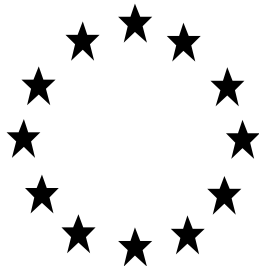
Directive 98/8/EC concerning the placing biocidal products on the market

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

Assessment Report[1]



lambda-cyhalothrin

Product-type 18 (Insecticide)

May 2011

Annex I - Sweden

lambda-cyhalothrin (PT18)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on May 6, 2011 in view of its inclusion in Annex I to Directive 98/8/EC

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of *lambda*-cyhalothrin 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[1], with a view to the possible inclusion of this substance into Annex I to the Directive.

Lambda-cyhalothrin (CAS no. 91465-08-6) was notified as an existing active substance, by Syngenta Limited, hereafter referred to as the applicant, in product-type **18**.

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

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

On the 5th of April 2006, the Swedish competent authority received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on the 2nd of October 2006.

On the 8th of September 2008, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on the 17th of September 2008. The competent authority report included a recommendation for the inclusion of *lambda*-cyhalothrin in Annex I to the Directive for PT **18**.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on the 22nd of September 2008. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

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

[2] Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market and amending Regulation (EC) No 1896/2000. OJ L 307, 24.11.2003, p. 1

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

On the basis of the final competent authority report, the Commission proposed the inclusion of *lambda*-cyhalothrin in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on May 6, 2011.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on May 6, 2011.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include *lambda*-cyhalothrin in Annex I to Directive 98/8/EC for product-type **18**. The aim of the assessment report is to facilitate the authorisation /registration in Member States of individual biocidal products in product-type **18** that contain *lambda*-cyhalothrin. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website[3], shall be taken into account.

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

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

The overall conclusion from the evaluation is that it may be expected that there are products containing *lambda*-cyhalothrin for the product-type **18**, which will fulfil the requirements laid down in Article 10(1) and (2) of Directive 98/8/EC. This conclusion is however subject to:

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

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

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

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

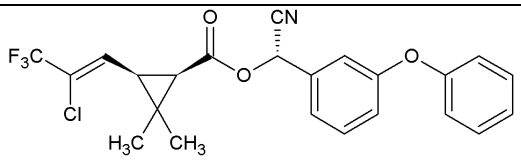
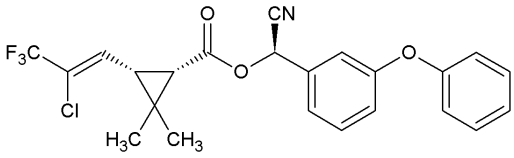
Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II, sections 2.2.1.3 and 2.2.1.8). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

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

Identity

CAS-No.	91465-08-6
EC No.	415-130-7
Other No. (CIPAC, ELINCS)	CIPAC: 463
IUPAC Name	Reaction mass of (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate (1:1)
CA Name	Cyclopropanecarboxylic acid, 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-, cyano(3-phenoxyphenyl)methyl ester, [1-alpha(S*),3-alpha(Z)]-(+-)-
Common name, synonyms	*lambda*-cyhalothrin (ISO)* cis-B (synonym)
Structural formula	 + 
Isomeric composition	Racemic mixture (50:50) of the two enantiomers. The (*S*)-α-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-[(*Z*)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate enantiomer is also known as gamma-cyhalothrin (ISO common name) There are indications that gamma-cyhalothrin is more potent than the other enantiomer of *lambda*-cyhalothrin (see section 2.1.2).
Molecular formula	$C_{23}H_{19}ClF_3NO_3$

Molecular weight (g/mol)	449.9
Purity of a.s.	min. 900 g/kg
Impurities	None of the impurities present in technical *lambda*-cyhalothrin are considered relevant. The information on impurities is found in the Annex Confidential Data and Information.
Additives	No additives
Representative biocidal products	OXYFLY/Demand/ICON 10 CS (a capsule suspension formulation containing 9.6% w/w *lambda*-cyhalothrin).

* The RMS has chosen to use the nomenclature given by the applicant, throughout the CAR (i.e. *lambda* in italics)

Physico-Chemical Properties

Lambda-cyhalothrin is a white (purified) to beige (technical) solid at room temperature with no characteristic odour. Purified *lambda*-cyhalothrin (purity 99.0%w/w) melts at 49.2 °C and decomposes before boiling (275 °C). The relative density (D_4^{20}) was determined as 1.288 for a technical material with low purity (85.9%), but as relative density is not considered as a crucial parameter no further data has been requested. The solubility in water is 4-5 µg/l at pH 4-9 and 20 °C (99.0%w/w). *Lambda*-cyhalothrin is not considered to be able to dissociate within the environmentally relevant pH range due to the lack of functional groups with acidic or alkaline properties. The vapour pressure is 2 x 10^{-7} Pa at 20 °C (extrapolated) and the Henry's law constant of 1.8 x 10^{-2} $Pa.m^3.mol^{-1}$ indicates that volatilisation is not expected to significantly contribute to the dissipation of *lambda*-cyhalothrin in the environment. The Log P_{ow} is 7.0 in distilled water (pH not stated) which indicates that *lambda*-cyhalothrin may bioaccumulate. The solubility of *lambda*-cyhalothrin is greater than 500 g/L at 21°C in methanol, acetone, dichloromethane, toluene, ethyl acetate and hexane. The flash-point was determined instead of flammability due to the low melting point and was found to be 83 ± 2 °C (85.9%w/w). The auto-ignition temperature was determined as 380°C (85.9%). The low purity of the technical material used in the assessment of flammability is not considered to be a concern given the results, which are far from any trigger for a classification. *Lambda*-cyhalothrin is not considered as explosive or oxidizing based on the structural properties. *Lambda*-cyhalothrin has been shown stable when mixed with iron and aluminium metals and salts and it is therefore not anticipated to react with the packaging material.

Analytical methods

Acceptable analytical methods, with respect to validation data, were provided for all required matrices, except for human and animal plasma and tissues.

The content of *lambda*-cyhalothrin in the technical material is determined by GC-FID using external calibration relative to internal standard. The analytical method for determining the content of impurities in the technical material is acceptable and is presented in the Annex Confidential Data and Information. The content of *lambda*-cyhalothrin in the representative formulations are determined by GC-FID, with external calibration relative to internal standard.

Parent *lambda*-cyhalothrin (denoted cis-B) is considered the only relevant residue for monitoring for all compartments and matrices except for water, in which cyhalothrin is formed (50:50 mixture of cis-B and cis-A).

The residues in soil are determined by GC-ECD and GC-MSD with a LOQ of 0.01 mg/kg. The residues in air are quantified by means of GC-MSD with a LOQ of 0.25 µg/m^3, which is considered acceptable with respect to the systemic AEL of 0.0025 mg/kg bw/day (i.e. a LOQ of 0.75 µg/m^3 is required). Additionally in the peer-review an inhalation toxicity study was provided which gave an $AEL_{inhalative}$ of 0.003 µg/L (0.0008 mg/kg bw), yielding a required LOQ of 0.24 µg/m^3, which also confirms the applicability of the available method.

The method for water provided in the original dossier is based on GC-MSD and was validated for river, sea, ground and drinking water and for monitoring purposes it has a LOQ of 2 ng/l expressed as cyhalothrin which is considered acceptable with respect to the lowest NOEC (2.0 ng/L; Daphnia magna). However, as only two fragment ions were presented for the mass detection it was concluded in the peer-review that further confirmatory data was required. In June 2010 the applicant provided full validation data using three fragment ions derived in ground, surface and drinking water which confirmed the LOQ of 2 ng/l.

The methods provided for animal plasma in the original dossier (Hall, 2002) and tissues (Sapiets, 1993) were not deemed acceptable due to insufficient reporting and/or insufficient validation data. In June 2010 the applicant provided a validation study on the multi residue method DFG Method S19 (GC-MS) for determination of *lambda*-cyhalothrin in various matrices of animal origin, among them blood. The method is considered acceptable for blood and tissues with an LOQ of 0.01 mg/l and 0.01 mg/kg for blood and tissues respectively.

No monitoring method is considered required for *lambda*-cyhalothrin in food and feeding stuffs as the intended uses is not anticipated to result in significant residues in those matrices. However, two methods were provided, both based on GC-MSD, for hops and dry crops and in crops of high lipid content which could be useful in case of suspected contamination. The LOQ of 0.01 mg/kg for both methods are acceptable with respect to the available Maximum Residue Levels (MRLs) for *lambda*-cyhalothrin (as set by Regulation (EC) No 396/2005 of the European Parliament and of the Council). However, the validation data is not completely in compliance with SANCO/825/00 rev.7.

Furthermore, additional validation data for *lambda*-cyhalothrin in various food matrices were provided by the applicant but the acceptance of the data could not be judged due to the lack of supporting studies. Nevertheless, no further data is considered required at this stage but it could be requested for product authorisation at MS-level, if appropriate.

In addition to this it was concluded that pending on the outcome of a food risk assessment a monitoring method for food and feeding stuffs of animal origin may be required. In case such a method will be needed DFG Method S 19 referred to for blood and tissues above is considered acceptable but an additional independent validation study (ILV) may be requested.

2.1.2. Intended Uses and Efficacy

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

The principal effect of pyrethroids is to delay sodium channel closure on nerve axons, which in turn delays membrane repolarisation following an action potential. This leads to spontaneous repetitive nerve firing and convulsions. The visible symptoms of pyrethroid poisoning are typically a lack of co-ordination of movements and normal behaviour (often termed the "knockdown or kd effect"), the appearance of convulsive activity, regurgitation of alimentary canal contents, and ultimately paralysis and death. Symptoms which inhibit feeding and movement occur within minutes of dosing, but death due to dehydration and other secondary effects may take up to 24 hours.

The innate efficacy of the active substance was tested against House fly (*Musca domestica*) and against German cockroach (*Blatella germanica*) and American cockroach (*Periplaneta americana*). Topical application with *lambda*-cyhalothrin on house flies resulted in LC_{50} and LC_{90} values of 8.7 ppm and 16.56 ppm respectively. Lower values were obtained for coachroaches. Although the results were very briefly reported and summarised, the data is considered sufficient to demonstrate that *lambda*-cyhalothrin is effective against these organisms.
Studies performed with products containing *lambda*-cyhalothrin indicated that for most species good efficacy was found at approximately 12 mg active substance /m^2 however a rate of 25 mg /m^2 was necessary to achieve 4 months residual control of *Aedes aegypti* when applied to a porous surface. The length of residual control was reduced when applied at the lower rates.

According to open literature and a preliminary version (non peer-reviewed) of the draft assessment report of gamma-cyhalothrin under Directive 91/414/EEC, the single 1R,cis,Z-S'-isomer (gamma-cyhalothrin) is the most insecticidally active and toxic isomer of *lambda*-cyhalothrin. In the absence of further information regarding possible preferential degradation and/or conversion of the enantiomers of *lambda*-cyhalothrin it has been assumed in this evaluation that the 1:1 ratio of the two enantiomers remains after application. The higher potency of the single enantiomer gamma-cyhalothrin has thus not been considered in the risk assessment of *lambda*-cyhalothrin. When further guidance on risk assessment of active substances with isomeric composition becomes available, this should be considered at product authorisation.

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

2.1.3. Classification and Labelling

On the basis of the available data and according to Directive 67/548/EEC, the classification and labelling of *lambda*-cyhalothrin shown in the table below was proposed by the RMS. Risk phrases were translated into GHS using the translation table in Annex VII of Regulation (EC) No 1272/2008 and safety phrases were translated into precautionary statements using the table in Annex V of the Guidance on the Application of Regulation (EC) No 1272/2008.

As in Directive 67/548/EEC:		**As in GHS***	
T+	Very toxic		
N	Dangerous for the environment		
R21	Harmful in contact with skin	Acute Tox. 4	H312 Harmful in contact with skin
R25 or R28	Toxic or Very Toxic/if swallowed	Acute Tox. 3, or Acute Tox.2	H301 or H300 Toxic or Fatal/if swallowed
R26	Very toxic by inhalation	Acute Tox. 2	H330 Fatal if inhaled
R50/53	Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.	Aquatic Chronic	H400/410
Safety phrases		**Precautionary statements**:**	
S 1/2	Keep locked up and out of the reach of children.	P405+P102	Store locked up/Keep out of reach of children.
S24	Avoid contact with skin	P262	Do not get in eyes, skin or on clothing.
S25	Avoid contact with eyes	P262	Do not get in eyes, skin or on clothing.
S28	After contact with skin, wash immediately with plenty of soap and water.	P302+P352	IF ON SKIN:wash immediately with plenty of soap and water.
S36/37/39	Wear suitable protective clothing, gloves and eye/face protection.		Wear protective gloves / protective clothing / eye protection / face protection.
		P281	Use personal protective equipment as required.

S38	In case of insufficient ventilation, wear suitable respiratory equipment.	P285	In case of inadequate ventilation wear respiratory protection.
S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).	P314	Get medical advice/attention if you feel unwell.
		P101	If medical advice is needed, have product container or label at hand.
		P308+P313	If exposed or concerned: Get medical advice/attention.
		P310	Immediately call a POISON CENTER or doctor/physician.
		P307+P311	If exposed: Call a POISON CENTER or doctor or physician
		P301+P310	If exposed: Immediately call a POISON CENTER or doctor/physician.
		P309+P311	If exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.
		P342+P311	If experiencing respiratory symptoms:Call a POISON CENTER or doctor/physician.
S60	This material and its container must be disposed of as hazardous waste.	P501	Dispose of contents/container to ... (in accordance with local/regional/national/international regulation (to be specified)).
S61	Avoid release to the environment. Refer to special instructions/safety data sheets.	P273	Avoid release to the environment.

Specific concentration limits based on acute toxicity of 0.000001-0.00001 mg/L
M-factor = 100 000

* Based on the translation tables in Annex VII of Regulation (EC) No 1272/2008 and in Annex V of the Guidance on the Application of Regulation (EC) No 1272/2008.
** According to paragraph 28 of CLP, not more than six precautionary statements shall appear on the label, unless necessary to reflect the nature and the severity of the hazards.

Additional information on the classification proposed

The classification proposed for acute oral toxicity is based on the results obtained in rats. However, mice exhibit a slightly higher susceptibility than rats and based on the results in the acute oral toxicity study in mice, *lambda*-cyhalothrin should be classified as “very toxic if swallowed” (T+, R28). A recommendation regarding the final classification for oral toxicity is needed from the Committee for Risk Assessment at the European Chemicals Agency (ECHA).

The mass median aerodynamic diameters (MMAD) of the particles generated in the acute inhalation toxicity study do not meet the standard given in the new version of OECD 403 and the guidance document developed by ECHA. However, since the LC_{50} obtained still indicates classification with T+, R26 the RMS considers the study acceptable for classification.

The dose used for challenge in the sensitisation study was very low (1%). According to information given by the applicant, topical application of higher doses (25, 50, 75% w/v) resulted in the animals becoming agitated within 2 hours of dosing (possibly as a result of paraesthesia) and they were humanely killed. Due to the large dose spacing the RMS can only conclude that *lambda*-cyhalothrin does not cause sensitisation at a challenge dose of 1%.

Safety phrases, S24 (avoid contact with skin) and S25 (avoid contact with the eyes) are proposed based on the dermal paresthesia effects described in human case reports and the paraesthesia effects observed in the eye irritation study.

The proposed specific concentration limits and the M-factor should be used for environmental classification of formulated products containing *lambda*-cyhalothrin.

Since the classification proposed differs from the current classification in Annex I of Directive 67/548/EEC (index number 607-252-00-6), an Annex VI dossier will be submitted to ECHA. The final classification of *lambda*-cyhalothrin will thus be decided by the European Comission following a recommendation from the Committee for Risk Assessment.

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

Read across

The human health effect assessment of *lambda*-cyhalothrin is based on data obtained for *lambda*-cyhalothrin or cyhalothrin. *Lambda*-cyhalothrin is the pure cis 1RαS and cis 1SαR enantiomeric pair whereas cyhalothrin is a 50/50 mixture of *lambda*-cyhalothrin and the R157836 (the cis 1RαR and cis 1SαS) enantiomeric pair. Read across between the two substances is considered justified based on the similarity between effects observed in the two 90 day studies performed in Alpk:APSD rats with identical dose levels of either *lambda*-cyhalothrin or cyhalothrin. Read across is further supported by a bridging study demonstrating that the absorption, tissue distribution, metabolism and excretion of *lambda*-cyhalothrin and cyhalothrin is quantitatively and qualitatively similar in rat. Results of existing studies on sub-chronic, long term and reproductive toxicity performed with cyhalothrin are therefore considered relevant for the toxicological evaluation of *lambda*-cyhalothrin.

However, although the effects of the two substances are similar, *lambda*-cyhalothrin appears to be approximately three times more potent than cyhalothrin in both rats and mice when comparing the acute oral toxicity of *lambda*-cyhalothrin reported in this dossier to the acute oral toxicity of cyhalothrin reported in literature[4]. Due to the dose spacing used in the two 90 day studies in rats (6.4.1 (01, 02)) it is not possible to deduce if the effects on bodyweight observed with both substances in fact occurred at a lower dose level with *lambda*-cyhalothrin. The three dog studies (6.3.1(01), 6.4.1(03) and 6.4.1(04)) give some support for a difference in potency but the exact magnitude of this difference cannot be deduced.

Since all reference values used were derived from NOAELs obtained in studies performed with *lambda*-cyhalothrin, the difference in potency has no impact on the risk assessment of the representative formulations containing *lambda*-cyhalothrin. However, in case specific endpoints are compared between *lambda*-cyhalothrin and other substances, the difference in potency should be borne in mind in case the NOAEL in question was obtained with cyhalothrin.

Absorption, Distribution, Excretion and Metabolism

The absorption, distribution and excretion of *lambda*-cyhalothrin and cyhalothrin were studied in rats, dogs and humans. All three species showed an incomplete oral absorption with large

[4] According to a Health and Safety Guide on Cyhalothrin and Lambda-Cyhalothrin (HSG 38, 1990) and a separate report on Cyhalothrin (EHC 99, 1990) the acute oral toxicities of lambda cyhalothrin and cyhalothrin in rat was 56-79 mg/kg bw and 144-243 mg/kg bw respectively. The corresponding LD_{50} values in mice were 20 mg/kg bw and 37-62 mg/kg bw respectively.

intra-species variations and an extensive metabolism with ester cleavage and rapid excretion of conjugates. Due to the large intra-species variations observed, oral absorption is suggested to be based on the lower-range values to represent a reasonable worst case situation. Consequently, the oral absorption is considered to be approximately 50% based on the (lower-range) absorptions of 40%, 48% and 50% in rats, dogs and humans respectively. The substance accumulated in fat tissue with a T½ of 23 days -30.5 days (rats).

Dermal absorption of the active substance was studied in five male volunteers and considered by the applicant to be represented by the amount of three metabolites in urine (<0.2%). However, since tissue residues were not taken into account, serial non-detects in urine was not observed in all volunteers, only one dose level was used, only males were included in the study and a large fraction of the dose (22%) was not recovered, the dermal absorption of *lambda*-cyhalothrin is considered to be less than 22%. It is however reasonable to assume a lower dermal absorption since this is commonly observed with other pyrethroids. Taking also the physicochemical properties of *lambda*-cyhalothrin into account (Log P_{ow} = 7.0, molecular weight 449.9g/mol), dermal absorption could be further reduced to 10%.

There is no data regarding the dermal absorption of representative formulations OXYFLY 10 CS and Demand/ICON 10CS. According to the applicant such data is not considered necessary with respect to the application pattern and the fact that the products are water-based formulations with the active substance kept inside a capsule. However, in case the contents are released from capsules upon mechanical pressure or upon contact with skin, exposure may occur during mix/load/application and during dermal contact with treated areas. Upon request from the RMS, *in vitro* data on dermal absorption through human skin for a concentrate and a diluted sample (0.4g/L) of a similar CS formulation was submitted by the participant. This formulation contains the same amount of *lambda*-cyhalothrin as OXYFLY 10CS and Demand/ICON 10C and the physical/chemical properties indicate that data obtained for this formulation could be considered conservative for OXYFLY 10CS and Demand/ICON 10CS. The dermal uptake of the concentrate and the dilution was 0.06% and 0.32% respectively after a 24 hour exposure period. Since residues remaining in skin was not analysed and a steady state level was not reached at the end of the experiment, a conservative value of 1% is suggested for both the undiluted and the diluted formulation.

Acute toxicity

In rats, *lambda*-cyhalothrin exhibited the highest toxicity when administered via the inhalatory route followed by the oral and dermal route as reflected by the classifications T+, R26, T,R25 and Xn, R21 respectively. A slightly higher toxicity was observed in an acute oral toxicity study in mice and based on this result, *lambda*-cyhalothrin would be classified T+, R28 (very toxic if swallowed).

The mass median aerodynamic diameters (MMAD) of the particles generated in the acute inhalation toxicity study do not meet the standard given in the new version of OECD 403 and the guidance document developed by ECHA. However, a new study is not considered necessary as the existing LC_{50} yet indicates classification with T+.

Lambda-cyhalothrin was not irritating to rabbit skin but a mild irritant to the rabbit eye. However, since the mean eye irritation scores were below the limits set in Council Directive

67/548/EC, no classification is required. The toxicity of *lambda*-cyhalothrin was displayed as clinical signs typical of abnormal motor function (ataxia, splayed gait, salivation etc) regardless of the route of administration. *Lambda*-cyhalothrin did not show any sensitising properties in the Magnusson and Kligman test performed however the dose used for challenge was low (1%). According to information given by the applicant during the peer-review process, this dose was chosen since topical application at the next dose level (25%) resulted in animals becoming agitated (possibly due to paraesthesia) and they had to be humanely killed. Due to the large dose spacing, the RMS can only conclude that *lambda*-cyhalothrin does not cause sensitisation at a challenge dose of 1%.

Repeated dose toxicity

Neurological effects were commonly observed in studies with dogs whereas the predominant effects in rats were reduced bodyweight gains and liver effects. The liver effects observed (i.e. increased liver weight, proliferation of smooth endoplasmic reticulum and increased hepatic aminopyrine-N-demethylase activity) were considered to represent an adaptive response to increased liver workload since reversibility of effects was demonstrated during a recovery period in a 28 day rat study. Reduced bodyweight gains were observed in all rat studies and occurred at approximately 14 mg/kg bw in the 90-day oral studies (NOAEL 3 mg/kg bw) and at 12-14 mg/kg bw in the long-term oral study (NOAEL 1.8 mg/kg bw). In the 21-day inhalation study, this was observed at 3.3 µg/L corresponding to an inhaled dose of 0.9 mg/kg bw (NOAEL 0.3 µg/L or 0.08 mg/kg bw).

There were no clinical signs of neurotoxicity observed in any of the repeated dose oral toxicity studies in Wistar-derived rats but they were detected in this strain when administered via inhalation or via the dermal route. In the 21-dermal toxicity study symptoms such as bizarre behaviour, reduced (postural) stability and splay reflex occurred at 50 mg/kg bw. Assuming approximately 10% dermal penetration of the active substance, the systemic LOAEL for clinical signs of neurotoxicity would be much lower than the LOAEL observed in the acute oral neurotoxicity study (35 mg/kg bw).

