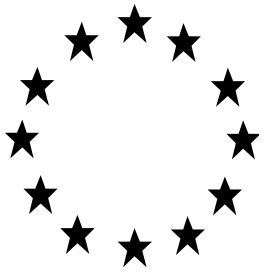
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Cyfluthrin

Product-type 18

(Insecticides, Acaricides and Products to control other Arthropods)

March 2016

Germany

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

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

Cyfluthrin (CAS no. 68359-37-5) was notified as an existing active substance, by Bayer SAS, Bayer CropScience, Environmental Science Division, France, 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, Germany 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 cyfluthrin as an active substance in product type 18 was 30 April 2006, in accordance with Annex V of Regulation (EC) No 1451/2007.

On 06 April 2006, the German competent authority received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 06 October 2006.

The representative products are the insecticides Solfac® EW 050 produced by Bayer CropScience and Cyfluthrin Foam produced by S.C. Johnson Limited.

On 23 December 2010, 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 on the Technical Meeting III/2011 were presented at the Biocidal Products Committee and the competent authority report was amended accordingly.

1.2. Purpose of the assessment report

The aim of the assessment report is to support the opinion of the Biocidal Products Committee and a decision on the approval of cyfluthrin 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 applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

[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

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

Identity, Physico-chemical Properties and Method of Analysis of Cyfluthrin

Identity and Physico-chemical Properties

The data on the reference specification of cyfluthrin (CAS-No.: 68359-37-5) are given in detail in the confidential part of the dossier. The evaluation has established that for the active substance notified by the applicant, none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

Cyfluthrin is a brown viscous mass with crystalline parts. Four diastereomers are stated. Cyfluthrin is nearly insoluble and does not dissociate in water. It has a low vapour pressure, and can safely be assumed to be essentially non-volatile from water, based on its Henry's Law constant. The logPow is about 6 for all diastereomers.

Cyfluthrin is neither flammable, explosive nor has oxidising properties.

In conclusion, no hazard indication is required for Cyfluthrin with regard to physical/chemical data.

Analytical Methods for Detection and Identification

Residue analytical methods are available for the active substance in soil, drinking water, air and body tissues. An analytical method for the metabolites DCCA (= DCVA or permethric acid) and FPBA in urine is also available. Validated confirmatory methods are presented for soil and air. The LOQ of analytical method for cyfluthrin in surface water of 0.02 µg/L exceeds the corresponding NOEC value of 0.01µg/L (O. mykiss). The method uses GC columns which differ only slightly in the retention behaviour and is not acceptable for confirmation. Therefore, for product authorisation a sufficiently sensitive analytical method for cyfluthrin in surface water is required.

Identity, Physico-chemical Properties and Method of Analysis of Solfac® EW 050 and Cyfluthrin Foam

Identity and Physico-chemical Properties

The identity of the insecticides, which contain less than 5 % of the active substance cyfluthrin, is given in detail in the confidential part of the dossier (see Confidential Section / Doc. II Appendix 2 and 3). Due to the nature of both biocidal products (aqueous solutions), the biocidal products Solfac® EW 050 and Cyfluthrin Foam are not expected to exhibit any hazardous physico-chemical properties.

Analytical Methods for Detection and Identification

Cyfluthrin is the only substance of concern and adequate analytical methods are provided for soil, drinking and surface water, air, body fluids and tissues. Therefore, additional analytical methods to determine residues of cyfluthrin from the biocidal products Cyfluthrin

Foam and Solfac® EW 050 in food and feeding stuffs are not considered necessary.

2.1.2. Intended Uses and Efficacy

Cyfluthrin is a pyrethroid insecticide acting by ingestion and contact. The intended uses of cyfluthrin based products are to control flying and crawling insects, such as house flies, litter beetles as well as fleas and red mites in animal housings (Solfac® EW 050, for use by professionals) as well as cockroaches (adults, nymphs), ants and termites indoors (Cyfluthrin Foam, ready to use for use by non-professionals in households). Application of Solfac® EW 050 is by spraying a strip of 1-2 m width on window frames and to ceilings using a low-pressure Knapsack (backpack) sprayer, while Cyfluthrin Foam is used as surface treatment and/or applied to crack and crevices.

The efficacy of cyfluthrin is well established and acceptable studies indicating sufficient efficacy of the active substance have been provided. Evaluation of the data submitted in support of the efficacy of the accompanying products establishes that the products are expected to be efficacious.

Solfac® EW 050, a spray product for professional use in animal housings against flies, litter beetles and red mites: While the list of intended uses claims efficacy against "flying and crawling insects", sufficient efficacy data have been supplied against the house fly (Musca domestica), German cockroaches (Blattella germanica), the Litter Beetle (Alphitobius diaperinus) and the red poultry mite (Dermanyssus gallinae). Data provided support the notion that the product can be considered efficacious for up to six weeks against litter beetles (three weeks for larvae), 10 weeks against house flies and 12 weeks against the German cockroach. Other claims would need support during the product authorisation phase.

Cyfluthrin Foam, a ready-for-use household foam spray is claimed being efficacious in controlling crawling insects, specifically cockroaches, ants and termites. The evaluation of the available data shows that efficacy against cockroaches, ants and termites was sufficiently demonstrated.

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

Resistance against pyrethroids can occur in relevant susceptible pests. In Europe, the main problems have occurred in some areas with pests of agricultural significance among some species of flies and cockroach populations. Cross-resistance of pest species to the group of synthetic pyrethroids is to be anticipated due to a common mode of action and instances of cross-resistance (or multiple resistance) between pyrethroids and organochlorine insecticides have been reported. Precautions have to be taken to reduce the possibility of insects developing resistance to synthetic pyrethroids. Appropriate management strategies are detailed in Section 7.5 of Doc II.

2.1.3. Classification and Labelling

Classification and Labelling of Cyfluthrin

Table 2-1 Current classification of cyfluthrin based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Acute Tox. 2* Acute Tox. 3* Aquatic Acute 1 Aquatic Chronic 1	
Hazard statements	H300 H331 H400 H410	Fatal if swallowed Toxic if inhaled Very toxic to aquatic life Very toxic to aquatic life with long lasting effects.
M-Factor:	1000 (acute and chronic	

Table 2-2 Proposed classification of cyfluthrin based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Acute Tox. 2 Acute Tox. 2 STOT-SE3 Lact. Aquatic Acute 1 Aquatic Chronic 1	
Hazard statements	H300 H330 H335 H362 H400 H410	Fatal if swallowed Fatal if inhaled May cause respiratory irritation May cause harm to breast-fed children Very toxic to aquatic life Very toxic to aquatic life with long lasting effects.
M-Factor:	1 000 000 acute 100 000 chronic	

Remark:

In Regulation (EC) No 1272/2008 (including a "translation into GHS" of the 29th ATP), the classification of cyfluthrin (Acute Tox. 3, H331; Acute Tox. 2, H300) is marked as a "minimum classification". This indicates that the direct translation which was not done case-by-case but in a categorized manner might have led to a less severe classification (in this case for inhalation: Acute Tox. 3, H331) than the existing data would imply (Acute Tox. 2, H330) because the hazard categories in GHS are not directly compatible with the criteria for classification in 67/548/EEC. As outlined in Regulation (EC) No 1272/2008, in cases where there is "access to data or other information as specified in Part 1 of Annex I that lead to classification in a more severe category compared to the minimum classification, "classification in the more severe category must then be applied". Thus, for cyfluthrin "Acute Tox. 2, H300" for acute oral toxicity and the more severe classification "Acute Tox. 2, H330" for acute inhalation toxicity based on an LC_{50} of 0.4 mg/L x 4 h aerosol has to be applied since the upper limit for Cat. 2 in GHS is 0.5 mg/L. Furthermore, cyfluthrin might evoke sensory irritation and might cause harm to breast-fed children.

Therefore, classification with STOT SE3, H335 and Lact., H362 is proposed, respectively.

Table 2-3 Proposed labelling of cyfluthrin based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	GHS06 GHS09	
Signal Word	Danger	
Hazard statements	H300 H330 H335 H362 H410	Fatal if swallowed Fatal if inhaled May cause respiratory irritation May cause harm to breast-fed children Very toxic to aquatic life with long lasting effects
Precautionary statements	(P102) P260 P263 P264 P270 P273 P284 P301 + P310 P330 P308 + P313 P391 P403 + P233 P405 P501	Keep out of reach of children. Do not breathe dust/fume/gas/mist/vapours/spray Avoid contact during pregnancy/while nursing. Wash … thoroughly after handling Do not eat, drink or smoke when using this product Avoid release to the environment Wear respiratory protection IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician Rinse mouth If exposed or concerned: Get medical advice/ attention. Collect spillage Store in a well-ventilated place. Keep container tightly closed Store locked up Dispose of contents/container as to …

Remark:

The list of the precautionary statements is quite long but they were all recommended in Annex I of Regulation (EC) No 1272/2008 based on the given hazard statements. When there were several precautionary statements with almost the same wording only the most severe one was included to reduce their overall number.

The classification and labelling based on ecotoxicological properties proposed by the RMS is in accordance with directive 67/548/EEC (up to 31st ATP) and Regulation (EC) No. 1272/2008 (up to 5th ATP). For the CLP Regulation (EC) 1272/2008 Cyfluthrin has already been classified in the corresponding 1st ATP as H400 and H410 with a M-factor of 1 000. The acute toxicity for crustacea (EC_{50} = 0.55 ng/L for *H. azteca*) and the prolonged toxicity for crustacea (NOEC = 0.41 ng β-cyfluthrin/L for *A. bahia*) justify the classification as "H400 aquatic acute I" and "H410 aquatic chronic I". However, considering the 3rd ATP, an M-factor of 1 000 000 for acute and 100 000 for chronic ecotoxicity is proposed.

Classification and Labelling of the biocidal products

Classification and Labelling of the biocidal product Cyfluthrin Foam (Non-prof. use)

Table 2-4 Proposed classification of Cyfluthrin Foam based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Flam. Aerosol 1 Eye Irritation 2 Aquatic Acute 1 Aquatic Chronic 1	
Hazard statements	H222 H229 H319 H400 H410	Extremely flammable aerosol Pressurized container: may burst if heated Causes serious eye irritation Very toxic to aquatic life Very toxic to aquatic life with long lasting effects

Remark:

The biocidal product Cyfluthrin Foam is proposed for classifying as Aquatic Acute 1 and Aquatic Chronic 1 under consideration the multiplying factors 1000000 (acute) and 100000 (chronic) for highly toxic components of mixtures and by applying the summation method. Due to the content of 2-propanol, the biocidal product Cyfluthrin Foam is proposed for classifying as Eye Irritation Cat. 2 according to Reg. 1272/2008.

Table 2-5 Proposed labelling of Cyfluthrin Foam based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	GHS02 GHS09 GHS07	
Signal Word	Danger	
Hazard statements	H222 H229 H319 H410	Extremely flammable aerosol Pressurized container: may burst if heated Causes serious eye irritation Very toxic to aquatic life with long lasting effects

	Labelling	Wording
Precautionary statements	P101	If medical advice is needed, have product container or label at hand
	P102	Keep out of reach of children
	P210	Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
	P211	Do not spray on an open flame or other ignition source.
	P251	Pressurized container: Do not pierce or burn, even after use.
	P264	Wash … thoroughly after handling.
	P280*	Wear protective gloves/protective clothing/eye protection/face protection.
	P273	Avoid release to the environment
	P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
	P337+P313	Continue rinsing. If eye irritation persists: Get medical advice/attention.
	P391	Collect spillage
	P410 + P412	Protect from sunlight. Do no expose to temperatures exceeding 50 °C/122 F.
	P501	Dispose of contents/container to …

Remark:

The labelling of the biocidal product is transformed based on the rules of the Regulation (EC) No 1272/2008 and the recommendations given in the Guidance to Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (IHCP, DG Joint Research Centre, European Commission, 2009).

* P280 is not suitable for the non-professional user, therefore other risk mitigation measures have to be considered if eye contact is possible/relevant.

Classification and Labelling of the biocidal product Solfac® EW 050

Table 2-6 Proposed classification of Solfac® EW 050 based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	
Hazard statements	H317 H400 H410	May cause an allergic skin reaction Very toxic to aquatic life Very toxic to aquatic life with long lasting effects.

Remark:

The biocidal product Solfac® EW 050 is proposed for classifying as Aquatic Acute 1 and Aquatic Chronic 1 under consideration the multiplying factors 1000000 (acute) and 100000 (chronic) for highly toxic components of mixtures and by applying the summation method.

Table 2-7 Proposed labelling of Solfac® EW 050 based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	 GHS07 GHS09	
Signal Word	Warning	
Hazard statements	H317 H410	May cause an allergic skin reaction Very toxic to aquatic life with long lasting effects.
Precautionary statements	(P102) P272 P273 P280 P285 P302 + P352 P363 P391 P501	Keep out of reach of children Contaminated work clothing should not be allowed out of the workplace Avoid release to the environment Wear protective gloves/protective clothing/eye protection/face protection In case of inadequate ventilation wear respiratory protection IF ON SKIN: Wash with plenty of soap and water Wash contaminated clothing before reuse Collect spillage Dispose of contents/container to …

Remark:

The labelling of the biocidal product is transformed based on the rules of the Regulation (EC) No 1272/2008 and the recommendations given in the Guidance to Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (IHCP, DG Joint Research Centre, European Commission, 2009).
Concerning the identified risk regarding the application of Solfac® EW 050 in stables and the release of waste water to STP or directly to surface water the following label has to be applied:
"DO NOT USE this biocidal product (and/or insert name) containing Cyfluthrin as the active substance where effluent/waste liquid from animal housing and/or manure storage areas can be discharged to sewage treatment plants or surface water".

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Justification for Read-across between toxicological studies on cyfluthrin (FCR 1272) and beta-cyfluthrin (FCR 4545)

Cyfluthrin consists of a mixture of four diastereoisomeric pairs of enantiomers (I, II, III, IV). Beta cyfluthrin contains more diasteromers II and IV in comparison to cyfluthrin. The toxicological profiles of cyfluthrin and beta-cyfluthrin appeared to be qualitatively similar. With respect to neurotoxicity, beta-cyfluthrin, being the biologically active component of cyfluthrin, is more potent than cyfluthrin (JMPR, 2006). Therefore, it is concluded that studies with beta-cyfluthrin might be applied for cyfluthrin risk assessment when no studies with cyfluthrin or insufficient data are available.

2.2.1.2. Effects assessment

Absorption, Distribution, Excretion, and Metabolism

Following oral administration, cyfluthrin was absorbed to nearly 100 % by male and 90 % by female rats based on comparison of the renally and faecal excreted radioactivity plus the radioactivity in the body at sacrifice (48 h) after i.v. and oral dosing. This was confirmed by the results of the study in rats with bile cannulation (90 % excretion in bile and urine). The radioactivity of cyfluthrin was slowly and uniformly distributed from the intravascular space to the tissues (half-life initially 2.1 h, later 20 h). The radioactivity was rapidly eliminated from the body within two days after oral and intravenous administration. Cyfluthrin was extensively metabolised in rats, the excreted amounts of unchanged parent compound were low (< 1 %). The main metabolite of the five identified metabolites was a 4'OH-FPB-acid-conjugate (FPB-acid = 4-fluoro-3-phenoxybenzoic acid), followed by 4'OH-FPB-acid (up to 11 % in urine and faeces), FPB-acid, hippuric acid and a conjugate of hydroxylated hippuric acid.

No dermal absorption studies are available for the active substance cyfluthrin. An in vitro skin penetration assay in human and rat skin and an in vivo skin penetration assay in the rat with a beta-cyfluthrin formulation (beta-cyfluthrin FS125) are submitted. Due to the high variability in the in vitro and in vivo data and the overestimated value of in vivo absorption in the rat study (only the amount of radioactivity in tape stripe 1 was reported separately and could be excluded) RMS proposes to use the in vitro data derived with human skin for risk assessment and refrain from a "triple pack" calculation. Based on the result from the in vitro study with human skin and considering uncertainties due to high variations, dermal absorption of cyfluthrin was estimated to be 1 % for both the high (1.25 mg/cm^2) and low dose (0.38 mg/cm^2) in humans. This dermal absorption is used for Solfac® EW.

For Cyfluthrin no studies were submitted and 10% dermal absorption was assumed based on expert judgement.

Acute Toxicity

Cyfluthrin was acutely very toxic when administered orally in aqueous emulsion (cremophor EL/distilled water) with an LD50 of 16.2 mg/kg bw, and of high to moderate toxicity following oral exposure in acetone/peanut oil (LD50: 155/160 mg/kg bw (M/F)), DMSO (LD50: 396 mg/kg bw) and N-methyl pyrrolidone (LD50: 590 mg/kg). Onset of death was within 2-3 hours for the aqueous emulsion and 1-2 days for the other preparations. The clinical signs were observed in all animals even within the lowest

treatment dose and indicated an effect on the central nervous system (tremor, rolling movements, disturbed motility and respiration). Onset of symptoms arose within one hour and was apparent for 1 to 5 days.

Cyfluthrin was acutely toxic when inhaled as an aerosol (LC50: 0.4 mg/L air/4 hrs). Piloerection, unpreened hair coat and reduced activity starting on the first day of observation were reported at 0.025 mg/L. In addition, the animals treated with 0.168 mg/L showed neurological and respiratory symptoms such as staggering gait, tremors, bloody noses, and irregular breathing.

Cyfluthrin was not acutely toxic by dermal route (LD50: > 5000 mg/kg bw). Poisoning symptoms were reported at 5000 mg/g bw and were characterized by apathy and ataxia which ceased 5-7 days after exposure.

Irritation, Corrosivity and Sensitisation

Irritation studies revealed that cyfluthrin is not irritating to the skin or to the eyes of rabbits. Cyfluthrin was not sensitising in a Magnusson-Kligman Maximisation test.

Medium-term Toxicity

The main target organ after repeated oral uptake of cyfluthrin was the nervous system. Movement disturbances, predominantly of the hind limbs, were observed in rats (3 months) and dogs (6 months, 1 year), increased salivation and degeneration of sciatic nerves in rats. Body weight gain and food consumption were affected and vomiting and diarrhoea were induced in dogs.

After repeated dermal exposure a red nasal discharge and histological dermal and epidermal changes were observed in rats. Food consumption was decreased.

Following repeated inhalation, female rats showed behavioural alterations such as restlessness and erected tail while male rats had a reduced body weight gain.

The oral NOAEL in rats was 19 mg/kg bw/d based on gait abnormalities and salivation, decreased food intake and body weight gain, degeneration of sciatic nerves and decreased serum glucose levels. The oral overall NOAEL in dogs was 6.5 mg/kg bw/d based on gait and co-ordination disturbances at 20 mg/kg bw/d in the 6 months study and 11 mg/kg bw/d in the 12 months study.

The dermal NOAEC in rats was 5.7% w/w based on local effects (corresponding to 113 mg/kg bw/d). The NOAEL for systemic effects after dermal exposure was established at 376 mg/kg bw/d based on red nasal discharge and reduced food consumption at 1077 mg/kg bw/d.

The inhalation NOAEC in rats was 0.09 µg/L based behavioural effects such as agitation and erected tail in females and decreased body weight gain in males at 0.7 µg/L.

Genotoxicity

The mutation frequency was tested in three independent studies in Salmonella typhimurium strains with GC base pair at the primary reversion site. Additionally, two studies included also Escherichia coli strains WP2 hcr- with AT base pair at the reversion site. Cyfluthrin did not induce mutations in all tests with and without S9 activation system. In vitro mammalian cytogenetic tests were performed in human primary lymphocytes and Chinese hamster lung cells (CHL) with and without S9 metabolic activation but an impaired

mitotic index makes their evaluation difficult. Additionally, the test substance precipitates in cell culture medium in concentrations of 500 µg/mL and above. Therefore, the efficacy of the treatment is questionable. In all submitted studies cyfluthrin did not increase the frequency of chromosomal aberrations; however, the results were in majority equivocal. Thus, the cytogenetic evaluation was primarily based on negative results of in vivo mice micronucleus and rodent dominant lethal tests. Cyfluthrin did not show mutagenic properties in vivo after low and high dose treatment up to 80 mg/kg body weight.

The tests for in vitro gene mutation in mammalian cells were performed in Chinese hamster ovary (CHO) cells. In the key study cells were treated with 0-9 µL/ml cyfluthrin in presence or absence of S9 mix. The relative cell survival was only marginally affected. No dose-related changes were seen in mutation frequency. The second study included treatment with five different concentrations of cyfluthrin in a dose range 0-40 µg/mL ±S9 mix. Because of precipitation of cyfluthrin in cell culture medium at the concentration of 50 µg/mL and higher, toxic treatment was not possible. Negative results were obtained in two independent trials with and without S9 metabolic activation.

Regarding published data, Ila et al. (2008) suggested that cyfluthrin could be clastogenic both in vitro and in vivo, but there are several reasons to question the validity of these results. It is therefore difficult to conclude whether these positive data do indicate a true clastogenic potential for cyfluthrin or whether the apparent clastogenic effects could be due indirectly to extreme conditions. Overall, the data of this study are considered not to be sufficiently robust and reliable for the assessment of the genotoxic potential of cyfluthrin.

Most of the submitted cytogenetic studies for cyfluthrin do not fulfil OECD requirements concerning the dose range of the tested compound or confirmation of negative results in 2nd trial. Thus, the evaluation of genotoxic potential of cyfluthrin is based on an overall weight of evidence of submitted data. As cyfluthrin was not mutagenic, did not show any dose-dependent effects in in vitro cytogenetic studies, was not genotoxic in vivo and not cancerogenic, the classification of cyfluthrin for genotoxicity is considered not required.

Chronic Toxicity/ Carcinogenicity

Cyfluthrin did not show a carcinogenic potential in rats and mice.

The long term non-neoplastic NOAEL in rats was 11.6 and 14.4 mg/kg bw/d for males and females, respectively, based on a reduced body weight gain (8-10 %) and an increased frequency of alopecia at 22.8/28.3 (M/F) mg/kg bw/d. The neoplastic NOAEL was 22.8/28.3 (M/F) mg/kg bw/d, the highest dose tested. In an 18 months carcinogenicity study in the mouse the neoplastic NOAEL was 233/310 (M/F) mg/kg bw/d.

Reproduction Toxicity

The NOAEC for dams after inhalation exposure to cyfluthrin was < 0.46 µg/L (LOAEC: 0.46 µg/L) based on reduced food intake and body weight gain. The food intake was reduced to a statistically significant extend and was 4.5% lower during the whole study period when compared to vehicle treated animals. The overall body weight gain reduction was only 13 % but the effect was particularly pronounced in the study period 6 - 15 days p.c. (26% compared to vehicle control). The clinical findings such as bloody snout, piloerection, ungroomed fur, hypothermia, and bradypnoea were evident at 2.55 µg/L and above and were accompanied by neurological symptoms (salivation, high stepping gait) in high-dose exposed animals at 11.9 µg/L.

The developmental NOAEC was determined to be 0.46 µg/L. The fetal adverse effects were

in the range of maternal toxicity and the reported symptoms with the exception for the eye malformations are common non-specific secondary effects (Guidance to Regulation NO 1272/2008 on CLP of substances and mixtures, 2009: Annex I :3.7.2.4). The placental and fetal weights were reduced, and the fetuses exhibited retarded ossification as well as an increased incidence of malformations, at levels of 2.55 µg/L and above. Microphtalmia and anophtalmia were reported in the group exposed to 11.9 µg/L. These effects cannot unequivocally related to maternal toxicity. The authors hypothesize that the embryonic effects were the consequence of the sensory irritation induced reflex bradypnoea, secondary to hypothermia and respiratory alkalosis in dams. A direct link between the maternal alkalosis and fetal toxicity was not shown. However, the adjustment of the oxygen level in the 12.8 µg/L group to 30% apparently diminished the test substance-related effects on the fetal and placental weight and reduced the incidence of microphtalmia and malformed fetuses of about 50% compared to normoxia conditions, providing some evidence for the secondary effects hypothesis. In addition, satellite groups of five females each were investigated to assess specific maternal toxicity parameters. Concentration dependent respiratory disturbances and impaired lung function as well as neurotoxic effects were observed, especially at the highest concentrations. As the effects occurred at higher concentrations, they are covered by the AEC derived for respiratory irritation in humans. In rabbits, the maternal NOAEL was 20 mg/kg bw/d as decreased food intake and body weight gain were observed at 60 mg/kg bw/d. The embryo-/foetotoxic NOAEL was the same as the maternal based on increased embryolethality at 60 mg/kg bw/d. Despite the increase in malformations that was observed in rats in the maternally toxic dose range cyfluthrin is not considered a specific teratogen or a selective embryofoetal toxicant.

In the multi-generation study with cyfluthrin conducted in rats, the parental NOAEL was 9 mg/kg bw/d for males and 10 mg/kg bw/d for females based on decreased body weight gains during the premating period at 29/33 (M/F) mg/kg bw/day and neurotoxic effects in females during lactation at approximately twice this the amount of cyfluthrin consumed. The reproductive NOAEL was 10 mg/kg bw/d based on a reduced number of implantation sites at 33 mg/kg bw/d. The offspring NOAEL was 10 mg/kg bw/d based on reduced postnatal growth and tremors in F1 and F2 pups at a maternal intake of approximately 20 mg/kg bw/d. The excretion of cyfluthrin in rat milk has not been determined but compound-related coarse tremors were observed in the F1 and F2 pups at and above 125 ppm. The tremors were observed as early as lactation day 5 and had ceased by lactation day 18 after weaning. Thus, cyfluthrin exposure through milk is considered to be the main determinant of offspring neurotoxicity and it is classified as reproductive toxicant in category for effects via lactation.

Neurotoxicity

In an acute neurotoxicity study with beta-cyfluthrin in rats a NOAEL of 2 mg/kg bw could be established based on FOB findings such as salivation, gait incoordination, diminished approach and touch response, impaired aerial righting, repetitive pawing movements and decreased activity at 10 mg/kg bw. In a subchronic (90 d) neurotoxicity study a NOAEL of 2 mg/kg bw/d was derived based on reduced body weight gain in female rats and self-inflicted lesions due to paraesthesia in males at 8 mg/kg bw/d.

In a developmental neurotoxicity study with beta-cyfluthrin in rats no maternal neurotoxicity was observed. The maternal NOAEL was 11 mg/kg bw/d based on a decrease in net weight gain between day 0 of pregnancy and day 0 of lactation. Effects on the offspring were noted beginning during the first week of lactation. The maternal substance intake that resulted in a NOAEL for the offspring during that time was 19 mg/kg bw/d. Higher maternal consumption of the test substance resulted in reduction in body weight

gain of the pups and neurotoxic signs (increased vocalisation when handled).

Mechanistic studies

To investigate hypothermia and transient respiratory changes observed in inhalation studies Sprague-Dawley rats with permanently implanted intra-arterial catheters were exposed nose-only to cyfluthrin (purity 96.2 %) aerosols at analytical concentrations of 13.2 mg/m3 air.

A distinct hypothermia was developed during the 4 h exposure period. The determinations of the blood gases resulted in a decrease in arterial partial pressure of carbon dioxide and a rise in arterial blood pH. These results give some indications for the hypothesis that the reflex bradypnoea, which in turn has been induced by sensory irritation, induces secondary hypothermia and respiratory alkalosis, but are not sufficient to conclude for a causal relationship between the systemic effects and sensory irritation.

