EEC, the test material is non-irritating to rabbit skin (doc IIIB.6.2.1); and the criteria of Directive 67/548/EEC for classification as an eye irritant are not fulfilled (doc IIIB.6.2.2).

Sensitisation

The test material, Tenopa, is not sensitising in the Buehler test on guinea pigs. No classification for skin sensitisation is required according to the criteria of Directive 67/548/EEC (doc IIIB.6.3).

2.2.1.2 Effects Assessment, AEL setting

2.2.1.2.1 Professional users

Repeated dose toxicity studies showed that the main target organ of alpha-cypermethrin is the nervous system (CNS and peripheral motor nerves). Signs of acute toxicity in rats

following oral administration included clonic convulsions, salivation, ataxia, lethargy, piloerection and diarrhoea. Alpha-cypermethrin was found to have a low magnitude of toxicity by dermal and inhalation routes of exposure. In repeated-dose studies, symptoms of toxicity were described as hypersensitivity to external stimuli, ataxia, nervousness, hyperactivity, tremors and splayed gait. Again, this was confirmed in an acute oral neurotoxicity study in rats. A 4-week neurotoxicity study aiming at the identification of the toxic mechanism showed that the effects of alpha-cypermethrin are rather due to a pharmacological effect than the consequence of structural damage, despite sporadic incidences of slight degeneration of the sciatic nerve.

Since its introduction into world-wide commercial use, there have been no reports of systemic intoxication resulting from occupational exposure of humans to alpha-cypermethrin. Dermal exposure to alpha-cypermethrin during preparation of formulated admixtures has on occasions resulted in transitory skin sensations at the contact sites. Clinical and haematological parameters were not affected, and no consistent adverse neurological signs were reported in studies on selected motor and peripheral sensory nerves.

Localised skin sensations experienced after dermal exposure have been interpreted as possibly resulting from prolonged repetitive firing of sensory nerve fibres or nerve endings. Again, these effects have been consistently reported as being transient. The sparse axonal degeneration observed in laboratory animals following administration of alpha-cypermethrin at relatively high oral dose levels is not believed to warrant concern for workers under conventional use conditions.

Reference doses:

Acute

In agreement with the toxic mechanism of alpha-cypermethrin (neurotoxicity), the following NOAEL of the acute neurotoxicity study is selected for the acute risk assessment:

$NOAEL_{acute}$ = 4.0 mg/kg bw

The systemic NOAEL, taking into account a factor of 0.45 for gastric absorption, is:

$NOAEL_{acute,\ systemic}$ = 4.0 x 0.45 = 1.8 mg/kg bw

Applying an assessment factor of 100 results in a systemic AEL of:

$AEL_{acute,\ systemic}$ = 0.018 mg/kg bw

Occupational

The occupational risk assessment for alpha-cypermethrin is based on results of short-term/subchronic toxicity testing which is the most relevant to typical short-term exposures that operators might experience. The most sensitive species in short-term toxicity tests was the dog, with a 90-d oral NOAEL of 3.5 mg/kg bw/d.

In order to derive a systemic reference dose, this needs to be corrected for the limited absorption in the gastro-intestinal tract (45 %):

$NOAEL_{medium\ term,\ systemic}$ = 3.5 x 0.45 = 1.575 mg/kg bw/day

In consideration of the absence of genotoxicity, developmental toxicity, prolonged effects in humans or carcinogenicity, and by applying an assessment factor of 100, this results in a systemic $AEL_{medium\ term}$ of

$AEL_{medium\ term,\ systemic}$ = 0.016 mg/kg bw/d

Chronic

Since the typical exposure pattern for operators is short-term exposure, chronic exposure is not considered to be relevant in an occupational context. The risk assessment for users of the biocidal product will therefore be based on the AOEL or the systemic NOAEL derived from sub-chronic toxicity testing as presented above, respectively.

Table 2.2.1-1 Summary of reference doses for professional users

Reference dose		Value	Unit
ACUTE	**$NOAEL_{acute}$**	4.0	mg/kg bw
	$NOAEL_{acute,\ systemic}$	1.8	mg/kg bw
	$AEL_{acute,\ systemic}$	0.018	mg/kg bw
OCCUPATIONAL	**$NOAEL_{90d,\ oral\ dog}$**	3.5	mg/kg bw/d
	$NOAEL_{medium\ term,\ systemic}$	1.575	mg/kg bw/d
	$AEL_{medium\ term,\ systemic}$	0.016	mg/kg bw/d
CHRONIC	Not relevant		

2.2.1.2.2 Non- users

Repeated dose toxicity studies showed that the main target organ of alpha-cypermethrin is the nervous system (CNS and peripheral motor nerves). Signs of acute toxicity in rats following oral administration included clonic convulsions, salivation, ataxia, lethargy, piloerection and diarrhoea. Alpha-cypermethrin was found to have a low magnitude of toxicity by dermal and inhalation routes of exposure. In repeated-dose studies, symptoms of toxicity were described as hypersensitivity to external stimuli, ataxia, nervousness, hyperactivity, tremors and splayed gait. Again, this was confirmed in an acute oral neurotoxicity study in rats. A 4-weeks neurotoxicity study aiming at the identification of the toxic mechanism showed that the effects of alpha-cypermethrin are likely due to a pharmacological effect rather than the consequence of structural damage, despite sporadic incidences of slight degeneration of the sciatic nerve.

Since its introduction into world-wide commercial use, there have been no reports of systemic intoxication resulting from occupational exposure of humans to alpha-cypermethrin. Dermal exposure to alpha-cypermethrin during preparation of formulated mixtures resulted in transitory skin sensations at the contact sites. Clinical and haematological parameters were not affected, and no consistent adverse neurological signs were reported in studies on selected motor and peripheral sensory nerves. Localised skin sensations experienced after dermal exposure have been interpreted as possibly resulting from prolonged repetitive firing of sensory nerve fibres or nerve endings. Again, these effects have been consistently reported as being transient. The sparse axonal degeneration observed in laboratory animals following administration of alpha-cypermethrin at relatively high oral dose levels is not believed to warrant concern for workers under conventional use conditions.

Reference doses:

Acute

In agreement with the toxic mechanism of alpha-cypermethrin (neurotoxicity), the NOAEL of the acute neurotoxicity study is selected for the acute risk assessment:

$NOAEL_{acute}$ = 4.0 mg/kg bw/d

$NOAEL_{acute,\ systemic}$ = 4.0 x 0.45 = 1.8 mg/kg bw/d

AEL_{acute} = 0.018 mg/kg bw/d

Occupational

For assessing the potential for chronic secondary exposure, short-term toxicity is not considered to be relevant. Instead, the risk assessment is based on the chronic no-effect levels identified to be relevant as presented below.

Chronic

The risk assessment for exposure of the general public to alpha-cypermethrin is based on results of chronic toxicity studies. The most sensitive species in chronic toxicity tests was the dog, with a 1-year oral NOAEL of 2.0 mg/kg bw/d. In consideration of the absence of genotoxicity, developmental toxicity, prolonged effects in humans or carcinogenicity, it is proposed to base the risk assessment for potential chronic exposure on a systemic chronic NOAEL by taking into account the oral absorption factor of 0.45. For the derivation of the systemic AEL, an assessment factor of 100 is used. This results in:

$NOAEL_{chronic,systemic}$ = 2.0 x 0.45 = 0.9 mg/kg bw/d

$AEL_{chronic,systemic}$ = 0.009 mg/kg bw/d

The adoption of the ADI is not considered appropriate for assessing the risks of chronic secondary exposure since not only the oral but also the dermal and the inhalation route needs to be taken into account.

Table 2.2.1-2 Summary of reference doses for non-users

Reference dose		Value	Unit
ACUTE	**$NOAEL_{acute}$**	4.0	mg/kg bw
	$NOAEL_{acute, systemic}$	1.8	mg/kg bw
	$AEL_{acute, systemic}$	0.018	mg/kg bw
OCCUPATIONAL	Not relevant		
CHRONIC	**$NOAEL_{1\ year, oral\ dog}$**	2.0	mg/kg bw/d
	$NOAEL_{chronic,systemic}$	0.9	mg/kg bw/d
	$AEL_{chronic,systemic}$	0.009	mg/kg bw/d

2.2.1.3 Human exposure assessment

2.2.1.3.1 Primary exposure

Tenopa is an insecticide that demonstrates a high level of initial activity, broad-spectrum of control, and long residual performance. Tenopa is formulated as a water-based suspension concentrate (SC) which is particularly suitable for use in domestic and public areas. It is to be used especially for surface, crack and crevice treatment. It will be used exclusively by professional pest-control personnel.

During and after application of alpha-cypermethrin-containing insecticides by professional operators, contamination of workers may theoretically occur by dermal, inhalation and oral routes. Exposure will be reduced by wearing impermeable coveralls, safety goggles, foot protection, gloves and respiratory protective equipment. Inhalation exposure is further reduced by the recommended application via low-pressure spraying at less than 2 bar (30 psi).

2.2.1.3.2 Secondary exposure

Secondary exposure may occur mainly via inhalation of volatilized residues. However, it is explicitly noted that alpha-cypermethrin is basically non-volatile and inhalation exposure should therefore be quantitatively irrelevant. Nevertheless the inhalation route is taken into account in the secondary exposure assessment. Dermal contact with treated surfaces is less likely because of the main use area of Tenopa being crack and crevice treatment. However, child-accessible surfaces may be treated to some extent. Dermal contact to treated surfaces

can be significant for small children (infant) who play on treated floor areas and dislodge some residual a.s. from the floor. Subsequently, oral uptake by infants can occur via hand-to-mouth transfer.

Table 2.2.1-3 Summary of human exposure paths to alpha-cypermethrin

Exposure path	Industrial use	Professional use	Secondary exposure	Via the environment
Inhalation	No	Relevant	Relevant	No
Dermal	No	Relevant	Relevant for children and infants	No
Oral	No	No	Relevant for infants	No

Table 2.2.1-4 Summary of systemic exposure of professionals using alpha-cypermethrin insecticide

Exposure scenario	a.s.* [%]	PPE	Estimated total intake mg/kg bw/d)
Spray application (indoor and outdoors, hand-held sprayer)	0.03	No PPE (tier 1)	0.0242
		Tier 2 (- RPE)	0.0030
		Tier 2 (+ RPE)	0.0018

* Concentration of active substance in the treatment solution

Table 2.2.1-5 Summary of Secondary Exposure

Secondary exposure scenario	Calculated exposure to alpha-cypermethrin [mg a.s./kg bw/day]	
ACUTE	**Adult**	
	Inhaling volatilised residues from treated carpet	**2.88×10^{-5}**
	Child	
	Inhaling volatilised residues from treated carpet	3.84×10^{-5}
	Playing on treated carpet (dermal)	0.0076
	Combined exposure (inhalation + dermal)	**7.60×10^{-3}**
	Infant	
	Inhaling volatilised residues from treated carpet	2.61×10^{-5}
	Playing on treated carpet and mouthing hands (dermal + ingestion)	0.0139
	Combined exposure (inhalation + dermal + oral)	**0.0139**
CHRONIC	**Adult**	
	Inhaling volatilised residues from treated carpet	**2.88×10^{-5}**

	Child	
	Inhaling volatilised residues from treated carpet	3.84×10^{-5}
	Playing on treated carpet (dermal)	0.0076
	Combined exposure (inhalation + dermal)	**7.60×10^{-3}**
	Infant	
	Inhaling volatilised residues from treated carpet	2.61×10^{-5}
	Playing on treated carpet and mouthing hands (dermal + ingestion)	0.0139
	Combined exposure (inhalation + dermal + oral)	**0.0139**

2.2.1.4 Risk characterisation

2.2.1.4.1 Human health risk for professionals (Primary exposure)

Tenopa is formulated as a water-based suspension concentrate (SC) which is particularly suitable for use in domestic and public areas. It is to be used especially for surface, crack and crevice treatment. It will be used exclusively by professional pest-control personnel.

1.1.1.1.1.1 INDUSTRIAL EXPOSURE: Production/Formulation of active substance

The active substance is manufactured outside the EU. No exposure data with respect to this production step are required and therefore characterisation of potential occupational risks is not subjected to Directive 98/8/EC. Appropriate PPE (Personal Protective Equipment) is used and adequate engineering controls and administrative procedures are implemented (see Document III, Section A2.10.1). Manufacturing personnel are regularly monitored for their health status. Since substance-related negative effects were not detected in the past, a significant risk during formulation of the biocidal product is not indicated.

Conclusion:

There is no concern for industrial workers in the production and formulation of the active substance.

1.1.1.1.1.2 PROFESSIONAL EXPOSURE from the use of the biocidal product

Tenopa is applied by professional PCOs (Pest Control Operators) using low-pressure spraying (< 2 bar). Any infested area (domestic and public), which typically constitutes, in view of the way of living of the target insects, cracks, crevices, spaces behind furnishing etc...

Table 2.2.1-6 Professional users PT18 (primary exposure) – risk characterisation

Exposure scenario		Estimated Internal Exposure			Relevant NOAEL/LOAEL [mg/kg.bw/d] Reference Value e.g: AEL (acute or medium or chronic)	AF MOE ref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg bw/d]	estimated dermal uptake [mg/kg bw/d]	estimated total uptake [mg/kg bw/d]				
Tier 1		0.00131	0.0229	0.0242	$NOAEL_{acute, systemic}$ = 1.8 mg/kg bw $NOAEL_{medium term, systemic}$ = 1.575 $AEL_{acute systemic}$ = 0.018 mg/kg bw/d $AEL_{medium term, systemic}$ = 0.016 mg/kg bw/d	100	Acute: 74 Repeated: 65	Acute:1.34 Repeated: 1.51
Tier 2 PPE no RPE	Manual spraying (indoor and outdoor, handheld sprayer)	0.00131	0.0017 †	0.0030 †		100	Acute: 600 Repeated: 525	Acute: 0.167 Repeated: 0.188
TIER 2 PPE + RPE	Manual spraying (indoor and outdoor, handheld sprayer)	0.0001	0.0017 †	0.0018 †		100	Acute: 1000 Repeated: 875	Acute: 0.1 Repeated: 0.113

† Spraying model 1 indicative values for dermal exposure: hand exposure inside gloves

Conclusion

In order to achieve an acceptable risk characterisation for PCOs using Tenopa for domestic insect control, it is considered necessary to wear protective clothing (at least a coverall and protective gloves).

However, it is explicitly noted that during low-pressure insecticide spraying PCOs wear protective clothing including gloves and RPE (Respiratory Protective Equipment) by default (see MSDS for Tenopa, recommending RPE type P2 of FFP2 according to EN 143, 149, safety gloves according to EN 374, safety goggles according to EN 166, and a chemical protection suit according to DIN-EN 465). Thus, the recommended personal protection measures will adequately minimise the occupational risk for pest control operators.

In these conditions, the risk of acute and repeated exposure to alpha-cypermethrin during pest control operations was estimated to be low and is therefore considered to be acceptable.

1.1.1.1.1.3 NON-PROFESSIONAL EXPOSURE from the use of the biocidal product

Tenopa is to be used by professional operators only. Thus, an assessment of non-professional exposure is not required due to lack of relevance

2.2.1.4.2 Human health risk from indirect exposure as a result of use (Secondary exposure)

Secondary exposure could occur in the residential environment following pest-control measures. These exposures include inhalation of volatilized residues and dermal contact of contaminated surfaces. Hand-to-mouth contact might apply to infants playing on the floor.

The following worst case exposure estimates from Document II-B are taken forward for risk characterisation:

Table 2.2.1-7 Indirect exposure as a result of use (secondary exposure) – risk characterisation

Exposure scenario		Estimated internal exposure				Relevant NOAEL/LOAEL [mg/kg.bw/d] Reference Value e.g: AEL (acute or medium or chronic)	AF MOE ref	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg bw/d]	estimated dermal uptake [mg/kg bw/d]	estimated oral uptake [mg/kg bw/d]	estimated total uptake [mg/kg bw/d]				
Acute	Adult	2.88×10^{-5}			2.88×10^{-5}	$NOAEL_{acute, systemic}$ = 1.8 mg/kg bw	100	62500	0.002
	Child	3.84×10^{-5}	7.60×10^{-3}		7.60×10^{-3}	$AEL_{acute\ systemic}$ = 0.018 mg/kg bw/d	100	237	0.422
	Infant	2.61×10^{-5}	0.0102	0.0036	1.39×10^{-2}		100	129	0.771
Chronic	Adult	2.88×10^{-5}			2.88×10^{-5}	$NOAEL_{chronic, systemic}$ = 0.9 mg/kg bw	100	31250	0.003
	Child	3.84×10^{-5}	7.60×10^{-3}		7.60×10^{-3}	$AEL_{chronic\ systemic}$	100	118	0.844

	Infant	2.61×10^{-5}	0.0102	0.0036	1.39×10^{-2}	= 0.009 mg/kg bw/d	100	65	1.542

Based on the results presented in the table above, it can be concluded that acute secondary exposure to residues of alpha-cypermethrin on surfaces treated with Tenopa and residues in air does not pose a significant risk to consumers even under worst case assumptions for infants playing on treated carpet and mouthing hands.

In relation to the relevant chronic systemic NOAEL of **2.0 x 0.45 = 0.9 mg/kg bw**, as derived from a 1-year study in dogs, the margins of exposure are calculated. Chronic secondary exposure to residues of alpha-cypermethrin on surfaces treated with Tenopa and residues in air does not pose a significant risk to adults (inhalation) and children (inhalation + dermal). A risk is calculated for the worst case scenario, infants playing on treated carpet and mouthing hands (inhalation + dermal + oral).

However, this chronic scenario overestimates the risk, since it considers that, while the active substance is only applied once per year, the infant will be exposed every day of the year to the maximum amount of active substance. Furthermore, a study demonstrated that after application the residue on the treated carpet will decrease with time (54 % within 6 weeks, cfr. Doc IIIB 6.6).

Moreover we can calculate the maximum amount of days that an infant can be exposed without exceeding the $AEL_{chronic,\ systemic}$ of 0.009 mg/kg bw/d:

Max.days = $AEL_{chronic,\ systemic}$ x 365 d / estimated total uptake for the infant

= 0.009 mg/kg bw/day x 365 d / 0.0139 mg/kg bw/d

= 236 days

This means the infant could be exposed during 236 days to this maximum applied amount of active substance (15 mg/m²) without exceeding the $AEL_{chronic,\ systemic}$.

Considering the facts that there will only be one treatment per year and that there will be a reduction of residue on the treated carpet over time, we can assume that the crawling infant will be exposed less than these 236 days. Thus we can conclude that the secondary exposure for an infant is acceptable at the maximum application rate of 15 mg a.s./m².

When considering the normal application rate of 7.5 mg a.s./m², no risks are calculated for the infant even under the assumption that exposure will take place every day of the year at the full amount of active substance applied.

Table 2.2.1-8 Chronic indirect exposure as a result of use, considering a normal application rate (secondary exposure) – risk characterisation

Exposure scenario	Estimated internal exposure				Relevant NOAEL/LOAEL [mg/kg.bw/d] Reference Value e.g: AEL (acute or	AF MOE ref	MOE	Exposure /AEL
	estimated inhalation uptake [mg/kg bw/d]	estimated dermal uptake [mg/kg bw/d]	estimated oral uptake [mg/kg bw/d]	estimated total uptake [mg/kg bw/d]				

						medium or chronic)			
Chronic	**Adult**	2.88×10^{-5}			2.88×10^{-5}	$NOAEL_{chronic, systemic}$ = 0.9 mg/kg bw $AEL_{chronic\ systemic}$ = 0.009 mg/kg bw/d	100	31250	0.003
	Child	3.84×10^{-5}	3.80×10^{-3}		3.82×10^{-3}		100	236	0.424
	Infant	2.61×10^{-5}	0.0051	0.0018	6.95×10^{-3}		100	129	0.772

Conclusion

Neither the acute, nor the chronic secondary exposure to residues of alpha-cypermethrin on surfaces treated with Tenopa and residues in air poses a significant risk to consumers.

2.2.2 Environmental Risk Assessment

2.2.2.1 Fate and distribution in the environment

2.2.2.1.1 Hydrolysis as a function of pH

Hydrolysis of alpha-cypermethrin takes place at alkaline buffer solutions (DT_{50}, pH 9 at 12 °C = 9.9 days), forming 3-phenoxybenzaldehyde (CAS-no. 39515-51-0) as the only major metabolite. Whereas at neutral and acidic conditions, alpha-cypermethrin is relatively stable (DT_{50} = 564.4 d, 12 °C, pH = 7) and stable to hydrolysis (DT_{50} > 1 year, 50 °C, pH = 4).

2.2.2.1.2 Photolysis in water

Aqueous photolysis contributes to degradation of alpha-cypermethrin in water. Three resulting metabolites were formed: 3-phenoxybenzaldehyde, 3-phenoxybenzoic acid and cis + trans-2,2-dimethyl-3-(2',2'-dichlorovinyl)cyclopropane carboxylic acid isomers. The former two metabolites are also sensitive to photodegradation. The latter metabolite demonstrated to be less sensitive.

Nevertheless, increasing amounts of carbon dioxide were formed, suggesting that alpha-cypermethrin and its photolytic transformation products are rapidly degraded, involving partial photochemical oxidation to CO_2.

2.2.2.1.3 Photolysis in air

Based on the vapour pressure (3.4×10^{-7} Pa at 25 °C) and the Henry constant (0.069 Pa × m^3/mol at 25 °C), volatilisation of alpha-cypermethrin is negligible. Calculations of the chemical lifetime in the troposphere resulted in a half-life of 3.47 hours (QSAR estimates). In addition and according to the TGD Part II chapter 3, 2.3.6.3, photolysis in air was calculated using the following:

$kdeg_{air} = k_{OH} \times OHCONC_{air} \times 24 \times 3600$

where: $OHCONC_{air} = 5 \times 10^5$ OH molecule/ cm^3

$k_{OH} = 37.0116 \times 10^{-12}$ cm^3/mol.sec

Resulting in a pseudo-first order rate of degradation in air of 1.60 day.

According to these result ($t_{1/2}$ < 2 days), alpha-cypermethrin is rapidly degraded by photochemical processes and no accumulation of alpha-cypermethrin in the air is to be expected.

2.2.2.1.4 Photodegradation in soil

Alpha-cypermethrin degraded slowly in soil (DT_{50}, sandy silty loam soil, 12 °C = 113.5 days) with 3-phenoxybenzoic acid as a major product of degradation and 3-phenoxybenzaldehyde as a minor product of degradation.

2.2.2.1.5 Biodegradation

Alpha-cypermethrin is not readily biodegradable according to OECD 301 B and D guidelines.

However, higher-tier water/sediment studies showed that alpha-cypermethrin moved rapidly from the water phase to the sediment phase with a DT_{50} in the water ranging between 0.88 and 4 days and in sediment between 12 and 67 days at the reference temperature of 12 °C. The main degradation products formed were cis-2,2-dimethyl-3-(2',2'-dichlorovinyl)cyclopropane carboxylic acid isomers (DT_{50} ranged 27 – 70 days) and 3-phenoxybenzoic acid (DT_{50} ranged 4 – 6 days), both of which underwent further degradation to CO_2.

In a laboratory experiment on the degradation of alpha-cypermethrin in sandy loam soil, the major degradation product after 120 days was CO_2 (DT_{50}, 12 °C = 39.1 days). Additionally to laboratory studies, field studies on the degradation of alpha-cypermethrin were conducted and included single annual applications for up to three years. DT_{50} ranged from < 14 to 112 days and in all of these studies 90 % of the dissipation occurred within a year.

2.2.2.1.6 Mobility

Based on reliable adsorption/desorption data, it can be concluded that alpha-cypermethrin is strongly adsorbed by soil components (K_{oc} = 26 492 – 144 652, n = 3, mean value = 76 344 mL/g). Therefore, leaching is not expected to occur.

2.2.2.1.7 Bioaccumulation

According to the experimentally derived BCF_{fish} (log P_{ow} = 5.5), alpha-cypermethrin is not considered to be a bioaccumulable substance with a BCF_{fish} value of 910 L/kg.

2.2.2.2 Effects Assessment

2.2.2.2.1 Aquatic compartment

Alpha-cypermethrin is highly toxic to aquatic organisms (except algae). The chronic NOECs, both for fish and invertebrates (*Daphnia*), were determined as 0.03 µg/L.

The effects of alpha-cypermethrin to aquatic ecosystems were also evaluated on a higher-tier level by two mesocosm studies, supporting toxicity studies on a range of macro-invertebrates, and a series of independent expert opinions. This resulted in a recommendation for an ecologically acceptable concentration (EAC) of alpha-cypermethrin in surface water of: EAC = 0.015 µg/L

This endpoint could not be considered for PNEC derivation (conventionally agreed at TM), but it could be considered as additional information to lower the assessment factor if the most sensitive species identified in other tests is also represented in the mesocosm study.