The clinical signs of neurotoxicity observed in the 21-day inhalation study (paw flicking and tail erections) occurred at a very low dose inhaled. Although the systemic absorption is higher following inhalation, it cannot fully explain the difference between the effect levels following inhalation (LOAEL 0.9 mg/kg bw) and oral administration (LOAEL 35 mg/kg bw). The apparently higher sensitivity following inhalation and dermal exposure to *lambda*-cyhalothrin could be a consequence of a first-pass effect of the liver being avoided. This first-pass effect may be specific for the Wistar-derived rat but is difficult to verify since all but one of the rat studies were performed with this strain.

In dogs administered *lambda*-cyhalothrin, clinical signs of neurotoxicity including ataxia, unsteadiness, lack of coordination, occasionally muscular spasms and convulsions occurred at dose levels of 1.5 mg/kg bw (6 week study) and 3.5 mg/kg bw (52 week study). Although these symptoms occurred occasionally and were reversible, they are considered adverse due to the severity of the effects. The NOAEL for clinical signs of neurotoxicity was 0.5 mg/kg based on the result of the 52 week study. Dogs administered *lambda*-cyhalothrin also suffered from gastrointestinal effects (i.e. vomiting/fluid faeces). It was argued that these effects were related to the method of administration (capsule solution) rather than to the test substance as similar

effects were seen in dog studies with another pyrethroid when administered via capsules but not via diet. Such association has however not been demonstrated for *lambda*-cyhalothrin and in the absence of evidence, the effects are considered to be related to treatment. Although the NOAEL derived is based on the neurological signs observed rather than the gastrointestinal effects, the frequency of vomiting does bring some uncertainty on the dose actually achieved and thus on the exact NOAEL. It is assumed that this uncertainty is compensated through the NOAEL being approximately 7 times lower than the LOAEL.

Genotoxicity

The genotoxic potential of *lambda*-cyhalothrin was investigated using the standard *in vitro* test package, reinforced with an UDS test as well as an *in vivo* mouse micronucleus test. Since all results were consistently negative, *lambda*-cyhalothrin was not considered to be mutagenic or clastogenic.

Long-term toxicity and carcinogenicity

The two long term/carcinogenicity studies presented were performed in rats and mice respectively. In both studies, cyhalothrin was used as test substance. The major causes of death in rats were a marked rhinitis with associated oro-nasal fistulation or pituitary adenomas and the effects increased the mortality rate to such extent that survival was less than 50 % at termination. The effects were however not considered to be related to treatment since the incidence of pituitary adenoma was within the range of historical control data and rhinitis and oro-nasal fistulation occurred subsequent to a change to a new diet containing a substantial number of fibrous particles. Changes in ALP levels and liver weights (only at interim sacrifice) were also observed but were considered to represent an adaptive response of the liver. There were no neurological effects observed. A NOAEL of 1.8 mg/kg bw was set based on a reduced bodyweight gain in males and females.

The predominant effects observed in mice included an increased incidence of mammary adenocarcinomas in females and an increased incidence of neurological signs in males (e.g. piloerection/hunched posture and aggressive behaviour). A NOAEL of 1.8 mg/kg bw was set based on the increased incidence of clinical signs of neurotoxicity. The total incidence of tumours was similar in treated and untreated mice but the incidence of malign tumours (mainly mammary adenocarcinomas and uterine leiomyosarcomas) was higher in treated animals. Both types of tumours were considered to be unrelated to treatment by the study author however the incidence of adenocarcinomas (13.5 and 12% at the two highest dose levels) is above the upper limit of historical data (2-12%) and well above the incidence in the concurrent controls (2%). Taking into consideration the absence of similar effects in rats, information that the tumour type is claimed to vary in this strain and the lack of genotoxic potential in tests performed, the RMS does not find the equivocal result in mice sufficient to propose classification for carcinogenicity.

Reproduction toxicity

The teratogenicity studies performed with CD rats and rabbits did not reveal any foetal effects. The major parental effects observed in both species included reduced bodyweight gains and

reduced food intake. Two rats administered the highest dose of cyhalothrin showed uncoordinated limb movements.

There were no major effects observed in the three-generation study. As in the other repeat-dose rat studies performed, a reduced bodyweight gain was observed. This was primarily noted during pre-mating whereas the body weight gain during pregnancy was similar in treated F0 and F1 animals and controls. Reduced pup weight gains during lactation were observed in some litters however there was no clear consistent pattern between A and B litters or between generations and the effects observed did not show a clear dose-response pattern. Although the total litter weights in F3 are claimed to be within the normal range of historical data and there was no apparent correlation with clinical condition or histopathological findings, it cannot be concluded with certainty that the effects are unrelated to treatment. Therefore, the reduced pup weight gain observed is considered to be an adverse effect related to treatment and a NOAEL of 30 ppm is set for both parent animals and pups.

Neurotoxicity

Type II pyrethroids bind the α subunit of the voltage sensitive sodium channel and induce a structural rearrangement of the segment responsible for channel closure (reviewed in Ray DE, Fry JR., Pharmacol Ther. 2006 Jul;111(1):174-93). In its new conformation, the channel is unable to close the gate resulting in a prolonged influx of sodium ions. When the sodium ”tail” manages to hold the cell membrane over the membrane potential, repetitive firing of action potentials occurs until conduction finally is blocked. The effects of pyrethroids are manifested clinically as excessive salivation, choreoathetosis and ataxia.

The neurotoxic effects are readily observed in studies performed with dogs or mice but not in the repeated dose oral toxicity studies performed with rats. While clinical signs of neurotoxicity are observed at dose levels of 1.5 mg/kg bw (6 week study) and 3.5 mg/kg bw (52 week study) in dogs, they are observed at a dose level of 15 mg/kg bw in CD rats (developmental study) and 35 mg/kg bw in Wistar-derived rats (acute neurotoxicity study). This suggests an inter-species variation in either receptor sensitivity or liver metabolism. A first pass metabolism is supported by the results of an inhalation study showing that when first-pass is avoided, clinical signs of neurotoxicity occur also in Wistar-derived rats at very low dose levels (0.9 mg/kg bw). The metabolism may be specific for the Wistar-derived rat strain but the hypothesis is difficult to verify since all rat studies included were performed with Wistar-derived rats with the exception of the developmental toxicity study. Further indications of an intra-species variation in rats are observed in a published study performed with adult Long-Evans rats[5]. In this study a decrease in motor activity was observed at a threshold oral dose of 0.5 mg/kg bw.

Despite that no clinical signs of neurotoxicity were observed in any of the oral repeated dose toxicity studies performed with Wistar-derived rats, this strain was used in both neurotoxicity studies submitted (i.e. acute neurotoxicity study and developmental neurotoxicity study). In the study on acute neurotoxicity, a single high dose of 35 mg/kg bw *lambda*-cyhalothrin resulted in neurological signs such as decreased activity, ataxia, reduced stability and/or tiptoe gait,

[5] Wolansky, M. J. et al (2006), Toxicological sciences 89(1), 271-277

salivation, piloerection, upward curvature of spine and/or urinary incontinence, tremors in one female and reversible changes in the functional battery test (i.e. reduced landing foot splay, increased tail flick response and reduced motor activity. The NOAEL was set at 10 mg/kg bw.

In the study on developmental neurotoxicity, dams were administered lower doses of *lambda*-cyhalothrin (i.e. 0-11.4 mg/kg bw/day) via diet. In similarity with the other repeated dose studies performed with rats, the effects observed included a reduced food intake and a reduced bodyweight gain. Furthermore, a decreased rate of learning/memory was present in females administered 150 ppm in the Y water maze test performed on day 21/24 but not on day 59/63. However, if the cut-off was related to the time taken to complete a straight channel, there was no longer any difference in rate thus the study author considered it possible that the effects rather reflected a difference in swimming performance than an effect on learning/memory. Considering that the bodyweights were reduced in this group, an association of the effect with a weaker swimming performance seems logical. With the type of study design used, pups would only have been exposed during the critical period of brain growth spurt (i.e. 3-4 weeks post partum) if the test substance was transferred via lactation but this was not verified by analysis of *lambda*-cyhalothrin levels in milk/ blood levels in pups. In order to demonstrate transfer of *lambda*-cyhalothrin to pups via lactation, a report of a preliminary study on developmental toxicity was submitted by the applicant. In this study, the level of *lambda*-cyhalothrin in blood plasma was inverstigated in dams and pups during day 1, 5, 11 and 22 of lactation. The results showed that the levels in pups appeared to be approximately the same as in dams. Although there was an extensive variation of data, the results indicate that *lambda*-cyhalothrin is transferred via lactation in rats. It is therefore concluded that the study on developmental neurotoxicity in Wistar-derived rats was negative.

However, the studies conducted were not performed with the species that raised concerns for neurotoxicity (i.e the dog according to the data submitted or mice considering published literature data and the study presented in IIIA 6.7(02)) as is discussed in paragraph 7 of OECD TG 426 (adopted 16 October 2007). DNT studies in dogs are not encouraged as they are neither ethical nor practical. However, since data indicate that neurotoxic effects are only evident in the rat strain used at dose levels above those used in the current study, the lack of findings in the DNT study does not reassure that effects on the developing nervous system would not occur in a more sensitive strain/species. In fact, several studies in mice have shown that pups are sensitive to pyrethroids during the critical time period of brain growth spurt (i.e. during days 6-10 post partum)[6]. Since the corresponding time period of brain growth spurt in humans occurs during the last trimester in utero and up to two years after birth, children may be exposed to *lambda*-cyhalothrin during the critical period not only via lactation but also directly via the environment or residues in food.

Due to the uncertainties perceived regarding the sensitivity of children, the RMS originally proposed (draft CAR) to use an extra safety factor of 3 to extrapolate the NOAEL for neurotoxicity set for adult dogs to a theoretical NOAEL in pups. The Technical Meeting I in 2010 however decided that the currently available evidence does not support the use of an extra

[6] Eriksson P. (1991) Toxicology and Applied Pharmacology 108, 78-85; Eriksson P. (1990) Toxicology and Applied Pharmacology 102, 456-463; Eriksson P. (1997) NeuroToxicology 18 (3): 719-726.

assessment factor but the RMS should formally express uncertainties perceived in the CAR. During the Technical Meeting II in 2010, it was decided that the conclusions of a survey on pyrethroids prepared by the Netherlands should be used in the assessment of DNT effects on pyrethroids. The conclusions of this survey were:

- Possible DNT effects induced by pyrethroids are covered by the AELs set on neurotoxicity in the acute neurotoxicity and medium-term studies since DNT effects from acceptable OECD TG 426 performed studies are taking place at higher LOAELs than other neurotoxicological effects.

- The DNT effects are also covered by the AELs set for long-term exposure (based on neurotoxic or other critical endpoints.

- As neurotoxic effects are critical effects after acute or medium-term exposure and the available data indicate that DNT effects are induced at higher LOAELs, it is unlikely that, in the absence of DNT studies, the potential DNT effects are not covered by AELs set on neurotoxic effects observed in acute and medium-term studies.

- The data also indicate that an additional assessment factor for species sensitivity is not required.

The RMS hesitates to consider these conclusions applicable to all pyrethroids. At least for *lambda*-cyhalothrin, there were no clinical signs of neurotoxicity observed in the DNT study in Wistar-derived rats, neither in adult animals nor in pups. Therefore, the RMS view is that it cannot be concluded that the NOAEL set for neurotoxicity in adult dogs would cover for the sensitivity of young animals and/or any DNT effects. Since the nervous system is sensitive during brain development, the RMS believes that the exposure level of children needs to be carefully considered in risk assessments of formulations containing *lambda*-cyhalothrin.

Medical data

The information originates from various sources including medical surveillance on manufacturing plant personnel, direct observation from clinical cases and published literature. A computer database of adverse reactions to chemicals (from 1983 to the present) including field trials workers is maintained within Stewardship and Safety department at Syngenta, Fernhurst. This records formal reports of clinical symptoms arising from chemical exposure at the research station, Jealott's Hill, Berkshire and the formulation factory at Yalding, Kent in the UK. Cases of subjective facial sensation (also known as 'SFS' or paraesthesia) have occurred at all stages of *lambda*-cyhalothrin handling, from small-scale laboratory work to commercial synthesis and formulation operations. Subjective facial sensation is a collection of skin-associated symptoms, including itching, tingling, burning, cold or numbness due to skin contact with *lambda*-cyhalothrin. The face is most commonly affected. These symptoms can cause discomfort and may in some individuals last for up to 24 hours after exposure. Recovery is apparently complete and there is no evidence of lasting damage. The results from the database reveal 223 cases of subjective facial sensation from -cyhalothrin, 30 of these were associated with eye irritation and 6 with headaches. Investigations of these reports indicate that the majority are caused during plant breakdown, maintenance work or failure of the individual to wear the appropriate protective clothing. Reports are individually investigated by the site.

These investigations have led to many modifications to plant operating procedures, protective equipment worn and plant cleaning which have all improved hygiene standards and reduced operator exposure. As only a very small amount of skin contamination with the active ingredient can lead to the development of subjective facial sensation, monitoring of these reports is a very sensitive indicator of general plant hygiene. During the last few years the general trend has been a reduction in reporting which would indicate improvements in plant hygiene overall. *Lambda*-cyhalothrin is currently synthesised at the Huddersfield, UK works of Syngenta. Thirty workers are involved working on a twelve hour shift system. The product is a viscous liquid which is drummed at elevated temperatures for transport to formulation factories worldwide. The active ingredient is formulated into a wide range of solid and liquid formulations handled at many locations worldwide. Approximately one hundred workers are involved in formulation of the active ingredient, filling and packing into sales packs.

Formulations were initially made at Yalding, UK before the site closed in 2003. Formulation activities are currently undertaken at the Syngenta sites of Seneffe, Belgium: Paulinia, Brazil and St. Gabriel, USA. The Occupational Health group of Syngenta has maintained a database of incidents involving chemical exposure of workers since 1983. At the time it was set up it was used to formally record reports of clinical conditions arising during work at the research station (at Jealott's Hill, Berkshire) and the formulation plant (at Yalding, Kent). From 1994 data has been collected from all the manufacturing, formulation and packing sites around the world. Information has been collected on the occurrence of occupationally related illnesses (to 10 categories) since 1994. Analysis of the Syngenta internal database produced 6 reports of adverse reactions that relate to the preparation of 'Karate' Zeon 5 CS formulation – a similar formulation to that detailed in this dossier. All reactions were recognised as paraesthesia.

Livestock and Pets

The biocidal use of OXYFLY 10 CS in animal houses may result in exposure of livestock and consequently also in exposure of humans via food of animal origin. Therefore, derivation of a maximum residue level (MRL) and a food risk assessment is necessary. In EU, a MRL of 0.5 mg/kg has been set relating to cyhalothrin (sum of isomers) for all meat except poultrymeat (which has an MRL of 0.02 mg/kg). However, since *lambda*-cyhalothrin is used in biocidal products as well as in veterinary medicinal products and plant protection products, the MRL may need to be revised in order to include all routes of possible exposure.

Harmonised guidance documents on animal exposure assessment and food risk assessment are expected to become available during 2011 and these should be used when authorising OXYFLY 10CS in Member States.

Exposure of pets is not considered in this assessment. Depending on the intended use, this may be a relevant scenario to include in the risk assessment at future authorisations of formulations containing *lambda*-cyhalothrin.

Human health effects of the biocidal products OXYFLY 10 CS and Demand/ICON 10CS

OXYFLY 10 CS and Demand/ICON 10CS are of low acute toxicity following exposure via oral and dermal routes. The products are currently classified with Xn, R20 (harmful by inhalation) based on the mortality pattern (2/5 females) and the marked effects observed in surviving animals administered the highest stable attainable concentration of the formulation (4.62 mg/l). The mass median aerodynamic diameters (MMAD) of the particles generated in the acute inhalation toxicity study do not meet the standard given in the new version of OECD 403 and the guidance document developed by ECHA. However, the result is still considered reliable since the particle size generated is stated to be the minimum size consistent with the physical characteristics of the microencapsulated formulation which preclude the use of cyclones or similar techniques to reduce particle size.

Despite observations of transient indications of dermal and ocular irritation, no classification for irritancy is required since the effects were below the thresholds defined in Directive 93/21/EEC. There were no effects of sensitisation observed in the Magnusson and Kligman Maximisation test submitted however the test methods are developed for active substances and are often not sufficiently sensitive for formulations. Therefore, classification according to the intrinsic properties of the formulants is considered more adequate. Since OXYFLY 10 CS and Demand/ICON 10CS contain a sensitiser above a certain limit, classification with R43 (may cause sensitisation by skin contact) is proposed despite the negative result obtained in the test. However, in November 2010 the applicant informed that from 2010, the level of the co-formulant which is responsible for the R43 classification has been reduced to below the classification threshold. The formulations also contain a co-formulant that, depending on the physical properties of the form used, may justify classification for carcinogenicity. This needs to be clarified at product authorisation.

2.2.1.2. Effects assessment

The extent of *lambda*-cyhalothrin absorbed after oral administration is approximately 50% and it is rapidly excreted following an extensive metabolism that includes ester cleavage and conjugation. The toxic effects of *lambda*-cyhalothrin are manifested primarily as reduced bodyweight gains in (Wistar-derived) rats and neurological effects in dogs. The lowest oral doses tolerated after acute or medium/long-term exposures in the most sensitive species (dog) are 0.75 and 0.5 mg/kg bw respectively

Although a lower NOAEL was set in the 21-day inhalation study in rats, this NOAEL is not considered relevant for the risk assessment of the representative formulations since the droplets generated during the intended use of the micro-encapsulated formulations (low pressure spraying (1-3bar)) are not assumed to be of respirable size (Doc IIB, section 8.2.2.2). The droplets inhaled are expected to be handled by the mucociliary escalator instead of reaching the alveoli thus exposure is assumed to result from gastrointestinal absorption of the mucus swallowed. Inhalation of *lambda*-cyhalothrin volatilised off treated surfaces is not anticipated due to the low vapour pressure of the active substance (2×10^{-7} Pa at 20 °C (extrapolated)). Therefore, AELs derived for the oral route are considered relevant for the risk assessment of *lambda*-cyhalothrin in OXYFLY 10CS and ICON/Demand 10CS during the intended uses included in this evaluation. When authorising formulations containing *lambda*-cyhalothrin, the intended uses and application methods must however be carefully reviewed in order to decide if the AEL derived for the inhalation route is more relevant for the risk assessment.

The representative formulations are not intended for direct application to foods or feedingstuffs or to surfaces and areas where foods or feedingstuffs are prepared or stored however since OXYFLY10CS is used in and around animal houses, exposure of animals and consequently residues in food of animal origin cannot be excluded. Therefore reference values representing the acute reference dose (ARfD) and the acceptable daily intake (ADI) are necessary.

AEL (acute): An AEL of 0.0038 mg/kg bw/day was derived based on the NOAEL obtained in the 6 week study (0.75 mg/kg bw/day), an oral absorption of 50% and a safety factor of 100 (compensating for inter/intra species variations). Although the NOAEL was based on a study using few animals (1/sex/dose level) it is considered relevant since the study was performed in the most sensitive species, the effects noted were consistent with effects observed in other dog studies of higher reliability and the effects appeared early after dosing.

AEL (medium-term/long-term): An AEL of 0.0025 mg/kg bw/day was derived based on the NOAEL obtained in the one-year dog study (0.5 mg/kg bw), an oral absorption of 50% and a safety factor of 100.

AEL (inhalation): An AEL of 0.0008 mg/kg bw (0.003 µg/L) was derived based on the NOAEC(L) set for reduced bodyweight gains and clinical signs of neurotoxicity at 0.3µg/L (corresponding to an inhaled dose of 0.08 mg/kg bw) in the 21-day inhalation study in Wistar-derived rats.

ARfD: An ARfD of 0.0075 mg/kg bw/day was derived based on the NOAEL obtained in the 6 week study (0.75 mg/kg bw/day) and a safety factor of 100 to compensate for inter/intra species variations.

ADI: An ADI of 0.005 mg/kg bw/day was derived based on the NOAEL obtained in the one-year study in dog (0.5 mg/kg bw) and a safety factor of 100 to compensate for inter/intra species variations.

Summary of reference values derived for *lambda*-cyhalothrin:

AEL (operator/worker exposure)	Value	Study	Safety factor
Acute	0.0038 mg/kg/day	Dog, 6 week	100
Medium-term	0.0025 mg/kg/day	Dog, 1 year	100
Long-term	0.0025 mg/kg/day	Dog, 1 year	100
Inhalation	0.0008 mg/kg/day	Rat, 21-day	100
ArfD	0.0075 mg/kg/day	Dog, 6 week	100
ADI	0.005 mg/kg/day	Dog, 1 year	100

2.2.1.3. Exposure assessment

OXYFLY 10CS and Demand/ICON 10CS, are suspensions containing microcapsules with *lambda* cyhalothrin (100g/L). They are applied by professional operators in and around different types of buildings. The use pattern originally described for OXYFLY 10 CS and Demand/ICON 10 CS were spraying overhead, upwards and downwards onto walls and floors and into cracks and crevices where pests may be present. During the commenting period, the the in-use concentration was changed by the applicant (from 0.1% to 0.05%) on the basis that the dilution rates originally provided were incorrect. In addition, the use area of Demand/ICON 10CS was changed to reflect new information given by the applicant during the Technical Meeting in February 2010. According to the revised information, OXYFLY 10CS is applied in and around animal houses such as open poultry houses, pig farms, cattle houses. For control of nuisance flies it is applied where flies congregate or settle such as floors, walls, ceilings and around doors and windows and for the control of other insects, it is applied as a crack and crevice treatment. Demand/ICON 10CS is applied in, on and around buildings (such as factories, hospitals or domestic properties) and their immediate surroundings as a spot or crack and crevice treatment against cockroaches, ants, and other crawling insects[7]. There are three groups of the population that may be potentially exposed to the products:

1. People involved in manufacture,

2. People who handle, apply and dispose of the product

3. People who may be incidentally exposed while the product is in use or after use.

In the draft CA report, the estimated exposure of groups 2 and 3 was calculated using models and/ default values derived from the Technical Notes for Guidance on Human Exposure (June 2002). The exposure assessment presented in the draft final CA report were revised to reflect agreements made at the Technical Meeting in February 2010 and the new information given by the applicant during the peer-review process. Models and parameters used in the exposure assessments are taken from the TNsG on Human Exposure (2002), the Human Exposure to Biocidal Products-User Guidance (version 1), the document "HEEG opinion on Choice of Secondary parameters for PTs 2, 3 and 4" and US EPA Exposure Factors Handbooks.

Exposure of manufacturers

Production of *lambda*-cyhalothrin as well as manufacture of formulations OXYFLY 10CS and Demand/ICON 10CS take place within the EU area (one of the sources of the active substance is manufactured outside of the EU). However, exposure of workers at the

[7] According to information given by the applicant at the Technical Meeting for Biocides in February 2010, the product was a cracks and crevices spray applied to wall-floor junctions, as spot treatment for inaccessible items, such as behind fridges, cookers, or under sinks. It was not intended to be used as a broadcast spray across large surfaces of living areas (minutes of TMI10)

production/formulation plants is not considered in the risk assessment as it is assumed to be within the scope of other legislation on worker safety.