Antidote studies

In studies in the rat substances with anti-inflammatory-analgesic (acetysalicylic acid, DL-lysinmonoacetylsalicylat), anti-epileptic (valproic acid), sedative (guaifenesin) or neuromuscular-regulatory (mephenesin, pancuronium) activity proved insufficient as antidotes to oral intoxication with cyfluthrin. Drugs with regulatory effects on the blood pressure or circulation (methyldopa, niconacid) as well as typical cyanide antidotes (methylene blue, sodium thiosulfate-5-hydrate, thionin) and calcium also failed to antagonise the acute effects of toxic oral doses of cyfluthrin.

Administration of a muscle relaxant (tetrazepam, 50 mg/kg body weight) succeeded in increasing the LD50 by a factor of 1.6 (30.5 mg/kg body weight as compared with 19.6 mg/kg body weight). Tetrazepam also proved able to suppress the toxic signs and delayed the onset of death.

Atropine sulphate and methocarbamol either individually or in combination exhibited moderate protective activity (twofold increase in the LD50 from 660 to 1280 mg/kg body weight). Due to fatalities caused by atropine intoxication after pyrethroid poisoning, the use of high dose atropine is contraindicated in pyrethroid intoxication treatment today.

Other studies

Anaesthesia potentiation was observed in cyfluthrin-treated mice in an acute safety pharmacology study (Polacek, 1982). Although CVMP (Committee on Veterinary Medicinal Products of EMA, formerly EMEA) regarded the extension of barbiturate sleeping time as the most relevant effect to derive the ADI for veterinary medicinal products or biocides used in food producing animals, it was not used for the assessment of cyfluthrin under BPD due to poor reporting quality. As there are neurotoxicity studies available which meet the requirements of current scientific knowledge regarding study conduction and reporting (Andrews, 1999, Sheets 1997), the study was not regarded as a key study to derive reference values under BPD.

Medical Data

Medical surveillance on manufacturing plant personnel

Reported annual medical examinations of workers involved in formulation/production of cyfluthrin between 2000 and 2005 did not reveal any exposure-related effects on clinical parameters including liver enzyme levels and basic function tests.

Skin symptoms such as paraesthesia/irritation, often described as 'cold burn' have been observed in people handling the active ingredient. The irritation can occur both on the skin and on the mucous membranes of the airways. In the latter case in sensible individuals an asthma-like unspecific response can be triggered. Paraesthesia or 'cold burn' may appear immediately or shortly after contact with the substance and may last for up to 48 hours.

Direct observations

Direct observations are reported from the USA (Das et al., 2006) and China (He et al., 1989). Farmworkers exposed to sprayed cyfluthrin developed low to moderate symptoms of pyrethroid poisoning. Symptoms most commonly reported were headache (96 %), nausea (89 %), respiratory irritation (89 %), eye irritation/tearing (85 %), muscle weakness (70 %), and anxiety (67 %).

The report from China describes 573 cases of intoxication with deltamethrin, fenvalerate or cypermethrin. After occupational exposure the first signs, appearing after 4-6 h, were burning, pruritus or tingling. The principal signs after ingestion were of gastrointestinal nature (abdominal pain, nausea, vomiting within 10 min to 1 h), no dermal manifestations being recorded. Systemic symptoms included dizziness, headache, nausea, and fatigue. Severe cases were characterised by coarse twitching of the extremities, which correlated with repetitive discharges in the electromyogram. Clouding of consciousness and convulsions (lasting between 30 sec and 2 min and occurring 10-30 times per day) were recorded in a few cases.

Treatment was of a symptomatic and supportive nature (gastric lavage, low dose atropine for salivation and pulmonary oedema, diazepam, baclofen, phenobarbital, chlorpromazine, phenytoin). Seven cases (2 x occupational exposure to deltamethrin, 2 x ingestion of fenvalerate, 1 x pulmonary oedema, 1 x mistaken diagnosis, 1 x high dose treatment with atropine) had a fatal outcome. In all other cases complete recovery occurred within 2-3 weeks, though in the majority of cases it took just 1-6 days. No late damage was observed.

In a human volunteer study, 1-h inhalation exposure to approx. 0.1 µg cyfluthrin/L air appeared to be in the range of an irritant threshold concentration for humans as 4 of 5 subjects experienced mild sensory irritation and 1 subject showed mild hyperaemia of the nasal mucosa. Symptoms experienced were transient and self-limiting. A concentration of 0.2 µg/L caused similar effects of greater (mild to moderate) intensity in all subjects. No clinically significant or drug-related abnormalities in vital signs, EKGs or clinical laboratory tests were observed after 1-h exposure to airborne cyfluthrin concentrations of up to 0.2 µg/L.

Epidemiological studies on the general population

In a prospective study sixty-one persons were monitored shortly before and up to one year after pest control operation (PCO) using pyrethroids at their working place or in their private home. Forty of them were exposed to cyfluthrin. Indoor PCO was carried out by professional pest control operators. At all times, concentrations of cyfluthrin in plasma of exposed persons were below the determination limit (DL) of 5µg/L (Leng et al., 2003). Before the pest control operation, the majority of the samples revealed metabolite concentrations (DCCA=DCVA or permethric acid, FBPA) below the DL of 0.2 µg/L in urine. The number of cases with detectable concentrations increased from 4 to 12 for cis-DCCA, from 2 to 18 for trans-DCCA and from 0 to 2 for FPBA 24 h after PCO. For cis-DCCA and trans-DCCA, the number of cases with concentrations above the detection limit decreased during the time course from 9 (72 h) to 1 (10-12 months) for cis-DCCA and from 13 (72

h) to 4 (10-12 months) for trans-DCCA. The isomeric cis/trans-DCVA ratio indicated for 5 subjects a predominantly dermal uptake and for 13 subjects a predominantly inhalation/oral uptake. The route of uptake remained unchanged for the same persons during the study. With respect to the exposure of cyfluthrin by the PCO, internal doses were increased but did not exceed the general background level which is assumed to be caused by dietary exposure. This study only presents biological monitoring data. No correlation with air monitoring or medical examinations are reported here. Multiparametric analysis of immune components before the PCO and after 1 day, 3 days, 4-6 months, and 10-12 months was performed and revealed subtle changes in immune parameters within the physiological range after PCO which are considered to underlie compensatory mechanisms of immunoregulation and thus, are considered to be without clinical relevance (Hadnagy et al., 2003).

Epidemiological studies on professional pest control operators

Seven male professional operators were exposed exclusively to cyfluthrin based formulations. The aim was to develop an analytical method for monitoring the exposure of operators to pyrethroids following usage representative of normal working practice. Any correlating clinical effects are not reported. During the first day after exposure the highest amount of all metabolites was eliminated. Fluorophenoxybenzoic acid (FPBA) could be measured for up to 3.5 days after exposure and cis- and trans-DCCA for up to 1.5 days (Leng, G. et al. 1996). Although it may not be exclusively specific for cyfluthrin, the metabolite FPBA is considered to be a suitable indicator of a possible cyfluthrin exposure.

Twenty-two male Pest Control Operators exposed to pyrethroids and 20 unexposed men were investigated (Wieseler et al 1998). Sixteen persons were exposed to cyfluthrin. The objective of this study was to compare the frequency of complaints. A questionnaire listing symptoms was used and medical examination as well as complete clinical laboratory analysis were performed. Furthermore, urinary metabolites of pyrethroids were measured. Overall, no correlation between symptoms reported by exposed subjects, the urinary concentration of cyfluthrin, or total amount of the eliminated metabolites could be found.

Hardt and Angerer (2003) compared concentrations of pyrethroid metabolites in urine samples from 36 pest control operators, agriculture and greenhouse workers, and control persons. During application (0.25-2.25 h) the 15 pest control operators wore work overalls and protective gloves. The amount of pyrethroids that had been taken up during occupational application was not considerably higher than the ADI set by WHO. Consequently, it was concluded that adverse health effects are not to be expected after workers' exposure in Germany, provided that the application is carried out properly.

In another study, professional pest control operators were exposed for 5 consecutive days to cyfluthrin. At the end of the exposure period, blood and urine samples were collected. In addition, one healthy volunteer took a single oral dose of 0.03 mg/kg bw (2.6 mg) cyfluthrin, approximately 40% of the ingested dose was recovered in the urine. The mean half-life of the metabolites in urine was 6.44 ± 0.64 hours, indicating that 94% of the metabolites were eliminated over the 48 hour period following 1st order kinetics. The isomeric ratio for trans-DCCA:cis-DCCA was 2.3. The total amount of FPBA was twice the total amount of cis-/trans-DCCA. A large excretion of trans-DCCA is a clear sign of significant oral/inhalation uptake, the most likely exposure in this study (Leng, G. et al 1997).

Biocidal Products

<u>Cyfluthrin Foam:</u>

In the absence of in vivo as well as in vitro data for dermal absorption of the product Cyfluthrin Foam a default value of 10% is considered adequate based on physico-chemical properties and additional information from other scientific sources.

A similar product to Cyfluthrin Foam was tested and it was shown that is has a low acute oral, dermal and inhalation toxicity. Bridging was therefore accepted. No studies on skin and eye irritation and skin sensitisation were submitted for Cyfluthrin Foam. According to Directive 1999/45/EC no classification of the biocidal product Cyfluthrin Foam is required, but acc. to Reg. 1272/2008 classification as Eye Irrit. Cat. 2 (H319) is necessary.

Solfac® EW 050:

Following dermal application of a product formulation (beta-cyfluthrin FS125) similar to Solfac® EW 050 in rat in vivo and in vitro with human and rat skin a dermal absorption of < 1% is estimated.

Solfac® EW 050 has a low acute oral, dermal and inhalation toxicity and no skin and eye irritation potential. According to results of the LLNA Solfac® EW 050 may cause sensitisation after skin contact and has to classified as R 43, May cause sensitisation by skin contact or Skin Sens., H317, May cause an allergic skin reaction, respectively.

Summary and conclusion

Cyfluthrin is almost completely absorbed, when administered orally, widely distributed and excreted quantitatively mainly via the urine. Cyfluthrin is acutely very toxic after oral exposure (LD50 in cremophor EL/distilled water: 16 mg/kg bw), it is toxic, when inhaled (LD50: 405 mg/m^3) and not acutely toxic after dermal exposure. It is not irritating or corrosive to skin or eyes and does not exhibit sensitising potential.

Cyfluthrin was found to be neither genotoxic nor specifically teratogenic. There was no evidence for a carcinogenic potential.

The NOAEL of 2.0 mg/kg bw from the acute neurotoxicity study in rats is considered as the relevant starting point for setting a systemic reference dose for acute exposure. The NOAEL of 2.0 mg/kg bw/d from the 90 d neurotoxicity study in rats is regarded as the relevant starting point for setting a systemic reference dose for medium-term exposure. By setting a default assessment factor of 100, an

Acute Systemic Acceptable Exposure Level (AEL_{acute}) of 0.02 mg/kg bw,

and a

Medium-term Systemic Acceptable Exposure Level ($AEL_{medium-term}$) of 0.02 mg/kg bw/d

are proposed for single and repeated (medium-term) exposure towards cyfluthrin.

Since the NOAELs derived from the 6 months dog study (6.5 mg/kg bw/d) and a 12 months dog study (6 mg/kg bw/d) would result in a higher Acceptable Exposure Level than the NOAELs relevant for the acute and medium-term AEL, a

Long-term Systemic Acceptable Exposure Level ($AEL_{long-term}$) of 0.02 mg/kg bw/d

is established based on the acute and medium-term AEL-S and providing a margin of safety of 600 and 325 to the relevant NOAELs derived from the 2 year rat study (12 mg/kg bw/d) and from the 6 months dog study (6.5 mg/kg bw/d), respectively.

Based on an acute inhalation study in man (LOAEC 0.1 µg/L (1 h)) an additional

Inhalation Acceptable Exposure Concentration ($AEC_{inhalation}$) of 0.01 µg/L

is proposed. An assessment factor of 10 is regarded adequate. No interspecies variation has to be taken into account since the study was performed in humans. Based on the fact that the observed effects are local and concentration-, not dose-dependent, neither a dynamic nor a kinetic sub factor needs to be applied for intra-species variation. A factor of 5 is applied for sensitive subpopulations (e.g. asthmatics) and a factor of 2 is considered reasonable for LOAEC to NOAEC extrapolation because the LOAEC of 0.1 µg/L in the human study is based on mild transient effects (sensory irritation in four out of five test subjects, clinical findings: mild hyperaemia of the nasal mucosa in one subject) while at 0.2 µg/L irritation symptoms and clinical findings were much more pronounced.

This $AEC_{inhalation}$ is supported by a NOAEC of 0.09 µg/L (6 h) in a 13-wk inhalation study in rat. For the local irritation effects in the acute human inhalation study and the 13 wk rat inhalation study the threshold concentration for local portal-of-entry effects is apparently in the same range for both species. For the embryotoxic effects (retarded ossification and decreased birth weight) seen in the teratogenicity inhalation study in rat at 2.5 µg/L and regarded as secondary as a result of maternotoxic effects the derived $AEL_{inhalation}$ provides a margin of safety of 70 to the NOAEC of 0.5 µg/L. Because of the large interspace between NOAEC (0.5 µg/L and LOAEC (2.5 µg/L) in this study and a higher sensitivity of rodents to metabolic rate depression and other systemic effects following irritant inhalation this margin of safety is considered as sufficient.

Taking into account the proposed use of the products for rural hygiene indoors as well as for indoor household use, it is not expected that residues of cyfluthrin in food or feeding stuffs will occur in relevant amounts. Anyhow, they cannot be excluded with certainty and therefore, based on the acute neurotoxicity studies in rats (NOAEL 2 mg/kg bw), an

ARfD of 0.02 mg/kg bw,

and an

ADI of 0.02 mg/kg bw

are proposed for intake of cyfluthrin in food or feed. Since the ADI value derived from the chronic studies would be higher than the acute reference dose it is adjusted at the same value as the ARfD.

2.2.1.3. Exposure assessment

Exposure of Professionals

Cyfluthrin and Cyfluthrin Foam are manufactured outside the EU. The biocidal products Cyfluthrin Foam (non-professional use) and Solfac® EW 050 (professional use) are applied to control insects. For the assessment of inhalation exposure, the focus is set on exposure to droplet aerosols, because, due to the low vapour pressure (vapour pressure of 9.6×10^{-7} Pa at 20°C), inhalation exposure to vapour is of minor relevance.

The following scenarios are covered by this exposure assessment:

- Cyfluthrin Foam - Consumer Product
- Solfac® EW 050 - Spray applications in animal housing (scenario 1)

- Secondary exposure to Solfac® EW 050 (scenario 2)

Cyfluthrin Foam is a ready-for use consumer product. It was assumed that if professionals (e.g. housekeeper) use this product, the frequency and duration is similar to the pattern of use of consumer using this product. Therefore, the exposure of professionals using this consumer product is in the same order of magnitude as for non-professionals.

According to the participant, Solfac® EW 050 is intended for a spray application in animal housing buildings, to control crawling and flying insects (scenario 1). After the dilution of the biocidal product (5% active substance) with water to a concentration of 0.08% active substance, the spray solution is applied using a backpack sprayer with a spray pressure of 2-3 bar. Based on Model 1 (Spraying) of the *TNsG Human Exposure to Biocidal Products Part 2*), the potential inhalation exposure is estimated to be 0.021 mg/m^3 during the spray application. The duration and the frequency of exposure to the active substance are assumed to be daily for 120 minutes in a season of 90 days per year. The dermal exposure could occur in all phases of the application process and is assessed with different models for the application phase including mixing and loading and the post-application phase. For all phases, a value of 26.4 mg/person/day results for the potential dermal exposure with the post-application phase not contributing significantly to the total exposure. The variables which influence the level of exposure are the duration of spraying and the spray pressure (for details please see Table 2-13 and Appendix I – List of endpoints Chapter 3 "Acceptable exposure scenarios").

A secondary exposure due to dermal contact to treated surfaces cannot be excluded. For secondary exposure (scenario 2), it is assumed that farmers and their employees are exposed on a daily basis. The inhalation exposure to dust contaminated with cyfluthrin is assessed as negligible. Dermal contact to treated surfaces may occur incidentally, and it is estimated that the palms of both hands are exposed to 1.7 mg active substance.

Exposure of Non-Professionals

The biocidal product Raid Cyfluthrin Foam is applied as a crack and crevice treatment product to prevent insects from entering the home. Raid Cyfluthrin Foam is used around doors and windows as well as into cracks and other difficult to reach areas using an extension tube. During application, airborne residues may occur. Hence inhalation and oral and dermal exposure are possible. Non-professional primary exposure is considered as acute and chronic (long-term).

For exposure estimation Consexpo 4.1 is applied (products database: pest control products; product category: sprays; default product: crack and crevice; scenario: application spray can). Calculations for primary acute and long-term exposure result in a total internal dose of 3.62 x 10^{-4} mg/kg bw/d.

Non-professional use of the biocidal product Solfac EW 050 is not intended. Use is restricted to professional operators.

For secondary exposure as a result of the use of the biocidal product Raid Cyfluthrin Foam the following scenario is assessed:

- infants crawling on the floor, exposed directly via the dermal route and orally by ingestion of residues on the skin whereas inhalation exposure does not occur.

Calculations result in the following total internal dose of cyfluthrin in infants after secondary exposure to the biocidal product Raid Cyfluthrin Foam: 5.40 x 10^{-3} mg/kg bw/d.

For secondary exposure as a result of the use of the biocidal product Solfac EW 050, the re-entry of animal houses (adults and children; acute/long-term exposure via inhalation

and dermal route) is assessed.
Calculations result in the following total internal dose of cyfluthrin in adults and children after secondary exposure to the biocidal product Solfac EW 050:

- adults; acute/long-term exposure: 1.76×10^{-4}
- children; acute/long-term exposure: 3.52×10^{-4}.

2.2.1.4. Risk characterisation

Risk Assessment for Professionals

The toxicological profile of cyfluthrin is both characterised by systemic effects (neurotoxicity) and by local effects (sensory irritation due to exposure to skin and by inhalation). The local effects (burning or stinging sensation, paraesthesia) arise immediately or within a few minutes following contact and may last for up to 48 hours (reversible effects).

Risk characterisation for systemic effects

The occupational risk assessment for the active substance cyfluthrin in the biocidal product Solfac® EW 050 is based upon the long-term AEL of 1.2 mg/person/day and the estimate of potential occupational exposure. The corresponding total internal body burden is mainly triggered by dermal exposure (Table 2-8). The long-term AEL is based on oral toxicity studies and the knowledge of a 100% oral absorption percentage.

Table 2-8 Potential exposure (professionals, cyfluthrin)

Exposure scenario		Inhalation shift average (mg/m^3)	Dermal exposure (mg/person/d)	Internal body burden (mg/kg/day)		
				Inhalation(1)	Dermal(1)	Total
Application of biocidal product Solfac® EW 050						
1a	Mixing & loading	negligible	26.2	-		
1b	Application	0.021		0.0035	0.0044	0.008
1c	Post-Application	negligible	0.17	-	2.8×10^{-5}	2.8×10^{-5}
1a-c	Total	0.021	26.4	0.0035	0.0044	0.008
Secondary exposure						
2	Working in animal housing	negligible	1.7	-	0.0003	0.0003

Based on the assumption of 100 % systemic availability after inhalation exposure and 1 % systemic availability after dermal exposure

The risk characterisation ratio (total internal body burden divided by AEL) for the application of the biocidal product Solfac® EW 050 is 0.39 for potential exposure (without dermal PPE). Thus, for systemic effects, there is no concern for the exposure scenario analysed (table 2-9).

Table 2-9 Risk characterisation for systemic effects (professionals, cyfluthrin, potential exposure)

Exposure scenario		Total internal body burden (mg/kg/day)	Long-term AEL (mg/kg/day)	Total internal body burden divided by AEL	Concern	
					Yes	No
1	Application of biocidal product Solfac® EW 050	0.008	0.02	0.39		x
2	Working in animal housing (secondary exposure)	0.0003	0.02	0.02		x

Risk characterisation for local effects (sensory irritation)

Sensory irritation in response to exposure by inhalation
It is essential to recognize, that sensory irritation in the upper respiratory tract occurs at lower air-borne concentrations than systemic effects. The corresponding AEC for acute local effects in the upper respiratory tract is 10 µg/m³. For the scenario 1, "application of the biocidal product", the potential exposure level reported for cyfluthrin is 21 µg/m³ (shift average value). Due to the risk reduction measures (see below, "Safety measures for Professionals") the actual inhalation exposure for the application of the biocidal product Solfac® EW 050 is calculated to 5.25 µg/m³ (shift average value) The corresponding exposure-to-AEC ratio is 0.5 (5.25/10). Based on this analysis with PPE (ratio is less than 1) there is no concern to upper respiratory tract sensory irritation

Sensory irritation in response to dermal contact
Classical irritation studies revealed that cyfluthrin is not irritating to the skin or to the eyes of rabbits. However, accidents with chemical products containing cyfluthrin resulted in paraesthesia of the skin exposed (local action on sensory nerve cells). The effect is characterised by a burning or stinging sensation in the affected areas. Areas most commonly effected were the face, and mucosal tissues. Principally, the intensity of cutaneous paraesthesia will depend on the concentration of cyfluthrin in the biocidal product and the emulsifier / vehicle used. So far, available data do not allow for a quantitative assessment as to the sensory irritation potential of the 5% and 0.08% aqueous formulation of cyfluthrin used and applied.

Safety Measures for Professionals

With regard to dermal protection, adequate chemical protective gloves and a type-4-coverall (spray-tight) should be recommended for 'application including mixing and loading' of the biocidal concentrate Solfac® EW 050 (5% and 0.08% w/w a.s.).

Gloves and overall are not necessary to protect against systemic effects but to prevent from sensory irritation. Data do not allow for a quantitative assessment as to the sensory irritation potential of the 5% and 0.08% aqueous formulation of cyfluthrin. According to European Legislation (1907/2006 REACH), gloves have to be described in more detail in the safety data sheet, at least: material, thickness and breakthrough time of the gloves (EN 374). Moreover, at least one commercially available gloves and coverall-product protecting against all hazardous components of the product should be indicated.

Respiratory protection is necessary for the scenario "Application of the biocidal product" assessed in this report (mask and filter type need to be specified).

Beyond the measures proposed for active substance approval, it is desirable for harmonization of the quality of safety measures on community level, to develop a 'Code of Good Practice' for pest control measures. It is proposed that member state experts should harmonize an according document on community level which should specify regulations on safety and health at work (instruction, training, exposure control, PPE) for users and give guidance to the competent authorities for authorization of biocidal products.

Conclusion

This risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of the approval of cyfluthrin (conclusions only apply to the active substance in the biocidal product - not to other ingredients) The overall conclusion is:

- There is no concern for systemic effects for the exposure scenarios specified.
- In order to avoid upper respiratory tract sensory irritation respiratory protection equipment is necessary
- For cutaneous paraesthesia, health risks to be anticipated due to dermal contact will essentially depend on the concentration of cyfluthrin in the biocidal product and on the emulsifier / vehicle used for formulation of the cyfluthrin.

Additional safety measures (protective gloves and a type-4-coverall) are required during the application phase (including mixing and loading)because of reversible local dermal effects (sensory irritation like burning or stinging sensation).

Risk Assessment for Non-Professionals

In all cases exposure of non-professionals to cyfluthrin is below the respective Acceptable Exposure Level (AEL). Thus, exposure to cyfluthrin by Cyfluthrin Foam and Solfac® EW 050 is considered acceptable with respect to human health.

Safety Measures for Non-Professionals

Specific safety measures for non-professionals are not required.

Risk assessment for secondary exposure

In all cases, exposure of the general public to cyfluthrin is below the respective Acceptable Exposure Level (AEL). Thus, secondary exposure to cyfluthrin by Cyfluthrin Foam and Solfac® EW 050 is considered acceptable with respect to human health.

Safety Measures for the general public

Specific safety measures for the general public are not required.

Risk assessment for local effects.

Based on the toxicological profile of cyfluthrin there is the necessity to have an additional analysis of local health effects (sensory irritation via inhalation and dermal route).

There is no concern to upper respiratory tract sensory irritation for the non-professional users and the general public.

Available data do not allow a quantitative assessment for the sensory irritation potential of the formulations containing cyfluthrin by primary and secondary dermal exposure.

Risk assessment combined exposure

In all cases, exposure to cyfluthrin is below the respective Acceptable Exposure Level (AEL). Thus, combined exposure is considered acceptable with respect to human health.

2.2.2. Environmental Risk Assessment

2.2.2.1. Fate and distribution in the environment

Biodegradation

The active substance cyfluthrin is considered to be neither readily nor inherently biodegradable on the basis of higher tier simulation studies in aquatic and soil systems.

Surface water

In surface water under aerobic conditions, cyfluthrin dissipated rapidly during the first days of incubation with a DT_{50} of 17.8 days (converted to an average EU outdoor temperature of 12°C). After day 7, dissipation clearly decelerated. No mineralisation to $^{14}CO_2$ was observed. The metabolite FPB-acid was formed up to 70 % of applied radioactivity.

In water/sediment systems (two Dutch and two German systems), cyfluthrin was rapidly transferred to a high extent from water to sediment. In the entire system, cyfluthrin showed fast metabolism mainly via cleavage of the ester bond with DT_{50}-values <10 days (converted to an average EU outdoor temperature of 12°C). Dissipation of cyfluthrin seemed to be predominantly caused by abiotic chemical processes. Depending on the label position of cyfluthrin and therefore on the metabolic pathway examined, mineralization to carbon dioxide took place to a limited (14-37%) or high extent (61-67%). Three relevant metabolites (>10% of applied radioactivity) were detected (FPB-acid: max. 44.5%, FPB-ald: max. 15.7%, permethric acid (DCVA): max. 47.6%). Permethric acid can be considered as persistent in water/sediment systems (DT_{50} 385 days, converted to an average EU outdoor temperature of 12°C).

Soil

Cyfluthrin degraded moderately to slowly in aerobic laboratory soil studies. Half-lives from 11.4 to 67.9 days at 20°C were derived from the laboratory key studies (corresponding to 21.7 - 128.6 days at 12°C average EU outdoor temperature). Another key study, performed at 10°C, resulted in a DT_{50} of 53 days (equivalent to 43.6 days converted to 12°C). The extent of CO_2 formation under aerobic conditions was 18% (after 365 days) – 48.5% (after 122 days) and depended on a high degree upon the water content of the soil samples In the dry soil only 18% CO_2 were formed. The amount of bound residues formed was between 24% and 34%. Two relevant metabolites, FPB-acid (4-fluoro-3-phenoxy-benzoic acid) and DCVA (permethric acid) were identified. For FPB-acid a DT_{50} of 39.1 days at 20°C (corresponding to 74.2 days converted to 12°C) was calculated. In a further study investigating the fate of DCVA in two Japanese soils, half-lives between 11.7 and 61.8 days were determined for the 1R- and 1S-trans isomers of DCVA at 25°C. For 1R-, 1S-cis isomers of DCVA DT_{50} values ranged from 13.5 to 16 days. The longest half-life times were found for 1S, trans-DCVA, showing DT50 values of 23.1 days and 61.8 days at test

temperature (25°C) (corresponding to 34.5 days and 92.2 days converted to 12°C). The $DT_{50\text{-modelling}}$ for DCVA amounted to 174.8 days at 12°C average EU outdoor temperature. In the two Japanese soils mineralisation rates of 20% CO_2 were observed for DCVA, the bound residues ranged from 20 – 35%.