Considering this approach, BE CA decided to use the endpoint from the chronic toxicity test to sediment-dwelling organisms (*Chironomus riparius*), which used spiked water and is thus relevant to derive the $PNEC_{aquatic}$. In addition, it is the same organism order (diptera: *Chironomus riparius*) as in the mesocosm study (diptera: *Chaoborus crystallinus*) and it can therefore be justified to lower the assessment factor by a factor of 2; from 10 to 5.

This study generated a 28d-NOEC of 0.024 µg/L. The proposed $PNEC_{aquatic}$ would then be derived as:

$PNEC_{aquatic}$ = 0.024/5 = 0.0048 µg/L = 4.8 x 10^{-6} mg/L

Alpha-cypermethrin showed no effect on the respiration of activated sludge micro-organisms up to the concentration of 1000 mg/L. Resulting in a $PNEC_{micro\text{-}organisms\ (STP)}$ of 100 mg/L after applying an assessment factor of 10. Therefore, any relevant negative effects to micro-organisms in STPs can be safely excluded.

2.2.2.2.2 Sediment

Three specific long-term and one short-term toxicity tests on sediment-dwelling organisms (*Chironomus riparius, Lumbriculus variegatus and Caenorhabditis elegans*) are available. The lowest available endpoint is the chronic $NOEC_{development\ rate}$ for *Chironomus riparius,* determined as 0.0225 mg/kg dwt, relating to exposure via the sediment compartment. Test substance concentrations in the sediment were analytically determined at the start and termination of study period and endpoints were calculated based on mean measured concentrations.

The rapid partitioning of alpha-cypermethrin to the sediment, as demonstrated in the water-sediment study (see chapter 4.1.1.2.2 above), indicates that in the current studies the test organisms were most likely predominantly exposed to the test substance via sediment. Furthermore, extensive partitioning of alpha-cypermethrin to the sediment was analytically confirmed in the mesocosm study. In view of the partitioning-degradation pattern established in the mesocosm study as well as a laboratory water-sediment degradation study, the sediment organisms in the mesocosm studies may thus be assumed to have been exposed to the active substance over extended time periods. Therefore, concentrations of alpha-cypermethrin in sediment, up to 0.0225 mg/kg dry sediment (corresponding to $NOEC_{development\ rate}$) is considered to lack in any significant potential to harm sediment-dwelling organisms.

Based on the available data, an assessment factor of 10 can be used to derive the $PNEC_{sediment}$ from the lowest available NOEC. Additionally, it was agreed that the higher tier mesocosm study could be used to lower the assessment factor by a factor 2; from 10 to 5. This results in

$PNEC_{sediment}$ = 0.0225/5 = 4.5 x 10^{-3} mg/kg dwt

When calculating PECs based on emission scenario's, these PECs for the sediment compartment will always be expressed in terms of amount of active substance to wet weight

sediment. To be able to compare these PECs correctly with the $PNEC_{sediment}$, this PNEC should also be expressed in terms of wet weight sediment. In order to do this, the TGD and MOTA recommend using a conversion factor of 4.6 kg_{wwt}/kg_{dwt} for the sediment, based on the default values for "suspended matter".

The applicant opposes against the use of this conversion factor and therefore submitted additional data for the Chironomids toxicity test.

The sediment used in the *Chironomus riparius* spiked sediment test had an average water content of 24.72 % ($Fwater_{sed}$). This water content was calculated from the weight difference of wet sediment and sediment after drying. Based on this, a new conversion factor can be calculated, through the same TGD equations: 1.13 kg_{wwt}/kg_{dwt}

This new conversion factor is substantially smaller than the default factor from the TGD – it is actually comparable to the soil conversion factor – and could potentially have a large impact on the risk assessment for the sediment dwelling organisms.

However, BE RMS objected against using this conversion factor, because it seems that this new conversion factor does not take into account the suspended matter, which is the most important part of the sediment in terms of the exposed organisms. Additionally, it would seem that this factor would only be applicable for the specific sediment used in this test.

A final argument against the use of this new conversion factor is that the PEC is calculated using default values for suspended matter, which would then mean that there would be a discrepancy against comparing this PEC with the PNEC converted with the test-specific conversion factor.

This issue was discussed during the BPC WG-1-2014. There it was concluded that a conversion factor of 4.6, as supported by BE RMS, should be applied. Additionally, a statement should be made that this factor could be revised for product authorisation stage, based on the outcome of future discussions at the Ad Hoc Environmental Exposure WG.

The $PNEC_{sediment}$ converted from dry weight to wet weight is thus equal to

$PNEC_{sediment} = 4.5 \times 10^{-3} / 4.6 = 9.78 \times 10^{-4}$ mg/kg wwt

2.2.2.2.3 Terrestrial compartment

Based on the lowest NOEC values derived from two long-term studies on soil micro-organisms C- and N-transformation (NOEC > 100 $mg/kg_{dry\ soil}$), the $PNEC_{soil}$, after converting the NOEC related to dry soil to an effect value for naturally wet soil and applying an assessment factor of 100, the PNEC for the terrestrial compartment has been determined to be > 0.882 mg/kgwwt.

2.2.2.2.4 Secondary poisoning of predators

The first step in an assessment of secondary poisoning risk is to consider whether a chemical has the potential to bioaccumulate. Alpha-cypermethrin is ultimately degraded in the aquatic environment and in soil. Furthermore, the active substance is of only moderate to

low toxicity to birds and mammals. Thus, the secondary poisoning hazard of alpha-cypermethrin may be expected to be intrinsically negligible. Nevertheless, an assessment for secondary poisoning of aquatic and terrestrial top predators was perfomed.

Based on the dietary long-term NOEC of 150 mg/kg diet obtained from the reproductive toxicity study in the Northern bobwhite quail, applying an assessment factor of 30 as prescribed by the TGD on Risk Assessment (part II, chapter 3, Table 23, p. 130), the avian dietary predicted no-effect concentration is given as **$PNEC_{birds}$ = 5.0 mg/kg feed** for general toxic effects.

Adverse effects to reproductive parameters in birds were not observed in the avian reproduction study.

The NOAEL from the subchronic toxicity study in dogs, allocated to the human health section (1-year study, dog, see chapter 3) is adopted as the basis for estimation of $PNEC_{mammal}$. Following the TGD on Risk Assessment (part II, chapter 3, equation 77 and 78), the 1-year NOAEL of 2.0 mg/kg b.w./d is converted to NOEC by multiplication with a conversion factor of 40 (Table 22 of TGD on Risk Assessment) for NOAELs derived from a dog study of > 6 weeks duration, thus resulting in $NOEC_{mammal, food, chronic}$ = 80 mg/kg food.

The PNEC is then derived by dividing the NOEC by an assessment factor of 30, resulting in

$PNEC_{mammal}$ = 2.67 mg/kg food

2.2.2.2.5 Summary of PNEC values

Environmental compartment	PNEC
Surface water	4.8×10^{-6} mg a.i./L
Sewage treatment plant (STP)	100 mg a.i./L
Sediment	9.78×10^{-4} mg/kg wwt
Soil	> 0.882 mg a.i./kgwwt
Birds	5 mg/kg_{feed}
Mammals	2.67 mg/kg_{food}

2.2.2.3 Environmental exposure assessment

The insecticide product Tenopa (3 % alpha-cypermethrin, 3 % flufenoxuron) is exclusively used for indoor applications against cockroaches and fleas in domestic and public areas. Tenopa is applied on hard surfaces, cracks and crevices, areas behind furnishings and equipment by professional pest-control operators (PCOs).

Two application rates for the product are recommended:

Rate	Product	Active ingredient
Normal application rate	25 mL TENOPA / 100 m²	7.5 mg alpha-cypermethrin / m²
Special application rate	50 mL TENOPA / 100 m²	15 mg alpha-cypermethrin / m²

The main emission route of the product Tenopa is via wastewater in sewage water treatment plants after the cleaning of the treated area or the spraying materials. Therefore, there are no direct emissions to surface water or sediment, and aquatic or sediment organisms are not directly exposed to the active substance. Direct exposures of the environment via the pathways air, soil or groundwater are considered to be negligible. However, STP sludge might be applied to soil and contaminate soil. Therefore, a predicted environmental concentration for soil (PEC_{soil}) and groundwater ($PEClocal_{soil,porewater}$ = $PEC_{groundwater}$) were calculated.

To estimate the emission rates the OECD ESD n°18 for insecticides for household and professional uses is used and calculations were made based on three approaches:

1. total surface application;
2. chemical barrier treatment; and
3. crack and crevices treatment

For each of these approaches, the following formulas (ESD for PT18 products, July 17, 2008) were used to calculate daily local emission to STP (as STP is regarded as the only pathway of direct alpha-cypermethrin emissions after indoor use of Tenopa):

(1) $E_{prep,air} = Q_{prod,prep} \times F_{AI} \times N_{prep,building} \times F_{prep,air} \times 10^{-3}$

(2) $E_{prep,applicator} = Q_{prod,prep} \times F_{AI} \times N_{prep,building} \times F_{prep,applicator} \times 10^{-3}$

(3) $E_{prep,floor} = Q_{prod,prep} \times F_{AI} \times N_{prep,building} \times F_{prep,floor} \times 10^{-3}$

(4) $E_{application,air} = N_{appl,building} \times F_{application,air} \times Q_{prod} \times F_{AI} \times AREA_{treated}$

(5) $E_{application,applicator} = N_{appl,building} \times F_{application,applicator} \times Q_{prod} \times F_{AI} \times AREA_{treated}$

(6) $E_{application,floor} = N_{appl,building} \times F_{application,floor} \times Q_{prod} \times F_{AI} \times AREA_{treated,\ wet\ rooms}$

(7) $E_{application,treated} = N_{appl,building} \times F_{application,treated} \times Q_{prod} \times F_{AI} \times AREA_{treated,\ wet\ rooms}$

(8) $E_{applicator,ww} = (E_{prep,applicator} + E_{application,applicator}) \times F_{applicator,ww}$

(9) $E_{treated,ww} = (E_{prep,floor} + E_{application,floor} + E_{application,treated}) \times F_{ww} \times F_{CE}$

(10) $Elocal_{\ waste\ water} = E_{applicator,ww} + E_{treated,ww}$

(11) $Elocal_{waste\ water,total} = ((Elocal_{waste\ water,\ houses} \times N_{houses}) + (Elocal_{waste\ water,\ larger\ buildings} \times N_{larger\ buildings}) \times F_{simultaneity}$

where the following symbols are detailed as (ESD, PT18, p. 97-100):

- Fraction emitted to waste waters by the applicator during the cleaning step: $F_{applicator\ ww}$. In the present case, $F_{applicator\ ww}$ is equal to 1 as 100% of the coveralls are washable;
- Fraction emitted to waste waters during the cleaning step: F_{ww}. In the present case, F_{ww} is equal to 1 as 100% of the treated surfaces are washed with water;
- Cleaning efficiency:
    - the total surface application: F_{CE} **= 0.5** (ESD PT 18, Table 3.3-8, p.64);
    - the chemical barrier application: F_{CE} **= 0.5** (ESD PT 18, Table 3.3-8, p.64);
    - the cracks and crevices application: F_{CE} **= 0.25** (ESD PT 18, Table 3.3-8, p.64);
- Simultaneity factor, $F_{simultaneity}$, represents the percentage of houses/buildings which are treated simultaneously (ESD PT18, p. 38-40). Initially, calculations were made with the default F_{sim} of 0.0552, due to lack of other information.

  After a meeting with the applicant (7th October 2013) to discuss possible safe-use scenarios, label restrictions were introduced by the applicant to reduce the default simultaneity factor: Only 1 to 2 applications per year are envisaged, resulting in an F_{sim} of 0.00204.
  This new proposed factor was discussed during the Environmental BPC-WG-1-2014. Even though some reservations to such a reduction in use was voiced, it was concluded that label restrictions are the applicants responsibility. Therefore, the new simultaneity factor of 0.00204, representing a use restriction of 1 to 2 applications per year, was accepted during the aforementioned working group.

Table 2.2.2-1 Summary of calculated daily emissions to waste water

	application rate 15 mg a.i./m²		application rate 7.5 mg a.i./m²	
	F_{sim} = 0.0552	F_{sim} = 0.00204 (1-2 applications per year)	F_{sim} = 0.0552	F_{sim} = 0.00204 (1-2 applications per year)
TOTAL SURFACE APPLICATION				
Elocal$_{waste\ water,\ total}$ [kg/d]	8.57×10^{-2}	3.17×10^{-3}	4.29×10^{-2}	1.59×10^{-3}
CHEMICAL BARRIER TREATMENT				
Elocal$_{waste\ water,\ total}$ [kg/d]	1.31×10^{-2}	4.85×10^{-4}	6.55×10^{-3}	2.43×10^{-4}
CRACKS & CREVICES TREATMENT				
Elocal$_{waste\ water,\ total}$ [kg/d]	2.21×10^{-3}	8.20×10^{-5}	1.11×10^{-3}	4.10×10^{-5}

Table 2.2.2-2 Summary of calculated PEC values

Compartment	F_{sim} [-]	PEC value		
		Total surface	Barrier application	Cracks and crevices application

		15 mg a.i./m²	7.5 mg a.i./m²	15 mg a.i./m²	7.5 mg a.i./m²	15 mg a.i./m²	7.5 mg a.i./m²
PEC_{STP} [mg/L]	0.0552	$6.43x10^{-3}$	$3.21x10^{-3}$	$9.83x10^{-4}$	$4.91x10^{-4}$	$1.66x10^{-4}$	$8.30x10^{-5}$
	0.00204	$2.38x10^{-4}$	$1.&9x10^{-4}$	$3.64x10^{-5}$	$1.82x10^{-5}$	$6.15x10^{-6}$	$3.07x10^{-6}$
$PEC_{surface\ water}$ [mg/L]	0.0552	$5.77x10^{-4}$	$2.88x10^{-4}$	$8.82x10^{-5}$	$4.41x10^{-5}$	$1.49x10^{-5}$	$7.45x10^{-6}$
	0.00204	$2.14x10^{-5}$	$1.07x10^{-5}$	$3.26x10^{-6}$	$1.63x10^{-6}$	$5.52x10^{-7}$	$2.76x10^{-7}$
$PEC_{sediment}$ [mg/kg wwt]	0.0552	0.958	0.479	0.146	$7.32x10^{-2}$	$2.47x10^{-2}$	$1.24x10^{-2}$
	0.00204	$3.55x10^{-2}$	$1.77x10^{-2}$	$5.42x10^{-3}$	$2.71x10^{-3}$	$9.16x10^{-4}$	$4.58x10^{-4}$
$PEC_{soil,\ 1}$ (0) * [mg/kg]	0.0552	$1.51x10^{-1}$	$7.55x10^{-2}$	$2.31x10^{-2}$	$1.15x10^{-2}$	$3.90x10^{-3}$	$1.95x10^{-3}$
	0.00204	$5.59x10^{-3}$	$2.79x10^{-3}$	$8.54x10^{-4}$	$4.27x10^{-4}$	$1.44x10^{-4}$	$7.22x10^{-5}$
$PEC_{soil,\ 10}$ (0) ** [mg/kg]	0.0552	$1.69x10^{-1}$	$8.43x10^{-2}$	$2.58x10^{-2}$	$1.29x10^{-2}$	$4.35x10^{-3}$	$2.18x10^{-3}$
	0.00204	$6.24x10^{-3}$	$3.12x10^{-3}$	$9.54x10^{-4}$	$4.77x10^{-4}$	$1.61x10^{-4}$	$8.06x10^{-5}$
$PEC_{soil,\ 10}$ (30) # [mg/kg]	0.0552	$1.40x10^{-1}$	$7.00x10^{-2}$	$2.14x10^{-2}$	$1.07x10^{-2}$	$3.66x10^{-3}$	$1.85x10^{-3}$
	0.00204	$5.22x10^{-3}$	$2.63x10^{-3}$	$8.32x10^{-4}$	$4.36x10^{-4}$	$1.74x10^{-4}$	$1.07x10^{-4}$
$PEC_{soil,\ 10}$ (180) ## [mg/kg]	0.0552	$5.55x10^{-2}$	$2.78x10^{-2}$	$8.61x10^{-3}$	$4.39x10^{-3}$	$1.59x10^{-3}$	$8.74x10^{-4}$
	0.00204	$2.21x10^{-3}$	$1.18x10^{-3}$	$4.73x10^{-4}$	$3.16x10^{-4}$	$2.12x10^{-4}$	$1.86x10^{-4}$
$PEC_{groundwater}$ [mg/L]	0.0552	$1.12x10^{-4}$	$5.60x10^{-5}$	$1.71x10^{-5}$	$8.57x10^{-6}$	$2.90x10^{-6}$	$1.45x10^{-6}$
	0.00204	$4.16x10^{-6}$	$2.08x10^{-6}$	$6.37x10^{-7}$	$3.19x10^{-7}$	$1.08x10^{-7}$	$5.39x10^{-8}$
PEC_{air}	0.0552	Not relevant					
	0.00204						
$PEC_{oral\ predator}$ (aquatic) [mg/kg]	0.0552	$5.25x10^{-1}$	$2.62x10^{-1}$	$8.02x10^{-2}$	$4.01x10^{-2}$	$1.36x10^{-2}$	$6.78x10^{-3}$
	0.00204	$1.94x10^{-2}$	$9.72x10^{-3}$	$2.97x10^{-3}$	$1.49x10^{-3}$	$5.02x10^{-4}$	$2.51x10^{-4}$
Refined $PEC_{oral\ predator}$ (aquatic) [mg/kg]	0.0552	$2.62x10^{-1}$	$1.31x10^{-1}$	$4.01x10^{-2}$	$2.01x10^{-2}$	$6.78x10^{-3}$	$3.39x10^{-3}$
	0.00204	$9.72x10^{-3}$	$4.86x10^{-3}$	$1.49x10^{-3}$	$7.43x10^{-4}$	$2.51x10^{-4}$	$1.26x10^{-4}$
$PEC_{oral\ predator}$ (terrestrial) [mg/kg]	0.0552	$3.97x10^{-1}$	$1.99x10^{-1}$	$6.08x10^{-2}$	$3.04x10^{-2}$	$1.03x10^{-2}$	$5.15x10^{-3}$
	0.00204	$1.48x10^{-2}$	$7.38x10^{-3}$	$2.26x10^{-3}$	$1.13x10^{-3}$	$3.82x10^{-4}$	$1.91x10^{-4}$
Refined $PEC_{oral\ predator}$ (terrestrial) [mg/kg]	0.0552	$1.99x10^{-1}$	$9.94x10^{-2}$	$3.04x10^{-2}$	$1.52x10^{-2}$	$5.14x10^{-3}$	$2.57x10^{-3}$
	0.00204	$7.38x10^{-3}$	$3.69x10^{-3}$	$1.13x10^{-3}$	$5.65x10^{-4}$	$1.91x10^{-4}$	$9.56x10^{-5}$

* = immediately after the first application = Csludgesoil (0)
** = immediately after the tenth application = Csludgesoil 10 (0)
# = average concentration over 30 days after the tenth application = Csludgesoil 10 (30)
=average concentration over 180 days after the tenth application = Csludgesoil 10 (180)

2.2.2.4 Risk characterisation for the environment

To allow quantitative risk assessment for the environment after alpha-cypermethrin use in the indoor insecticide product Tenopa, the PEC values are compared to the respective PNEC values for the different compartments.

The different PEC/PNEC ratios are summarised in Table 2.3-3 below.

Table 2.2.2-3 Summary of the PEC/PNEC ratios for the different environmental compartments.

Compartment	PEC/PNEC ratio					
	Total surface		Barrier application		Cracks and crevices application	
	15 mg a.i./m²	7.5 mg a.i./m²	15 mg a.i./m²	7.5 mg a.i./m²	15 mg a.i./m²	7.5 mg a.i./m²
No use restriction: $F_{simultaneity}$ = 5.52 %						
STP	$6.43x10^{-5}$	$3.21x10^{-5}$	$9.83x10^{-6}$	$4.91x10^{-6}$	$1.66x10^{-6}$	$8.30x10^{-7}$
Surface water	**120.18**	**60.09**	**18.37**	**9.18**	**3.10**	**1.55**
Sediment	**979.10**	**489.55**	**149.64**	**74.82**	**25.29**	**12.65**
$Soil_1$ (0)	$1.71x10^{-1}$	$8.55x10^{-2}$	$2.61x10^{-2}$	$1.31x10^{-2}$	$4.42x10^{-3}$	$2.21x10^{-3}$
$Soil_{10}$ (0)	$1.91x10^{-1}$	$9.55x10^{-2}$	$2.92x10^{-2}$	$1.46x10^{-2}$	$4.93x10^{-3}$	$2.47x10^{-3}$
$Soil_{10}$ (30)	$1.59x10^{-1}$	$7.94x10^{-2}$	$2.43x10^{-2}$	$1.22x10^{-2}$	$4.14x10^{-3}$	$2.09x10^{-3}$
$Soil_{10}$ (180)	$6.29x10^{-2}$	$3.15x10^{-2}$	$9.76x10^{-3}$	$4.97x10^{-3}$	$1.80x10^{-3}$	$9.90x10^{-4}$
Groundwater	**1.12**	$5.60x10^{-1}$	$1.71x10^{-1}$	$8.57x10^{-2}$	$2.90x10^{-2}$	$1.45x10^{-2}$
Air	Not relevant					
Refined Aquatic Predator-BIRDS	$5.25x10^{-2}$	$2.62x10^{-2}$	$8.02x10^{-3}$	$4.01x10^{-3}$	$1.36x10^{-3}$	$6.78x10^{-4}$
Refined Aquatic Predator-MAMMALS	$9.84x10^{-2}$	$4.92x10^{-2}$	$1.50x10^{-2}$	$7.52x10^{-3}$	$2.54x10^{-3}$	$1.27x10^{-3}$
Refined Terrestrial Predator-BIRDS	$3.97x10^{-2}$	$1.99x10^{-2}$	$6.08x10^{-3}$	$3.04x10^{-3}$	$1.03x10^{-3}$	$5.15x10^{-4}$
Refined Terrestrial Predator-MAMMALS	$7.45x10^{-2}$	$3.73x10^{-2}$	$1.14x10^{-2}$	$5.70x10^{-3}$	$1.93x10^{-3}$	$9.65x10^{-4}$
Restricting use to 1 to 2 applications per year: $F_{simultaneity}$ = 0.204 %						
STP	$2.38x10^{-6}$	$1.19x10^{-6}$	$3.64x10^{-7}$	$1.82x10^{-7}$	$6.15x10^{-8}$	$3.07x10^{-8}$
Surface water	**4.45**	**2.22**	0.68	0.34	0.11	0.06
Sediment	**36.25**	**18.12**	**5.54**	**2.77**	0.94	0.47
$Soil_1$ (0)	$6.33x10^{-3}$	$3.17x10^{-3}$	$9.68x10^{-4}$	$4.84x10^{-4}$	$1.64x10^{-4}$	$8.18x10^{-5}$
$Soil_{10}$ (0)	$7.07x10^{-3}$	$3.54x10^{-3}$	$1.08x10^{-3}$	$5.40x10^{-4}$	$1.83x10^{-4}$	$9.13x10^{-5}$
$Soil_{10}$ (30)	$5.92x10^{-3}$	$2.98x10^{-3}$	$9.43x10^{-4}$	$4.94x10^{-4}$	$1.97x10^{-4}$	$1.21x10^{-4}$
$Soil_{10}$ (180)	$2.50x10^{-3}$	$1.34x10^{-3}$	$5.36x10^{-4}$	$3.58x10^{-4}$	$2.41x10^{-4}$	$2.11x10^{-4}$

Groundwater	$4.16x10^{-2}$	$2.08x10^{-2}$	$6.37x10^{-3}$	$3.19x10^{-3}$	$1.08x10^{-3}$	$5.39x10^{-4}$
Air	Not relevant					
Refined Aquatic Predator-BIRDS	$1.94x10^{-3}$	$9.72x10^{-4}$	$2.97x10^{-4}$	$1.49x10^{-4}$	$5.02x10^{-5}$	$2.51x10^{-5}$
Refined Aquatic Predator-MAMMALS	$3.64x10^{-3}$	$1.82x10^{-3}$	$5.57x10^{-4}$	$2.78x10^{-4}$	$9.41x10^{-5}$	$4.71x10^{-5}$
Refined Terrestrial Predator-BIRDS	$1.48x10^{-3}$	$7.38x10^{-4}$	$2.26x10^{-4}$	$1.13x10^{-4}$	$3.82x10^{-5}$	$1.91x10^{-5}$
Refined Terrestrial Predator-MAMMALS	$2.77x10^{-3}$	$1.38x10^{-3}$	$4.23x10^{-4}$	$2.12x10^{-4}$	$7.16x10^{-5}$	$3.58x10^{-5}$

For all scenarios and input values considered, no unacceptable risks are calculated for the STP micro-organisms, air, the soil compartment and predators. In several scenarios risks are calculated for the surface water and sediment compartment. In a single scenario, risk is also calculated for the groundwater.

