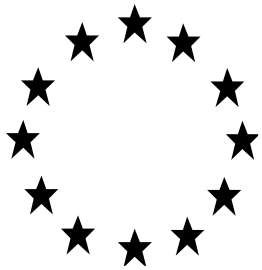
Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Transfluthrin

(insecticides, acaricides and products to control other arthropods)

Updated 2019

RMS: the Netherlands

October 2019: *During the product authorisation process of products with transfluthrin an OECD314 test on the biodegradation in the STP and soil, and ecotoxicity data for aquatic and terrestrial organisms have been submitted as refinement. These data have been evaluated and agreed upon at different WGs in the period of 2016 to 2018, resulting in harmonised updated DT50 values in the STP and PNECs for the aquatic and terrestrial environment.*

Transfluthrin (PT18)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on [Date SCB]

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Principle of evaluation

This assessment report has been established as a result of the evaluation Transfluthrin as product-type 18 (insecticides, acaricides and products to control other arthropods), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market , with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

The evaluation has therefore been conducted in the view to determine whether it may be expected, in light of the common principles laid down in Annex VI to Directive 98/8/EC, that there are products in product-type 18 containing transfluthrin that will fulfil the requirements laid down in Article 5(1) b), c) and d) of that Directive.

1.2. Purpose of the assessment report

The aim of the assessment report is to support a decision on the approval of Transfluthrin as product-type 18, and should it be approved, to facilitate the authorisation of individual biocidal products in product-type 18 that contain Transfluthrin. 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.

The conclusions of this report were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Regulation (EU) No 528/2012.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report 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 has been granted.

1.3. Procedure followed

This assessment report has been established as a result of the evaluation of Transfluthrin as product-type 18 (insecticides, acaricides and products to control other arthropods), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market , with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Transfluthrin (CAS no. 118712-89-3) was notified as an existing active substance, by Bayer Environmental Science, hereafter referred to as the applicant, in product-type 18.

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

In accordance with the provisions of Article 5(2) of that Regulation, the Netherlands 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 Transfluthrin as an active substance in Product Type 18 was 30 April 2006, in accordance with Annex V of Regulation (EC) No 2032/2003.

On 13 April 2006, the Netherlands' competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 11 September 2006.

On 13 July 2010, the Rapporteur Member State submitted, in accordance with the provisions of Article 10(5) and (7) of Regulation (EC) No 2032/2003, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 24 August 2010. The competent authority report included a recommendation for the inclusion of Transfluthrin in Annex I to the Directive for PT 18.

In accordance with Article 12 of Regulation (EC) No 2032/2003, the Commission made the competent authority report publicly available by electronic means on 7 September 2010. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

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

In accordance with Article 11(4) of Regulation (EC) No 2032/2003, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on [date SCB].

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

2.1.1.1. Identity of the active substance

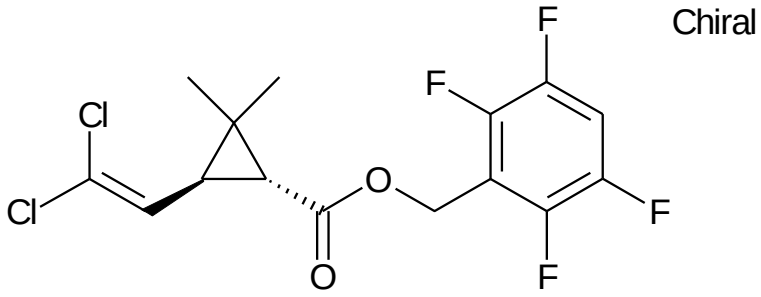
ISO-name	Transfluthrin
CAS-No.	118712-89-3 *
EU-Index-No.	607-223-00-8 *
Other No.	ELINCS: 405-060-5*
	CIPAC: 741

** The EU index no. and ELINCS no. refer to the 1R,trans and 1S,trans configurations, which is not in agreement with the definition of transfluthrin, which is exclusively the 1R,trans isomer. The CAS registry no. does refer to the correct isomer.*

Chemical names

IUPAC:	2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate, or, 2,3,5,6-tetrafluorobenzyl (1R)-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
CA:	(1R-trans)-(2,3,5,6-tetrafluorophenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate
Other:	Cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, (2,3,5,6-tetrafluorophenyl) methyl ester, (1R, 3S)
Molecular weight	371.2 g/mol
Molecular formula	$C_{15}H_{12}Cl_2F_4O_2$

Structural formula



Transfluthrin (ISO) is produced at a minimum purity of 96.5%, referring to a 1R, trans-configuration. The cis/trans, S-isomers and 1R,cis-isomer are considered impurities.

2.1.1.2. Physico-chemical properties of the active substance

Transfluthrin is a white solid, with no characteristic odour (pure substance) or a toluene-like odour (technical substance). The relative density at 20 °C was determined to be 1.3856. Transfluthrin does not self-ignite. An exothermal decomposition was observed between 250 and 390 °C (breakdown products are unknown). Transfluthrin is not classified as flammable, auto-flammable, explosive or oxidising.

Melting and boiling point are 32 and 242 °C, respectively. The vapour pressure was determined at $9x10^{-4}$ Pa at 20 °C and $2x10^{-3}$ Pa at 25 °C, based on extrapolation. The water solubility is 0.057 mg/L (20 °C). Subsequently, a Henry's Law Constant of 5.86 $Pa.m^3.mol^{-1}$ at 20 °C could be calculated.

The log Pow of transfluthrin is > 5. A more accurate log Pow is not required for the risk assessment as a BCF is derived. Estimation with Bioloom yields a calculated log Pow of 5.94, EPIWIN v3.2 yields a value of 6.17.

Transfluthrin does not dissociate within an environmentally relevant pH range.

2.1.1.3. Methods of analysis

Analysis of the active substance as manufactured

One valid GC-FID method is available for analysis of the active substance in the technical material. Furthermore, a valid GC-FID method to determine the R/S ratio of the active substance in the technical material is available.

Valid methods were available for all significant (> 1 g/kg) impurities and impurities included in the specification of the technical material.

Residue analysis

Soil

An acceptable GC-ECD method (DFG Method S 19 (extended Revision)) is available for the analysis of the active substance in soil. It was tested in one soil type and has an LOQ of 0.005 mg/kg and confirmation is performed by GC-MS.

Water

A study summary for a GC-MS method (analytical method 01026) to analyse the active substance in surface and in drinking water was submitted. This analytical method is considered to be valid at a LOQ of 0.05 µg/L. The method is considered highly specific as three mass fragments were monitored (target 207 m/z, confirmatory fragments 209 and 211 m/z).

Air

A valid GC-MS method (PTRL Europe Study No. 911 G) is available for the analysis of the active substance in air. This method has an LOQ of 0.5 µg/m^3. The method is considered highly specific as three mass fragments were monitored (target 163 m/z, confirmatory fragments 127 and 143 m/z)

Body fluids and tissues

Methods for analysis of transfluthrin residues in animal and human body fluids and tissues are not required, since transfluthrin is not classified as toxic or highly toxic.

Food and feed

The biocidal products will not be used on any food or feed of plant and/or animal origin. Indirect exposure to transfluthrin as a result of contamination of food is possible.

The estimation of potential exposure of the active substance to humans through diet and other means has been carried out. Worst case intake calculations showed that potential residue levels in food will be negligible.

Therefore analytical methods for the analysis of transfluthrin residues in food or feed of plant and/or animal origin are not required.

2.1.2. Intended Uses and Efficacy

Product type and field of use envisaged

Main group : 3 (pest control)
Product type : 18 (insecticides, acaricides and products to control other arthropods)
Transfluthrin is intended for use as insecticide by non-professional users.

The active substance transfluthrin at the proposed concentration of 1 mg/m^3 (mosquito coil and vaporiser) and at 0.4 mg/m^2 paper (mothpaper) has been shown to give an immediate knockdown effect for the target organisms. In these tests the following species have been used: Mosquitoes (*Aedes aegypti*, *Culex quinquefasciatus*), house flies (*Musca domestica*), cockroaches (*Blattella germanica*), and moth (*Tineola bisselliella*).

No known resistance in the target species has been observed to-date for this active substance.

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

2.1.3. Classification and Labelling

Transfluthrin is currently classified as Xn; R38 (Irritating to skin) and N; R50/53 (Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment) according to Directive (EC) 99/45.

On the basis of a review of the submitted data, the classification and labelling is proposed: R22 (Harmful if swallowed) and N; R50/53 (Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment) according to Directive (EC) 99/45.

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Transfluthrin is currently classified as GHS07; H315 (Skin Irrit. 2) and GHS09; H400 (Very toxic to aquatic life) and H410 (Very toxic to aquatic life with long lasting effects) according to Regulation (EC) No 1272/2008, Annex VI.

On the basis of a review of the submitted data, the following CLP classification and labelling is proposed: GHS07; H302 (Acute Tox. 4) and GHS09; H400 and H410 according to Regulation (EC) No 1272/2008, Annex VI.
.
RMS will propose a change of the current classification to RAC and highlight carcinogenicity, irritation and acute oral toxicity. Classification will be further discussed at ECHA (TM decision March 2011).
Based on the profile of the active substance, the provided toxicology of the preparation, the characteristics of the co-formulants, the method of application and the risk assessment for the operator, the following labeling of the preparations is proposed:

Proposal for the classification and labelling of the formulation **Turbo 4 seasons**			
Pictogram:	GHS09	Signal word:	Warning

H-statements:	H410		Very toxic to aquatic life with long lasting effects
P-statements:	P102		Keep out of reach of children
	P264		Wash hands thoroughly after handling
	P273		Avoid release to the environment
	P301	+	IF SWALLOWED: Call a poison center or
	P312		doctor / physician if you feel unwell
	P501		Dispose of contents/container to hazardous or special waste collection point
Supplemental Hazard information:	-		
CHILD-RESISTANT FASTENING OBLIGATORY?			**No**
Tactile warning of danger obligatory?			**No**

Explanation:	
Pictogram:	GHS09 is obligatory with the assigned H410
H-statements:	H410 is based on toxicity of the active substance and the triggers laid down in Regulation (EC) 1272/2008
P-statements:	P102 is a P-statement for non-professional application. P273 is recommended and can be added to the label in case this would not lead to more than 6 P-statements. P264 and P301 + P312 based on proposal from the applicant. P501 is highly recommended for products classified for environmental hazards that apply to non-professional use.

Proposal for the classification and labelling of the formulation

Baygon mosquito coil

Pictogram:	GHS09		Signal word: Warning
H-statements:	H410		Very toxic to aquatic life with long lasting effects
P-statements:	P102		Keep out of reach of children
	P264		Wash hands thoroughly after handling
	P271		Use only outdoors or in a well-ventilated area
	P301	+	IF SWALLOWED: Call a poison center or
	P312		doctor / physician if you feel unwell
	P501		Dispose of contents/container to hazardous or special waste collection point
Supplemental Hazard information:	-		
CHILD-RESISTANT FASTENING OBLIGATORY?			**No**
Tactile warning of danger obligatory?			**No**

Explanation:	
Pictogram:	GHS09 is obligatory with the assigned H410
H-statements:	H410 is based on toxicity of the active substance and the

	triggers laid down in Regulation (EC) 1272/2008
P-statements:	P102 is a P-statement for non-professional application. P271 is part of the risk assessment . P264 and P301 + P312 are based on proposal from the applicant P501 is highly recommended for products classified for environmental hazards that apply to non-professional use.

Proposal for the classification and labelling of the formulation

Raid Portable Electric

Pictogram:	GHS09	Signal word: Warning
H-statements:	H410	Very toxic to aquatic life with long lasting effects
P-statements:	P102	Keep out of reach of children
	P264	Wash hands thoroughly after handling
	P271	Use only outdoors or in a well-ventilated area
	P301 + P312	IF SWALLOWED: Call a poison center or doctor / physician if you feel unwell
	P501	Dispose of contents/container to hazardous or special waste collection point
Supplemental Hazard information:	-	
CHILD-RESISTANT FASTENING OBLIGATORY?		**No**
Tactile warning of danger obligatory?		**No**

Explanation:	
Pictogram:	GHS09 is obligatory with the assigned H410
H-statements:	H410 is based on toxicity of the active substance and the triggers laid down in Regulation (EC) 1272/2008
P-statements:	P102 is a P-statement for non-professional application. P271 is part of the risk assessment . P264 and P301 + P312 are based on proposal from the applicant. P501 is highly recommended for products classified for environmental hazards that apply to non-professional use.

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

Oral absorption of transfluthrin and/or its hydrolysis products is rapid, and is assumed to be 100%. For the inhalation route 100% absorption is assumed. Route to route extrapolation for effects exerted by intact transfluthrin is not possible. Dermal absorption of transfluthrin is assumed to be 10%, on the basis of a MW of 371 and log P_{ow} of 5.4, and data from other pyrethroids in other formulations. Highest levels of transfluthrin in tissues (in total less than

2%) are found in liver and kidney, lowest levels are found in brain. Excretion is rapid; 74-90% in urine within 48h. There is no indication for accumulation. The benzylmethylene moiety is predominantly metabolized to tetrafluorobenzoic acid and the glucuronic acid conjugate of tetrafluorobenzyl alcohol. The carboxyl moiety is probably metabolised to dichlorochrysanthemic acid (DCCA). Radioactivity was found in the milk. The liver is the main organ responsible for metabolism.

Acute toxicity

There is acute toxicity after oral exposure. The acute dermal and inhalation toxicity is low. Transfluthrin is not irritating to the eyes and skin, and is not a skin sensitiser.

The procedure for classification – reclassification was discussed during TM1 2011. TM agreed that the RMS will propose a change of the current classification to RAC and highlight irritation and acute oral toxicity. Classification will be further discussed at ECHA.

Repeated dose toxicity and carcinogenicity

The main targets for repeated dose toxicity appear to be the liver and the kidney. For inhalation exposure, neurotoxicity appears to be the critical endpoint.

In a 13-week inhalation study (rat), immediately post-dosing hyperactivity, tremors, bristling and ungroomed coat were observed, with a NOAEC of 47.6 mg/m^3, equivalent to 17 mg/kg bw/day.

A 3-week dermal study performed on rabbits, demonstrated no systemic toxicity at doses up to and including 1000 mg/kg bw/day. Skin irritation was observed at doses of 200 mg/kg bw/day and above.

The overall NOAEL for oral long-term toxicity was 1.0 mg/kg bw/day, based on effects in the kidney, i.e. glomerulonephrosis, pigment deposition, and increased absolute and relative weight, observed in a 2-year study in the rat.

In an oncogenicity study in mice increased incidences in haemangiosarcomas in the spleen, adenomas of the Harderian gland, and sarcomas of the subcutis were observed in females at 1000 ppm (equal to 279 mg/kg bw/day). None of the increased incidences of tumours reported in the mouse 2-years study can be considered of biological significance. Background data show that in other studies where these findings occur, an equal or higher incidence of the tumour types as haemangiosarcomas in the spleen and sarcomas of the subcutis is found in controls, indicating the spontaneous nature of these lesions. The Harderian gland is not present in humans and has therefore no relevance for human risk (see for more details doc IIIA 6.10 appendix mechanistic considerations 19-2-2010 and doc IIA 3.7.1 mechanistic studies on carcinogenicity).

In the rat carcinogenicity study, increased incidence of urinary bladder urothelial hyperplasia, as well as an increased incidence of urothelial tumours papilloma and carcinoma, and thyroid follicular hyperplasia and increased cuboidal cells in the thyroid were seen at 2000 ppm (equal to 100.4 mg/kg bw/day). None of the increased incidences of tumours reported in the rat 2-

years study can be considered of human relevance (see doc IIIA 6.10 appendix mechanistic considerations and doc IIA 3.7.2 mechanistic studies on carcinogenicity).

Mechanistic studies indicate that transfluthrin may have a tumour promoting action and clearly support a) urothelial cytotoxicity and associated regenerative proliferation caused by high, sustained urinary concentrations of TFBA as the mechanism of urinary bladder tumour formation in rats exposed for two years a very high dose level of transfluthrin, coupled to b) the weight of evidence that this process should not be extrapolated to man. These are the precise criteria for a substance not being classified in any of the categories for carcinogenicity according to Commission Directive 2001/59/EC (6th August 2001) (see doc IIIA 6.10 appendix mechanistic considerations and doc IIA 3.7.1 mechanistic studies on carcinogenicity).

This conclusion is further supported by the absence of similar findings in the chronic mouse studies on transfluthrin (see doc IIIA 6.10 appendix mechanistic considerations 19-2-2010 and doc IIA 3.7.1 mechanistic studies on carcinogenicity).

The procedure for classification – reclassification was discussed during TM1 2011. Some MSs considered that the carcinogenic potential of the substance was not completely clean or not relevant to humans. TM agreed that the RMS will propose a change of the current classification to RAC and highlight carcinogenicity. Classification will be further discussed at ECHA.

Genotoxicity

Transfluthrin is considered to be genotoxic in vitro but not genotoxic in vivo.

Reproductive toxicity

No developmental toxicity nor teratogenic effects of transfluthrin were observed in two oral teratogenicity studies in rats and rabbits.

In a multigeneration study, effects on reproduction (increased incidence of total litter loss) were observed at 1000 ppm (equal to 45 mg/kg bw/day). Pups from the 2 litters lost died perinatally (i.e. pups were born dead or died in the first 3 days post parturition) could result in labeling of transfluthrin for reproduction toxicity., however the transfluthrin DNT study confirms that at dose levels in the range and above the highest dose level tested in the multiple generation reproduction study the viability of the fetuses is not affected by transfluthrin. Therefore, labeling is not proposed.

The NOAEL for systemic toxicity is 20 ppm, equal to 1-2 mg/kg bw/day (i.e. the lowest dose tested), based on the no significant adverse histopathological effects in the kidney at 20 ppm in parental animals (and also the NOAEL set on the 2 years rat study).

Neurotoxicity

Neurotoxicity was only observed in oral gavage studies (rat) and an inhalation study (rat). The neurotoxic effects became apparent immediately after dosing The overall NOAEL for acute toxic effects was 15 mg/kg bw, observed in a developmental toxicity study in the rabbit. Transfluthrin did not induce (neuro-)developmental or reproductive toxicity in oral studies. Daily inhalation exposure (6.5h/day) of pups from postnatal days (PND) 10-16, induced

increased muscarinic receptor levels in the brain cortex at PND17. The NOAEC for this effect was 15 mg/m^3.

2.2.1.2. Risk assessment

Critical endpoints and acceptable exposure levels

The human health risk characterisation is performed using the AEL approach.

For all products indirect exposure to transfluthrin as a result of residues in food is considered negligible. Therefore it is not necessary to determine an ADI and ARfD (although for the assessment of the statement of negligible exposure RMS used an ADI and ARfD).