The results of the studies demonstrated that the major degradation path of cyfluthrin was hydrolysis at the ester linkage or diphenyl ether bond, hydroxylation at the phenoxy ring and hydrolysis of the cyano group leading to the formation of the major metabolites FPB-acid and DCVA. Further degradation mainly resulted in generation of CO_2 and bound residues.

Under anaerobic conditions cyfluthrin decreased from 39.1% after 30 days to 21.3% after 60 days. Mineralisation was not detected. The amount of bound residues increased to 64% after 60 days. FPB-acid was identified as relevant metabolite.

Abiotic Degradation

Cyfluthrin is stable at pH 4 and relatively stable at pH 7. The hydrolysis rates increase at pH 9, mean half-life of around 2.6 days was calculated at EU outdoor temperature of 12°C. Significant hydrolysis products were 4-fluoro-3-phenoxy benzaldehyd (FPB-ald, FCR 1260) and permethric acid (DCVA). While FPB-ald was found stable to hydrolysis, the hydrolysis half-life for DCVA is greater than 1 year.

In pure water cyfluthrin is directly photolytically degraded with half-lives between 2 and 60 days in dependence on degree of latitude and seasonal conditions. Photolysis of cyfluthrin results in rapid cleavage of the ester bond and formation of FPB-ald and 4-fluoro-3-phenoxybenzoic acid (FPB-acid), which are formed sequentially. However, indirect photodegradation should also contribute to degradation processes in the environment. In conclusion, solar radiation will contribute to the degradation of cyfluthrin in aquatic systems.

A photodegradation study of cyfluthrin in one soil provides an indication that cyfluthrin adsorbed to soil will be readily degraded if exposed to sunlight. A biphasic degradation pattern was derived with half-life of 12.3 days (converted to an average EU outdoor temperature of 12°C).

In air cyfluthrin will be degraded by indirect photodegradation.

Distribution and Mobility

Based on the adsorption/desorption study, cyfluthrin could be classified as being immobile in soil. The substance is strongly adsorbed to the soil (arithmetic mean K_{aOC}: 123930 mL/g). The value for arithmetic mean of K_{dOC} is 122146 mL/g. Cyfluthrin as well as the distribution of isomers of cyfluthrin (diastereomers I-IV) remained unchanged in the soil.

The K_{OC} of DCVA is 133.7 mL/g. Therefore, the metabolite is classified as mobile in soil. DCVA was stable during the adsorption/desorption study. The metabolite FPB-acid was found to be mobile in soil (K_{OC} = 73 mL/g).

Bioaccumulation

Based on a study with β-Cyfluthrin and *Lepomis macrochirus*, a kinetic bioconcentration factor (BCF_{fish}) of1822 $L/kg_{wet\ fish}$ was determined for the aquatic compartment. Due to a technical deficiency within the study, a BCF based on steady state cannot be derived. For

the terrestrial compartment a $BCF_{earthworm}$ of 13159 L/$kg_{wet\ earthworm}$ was estimated based on log K_{ow} = 6.04 (highest value of the four diastereomers). The BCF values indicate that cyfluthrin has a high potential to bioaccumulate, at least in terrestrial organisms.

2.2.2.2. Effects assessment

Aquatic Compartment

Cyfluthrin is of very high acute and long-term toxicity to fish (*O. mykiss*, LC_{50} = 302 ng/L; NOEC = 10 ng/L) and to invertebrates (*Hyalella azteca*, LC_{50} = 0.55 ng/L; *Americamysis bahia*, NOEC = 0.41 ng/L for β-cyfluthrin). The toxicity to algae is low (E_rC_{50} > 8.05 mg/L). Further results from microcosm studies revealed that insects are representing the most sensitive group of organisms, whereas crustaceae are less sensitive. However, available laboratory studies are mainly focused on crustaceae. Therefore it was agreed (BPC WG III 2015) that these microcosms cannot be used to lower the assessment factor to be applied on laboratory studies for crustaceae. In addition, further data on aquatic insects should be provided at renewal stage. A $PNEC_{water}$ of 0.041 ng/L is derived from the available studies considering an assessment factor of 10.

A PNEC calculation is not possible for both cyfluthrin metabolites DCVA (3-(2,2-dichloroethenyl)-2,2-dimethyl-cyclopropanecarboxylic acid, Permethric acid) and FPB-ald (4-fluoro-3-phenoxy-benzaldehyde, FCR 1260) as the base set is not complete. Because the acute toxicity of both metabolites is by orders of magnitude less toxic than the parent substance, the PNEC-derivation is not required.

Sediment

The toxicity of cyfluthrin to sediment organisms in a water sediment system was determined based on three long-term tests covering two trophic levels and performed with spiked sediment. Despite its strong binding properties to sediment, uncontaminated food was provided to the test organisms. Therefore, it was concluded that the exposure pathway via sediment ingestion was underestimated and it was agreed at BPC WG III 2015 that an increased assessment factor of 50 should be applied (instead of 10). *Chironomus dilutus* was the most sensitive of the tested organisms. Emergence of the midges was the most sensitive parameter with a NOEC of 6.2 µg/kg dw. Based on the available studies an assessment factor of 50 has been chosen. Considering a default conversion factor of 4.6 for the conversion from wet to dry weight, a $PNEC_{sediment}$ of 27 ng/kg ww was derived from this NOEC.

Inhibition of microbial activity (STP)

In a standard activated sludge respiration inhibition test with sludge from domestic sewage treatment plant an EC_{50} of >10 000 mg a.s./L was found. The NOEC was determined being ≥ 10 000 mg/L. Both values based on nominal concentrations. Considering the limit of water solubility, a $PNEC_{m\ croorganism}$ = 0.00023 mg/L was derived.

Atmosphere

Cyfluthrin is not considered to be used as fumigant. The vapour pressure of the diastereomers of cyfluthrin ranges from 1.4 x 10^{-8} to 9.6 x 10^{-7} Pa, direct evaporation is not expected, consequently. The Henry's Constants between 3.2 x 10^{-3} and 1.9 x 10^{-1} Pa × m^3 mol^{-1} at 20°C point to potential of volatility from water. The strong tendency to soil partition minimizes atmospheric entry. The chemical lifetime of cyfluthrin in the troposphere was estimated to be 44.4 hours.

The atmosphere is no compartment of concern as there is no accumulation of cyfluthrin in the air expected.

Terrestrial Compartment

Tests with earthworms, springtails and soil microorganisms have been provided for cyfluthrin. The lowest effect value was obtained in the study with soil microorganisms. A $PNEC_{soil}$ of 0.0882 mg/kg wet weight soil is derived from the available data considering an assessment factor of 50.

For the metabolite β-cyfluthrin-FPB-acid one study with the predaceous mite *Hypoaspis aculeifer* is available, with an EC_{50} value and a reproduction-NOEC and so an assessment factor of 100 can be used. This results in a $PNEC_{soil}$ for the metabolite β-cyfluthrin-FPB-acid of 2.63 mg/kg soil ww. Also for the metabolite β-cyfluthrin-permethric-acid one study with the predaceous mite *Hypoaspis aculeifer* is available, with an EC_{50} value and a reproduction-NOEC and so an assessment factor of 100 can be used. This results in a $PNEC_{soil}$ of 2.8 mg/kg soil ww.

2.2.2.3. PBT, vPvB and POP assessment

P/vP Criteria

Cyfluthrin

In an aquatic laboratory study under aerobic conditions a DT50 of 17.8 days (12 °C, in the dark) was measured for cyfluthrin. In the water/sediment system DT50 values of 4.3 and 9.3 days for the whole system and in the water phase DT50 from 0.2 to 0.3 days under aerobic conditions at a temperature of 12°C were determined. It can be assumed that the P criteria (>40 d in freshwater or >120 d in freshwater sediment) and the vP criteria (> 60 d in freshwater or >180 d in freshwater sediment) for aerobic freshwater-sediment systems are not fulfilled.

DT_{50} values in soil aerobic laboratory key studies ranged from 21.7 to 128.6 days (Trigger Half-life) and 43.6 to 195.2 days (Modelling Half-life), respectively, at 12°C The geometric mean delivered from half-lives of the key studies (n=5) is 54.4 days (Trigger Half-life), and 98.5 days (Modelling Half-life), respectively. Therefore, the P criterion (DT_{50} > 120 d – according to REACH regulation) and vP criterion in soil (DT_{50} > 180 d - according to REACH regulation) can be considered to be not fulfilled.

Metabolites

In water/sediment system three main metabolites were identified, permethric acid (DCVA), FPB-acid and FPB-ald.

The estimated DT_{50} values (whole system) amounted to 8.9 – 18 days for FPB- acid and ranged from 7.3 to 22.3 days for FPB-ald at an EU outdoor temperature of 12°C. For DCVA a half-life (total system) of 385 days at 12°C was calculated. Therefore, the P and vP criteria are not met for FPB-acid and FPB-ald in freshwater. The metabolite permethric acid (DCVA) can be considered as persistent in freshwater-sediment systems; P and vP criteria are fulfilled.

In soil two main metabolites, FPB-acid and DCVA, were identified. The half-life for FPB-acid in soil amounted to 74.2 days at 12°C. The P and vP criteria are not fulfilled. For DCVA, a worst case DT_{50} of 174.8 days (1S-trans cyfluthrin) at 12°C was calculated. The P criterion in soil can be considered to be fulfilled for the metabolite DCVA, but not the vP criterion.

B/vB criteria:

Cyfluthrin

The measured bioconcentration factor in fish of 1822 L/$kg_{wet\ fish}$ was lower than the calculated values for the four isomers of 21062 to 27164 L/$kg_{wet\ fish}$. Based on the available data, neither the B-criterion (BCF > 2000 L/kg_{ww}) nor the vB-criterion (BCF > 5000 L/kg_{ww}) are fulfilled.

Metabolites:

No bioaccumulation studies are available for the metabolites. The bioaccumulation study for the active substance suggests that bioaccumulation is only relevant for the parent substance. By estimating the octanol-water partitioning coefficient with KOWWIN (EPIWEB v4.1), a log K_{ow} value of 3.4 for DCVA, 3.3 for FPB-acid and 3.1 for FPB-ald has been calculated. Based on screening criteria, the metabolites FPB-acid, FPB-ald and permethric acid (DCVA) are therefore not B and vB

T Criterion:

Cyfluthrin

The lowest LC_{50} = 0.00055 µg Cyfluthrin/L and the lowest NOEC = 0.00041 µg β-Cyfluthrin/L are based on aquatic invertebrates. Therefore, the T criterion is fulfilled.

Metabolites

For DCVA *Daphnia magna* was the most sensitive species. A $LC_{50,acute}$ of 25 mg/L was determined.

The lowest LC_{50} for FPB-ald was measured in fish (*O. mykiss),* $LC_{50\ acute}$, = 0.792 mg/L.

The two metabolites DCVA and FPB-ald are less toxic than cyfluthrin by orders of magnitude. They can be considered as not potentially toxic ($LC_{50\ short\text{-}term}$ not < 0.1 mg/L). Therefore the T screening criterion is not fulfilled for DCVA and FPB-ald. For FPB-acid no ecotoxicity studies are available.

Conclusion for the risk characterisation:

Cyfluthrin fulfills the T-criterion and therefore one out of three PBT-criteria. The active substance cyfluthrin is **neither PBT - nor vP/vB - candidate** as the P, vP, B and vB criteria are not fulfilled.

Based on the available data the metabolites FPB-acid and FPB-ald can neither be considered as PBT nor as vPvB-candidate since the P and vP criteria are not fulfilled, even if no statement about B is possible. For permethric acid (DCVA) P and vP criteria are fulfilled, but T criterion is not met. Therefore, DCVA is no PBT-candidate. A statement on vP/vB behaviour is not possible, since no information on bioaccumulation in fish is available.

POP Criteria:

Cyfluthrin does not fulfil the criterion for being a B substance. It is neither P nor does it show a potential for long-range transport. Hence, Cyfluthrin does not meet the criteria for being a persistent organic pollutant.

2.2.2.4. Exposure assessment

For environmental exposure estimation data about two representative biocidal products are provided by the applicant. For the life cycle stage "production", no exposure assessment has been performed as the active substance is produced outside the EU. The same applies to the life cycle stage "formulation" of the biocidal product Cyfluthrin Foam. For the formulation process of the biocidal product Solfac® EW 050, the applicant stated no direct emission to the environmental compartments surface water and soil. Emissions are only possible by deposition from air. The applicant's statement is deemed to be plausible to the German CA during active substance evaluation. As information about the formulation process of Solfac® EW 050 are stated as confidential, the estimated PECs concerning the formulation process are listed in the directory for confidential data.

For the life cycle stage "professional and private use", different environmental exposure assessments have been performed for the two representative products depending on intended uses and applications. The environmental exposures are assessed applying the EU Technical Guidance Document (TGD) on Risk Assessment (2003) and the OECD Emission Scenario Document Number 18 for Insecticides, Acaricides and Products to Control Other Arthropods (PT 18) for Household and Professional Uses (July 2008) for the representative product Cyfluthrin Foam as well as the OECD Emission Scenario Document Number 14 for Insecticides for Stables and Manure Storage Systems (January 2006) for the representative product Solfac® EW 050.

Cyfluthrin Foam

The exposure of a.s. in the life cycle stage "private or non-professional use" of the biocidal product Cyfluthrin Foam is estimated considering the application steps by non-professionals indoor and subsequent cleaning steps of the product Cyfluthrin Foam.

The application of the b.p. as insecticide is envisaged for the control of crawling insects inside domestic premises, applied as a spray foam in cracks and crevices around skirting and door frames. The recommended application of the aerosol foam (content of cyfluthrin 0.04 % w/w in b.p.) is spraying with a directional tube applicator five seconds per one meter strip of 0.25 m width, delivering approximately 5 g of spray. This is equivalent to 20 g spray per m^2 and 0.008 g a.s. per m^2 surface. Due to the proposed non-professional indoor use of the ready-to-use product (RTU) the application could be described as:

- spray foam with targeted spot application in crack and crevices

A detailed description of emission scenarios for surface spray application including the input and output values is given in chapter II-8 (Cyfluthrin Foam).

Regarding the cleaning step, two general cleaning methods (wet and dry cleaning with emission to waste water or wastes) are described in the OECD ESD No.18. Generally, cleaning steps take place at the same day as the application. It is not expected that residues of Cyfluthrin Foam can be removed by dry cleaning methods. Thus, the exposure pathway of solid waste to municipal landfill is negligible. The wet room cleaning process is relevant for the environmental risk assessment. The emission rates to waste water by foam spray application were used for the exposure assessment taking into account fate and behaviour of a.s. in the environment. Assuming that residues of a.s. removed through wet cleaning may be emitted to waste water, the STP is considered as the primary receiving compartment for a.s. Hence, PECs have been estimated for the aquatic compartment including STP, surface water, and sediment, and for the terrestrial compartment including soil and groundwater.

Solfac® EW 050

An exposure estimation has been performed for the life cycle stage "professional use" of the biocidal product indoors in commercial animal housings. The application mode is spraying a strip on window frames and to ceilings using a low pressure Knapsack (backpack) sprayer. After the dilution of the biocidal product (5 % active substance) with water the b.p. contains a.s. at a concentration of maximal 0.08 % w/w. The application rate of b.p. for the recommended application is 4 g a.s. per 100 m² floor area. In July 2015 the applicant provided additional information with reference to the recommended application rate on the label of b.p. Solfac EW 050 where a lowest application rate of 20 mg a.s./m² is also recommended in rural hygiene. Efficacy data were provided supporting both rates (40 mg a.s./m² and 20 mg a.s./m²). Thus and due to the late information by the applicant, the eCA decided to consider the reduced application rate of 2 g a.s. per 100 m² floor area in a semi-quantitative approach. The application frequency is limited to a maximum of 7 applications per year from April to October with an interval of 21 days.

Predicted environmental concentrations (PECs) have been estimated for the terrestrial compartment including soil and groundwater, and for the aquatic compartment including sewage treatment plant (STP), surface water, and sediment. The estimation of PECs is based on two emission models:

- soil, due to manure applications carried out according to maximum nitrogen immission limits (Europe), afterwards to ground water and surface water and

- waste water, which is subsequently treated in a STP, leading to releases to soil (via sludge deposition), surface water, sediment, and ground (pore) water.

The releases of cyfluthrin during manure and slurry applications were calculated for all animal categories and subcategories according to OECD ESD No. 14. A detailed description of the emission scenario for insecticidal application in animal housings including the input and output values is given in chapter II-8 (Solfac® EW 050). For the soil compartment, the PEC calculation assumes application of manure/slurry onto agricultural soils (arable land and grassland). Different approaches have been calculated:

- an unrealistic worst case situation without consideration of degradation of a.s. in soil;

- a more realistic situation taking into account the degradation of a.s. in soil and a carry over of a.s. residues due to successive manure application;

The CA has chosen the realistic approach taking into account the degradation of a.s. in soil after manure applications to agricultural soil. The corresponding PEC soil values were used for further calculations of PEC groundwater and PEC surface water considering nitrogen limited immissions(2). Regarding the release via manure to soil, the maximum PEC values in arable and grassland soil for nitrogen limited immission are associated with application of veal calves slurry.. For PEC groundwater estimation, the approach was accomplished according to the pore water calculation model. For all scenarios, the predicted concentrations in groundwater were significantly below the threshold criteria of 0.1 $\mu g.L^{-1}$. The release to surface water is equivalent to the worst-case prediction for groundwater

[2] The CA took into account the decisions made at the Technical Meeting I/2008 to use the lower N immission limits according to the EU Nitrate Directive (91/676/EC). The maximum N immission standards used for PEC estimation amount to 170 kg N per ha and year both in case of grassland and of arable land. The maximum Phosphate immission standards (as provided in OECD ESD No. 14) were not be used as these are only applied in NL.

based upon the pore water model, adjusted by a default dilution factor of 10. Emission to air is negligible.

Particularly during the cleaning procedure of poultry housing systems with high-pressure cleaning equipment a fraction of the applied b.p. can be released to waste water that is discharged to a STP or directly released to surface water. These release fractions to waste water were calculated according to recommendations in the OECD ESD No. 14. For the PEC calculation in the environmental compartments, it is assumed that only one farm releases liquid wastes into the sewer at one day. The PEC estimation is based on the worst-case assumption that untreated waste water is released to STP and that the influent concentration of a.s. is representative for the PEC for micro-organisms. PEC_{STP} and $PEC_{surface\ water}$ as well as $PEC_{sediment}$ were calculated for the poultry categories-subcategories according to equations 38 and 48 as well as 50 EU TGD (2003). No higher tier approach for the STP scenario is available.

For the terrestrial compartment, the PECs for soil and groundwater were calculated according to equation 66 and 68 EU TGD (2003) after sewage sludge application.

2.2.2.5. Risk characterisation

For cyfluthrin the applicant provided data for two representative products used in different application areas and with different application rates. For the production process of a.s. as well as the formulation process of Cyfluthrin Foam no environmental exposure assessment and thus no risk characterisation was carried out. In spite of no requirement for a risk characterisation in the frame of Regulation (EU) 528/2012, an environmental exposure assessment was accomplished for the formulation process of Solfac® EW 050. Within the scope of the product authorisation it has to be checked again whether the production and formulation processes as described by the applicant still apply.

Aquatic Compartment

Two different emission pathways were identified regarding the aquatic compartment:

- Emission via wastewater to STP and subsequently to surface water and sediment (indoor application in animal housings / indoor application in domestic areas with wet cleaning of treated surfaces)
- Emission via manure application to soil leading to releases to groundwater and subsequently to surface water and sediment (indoor application in animal housings).

The PEC/PNEC ratios for both emission paths and representative products are shown in Tables 2-10 and 2-11.

Table 2-10 Cyfluthrin Foam: Risk characterisation for the aquatic compartment from releases via waste water to STP

PEC_{STP} [mg/L]	$PNEC_{microorganism}$ [mg/L]	PEC / PNEC
2.56×10^{-5}	2.3×10^{-4}	1.11×10^{-1}
$PEC_{surface\ water}$ [µg/L]	$PNEC_{water}$ [µg/L]	PEC / PNEC

2.82×10^{-4}	4.1×10^{-5}	**6.88**
$PEC_{sediment}$ [µg/kg ww]	**$PNEC_{sediment}$ [µg/kg ww]**	**PEC / PNEC**
7.60×10^{-1}	2.7×10^{-2}	**28.1**

Table 2-11 Cyfluthrin Solfac® EW50: Risk characterisation for the aquatic compartment from releases via waste water to STP

Exposure scenario (animal category)	**PEC_{STP} [mg/L]**	**$PNEC_{microorganism}$ [mg/L]**	**PEC / PNEC**
Laying hen – battery + aeration (8)	3.75×10^{-3}	2.3×10^{-4}	**1.63×10^{1}**
Laying hen – free range litter (11)	7.00×10^{-3}		**3.04×10^{1}**
Broilers – free range (12)	5.48×10^{-3}		**2.38×10^{1}**
Turkeys (16)	1.61×10^{-2}		**7.00×10^{1}**
Considering lower insecticide application rate of 20 mg a.s./m²	8.10×10^{-3}		**3.52×10^{1}**
Ducks (17)	9.75×10^{-3}		**4.24×10^{1}**
Geese (18)	1.21×10^{-2}		**5.26×10^{1}**
Exposure scenario	**$PEC_{surface\ water}$ [µg/L]**	**$PNEC_{water}$ [µg/L]**	**PEC / PNEC**
Laying hen – battery + aeration (8)	4.24×10^{-2}	4.1×10^{-5}	**$1.02 \times 10^{+3}$**
Laying hen – free range litter (11)	7.79×10^{-2}		**$1.90 \times 10^{+3}$**
Broilers – free range (12)	6.10×10^{-2}		**$1.49 \times 10^{+3}$**
Turkeys (16)	1.80×10^{-1}		**$4.39 \times 10^{+3}$**
Considering lower insecticide application rate of 20 mg a.s./m²	9.00×10^{-2}		**$2.20 \times 10^{+3}$**
Ducks (17)	1.08×10^{-1}		**$2.63 \times 10^{+3}$**
Geese (18)	1.35×10^{-1}		**$3.29 \times 10^{+3}$**
Exposure scenario	**$PEC_{sediment}$ [mg/kg ww]**	**$PNEC_{sediment}$ [mg/kg ww]**	**PEC / PNEC**
Laying hen – battery + aeration (8)	1.14×10^{-1}	2.7×10^{-5}	**$4.22 \times 10^{+3}$**
Laying hen – free range litter (11)	2.1×10^{-1}		**$7.78 \times 10^{+3}$**
Broilers – free range (12)	1.64×10^{-1}		**$6.07 \times 10^{+3}$**
Turkeys (16)	4.85×10^{-1}		**$1.80 \times 10^{+4}$**
Considering lower insecticide application rate of 20 mg a.s./m²	2.43×10^{-1}		**$9.00 \times 10^{+3}$**

Ducks (17)	2.91×10^{-1}		**$1.08 \times 10^{+4}$**
Geese (18)	3.64×10^{-1}		**$1.35 \times 10^{+4}$**

Regarding the emission pathway via wastewater to STP and subsequently to surface water and sediment unacceptable risks for the function of the STP, surface water and sediment were identified from the use of cyfluthrin in poultry stables with a wastewater discharge to sewage treatment plants (product for indoor application in animal housings). After consultation with the applicant, it was decided to include a label restriction that prevents the use of biocidal products containing cyfluthrin as the active substance in animal housings where exposure to the STP and/or surface water cannot be prevented. Consequently, direct releases from animal housings to surface water have to be avoided as well.

To refine the environmental exposure assessment, i.e. to demonstrate a potential degradation of cyfluthrin in STP, it is suggested to perform an aerobic sewage treatment plant simulation study (OECD 303 A) at the stage of product authorisation.

Regarding the emission pathway via manure/slurry to agricultural soil and subsequently to surface water and sediment, the risk assessment was performed both for worst-case and best-case animal (sub)categories and also a reduced application rate was considered. Acceptable risks for surface water and sediment were identified for 2 specific animal (sub)categories: beef cattle and laying hen – battery (no treatment). For sediment, all other animal (sub)categories showed unacceptable risks, even for the reduced application rate. Thus, in the aquatic compartment acceptable risks can be estimated only for 2 animal (sub)categories. Considering the use of cyfluthrin in domestic areas (as Cyfluthrin Foam) with wet cleaning of treated surfaces, the risk was only acceptable for STP. An unacceptable risk for surface water and sediment was identified. No risk mitigating measures were considered as appropriate; therefore, no safe use of the product Cyfluthrin Foam could be demonstrated.

In summary, the use of cyfluthrin formulated as Solfac® EW 050 revealed an acceptable risk for the aquatic compartment when implementing the necessary restriction for animal housings as mentioned above. Thus, in case of poultry housings an acceptable risk can only be considered on the condition of releases of waste water to the manure/slurry storage facility and subsequent deposition of manure/slurry mixed with the waste water to agricultural land and this is only valid for the poultry (sub)category 7 "laying hen – battery (no treatment)". An acceptable risk for the aquatic compartment in case of application of cyfluthrin formulated as Solfac® EW 050 in animal housing other than poultry housings can only be considered for the animal category beef cattle. With regard to the product Cyfluthrin Foam no safe use could be demonstrated.

The available data sets for metabolites DCVA (3-(2,2-dichloroethenyl)-2,2-dimethyl-cyclopropanecarboxylic acid, Permethric acid), FPB-ald (4-fluoro-3-phenoxy-benzaldehyde, FCR 1260) and FPB-acid (4-fluoro-3-phenoxy-bencoic acid, COE 538/78), which are present in the aquatic compartment, show that DCVA and FPB-ald are less toxic than the parent substance. The same was supposed for FPB-acid. Thus, a risk characterisation was not carried out.

Terrestrial Compartment including Groundwater

Two different emission pathways were identified regarding the terrestrial compartment:

- Emission via wastewater to STP leading to releases to soil via sewage sludge deposition and subsequently, to groundwater (indoor application in animal housings / indoor application in domestic areas with wet cleaning of treated surfaces)

- Emission via manure application leading to releases to soil and subsequently, to groundwater (indoor application in animal housings)

The PEC/PNEC ratios for both emission pathways and products are presented in Tables 2-12 to 2-14.