The compartment most in danger is the sediment compartment. Of all scenario's considered, only when use is restricted to cracks and crevices and a label restriction allows just 1 to 2 applications per year, then no unacceptable risk for the sediment compartment or any of the other environmental compartments are calculated.

Table 2.2.2-4: Compartments at risk for all considered scenario's

	Total surface		**Barrier application**		**Cracks and crevices application**	
	15 mg a.i./m²	**7.5 mg a.i./m²**	**15 mg a.i./m²**	**7.5 mg a.i./m²**	**15 mg/m²**	**7.5 mg/m²**
$F_{simultaneity}$ = 5.52 %						
Risk?	Surface water Sediment Groundwater	Surface water Sediment	Surface water Sediment	Surface water Sediment	Surface water Sediment	Surface water Sediment
$F_{simultaneity}$ = 0.204 %						
Risk?	Surface water Sediment	Surface water Sediment	Sediment	Sediment	None	None

2.2.3 List of Endpoints

The most important endpoints, as identified during the evaluation process, are listed in appendix I.

2.3 Overall conclusions

In the table below an overall summary of the risk assessment is presented.

Table 2.3-1: Overall Summary

Scenario	Efficacy	Human primary exposure		Human secondary exposure		STP	Aquatic compartment (including sediment)	Terrestrial compartment	Groundwater	Atmosphere	Secondary poisoning
		Professional (with PPE)	Non-professional	Adult	Child						
TOTAL SURFACE APPLICATION											
15 mg a.i. / m² no-use restriction	Acceptable	Acceptable	N/A	Acceptable	Acceptable	Acceptable	**Unacceptable**	Acceptable	**Unacceptable**	Acceptable	Acceptable
7.5 mg a.i. / m² no-use restriction	Acceptable	Acceptable	N/A	Acceptable	Acceptable	Acceptable	**Unacceptable**	Acceptable	Acceptable	Acceptable	Acceptable
15 mg a.i. / m² restricted to 1-2 applications/year	Acceptable	Acceptable	N/A	Acceptable	Acceptable	Acceptable	**Unacceptable**	Acceptable	Acceptable	Acceptable	Acceptable
7.5 mg a.i. / m² restricted to 1-2 applications/year	Acceptable	Acceptable	N/A	Acceptable	Acceptable	Acceptable	**Unacceptable**	Acceptable	Acceptable	Acceptable	Acceptable
Overall conclusion of total surface application: Unacceptable risks to the aquatic compartment (including sediment) at all envisaged uses are identified, even when restricting use to 1 to 2 applications per year. In one instance a concentration exceeding the EU threshold acceptable limit for drinking water was calculated. Based on these results, the use of TENOPA (3 % alpha-cypermethrin, 3 % flufenoxuron) is not deemed safe to use as a total surface application.											
BARRIER APPLICATION											
15 mg a.i. / m² no-use restriction	Acceptable	Acceptable	N/A	Acceptable	Acceptable	Acceptable	**Unacceptable**	Acceptable	Acceptable	Acceptable	Acceptable
7.5 mg a.i. / m² no-use restriction	Acceptable	Acceptable	N/A	Acceptable	Acceptable	Acceptable	**Unacceptable**	Acceptable	Acceptable	Acceptable	Acceptable
15 mg a.i. / m² restricted to 1-2 applications/year	Acceptable	Acceptable	N/A	Acceptable	Acceptable	Acceptable	**Unacceptable**	Acceptable	Acceptable	Acceptable	Acceptable
7.5 mg a.i. / m² restricted to 1-2 applications/year	Acceptable	Acceptable	N/A	Acceptable	Acceptable	Acceptable	**Unacceptable**	Acceptable	Acceptable	Acceptable	Acceptable

Overall conclusion of barrier application: Unacceptable risks to the aquatic compartment (including sediment) at all envisaged uses are identified, even when restricting use to 1 to 2 applications per year

Based on these results, the use of TENOPA (3 % alpha-cypermethrin, 3 % flufenoxuron) is not deemed safe to use as a barrier application.

CRACKS AND CREVICES APPLICATION

15 mg a.i. / m² no-use restriction	Acceptable	Acceptable	N/A	Acceptable	Acceptable	Acceptable	**Unacceptable**	Acceptable	Acceptable	Acceptable	Acceptable
7.5 mg a.i. / m² no-use restriction	Acceptable	Acceptable	N/A	Acceptable	Acceptable	Acceptable	**Unacceptable**	Acceptable	Acceptable	Acceptable	Acceptable
15 mg a.i. / m² restricted to 1-2 applications/year	Acceptable	Acceptable	N/A	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable
7.5 mg a.i. / m² restricted to 1-2 applications/year	Acceptable	Acceptable	N/A	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

Overall conclusion of cracks and crevices application: Unacceptable risks to the aquatic compartment (including sediment) are identified at both use-concentrations and when not restricting use. When considering a label restriction of 1 to 2 applications per year, no unacceptable risks for the environment are calculated.

Based on these results, the use of TENOPA (3 % alpha-cypermethrin, 3 % flufenoxuron) can be considered acceptable for cracks and crevices treatments, providing that a restriction on use is labelled.

3 ASSESSMENT OF EXCLUSION AND SUBSTITUTION CRITERIA

3.1 Exclusion Criteria

3.1.1 Assessment of CMR properties

Criteria (BPR Article 5[1])	**Assessment**
Active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, carcinogen category 1A or 1B	Active substance is not classified and does not meet the criteria to be classified as Carc. Cat. 1A or 1B.
Active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B	Active substance is not classified and does not meet the criteria to be classified as Muta. Cat. 1A or 1B.
Active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B	Active substance is not classified and does not meet the criteria to be classified as Repr. Cat. 1A or 1B.

Conclusion on CMR properties	The exclusion criteria in BPR Article 5(1)a-c are not met.

3.1.2 Assessment of endocrine disrupting properties

Criteria (BPR Article 5)	**Assessment**
Active substances which, on the basis of the criteria specified pursuant to the first subparagraph of paragraph 3 are considered as having endocrine-disrupting properties that may cause adverse effects in humans	(The criteria are not yet published)
Pending the adoption of those criteria[1], active substances that are classified in accordance with Regulation (EC) No 1272/2008 as, or meet the criteria to be classified as, carcinogen category 2 and toxic for reproduction category 2[2].	Active substance is not classified and does not meet the criteria to be classified as Carc. Cat. 2. Active substance is not classified and does not meet the criteria to be classified as Repr. Cat. 2.
Substances such as those that are classified in accordance with Regulation (EC) No 1272/2008 as, or that meet the criteria to be classified as, toxic for reproduction category 2 and that have toxic effects on the endocrine organs[3].	Active substance is not classified and does not meet the criteria to be classified as Repr. Cat. 2. Active substance has not been shown to have toxic effects on endocrine organs.
Active substances which are identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties	Active substance has not been identified as having endocrine disrupting properties.

[1] This refers to the criteria mentioned in the first row.

[2] These active substances shall be considered as having endocrine-disrupting properties

[3] These active substances may be considered as having endocrine-disrupting properties

Conclusion on ED properties	The exclusion criteria in BPR Article 5(1)d are not met.

3.1.3 PBT Assessment (following Annex XIII to Regulation (EC) No 1907/2006)

3.1.3.1 Assessment of persistence

Aquatic compartment (including sediment):

- Alpha-cypermethrin is not readily biodegradable (Doc. II-A section 4.1.1.2.1). No degradation occurred in the two tests conducted to assess the ready biodegradability of Alpha-cypermethrin after 28 days (OECD 301 D and OECD 301 B).
- No inherent biodegradability test is available.
- Alpha-cypermethrin is hydrolytically stable at neutral and acidic pH (Doc. II-A section 4.1.1.1.1).
- In the water-sediment degradation studies using samples from natural aquatic systems, Alpha-cypermethrin incubated in the dark disappeared rapidly from the water phase due to strong adsorption to the sediment and metabolisation (Doc. II-A section 4.1.1.2.2), DT_{50} was calculated at 2.22 days at normalized temperature of 12 °C.
- Alpha-cypermethrin is also readily eliminated in the sediment phase, by metabolisation and formation of bound residues (Doc. II-A section 4.1.1.2.2), DT_{50} was calculated at 28.13 days at the environmentally relevant temperature of 12 °C.
- Alpha-cypermethrin degrades rapidly in water under artificial light (Doc. II-A section 4.1.1.1.2). However, due to strong binding potential of Alpha-cypermethrin to the sediment, such degradation is not likely to occur under environmental conditions.
- No studies are available for biodegradation in seawater or anaerobic biodegradation in STP.

Terrestrial compartment (soil):

- In aerobic degradation study in soil (Doc. III-A.7.2.1/01), DT_{50} (12°C) was calculated at 39.1 days after 120 days. In addition to laboratory studies, field soil dissipation studies were performed. Three different soils were monitored during three years after annual applications of Alpha-cypermethrin. DT_{50} ranged from <14 to <112 days.

Enantiomers:

No information is available on the persistency of the individual alpha-cypermethrin enantiomers.

P Criteria	Assessment
T1/2 > 60 days in marine water, or	No simulation data is available for marine water compartments.
T1/2 > 40 days in fresh- or estuarine water, or	In water-sediment studies, rapid dissipation with ultimate mineralisation could be demonstrated. These water-sediment degradation studies revealed that alpha-cypermethrin does not meet the degradation half-life criteria to be identified as a P-substance. Half-life for fresh water (2.22 days at 12 °C) is below the 40-day limit.
T1/2 > 180 days in marine sediment, or	No simulation data is available for marine water compartments.
T1/2 > 120 days in fresh- or estuarine sediment, or	In water-sediment studies, rapid dissipation with ultimate mineralisation could be demonstrated. These water-sediment degradation studies revealed that alpha-cypermethrin does not meet the degradation half-life criteria to be identified as a P-substance. Half-life for fresh sediment (28.13 days at 12 °C) is below the 120-day limit.
T1/2 <= 120 days in soil.	Soil degradation studies showed DT_{50} values below the 120-day limit.

vP Criteria	Assessment
T1/2 > 60 days in marine-, fresh- or estuarine water water, or	No simulation data is available for marine water compartments. Water-sediment degradation studies revealed that alpha-cypermethrin does not meet the degradation half-life criteria to be identified as a vP-substance.
T1/2 > 180 days in marine-, fresh- or estuarine sediment, or	No simulation data is available for marine water compartments. Water-sediment degradation studies revealed that alpha-cypermethrin does not meet the degradation half-life criteria to be identified as a vP-substance.
T1/2 > 180 days in soil.	Soil degradation studies showed DT_{50} values below the 120-day limit.

Conclusion on P / vP properties	Not persistent (not P) and not very persistent (not vP) in the environment

3.1.3.2 Assessment of bioaccumulation

Based on its physical-chemical properties (log P_{ow}), alpha-cypermethrin is expected to exhibit significant bio-accumulation potential. The log octanol-water partitioning coefficient (Log K_{ow}) for alpha-cypermethrin was determined at 5.5, which would indicate, according to the screening criteria, that alpha-cypermethrin is a possible B-substance, because it is larger than the cut-off value of 4.5.

A BCF_{fish} of 9440 L/kg was calculated based on a QSAR and the log P_{ow}. Additionally, an experimental BCF_{fish} using carps is available: 910 L/kg.

No laboratory study on terrestrial bio-concentration is available. A theoretical $BCF_{earthworm}$ of 3796 L/kg was calculated.

No information is available on the bioaccumulation properties of the individual alpha-cypermethrin enantiomers.

B Criteria	**Assessment**
BCF > 2000	The BCF_{fish} derived from an accumulation test was 910 L/kg, which is well below the B cut-off criterion.

vB Criteria	**Assessment**
BCF > 5000	The BCF_{fish} derived from an accumulation test was 910 L/kg, which is well below the vB cut-off criterion.

Conclusion on B / vB properties	Not bioaccumulative (not B) and not very bioaccumulative (not vB) in the environment.

3.1.3.3 Assessment of toxicity

The lowest short term aquatic toxicity values for alpha-cypermethrin are as follows:

- 96h LC_{50} fish: 0.00093 mg/L
- 48h EC_{50} invertebrates: 0.0003 mg/L
- 72h E_rC_{50} algae: >1.0 mg/L

According to the screening criteria, when the short term aquatic toxicity is below 0.01 mg/L then the T-criterion for the substance is definitely fulfilled and when it is below 0.1 mg/L the T-criterion is fulfilled. Alpha-cypermethrin should thus be classified as toxic according to the screening criteria.

Additionally, long term data are available. Based on ecotoxicity data on *Daphnia magna* and *Chironomus riparius*, NOEC (21 days, reproduction and 28 days development, respectively) are respectively equal to 0.03 µg/L (nominal) and 0.024 µg/L (nominal).

No information is available on the toxicity of the individual alpha-cypermethrin enantiomers.

T Criteria	**Assessment**
NOEC/EC10 (long-term) < 0.01 mg/L for marine or freshwater organisms, or	The lowest observed aquatic NOEC is the one for *Chironomus riparius* equal to 0.024×10^{-3} mg/L, which is well below the cut-off value presented.
substance meets the criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2) according to the CLP Regulation, or	No
there is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification:specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to the CLP Regulation.	Yes, classification as STOT RE 2

Conclusion on T properties	Alpha-cypermethrin is a toxic substance.

3.1.3.4 Summary and overall conclusions on PBT or vPvB properties

- The P or vP criteria are not fulfilled
- The B or vB criteria are not fulfilled
- The T cirterium is fulfilled

Overall conclusion:

Based on the assessment described in the subsections above alpha-cypermethrin is not a PBT / vPvB substance.

No information is available on the persistency, bioaccumulation or toxicity of the individual alpha-cypermethrin enantiomers. However, guidance on PBT assessment (ECHA Guidance: Chapter R.11: PBT Assessment, v.1.1, November 2012) indicates that isomer constituents present at amounts ≥0.1 % w/w for multi-constituent substances should also be treated as potentially persistent, bioaccumulative or toxic. In this case alpha-cypermethrin would need to have its individual isomers further investigated to determine the PBT nature of the constituent components of this isomeric substance.

3.2 Substitution Criteria

Substitution criteria (BPR, Article 10)	**Assessment**
One of the exclusion criteria listed in Article 5(1) is met but AS may be approved in accordance with Article 5(2)	No
The criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as a respiratory sensitiser is met	No
The acceptable daily intake, acute reference dose or acceptable operator exposure level, as appropriate, is significantly lower than those of the majority of approved active substances for the same product-type and use scenario	
Two of the criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006 are met	Alpha-cypermethrin is not persistent (not P, not vP) and not bioaccumulative (not B, not vB). Alpha-cypermethrin is toxic (T)
There are reasons for concern linked to the nature of the critical effects which,	

Substitution criteria (BPR, Article 10)	**Assessment**
in combination with the use patterns, amount to use that could still cause concern, such as high potential of risk to groundwater, even with very restrictive risk management measures	
The AS contains a significant proportion of non-active isomers or impurities.	No

Conclusion on substitution criteria	The substitution criteria in BPR Article 10(1)a-f are not met.

3.3 Assessment of long range environmental transportation and impact on environmental compartments

	Assessment
The active substance or a degradation product is a persistent organic pollutant (POP) listed in Annex I of EC 850/2004	No
Assessment of long-range transport potential (LRTAP): • Vapour pressure <1000 Pa and • half-life in air > 2 days or • Monitoring data in remote area showing that the substance is found in remote regions or • Result of multi media modelling	• Vapour pressure of alpha-cypermethrin is $5.6x10^{-7}$ Pa, well below the cut-off value of 1000 • Estimation through AOPWIN shows that half-life of alpha-cypermethrin in air in reaction with OH-radicals is well below the criterion: 3.47 hours
The active substance or a degradation product is vP/vB or T?	Alpha-cypermethrin is not vP or vB. Alpha-cypermethrin is T.

Conclusion on LRTAP/POP asessment	Due to the rapid degradation in the atmosphere alpha-cypermethrin is not considered to pose a risk for LRTAP.

4 INTERACTION WITH THE WATER FRAMEWORK DIRECTIVE

In Directive 2013/39/EU amending Directive 2000/60/EC and Directive 2008/105/EC, cypermethrin is introduced as a priority substance. In this instance, no distinction is made between cypermethrin and its individual isomers, including alpha-cypermethrin, meaning that alpha-cypermethrin itself can be seen as listed as a priority substance under the Water Framework Directive.

Under this Directive, two types of quality standards are established to ensure good water quality: AA-EQS (annual average environmental quality standard) and MAC-EQS (maximum allowable concentration environmental quality standard).

In the case of cypermethrin the AA-EQS of $8x10^{-8}$ mg/L(inland surface waters, total concentration of all isomers). This means that the arithmetic mean of all measured concentrations over a twelve month monitoring period within a body of water may not exceed this value.

This AA-EQS is 60 times smaller than the aquatic PNEC established for alpha-cypermethrin. The reason for this difference is not so much based on a difference in the endpoints, but more to do with the choice of assessment factor. While for the derivation of the PNECaquatic an AF of 5 was accepted, the AA-EQS was derived with an AF of 50. The choice of this higher AF is explained by many low EC_{50}s or NOECs for species from sensitive taxa, that were either not assignable or had exposure concentrations that were likely not maintained during the course of the experiments. Additionally, for the derivation of PNECs for biocide active substances, mesocosm studies can be accepted to lower the AF, while for the derivation of EQS the mesocosm studies are merely used as a confirmation of toxicity.

Incidentally it should also be noted that the endpoints from the EQS-document were not used for the PNECaquatic derivation for alpha-cypermethrin. It was agreed during peer review to not use the data from the EQS document for various reasons, but mainly because the tested substance was not defined (isomeric ratio and impurities).

In addition to an AA-EQS, also a MAC-EQS for cypermethrin was established. The MAC-EQS ($6x10^{-7}$ mg/L) may not be exceeded by any measured concentration at any point of the water body or at any point in time.

Again, this standard is smaller than the established aquatic PNEC, this time by a factor of 8. Also here this is a result of the choice of assessment factor, which is more conservative for the EQS-derivation.

Before comparing the calculated aquatic PECs from this CAR with any quality standard, one should first consider what this PEC represents and if it can fairly be compared with the established standards.

In the case of alpha-cypermethrin, the aquatic PECs are derived from a daily, local emission and represent a concentration in surface water during an emission period: the emission pattern can be considered as intermittent. Therefore, the comparison between the AA-EQS and the MAC-EQS and the PEC may not be appropriate.

Considering the above and when comparing the lowest calculated PEC ($2.76x10^{-7}$ mg/L) with the AA-EQS, it can be concluded that, because the PEC exceeds the AA-EQS over 3 times, a single source of alpha-cypermethrin already exceeds the established standard, allowing no more room for other sources of the substance (e.g. plant protection). However, as indicated, the PEC calculated here is the concentration resulting from an emission episode, while the AA-EQS is an annual average. Comparing the two and drawing conclusions merely on these numbers does not seem correct.

Comparing the same PEC with the MAC-EQS seems much more relevant, as this EQS represents a single concentration that may not be exceeded. For alpha-cypermethrin, neither of the two PECs calculated in the identifiedsafe-use scenario for crack and crevice treatment ($5.52x10^{-7}$ and $2.76x10^{-7}$ mg/L) exceed the MAC-EQS.

In conclusion and based on the fact that at the time of writing this CAR no monitoring data for this substance are available, the listing of alpha-cypermethrin as a priority substance in the WFD alone is not reason enough to propose a non-inclusion of alpha-cypermethrin.

It is however necessary to keep an eye out for monitoring data when it becomes available and consider it at product authorisation stage.

APPENDIX I: LISTING OF ENDPOINTS

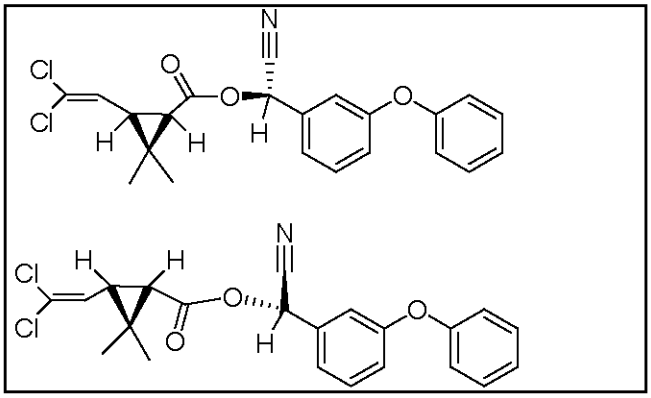
Chapter 1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling

Active substance (ISO Common Name)	alpha-cypermethrin
Function (e.g. fungicide)	Insecticide
Rapporteur Member State	Belgium

Identity (Annex IIA, point II.)

Chemical name (IUPAC)	1:1 mixture (racemate) of the pair of enantiomers (S)-α-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(1S,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
Chemical name (CA)	(S)-alpha-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (R)-alpha-cyano-3-phenoxybenzyl-(1S,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
CAS No	67375-30-8
EC No	Not allocated
Other substance No.	CIPAC: 454
Minimum purity of the active substance as manufactured (g/kg or g/L)	≥ 930 g/kg (93.0 % w/w) (sum of the isomers in a 1:1 ratio)
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	none
Molecular formula	$C_{22}H_{19}Cl_2NO_3$
Molecular mass	416.3 g/mol

Structural formula



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

Melting point (state purity)	82.3 °C (99.3 %)	
Boiling point (state purity)	None (decomposes before boiling at atmospheric pressure)	
Temperature of decomposition	Onset: 220 °C	
Appearance (state purity)	White fine powder (99.8 %)	
Relative density (state purity)	1.33 (99.7 %)	
Surface tension	Not required in view of water solubility < 1 mg/l	
Vapour pressure (in Pa, state temperature)	5.6×10^{-7} Pa (25 °C)	
Henry's law constant (Pa m^3 mol^{-1})	0.069	
Solubility in water (g/L or mg/L, state temperature)	pH 4: 4.59 µg/L (20 °C)	
	pH 7: 5.80 µg/L (20 °C)	
	pH 9: 7.87 µg/L (20 °C)	
Solubility in organic solvents (in g/L or mg/L, state temperature) (Annex IIIA, point III.1)	Toluene:	596 g/L (21 °C)
	Methanol:	21.3 g/L (21 °C)
	Ethyl acetate:	584 g/L (21 °C)
	n-hexane:	6.5 g/L (21 °C)
	2-propanol:	9.6 g/L (21 °C)
	Acetone:	miscible
	Dichloromethane:	miscible
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	Not available; biocidal products do not contain organic solvents	
Partition coefficient (log P_{OW}) (state temperature)	5.5 ± 0.4 (room temperature)	
	No relevant pH-dependence due to absence of dissociating groups	
Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	pH 4: stable (50 °C)	
	pH 7: DT_{50} = 101 d (20 °C)	
	pH 9: DT_{50} = 7.3 d (20 °C)	
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	Not required due to absence of dissociating groups	
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	None	
Photostability (DT_{50}) (aqueous, sunlight, state pH) (point VII.7.6.2.2)	Environmental DT_{50} = 3.4 – 6.3 d	

Quantum yield of direct phototransformation in water at S > 290 nm (point VII.7.6.2.2)	8.12×10^{-3}
Flammability	Not “highly flammable” Not “auto-flammable”
Explosive properties	Not explosive

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

with regard to physical/chemical data	Not required
with regard to toxicological data	T; R25 Xn; R48/22, R20 Xi; R37, R38
	GHS06 GHS08 Acute tox. 3; H301 Acute tox. 4; H332 Stot Re. 2; H373 Stot Se. 3; H335
with regard to fate and behaviour data	
with regard to ecotoxicological data	N; R50/53
	GHS09 Aquatic acute 1; H400 (M = 1000) Aquatic chronic 1; H410 (M = 1000)

Chapter 2: Methods of Analysis

Analytical methods for the active substance

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

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	GC-ECD, GC-MS LoQ = 0.05 mg/kg
Air (principle of method and LOQ) (Annex IIA, point 4.2)	GC-NPD LoQ = 0.02 µg/m³ TM I 2013: Confirmatory method is required at the latest 6 months before product authorization stage.
Water (principle of method and LOQ) (Annex IIA, point 4.2)	GC-ECD, GC-MS LoQ = 0.01–0.05 µg/L
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	GC-ECD, GC-MS LoQ = 0.005 mg/L (blood, urine) LoQ = 50.0 ppb (0.05 mg/kg) (tissues) LoQ = 10.0 ppb (0.01 mg/kg) (milk)
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not required for lack of exposure
Food/feed of animal origin (principle of	Not required for lack of exposure

method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	

Chapter 3: Impact on Human Health

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

Rate and extent of oral absorption:	43 % within 24 h
Rate and extent of dermal absorption:	Low to moderate (1.9 % for the formulation concentrate and 14.2 % for the spray dilution)
Distribution:	Widely distributed, highest residue in fat and skin
Potential for accumulation:	High accumulation in fat
Rate and extent of excretion:	rapidly excreted via urine (52.7 % in males, 50.0 % in females) and via faeces (38.2 % in males, 42.6 % in females)
Toxicologically significant metabolite	None identified

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral	57 mg/kg bw (corn oil) T, R25
Rat LD_{50} dermal	> 2000 mg/kg bw
Rat LC_{50} inhalation	[>1.16-1.21]mg/L, Xn, R20
AEL_{acute}	0.018 mg/kg bw
Skin irritation	Irritating, Xi, R38
Eye irritation	Not irritating
Skin sensitization (test method used and result)	Not sensitising (M&K)

Repeated dose toxicity, short-term (Annex IIA, point 6.3)

Species/ target / critical effect	Rat / 35–42 day studies / symptoms of neurotoxicity
Lowest relevant oral NOAEL / LOAEL	NOAEL = 200 ppm equivalent to17.6 mg/kg bw/d LOAEL= > 200 ppm equivalent to > 17.6 mg/kg bw/d
Lowest relevant dermal NOAEL / LOAEL	n.a.
Lowest relevant inhalation NOAEL / LOAEL	n.a.