It is considered necessary to derive acceptable exposure levels (AELs) for acute exposure, for chronic systemic exposure and for the chronic inhalation exposure for children.

The following AELs were established:

$AEC_{acute,\ inhalation}$: 0.5 mg/m^3

In a 13-week inhalation study in the rat, with an exposure duration of 6h/day, the NOAEC for neurotoxicity was 46.7 mg/m^3 (equivalent to 17 mg/kg bw/day). This NOAEC is used as a basis for risk assessment for acute inhalation exposure. A default assessment factor of 100 is applied to account for inter- and intraspecies differences. Thus, for inhalation exposure, based on the NOAEC of 46.7 mg/m^3 and the default assessment factor of 100, an $AEC_{acute,\ inhalation}$ of 0.5 mg/m^3 is derived.

$AEL_{acute,\ dermal}$: 1 mg/kg bw (including 10% dermal absorption)

In a 3 week dermal toxicity study in the rabbit the NOAEL for systemic effects was 1000 mg/kg bw/day NOAEC local 20 mg/kg bw/day). This NOAEL is used as a basis for risk assessment for acute dermal exposure. A default assessment factor of 100 is applied to account for inter- and intraspecies differences. Thus, for dermal exposure, based on the NOAEL of 1000 mg/kg bw/day and the default assessment factor of 100, an $AEL_{acute,\ dermal}$ of 1 mg/kg bw is derived (10% dermal absorption).

The external $AEL_{acute,\ dermal}$ and the internal $AEL_{acute,\ dermal}$ are 10 mg/kg bw/day and 1 mg/kg bw/day (10% dermal absorption included), respectively.

The $AEL_{acute\ dermal}$ is considered to be also adequately protective with respect to local effects (local NOAEC of 20 mg/kg bw/day).

$AEL_{acute,\ oral}$: 0.15 mg/kg bw

In oral gavage studies the overall NOAEL for neurotoxicity was 15 mg/kg bw/day, observed in a developmental toxicity study in the rabbit. This NOAEL is used as a basis for risk assessment for acute oral exposure. A default assessment factor of 100 is applied to account for inter- and intraspecies differences. Thus, for oral exposure, based on the NOAEL of 15 mg/kg bw/day and the default assessment factor of 100, an $AEL_{acute,\ oral}$ of 0.15 mg/kg bw is derived.

$AEL_{chronic, systemic}$: 0.01 mg/kg bw/day

The use pattern of Turbo 4 Seasons, Baygon Mosquito Coil, and Raid Portable Electric indicates exposure of the user for 5-12 months/year. Therefore an AEL should be based on data from studies with long-term exposure. In this respect the NOAEL of 20 ppm was observed in a 2-year dietary study in rats, equal to 1.0 mg/kg bw/day on the basis of glomerulonephrosis, pigment deposition, increased absolute and relative weight of the kidneys at 200 ppm, equal to 9.9 mg/kg bw/day. A default assessment factor of 100 is applied to account for inter- and intraspecies differences. As the toxicokinetic studies indicate almost complete absorption of radiolabel, no correction for incomplete oral absorption is needed.

Based on these considerations an $AEL_{chronic}$ of 1/ 100= 0.01 mg/kg bw/day is established.

For the calculation of the systemic exposure following inhalation and dermal exposure, absorption is assumed to be 100 and 10%, respectively.

Although there is no semi-chronic (medium) exposure scenario for the representative product(s), the $AEL_{medium\ term}$ will be the same value as for the chronic AEL.

The $AEL_{chronic}$ is considered to be also adequately protective with respect to local effects (local NOAEC of 20 mg/kg bw/day).

For acute exposures external AELs are established. No route-to-route extrapolation is required. For chronic exposure a systemic AEL is established.

According to the intended uses, Baygon Mosquito Coil, Turbo 4 Seasons and Raid Portable Electric will only be applied by non-professionals.

Acute exposure risk characterisation

In the table below the risk indices for acute exposure are presented. It should be noted that the external dermal and inhalation exposure of the consumer is related to the external $AEL_{acute, inhalation}$ and the external $AEL_{acute, dermal}$.

Table 2.2.1.2.2-1. Acute inhalation exposure (external)

exposure duration	Inhalation exposure (mg/m^3)	AELacute, inhalation, (mg/m^3)	% of AEL
Turbo 4 Seasons: loading and during use (adult)			
5 min/day	0.0154	0.5	4
Baygon Mosquito Coil: loading (adult)			
	--	0.5	--
Baygon Mosquito Coil: during use (child)			
8h/day	0.024	0.5	5
Raid Portable Electric: loading (adult)			
	--	0.5	--
Raid Portable Electric: during use (child)			
6h/day	0.038	0.5	8

Table 2.2.1.2.2-2. Acute dermal exposure (external)

	Dermal exposure (mg/kg bw)	AELacute, dermal (external) (mg/ kg bw/day)	% of AEL
Turbo 4 Seasons: loading and during use (adult)			
	< 0.0045	10	<<1
Baygon Mosquito Coil: loading (adult)			
	< 0.003	10	<<1
Baygon Mosquito Coil: during use (child)			
	--	10	--
Raid Portable Electric: loading (adult)			
	< 0.067	10	<<1
Raid Portable Electric: during use (child)			
	--	10	--

Conclusion

It can be concluded that acute neurotoxic effects for the consumer (adult and child), due to inhalation or dermal exposure as a result of the use of Turbo 4 Seasons, Baygon Mosquito Coil, and Raid Portable Electric are not expected. Since the estimated exposure to transfluthrin due to the use of Baygon Mosquito Coil is only 5% of the $AEL_{acute,\ inhalation}$ there is no need to correct for the duration of exposure (8h consumer exposure vs 6.5h exposure in the animal study).

It should be noted that in acute and sub-chronic inhalation studies in rats and mice with smouldering Baygon mosquito-coil, respiratory effects (e.g. bradypnoea, laboured breathing, decreased respiratory rate) were observed. The data show that the sensory irritation potency of smokes generated by the carrier coil and coil containing transfluthrin are virtually indistinguishable. A wide range of combustion products, due to burning of transfluthrin and the coil can be expected (e.g. formaldehyde, acrolein, benz(a)pyrene) which are known have a variety of toxic properties, some of which may only become apparent after repeated exposure. Although no exposure estimates to the levels of smoke generated during the smouldering of Baygon Mosquito coil have been performed it is concluded that adverse health effects due combustion products generated during the use of Baygon Mosquito coil cannot be excluded.

Chronic exposure risk characterisation

General chronic toxicity

Table 2.2.1.2.3-1. Internal chronic exposures and risk assessment of transfluthrin (non-professional use)

Route	Estimated internal chronic exposure (mg a.s./ kg bw- day)	AEL-systemic (mg a.s./ kg bw/ day)	% of AEL
Turbo 4 Seasons: loading and during use (adult[a])			
Inhalation	2.7×10^{-5}	0.01	0.3
Dermal	--	0.01	--
Total	2.7×10^{-5}	0.01	0.3
Baygon Mosquito Coil: loading (adult)[c]			
Inhalation	--	0.01	--
Dermal	$< 3.0 \times 10^{-4}$ [b]	0.01	<3
Total	$< 3.0 \times 10^{-4}$ [b]	0.01	<3
Baygon Mosquito Coil: during use (child)			
Inhalation	0.0027 [b]	0.01	27
Dermal	--	0.01	--
Total	0.0027 [b]	0.01	27
Raid Portable Electric: loading (adult)[d]			
Inhalation	--	0.01	--
Dermal	--	0.01	--
Total	--	0.01	--
Raid Portable Electric: during use (child) 24 hours exposure (Tier 1)			
Inhalation	0.013 [b]	0.01	130
Dermal	--	0.01	--
Total	0.013 [b]	0.01	130
Raid Portable Electric: during use (child) 8 hours exposure (Tier 2)			
Inhalation	0.0043 [b]	0.01	43
Dermal	--	0.01	--
Total	0.0043 [b]	0.01	43

--: negligible

a:The exposure of the child will be higher than the exposure of the adult due to bodyweight. The exposure of the adult is negligible and no risk. For the child and teenagers also no adverse effects are expected (covered by the low risk of adults). The acute internal exposure is estimated for user placing 2 discs in a closet. Although the calculation makes several protective assumptions, a user may treat several closets at the same time. Therefore, a reverse reference scenario could help to assess the risk by determining number of discs a user would need to handle in a day to achieve an appropriate NOAEL modified by an Assessment Factor (usually 10 x 10). Taken into account the external dermal exposure of 0.0045 mg/kg bw/day for 2 discs and 10% dermal absorption resulting in an internal dermal exposure of 0.00023 mg/kg bw/day for one disc. This means that more than 4000 discs could be handled to achieve the AEL of 1 mg/kw bw/day. This seems an unrealistic scenario.

b: daily exposure during the 5 months/year that exposure takes place.

c:Taken into account the internal dermal exposure of 0.0003 mg/kg bw/day. This means that more than 3000 coils could be handled to achieve the AEL $_{\text{oral acute}}$ of 1 mg/kw bw/day. This seems an unrealistic scenario.

d:Taken into account the internal dermal exposure of 0.0067 mg/kg bw/day. This means that more than 110 refills could be handled to achieve the AEL $_{\text{oral acute}}$ of 1 mg/kw bw/day. This seems an unrealistic scenario.Based on

additional information from the applicant the total surface of the impregnated cardboard is approximately 107 cm². Because the refill is equipped with a grip, the user is not supposed to get into any contact with the surface of the cardboard. And even if, due to the structure of the surface, the contact area is minimal. The calculation represents a worst-case estimate. It is assumed that the dermal exposure during loading will certainly be smaller than the calculated values

Based on the risk assessment considering the worst case approach of 24 hours exposure it can be concluded that adverse health effects for the child due to chronic inhalation exposure to transfluthrin as a result of the use of Raid Portable Electric cannot be excluded (%AEL > 100). It should be noted, however, that the exposure calculation was performed assuming, "worst case", that Raid Portable Electric is used for 24 h in a children's bedroom, with the windows closed. Furthermore, there are more consideration to be taken into account as:

- It seems unrealistic that people who are ill/invalid are exposed for more than 8 hours, because mosquitos are mainly present during the night and not the whole day. It is difficult to forget switching the device of, as there is significant noise of operation.
- Even in case somebody would use the product longer then 8 hours, it is very unlikely that the same person is sitting in a 17m³ room as the default for the risk assessment.
- There could be exposure for 24 hours but this is often not the case for more days.
- It is a conservative approach to assume that 100% of the active ingredient evaporates over the 45 nights of use. There is indication (non GLP data) that after 45 nights the airstream could not remove about 50% of the active ingredient from the cardboard. This means that in an optimized system, the desired efficacy can be obtained with half the amount of active ingredient.
- Raid Potable Electric is not in the market anymore. For authorization of similar products at stage of product authorization, the applicant should provide data on evaporation kinetics or data on concentration of the active ingredient in the air.
- The applicant does not want to use it in children's bed rooms (restriction to the age of 2).

Based on above considerations, the RMS performed a tiered approach and a refinement. Based on the refinement with 8 hours exposure adverse health effects for the child due to chronic inhalation exposure to transfluthrin as a result of the use of Raid Portable Electric can be excluded (%AEL = 43).

Adverse health effects for the consumer, (adult and child) due to transfluthrin exposure as a result of the use of Turbo 4 Seasons and Baygon Mosquito Coil are not expected.

In addition it was concluded that adverse health effects due combustion products generated during the use of Baygon Mosquito Coil cannot be excluded (see conclusion acute toxicity). Although it seems not unrealistic that transfluthrin evaporates before it burns and generates

combustion products and the risk caused by the coil smoke should be comparable to the risk from a burning incense stick. However, a wide range of combustion products, due to burning of transfluthrin and the coil can be expected (e.g. formaldehyde, acrolein, benz(a)pyrene) which are known have a variety of toxic properties, some of which may only become apparent after repeated exposure.

Indirect exposure as a result of use

Indirect exposure as a result of the use of Turbo 4 Seasons or Raid Portable Electric is considered to be negligible. Estimates for Baygon Mosquito Coil are given in the tables below. As a worst case scenario the risk of indirect exposure is estimated for a child of 10.5 months of age.

Table 2.2.1.2.3-3. Indirect acute exposure as a result of use of Baygon Mosquito Coil

	Estimated acute internal exposure (mg a.s. / kg bw / day)	AEL-acute (mg a.s./ kg bw- day)	% of AEL
Baygon Mosquito Coil			
Dermal	0.0010	1	<<1
Oral	0.0011	0.15	<1
Total			<1

Table 1.5.1-2 Indirect chronic exposure as a result of use of Baygon Mosquito Coil

	Estimated chronic internal exposure (mg a.s. / kg bw / day)	AEL-systemic (mg a.s./ kg bw- day)	% of AEL
Baygon Mosquito Coil			
Dermal	0.0010 a	0.01	10
Oral	0.0011 a	0.01	11
Total	0.0021 a	0.01	21

a daily exposure during the 5 months/year that exposure takes place.

It can be concluded that no adverse health effects solely due to indirect acute or chronic exposure to transfluthrin as the result of the use of Baygon Mosquito Coil are expected.

Also for Turbo 4 Seasons, Raid Portable Electric and Baygon Mosquito Coil indirect exposure to transfluthrin as a result of residues in food is considered negligible.

Combined direct and indirect exposure as a result of use

Indirect exposure to transfluthrin is only expected for the use of Baygon Mosquito Coil. The risk of acute indirect exposure of a child is considered to be negligible. The total exposure of a child to transfluthrin as a result of chronic indirect exposure to Baygon Mosquito Coil is estimated to be 21% of the $AEL_{chronic,\ systemic}$. The direct exposure to transfluthrin during the use of Baygon Mosquito Coil is estimated to be 27% of the $AEL_{chronic,\ systemic}$. Thus the total exposure to transfluthrin as a result of the use of Baygon Mosquito Coil is calculated to be 48 of the $AEL_{chronic,\ systemic}$. This could indicate that adverse health effects for the consumer (i.e. a child of 10.5 months of age) cannot be excluded. However, it should be noted that the exposure

assessment for both direct and indirect exposure to transfluthrin is based on "worst case" assumptions (e.g. 8h exposure in a children's bedroom with the windows closed, 25% deposition of transfluthrin on the floor). Therefore, it is concluded that also the combined direct and indirect exposure to transfluthrin as a result of the use of Baygon Mosquito Coil is not likely to result in adverse health effects.

However, it is concluded that adverse health effects due combustion products generated during the use of Baygon Mosquito Coil cannot be excluded (see conclusion on acute toxicity).

2.2.1.3. Conclusions of the risk assessment

The risk assessment indicates that for the use of Turbo 4 Seasons, no adverse health effects for the consumer are expected.

For Raid Portable Electric, the risk assessment indicates that the calculated exposure is 130 % of the $AEL_{chronic,\ systemic.}$ Accordingly, it could be concluded that for the use of this product adverse health effects for children, due to inhalation exposure, cannot be excluded. It was noted, however, that the exposure calculation was performed assuming, "worst case", that Raid portable electric is used for 24h in a children's bedroom, with the windows closed. Therefore, it is concluded that exposure to transfluthrin as a result of the use of Raid portable electric is not likely to result in adverse health effects. With refinement of the exposure (8 hours in stead of 24 hours) adverse health effects for children can be excluded.

The total combined direct and indirect exposure to transfluthrin as a result of the use of Baygon Mosquito Coil is calculated to be 48% of the $AEL_{chronic,\ systemic}$. This indicates that adverse health effects for the consumer (i.e. a child of 10.5 months of age) can be excluded.
However, it is concluded that adverse health effects due combustion products generated during the use of Baygon Mosquito coil cannot be excluded (see conclusion acute exposure risk characterisation).

2.2.2. Environmental Risk Assessment

During the product authorisation process of products with transfluthrin an OECD314 test on the biodegradation in the STP and soil, and ecotoxicity data for aquatic and terrestrial organisms have been submitted as refinement. These data have been evaluated and agreed upon at different WGs in the period of 2016 to 2018, resulting in harmonised updated DT50 values in the STP and PNECs for the aquatic and terrestrial environment. In the underlying document only these parameters are updated. Whereas PECs and PEC/PNEC ratios have remained unchanged. Update of these data does not change the approval of the substance.

2.2.2.1. Fate and distribution in the environment

<u>Biodegradation in sewage sludge</u>

Transfluthrin is considered not readily biodegradable, but still degrades rapidly during sewage treatment (DT_{50} is 0.284 days at 21.7°C). The proposed degradation pathway is to trans-DCVA and 2,3,4,6-tetrafluorobenzyl alcohol (NAK 4452). Trans-DCVA subsequently degrades into cis-OH-DCVA or trans-OH-DCVA. Trans-DCVA may be regarded as transient (DT_{50}=0.897 d, ff=0.968) and trans-OH-DCVA degrades rapidly as well (DT_{50} = 0.341 d, ff=0.261). Cis -OH-DCVA is however persistent in sewage sludge (DT_{50} >10000 d, ff=0.619). Degradation of NAK 4452 was not addressed as only the

phenyl-moiety was radioactively labelled. Consequently, NAK 4452 must be regarded as persistent (DT_{50} >10000 d) with a formation fraction of one as one mole transfluthrin produces one mole NAK 4452.

Biodegradation in water

Transfluthrin is considered not readily biodegradable. In natural water/sediments systems, the dissipation of transfluthrin from the water phase was dominated by sorption, the $DT_{50,water}$ was < 7 days. The average $DT_{50,system}$ was 11.1 days, the $DT_{50,sediment}$ 14.1 days. Transfluthrin is therefore Not P.

Metabolites NAK 4452 (2,3,5,6-tetrafluorobenzyl alcohol; TFB-OH) and NAK 4723 (2,3,5,6-tetrafluorobenzoic acid; TFB-COOH) were detected in amounts > 10 % of AR in the water phase, maximum levels were 38 and 59% of AR, respectively. The same metabolites were found in sediment, maximum level was 2.9% of AR for TFB-OH and 26% of AR for TFB-COOH. Bound residues after 100 days were 4.4 and 7.9% of AR, mineralisation after 100 days was 3.0 and 12.6% of AR for the respective systems.

The DT50,system of metabolite TFB-OH was estimated to be < 14 days, a reliable estimate of the DT50, system of metabolite TFB-COOH could not be obtained because of few data points. Analytical results obtained in the water/sediment system indicate that metabolite TFB-COOH has a low degradation rate and is persistent in a water/sediment system.