Table 2-12 Cyfluthrin Foam: Risk characterisation for the terrestrial compartment from releases via waste water to STP

PEC_{soil} [µg/kg ww] *	$PNEC_{soil}$ [µg/kg ww]	PEC / PNEC
8.98×10^{-2}	8.82×10^{1}	1.02×10^{-3}
$PEC_{groundwater}$ [µg/L]	**Trigger $value_{groundwater}$ [µg/L]**	**RQ**
2.58×10^{-5}	1.00×10^{-1}	2.58×10^{-4}

* Calculation on basis of wet soil density: 1700 kg/m³

Table 2-13 Cyfluthrin Solfac® EW50: Risk characterisation for the terrestrial compartment from releases via waste water to STP

Exposure scenario	PEC_{soil} [µg/kg ww]	$PNEC_{soil}$ [µg/kg ww]	PEC / PNEC
Turkeys (16)	5.66×10^{1}	8.82×10^{1}	6.42×10^{-1}
Exposure scenario	**$PEC_{groundwater}$ [µg/L]**	**Trigger $value_{groundwater}$ [µg/L]**	**RQ**
Turkeys (16)	1.63×10^{-2}	1.00×10^{-1}	1.63×10^{-1}

Table 2-14 Cyfluthrin Solfac® EW50: Risk characterisation for the terrestrial compartment from slurry/manure application on grassland and arable land in Nitrogen (N) limited system

Exposure scenario	PEC_{soil} [µg/kg ww]	$PNEC_{soil}$ [µg/kg ww]	PEC / PNEC
Grassland (N, veal calf)	1.38×10^{1}	8.82×10^{1}	1.56×10^{-1}
Arable land (N, veal calf)	4.37×10^{0}		4.95×10^{-2}
Exposure scenario	**$PEC_{groundwater}$ [µg/L]**	**Trigger $value_{groundwater}$ [µg/L]**	**RQ**
Nitrogen limited immission, grassland	6.32×10^{-3}	1.00×10^{-1}	6.32×10^{-2}
Nitrogen limited immission, arable land	2.00×10^{-3}		2.00×10^{-2}

From the use of cyfluthrin for both applications (in animal housings as well as in domestic areas) with releases to soil from sewage sludge application no unacceptable risks for the terrestrial compartment including groundwater were identified.

In the terrestrial compartment, a risk characterisation was carried out for the relevant metabolites DCVA (Permethric acid) and FPB acid (4-fluoro-3-phenoxy-bencoic acid, COE 538/78). For that purpose, a worst-case assumption was made, that both metabolites were formed in soil at a quantity of 100% in regard to cyfluthrin:

Table 2-15 Cyfluthrin Solfac® EW50: Risk characterisation for the terrestrial compartment for metabolites DCVA and FPB-acid

Metabolite	PEC_{soil} [mg/kg ww]	$PNEC_{soil}$ [mg/kg ww]	PEC / PNEC
DCVA	6.64×10^{-3}	2.63×10^{0}	2.52×10^{-3}
FPB-acid	7.38×10^{-3}	2.80×10^{0}	2.64×10^{-3}
Exposure scenario	**$PEC_{groundwater}$ [µg/L]**	**Trigger $value_{groundwater}$ [µg/L]**	**RQ**
DCVA	4.00×10^{-3}	1.00×10^{-1}	4.00×10^{-2}
FPB-acid	$< 1.00 \times 10^{-4}$	1.00×10^{-1}	$< 1.00 \times 10^{-3}$

No unacceptable risk for soil was identified. The calculation of $PEC_{groundwater}$ for the metabolites was accomplished by use of FOCUS model PEARL (transport and fate simulation tool). The predicted concentrations in groundwater were below the threshold criteria of 0.1 µg.L^{-1} for all scenarios. That means no unacceptable risk is expected for the terrestrial compartment including groundwater from releases of the degradation products of cyfluthrin.

In summary, no unacceptable risk for the terrestrial compartment including groundwater is identified for the use of cyfluthrin in animal housings and domestic areas.

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

Secondary poisoning was asssed for aquatic and terrestrial food chains (Table 2-16 and 2-17):

Table 2-16 Assessment of secondary poisoning for aquatic food chain following b.p. application

Exposure scenario		$PEC_{oral,predator}$ [mg/kg]	$PNEC_{oral,mammal}$ [mg/kg food]	PEC / PNEC
Cyfluthrin Solfac® EW50	manure application on grassland	1.15×10^{-3}	6.67	1.72×10^{-4}
	waste water releases to STP from poultry housing	3.28×10^{-1}		4.92×10^{-2}
Cyfluthrin Foam	waste water releases to STP from household spray application	1.54×10^{-4}		2.31×10^{-5}

Table 2-17 Assessment of secondary poisoning for terrestrial food chain following b.p. application

Exposure scenario		$PEC_{oral,predator}$ [mg/kg]	$PNEC_{oral,mammal}$ [mg/kg food]	PEC / PNEC
Cyfluthrin Solfac® EW50	manure application on grassland	3.11×10^{-2}	6.67	4.66×10^{-3}
	waste water releases to STP with subsequent sludge application on soil	8.12×10^{-2}		1.22×10^{-2}
Cyfluthrin Foam	waste water releases to STP from household spray application with subsequent sludge application on soil	3.86×10^{-5}		5.79×10^{-6}

Although values for BCF_{fish} and $BCF_{earthworm}$ indicate that cyfluthrin has a potential for bioaccumulation via terrestrial and aquatic food chain and aquatic BCF_{fish} is only slightly lower than the trigger value for the B criterion, an assessment for secondary poisoning in both the aquatic and terrestrial food chain indicate no unacceptable risk from the intended uses.

2.2.3. Assessment of endocrine disruptor properties

No specific studies for potential endocrine disruption were carried out. Indications for endocrine disrupting properties are currently not available. In addition, Cyfluthrin does not meet the transitional criteria of Regulation (EU) No 528/2012. Therefore, Cyfluthrin shall not be considered as having endocrine-disrupting properties.

2.3. Overall conclusions

The outcome of the assessment for cyfluthrin in product-type 18 is specified in the BPC opinion following discussions at the 14th meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA web-site.

2.4. List of endpoints

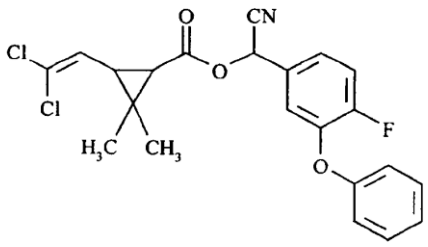
The most important endpoints, as identified during the evaluation process, are listed in Appendix I.

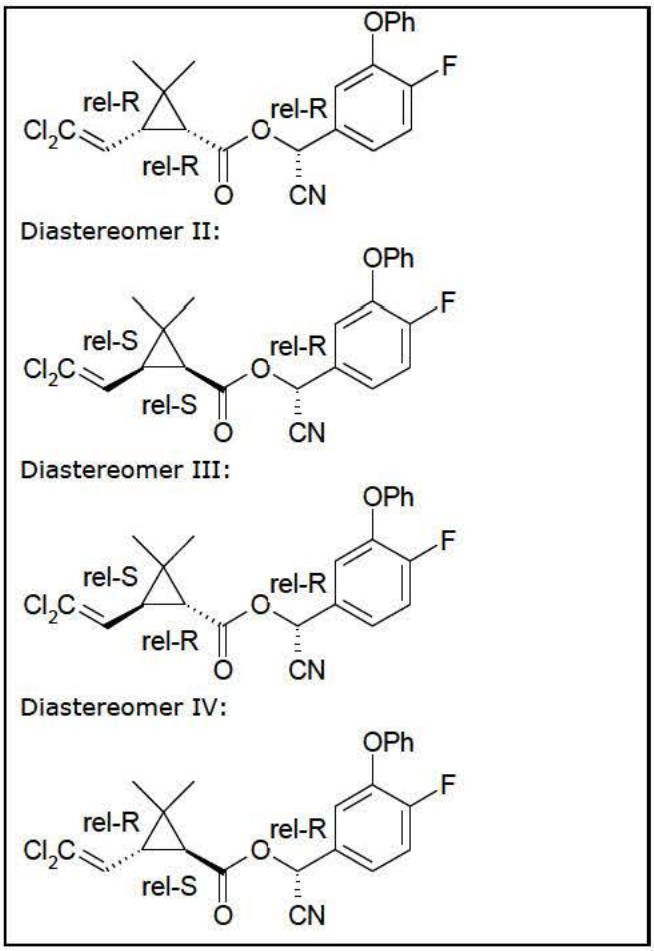
Appendix I: List of endpoints

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

Active substance (ISO Common Name)	Cyfluthrin
Product-type	18 (insecticide)

Identity

Chemical name (IUPAC)	(RS)-α-Cyano-4-fluoro-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
Chemical name (CA)	Cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2- dimethyl-, cyano(4-fluoro-3-phenoxyphenyl)methyl ester
CAS No	68359-37-5 (unstated stereochemistry) Diastereomer I: 86560-92-1 Diastereomer II: 86560-93-2 Diastereomer III: 86560-94-3 Diastereomer IV: 86560-95-4
EC No	269-855-7
Other substance No.	CIPAC-No.: 385 EU Index No. 607-253-00-1
Minimum purity of the active substance as manufactured (g/kg or g/l)	955 g/kg Diastereomer I: 230- 270 g/kg Diastereomer II: 170-210 g/kg Diastereomer III: 320-360 g/kg Diastereomer IV: 210-250 g/kg each diastereomer (I, II, III, IV) is composed of two enantiomers with an enantiomeric ratio of approximately 1:1
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	No relevant impurities were identified. Significant impurities are summarised in DocIIIA.
Molecular formula	$C_{22}H_{18}Cl_2FN0_3$
Molecular mass	434.3 g/mol
Structural formula	 Diastereomer I:


OPh
F
rel-R
rel-R
Cl_2C
O
rel-R
O
CN
Diastereomer II:
OPh
F
rel-S
rel-R
Cl_2C
O
rel-S
O
CN
Diastereomer III:
OPh
F
rel-S
rel-R
Cl_2C
O
rel-R
O
CN
Diastereomer IV:
OPh
F
rel-R
rel-R
Cl_2C
O
rel-S
O
CN

Physical and chemical properties

Melting point (state purity)	Diastereomer I: 64.40 °C Diastereomer II: 80.71 °C Diastereomer III: 64.04 °C Diastereomer IV: 106.19 °C
Boiling point (state purity)	not applicable (decomposition above 250°C)
Temperature of decomposition	250 °C
Appearance (state purity)	brown viscous mass with crystalline parts (> 92 %)
Relative density (state purity)	1.26 (94.3 %)
Surface tension	not applicable (solubility less than 1 mg/l)
Vapour pressure (in Pa, state temperature)	Diastereomer I: 2.1 x 10^{-6} Pa at 25°C Diastereomer II: 3.4 x 10^{-7} Pa at 25°C Diastereomer III: 4.7 x 10^{-7} Pa at 25°C Diastereomer IV: 2.0 x 10^{-7} Pa at 25°C
Henry's law constant (Pa m^3 mol^{-1})	Diastereomer I: 1.9 x10^{-1} Pa.m^3.mol^{-1} Diastereomer II: 3.2 x10^{-3} Pa.m^3.mol^{-1} Diastereomer III: 4.2 x10^{-3} Pa.m^3.mol^{-1} Diastereomer IV: 1.3 x10^{-2} Pa.m^3.mol^{-1}
Solubility in water (g/l or mg/l, state temperature)	pH 3: Diastereomer I = 0.0025 mg/l at 20 °C Diastereomer II = 0.0021 mg/l at 20 °C Diastereomer III = 0.0032 mg/l at 20 °C Diastereomer IV = 0.0043 mg/l at 20 °C
	pH 7: Diastereomer I = 0.0022 mg/l at 20 °C Diastereomer II = 0.0019 mg/l at 20 °C Diastereomer III = 0.0022 mg/l at 20 °C Diastereomer IV = 0.0029 mg/l at 20 °C
Solubility in organic solvents (in g/l or mg/l, state temperature)	toluene : > 200 g/l (Diastereomer I, II, III); 100-200 g/l (Diastereomer IV) n-hexane : 10 - 20 g/l (Diastereomer I, II, III); 1-2 g/l (Diastereomer IV) 2-propanol: 20 - 50 g/l (Diastereomer I) 5 -10 g/l (Diastereomer II) 10 -20 g/l (Diastereomer III) 2 - 5 g/l (Diastereomer IV) dichloromethane > 200 g/l (Diastereomer I, II, III, IV)
Stability in organic solvents used in biocidal products including relevant breakdown products	The cyfluthrin content is not affected after storage at ambient conditions for 1 year.
Partition coefficient (log P_{OW}) (state temperature)	Diastereomer I: logPow 6.0 at 20 °C Diastereomer II: logPow 5.9 at 20 °C Diastereomer III: logPow 6.0 at 20 °C Diastereomer IV: logPow 5.9 at 20 °C
Hydrolytic stability (DT_{50}) (state pH and temperature)	pH 4, 20°C: > 1 year (all isomers) pH 4, recalculated to 12°C: > 2 year (all isomers)
	pH 7, 20°C: 270 d (diastereomers I + II)

	200 d (diastereomers III + IV) pH 7, recalculated to 12°C: 339 - 512 d (diastereomers I + II) 212 - 303 d (diastereomers III + IV)
	pH 9, 20°C: 42 h (diastereomers I + II) 33 h (diastereomers III + IV) pH 9, recalculated to 12°C: 2.5 – 3.3 d (diastereomers I + II) 2.0 – 2.6 d (diastereomers III + IV)
Dissociation constant	Not applicable
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	All Diastereomers (methanol): No absorption above 290 nm.
Photostability (DT_{50}) (aqueous, sunlight, state pH)	In water (pH 5, 1 % acetonitrile): DT50: 12.2 d (medium-pressure mercury lamp) DT50: < 1d (natural sunlight, August/September, Kansas, 38°49' North)
Quantum yield of direct phototransformation in water at Σ > 290 nm	0.0052
Flammability	not a highly flammable solid Auto-ignition temperature (liquids and gases): 375°C (DIN 51 794).
Explosive properties	not explosive

Classification and proposed labelling

with regard to physical/chemical data	none
with regard to toxicological data	*Proposed classification and labelling of cyfluthrin based on Regulation (EC) No. 1272/2008:* Classification: Acute Tox. 2, Acute Tox. 2, STOT SE 3, Lact. Labelling: GHS06, Danger Hazard statements: H300 (Fatal if swallowed), H330 (Fatal if inhaled), H335 (May cause respiratory irritation), H362 (May cause harm to breast-fed children) Precautionary statements: (P102), P260, P263, P264, P270, P284, P301 + P310, P330, P308 + P313, P403 + P233, P405
with regard to fate and behaviour data	none
with regard to ecotoxicological data	*Proposed classification and labelling of cyfluthrin based on Regulation (EC) No. 1272/2008:* Classification: Aquatic Acute 1, Aquatic Chronic 1 Labelling: GHS09, Warning Hazard statements: H400 (Very toxic to aquatic life), H410 (Very toxic to aquatic life with long lasting effects) M-Factor = 1000000 acute and 100000 chronic Precautionary statements: P 273, P 391, P 501

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	CIPAC method 385 TC/M/31 based on normal phase HPLC using UV detection at 235 nm.
Impurities in technical active substance (principle of method)	gas chromatography

Analytical methods for residues

Soil (principle of method and LOQ)	residue definition: cyfluthrin GC-ECD LOQ = 0.05 mg/kg GC-MSD LOQ = 0.05 mg/kg
Air (principle of method and LOQ)	residue definition: cyfluthrin GC-ECD LOQ = 0.7 µg/m³ GC-MSD LOQ = 0.7 µg/m³
Water (principle of method and LOQ)	residue definition: cyfluthrin GC-ECD LOQ = 0.05 µg/L (drinking water) GC-ECD LOQ = 0.02 µg/L (surface water) A confirmatory method and additional validation at 0.01 µg/L is required.
Body fluids and tissues (principle of method and LOQ)	residue definition for body tissues: cyfluthrin GC-ECD LOQ = 0.01 mg/kg (meat, liver) residue definition for body fluids (urine): metabolites DCCA and FPBA GC-MSD LOQ = 0.5 µg/L (DCCA) LOQ = 1 µg/L (FPBA)
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	not required
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	not required

Chapter 3:Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	≥ 90% based on urinary (60-70%), biliary and faecal (25-35%) excretion within 48 h
Rate and extent of dermal absorption for the active substance:	1% for high (1.25 mg/cm^2) and low dose (0.38 mg/cm^2) of cyfluthrin based on the read-across to beta-cyfluthrin (beta-cyfluthrin FS125).‡ *Solfac® EW 050:* 1% based on in vitro skin penetration assay in with a beta-cyfluthrin formulation (beta-cyfluthrin FS125) *Cyfluthrin Foam:* 10% (based on expert judgement)
Distribution:	Small apparent distribution volume, high plasma concentrations; highest residue in fat tissue
Potential for accumulation:	No evidence of accumulation
Rate and extent of excretion:	≥ 90 % within 48 h, mainly via urine (60-70 %)
Metabolism	Extensively metabolised and excreted: *Major metabolites:* 4'OH-FPB-acid-conjugate: 36 - 52.0 % in urine, 4'OH-FPB-acid: up to 11 % in urine and faeces, FPB-acid: 12-24.1 % in urine , hippuric acid: up to 7 % conjugate of hydroxylated hippuric acid: up to 3 % *Unchanged parent compound:* < 1 %: single low dose, oral, i.v. 11.6 % multiple low dose, oral 16 % oral high dose
Toxicologically significant metabolite(s)	Parent compound and metabolites

Acute toxicity

Rat LD_{50} oral	16.2 mg/kg bw (cremophor EL/H20), 155 mg/kg bw (peanut oil/acetone)
Rat LD_{50} dermal	> 5000 mg/kg bw
Rat LC_{50} inhalation	405 µg/L air (4 h)
Skin irritation	Not irritating
Eye irritation	Not irritating
Skin sensitization (test method used and result)	Not sensitising (M+K)

Repeated dose toxicity

Species/ target / critical effect	Dog: nervous system: gait and posture abnormalities, Rat: nervous system: gait abnormalities, salivation, sciatic nerve degeneration; general: decreased weight gain

‡ As no studies on dermal absorption were performed with a formulation containing α-cyfluthrin a dermal absorption study with the respective product/formulation has to be performed at product authorisation stage.

Lowest relevant oral NOAEL / LOAEL	Medium-term: 6.5 mg/kg bw/d in a 6 months/1 year dog study Long-term: 12 mg/kg bw/d in a 2 year rat study
Lowest relevant dermal NOAEL / LOAEL	376 mg/kg bw/d in a 3-week rat study
Lowest relevant inhalation NOAEL / LOAEL	0.09 µg/L air (6 h/d) in a 13 week rat study

Genotoxicity	No evidence of a genotoxic potential

Carcinogenicity

Species/type of tumour	Rat, mouse: no tumours
Lowest dose with tumours	Not applicable
Relevant carcinogenic NOAELs (rat, mouse)	22.8 mg/kg bw/d in a 2 year rat study,

Reproductive toxicity

Species/ Reproduction target / critical effect	Rat: parental: reduced body weight gain, reproductive: reduced number of implantation sites, offspring: reduced birth weight, tremors
Relevant parental NOAEL	10 mg/kg bw/d
Lowest relevant reproductive NOAEL / LOAEL	10 mg/kg bw/d
Relevant offspring NOAEL	10 mg/kg bw/d
Species/Developmental target / critical effect	Rat, oral: maternal: mortality, decreased body weight gain, salivation, locomotor incoordination, developmental: decreased foetal weight, reduced ossification Rat, inhalation: maternal: reduced food intake and body weight gain, developmental: retarded ossification, reduced birth weight Rabbit, oral: maternal: decreased food intake and body weight gain, developmental: increased post implantation loss
Relevant maternal NOAEL/NOAEC	Oral: 3 mg/kg bw/d; inhalation: < 0.46 µg/L air (6 h/d)
Lowest relevant developmental NOAEL / LOAEL	Oral: 10 mg/kg bw/d, inhalation: 0.46 µg/L air (6 h/d)

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	Rat, acute: reduced motor and locomotor activities, self-inflicted lesions due to paraesthesia, reduced slip angle, salivation, gait abnormalities
Relevant acute neurotoxicity NOAEL	2 mg/kg bw
Relevant medium-term neurotoxicity NOAEL	2 mg/kg bw/d (90-d oral neurotoxicity rat)

Other toxicological studies

Developmental neurotoxicity study	Increased vocalisation of pups Relevant developmental neurotoxicity NOAEL:

	19.0 mg/kg bw/d
Mechanistic study on hypothermia and transient respiratory changes	Reflex bradypnoea by sensory irritation induces secondary hypothermia and respiratory alkalosis.
Antidotal studies	Moderate (≤ 2fold) protective activity of tetrazepam, atropine sulphate and methocarbamol
Inhalation study in humans (1hr)	LO(A)EC: 0.1 µg/L air/1h

Medical data

Medical surveillance data on manufacturing plant personnel.	Paraesthesia of exposed skin was observed in five workers without systemic symptoms or sequelae
Studies on professional pest control operatives	Different metabolite ratio after oral vs. inhalation exposure, excretion within 48 h

Summary	Value	Study	Safety factor
Non-professional user			
AEL_{acute}*	0.02 mg/kg bw	Acute neurotox rat	100
$AEL_{medium\text{-}term}$*	0.02 mg/kg bw/d	90-d. neurotox rat	100
$AEL_{long\text{-}term}$*	0.02 mg/kg bw/d	Acute neurotox rat, 90-d. neurotox rat **	100
ADI (acceptable daily intake, external long-term reference dose)	0.02 mg/kg bw	Acute neurotox rat, 90-d. neurotox rat **	100
ARfD (acute reference dose)	0.02 mg/kg bw	Acute neurotox rat	100
$AEC_{inhalation}$+	0.010 mg/m³ air	Acute inhalation study, man	10^{++}
Professional user			
Reference value for inhalation (proposed OEL)	7 µg/m3	sensory irritation	
Reference value for dermal absorption concerning the active substance:			
Reference value for dermal absorption concerning the representative product(s):			

* AEL: Systemic (= Internal) Acceptable Exposure Level

** Since the relevant NOAELs for chronic toxicity are higher than those for acute/subacute neurotoxicity the ADI and the $AEL_{long\text{-}term}$ are derived from acute/subacute studies and have the same values as the ARfD and the $AEL_{short\text{-}term/medium\text{-}term}$, respectively.

+ $AEC_{inhalat\ on}$: Inhalation (= External) Acceptable Exposure Concentration. Since similar effects at the same concentrations are evident in acute (human) and long-term studies (13-weeks, rat) this $AEC_{inhalat\ on}$ accounts for short-, medium- and long-term exposure.

++ Chemical Specific Adjustment Factor

Acceptable exposure scenarios (including method of calculation)	
Professional users	
Production of active substance:	Not assessed by the rapporteur under the requirements of the BPD
Formulation of biocidal product	Not assessed by the rapporteur under the requirements of the BPD
Intended uses	**Spray application** Dilution of biocidal product (5 % active substance) with water to a concentration of 0.08 % active substance ***Application (including mixing and loading):*** Diluting biocidal product with water, loading sprayer with biocidal product priming pump and spray line / Spraying (indoor) Form of exposure: dermal contact to concentrate (5 % and 0.08% a.s.), aerosol (0.08 % a.s.) Duration: 120 min Frequency: daily Model: Model 1 (Spraying) TNsG Human Exposure Part 2 ***Post-application:*** Unblock spray nozzle and cleaning Form of exposure: dermal contact to spray solution (0.08 % a.s.) Duration: Frequency: daily Assessment according to Marquart et al. (2006)
	Inhalation exposure (application phase): 0.016 mg/m^3 Dermal exposure (all phases): 50.9 mg/person/day
Secondary exposure	Working in animal housing e.g. cleaning of animal housing Form of exposure: inhalation of dust with cyfluthrin, dermal contact to treated surfaces (0.08 % a.s.) Duration: -- Frequency: incidental Model: Expert judgement based on the information that 0.04g cyfluthrin/m^2 is used and the palm of both hands (420 cm^2) could be exposed
	Inhalation exposure: negligible Dermal exposure: 1.7 mg/kg/day
Non-professional users	**Cyfluthrin Foam** Spraying (inhalation, dermal, oral exposure) acc. to Consexpo 4.1 Acute exposure: Adults: 1.8% of AEL Chronic (long-term) exposure: Adults: 1.48% of AEL

	Solfac® EW 050 Non-professional use/exposure is not intended.
Indirect exposure as a result of use	**Cyfluthrin Foam** Dermal and oral exposure of infants by contact to treated surfaces Acute exposure: Infants: 27% of AEL Chronic (long-term) exposure: Infants: 27% of AEL **Solfac® EW 050** Inhalation and dermal exposure from treated surfaces after re-entry: Acute exposure: Adults: 0.9% of AEL Children: 1.8% of AEL Chronic (long-term) exposure: Adults: 0.09% of AEL Children:1.8% of AEL
Combined Exposure	**Cyfluthrin Foam** Combined primary and secondary exposure (oral, dermal, inhalation) as listed above Acute exposure: Adults: 1.8% of AEL Infants: 27% of AEL Chronic (long-term) exposure: Adults: 1.48% of AEL Infants: 27% of AEL

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 4, 20°C: > 1 year (all isomers) recalculated to 12°C: > 2 year (all isomers)
	pH 7, 20°C: 270 d (diasteremers I + II) 160 d (diastereomers III + IV) recalculated to 12°C: 339 - 512 d (diastereomers I + II) 212 - 303 d (diastereomers III + IV)
	pH 9, 20°C: 42 h (diastereoisomers I + II) 33 h (diastereoisomers III + IV) recalculated to 12°C: 2.5 – 3.3 d (diastereomers I + II) 2.0 – 2.6 d (diastereomers III + IV)
	FPB-ald: 11 % at pH 7 after 35 d, 89 % at pH 9 after 14 and 21 d DCVA: Half-life at 25 °C > 1 year at pH 4, 7, 9 FPB-ald: FPB-ald was found stable to hydrolysis.
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	In water (pH 5, 1 % acetonitrile): DT50: 12.2 d (medium-pressure mercury lamp) DT50: < 1d (natural sunlight, August/September, Kansas, 38°49' North) formation of FPB-ald, sequentially FPB-acid and DCVA
Readily biodegradable (yes/no)	considered to be not readily biodegradable
Biodegradation in seawater	No exposure
Aerobic aquatic degradation (surface water)	**fluorobenzene-UL-^{14}C] cyfluthrin** DT_{50} (25°C) = 6.3 d DT_{50} (12°C) = 17.8 d No mineralisation to CO_2. Metabolite: FPB-acid (maximum 70%, day 21)
Non-extractable residues	**fluorobenzene-UL-^{14}C] cyfluthrin :** 21-29% of applied radioactivity after 70 days **cyclopropane-1-^{14}C] cyfluthrin :** 12-26% of applied radioactivity after 100 days
Mineralisation to CO_2	**fluorobenzene-UL-^{14}C] cyfluthrin :** 61-67% of applied radioactivity after 70 days **cyclopropane-1-^{14}C] cyfluthrin :** 14-37% of applied radioactivity after 100 days
Dissipation in water/sediment systems (active substance)	**fluorobenzene-UL-^{14}C] cyfluthrin** whole system DT_{50} (22°C) = 1.95 – 3.3 d DT_{50} (12°C) = 4.3 – 7.3 d **[cyclopropane-1-^{14}C] cyfluthrin** whole system