Exposure of professionals

Exposure to *lambda*-cyhalothrin may occur via the oral, dermal and inhalation routes during mixing, loading and application of OXYFLY 10CS and Demand/ICON 10CS. While oral exposure of professionals is considered negligible, exposure via the other routes is relevant. Dermal exposure will be reduced if suitable gloves are worn and due to the cases of subjective facial sensation (paraesthesia) reported (Doc. IIIA section 6.12), this is strongly recommended when handling formulations containing *lambda*-cyhalothrin. The dermal uptake was considered to be 1% both for the concentrated and the diluted formulation based on data obtained for a similar CS formulation.

The level of exposure via inhalation is affected by the proportion of droplets of inhalable or respirable size and the droplet size is affected by factors such as pressure and type of equipment used. Applications are stated to be made at low pressure (hand-held knapsack sprayer at low pressure (1 to 3 bar) using a compression sprayer) and with high water volumes (medium or coarse spray). According to the participant, the droplet sizes generated at low pressures have been measured and the volume median diameter of the droplets generated was considered to be larger than the size of respirable droplets (Doc IIA, section 8.2.2.2). Therefore, the proportion droplets of inhalable size is expected to be low reducing the potential for exposure via inhalation.
The estimated exposure in professionals were calculated based on Spraying Model 1 of the Technical Notes for Guidance on Human Exposure, Section 3.3 of Part 2 June 2002 and indicative exposure values were taken from the guidance document “Human Exposure to Biocidal Products-User Guidance version 1.

The following scenarios were considered in the exposure assessment of professionals:

Tier I: professional user, normal clothing without personal protective equipment
Tier IIa: professional user wearing normal clothing and gloves
Tier IIb: professional user wearing gloves and cotton overall
Tier IIc professional user wearing gloves and impermeable overall
Tier IId professional user wearing normal clothing and respiratory protection
Tier IIe professional user wearing normal clothing, gloves and respiratory protection

Incidental exposure of non-professionals

OXYFLY 10CS and Demand/ICON 10CS are applied by professionals and bystanders (i.e. adults or children) are not expected to be present during or immediately after application when surfaces inside buildings may be wet. The risk of inhalation exposure to dried residues of *lambda*-cyhalothrin after application is assumed to be low considering the type of formulation used and that *lambda*-cyhalothrin is a non-volatile substance.

People working in animal premises may be exposed to residues of OXYFLY 10CS daily during normal working activities. Exposure of infants, children and adults are assumed to occur

accidentally upon a visit to a farm. According to the product label, OXYFLY 10CS is applied in areas where flies congregate or settle and as a crack and crevice treatment for other insects and mites. If an infant is brought to a farm, parents are assumed to keep careful watch of them and the risk of getting in dermal contact with these treated areas is therefore assumed to be low.

Demand/ICON 10CS is used in, on and around general buildings (including domestic properties) thus children and adults are expected to stay in treated areas. According to the applicant, the product is used for cracks and crevices treatments at wall/floor junctions and spot applications at inaccessible locations. Adults and children are thus not expected to be exposed to the substance during normal activities but infants can be exposed if poking in cracks and crevices and subsequently transferring residues on fingertips to the mouth. Due to the normal behaviour (oral exploration) and the physiology (large body surface relative to bodyweight) of an infant, the exposure of infants is considered to be higher than for toddlers, schoolchildren and adults. In view of the assumptions above, bystanders are not expected to be easily exposed to residues of Demand/ICON 10CS or OXYFLY 10CS however due to the toxicity of *lambda*-cyhalothrin, a low level of exposure can still constitute a risk to human health.

The exposure assessment of an infant in contact with residues of *lambda*-cyhalothrin was first made based on parameters and models discussed in the document prepared by the Human Expert Exposure Group (HEEG). Since the ConsExpo “rubbing off” model and the US EPA SOP 8.1 model discussed in the HEEG document are applicable to treatments of carpets and floors and countertops (for recreation, housework or other occupant activities) respectively, the exposure level calculated for Demand/ICON 10CS was adjusted to fit crack and crevice treatment. It was assumed that exposure via cracks and crevices represents 9% of the exposure following treatment of general surfaces. This figure was chosen since the surface area for ”targeted spot application“/“cracks and crevice treatment“ ($2m^2$) constitutes 9% of the area for ”general surface treatment“ ($22m^2$, living room) in the ConsExpo scenarios.

Another approach to assess the risk for an infant was to calculate the total skin surface area of an infant to which residues could be transferred from a contaminated area and be ingested without exceeding the AEL.

The following scenarios were considered in the assessment of incidental exposure:

<u>OXYFLY 10CS:</u>

Scenario I (infant/schoolchild): Incidental exposure of infant/schoolchild visiting animal premises treated on general surfaces.

Tier I: Exposure via dermal contact (hands only) with treated surfaces and subsequent hand to mouth transfer.
Tier II: Exposure via dermal contact (palms only) with treated surfaces and subsequent hand to mouth transfer.
Tier III: For a schoolchild, normal hygiene restrictions are assumed to be respected and exposure only results from dermal contact (palms) with treated areas.

Scenario II (adult): Exposure of adult visiting/working in animal premises treated with OXYFLY 10CS on general surfaces. Exposure of visitor is considered to be incidental whereas exposure of worker is of medium-term duration.

Tier I: Exposure via dermal contact (hands only) with treated surfaces and subsequent hand to mouth transfer.
Tier II: Exposure via dermal contact (palms only) with treated surfaces and subsequent hand to mouth transfer.
Tier III: Normal hygiene routines are assumed to be respected and exposure only occurs via dermal contact (palms) with treated areas.

Demand/ICON 10CS

Scenario (infant): Exposure of an infant playing in a room treated in cracks and crevices at wall/floor junctions and spots at inaccessible locations.

Approach 1: Exposure calculated according to the ConsExpo (a) or SOP model (b) adjusted for cracks and crevice treatment.
Approach 2: Calculation of the total skin surface area of an infant from which residues transferred from a contaminated area can be ingested without exceeding the AEL. Since the product is applied in cracks and crevices at wall/floor junctions, it is assumed that dermal contact is made by fingertips only. Exposure following spot treatment is not assumed to occur as this treatment is made to inaccessible locations only.

2.2.1.4. Risk characterisation

The exposure levels and risk indices/margins of exposure obtained for professional operators and adults/children incidentally exposed to *lambda*-cyhalothrin are considered in this section.

Professional operators

The exposure level in professional operators spraying surfaces and into cracks and crevices during 120 minutes per day is acceptable provided that gloves and a cotton overall is worn. The exposure level is only slightly below the AEL but is acceptable considering that the exposure levels were calculated assuming 100% absorption of the amount inhaled. This is considered a worst case assumption since droplets inhaled are rather expected to be swallowed and absorbed in the gastrointestinal tract than to reach the alveoli. The results of the exposure assessments also show that use of cotton overall or impermeable coverall reduces exposure to some extent but a significant reduction of the exposure level is achieved if respiratory protection is applied.

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] Reference Value e.g: AEL (acute or medium-term or long-term)	AF MOE_{ref}	MOE ((NOAEL x oral abs) /Exp)	Exposure /AEL
		estimated oral uptake [mg/kg b.w/day]	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (no PPE)	Operator spraying surfaces and into cracks and crevices (120 minutes)	n.a	0.00217	0.00227	0.0044	0.5/3.5 AOEL (medium-term): 0.0025	100	57	1.8
Tier 2a (gloves)	Operator spraying surfaces and into cracks and crevices (120 minutes)	n.a	0.00217	0.000567	0.00273	0.5/3.5 AOEL (medium-term): 0.0025	100	92	1.1
Tier 2b (gloves coverall)	Operator spraying surfaces and into cracks and crevices (120 minutes)	n.a	0.00217	0.000291	0.00246	0.5/3.5 AOEL (medium-term): 0.0025	100	102	0.98
Tier 2c (gloves impermeable coverall)	Operator spraying surfaces and into cracks and crevices (120 minutes)	n.a	0.00217	0.000153	0.00232	0.5/3.5 AOEL (medium-term): 0.0025	100	108	0.93
Tier 2d (RPE)	Operator spraying surfaces and into cracks and crevices (120 minutes)	n.a	0.000217	0.00227	0.00249	0.5/3.5 AOEL (medium-term): 0.0025	100	100	0.99
Tier 2e (RPE, gloves)	Operator spraying surfaces and into cracks and crevices (120 minutes)	n.a	0.000217	0.000567	0.000784	0.5/3.5 AOEL (medium-term): 0.0025	100	319	0.39

Incidental exposure of non-professionals

OXYFLY 10 CS:

The exposure calculations made for bystanders show that in case an infant would ingest all residues transferred to the total skin surface area of the palms, the exposure level would be equal to the AEL derived. Since parents are assumed to keep careful watch of infants during a visit to animal premises, this is considered to represent a worst case situation. Therefore, the exposure level calculated is not considered to indicate an unacceptable risk for infant visiting animal premises.

For a schoolchild and an adult, calculations show that dermal exposure of a skin surface area corresponding to the surface areas of 60 and 72 palms is acceptable without exceeding the AEL. Calculations also show that even if a schoolchild or an adult would lick their fingers during a visit, dermal exposure of a surface corresponding to the size of their palms followed by ingestion of all residues is acceptable. Therefore, a visit to animal premises is not expected to bring any unacceptable risk for a schoolchild or an adult.

People working in animal premises are expected to be aware of and respect normal hygiene routines thus exposure via the oral route should be negligible. Calculations show that a worker can be exposed on a skin surface area corresponding to the surface area of 48 palms without exceeding the AEL. It is considered unlikely to exceed this number during a working day thus there should be no unacceptable risk for a person working in animal premises.

Exposure of workers and bystanders may however be avoided if treated areas are indicated by signs. Moreover, workers could be advised to wear gloves and respect standard hygiene routines when entering treated animal premises.

Demand/ICON 10CS:

The exposure assessment of an infant in contact with residues of *lambda*-cyhalothrin was first made based on parameters and models discussed in the document prepared by the Human Expert Exposure Group (HEEG).

Since the ConsExpo “rubbing off” model and the US EPA SOP 8.1 model discussed in the HEEG document are applicable to treatments of carpets and floors and countertops (for recreation, housework or other occupant activities) respectively, the exposure level calculated for Demand/ICON 10CS was adjusted to fit crack and crevice treatment. It was assumed that exposure via cracks and crevices represents 9% of the exposure following treatment of general surfaces. This figure was chosen since the surface area for ”targeted spot application“/“cracks and crevice treatment“ ($2m^2$) constitutes 9% of the area for ”general surface treatment“ ($22m^2$, living room) in the ConsExpo scenarios. The results of both calculations indicate an exposure level only slightly below the AEL.

Another approach to assess the risk for an infant was to calculate the total skin surface area of an infant from which residues transferred from a contaminated area can be ingested without exceeding the AEL. Assuming that the fingertips area represents 10% of the total area of the

palm, it can be calculated that 67 fingertips/"poking events"would be acceptable without exceeding the AEL. It is considered unlikely that an infant would be exposed to this extent while playing in a room treated only in cracks and crevices and at inaccessible spots.

Summary of exposure assessments made for OXYFLY 10CS

Exposure Scenario (indicate duration)			Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE (NOAEL x oral abs) /Exp	Exposure /AEL
			estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
OXYFLY 10CS										
Tier 1 (Worst Case)	Child visiting farn exposure on hands and ingestion of residues on hands	Infant (10kg)	n.a	0.00015	0.0075	0.00765	0.75/1.5 AEL (acute) 0.0038	100	49	2
		Schoolchild (31.8 kg)	n.a	0.00013	0.0064	0.0065			58	1.7
	Adult visiting/working in animal premises.	Adult visitor	n.a	0.000105	0.00525	0.00536	0.75/1.5 AEL (acute) 0.0038	100	70	1.4
		Adult worker	n.a	0.000105	0.00525	0.00536	0.5/3.5 AEL (medium-term) 0.0025		47	2.1

Tier 1I (Worst Case)	Child exposed on palms followed by ingestion of residues on palms	Infant (10kg)	n.a	0.000075	0.00375	0.0038	0.75/1.5 AEL (acute) 0.0038	100	99	1
		Schoolchild (31.8 kg)	n.a	0.000064	0.0032	0.0032			117	0.84
	Adult exposed on palms followed by ingestion of residues on palms	Adult visitor	n.a	0.0000525	0.002625	0.0027	0.75/1.5 AEL (acute) 0.0038	100	139	0.71
		Adult worker	n.a	0.0000525	0.002625	0.0027	0.5/3.5 AEL (medium-term) 0.0025		93	1.1
Tier 1II (Worst Case)	Adult exposed on palms	Schoolchild (31.8 kg)	Dermal exposure of a surface corresponding to the surface area of 60 palms (pairs) is acceptable without exceeding the AEL.							
		Adult visitor	Dermal exposure of a surface corresponding to the surface area of 72 palms (pairs) is acceptable without exceeding the AEL.							
		Adult worker	Dermal exposure of a surface corresponding to the surface area of 48 palms (pairs) is acceptable without exceeding the AEL.							

Summary of exposure assessments made for Demand/ICON 10CS

Exposure Scenario (indicate duration)			Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE (NOAEL x oral abs) /Exp	Exposure /AEL
			estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Demand/ICON 10CS										
Tier 1 (Worst Case)	Child playing in room treated in cracks and crevices at wall/floor junctions	Infant (10kg) ConsExpo "rubbing off" (adjusted for cracks and crevices)	n.a	0.00041	0.00205	0.00243	0.5/3.5 AEL (medium-term) 0.0025	100	104	0.97
		Infant (10 kg) US EPA SOP 8.1 (adjusted for cracks and crevices)	n.a			0.0023			109	0.94
		Infant (10 kg)	Intake of residues transferred to a skin surface area corresponding to the surface area of 67 fingertips is acceptable without exceeding the AEL.							

Conclusion:

Application of OXYFLY or Demand/ICON 10CS is not associated with any risk to human health for professionals provided that gloves and cotton overalls are worn. Considering that some users can be exposed also during post-application activities (e.g. work in treated areas, launder of contaminated working clothes), Member States should recommend the use of respiratory protection when authorising products.

In view of the assumptions made in the scenarios identified for incidental exposure, no unacceptable risks were identified for bystanders visiting or working in animal premises treated with OXYFLY 10CS or for infants poking in cracks and crevices at wall/floor junctions treated with Demand/ICON 10CS.

However, although a safe use of *lambda*-cyhalothrin in Demand/ICON 10 CS can be demonstrated it is obvious from the calculations that children would be at risk if the intended use would change to a use pattern slightly increasing the risk of exposure. Since the area of 67 fingertips represents 67% of the surface area of the palms, applications other than into cracks and crevices at wall/floor junctions and at inaccessible spots would not be possible with this dose. Therefore, the intended use (including formulation type, application rate, use area, application method etc) of formulations containing *lambda*-cyhalothrin needs to be carefully reviewed at product authorisation.

Moreover, if multiple exposures of infants occur as a result of exposure both in common areas (day-care centres, libraries, hospitals) and in domestic properties, ingestion of residues transferred to a skin surface area corresponding to 67 finger tips may no longer be a worst case situation.

Lambda-cyhalothrin causes clinical signs of neurotoxicity in adult animals of several species and the RMS considers that there are uncertainties regarding the sensitivity of young animals and/or effects during brain growth spurt (see section 2.2.1.1.8). Therefore, the RMS recommends Member States to pay particular attention to the exposure of infants and pregnant women (during last trimester and the lactation period) when authorising products with this active substance. Protection of vulnerable groups of the population, including pregnant women, infants and children is indicated in related legislation for plant protection products[8].

[8] Regulation (EC) no 1107/2009 of the European Parliament and of the Council for plant protection products recital number 8).

Environmental Risk Assessment

2.2.1.5. Fate and distribution in the environment

Abiotic degradation

Aqueous hydrolysis is not expected to be a significant degradation route for *lambda*-cyhalothrin at environmentally relevant pH (around 7). Hence, no major hydrolysis products were identified that need further consideration.

The available studies on photolysis indicate a potential for photochemical transformation of *lambda*-cyhalothrin in pure water, but the half-lives are not considered reliable and representative for environmental conditions. Phototransformation in water was not considered in the further evaluation of *lambda*-cyhalothrin, and no further studies are required. Also on soil, photochemical transformation processes are considered to be negligible.

Biodegradation

Based on available data *lambda*-cyhalothrin disappears rapidly from the water column via adsorption to the sediments with dissipation DT_{50} of only a few hours. *Lambda*-cyhalothrin is also expected to be adsorbed to aquatic plants. The fate of *lambda*-cyhalothrin in the water/sediment test systems of the key study was best described by FOMC kinetic model, however most models for exposure assessment requires input DT_{50} estimated by SFO kinetic model, and this is also required for re-calculation to 12°. The DT_{50}s for degradation in the whole water/sediment systems calculated by FOMC or SFO are shown in the table below. *Lambda*-cyhalothrin was degraded by ring hydroxylation and cleavage of the ester link followed by mineralisation. The major metabolite formed was Compound Ia, reaching a maximum of 29% of applied in the water phase on day 14 and a maximum of 11% of applied in the sediment on day 30.

Degradation of *lambda*-cyhalothrin in two water/sediment systems (DT_{50}s refers to whole systems): "Old Basing" (7.5% organic carbon content of sediment) and "Virginia Waters" (0.5% OC in sediment)

System	DT_{50} (FOMC)*	DT_{90} (FOMC)*	DT_{50} (SFO)**	DT_{90} (SFO)**
"Old Basing"	17 days	138 days	21 days	71 days
"Virginia Waters"	12 days	43 days	13 days	42 days
Geometric mean (20°C):	14 days	-	17 days	-
Geometric mean (12°C):	-	-	32 days	-

* First-Order Multi-Compartment (FOMC) kinetic model describing a bi-phasic decline.
** Single First Order (SFO) kinetic model.

Due to the lack of data on aerobic and anaerobic biodegradation in sewage sludge as a worst case approach it is assumed that no biodegradation takes place in sewage treatment plants or in manure.

The DT_{50} of 36 days determined for *lambda*-cyhalothrin in one soil at the laboratory (re-calculated to 69 days at 12°C) was used as input to models for estimation of PEC. The absence of studies on the rate of degradation of *lambda*-cyhalothrin on additional number of soils was not accepted during peer review. TM II 2010 agreed that an additional laboratory study on rate of degradation in soil should be requested, since DT_{50} > 21 days and a risk for the soil compartment was identified for some scenarios (TGD on Data Requirements, 2000, Chapter 3, p. 7.2.2.1). The additional laboratory data available on cyhalothrin showed that anaerobic degradation can be expected to proceed at a slower rate (DT_{50} was increased by a factor 3.4). This additional material also gave an indication of the potential variation in DT_{50}s between soils (the DT_{50} of cyhalothrin was increased by a factor 3.7 in a second soil). Field dissipation study carried out on *lambda*-cyhalothrin in Germany resulted in indicative DT_{50}s of approximately 25, 28, 30, and 82 days in four different soils, hence these data confirmed the natural variability in DT_{50}s between different soils. The applicant informed (March and May, 2010, and February, 2011) that a new laboratory study on route and rate of degradation of [^{14}C]-*lambda*-cyhalothrin is on-going and that the final report is expected to be available in Q2/Q3 of 2011. The study is being conducted in accordance with OECD TG No 307 on three European soils (sandy clay loam, loam, and silty clay loam) and on one US soil (loam).
In the available study, the route of degradation in soil was the same as in water; *lambda*-cyhalothrin was degraded by ring hydroxylation and cleavage of the ester link followed by mineralisation. Compound XV was the only metabolite identified as >10% of the applied radioactivity (max 12% day 60). The non-extractable residue is also to be counted as a "sink" for *lambda*-cyhalothrin in soil. In studies which used ^{14}C-labelled substance 17-32% of the applied radioactivity was unextractable and further studies on the extent and nature of bound residues (7.2.2.3) are not considered necessary.

Distribution

The available data clearly show that *lambda*-cyhalothrin adsorbs strongly to soils and sediments, and that the adsorption generally can be expected to be not reversible. All results from the studies on *lambda*-cyhalothrin are more or less uncertain mainly due to indirect measurement of adsorption in most of the experiments and also due to the inherent difficulties to determine accurately the adsorption for such an hydrophobic substance. The results are accepted as best available estimates of the magnitude of adsorption. In one study on adsorption of *lambda*-cyhalothrin mean Koc from different test concentrations were in the range 70100-430000 ml/g for four soils (or 56000-520000 ml/g for individual concentrations). In a second study mean Koc from different test concentrations in five soils and five sediments ranged from 110000 to 724000 ml/g (or 84000-840000 ml/g as determined in individual test concentrations). To take account of the uncertainty of the estimated Koc values, the RMS has used Koc values in the extreme ends as input to exposure assessment; for instance, lowest Koc of 70100 for calculation of PECsw and highest Koc of 724000 for calculations of PECsoil, to provide worst case estimates of exposure.

From the data on adsorption presented on metabolites, it is concluded that Compound XV (hydroxylated *lambda*-cyhalothrin) adsorbs strongly to soil (Koc in the range of 58000-92000 ml/g), and that adsorption of Compound Ia (cyclopropane acid) is only weak, but with a

slightly higher degree of adsorption in acidic soils (Koc 14-16 at pH 7.1-7.6, and Koc 92 ml/g at pH 5.4).

Accumulation

The available data indicate that *lambda*-cyhalothrin has a high potential for bioaccumulation, with whole body BCF ranging from 2240 (total ^{14}C) – 4982 (^{14}C-*lambda*-cyhalothrin) in fish and 1300 – 3400 (^{14}C-*lambda*-cyhalothrin) in invertebrates, based on measured concentrations in the water phase.

2.2.1.6. Effects assessment

Aquatic organisms

The available laboratory data show that ***lambda*-cyhalothrin** is very toxic to fish, with a **96 hour LC_{50} of 0.078 (0.056-0.11) µg a.i./L** for *Leuciscus idus* (golden orfe). The acute LC_{50} values for tested species ranged from 0.078 – 2.3 µg a.i./L (n=10). The lowest chronic **NOEC value was 0.031 µg a.i./L** (fathead minnow, *Pimephales promelas*). The most sensitive endpoint in the long term test was survival of the F1 generation in the fish full life cycle study. The main metabolite, **Compound Ia** is less toxic to fish, with **96 hour LC_{50} >10 800 µg/L.**

The available laboratory data show that *lambda*-cyhalothrin is very toxic to aquatic invertebrates, with **48 hour EC_{50} values between 0.002 and 3.33 µg a.i./L** for a range of arthropod species (n=11). The most sensitive of the tested species in laboratory studies were *Hyalella azteka* (freshwater shrimp) and *Chaoborus* **sp**. (phantom midge larva). In a reproduction study with *Daphnia magna,* the **21-day NOEC** (based on reproduction) was **0.00198 µg/L**. The tested metabolites (Compound 1a and Compound V) were much less toxic to *Daphnia* compared to the parent compound (48 hour EC_{50} 105 and 85 mg/L, respectively).