Biodegradation in soil

Degradation in four soils was determined according to OECD 307. The following DT50 values and formation fractions were concluded for transfluthrin and the metabolite 2,3,5,6-tetrafluorobenzoic acid (TFB-COOH; NAK 4723): parent-DT50: 5.17 d (12°C), metabolite-DT50: 3.23 d (12°C), formation fraction: 0.6190. Degradation of metabolite DCVA (3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylic acid) was not addressed in this study as only the fluorbenze moiety was labelled. Nevertheless, half-life for DCVA is available from a study submitted for cyfluthrin. In this study, degradation of all four isomers of DCVA was investigated in two soils. For PEC calculation, the worst case DT50 of 174.8 days at 12°C (61.8 days at 20°C) was used (WGIV item 6.6b).

Abiotic degradation

Transfluthrin is hydrolytically stable at 25 °C, pH 5 and 7. The $DT_{50,hydrolysis}$ at pH 9, 25 °C is 14 days. There is no reliable information on aqueous or soil photolysis, but this is not considered necessary for risk assessment. Furthermore, the notifier submitted a waiver for not repeating an aqueous photolysis study on transfluthrin concluding that direct photolytic degradation in water is not expected to be a relevant route of degradation of transfluthrin in water.

Distribution

Due to the low water solubility and high log P_{ow} of transfluthrin, the sorption to soil could not be determined in a batch equilibrium experiment. A log K_{oc} of 4.7 L/kg obtained at pH 6 using the HPLC-method according to OECD 121, is used in the environmental risk assessment.

Accumulation

The average experimental bioconcentration factor (BCF) for fish is average 1783 L/kg, based on Total Radioactive Residues in whole fish (transfluthrin and transformation products). Based on the information of a transformation study, the BCF based on TRR is considered to be a reasonable estimate of the BCF for the parent compound.

No experimental data are available on terrestrial bioconcentration. The BCF for earthworms, estimated according to the TGD, is 10452 L/kg.

2.2.2.2. Effects assessment

Aquatic compartment

Since the approval decision for transfluthrin additional chronic tests with fish and Daphnia were submitted. Based on the lowest NOEC of 0.0175 µg/L for Daphnia with an assessment factor of 10, the $PNEC_{aquatic}$ for transfluthrin is 1.75 ng/L. It should be noticed that no toxicity data are available on non-target insects. Although transfluthrin has a specific mode of action against insects, the confined use and indirect emission to surface water are accepted arguments that no further data are required.

Applying an assessment factor of 1000 to the L/EC_{50} of > 100 mg/L for fish, daphnids and algae, the $PNEC_{aquatic}$ for metabolite 2,3,5,6-tetrafluorobenzoic acid (TFB-COOH) is 0.1 mg/L.

No ecotoxicity data are available for TFB-OH, but in view of the chemical structure similarity with TFB-COOH and the comparable physico-chemical characteristics, it is proposed that TFB-OH also has a PNECaquatic of 0.1 mg/L. For permethric acid (DCVA consisting of trans –DCVA and cis-CH_2OH-trans-DCVA) an acute LC50 for daphnia of 25 mg/L was reported. This incomplete data set was complemented with QSARs (Epiwin) based on baseline toxicity. The lowest LC_{50} of 6.42 mg/L for Daphnia and an assessment factor of 1000 results in a $PNEC_{aquatic}$ of 0.0064 mg/L. It should be noted that the baseline QSAR might not be representative for this type of molecule, but this is accepted for now.

Sediment

Since the approval decision for transfluthrin chronic tests with *Chironomus* and *Lumbriculus* were submitted. Based on the lowest NOEC of 0.164 mg/kg dw for *Chironomus riparius* with an assessment factor of 100, the $PNEC_{sediment}$ for transfluthrin is 1.64 µg/kg dw. The WG agreed on an higher assessment factor of 100 (instead of 50) as the chironomids in the test system were fed three times per week with fresh, uncontaminated food thus reducing the exposure via sediment/particle ingestion.

Sewage Treatment Plant

As a worst-case estimate, the NOEC for respiration of activated sludge is set to the water solubility of 0.057 mg/L. Applying an assessment factor of 1 to this value, leads to a $PNEC_{stp}$ for transfluthrin of 0.057 mg/L. In line with discussions held at the TMII08 for Flocoumafen a $PNEC_{stp}$ based on the reported endpoint of EC_{50} > 10,000 mg/L is included additionally. Application of an assessment factor of 100 leads to a $PNEC_{stp}$ for transfluthrin of 100 mg/L.

Atmosphere

In view of the proposed uses significant exposure of the environment via air is not expected.

Terrestrial compartment

Additional studies have been conducted on earthworms (sub-lethal effect), collembolans (reproduction study) and micro-organisms (Nitrogen effects), as well as a non-target plants study. The $PNEC_{soil}$ of 0.10 mg/kg dw (0.088 mg/kg ww) is derived based on a NOEC nitrogen mineralization of 5.24 mg/kg dw standard soil with an assessment factor of 50.

No ecotoxicity data have been generated on terrestrial organisms for the metabolites 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH) and permethric acid (trans-DCVA), but these metabolites have been identified in the new OECD314 degradation study. Therefore a $PNEC_{soil}$ of 0.012 mg/kg ww and 0.0128 mg/kg ww were derived for TFB-COOH and trans-DCVA, respectively based on Equilibrium Partitioning Method.

Non compartment specific effects relevant to the food chain (secondary poisoning)

The concentration in fish is calculated to be 0.86 µg/kg, the concentration in worms is 8.43 µg/kg for indoor use and 2.37 µg/kg for outdoor use. In the absence of short-term or long-term dietary toxicity data for birds, a $PNEC_{oral,\ bird}$ cannot be derived. However, for the $PNEC_{oral,bird}$ to fall below the PEC, the NOEC should be lower than the $PEC_{oral,bird}$ x 30, and should thus be < 0.03 mg/kg feed in case of fish and < 0.26 mg/kg feed (indoor use) and < 0.07 mg/kg feed (outdoor use) in case of earthworms. Following a similar reasoning for short-term tests, the LC_{50} should be < 3, 26 and 7 mg/kg feed, respectively (< $PEC_{oral,bird}$ x 3000). In view of the absence of acute toxicity to birds at doses up to 1890 mg/kg bw, it is not expected that chronic toxicity levels as low as 0.03 mg/kg feed will be reached.

Furthermore, there are several reasons to assume that the calculated PECs in water and soil (and therefore the concentrations in fish and earthworms) may be worst-case estimates. In view of this, a risk of secondary poisoning of birds is not expected. From the viewpoint of animal welfare, it is not considered justified to require further studies on birds.

Effects on bees and other non-target arthropods

In view of the proposed uses significant exposure of bees and other non-target arthropods is not expected.

Groundwater

The PEC_{grw} is evaluated according to the requirements with respect to drinking water quality.

2.2.2.3. PBT, POPs and Endocrine Disruption assessment

Since December 2010 it is agreed that the PBT assessment is carried out on basis of REACH guidance. This means that the following criteria apply:

Table R. 11-1: PBT and vPvB criteria according to Annex XIII

Property	PBT-criteria	vPvB-criteria
Persistence The assessment of the persistency in the environment shall be based on available half-life data collected under the adequate conditions, which shall be described by the registrant.	- $T_{1/2}$ > 60 days in marine water, or - $T_{1/2}$ > 40 days in fresh- or estuarine water, or - $T_{1/2}$ > 180 days in marine sediment, or - $T_{1/2}$ > 120 days in fresh- or estuarine sediment, or - $T_{1/2}$ > 120 days in soil.	- $T_{1/2}$ > 60 days in marine, fresh- or estuarine water, or - $T_{1/2}$ > 180 days in marine, fresh- or estuarine sediment, or - $T_{1/2}$ > 180 days in soil.
Bioaccumulation The assessment of bioaccumulation shall be based on measured data on bioconcentration in aquatic species. Data from freshwater as well as marine water species can be used.	BCF > 2000 L/kg	BCF > 5000 L/kg
Toxicity	- NOEC (long-term) < 0.01 mg/L for marine or freshwater organisms, or - substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2 or 3), or - there is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC.	-

Substances which fulfil the PBT or vPvB criteria or POPs criteria shall not be approved, unless releases to the environment can be effectively prevented.

P/vP criteria:

Transfluthrin

The $DT_{50,water}$ of transfluthrin as determined in freshwater water/sediment systems is < 7 days. The average $DT_{50,system}$ is 11.1 days at 20 °C, the $DT_{50,sediment}$ is 14.1 days. As information on the biodegradation in soil is not available persistence of transfluthrin in soil **cannot be excluded**.

Metabolites

Major metabolite NAK 4452 (2,3,5,6-tetrafluorobenzyl alcohol (TFB-OH) has a $DT_{50,system}$ < 14 days, metabolite NAK 4723 (2,3,5,6-tetrafluorobenzoic acid; TFB-COOH) is considered persistent in freshwater-sediment systems; P and vP criteria are fulfilled. DCVA or permethric acid: (1R,3S)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylic acid is probably formed under environmental conditions, but not measured in the water-sediment study. In the dCAR of cyfluthrin this metabolite is considered as persistent in freshwater-sediment systems; **P and vP criteria are fulfilled**.

As information on the biodegradation in soil is not available persistence of transfluthrin metabolites TFB-OH, TFB-COOH and DCVA in soil **cannot be excluded**.

B/vB criteria:

Transfluthrin

The experimentally derived BCF for fish is 1704 to 1861 L/kg ww, based on Total Radioactive Residues in whole fish.

Metabolites

Both metabolites TFB-OH and TFB-COOH are not expected to bioaccumulate: the estimated log P_{ow} is 1.85 for TFB-COOH and 1.54 for TFB-OH1. Epiwin calculates for DCVA a log Pow of 3.38.

On basis of this information the B and vB criterion is not fulfilled for transfluthrin and its metabolites.

T criteria:

Transfluthrin

A chronic NOEC of 50 µg/L is available for algae. Furthermore acute LC50 values for fish and daphnia were below the 0.01 mg/L trigger. Therefore the **T criterion is fulfilled**.

Metabolites

For TFB-COOH Limit tests for fish and daphnia show acute L(E)C50 values of >100 mg/L. For TFB-OH no ecotoxicity tests are available, but this molecule is structurally very similar to TFB-COOH.

For DCVA *Daphnia magna* was the most sensitive species. A LC50, acute of 25 mg/L was determined.

The metabolites TFB-COOH, TFB-OH and DCVA are less toxic than Cyfluthrin by orders of magnitude. They can be considered as not potentially toxic (LC50 short-term not < 0.1 mg/L). Therefore the T screening criterion is not fulfilled for TFB-COOH, TFB-OH and DCVA.

Conclusion for the PBT characterisation:

As information on the biodegradation in soil is not available persistence of transfluthrin and metabolites TFB-OH, TFB-COOH and DCVA in soil cannot be excluded.

T criteria are fulfilled for transfluthrin, the active substance is no PBT - candidate as the B and vB criteria are not fulfilled. P, vP criteria for transfluthrin and its metabolites should be further investigated.

1 Biobyte. 2006. Bio-Loom for Windows. Version 1.5. Claremont, USA: Biobyte Corp.

For TFB-OH, TFB-COOH and DCVA, the B and T criterion are not met. Therefore TFB-OH, TFB-COOH and DCVA are no PBT-candidates.

Conclusion for the POP characterisation:

The initial criteria for long-range transport potential, toxicity and bioaccumulation are met for transfluthrin. The active substance is however, not persistent and therefore not a POPs candidate. This also holds for it metabolites.

Conclusion on endocrine disruptive properties:

Transfluthrin is not included in the Commission staff working document on implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706). Transfluthrin and its metabolite DCVA have no detectable endocrine disrupting effects in in-vivo systems based on an overview report incorporating the results from studies conducted with cyfluthrin or transfluthrin as part of the US EPA's Endocrine Disruption Screening (EDSP) Program..

2.2.2.4. Exposure assessment

The environmental exposure assessment was carried out according to the draft Emission Scenario Document (ESD) for Insecticides, acaricides and products to control other arthropods (Pt 18) for household and professional users (4th Draft, 6 July, 2007), using the scenarios for diffusers.

Outdoor use, which is only applicable to Baygon Mosquito Coil, is not considered to result in significant direct contamination of water or air.

For the indoor use of Raid Portable Electric, Turbo 4 Seasons and Baygon Mosquito Coil, indirect emission to the environment is considered via discharge of waste water to the Sewage Treatment Plant (STP) upon cleaning of floors to which part of the active substance has deposited. The Predicted Environmental Concentrations (PECs) were calculated with EUSES 2.1.2. Resulting PECs in the respective compartments are summarised in Table 2.2.2.4-1.

Table 2.2.2.4-1. PECs for transfluthrin in the STP, the aquatic and soil compartment and groundwater from indoor and outdoor uses

Product	PEC_{stp} [mg/L]	$PEC_{aquatic}$ [mg/L]	$PEC_{sediment}$ [mg/kg ww sed]	PEC_{soil} [mg/kg ww soil]	PEC_{grw} [mg/L]
Indoor use					
Raid Portable Electric	1.03E-05	9.61E-07	1.05E-03	1.57E-03	1.78E-06
Turbo 4 Seasons	3.52E-07	3.27E-08	3.57E-05	5.36E-05	6.06E-08
Baygon Mosquito Coil	7.92E-06	7.37E-07	8.03E-04	1.21E-03	1.36E-06
Outdoor use					
Baygon Mosquito Coil	-	-	-	2.21E-04	2.50E-07

The PECs of the major metabolites were calculated based on the highest PECs calculated for the parent for Raid Portable Electric (indoor use) and Baygon coil (outdoor use) multiplied by a formation factor and a correction for the molecular weight. The resulting concentrations are given in Table 2.2.2.4-2.

Table 2.2.2.4-2. PECs for transfluthrin and major metabolites in the STP, the aquatic and soil compartment and groundwater from indoor and outdoor uses

Product	PEC_{stp} [mg/L]	$PEC_{aquatic}$ [mg/L]	$PEC_{sediment}$ [mg/kg ww sed]	PEC_{soil} [mg/kg ww soil]	PEC_{grw} [mg/L]
Indoor use (Raid Portable electric)					
Transfluthrin	1.03E-05	9.61E-07	1.05E-03	1.57E-03	1.78E-06
TFB-OH	1.89E-06	1.76E-07	1.92E-04	2.88E-04	3.26E-07
TFB-COOH	3.20E-06	2.98E-07	3.26E-04	4.88E-04	5.53E-07
Outdoor use (Baygon Mosquito coil)					
Transfluthrin	-	-	-	2.21E-04	2.50E-07
TFB-OH	-	-	-	4.05E-05	4.58E-08
TFB-COOH	-	-	-	6.86E-05	7.76E-08

2.2.2.5. Risk characterisation

STP, surface water and sediment

Based on the PNECs and the PECs as derived above, the following PEC/PNEC ratios are calculated (Table 2.2.2.5-1). Because no experimental data are available on the toxicity of transfluthrin for sediment dwelling organisms, the risk assessment is covered by that for the water phase. The $PEC_{sed}/PNEC_{sed}$ is derived from the $PEC_{aquatic}/PNEC_{aquatic}$ with an additional assessment factor of 10 as a consequence of the log P_{ow} of transfluthrin >5. PEC/PNEC ratios > 1 are indicated in bold.

Table 2.2.2.5-1. PEC/PNEC ratios for Transfluthrin in STP, surface water and sediment

Compartment	Product PNEC	Raid Portable Electric PEC/PNEC	Turbo 4 Seasons PEC/PNEC	Baygon Mosquito Coil PEC/PNEC
STP*	PNEC 0.057 (100) mg/L	1.81E-04 (1.03E-07)	6.18E-06 (3 52E-09)	1.39E-04 (7.92E-08)
aquatic	PNEC 7.0E-7 mg/L	**1.37**	4.67E-02	**1.05**
Sediment	10 x $PEC/PNEC_{aquatic}$	**13.7**	4.67E-01	**10.5**

*: $PEC/PNEC_{stp}$ ratios based on maximum solubility and between brackets on $PNEC_{stp}$ = EC_{50}/AF 100

For *water and sediment*, the $PEC/PNEC_{aquatic}$ is above 1 for Raid Portable Electric and Baygon Mosquito Coil.. A potential risk cannot be excluded for Raid Portable Electric and Baygon Mosquito Coil. Risks for Turbo 4 Seasons are considered acceptable.

PEC/PNEC ratios for the highest PECaquatic, are presented in Table 2.2.2.5-2. PEC/PNEC ratios for sediment are a factor 10 higher then for the aquatic compartment (values not shown). The risks for *surface water and sediment* caused by the major metabolites TFB-OH and TFB-COOH are considered acceptable for all proposed uses.

Table 2.2.2.5-2. PEC/PNEC ratios for metabolites TFB-OH and TFB-COOH in surface water

		PEC	PNEC	PEC/PNEC
Compartment	Compound	mg/L	mg/L	-
aquatic	TFB-OH	1.76E 07	> 0.1 mg/L	1.76E 08
aquatic	TFB-COOH	2.98E-07	> 0.1 mg/L	2.98E-08

Discussion on the aquatic risk assessment

There are a number of arguments (see below) indicating that the risk assessment is based on worst-case assumptions.

1. In the absence of sufficient chronic data, the PNECaquatic is derived applying the highest assessment factor of 1000.
2. In the scenario overestimations are incorporated such as - 10% of the active substance is emitted to the floor after condensation of the vaporised product; - daily cleaning performed and – 100% cleaning efficiency is applied. Raid Portable Electric induces vaporisation of the active substance without heating, and the fraction emitted to the floor is therefore likely to be overestimated.
3. In the STP module of EUSES, the emission of treated waste water from the STP to surface water is assumed to occur on a daily basis over a certain period of time. Because this is a continuous process, degradation in water and/or sediment is not taken into account in the calculations. The products are used against mosquitoes, the presence of which is not constant (a.o. depending on weather conditions). Continuous use is therefore considered to be a worst-case, and days with emissions are considered to be followed by periods without. In view of the $DT_{50,system}$ of 11.1 days and the $DT_{50,sediment}$ of 14.1 days, degradation in water and sediment is relevant for transfluthrin, and if emissions are not continuous, the actual concentrations will be lower than calculated.

On the other hand the TM (TMI 2011) noted that the present calculations take into account one use per household only. This use can also be higher if for instance more then one Raid Portable Electric system or more Mosquito Baygon Coils are used per household, which could lead to higher emissions to the environment. It should be emphasised that the ESD does address the frequency and simultaneity in which insecticidal products are used in households. The RMS welcomes it if refined data on use frequency and simultaneity for this type of use become available. Analysis of product sales data over a representative period with an appropriate level of spatial and temporal resolution can be used to improve estimates of emissions to STP. Additionally the removal rate from (contaminated) surfaces could be an important parameter to refine the risk assessment. This information can be provided at the point of product registration.