	DT_{50} (20°C) = 2.5 - 4.9 d DT_{50} (12°C) = 4.7 - 9.3 d
Distribution in water / sediment systems (active substance)	**[fluorobenzene-UL-^{14}C] cyfluthrin** water phase: residues of a. s. (% of applied): maximum: <1.1% (system I, day 11) and 0.5% (system II, day 1) not detected at day 70 sediment: residues of a. s. (% of applied): maximum: 20% (system I) and 12.6% (system II), day 1 0.9-1.1% at day 70 **[cyclopropane-1-^{14}C] cyfluthrin** water phase: residues of a. s. (% of applied): maximum: 40.1% (system III, 0.5 h) and 31.6% (system IV, 3h) not detected at day 100. sediment: residues of a. s. (% of applied): maximum of 68.4% (system III) and 63% (system IV), 6 h 7.1-15.9% at day 100.
Dissipation in water/sediment systems (metabolites)	FPB-acid, total system DT_{50} (22°C) = 4.0 – 8.1 d DT_{50} (12°C) = 8.9 – 18.0 d FPB-ald, total system DT_{50} (22°C) = 3.3 – 10.0 d DT_{50} (12°C) = 7.3 – 22.3 d DCVA, total system DT_{50} (20°C) = 203.2 d DT_{50} (12°C) = 385.4 d
Distribution in water / sediment systems (metabolites)	Maxima observed (% of applied radioactivity): Sediment: FPB-acid: 16.5% (system I) and 24.3% (system II), day 1 FPB-ald : 15.7% (system I) and 8.4% (system II), day 1 DCVA : 8% (system III) and 24 % (system IV), day 100 Water: FPB-acid: 29.1% (system I) and 11.7% (system II), day 11 DCVA : 36 % (system III, day 2) and 32.2 % (system IV, day 28)

Route and rate of degradation in soil

Mineralization (aerobic)	**[phenyl-UL-^{14}C] Cyfluthrin** silt loam: max. 39.8% at day 121, 9.4 °C 34.2% at day 90, 9.4 °C **[fluoro-benzene-UL-^{14}C] Cyfluthrin** **wet soil**: sandy loam: max. 36% at day 190, 20°C ± 2 °C 23% at day 84, 20°C ± 2 °C

	loam: max. 32% at day 190, 20°C ± 2 °C 20% at day 84, 20°C ± 2 °C **dry soil:** loam, sandy loam: max: 18% at days 365, 20°C ± 2 °C **[cyclopropane-1-^{14}C]Cyfluthrin** sandy loam: 48.5% at day 122, 20°C ± 2 °C loam: 39.9% at day 122, 20°C ± 2 °C **Metabolite [cyclopropane-1-^{14}C] DCVA** silty loam: 20% after 42 days clay loam: 20% after 42 days
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic); Germany **Cyfluthrin** **[fluoro-benzene-UL-^{14}C] Cyfluthrin** taking into account only time points under wet conditions Laacherhof B (loam): 58.9 days (SFO kinetics, 20°C ± 2 °C) Laacherhof C (sandy loam): 67.9 days (SFO kinetics, 20°C ± 2 °C) **[cyclopropane-1-14C]Cyfluthrin** Fresno California (sandy loam): 11.4 days (HS kinetics) North Dakota (loam): 18.4 days (HS kinetics) Converted to 12°C average EU outdoor temperature: Laacherhof B (loam): 111.7 days (SFO kinetics) Laacherhof C (sandy loam): 128.6 days (SFO kinetics) **[phenyl-UL-^{14}C] Cyfluthrin** Laacherhof A-II (silt loam): 43.6 days (12°C); derived from DT_{50lab} at 10°C, aerobic) **[cyclopropane-1-14C]Cyfluthrin** Fresno California (sandy loam): 76 days (Modelling Half-life, HS kinetics) North Dakota (loam): 195 days (Modelling Half-life, HS kinetics) **Cyfluthrin: Geo_{mean} $DT_{50\ modelling}$ for PEC estimation**: **98.5 days at 12°C** average EU outdoor temperature (n=5) **Metabolite FPB-acid** Derived from study with **[fluoro-benzene-UL-^{14}C] Cyfluthrin** Laacherhof B (loam): 39.1 days (SFO kinetics, 20°C ± 2 °C) Laacherhof C (sandy loam): 34.4 days (SFO kinetics, 20°C ± 2 °C) converted to 12°C average EU outdoor temperature: Laacherhof B (loam): 74.2 days (SFO kinetics) Laacherhof C (sandy loam): 69.0 days (SFO kinetics)

FPB-acid: worst case $DT_{50modelling}$ for PEC estimation: **74.2 days at 12°C** average EU outdoor temperature (n=2) DT_{50lab} (25°C, aerobic) **Metabolite [cyclopropane-1-^{14}C] DCVA** **silty loam** **clay loam** Isomers (Ushiku soil) (Noichi soil) **1 R, trans:** 11.7 31.4 **1 S, trans**: 23.1 61.8 **1 R, cis**: 13.5 15.7 **1S, cis**: 16.5 16.0 **Worst case 25°C: 23.1 61.8** **Worst case 12°C: 65.4 174.8** **DCVA: worst case $DT_{50\ modelling}$ for PEC estimation**: **174.8 days at 12°C** average EU outdoor temperature (n=2)
DT_{90lab} (20°C, aerobic): **Cyfluthrin:** **[fluoro-benzene-UL-^{14}C] Cyfluthrin** Laacherhof B (loam): 195.8 days (SFO kinetics) Laacherhof C (sandy loam): 225.1 days (SFO kinetics) DT_{90lab} (10°C, aerobic): **[phenyl-UL-^{14}C] Cyfluthrin** Laacherhof A-II (silt loam): 176 days (at DT_{50lab} at 10°C, aerobic) **[cyclopropane-1-14C]Cyfluthrin** Fresno California (sandy loam): 102.8 days (HS kinetics) North Dakota (loam): 230 days (HS kinetics) **Metabolite FPB-acid:** Laacherhof B (loam): 129.9 days (SFO kinetics, 20°C ± 2 °C) Laacherhof C (sandy loam): 120.8 days (SFO kinetics, 20°C ± 2 °C) **Metabolite DCVA:** Ushiku soil (silty loam): 114.5 days (20°C) Noichi soil (clay loam): 306.1 days (20°C)
DT_{50lab} (10°C, aerobic): **[phenyl-UL-^{14}C] Cyfluthrin** Laacherhof A-II (silt loam): 53 days (first order kinetics, 9.4 °C) Converted to 12°C average EU outdoor temperature: Laacherhof A-II (silt loam): 43.6 days (12°C)
degradation in the saturated zone: not required

Field studies (state location, range or median with number of measurements)	Not triggered
Anaerobic degradation	DT_{50lab} (20°C, anaerobic): **[fluoro-benzene-UL-^{14}C] Cyfluthrin** Laacherhof B (loam): 39.1% AR after 30 days, 21.3% AR after 60 days (duration of anaerobic conditions) Mineralisation rate: n/a Bound residues: 64% after 90 days FPB-acid was identified as the main transformation product (up to 19 % of the applied radioactivity at 60) days).
Soil photolysis	DT_{50} = 12.3 days (EU outdoor temperature of 12°C)
Non-extractable residues	**[phenyl-UL-^{14}C] Cyfluthrin** silt loam: max. 34.5% at day 90, 9.4°C **[fluoro-benzene-UL-^{14}C] Cyfluthrin** sandy loam: max. 33% at day 365, 20°C ± 2 °C loam: max. 34% at day 84, 20°C ± 2 °C **Metabolite [cyclopropane-1-^{14}C] DCVA** silty loam: 35% after 42 days clay loam: 20% after 42 days
Relevant metabolites - name and/or code, % of applied active ingredient (range and maximum)	**FPB acid** (from fluoro-benzene-UL-^{14}C] Cyfluthrin) **Aerobic:** **Wet soil:** max. 10% day 1 **Dry soil**: max. 31% day 118 **Anaerobic:** Max. 19% after day 60 **DCVA** (derived from [cyclopropane-1-^{14}C] labelled cypermethrin), aerobic Expected to be formed, based on structure and comparison to other pyrethroids.
Soil accumulation and plateau concentration	Not required

Adsorption/desorption

Ka , Kd Ka_{oc} , Kd_{oc} [L/kg] pH dependence (yes / no) (if yes type of dependence)	Ka :1116-1793 ; Kd : 974-1705 Ka_{oc} : 73484-180290, mean 123930 ; Kd_{oc} : 69877-160889 Ka_{oc}: 180290 (Loamy sand, pH 5.9), 124000 (Silt loam, pH 8.1), 117946 (Sand, pH 6.7), 73484 (Clay loam, pH 6.5) pH dependence: No DCVA : Ka_{oc} : 31.05, 13.95 and 356.15, mean 133.7 FPB-acid : Ka_{oc} : 39-123 , mean 73

Fate and behaviour in air

Direct photolysis in air	Not relevant
Quantum yield of direct photolysis	

Photo-oxidative degradation in air	Tropospherical half-life of beta-cyfluthrin: 30.8 h Chemical lifetime in troposphere: 44.4 h (according to Atkinson, reaction with OH radicals, concentration: $5 \cdot 10^5$ OH/cm^3)
Volatilization	Not relevant

Monitoring data, if available

Soil (indicate location and type of study)	None
Surface water (indicate location and type of study)	None
Ground water (indicate location and type of study)	None
Air (indicate location and type of study)	None

Chapter 5:Effects on Non-target Species

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

Species	Time-scale	Endpoint	Toxicity
Fish			
Oncorhynchus mykiss *Oncorhynchus mykiss*	96 h 58 d	LC_{50} NOEC	0.302 µg/L 0.010 µg/L
Invertebrates			
Procambarus clarkii	96 h	LC_{50}	0.062 µg/L
Hyalella azteca	96 h	LC_{50}	0.00055 µg/L
Daphnia magna	21 d	NOEC	0.02 µg/L
Americamysis bahia	28 d	NOEC	0.00041 µg/L β-Cyfluthrin
Algae			
Pseudokirchneriella subcapitata	72 h	E_rC_{50} NOE_rC	>8050 µg/L 4450 µg/L
Sediment organisms			
Chironomus dilutus	63 d	NOEC	6.2 µg/kg dw
Microorganisms			
activated sludge	3 h (static)	EC_{50}	10 000 mg/l (nominal)

Effects on earthworms or other soil non-target organisms

Acute toxicity to Collembola *(Folsomia candida)*	LC_{50}= 599 mg/kg dry weight soil LC_{50}= 203.7 mg/kg dry weight soil (normalized to organic matter)
Reproductive toxicity to Collembola *(Folsomia candida)*	NOEC = 90 mg/kg dry weight soil NOEC = 30.6 mg/kg dry weight soil (normalized to organic matter)

Effects on soil micro-organisms

Nitrogen mineralization	NOEC ≥300 mg/kg dry weight soil
Carbon mineralization	NOEC = 3 mg/kg dry weight soil/ NOEC (2% org. C) = 5 mg/kg dry weight soil

Effects on terrestrial vertebrates

Acute toxicity to mammals	Refer to mammalian toxicity package
Acute toxicity to birds	No exposure
Dietary toxicity to birds	No exposure
Reproductive toxicity to birds	No exposure

Effects on honeybees

Acute oral toxicity	No exposure
Acute contact toxicity	No exposure

Effects on other beneficial arthropods

Acute oral toxicity	No exposure
Acute contact toxicity	No exposure
Acute toxicity to ……..	No exposure

Bioconcentration

Bioconcentration factor (BCF)	BCF_{fish} calc.: Diastereomer 1: BCF_{fish} = 25119 $L.kg_{wet\ fish}^{-1}$ Diastereomer 2: BCF_{fish} = 22336 $L.kg_{wet\ fish}^{-1}$ Diastereomer 3: BCF_{fish} = 27164 $L.kg_{wet\ fish}^{-1}$ Diastereomer 4: BCF_{fish} = 21062 $L.kg_{wet\ fish}^{-1}$ $BCF_{earthworm}$ calc.: Diastereomer 1: $BCF_{earthworm}$ = 12000 $L.kg_{earthworm}^{-1}$ Diastereomer 2: $BCF_{earthworm}$ = 10452 $L.kg_{earthworm}^{-1}$ Diastereomer 3: $BCF_{earthworm}$ = 13159 $L.kg_{earthworm}^{-1}$ Diastereomer 4: $BCF_{earthworm}$ = 9755 $L.kg_{earthworm}^{-1}$ BCF_{fish} measured: β-Cyfluthrin: $\underline{BCF_{fish,kinet\ c}}$ = 1822 $L/kg_{wet\ fish}$
Depuration time (DT_{50}) (DT_{90})	DT_{50} = 8.66 days
Level of metabolites (%) in organisms accounting for > 10 % of residues	No metabolites identified

Chapter 6:Other End Points

It is not expected that Cyfluthrin Foam and Solfac® EW 050 lead to measurable residues in food or feed.

Appendix II: List of Intended Uses

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks:
(a)			(c)	Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	number min max (k)	interval between applications (min)	g a.s./L min max	water L/m^2 min max	g a.s./m^2 min max	(m)
Rural hygiene treatment indoor in animal housing	EU	Solfac® EW 050	German cockroaches, litter beetles, house flies, red poultry	EW	50 g/L	spraying	Max 7	21 days	0.4-0.8 g/l	0.05 l/m^2	0.02-0.04 g/m^2	Treatment period : April to October for flying insects
Crawling insects Residential - indoor	EU	Cyfluthrin Foam	Cockroaches, ants	AE	0.4 g/l	Surface treatment, cracks and crevices	As required*	None specified*	n/a	n/a	0.008 g a.s./m^2 ^	Recommended dose is 5 seconds spray per strip (of 0.25 m x 1 m) *Residual activity up to 2-3 months is claimed ^ 5s spray @ 1 g spray/s delivers 0.002 g a.s.

(a) e.g. biting and suckling insects, fungi, molds; (b) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(c) GCPF Codes - GIFAP Technical Monograph No 2, 1989 ISBN 3-8263-3152-4); (d) All abbreviations used must be explained
(e) g/kg or g/l;(f) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench;
(g) Kind, e.g. overall, broadcast, aerial spraying, row, bait, crack and crevice equipment used must be indicated;
(h) Indicate the minimum and maximum number of application possible under practical conditions of use;
(i) Remarks may include: Extent of use/economic importance/restrictions

Appendix III: Human health tables for risk characterisation

Table 1: Professional Users – Primary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated oral uptake [mg/kg b.w/day]	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (no PPE)	Mixing & loading, Loading sprayer with biocidal product, diluting biocidal product with water, priming pump and spray line, Liquid (5 % active substance), daily	-	negligible	0.0044	0.008	$NOAEL_{long-term}$: 2 $AEL_{long-term}$: 0.02	100	250	0.40
	Application, Spraying in animal housing, aerosol (0.08 % active substance), daily	-	0.0035						
	Post-application, Unblock spray nozzle and cleaning, Liquid (0.08 % active substance), daily	-	negligible	$2.8x10^{-5}$	$2.8x10^{-5}$			71000	0.0014
	Total	-	0.0035	0.0044	0.008			250	0.40
Tier 2 (Refinement, PPE or other risk mitigation measures – Specify)	Tier 2 is not required.								

Table 2: Non Professional Users – Primary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated oral uptake [mg/kg b.w/day]	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (no PPE)	Cyfluthrin Foam : spray application, acute exposure, adult	1.31×10^{-5}	8.23×10^{-5}	2.67×10^{-4}	3.682×10^{-4}	$NOAEL_{acute}$: 2 AEL_{acute}: 0.02	100	5525	0.018
	Cyfluthrin Foam : spray application, chronic (long-term) exposure, adult	1.31×10^{-5}	8.23×10^{-5}	2.67×10^{-4}	3.62×10^{-4}	$NOAEL_{long\text{-}term}$: 2 $AEL_{long\text{-}term}$: 0.02	100	5525	0.018
	Solfac® EW 050: Primary exposure is not expected since the biocidal product is for professional use only.								
Tier 2 Refinement or other risk mitigation measures – Specify)	Tier 2 is not required.								

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

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (Worst Case) Short term Scenario	Secondary exposure of professionals during working in animal housing, incidental dermal contact	negligible	3.0×10^{-4}	n.a.	3.0×10^{-4}	$NOAEL_{acute}$: 2 AEL_{acute}: 0.02	100	6667	0.015
	Cyfluthrin Foam : dermal and oral contact to residues, infant, acute		3.60×10^{-3}	1.8×10^{-3}	5.40×10^{-3}	$NOAEL_{acute}$: 2 AEL_{acute}: 0.02	100	370	0.27
	Solfac® EW 050: re-entry after application, adult, acute	1.07×10^{-5}	1.69×10^{-4}		1.76×10^{-4}	$NOAEL_{acute}$: 2 AEL_{acute}: 0.02	100	11400	0.009
	Solfac® EW 050: re-entry after application, child, acute	1.37×10^{-5}	3.38×10^{-4}		3.52×10^{-4}	$NOAEL_{acute}$: 2 AEL_{acute}: 0.02	100	5680	0.018
Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 2 (Refinement - Specify) Short Term Scenario	Tier 2 is not required.								

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

Exposure Scenario (indicate duration)	Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (Worst Case) Medium-term Scenario	See acute exposure scenarios.							

Exposure Scenario (indicate duration)	Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 2 (Refinement- Specify) Medium-term Scenario	Tier 2 is not required.							

Table 5: Indirect Exposure as a result of use – Secondary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (Worst Case) Chronic Scenario	Cyfluthrin Foam: dermal and oral contact to residues, infant, long-term	-	3.60×10^{-3}	1.80×10^{-3}	5.4×10^{-3}	$NOAEL_{long-term}$: 2 $AEL_{long-term}$: 0.02	100	370	0.270
	Solfac® EW 050: re-entry after application, adult, long-term	1.07×10^{-5}	1.69×10^{-4}	-	1.76×10^{-4}	$NOAEL_{long-term}$: 2 $AEL_{long-term}$: 0.02	100	11400	0.009
	Solfac® EW 050: re-entry after application, infant, long-term	1.37×10^{-5}	3.38×10^{-4}	-	3.52×10^{-4}	$NOAEL_{long-term}$: 2 $AEL_{long-term}$: 0.02	100	141000	0.018
Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 2 (Refinement- Specify) Chronic Scenario	Tier 2 is not required.								

Appendix IV: List of terms and abbreviations

Stand. term / Abbreviation	**Explanation**
A	ampere
ACh	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADME	administration distribution metabolism and excretion
ADP	adenosine diphosphate
AE	acid equivalent
AEL	Systemic (= Internal) Acceptable Exposure Level
AF	assessment factor
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
a.i.	active ingredient
ALD_{50}	approximate median lethal dose, 50%
ALT	alanine aminotransferase (SGPT)
Ann.	Annex
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
a.s.	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BAF	bioaccumulation factor
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point
BPD	Biocidal Products Directive
BSAF	biota-sediment accumulation

Stand. term / Abbreviation	**Explanation**
	factor
BSE	bovine spongiform encephalopathy
BSP	bromosulfophthalein
Bt	*Bacillus thuringiensis*
Bti	*Bacillus thuringiensis israelensis*
Btk	*Bacillus thuringiensis kurstaki*
Btt	*Bacillus thuringiensis tenebrionis*
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10^{-2})
°C	degrees Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DANN
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
d	day(s)
DES	diethylstilboestrol
DIS	draft international standard *(ISO)*

Stand. term / Abbreviation	**Explanation**
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days post inoculation
DRP	detailed review paper *(OECD)*
$DT_{50(lab)}$	period required for 50 percent dissipation (under laboratory conditions) (define method of estimation)
$DT_{90(field)}$	period required for 90 percent dissipation (under field conditions) (define method of estimation)
dw	dry weight
DWQG	drinking water quality guidelines
ε	decadic molar extinction coefficient
EC_{50}	median effective concentration
ECD	electron capture detector
ED_{50}	median effective dose
EDI	estimated daily intake
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EN	European norm
EPMA	electron probe micro-analysis
ERL	extraneous residue limit
ESPE46/51	evaluation system for pesticides
EUSES	European Union system for the evaluation of substances
F	field
F_0	parental generation
F_1	filial generation, first

Stand. term / Abbreviation	**Explanation**
F_2	filial generation, second
FBS	full base set
FELS	fish early-life stage
FIA	fluorescence immuno-assay
FID	flame ionisation detector
F_{mol}	fractional equivalent of the metabolite´s molecular weight compared to the active substance
FOB	functional observation battery
f_{oc}	organic carbon factor (compartment dependent)
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram(s)
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GMO	genetically modified organism
GMM	genetically modified micro-organism
GPC	gel-permeation chromatography
GPS	global positioning system

Stand. term / Abbreviation	**Explanation**
GSH	glutathione
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value)
ha	hectare(s)
Hb	haemoglobin
HC5	concentration which will be harmless to at least 95 % of the species present with a given level of confidence (usually 95 %)
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionisation detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H_S	Shannon-Weaver index
Ht	haematocrit
HUSS	human and use safety standard
I	indoor
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilisation concentration or median inhibitory concentration 1
ICM	integrated crop management
ID	ionisation detector
IEDI	international estimated daily

Stand. term / Abbreviation	**Explanation**
	intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
INT	2-p-iodophenyl-3-p-nitrophenyl-5-phenyltetrazoliumchloride testing method
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
IUCLID	International Uniform Chemical Information Database
iv	intravenous
IVF	*in vitro* fertilisation
k *(in combination)*	kilo
k	rate constant for biodegradation
K	Kelvin
Ka	acid dissociation constant
Kb	base dissociation constant
K_{ads}	adsorption constant
K_{des}	apparent desorption coefficient
kg	kilogram
K_H	Henry´s Law constant (in atmosphere per cubic metre per mole)
K_{oc}	organic carbon adsorption coefficient
K_{om}	organic matter adsorption coefficient
K_{ow}	octanol-water partition coefficient
Kp	solid-water partition coefficient
kPa	kilopascal(s)
l, L	litre
LAN	local area network

Stand. term / Abbreviation	**Explanation**
LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry
LC_{50}	lethal concentration, median
LCA	life cycle analysis
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
ln	natural logarithm
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
log	logarithm to the base 10
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar
µm	micrometre (micron)
MAC	maximum allowable concentration
MAK	maximum allowable concentration
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin

Stand. term / Abbreviation	**Explanation**
	concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
MIC	minimum inhibitory concentration
min	minute(s)
MKC	minimum killing concentration
mL	millilitre
MLT	median lethal time
MLD	minimum lethal dose
mm	millimetre
MMAD	mass median aerodynamic diameter
mo	month(s)
MOE	margin of exposure
mol	mole(s)
MOS	margin of safety
mp	melting point
MRE	maximum residue expected
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MT	material test
MW	molecular weight
n.a.	not applicable
n-	normal (defining isomeric configuration)
n	number of observations
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level

Stand. term / Abbreviation	**Explanation**
ng	nanogram
nm	nanometre
NMR	nuclear magnetic resonance
no, n°	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OEL	occupational exposure limit
OH	hydroxide
OJ	Official Journal
OM	organic matter content
Pa	pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the acid dissociation constant
pKb	negative logarithm (to the base 10) of the base dissociation constant
PNEC	predicted no effect concentration (compartment to be added as subscript)
po	by mouth
POP	persistent organic pollutants
ppb	parts per billion (10^{-9})
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PPP	plant protection product
ppq	parts per quadrillion (10^{-24})
ppt	parts per trillion (10^{-12})
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	product type
PT(CEN)	project team CEN
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QA	quality assurance
QAU	quality assurance unit
(Q)SAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RA	risk assessment
RBC	red blood cell

Stand. term / Abbreviation	**Explanation**
REI	restricted entry interval
RENI	Registry Nomenclature Information System
Rf	retardation factor
RfD	reference dose
RH	relative humidity
RL_{50}	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rpm	revolutions per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
S	solubility
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SCAS	semi-continous activated sludge
SCTER	smallest chronic toxicity exposure ratio (TER)
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
S/L	short term to long term ratio
SMEs	small and medium sized enterprises
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STER	smallest toxicity exposure ratio (TER)
STMR	supervised trials median residue
STP	sewage treatment plant
t	tonne(s) (metric ton)
$t_{½}$	half-life (define method of estimation)
T_3	tri-iodothyroxine
T_4	thyroxine
T_{25}	tumorigenic dose that causes tumours in 25 % of the test animals
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TG	technical guideline, technical group
TGD	Technical guidance document
TID	thermionic detector, alkali flame detector
TDR	time domain reflectrometry
TER	toxicity exposure ratio
TER_I	toxicity exposure ratio for initial exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format

Stand. term / Abbreviation	**Explanation**
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TNsG	technical notes for guidance
TOC	total organic carbon
Tremcard	transport emergency card
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)
TTC	2,3,5-triphenylterazoliumchloride testing method
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume

Stand. term / Abbreviation	**Explanation**
UR	unit risk
UV	ultraviolet
UVC	unknown or variable composition, complex reaction products
UVCB	undefined or variable composition, complex reaction products in biological material
v/v	volume ratio (volume per volume)
vis	visible
WBC	white blood cell
wk	week
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

Appendix V: List of studies

Data protection is claimed by the applicant in accordance with Article 60 of Regulation (EU) No 528/2012.