Algae were shown to be much less sensitive to *lambda*-cyhalothrin than other aquatic organisms, with **96 hour E_bC_{50} and 72 hour E_rC_{50}** values for area under the growth curve and growth rate, respectively, were both **>130 µg/L**, based on geometric mean concentrations in the available study (only one tested species). Also micro-organisms in STP are less sensitve to *lambda*-cyhalothrin compared to aquatic organisms, with a 6 hour **EC_{10} >1 mg/L to** *Pseudomonas putida.*

The available laboratory data show that *lambda*-cyhalothrin is very toxic to sediment dwelling invertebrates, with **28 days NOEC of 93 µg/kg ww** in a sediment spiked test, and **0.015 µg/L** in a water-spiked test.

No NOEC value could be established from the available higher tier studies since effects were observed on a number of species at the lowest treatment level **(<0.010 µg/L**) in a field enclosure study. *Chaoborus* was identified as the most sensitive species. In bioassays with water from the same ditches as in the field enclosure study the populations of *Chaoborus* and

Asellus, a potential for re-colonisation after 14 days was indicated, resulting in an **overall NOAEC of 0.0175 µg/L based on *Chaoborus*** in the macrophyte dominated ditch.

Terrestrial organisms

The available data indicate that *lambda*-cyhalothrin has a low acute toxicity to earthworms, with a **14 days LC_{50} value >247 mg/kg ww soil**. Based on effects seen in a three year field study, a **NOAEC value of 0.029 mg/kg ww soil** could be determined. The available data on micro-organisms indicate that the effects of *lambda*-cyhalothrin on soil respiration and nitrogen transformation are not ecologically significant. The **28 days NOEC** value was determined to be **1.1 mg/kg ww soil**.

In a new reproduction study on the soil dwelling arthropod *Folsomia candida*, the **28 day NOEC** was determined to be **1.29 mg/kg ww soil**.

The available data on acute and short term toxicity of *lambda*-cyhalothrin to birds resulted in an **acute oral LC_{50} >3950 mg/kg bw** and a **short term dietary LC_{50} of 3978 mg/kg diet** for mallard duck. In an avian reproduction study with mallards, no treatment related effects were observed, and the reproductive NOEC can therefore be set to the highest dietary concentration, 30 mg/kg diet. This corresponds to a **NOEL of approximately 3 mg/kg bw per day**.

In the available studies on **terrestrial plants**, the **28 day EC_{50} value** for germination, growth, plant size and leaf area in the pre- and post-emergence plant growth regulator screening test was considered to be **>90 g as/ha for all tested species**. This value corresponds to **0.11 mg/kg ww** of soil assuming a mixing depth of 5 cm and a soil bulk density of 1.7 kg/L of wet soil.

Lambda-cyhalothrin is highly toxic to bees and other terrestrial arthropods. The technical *lambda*-cyhalothrin gave **LD_{50} (48 hours) values of 0.91 and 0.038 µg a.s./bee in the oral and contact toxicity test** respectively. The most sensitive of the other tested arthropod species was the predatory mite ***T. pyri*, with a 48 hour LR_{50} = 0.0037 g a.s./ha** in a study with direct exposure of dried residues on glass plates.

PNEC

The calculated PNEC values for *lambda*-cyhalothrin based on available data are given in the table below.

Table 4.3.5-1: Summary of the predicted no effect concentrations (PNEC) in the different environmental compartments. Values proposed to be used in the risk assessment are in bold.

Compartment	Experimental endpoint	Assessment factor	PNEC experimental	PNEC estimated, EPM
Aquatic organisms, exposure via STP	NOEC 0.00198 µg/L	10	**0.0002**µg/L	-
Sediment dwellers,	NOEC	100	**0.93** µg/kg ww	0.014 µg/kg ww

continuous exposure via sediment	93 µg/kg ww (105 µg/kg dw)			(standard EPM)
STP organisms	EC_{50} 5* µg/L	Not relevant	**5** µg/L	-
Soil organisms	NOAEC 29 µg/kg ww (33 µg/kg dw)	10	2.9 µg/kg ww	0.017 µg/kg ww

*the PNEC for STP was set to the water solubility limit (Wollerton 1984) as agreed during peer review.

2.2.1.7. PBT assessment

Lambda-cyhalothrin does not meet any of the criteria for Persistent substances related to the sediment compartment, whereas for the water compartment there is a lack of knowledge regarding the degradation rate. *Lambda*-cyhalothrin disappears rapidly from water and the degradation observed in water/sediment systems is considered to mainly have taken place in the sediments.

According to the available data on rate of degradation of *lambda*-cyhalothrin in one sandy loam soil the substance does not meet the criteria for Persistent substances related to the soil compartment. However, one on-going study conducted on four additional soils has been requested (final report expected Q2/Q3 of 2011). An overall assessment of the rate of degradation in soil can be made once the study has been made available.

Lambda-cyhalothrin meets the criterion for Bioaccumulating substances, but not the criterion for very Bioaccumulating substances (vB).

Lambda-cyhalothrin meets the criterion for very toxic substances (T).

In conclusion, since *lambda*-cyhalothrin does not fulfil the criteria for Persistent substances, it does not fulfil the PBT/vPvB criteria.

2.2.1.8. Exposure assessment

The environmental exposure assessment of *lambda*-cyhalothrin in the representative products Demand/ICON 10CS and OXYFLY 10CS was done in accordance with the approach and recommendations of the OECD Emission Scenario Document (ESD) No 14 and 18, and further calculations of the Predicted Environmental Concentrations (PEC) in various environmental compartments were done in accordance with the Technical Guidance Document on Risk Assessment (TGD). The area of use considered was spraying of the diluted products Demand/ICON 10CS as a crack and crevice, or spot treatment using conventional compression sprayer equipment to control nuisance flies, ants and cockroaches in and around buildings. For OXYFLY 10CS spraying of the diluted product in and around animal houses was considered, for fly control in areas where flies congregate or settle, and for the control of other pests as a crack and crevice treatment. The scenarios considered were:

Demand/ICON 10CS:

Outdoor use in rural areas (not connected to STP via storm drains):
Treatment of large buildings - Spraying of wall (flying insects); 10% of wall area sprayed.
The assessment for large buildings is assumed to also cover treatment to domestic buildings.

Indoor use in urban areas (waste water emissions to STP):
Treatment of small buildings, spraying to cracks & crevices, or spot treatment (2 m^2)

Indoor use in urban areas (waste water emissions to STP):
Treatment of large buildings, spraying to cracks & crevices, or spot treatment (9.3 m^2)

Outdoor use in urban areas (storm drains to STP):
Treatment of small buildings, spraying of wall (10% of area) against flying insects

Outdoor use in urban areas (storm drains to STP):
Treatment of large buildings, spraying of wall (10% of area) against flying insects

For the use in urban areas PEC values were calculated also for the general use (combined emissions from small/large buildings, indoor/outdoor use).

OXYFLY 10CS:

Outdoor use (not connected to STP via storm drains):
Treatment of large buildings - Spraying of wall (flying insects); 10% of wall area sprayed.

Indoor use in animal houses - Cattle (dairy); Pigs (sows, group); Poultry (chicken, broilers): 30% of roof and wall area treated - Release to manure/slurry, in the case of poultry also to waste water (connected to STP).

Assumptions of the environmental risk assessment

The applicant has suggested that there are several assumptions and default values resulting in a worst-case environmental risk assessment, some of these are:
- the maximum application rate was assumed (0.25 mL product/m^2),
-for applications indoor in domestic/public houses/buildings, it is assumed (by default) that 25% of the applied product is exposed to cleaning using water (F_{CE} = 0.25), but it should be noted that the product is a crack and crevice/spot application that will be targeted to areas of infestation that are by their nature inaccessible or infrequently cleaned,
- for applications indoor in domestic/public houses/buildings 100% removal efficiency of the fraction exposed to cleaning (F_{CE} = 0.25) was assumed (this is however the current default assumption),
- use of extreme end Koc values instead of mean values. This results in conservative estimates of the porewater concentrations in soil, and conservative estimates of PECsw and PECsed. However, for the partitioning between sludge and water in the STP the choice of Koc has marginal impact only,
- the default value for $F_{simultaneity}$ used in the calculations is based on a survey of domestic use by the general public (described in the ESD), and therefore there is a degree of uncertainty regarding its applicability to professional use products and non-domestic situations,

- the refined value of $F_{spray,wash-off}$ used (0.27) for the application outdoor did not take adsorption to wall material into account,
- for the effects assessment there is a large data base available, including higher tier studies, and yet the PNECs are derived from lower tier tests.

The RMS agrees that the current approach for environmental exposure assessment is uncertain, but is unable to conclude on the overall degree of conservatism in the assessment.

A "back-calculation" of the tonnage put on the market based on the default assumptions of the ESD No 18, as well as EUSES modelling based on actual tonnage put on the market were presented. These assessments – in particular the "back-calculation" - demonstrated the conservative nature of the approach of the ESD No 18. The results from the "back-calculation" and the EUSES modelling were however not used for risk assessment.

Instantaneous environmental exposure to the active ingredient has been assumed. Hence, potential slow release of *lambda*-cyhalothrin from the micro-encapsulated formulation was not taken into account. It was not considered possible to take any such potential slow release into account since there were no data on potential release rate in various environmental media.

The risk assessment was based on the following restrictions in use which need to be recognised at product authorisation:
- only targeted applications was assumed for both products (Demand/ICON 10CS and OXYFLY 10CS),
- for OXYFLY 10CS the indoor risk assessment was focussed on (only) three animal categories,
- $F_{spray,run-off}$ (default 0.2) for the outdoor applications was omitted since label should recommend "Spray to just before run-off"

2.2.1.9. Risk characterisation

Aquatic compartment

Sewage Treatment Plant (STP)
Since all PEC/PNEC ratios for micro-organisms in STP are below 1 for all the representative use of *lambda*-cyhalothrin, no risk is considered identified.

Surface water
Since all PEC/PNEC ratios for aquatic organisms are above 1 at the representative uses of *lambda*-cyhalothrin in Demand/ICON 10CS that result in emissions to STP, a risk is considered identified.

The PEC/PNEC ratio for aquatic organisms at the indoor use of OXYFLY 10CS in animal houses (poultry) connected to STP is above 1, indicating that a risk is identified.

For aquatic organisms exposed via distribution of manure/slurry to arable land/grassland the PEC/PNEC ratios were below 1, and hence no risk is considered identified for the indoor use of OXYFLY 10CS in animal houses without release of waste to STP.

No risk for secondary poisoning in the aquatic food chain was identified for any of the scenarios, since the ETE/PNEC ratios were below 1 for fish-eating birds and mammals for all scenarios.

Sediment
Since all PEC/PNEC ratios for sediment organisms are above 1 at the representative uses of *lambda*-cyhalothrin in Demand/ICON 10CS that result in emissions to STP, a risk is considered identified.

For sediment organisms exposed via distribution of manure/slurry from the animal categories considered to arable land/grassland the PEC/PNEC ratios were below 1, and no risk is considered identified.

The PEC/PNEC ratio for sediment organisms at the indoor use of OXYFLY 10CS in animal houses (poultry) connected to STP is above 1, indicating that a risk is identified.

Terrestrial compartment

The PEC/PNEC ratio for soil living organisms at outdoor use of Demand/ICON 10CS and OXYFLY 10CS in areas not connected to STP is above 1, indicating that a risk is identified. However, based on the fact that the exposure assessment for this scenario takes into account residues in the 0-0.5 m area from the treated wall, and that the PEC/PNEC ratio was within one order of magnitude, it is considered likely that there is a sufficient potential for re-colonisation of soil organisms. This approach is similar to that used for plant protection products, where an identified risk for terrestrial organisms within a treated field is considered to be acceptable if

there is a sufficient potential for recovery or re-colonisation from untreated areas (ie no significant effects in untreated areas) adjacent to the treated field.

It should be recognised that the PEC for the outdoor uses of *lambda*-cyhalothrin was calculated for the 0.5 m wide soil zone around the house, exposed by deposition during spray and wash-off by rain, and were based on a soil depth of 0.1 m. The PEC/PNEC ratio for the untreated zone (also 0.5 m wide) outside this area was well below 1 indicating a low risk for effects. From the RMS' point of view, compared to agricultural fields treated with insecticides, the exposed area around treated buildings is narrower and should therefore even more likely have a potential to be re-colonised by populations of terrestrial organisms.

Similarly, a risk for secondary poisoning in the terrestrial food chain (earthworm-eating birds and mammals) was identified for this scenario (outdoor application of Demand/ICON 10CS and OXYFLY 10CS in areas not connected to STP). Considering that no risk was identified for the adjacent untreated zone and that wild animals would be expected to spend most of their time searching for food at distances more than 0.5 m from buildings, the risk assessment for the untreated zone is considered more relevant.

A risk was also identified for soil living organisms following outdoor application of Demand/ICON 10CS around domestic houses in areas with emissions via storm drains to STP (exposure via application of sludge). A risk for earthworm-eating mammals was also identified for this scenario.

For the other application scenarios of Demand/ICON 10CS (indoors in domestic/commercial buildings, outdoor around commercial buildings with emissions of water to STP) no risk for soil living organisms was identified. Similarly, there was no risk for secondary poisoning of the terrestrial food chain identified for these individual scenarios, except when the cumulative (added) emission to STP was considered.

The PEC/PNEC ratios for soil living organisms at indoor use of OXYFLY 10CS are below 1, indicating that no risk is identified.

There was also no risk identified for secondary poisoning of the terrestrial food chain following indoor application of OXYFLY 10CS in animal houses.

2.2.2. List of endpoints

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

3. DECISION

3.1. Background to the Decision

Lambda-cyhalothrin is a synthetic type II pyrethroid insecticide. The principal effect of pyrethroids is to delay sodium channel closure on nerve axons which in turn delays membrane repolarisation following an action potential. This leads to spontaneous repetitive nerve firing and convulsions. The visible symptoms of pyrethroid poisoning are typically a lack of co-ordination of movements and normal behaviour (often termed the "knockdown or kd effect"), the appearance of convulsive activity, regurgitation of alimentary canal contents, and ultimately paralysis and death.

Two representative formulations have been assessed: OXYFLY 10CS and Demand/ICON 10CS. Both are capsule suspension (CS) formulations applied by professional operators in, on and around different types of buildings. In the original dossier the intended uses were not clearly defined. During the peer-review process, the use patterns of the two formulations were more clearly specified by the applicant and the intended uses considered in the final risk assessments are:

OXYFLY 10CS: For insect control in and around animal houses such as open poultry houses, pig farms, cattle houses. Spray application is intended where flies congregate or settle such as floors, walls, ceilings, around doors and windows and for the control of other insects application as a crack and crevice treatment.

Demand/ICON 10CS: application as a crack and crevice or spot treatment in, on and around buildings including domestic properties against cockroaches, ants and other crawling insects. Application is made as a crack and crevice spray to wall-floor junctions and as spot treatment for inaccessible items, such as behind fridges, cookers, or under sinks.

The proposed classification for *lambda*-cyhalothrin is T+, R26; T, R25 (or T+, R28) and Xn, R21 for the inhalation, oral and dermal route respectively, and N; R50/53 for the environment.

The toxicity is, regardless of the exposure route, shown mainly as clinical signs typical of abnormal motor function. Dogs and mice have been shown to be more sensitive to the neurological effects of *lambda*-cyhalothrin following oral exposure than the rat strain used (i.e. Wistar-derived rat) in all but one of the rat studies included in this report. The degree of sensitivity in humans and, in particular, in children during brain growth spurt (i.e. last trimester in utero and up to two years after birth), is not known.

A negative result was obtained in the developmental neurotoxicity study but this result is considered compromised by the use of the Wistar-derived strain in which no clinical signs of neurotoxicity were observed in any oral studies performed at comparable dose levels. Therefore, the RMS considers that uncertainties regarding the sensitivity of young animals and/or effects during brain growth spurt remain. No further testing is considered necessary however since *lambda*-cyhalothrin causes clinical signs of neurotoxicity in adult animals of several species and since there are uncertainties regarding the sensitivity of young animals, the

RMS considers that mitigation measures may be necessary to reduce exposure of children and pregnant women during the last trimester and during the lactation period.

The final human exposure assessments for professional users were performed for six different scenarios of various protective degrees. The results show that for the intended uses assessed, application of OXYFLY or Demand/ICON 10CS is not associated with any risk to human health provided that gloves and cotton overalls are worn.

Exposure of bystanders to OXYFLY 10CS was assessed based on two different scenarios. In the first scenario, the incidental exposure of an infant or schoolchild visiting animal premises treated on general surfaces was considered. The exposure assessments were performed using a tiered approach in which exposure was assumed to result from hand to mouth transfer of residues on hands (tier I), palms (tier II) or from dermal exposure of palms only (tier III). In the second scenario, incidental/medium-term exposure of adult visiting/working in animal premises treated with OXYFLY 10CS on general surfaces was assessed. The tiered approach used for infant or schoolchild was used also in this assessment.

Exposure of bystanders to Demand/ICON 10CS was assessed using two different approaches. In the first approach, the exposure level was calculated according to the ConsExpo or SOP model discussed in the document prepared by the Human Expert Exposure Group (HEEG) but adjusted for cracks and crevice treatment. In the second approach, the total skin surface area of an infant from which residues transferred from a contaminated area can be ingested without exceeding the AEL was calculated. Based on information given by the applicant during the peer review period, calculations assume that treatments are made in cracks and crevices at wall/floor junctions and spots at inaccessible locations. Therefore, exposure is assumed to be restricted to finger-tips of an infant.

In view of the assumptions made in the assessments of incidental exposure, no unacceptable risks were identified for bystanders visiting or working in animal premises treated with OXYFLY 10CS or for infants poking in cracks and crevices at wall/floor junctions treated with Demand/ICON 10CS.

The environmental risks identified in the final assessment were as follows:

Demand/ICON 10CS:

Outdoor use in rural areas (not connected to STP via storm drains):
Risk was identified for the soil compartment, however, it is considered likely that possible effects are only temporary since there is most likely a re-colonisation of soil organisms from the untreated zone for this scenario. Similarly, a potential risk for secondary poisoning of the terrestrial food chain is considered unlikely since the ETE/PNEC ratio was <1 in the untreated zone and wild mammals would not be expected to predominantly feed in the close vicinity of buildings.

Indoor use in urban areas (waste water emissions to STP):
Risk was identified for the surface water and sediment compartments for use in domestic houses and commercial buildings, respectively.

Outdoor use in urban areas (storm drains to STP):
Risk was identified for the surface water and sediment compartments for use on domestic houses and commercial buildings, respectively. For treatment around small houses risk was also identified for the soil compartment, and for secondary poisoning in the terrestrial food chain.

"General use" (added emissions to STP from uses in and on domestic houses/commercial buildings indoor/outdoor):
Risk was identified for the surface water and sediment compartments. A risk for secondary poisoning in the terrestrial food chain was also identified.

OXYFLY 10CS:

Outdoor use (not connected to STP via storm drains):
Risk was identified for the soil compartment, however, it is considered likely that possible effects are only temporary since there is most likely a re-colonisation of soil organisms from the untreated zone for this scenario. Similarly, a potential risk for secondary poisoning of the terrestrial food chain is considered unlikely since the ETE/PNEC ratio was <1 in the untreated zone and wild mammals would not be expected to predominantly feed in the close vicinity of buildings.

Indoor use in animal houses:
No risks were identified for the main scenario (waste water not connected to STP).
For the separate scenario in which waste water from poultry farming was assumed to be directed to STP risk was identified for the surface water and sediment compartments.

Finally, there was no risk identified for contamination of groundwater at levels of 0.1 µg/L or above from the use of Demand/ICON 10CS and OXYFLY 10CS.

Based on the risk assessment done it can therefore be concluded that for the representative use of OXYFLY 10CS in animal houses (dairy cattle; pigs (sows in group); poultry (chicken, broilers); 30% of wall + roof area treated with no waste directed to STP) no environmental risks were identified.

Lambda-cyhalothrin is not characterised as a PBT substance. It meets the criteria related to toxicity (T) and potential for bioaccumulation (B), but not the criterion related to persistence (P). The PBT assessment may need to be reconsidered when an on-going study on rate of degradation in soils has been made available (expected in 2011).

Hence it can be concluded that among the intended uses considered in the exposure assessments, the indoor use of OXYFLY 10CS in animal houses was the only scenario for which no risks were identified either from the human health perspective (provided PPE are worn) or from the perspective of environmental protection.

Endocrine disruption statement

Initial work carried out under the EU Strategy for Endocrine Disruptors has identified and included cyhalothrin in Group III of a list of 553 candidate priority substances with the potential to act as endocrine disruptors in both humans and animals[9] .

In a follow-up to the first prioritising exercise, further information was gathered and presented for chemicals not previously prioritised[10] . Substances were categorized specifically in relation to human health and wildlife. Overall, cyhalothrin was identified as Category 1.

As part of the evaluation of the application for the inclusion of lambda-cyhalothrin in Annex I of the Biocidal Products Directive (98/8/EC) toxicology and ecotoxicology data are assessed. It is concluded that there was no clear evidence of endocrine disruption effects from these studies. However, it should be noted that due to limitations in the test guidelines available at the time, the potential for endocrine effects may not have been fully investigated.

The RMS recommends that the potential for endocrine disruption of lambda-cyhalothrin is reconsidered when EU harmonised guidance is established based on the work and final conclusions of the EC work on defining criteria to identify endocrine disrupting substances.

9 Okkerman, P.C. and Groshart, Ch., 2000, Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption – preparation of a candidate list of substances as a basis for priority setting. BKH, The Netherlands.

10 Okkerman, P.C. and van der Putte, I., 2002, Endocrine disrupters: Study on gathering information on 435 substances with insufficient data. RPS BKH, The Netherlands.

3.2. Decision regarding Inclusion in Annex I

The active substance *lambda*-cyhalothrin shall be included in Annex I to Directive 98/8/EC as an active substance for use in product-type **18** (insecticides, acaricides and products to control other arthropods), subject to the following specific provisions:

- The active substance, *lambda*-cyhalothrin, as manufactured, shall have a minimum purity of 900 g/kg.

- Products authorised for professional use shall be used with appropriate personal protective equipment unless it can be demonstrated in the application for product authorization that risks to professional users can be reduced to an acceptable level by other means.

- In view of the risks identified for aquatic and terrestrial ecosystems for the indoor/outdoor uses in, on or around domestic/commercial buildings which may result in emissions to STP, products shall not be authorised for this use unless it can be demonstrated that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

- In view of the risks identified for aquatic ecosystems for the use in poultry farming connected to STP, products shall not be authorised for this use unless it can be demonstrated that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

- When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment.

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

Study reports submitted to demonstrate the efficacy of formulations OXYFLY and Demand/ICON CS were brief and studies were generally not performed according to guidelines. The data is considered sufficient for a decision on Annex I inclusion of *lambda*-cyhalothrin, but efficacy data should be thoroughly assessed at product authorisation to check that the product claims are justified.

Since the intended uses of OXYFLY and Demand/ICON CS has been changed during the review of *lambda*-cyhalothrin, Member States should evaluate the product labels at product authorisation, in particular intended uses and provisions.