A risk for the aquatic and sediment compartment for the use of Raid Portable Electric and Baygon Mosquito Coil cannot be excluded.

<u>Assessment of drinking water criterion and persistence in sediment</u>

In addition to the risk assessment based on the PEC/PNEC comparison, Annex VI to the Directive states that:

An active substance shall not be included into Annex I if the foreseeable concentration of the active substance or…. of relevant metabolites, breakdown or reaction products to be expected in surface water or its sediments after use of the biocidal product under the proposed conditions of use:

- *exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, the values fixed by*
    - *Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the member states,*
    - *Directive 98/83/EC or*
- *has an impact deemed unacceptable on non-target species*

unless it is scientifically demonstrated that under relevant field conditions this concentration is not exceeded.

According to the TNsG on Annex I inclusion, the Water Framework Directive 2000/60/EC may also be relevant for limit concentrations in surface water.

No specific limit value is established for transfluthrin under Directive 98/83/EC, and therefore the general limit of 0.1 µg/L for organic pesticides applies. The PEC/drinking water limit ratio does not exceed 1 for any of the intended products.

Major metabolite NAK 4723 (2,3,5,6-tetrafluorobenzoic acid; TFB-COOH) is less toxic than the parent and concentrations will be lower, therefore an unacceptable risk due to this metabolite is not expected. No data are available for metabolite NAK 4452 (2,3,5,6-tetrafluorobenzyl alcohol (TFB-OH), but based on the structure, a higher toxicity as compared to the parent is not expected.

It is concluded that transfluthrin does comply with the drinking water criteria.

In the TNsG on Annex I inclusion it is further stated that:

An active substance should not be included in Annex I if

- *it shows in the sediment of a laboratory water/sediment system a DT_{50} > 6 months at 20 °C or*
- *during laboratory tests in aerobic sediment/water system (20-25 °C) it forms non-extractable residues in amounts exceeding 70% of the initial dose after 100 days with a mineralisation rate of less than 5% in 100 days*

unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable accumulation in sediment.

The average $DT_{50,system}$ and $DT_{50,sediment}$ at 20 °C are 11.1 and 14.1 days, respectively, which is < 6 months. Mineralisation was < 5 % for one system, but non-extractable residues were never > 70%. This means that transfluthrin does comply with the criteria for persistence in sediment. Major metabolite TFB-COOH is considered persistent, but has a considerably lower toxicity than the parent. Unacceptable risks are not identified and therefore also the metabolite TFB-COOH complies with the criteria for persistence in sediment.

<u>Atmosphere</u>

Under the proposed conditions of use, transfluthrin will be emitted to air. According to the ESD, the concentration in air upon outdoor use will be not relevant because of instant dilution. This also applies to indoor use. No ecotoxicity data are available based on atmospheric exposures and there is no agreed method available to derive a PEC_{air}. A $PEC_{air}/PNEC_{air}$ cannot be calculated.

The FOCUS Working group on Pesticides (EC Document Reference SANCO/10553/2006 Rev 2 June 2008) recommends a trigger of a DT_{50} in air of 2 days to identify substances of potential concern for long-range transport. Substances having a longer DT_{50} require further evaluation to assess their potential impact upon remote areas; recommendations on how to assess and evaluate transport at the extremes of the range were provided in the FOCUS Air Group.

Additionally the FOCUS air working group developed a guidance methodology to determine the potential of a substance for atmospheric ozone depletion. The following issues are considered relevant:

1. The atmospheric life time of a substance should be long enough to transport the substance to the atmosphere;

2. The substance contains one or more of the following substituents: F, Cl of Br;

3. Substances containing N and S are relevant in stratospheric ozone depletion (e.g. N_2O);

Exemplified substances are $CFCl_3$, tetrachloromethane, HCFC142b, Halon 1211 and methyl bromide with a atmospheric life time of 2 to 50 year.

The estimated half-life time in air is 2.4 days (24-hr day; 0.5E06 OH/cm^3) (Atkinson calculation), which is borderline for the FOCUS air criteria, for long range transport requiring a further evaluation. Transfluthrin has a vapour pressure of 9×10^{-4} Pa at 20°C (doc IIA 1.3), indicating relatively low volatility. The calculated Henry's law constant is 5.86 $Pa.m^3.mole^{-1}$ (doc IIA 1.3) indicating that the substance has a tendency to volatilise from water.

Transfluthrin has a high Koc value indicating that the substance has tendency to bind to solid particles, hard surfaces and soils and a low tendency to evaporate from soils. Thus the long-range transport in the air is expected to be rather limited. Transfluthrin has a potential for short to medium-range environmental transport.

As for the atmospheric ozone depletion potential transfluthrin fulfils the criteria, because it contains "F" substituents. Its atmospheric life time is, however, too short and transfluthrin is not listed by the FOCUS air group as causing ozone depletion. Furthermore, considering the relative small total amounts used and the volume of the atmospheric compartment, possible abiotic effects of transfluthrin on the atmosphere are expected to be negligible.

Terrestrial compartment (incl. groundwater)

PEC/PNEC ratios for soil and risks to groundwater

Risk quotients for direct exposure of soil and indirect exposure of soil via the sludge from the STP are calculated based on the calculated $PNEC_{soil,EP}$ is 0.62 µg/kg ww soil as derived in Doc

IIA and the PEC_{soil} as estimated in Doc IIB, the following PEC/PNEC ratios are calculated (Table 2.2.2.5-3). For transfluthrin, with a log P_{ow} > 5, the $PEC/PNEC_{soil}$ is increased by a factor of 10. PEC/PNEC ratios > 1 are indicated in bold.

Table 2.2.2.5-3. PEC/PNEC ratios for soil

Product	$PEC/PNEC_{soil}$
Indoor use	
Raid Portable Electric	**25.4**
Turbo 4 Seasons	8.69E-01
Baygon Mosquito Coil	**19.6**
Outdoor use	
Baygon Mosquito Coil (one time)	**3.58**
Baygon Mosquito Coil (7 times)	**25.1**

Under the proposed conditions of use of Turbo 4 Seasons, risks to soil are not expected. Indoor and outdoor use of Raid Portable Electric and Baygon Mosquito Coil will result in a unacceptable risk for the soil compartment.

The calculated PEC_{grw} is below the general limit of 0.1 µg/L for organic pesticides in all cases and a risk is not expected.

Discussion on the terrestrial risk assessment

There are arguments (see below) indicating that the risk assessment is based on worst-case assumptions. A Risk for the terrestrial compartment for the use of Raid Portable Electric and Baygon Mosquito Coil, with PEC/PNEC ratios of 2.54 and1.96 respectively in soil, which cannot be ignored.

1. In the absence of ecotoxicity data for non target insects in and on soil, the $PNEC_{soil}$ is derived from the $PNEC_{aquatic}$ applying equilibrium partitioning.
2. The $PNEC_{aquatic}$ is derived from acute toxicity data applying the highest assessment factor of 1000. Possibly chronic data, which require lower assessment factors, may result in a less strict $PNEC_{aquatic}$.
3. The above calculation makes the worst-case assumption that 100% of the emitted substance is deposited on the receiving soil. In reality, it is expected that only a fraction of the residue would reach the soil. As an indication, it is proposed to take account of the results of the orienting study (Johnson, 2011[2]), which investigated deposition of transfluthrin in indoor situations. The study revealed that 16% of the active substance was deposited to the floor of an 8.5 x 8.5 m^2 room. It is proposed that the results of this study represent a worst case, since it was conducted indoors. In outdoor situations it might be reasonably expected that the effect of atmospheric turbulence would be much more significant, resulting in deposition over a wider area at lower concentrations. However, it is recognised that there is

2 [redacted] 2011) Assessment of insecticide deposition for two insecticide vaporisers. Health and Safety Laboratory, Harpur Hill, Buxton (UK). Report no. AS/2011/17, date: 2011-12-01 (unpublished).

some uncertainty about this hypothesis, which may require further consideration at the product authorisation stage.

4. It is unlikely that the receiving area of soil will not be vegetated. In reality it could be expected that the receiving area will be covered by an ornamental lawn, grass, shrubs or other plants, particularly in the case of unmixed soil (consistent with the proposed mixing depth of 0.1 m). This vegetation will intercept a proportion of the residue, reducing the loading to soil. FOCUS Surface Water – Appendix I) provides default interception figures of 0.4, 0.6 and 0.75 for minimal crop cover, average crop cover and full canopy, respectively. These values are consistent with those defined in USES 4.0.
5. The calculated PEC_{soil} presented above does not take account of dissipation processes that could occur on or within the soil, such as biodegradation and photodegradation. Should data characterising these processes become available at the product registration stage it may be possible to generate a more refined estimate of soil exposure and, hence, risk. Regarding indirect emission to soil, it should be noted that the relative risk to soil compartment via sludge compared to the sediment compartment is dependent on the dissipation properties assumed for transfluthrin. Assumption of the default degradation rate in soil described in EUSES (DT_{50} 1000000 days) results in highest RCRs being calculated for indirect exposure to soil (via sludge). This is a result of assumed accumulation between successive annual sludge application events. Furthermore, it should be noted that Bayer is planning to conduct an aerobic soil degradation study in 2014. Therefore, a DT_{50} value will be available for use in environmental risk assessment at the product authorisation stage and should be used to review theapproval of the active substance, as appropriate.

Assessment of persistence in soil

Annex VI to the Directive states that:

An active substance shall not be included into Annex I if

- *during tests in the field, it persists in soil for more than one year (a substance can be considered to persist for more than a year if, in soil field tests, its DT_{90} > 1 year and DT_{50} > 3 months), or*
- *during laboratory tests, it forms not extractable residues in amounts exceeding 70% of the initial dose after 100 days with a mineralisation rate of less than 5% in 100 days, or*
- *has unacceptable consequences or effects on non-target organisms*

unless it is scientifically demonstrated under field conditions that there are no unacceptable effects or unacceptable accumulation in soil.

In addition to the above criteria, in the TNsG on Annex I inclusion it is further stated that:

the active substance shall not be included into Annex I if it has a DT_{50} > 6 months at 20 ºC in soil metabolism studies. However, this does not necessarily apply if the active substance is included in Annex I with regard to areas of use where a long lasting service-life of the treated material is essential and it is scientifically demonstrated that under field conditions there is no unacceptable accumulation in soil (e.g. that the PEC/PNEC < 1 in soil during the service-life of the treated article). This derogation is an interpretation of the above mentioned "unless clause).

Similarly, an active substance containing a metal or a semi-metal element shall not be included in Annex I if the use will cause significant accumulation above the natural background levels.

There are no data available on the degradation rate of transfluthrin in soil. For the exposure calculations transfluthrin was therefore considered non-biodegradable in soil. Under the proposed conditions of use direct emission to soil may occur from the outdoor use of Baygon Mosquito Coils resulting in risk for the terrestrial ecosystem. Additionally risk for the terrestrial ecosystem are expected as a result of indirect emissions via application of sludge from the use of Raid Portable Electric and Baygon Mosquito Coil. For these uses transfluthrin does not comply with the persistence criteria and therefore a soil degradation study is required.

No direct emission to soil and no risk for the terrestrial ecosystem are expected as a result of indirect emissions via application of sludge for use of Turbo 4 Seasons against moths in drawers and closets. For the latter type of use, transfluthrin complies with the persistence criteria that are laid down in paragraph 85 of Annex VI to the Biocides Directive and in the TNsG on Annex I inclusion.

Non compartment specific effects relevant to the food chain (secondary poisoning)

Using the concentration in fish and worms and the $PNEC_{oral,mammal}$ of 6.67 mg/kg feed, the $PEC/PNEC_{oral,mammal}$ is < 1 and a risk is not expected.

In the absence of short-term or long-term toxicity data for birds, a $PEC/PNEC_{oral,bird}$ cannot be derived. As argued in Section 2.2.2.2, a risk of secondary poisoning of birds is not expected. From the viewpoint of animal welfare, it is not considered justified to require further studies on birds.

Non compartment specific effects relevant to the food chain (primary poisoning)

Use of the products Turbo 4 seasons, Baygon Mosquito Coil and Raid Portable Electric will not result in primary poisoning of birds and mammals.

Effects on bees and other non-target arthropods

For the proposed indoor uses of transfluthrin in Turbo 4 seasons, Raid Portable Electric and Baygon Mosquito Coils exposure of bees and other non-target arthropods is not considered likely. The outdoor use of Baygon Mosquito Coil will most likely take place during evenings when abundance of actively foraging bees is not expected. Furthermore, the product will most likely be placed in the vicinity of the users (i.e. on terrace tables or verandas), where exposure of leaf and soil dwelling non-target arthropods is reduced. It cannot be excluded that bees and/or arthropods are incidentally affected. Transfluthrin has a tendency to adsorb to surfaces, which may cause exposure of foraging bees at day time and surface dwelling non target arthropods. Due to lack of ecotoxicity data and scenarios to calculate exposure concentrations, it is at present not possible to determine the risk for bee populations or the arthropod community. Considering that for outdoor use of Baygon Mosquito Coils as smoke generating coil an unacceptable risk was identified for soil organisms, may imply that also for bees and non target arthropods a risk cannot be excluded. Further consideration of the potential risk to bees and non target arthropods should be made in relation with the conditions of use of the biocidal products.

2.2.3. List of endpoints

In order to facilitate the work of granting or reviewing authorisations, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.

3. PROPOSED DECISION

3.1. Background to the proposed Decision

Identity and physical chemical properties

Based on the evaluation of the information on identity and physical-chemical properties, inclusion of transfluthrin in Annex I is acceptable.

Methods of analysis

Based on the evaluation of the information on identity and physico-chemical properties, inclusion of transfluthrin in Annex I is acceptable.

Efficacy

Efficacy of transfluthrin was proven for the target organisms: Mosquitoes (*Aedes aegypti*, *Culex quinquefasciatus*), house flies (*Musca domestica*), cockroaches (*Blattela germanica*), and moth (*Tineola bisselliella*).

Labelling and classification

Transfluthrin is classified as Xn; R22 and N; R50/53 according to Regulation (EC) No 1999/45 and GHS07; H302 and GHS09; H400 and H410 according to Regulation (EC) No 1272/2008, Annex VI..

Human health

The human health risk assessment is performed according to the methods of the TGD and TNsG's. Inclusion of transfluthrin in Annex I of directive 98/8/EC is feasible for the human health aspect because several safe uses are identified.

Although for Raid Portable Electric the calculated exposure to transfluthrin exceeded the AELs by 30%, it was noted that the exposure calculations were based on rather "worst-case" assumptions (tier 1). At tier 2 the exposure did not exceed the AEL. It was therefore concluded that exposure to transfluthrin as a result of the use of Raid Portable Electric, Baygon Mosquito Coil and Turbo 4 Seasons is not likely to result in adverse health effects.

It was noted that in acute and sub-chronic inhalation studies in rats and mice with smouldering Baygon Mosquito Coil, respiratory effects (e.g. bradypnoea, laboured breathing, decreased respiratory rate) were observed. The data suggested that the sensory irritation potency of smokes generated by the carrier coil and coil containing transfluthrin are virtually indistinguishable. A wide range of combustion products, due to burning of transfluthrin and the coil can be expected (e.g. formaldehyde, acrolein, benz(a)pyrene) which are known have a variety of toxic properties, some of which may only become apparent after repeated exposure. Although no exposure estimates to the levels of smoke generated during the smouldering of Baygon Mosquito Coil have been performed it is concluded that adverse health effects due combustion products generated during the use of Baygon Mosquito Coil cannot be excluded.

RMS will propose a change of the current classification to RAC. Carcinogenicity, irritation and acute oral toxicity Classification will be further discussed at ECHA (TM decision of March 2011).

Environment

The environmental risk assessment is performed according to the methods of the TGD and TNsG's. Inclusion of transfluthrin in Annex I is feasible for the environmental aspect because at least one safe use is identified.

No risks of transfluthrin for Turbo 4 Seasons are expected for sewage treatment plants, surface water, air, soil and groundwater. Transfluthrin meets the drinking water criterion and the criteria for persistence in sediment and soil for this product.

A potential risk for water, sediment and soil is identified for two products (Raid Portable Electric and Baygon Mosquito Coil), based on an initial assessment in which the $PEC/PNEC_{sed}$ is derived by multiplying the $PNEC/PNEC_{aquatic}$ by a factor of 10. The risks for water, sediment and soil should be further addressed upon product authorisation.

Transfluthrin is therefore classified as not P, not B, but is T.

3.2. Proposed decision

The overall conclusion from the evaluation of Transfluthrin for use in Product Type 18 (insecticides, acaricides and products to control other arthropods), is that it may be possible to issue authorisations of products containing transfluthrin in accordance with the conditions laid down in Article 5(1) b), c) and d) of Dir. 98/8/EC.

It is therefore proposed to approve Transfluthrin as an active substance for use in product-type 18 (insecticides, acaricides and products to control other arthropods), subject to the following specific conditions:

The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

Authorisations are subject to the following condition:

In the view of the risks for water, sediment and soil compartments, transfluthrin shall not be used in vaporisers for indoor use or insecticidal coils unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level.

3.3. Elements to be taken into account when authorising products

As information on the biodegradation in soil is not available persistence of transfluthrin metabolites TFB-OH, TFB-COOH and DCVA in soil cannot be excluded. P, vP criteria for transfluthrin and its metabolites should be further investigated.

Elements, which were not mentioned under the specific provisions of the decision but which need be taken into account at product authorisation level:

Efficacy

Raid Portable Electric and Baygon Mosquito Coil

1. No efficacy data have been provided confirming the label claim "knockdown and kill of gnats and other small flying insects". For product authorisation all proposed label claims should be substantiated with data.
2. The conditions of several tests (temperatures of around 30 °C) are not representative for all homes throughout Europe. This should be considered for product authorisation by each country. Additional trials could be required, performed where temperatures are maintained between approximately 19 and 22 °C.

Turbo 4 Seasons

Although efficacy against moth was achieved in the test, it was also shown that repetitive opening of the closet doors increased the exposure time required to achieve the desired level of control. Efficacy is likely to be significantly reduced in treated areas when doors/drawers are opened very often or remain open for long periods of time. In the instructions for use it should be stated that treated drawers and wardrobes/closets should be kept closed as much as possible so that vapour levels are maintained to provide maximum effectiveness.

Physical and chemical properties

Baygon Mosquito Coil:

1. The applicant stated that the product is not oxidizing, because it does not contain components with oxidising properties. However, according to Doc IVB 2.2-01 (confidential), one of the components of the product is labelled with O (oxidizing). The applicant is requested to submit a study according to EC method A17.
2. For mosquito coils, information on the separation of the coils has to be presented. This information is currently missing and the applicant is requested to provide this information.
3. Information on combustion products should be provided

Raid Portable Electric:

1. In the storage stability study insufficient information is available on the used package material. The applicant is requested to provide information.
2. The evaporation rate should be experimentally determined.