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source** (where different from company) **Company name, Report No., Date,** **GLP status** (where relevant)**, published or not**	**Data protect. claimed**	**Owner**
Doc IIIA					
A 2.6. /01	Grosse, J.	2004	Description of the manufacturing process of cyfluthrin - AE F057122 Bayer CropScience AG, Report No.: MO-04-007898, Edition Number: M-082673-02-1 Date: 15.06.2004 Non GLP, unpublished confidential	Yes	BCS
A 2.7. /01	Haustein, M.	1999	Material accountability of Cyfluthrin Bayer AG, Dormagen, Germany Bayer CropScience AG, Report No.: D97/0125/00DOR, Edition Number: M-012062-01-1 Date: 11.08.1999 GLP, unpublished confidential	Yes	BCS
A 2.7. /02	Bissinger, H.	2004	Material accountability of cyfluthrin (FCR 1272 / AE F057122) - Analytical profile of production batches from Vapi / India Bayer Industry Services, Dormagen, Germany Bayer CropScience AG, Report No.: D04/0026/00DOR, Edition Number: M-083514-02-1 Date: 10.08.2004 GLP, unpublished confidential	Yes	BCS
A 2.7. /03	Nuesslein, F.	2004	Composition Statement Technical Grade Active Ingredient (TGAI) - Cyfluthrin (Cyfluthrin techn., Cyfluthrin I) Bayer CropScience AG, Report No.: MO-04-008295, Edition Number: M-085348-01-1 Date: 24.08.2004 Non GLP, unpublished confidential	Yes	BCS

A 2.8. /01	Grosse, J.	2004	Origin of impurities in cyfluthrin Bayer CropScience AG, Report No.: MO-04-007564, Edition Number: M-082705-01-1 Date: 07.07.2004 Non GLP, unpublished confidential	Yes	BCS
A 3.1.1 /01	Krohn, J.	1984	Purity test, melting point - Cyfluthrin Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC 180, Edition Number: M-043015-01-1 Date: 02.04.1984 Non GLP, unpublished	Yes	BCS
A 3.1.3 /01	Smeykal, H.	2005	The relative density of AE F057122, cyfluthrin technical Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: 20051029.01, Edition Number: M-262849-01-1 Date: 19.12.2005 GLP, unpublished	Yes	BCS
A 3.2. /01	Sewekow, B.	1981	Vapour pressure of Cyfluthrin (Diastereomer I) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: MO-04-003151, Edition Number: M-001479-01-1 Date: 04.02.1981 Non GLP, unpublished	Yes	BCS
A 3.2.1 /01	Krohn, J.	1987	Calculation of the Henry Law Constant of Cyfluthrin Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC 182, Edition Number: M-043077-01-1 Date: 27.05.1987 Non GLP, unpublished	Yes	BCS
A 3.3. /01	Anon.	2005	Cyfluthrin TC Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-266769-01-1, Edition Number: M-266769-01-1 Date: 18.11.2005 Non GLP, unpublished also filed: A 8.1. /01 also filed: A 8.3. /01 also filed: A 8.5. /01 also filed: A 9. /01	No	BCS
A 3.3. /02	Weilbaecher, R.	2003	FCR1272-3-Diastereomer (AE 1421343 00 1B99 0001) Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: AZ 10974, Edition Number: M-108556-01-1 Date: 20.08.2003 Non GLP, unpublished	Yes	BCS

A 3.3. /03	Weilbaecher, R.	2003	FCR1272-4-diastomer (AE 1421344 00 1B98 0001) Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: AZ 10976, Edition Number: M-109086-01-1 Date: 28.08.2003 Non GLP, unpublished	Yes	BCS
A 3.3. /04	Weilbaecher, R.	2003	FCR1272-1-Diastereomer (AE 1421341 00 1B99 0001) Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: AZ 10975, Edition Number: M-110347-01-1 Date: 28.08.2003 Non GLP, unpublished	Yes	BCS
A 3.3. /05	Weilbaecher, R.	2003	FCR1272-2-Diastereomer (AE 1421342 00 1B99 0001) Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: AZ 11028, Edition Number: M-110805-01-1 Date: 04.09.2003 Non GLP, unpublished	Yes	BCS
A 3.4.1 /01	Krohn, J.	1985	Cyfluthrin - Spectra of the diastereomers of the active ingredient Bayer AG, Wuppertal, Germany Bayer CropScience AG, Report No.: PC2037, Edition Number: M-004852-01-2 Date: 29.03.1985 Non GLP, unpublished also filed: A 3.4.2 /01 also filed: A 3.4.3 /01 also filed: A 3.4.4 /01	Yes	BCS
A 3.4.1 /02	Hellpointner, E.	1991	Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation of cyfluthrin in water Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3555, Edition Number: M-073620-01-2 Date: 04.09.1991 GLP, unpublished also filed: A 7.1.1.1.2. /04	Yes	BCS
A 3.4.2 /01	Krohn, J.	1985	Cyfluthrin - Spectra of the diastereomers of the active ingredient Bayer AG, Wuppertal, Germany Bayer CropScience AG, Report No.: PC2037, Edition Number: M-004852-01-2 Date: 29.03.1985 Non GLP, unpublished also filed: A 3.4.1 /01 also filed: A 3.4.3 /01 also filed: A 3.4.4 /01	Yes	BCS

A 3.4.3 /01	Krohn, J.	1985	Cyfluthrin - Spectra of the diastereomers of the active ingredient Bayer AG, Wuppertal, Germany Bayer CropScience AG, Report No.: PC2037, Edition Number: M-004852-01-2 Date: 29.03.1985 Non GLP, unpublished also filed: A 3.4.1 /01 also filed: A 3.4.2 /01 also filed: A 3.4.4 /01	Yes	BCS
A 3.4.4 /01	Krohn, J.	1985	Cyfluthrin - Spectra of the diastereomers of the active ingredient Bayer AG, Wuppertal, Germany Bayer CropScience AG, Report No.: PC2037, Edition Number: M-004852-01-2 Date: 29.03.1985 Non GLP, unpublished also filed: A 3.4.1 /01 also filed: A 3.4.2 /01 also filed: A 3.4.3 /01	Yes	BCS
A 3.5. /01	Krohn, J.	1987	Watersolubility of Cyfluthrin (FCR 1272, Baythroid) at 20 °C and pH 3 and pH 7 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC 109, Edition Number: M-043101-01-2 Date: 21.01.1987 Non GLP, unpublished	Yes	BCS
A 3.6 /01	Krohn, J.	1988	Dissociation constant of Cyfluthrin (FCR 1272) Bayer CropScience AG Report No.: PC 108 Edition Number: M-043092-01-1 Date: 10.10.1988 Non GLP, unpublished	Yes	BCS
A 3.7. /01	Krohn, J.	1981	Solubility of Cyfluthrin in representative organic solvents Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PC 362, Edition Number: M-043109-02-1 Date: 05.01.1981, Amended: 02.09.1994 Non GLP, unpublished	Yes	BCS
A 3.8. /01	Ryckel, B. de	2004	Accelerated and shelf-life storage stability of solfac EW 050 - Interim report - Analysis on the fresh test item, after 14 days at 54 degrees celsius +- 2 degrees celsius and 6 months and 1 year at room temperature Wallon Agricultural Research centre, Gembloux, Belgique Bayer CropScience AG, Report No.: M-257699-02-1, Edition Number: M-257699-02-1 Date: 25.11.2004, Amended: 22.11.2005 GLP, unpublished	Yes	BCS

A 3.9. /01	Krohn, J.	1987	Partition coefficient of Cyfluthrin Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: M 7120, Edition Number: M-043120-01-1 Date: 27.05.1987 Non GLP, unpublished	Yes	BCS
A 3.10. /01	Sommer, J.; Berg, G.	1988	Thermal stability of agrochemical active ingredient FCR 1272 Baythroid (Cyfluthrin) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 88/10429, Edition Number: M-021955-01-2 Date: 17.10.1988 Non GLP, unpublished	Yes	BCS
A 3.11. /01	Smeykal, H.	2005	The flammability (solids) of AE F057122, cyfluthrin technical Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: 20051029.03, Edition Number: M-262858-01-1 Date: 19.12.2005 GLP, unpublished	Yes	BCS
A 3.11. /02	Smeykal, H.	2005	The auto-flammability of AE F057122, cyfluthrin technical Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: 20051029.05, Edition Number: M-262862-01-1 Date: 19.12.2005 GLP, unpublished	Yes	BCS
A 3.12. /01	Smeykal, H.	2005	The flash point of AE F057122, cyfluthrin technical Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: 20051029.02, Edition Number: M-262854-01-1 Date: 19.12.2005 GLP, unpublished	Yes	BCS
A 3.14. /01	Bascou, J. Ph.	2006	Statement on viscosity - Code: AE F057122 Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-265460-01-1, Edition Number: M-265460-01-1 Date: 13.01.2006 Non GLP, unpublished	Yes	BCS
A 3.15. /01	Smeykal, H.	2005	The explosive properties of AE F057122, cyfluthrin technical Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany Bayer CropScience AG, Report No.: 20051029.04, Edition Number: M-262859-01-1 Date: 19.12.2005 GLP, unpublished	Yes	BCS

A 3.16. /01	Heinz, U.	2005	Determination of safety-relevant data of cyfluthrin Bayer Industry Services GmbH & Co. OHG, Monheim, Germany Bayer CropScience AG, Report No.: 05/00009, Edition Number: M-246243-01-1 Date: 03.02.2005 GLP, unpublished	Yes	BCS
A 3.17. /01	Greevy, J. P.; Swan, J. L.	1986	Compatibility of Baythroid technical with metals, plastics and coatings Mobay Chemical Corporation, USA Bayer CropScience AG, Report No.: 91389, Edition Number: M-250521-01-1 Method Report No US: 91389 Date: 18.09.1986 Non GLP, unpublished	Yes	BCS
A 4.1. /01	Anon.	1996	Cyfluthrin ; CIPAC 385 CIPAC Bayer CropScience AG, Report No.: CIPAC 385, Edition Number: M-027450-01-1 Date: 01.01.1996 Non GLP, unpublished	Yes	BCS
A 4.1. /02	Haustein, M.	1999	Validation-report V01-CIPAC 385 TC/M/3.1 Bayer AG, Dormagen, Germany Bayer CropScience AG, Report No.: V01-CIPAC 385, Edition Number: M-009736-01-1 Date: 19.07.1999 Non GLP, unpublished	Yes	BCS
A 4.1. /03	Nonn, E.	1997	Cyfluthrin, Active Ingredient Technical; Byproducts - Capillary Gas Chromatography Bayer AG, Dormagen, Germany Bayer CropScience AG, Report No.: 2201-0281802-97, Edition Number: M-012450-01-2 Date: 19.06.1997 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /04	Nonn, E.	2000	Cyfluthrin, Active Component Techn. ; By-products - Capillary Gas Chromatography Bayer AG, Dormagen, Germany Bayer CropScience AG, Report No.: 2201-0281803-99, Edition Number: M-030072-01-1 Date: 14.04.2000 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /05	Plass, E.; Warning, U.	2004	Cyfluthrin, active ingredient, techn. - Determination of volatile byproducts by capillary gas chromatography Bayer Industry Services GmbH & Co. OHG, Dormagen, Germany Bayer CropScience AG, Report No.: AM002004DB1, Edition Number: M-083829-01-1 Date: 06.08.2004 Non GLP, unpublished confidential	Yes	BCS

A 4.1. /06	Nonn, E.	1997	Validation-report VB1-2201-0281802E Bayer AG, Dormagen, Germany Bayer CropScience AG, Report No.: VB1-2201-0281802, Edition Number: M-027262-01-1 Date: 26.06.1997 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /07	Haustein, M.	2000	Cyfluthrin ; Difficulty Volatile By-products - HPLC, External Standard Bayer AG, Dormagen, Germany Bayer CropScience AG, Report No.: 2201-0308102-99, Edition Number: M-023322-02-2 Date: 18.01.2000 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /08	Plass, E.; Warning, U.	2004	Cyfluthrin - Determination of low volatile byproducts by HPLC, External standard Bayer Industry Services GmbH & Co. OHG, Dormagen, Germany Bayer CropScience AG, Report No.: AM001904DB1, Edition Number: M-083837-01-1 Date: 06.08.2004 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /09	Haustein, M.	1999	Validation-report V01-2201-0308101E Bayer AG, Dormagen, Germany Bayer CropScience AG, Report No.: V01-2201-0308101, Edition Number: M-016089-01-1 Date: 10.08.1999 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /10	Haustein, M.	1996	Cyfluthrin; [redacted] Bayer AG, Dormagen, Germany Bayer CropScience AG, Report No.: 2201-0281703-96, Edition Number: M-012445-01-1 Date: 31.10.1996 Non GLP, unpublished confidential	Yes	BCS
A 4.1. /11	Haustein, M.	1997	Validation-report VB1-2201-0281703E Bayer AG, Dormagen, Germany Bayer CropScience AG, Report No.: VB1-2201-0281703, Edition Number: M-027260-01-1 Date: 05.02.1997 Non GLP, unpublished confidential	Yes	BCS
A 4.2.1. /01	Bachlechner, G.	1990	Method for gas-chromatographic determination of the active ingredients cyfluthrin and beta-cyfluthrin in soil Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00195, Edition Number: M-017140-01-2 Method Report No.: RA-498/90 Date: 05.03.1990 Non GLP, unpublished	Yes	BCS

A 4.2.1. /02	Nolting, H. G.; Siebers, J.; Koehle, H.	1991	Pyrethroids - Gas-chromatographic determination - DFG method S 23 Publisher:VCH Verlagsgesellschaft mbH, Location:Weinheim, Volume:II, Pages:333-342, Year:1991, Report No.: MO-99-003969, Edition Number: M-008975-01-1 Non GLP, published	No	
A 4.2.1. /03	Weeren, R. D.; Pelz, S.	1999	Supplement E050 to method 00086: Validation of DFG method S 19 with modified extraction for the determination of residues of cyfluthrin in soil Dr. Specht & Partner, Chemische Laboratorien GmbH, Hamburg, Germany Bayer CropScience AG, Report No.: 00086/E050, Edition Number: M-009717-01-1 Method Report No.: Az.M7706/99 Date: 27.07.1999 GLP, unpublished	Yes	BCS
A 4.2.1. /04	Gronberg, R. R.; Pfankuche, L. K.	1983	An analytical residue method for Baythroid and its major metabolites in soil Mobay Chemical Corporation, USA Bayer CropScience AG, Report No.: 85886, Edition Number: M-064739-01-1 Date: 15.06.1983 Non GLP, unpublished	Yes	BCS
A 4.2.2. /01	Riegner, K.	1993	Method for the determination of cyfluthrin in air Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00309, Edition Number: M-012501-01-2 Method Report No.: RA-791/92 Date: 01.02.1993 GLP, unpublished	Yes	BCS
A 4.2.2. /02	Hellpointner, E.	1999	Confirmatory method for the determination of cyfluthrin in air (confirmed method 00309) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00309C, Edition Number: M-069734-01-1 Method Report No.: MR-390/99 Date: 02.08.1999 GLP, unpublished	Yes	BCS
A 4.2.3. /01	Koenig, T.	1992	Method for gas chromatographic determination of cyfluthrin in drinking water Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00271, Edition Number: M-012493-02-1 Method Report No.: RA-337/92 Date: 12.06.1992 Non GLP, unpublished	Yes	BCS

A 4.2.3. /02	Sommer, H.	1999	Enforcement and confirmatory method for determination of cyfluthrin in surface water by GC/ECD [Tox/Ecotox method] Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00587, Edition Number: M-015201-01-1 Method Report No.: MR-334/99 Date: 03.09.1999 GLP, unpublished	Yes	BCS
A 4.2.4. /01	Maasfeld, W.	1989	Method for the gas-chromatographic determination of residues of BAYOFLY in bovine tissues and milk Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00553, Edition Number: M-012515-02-1 Method Report No.: RA-653 Date: 11.08.1989 Non GLP, unpublished	Yes	BCS
A 4.2.4. /02	Schoening, R.	2001	Amendment No.1: Supplement E001 of method 00553 for the determination of residues of cyfluthrin in/on animal materials Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00553/E001, Edition Number: M-006300-02-1 Method Report No.: MR-871/98 Date: 15.01.2001 GLP, unpublished	Yes	BCS
A 4.2.4. /03	Schoening, R.	2001	Amendment No.1: Supplement E002 of method 00553 for the determination of residues of cyfluthrin in/on animal material Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 00553/E002, Edition Number: M-015544-02-1 Method Report No.: MR-355/99 Date: 15.01.2001 GLP, unpublished	Yes	BCS
A 4.2.4. /04	Frenzel T.; Sochor H.; Speer K.; Uihlein M.	1999	Rapid multimethod for verification and determination of toxic pesticides in whole blood by means of capillary GC-MS Journal:Journal of Analytical Toxicology, Volume:24, Issue:5, Pages:365;371, Year:2000, Report No.: C011634, Edition Number: M-201215-01-1 Date: 30.08.1999 Non GLP, published	No	

A 4.2.4. /05	Brennecke, R.	1998	Independent laboratory validation of method EM F-05/98-0 "rapid multimethod for verification and determination of toxic pesticides in whole blood by means of capillary GC-MS" according to European guidelines Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: MR-918/98, Edition Number: M-005693-01-1 Date: 21.12.1998 Non GLP, unpublished	Yes	BCS
A 4.2.4. /06	Kühn, K.H.. et al	1996	Determination of Pyrethroid Metabolites in Human Urine by Capillary Gas Chromatography-Mass Spectrometry Chromatographia, Volume 43, Number 5-6, 285 – 292 September 1996	No	
A 5.3.1. /01	Behrenz, W.; Elbert, A.; Fuchs, R.	1983	Cyfluthrin (FCR 1272), a new pyrethroid with long-lasting activity for the control of public health and stored-product pests Location:Germany, Journal:Bayer Pflanzenschutz-Nachrichten, Volume:36, Pages:127-176, Year:1983, Report No.: MO-03-000599, Edition Number: M-075183-01-1 Non GLP, published	No	
A 5.3.1. /02	Franken, E. M.	2006	Biological activity of the metabolite permethric acid (DCVA) Bayer CropScience AG, Report No.: M-266539-01-1, Edition Number: M-266539-01-1 Date: 20.01.2006 Non GLP, unpublished	Yes	BCS
A 5.4. /01	Naumann, K.	1990	Synthetic pyrethroid insecticides: structures and properties Springer Verlag Bayer CropScience AG, Report No.: MO-04-003159, Edition Number: M-001489-01-1 Date: 01.10.1990 Non GLP, unpublished	Yes	BCS
A 5.7. /01	Staetz, C. A.	2004	Insecticide mode of action classification: A key to insecticide resistance management Publisher:for more information from the customer see page note, Location:Salt Lake City, UT, USA, Journal:Insecticide Resistance Action Committee (IRAC), Year:2004, Report No.: M-267712-01-1, Edition Number: M-267712-01-1 Non GLP, published	No	

A 5.7. /02	Anon.	1992	Vector resistance to pesticides - Fifteenth report of the WHO expert committee on vector biology and control Journal:WHO Technical Report Series 818, Year:1992, Report No.: M-267730-01-1, Edition Number: M-267730-01-1 Non GLP, published	No	
A 5.7. /03	Brogdon, W. G.; McAllister, J. C.	1998	Insecticide resistance and vector control Journal:Emerging Infectious Diseases, Volume:4, Issue:4, Pages:605-613, Year:1998, Report No.: M-267737-01-1, Edition Number: M-267737-01-1 Non GLP, published	No	
A 5.7. /04	Anon	1987	Insecticide/acaricide resistance: survey and recommendations by industry GIFAP IRAC, Bruessel Bayer CropScience AG, Report No.: MO-04-003174, Edition Number: M-001507-01-1 Date: 14.12.1987 Non GLP, unpublished	Yes	BCS
A 5.7. /05	Anon.	2000	Guidelines for preventing and managing insecticide resistance in the peach-potato aphid, Myzus persicae Publisher:British Agrochemicals Association, Location:Peterborough, USA, Journal:Insecticide Resistance Action Group, Year:2000, Report No.: MO-02-003942, Edition Number: M-041872-01-1 Non GLP, published	No	
A 6.1.1. /01*	[redacted]	1987	FCR 1272 (c.n. cyfluthrin) - Study for acute oral toxicity to rats (formulation acetone and peanut oil) [redacted] Bayer CropScience AG, Report No.: 15847, Edition Number: M-038006-01-1 Date: 24.06.1987 GLP, unpublished	Yes	BCS
A 6.1.1. /02*	[redacted]	1982	FCR 1272 - Comparative tests for acute toxicity with various formulation aids [redacted] Bayer CropScience AG, Report No.: 10931, Edition Number: M-021687-01-1 Date: 07.06.1982 Non GLP, unpublished	Yes	BCS

A 6.1.2 /01*	[redacted]	1980	FCR 1272 - Acute toxicity studies [redacted] Bayer CropScience AG, Report No.: 8800, Edition Number: M-038979-01-1 Date: 07.01.1980 Non GLP, unpublished also filed: A 6.1.4. /02 also filed: A 6.11. /01	Yes	BCS
A 6.1.3. /01*	[redacted]	1987	FCR 1272 (common name: Cyfluthrin) - Acute inhalation toxicity study on rats according to OECD guideline no. 403 [redacted] Bayer CropScience AG, Report No.: 15612, Edition Number: M-039805-02-1 Date: 04.03.1987, Amended: 22.04.1993 GLP, unpublished	Yes	BCS
A 6.1.4. /01*	[redacted]	1982	FCR 1272 - Eye and skin irritation study on rabbits [redacted] Bayer CropScience AG, Report No.: JAP233, Edition Number: M-044691-01-1 Date: 10.06.1982 Non GLP, unpublished	Yes	BCS
A 6.1.4. /02*	[redacted]	1980	FCR 1272 - Acute toxicity studies [redacted] Bayer CropScience AG, Report No.: 8800, Edition Number: M-038979-01-1 Date: 07.01.1980 Non GLP, unpublished also filed: A 6.1.2 /01 also filed: A 6.11. /01	Yes	BCS
A 6.1.5. /01*	[redacted]	1994	FCR 1272 - Study for skin-sensitizing effects in guinea pigs (Magnusson-Kligman Maximization Test) [redacted] Bayer CropScience AG, Report No.: 23060, Edition Number: M-038800-01-1 Date: 31.05.1994 GLP, unpublished	Yes	BCS
A 6.2. /01*	[redacted]	1983	[U- 14C] cyfluthrin ([U-14C]) FCR 1272; fluorobenzene label) : Biokinetic part of the general metabolism studies in the rat [redacted] Bayer CropScience AG, Report No.: PH 11872 (F), Edition Number: M-038565-01-1 Date: 09.06.1983 Non GLP, unpublished	Yes	BCS

A 6.2. /02*	[redacted]	1983	<fluorobenzene-UL-14C>FCR1272; <fluorobenzene-UL-14C>cyfluthrin: metabolism part of the general metabolism studies in the rat [redacted] Bayer CropScience AG, Report No.: PF-2059, Edition Number: M-034022-01-1 Date: 14.09.1983 Non GLP, unpublished	Yes	BCS
A 6.2. /03*	[redacted]	1983	The distribution and metabolism of Baythroid in laying hens [redacted] Bayer CropScience AG, Report No.: MR-86044, Edition Number: M-054113-01-1 Date: 20.09.1983 Non GLP, unpublished	Yes	BCS
A 6.2. /04*	[redacted]	1995	Addemdum 1: The distribution and metabolism of Baythroid in laying hens . Further characterization of residues in liver [redacted] Bayer CropScience AG, Report No.: BR-86044-1, Edition Number: M-053840-01-1 Date: 23.10.1995 Non GLP, unpublished	Yes	BCS
A 6.2. /05*	[redacted]	1983	Metabolism of Baythtroid in a dairy cow [redacted] Bayer CropScience AG, Report No.: MR86043, Edition Number: M-052654-01-1 Date: 27.09.1983 GLP, unpublished	Yes	BCS
A 6.2. /06*	[redacted]	1985	Baythroid - Identity of major components in cow liver [redacted] Bayer CropScience AG, Report No.: MR-88970, Edition Number: M-053779-01-1 Date: 05.03.1985 Non GLP, unpublished also filed: A 6.15.5. /06	Yes	BCS
A 6.3.2. /01*	[redacted]	1996	21-day dermal toxicity study with technical grade Baythroid in rats [redacted] Bayer CropScience AG, Report No.: 107437, Edition Number: M-041225-01-1 Date: 06.06.1996 GLP, unpublished	Yes	BCS

A 6.4.1.1. /01*	[redacted]	1983	Three-month subacute toxicity study of FCR 1272 in rats [redacted] Bayer CropScience AG, Report No.: JAP264, Edition Number: M-044018-01-1 Date: 31.07.1983 Non GLP, unpublished	Yes	BCS
A 6.4.1.2. /01*	[redacted]	1981	FCR 1272 - Chronic study on dogs (six-month feeding experiment) [redacted] Bayer CropScience AG, Report No.: 9991, Edition Number: M-074935-01-1 Date: 02.06.1981 Non GLP, unpublished	Yes	BCS
A 6.4.3. /01*	[redacted]	1984	FCR 1272 (common name: Cyfluthrin, the active ingredient of Baythroid) - Study of the subchronic inhalation toxicity in accordance with OECD guideline no. 413 [redacted] Bayer CropScience AG, Report No.: 12436, Edition Number: M-037526-03-1 Date: 01.02.1984, Amended: 30.07.1987 GLP, unpublished	Yes	BCS
A 6.5. /01*	[redacted]	1997	Technical grade Cyfluthrin (FCR 1272) - A chronic toxicity feeding study in the beagle dog [redacted] Bayer CropScience AG, Report No.: BC8365, Edition Number: M-044511-02-1 Date: 10.11.1997, Amended: 20.07.2000 GLP, unpublished	Yes	BCS
A 6.5. /02*	[redacted]	1997	Technical grade Cyfluthrin - A combined chronic toxicity/oncogenicity testing study in the rat [redacted] Bayer CropScience AG, Report No.: BC8384, Edition Number: M-044524-02-1 Date: 12.12.1997, Amended: 19.07.2000 GLP, unpublished also filed: A 6.7.1. /01	Yes	BCS

A 6.5. /03*	[redacted]	1983 1994	FCR 1272 (Cyfluthrin, the active ingredient of Baythroid) chronic study on rats. [redacted] Unpublished Bayer AG Report No.: 11949, Report date: 19 July 1983, [BES Ref.: M-039641-02-1] Addendum to report No.: 11949, Unpublished Bayer AG Report No.: 11949A, Report date: 26 October 1994 [BES Ref.: M-039641-02-1]	Yes	BCS
A 6.6.1. /01*	[redacted]	1980	FCR 1272 - Salmonella/microsome test for detection of point-mutagenic effects [redacted] Bayer CropScience AG, Report No.: 9273, Edition Number: M-039114-01-1 Date: 27.06.1980 Non GLP, unpublished	Yes	BCS
A 6.6.2. /01*	[redacted]	1988	FCR 1272 (C.N. Cyfluthrin) - In vitro cytogenetic study with human lymphocytes for the detection of induced clastogenic effects [redacted] Bayer CropScience AG, Report No.: 17358, Edition Number: M-038539-01-1 Date: 11.11.1988 GLP, unpublished	Yes	BCS
A 6.6.3. /01*	[redacted]	1985	Baythroid (FCR 1272), technical Cyfluthrin - CHO/HPGRT mutation assay in the presence an absence of exogenous metabolic activation [redacted] Bayer CropScience AG, Report No.: BC694, Edition Number: M-039037-01-1 Date: 30.09.1985 GLP, unpublished	Yes	BCS
A 6. 7. /01*	[redacted]	1997	Technical grade Cyfluthrin - A combined chronic toxicity/oncogenicity testing study in the rat [redacted] Bayer CropScience AG, Report No.: BC8384, Edition Number: M-044524-02-1 Date: 12.12.1997, Amended: 19.07.2000 GLP, unpublished also filed: A 6.5. /02	Yes	BCS

A 6.7. /02*	[redacted]	1998	Technical grade Cyfluthrin - An oncogencity testing study in the mouse [redacted] Bayer CropScience AG, Report No.: BC8492, Edition Number: M-027231-02-1 Date: 28.05.1998, Amended: 06.09.2000 GLP, unpublished	Yes	BCS
A 6.8.1. /01*	[redacted]	1993	FCR 1272 (c.n. Cyfluthrin) - Inhalation study for embryotoxic effects in rats [redacted] Bayer CropScience AG, Report No.: 22581, Edition Number: M-038947-01-1 Date: 05.10.1993 GLP, unpublished	Yes	BCS
A 6.8. 1. /02*	[redacted]	1996	A developmental toxicity study with FCR 4545 technical in the Wistar rat [redacted] Bayer CropScience AG, Report No.: BC7989, Edition Number: M-136592-01-1 Date: 04.09.1996 GLP, unpublished	Yes	BCS
A 6.8.1. /03*	[redacted]	1992	Embryotoxicity study (including teratogenicity) with FCR 1272 in the rabbit [redacted] Bayer CropScience AG, Report No.: R5770, Edition Number: M-039695-01-1 Date: 03.12.1992 GLP, unpublished	Yes	BCS
A 6.8.2. /01*	[redacted]	1996	A two-generation reproduction study in rats using technical grade Cyfluthrin administered via the diet [redacted] Bayer CropScience AG, Report No.: BC7910, Edition Number: M-032017-01-1 Date: 08.03.1996 GLP, unpublished	Yes	BCS
A 6.8.2. /02*	[redacted]	1997	A supplementary two-generation dietary reproduction study in rats using technical grade Cyfluthrin [redacted] Bayer CropScience AG, Report No.: BC8077, Edition Number: M-032020-01-1 Date: 30.01.1997 GLP, unpublished	Yes	BCS