Exposure during manufacture of the active substance and formulations has not been considered in this CA report as it is assumed to be within the scope of other legislation on worker safety.

Exposure of non-professional operators has not been considered in this CA report since the intended use stated for OXYFLY and Demand/ICON CS is professional use only. If the intended use will be extended in the future, exposure of non-professional operators must be assessed.

Exposure of livestock and human exposure via food of animal origin has not been considered as there is currently no common procedure available for animal exposure assessments and food risk assessments of biocides. Harmonised guidance is expected to become available during 2011 and where relevant, this guidance should be applied at authorisation of biocidal products containing *lambda*-cyhalothrin.

Exposure of pets has not been considered in this CA report. Depending on the intended use of a biocidal product, this scenario may be relevant for the risk assessment at future authorisation processes.

When authorizing products containing *lambda*-cyhalothrin, Member States should review the uses assessed, input parameters and the assumptions made in the exposure assessments presented in Doc IIB. In case more recent harmonized guidance is available, this should be considered at product authorization.

In the absence of further information regarding possible preferential degradation and/or conversion of the enantiomers of *lambda*-cyhalothrin it has been assumed in this evaluation that the 1:1 ratio of the two enantiomers remains after application. The higher potency of the single enantiomer gamma-cyhalothrin has thus not been considered in this risk assessment of *lambda*-cyhalothrin. When further guidance on risk assessment of active substances with isomeric composition becomes available, this should be considered at product authorisation.

The human health risk assessments performed are based on an in-use concentration of 0.05% (50 ml product in 10L water for treating 200m^2 (25 mg a.i./m^2)) for all intended uses of OXYFLY 10CS and Demand/ICON10CS. For higher in-use concentrations/application rates, new human health risk assessments are needed.

When authorizing products containing *lambda*-cyhalothrin, the relevance of the AEL derived for the inhalation route should be considered in the risk assessments. The operator assessments in this CA report have been made assuming application of OXYFLY 10CS and Demand/ICON10CS at low pressure (knapsack sprayer, 1-3 bar). Due to the expected droplet size generated, droplets inhaled are assumed to be managed by the mucociliary escalator and should thus not reach the alveoli. At product authorisation, Member States can prescribe that equipment appropriate to prevent formation of droplets of respirable size should be used.

The secondary exposure assessments of bystanders to OXYFLY 10CS and Demand/ICON10CS are made assuming limited access to treated areas. The use considered for Demand/ICON10CS is indoor treatment (living room, non-food area) in cracks and crevices at wall/floor junctions and spot treatment at inaccessible locations. It is assumed that crack and crevice treatments at wall/floor junctions can result in exposure via intake of residues transferred to finger-tips only. At product authorisation, Member States can prescribe that appropriate equipment should be used to ensure that treatments are targeted to cracks and

crevices. For spot treatment at locations inaccessible after treatment, it is assumed that no exposure occurs. For all other use areas, new risk assessments of secondary exposure are needed.

When authorising formulations containing *lambda*-cyhalothrin, Member States should evaluate the need for appropriate risk reducing measures. In case dermal exposure can be expected, dermal protective equipment should be used to avoid paraesthesia reactions. The results of the exposure assessments show that gloves and cotton overalls should be worn by operators applying formulations containing 0.05% OXYFLY and Demand/ICON CS. Considering that the exposure level is only slightly below the AEL and that some users may be exposed also during post-application activities, respiratory protection should be recommended at product authorisation.

When authorising formulations containing *lambda*-cyhalothrin, Member States should pay particular attention to the exposure of children and pregnant women bearing in mind the uncertainties perceived by the RMS from the submitted data regarding the sensitivity of immature animals and that multiple exposures of children may occur as a result of the various uses of the active substance. In order to protect children from exposure to *lambda*-cyhalothrin, Member States may consider risk mitigation measures such as specifying conditions on use area, application method, type of formulation etc when granting authorisation of a product.

The environmental exposure assessment for both products was based on the maximum application rate of 0.25 mL product/m^2. Default areas treated were assumed for the application of Demand/ICON 10CS indoor; 2 m^2 (domestic houses) and 9.3 m^2 (commercial buildings). Default removal by wet cleaning (25%) was assumed. For Demand/ICON 10CS it was assumed that 0.815% of houses/buildings within an STP catchment are treated on the same day. For indoor applications of OXYFLY 10CS in animal houses (dairy cattles; pigs (sows in group); poultry (chicken, broilers)) it was assumed that 30% of the wall+roof area is treated. For the outdoor applications of both products, it was assumed that 10% of the wall area is treated. Further, the run-off fraction from walls during application outdoors was assumed to be zero, reflecting the label instruction “Spray to just before run off”, and the fraction washed-off by rain was refined to a value 0.27.

Risks to aquatic and terrestrial ecosystems were identified for several of the scenarios assessed and these risks need to be considered when products are authorised at MS level. All other areas of use/scenarios than those covered by this CA report need to be carefully assessed with regard to environmental risks in case of future product authorisations.

The need to address any specific national conditions and/or undertake regional assessments should be considered, as only local environmental risk assessments have been carried out in this evaluation.

When evaluating products containing *lambda*-cyhalothrin, Member States should take into account cumulative exposure from biocidal uses of *lambda*-cyhalothrin (in accordance with Article 10(1) of Directive 98/8/EC) using agreed EU guidance where possible.

3.4. Requirement for further information

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

As agreed at TM II 2010 an on-going study on rate of degradation in soils may be requested and considered at MS level (expected date of finalisation: Q2/Q3 of 2011).

3.5. Updating this Assessment Report

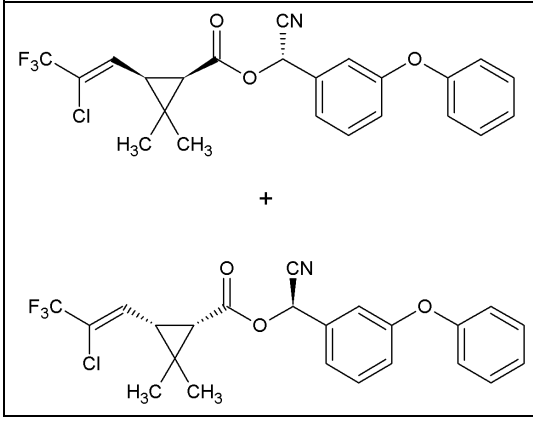
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any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

Appendix I: List of endpoints

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

Active substance (ISO Common Name)	*lambda*-cyhalothrin
Product-type	PT 18

Identity

Chemical name (IUPAC)	Reaction mass of (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate (1:1)
Chemical name (CA)	Cyclopropanecarboxylic acid, 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-, cyano(3-phenoxyphenyl)methyl ester, [1-alpha(S*),3-alpha(Z)]-(+-)-
CAS No	91465-08-6
EC No	415-130-7
Other substance No.	CIPAC: 463
Minimum purity of the active substance as manufactured (g/kg or g/l)	900 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None of the impurities in technical *lambda*-cyhalothrin are considered relevant
Molecular formula	$C_{23}H_{19}ClF_3NO_3$
Molecular mass	449.9 g/mol
Structural formula	

Physical and chemical properties

Melting point (state purity)	49.2°C (99.0%)
Boiling point (state purity)	Not relevant; decomposition
Temperature of decomposition	275°C (99.0%)
Appearance (state purity)	White solid with no characteristic odour (99.0%) Beige solid with no characteristic odour (96.5%)
Relative density (state purity)	1.288 (85.9%)
Surface tension	Not relevant as the solubility in water is < 1 mg/l
Vapour pressure (in Pa, state temperature)	2 x 10^{-7} Pa at 20°C (extrapolated; 99.0%)
Henry's law constant (Pa m^3 mol^{-1})	1.8 x 10^{-2} (solubility at pH 6.5)
Solubility in water (g/l or mg/l, state temperature)	At 20°C (99.0%): pH 5 buffer: 4 µg/l
	pH 9.2 buffer: 4 µg/l
	pH 6.5 distilled water: 5 µg/l
Solubility in organic solvents (in g/l or mg/l, state temperature)	At 21°C (96.5%): > 500 g/l in methanol, acetone, dichloromethane, toluene, ethyl acetate and hexane
Stability in organic solvents used in biocidal products including relevant breakdown products	Based on the storage stability of the formulated products (see respective document II-B), *lambda*-cyhalothrin is considered chemically stable in the solvent which is used/present in the product.
Partition coefficient (log P_{OW}) (state temperature)	In distilled water and 20°C (pH not stated; 99.0%): log Pow = 7.0
	No pH-effect anticipated as *lambda*-cyhalothrin cannot dissociate within the environmentally relevant pH range
Hydrolytic stability (DT_{50}) (state pH and temperature)	See chapter 4 below
Dissociation constant	Not relevant as *lambda*-cyhalothrin has no functional groups with alkaline or acidic properties
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	In methanol (99.0%): λmax [nm] ε (l mol-1.cm-1) 254 1090 277 2070

	Very low to no absorption above 290 nm.
Photostability (DT_{50}) (aqueous, sunlight, state pH)	See chapter 4 below
Quantum yield of direct phototransformation in water at Σ > 290 nm	See chapter 4 below
Flammability	Flammability: Not considered appropriate as *lambda*-cyhalothrin, depending on purity and the manufacturing process, is either a low melting point solid or a viscous liquid Flash-point: 83 ± 2°C (85.9%) Auto-flammability: 380°C (85.9%)
Explosive properties	Based on the structure *lambda*-cyhalothrin is not considered explosive

Classification and proposed labelling

with regard to physical/chemical data	None
with regard to toxicological data	T+, R28 or T, R25, T+, R26 and Xn, R21 GHS[11]: Acute Tox. 3, H301 or Acute Tox.2, H300 Acute Tox. 2, H330, Acute Tox. 4, H312
with regard to fate and behaviour data	N, R53
with regard to ecotoxicological data	N, R50
	GHS[9]:Aquatic Chronic, H400/410

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	GC-FID
Impurities in technical active substance (principle of method)	See the confidential annex

Analytical methods for residues

Soil (principle of method and LOQ)	GC-ECD and GC-MSD (LOQ 0.01 mg/kg)
Air (principle of method and LOQ)	GC-MSD (LOQ 0.25 µg/m^3)
Water (principle of method and LOQ)	GC-MSD with three fragment ions for quantification/confirmation (LOQ 2 ng/l expressed as cyhalothrin which is the formed mixture in water at pH >8 due to epimerisation)
Body fluids and tissues (principle of method and LOQ)	Multi residue method DFG Method S 19 (modular extraction, GPC and GC-MS with three fragment ions for quantification/confirmation) LOQ 0.01 mg/l blood, 0.01 mg/kg tissues
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not considered required as the intended uses are not anticipated to result in significant residues. However two methods are provided which can be used in case of suspected contamination: GC-MSD (LOQ 0.01 mg/kg for hops, dry beans and wheat grain) GC-MSD (LOQ 0.01 mg/kg for oil seed-rape, soy bean and olive) The validation data is not in compliance with SANCO/825/00 rev.7 but no further data is required at this stage

11 Based on the translation table in Annex VII of Regulation (EC) No 1272/2008.

Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not confirmed needed due to the lack of a food risk assessment (method referred to for blood and tissues is applicable with the possible need for an additional independent laboratory validation)

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Incomplete oral absorption in rats, dogs and humans with large intra-species variations. Extensive metabolism with ester cleavage and rapid excretion of conjugates. Due to the large intra-species variation observed, a reasonable worst case oral absorption of approximately 50% (based on the lower range values of 40%, 48 and 50% in rats, dogs and humans respectively) is proposed.
Rate and extent of dermal absorption:	Active substance: <22% (human volunteers) Concentrate (100 g/L)/dilution (0.4 g/L) of similar CS formulation: 1% (in vitro study, human epidermis)
Distribution:	Widely distributed, rapidly cleared.
Potential for accumulation:	Approximately 2-3% of dose retained in white fat for 7 days after single administration. Half-lives of 23 and 30.5 days for cyhalothrin in fat demonstrated in two separate studies in rats.
Rate and extent of excretion:	Approximately 90 % of the administered dose recovered in urine and faeces after seven days. No excretion via expired air.
Toxicologically significant metabolite(s)	Metabolites not considered toxicologically significant.

Acute toxicity

Rat LD_{50} oral	Males: 79 mg/kg bw Females: 56 mg/kg bw Classification: T, R25; Acute Tox. 3, H301 Mouse: M/F: 19.9 mg/kg bw Classification: T+, R28; Acute Tox.2, H300
Rat LD_{50} dermal	Males: 632 mg/kg bw Females: 696 mg/kg bw Classification: Xn, R21; Acute Tox. 4, H312
Rat LC_{50} inhalation	0.066 mg/l (4 hours exposure, nose-only) Classification: T+, R26; Acute Tox. 2, H330
Skin irritation	Non-irritant Classification not required
Eye irritation	Slight irritant Classification not required
Skin sensitization (test method used and result)	Negative at 1% challenge (Guinea pig maximisation test)

Repeated dose toxicity

Species/ target / critical effect	Rat (oral): Reduced bodyweight gain. Hepatic changes including increased liver weight; increased aminopyrine-N-demethylase activity and smooth endoplamic reticulum proliferation considered to represent adaptive responses to increased liver work load. Rat (dermal): Reduced bodyweight gain, neurological effects. Rat (inhalation): Reduced bodyweight gain, neurological effects. alveolitis Dog (oral): neurological effects (unsteadiness, lack of muscular co-ordination), gastro-intestinal effects and reduced food intake.
Lowest relevant oral NOAEL / LOAEL	Dog, 52 week (capsule) NOAEL: 0.5 mg/kg bw/day LOAEL: 3.5 mg/kg bw/day Dog, 6 week (capsule) NOAEL: 0.75 mg/kg bw/day LOAEL: 1.5 mg/kg bw/day
Lowest relevant dermal NOAEL / LOAEL	Rat, 21 day: NOAEL: 10 mg/kg bw/day LOAEL: 50 mg/kg bw/day
Lowest relevant inhalation NOAEL / LOAEL	Rat, 21 day NOAEL: 0.3 µg/L (0.08 mg/kg bw) LOAEL: 3.3 µg/L (0. 9 mg/kg bw)

Genotoxicity	No genotoxic effects of *lambda*-cyhalothrin observed in the standard in vitro test package, reinforced with additional UDS test and in vivo mouse micronucleus test.

Carcinogenicity

Species/type of tumour	No evidence of carcinogenicity in rats. Increased incidence of mammary adenocarcinomas in female mice (above incidence in concurrent and historical controls). The results of the studies performed do not give sufficient evidence for classification of

	lambda cyhalothrin as a carcinogenic substance.
lowest dose with tumours	Mice (cyhalothrin): 100 ppm (11 mg/kg/day)[12]

Reproductive toxicity

Species/ Reproduction target / critical effect	Rat/reduced bodyweights with associated effects on mean litter weight. No adverse effects on adult fertility or reproduction.
Lowest relevant reproductive NOAEL / LOAEL	Parental reproductive effects (cyhalothrin): NOAEL: 2 mg/kg bw/day (30 ppm)[12] LOAEL: 5 mg/kg bw/day (100 ppm) [12] Offspring (cyhalothrin): NOAEL: 2 mg/kg bw/day (30 ppm) [12] LOAEL:5 mg/kg bw/day (100 ppm) [12]
Species/Developmental target / critical effect	Rat/no adverse foetal findings/reduced maternal body weight gain and food intake, uncordinated movements observed in two adult animals Rabbit/no adverse foetal findings/maternal body weight loss and reduced food consumption
Developmental toxicity	
Lowest relevant developmental NOAEL / LOAEL	Maternal (cyhalothrin): NOAEL: 10 mg/kg bw/day (rat, rabbit) [12] LOAEL: 15 mg/kg bw/day (rat) [12]; 30 mg/kg bw/day (rabbit) [12] Developmental (cyhalothrin): NOAEL/LOAEL: >15 mg/kg (rat)[12]/ ≥30 mg/kg/day (rabbit)[12]

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	Dog Neurological effects noted in the repeated dose toxicity studies: Ataxia (unsteady gait, incoordination or straddled gait/recumbancy) subdued behaviour, convulsions, whole body tremors, often severe and accompanied by recumbancy and hyperaesthesia.

[12] It has been observed that data indicate a higher potency of *lambda*-cyhalothrin compared to cyhalothrin (Doc I, section 2.2.1.1.1)"

	Mouse (cyhalothrin) Increased incidence of piloerection, slightly higher incidence of fighting, emaciation, pallor and hyperactivity in all cyhalothrin-treated males Rat Neurological effects in the acute neurotoxicity study: Decreased activity, ataxia, reduced stability and/or tiptoe gait, salivation, piloerection, upward curvature of spine and/or urinary incontinence. Tremors in one female. Effects observed in the developmental neurotoxicity study: Dams: reduced overall bodyweight gain during gestation. Offspring: reduced bodyweights and reduced pup survival, no DNT effects observed,
Lowest relevant developmental NOAEL / LOAEL.	<u>Repeated dose toxicity:</u> NOAEL (dog) 0.5 mg/kg bw LOAEL (dog) 3.5 mg/kg bw NOAEL (mouse) 20 ppm (1.8 mg/kg bw) LOAEL (mouse) 100 ppm (9 mg/kg bw) <u>Acute neurotoxicity:</u> NOAEL: 10 mg/kg bw LOAEL: 35 mg/kg bw <u>DNT study (maternal, reduced body weight gain):</u> NOAEL maternal: 60 ppm (4.9mg/kg bw/day) LOAEL maternal: 150 ppm (11.4 mg/kg bw/day) NOAEL/LOAEL developmental: maternal dose levels ≥150 ppm (11.4) NOAEL offspring: 60 ppm (10.7 mg/kg bw) LOAEL offspring: 150 ppm (26.3 mg/kg bw/day)

Other toxicological studies

.....	

Medical data

.....	Cases of subjective facial sensation (also known as 'SFS' or paraesthesia) have occurred at all stages of *lambda*-

cyhalothrin handling, from small-scale laboratory work to commercial synthesis and formulation operations. Subjective facial sensation is a collection of skin-associated symptoms, including itching, tingling, burning, cold or numbness due to skin contact with *lambda*-cyhalothrin. The face is most commonly affected. These symptoms can cause discomfort and may in some individuals last for up to 24 hours after exposure. Recovery is apparently complete and there is no evidence of lasting damage.

Summary	Value	Study	Safety factor
Non-professional user	No	No	No
ADI (acceptable daily intake, external long-term reference dose)	0.005	Dog, 1 year (IIIA, 6.4.1-04)	100
AEL-S (operator, bystander) Acute exposure	0.0038	Dog, 6 weeks (IIIA, 6.4.1-04)	100
Medium-term/Long-term	0.0025	Dog, 1 year (IIIA, 6.4.1-04)	100
ARfD (acute reference dose)	0.0075	Dog, 6 weeks (IIIA, 6.4.1-04)	100
Professional user	Yes	Yes	Yes
Reference value for inhalation (proposed OEL)	0.0008 mg/kg bw (0.003 µg/L)	21-day rat	100
Reference value for dermal absorption	1% (concentrate, dilution of similar CS formulation (0.4 g/L))	In vitro, human epidermis (IIIB, 6.4-02 (addendum))	

Acceptable exposure scenarios (including method of calculation)

Professional users	The exposure level in professional operators spraying surfaces and into cracks and crevices during 120 minutes per day is acceptable provided that gloves and a cotton overall is worn. (modelling conducted according to the TNsG, Spray Model 1 "Low pressure insecticide application. Professional operators mixing and loading liquids and powders in compression applicators, and applying at 1 or 3 bar pressure as a coarse or medium spray, indoors and outdoors, overhead and downwards")

Production of active substance:	Scenario not included in the assessment as it is assumed to be within the scope of other legislation on worker safety.
Formulation of biocidal product	Scenario not included in the assessment as it is assumed to be within the scope of other legislation on worker safety.
Intended uses	**OXYFLY 10CS** is intended for use as a low pressure spray in and around animal housing in areas where flies congregate or settle such as floors, walls, ceilings and around doors and windows or as a low pressure spray in crack and crevice treatment for the control of other insects. **Demand/ICON 10 CS** is intended for crack and crevice, or spot treatment in, on, and around buildings and structures and their immediate surroundings. Exposure assessment is made assuming exposure via finger-tips following treatment into crack and crevices at wall/floor junctions and that spot treatment at inaccessible locations results in no exposure.
Secondary exposure	**OXYFLY 10CS:** Infant (10 kg): Acceptable (calculation based on ingestion of all residues transferred to a skin surface area corresponding to the surface of palms (MOE=99, Risk ratio=1)) Schoolchild (31.8 kg): Acceptable (calculation based on ingestion of all residues transferred to a skin surface area corresponding to the surface of palms (MOE=117, Risk ratio=0.84) Alt. dermal exposure of a skin surface area corresponding to the surface of 60 palms) Adult (60 kg): Acceptable (calculation based on ingestion of all residues transferred to a skin surface area corresponding to the surface of palms (MOE=139, Risk ratio=0.71 for adult and MOE=93, Risk ratio=1.1 for adult worker) Alt. dermal exposure of a skin surface area corresponding to the surface of 72 palms in adult and 48 palms in workers) **Demand/ICON 10CS:** Infant: Acceptable (ingestion of all residues transferred to a skin surface area corresponding to the surface of 67 finger-tips).
Non-professional users	Not relevant. Professional use only.
Indirect exposure as a result of use	Low predicted exposure since groundwater and surface

	water used for drinking water are predicted to contain negligible levels of *lambda*-cyhalothrin from its use in biocidal products.

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 5 (25°): stable
	pH 7 (25°): essentially stable
	pH 9 (25°): DT_{50} 8.6 days (uncertain)
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Only little absorption above 290 nm wave-lengths. Photolytic degradation not expected to be a significant route of degradation in water.
Readily biodegradable (yes/no)	no study available
Biodegradation in seawater	no study available
Non-extractable residues	max. 33% of the AR on day 30, decrease to 17% day 98
Distribution in water / sediment systems (active substance)	Rapid dissipation from water: after 1 day 10-13% of AR was present as a.s. in the water phase, this amount decreased further thereafter. System with low organic carbon content in sediment: $DisT_{50}$ (dissipation from water): 14 hours $DegT_{50}$ (degradation in whole system): 13 days System with sediment rich in organic carbon: $DisT_{50}$ (dissipation from water): 5.6 hours $DegT_{50}$ (degradation in whole system): 21 days Geomean $DegT_{50}$: 17 days (20°), re-calculated to 32 days (12°) All DT_{50} values above single first order kinetics.
Distribution in water / sediment systems (metabolites)	Compound Ia13 : identified at max. 29% of AR (day 14), thereafter decreasing amounts. In system with sediment having low organic carbon content it was almost exclusively present in the water; in system with sediment rich in organic carbon the metabolite was present equally in sediment and water.