Turbo 4 Seasons:

A shelf-life study should be provided for product authorization.

Human Health risk assessment

Baygon Mosquito Coil:

Information on combustion products should be provided, including exposure estimates and the toxicological/adverse health effects to the levels of "combustion products" generated.

Raid Portable Electric:

For authorisation of similar products at stage of product authorization, the applicant should provide data on evaporation kinetics or data on concentration of the active ingredient in the air. To alleviate exposure realistic risk control measures are necessary to be assessed at product authorisation

All products

In this report the products have been evaluated with the dermal absorption value of 10% on the basis of a MW of 371 and log P_{ow} of 5.4, and data from other pyrethroids in other formulations. For all products it is important that dermal absorption is re-evaluated at product authorisation.

For products containing transfluthrin that may lead to residues in food or feed, Member States shall verify the need to set new and/or amended existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 and/or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.

Environmental risk assessment:

Raid Portable Electric and Baygon Mosquito Coil

A risk for water, sediment and soil was identified. It is not possible to determine the risk for bee populations or the non target arthropod community for the three products assessed. Furthermore as part of the PBT assessment data on the degradation in soil of transfluthrin and its metabolites is lacking. Therefore additional studies are required that may provide sufficient evidence for a safe use of Raid Portable Electric and Baygon Mosquito Coil. Next to that development of exposure scenarios for bees and non target arthropods is required for these types of uses.

The following studies are considered necessary for product authorisations: chronic studies with aquatic organisms, a test with benthic organisms using spiked sediment, a test with soil insects, ecotoxicity data for bees and non target arthropods and a soil degradation study.

Refinement of parameters used for the emission scenarios are recommended such as use frequency and simultaneity. Analysis of product sales data over a representative period with an appropriate level of spatial and temporal resolution can be used to improve estimates of emissions to STP. Additionally the removal rate from (contaminated) surfaces could be an important parameter to refine the risk assessment for product authorisation.

This can be substantiated with monitoring data of STP influents and effluents, also related to indoor uses, and in soils and surfaces around Baygon Mosquito Coil when used outside.

The present ED evaluation is not based on an in-depth evaluation of the new studies concerning ED studies nor the US EPA evaluation. Transfluthrin should be further assessed with regards to its potential endocrine disruptor properties once further guidance is available and preferably before the product authorisation stage. The conclusion of that assessment might lead to review the active substance approval

Measures necessary to protect man, animals and the environment

Baygon Mosquito Coil:

Information in Doc IIIB8 was more elaborate and sometimes even contradicting the information in the MSDS (see Doc IIIB8). The applicant is requested to harmonise these documents.

Turbo 4 Seasons, Baygon Mosquito Coil and Raid Portable Electric:

Although for Turbo 4 Seasons and Baygon Mosquito Coil the risk index values are <1, the risk index value is > 1 for the child exposure for the Raid portable Electric in the Tier 1 . Nevertheless it was an unrealistic worst case scenario to take 24 hours as exposure period as in Tier 2 (8 hour exposure), there is no unacceptable risks for Raid Portable Electric. Although based on this point measures should be ensured to minimise the risk for children.

3.4. Requirement for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the approval of transfluthrin for use in product-type PT 18 (insecticides, acaricides and products to control other arthropods).

Some additional information is requested on the reference products presented if applications are submitted to require their authorisation, as indicated in section 3.3.

3.5. Updating this Assessment Report

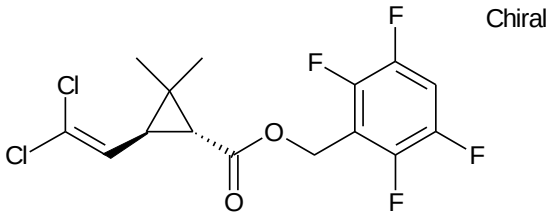
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information submitted in relation with Regulation (EU) No 528/2012. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the approval of transfluthrin

Appendix I: List of endpoints

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

Active substance (ISO Common Name)	transfluthrin
Product-type	PT18

Identity

Chemical name (IUPAC)	2,3,5,6-tetrafluorobenzyl (1*R*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or 2,3,5,6-tetrafluorobenzyl (1*R*)-*trans*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
Chemical name (CA)	(1*R*-*trans*)-(2,3,5,6-tetrafluorophenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate
CAS No	118712-89-3 *
EC No	ELINCS No: 405-060-5*
Other substance No.	CIPAC No: 741
Minimum purity of the active substance as manufactured (g/kg or g/l)	965 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	no relevant impurities or additives present
Molecular formula	$C_{15}H_{12}Cl_2F_4O_2$
Molecular mass	371.2 g/mol
Structural formula	

** The ELINCS no. refesr to the 1R,trans and 1S,trans configurations, which is not in agreement with the definition of transfluthrin, which is exclusively the 1R,trans isomer. The CAS registry no. does refer to the correct isomer.*

Physical and chemical properties

Melting point (state purity)	32 °C (purity 99.1% w/w)
Boiling point (state purity)	242 °C at 1033 hPa (purity 98.0% w/w)
Temperature of decomposition	Exothermal decomposition in the temperature range of 250 to 390 °C
Appearance (state purity)	Pure substance (purity 99.3% w/w): crystalline, white needles with no characteristic odour. Technical (purity 99.1% w/w): off-white needles with a toluene-like odour.
Relative density (state purity)	1.3856 at 20 °C (purity 99.1% w/w) 1.3624 at 40 °C (purity 99.1% w/w)
Surface tension	not applicable (water solubility < 1 mg/L)
Vapour pressure (in Pa, state temperature)	9x10 $^{-4}$ Pa at 20 °C
Henry's law constant (Pa m^3 mol^{-1})	5.86 Pa.m^3 mol^{-1} at 20 °C
Solubility in water (g/l or mg/l, state temperature)	0.057 mg/L at 20 °C (pH independent)
Solubility in organic solvents (in g/l or mg/l, state temperature)	Solubility at 20 °C: Ethanol: completely miscible in any ratio n-Hexane: completely miscible in any ratio Toluene: completely miscible in any ratio Dichloromethane: completely miscible in any ratio Acetone: completely miscible in any ratio Ethyl acetate: completely miscible in any ratio Dimethylsulfoxide: completely miscible in any ratio
Stability in organic solvents used in biocidal products including relevant breakdown products	not applicable
Partition coefficient (log P_{OW}) (state temperature)	Log Pow is > 5 based on data provided. As a BCF was determined, no more accurate data is required for the risk assessment. Model estimations: Bioloom: 5.94 EPIWIN v3.2: 6.17
Hydrolytic stability (DT_{50}) (state pH and temperature)	pH 5, 25 °C: hydrolytically stable pH 7, 25 °C: hydrolytically stable pH 9, 25 °C: DT_{50} 14 days
Dissociation constant	not applicable, structure indicates that transfluthrin does not dissociate.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Molar extinction (ε) was calculated by RMS (based on A = ε x d x c). A ($mol^{-1}cm^{-1}$) @ > 290nm = 0 -> ε = 0 L/mol.cm A ($mol^{-1}cm^{-1}$) @ 277.5nm = 0 -> ε = 0 L/mol.cm A ($mol^{-1}cm^{-1}$) @ 270.0nm = 0.05 -> ε = 130 L/mol.cm A ($mol^{-1}cm^{-1}$) @ 250.0nm = 0.01 -> ε = 26 L/mol.cm A ($mol^{-1}cm^{-1}$) @ 210.0nm = 0.70 -> ε = 1819 L/mol.cm
Photostability (DT_{50}) (aqueous, sunlight, state pH)	Not applicable; no absorption above 290 nm.

Quantum yield of direct phototransformation in water at Σ > 290 nm	no information available; not required.
Flammability	Auto-ignition temperature = 415 °C Flash point = 119.0ºC under atmospheric conditions (1013.3 hPa).
Explosive properties	not explosive

Classification and proposed labelling

with regard to physical/chemical data	-
with regard to toxicological data	Xn: Harmful R22: Harmful if swallowed GHS07: Warning H302 (Acute Tox. 4)
with regard to fate and behaviour data	-
with regard to ecotoxicological data	N: Dangerous for the environment R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. GHS09: Warning H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	Chiral HPLC-UV method
Impurities in technical active substance (principle of method)	Chiral HPLC-UV method (1R, cis and 1RS, cis isomers) GC-FID (organic impurities).

Analytical methods for residues

Soil (principle of method and LOQ)	DFG Method S 19 (extended Revision) Extraction with acetone after adding water (2/1 v/v). Liquid-liquid partitioning using ethylacetate/cyclohexane (1/1 v/v) and sodium chloride. After repeated mixing, excess water was separated. After evaporation of an aliquot of organic phase, residue was cleanup by gel permeation chromatography on Bio Beads S-X3 polystyrene gel, using ethyl acetate/cyclohexane (1/1 v/v) as eluent. After concentrating and further cleanup analysis by GC-MS (LOQ 0.005 mg/kg).
Air (principle of method and LOQ)	PTRL Europe Study No. 911 G Air drawn through XAD adsorption tubes (1 L/min for 6h). Adsorption material extracted with acetone and extract analysed by GC-MS (LOQ = 0.5 µg/m^3). Confirmatory method: monitoring of 3 mass fragments.
Water (principle of method and LOQ)	After addition of methanol liquid-liquid extraction with

	dichloromethane. After evaporation of the organic phase, the residue is transferred and LiChrosorb RP18 is added. After evaporation the residue is reconstituted in ethyl acetate and analysed by GC-MS. (LOQ = 0.05 µg/L). Confirmatory method: monitoring of 3 mass fragments.
Body fluids and tissues (principle of method and LOQ)	not required, since transfluthrin is not classified as toxic or highly toxic.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	not required, since the biocidal product will not be used on any food or feed of plant origin and since indirect exposure due to contaminated food is negligible.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	not required, since the biocidal product will not be used on any food or feed of animal origin and since indirect exposure due to contaminated food is negligible.

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Rapid, 74-90% for transfluthrin and/or its hydrolysis products (based on urinary excretion) For risk assessment 100% oral absorption is assumed.
Rate and extent of dermal absorption:	No data are available. On the basis of a MW of 371 and log P_{ow} of 5.4, and data from other pyrethroids a dermal absorption of 10% is assumed
Distribution:	Less than 2% of administered dose was found in tissues. Highest levels in liver and kidneys, lowest level in the brain
Potential for accumulation:	limited (rapid excretion)
Rate and extent of excretion:	Rapid: 74-90% in urine within 48h
Toxicologically significant metabolite(s)	parent compound and metabolites (metabolites formed from the benzylmethylene moiety; tetrafluorobenzoic acid and the glucuronic acid conjugate of tetrafluorobenzyl alcohol. The carboxyl moiety is probably metabolized to dichlorochrysanthemic acid (DCCA).

Acute toxicity

Rat LD_{50} oral	583 mg/kg bw (mouse)
Rat LD_{50} dermal	> 4000 mg/kg bw (mouse)
Rat LC_{50} inhalation	> 513 mg/m^3 (rat)
Skin irritation	Not irritating
Eye irritation	Not irritating
Skin sensitization (test method used and result)	Not sensitising (Buehler, M & K)

Repeated dose toxicity

Species/ target / critical effect	Kidney (glomerulonephrosis, pigment deposition, increased absolute and relative weight of the kidneys at 200 ppm, equal to 9.9 mg/kg bw/day, liver (increased weight, clinical chemistry parameters related to liver damage).

Lowest relevant oral NOAEL / LOAEL	NOAEL: 1.0 mg/kg bw/day (2-years dietary rat)
Lowest relevant dermal NOAEL / LOAEL	1000 mg/kg bw/day (21-day, rabbit)
Lowest relevant inhalation NOAEL / LOAEL	46.7 mg/m^3 (equal to 17 mg/kg bw/day; 14 week, rat)

Genotoxicity	No genotoxic potential in vivo, genotoxic in vitro

Carcinogenicity

Species/type of tumour	Urinary bladder tumours in the rat
lowest dose with tumours	2000 ppm (equal to 100.4 mg/kg bw/day; 2-year rat).

Reproductive toxicity

Species/ Reproduction target / critical effect	-
Lowest relevant reproductive NOAEL / LOAEL	-
Species/Developmental target / critical effect	Increased incidence of total litter loss (pups were born dead or died in the first 3 days post parturition
Developmental toxicity	
Lowest relevant developmental NOAEL / LOAEL	9 mg/kg bw/day (200 ppm)

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	Clinical signs of acute neurotoxicity (tremors, seizures apathy, prostration, dyspnoea, and bristling coats) in oral and inhalation studies.
Lowest relevant developmental NOAEL / LOAEL.	Acute, oral: 15 mg/kg bw/day (dev. tox, rabbit) Acute, inhalation: 46.7 mg/m^3 (equal to 17 mg/kg bw/day, 14-week, rat)

Other toxicological studies

.....	Mechanistic studies indicate that transfluthrin has a tumour promoting action on bladder epithelial cells development in the rat (not relevant for man) TFBA causes cytotoxicity of the superficial cell layer of the urothelium, resulting in regenerative proliferation of the urothelium and ultimately leading to the production of a low incidence of bladder tumors over two years.

Medical data

.....	No reports of adverse effects in manufacturing, workers or users

Summary	Value	Study	Safety factor
ADI (if residues in food or feed)	Although there are no residues	2-year dietary rat	100

	in food or feed expected an ADI of 0.01 mg/kg bw/day is used in the statement of negligible exposure (Doc IIB 3.1.4)		
AEL (acceptable exposure level) AELacute, oral AECacute, inhalation AELacute, dermal AELmedium/chronic, systemic	0.15 mg/kg bw/day 0.5 mg/m3 1 mg/kg bw/day 0.01 mg/kg w/day	Dev. study,rabbit 14-week, rat 3-week, rabbit, 10% DA 2-year dietary rat	100 100 100 100
ARfD (acute reference dose)	Although there are no residues in food or feed expected an ARfD of 0.15 mg/kg bw/day is used in the statement of negligible exposure (Doc IIB 3.1.4)	Dev. Study rabbit	100
Reference value for dermal absorption	10%	based on MW of 371 and log Pow of 5.4, and data from other (fluorinated)pyrethroids.	

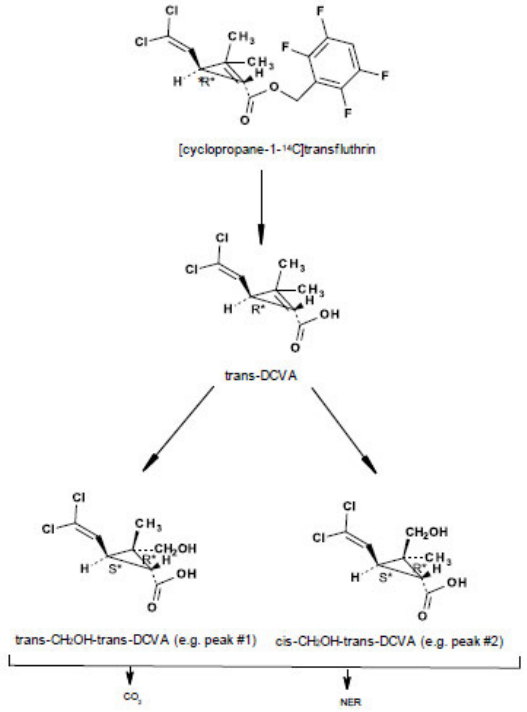
Acceptable exposure scenarios (including method of calculation)

Professional users	Baygon Mosquito Coil, Turbo 4 seasons and Raid portable electric will only be applied by non-professionals
Production of active substance:	no data
Formulation of biocidal product	not applicable
Intended uses	Only non-professional use
Secondary exposure	not applicable
Non-professional users	No adverse health effects due to transfluthrin exposure are expected. Acceptable dermal and inhalatory exposure of using Baygon Mosquito Coil, Turbo 4 seasons and Raid portable electric. Adverse health effects due combustion products generated during the use of Baygon Mosquito coil cannot be excluded.
Indirect exposure as a result of use	No adverse health effect due to dietary or non-dietary exposure to transfluthrin are expected.

Acceptable dietary exposure of using Raid portable electric. Acceptable exposure through skin contact with a contaminated area, and subsequent hand-to mouth contact for a child of 10.5 months of age by using Baygon Mosquito Coil.