Subchronic toxicity (Annex IIA, point 6.4)

Species/ target / critical effect	Dog / 90-day study / symptoms of neurotoxicity
Lowest relevant oral NOAEL / LOAEL	NOAEL = 90 ppm, equivalent to 3.5 mg/kg bw/d LOAEL= 270 ppm, equivalent to 13.3 mg/kg bw/d
Lowest relevant dermal NOAEL / LOAEL	n.a.
Lowest relevant inhalation NOAEL / LOAEL	n.a.

Chronic toxicity (Annex IIA, point 6.5)

Species/ target / critical effect	Dog / 1-year study / Irritation secondary to

	systemic toxicity
Lowest relevant oral NOAEL / LOAEL	NOAEL = 60 ppm, equivalent to 2.0 mg/kg bw/d LOAEL = 120 ppm, equivalent to 4.1 mg/kg bw/d

Genotoxicity (Annex IIA, point 6.6)	No genotoxic potential

Carcinogenicity (Annex IIA, point 6.4)

Species / type of tumour	Mouse / no tumours
Lowest dose with tumours	n.a.

Reproductive toxicity (Annex IIA, point 6.8)

Species/ Reproduction target / critical effect	Rat / No reproductive toxicity
Lowest relevant reproductive NOAEL / LOAEL	NOAEL = 10 mg/kg bw/d
Species / Developmental target / critical effect	Rat / Reduced foetal weight at maternal toxic doses
Lowest relevant developmental NOAEL / LOAEL	NOAEL = 9 mg/kg bw/d LOAEL = 15 mg/kg bw/day

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

Species/ target/critical effect	Rat alpha-cypermethrin is toxic for CNS and peripheral motor nerves; neurobehavioral changes are reversible within 3 days following single dose.
Lowest relevant developmental NOAEL / LOAEL.	Acute rat study : NOAEL= 4 mg/kg bw (in corn oil)

Other toxicological studies (Annex IIIA, VI/XI)

Not required

Medical data (Annex IIA, point 6.9)

Paresthesiae and peripheral sensory phenomena and irritation of respiratory tract; R37

Summary (Annex IIA, point 6.10)	Value	Study	Safety factor
ADI (if residues in food or feed)			
$AEL_{medium\ term}$ (Operator/Worker Exposure)	0.016 mg/kg	Dog, 90 days	100 / 0.45

	bw/d	study	
Drinking water limit			
ARfD (acute reference dose)	0.04 mg/kg bw/d	Rat, acute neurotoxicity study	100

Acceptable exposure scenarios (including method of calculation)

Professional users	<u>Acute and repeated exposure:</u> Application scenario: Low-pressure insecticide spraying indoors Application concentration of a.s.: 0.03 % (w/v) Duration: 2 hours Frequency of application: Daily Level of personal protection: PPE (protective coverall, gloves, boots); RPE additionally recommended Systemic dose: 0.0030-0.0018 mg/kg bw/d
Non-professional users	Not appropriate

Indirect exposure as a result of use	<u>Acute phase:</u> Adult inhaling volatilised residues indoors Systemic dose: 2.88 × 10^{-5} mg a.s./kg bw Children inhaling volatilised residues from treated carpet: Systemic dose: 3.84× 10^{-5} mg a.s./kg bw Infant inhaling volatilised residues from treated carpet: Systemic dose: 2.61 × 10^{-5} mg a.s./kg bw Infant playing on treated carpet and mouthing hands (dermal + ingestion) Systemic dose: 0.0139 mg a.s./kg bw <u>Chronic phase:</u> Adult inhaling volatilised residues indoors Systemic dose: 2.88 × 10^{-5} mg a.s./kg bw Children inhaling volatilised residues from treated carpet: Systemic dose: 3.84 × 10^{-5} mg a.s./kg bw Infant inhaling volatilised residues from treated carpet: Systemic dose: 2.61 × 10^{-5} mg a.s./kg bw Infant playing on treated carpet and mouthing hands (dermal +ingestion) Systemic dose: 0,0069 mg a.s./kg bw/d

Chapter 4: Fate and Behaviour in the Environment

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 4: stable (50 °C) pH 4: stable (12 °C) A half-life over a year at 25°C is expected. In the aqueous solution at pH 4, exclusively the parent compound was found until 10 days of incubation at 50°C (total recovery 83–88%). **Sampling procedure:** **pH 4, 50°C** 3, 10 d
	pH 7: DT_{50} = 27 d (50 °C) pH 7: DT_{50} = 67 d (25 °C) pH 7: DT_{50} = 101 d (20 °C) pH 7: DT_{50} = 564.4 d (12 °C) **Sampling procedure:** **pH 7, 50°C** 3, 5, 7 and 10d **pH 7, 60°C** 0, 2, 4, 7, 9 and 11d **pH 7, 75°C** 1, 2, 3 and 4d
	pH 9: DT_{50} = 3 h (50 °C) pH 9: DT_{50} = 3.5 d (25 °C) pH 9: DT_{50} = 7.3 d (20 °C) pH 9: DT_{50} = 9.9 d (12 °C) **Sampling procedure:** **pH 9, 25°C** 0, 1, 2, 3, 4, 7.2 and 11d **pH 9, 50°C** 0, 1, 2, 3, 4, 6, 8, 10 and 24h
	Hydrolysis products (supportive information Doc IVA-7.1.1.1.1-02): Alkaline conditions: • cyclopropane carboxylic acid; • meta-phenoxybenzaldehyde. Acidic conditions: • dichlorovynil carboxylic acid; • meta-phenoxybenzaldehyde. • Major product 3-phenoxybenzaldehyde occured at the selected concentration at all pH values and all temperatures. Acurrate hydrolysis data, due to low solubility and thus concentrations, were only available at very high temperatures (50 - 80 °C). The half-lives at 22°C were calculated to be 162 days, 46 days and 2.9 hours, respectively, in pH 5, 7 and 9 buffers. pH 5, 60°C, n=8 samples taken from 0 h to 280 h pH 5, 70°C, n=8 samples taken from 0 h to 188 h

	pH 5, 80°C, n=7 samples taken from 6 h to 95 h pH 7, 50°C, n=8 samples taken from 1.5 h to 140.5 h pH 7, 60°C, n=7 samples taken from 1.5 h to 116.5 h pH 5, 70°C, n=8 samples taken from 0 h to 125 h pH 9, 50°C, n=7 samples taken from 0 h to 1 h pH 9, 60°C, n=8 samples taken from 0 h to 0.917h pH 9, 70°C, n=9 samples taken from 0 h to 0.917 h
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Environmental DT_{50} = 3.4 – 6.3 d Mean DT_{50} = 4.85 d Sampling procedure: 1. [Bz-14C]-alphacypermethrin: 0, 8 and 16h, 1, 2, 4, 7 and 15 days of exposure. dark control: 8 and 16h, 1, 2, 4, 7 and 18 days of exposure 2. [Cp-14C]-alphacypermethrin: 0, 1, 2, 4, 8, 15 and 28 days of exposure. dark control: 1, 2, 4, 8, 15 and 28 days of exposure Relevant metabolites: cis + trans-2,2-dimethyl-3-(2',2'-dichlorovinyl)cyclopropane carboxylic acid isomers (CL 901649): DT_{50} = 96 d 3-phenoxybenzaldehyde (CL 206969): DT_{50} = 10.9 d 3-phenoxybenzoic acid (CL 206128): DT_{50} = 6.3 d
Readily biodegradable (yes/no)	No
Biodegradation in seawater	Not required
Non-extractable residues	No accumulation in water or sediment
Water/sediment study: DT_{50} water: DT_{90} water: DT_{50} whole system: DT_{90} whole system: DT_{50} 3-phenoxybenzoic acid (20 °C): DT_{90} 3-phenoxybenzoic acid (20 °C): DT_{50} dimethylcyclopropane carboxylic acid (20 °C): DT_{90} dimethylcyclopropane carboxylic acid (20 °C):	 0.4 – 2.1 d 1.5 – 6.9 d 6.4 – 35.4 d 21.1 – 117.5 d 2.1 – 3.0 d 7.0 – 10.1 d 14.3 – 36.8 d 61.5 – 105.9 d BE CA calculated geometric mean according to Sanco/10058/2005 version 1.0: DT_{50} water (12°C):2.22 d DT_{50} sediment (12°C):28.13 d Sampling procedure

	a) Benzyl-^{14}C-alphacypermethrin 0h, 6h, 24h and 2, 7, 14, 30, 61and 105 days after the treatment in duplicate. Additional samples were taken from the reserves on day 28 and 29, respectively. Sodium hydroxide solutions: Sampled and analysed at each sampling interval and on day 44, 72 and 89. Ethylene glycol solutions: Sampled and measured at each sampling interval and replaced only after 7, 44, 57, 72 and 89. b) Cyclopropyl-1-^{14}C-alphacypermethrin 0h, 6h, 24h and 2, 7, 14, 30, 62 and 105 days after the treatment in duplicate. Sodium hydroxide solutions/ Ethylene glycol solutions: Sampled and analysed at each sampling interval or about every two weeks.
Distribution in water / sediment systems (active substance)	up to 55 – 62 % in sediment at day 2
Distribution in water / sediment systems (metabolites)	3 phenoxybenzoic acid (up to 23 % at day 7 in whole system), dimethylcyclopropane carboxylic acid (up to 47 % at day 14 in water phase and up to 19.5 % at day 14 in sediment)

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

Mineralization (aerobic)	32–51 % within 120 days
Laboratory studies (estimated values with regression coefficient according to ModelMaker 4.0)	DT_{50lab} (20 °C, aerobic): 20.6 d, r^2 = 0.987 DT_{50lab} (12 °C, aerobic): 39.1 d
	DT_{90lab} (20 °C, aerobic): 68.3 d, r^2 = 0.987
	DT_{50lab} (10 °C, aerobic): 54.9 d, r^2 = 0.962 DT_{90lab} (10 °C, aerobic): 182.5 d, r^2 = 0.962
	DT_{50lab} (20 °C, anaerobic): 31 d
	degradation in the saturated zone:
Field studies (state location, range or median with number of measurements)	$DT_{50,field}$ < 14 - 112 d, median = 35 d, 9 measurements 3-year study in 3 locations in UK
	$DT_{90,field}$: 35 –< 385 d, 9 measurements 3-year study in 3 locations in UK

Anaerobic degradation	(Cypermethrin): Half-lives under aerobic and anaerobic conditions are similar. Formation of metabolite 3-phenoxybenzoic acid (67.6 % at day120), bound residue (11 % at day 120), no mineralisation
Soil photolysis	DT_{50} = 31 d Formation of metabolites 3-phenoxybenzoic acid (17 % at day 30), phenoxybenzoic alcohol (2.7 % at day 30), bound residue (13.3 % at day 30), mineralisation (6.2 % at day 30). Sampling procedure: Samples were taken and analysed after 0, 2, 4, 8, 16 and 30 days of illumination. Control samples: 2, 4, 8, 17* and 39* days *) Due to technical defect in the illumination system, samples had to be illuminated for additional 9 days to obtain a total of 30 illumination days. Consequently, time points of the dark control changed to 17 and 39 days.
Non-extractable residues	Up to 36 % in laboratory study; Bound residues are further mineralised Mineralisation rate: 21–37 % within 18 weeks
Relevant metabolites – name and/or code, % of applied a.i. (range and maximum)	No metabolite ≥ 10 %
Soil accumulation and plateau concentration	No accumulation was observed

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

Ka , Kd	K_{oc} (a.s.)= 26492–144652
Ka_{oc} , Kd_{oc}	Median K_{oc} = 57889
pH dependence (yes / no) (if yes type of dependence)	Mean K_{oc} = 76344
	Median K_{oc} (phenoxybenzoic acid): 73
	Kd = 821–1042
	No pH dependence

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

Direct photolysis in air	Not required
Quantum yield of direct photolysis	Not required
Photo-oxidative degradation in air	DT_{50} (● OH) = 3.47 h (QSAR estimation, software AOPWIN))
Volatilization	Vapour pressure = 3.4 x 10^{-7} Pa at 25 °C

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

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

Chapter 5: Effects on Non-target Species

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

Species	Time-scale	Endpoint	Toxicity
Fish			
Pimephales promelas	96 h	Mortality (LC_{50})	0.93 µg/L (measured)
Pimephales promelas	34 d	Overall mortality across development stages (NOEC)	0.03 µg/L (measured)
Invertebrates			
Daphnia magna	48 h	Immobilisation (EC_{50})	0.3 µg/L (nominal)
Daphnia magna	21 d	Reproduction (NOEC)	0.03 µg/l (nominal)
Algae			
Pseudokirchneriella subcapitata	72 h	Cell multiplication inhibition (E_rC_{50})	> 1.0 mg/L (nominal)
Microorganisms			
Activated sludge micro-organisms	3 h	Respiration inhibition (EC_{50})	> 1000 mg/L (nominal)

Toxicity data for aquatic species exposed to major metabolites

Species/metabolite	Time-scale	Endpoint	Toxicity
Fish			
Lepomis macrochirus:			
Metabolite CL 912554	96 h	Mortality (LC_{50})	> 102.8 mg/L (measured)
Metabolite CL 206128	96 h	Mortality (LC_{50})	> 103.2 mg/L (measured)
Invertebrates			
Daphnia magna :			
Metabolite CL 912554	48 h	Immobilisation (EC_{50})	61.9 mg/L (nominal)
		NOEC	25 mg/L (nominal)
Metabolite CL 206128	48 h	Immobilisation (EC_{50})	39 mg/L (nominal)
		NOEC	12.5 mg/L (nominal)
Metabolite CL 206969	48 h	Immobilisation (EC_{50})	0.8 mg/l (measured)
		NOEC	0.286 mg/L (measured)
Algae			
Pseudokirchneriella subcapitata :			
Metabolite CL 912554	72 h	E_rC_{50}	70 mg/L (nominal)
		E_bC_{50}	31.6 mg/L (nominal)
Metabolite CL 206128		E_rC_{50}	85 mg/L (nominal)
		E_bC_{50}	38.1 mg/L (nominal)

Effects on earthworms or other soil non-target organisms

Acute toxicity to *Eisenia fetida* (Annex IIIA, point XIII.3.2)	LC_{50} (14 d) > 1000 mg/kg dry soil
Reproductive toxicity to …… (Annex IIIA, point XIII.3.2)	Not required

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

Nitrogen mineralization	EC_{50} (28 d) > 100 mg/kg NOEC (28 d) > 100 mg/kg
Carbon mineralization	EC_{50} (28 d) > 100 mg/kg NOEC (28 d) > 100 mg/kg

Effects on terrestrial vertebrates

Acute toxicity to mammals (Annex IIIA, point XIII.3.3)	LD_{50} (rat) = 57 mg a.s./kg bw
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	LD_{50} (*Colinus virginianus*) > 2025 mg a.s./kg bw
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	LC_{50} (*Colinus virginianus*, 5 d) > 5000 mg a.s./kg feed
Reproductive toxicity to birds (Annex IIIA, point XIII.1.3)	NOEC (*Colinus virginianus*, 22 weeks) = 150 mg a.s./kg feed

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

Acute oral toxicity	Not required for lack of exposure (indoor use only)
Acute contact toxicity	Not required for lack of exposure (indoor use only)

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

Acute oral toxicity	Not required for lack of exposure (indoor use only)
Acute contact toxicity	Not required for lack of exposure (indoor use only)
Acute toxicity to ……	Not required for lack of exposure (indoor use only)

Bioconcentration (Annex IIA, point 7.5)

Aquatic Bioconcentration factor (BCF_{fish})	≤ 910 L/kg (experimentally determined Doc III-A7.4.3.3.1/01)

	9440 L/kg (QSAR estimation, Doc III-A7.4.2/01)
Depuration time (DT_{50}) (DT_{90})	6.9–8.6 d Not determined
Level of metabolites (%) in organisms accounting for > 10 % of residues	Not available
Terrestrial bioconcentration factor ($BCF_{earthworm}$)	3796 L/kg (estimated)

Chapter 6: Other End Points

Long-term effects on the aquatic environment (Annex IIIA, point XIII.3.4)

Chronic toxicity sediment dwelling organisms	NOEC = 0.024 µg/L (28 d, *Chironomus* larvae)
Higher tier testing on aquatic and benthic invertebrates and algae	EAC = 0.015 µg/L (126 d, mesocosm studies)

APPENDIX II: LIST OF INTENDED USES[2]

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks
				Type	Conc. of a.s.	Method Kind	Number min max	Interval between applications (min)	g a.s./L min max	Water L/m^2 min max	g a.s./m^2 min max	(m)
Insects in domestic and/or public environments	All	TENOPA	Insects in domestic and/or public environments	SC *	30 g/L	Low-pressure spraying onto surfaces (< 2 bar)	1	n.a.	n.a.	n.a.	0.0075–0.015	Application rate: The lower figure (0.0075) is the standard case, whereas the higher figure is recommended for severely draggled or strongly absorbing, porous surfaces