Route and rate of degradation in soil

Mineralization (aerobic)	36% of AR after 90 days (20°C)
Laboratory studies (range or median, with number	DT_{50lab} (20°C, aerobic): 36 days (1 soil)

13 Compound Ia: (1RS)-cis-3-(ZE-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylic acid; "cyclopropane acid"

of measurements, with regression coefficient)	Single first order kinetics. (Error level at which Chi^2-test passed: 8.6% (α=0.05)14) Compound Ia: DT_{50lab} (20°C, aerobic): 3.1, 4.0, 16 days (3 soils) Single first order kinetics15
	DT_{90lab} (20°C, aerobic): 121 days
	DT_{50lab} (12°C, aerobic): 69 days (calculated)
	degradation in the saturated zone: no study available
Field studies (state location, range or median with number of measurements)	DT_{50f}: 25, 28, 30, 82 days (4 locations in Germany) Single first order (linear regression r^2 = 0.82-0.98) Values only indicative, not used for risk assessment. DT_{50f}: 12, 33 days (2 sites, US, high summer temperatures) Single first order (linear regression r^2 = 0.99-1.0, but at one site late sampling points excluded, bi-phasic pattern of dissipation) Values only indicative, not used for risk assessment.
	DT_{90f}: 83, 84, 97, 272 days (Germany) DT_{90f}: 41, 110 days (US)
Anaerobic degradation	no study available; but study on cyhalothrin showed that degradation was slower when conditions were anaerobic: DT_{50} increased x 3.4. The same decrease in degradation rate can be expected for lambda-cyhalothrin.
Soil photolysis	no significant degradation observed
Non-extractable residues	lab study (20°C, aerobic): 17% after 90 days 17-32% of AR after 155 and 279 in US field study
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	Hydroxylated *lambda*-cyhalothrin (Compound XV) was the only metabolite accounting for >10% of AR; max. 12% of AR (day 60), thereafter decreased to 4.2% at the end of incubation (90 days). Comp. XV was found at lower amounts in US field study.
Soil accumulation and plateau concentration	no study available

Adsorption/desorption

Ka , Kd	Kd (distribution coefficient for adsorption, in mL/g): 1245-3180 in 4 soils,

14 Curve fitting was non-linear (data not log-transformed) therefore coefficient of determination is less relevant. Chi^2 statistics was used instead, as a measurement of goodness of fit (see FOCUS report Degradation kinetics, SANCO/10058/2005, June 2006).

15 In the study on Compound Ia r^2 were 0.96-0.98 (n=3) but curve fitting was non-linear with data not log-transformed so r^2 does not represent the "coefficient of determination" but is a measure of the fraction of the variation that is explained by the model. Visually the fit was good so DT_{50}s are considered acceptable.

Ka_{oc} , Kd_{oc}	1970-5880 in 5 other soils, 2400-7610 in 5 sediments; overall range (n=14): 1245-7610. Koc (Kd normalised for organic carbon content, in mL/g): 70,092-429,730 in 4 soils, 200,000-724,000 in 5 other soils, 110,000-518,000 in 5 sediments; overall range (n=14): 70,100-724,000.
pH dependence (yes / no) (if yes type of dependence)	*lambda*-cyhalothrin: no <u>Compond XV</u> Koc: 58000 - 92000 mL/g (6 soils, no pH dependence) <u>Compound Ia</u> Koc: 14 and 16 mL/g (pH 7.1 and 7.6) and 92 mL/g in a more acidic soil (pH 5.4)

Fate and behaviour in air

Direct photolysis in air	not likely to occur; only little absorption at wave-lengths above 290 nm
Quantum yield of direct photolysis	result considered uncertain
Photo-oxidative degradation in air	estimated T½ 0.51 days (12.2 hours), based on rate constant for gas-phase reaction with hydroxyl radicals 31.46 cm^3/molecule x sec and assuming a global (day + night) annual average OH-radical concentration of 0.5 x 10^6 molecules/cm^3.
Volatilization	≤12% loss from plants over 24 hours; essentially no volatilisation observed from soil (lab studies; wind speed 1-2 m/sec, 15-25°C)

Monitoring data, if available

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

Chapter 5: Effects on Non-target Species

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

Species	Time-scale	Endpoint	Toxicity[1] (µg/L)
Fish			
Leuciscus idus (Golden orfe)	Acute	96 h LC_{50}	0.078 (0.056-0.11)
Pimephales promelas (Fathead minnow)	Chronic	300 days NOEC	0.031
Invertebrates			
Gammarus pulex (Freshwater shrimp)	Acute	96 h, static EC_{50}	Neonates 0.0066 Juveniles 0.012 Adults 0.022
Gammarus pulex (Freshwater shrimp)	Acute	Various exposure durations, static	1 h - 0.253 3 h - 0.200 6 h - 0.044 12 h - 0.031 96 h - 0.0065
Hyalella azteca (Freshwater shrimp)	Acute	48h static EC_{50}	0.0019
Chaoborus sp. (phantom midge)	Acute	48h static EC_{50}	0.0022
Chironomus riparius	Acute	48h static EC_{50}	0.5 – 5.0
Daphnia magna (waterflea)	Chronic	21 days NOEC	0.00198
Chironomus riparius	Chronic	28 days NOEC	0.015 total emergence
Chironomus riparius	Chronic, spiked sediment	28 days NOEC	93 µg/kg ww total emergence
Algae			
Pseudokirchneriella subcapitata	Chronic	72 h EC_{50}	>130 (biomass & growth)
Microorganisms			
Pseudomonas putida	6 hours	EC_{50}	5
Higher tier data			

Ditch microcosm, Macrophyte-dominated system	Chronic	Invertebrate NOEC and NOAEC	No NOEC could be established (<0.010 µg/L nominal) due to effects at the lowest test concentration NOAEC 0.010 µg/L (nominal) Based on *Chaoborus obscuripes* Recovery at higher test concentrations 45 days after the 1st treatment.
In situ bioassays, Macrophyte-dominated system	Acute	NOEC	No NOEC could be established (<0.010 µg/L nominal) due to observed effects at the lowest test concentration.
In situ bioassays, Macrophyte-dominated system	Chronic	NOAEC	NOAEC 0.050 µg/L (nominal); 0.0175 µg/L (mean measured) Based on *Chaoborus obscuripes* Re-colonisation potential after 8-14 days at higher test concentrations.

[1] results reported as mean measured unless otherwise stated

Metabolites

Species	Time-scale	Endpoint	Toxicity[1] (µg/L)
Compound 1a			
Oncorhynchus mykiss (Rainbow trout)	Acute	96 h LC_{50}	>10800
Lepomis macrochirus (Bluegill sunfish)	Acute	96 h LC_{50}	>14000
Daphnia magna (waterflea)	Acute	48 h, static, EC_{50}	105000 (nom)
Oncorhynchus mykiss (Rainbow trout)	Acute	96 h LC_{50}	>10800
Compound V			
Daphnia magna (waterflea)	Acute	48 h, static, EC_{50}	85000

[1] results reported as mean measured unless otherwise stated

Effects on earthworms or other soil non-target organisms

Acute toxicity to *Eisenia foetida* (Annex IIIA, point XIII.3.2)	LC_{50} technical >247 mg/kg ww soil (corrected to standard moisture and organic carbon according to TGD)
Reproductive toxicity to *Eisenia foetida* (Annex IIIA, point XIII.3.2)	See field studies for long-term effects data
Reproductive toxicity to *Folsomia candida* (Annex IIIA, point 3.2)	28 day NOEC 1.29 mg/kg ww soil
Field studies	
Three year study on earthworms - No adverse effects on natural populations of earthworms following annual spray applications of *lambda*-cyhalothrin at a rate of 250 g a.s./ha (equivalent to 0.029 mg/kg ww soil assuming an incorporation depth of 5cm and a TGD default bulk density of 1.7 g/cm^3).	

Effects on soil micro-organisms

Nitrogen mineralization	No relevant effects at **1.1 mg/kg ww soil**
Carbon mineralization	No relevant effects at **1.1 mg/kg ww soil**

Effects on terrestrial vertebrates

Acute toxicity to mammals	Mice LD_{50}: 20 mg/kg bodyweight
Acute toxicity to birds	Mallard duck: LD_{50}: >3950 mg/kg bw
Dietary toxicity to birds	Mallard duck and Bobwhite quail: 3978 and >5300 ppm
Reproductive toxicity to birds	Mallard duck NOEC =30 ppm in the diet, corresponding to an estimated daily dose of 3 mg as/kg bw per day.
Long term toxicity to mammals	Rat and mouse NOAEL: 0.6 mg/kg bw/day

Effects on honeybees

Acute oral toxicity	LD_{50} oral = 0.91 µg as/bee
Acute contact toxicity	LD_{50} contact = 0.038 µg as/bee

Field

A considerable amount of field data were submitted by the applicant, but were not further evaluated by the RMS. Based on the available laboratory studies, the risk is considered to be acceptable for the biocidal use of *lambda*-cyhalothrin.

Effects on other beneficial arthropods

Acute contact toxicity to juvenile *Typhlodromus pyri*	LR_{50} = 0.0037 g as/ha in a study with Karate' with Zeon Technology 100 g/L

Field tests

A considerable amount of field data were submitted by the applicant, but were not further evaluated by the RMS.

Bioconcentration

Bioconcentration factor (BCF)	850, 7340 and 2240 in muscle, viscera and whole fish respectively for carp 4299-4982 in whole body in fathead minnow (FFL-study) 1300 – 3400 (^{14}C-*lambda*-cyhalothrin) in invertebrates Normalised for fat content according to OECD TG, the corresponding whole fish values for carp was 1672. For fathead minnow, normalisation was not possible due to lack of information on fat content. These values are used for the PBT assessment.
Depuration time (DT_{50}) (DT_{90})	Not stated in the report During 28 days depuration approximately 80% of the accumulated radioactivity was eliminated from the fish tissues in the carp study.
Level of metabolites (%) in organisms accounting for > 10 % of residues	Not stated in study report

Chapter 6: Other End Points

Appendix II: List of Intended Uses

The innate efficacy of the active substance was tested against House fly (*Musca domestica*) and against German cockroach (*Blatella germanica*) and American cockroach (Periplaneta *americana*). Although the results were very briefly reported and summarised, the data is considered sufficient to demonstrate that *lambda*-cyhalothrin is effective against these organisms.

The representative formulations OXYFLY 10CS and Demand/ICON 10CS are water based suspensions with microcapsules containing *lambda*-cyhalothrin.

OXYFLY 10CS is used in and around animal houses (e.g. open poultry houses, pig farms, cattle houses and other animal premises) and Demand/ICON 10CS is used in, on and around buildings such as factories, hospitals or domestic properties.

OXYFLY 10CS is applied as a low pressure spray in areas where flies congregate or settle such as floors, walls, ceilings and around doors and windows or as a low pressure spray in crack and crevice treatment for the control of other insects. Demand/ICON 10CS is used as crack and crevice treatment or spot treatment but the main use is claimed to be as a crack and crevice treatment against cockroaches.

A number of field or laboratory studies performed with products containing *lambda*-cyhalothrin were included to support the efficacy of the accompanying products OXYFLY 10CS and ICON/Demand 10CS against Garden ant (*Lasius niger*) House fly (*Musca domestica*), Oriental Cockroach (*Blatta orientalis*) yellow fever mosquito (*Aedes aegypti*), German cockroach (*Blatta germanica*) and a range of incidental pests. Some of the tests were performed with EC (emulsifiable concentrate) or WP (wettable powder) formulations. The relevance of this data for OXYFLY 10CS and Demand/ICON 10CS was justified by bridging data demonstrating that the biological effect of *lambda*-cyhalothrin in DEMAND CS and a 10% WP formulation was similar in treatment of *Blatella germanica*.

Studies performed with the products indicated that for most species good efficacy was found at approximately 12 mg active substance /m^2 however a rate of 25 mg /m^2 was necessary to achieve 4 months residual control of *Aedes aegypti* when applied to a porous surface. When applied at the lower rates the length of residual control was reduced. In general, study reports were brief and the studies were not performed according to any guidelines or GLP standards. No further data is required at this stage of the process however efficacy of products should be thoroughly checked at product authorisation to verify that label claims are justified.

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application				Remarks
(a)			(c)	Type (d-f)	Conc. of as (i)	method kind (f-h)	number min max	interval between applications (min)	mg as/L or m^2	(m)
Insecticide	all	OXYFLY 10CS	Flies and other insects in and around animal housing.	CS	9.6% w/w	For fly control, application is as a low pressure spray in areas where flies congregate or settle such as floors, walls, ceilings and around doors and windows. For other insects, the product is applied as a low pressure spray as a crack and crevice treatment. Professional - in situ spraying. Spray until just before run off.	1	In general, from 6 weeks up to 4 months during fly season	50 mL prod/ 10 L water ca 25 mg as/m^2	Not used in mixtures
Insecticide	all	Demand/ ICON 10CS	Cockroaches, ants, and other crawling insects	CS	9.6% w/w	For use as a crack and crevice, or spot treatment in, on, and around buildings and structures and their immediate surroundings[1]. Professional - in situ spraying. Spray to just before run-off.	1	From 6 weeks up to 4 months	Clean-out rate: 25mL prod/10 L water (ca 10 mg as/ m^2) Main-tenance rate: 50 mL prod/10 L water (ca 20 mg as/ m^2)	Not used in mixtures

[1] According to information given by the applicant at the Technical Meeting for Biocides in February 2010, the product is a cracks and crevices spray applied to wall-floor junctions, as spot treatment for inaccessible items, such as behind fridges, cookers, or under sinks. It is not intended to be used as a broadcast spray across large surfaces of living areas (TMI10 minutes)

[2] According to information given by the applicant in April 2010, applications for heavy infestations, outdoor infestations, and difficult surfaces, require the use of higher rates than routine treatments and those conducted indoors. Routine treatments, which may be preventative in nature, are made at the lower 'maintenance rate' (see table). The treatments of established infestations, or where longer residual effect is required, require the use of the higher 'clean out' rate. Application volume should be as a minimum 40ml/m2 (4 litres diluted product per 100m^2).
However, if 50 mL diluted product would be applied per m^2, the "clean out" application rate would equal that of OXYFLY 10CS

(approx 25 mg *lambda*-cyhalothrin/m^2) Concentrations used in exposure assessments are 25 mg/m^2 and in-use concentration of 0.05%.

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

Appendix III: List of studies

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

Section No.	**Author(s)**	**Year**	**Title.** **Source (where different from company)** **Company, Report No.** **GLP (where relevant) / (Un)Published**	**Data protection claimed** **Y/N**	**Owner**
IIIA 3.1.1(01)	Wollerton C.	1984	PP321: Physico-Chemical Data File. ICI plant protection division Report No. RJ0366B, 18/07/1984 GLP, Not Published	Y	SYN
IIIA 3.1.2(01)	Wollerton C.	1984	PP321: Physico-Chemical Data File. ICI plant protection division Report No. RJ0366B, 18/07/1984 GLP, Not Published	Y	SYN
IIIA 3.1.3(01)	Jackson W A	1994	Determination of Some Physico-Chemical Properties of *Lambda*-cyhalothrin TGAI. Zeneca Fine Chemicals Report number HT 94/140. R1C0719 28/9/1994 GLP, Not Published	Y	SYN
IIIA 3.2(01)	Wollerton C.	1984	PP321: Physico-Chemical Data File. ICI plant protection division Report No. RJ0366B, 18/07/1984 GLP, Not Published	Y	SYN
IIIA 3.3.1(01)	Wollerton C.	1984	PP321: Physico-Chemical Data File. ICI plant protection division Report No. RJ0366B, 18/07/1984 GLP, Not Published	Y	SYN
IIIA 3.3.2(01)	Wollerton C.	1984	PP321: Physico-Chemical Data File. ICI plant protection division Report No. RJ0366B, 18/07/1984 GLP, Not Published	Y	SYN
IIIA 3.3.3(01)	Wollerton C.	1984	PP321: Physico-Chemical Data File. ICI plant protection division Report No. RJ0366B, 18/07/1984 GLP, Not Published	Y	SYN
IIIA 3.4(01)	Wollerton C.	1984	PP321: Physico-Chemical Data File. ICI plant protection division Report No. RJ0366B, 18/07/1984 GLP, Not Published	Y	SYN

Section No.	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data protection claimed Y/N	Owner
IIIA 3.5(01)	Wollerton C.	1984	PP321: Physico-Chemical Data File. ICI plant protection division Report No. RJ0366B, 18/07/1984 GLP, Not Published	Y	SYN
IIIA 3.6(01)	Wollerton C.	1984	PP321: Physico-Chemical Data File. ICI plant protection division Report No. RJ0366B, 18/07/1984 GLP, Not Published	Y	SYN
IIIA 3.7(01)	Wollerton C.	1984	PP321: Physico-Chemical Data File. ICI plant protection division Report No. RJ0366B, 18/07/1984 GLP, Not Published	Y	SYN
IIIA 3.9(01)	Wollerton C.	1984	PP321: Physico-Chemical Data File. ICI plant protection division Report No. RJ0366B, 18/07/1984 GLP, Not Published	Y	SYN
IIIA 3.10(01)	Wollerton C.	1984	PP321: Physico-Chemical Data File. ICI plant protection division Report No. RJ0366B, 18/07/1984 GLP, Not Published	Y	SYN
IIIA 3.10(02)	Jackson W A	1994	Determination of Some Physico-Chemical Properties of *Lambda*-cyhalothrin TGAI. Zeneca Fine Chemicals Report number HT 94/140. R1C0719 28/9/1994 GLP, Not Published	Y	SYN
IIIA 3.11(01)	Jackson W A	1994	Determination of Some Physico-Chemical Properties of *Lambda*-cyhalothrin TGAI. Zeneca Fine Chemicals Report number HT 94/140. R1C0719 28/9/1994 GLP, Not Published	Y	SYN
IIIA 3.12(01)	Jackson W A	1994	Determination of Some Physico-Chemical Properties of *Lambda*-cyhalothrin TGAI. Zeneca Fine Chemicals Report number HT 94/140. R1C0719 28/9/1994 GLP, Not Published	Y	SYN
IIIA 3.13(01)	Wollerton C.	1984	PP321: Physico-Chemical Data File. ICI plant protection division Report No. RJ0366B, 18/07/1984 GLP, Not Published	Y	SYN
IIIA 3.15(01)	Jackson W A	1994	Determination of Some Physico-Chemical Properties of *Lambda*-cyhalothrin TGAI. Zeneca Fine Chemicals Report number HT 94/140. R1C0719 28/9/1994 GLP, Not Published	Y	SYN
IIIA 3.16(01)	Jackson W A	1994	Determination of Some Physico-Chemical Properties of *Lambda*-cyhalothrin TGAI. Zeneca Fine Chemicals Report number HT 94/140.	Y	SYN

Section No.	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data protection claimed Y/N	Owner
			R1C0719 28/9/1994 GLP, Not Published		
IIIA 4.1(01)	Duffin M R	1995	The Determination of *Lambda*-Cyhalothrin in Technical Material by Capillary Gas Chromatography. Ref AMP10019-01A. GLP, Unpublished	Y	SYN
IIIA 4.1(02a)	Duffin M R	2002c	The determination of lambda-cyhalothrin and associated impurities in technical material by capillary gas chromatography Syngenta, Jealott's Hill International, Bracknell, Berkshire, UK Report No AMP10020-02B Not GLP, Unpublished CONFIDENTIAL	Y	SYN
IIIA 4.1(02b)	Duffin M R	2002e	Validation of method - The determination of lambda-cyhalothrin and associated impurities in technical material by capillary gas chromatography Syngenta, Jealott's Hill International, Bracknell, Berkshire, UK Report No RJ3285B GLP, Unpublished CONFIDENTIAL	Y	SYN
IIIA 4.1(03)	Duffin M R	1995	The Determination of *Lambda*-Cyhalothrin and associated impurities in Technical Material by Capillary Gas Chromatography. Ref AMP10020-01B. (see confidential attachment) GLP, Unpublished	Y	SYN
IIIA 4.2(01)a	Sapiets A	1997	Standard Operating Procedure Residue Analytical Method Number 93/03. The Determination of Residues of *Lambda*-cyhalothrin (PP321) in Soil. GLP, Unpublished	Y	SYN
IIIA 4.2(02)a	Crook S J	2000a	Provision of Additional Validation Data to Supplement Residue Analytical Method SOP RAM 93/03. Technical Letter J5838/01 GLP, Unpublished	Y	SYN
IIIA 4.2(03)a	Sapiets A	1998	Standard Operating Procedure Residue Analytical Method Number 124/02. The Determination of Residues of PP321 in Hydrosoil. GLP, Unpublished	Y	SYN

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IIIA 4.2(01)b	Ryan J & Sapiets A	1993	*Lambda*-cyhalothrin: Validation of a Stepped Model to Determine Residues in Air. Jealott's Hill Research Station Report No RJ1525B GLP, Unpublished	Y	SYN
IIIA 4.2(02)b	Crook S J	2000b	Provision of Additional Validation Data and Confirmatory Analytical Conditions to Supplement Report RJ1525B: 'Lambda-cyhalothrin: Validation of a Stepped Model to Determine Residues in Air.' Technical Letter J5831/01. GLP, Unpublished	Y	SYN
IIIA 4.2(01)c	Robinson N J	2000	*Lambda*-cyhalothrin: Validation of a Residue Analytical Method for the determination of Residues in Environmental Water Samples. Jealott's Hill Report No. TMJ4367B. GLP, Unpublished	Y	SYN
IIIA 4.2(02)c	Robinson N Gemrot F Braid S	2010	Lambda-cyhalothrin – Analytical Method for the Determination of Residues of Lambda-cyhalothrin in Water. Final Determination by GC-MS GRM043.02A, January 2010 Syngenta Ltd, Jealott's Hill International Research Centre, Bracknell, Berkshire, RG42 6EY, UK	Y	SYN
IIIA 4.2(01)d	Hall M G	2000	*Lambda*-cyhalothrin: Determination in Human and Animal Plasma by GC-MS. Central Toxicology Laboratory Report No. CTL/R/1472 [TOX SERIES] GLP, Unpublished	Y	SYN
IIIA 4.2(02)d	Sapiets A	1993	The determination of residues of PP321 in products of animal origin – a GLC method using internal standard, ICI Agrochemicals, standard operating procedure no. RAM/086/02 Not GLP, Unpublished	Y	SYN
IIIA 4.2(03)d	Class T Kuhn T	2010	Lambda-cyhalothrin – Validation of the multi-Residue Enforcement DFG Method S19 for the Determination of Residues of Lambda-cyhalothrin in Animal Matrices and Blood. PTRL Europe Report No. B 1866 G. Syngenta File No. PP321_11381 GLP, Unpublished	Y	SYN
IIIA 4.3(01)	Crook, S. J.	1998a	RAM 302/01: Residue Analytical Method for the Determination of lambda-cyhalothrin in hops and dry crops Not GLP, Unpublished	Y	SYN
IIIA 4.3(02)	Crook, S. J.	1998b	RAM 311/01: Residue Analytical Method for the Determination of lambda-cyhalothrin in crops of	Y	SYN