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (25 °C)	pH 5, 25 °C: hydrolytically stable
	pH 7, 25 °C: hydrolytically stable
	pH 9, 25 °C: DT_{50} 14 days
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Not relevant as transfluthrin does not show any UV-absorption in the environmentally relevant wavelengths occurring on earth's surface and is regarded stable with respect to direct phototransformation in water
Quantum yield of direct phototransformation in water at $\lambda > 290$ nm (point VII.7.6.2.2)	Not relevant as transfluthrin does not show any UV-absorption in the environmentally relevant wavelengths occurring on earth's surface and is regarded stable with respect to direct phototransformation in water
Readily biodegradable (yes/no)	No
Biodegradation in active sludge	Simulation study according to OECD 314B: Labelling and proposed metabolic pathway.  $DT_{50,\ active\ sludge}$ (at 21.7°C): - Transfluthrin 0.284 d (=0.118/h) - Trans-DCVA 0.897 d, f_{parent} = 0.968 - Cis-OH-DCVA persistent (>10000d), $f_{trans\text{-}DCVA}$ = 0.619 - Trans-OH-DCVA 0.341 d, $f_{trans\text{-}DCVA}$ = 0.261

	- NAK 4452 persistent (>10000d), f_{parent} = 1 NAK 4452 was not addressed in the study as transfluthirn was labelled at the cyclopropyl-moiety. NAK 4452 was therefore considered as persistent.
Biodegradation in seawater	-
Degradation in water/sediment (range or median, with n value, with r2 value, state temperature)	$DT_{50, water}$: < 7 days (20 °C)
	$DT_{50,sediment}$: 14.1 d (17.7 and 10.5 d; 20 °C
	$DT_{50,whole\ system}$: 11.1 d (14.8 and 7.3 d; 20°C)
Non-extractable residues	4.4 and 7.9% of AR after 100 d
Distribution in water / sediment systems (active substance)	not detectable in water after 7 days 2.3% in sediment after 100 d, max. 42 and 47 % on day 1
Distribution in water / sediment systems (metabolites)	NAK 4452 (2,3,5,6-tetrafluorobezyl alcohol; TFB-OH): transient in water (max. 38% of AR), sediment (max. 2% of AR) and system (max. 39% of AR) $DT_{50,system}$ < 14 d NAK 4723 (2,3,5,6-tetrafluorobenzoic acid; TFB-COOH): max. formation between 28 and 70d; 59% of AR in water, 26% of AR in sediment 82% of AR in total system; decline towards study end 100 d

Route and rate of degradation in soil

Mineralization (aerobic)	no information available
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (12°C, aerobic): geometric mean from three soils using FOMC and one soil using DFOP Parent-DT50: 5.17 d (12°C), Metabolite NAK 4723 (2,3,5,6-tetrafluorobenzoic acid, BCS-AA52185)-DT50: 3.23 d (12°C), Formation fraction: 0.6190 Metabolite DCVA DT_{50lab} 174.8 d (12°C) (61.8 d (20°C).
	DT_{90lab} (20°C, aerobic): no information available
	DT_{50lab} (10°C, aerobic): no information available
	DT_{50lab} (20°C, anaerobic): no information available
	degradation in the saturated zone:
Field studies (state location, range or median with number of measurements)	DT_{50f}: no information available
	DT_{90f}: no information available
Anaerobic degradation	no information available
Soil photolysis	no information available
Non-extractable residues	no information available
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	based on read-across: 2,3,5,6-tetrafluorobenzyl alcohol; TFB-OH 2,3,5,6-tetrafluorobenzoic acid; TFB-COOH
Soil accumulation and plateau concentration	no accumulation expected in view of low indirect

	emissions to soil

Adsorption/desorption

Ka , Kd	HPLC method
Ka_{oc} , Kd_{oc}	K_{oc} = 50,119-79,433 L/kg
pH dependence (yes / no) (if yes type of dependence)	log K_{oc} 4.7 (pH 6) and 4.8 (pH 4)

Fate and behaviour in air

Direct photolysis in air	no information available
Quantum yield of direct photolysis	no information available
Photo-oxidative degradation in air	2.4 days (based on 24-hr day and 0.5E6 OH/cm³ according to TGD)
Volatilization	no information available

Monitoring data, if available

Soil (indicate location and type of study)	no information available
Surface water (indicate location and type of study)	no information available
Ground water (indicate location and type of study)	no information available
Air (indicate location and type of study)	no information available

Chapter 5: Effects on Non-target Species

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

Species	Substance	Time-scale	Endpoint	Toxicity
Fish				
Oncorhynchus mykiss	transfluthrin	acute	LC_{50}	0.7 µg/L
Pimephales promelas	transfluthrin	Chronic, ELS	NOEC	0.399 µg/L
Oncorhynchus mykiss	TFB-COOH[1]	acute	LC_{50}	> 100 mg/L
Invertebrates				
Daphnia magna	transfluthrin	acute	EC_{50}	1.2 µg/L
Daphnia magna	transfluthrin	chronic	NOEC	0.0175 µg/L
Daphnia magna	TFB-COOH	acute	EC_{50}	> 100 mg/L
Daphnia magna	DCVA	acute	LC_{50}	0.97 mg/L
Algae				
Scenedesmus subspicatus	transfluthrin	acute	E_rC_{50}	> 100 µg/L
Scenedesmus subspicatus	transfluthrin	chronic	NOE_rC	50 µg/L
Pseudokirchneriella subcapitata	TFB-COOH	acute	E_rC_{50}	> 100 mg/L
Pseudokirchneriella subcapitata	TFB-COOH	chronic	NOE_rC	3.05 mg/L
Micro-organisms				
respiration activated sludge	transfluthrin	acute	NOEC EC_{50}	57 µg/L (water solubility) >10000 mg/L

1: 2,3,5,6-tetrafluorobenzoic acid (NAK 4723)

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

Species	Substance	Time-scale	Endpoint	Toxicity
Insects				
Chironomus riparius	transfluthrin	chronic	NOEC	0.164 mg/kg dw sed (2.05% OC)
Worms				
Lumbriculs variegatus	transfluthrin	chronic	NOEC	2.21 mg/kg dw sed

Effects on earthworms or other soil non-target organisms	
Acute toxicity to *Eisenia fetida*	LC_{50} 184 mg/kg dw soil (10 % OM); equivalent to 62.6 mg/kg dw at 3.4 % OM
Reproductive toxicity to *Eisenia fetida*	NOEC 10 mg/kg dw soil (10 % OM); equivalent to 3.4 mg/kg dw at 3.4 % OM
Reproductive toxicity to Folsomia candida	NOEC 18 mg/kg dw soil (5 % OM); equivalent to 12.24 mg/kg dw at 3.4 % OM

Effects on soil micro-organisms	
Nitrogen mineralization	NOEC 3.8 mg/kg dw soil (1.4 % OM); equivalent to 5.24 mg/kg dw at 3.4 % OM
Carbon mineralization	no information available

Effects on terrestrial plants	
Acute toxicity to plants (*Brassica napus, Glycine max, Lycopersicon esculentum, Avena sativa)*	EC_{50} 75 mg/kg dw soil (0.72 % OM); equivalent to 210 mg/kg dw at 3.4 % OM

Effects on terrestrial vertebrates	
Acute toxicity to mammals	no information available
Acute toxicity to birds	LD50 > 1890 mg/kg bw (*Colinus virginianus* and *Serinus canarius*)
Dietary toxicity to birds	no information available
Reproductive toxicity to birds	no information available

Effects on honeybees	
Acute oral toxicity	no information available
Acute contact toxicity	no information available

Effects on other beneficial arthropods	
Acute oral toxicity	no information available
Acute contact toxicity	no information available
Acute toxicity to …	

Bioconcentration	
Bioconcentration factor (BCF)	1704 and 1861 L/kg ww based on 6.95% lipid content (based on Total Radioactive Residue) 1226 and 1339 L/kg ww normalised to 5 % lipid content
Depuration time (DT_{50})	3.1-3.8 days

(DT_{90})	10.1-12.7 days
Level of metabolites (%) in organisms accounting for > 10 % of residues	TFB-OH and TFB-COOH < 5%

Appendix II: List of Intended Uses

Table II.1 Intended uses for transfluthrin containing products as proposed by the RMS

Product name	Use	Application type	Number and timing of application	Target organisms	Waiting periods	Information on recommended variations of the application rate in different locations	Remarks
Raid portable electric	General public	Battery-operated fan vapouriser	Evening/night Use nightly as required	Mosquitoes e.g. *Culex pipiens* (House mosquito), *Aedes aegypti* (Yellow fever mosquito) and *Aedes albopictus* (Tiger mosquito) Adult stages controlled	None	Recommended for use for ~8 hours per night. Provides 45 nights use @ 8h per night	Do not use in rooms with aquaria
Turbo 4 seasons	General public	Natural vapourisation of active ingredient	Evening/ night.	Common clothes moth (*Tineola bisselliella*) Adult and larval stages controlled	None	1 unit (7.5 mg transfluthrin) for drawers and small wardrobes 2 units (15 mg transfluthrin) in medium/large size wardrobes Provides at least 90 days control/protection	
Baygon Mosquito coil	General public	Coil	One coil is enough for about 40m^3 room Burn time approx. 8 hours	Mosquitoes (e.g. *Culex pipiens pallens, Aedes aegypti*) Adult stages controlled	None	None	Do not use in rooms with aquaria

Appendix III: List of studies

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

Doc IIIA References listed by section number

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
A2.6/01	[redacted]	1989	Transfluthrin Manufacturing Description Bayer AG PF-P/VE B 202, BES Ref: MO-03-009891 25.10.89 Non-GLP. Unpublished	Y	1.7.2	Y	BES
A2.6/02	[redacted]	1998	Purification of Technical Grade NAK 4455 Bayer AG PF-E/FT, BES Ref: MO-03-010370] 17.11.98 Non-GLP. Unpublished	Y	1.7.2	Y	BES
A2.7/01	[redacted]	2004	Composition Statement: Technical Material Bayer AG Report 2004-10-26, BES Ref: MO-04-011790 26-10-2004 Non-GLP. Unpublished	Y	1.7.2	Y	BES
A2.7/02	[redacted]	2003	Final Report: Material Accountability of Bayothrin Techn. Bayer AG Study No. D022/0138/00DOR BES Ref: MO-04-004077 GLP. Unpublished	Y	1.7.2	Y	BES
A2.7/03	[redacted]	2004	Material Accountability of NAK 4455/AE 0035474 (Transfluthrin); Analysis profile of production batches from BILAG Bayer CropScience GMBH Report No. PA04/026 BES Ref: MO-04-007751 GLP. Unpublished	Y	1.7.2	Y	BES
A2.8/01	[redacted]	2003	Final Report: Material Accountability of Bayothrin Techn. Bayer AG	Y	1.7.2	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			Study No. D022/0138/00DOR BES Ref: MO-04-004077 GLP. Unpublished				
A2.8/02	[redacted]	2004	Material Accountability of NAK 4455/AE 0035474 (Transfluthrin); Analysis profile of production batches from BILAG Bayer CropScience GMBH Report No. PA04/026 BES Ref: MO-04-007751 GLP. Unpublished	Y	1.7.2	Y	BES
A2.8/03	[redacted]	2005	AE 0035474 (Transfluthrin): Additional analytical information on MA study PA04/026 (MO-04-007751). Bayer CropScience GmbH Report No. AF04/074 BES Ref: MO-05-004268 GLP. No Unpublished	Y	1.7.2	Y	BES
A2.10/01	[redacted]	1996	Study of the degradation and evaporation behaviour of transfluthrin in/on representative indoor surfaces. BAYER AG, Crop Protection Development, Institute of Metabolism Research and Residue Analysis, D-51368 Leverkusen – Bayerwerk. Report number: MR-691/96. [BES Ref: MO-04-012339]. Unpublished	Y	1.10	Y	BES
A2.10/02	[redacted]	1996	Experiment to draw up balance sheets for the residue of transfluthrin (NAK 4455) after its use indoors. BAYER AG, Pesticides Development, Institute of Metabolism Research and Residue Analysis, D-51368 Leverkusen – Bayerwerk. Report number: MR-569/96. [BES Ref MO-03-010512]. Unpublished [IN GERMAN]	Y	1.10	Y	BES
A2.10/03	[redacted]	1994	Provisional Results on the desorption behaviour of NAK 4455 BAYER AG, Pesticides Development, Institute for Product Information and	Y	1.10	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			Residuum Analysis, Monheim. Report number: RA 060/94. [BES Ref MO-03-011156]. Unpublished [IN GERMAN]				
A2.10/04	[redacted]	1993	Establishment of room air concentration and user exposure when NAK 4455 is applied in spray cans. BAYER AG,.Pesticides Development, Institute for Product Information and Residuum Analysis, Bayerwerk. Report Number:. RA 349/93. [BES Ref MO-03-010192]. Unpublished	Y	1.10	Y	BES
A2.10/05	[redacted]	1993	Determination of room air concentration of NAK 4455 when mosquito coils containing NAK 4455 are used. BAYER AG, Crop Protection Research, Institute for Product Information and Residue Analysis, Monheim. Report Number: RA 150/93. [BES Ref MO-03-010197]. Unpublished	Y	1.10	Y	BES
A3.1.1	[redacted]	2005	Transfluthrin (Bayothrin), NAK 4455; Substance, Technical AE 003547 00 1D99 0004: Melting Point (OECD 102) ; Thermal Stability (OECD 113), Siemens AG, Prozess-Sicherheit, Report No. 20050216.01 BES Ref: M-254400-01-1 30.05.05 GLP. Unpublished	Y	2.1	Y	BES
A3.1.2	[redacted]	1991	Boiling Point of NAK 4455 Bayer AG, Business Group Crop Protection, Report No. 14 150 0724 BES Ref: MO-04-012197 10.12.91 GLP. unpublished	Y	2.2	Y	BES
A3.1.3	[redacted]	2005	Physical, Chemical and Technical Properties of Transfluthrin, Bayer CropScience GmbH Report No. WIR0132 (PC) 01 BES Ref: M-253445-01-1	Y	2.3	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			02.06.05 GLP, unpublished				
A3.2	[redacted]	1995	Vapour Pressure Curve of NAK 4455, Bayer AG Report AP No. 682 260. BES Ref: MO-04-003000 20.09.95 GLP. Unpublished	Y	2.4	Y	BES
A3.2.1	[redacted]	[redacted] 2005	Henry's Law Constant of Transfluthrin, NAK 4455 (AE 0035474) Bayer CropScience GmbH Report No. AF05/041; BES Ref: M-254216-01-1. 14.07.05 GLP. Unpublished	Y	2.14	Y	BES
A3.3	[redacted]	2005	Physical Characteristics Color, Appearance and Odor of Transfluthrin, Bayer CropScience GmbH, Report No. PA05/010; BES Ref: M-254180-01-1 02.06.05 GLP, unpublished	Y	1.1.1	Y	BES
A3.4	[redacted]	1987	NAK4455 UV-Vis Spectrum. Bayer AG Report PF-F.CE/QS 1 BES Ref: MO-99-015149 10.03.87 Non-GLP Unpublished	Y	1.1.2	Y	BES
A3.5	[redacted]	1995	Water Solubility of NAK 4455, Bayer AG Report No. 5/0124. BES Ref: MO-03-010371 29.09.95 GLP, Unpublished.	Y	2.6.1	Y	BES
A3.6	[redacted]	2005	Transfluthrin, NAK 4455: Statement on the Dissociation Constant, Bayer CropScience GmbH, Report No. AF05/009 BES Ref: MO-05-007364 14.04.05 GLP. Unpublished	Y	2.12	Y	BES
A3.7	[redacted]	2005	Solubility of Transfluthrin NAK 4455 (AE 0035474) in Organic Solvents, Bayer CropScience GmbH, Report No. PA05/009 ; BES Ref: M-254129-01-1 02.06.05 GLP. Unpublished	Y	2.6.1	Y	BES
A3.9	[redacted]	1995	Krohn, J (1995).	Y	2.5	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			Partition Coefficient of NAK 4455 Bayer AG Report No. 5/0125 BES Ref: MO-03-011157 29.09.95 GLP. Unpublished				
A3.10	[redacted]	2005	Transfluthrin (Bayothrin), NAK 4455; Substance, Technical AE 003547 00 1D99 0004: Melting Point (OECD 102) ; Thermal Stability (OECD 113), Siemens AG, Prozess-Sicherheit, Report No. 20050216.01 BES Ref: M-254400-01-1 30.05.05 GLP. Unpublished	Y	2.14	Y	BES
A3.11	[redacted]	2001	Determination of Safety-Relevant Data of NAK 4455 techn, Bayer AG Report No. 01/00146 BES Ref: MO-03-010048 12.04.01 GLP. Unpublished	Y	2.8	Y	BES
A3.12	[redacted]	2005	Transfluthrin (Bayothrin), NAK 4455: Flash Point , Siemens AG Report No. 20050216.02 BES Ref: M-254399-01-1 30.05.05 GLP. Unpublished	Y	2.7	Y	BES
A3.14	[redacted]	2005	Physical, Chemical and Technical Properties of Transfluthrin, Bayer CropScience GmbH, Report No. WIR0132 (PC) 01 BES Ref: M-253445-01-1 02.06.05 GLP. Unpublished	Y	2.13	Y	BES
A3.15	[redacted]	2005	Transfluthrin (Bayothrin), NAK 4455: Explosive Properties A.14., Siemens AG Prozess-Sicherheit, Report No. 20050216.03 BES Ref: M-251690-01-1 30.05.05 GLP. unpublished	Y	2.10	Y	BES
A3.16	[redacted]	2006	Transfluthrin (Bayothrin), NAK 4455; Substance, technical AE 0035474 00 1D99 0004. Oxidizing	Y	2.11	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			properties of liquids A.21., Siemens AG Prozess-Sicherheit, Report No. 20050216.03 BES Ref: M-268646-01-1 29.03.06 GLP. unpublished				
A3.17	[redacted]	1998	Final Stability Report, NAK 4455 Techn., A & M Stabtest, Bayer AG, Study No. ST 033/97. BES Ref: MO-03-010451 09.12.98 GLP. Unpublished	Y	8.8	Y	BES
A4.1/01	[redacted]	2002	Bayothrin technical - capillary gas chromatography Bayer AG Analytical Method 2201-0342301-02E Report No. VB1-2201-0342301-02E BES Ref. MO-02-018100 Non-GLP. Unpublished. [Method] Validation of GLC method 2201-0342301-02 – Determination of a.i. in Bayothrin, industrial Bayer AG Report No. VB1-2201-0342301 BES Ref. MO-04-011186 Non-GLP. Unpublished [Validation] Validation of GLC method 2201-0342301-02E – Determination of active ingredient in Bayothrin, industrial Amendment of Report No. VB1-2201-0342301 Bayer CropScience Report No. VS1-2201-0342301 BES Ref. M-226183-01-1 Non-GLP. Unpublished [Validation]	Y	6.1	Y	BES
A4.1/02a	[redacted]	2000a	R/S Ratio of Bayothrin (NAK 4455) Cis- and Trans Isomers (assay Chiral GLC), Bayer AG Report No. 2005-0010901-00 E BES Ref. MO-00-007975, 19.05.00. Non-GLP. Unpublished. [Method]	Y	6.1	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
A4.1/02b	[redacted]	2000b	Validation Report: Bayothrin Technical, R/S-ratio by Chiral GC, Bayer AG, Report No. V01.01-2005-0010901E BES Ref. MO-00-007977 19.05.00. GLP. Unpublished. [Validation]	Y	6.1	Y	BES
A4.1/03	[redacted]	2003a	Bayothrin Industrial: By-products – Capillary Gas Chromatography, Bayer AG Report No. 2201-0342401-02 E BES Ref MO-03-003552, 02.10.03. Non-GLP. Unpublished. [Method]	Y	6.1	Y	BES
A4.1/04	[redacted]	2003b	Validation of GLC-method 2201-0342401-02 - Determination of byproducts in Bayothrin Bayer AG Report No. VB1-2201-0342401 BES Ref MO-04-011193, 04.02.03 Non-GLP. Unpublished. [Validation]	Y	6.1	Y	BES
A4.2/01	[redacted]	2001	Validation of DFG Method S 19 (extended Revision) for the Determination of Residues of Transfluthrin in Soil, Dr. Specht and Partner Chemische Laboratorien GmbH, Bayer AG, Report No. BAY-00106V Az G01-0009 BES Ref. MO-01-009826. 30.04.01. GLP. Unpublished. [Validation]	Y	6.2	Y	BES
A4.2/02	[redacted]	2005	Transfluthrin: Analytical method for the determination of Transfluthrin in air. Report PTRL Europe Study/Report No. P/B 911 G BES Ref. MO-05-010149, 27.06.2005 GLP. Unpublished [Method]	Y	6.2	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
A4.2/03	[redacted]	1998	Method for the Determination of Transfluthrin in Drinking Water and Test Water from Aquatic Toxicity Tests by GLC with On-line Solid Phase Microextraction (SPME), Bayer AG, Method 00512/ P 604 87015 BES Ref. MO-99-018150 03.03.98. Non-GLP. Unpublished. [Method and validation]	Y	6.2	Y	BES
A4.2/03	[redacted]	2006	Analytical Method 01026 for the Determination of Transfluthrin in Drinking and Surface Water by GC-MS. Bayer CropScience AG Report: MR-06/174 [BES Ref. M-275106-01-1] Report date: November, 27th 2006 [Method and validation] Unpublished.	Y		Y	BES
A4.2/04	[redacted]	2000	Determination of Transfluthrin in Plasma, Bayer AG Medical Sciences Institute of Biological Monitoring, Method SPE with Oasis HLB, Auto Spec, NCI mode, BES Ref MO-03-011204 28.09.00. Non-GLP. Unpublished [Method and Validation]	Y	6.2	Y	BES
A5.3	[redacted]	1995	Pflanzenschutz Nachrichten Bayer, Special Edition NAK 4455 (transfluthrin): a fast-acting insecticide for use in household and hygiene products Bayer AG, 1995. Published	Y	7.2	N	BES
A5.4.1	Reigart and Roberts.	1999	Recognition and management of pesticide poisonings. Washington, DC: US Environmental Protection Agency, Office of Prevention, Pesticides, and Toxic Substances (March). Fifth Edition	Y	7.5	N	n.a.
A5.7.2	Anon.	2006	Web publication: http://www.irac-online.org/	Y	7.5	N	n.a.