A 6.9. /01*	[redacted]	1999	Cyfluthrin (c.n.: Cyfluthrin) - Special study for acute oral toxicity in rats (slip angle test) [redacted] Bayer CropScience AG, Report No.: 29371, Edition Number: M-035139-01-1 Date: 13.12.1999 GLP, unpublished	Yes	BCS
A 6.9. /02*	[redacted]	1997	An acute oral neurotoxicity screening study with technical grade FCR 4545 in Fischer 344 rats [redacted] Bayer CropScience AG, Report No.: BC8265, Edition Number: M-038521-01-1 Date: 02.10.1997 GLP, unpublished	Yes	BCS
A 6.9. /03*	[redacted]	1997	A subchronic dietary neurotoxicity screening study with technical grade FCR 4545 (Beta-Cyfluthrin) in Fischer 344 rats [redacted] Bayer CropScience AG, Report No.: BC8157, Edition Number: M-038537-01-1 Date: 09.05.1997 GLP, unpublished	Yes	BCS
A 6.9. /04*	[redacted]	2003	A developmental neurotoxicity screening study with technical grade beta-cyfluthrin in Wistar rats [redacted] Bayer CropScience AG, Report No.: 200620, Edition Number: M-103213-01-1 Date: 29.07.2003 GLP, unpublished	Yes	BCS
A 6.9. /05	[redacted]	1982	Safety pharmacology study with FCR 1272 on oral administration. [redacted] Unpublished Report No. R 2405, Study No. 92088-92096, Report date: December 01, 1982 [BES Ref: M-039504-01-1]	Yes	BCS
A 6.9. /06	[redacted]	1985	CNS safety pharmacology study with BAY VL 1704 on oral administration. [redacted] Unpublished report No. R 3459, Experiments No. B-00585 to 01385, Report date: July 19, 1985 [BES Ref: M-039515-01-1]	Yes	BCS

A 6.10. /01*	[redacted]	1992	FCR 1272 (c.n.: Cyfluthrin) - Pilot study for acid-base status following inhalation exposure to the rat [redacted] Bayer CropScience AG, Report No.: 21865, Edition Number: M-038738-01-1 Date: 24.11.1992 GLP, unpublished	Yes	BCS
A 6.11. /01*	[redacted]	1980	FCR 1272 - Acute toxicity studies [redacted] Bayer CropScience AG, Report No.: 8800, Edition Number: M-038979-01-1 Date: 07.01.1980 Non GLP, unpublished also filed: A 6.1.2 /01 also filed: A 6.1.4. /02	Yes	BCS
A 6.12.1. /01*	Kehrig, B.; Steffens, W.	2003	Occupational medical experiences with Cyfluthrin Bayer AG, BIS-SIC AID-RMC, Dormagen, Germany Bayer CropScience AG, Report No.: MO-03-010675, Edition Number: M-106507-01-1 Date: 13.08.2003 Non GLP, unpublished	Yes	BCS
A 6.12.1. /02	Kehrig, B.; Steffens, W.	2005	Occupational medical experiences with cyfluthrin Bayer Industry Services, Dormagen, Germany Bayer CropScience AG, Report No.: M-257642-01-1, Edition Number: M-257642-01-1 Date: 15.09.2005 Non GLP, unpublished	Yes	BCS
A 6.12.1. /03	Saiyad, H. M.; Steffens, W.	2006	Occupational medical experiences with cyfluthrin Bayer CropScience AG, Report No.: M-267221-01-1, Edition Number: M-267221-01-1 Date: 02.03.2006 Non GLP, unpublished	Yes	BCS
A 6.12.1. /04	Steffens, W.	2006	Occupational medical experiences with Solfac EW 50 Bayer CropScience AG, Report No.: M-267224-01-1, Edition Number: M-267224-01-1 Date: 23.01.2006 Non GLP, unpublished	Yes	BCS
A 6.12.2. /01	He, F.; Wang, S.; Liu, L.; Chen, S.; Zhang, Z.; Sun, J.	1989	Clinical manifestations and diagnosis of acute pyrethroid poisoning Publisher:Springer-Verlag, Journal:Archives of Toxicology, Volume:63, Pages:54-58, Year:1989, Report No.: MO-01-006440, Edition Number: M-048869-01-1 Non GLP, published	No	

A 6.12.3	B. Wieseler; K-H. Kuhn; G. Leng; H. Idel	1998	Effects of Pyrethroid Insecticides on Pest Control Operators Publisher: Bulletin of Environmental Contamination and Toxicology, Volume: 60, Pages: 837-844, Year: 1998 Non GLP, published	No	
A 6.12.4. /01	Leng, G.; Ranft, U.; Suigiri, D.; Hadnagy, W.; Berger-Preiss, E.; Idel, H.	2003	Pyrethroids used indoors - Biological monitoring of exposure to pyrethroids following an indoor pest control operation Publisher:Urban & Fischer Verlag, Journal:International Journal of Hygiene and Environmental Health, Volume:206, Pages:1-8, Year:2003, Report No.: M-258943-01-1, Edition Number: M-258943-01-1 Non GLP, published	No	
A 6.12.4. /02	Leng, G.; Kuehn, K. H.; Idel, H.	1996	Biological monitoring of pyrethroid metabolites in urine of pest control operators Publisher:Elsevier Ireland Ltd., Location:Ireland, Journal:Toxicology Letters, Volume:88, Issue:--, Pages:215 - 220, Year:1996, Report No.: MO-02-010814, Edition Number: M-074664-01-1 Non GLP, published	No	
A 6.12.4. /03	Leng, G.; Kuehn, K. H.; Idel, H.	1997	Biological monitoring of pyrethroids in blood and pyrethroid metabolites in urine: applications and limitations Publisher:Elsevier Science B.V., Location:--, Journal:The Science of the Total Enviroment, Volume:199, Issue:--, Pages:173 - 181, Year:1997, Report No.: MO-02-010815, Edition Number: M-074666-01-1 Non GLP, published	No	
A 6.12.4. /04*	[redacted]	1998	Safety and tolerability study of FCR 1272 0.04 AE in healthy volunteers [redacted] Bayer CropScience AG, Report No.: 11590, Edition Number: M-031568-01-1 Date: 07.10.1998 GLP, unpublished	Yes	BCS

A 6.12.4. /05	Hadnagy, W.; Leng, G.; Sugiri, D.; Ranft, U.; Idel, H.	2003	Pyrethroids used indoors - Immune status of humans exposed to pyrethroids following a pest control operation - a one year follow-up study Publisher:Urban & Fischer Verlag, Journal:International Journal of Hygiene and Environmental Health, Volume:206, Issue:2, Pages:93-102, Year:2003, Report No.: M-259521-01-1, Edition Number: M-259521-01-1 Non GLP, published	No	
A 6.12.5. /01	Steffens, W.	2005	Global QHSE - Intoxication treatment database - Cyfluthrin Bayer Crop Science Bayer CropScience AG, Report No.: M-258944-01-1, Edition Number: M-258944-01-1 Date: 01.04.2005 Non GLP, unpublished also filed: A 6.12.8. /01	Yes	BCS
A 6.12.7. /01*	[redacted]	1983	Tests to determine antidote effect against FCR 1272 toxicity in rats [redacted] Bayer CropScience AG, Report No.: 11854, Edition Number: M-037789-01-1 Date: 01.06.1983 Non GLP, unpublished	Yes	BCS
A 6.12.7. /02*	[redacted]	1984	FCR 1272 - Antidotal test [redacted] Bayer CropScience AG, Report No.: JAP271, Edition Number: M-044706-01-1 Date: 23.02.1984 Non GLP, unpublished	Yes	BCS
A 6.12.8. /01	Steffens, W.	2005	Global QHSE - Intoxication treatment database - Cyfluthrin Bayer Crop Science Bayer CropScience AG, Report No.: M-258944-01-1, Edition Number: M-258944-01-1 Date: 01.04.2005 Non GLP, unpublished also filed: A 6.12.5. /01	Yes	BCS
A 6.15.3. /01	Leslie, W. L.	1988	Baythroid R - residues in field rotational crops: field Cambridge Analytical Associates, Boston, USA Bayer CropScience AG, Report No.: MR98429, Edition Number: M-067638-01-1 Method Report No.: MR98429 Date: 28.11.1988 GLP, unpublished	Yes	BCS

A 6.15.5. /01	[redacted]	1984	A 28 day Baythroid TM poultry feeding study, [redacted] Bayer CropScience AG, Bayer AG Report No.: MR86046, Edition Number: M-060241-02-1 Report Date: 14.09.1983, Amended: 05.07.1984 Unpublished	Yes	BCS
A 6.15.5. /02	[redacted]	1983	Baythroid 28 day feeding study [redacted] Bayer CropScience AG, Report No.: MR-86045, Edition Number: M-055028-02-1 Date: 14.09.1983, Amended: 23.01.1984 Non GLP, unpublished	Yes	BCS
A 6.15.5. /03	[redacted]	1994	Cyfluthrin - A 28 - day dairy cattle feeding study [redacted] Bayer CropScience AG, Report No.: 106628, Edition Number: M-054521-01-1 Date: 13.12.1994 GLP, unpublished	Yes	BCS
A 6.15.5. /04	Shaw, H. R.; Chopade, H. M.; Ayers, J. E.; Gentile, C.C.	1985	An analytical method for Baythroid in bovine and poultry tissues, milk and eggs Mobay Chemical Corporation, USA Bayer CropScience AG, Report No.: I476, Edition Number: M-066143-01-1 Method Report No.: MR-303/95 Date: 02.04.1985 Non GLP, unpublished	Yes	BCS
A 6.15.5. /05	Shaw, H. R.; Gronberg, R. R.; Harbin, A. M.; Ayers, J. E.; Pfankuche, L. K.; Freeseman, P. L.	1983	An analytical method for quantitating Baythroid metabolite residues in animal tissues Mobay Chemical Corporation, USA Bayer CropScience AG, Report No.: I488, Edition Number: M-066384-01-1 Date: 14.11.1983 Non GLP, unpublished	Yes	BCS
A 6.15.5. /06	Murphy, J. J.	1985	Baythroid - Identity of major components in cow liver Mobay Chemical Corporation, USA Bayer CropScience AG, Report No.: MR-88970, Edition Number: M-053779-01-1 Date: 05.03.1985 Non GLP, unpublished also filed: A 6.2. /06	Yes	BCS
A 7.1.1.1.1. /01	Krohn, J.	1997	Hydrolysis of Cyfluthrin and Betacyfluthrin as a function of pH Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 145000926, Edition Number: M-043171-01-1 Date: 02.10.1997 GLP, unpublished	Yes	BCS

A 7.1.1.1.1. /02	Sandie, F. E.	1983	Hydrolysis of Baythroid TM in sterile, aqueous buffered solutions Mobay Chemical Corporation, USA Bayer CropScience AG, Report No.: MR86051, Edition Number: M-073571-01-1 Date: 07.10.1983 Non GLP, unpublished	Yes	BCS
A 7.1.1.1.1. /03	Krohn, J.	1997	Hydrolysis of Permethric acid as a function of pH Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 145000921, Edition Number: M-043185-01-1 Date: 16.06.1997 GLP, unpublished	Yes	BCS
A 7.1.1.1.2. /01	Gronberg, R. R.	1984	Photodecomposition of [Phenyl-UL-14C] Baythroid in aqueous solution by sunlight Mobay Chemical Corporation, USA Bayer CropScience AG, Report No.: 88598, Edition Number: M-040090-01-1 Date: 18.10.1984 Non GLP, unpublished	Yes	BCS
A 7.1.1.1.2. /02	Puhl, R. J.; Hurley, J. B.; Dime, R. A.	1983	Photodecomposition of Baythroid-14C in aqueous solution and on soil Mobay Chemical Corporation, USA Bayer CropScience AG, Report No.: 86182, Edition Number: M-072776-01-1 Date: 02.12.1983 Non GLP, unpublished	Yes	BCS
A 7.1.1.1.2. /03	Takahashi, N.; Mikami, N.; Matsuda, T.; Miyamoto, J.	1985	Photodegradation of the pyrethroid insecticide cypermethrin in water and on soil surface Journal:Journal of Pesticide Science, Volume:10, Issue:4, Pages:629-642, Year:1985, Report No.: M7834, Edition Number: M-072742-01-1 Non GLP, published also filed: A 7.2.2.4. /04	No	
A 7.1.1.1.2. /04	Hellpointner, E.	1991	Determination of the quantum yield and assessment of the environmental half-life of the direct photodegradation of cyfluthrin in water Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3555, Edition Number: M-073620-01-2 Date: 04.09.1991 GLP, unpublished also filed: A 3.4.1 /02	Yes	BCS

A 7.1.2.2.1. /01	Anderson, C. A.	1986	Degradation of 14C-Cyfluthrin in natural water Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF2542, Edition Number: M-073248-01-2 Date: 26.02.1986 Non GLP, unpublished	Yes	BCS
A 7.1.2.2.2. /01	Anderson. C.	1987	Degradation characteristics of cyfluthrin (Baythroid) in water/sediment systems Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF2875, Edition Number: M-071937-01-2 Date: 01.10.1987 Non GLP, unpublished	Yes	BCS
A 7.1.2.2.2. /02	Sneikus, J.	2000	Aerobic aquatic degradation and metabolism of cyfluthrin in the water-sediment system Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: MR-268/00, Edition Number: M-022319-02-1 Date: 15.09.2000, Amended: 24.10.2000 GLP, unpublished	Yes	BCS
A 7.1.3. /01	Burhenne, J.	1996	Adsorption/desorption of cyfluthrin on soils Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: IM1972, Edition Number: M-022224-01-1 Date: 29.04.1996 GLP, unpublished	Yes	BCS
A 7.1.3. /02	Slangen, P. J.	1999	Adsorption/desorption of FCR 1272-permethric acid on soil NOTOX Safety & Environmental Research B.V., 's-Hertogenbosch, Netherlands Bayer CropScience AG, Report No.: IM1983, Edition Number: M-015423-01-1 Date: 30.08.1999 GLP, unpublished	Yes	BCS
A 7.1.3. /03	Oddy, A.; Brett, R.	2005	[14C]-AE F105561: Adsorption to and desorption from five soils Battelle UK Ltd., Ongar, United Kingdom Bayer CropScience AG, Report No.: CX/05/054, Edition Number: M-263792-01-1 Date: 05.12.2005 GLP, unpublished	Yes	BCS
A 7.2.1. /01	Wagner, K.; Neitzel, H.; Oehlmann, L.	1983	Degradation of Baythroid R in soil under aerobic and anaerobic test conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: RA-87/83, Edition Number: M-072890-01-2 Date: 19.01.1983 Non GLP, unpublished also filed: A 7.2.2.4. /01	Yes	BCS

A 7.2.1. /02	Sakata, S., Mikami, N., Yamada, H.	1992	Degradation of pyrethroid optical isomers in soils Sumitomo Chemical Co., Ltd., Takatsukasa, Japan Bayer CropScience AG, Report No.: MO-04-003278, Edition Number: M-001653-01-1 Date: 06.03.1992 Non GLP, unpublished	Yes	BCS
A 7.2.1. /03	Roberts. T. R.; Standen, M E.	1980	Further studies of the degradation of the pyrethroid insecticide cypermethrin in soils Location:USA, Journal:Pesticide Science, Volume:12, Pages:285-296, Year:1981, Report No.: M2330, Edition Number: M-073380-01-1 Non GLP, published	No	
A 7.2.1. /04	Sakata, S.; Mikami, N.; Matsuda, T.; Miyamoto, J.	1986	Degradation and leaching behavior of the pyrethroid insecticide cypermethrin in soils Journal:Journal of Pesticide Science, Volume:11, Pages:71 - 79, Year:1986, Report No.: MO-02-010564, Edition Number: M-074042-01-1 Non GLP, published	No	
A7.2.1/09	Hiler T.	2013	Aerobic Soil Metabolism of [Cyclopropyl-14C]Cyfluthrin in Two Soils Bayer CropScience, Alexander Drive, RTP, NC 27709, USA PTRL West, Alfred Nobel Drive, Hercules, CA 94547, USA PTRL West Study No.: 2332W, , BES Ref.: M-471225-01-1 Report date: November 27, 2013. GLP, unpublished	Yes	BCS
A 7.2.2.4. /01	Wagner, K.; Neitzel, H.; Oehlmann, L.	1983	Degradation of Baythroid R in soil under aerobic and anaerobic test conditions Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: RA-87/83, Edition Number: M-072890-01-2 Date: 19.01.1983 Non GLP, unpublished also filed: A 7.2.1. /01	Yes	BCS
A 7.2.2.4. /02	Laskowski, D. A.	2002	Physical and chemical properties of pyrethroids Publisher:Springer-Verlag, Journal:Reviews of environmental contamination and toxicology, Volume:174, Pages:49-170, Year:2002, Report No.: M-268086-01-1, Edition Number: M-268086-01-1 Non GLP, published	No	

A 7.2.2.4. /03	Chopade, H. M.	1986	Photodecomposition of (14C) R Baythroid on soil Mobay Chemical Corporation, USA Bayer CropScience AG, Report No.: 88981, Edition Number: M-072660-01-1 Date: 09.01.1986 Non GLP, unpublished	Yes	BCS
A 7.2.2.4. /04	Takahashi, N.; Mikami, N.; Matsuda, T.; Miyamoto, J.	1985	Photodegradation of the pyrethroid insecticide cypermethrin in water and on soil surface Journal:Journal of Pesticide Science, Volume:10, Issue:4, Pages:629-642, Year:1985, Report No.: M7834, Edition Number: M-072742-01-1 Non GLP, published also filed: A 7.1.1.1.2. /03	No	
A 7.2.3.2. /01	Scholz, K.; Umgelder, U.	1985	Leaching characteristics of cyfluthrin (FCR 1272; Baytthroid) aged in soil Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF2474, Edition Number: M-073678-01-2 Date: 27.09.1985 Non GLP, unpublished	Yes	BCS
A 7.3.1. /01	Hellpointner, E.	1992	Calculation of the chemical lifetime of betacyfluthrin in the troposphere Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: PF3766, Edition Number: M-033634-01-1 Date: 25.09.1992 Non GLP, unpublished	Yes	BCS
A 7.4.1.1. /01	[redacted]	1994	Acute toxicity of 14C-cyfluthrin to the rainbow trout (Oncorhynchus mykiss) under flow-through conditions [redacted] Bayer CropScience AG, Report No.: 106652, Edition Number: M-021549-01-1 Date: 22.11.1994 GLP, unpublished	Yes	BCS
A 7.4.1.1. /02	[redacted]	1994	Acute toxicity of 14C-cyfluthrin to the bluegill (Lepomis macrochirus) under flow-through conditions [redacted] Bayer CropScience AG, Report No.: 106774, Edition Number: M-022924-01-1 Date: 15.07.1994 GLP, unpublished	Yes	BCS

A 7.4.1.1. /03	[redacted]	2004	Acute toxicity of cyfluthrin (tech.) to fish (Cyprinus carpio) [redacted] Report No.: EBBDU004, Edition Number: M-192050-02-1 Date: 22.12.2004, Amended: 21.01.2005 GLP, unpublished	Yes	BCS
A 7.4.1.1. /04	[redacted]	1984	Acute toxicity of Dichlorovinylcarboxylic acid to rainbow trout [redacted] Bayer CropScience AG, Report No.: 515, Edition Number: M-034724-01-1 Date: 07.09.1984 GLP, unpublished	Yes	BCS
A 7.4.1.1. /05	[redacted]	1984	Acute toxicity of Fluorphenoxybenzaldehyde to Rainbow trout [redacted] Bayer CropScience AG, Report No.: 502, Edition Number: M-034806-01-1 Date: 03.08.1984 GLP, unpublished	Yes	BCS
A 7.4.1.2. /01	Burgess, D.	1990	Acute flow-through toxicity of 14C-cyfluthrin to Daphnia magna Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, USA Bayer CropScience AG, Report No.: 100321, Edition Number: M-008776-01-1 Date: 05.09.1990 GLP, unpublished	Yes	BCS
A 7.4.1.2. /02	[redacted]	1990	Acute toxicity of 14C-Baythroid to crayfish (Procambarus clarkii) under flow-through conditions [redacted] Bayer CropScience AG, Report No.: 100108, Edition Number: M-022918-01-1 Date: 14.04.1990 GLP, unpublished	Yes	BCS
A 7.4.1.2. /03	Forbis, A.D.; Burgess, D.	1984	Acute toxicity of DCVA to Daphnia magna ABC Laboratories, Inc., Columbia, MO, USA Bayer CropScience AG, Report No.: 505, Edition Number: M-034747-01-1 Date: 25.06.1984 GLP, unpublished	Yes	BCS

A 7.4.1.2. /04	Forbis, A.D.; Burgess, D.	1984	Acute toxicity of FPB ALD to Daphnia magna ABC Laboratories, Inc., Columbia, MO, USA Bayer CropScience AG, Report No.: 504, Edition Number: M-034810-01-1 Date: 25.06.1984 GLP, unpublished	Yes	BCS
A 7.4.1.3. /01	Dorgerloh, M.	2004	Pseudokirchneriella subcapitata growth inhibition test with cyfluthrin (tech.) Bayer CropScience AG, Report No.: DOM 24066, Edition Number: M-192048-01-1 Date: 22.12.2004 GLP, unpublished	Yes	BCS
A 7.4.1.4. /01	Mueller	1994	Studies on the ecological behaviour of cyfluthrin Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 478 A/94, Edition Number: M-021811-01-1 Date: 06.09.1994 GLP, unpublished	Yes	BCS
A 7.4.2. /01	[redacted]	1984	Bioconcentration of cyfluthrin (Baythroid) by bluegill sunfish [redacted] Bayer CropScience AG, Report No.: 455, Edition Number: M-024032-01-1 Date: 12.01.1984 Non GLP, unpublished	Yes	BCS
A 7.4.3.2. /01	[redacted]	1985	Toxicity of Cyfluthrin (Baythroid) technical to early life stages of rainbow trout [redacted] Bayer CropScience AG, Report No.: 683, Edition Number: M-008695-01-1 Date: 24.10.1985 GLP, unpublished	Yes	BCS
A 7.4.3.2. /02	[redacted]	1990	Full life-cycle toxicity of 14C-Cyfluthrin (Baythroid) to the fathead minnow (pimephales promelas) under flow-through conditions [redacted] Bayer CropScience AG, Report No.: 100097, Edition Number: M-022913-01-1 Date: 02.04.1990 GLP, unpublished	Yes	BCS

A 7.4.3.4. /01	Forbis, A. D.	1984	Chronic toxicity of 14C-cyfluthrin to Daphnia magna under flow-through test conditions ABC Laboratories, Inc., Columbia, MO, USA Bayer CropScience AG, Report No.: 557, Edition Number: M-025043-01-1 Date: 07.11.1984 GLP, unpublished	Yes	BCS
A 7.4.3.5.1 /01	Putt, A.E.	2005	Cyfluthrin - Toxicity to midge (Chironomus tentans) during a 10-day sediment exposure Springborn Smithers Laboratories, Warcham, Massachusetts, USA Bayer CropScience AG, Report No.: 46591507, Edition Number: M-262694-01-1 Date: 29.06.2005 GLP, unpublished	Yes	BCS
A 7.4.3.5.1 /02	Picard, C.R.	2013	Life-Cycle Toxicity Test Exposing Midges (*Chironomus dilutus*) to Cyfluthrin Applied to Sediment Under Static-Renewal Conditions Following EPA Test Methods. Smithers Viscient, Wareham, Massachusetts, USA Bayer CropScience, RTP, North Carolina, USA Study No. 13798.6304, Bayer Report No. EBBDL012. BES Ref M-464182-01-1 Date: 29.07.2013 GLP, unpublished	Yes	BCS
A 7.4.3.5.1 /03	Picard, C.R.	2013	42-Day Toxicity Test Exposing Freshwater Amphipods (*Hyalella azteca*) to Cyfluthrin Applied to Sediment Under Static-Renewal Conditions Following EPA Test Methods. Smithers Viscient, Wareham, Massachusetts, USA Bayer CropScience, RTP, North Carolina, USA Study No. 13798.6305, Bayer Report No. EBBDL013. BES Ref M-466330-01-1 Date: 26.08.2013 GLP, unpublished	Yes	BCS
A 7.4.3.5.1 /04	[redacted]	2005	Cyfluthrin - [redacted] Pyrethroid Working Group, Washington, DC 20005, USA Study No. 13656.6116. BES Ref M-262690-01-1 Date: 29.06.2005 GLP, unpublished	Yes	Pyrethroid Working Group / BCS

A 7.5.1.1. /01	Heimbach, F.	2006	Cyfluthrin tech.: Determination of effects on carbon transformation in soil Bayer CropScience AG, Report No.: LKC-C-54/06, Edition Number: M-265819-01-1 Date: 08.02.2006 GLP, unpublished	Yes	BCS
A 7.5.1.1. /02	Heimbach, F.	2006	Cyfluthrin tech.: Determination of effects on nitrogen transformation in soil Bayer CropScience AG, Report No.: LKC-N-62/06, Edition Number: M-265333-01-1 Date: 08.02.2006 GLP, unpublished	Yes	BCS
A 7.5.1.2. /01	Heimbach, F.	1985	Akute Toxizitaet von cyfluthrin (techn.) fuer Regenwuermer Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: HBF/RG 54, Edition Number: M-008890-01-1 Date: 25.11.1985 Non GLP, unpublished	Yes	BCS
A 7.5.1.2. /02	Heimbach, F.	1985	Akute Toxizitaet von cyfluthrin (techn.) fuer Collembolen (Folsomia candida) Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: HBF/CO 03, Edition Number: M-032023-01-1 Date: 09.12.1985 Non GLP, unpublished	Yes	BCS
A 7.5.1.2. /03	Moser, T. & Scheffczyk, A.	2005	Beta-Cyfluthrin FPB-acid: Effects on survival and reproduction of the predaceous mite Hypoaspis aculeifer CANESTRINI (Acari: Laelapidae) in standard soil (LUFA 2.1) ECT Oekotoxikologie GmbH, Floersheim, Germany Bayer CropScience AG, Report No.: P14HR, Edition Number: M-258697-01-1 Date: 12.10.2005 GLP, unpublished also filed: A 7.5.2.1. /02	Yes	BCS
A 7.5.1.2. /04	Moser, T.; Scheffczyk, A.	2005	Beta-Cyfluthrin Permethric-acid: Effects on survival and reproduction of the predaceous mite Hypoaspis aculeifer CANESTRINI (Acari: Laelapidae) in standard soil (LUFA 2.1) ECT Oekotoxikologie GmbH, Floersheim, Germany Bayer CropScience AG, Report No.: P15HR, Edition Number: M-259607-01-1 Date: 27.10.2005 GLP, unpublished also filed: A 7.5.2.1. /03	Yes	BCS