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IIIA 5.3(01)	Weeks S Cross N Wege P	2002a	Evaluation of the contact activity of thiamethoxam against the house fly, *Musca domestica*. Syngenta Crop Protection Reprt no. IP/01/013B Not GLP, Unpublished	Y	SYN
IIIA 5.3(02)	Weeks S Cross N Wege P	2002b	Thiamethoxam: intrinsic activity against German and American cockroaches. Syngenta Crop Protection Reprt no. IP/01/012A Not GLP, Unpublished	Y	SYN
IIIA 5.3(03)	Weeks S Palmer J Wege P	2002c	The efficay of thiamethoxam against the yellow fever mosquito, *Aedes aegypti*. Syngenta Crop Protection Reprt no. IPP/01/02A Not GLP, Unpublished	Y	SYN
IIIA 6.1.1(01)		1985	PP321: Acute Oral Toxicity Studies.	Y	SYN
IIIA 6.1.1(02)		1984	PP321: Acute Oral Toxicity Studies.	Y	SYN
IIIA 6.1.2(01)		1985	PP321: Acute Dermal Toxicity Study.	Y	SYN
IIIA 6.1.3(01)		1987	PP321: 4-Hour Acute Inhalation Toxicity Study in the Rat.	Y	SYN
IIIA 6.1.4(01)		1985a	PP321 and Cyhalothrin: Skin Irritation Study.	Y	SYN
IIIA 6.1.4(02)		1985b	PP321: Eye Irritation Study.	Y	SYN
IIIA 6.1.5(01)		1984	PP321: Skin Sensitisation Study.	Y	SYN
IIIA 6.2(01)a		1981	Cyhalothrin: The Disposition and Metabolism of ^{14}C-ICI 146,814 in Rats Part I.	Y	SYN
IIIA 6.2(01)b		1984a	Cyhalothrin: The Metabolism and Disposition ICI 146,814 in Rats; Part II. Tissue residues derived from [^{14}C-benzyl] or [^{14}C-cyclopropyl] ICI 146,814, after a single oral dose of 1 or 25 mg/kg.	Y	SYN
IIIA 6.2(02)		1984b	Cyhalothrin: The Metabolism and Disposition of [^{14}C]-ICI 146,814 in Rats; Part III. Studies to Determine the Radioactive Residues in the Rat Following 14 Days Repeated Oral administration.	Y	SYN
IIIA 6.2(03)		1983	Cyhalothrin: The Metabolism and Disposition of ICI 146,814 in the Rats; Part IV.	Y	SYN
IIIA 6.2(04)		1989a	Cyhalothrin: Tissue Distribution and Elimination Following a Single Oral Dose (1 mg/kg) in the Rat.	Y	SYN
IIIA 6.2(05)		1989b	Cyhalothrin: Tissue Distribution and Elimination Following a Single Oral Dose (25 mg/kg) in the Rat.	Y	SYN

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IIIA 6.2(06)		1985	PP321: Comparative Absorption Study in the Rat.	Y	SYN
IIIA 6.2(07)		1994	The Metabolism and Pharmacokinetics of *Lambda*-Cyhalothrin in Man.	Y	SYN
IIIA 6.2(08)		1984c	Cyhalothrin: The Metabolism and Disposition of ICI 146,814 inn the dog.	Y	SYN
IIIA 6.2(09)		1984	Cyhalothrin: Bioaccumulation in the Rat.	Y	SYN
IIIA 6.3.1(01)		1982	Cyhalothrin Induced Liver Changes: Reversibility Study in Male Rats	Y	SYN
IIIA 6.3.1(02)		1996	*Lambda*-cyhalothrin: 6 Week Oral Toxicity Study in Dogs.	Y	SYN
IIIA 6.3.2(01)		1989	Lambda-Cyhalothrin: 21-day dermal toxicity to the rat.	Y	SYN
IIIA 6.3.3(01) in addendum to section 6		1990	Lambda Cyhalothrin Production Material: 21 Day Sub-Acute Inhalation Toxicity in the Rat	Y	SYN
IIIA 6.3.3(01) in addendum to section 6		1990	Lambda Cyhalothrin Production Material: 21 Day Sub-Acute Inhalation Toxicity in the Rat. Individual Animal Data Supplement.	Y	SYN
IIIA 6.4.1(01)		1985	PP321: 90 Day Feeding Study in Rats.	Y	SYN
IIIA 6.4.1(02)		1981	Cyhalothrin: 90 Day Feeding Study in Rats.	Y	SYN
IIIA 6.4.1(03)		1981	Cyhalothrin: Oral toxicity study in Beagle dogs.	Y	SYN
IIIA 6.4.1(04)		1985	PP321: 1 Year oral dosing study in dogs.	Y	SYN
IIIA 6.6.1(01)		1984	PP321 - An Evaluation in the *Salmonella* Mutagenicity Assay.	Y	SYN
IIIA 6.6.2(01)		1985	PP321: A Cytogenetic Study in Human Lymphocytes *In Vitro*.	Y	SYN
IIIA 6.6.3(01)		1985	PP321: Assessment of Mutagenic Potential using L5178Y MOUSE LYMPHOMA Cells.	Y	SYN
IIIA 6.6.3(02)		1989	*Lambda*-cyhalothrin: Assessment for the Induction of Unscheduled DNA Synthesis in Primary Rat Hepatocyte Cultures.	Y	SYN
IIIA 6.6.4(01)		1984	An Evaluation of PP321 in the Mouse Micronucleus Test.	Y	SYN
IIIA 6.6.5(01)		2005	Induction of micronuclei by lambda-cyhalothrin in Wistar rat bone marrow and gut epithelial cells	N	PD
IIIA 6.7(01)		1984	CYHALOTHRIN: Two Year Feeding Study in Rats.	Y	SYN

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IIIA 6.7(02)		1984	CYHALOTHRIN: Potential Tumorigenic and Toxic Effects in Prolonged Dietary Administration to Mice.	Y	SYN
IIIA 6.8(01)		1981a	CYHALOTHRIN: Oral (Gavage) Teratology Study in the Rat.	Y	SYN
IIIA 6.8.1(02)		1981b	CYHALOTHRIN: Oral (Gavage) Teratology Study in the New Zealand White Rabbit	Y	SYN
IIIA 6.8.2(01)		1984	CYHALOTHRIN: Three Generation Reproduction Study in the Rat.	Y	SYN
IIIA 6.9(01)		1999	*Lambda*-cyhalothrin: Acute Neurotoxicity Study in Rats.	Y	SYN
IIIA 6.9(02)		2004	Lambda-Cyhalothrin: Developmental Neurotoxicity study in rats.	Y	SYN
IIIA 6.9(03)		2001	Lambda-Cyhalothrin: Second Preliminary Development Neurotoxicity Study in Rats.	Y	SYN
IIIA 7.1.1.1.1(01)	Collis W M D Leahey J P	1984	PP321: Hydrolysis in water at pH 5, 7 and 9. Jealott's Hill Research Station Report No. RJ0338B. GLP, Unpublished.	Y	SYN
IIIA 7.1.1.1.2(01)	Priestley D B Leahey J P	1988	PP321: Aqueous photolysis at pH 5 Jealott's Hill Research Station Report No. RJ0605B. GLP, Unpublished.	Y	SYN
IIIA 7.1.1.1.2(02)	Moffatt F.	1994	*Lambda*-cyhalothrin: environmental half-life and quantum yield for direct phototransformation in aqueous solution. Jealott's Hill Research Station Report No. RJ1617B. GLP, Unpublished.	Y	SYN
IIIA 7.1.2.2.2(01)	Hall J S Leahey J P	1983	Cyhalothrin: Fate in River Water. Jealott's Hill Research Station Report No. RJ0320B. GLP, Unpublished.	Y	SYN
IIIA 7.1.2.2.2(02)	Marriott S H Duley J Hand L	1998	*Lambda*-cyhalothrin: Degradation in Water-Sediment Systems Under Laboratory Conditions. Jealott's Hill Research Station Report No. RJ2640B. GLP, Unpublished.	Y	SYN
IIIA 7.1.2.2.2(03)	Leistra, M. *et.al*	2003	Fate of the insecticide *lambda*-cyhalothrin in ditch enclosures differing in vegetation and nutrient level. Pest Management Science, 1526-498X Non-GLP, published.	N	SYN
IIIA 7.1.2.2.2(04)	Kuet S F	1998	*Lambda*-cyhalothrin: Adsorption and Desorption in Aquatic Plants. Jealott's Hill Research Station Report No RJ2716B. GLP, Unpublished.	Y	SYN
IIIA 7.1.2.2.2(05)	Hand, L.H. and Mehta, P	1998a	*Lambda*-cyhalothrin: Metabolism in Aquatic Plants Jealott's Hill Research Station Report No. RJ2626B. GLP, Unpublished.	Y	SYN

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IIIA 7.1.2.2.2(06)	Hand L H Mehta P	1998b	*Lambda*-cyhalothrin: Degradation in an Aquatic Microcosm. Jealott's Hill Research Station Report No RJ2730B GLP, Unpublished.	Y	SYN
IIIA 7.2.1(01)	Bharti H, Bewick D W, White R D.	1985	PP563 and PP321: Degradation in Soil Jealott's Hill Research Station Report No. RJ0382B. GLP, Unpublished.	Y	SYN
IIIA 7.2.1(02)	Völkel, W.	2005a	Tefluthrin: Degradation of PP890, a Metabolite of Tefluthrin and *Lambda* Cyhalothrin in Three Soils Incubated Under Aerobic Conditions. RCC unpublished report number 856646 GLP, Unpublished	Y	SYN
IIIA 7.2.2.1(01)	Tyldesley D Sapiets A	1986	PP321: Laboratory Degradation in Two Standard Soils. Jealott's Hill Research Station Report No. RJ0509B. GLP, Unpublished.	Y	SYN
IIIA 7.2.2.1(02)	Bharti H, Bewick D W, White R D.	1986	Cyhalothrin: Degradation in a Japanese Soil Jealott's Hill Research Station Report No. RJ0491B. GLP, Unpublished.	Y	SYN
IIIA 7.2.2.1(03)	Harvey, B.R., Zinner, C.K.J., White, R.D., Hill, I.R.	1981	Cypermethrin: Degradation in Soil in the Laboratory. Syngenta unpublished report number RJ0162B. GLP, Unpublished.	Y	SYN
IIIA 7.2.2.2(01)	Burke S Sapiets A	1990	*Lambda*-cyhalothrin: Soil Dissipation Studies (West Germany 1989) Jealott's Hill Research Station Report No. RJ0879B. GLP, Unpublished.	Y	SYN
IIIA 7.2.2.2(02)	Bewick D W, Bartlett D W, Hendley P.	1986	PP321: Fate of Radiolabelled Material in Soil Under Field Conditions. Jealott's Hill Research Station Report No. RJ0529B. GLP, Unpublished.	Y	SYN
IIIA 7.2.2.4(01)	Parker S Leahey J P.	1986	PP321: Photodegradation on a Soil Surface Jealott's Hill Research Station Report No. RJ0537B. GLP, Unpublished.	Y	SYN
IIIA 7.2.3.1(01)	Vickers J A, Bewick D W.	1986	PP321: Adsorption and desorption in soil. Jealott's Hill Research Station Report No. RJ0535B GLP, Unpublished.	Y	SYN
IIIA 7.2.3.1(02)	Muller K Goggin U Lane M C G	1996	*Lambda*-cyhalothrin: Adsorption and Desorption in Soil and Sediment. Jealott's Hill Research Station Report No. RJ1913B GLP, Unpublished	Y	SYN
IIIA 7.2.3.1(03)	Feeney, E., Lane, M.C.G.	1998	Lambda-Cyhalothrin: Adsorption and Desorption Properties of Compound XV (R211133), a Soil Degradate, in Six Soils.	Y	SYN

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			Syngenta unpublished report number RJ2622B GLP, Unpublished		
IIIA 7.2.3.1(04)	Bow, N.L.	2003	Tefluthrin: Adsorption Properties of R119890 and R613840 in Six Soils. Syngenta unpublished report number TMJ4898B Not GLP, Unpublished	Y	SYN
IIIA 7.2.3.1(05)	Völkel, W.	2005b	Tefluthrin: Adsorption/Desorption of 14C-PP890 a Metabolite of Tefluthrin and Lambda-Cyhalothrin on Three Soils. RCC unpublished report number 856645 GLP, Unpublished	Y	SYN
IIIA 7.2.3.2(01)	Stevens J E B, Bewick D W.	1985	PP563 and PP321: Leaching of PP563 and PP321 and their Degradation Products in Soil Columns. Jealott's Hill Research Station Report No. RJ0408B. GLP, Unpublished.	Y	SYN
IIIA 7.3.1(01)	Hayes S E	1998	*Lambda*-cyhalothrin: Calculation of Half-Life by Reaction with Atmospheric Hydroxyl Radicals. Jealott's Hill Research Station Report No. RIC0461 Non-GLP, Unpublished	Y	SYN
IIIA 7.3.2(01)	Heath, J, and Ahmed, A	1992	Fluorochloridone, Pirimicarb, *Lambda*-Cyhalothrin, Prosulfocarb, Fluazifop-p-Butyl: Volatility from French Bean Leaves and Speyer 2.1 Soil Jealott's Hill Research Station Report No. RJ1046B. GLP Unpublished.	Y	SYN
IIIA 7.3.2(02)	Mound E L Skidmore M W	1992	*Lambda*-cyhalothrin: Volatilization from Soil and Leaf Surfaces Following Application as a WG Formulation. Jealott's Hill Research Station Report No. RJ1346B GLP, Unpublished	Y	SYN
IIIA 7.4.1.1(01)	Kent, S.J., Shillabeer, N.	1997a	*Lambda*-Cyhalothrin: Acute toxicity to golden orfe (*Leuciscus idus*) Brixham Environmental Laboratory Report No. BL6142/B GLP, Unpublished.	Y	SYN
IIIA 7.4.1.1(02)	Long, K.W.J., Shillabeer, N.	1997a	*Lambda*-Cyhalothrin: Acute toxicity to channel catfish (*Ictalurus punctatus*) Brixham Environmental Laboratory Report No. BL6147/B GLP, Unpublished.	Y	SYN
IIIA 7.4.1.1(03)	Long, K.W.J., Shillabeer, N.	1997b	*Lambda*-Cyhalothrin: Acute toxicity to three-spined stickleback (*Gasterosteus aculeatus*) Brixham Environmental Laboratory Report No. BL6146/B GLP, Unpublished.	Y	SYN
IIIA	Hill, R.W.	1985	PP321: Determination of acute toxicity to mirror carp (*Cyprinus carpio*) of a 5%EC formulation	Y	SYN

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7.4.1.1(04)			Brixham Environmental Laboratory Report No. BL/B/2784 GLP, Unpublished.		
IIIA 7.4.1.1(05)	Kent, S.J., Shillabeer, N.	1997b	*Lambda*-Cyhalothrin: Acute toxicity to zebra danio (*Brachydanio rerio*) Brixham Environmental Laboratory Report No. BL6144/B GLP, Unpublished.	Y	SYN
IIIA 7.4.1.1(06)	Kent, S.J., Shillabeer, N.	1997c	*Lambda*-Cyhalothrin: Acute toxicity to fathead minnow (*Pimephales promelas*) Brixham Environmental Laboratory Report No. BL6246/B GLP, Unpublished.	Y	SYN
IIIA 7.4.1.1(07)	Kent, S.J., Shillabeer, N.	1997d	*Lambda*-Cyhalothrin: Acute toxicity to Japanese rice fish (*Oryzias latipes*) Brixham Environmental Laboratory Report No. BL6145/B GLP, Unpublished.	Y	SYN
IIIA 7.4.1.1(08)	Kent, S.J., Shillabeer, N.	1997e	*Lambda*-Cyhalothrin: Acute toxicity to the guppy (*Poecilia reticulata*) Brixham Environmental Laboratory Report No. BL6143/B GLP, Unpublished.	Y	SYN
IIIA 7.4.1.1(09)	Hill, R.W.	1984a	PP321: Determination of acute toxicity to rainbow trout (*Salmo gairdneri*) Brixham Environmental Laboratory Report No. BL/B/2405 GLP, Unpublished.	Y	SYN
IIIA 7.4.1.1(10)	Hill, R.W.	1984b	PP321: Determination of acute toxicity to bluegill sunfish (*Lepomis macrochirus*) Brixham Environmental Laboratory Report No. BL/B/2406 GLP, Unpublished.	Y	SYN
IIIA 7.4.1.1(11)	Yamauchi, F., Shigeoka, T.	1984	PP-563 (Cyhalothrin): Toxicity to *Daphnia* and fish (carp) in the presence and absence of soil Mitsubishi Kasei Institute of Toxicological and Environmental Sciences Report No. 58-367 GLP, Unpublished.	Y	SYN
IIIA 7.4.1.1(12)	Hill, R.W.	1984c	PP890: Determination of acute toxicity to rainbow trout (*Salmo gairdneri*) Brixham Environmental Laboratory Report No. BL/B/2457 GLP, Unpublished.	Y	SYN
IIIA 7.4.1.1(13)	Tapp, J. F., Caunter, J. E.	1984	PP890: Determination of acute toxicity to bluegill sunfish (*Lepomis macrochirus*) Brixham Environmental Laboratory Report No. BL/B/3029 GLP, Unpublished.	Y	SYN
IIIA 7.4.1.2(01)	Farrelly, E., Hamer, M.J., Hill, I.R.	1984	PP321: Toxicity to first instar *Daphnia magna* Jealott's Hill Research Station Report No. RJ0359B	Y	SYN

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			GLP, Unpublished.		
IIIA 7.4.1.2(02)	Stewart, K.M., Kent, S.J., Johnson, P.A., Morris, D.S.	1995	*Lambda*-Cyhalothrin: Acute toxicity to *Daphnia magna* in water only and water-sediment systems Brixham Environmental Laboratory Report No. BL4912/B GLP, Unpublished.	Y	SYN
IIIA 7.4.1.2(03)	Yamauchi, F., Suzuki, Y.	1984	PP-563 (Cyhalothrin 'acid'): Acute toxicity to *Daphnia* Mitsubishi Kasei Institute of Toxicological and Environmental Sciences Report No. MITES 58-367 GLP, Unpublished.	Y	SYN
IIIA 7.4.1.2(04)	Yamauchi, F., Shigeoka, T.	1984	PP-563 (Cyhalothrin): Toxicity to *Daphnia* and fish (carp) in the presence and absence of soil Mitsubishi Kasei Institute of Toxicological and Environmental Sciences Report No. 58-367 GLP, Unpublished.	Y	SYN
IIIA 7.4.1.2(05)	Goggin, U.M., Hamer, M.J.	1998	*Lambda*-Cyhalothrin: Acute toxicity of short-term exposures to *Gammarus pulex* Jealott's Hill Research Station Report No. RJ2542B GLP, Unpublished.	Y	SYN
IIIA 7.4.1.2(06)	Hamer, M.J., Goggin, U.M.	1998a	*Lambda*-Cyhalothrin. Acute toxicity to different life-stages of *Gammarus pulex* Jealott's Hill Research Station Report No. RJ2483B GLP, Unpublished.	Y	SYN
IIIA 7.4.1.2(07)	Hamer, M.J., Goggin, U.M.	1998b	*Lambda*-Cyhalothrin. Acute toxicity to *Gammarus pulex* in a sediment-water system Jealott's Hill Research Station Report No. RJ2484B GLP, Unpublished.	Y	SYN
IIIA 7.4.1.2(08)	Hamer, M.J., Ashwell, J.A., Gentle, W.E.	1998	*Lambda*-Cyhalothrin. Acute toxicity to aquatic arthropods Jealott's Hill Research Station Report No. RJ2437B GLP, Unpublished.	Y	SYN
IIIA 7.4.1.2(09)	Kedwards, T.J.	2000	*Lambda*-Cyhalothrin: Investigation into the effects on and recovery of *Gammarus pulex* (L.) using a stage-structured population model Jealott's Hill Research Station Report No. TMJ4491B Non-GLP, Unpublished.	Y	SYN
IIIA 7.4.1.2(10)	Everett, C.J., Hamer, M.J., Hill, I.R.	1983	3-Phenoxybenzoic acid: Toxicity to first instar *Daphnia magna* (II) Jealott's Hill Research Station Report No. RJ0318B GLP, Unpublished	Y	SYN
IIIA 7.4.1.3(01)	Thompson, R.S., Williams, T.D.	1985	PP321: Toxicity to the green alga *Selenastrum capricornutum* Brixham Environmental Laboratory Report No. BL/B/2584	Y	SYN

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			GLP, Unpublished.		
IIIA 7.4.1.4(01)	Wallace, S.J.	2002	ZA0321 (*Lambda*-Cyhalothrin technical): Effect on the respiration rate of activated sludge Brixham Environmental Laboratory Report No. BL7331/B GLP, Unpublished.	Y	SYN
IIIA 7.4.1.4(02)	Mather, J.I., Tapp, J.F.	1989	*Lambda* Cyhalothrin: Determination of the toxicity to *Pseudomonas putida* Brixham Environmental Laboratory Report No. BL/B3467 GLP, Unpublished.	Y	SYN
IIIA 7.4.3(01)	Kennedy, J.H., Cole, J.F.H., Ekoniak, P., Hadfield, S.T., Sadler, J.K., Francis, P D., Moore, M. , Hill, I.R.	1988	Evaluation of the impact of run-off and spray-drift on aquatic mesocosms, using USA experimental ponds. Jealott's Hill Research Station Report No. RJ0614B GLP, Unpublished. Plus addendum Runnals JK (1992), Lambda-cyhalothrin: Addendum to RJ0614B. ICI Agrochemicals, Jealott's Hill Research Station, UK; unpublished report No. RJ0614B Addendum; study dates October 1989 to June 1992.	Y	SYN
IIIA 7.4.3(02)	Farmer D., Coulson J.M., Runnalls J.K., Hill S.E., McIndoe E.C., Hill I.R.	1993	*Lambda*-Cyhalothrin and cypermethrin: Evaluation and comparison of the impact of multiple drift applications on aquatic ecosystems (experimental ponds) Jealott's Hill Research Station Report No. RJ0571B GLP, Unpublished.	Y	SYN
IIIA 7.4.3(03)	Van Wijngaarden, RPA, Cuppen, JGM, Arts, GHP, Crum, SJH, van den Hoorn, MW, van den Brink, PJ and Brock, TCM	2004	Aquatic risk assessment of a realistic exposure to pesticides used in bulb crops: A microcosm study. GLP, Published	Y	SYN
IIIA 7.4.3(04)	Roessink, I., Arts, G.H.P., Belgers, J.D.M., Bransen, F , Maund, S.J., Brock, T.C.M.	2004	Effects of *lambda*-Cyhalothrin in two ditch microcosm systems of different trophic status. Jealott's Hill Research Station Report No. TMJ4971B GLP, Published.	Y	SYN
IIIA 7.4.3.1(01)	Hill, R.W., Caunter, J.E., Cumming, R.I.	1985	PP321: Determination of the chronic toxicity to sheepshead minnow (*Cyprinodon variegatus*) embryos and larvae Brixham Environmental Laboratory Report No. BL/B/2677	Y	SYN