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
A6.1.1/01	[redacted]	1988a	NAK 4455 techn. Study for acute oral toxicity to mice. [redacted] Report No. 17156 [BES Ref: MO-03-009933] GLP, Unpublished	Y	5.1.1	Y	BES
A6.1.1/02	[redacted]	1988b	NAK 4455 techn. Study for acute oral toxicity to rats. [redacted], Report No. 17160 [BES Ref: MO-03-009935] GLP, Unpublished	N	5.1.1	Y	BES
A6.1.1/03	[redacted]	1988	NAK 4455 techn. Study for acute oral toxicity to the chicken (Gallus domesticus). [redacted] Report No. 16486 [BES Ref: MO-03-009808] GLP, Unpublished	N	5.1.1	Y	BES
A6.1.1/04	[redacted]	1995	Bisalkoholnebenkomponente (By-product of NAK 4455) Study for acute oral Toxicity in rats. [redacted], Report No. 23870 [BES Ref: MO-03-009810] GLP, Unpublished	N	5.1.1	Y	BES
A6.1.1/05	[redacted]	1998a	Tetrafluorbenzyl Mixture (By-product of NAK 4455 D) Study for Acute Oral Toxicity in Rats. [redacted] Report No. 27434 [BES Ref: MO-03-009793] GLP, Unpublished	N	5.1.1	Y	BES
A6.1.1/06	[redacted]	1998b	Baroda-Verbindung (By-product of NAK 4455 D) Study for Acute Oral Toxicity in Rats. [redacted] Report No. 27099 [BES Ref: MO-03-006775] GLP, Unpublished	N	5.1.1	Y	BES
A6.1.2/01	[redacted]	1999	NAK 4455 (c n.: Transfluthrin (prop)). Study for acute dermal toxicity in mice. [redacted] Report No. 28471 [BES Ref: MO-03-009373] GLP, Unpublished	Y	5.1.3	Y	BES
A6.1.2/02	[redacted]	1988c	NAK 4455 techn. Study for acute dermal toxicity to rats. [redacted], Report No.	N	5.1.3	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			17155 [BES Ref: MO-03-009930] GLP, Unpublished				
A6.1.3/01	[redacted]	1988a	NAK 4455 (c n. benfluthrin, proposed Study for acute inhalation toxicity to OECD guideline No. 403. [redacted] Report No. 17216 [BES Ref: MO-03-009218] German [BES Ref: MO-04-012169] GLP, Unpublished	Y	5.1.2	Y	BES
A6.1.3/02	[redacted]	1990a	Trans-Permethrinsäurechlorid/ NAK Zwischenprodukt Untersuchungen zur akuten Inhalationstoxizität an der Ratte nach OECD-Richtlinie No. 403 [redacted], Report No. 18649 [BES Ref: MO-03-009138] Translation BES Ref: MO-04-012179 GLP, Unpublished	N	5.1.2	Y	BES
A6.1.3/03	[redacted]	1990b	Trans-Permethrinsäureanhydrid/ NAK Zwischenprodukt Untersuchungen zur akuten Inhalationstoxizität an der Ratte nach OECD-Richtlinie No. 403 [redacted], Report No. 18738 [BES Ref: MO-03-009141] Translation [BES Ref:MO-04-012828] GLP, Unpublished	N	5.1.2	Y	BES
A6.1.4/01 A6.1.4/02	[redacted]	1987	NAK 4455. Study for irritant/corrosive potential for skin and eye (rabbit) to OECD guideline nos. 404 and 405. [redacted] Report No. 15804. [BES Ref: MO-03-010099] GLP, Unpublished	Y	5.2.1 5.2.2	Y	BES
A6.1.5/01	[redacted]	1989	NAK 4455 techn. Study for skin-sensitising effect on guinea pigs (Buehler test). [redacted] Report No. 17920. [BES Ref: MO-03-006776] GLP, Unpublished	Y	5.3	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
A6.1.5/02	[redacted]	1989	NAK 4455 techn. and Permethric acid anhydride Study for skin-sensitising effect on guinea pigs (Magnusson and Kligman's maximisation test). [redacted] Report No. 17964 [BES Ref: MO-03-009898] Not GLP, Unpublished	N	5.3	Y	BES
A6.1.5/03	[redacted]	1988b	NAK 4455 techn. Study for sensory irritant potential for the mouse (RD50 determination). [redacted], Report No. 16550 [BES Ref: MO-03-009213] GLP, Unpublished	N	5.1.2	Y	BES
A6.1.5/04	[redacted]	1996	NAK 4455 spiked with PERMETHRINIC ACID ANHYDRIDE - Evaluation of Respiratory sensitization in Guinea Pigs following intradermal Induction [redacted] Report No. 24946 [BES Ref: MO-03-009119] GLP, Unpublished	N	5.3	Y	BES
A6.1.5/05	[redacted]	2000a	R-trans-DV-Säure (raw material for Transfluthrin)Study for the skin sensitization effect in guinea pigs (guinea pig maximisation test according to Magnusson and Kligman [redacted], Report No. 30067 [BES Ref: MO-03-010494] GLP, Unpublished	N	5.3	Y	BES
A6.1.5/06	[redacted]	2000b	Tetraflourbenzylalkohol (Abbauprodukt)Study for the skin sensitization effect in guinea pigs, study T 0069609(Guinea Pig Maximization Test according to Magnusson + Kligman) [redacted], Report No. 30407 [BES Ref: MO-03-010488] GLP, Unpublished	N	5.3	Y	BES
A6.2/01	[redacted]	1991	Disposition of [Methlene-14C] beneluthrin (NAK 4455) in rats. [redacted] Report No. 101310	Y	5.0	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			[BES Ref: MO-03-010378] Not GLP, Unpublished				
A6.2/02	[redacted]	1997	[methylen-14-C]Transfluthrin: Biokinetic behaviour and metabolism in the rat after i.v.-administration. [redacted], Report No. 4257 [BES Ref: MO-03-009851] GLP, Unpublished	N	5.0	Y	BES
A6.2/03	[redacted]	1999a	[14C]NAK 4455 (Transfluthrin): Secretion of radioactivity into milk of lactating rats after a single oral administration. [redacted], Report No. PH-27218A [BES Ref: MO-03-009907] Not GLP, Unpublished	N	5.0	Y	BES
A6.2/04	[redacted]	1998	[14C]NAK 4455 (Transfluthrin): Plasma concentrations and excretion of substance-associated radioactivity after a single oral administration to male rats. [redacted], Report No. PH-27213 [BES Ref: MO-03-010040] Not GLP, Unpublished	N	5.0	Y	BES
A6.2/05	[redacted]	1998	Whole-body autoradiography in rats after single intravenous and oral administration. [14C] NAK 4455 (Transfluthrin). [redacted], Report No. PH-27356 [BES Ref: MO-03-010438] Not GLP, Unpublished	N	5.0	Y	BES
A6.2/06	[redacted]	1998a	[14C]NAK 4455 ([14C] transfluthrin): Whole-body autodiography in pregnant rats single oral administration. [redacted], Report No. PH-27355 [BES Ref: MO-03-010437] Not GLP, Unpublished	N	5.0	Y	BES
A6.2/07	[redacted]	2009	[Methylene-14C]-Transfluthrin – Metabolism in Organs and Tissues of Female Rats, [redacted]	Y	?	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			[redacted], Study report No: MEF-09/483, Report date 2009-12-03 (unpublished).				
A6.3.1/01	[redacted]	1990	NAK 4455 Subacute oral study of toxicity to rats., [redacted], Report No. 19187 [BES Ref: MO-03-009936] GLP, Unpublished	Y	5.4	Y	BES
A6.3.2/01	[redacted]	1990	NAK 4455 Subacute dermal study of toxicity to rabbits. [redacted] Report No. 19236 [BES Ref: MO-03-009897] GLP, Unpublished	Y	5.4	Y	BES
A6.3.3/01	[redacted]	1989	NAK 4455 (c n. benfluthrin, proposed) - Study for subacute inhalation toxicity to the rat to OECD guideline No.412. [redacted], Report No. 17588 [BES Ref: MO-03-010122] GLP, Unpublished	N	5.4	Y	BES
A6.4.1/01	[redacted]	1990	NAK 4455 Subchronic toxicological study in rats (administration in diet for up to 18 weeks). [redacted] Report No. 19756 [BES Ref: MO-03-009872] GLP, Unpublished	Y	5.4	Y	BES
A6.4.1/02	[redacted]	1989	13-week oral toxicity (feeding) study with NAK 4455 tech. in the dog. [redacted] Report No. 4723 [BES Ref: MO-03-009770] GLP, Unpublished	Y	5.4	Y	BES
A6.4.3/01	[redacted]	1989	NAK 4455 (c n. benfluthrin, proposed) Study for subchronic inhalation toxicity to the rat. [redacted] Report No. 18417 [BES Ref: MO-03-009231] GLP, Unpublished	Y	5.4	Y	BES
A6.5/01	[redacted]	1993	NAK 4455 Study for chronic toxicity and carcinogenicity in	Y	5.4	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			Wistar rats (administration in diet for 2 years). [redacted] Report No. 22375 [BES Ref: MO-03-009856] GLP, Unpublished				
A6.5/02	[redacted]	1999	NAK 4455 Study for oncogenicity in B6C3F1 mice after administration in the diet for two years. [redacted], Report No. 22744 [BES Ref: MO-03-010149] GLP, Unpublished	Y	5.4	Y	BES
A6.5/03	[redacted]	1993	NAK 4455 Chronic toxicity study in dogs (52-week feeding study). [redacted], Report No. 22638, [BES Ref: MO-03-010104] GLP, Unpublished	Y	5.4	Y	BES
A6.5/04	[redacted]	1993	NAK 4455 Chronic toxicity study in dogs with oral administration (53-week feeding study). [redacted] Report No. 22678 [BES Ref: MO-03-010096] GLP, Unpublished	N	5.4	Y	BES
A6.5/05	Bannasch, P.	1986	Preneoplastic lesions as end points in carcinogenicity testing I. Hepatic preneoplasia. Carcinogenesis 7(5) 689-695 [BES Ref: MO-03-009801] Published	N	5.11	N	n.a
A6.6.1/01	[redacted]	1987a	NAK 4455 techn. - Salmonella/microsome test to evaluate for point-mutagenic. BAYER AG, Report No. 16084 [BES Ref: MO-03-009702] GLP Unpublished	Y	5.5	Y	BES
A6.6.1/02	[redacted]	1986	NAK4455- Salmonella/microsome test to evaluate for point-mutagenic effect. BAYER AG, Report No. 15144 [BES Ref: MO-03-010007] Non-GLP, Unpublished	N	5.5	Y	BES
A6.6.1/03	[redacted]	1997a	Baroda-compound,	N	5.5	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			Salmonella/microsome test, plate incorporation and preincubation method. BAYER AG, Report No. 26713 [BES Ref: MO-03-010010] GLP, Unpublished				
A6.6.1/04	[redacted]	1997b	Tetrafluorobenzyl-mixture, Salmonella/ microsome test, plate incorporation and preincubation method. BAYER AG, Report No. 26739 [BES Ref: MO-03-010054] GLP, Unpublished	N	5.5	Y	BES
A6.6.1/05	[redacted]	1987b	NAK 4455 Test on S.cerevisiae D7 for the induction of mitotic recombination. BAYER AG, Report No. 16083 [BES Ref: MO-03-009998] GLP, Unpublished	N	5.5	Y	BES
A6.6.2/01	[redacted]	1990	NAK 4455 techn. In vitro cytogenetic study with human lymphocytes for the detection of induced clastogenic effects. BAYER AG, Report No. 18742 [BES Ref: MO-03-010002] GLP, Unpublished	Y	5.5	Y	BES
A6.6.2/02	[redacted]	1989	Mutagenicity test on NAK 4455 in an in vitro cytogenetic assay measuring sister chromatid exchange frequencies in Chinese hamster ovary (CHO) cells. Hazelton Laboratories America, Inc., Report No. R4718 [BES Ref: MO-03-010415] GLP, Unpublished	N	5.5	Y	BES
A6.6.2/02	[redacted]	2012	Transfluthrin: Induction of micronuclei in cultured human peripheral blood lymphocytes.	Y		Y	BES
A6.6.3/01	[redacted]	1989	NAK 4455 Mutagenicity study for the detection of induced forward mutations in the CHO-HGPRT assay in vitro. BAYER AG, Report No. 18148 [BES Ref: MO-03-010377] GLP, Unpublished	Y	5.5	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
A6.6.3/02	[redacted]	1992	NAK 4455 Mutagenicity test on unscheduled DNA synthesis in rat liver primary cell cultures in vitro. BAYER AG, Report No. 21313 [BES Ref: MO-03-009812] GLP, Unpublished	N	5.5	Y	BES
A6.6.4/01	[redacted]	1988	NAK 4455 Micronucleus test on the mouse to evaluate for clastogenic effects. BAYER AG, Report 16912 [BES Ref: MO-03-010004] GLP, Unpublished	Y	5.6	Y	BES
A6.6.4/02	[redacted]	2012	Micronucleus Assay In Bone Marrow Cells Of The Mouse With Transfluthrin-a.i. (NAK4455) Harlan, Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Lab Report No. 146500 [BES Ref: M-437175-01-1] Report date: August 24, 2012 Unpublished	Y		Y	BES
A6.6.4/02	[redacted]	1986	Influence of NAK 4455 on DNA metabolism. BAYER AG, Report No. R 3658 [BES Ref: MO-03-010180] GLP, Unpublished	N	5.6	Y	BES
A6.6.7/01	[redacted]	2001	Tetrafluorbenzlalkohol (NAK 4455 intermediate) in vitro chromosome aberration test with Chinese hamster V79 cells. BAYER AG, Report No. PH 30715 [BES Ref: MO-01-001669] GLP, Unpublished	N	5.5	Y	BES
A6.7/01	[redacted]	1993	NAK 4455 Study for chronic toxicity and carcinogenicity in Wistar rats (administration in diet for 2 years). [redacted] Report No. 22375 [BES Ref: MO-03-009856] GLP, Unpublished	Y	5.7	Y	BES
A6.7/02	[redacted]	1999	NAK 4455 Study for oncogenicity in B6C3F1 mice after	Y	5.7	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			administration in the diet for two years. [redacted] Report No. 22744 [BES Ref: MO-03-010149] GLP, Unpublished				
A6.8.1/01	[redacted]	1988	Teratology oral study in the rat with NAK 4455. [redacted], Report No. MTD0058 [BES Ref: MO-03-009816] GLP, Unpublished	Y	5.8.2	Y	BES
A6.8.1/02	[redacted]	1989	Untersuchungen auf embryotoxische Wirkung an Kaninchen nach oraler Verabreichung: Rabbit, oral test. [Study for embryotoxic effects on rabbits after oral administration] [redacted], Report No. 18069 [BES Ref: MO-03-010420] GLP, unpublished	Y	5.8.2	Y	BES
A6.8.2/01	[redacted]	1991	NAK 4455 technical (proposed c.n. Benfluthrin) - Multiple generation reproduction study in rats. [redacted] Report No. R 5352 [BES Ref: MO-03-010477] GLP, Unpublished	Y	5.8.1	Y	BES
A6.8.2/02	[redacted]	1990	NAK 4455 technical (proposed c.n. Benfluthrin) - Range finding study to the multiple generation study in the rat. [redacted] Report No. 5110 [BES Ref: MO-03-010485] Non-GLP, Unpublished	N	5.8.1	Y	BES
A6.9/01	[redacted]	1998a	BAY U 4619 (NAK 4455): CNS-safety pharmacology after a single oral administration in rats. [redacted], Report No. PH-27592 [BES Ref: MO-03-009700] GLP, Unpublished	Y	5.9	Y	BES
A6.9/02	[redacted]	1999	Amendment to Report No.: PH-27592 CNS-safety pharmacology after a single oral administration in rats. Bay U 4619 (NAK 4455). [redacted], Report No.	Y	5.9	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			PH-27592A [BES Ref: MO-04-002968] GLP, Unpublished				
A6.9/03	[redacted]	1998b	BAY (NAK 4455): CNS-safety pharmacology after a single oral administration in mice. [redacted] Report No. PH-27591 [BES Ref: MO-03-009696] GLP, Unpublished	N	5.9	Y	BES
A6.9/04	[redacted] [redacted] [redacted] [redacted]	1999 1996	Amendment to Report No. 25761 Motor activity measurements in male and female mice postnatally exposed to NAK 4455 (common name Transfluthrin) by inhalation (including measurements of muscarinic acetylcholine receptors in the brain). [redacted], Report No. 25761A [BES Ref: MO-03-010177] Motor activity measurements in male and female mice postnatally exposed to NAK 4455 (common name Transfluthrin) by inhalation (including measurements of muscarinic acetylcholine receptors in the brain). [redacted] Report No. 25761 [BES Ref: MO-03-010055] GLP, Unpublished	N	5.9	Y	BES
A6.9/05	[redacted]	1996	Motor activity measurements in male and female mice postnatally exposed to NAK 4455 (c.n.: Transfluthrin) by inhalation (including measurement of muscarinic acetylcholine receptors in the brain) Amendment to above [BES Ref: MO-03-008995]	N	5.9	Y	BES
A6.9/06	[redacted]	2007	A developmental neurotoxicity study with technical grade transfluthrin in Wistar rats Report No. 201619 [BES Ref: M-285100-01-1] GLP, Unpublished	Y	5.9	Y	BES
A6.10/01	[redacted]	2002	NAK 4455	Y	5.9	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
	[redacted]		Special toxicity study in female rats for the determination of transitional cell proliferation in the urinary bladder, Dietary administration for 1 and 4 weeks. [redacted], Report No. PH-32467 [BES Ref: MO-04-007453] GLP, Unpublished				
A6.10/02	[redacted]	1994	NAK 4455 (Transfluthrin) - Test on proliferative effects in the liver of male rats after oral application for four weeks. [redacted], Report No. 23427 [BES Ref: MO-03-009811] GLP, Unpublished	N	5.9	Y	BES
A6.10/03	[redacted]	1995	32P Postlabeling assay for detection of adduct formation by transfluthrin (NAK 4455) in rat liver and urinary bladder DNA. BAYER AG, Report No. R 6335 [BES Ref: MO-03-010418] GLP, Unpublished	N	5.9	Y	BES
A6.10/04	[redacted]	1994	NAK 4455 - Study for possible promotion effect in the liver of male Wistar rats (administration in diet for 16 weeks from 2 weeks after one diethylnitrosamine dose [redacted] Report No. 22910 [BES Ref: MO-03-009871] GLP, Unpublished	N	5.9	Y	BES
A6.10/05	[redacted]	1999b	Amendment to Report No. PH-27425 [14C]NAK4455 (Transfluthrin): Distribution and placental transfer of radioactivity in pregnant rats (Quantitative determination). [redacted], Report No. PH-27425A	N	5.9	Y	BES
	[redacted]	1998	[14C]NAK4455 (Transfluthrin): Distribution and placental transfer of radioactivity in pregnant rats (Quantitative determination). [redacted], Report No. PH-27425 [BES Ref: MO-03-010039]				