*) SC = Suspension concentrate

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

APPENDIX III: LIST OF STUDIES

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

Reference list by author

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Al-Hamdani et al.	A6.8.2/02	2010	Cypermethrin reversibly alters sperm count without altering fertility in mice. Ecotoxicol Environ Saf. 2010 Jul;73(5):1092-7 Not GLP, open literature	-	
Anonymous	B8.1(01) IIB, VIII 8.1 also filed: B8.2(01), also filed: B8.4(01), also filed: B8.5(01), also filed: B8.6(01)	2006	Safety data sheet TENOPA® 30/30 g/L SC (NPE free). Date: 2006-04-19	-	BASF
Anonymous	B8.2(01) IIB, VIII 8.2 also filed: B8.1(01), also filed: B8.4(01), also filed: B8.5(01), also filed: B8.6(01)	2006	Safety data sheet TENOPA® 30/30 g/L SC (NPE free). Date: 2006-04-19	-	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Anonymous	B8.4(01) IIB, VIII 8.4 also filed: B8.1(01), also filed: B8.2(01), also filed: B8.5(01), also filed: B8.6(01)	2006	Safety data sheet TENOPA® 30/30 g/L SC (NPE free). Date: 2006-04-19	-	BASF
Anonymous	B8.5(01) IIB, VIII 8.5 also filed: B8.1(01), also filed: B8.2(01), also filed: B8.4(01), also filed: B8.6(01)	2006	Safety data sheet TENOPA® 30/30 g/L SC (NPE free). Date: 2006-04-19	-	BASF
Anonymous	B8.6(01) IIB, VIII 8.6 also filed: B8.1(01), also filed: B8.2(01), also filed: B8.4(01), also filed: B8.5(01)	2006	Safety data sheet TENOPA® 30/30 g/L SC (NPE free). Date: 2006-04-19	-	BASF
Baker, I.P.	B3.7(02) IIB, III 3.7	1998	The physical and chemical stability of alphacypermethrin / flufenoxuron 30/30g/l SC in HDPE packs – 52 weeks report. Date: 1998-04-19	Yes	BASF
Baker, I.P.	B3.7(03) IIB, III 3.7	1999	The physical and chemical stability of alphacypermethrin / flufenoxuron 30/30g/l SC in HDPE packs – 104 weeks report. Date: 1999-06-09	Yes	BASF
Baldwin, M.K.	A3.5/01	1990	Alphacypermethrin (FASTAC) water solubility at various pH values Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.90.158 GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Beigel, C.	A7.2.2.1/05	2002	Calculation of DT50 and DT90 values of 3-phenoxybenzoic acid (metabolite of cypermethrin and alphacypermethrin) in two soils treated with cis-cypermethrin BASF Agro Research, Princeton, NJ, USA, Report No.: EXA02-006 Not GLP, Unpublished	Y (Exist./First)	BASF
Beigel, C.	A7.1.2.2.2/04	2001	Calculation of DT50 and DT90 values of Alphacypermethrin metabolites CL 206128 and CL 912554 in river sediment and pond sediment aquatic systems BASF Agro Research, Princeton, NJ, USA, Report No.: EXA-01-006 GLP, Unpublished	Y (Exist./First)	BASF
Beigel, C.	A7.1.2.2.2/03	2001	Calculation of first-order DT50 and DT90 values of Alphacypermethrin in the water and sediment phases of river-sediment and pond-sediment aquatic systems BASF Agro Research, Princeton, NJ, USA, Report No.: EXA-01-023 GLP, Unpublished	Y (Exist./First)	BASF
Bixler, T.A., Kukel, C.	A3.7/02	2001	CL 900049 (α-cypermethrin): solubility in acetone:hexane, stability in hexane and freezer storage stability of CL 900049 residues in cattle tissues (muscle, liver, kidney and fat) and milk BASF Agro Research, Princeton, NJ, USA, Report No.: RES01-002 GLP, Unpublished	Y (Exist./First)	BASF
Bohle, J.F.	A3.7/01	1991	Alphacypermethrin (FASTAC): determination of the solubility in different solvents RCC NOTOX B.V., 's-Hertogenbosch, The Netherlands, Report No.: 057263 GLP, Unpublished	Y (Exist./First)	BASF
Bosio, P.	A7.2.2.2/01	1983	Residues of WL 85871 and metabolites in soil from U.K. treated with FASTAC - 1981/82 trials Shell Chimie, Berre, France, Report No.: BEGR.83.040 Not GLP, Unpublished	Y (Exist./First)	BASF
Brem, G.	A3.2.1	2005	Henry's law constant for alpha-Cypermethrin 23/03/2005	Y	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Bremmer et al.	Doc II B 3.2.5.1	2002	Pest Control Products Fact Sheet. RIVM report 613340 003. RIVM, Bilthoven, The Netherlands.	N	-
Brooks, T.M.	A6.6.1/01	1993	FASTAC TM: bacterial mutagenicity studies Shell Research Ltd, Sittingbourne, UK, Report No.: SBTR.92.022 GLP, Unpublished	Y (Exist./First)	BASF
Brooks, T.M., Wiggins, D.E.	A6.6.2/01	1993	FASTAC TM: in vitro chromosome studies using cultured human lymphocytes Shell Research Ltd, Sittingbourne, UK, Report No.: SBTR.93.007 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.5/02	1979	Corrigendum and addendum I: Toxicity studies on the insecticide WL 43467: A 2 year feeding study in rats [redacted] Report No.: TLGR.0189.78 Not GLP, Unpublished	Y (Exist./First)	BASF
Cevasco, A.	A3.3.1/01	1999	Determination of the physical state, color, and odor for alpha-cypermethrin (AC 900049) purified active substance (PAS) and technical active substance (TAS) Cyanamid Co., Agricultural Products Research Division Princeton, NJ, USA, Report No.: P 285 Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.6.4/02	1984	Genotoxicity studies with Fastac: in vivo cytogenetic test using rat bone marrow [redacted] Report No.: SBGR.84.120 Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.4.1/01	1982	A 90 day feeding study in rats [redacted] Report No.: SBGR.81.293 Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	B6.3(01) IIB, VI 6.3	1997	Closed-Patch Dermal Sensitization Study with Alphacypermethrin / Flufenoxuron 30/30 g/l SC (RLF 12299) in Guinea Pigs (Modified Buehler Method). Date: 1997-06-19	Yes	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Concha, M. et al.	A7.1.1.1.2/01	2001	BAS 310 I (Alphacypermethrin): aqueous photolysis PTRL West, Inc., Hercules, CA, USA, Report No.: ENV01-037 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.5/06	1999	First amendment: Alphacypermethrin: oncogenicity study by dietary administration to CD 1 mice [redacted] Report No.: 95/SHL010/0596 GLP, Unpublished	Y (Exist./First)	BASF
Coveney, P.C., Forbes, S.	A7.2.2.2/09	1986	Analysis of soil from UK (Coates) for residues of "FASTAC" (WL85871) - soil persistence trial - third year Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.86.201 Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.2/06	1977	The metabolic fate of the cis and trans isomers of WL 43467 (Cypermethrin). Metabolism and elimination of 14C-aryl-labelled cis and trans-isomers in rats, [redacted] report no.: TLGP.0131.77, December 1977, BASF no: CY-440-004. No GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.2/07	1977	The metabolism of WL 43467 in mammals. The fate of a single oral dose of (14C-cyclopropyl) WL 43467 in the rat [redacted] Report no.: TLGR.0004.77, January 1977, BASF RDI No.: CY-440-003. No GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.2/09	1978	The metabolic fate of the cis and trans-isomers of Cypermethrin in the rat. Metabolites derived from the ^{14}C-labelled cyclopropyl ring. [redacted] Report no.: TLGR.0183.78, November 1978, BASF RDI No.:CY-440-026. No GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	A6.2/10	1978	A study of the metabolism of 3-phenoxybenzoic acid and its glucoside conjugate in rats. [redacted] Report no.: TLGR.0186.78, December 1978, BASF RDI No.:CY-440-029. No GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.2/11	1979	The identification of metabolites in the tissues of rats treated orally with 3-phenoxybenzoic acid. [redacted] Report no.: TLGR.0043.79, March 1979, BASF RDI No.: CY-440-030. No GLP, Unpublished	Y (Exist./First)	BASF
Daum, A.	A3.7	2005	Determination of the solubility in organic solvents at 20°C of alpha-Cypermethrin (BAS 310 I, Reg.No. 4 078 193) TGAI 21/03/2005	Y	BASF
Daum, A.	A3.9	2005	Determination of the octanol/water partitioning coefficient of alpha-Cypermethrin (BAS 310 I, Reg.No. 4 078 193) TGAI at 20°C 09/02/2005	Y	BASF
[redacted]	A6.4.1/03	1995	WL85871: 52 week oral (dietary) toxicity study in dogs [redacted] Report No.: 11110 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.8.2/05	1985	Corrigendum IV: Toxicity studies on the insecticide WL43467: a three generation reproduction study in rats [redacted] Report No.: TLGR.0188.78 Not GLP, Unpublished	Y (Exist./First)	BASF
Doran, A.M. et al.	A4.2/06	1999	RENEGADE Alphacypermethrin (CL 900049): validation of analytical methods SAMS 461-1 and SAMS 456-1 for the determination of Alphacypermethrin residues in cattle tissues (muscle, fat, kidney and liver) and milk Inveresk Research, Tranent, UK, Report No.: RES 99-014 GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Eadsforth, C.V. et al.	A6.12.2/01	1988	Human dose-excretion studies with pyrethroids insecticides cypermethrin and alphacypermethrin: relevance for biological monitoring Xenobiotica 18, 603-614, Not GLP, Published	Y (Exist./First)	
Edwards, J.	B4.1(01) IIB, IV 4.1	1996a	HPLC method for the assay of alphacypermethrin / flufenoxuron SC formulations. Date: 1996-06-12	Yes	BASF
Edwards, J.	B4.1(02) IIB, IV 4.1	1996b	Validation of RLA 12454.00 (HPLC method for the assay of alphacypermethrin / flufenoxuron SC formulations). Date: 1996-07-16	Yes	BASF
Elbetieha, A et al.	A6.8.2/03	2001	Evaluation of the toxic potentials of Cypermethrin pesticide on some reproductive and fertility parameters in the male rats. Arch Environ Contam Toxicol. 2001 Nov;41(4):522-8. Not GLP, open literature	-	
[redacted]	B6.4(01) IIB, VI 6.4	2006	Study on the demal penetration of ^{14}C-BAS310 I and BAS 307 I in BAS 308 04 I. Date: 2006-02-20	Yes	BASF
Ferri, J., Zhang, Y.	A3.4/02	1994	Spectral database for FASTAC Technical (CL 900,049) American Cyanamid Company, Princeton, NJ, USA, Report No.: APBR#342 Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.8.2/02	1979	Corrigendum I: Toxicity studies on the insecticide WL43467: a three generation reproduction study in rats [redacted] Report No.: TLGR.0188.78 Not GLP, Unpublished	Y (Exist./First)	BASF
Flannigan, S.A., Tucker, S.B.	A6.12.7/01	1985	Variation in cutaneous sensation between synthetic pyrethroids insecticides Contact Derm. 13, 140-147, Not GLP, Published	Y (Exist./First)	
[redacted]	A6.8.2/04	1979	Corrigendum III: Toxicity studies on the insecticide WL43467: a three generation reproduction study in rats [redacted] Report No.: TLGR.0188.78 Not GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	A6.8.2/03	1979	Corrigendum II: Toxicity studies on the insecticide WL43467: a three generation reproduction study in rats [redacted] Report No.: TLGR.0188.78 Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted].	A6.3.1/01	1993	WL85871 (FASTAC): a 6 week range finding feeding study in the rat [redacted] Report No.: SBTR.93.002 Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.9/01	1994	WL85871 (FASTAC): an acute oral (gavage) neurotoxicity study in the rat [redacted], Report No.: SBTR.92.027 GLP, Unpublished	Y (Exist./First)	BASF
Forbes, S., Burden, A.	A7.2.2.2/05	1983	Analysis of soil from UK (Hoath) for residues of WL85871 (FASTAC) - soil persistence trial - second year Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.84.006 Not GLP, Unpublished	Y (Exist./First)	BASF
Forbes, S., Burden, A.	A7.2.2.2/04	1983	Analysis of soil from UK (Reculver) for residues of WL85871 (FASTAC) - soil persistence trial - second year Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.84.005 Not GLP, Unpublished	Y (Exist./First)	BASF
Forbes, S., Knight, C.	A7.2.2.2/02	1983	Analysis of soil from UK for residues of WL85871 - soil persistence trial - first year Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.83.162 Not GLP, Unpublished	Y (Exist./First)	BASF
Forbes, S., MacKay, C.	A7.2.2.2/03	1983	Analysis of soil from UK (Coates) for residues of WL85871 (FASTAC) - soil persistence trial - first year Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.83.418 Not GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Forbes, S., Wales, G.H.	A7.2.2.2/08	1985	Analysis of soil from UK (Hoath) for residues of FASTAC* (WL85871) - soil persistence trial - third year Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.85.072 Not GLP, Unpublished	Y (Exist./First)	BASF
Forbes, S., Wales, G.H.	A7.2.2.2/07	1985	Analysis of soil from UK (Coates) for residues of FASTAC* (WL85871) - soil persistence trial - second year Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.85.071 Not GLP, Unpublished	Y (Exist./First)	BASF
Forbes, S., Wales, G.H.	A7.2.2.2/06	1985	Analysis of soil from UK (Reculver) for residues of FASTAC* (WL85871) - soil persistence trial - third year Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.85.070 Not GLP, Unpublished	Y (Exist./First)	BASF
Fotiou, F.	A4.1/02	1995	Validation of HRGC method M-2447.03 to assay for residual solvents and other minor components in technical grades of the active ingredients, of FASTAC (CL 900,049, Alphacypermethrin) and RIPCORD (CL 900,051, Cypermethrin) American Cyanamid Company, Princeton, NJ, USA, Report No.: APBR456 GLP, Unpublished	Y (Exist./First)	BASF
Funk, M. et al.	A7.4.3.5/10	2000	Acute toxicity of alphacypermethrin (AC900049) in a 100 g/L OESC formulation (CF06677) to aquatic macroinvertebrates Technical University of Munich-Weihenstephan, Freising, Germany, Report No.: 98-I Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.1.2/01	2005	BAS 310 I (alpha-Cypermethrin) - acute dermal toxicity study in rats [redacted] Report No.: 11A0563/041084 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.1.5/02	2005	BAS 310 I (alpha-Cypermethrin) - maximization test in guinea pigs [redacted] Report No.: 30H0563/042243 GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	A6.1.5/01	2005	BAS 310 I (alpha-Cypermethrin) - maximization test in guinea pigs [redacted] Report No.: 30H0562/042240 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.1.2/02	2005	BAS 310 I (alpha-Cypermethrin) - acute dermal toxicity study in rats [redacted] Report No.: 11A0562/041082 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.1.1/02	2005	BAS 310 I (alpha-Cypermethrin) - acute oral toxicity study in rats [redacted] Report No.: 10A0563/041083 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.1.1/03	2005	BAS 310 I (alpha-Cypermethrin) - acute oral toxicity study in rats [redacted] Report No.: 10A0562/041081 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.1.3/02	2005	BAS 310 I (alpha-Cypermethrin) - acute inhalation toxicity study in Wistar rats [redacted] Report No.: 13I0562/047014 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.1.1/01	1993	FASTAC technical: acute oral and dermal toxicity in rat, skin and eye irritancy in rabbit and skin sensitisation potential in guinea pig [redacted] Report No.: SBTR.92.033 GLP, Unpublished	Y (Exist./First)	BASF
Garforth, B.	A7.4.3.4/01	1982	WL 85871 and cypermethrin: chronic toxicity to Daphnia magna Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.82.119 Not GLP, Unpublished	Y (Exist./First)	BASF
Gedik, L., Keirs, D.C.	A7.2.1/01	2001	14C-Alphacypermethrin (BAS 310 I): degradation in soil under aerobic conditions Inveresk Research, Tranent, UK, Report No.: ENV01-012 GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Gödde, M.	B3.2(01) IIB, III 3.2 also filed: B3.3(01) also filed: B3.4(02)	2005	Evaluation and physical and chemical properties according to Directive 94/37/EC – Test substance BAS 308 04 I. Date: 2005-08-04	Yes	BASF
Gödde, M.	B3.3(01) IIB, III 3.3 also filed: B3.2(01) also filed: B3.4(02)	2005	Evaluation and physical and chemical properties according to Directive 94/37/EC – Test substance BAS 308 04 I. Date: 2005-08-04	Yes	BASF
Gödde, M.	B3.4(01) IIB, III 3.4	2006	Flash point	Yes	BASF
Gödde, M.	B3.4(02) IIB, III 3.4 also filed: B3.2(01) also filed: B3.3(01)	2005	Evaluation and physical and chemical properties according to Directive 94/37/EC – Test substance BAS 308 04 I. Date: 2005-08-04	Yes	BASF
Goldsmith, A.E.	B3.1(01) IIB, III 3.1 also filed B3.5(01) also filed B3.6(01) also filed B3.7(01) also filed B3.8(01) also filed B3.10(01) also filed B3.11(01)	2005	Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2005-02-04	Yes	BASF
Goldsmith, A.E.	B3.5(01) IIB, III 3.5 also filed B3.1(01) also filed B3.6(01) also filed B3.7(01) also filed B3.8(01) also filed B3.10(01) also filed B3.11(01)	2005	Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2005-02-04	Yes	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Goldsmith, A.E.	B3.6(01) IIB, III 3.6 also filed B3.1(01) also filed B3.5(01) also filed B3.7(01) also filed B3.8(01) also filed B3.10(01) also filed B3.11(01)	2005	Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2005-02-04	Yes	BASF
Goldsmith, A.E.	B3.6(02) – also filed B3.10(02) also filed B3.11(02)	2006	Battelle UK Report Amendment Certification: Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2006-03-14	Yes	BASF
Goldsmith, A.E.	B3.7(01) IIB, III 3.7 also filed B3.1(01) also filed B3.5(01) also filed B3.6(01) also filed B3.8(01) also filed B3.10(01) also filed B3.11(01)	2005	Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2005-02-04	Yes	BASF
Goldsmith, A.E.	B3.8(01) IIB, III 3.8 also filed B3.1(01) also filed B3.5(01) also filed B3.6(01) also filed B3.7(01) also filed B3.10(01) also filed B3.11(01)	2005	Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2005-02-04	Yes	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Goldsmith, A.E.	B3.10(01) – also filed B3.1(01) also filed B3.5(01) also filed B3.6(01) also filed B3.7(01) also filed B3.8(01) also filed B3.11(01)	2005	Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2005-02-04	Yes	BASF
Goldsmith, A.E.	B3.10(02) – also filed B3.6(02) also filed B3.11(02)	2006	Battelle UK Report Amendment Certification: Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2006-03-14	Yes	BASF
Goldsmith, A.E.	B3.11(01) – also filed B3.1(01) also filed B3.5(01) also filed B3.6(01) also filed B3.7(01) also filed B3.8(01) also filed B3.10(01)	2005	Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2005-02-04	Yes	BASF
Goldsmith, A.E.	B3.11(02) – also filed B3.6(02) also filed B3.10(02)	2006	Battelle UK Report Amendment Certification: Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2006-03-14	Yes	BASF
[redacted]	A6.4.1/04	1984	Alphacypermethrin: preliminary toxicity study by dietary administration to CD-1 mice for 13 weeks [redacted] Report No.: 92/SHL009/0849 GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	A6.5/05	1996	Alphacypermethrin: oncogenicity study by dietary administration to CD 1 mice [redacted] Report No.: 95/SHL010/0596 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.4.1/02	1984	WL85871: 13 week oral dietary toxicity study in dogs [redacted] Report No.: 3197 Not GLP, Unpublished	Y (Exist./First)	BASF
Hahn, T.	A7.4.3.5/11	2002	Effects of Alphacypermethrin (BAS 310 03 I) applied as FASTAC OESC on aquatic macroinvertebrates (Ephemeroptera and Trichoptera) in extended "standard" laboratory testsZoologisches Institut der TU Braunschweig Zoologisches Institut der TU Braunschweig, Braunschweig, Germany, Report No.: 14-53-81 Not GLP, Unpublished	Y (Exist./First)	BASF
Harteveld, J.L.N.	A3.2/01	1992	Determination of the vapour pressure of Alphacypermethrin TNO, Rijswijk, The Netherlands, Report No.: PML1992-C39 GLP, Unpublished	Y (Exist./First)	BASF
Hausmann, S. and Class, T.	B6.6 IIB, VI 6.6	1998	Decontamination of Surfaces Treated with Tenopa®. Date: 1998-11-23	Yes	BASF
Heintze, A.	A7.4.3.5.1/01	1997	Alphacypermethrin (AC 900049): effects on the development of sediment-dwelling larvae of Chironomus riparius in a water-sediment system GAB, Niefern-Öschelbronn, Germany, Report No.: ECO96-325 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A7.5.3.1.1/01	2000	Avian acute oral toxicity test with Alphacypermethrin (AC 900049) technical in Northern bobwhites (Colinus virginianus) [redacted] Report No.: 105-046-03 GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	A6.8.2/01	1978	Toxicity studies on the insecticide WL43467: a three generation reproduction study in rats [redacted] Report No.: TLGR.0188.78 Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.5/03	1981	Corrigendum and addendum II: Toxicity studies on the insecticide WL 43467: A 2 year feeding study in rats [redacted], Report No.: TLGR.0189.78 Not GLP, Unpublished	Y (Exist./First)	BASF
Hill, A.D.	A7.2.3.1/01	1993	Benzyl-14C WL85871 (FASTAC): adsorption/desorption in three soils Shell Research Ltd, Sittingbourne, UK, Report No.: SBTR.93.042 GLP, Unpublished	Y (Exist./First)	BASF
Hu JX, Li et al.	A6.8.2/04	2011	Toxic effects of Cypermethrin on the male reproductive system: with emphasis on the androgen receptor. J Appl Toxicol. 2011 Dec 6. doi: 10.1002/jat.1769. Not GLP, open literature	-	
Huber, W.	A7.4.3.5/03	2000	Summary of an expert panel opinion of the study "Evaluation of possible effects of a 100 g/L SC formulation (CF 06677) of AC 900049 (alphacyp.) on makroinvertebrates, zooplankton, and algae in pond-enclosures and determination of the EAC Institute of Aquatic Ecotoxicology, Buch am Erlbach, Germany, Report No.: 2000/I Not GLP, Unpublished	Y (Exist./First)	BASF
Huber, W.	A7.4.3.5/04	2000	Evaluation of an Ecologically Acceptable Concentration (EAC) for alphacypermethrin in aquatic environments Institute of Aquatic Ecotoxicology, Buch am Erlbach, Germany, Report No.: 2000/II Not GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Huber, W. et al.	A7.4.3.5/02	2000	Evaluation of possible effects of a 100 g/l SC formulation (CF 06677) of AC 900049 (alphacypermethrin) on macroinvertebrates, zooplankton and algae in pond-enclosures and determination of the ecologically acceptable concentration (EAC) Technical University of Munich-Weihenstephan, Germany, Report No.: ETX-99-101 GLP, Unpublished	Y (Exist./First)	BASF
Huber, W. et al.	A7.4.3.5/08	2001	Evaluation of the effects of multiple applications of a 100 g/L SC formulation (FASTAC, OESC, CF 06677) of alphacypermethrin (AC 900049) on macroinvertebrates, zooplankton and algae in pond-enclosures Technical University of Munich-Weihenstephan, Germany, Report No.: ECO00-268 Not GLP, Unpublished	Y (Exist./First)	BASF
Huber, W., Grünwald, H.	A7.4.3.5/09	2002	Toxicity of Alphacypermethrin (BAS 310 I, AC 900049) in a 100 g/L OESC formulation (FASTAC OESC insecticide, CF 06677) to aquatic macroinvertebrates (Cloeon, Gammarus) in laboratory microcosms Technical University of Munich-Weihenstephan, Freising, Germany, Report No.: LSÖ 02/3 Not GLP, Unpublished	Y (Exist./First)	BASF
Huber, W.	A7.4.3.5/05	2003	Expert opinion on the results from modified laboratory toxicity tests and population modeling with aquatic macroinvertebrates and FASTAC® OESC insecticide (alphacypermethrin) Institute of Aquatic Ecotoxicology, Buch am Erlbach, Germany, Report No.: 03/1 Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.2/01	1982	WL 85871: Metabolism of a single oral dose in the rat [redacted], Report No.: SBGR.82.205 Not GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Hutson DH, Logan CJ	A6.2/03	1986	The metabolic fate in rats of the pyrethroid insecticide WL85871, a mixture of two isomers of cypermethrin. Pesticide Science 17: 548-558, BASF RDI No.: AL-905-066.	N	BASF
[redacted]	A6.8.1/02	1994	Alphacypermethrin - Oral gavage rat developmental toxicity (teratogenicity) study [redacted] Report No.: SLN/2/92 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.8.1/01	1994	Alphacypermethrin - Oral gavage rabbit developmental toxicity (teratogenicity) study [redacted], Report No.: SLN/4/93 GLP, Unpublished	Y (Exist./First)	BASF
Jackson, C.	A7.2.3.2/01	1977	The leaching of WL 43467 through laboratory soil columns Shell Research Ltd, Sittingbourne, UK, Report No.: BLGR.0150.77 Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.1.3/03	1993	Alphacypermethrin: acute inhalation toxicity in rats, 4-hour exposure [redacted] Report No.: SLL266/930770 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	B6.1.3(01) IIB, VI 6.1.3	1997	(Acute (4-Hour) Inhalation Toxicity Study with Alphacypermethrin/Flufenoxuron 30/30 g/l SC (RLF 12299) in the Rat via Nose-Only Exposure. Date: 1997-06-16	Yes	BASF
Jatzek, J.	A7.4.1.3/01	2002	BAS 310 I - determination of inhibitory effect on the cell multiplication of unicellular green algae BASF AG, Ludwigshafen, Germany, Report No.: 01/0265/60/1 GLP, Unpublished	Y (Exist./First)	BASF
Jones, M.T.	A3.4/01	1995	Spectral database for Alphacypermethrin (CL 900,049) pure active substance Cyanamid Forschung GmbH, Schwabenheim, Germany, Report No.: APBR466 Not GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Jung, R.	B5.10(01) IIB, V 5.10	2006	Efficacy of Product Tenopa on German cockroaches. Date: March 2006	Yes	BASF
Kaestel, R.	A3.1.1 A3.2	2005	Melting point and vapour pressure of Alpha-cypermethrin (TGAI, Source: Gujarat Agrochem) 07/01/2005	Y	BASF
Kemény M et al	A6.8.2/06	2012	Alphacypermethrin (BAS 310 I) - Evaluation of the endocrine disrupting potential of Alphacypermethrin (BASF Doc ID: 2012/1220476 and Amendment: 2013/1071382)	Y (Exist./First)	BASF
Kirzecky, N.	A4.1/03	1995	Validation of the high performance liquid chromatographic (HPLC) method M-2480.01 to assay for cis I, trans III, and trans IV Cypermethrin isomers in CL 900,049 (Alphacypermethrin, Cis II) technical grade active ingredient (TGAI) American Cyanamid Company, Princeton, NJ, USA, Report No.: APBR458 GLP, Unpublished	Y (Exist./First)	BASF
Kölzer, U.	A7.5.1.1/02	2006	Effects of BAS 310 I (Reg. No. 4078193) on the activity of the soil microflora - carbon transformation test (ECx) GAB, Niefern-Öschelbronn, Germany, Report No.: 20061048/02-ABMF GLP, Unpublished	Y (Exist./First)	BASF
Kölzer, U.	A7.5.1.1/01	2006	Effects of BAS 310 I (Reg. No. 4078193) on the activity of the soil microflora - nitrogen transformation test (ECx) GAB, Niefern-Öschelbronn, Germany, Report No.: 20061048/01-ABMF GLP, Unpublished	Y (Exist./First)	BASF
Kroehl, T.	A3.10/01	2006	Thermal stability of alpha-cypermethrin (Reg. No. 4078193, BAS 310 I) according to OECD guideline 113 BASF AG, Limburgerhof, Germany, Report No.: 168571_2 GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Kwasniok, A. et al.	A4.2/04	1997	Validation of method SAMS 469-2 for determination of AC 900049 (Alphacypermethrin) applied as a formulation (FASTACTM 100 g/L OESC insecticide) in pond water Chemische Laboratorien GmbH, Hamburg, Germany, Report No.: ECO97-138 GLP, Unpublished	Y (Exist./First)	BASF
Langner, E.J., Fisk, P.R.	A3.9/01	1993	Alphacypermethrin (FASTAC): estimation of the octanol-water partition coefficient Shell Research Ltd, Sittingbourne, UK, Report No.: SBTR.92.030 GLP, Unpublished	Y (Exist./First)	BASF
Lebertz, H., Zhjixing, Y.	A7.4.1.4/01	2001	Alphacypermethrin (BAS 310 I): activated sludge, respiration inhibition test Institut Fresenius, Taunusstein, Germany, Report No.: IF-100/29753-00 GLP, Unpublished	Y (Exist./First)	BASF
LeQuesne L.C.	B5.10(02) IIB, V 5.10	1997	Tenopa - A new high performance residual insecticide for the effective control of public health insect pests. Date: September/October 1997	No	published
LeQuesne, L.C., Twydell, R.S. and Porter, A.	B5.10(06) IIB, V 5.10	1996	Alphacypermetrin/Flufenoxuron - A new high performance residual insecticide combination for cockroach control. Date: 1996	No	published
[redacted]	A6.2/08	1980	Cypermethrin – excretion and retention of Cypermethrin and its metabolites in rats following a single oral dose (ca. 200 mg/kg). [redacted] Report no.: TLER.80.083, October 1980 BASF RDI No.:CY-440-033. No GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.2/02	1983	WL85871 : Depletion from tissues of female rats after a single oral dose [redacted] Report No.: SBGR.83.075 Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.1.3/01	2005	BAS 310 I (alpha-Cypermethrin) - acute inhalation toxicity study in Wistar rats [redacted], Report No.: 13I0563/047013 GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Mamouni, A.	A7.1.2.2.2/01	1993	FASTAC (Benzyl-14C): degradation and metabolism in aquatic systems RCC Umweltchemie AG, Itingen, Switzerland, Report No.: 305864 GLP, Unpublished	Y (Exist./First)	BASF
Mangels, G.	A7.3.1/01	1995	Alphacypermethrin: estimation of the photochemical oxidation rate in the atmosphere American Cyanamid Company, Princeton, NJ, USA, Report No.: ENV95-017 Not GLP, Unpublished	Y (Exist./First)	BASF
Martin, C.A.	A3.2.1/01	1999	Alphacypermethrin (AC 900049): calculation of Hernry's Law constant American Cyanamid Company, Princeton, NJ, USA, Report No.: ENV99-004 Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.5/01	1978	Toxicity studies on the insecticide WL 43467: A 2 year feeding study in rats [redacted] Report No.: TLGR.0189.78 Not GLP, Unpublished	Y (Exist./First)	BASF
McMinn, A.L.	A7.2.2.1/01	1983	The degradation of the pyrethroid insecticides WL 85871 (FASTAC) and WL 43481 in soil Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.83.395 Not GLP, Unpublished	Y (Exist./First)	BASF
Mitchell, G.C.	A7.4.3.5/07	2003	Alphacypermethrin: an overview of effects of FASTAC on aquatic macroinvertebrates, with particular reference to the midge Chaoborus crystallinus (Chaoboriedae: Diptera) Ecotoxicology Services, Yardley, PA, USA, Report No.: ES060301 Not GLP, Unpublished	Y (Exist./First)	BASF
Müller-Kallert, H.M.	A4.2/02	1992	Development of a method for the determination of Alphacypermethrin in air RCC Umweltchemie AG, Itingen, Switzerland, Report No.: 249120 GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Ohnsorge, U.	B3.7(04) IIB, III 3.7	2004	™Tenopa, Minor change reasoning. Date: 2004-04-06 Business Confidential Information – See BCI folder	Yes	BASF
[redacted]	B6.2.1(01) IIB, VI 6.2	1997a	Primary Dermal Irritation Study with Alphacypermethrin / Flufenoxuron 30/30 g/l SC (RLF 12299) in Rabbits. Date: 1997-05-28	Yes	BASF
[redacted]	B6.2.2(01) IIB, VI 6.2	1997b	Primary Eye Irritation Study with Alphacypermethrin / Flufenoxuron 30/30 G/L SC (RLF 12299) in Rabbits. Date: 1997-06-20	Yes	BASF
Petersen-Thiery, M.	A3.1.3	2009	Alpha-Cypermethrin – Determination of density 24/04/2009	Y	BASF
[redacted]	A6.3.1/02	1982	A 5 week feeding study with WL 85871 in rats [redacted] Report No.: SBGR.81.212 Not GLP, Unpublished	Y (Exist./First)	BASF
Ratte, H.T., Strauss, T.	A7.4.3.5/06	2002	The response and recovery of a mesocosm population of Chaoborus crystallinus (Diptera) at multiple applications of 0.015 µg a.i./L FASTAC OESC (active ingredient; alphacypermethrin, BAS 310 I) - a modeling approach Dept. of Biology V, University of Technology, Aachen, Germany, Report No.: 145555 Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.1.4/02	2005	BAS 310 I (alpha-Cypermethrin) - acute dermal irritation / corrosion in rabbits [redacted], Report No.: 18H0563/042241 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.1.4/03	2005	BAS 310 I (alpha-Cypermethrin) - acute eye irritation in rabbits [redacted], Report No.: 11H0563/042242 GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	A6.1.4/04	2005	BAS 310 I (alpha-Cypermethrin) - acute eye irritation in rabbits [redacted] Report No.: 11H0562/042239 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.1.4/01	2005	BAS 310 I (alpha-Cypermethrin) - acute dermal irritation / corrosion in rabbits [redacted], Report No.: 18H0562/042238 GLP, Unpublished	Y (Exist./First)	BASF
Roberts, T.R.	A7.2.2.1/03	1980	Appendices to Shell report no. WKGR.0094.76: The degradation of the insecticide WL 43467 in soil under laboratory conditions Shell Research Ltd, Sittingbourne, UK, Report No.: WKGR.0094.76 Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A7.5.3.1.2/01	2001	Alphacypermethrin (BAS 310 I) dietary toxicity (LC50) to the Northern bobwhite (Colinus virginianus) [redacted] Report No.: CYD/632 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A7.5.3.1.3/01	2001	Alphacypermethrin (BAS 310 I) assessment to determine the effects on reproduction in northern bobwhite (Colinus virginianus) [redacted] Report No.: ETX-00-183 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A6.9/02	1983	Neurotoxicity of WL85871 comparison with L43467: the effect of 20 oral doses of WL85871 or WL43467 over 4 weeks on the rat sciatic/ posterior tibial nerve, trigeminal nerve and trigeminal ganglion [redacted], Report No.: SBGR.83.185 Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A7.4.3.3.1/01	1997	Bioconcentration study of alpha-cypermethrin with carp [redacted] Report No.: 6B332G GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Salisbury, K. et al.	A3.1.2/01	1982	Physical and chemical properties of WL85871 and some compounds important in its synthesis Shell Research Ltd, Sittingbourne, UK, Report No.: SBRN.82.087 Not GLP, Unpublished	Y (Exist./First)	BASF
Sendor, T.	A7.4.2/01	2005	Estimation of the bioconcentration factor (BCF) of Alphacypermethrin. EBRC Consulting GmbH, Hannover, Germany, Report No.: BAS-051114-01 Not GLP, Unpublished	Y (Exist./First)	BASF
Sendor, T.	A2.10.2/01	2005	Estimation of distribution in the environment of Alphacypermethrin EBRC Consulting GmbH, Hannover, Germany, Report No.: BAS-051213-01 Not GLP, Unpublished	Y (Exist./First)	BASF
Sendor, T.	A7.5.5.1/01	2005	Estimation of the terrestrial bioconcentration factor (BCF) of Alphacypermethrin EBRC Consulting GmbH, Hannover, Germany, Report No.: BAS-20051214-01 Not GLP, Unpublished	Y (Exist./First)	BASF
Seutin, E	B5.10(03) IIB, V 5.10	1993	Evaluation of Insecticidal Efficacy Against Household Insects (German Cockroach, *Blattella germanica*). Date: 1993-06-11	Yes	BASF
Standen, M.E.	A7.2.2.1/02	1976	The degradation of the insecticide WL 43467 in soil under laboratory conditions Shell Research Ltd, Sittingbourne, UK, Report No.: WKGR.0094.76 Not GLP, Unpublished	Y (Exist./First)	BASF
Standen, M.E.	A7.2.2.1/04	1978	Further studies of the degradation of the insecticide WL43467 (Cypermethrin) in soil under laboratory conditions Shell Research Ltd, Sittingbourne, UK, Report No.: BLGR.0034.78 Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A7.4.1.1/02	1981	WL85871 and cypermethrin: a comparison of their acute toxicity to Salmon gairdneri, Daphnia magna and Selenastrum capricornutum [redacted], Report No.: SBGR.81.277 Not GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	A7.4.1.1/01	1983	WL85871 and cypermethrin: a comparative study of their toxicity to the Fathead minnow Pimephales promelas (Rafinesque) [redacted] Report No.: SBGR.82.298 Not GLP, Unpublished	Y (Exist./First)	BASF
Stevens, J.E.B., Hill, I.R.	A7.2.3.2/02	1980	Cypermethrin: mobility of cypermethrin and its degradation products in soil columns ICI Plant Protection Division, Report No.: RJ0166B Not GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	B6.1.1(01) IIB, VI 6.1.1	1997a	Acute Oral Toxicity Study with Alphacypermethrin / Flufenoxuron 30/30 g/l SC (RLF 12299) in Rats. Date: 1997-05-22	Yes	BASF
[redacted]	B6.1.2(01) IIB, VI 6.1.2	1997b	Acute Dermal Toxicity Study with Alphacypermethrin / Flufenoxuron 30/30 g/l SC (RLF 12299) in Rats. Date: 1997-05-09	Yes	BASF
Stone, C.M., Watkinson, R.J.	A7.1.1.2.1/01	1983	WL85871: an assessment of ready biodegradability Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.83.206 Not GLP, Unpublished	Y (Exist./First)	BASF
TEC Laboratories	B5.10(04) IIB, V 5.10	1997	Etude en laboratoire de l´efficacite biologique d´une spécialité destinée à la lutte contre les blattes et les insectes nuisible dans les locaux de stockage des denrées alimentaires d´origine animale ou végétale. Date: October 1997	Yes	BASF
TEC Laboratories	B5.10(05) IIB, V 5.10	1998	Laboratory Study Regarding Biological Efficacy of a Speciality Intended for Striving Against Cockroaches and Prejudicial Insects in Stock Premises for Food Products of Animal or Vegetable Origin. - Additional information to Report TEC 452/0797R: action persistence up to 6 months after application/interest of the growth regulator. Date: January 1998	Yes	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	A6.5/04	1985	Corrigendum and addendum III: Toxicity studies on the insecticide WL 43467: A 2 year feeding study in rats [redacted], Report No.: TLGR.0189.78 Not GLP, Unpublished	Y (Exist./First)	BASF
Tordoir	A6.12.5/01	1990	Occupational health aspects of handling pesticides in Shell Agrochemical formulation plants Shell International Petroleum Maatschapij, The Hague, The Netherlands, Report No.: HSE90.009 Not GLP, Published	Y (Exist./First)	BASF
[redacted]	A6.6.4/01	1995	Micronucleus test in bone marrow cells of the mouse with FASTAC technical [redacted] Report No.: 087378 GLP, Unpublished	Y (Exist./First)	BASF
van de Waart, E.J.	A6.6.3/01	1994	Evaluation of the mutagenic activity of FASTAC technical in an in vitro mammalian cell gene mutation test with L5178Y mouse lymphoma cells (with independent repeat) Notox B.V., 's Hertogenbosch, The Netherlands, Report No.: 087367 GLP, Unpublished	Y (Exist./First)	BASF
van Dijk, A.	A7.1.1.1.1/01	1993	Hydrolysis determination of 14C-alphacypermethrin at different pH values RCC Umweltchemie AG, Itingen, Switzerland, Report No.: 307383 GLP, Unpublished	Y (Exist./First)	BASF
van Dijk, A., Burri, R.	A7.2.2.4/01	1993	14C-Alphacypermethrin: study of its photodegradation in soil RCC Umweltchemie AG, Itingen, Switzerland, Report No.: 299777 GLP, Unpublished	Y (Exist./First)	BASF
van Helvoirt, J.A.M.W	A3.16/01	1991	Alphacypermethrin (FASTAC): determination of the oxidizing properties RCC NOTOX B.V., 's-Hertogenbosch, The Netherlands, Report No.: 057329 GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
van Helvoirt, J.A.M.W	A3.15/01	1991	Determination of the explosive properties of Alphacypermethrin RCC NOTOX B.V., 's-Hertogenbosch, The Netherlands, Report No.: 057307 GLP, Unpublished	Y (Exist./First)	BASF
van Helvoirt, J.A.M.W.	A3.11/01	1991	Determination of the flammability of Alphacypermethrin RCC NOTOX B.V., 's-Hertogenbosch, The Netherlands, Report No.: 057296 GLP, Unpublished	Y (Exist./First)	BASF
van Helvoirt, J.A.M.W.	A3.1.1/01	1992	Alphacypermethrin (FASTAC): determination of the melting point / melting range RCC NOTOX B.V., 's-Hertogenbosch, The Netherlands, Report No.: 057239 GLP, Unpublished	Y (Exist./First)	BASF
van Helvoirt, J.A.M.W.	A3.1.3/01	1992	Alphacypermethrin (FASTAC): determination of the density RCC NOTOX B.V., 's-Hertogenbosch, The Netherlands, Report No.: 057241 GLP, Unpublished	Y (Exist./First)	BASF
van Helvoirt, J.A.M.W.	A3.11/02	1991	Determination of the auto-flammability of Alphacypermethrin RCC NOTOX B.V., 's-Hertogenbosch, The Netherlands, Report No.: 057318 GLP, Unpublished	Y (Exist./First)	BASF
[redacted]	A.6.2/04	1984	Human oral dose-excretion study with Fastac. [redacted], Report no. HSE 85.010, November 1984 BASF RDI No.: AL-445-003. No GLP, Unpublished	Y (Exist./First)	BASF
Völkl,S.	A7.1.2.2.2/02	1993	14C-Alphacypermethrin (Cyclopropyl-1-14C): degradation and metabolism in aquatic systems RCC Umweltchemie AG, Itingen, Switzerland, Report No.: 316326 GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Walker, B., Linkerhägner, M.	A4.2/05	2000	Alphacypermethrin (AC 900049): validation of the DFG method S 19 (extended revision) for the determination of residues of Alphacypermethrin in blood and urine of animal origin (swine) Dr. Specht & Partner, Hamburg, Germany, Report No.: CYA-0001V GLP, Unpublished	Y (Exist./First)	BASF
Wang H et al.	A6.8.2/05	2011	Maternal Cypermethrin exposure during lactation impairs testicular development and spermatogenesis in male mouse offspring. Environ Toxicol. 2011 Aug; 26(4):382-94. Not GLP, open literature	-	
Werle, H.	A4.2/01	1999	Alphacypermethrin (CL 900049): validation of method SAMS 354-2 for the determination of residues in soils BioChem GmbH, Karlsruhe, Germany, Report No.: 985040421 GLP, Unpublished	Y (Exist./First)	BASF
Werle, H.	A4.2/03	1999	Alphacypermethrin (CL 900049): validation of method SAMS 469-2 for the determination of residues in surface water BioChem GmbH. Karlsruhe, Germany, Report No.: 985040420 GLP, Unpublished	Y (Exist./First)	BASF
Western, N.J.	A6.12.1/01	1984	Report on the assessment of FASTAC exposures during formulation of technical concentrate (TC) and technical material (TM) at Durban, South Africa - September 1983 Shell International Petroleum Maatschapij, The Hague, The Netherlands, Report No.: HSE84.003 Not GLP, Unpublished	Y (Exist./First)	BASF
Weyman, G.S., Canez, V.M.	A7.5.1.2/01	1998	14-day earthworm (Eisenia foetida) acute toxicity study with Alphacypermethrin (AC 900049) in a 150 g/kg WG formulation (RLF 12152) Covance, Harrogate, UK, Report No.: ECO97-196 GLP, Unpublished	Y (Exist./First)	BASF