A 7.5.2.1. /01	Frommholz, U.	2006	Cyfluthrin tech.: Influence on the reproduction of the collembola species Folsomia candida tested in artificial soil. Bayer CropScience AG, Report No.: FRM-Coll-45/06, Edition Number: M-265191-01-1 Date: 02.02.2006 GLP, unpublished	Yes	BCS
A 7.5.2.1. /02	Moser, T. & Scheffczyk, A.	2005	Beta-Cyfluthrin FPB-acid: Effects on survival and reproduction of the predaceous mite Hypoaspis aculeifer CANESTRINI (Acari: Laelapidae) in standard soil (LUFA 2.1) ECT Oekotoxikologie GmbH, Floersheim, Germany Bayer CropScience AG, Report No.: P14HR, Edition Number: M-258697-01-1 Date: 12.10.2005 GLP, unpublished also filed: A 7.5.1.2. /03	Yes	BCS
A 7.5.2.1. /03	Moser, T.; Scheffczyk, A.	2005	Beta-Cyfluthrin Permethric-acid: Effects on survival and reproduction of the predaceous mite Hypoaspis aculeifer CANESTRINI (Acari: Laelapidae) in standard soil (LUFA 2.1) ECT Oekotoxikologie GmbH, Floersheim, Germany Bayer CropScience AG, Report No.: P15HR, Edition Number: M-259607-01-1 Date: 27.10.2005 GLP, unpublished also filed: A 7.5.1.2. /04	Yes	BCS
A 8.1. /01	Anon.	2005	Cyfluthrin TC Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-266769-01-1, Edition Number: M-266769-01-1 Date: 18.11.2005 Non GLP, unpublished also filed: A 3.3. /01 also filed: A 8.3. /01 also filed: A 8.5. /01 also filed: A 9. /01	No	BCS
A 8.2. /01	Bascou, J. P.	2004	Cyfluthrin - Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: MO-04-004463, Edition Number: M-066112-01-1 Date: 23.04.2004 Non GLP, unpublished also filed: A 8.4. /01 also filed: A 9. /02	Yes	BCS

A 8.3. /01	Anon.	2005	Cyfluthrin TC Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-266769-01-1, Edition Number: M-266769-01-1 Date: 18.11.2005 Non GLP, unpublished also filed: A 3.3. /01 also filed: A 8.1. /01 also filed: A 8.5. /01 also filed: A 9. /01	No	BCS
A 8.4. /01	Bascou, J. P.	2004	Cyfluthrin - Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: MO-04-004463, Edition Number: M-066112-01-1 Date: 23.04.2004 Non GLP, unpublished also filed: A 8.2. /01 also filed: A 9. /02	Yes	BCS
A 8.5. /01	Anon.	2005	Cyfluthrin TC Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-266769-01-1, Edition Number: M-266769-01-1 Date: 18.11.2005 Non GLP, unpublished also filed: A 3.3. /01 also filed: A 8.1. /01 also filed: A 8.3. /01 also filed: A 9. /01	No	BCS
A 9. /01	Anon.	2005	Cyfluthrin TC Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-266769-01-1, Edition Number: M-266769-01-1 Date: 18.11.2005 Non GLP, unpublished also filed: A 3.3. /01 also filed: A 8.1. /01 also filed: A 8.3. /01 also filed: A 8.5. /01	No	BCS
A 9. /02	Bascou, J. P.	2004	Cyfluthrin - Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: MO-04-004463, Edition Number: M-066112-01-1 Date: 23.04.2004 Non GLP, unpublished also filed: A 8.2. /01 also filed: A 8.4. /01	Yes	BCS

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Doc IIIB					
B 2.2. /01	Blondaz, P.	2006	Product Composition Solfac EW 050 Bayer EnvironmentalScience SA, Lyon, France Bayer CropScience AG, Report No.: M-267652-01-1, Edition Number: M-267652-01-1 Date: 25.02.2006 Non GLP, unpublished confidential	Yes	BCS
B 2.2. /02	Anon.	2005	[redacted] Bayer CropScience AG, Report No.: M-267222-01-1, Edition Number: M-267222-01-1 Date: 21.10.2005 Non GLP, unpublished confidential	Yes	BCS
B 2.2. /03	Anon.	2004	[redacted] Bayer CropScience AG, Report No.: M-267225-01-1, Edition Number: M-267225-01-1 Date: 17.09.2004 Non GLP, unpublished confidential	Yes	BCS
B 2.2. /04	Anon.	2006	[redacted] Bayer CropScience AG, Report No.: M-267944-01-1, Edition Number: M-267944-01-1 Date: 14.03.2006 Non GLP, unpublished confidential	Yes	BCS
B 2.2. /05	Anon.	2006	[redacted] Bayer CropScience AG, Report No.: M-267941-01-1, Edition Number: M-267941-01-1 Date: 14.03.2006 Non GLP, unpublished confidential	Yes	BCS
B 2.2. /06	Anon.	2003	[redacted] Bayer CropScience AG, Report No.: M-267220-01-1, Edition Number: M-267220-01-1 Date: 03.03.2003 Non GLP, unpublished confidential	Yes	BCS

Annex point/ reference number	Author(s)	Year	Title **Source** (where different from company) **Company name, Report No., Date,** **GLP status** (where relevant)**, published or not**	Data protect. claimed	Owner
Doc IIIB					
B 2.2. /07	Anon.	2003	[redacted] Bayer CropScience AG, Report No.: 010700/27, Edition Number: M-090851-04-1 Date: 02.07.2003 Non GLP, unpublished confidential	Yes	BCS
B 2.2. /08	Anon.	2005	[redacted] Bayer CropScience AG, Report No.: M-267228-01-1, Edition Number: M-267228-01-1 Date: 28.11.2005 Non GLP, unpublished confidential	Yes	BCS
B 2.2. /09	Anon.	2005	Water Bayer HealthCare AG, Wuppertal, Germany Bayer CropScience AG, Report No.: 337874/03, Edition Number: M-090872-04-1 Date: 26.01.2005 Non GLP, unpublished confidential	Yes	BCS
B 3.1.1. /01	Gueldner, W.	2003	Characterization of an EW-Formulation Baythroid EW 050 - Amendment No. 1 Bayer CropScience AG, Report No.: 14 1050 5268, Edition Number: M-117163-02-1 Date: 12.11.2003, Amended: 09.01.2006 GLP, unpublished also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.10.1 /01 also filed: B 3.10.2. /01 also filed: B 3.11. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.8. /01	Yes	BCS

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Doc IIIB					
B 3.1.2. /01	Gueldner, W.	2003	Characterization of an EW-Formulation Baythroid EW 050 - Amendment No. 1 Bayer CropScience AG, Report No.: 14 1050 5268, Edition Number: M-117163-02-1 Date: 12.11.2003, Amended: 09.01.2006 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.3. /01 also filed: B 3.10.1 /01 also filed: B 3.10.2. /01 also filed: B 3.11. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.8. /01	Yes	BCS
B 3.1.3. /01	Gueldner, W.	2003	Characterization of an EW-Formulation Baythroid EW 050 - Amendment No. 1 Bayer CropScience AG, Report No.: 14 1050 5268, Edition Number: M-117163-02-1 Date: 12.11.2003, Amended: 09.01.2006 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.10.1 /01 also filed: B 3.10.2. /01 also filed: B 3.11. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.8. /01	Yes	BCS
B 3.2. /01	Mix, K. H.	1996	Determination of safety-relevant parameters of Baythroid EW 050 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 96/00043, Edition Number: M-016656-01-1 Date: 13.03.1996 GLP, unpublished also filed: B 3.4. /01	Yes	BCS
B 3.3. /01	Blondaz, P.	2005	Assessment of the oxidising properties of Solfac EW 050 Code: UVP 00787809 Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-261101-01-1, Edition Number: M-261101-01-1 Date: 23.11.2005 Non GLP, unpublished	Yes	BCS

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Doc IIIB					
B 3.4. /01	Mix, K. H.	1996	Determination of safety-relevant parameters of Baythroid EW 050 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 96/00043, Edition Number: M-016656-01-1 Date: 13.03.1996 GLP, unpublished also filed: B 3.2. /01	Yes	BCS
B 3.4. /02	Heinz, U.	2003	Determination of Safety-Relevant Data of Cyfluthrin EW 050 (PCO) - Final GLP Report Bayer Industry Sevices, BIS-SUA, Leverkusen, Germany Bayer CropScience AG, Report No.: 03/00276, Edition Number: M-103146-01-1 Date: 14.11.2003 GLP, unpublished	Yes	BCS
B 3.5. /01	Gueldner, W.	2003	Characterization of an EW-Formulation Baythroid EW 050 - Amendment No. 1 Bayer CropScience AG, Report No.: 14 1050 5268, Edition Number: M-117163-02-1 Date: 12.11.2003, Amended: 09.01.2006 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.10.1 /01 also filed: B 3.10.2. /01 also filed: B 3.11. /01 also filed: B 3.6. /01 also filed: B 3.8. /01	Yes	BCS
B 3.6. /01	Gueldner, W.	2003	Characterization of an EW-Formulation Baythroid EW 050 - Amendment No. 1 Bayer CropScience AG, Report No.: 14 1050 5268, Edition Number: M-117163-02-1 Date: 12.11.2003, Amended: 09.01.2006 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.10.1 /01 also filed: B 3.10.2. /01 also filed: B 3.11. /01 also filed: B 3.5. /01 also filed: B 3.8. /01	Yes	BCS

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Doc IIIB					
B 3.7. /01	Ryckel, B. de	2004	Accelerated and shelf-life storage stability of solfac EW 050 - Interim report - Analysis on the fresh test item, after 14 days at 54 degrees celsius +- 2 degrees celsius and 6 months and 1 year at room temperature Wallon Agricultural Research centre, Gembloux, Belgique Bayer CropScience AG, Report No.: M-257699-02-1, Edition Number: M-257699-02-1 Date: 25.11.2004, Amended: 22.11.2005 GLP, unpublished	Yes	BCS
B 3.8. /01	Gueldner, W.	2003	Characterization of an EW-Formulation Baythroid EW 050 - Amendment No. 1 Bayer CropScience AG, Report No.: 14 1050 5268, Edition Number: M-117163-02-1 Date: 12.11.2003, Amended: 09.01.2006 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.10.1 /01 also filed: B 3.10.2. /01 also filed: B 3.11. /01 also filed: B 3.5. /01 also filed: B 3.6. /01	Yes	BCS
B 3.10.1 /01	Gueldner, W.	2003	Characterization of an EW-Formulation Baythroid EW 050 - Amendment No. 1 Bayer CropScience AG, Report No.: 14 1050 5268, Edition Number: M-117163-02-1 Date: 12.11.2003, Amended: 09.01.2006 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.10.2. /01 also filed: B 3.11. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.8. /01	Yes	BCS

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Doc IIIB					
B 3.10.2. /01	Gueldner, W.	2003	Characterization of an EW-Formulation Baythroid EW 050 - Amendment No. 1 Bayer CropScience AG, Report No.: 14 1050 5268, Edition Number: M-117163-02-1 Date: 12.11.2003, Amended: 09.01.2006 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.10.1 /01 also filed: B 3.11. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.8. /01	Yes	BCS
B 3.11. /01	Gueldner, W.	2003	Characterization of an EW-Formulation Baythroid EW 050 - Amendment No. 1 Bayer CropScience AG, Report No.: 14 1050 5268, Edition Number: M-117163-02-1 Date: 12.11.2003, Amended: 09.01.2006 GLP, unpublished also filed: B 3.1.1. /01 also filed: B 3.1.2. /01 also filed: B 3.1.3. /01 also filed: B 3.10.1 /01 also filed: B 3.10.2. /01 also filed: B 3.5. /01 also filed: B 3.6. /01 also filed: B 3.8. /01	Yes	BCS
B 4.1. /01	Anon.	1996	Cyfluthrin ; CIPAC 385 CIPAC Bayer CropScience AG, Report No.: CIPAC 385, Edition Number: M-027450-01-1 Date: 01.01.1996 Non GLP, unpublished	Yes	BCS
B 4.1. /02	Oebels, D.	1994	Cyfluthrin-Formulations; Assay - Capillary Gas Chromatography Bayer AG, Dormagen, Germany Bayer CropScience AG, Report No.: 2201-0278801-94, Edition Number: M-012982-01-2 Date: 12.09.1994 Non GLP, unpublished	Yes	BCS

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Doc IIIB					
B 4.1. /03	Nonn, E.	1997	Validation-report VS1.1-2201-0278801E Bayer AG, Dormagen, Germany Bayer CropScience AG, Report No.: VS1.1-2201-0278801, Edition Number: M-023337-01-1 Date: 13.05.1997 Non GLP, unpublished	Yes	BCS
B 5.10.2. /01	Smith, G. B.	1986	Comparison of Baythroid H 100 WP, 50 EC, 50 EW with Coopex 250 WP and Alfacron for the control of houseflies (Musca domestica) in a laboratory trial Bayer Australia, Botany, N.S.W., Australia Bayer CropScience AG, Report No.: GBS 2/86, Edition Number: M-106137-01-1 Date: 13.03.1986 Non GLP, unpublished	Yes	BCS
B 5.10.2. /02	Mrusek, K.	1993	Evaluation of the residual activity of Solfac EW with and without PBO against houseflies and cockroaches Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: M-267020-01-2, Edition Number: M-267020-01-2 Date: 02.08.1993 Non GLP, unpublished	Yes	Bayer Animal Health
B 5.10.2. /03	Behrenz, W.	1984	Evaluation of various FCR 1272 formulations (EW, EC and WP) for residual activity against flies and cockroaches Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: AH-D-ID-028169e, Edition Number: M-266967-01-1 Date: 26.06.1984 Non GLP, unpublished	Yes	BCS
B 5.10.2. /04	Mrusek, K.	1990	Contact-Period test on german cockroaches, using Solfac WP and EW, FCR 4545 SC, Detamethrin SC and Baygon EC and WP on different substrates Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: 142, Edition Number: M-116397-01-1 Date: 22.03.1990 Non GLP, unpublished	Yes	BCS

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Doc IIIB					
B 5.10.2. /05	Van der Linde, D.	1988	To compare the biological efficacy of the samples, phoxim EC, cyfluthrin WP, azamethiphos WP and deltamethrin EC with regard to their contact and residual properties South African Bureau of Standards, Pretoria, South Africa Bayer CropScience AG, Report No.: BES-ES-Mo01203, Edition Number: M-106521-01-2 Date: 03.08.1988 Non GLP, unpublished	Yes	BCS
B 5.10.2. /06	Dale, W. E.; Gamero, O.	1983	Field and laboratory evaluations of the pyrethroids cyfluthrin, deltamethrin and cypermethrin against housefly adults (Musca domestica) Universidad Nacional Agratia, Lima, Peru Bayer CropScience AG, Report No.: AH-D-ID26482, Edition Number: M-267023-01-1 Date: 31.12.1983 Non GLP, unpublished	Yes	BCS
B 5.10.2. /09	Salin, C., Delettre, Y. R. and Vernon, P.	2003	Controlling the mealworm Alphitobius diaperinus (Coleoptera Tenebrionidae) in broiler and turkey houses: field trials with a combined insecticide treatment: insect growth regulator and pyrethroid Publisher:Entomological Society of America, Location:Anon., Journal:Journal of Economical Entomology, Volume:96, Issue:Anon., Pages:126-130, Year:2003, Report No.: BES-EH-Mo-00323, Edition Number: M-267027-01-1 Non GLP, published	No	
B 5.10.2. /10	Illarregi, I. E.	1998	Efficacy of Baycidal 25 WP and Solfac 10 WP against the litter beetle Alphitobius diaperinus in poultry IRATI, Lasarte-Oria, Spain Bayer CropScience AG, Report No.: 18784, Edition Number: M-267042-01-1 Date: 30.01.1998 Non GLP, unpublished	Yes	BCS

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Doc IIIB					
B 5.10.2. /11	Meus, Mr. and Froyman R.	1989	Efficacy of SOLFAC® S.P. 10 against *Alphitobius diaperinus* (lesser mealworm). Internal report Bayer, Belgium [BES Ref. M-106478-01-2] November 1989 (unpublished). Non GLP	Yes	BCS
B 5.10.2. /12	Pflueger, E.	1985	Experiments under practical conditions on the efficacy of FCR 1272 WP and EW formulations against Blattella germanica Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: MO-03-007004, Edition Number: M-105975-01-1 Date: 11.06.1985 Non GLP, unpublished	Yes	BCS
B 5.10.2. /13	Pospischil, R.	1989	Wirkung von Bayticol (Flumethrin) auf die rote Vogelmilbe *Dermanyssus gallinae* (de Geer) [Effect of Bayticol (flumethrin) on the red poultry mite *Dermanyssus gallinae* (de Geer).] Bayer, Division VT, Institut für Parasitologie, Internal Report TG/F, No.: 41 [BES Ref. not yet allocated] 16 February 1989 (unpublished) Non GLP	Yes	BCS
B 6.1.1. /01	[redacted]	1985	FCR 1272 00050 EW 0038 A (c.n. cyfluthrin) - Study for formulation toxicity [redacted] Bayer CropScience AG, Report No.: 13515, Edition Number: M-042320-01-1 Date: 29.05.1985 Non GLP, unpublished also filed: B 6.1.2 /01 also filed: B 6.1.3. /01	Yes	BCS
B 6.1.2 /01	[redacted]	1985	FCR 1272 00050 EW 0038 A (c.n. cyfluthrin) - Study for formulation toxicity [redacted] Bayer CropScience AG, Report No.: 13515, Edition Number: M-042320-01-1 Date: 29.05.1985 Non GLP, unpublished also filed: B 6.1.1. /01 also filed: B 6.1.3. /01	Yes	BCS

Annex point/ reference number	Author(s)	Year	Title **Source** (where different from company) **Company name, Report No., Date,** **GLP status** (where relevant)**, published or not**	Data protect. claimed	Owner
Doc IIIB					
B 6.1.3. /01	[redacted]	1985	FCR 1272 00050 EW 0038 A (c.n. cyfluthrin) - Study for formulation toxicity [redacted] Bayer CropScience AG, Report No.: 13515, Edition Number: M-042320-01-1 Date: 29.05.1985 Non GLP, unpublished also filed: B 6.1.1. /01 also filed: B 6.1.2 /01	Yes	BCS
B 6.2. /01	[redacted]	1992	Solfac EW 050 - Study for skin and eye irritation/corrosion in rabbits [redacted] Bayer CropScience AG, Report No.: 21897, Edition Number: M-267199-01-1 Date: 03.12.1992 GLP, unpublished	Yes	BCS
B 6.3. /01	[redacted]	2005	Solfac EW 50 (Project: Cyfluthrin (FCR 1272)) - Local lymph node assay in mice (LLNA/IMDS) [redacted] Bayer CropScience AG, Report No.: AT02362, Edition Number: M-257692-01-1 Date: 08.08.2005 GLP, unpublished	Yes	BCS
B 6.4. /01*	[redacted]	2004	[14C]-beta-cyfluthrin in vivo dermal absorption in the male rat [redacted] Bayer CropScience AG, Report No.: BAG379/042441, Edition Number: M-079619-01-1 Date: 09.07.2004 GLP, unpublished	Yes	BCS
B 6.4. /02*	[redacted]	2004	[14C]-beta-cyfluthrin - Comparative in vitro dermal penetration study using human and rat skin [redacted] Bayer CropScience AG, Report No.: BAG380/042686, Edition Number: M-079636-01-1 Date: 09.07.2004 GLP, unpublished	Yes	BCS

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source** (where different from company) **Company name, Report No., Date,** **GLP status** (where relevant)**, published or not**	**Data protect. claimed**	**Owner**
Doc IIIB					
B 8.1. /01	Anon.	2005	Solfac EW 050 Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-267215-01-1, Edition Number: M-267215-01-1 Date: 23.05.2005 Non GLP, unpublished also filed: B 8.2. /01 also filed: B 8.4. /01 also filed: B 8.5. /01 also filed: B 8.6. /02	Yes	BCS
B 8.2. /01	Anon.	2005	Solfac EW 050 Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-267215-01-1, Edition Number: M-267215-01-1 Date: 23.05.2005 Non GLP, unpublished also filed: B 8.1. /01 also filed: B 8.4. /01 also filed: B 8.5. /01 also filed: B 8.6. /02	Yes	BCS
B 8.4. /01	Anon.	2005	Solfac EW 050 Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-267215-01-1, Edition Number: M-267215-01-1 Date: 23.05.2005 Non GLP, unpublished also filed: B 8.1. /01 also filed: B 8.2. /01 also filed: B 8.5. /01 also filed: B 8.6. /02	Yes	BCS
B 8.5. /01	Anon.	2005	Solfac EW 050 Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-267215-01-1, Edition Number: M-267215-01-1 Date: 23.05.2005 Non GLP, unpublished also filed: B 8.1. /01 also filed: B 8.2. /01 also filed: B 8.4. /01 also filed: B 8.6. /02	Yes	BCS

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Doc IIIB					
B 8.6. /01	Bascou, J. P.	2004	Cyfluthrin - Incineration as a safe means of disposal and pyrolytic behaviour under controlled conditions Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: MO-04-004463, Edition Number: M-066112-01-1 Date: 23.04.2004 Non GLP, unpublished	Yes	BCS
B 8.6. /02	Anon.	2005	Solfac EW 050 Bayer CropScience SA, Lyon, France Bayer CropScience AG, Report No.: M-267215-01-1, Edition Number: M-267215-01-1 Date: 23.05.2005 Non GLP, unpublished also filed: B 8.1. /01 also filed: B 8.2. /01 also filed: B 8.4. /01 also filed: B 8.5. /01	Yes	BCS
B 9. /01	Anon.	2005	PE/EV-Bottles,1L,KS50.natural colour,UN 1H1 Material: BOTEV_N_1L_KS50_natural_UN 1H1 Material-No.: 00888910 Bayer CropScience Bayer CropScience AG, Report No.: M-267658-01-1, Edition Number: M-267658-01-1 Date: 21.10.2005 Non GLP, unpublished	Yes	BCS

Section No / Reference No	Author(s)	Year	Title. **Source (where different from company)** **Company, Report No.** **GLP (where relevant) / (Un)Published**	Data Protection Claimed (Yes/No)	Owner
Doc II					
Chap.3	Pauluhn, J., Machemer, L.H.	1998	Assessment of pyrethroid-induced paraesthesias: comparison of animal model and human data. Toxicology Letters 96,97:361-368.	No	Public
Chap.3	Acutex (Acute Exposure Project), EU	2006	TGD: Methodology to develop AETLs	No	Public

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Doc II					
Chap.3		1999	Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.	No	Public
Chap.4	ECB	2000	Technical Guidance Document in support of the Directive 98/8/EC concerning the placing of biocidal products on the market, Guidance on data requirements for active substances and biocidal products (TNsG) , October 2000	No	Public
Chap.4	FOCUS Work Group on Degradation Kinetics, EC	2006	Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration; EC Document Reference Sanco/10058/2005 version 2.0	No	Public
Chap. 4	Anonymus	1993-2000	Model Maker User Manual, Version 4.0. Cherwell Scientific Publishing Limited. Not GLP Published	No	Public
Chap.4	ECB	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Part II; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2	No	Public
Chap.4	EC	1967	Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances	No	Public
Chap.4	EC	2006	Directive 2006/8/EEC amending, for the purposes of their adaptation to technical progress, Annexes II, III and V to Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations	No	Public

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Doc II					
Chap.4	EU	2007	Proposal for a Regulation of the European Parliament and of the Council on classification, labelling and packing of substances and mixtures, and amending Directive 67/548/EEC and Directive 2006/8/EEC	No	Public
Chap.6	Wieseler, B., Kühn, K.-H., Leng, G., Idel, H.	1998	Effects of Pyrethroid Insecticides on Pest Control Operators. . Bull. Environ. Contam. Toxicol. (1998) 60:837-844	No	Public
Chap.6	Hardt, J.; Angerer, J.	2003	Biological monitoring of workers after the application of insecticidal pyrethroids. Int. Arch. Occup. Environ. Health 76(7):492-8	No	Public
Chap.8	OECD	2007	4th draft Emission Scenario Document of Insecticides, acaricides and products to control other arthropods (PT 18) for household and professional uses	No	Public
Chap.8	OECD	2006	Emission Scenario Document Number 14 for Insecticides for Stables and Manure Storage Systems	No	Public
Chap.8	Marquart H., Warren, N., Laitinen, J., Van Hemmen, J.	2006	Default values for assessment of potential dermal exposure of the hand to industrial chemicals in the scope of regulatory risk assessments, Ann.Occup.Hyg. (2006), Vol. 50, No. 5, pp. 469-489	No	Public
Chap.8	EC	2003	FOCUS Surface water scenarios in the EU evaluation process under 91/414/EEC; SANCO/4802/2001-rev.2 final	No	Public
Chap.8	EC	2000	FOCUS groundwater scenarios in the EU review of active substances ". Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000 Rev.2	No	Public
Chap.8	EC	2002	Technical Notes for Guidance: Human Exposure to Biocidal Products - Guidance on Exposure Estimation [„Report 2002" http://ecb.jrc.it/biocides]	No	Public
Chap.8	EC	2004	Human Exposure to Biocidal Products (TNsG June 2002), User Guidance Document	No	Public
Chap.8	Llewellyn, D.M.; Brazier, A.; Brown, R.H.; Cocker, J.; Evans, M.L.; Hampton, J.; Nutley, B.P.; White,J.	1996	Occupational exposure to permethrin during its use as a public hygiene insecticide, Ann. occup. Hyg. 40 No. 5, (1996) 499-509	No	Public
Chap.12	ECB 2002 b	2002	TNsG Human Exposure to Biocidal Products, Part 1, p. 5-6, June 2002	No	Public

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Doc II					
Chap.13	EC	1998	Directive 1998/83/EC on the quality of water intended for human consumption	No	Public
Chap. 13	EC	2006	REACH-VO Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, authorisation and restriction of chemicals (REACH) establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC, Commission Directives 91/155/EEC, 93/105/EC and 2000/21/EC	No	Public
Chap. 13	ECB	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Part II; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2	No	Public
Chap.15	Gerritsen-Ebben, R.; Brouwer, D.H.; van Hemmen J.J.	2006	Effective Personal Protective Equipment (PPE) – Discussion document on the use of PPE in registration purposes for handling of agrochemical, microbiological and biocidal pesticides	No	Public
Chap.15	Human Exposure Expert Group (HEEG), Ad hoc working group exposure	2010	Nr.9: "Default protection factors for protective clothing and gloves"; http://echa.europa.eu/documents/10162/19680902/heeg_opinion_9_default_protection_factors_for_clothing_and_gloves_en.pdf	No	Public
Chap.15	EC	2007	TECHNICAL NOTES for GUIDANCE (TNsG), http://echa.europa.eu/documents/10162/16960215/bpd_guid_tnsg-human-exposure-2007_en.pdf	No	Public