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			Not GLP, Unpublished				
A6.10/06	[redacted]	1998	Effects on respiration and lung mechanics of BAY U 4619 in rats within the framework of a safety pharmacology study. [redacted] Report No. R-7299 [BES Ref: MO-03-010400] GLP, Unpublished	N	5.9	Y	BES
A6.10/07	[redacted]	1998b	[14C]NAK 4455 ([14C] transfluthrin): Whole-body autoradiography in pregnant rats single oral administration. [redacted], Report No. PH-27355 [BES Ref: MO-03-010437] Not GLP, Unpublished	N	5.9	Y	BES
A6.10/08	[redacted]	1998c	Effects of a single oral administration of BAY U 4619 (NAK 4455) on the intestinal motility in rats. [redacted] Report Ho. PH-27587 [BES Ref: MO-03-009683] GLP, Unpublished	N	5.9	Y	BES
A6.10/09	[redacted]	1998d	Effect of a single oral administration of BAY U 4619 (NAK 4455) on diuresis and blood pharmacological parameters of rats. [redacted] Report No. PH-27590 [BES Ref: MO-03-009689] GLP, Unpublished	N	5.9	Y	BES
A6.10/10	[redacted]	1998e	Effect of BAY U 4619 (NAK 4455) on the isolated guinea pig ileum. [redacted] Report No. 27588 [BES Ref: MO-03-009685] GLP, Unpublished	N	5.9	Y	BES
A6.10/11	[redacted]	2002	Effects of tetrafluorobenzoic acid (TFBA, NAK 4723), a metabolite of transfluthrin (NAK 4455), on rat urinary bladder epithelium in vitro. BAYER AG, Report No. PH 31925 [BES Ref: MO-04-000050] GLP, Unpublished	Y	5.9	Y	BES
A6.10/12	[redacted]	1999	Effects of a single oral administration of BAY U 4619 on the intestinal	N	5.9	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			motility of rats. [redacted] Report No. PH-28404 [BES Ref: MO-03-009682] GLP, Unpublished.				
A6.10/13	[redacted]	1992	Cell proliferation study in rats treated with NAK 4455. Microbiological Associates, Report No. G-7364.361 [BES Ref: MO-03-010498] GLP, Unpublished.	N	5.9	Y	BES
A6.10/14	[redacted]	2010	A subchronic study in rats and mice to investigate the mechanism of blader tumors with technical grade Transfluthrin. [redacted], Study No. 09-S72-RQ,	Y	?	Y	BES
A6.10/15	[redacted]	2009	Transfluthrin comparison of the in vitro metabolism in liverbeads™ from male rat, mouse, dog and human. BayerCropScience S.A., Sophia Antipolis, France. Study No. SA 09122, Document No. M-359222-01-1.	Y	?	Y	BES
A6.10/16	[redacted]	2010	The effects of treatment with transfluthrin and tetrafluorobenzoic acid on rat and human urothelial cell lines. University of Nebraska Medical Center, USA, Stduy No. 299, Document No. 1.	Y	?	Y	BES
A6.11/01	[redacted]	1998	NAK 4455 techn. Study for acute intraperitoneal toxicity to rats. [redacted] Report No. 17139 [BES Ref: MO-04-000030] GLP, Unpublished	N	5.1.4	Y	BES
A6.11/02	[redacted]	1998	BAY U 4619 (Bayothrin) Influence on haemodynamics, cardiac	N	5.9	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			contractility and ECG in anaesthetized dogs after intraduodenal administration. [redacted] Report No. PH-27493 [BES Ref: MO-03-010183] GLP, Unpublished				
	[redacted]	1999	Analysis of the results of the study P 7011681 (Report PH-27493) BAY U 4619 (Bayothrin) Influence on haemodynamics, cardiac contractility and ECG in anaesthetized dogs after intraduodenal administration. [BES Ref: MO-03-010045]				
A6.12/01	[redacted]	1998	Letter from W. Steffens to K. Roder re: Transfluthrin, dated 26.08.1998 [BES Ref: MO-03-010433] Non-GLP. Unpublished	N	5.10	Y	BES
A6.12/02	[redacted]	2006	Letter from W. Steffens re: Transfluthrin, dated 24.01.2006 [BES Ref: M-1-266138-01-1] Non-GLP. Unpublished	Y	5.10	Y	BES
A6.12/03	[redacted]	2006	Transfluthrin. Medical information. Poisoning – diagnosis, treatment and prognosis [BES Ref: M-266732-01-1] Non-GLP. Unpublished	Y	5.10	Y	BES
A6.18/01	[redacted]	2000	Transfluthrin Review of assessment of the toxicological data [BES Ref: MO-03-009788] Non-GLP. Unpublished	N	5.11	Y	BES
A7.1.1.1.1	[redacted]	1989	Benfluthrin: Hydrolysis in Buffers, Bayer AG, Pflanzenschutz-Forschung, Chemische Produktentwicklung und Ökobiologie, Institut für Metabolismusforschung, FRG, Germany Bayer AG Report No.: M 111 0290-4 [BES Ref: MO-03-009363] GLP, Unpublished	Y	1.9.1 3.1.2	Y	BES
A7.1.1.1.2/01	[redacted]	1987	Preliminary study on abiotic degradation of NAK 4455, Bayer AG, Institut für	Y	1.9.1 3.1.1	Y	BES

Document IIIA Section No /Reference No	[redacted])	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			Metabolismusforschung, Leverkusen, Germany Bayer AG Report No.: 2888 [BES Ref: MO-04-007423] Non-GLP, Unpublished				
A7.1.1.1.2/02	[redacted]	1991	Experiments concerning the indirect photodegradation of BENFLUTHRIN in aqueous solution, Bayer AG, Crop Protection-Research, Leverkusen, Germany Bayer AG Report No.: HPO/046 (PF-report No.: 3467) [BES Ref: MO-03-009362] Non-GLP, Unpublished	Y	3.1.1	Y	BES
A7.1.1.2.1	[redacted]	1990	Biodegradation of transfluthrin. Bayer AG, WD-UWS, Institute of Environmental Analysis, Leverkusen, Germany. Bayer AG Report No.: 90104217 [BES Ref: MO-03-010179] Non-GLP, Unpublished	Y	3.5	Y	BES
A7.1.1.2.4	[redacted]	2017	Transfluthrin: Degradation in activated sludge. Bayer Crop Science Division, Monheim, Germany. Bayer Report No.: EnSa-17-0107 Report date: May 5, 2017 GLP, Unpublished	Y		Y	BCS
A7.1.2.2.2	[redacted]	1993	Aerobic metabolism of ^{14}C-Benfluthrin in an aquatic model ecosystem, Bayer AG Crop Protection, Development Institute for Metabolism Research, Leverkusen, Germany. Bayer AG Report No.: M 151 0481-0 (MO-03-009370) GLP, Unpublished With Kinetic evaluation of these data from: Buerkle, L. (2005), Transfluthrin (Benfluthrin), Kinetic Evaluation of the Data in Report PF 3920 (MO-03-009370): "Aerobic Aquatic Metabolism of E. Hellpointner (July 14, 1993)", Bayer CropScience AG, Research &	Y	1.9.1 3.3.2	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			Development – Development Metabolism and Environmental Fate, Monheim, Germany. Bayer AG Report No.: MEF-05/530 (M-26171-01-1) Non-GLP, Unpublished				
A7.1.3	[redacted]	2001	Transfluthrin: Adsorption/desorption. Bayer AG, ZF-Zentrale Analytik Leverkusen, Leverkusen, Germany. Bayer AG Report No.: N 01/0081/00 LEV, [BES Ref: MO-03-011152] GLP, Unpublished	Y	3.3.1	Y	BES
A7.2.1	[redacted]		A Summary of the Environmental Fate of Various Synthetic Pyrethroids in Soil and Water Compartments with a Proposal for Bridging of Data to Transfluthrin. Bayer Environmental Science SA. Non-GLP, Unpublished	N	3.8	Y	BES
A7.3.1	[redacted]	2005	Transfluthrin: Calculation of the chemical lifetime in the troposphere, Bayer CropScience AG, Research & Development, Monheim, Germany Bayer AG Report No. MEF-05/118 [BES study No.: MO-05-005448] Non-GLP, Unpublished	Y	3.1.1	Y	BES
A7.4.1.1/01	[redacted]	1988	Acute Toxicity of NAK 4455 to Rainbow trout (Salmo gairdneri) in a flow-through test, [redacted] Bayer Report No.: FF-220, MO-03-010110 Report date: 10 June 1988 GLP, Unpublished	Y	4.1	Y	BES
A7.4.1.1/02	[redacted]	1988	Acute Toxicity of NAK 4455 to Golden Orfe (Leuciscus idus melanotus) in a flow-through test, [redacted]	Y	4.1	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			[redacted]. Bayer Report No.: F0-1108, MO-03-010113 Report date: 10 June 1988 GLP, Unpublished				
A7.4.1.1/03	[redacted]	2005	Acute toxicity of AE 1371427 to fish (Oncorhynchus mykiss) under static conditions (product code: AE 1371427 00 1B), [redacted] Bayer Report No.: EBTBX003 Report date: 06 October 2005 GLP, Unpublished	Y	4.1	Y	BES
A7.4.1.2/01	[redacted]	1987	Acute Toxicity of NAK 4455 to water fleas, Bayer AG, GB Pflanzenschutz Chemischeforschung, Institut fur Ökobiologie, Leverkusen, Germany. Bayer Report No.: HBF/Dm 69, MO-03-009344 Report date: 20 July 1987 GLP, Unpublished	Y	4.2	Y	BES
A7.4.1.2/02	[redacted]	2001	NAK4455 (Bayothrin) Acute Daphnia Toxicity, Bayer AG, WD-UWS, Institute of Environmental Analysis and Evaluation, Leverkusen, Germany. Bayer Report No.: 1091 A/01 D, MO-03-009813 Report date: 06 July 2001 GLP, Unpublished	Y	4.2	Y	BES
A7.4.1.2/03	[redacted]	2005	Acute Toxicity of Tetrafluorobenzoic acid to the Waterflea Daphnia magna in a Static Laboratory Test System, Limit Test, Bayer CropScience AG, Research and Development Ecotoxicology, 40789 Monheim, Germany. Bayer Report No.: E 320 2953-4, M-260372-01-1 Report date: 09 November 2005 GLP, unpublished	Y	4.2	Y	BES
A7.4.1.3/01	[redacted]	1987	Growth inhibition of green algae (Scenedesmus	Y	4.3	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			subspicatus) caused by NAK 4455 (techn.), Bayer AG, Crop-Protection Research, Chemical Product Development and Environmental Biology, Institute for Environmental Biology, Leverkusen, Germany. Bayer Report No.: HBF/A1 38, MO-03-009348 Report date: 20 August 1987 GLP, Unpublished				
A7.4.1.3/02	[redacted]	2001	NAK4455 (Bayothrin) Alga, Growth Inhibition Test, Bayer AG, WD-UWS, Institute of Environmental Analysis and Evaluation, Leverkusen, Germany. Bayer Report No.: 1091 A/01 A1, MO-03-009814 Report date: 20 June 2001 GLP, Unpublished	Y	4.3	Y	BES
A7.4.1.4	[redacted]	2001	NAK4455 (Bayothrin) Toxicity to Bacteria, Bayer AG, WD-UWS, Institute of Environmental Analysis and Evaluation, Leverkusen, Germany. Bayer Report No.: 1091 A/01 B, MO-03-010384 Report date: 26 April 2001 GLP, Unpublished	Y	4.4	Y	BES
A7.4.2	[redacted]	2006	[Methylene-^{14}C]– Transfluthrin - Bioconcentration and Biotransformation in Fish (Lepomis macrochirus), [redacted] Bayer Report No.: METBS004 / Nie BES ref: M-264658-01-1 Report date: January 18, 2006 GLP, Unpublished	Y	3.7 4.8	Y	BES
A7.5.1.2	[redacted]	1991	Toxicity of NAK 4455 (tech.) to Earthworms, Bayer AG, Crop Protection Research, Environmental Research Institute for Environmental Biology,	Y	4.6.3	Y	BES

Document IIIA Section No /Reference No	[redacted]	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			Leverkusen, Germany. Bayer Report No.: HBF/Rg 152, MO-03-009355 Report date: 22 November 1991 GLP, Unpublished				
A7.5.3.1.1/01	[redacted]	1987	Acute oral LD50 of NAK 4455 to Bobwhite quail, [redacted]. Bayer Report No.: VB-003, MO-03-009681 Report date: 16 November 1987 GLP, Unpublished	Y	4.6.4	Y	BES
A7.5.3.1.1/02	[redacted]	1987	Acute oral LD50 of NAK 4455 to the Canary bird (Serinus canarius), [redacted]. Bayer Report No.: VK 315, MO-04-009186 Report date: 20 July 1987 GLP, Unpublished	Y	4.6.4	Y	BES
A7.5.4.1	[redacted]	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, Germany. Bayer Report No.: P15HR [BES Ref. M-259607-01-1] Report date: 27 October 2005 GLP, Unpublished	Y	4.6.3	Y	BES
A7.6.1	[redacted]	2009	Position Paper: Transfluthrin – Assessment of the Metabolite TFB OH in Surface Water laboratory Bayer CropScience AG. Metabolism and Environmental Fate Ecotoxicology Alfred-	y		Y	BES

Document IIIA Section No /Reference No	[redacted])	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key Study Y/N	IUCLID	Data Protection Claimed (Yes/No)	Owner
			Nobel-Strasse 50 D-40789 Monheim Germany. Report nr. MEF-08/564				
A8	Anon	2005	Safety Data Sheet according to EC Directive 2001/58/EC. Transfluthrin TC. Version 1/D Revision date 18 October 2005	N	8	Y	BES
A9	Anon	2005	Safety Data Sheet according to EC Directive 2001/58/EC. Transfluthrin TC. Version 1/D Revision date 18 October 2005	N	1.6.1 1.6.2	Y	BES
[redacted]							
IIIA 9.1.3	[redacted]	2015	Toxicity of Transfluthrin - Tetrafluorobenzoic acid to the Green Algae *Pseudokirchneriella subcapitata* during a 96 hour exposure Bayer CropScience Alfred-Nobel-Str. 50 40789 Monheim am Rhein Germany report nr. EBTBN007	N		Y	BCS
IIIA 9.1.9	[redacted]	2015	A study on the chronic toxicity to the sediment dweller Lumbriculus variegatus. ECT Oekotoxikologie GmbH, unpublished report No.: 14P4LA.. Bayer CropScience AG BCS AG-R&D-CPD-EnSa-ETX-AQ 15E07123-01-RACW	Y		Y	BCS
IIIA 9.1.6.1	[redacted]	2015	Early Life Stage Toxicity of Transfluthrin Technical to the Fathead minnow (Pimephales promelas) Under Flow-Through Conditions. [redacted] EBTBL007	N		Y	BCS
IIIA 9.1.6.2	[redacted]	2015	Chronic Toxicity of Transfluthrin Technical to Daphnia magna, Under Flow-Through Conditions SynTech Research Laboratory Services EBTBL006 Bayer CropScience, Alfred-Nobel-Str. 50 40789 Monheim am Rhein Germany 007SRLS14C28	Y		Y	BCS
IIIA 9.1.9	[redacted]	2015	Chironomus riparius 28-day chronic toxicity test with	Y		Y	BCS

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			transfluthrin (tech.) in a water-sediment system using spiked sediment Unpublished. Bayer CropScience AG EBTBL005 Bayer CropScience AG. E 218 4629-2				
IIIA 9.2.2		2014	Transfluthrin a.s. (BCS-AW53131): Sublethal toxicity to the earthworm Eisenia fetida in artificial soil BioChem agrar Labor für biologische und chemische Analytik GmbH 205 S Bayer CropScience AG Development Environmental Safety Testing EBTBL008	N		Y	BCS
IIIA 9.5		2014	Transfluthrin a.s.: Effects on the reproduction of the collembolan Folsomia candida BioChem agrar Labor für biologische und chemische Analytik GmbH EBTBL002 Bayer CropScience AG Development 14 10 48 204 S	N		Y	BCS
IIIA 9.2.1		2014	Transfluthrin a.s. (BCS-AW53131): Effects on the activity of soil microflora (Nitrogen transformation test). BioChem agrar Labor für biologische und chemische Analytik GmbH EBTBL004 Bayer CropScience AG Development 14 10 48 069 N			Y	BCS
IIIA 9.1.1		2015	Transfluthrin a.s. Effects on the seedling emergence and growth of five species of non-target terrestrial plants (Tier 2). Bayer CropScience, Germany. Study ID. SE15/030. GLP. Unpublished	N		Y	BCS