Author(s)	Section No / Reference No	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	A6.6.5/01	1982	Studies on the effect of WL 85871 on the integrity of rat liver DNA in vivo [redacted] Report No.: SBGR.81.225 Not GLP, Unpublished	Y (Exist./First)	BASF
Worst, S.A.	A4.1/01	1995	Validation of high resolution gas chromatographic method M-2420.01 for the determination of CL 900,049 and CL 900,051 in technical grades of CL 900,049 (FASTAC, Alphacypermethrin) and CL 900,051 (RIPCORD, Cypermethrin) insecticides American Cyanamid Company, Princeton, NJ, USA, Report No.: APBR448 GLP, Unpublished	Y (Exist./First)	BASF
Xu, B.	A4.2/07	2001	BAS 310 I (Alpha-cypermethrin): validation of method M 3499 for the confirmation of BAS 310 I residues in water, soils and blood by GC/MS BASF Agro Research, Princeton, NJ, USA, Report No.: RES01-058 GLP, Unpublished	Y (Exist./First)	BASF

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Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A2.6/01	Cevasco, A.A.	1994	Manufacturing process for FASTAC Alphacypermethrin (NRDC-160) American Cyanamid Company, Princeton, NJ, USA, Report No.: P-134 Not GLP, Unpublished	Y (Exist./First)	BASF
A2.7/01	Fotiou, F.	1995	Specification, impurities, and analytical profiles for technical grade CL 900,049 (Alphacypermethrin, FASTAC) and CL 900,051 (Cypermethrin, RIPCORD) American Cyanamid Company, Princeton, NJ, USA, Report No.: APBR457 Not GLP, Unpublished	Y (Exist./First)	BASF

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A2.7/02	Genari, G.	2003	Analytical characterisation of five batches alpha-cypermethrin TGAI source Tagros Chemicals and comparison with five batches alpha-cypermethrin TGAI source Resende BASF BASF Agricultural Center, Limburgerhof, Germany, Report No.: 168184_2 GLP, Unpublished	Y (Exist./First)	BASF
A2.7/03	Genari, G.	2003	Analytical characterisation of five batches alpha-cypermethrin TGAI source Gujarat Agrochem and comparison with five batches alpha-cypermethrin TGAI source Resende BASF BASF Agricultural Center, Limburgerhof, Germany, Report No.: 168184_1 GLP, Unpublished	Y (Exist./First)	BASF
A2.7/04	Genari, G.	2005	Alphacypermethrin: composition of the Technical Grade Active Ingredient (TGAI) BASF Agricultural Center, Limburgerhof, Germany, Not GLP, Unpublished	Y (Exist./First)	BASF
A2.10.2/01	Sendor, T.	2005	Estimation of distribution in the environment of Alphacypermethrin EBRC Consulting GmbH, Hannover, Germany, Report No.: BAS-051213-01 Not GLP, Unpublished	Y (Exist./First)	BASF
B3.1(01) IIB, III 3.1 also filed B3.5(01) also filed B3.6(01) also filed B3.7(01) also filed B3.8(01) also filed B3.10(01) also filed B3.11(01)	Goldsmith, A.E.	2005	Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2005-02-04	Yes	BASF
A3.1.1	Kaestel, R	2005	Melting point and vapour pressure of Alpha-cypermethrin (TGAI, Source: Gujarat Agrochem) Date: 2005-01-07		BASF

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A3.1.1/01	van Helvoirt, J.A.M.W.	1992	Alphacypermethrin (FASTAC): determination of the melting point / melting range RCC NOTOX B.V., 's-Hertogenbosch, The Netherlands, Report No.: 057239 GLP, Unpublished	Y (Exist./First)	BASF
A3.1.2/01	Salisbury, K. et al.	1982	Physical and chemical properties of WL85871 and some compounds important in its synthesis Shell Research Ltd, Sittingbourne, UK, Report No.: SBRN.82.087 Not GLP, Unpublished	Y (Exist./First)	BASF
A3.1.3	Petersen-Thiery, M.	2009	Alpha-Cypermethrin – Determination of density Date: 2009-04-24		BASF
A3.1.3/01	van Helvoirt, J.A.M.W.	1992	Alphacypermethrin (FASTAC): determination of the density RCC NOTOX B.V., 's-Hertogenbosch, The Netherlands, Report No.: 057241 GLP, Unpublished	Y (Exist./First)	BASF
B3.2(01) IIB, III 3.2 also filed: B3.3(01) also filed: B3.4(02)	Gödde, M.	2005	Evaluation and physical and chemical properties according to Directive 94/37/EC – Test substance BAS 308 04 I. Date: 2005-08-04	Yes	BASF
A3.2	Kaestel, R	2005	Melting point and vapour pressure of Alpha-cypermethrin (TGAI, Source: Gujarat Agrochem) Date: 2005-01-07		BASF
A3.2/01	Harteveld, J.L.N.	1992	Determination of the vapour pressure of Alphacypermethrin TNO, Rijswijk, The Netherlands, Report No.: PML1992-C39 GLP, Unpublished	Y (Exist./First)	BASF
A3.2.1	Brem, G.	2005	Henry's law constant for alpha-Cypermethrin Date: 2005-03-23		BASF

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A3.2.1/01	Martin, C.A.	1999	Alphacypermethrin (AC 900049): calculation of Hernry's Law constant American Cyanamid Company, Princeton, NJ, USA, Report No.: ENV99-004 Not GLP, Unpublished	Y (Exist./First)	BASF
A3.3.1/01	Cevasco, A.	1999	Determination of the physical state, color, and odor for alpha-cypermethrin (AC 900049) purified active substance (PAS) and technical active substance (TAS) Cyanamid Co., Agricultural Products Research Division Princeton, NJ, USA, Report No.: P 285 Not GLP, Unpublished	Y (Exist./First)	BASF
B3.3(01) IIB, III 3.3 also filed: B3.2(01) also filed: B3.4(02)	Gödde, M.	2005	Evaluation and physical and chemical properties according to Directive 94/37/EC – Test substance BAS 308 04 I. Date: 2005-08-04	Yes	BASF
A3.4/01	Jones, M.T.	1995	Spectral database for Alphacypermethrin (CL 900,049) pure active substance Cyanamid Forschung GmbH, Schwabenheim, Germany, Report No.: APBR466 Not GLP, Unpublished	Y (Exist./First)	BASF
B3.4(01) IIB, III 3.4	Gödde, M.	2006	Flash point	Yes	BASF
A3.4/02	Ferri, J., Zhang, Y.	1994	Spectral database for FASTAC Technical (CL 900,049) American Cyanamid Company, Princeton, NJ, USA, Report No.: APBR#342 Not GLP, Unpublished	Y (Exist./First)	BASF
B3.4(02) IIB, III 3.4 also filed: B3.2(01) also filed: B3.3(01)	Gödde, M.	2005	Evaluation and physical and chemical properties according to Directive 94/37/EC – Test substance BAS 308 04 I. Date: 2005-08-04	Yes	BASF

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.5/01	Baldwin, M.K.	1990	Alphacypermethrin (FASTAC) water solubility at various pH values Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.90.158 GLP, Unpublished	Y (Exist./First)	BASF
B3.5(01) IIB, III 3.5 also filed B3.1(01) also filed B3.6(01) also filed B3.7(01) also filed B3.8(01) also filed B3.10(01) also filed B3.11(01)	Goldsmith, A.E.	2005	Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2005-02-04	Yes	BASF
B3.6(01) IIB, III 3.6 also filed B3.1(01) also filed B3.5(01) also filed B3.7(01) also filed B3.8(01) also filed B3.10(01) also filed B3.11(01)	Goldsmith, A.E.	2005	Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2005-02-04	Yes	BASF
B3.6(02) IIB, III 3.6 also filed B3.10(02) also filed B3.11(02)	Goldsmith, A.E.	2006	Battelle UK Report Amendment Certification: Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2006-03-14	Yes	BASF
A3.7	Daum, A.	2005	Determination of the solubility in organic solvents at 20°C of alpha-Cypermethrin (BAS 310 I, Reg. No. 4 078 193) TGAI Date: 2005-03-21		BASF

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A3.7/01	Bohle, J.F.	1991	Alphacypermethrin (FASTAC): determination of the solubility in different solvents RCC NOTOX B.V., 's-Hertogenbosch, The Netherlands, Report No.: 057263 GLP, Unpublished	Y (Exist./First)	BASF
B3.7(01) IIB, III 3.7 also filed B3.1(01) also filed B3.5(01) also filed B3.6(01) also filed B3.8(01) also filed B3.10(01) also filed B3.11(01)	Goldsmith, A.E.	2005	Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2005-02-04	Yes	BASF
B3.7(02) IIB, III 3.7	Baker, I.P.	1998	The physical and chemical stability of alphacypermethrin / flufenoxuron 30/30g/l SC in HDPE packs – 52 weeks report. Date: 1998-04-19	Yes	BASF
A3.7/02	Bixler, T.A., Kukel, C.	2001	CL 900049 (α-cypermethrin): solubility in acetone:hexane, stability in hexane and freezer storage stability of CL 900049 residues in cattle tissues (muscle, liver, kidney and fat) and milk BASF Agro Research, Princeton, NJ, USA, Report No.: RES01-002 GLP, Unpublished	Y (Exist./First)	BASF
B3.7(03) IIB, III 3.7	Baker, I.P.	1999	The physical and chemical stability of alphacypermethrin / flufenoxuron 30/30g/l SC in HDPE packs – 104 weeks report. Date: 1999-06-09	Yes	BASF
B3.7(04) IIB, III 3.7	Ohnsorge, U.	2004	TMTenopa, Minor change reasoning. Date: 2004-04-06 Business Confidential Information – See BCI folder	Yes	BASF

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B3.8(01) IIB, III 3.8 also filed B3.1(01) also filed B3.5(01) also filed B3.6(01) also filed B3.7(01) also filed B3.10(01) also filed B3.11(01)	Goldsmith, A.E.	2005	Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2005-02-04	Yes	BASF
A3.9	Daum, A.	2005	Determination of the octanol/water partition coefficient of alpha-Cypermethrin (BAS 310 I, Reg. No. 4 078 193) TGAI at 20°C Date: 2005-02-09		BASF
A3.9/01	Langner, E.J., Fisk, P.R.	1993	Alphacypermethrin (FASTAC): estimation of the octanol-water partition coefficient Shell Research Ltd, Sittingbourne, UK, Report No.: SBTR.92.030 GLP, Unpublished	Y (Exist./First)	BASF
B3.10(01) – also filed B3.1(01) also filed B3.5(01) also filed B3.6(01) also filed B3.7(01) also filed B3.8(01) also filed B3.11(01)	Goldsmith, A.E.	2005	Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2005-02-04	Yes	BASF
A3.10/01	Kroehl, T.	2006	Thermal stability of alpha-cypermethrin (Reg. No. 4078193, BAS 310 I) according to OECD guideline 113 BASF AG, Limburgerhof, Germany, Report No.: 168571_2 GLP, Unpublished	Y (Exist./First)	BASF

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B3.10(02) – also filed B3.6(02) also filed B3.11(02)	Goldsmith, A.E.	2006	Battelle UK Report Amendment Certification: Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2006-03-14	Yes	BASF
A3.11/01	van Helvoirt, J.A.M.W.	1991	Determination of the flammability of Alphacypermethrin RCC NOTOX B.V., 's-Hertogenbosch, The Netherlands, Report No.: 057296 GLP, Unpublished	Y (Exist./First)	BASF
B3.11(01) – also filed B3.1(01) also filed B3.5(01) also filed B3.6(01) also filed B3.7(01) also filed B3.8(01) also filed B3.10(01)	Goldsmith, A.E.	2005	Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2005-02-04	Yes	BASF
A3.11/02	van Helvoirt, J.A.M.W.	1991	Determination of the auto-flammability of Alphacypermethrin RCC NOTOX B.V., 's-Hertogenbosch, The Netherlands, Report No.: 057318 GLP, Unpublished	Y (Exist./First)	BASF
B3.11(02) – also filed B3.6(02) also filed B3.10(02)	Goldsmith, A.E.	2006	Battelle UK Report Amendment Certification: Physical and chemical properties of flufenoxuron/ alphacypermethrin 30/30 g/L SC, BAS 308 04 I Accelerated storage stability up to 2 weeks at 54 °C. Date: 2006-03-14	Yes	BASF
A3.15/01	van Helvoirt, J.A.M.W	1991	Determination of the explosive properties of Alphacypermethrin RCC NOTOX B.V., 's-Hertogenbosch, The Netherlands, Report No.: 057307 GLP, Unpublished	Y (Exist./First)	BASF
A3.16/01	van Helvoirt, J.A.M.W	1991	Alphacypermethrin (FASTAC): determination of the oxidizing properties RCC NOTOX B.V., 's-Hertogenbosch, The Netherlands, Report No.: 057329 GLP, Unpublished	Y (Exist./First)	BASF

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A4.1/01 cross reference to conf. data	Worst, S.A.	1995	Validation of high resolution gas chromatographic method M-2420.01 for the determination of CL 900,049 and CL 900,051 in technical grades of CL 900,049 (FASTAC, Alphacypermethrin) and CL 900,051 (RIPCORD, Cypermethrin) insecticides American Cyanamid Company, Princeton, NJ, USA, Report No.: APBR448 GLP, Unpublished	Y (Exist./First)	BASF
B4.1(01) IIB, IV 4.1	Edwards, J.	1996a	HPLC method for the assay of alphacypermethrin / flufenoxuron SC formulations. Date: 1996-06-12	Yes	BASF
A4.1/02 cross reference to conf. data	Fotiou, F.	1995	Validation of HRGC method M-2447.03 to assay for residual solvents and other minor components in technical grades of the active ingredients, of FASTAC (CL 900,049, Alphacypermethrin) and RIPCORD (CL 900,051, Cypermethrin) American Cyanamid Company, Princeton, NJ, USA, Report No.: APBR456 GLP, Unpublished	Y (Exist./First)	BASF
B4.1(01) IIB, IV 4.1	Edwards, J.	1996a	HPLC method for the assay of alphacypermethrin / flufenoxuron SC formulations. Date: 1996-06-12	Yes	BASF
A4.1/03 cross reference to conf. data	Kirzecky, N.	1995	Validation of the high performance liquid chromatographic (HPLC) method M-2480.01 to assay for cis I, trans III, and trans IV Cypermethrin isomers in CL 900,049 (Alphacypermethrin, Cis II) technical grade active ingredient (TGAI) American Cyanamid Company, Princeton, NJ, USA, Report No.: APBR458 GLP, Unpublished	Y (Exist./First)	BASF
A4.2/01	Werle, H.	1999	Alphacypermethrin (CL 900049): validation of method SAMS 354-2 for the determination of residues in soils BioChem GmbH, Karlsruhe, Germany, Report No.: 985040421 GLP, Unpublished	Y (Exist./First)	BASF
A4.2/02	Müller-Kallert, H.M.	1992	Development of a method for the determination of Alphacypermethrin in air RCC Umweltchemie AG, Itingen, Switzerland, Report No.: 249120 GLP, Unpublished	Y (Exist./First)	BASF

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A4.2/03	Werle, H.	1999	Alphacypermethrin (CL 900049): validation of method SAMS 469-2 for the determination of residues in surface water BioChem GmbH. Karlsruhe, Germany, Report No.: 985040420 GLP, Unpublished	Y (Exist./First)	BASF
A4.2/04	Kwasniok, A. et al.	1997	Validation of method SAMS 469-2 for determination of AC 900049 (Alphacypermethrin) applied as a formulation (FASTACTM 100 g/L OESC insecticide) in pond water Chemische Laboratorien GmbH, Hamburg, Germany, Report No.: ECO97-138 GLP, Unpublished	Y (Exist./First)	BASF
A4.2/05	Walker, B., Linkerhägner, M.	2000	Alphacypermethrin (AC 900049): validation of the DFG method S 19 (extended revision) for the determination of residues of Alphacypermethrin in blood and urine of animal origin (swine) Dr. Specht & Partner, Hamburg, Germany, Report No.: CYA-0001V GLP, Unpublished	Y (Exist./First)	BASF
A4.2/06	Doran, A.M. et al.	1999	RENEGADE Alphacypermethrin (CL 900049): validation of analytical methods SAMS 461-1 and SAMS 456-1 for the determination of Alphacypermethrin residues in cattle tissues (muscle, fat, kidney and liver) and milk Inveresk Research, Tranent, UK, Report No.: RES 99-014 GLP, Unpublished	Y (Exist./First)	BASF
A4.2/07	Xu, B.	2001	BAS 310 I (Alpha-cypermethrin): validation of method M 3499 for the confirmation of BAS 310 I residues in water, soils and blood by GC/MS BASF Agro Research, Princeton, NJ, USA, Report No.: RES01-058 GLP, Unpublished	Y (Exist./First)	BASF
A5.4/01	van Heemstra-Lequin E.A.H., van Esch, G.T.	1992	Alphacypermethrin. Environmental Health Criteria 142 WHO ICPS, Geneva, Switzerland, Not GLP, Published	N	-
A5.4/02	Tomlin, C.	1994	Alphacypermethrin In: The Pesticide Manual, 10th Ed., BCPC, Farnham, UK, Not GLP, Published	N	-

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B5.10(01) IIB, V 5.10	Jung, R.	2006	Efficacy of Product Tenopa on German cockroaches. Date: March 2006	Yes	BASF
B5.10(02) IIB, V 5.10	LeQuesne L.C.	1997	Tenopa - A new high performance residual insecticide for the effective control of public health insect pests. Date: September/October 1997	No	published
B5.10(03) IIB, V 5.10	Seutin, E	1993	Evaluation of Insecticidal Efficacy Against Household Insects (German Cockroach, Blattella germanica). Date: 1993-06-11	Yes	BASF
B5.10(04) IIB, V 5.10	TEC Laboratories	1997	Etude en laboratoire de l´efficacite biologique d´une spécialité destinée à la lutte contre les blattes et les insectes nuisible dans les locaux de stockage des denrées alimentaires d´origine animale ou végétale. Date: October 1997	Yes	BASF
B5.10(05) IIB, V 5.10	TEC Laboratories	1998	Laboratory Study Regarding Biological Efficacy of a Speciality Intended for Striving Against Cockroaches and Prejudicial Insects in Stock Premises for Food Products of Animal or Vegetable Origin. - Additional information to Report TEC 452/0797R: action persistence up to 6 months after application/interest of the growth regulator. Date: January 1998	Yes	BASF
B5.10(06) IIB, V 5.10	LeQuesne, L.C., Twydell, R.S. and Porter, A.	1996	Alphacypermetrin/Flufenoxuron - A new high performance residual insecticide combination for cockroach control. Date: 1996	No	published
A6.1.1/01	[redacted]	1993	FASTAC technical: acute oral and dermal toxicity in rat, skin and eye irritancy in rabbit and skin sensitisation potential in guinea pig [redacted] Report No.: SBTR.92.033 GLP, Unpublished	Y (Exist./First)	BASF
B6.1.1(01) IIB, VI 6.1.1	[redacted]	1997a	Acute Oral Toxicity Study with Alphacypermethrin / Flufenoxuron 30/30 g/l SC (RLF 12299) in Rats. Date: 1997-05-22	Yes	BASF

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A6.1.1/02	[redacted]	2005	BAS 310 I (alpha-Cypermethrin) - acute oral toxicity study in rats [redacted] Report No.: 10A0563/041083 GLP, Unpublished	Y (Exist./First)	BASF
A6.1.1/03	[redacted]	2005	BAS 310 I (alpha-Cypermethrin) - acute oral toxicity study in rats [redacted], Report No.: 10A0562/041081 GLP, Unpublished	Y (Exist./First)	BASF
A6.1.1/04	[redacted]	1982	Toxicology of pyrethroids: the acute oral and percutaneous toxicity of cis-2-Ripcord comparison with Ripcord [redacted] Report No.: SBGR.82.130 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.1.2 cross reference to A6.1.1/01	[redacted]	1993	FASTAC technical: acute oral and dermal toxicity in rat, skin and eye irritancy in rabbit and skin sensitisation potential in guinea pig [redacted] Report No.: SBTR.92.033 GLP, Unpublished	Y (Exist./First)	BASF
B6.1.2(01) IIB, VI 6.1.2	[redacted]	1997b	Acute Dermal Toxicity Study with Alphacypermethrin / Flufenoxuron 30/30 g/l SC (RLF 12299) in Rats. Date: 1997-05-09	Yes	BASF
A6.1.2/01	[redacted]	2005	BAS 310 I (alpha-Cypermethrin) - acute dermal toxicity study in rats [redacted] Report No.: 11A0563/041084 GLP, Unpublished	Y (Exist./First)	BASF
A6.1.2/02	[redacted]	2005	BAS 310 I (alpha-Cypermethrin) - acute dermal toxicity study in rats [redacted], Report No.: 11A0562/041082 GLP, Unpublished	Y (Exist./First)	BASF
B6.1.3(01) IIB, VI 6.1.3	[redacted]	1997	(Acute (4-Hour) Inhalation Toxicity Study with Alphacypermethrin/Flufenoxuron 30/30 g/l SC (RLF 12299) in the Rat via Nose-Only Exposure. Date: 1997-06-16	Yes	BASF
A6.1.3/01	[redacted]	2005	BAS 310 I (alpha-Cypermethrin) - acute inhalation toxicity study in Wistar rats [redacted], Report No.: 13I0563/047013 GLP, Unpublished	Y (Exist./First)	BASF

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A6.1.3/02	[redacted]	2005	BAS 310 I (alpha-Cypermethrin) - acute inhalation toxicity study in Wistar rats [redacted] Report No.: 13I0562/047014 GLP, Unpublished	Y (Exist./First)	BASF
A6.1.3/03	[redacted]	1993	Alphacypermethrin: acute inhalation toxicity in rats, 4-hour exposure [redacted] Report No.: SLL266/930770 GLP, Unpublished	Y (Exist./First)	BASF
A6.1.4 cross reference to A6.1.1/01	[redacted]	1993	FASTAC technical: acute oral and dermal toxicity in rat, skin and eye irritancy in rabbit and skin sensitisation potential in guinea pig [redacted] Report No.: SBTR.92.033 GLP, Unpublished	Y (Exist./First)	BASF
A6.1.4/01	[redacted]	2005	BAS 310 I (alpha-Cypermethrin) - acute dermal irritation / corrosion in rabbits [redacted], Report No.: 18H0562/042238 GLP, Unpublished	Y (Exist./First)	BASF
A6.1.4/02	[redacted]	2005	BAS 310 I (alpha-Cypermethrin) - acute dermal irritation / corrosion in rabbits [redacted] Report No.: 18H0563/042241 GLP, Unpublished	Y (Exist./First)	BASF
A6.1.4/03	[redacted]	2005	BAS 310 I (alpha-Cypermethrin) - acute eye irritation in rabbits [redacted], Report No.: 11H0563/042242 GLP, Unpublished	Y (Exist./First)	BASF
A6.1.4/04	[redacted]	2005	BAS 310 I (alpha-Cypermethrin) - acute eye irritation in rabbits [redacted], Report No.: 11H0562/042239 GLP, Unpublished	Y (Exist./First)	BASF
A6.1.5 cross reference to A6.1.1/01	[redacted]	1993	FASTAC technical: acute oral and dermal toxicity in rat, skin and eye irritancy in rabbit and skin sensitisation potential in guinea pig [redacted] Report No.: SBTR.92.033 GLP, Unpublished	Y (Exist./First)	BASF

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A6.1.5/01	[redacted]	2005	BAS 310 I (alpha-Cypermethrin) - maximization test in guinea pigs [redacted], Report No.: 30H0562/042240 GLP, Unpublished	Y (Exist./First)	BASF
A6.1.5/02	[redacted]	2005	BAS 310 I (alpha-Cypermethrin) - maximization test in guinea pigs [redacted] Report No.: 30H0563/042243 GLP, Unpublished	Y (Exist./First)	BASF
A6.2/01	[redacted]	1982	WL85871: metabolism of a single oral dose in the rat [redacted] Report No.: SBGR.82.205 Not GLP, Unpublished	Y (Exist./First)	BASF
B6.2.1(01) IIB, VI 6.2	[redacted]	1997a	Primary Dermal Irritation Study with Alphacypermethrin / Flufenoxuron 30/30 g/l SC (RLF 12299) in Rabbits. Date: 1997-05-28	Yes	BASF
A6.2/02	[redacted]	1983	Depletion from tissues of female rats after a single oral dose [redacted] Report No.: SBGR.83.075 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.2/03	Hutson, D.H., Logan, C.J.	1986	The metabolic fate in rats of the pyrethroid insecticide WL85871, a mixture of two isomers of cypermethrin Pest. Sci. 17, 548-558, Not GLP, Published	Y (Exist./First)	
A6.2/04	[redacted]	1985	Human oral dose-excretion study with FASTAC [redacted], Report No.: HSE85.010 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.2/05	[redacted]	1985	WL85871: percutaneous absorption, metabolism and elimination of WL85871 in the rat [redacted] Report No.: SBGR.85.217 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.2/06	[redacted]	1977	The metabolic fate of the cis and trans isomers of WL 43467 (Cypermethrin). Metabolism and elimination of 14C-aryl-labelled cis and trans-isomers in rats [redacted] Report No.: TLGP.0131.77 Not GLP, Unpublished	Y (Exist./First)	BASF

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A6.2/07	[redacted]	1977	The metabolism of WL 43467 in mammals. The fate of a single oral dose of (14C-cyclopropyl) WL 43467 in the rat [redacted], Report No.: TLGR.0004.77 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.2/08	[redacted]	1980	Cypermethrin - excretion and retention of Cypermethrin and its metabolites in rats following a single oral dose (ca. 200 mg/kg) [redacted] Report No.: TLER.80.083 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.2/09	[redacted]	1978	The metabolic fate of the cis and trans-isomers of Cypermethrin in the rat. Metabolites derived from the 14C-labelled cyclopropyl ring [redacted], Report No.: TLGR.0183.78 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.2/10	[redacted]	1978	A study of the metabolism of 3-phenoxybenzoic acid and its glucoside conjugate in rats [redacted] Report No.: TLGR.0186.78 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.2/11	[redacted]	1979	The identification of metabolites in the tissues of rats treated orally with 3-phenoxybenzoic acid [redacted], Report No.: TLGR.0043.79 Not GLP, Unpublished	Y (Exist./First)	BASF
B6.2.2(01) IIB, VI 6.2	[redacted]	1997b	Primary Eye Irritation Study with Alphacypermethrin / Flufenoxuron 30/30 G/L SC (RLF 12299) in Rabbits. Date: 1997-06-20	Yes	BASF
A6.3.1/01	[redacted]	1993	WL85871 (FASTAC): a 6 week range finding feeding study in the rat [redacted], Report No.: SBTR.93.002 Not GLP, Unpublished	Y (Exist./First)	BASF
B6.3(01) IIB, VI 6.3	[redacted]	1997	Closed-Patch Dermal Sensitization Study with Alphacypermethrin / Flufenoxuron 30/30 g/l SC (RLF 12299) in Guinea Pigs (Modified Buehler Method). Date: 1997-06-19	Yes	BASF

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A6.3.1/02	[redacted]	1982	A 5 week feeding study with WL 85871 in rats [redacted] Report No.: SBGR.81.212 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.3.1/03	[redacted]	1984	WL85871: oral maximum tolerated dose study in dogs [redacted] Report No.: 3107 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.3.1/04	[redacted]	1993	Alphacypermethrin: preliminary toxicity study by dietary administration to CD-1 mice for four weeks [redacted] Report No.: 92/0346 GLP, Unpublished	Y (Exist./First)	BASF
A6.4.1/01	[redacted]	1982	A 90 day feeding study in rats [redacted], Report No.: SBGR.81.293 Not GLP, Unpublished	Y (Exist./First)	BASF
B6.4(01) IIB, VI 6.4	[redacted]	2006	Study on the demal penetration of 14C-BAS310 I and BAS 307 I in BAS 308 04 I. Date: 2006-02-20	Yes	BASF
A6.4.1/02	[redacted]	1984	WL85871: 13 week oral dietary toxicity study in dogs [redacted], Report No.: 3197 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.4.1/03	[redacted]	1995	WL85871: 52 week oral (dietary) toxicity study in dogs [redacted] Report No.: 11110 GLP, Unpublished	Y (Exist./First)	BASF
A6.4.1/04	[redacted]	1984	Alphacypermethrin: preliminary toxicity study by dietary administration to CD-1 mice for 13 weeks [redacted], Report No.: 92/SHL009/0849 GLP, Unpublished	Y (Exist./First)	BASF
A6.4.2/01	[redacted]	1981	Subacute dermal toxicity study in rabbits with technical cypermethrin [redacted] Report No.: CTL/P/588 Not GLP, Unpublished	Y (Exist./First)	BASF

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A6.5/01	[redacted]	1978	Toxicity studies on the insecticide WL 43467: A 2 year feeding study in rats [redacted] Report No.: TLGR.0189.78 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.5/02	[redacted]	1979	Corrigendum and addendum I: Toxicity studies on the insecticide WL 43467: A 2 year feeding study in rats [redacted] Report No.: TLGR.0189.78 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.5/03	[redacted]	1981	Corrigendum and addendum II: Toxicity studies on the insecticide WL 43467: A 2 year feeding study in rats [redacted] Report No.: TLGR.0189.78 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.5/04	[redacted]	1985	Corrigendum and addendum III: Toxicity studies on the insecticide WL 43467: A 2 year feeding study in rats [redacted], Report No.: TLGR.0189.78 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.5/05	[redacted]	1996	Alphacypermethrin: oncogenicity study by dietary administration to CD 1 mice [redacted] Report No.: 95/SHL010/0596 GLP, Unpublished	Y (Exist./First)	BASF
A6.5/06	[redacted]	1999	First amendment: Alphacypermethrin: oncogenicity study by dietary administration to CD 1 mice [redacted] Report No.: 95/SHL010/0596 GLP, Unpublished	Y (Exist./First)	BASF
B6.6(01) IIB, VI 6.6	Hausmann, S. and Class, T.	1998	Decontamination of Surfaces Treated with Tenopa®. Date: 1998-11-23	Yes	BASF
A6.6.1/01	Brooks, T.M.	1993	FASTAC TM: bacterial mutagenicity studies Shell Research Ltd, Sittingbourne, UK, Report No.: SBTR.92.022 GLP, Unpublished	Y (Exist./First)	BASF
A6.6.1/02	Brooks, T.M.	1984	Genotoxicity studies with Fastac: the induction of gene mutation in the yeast Saccharomyces cerevisiae XV185-14C Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.84.117 Not GLP, Unpublished	Y (Exist./First)	BASF

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A6.6.2/01	Brooks, T.M., Wiggins, D.E.	1993	FASTAC TM: in vitro chromosome studies using cultured human lymphocytes Shell Research Ltd, Sittingbourne, UK, Report No.: SBTR.93.007 GLP, Unpublished	Y (Exist./First)	BASF
A6.6.3/01	van de Waart, E.J.	1994	Evaluation of the mutagenic activity of FASTAC technical in an in vitro mammalian cell gene mutation test with L5178Y mouse lymphoma cells (with independent repeat) Notox B.V., 's Hertogenbosch, The Netherlands, Report No.: 087367 GLP, Unpublished	Y (Exist./First)	BASF
A6.6.4/01	[redacted]	1995	Micronucleus test in bone marrow cells of the mouse with FASTAC technical [redacted] Report No.: 087378 GLP, Unpublished	Y (Exist./First)	BASF
A6.6.4/02	[redacted]	1984	Genotoxicity studies with Fastac: in vivo cytogenetic test using rat bone marrow [redacted], Report No.: SBGR.84.120 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.6.5/01	[redacted]	1982	Studies on the effect of WL 85871 on the integrity of rat liver DNA in vivo [redacted], Report No.: SBGR.81.225 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.7 cross reference to A6.5/01	[redacted]	1978	Toxicity studies on the insecticide WL 43467: A 2 year feeding study in rats [redacted], Report No.: TLGR.0189.78 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.7 cross reference to A6.5/02	[redacted]	1979	Corrigendum and addendum I: Toxicity studies on the insecticide WL 43467: A 2 year feeding study in rats [redacted] Report No.: TLGR.0189.78 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.7 cross reference to A6.5/03	[redacted]	1981	Corrigendum and addendum II: Toxicity studies on the insecticide WL 43467: A 2 year feeding study in rats [redacted] Report No.: TLGR.0189.78 Not GLP, Unpublished	Y (Exist./First)	BASF

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A6.7 cross reference to A6.5/04	[redacted]	1985	Corrigendum and addendum III: Toxicity studies on the insecticide WL 43467: A 2 year feeding study in rats [redacted] Report No.: TLGR.0189.78 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.7 cross reference to A6.5/05	[redacted]	1996	Alphacypermethrin: oncogenicity study by dietary administration to CD 1 mice [redacted] Report No.: 95/SHL010/0596 GLP, Unpublished	Y (Exist./First)	BASF
A6.7 cross reference to A6.5/06	[redacted]	1999	First amendment: Alphacypermethrin: oncogenicity study by dietary administration to CD 1 mice [redacted] Report No.: 95/SHL010/0596 GLP, Unpublished	Y (Exist./First)	BASF
A6.8.1/01	[redacted]	1994	Alphacypermethrin - Oral gavage rabbit developmental toxicity (teratogenicity) study [redacted], Report No.: SLN/4/93 GLP, Unpublished	Y (Exist./First)	BASF
A6.8.1/02	[redacted]	1994	Alphacypermethrin - Oral gavage rat developmental toxicity (teratogenicity) study [redacted] Report No.: SLN/2/92 GLP, Unpublished	Y (Exist./First)	BASF
A6.8.1/03	[redacted]	1994	Alphacypermethrin - Oral gavage rabbit developmental toxicity dose ranging study [redacted], Report No.: SLN/3/92 GLP, Unpublished	Y (Exist./First)	BASF
A6.8.1/04	[redacted]	1994	Alphacypermethrin - Oral gavage rat developmental toxicity dose ranging study [redacted] Report No.: SLN/1/92 GLP, Unpublished	Y (Exist./First)	BASF
A6.8.2/01	[redacted]	1978	Toxicity studies on the insecticide WL43467: a three generation reproduction study in rats [redacted], Report No.: TLGR.0188.78 Not GLP, Unpublished	Y (Exist./First)	BASF

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A6.8.2/02	[redacted]	1979	Corrigendum I: Toxicity studies on the insecticide WL43467: a three generation reproduction study in rats [redacted] Report No.: TLGR.0188.78 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.8.2/02	Al-Hamdani et al.	2010	Cypermethrin reversibly alters sperm count without altering fertility in mice. Ecotoxicol Environ Saf. 2010 Jul;73(5):1092-7 Not GLP, open literature	-	
A6.8.2/03	[redacted]	1979	Corrigendum II: Toxicity studies on the insecticide WL43467: a three generation reproduction study in rats [redacted] Report No.: TLGR.0188.78 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.8.2/03	Elbetieha, A et al.	2001	Evaluation of the toxic potentials of Cypermethrin pesticide on some reproductive and fertility parameters in the male rats. Arch Environ Contam Toxicol. 2001 Nov;41(4):522-8. Not GLP, open literature	-	
A6.8.2/04	[redacted]	1979	Corrigendum III: Toxicity studies on the insecticide WL43467: a three generation reproduction study in rats [redacted], Report No.: TLGR.0188.78 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.8.2/04	Hu JX, Li et al.	2011	Toxic effects of Cypermethrin on the male reproductive system: with emphasis on the androgen receptor. J Appl Toxicol. 2011 Dec 6. doi: 10.1002/jat.1769. Not GLP, open literature	-	
A6.8.2/05	[redacted]	1985	Corrigendum IV: Toxicity studies on the insecticide WL43467: a three generation reproduction study in rats [redacted], Report No.: TLGR.0188.78 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.8.2/05	Wang H et al.	2011	Maternal Cypermethrin exposure during lactation impairs testicular development and spermatogenesis in male mouse offspring. Environ Toxicol. 2011 Aug; 26(4):382-94. Not GLP, open literature	-	

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A6.8.2/06	Kemény M et al.	2012	Alphacypermethrin (BAS 310 I) - Evaluation of the endocrine disrupting potential of Alphacypermethrin (BASF Doc ID: 2012/1220476 and Amendment: 2013/1071382)	Y (Exist./First)	BASF
A6.9/01	[redacted]	1994	WL85871 (FASTAC): an acute oral (gavage) neurotoxicity study in the rat [redacted] Report No.: SBTR.92.027 GLP, Unpublished	Y (Exist./First)	BASF
A6.9/02	[redacted]	1983	Neurotoxicity of WL85871 comparison with L43467: the effect of 20 oral doses of WL85871 or WL43467 over 4 weeks on the rat sciatic/ posterior tibial nerve, trigeminal nerve and trigeminal ganglion [redacted], Report No.: SBGR.83.185 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.12.1/01	Western, N.J.	1984	Report on the assessment of FASTAC exposures during formulation of technical concentrate (TC) and technical material (TM) at Durban, South Africa - September 1983 Shell International Petroleum Maatschapij, The Hague, The Netherlands, Report No.: HSE84.003 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.12.2/01	Eadsforth, C.V. et al.	1988	Human dose-excretion studies with pyrethroids insecticides cypermethrin and alphacypermethrin: relevance for biological monitoring Xenobiotica 18, 603-614, Not GLP, Published	Y (Exist./First)	
A6.12.5/01	Tordoir	1990	Occupational health aspects of handling pesticides in Shell Agrochemical formulation plants Shell International Petroleum Maatschapij, The Hague, The Netherlands, Report No.: HSE90.009 Not GLP, Published	Y (Exist./First)	BASF
A6.12.7/01	Flannigan, S.A., Tucker, S.B.	1985	Variation in cutaneous sensation between synthetic pyrethroids insecticides Contact Derm. 13, 140-147, Not GLP, Published	Y (Exist./First)	
A6.12.7/02	Hiromori, T. et al.	1985	Therapeutic effects of methocarbamol on acute intoxication by pyrethroids in rats J. Pestic. Sci. 11, 9-14, Not GLP, Published	Y (Exist./First)	

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A6.12.8 cross reference to A5.4/01	van Heemstra-Lequin E.A.H., van Esch, G.T.	1992	Alphacypermethrin. Environmental Health Criteria 142 WHO ICPS, Geneva, Switzerland, Not GLP, Published	N	-
A6.12.8 cross reference to A6.2/04	[redacted]	1985	Human oral dose-excretion study with FASTAC [redacted], Report No.: HSE85.010 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.12.8 cross reference to A6.12.1/01	Western, N.J.	1984	Report on the assessment of FASTAC exposures during formulation of technical concentrate (TC) and technical material (TM) at Durban, South Africa - September 1983 Shell International Petroleum Maatschapij, The Hague, The Netherlands, Report No.: HSE84.003 Not GLP, Unpublished	Y (Exist./First)	BASF
A6.12.8 cross reference to A6.12.2/01	Eadsforth, C.V. et al.	1988	Human dose-excretion studies with pyrethroids insecticides cypermethrin and alphacypermethrin: relevance for biological monitoring Xenobiotica 18, 603-614, Not GLP, Published	Y (Exist./First)	
A6.12.8 cross reference to A6.12.5/01	Tordoir	1990	Occupational health aspects of handling pesticides in Shell Agrochemical formulation plants Shell International Petroleum Maatschapij, The Hague, The Netherlands, Report No.: HSE90.009 Not GLP, Published	Y (Exist./First)	BASF
A6.12.8 cross reference to A6.12.7/01	Flannigan, S.A., Tucker, S.B.	1985	Variation in cutaneous sensation between synthetic pyrethroids insecticides Contact Derm. 13, 140-147, Not GLP, Published	Y (Exist./First)	
A7.1.1.1.1/01	van Dijk, A.	1993	Hydrolysis determination of 14C-alphacypermethrin at different pH values RCC Umweltchemie AG, Itingen, Switzerland, Report No.: 307383 GLP, Unpublished	Y (Exist./First)	BASF
A7.1.1.1.1/02	Salisbury, K. et al.	1984	The hydrolysis of Fastac (WL85871) Shell Research Ltd, Sittingbourne, UK, Report No.: SBRN.84.172 Not GLP, Unpublished	Y (Exist./First)	BASF

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A7.1.1.1.2/01	Concha, M. et al.	2001	BAS 310 I (Alphacypermethrin): aqueous photolysis PTRL West, Inc., Hercules, CA, USA, Report No.: ENV01-037 GLP, Unpublished	Y (Exist./First)	BASF
A7.1.1.1.2/02	Fisk, P.R.	1994	Alphacypermethrin (FASTAC): photodegradation in water (preliminary experiment), including a comparison with esfenvalerate Shell Research Ltd, Sittingbourne, UK, Report No.: SBTR.93.030 GLP, Unpublished	Y (Exist./First)	BASF
A7.1.1.2.1/01	Stone, C.M., Watkinson, R.J.	1983	WL85871: an assessment of ready biodegradability Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.83.206 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.1.2.2.2/01	Mamouni, A.	1993	FASTAC (Benzyl-14C): degradation and metabolism in aquatic systems RCC Umweltchemie AG, Itingen, Switzerland, Report No.: 305864 GLP, Unpublished	Y (Exist./First)	BASF
A7.1.2.2.2/02	Völkl,S.	1993	14C-Alphacypermethrin (Cyclopropyl-1-14C): degradation and metabolism in aquatic systems RCC Umweltchemie AG, Itingen, Switzerland, Report No.: 316326 GLP, Unpublished	Y (Exist./First)	BASF
A7.1.2.2.2/03	Beigel, C.	2001	Calculation of first-order DT50 and DT90 values of Alphacypermethrin in the water and sediment phases of river-sediment and pond-sediment aquatic systems BASF Agro Research, Princeton, NJ, USA, Report No.: EXA-01-023 GLP, Unpublished	Y (Exist./First)	BASF
A7.1.2.2.2/04	Beigel, C.	2001	Calculation of DT50 and DT90 values of Alphacypermethrin metabolites CL 206128 and CL 912554 in river sediment and pond sediment aquatic systems BASF Agro Research, Princeton, NJ, USA, Report No.: EXA-01-006 GLP, Unpublished	Y (Exist./First)	BASF
A7.1.2.2.2/05	Dutton, A.J., Pearson, N.	1987	An outdoor tank experiment to study the fate of "FASTAC" in the aquatic evironment Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.87.125 Not GLP, Unpublished	Y (Exist./First)	BASF

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.1.2.2.2/06	Pearson, N.	1990	The fate of FASTAC in experimental ponds Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.88.177 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.2.1/01	Gedik, L., Keirs, D.C.	2001	14C-Alphacypermethrin (BAS 310 I): degradation in soil under aerobic conditions Inveresk Research, Tranent, UK, Report No.: ENV01-012 GLP, Unpublished	Y (Exist./First)	BASF
A7.2.2.1/01	McMinn, A.L.	1983	The degradation of the pyrethroid insecticides WL 85871 (FASTAC) and WL 43481 in soil Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.83.395 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.2.2.1/02	Standen, M.E.	1976	The degradation of the insecticide WL 43467 in soil under laboratory conditions Shell Research Ltd, Sittingbourne, UK, Report No.: WKGR.0094.76 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.2.2.1/03	Roberts, T.R.	1980	Appendices to Shell report no. WKGR.0094.76: The degradation of the insecticide WL 43467 in soil under laboratory conditions Shell Research Ltd, Sittingbourne, UK, Report No.: WKGR.0094.76 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.2.2.1/04	Standen, M.E.	1978	Further studies of the degradation of the insecticide WL43467 (Cypermethrin) in soil under laboratory conditions Shell Research Ltd, Sittingbourne, UK, Report No.: BLGR.0034.78 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.2.2.1/05	Beigel, C.	2002	Calculation of DT50 and DT90 values of 3-phenoxybenzoic acid (metabolite of cypermethrin and alphacypermethrin) in two soils treated with cis-cypermethrin BASF Agro Research, Princeton, NJ, USA, Report No.: EXA02-006 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.2.2.2/01	Bosio, P.	1983	Residues of WL 85871 and metabolites in soil from U.K. treated with FASTAC - 1981/82 trials Shell Chimie, Berre, France, Report No.: BEGR.83.040 Not GLP, Unpublished	Y (Exist./First)	BASF

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.2.2.2/02	Forbes, S., Knight, C.	1983	Analysis of soil from UK for residues of WL85871 - soil persistence trial - first year Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.83.162 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.2.2.2/03	Forbes, S., MacKay, C.	1983	Analysis of soil from UK (Coates) for residues of WL85871 (FASTAC) - soil persistence trial - first year Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.83.418 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.2.2.2/04	Forbes, S., Burden, A.	1983	Analysis of soil from UK (Reculver) for residues of WL85871 (FASTAC) - soil persistence trial - second year Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.84.005 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.2.2.2/05	Forbes, S., Burden, A.	1983	Analysis of soil from UK (Hoath) for residues of WL85871 (FASTAC) - soil persistence trial - second year Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.84.006 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.2.2.2/06	Forbes, S., Wales, G.H.	1985	Analysis of soil from UK (Reculver) for residues of FASTAC* (WL85871) - soil persistence trial - third year Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.85.070 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.2.2.2/07	Forbes, S., Wales, G.H.	1985	Analysis of soil from UK (Coates) for residues of FASTAC* (WL85871) - soil persistence trial - second year Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.85.071 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.2.2.2/08	Forbes, S., Wales, G.H.	1985	Analysis of soil from UK (Hoath) for residues of FASTAC* (WL85871) - soil persistence trial - third year Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.85.072 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.2.2.2/09	Coveney, P.C., Forbes, S.	1986	Analysis of soil from UK (Coates) for residues of "FASTAC" (WL85871) - soil persistence trial - third year Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.86.201 Not GLP, Unpublished	Y (Exist./First)	BASF

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.2.2.3/01	Standen, M.E.	1978	The bioavailability and further degradation of bound residues arising from WL43467 in soils Shell Research Ltd, Sittingbourne, UK, Report No.: BLGR.0079.78 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.2.2.4/01	van Dijk, A., Burri, R.	1993	14C-Alphacypermethrin: study of its photodegradation in soil RCC Umweltchemie AG, Itingen, Switzerland, Report No.: 299777 GLP, Unpublished	Y (Exist./First)	BASF
A7.2.3.1/01	Hill, A.D.	1993	Benzyl-14C WL85871 (FASTAC): adsorption/desorption in three soils Shell Research Ltd, Sittingbourne, UK, Report No.: SBTR.93.042 GLP, Unpublished	Y (Exist./First)	BASF
A7.2.3.1/02	Holman,J.C.	2002	14C-CL 206128 (Metabolite of BAS 310 I, alphacypermethrin): adsorption/desorption on soils BASF Agro Research, Princeton, NJ, USA, Report No.: ENV02-004 GLP, Unpublished	Y (Exist./First)	BASF
A7.2.3.2/01	Jackson, C.	1977	The leaching of WL 43467 through laboratory soil columns Shell Research Ltd, Sittingbourne, UK, Report No.: BLGR.0150.77 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.2.3.2/02	Stevens, J.E.B., Hill, I.R.	1980	Cypermethrin: mobility of cypermethrin and its degradation products in soil columns ICI Plant Protection Division, Report No.: RJ0166B Not GLP, Unpublished	Y (Exist./First)	BASF
A7.3.1/01	Mangels, G.	1995	Alphacypermethrin: estimation of the photochemical oxidation rate in the atmosphere American Cyanamid Company, Princeton, NJ, USA, Report No.: ENV95-017 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.4.1.1/01	[redacted]	1983	WL85871 and cypermethrin: a comparative study of their toxicity to the Fathead minnow Pimephales promelas (Rafinesque) [redacted], Report No.: SBGR.82.298 Not GLP, Unpublished	Y (Exist./First)	BASF

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A7.4.1.1/02	[redacted]	1981	WL85871 and cypermethrin: a comparison of their acute toxicity to Salmon gairdneri, Daphnia magna and Selenastrum capricornutum [redacted] Report No.: SBGR.81.277 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.4.1.1/03	[redacted]	2002	CL 912554 (metabolite of BAS 310I, Alpha-Cypermethrin) - acute toxicity study on the bluegill sunfish (Lepomis macrochirus) in a static system over 96 hours [redacted], Report No.: 14F0420/015033 GLP, Unpublished	Y (Exist./First)	BASF
A7.4.1.1/04	[redacted]	2002	CL 206128 (metabolite of BAS 310I, Alpha-Cypermethrin) - acute toxicity study on the bluegill sunfish (Lepomis macrochirus) in a static system over 96 hours [redacted], Report No.: 14F0418/015034 GLP, Unpublished	Y (Exist./First)	BASF
A7.4.1.2 cross reference to A7.4.1.1/02	[redacted]	1981	WL85871 and cypermethrin: a comparison of their acute toxicity to Salmon gairdneri, Daphnia magna and Selenastrum capricornutum [redacted], Report No.: SBGR.81.277 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.4.1.2/01	Jatzek, J.	2001	Reg. No. 4080830: determination of the acute effect on the swimming ability of the water flea Daphnia magna STRAUS BASF AG, Ludwigshafen, Germany, Report No.: 01/0420/50/1 GLP, Unpublished	Y (Exist./First)	BASF
A7.4.1.2/02	Jatzek, J.	2001	CL 206128 (metabolite of BAS 310I, Alpha-Cypermethrin) - determination of the acute effect on swimming ability of the water flea Daphnia magna STRAUS BASF AG, Ludwigshafen, Germany, Report No.: 01/0418/50/1 GLP, Unpublished	Y (Exist./First)	BASF
A7.4.1.2/03	Jatzek, J.	2002	CL 206969 - determination of the acute effect on swimming ability of the water flea Daphnia magna STRAUS BASF AG, Ludwigshafen, Germany, Report No.: 01/0419/50/2 GLP, Unpublished	Y (Exist./First)	BASF

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A7.4.1.3/01	Jatzek, J.	2002	BAS 310 I - determination of inhibitory effect on the cell multiplication of unicellular green algae BASF AG, Ludwigshafen, Germany, Report No.: 01/0265/60/1 GLP, Unpublished	Y (Exist./First)	BASF
A7.4.1.3/02	Werner, D.I.	2002	CL 912554 (metabolite of BAS 310I, α-Cypermethrin) – determination of the inhibitory effect on the cell multiplication of unicellular green algae BASF AG, Ludwigshafen, Germany, Report No.: 01/0420/60/2 GLP, Unpublished	Y (Exist./First)	BASF
A7.4.1.3/03	Werner, D.I.	2002	CL 206128 (metabolite of BAS 310I, α-Cypermethrin) – determination of the inhibitory effect on the cell multiplication of unicellular green algae BASF AG, Ludwigshafen, Germany, Report No.: 01/0421/60/2 GLP, Unpublished	Y (Exist./First)	BASF
A7.4.1.4/01	Lebertz, H., Zhjixing, Y.	2001	Alphacypermethrin (BAS 310 I): activated sludge, respiration inhibition test Institut Fresenius, Taunusstein, Germany, Report No.: IF-100/29753-00 GLP, Unpublished	Y (Exist./First)	BASF
A7.4.2/01	Sendor, T.	2005	Estimation of the bioconcentration factor (BCF) of Alphacypermethrin. EBRC Consulting GmbH, Hannover, Germany, Report No.: BAS-051114-01 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.4.3.2 cross reference to A7.4.1.1/01	[redacted]	1983	WL85871 and cypermethrin: a comparative study of their toxicity to the Fathead minnow Pimephales promelas (Rafinesque) [redacted] Report No.: SBGR.82.298 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.4.3.3.1/01	[redacted]	1997	Bioconcentration study of alpha-cypermethrin with carp [redacted] Report No.: 6B332G GLP, Unpublished	Y (Exist./First)	BASF
A7.4.3.4/01	Garforth, B.	1982	WL 85871 and cypermethrin: chronic toxicity to Daphnia magna Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.82.119 Not GLP, Unpublished	Y (Exist./First)	BASF

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A7.4.3.5/01	Huber, W. et al.	2000	Evaluation of effects of a 100 g/L SC formulation (CF 06677) of AC 900049 (alphacypermethrin) on macroinvertebrates, zooplankton and algae in enclosures in ponds Technical University of Munich Weihenstephan, Freising, Germany, Report No.: ECO-97-144 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.4.3.5/02	Huber, W. et al.	2000	Evaluation of possible effects of a 100 g/l SC formulation (CF 06677) of AC 900049 (alphacypermethrin) on macroinvertebrates, zooplankton and algae in pond-enclosures and determination of the ecologically acceptable concentration (EAC) Technical University of Munich-Weihenstephan, Germany, Report No.: ETX-99-101 GLP, Unpublished	Y (Exist./First)	BASF
A7.4.3.5/03	Huber, W.	2000	Summary of an expert panel opinion of the study "Evaluation of possible effects of a 100 g/L SC formulation (CF 06677) of AC 900049 (alphacyp.) on makroinvertebrates, zooplankton, and algae in pond-enclosures and determination of the EAC Institute of Aquatic Ecotoxicology, Buch am Erlbach, Germany, Report No.: 2000/I Not GLP, Unpublished	Y (Exist./First)	BASF
A7.4.3.5/04	Huber, W.	2000	Evaluation of an Ecologically Acceptable Concentration (EAC) for alphacypermethrin in aquatic environments Institute of Aquatic Ecotoxicology, Buch am Erlbach, Germany, Report No.: 2000/II Not GLP, Unpublished	Y (Exist./First)	BASF
A7.4.3.5/05	Huber, W.	2003	Expert opinion on the results from modified laboratory toxicity tests and population modeling with aquatic macroinvertebrates and FASTAC® OESC insecticide (alphacypermethrin) Institute of Aquatic Ecotoxicology, Buch am Erlbach, Germany, Report No.: 03/1 Not GLP, Unpublished	Y (Exist./First)	BASF

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.4.3.5/06	Ratte, H.T., Strauss, T.	2002	The response and recovery of a mesocosm population of Chaoborus crystallinus (Diptera) at multiple applications of 0.015 µg a.i./L FASTAC OESC (active ingredient; alphacypermethrin, BAS 310 I) - a modeling approach Dept. of Biology V, University of Technology, Aachen, Germany, Report No.: 145555 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.4.3.5/07	Mitchell, G.C.	2003	Alphacypermethrin: an overview of effects of FASTAC on aquatic macroinvertebrates, with particular reference to the midge Chaoborus crystallinus (Chaoboriedae: Diptera) Ecotoxicology Services, Yardley, PA, USA, Report No.: ES060301 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.4.3.5/08	Huber, W. et al.	2001	Evaluation of the effects of multiple applications of a 100 g/L SC formulation (FASTAC, OESC, CF 06677) of alphacypermethrin (AC 900049) on macroinvertebrates, zooplankton and algae in pond-enclosures Technical University of Munich-Weihenstephan, Germany, Report No.: ECO00-268 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.4.3.5/09	Huber, W., Grünwald, H.	2002	Toxicity of Alphacypermethrin (BAS 310 I, AC 900049) in a 100 g/L OESC formulation (FASTAC OESC insecticide, CF 06677) to aquatic macroinvertebrates (Cloeon, Gammarus) in laboratory microcosms Technical University of Munich-Weihenstephan, Freising, Germany, Report No.: LSÖ 02/3 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.4.3.5/10	Funk, M. et al.	2000	Acute toxicity of alphacypermethrin (AC900049) in a 100 g/L OESC formulation (CF06677) to aquatic macroinvertebrates Technical University of Munich-Weihenstephan, Freising, Germany, Report No.: 98-I Not GLP, Unpublished	Y (Exist./First)	BASF

Section No / Reference No	Author(s)	Year	Title. Source, Report No. GLP / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.4.3.5/11	Hahn, T.	2002	Effects of Alphacypermethrin (BAS 310 03 I) applied as FASTAC OESC on aquatic macroinvertebrates (Ephemeroptera and Trichoptera) in extended "standard" laboratory testsZoologisches Institut der TU Braunschweig Zoologisches Institut der TU Braunschweig, Braunschweig, Germany, Report No.: 14-53-81 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.4.3.5.1/01	Heintze, A.	1997	Alphacypermethrin (AC 900049): effects on the development of sediment-dwelling larvae of Chironomus riparius in a water-sediment system GAB, Niefern-Öschelbronn, Germany, Report No.: ECO96-325 GLP, Unpublished	Y (Exist./First)	BASF
A7.5.1.1/01	Kölzer, U.	2006	Effects of BAS 310 I (Reg. No. 4078193) on the activity of the soil microflora - nitrogen transformation test (ECx) GAB, Niefern-Öschelbronn, Germany, Report No.: 20061048/01-ABMF GLP, Unpublished	Y (Exist./First)	BASF
A7.5.1.1/02	Kölzer, U.	2006	Effects of BAS 310 I (Reg. No. 4078193) on the activity of the soil microflora - carbon transformation test (ECx) GAB, Niefern-Öschelbronn, Germany, Report No.: 20061048/02-ABMF GLP, Unpublished	Y (Exist./First)	BASF
A7.5.1.2/01	Weyman, G.S., Canez, V.M.	1998	14-day earthworm (Eisenia foetida) acute toxicity study with Alphacypermethrin (AC 900049) in a 150 g/kg WG formulation (RLF 12152) Covance, Harrogate, UK, Report No.: ECO97-196 GLP, Unpublished	Y (Exist./First)	BASF
A7.5.1.2/02	Inglesfield, C., Sherwood, C.	1983	Toxicity of Cypermethrin and WL85871 to the earthworm Eisenia foetida L. (Oligochaeta: Lumbriculidae) in laboratory tests Shell Research Ltd, Sittingbourne, UK, Report No.: SBGR.83.071 Not GLP, Unpublished	Y (Exist./First)	BASF
A7.5.1.2/03	Staab, F.	2001	Effect of metabolite CL 206 128 (metabolite of α-Cyper-methrine) on the mortality of the earthworm Eisenia fetida BASF AG, Limburgerhof, Germany, Report No.: 108413 GLP, Unpublished	Y (Exist./First)	BASF

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A7.5.1.2/04	Staab, F.	2001	Effect of metabolite CL 912554 (metabolite of α-Cypermethrine) on the mortality of the earthworm Eisenia fetida BASF AG, Limburgerhof, Germany, Report No.: 108441 GLP, Unpublished	Y (Exist./First)	BASF
A7.5.3.1.1/01	[redacted]	2000	Avian acute oral toxicity test with Alphacypermethrin (AC 900049) technical in Northern bobwhites (Colinus virginianus) [redacted] Report No.: 105-046-03 GLP, Unpublished	Y (Exist./First)	BASF
A7.5.3.1.2/01	[redacted]	2001	Alphacypermethrin (BAS 310 I) dietary toxicity (LC50) to the Northern bobwhite (Colinus virginianus) [redacted] Report No.: CYD/632 GLP, Unpublished	Y (Exist./First)	BASF
A7.5.3.1.3/01	[redacted]	2001	Alphacypermethrin (BAS 310 I) assessment to determine the effects on reproduction in northern bobwhite (Colinus virginianus) [redacted], Report No.: ETX-00-183 GLP, Unpublished	Y (Exist./First)	BASF
A7.5.5.1/01	Sendor, T.	2005	Estimation of the terrestrial bioconcentration factor (BCF) of Alphacypermethrin EBRC Consulting GmbH, Hannover, Germany, Report No.: BAS-20051214-01 Not GLP, Unpublished	Y (Exist./First)	BASF
B8.1(01) IIB, VIII 8.1 also filed: B8.2(01), also filed: B8.4(01), also filed: B8.5(01), also filed: B8.6(01)	Anonymous	2006	Safety data sheet TENOPA® 30/30 g/L SC (NPE free). Date: 2006-04-19	-	BASF
A8.1/01	Anonymous	2006	Safety data sheet according to 91/155/EEC – Alphacypermethrin technical BASF AG, Not GLP, Unpublished	N	BASF

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B8.2(01) IIB, VIII 8.2 also filed: B8.1(01), also filed: B8.4(01), also filed: B8.5(01), also filed: B8.6(01)	Anonymous	2006	Safety data sheet TENOPA® 30/30 g/L SC (NPE free). Date: 2006-04-19	-	BASF
A8.4/01	Schenk, W.	2001	Possible procedures for the decontamination of water from Alpha-Cypermethrin BASF AG, Ludwigshafen, Germany, Report No.: 900049 Not GLP, Unpublished	Y (Exist./First)	BASF
B8.4(01) IIB, VIII 8.4 also filed: B8.1(01), also filed: B8.2(01), also filed: B8.5(01), also filed: B8.6(01)	Anonymous	2006	Safety data sheet TENOPA® 30/30 g/L SC (NPE free). Date: Date: 2006-04-19	-	BASF
B8.5(01) IIB, VIII 8.5 also filed: B8.1(01), also filed: B8.2(01), also filed: B8.4(01), also filed: B8.6(01)	Anonymous	2006	Safety data sheet TENOPA® 30/30 g/L SC (NPE free). Date: Date: 2006-04-19	-	BASF
B8.6(01) IIB, VIII 8.6 also filed: B8.1(01), also filed: B8.2(01), also filed: B8.4(01), also filed: B8.5(01)	Anonymous	2006	Safety data sheet TENOPA® 30/30 g/L SC (NPE free). Date: Date: 2006-04-19	-	BASF