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			GLP, Unpublished.		
IIIA 7.4.3.1(02)	Tapp, J.F., Maddock, B.G., Harland, B.J., Stembridge, H.M., Gillings, E.	1990	*Lambda*-Cyhalothrin (Karate PP321): Determination of chronic toxicity to fathead minnow (*Pimephales promelas*) full lifecycle Brixham Environmental Laboratory Report No. BL/B/3476 GLP, Unpublished.	Y	SYN
IIIA 7.4.3.3.1(01)	Yamauchi, F.	1984	PP563 (Cyhalothrin) : Accumulation in fish (carp) in a flow-through water system Mitsubishi Kasei Institute of Toxicological and Environmental Sciences Report No. MITES/58-367 GLP, Unpublished.	Y	SYN
IIIA 7.4.3.3.1(02)	Hamer, M.J., Hill, I.R.	1985	Cyhalothrin: The accumulation of cyhalothrin and its degradation products by channel catfish and *Daphnia magna* in a soil/water system Jealott's Hill Research Station Report No. RJ0427B GLP, Unpublished.	Y	SYN
IIIA 7.4.3.3.2(01)	Muller, K., Hamer, M. J., Goggin, U., Lane, M.C.G.	1995	Bioavailability and bioconcentration by Chironomus riparius in water-only sediment/water systems Zeneca Agrochemicals, Report No.: RJ1933B GLP, Unpublished.	Y	SYN
IIIA 7.4.3.4(01)	Farrelly, E., Hamer, M.J.	1989	PP321: *Daphnia magna* life-cycle study using a flow-through system Jealott's Hill Research Station Report No. RJ0764B GLP, Unpublished.	Y	SYN
IIIA 7.4.3.5.1(01)	Hamer, M.J., Rapley, J.H.	1997	*Lambda*-Cyhalothrin: BBA toxicity test with sediment-dwelling *Chironomus riparius* Jealott's Hill Research Station Report No. RJ2234B GLP, Unpublished.	Y	SYN
IIIA 7.4.3.5.1(02)	Hamer, M.J., Gentle, W.E.	1997	*Lambda*-Cyhalothrin: Sediment toxicity test with *Chironomus riparius* Jealott's Hill Research Station Report No. RJ2227B GLP, Unpublished.	Y	SYN
IIIA 7.5.1.1(01)	Aze, C.J., Tarry, A.R., Lewis, F.J.	1990	PP321: Studies on microorganisms and their activities in soil Jealott's Hill Research Station Report No. RJ0853B GLP, Unpublished.	Y	SYN
IIIA 7.5.1.2(01)	Yearsdon, H.A., Coulson, J.M., Edwards, P.J.	1993	*Lambda*-Cyhalothrin: Toxicity to the earthworm *Eisenia foetida* Jealott's Hill Research Station Report No. TMJ3062B GLP, Unpublished.	Y	SYN
IIIA 7.5.1.3(01)	Rea, D., Mannion, S K., Martin, E.A., Hill, I.R.	1989	PP321: Effects on the plants in the weed science and plant growth regulator screens of the Biological Group Jealott's Hill Research Station Report No. RJ0565B GLP, Unpublished.	Y	SYN

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IIIA 7.5.2.1(01)	Coulson, J.M., Collins, I.G., Edwards, P.J.	1986	PP321:- Effects on earthworms *Lumbricidae* of repeated annual field applications Jealott's Hill Research Station Report No. RJ0511B GLP, Unpublished.	Y	SYN
AIII 7.5.2.1	Friedrich, S.	2009	*Lambda*-cyhalothrin SC (A12690B) - Effects on the reproduction of the collembolans *Folsomia candida*, Report Number 09 10 48 038 S. BioChem agrar GmbH, Kupferstraße 6, 04827 Gerichshain, Germany GLP, Unpublished.	Y	SYN
IIIA 7.5.3.1.1(01)	Roberts, N.L , Fairley, C.	1984	The acute oral toxicity (LD_{50}) of PP321 to the mallard duck Huntingdon Research Centre plc. Report No. CTL/C/1240 GLP, Unpublished.	Y	SYN
IIIA 7.5.3.1.2(02)	Roberts, N.L , Fairley, C., Anderson, A., Dawe, I.S.	1985a	The subacute dietary toxicity of PP321 to the mallard duck Huntingdon Research Centre plc. Report No. CTL/C/1357 GLP, Unpublished.	Y	SYN
IIIA 7.5.3.1.2(02)	Roberts, N.L , Fairley, C., Anderson, A., Dawe, I.S.	1985b	The subacute dietary toxicity of PP321 to the bobwhite quail Huntingdon Research Centre plc. Report No. CTL/C/1358 GLP, Unpublished.	Y	SYN
IIIA 7.5.3.1.3(01)	Beavers, J.B., Hoxter, K.A., Jaber, M.J.	1989	PP321: A one-generation reproduction study with the mallard (*Anas platyrhynchos*) Wildlife International Ltd. Report No. 123-143 GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(01)	Gough, H.J., Collins, I.G., Everett, C.J., Wilkinson, W.	1984	PP321: Acute contact and oral toxicity to honey bees (*Apis mellifera*) Jealott's Hill Research Station Report No. RJ0390B GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(02)	Gough, H.J., Collins, I.G., Wilkinson, W.	1986	PP321: Effects on honey bees (*Apis mellifera*) foraging on simulated honeydew on winter wheat, 1985 Jealott's Hill Research Station Report No. RJ0464B GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(03)	Gough, H.J., Collins, I.G., Wilkinson, W.	1985	PP321: Field test of toxicity to honey bees (*Apis mellifera*) on flowering oilseed rape (*Brassica napus*) Jealott's Hill Research Station Report No. RJ0413B GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(04)	Nengel, S.	1999a	Assessment of side effects of Karate WG on the honey bee (*Apis mellifera* L.) in the field following application during bee-flight in Spain GAB Report No. 98139/S1-BFEU/C GLP, Unpublished.	Y	SYN
IIIA	Tornier, I.	1993	Assessment of the side-effects of ICI 90420 I O WG on the honey bee (*Apis mellifera*) in the semi-field	Y	SYN

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7.5.4.1(05)			GAB Report No. 93041/01-AmZ GLP, Unpublished.		
IIIA 7.5.4.1(06)	Gough, H.J., Yearsdon, H.A., Jackson, D., Lewis, G.B.	1993	*Lambda*-Cyhalothrin: comparison of the effects of an EC and a WG formulation on honey bees (*Apis mellifera*) foraging on simulated aphid honeydew on winter wheat Jealott's Hill Research Station Report No. RJ1406B GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(07)	Nengel, S.	1998	Assessment of side effects of Karate CS on the honey bee (*Apis mellifera* L.) in the field following application during bee-flight GAB Report No. 97146/01-BFEU/C GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(08)	Nengel, S.	1999b	Assessment of side effects of Karate 10CS on the honey bee (*Apis mellifera* L.) in the field following application during bee-flight GAB Report No. 98189/01-BFCe/C GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(09)	Nengel, S.	1999c	Assessment of side effects of Karate 10CS on the honey bee (*Apis mellifera* L.) in the field following application during bee-flight GAB Report No. 98189/01-BFEU/C GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(10)	Gough, H.J., Yearsdon, H.A., Jackson, D., Lewis, G.B.	1994	*Lambda*-Cyhalothrin: effects on honey bees (*Apis mellifera* L.) foraging on flowering oilseed rape (*Brassica napus*) in a large-scale field study Jealott's Hill Research Station Report No. RJ1547B GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(11)	Collins, I.G., Brown, R.A.	1988	Acute contact and oral toxicity to honey bees (*Apis mellifera*) of an EW formulation (JF 10681) Jealott's Hill Research Station. Report No. RJ0691B GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(12)	Thompson, H.M.	1997	*Lambda*-Cyhalothrin: acute contact and oral toxicity to honey bees (*Apis mellifera*) of a 100 g/L CS formulation Central Science Laboratory, National Bee Unit. Report No. EL8800 GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(13)	Tornier, I	1992	Assessment of side effects of ICI 90420-I-O-WG on the honey bee, (*Apis mellifera* L., with the laboratory test method GAB Report No. 92038/01-Am GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(14)	Tornier, I	1993a	Assessment of side effects of ICI 90420-I-O-WG on the honey bee (*Apis mellifera* L.) in the field by application after the daily bee-flight GAB Report No. 92038/01-AmF GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(15)	Tornier, I	1993b	Assessment of side effects of ICI 90420-I-O-WG on the honey bee (*Apis mellifera* L.) in the field during daily bee-flight	Y	SYN

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			GAB Report No. 93041/01-AmF GLP, Unpublished.		
IIIA 7.5.4.1(16)	Tornier, I	1993c	Assessment of side effects of ICI 90420-I-O-WG on the honey bee (*Apis mellifera* L.) in the field by application during bee-flight GAB Report No. 92038/02-AmF GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(17)	Balluff, M.	2000	Assessment of side effects of Karate WG on the Honey Bee (*Apis mellifera* L.) in the field following application during bee flight in Spain GAB Report No. 98139/S2-BFEU/C GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(18)	Aldershof, S A.	1999	A laboratory dose-response study to evaluate the effects of *lambda*-Cyhalothrin (CS formulation) on the predatory mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae) MITOX Report No. Z005TPL-CV GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(19)	Bakker, F.M.	1999	A laboratory dose-response study to evaluate the effects of *lambda*-Cyhalothrin on the predatory mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae) MITOX Report No. Z004TPL-CV GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(20)	Baxter, I.	1999	A laboratory test to determine the effects of *lambda*-Cyhalothrin 100 g/L CS (WF2639) on the parasitoid, *Aphidius rhopalosiphi* AEUReport No. ZEN-99-1/C GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(21)	Mead-Briggs, M.A.	1999	A laboratory test to determine the effects of *lambda*-Cyhalothrin 50 g/kg WG (YF8048A) on the parasitoid, *Aphidius rhopalosiphi* AEU Report No. ZEN-98-3/C GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(22)	Yearsdon, H.A., Farrelly, L.C.	1996	*Lambda*-Cyhalothrin: A laboratory test on four beneficial arthropod species Jealott's Hill Research Station Report No. TMJ3456B GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(23)	White, J.S., Boersma, A.H.R., Brown, R.A.	1989	PP321: Laboratory LD_{50} test on the aphid pest *Rhopalosiphum padi* and a range of its enemies Jealott's Hill Research Station Report No. RJ0686B GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(24)	Deprez, C., McMullin, L.C.	1993	Lambda-Cyhalothrin: Investigation into the Toxicity of a 5% WG Formulation to the Larvae of the Hoverfly *Episyrphus balteatus* De Geer. Jealott's Hill Research Station Report No. RJ1399B GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(25)	Solomon, M. G., Fitzgerald, J.D.		Laboratory determination of LC_{50} for PP321 against *Panonychus ulmi* and *Typhlodromus pyri* AFRC Institute of Horticultural Research Report	Y	SYN

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IIIA 7.5.4.1(26)	Everett, C.J , Cole, J.F.H.	1993a	*Lambda*-Cyhalothrin: Laboratory test on the effects on the ground beetle *Pterostichus melanarius* Jealott's Hill Research Station Report No. RJ1327B GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(27)	Everett, C.J , Cole, J.F.H.	1993b	*Lambda*-Cyhalothrin: Laboratory test on the effects on lycosid spiders Jealott's Hill Research Station Report No. RJ1329B GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(28)	Busschers, M., Farrelly, L.C.	1994	*Lambda*-Cyhalothrin: Laboratory test on the effects of 3 different formulations on predatory lycosid spiders (Lycosidae, Araneae) Jealott's Hill Research Station Report No. RJ1580B GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(29)	White, J.S., Everett, C.J., Jackson, D , Brown, R.A.	1989	PP321: Effects of autumn application to cereals on the beneficial arthropod fauna Jealott's Hill Research Station Report No. RJ0728B GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(30)	McMullin, L.C., Everett, C.J., White, J.S., Brown, R.A.	1991	*Lambda*-Cyhalothrin: Effects of a summer application to cereals on the beneficial arthropod fauna Jealott's Hill Research Station Report No. RJ0956B GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(31)	McMullin, L.C., Everett, C.J., Canning, L., Brown, R.A.	1992a	*Lambda*-Cyhalothrin: The effects of a summer application on the beneficial arthropod fauna in cereals using three different spray rates Jealott's Hill Research Station Report No. RJ1250B GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(32)	White, J.S., Brown, R.A.	1992b	*Lambda*-Cyhalothrin: Effects of application in soybean on the principal target pests and their key natural enemies Jealott's Hill Research Station Report No. TMJ2969A GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(33)	Pilling, E.D.	1995	*Lambda*-Cyhalothrin: A study of the effects on natural enemies of rice insect pests in the Philippines Jealott's Hill Research Station Report No. TMJ3453B GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(34)	Cole, J.F.H.	2001	*Lambda*-Cyhalothrin: The effects on beneficial and pest arthropods in *Bt*-cotton Jealott's Hill Research Station Report No TMJ3951B Non-GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(35)	Farrelly, L.C.	1994	*Lambda*-Cyhalothrin: Investigation into the toxicity of a 5% emulsifiable concentrate to predatory lycosid spiders (Lycosidae, Araneae) and the carabid beetle *Pterostichus melenarius* Jealott's Hill Research Station Report No.	Y	SYN

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IIIA 7.5.4.1(36)	Tornier, I.	1994a	Assessment of side effects (initial toxicity) of Karate 5EC on the larvae of the hoverfly *Episyrphus balteatus* Deg. (Diptera, Syrphidae) under semi-field conditions GAB Report No. 93074/01-EbHF GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(37)	Tornier, I.	1994b	Assessment of side effects (initial toxicity) of Karate WG on the larvae of the hoverfly *Episyrphus balteatus* Deg. (Diptera, Syrphidae) under semi-field conditions GAB Report No. 93041/01-EbHF GLP, Unpublished.	Y	SYN
IIIA 7.5.4.1(38)	Kedwards, H., Coulson, J.M., Fleming, T.M., Lavendar, K.H.	2000	A comparison between the effects of the CS and EC formulations of *lambda*-Cyhalothrin on selected beneficial insects Jealott's Hill Research Station Report No. TMJ3357B Non-GLP, Unpublished.		

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IIIB1 3.1(01)	Gerhardt, P.	2004	A12690A: Color, odour, physical state, wetsieve, foam and pourability. Syngenta Crop Protection Münchwilen AG, Report No. 157390, 05/03/2004 Not GLP, Not Published	Y	SYN
IIIB1 3.1(02)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN
IIIB1 3.2(01)	Jackson, W.A.	2004	Explosive properties – A12690A. Syngenta PHS Report number HT 04/109. 20/05/04 GLP, Not Published	Y	SYN
IIIB1 3.3(01)	Jackson, W.A.	2004	Oxidising properties – A12690A. Syngenta PHS Report number HT 04/111. 21/05/04 GLP, Not Published	Y	SYN

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IIIB1 3.4(01)	Jackson, W.A.	2004	Auto-ignition temperature– A12690A. Syngenta PHS Report number HT 04/110. 21/05/04 GLP, Not Published	Y	SYN
IIIB1 3.5(01)	Wochner, F.	2004	A12690A: pH(1%), pH(undiluted) and density. Syngenta Crop Protection Münchwilen AG, Report No. 111887, 15/03/2004 GLP, Not Published	Y	SYN
IIIB1 3.6(01)	Wochner, F.	2004	A12690A: pH(1%), pH(undiluted) and density. Syngenta Crop Protection Münchwilen AG, Report No. 111887, 15/03/2004 GLP, Not Published	Y	SYN
IIIB1 3.6(02)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN
IIIB1 3.7(01)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN
IIIB1 3.7(02)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN
IIIB1 3.7(03)	Mullee, D.M., Bartlett, A.J.	1996	DEMAND 10CS: Determination of long term storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/008, 04/05/1996 GLP, Not Published	Y	SYN
IIIB1 3.7(04)	Lumsden, A.M.	1998	ICON 10CS (lambda-cyhalothrin): Determination of long term storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/047, 07/08/1998 GLP, Not Published	Y	SYN
IIIB1 3.8(01)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN
IIIB1 3.8(02)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN

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IIIB1 3.10.1(01)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN
IIIB1 3.10.2(01)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN
IIIB1 4.1(01)	Fox, D. Swanson, M.	1993	The Weight Percent Determination of Lambda-Cyhalothrin in Microcapsule Formulations By Capillary Gas Chromatography (WRC-92-156) Zeneca Ag Products, Richmond, United States TMR0457A, 02.03.1993 not GLP, not published Syngenta File N PP321/1890	Y	SYN
IIIB1 4.1(02)	Garton, P.K.	1998	The Determination of Lambda-cyhalothrin in Karate and Warrior Microcapsule Formulations by Capillary Gas Chromatography. Method Addendum for WRC 92-156 Zeneca Ag Products, Richmond, United States TMR0457A, 10.03.1998 not GLP, not published Syngenta File N PP321/1891	Y	SYN
IIIB1 4.1(03)	Zhang, J. and Garton P K.	1999	The Determination of *Lambda*-Cyhalothrin in Formulations by Gas Chromatography (WRC-99-070) Zeneca Ag Products, Richmond, United States AMW00038-01A, 04.29.1999 not GLP, not published Syngenta File N Not stated	Y	SYN
IIIB1 4.1(04)	Johnson, N.	2005a	Analytical Method SF-121/1 Lambda Cyhalothrin CS (100) in Formulation A12690A by GC Analytical & Product Chemistry Department, Syngenta Crop Protection Inc., Greensboro, NC 27419 U.S.A. not GLP, not published Syngenta File N Not stated	Y	SYN
IIIB1 4.1(05)	Johnson, N.	2005b	A12690A: Validation of analytical method SF-121/1 Final report Analytical & Product Chemistry Department, Syngenta Crop Protection Inc., Greensboro, NC	Y	SYN

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IIIB1 5.10.2(01)	Le Quesne, L.	2002	Field trial study to determine the efficacy of Demand CS vs *Lasius niger* (the garden or black ant), Sorex Limited Product Development Laboratory report no. LR 058/02, 7 October, 2002 non GLP, not published	Y	SYN
IIIB1 5.10.2(02)	Le Quesne, L.	2002	Field trial study to determine the efficacy of Demand CS vs *Lasius niger* (the garden or black ant), Sorex Limited Product Development Laboratory report no. LR 059/02, 9 October, 2002 non GLP, not published	Y	SYN
IIIB1 5.10.2(03)	Le Quesne, L.	2002	Field trial study to determine the efficacy of Demand CS vs *Lasius niger* (the garden or black ant). Sorex Limited Product Development Laboratory report no. LR 060/02, 9 October, 2002 non GLP, not published	Y	SYN
IIIB1 5.10.2(04)	Le Quesne, L.	2002	Field trial study to determine the efficacy of Demand CS vs *Lasius niger* (the garden or black ant). Sorex Limited Product Development Laboratory report no. LR 061/02, 9 October, 2002 non GLP, not published	Y	SYN
IIIB1 5.10.2(05)	Le Quesne, L.	2002	Field trial study to determine the efficacy of Demand CS vs *Lasius niger* (the garden or black ant). Sorex Limited Product Development Laboratory report no. LR 062/02, 9 October, 2002 non GLP, not published	Y	SYN
IIIB1 5.10.2(06)	Le Quesne, L.	2002	A study to determine the efficacy of fresh and aged residual deposits of Demand CS vs the black ant *Lasius niger*. Sorex Limited Product Development Laboratory report no. LR 057/02, 1 October, 2002 non GLP, not published	Y	SYN
IIIB1 5.10.2(07)	Sievert, K., Gfeller, F.J	2004	*Lambda*-Cyhalothrin formulation (DEMAND 10 CS) and thiamethoxam (AGITA® 10 WG): Residual deposit test with *Dermanyssus gallinae* Novartis Animal Health Inc.laboratory report no. IDL 754, 2 December 2004 non GLP, not published	Y	SYN
IIIB1 5.10.2(08)	Anon	-	Demand CS: Activity on flies Syngenta Crop Protection,	Y	SYN

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IIIB1 5.10.2(10)	Williams, N.G.	1994	Bioefficacy evaluation: Demand 10cs against blatta orientalis (oriental cockroach). Zeneca Agrochemicals test reference no. IJ/94/0033, 26 June 1994, non GLP, not published	Y	SYN
IIIB1 5.10.2(11)	Wege, P.J.	2000	Demand 10CS: Efficacy against incidental pests, Syngenta Crop Protection report number TMJ 4380 B, February 2000 non GLP, not published	Y	SYN
IIIB1 5.10.2(12)	Hoppé, M.A.	2002	*Lambda*-cyhalothrin residual space spray project: (3), Control of *Aedes aegypti* and *Blattella germanica* with low rate residual deposits of Icon CS. Syngenta Crop Protection report number TMJ 4733 B, May 2002 non GLP, not published	Y	SYN
IIIB1 6.1.1(01)		1996	Lambda-Cyhalothrin: Acute Oral Toxicity to the Rat of a 100g/l CS Formulation	Y	SYN
IIIB1 6.1.2(01)		1996c	Lambda-Cyhalothrin: Acute Dermal Toxicity to the Rat of a 100g/l CS Formulation	Y	SYN
IIIB1 6.1.3(01)		1992	Lambda-Cyhalothrin: 4-hour inhalation toxicity in the Rat of a 100g/l CS Formulation	Y	SYN
IIIB1 6.2(01)		1996e	Lambda-Cyhalothrin: Skin Irritation to the Rabbit of a 100g/l CS Formulation	Y	SYN
IIIB1 6.2(02)		1996a	Lambda-Cyhalothrin: Eye Irritation to the Rabbit of a 100g/l CS Formulation	Y	SYN
IIIB1 6.3(01)		1996b	Lambda-Cyhalothrin: Skin Sensitisation to the Guinea Pig of a 100g/l Cs Formulation	Y	SYN
IIIB1 6.4(01)		1997	*Lambda*-cyhalothrin 100g/L CS Formulation: In Vitro Absorption of Lambda-cyhalothrin Through Human Epidermis	Y	SYN
IIIB1 6.7(01)		2005	Induction of micronuclei by lambda-cyhalothrin in Wistar rat bone marrow and gut epithelial cells	N	PD

Section No.	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data protection claimed Y/N	Owner
IIIB1 7.7.1.1 (01)	Kent, S.J. and Shillabeer, R.	1998	Lambda-cyhalothrin: Acute toxicity to *Daphnia magna* of a 100 g l-1 CS formulation Brixham Environmental Laboratory, BL6219/B, 05.1998 GLP, not published	Y	SYN
IIIB1 7.8.2 (01)	Thompson, H.M.	1997	Lambda-Cyhalothrin: Acute contact and oral toxicity to honey bees (*Apis mellifera*) of a 100 g/l CS formulation. Central Science Laboratory, EL8800, 12.1997 GLP, not published	Y	SYN

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IIIB2 3.1(01)	Gerhardt, P.	2004	A12690A: Color, odour, physical state, wetsieve, foam and pourability. Syngenta Crop Protection Münchwilen AG, Report No. 157390, 05/03/2004 Not GLP, Not Published	Y	SYN
IIIB2 3.1(02)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN
IIIB2 3.2(01)	Jackson, W.A.	2004	Explosive properties – A12690A. Syngenta PHS Report number HT 04/109. 20/05/04 GLP, Not Published	Y	SYN
IIIB2 3.3(01)	Jackson, W.A.	2004	Oxidising properties – A12690A. Syngenta PHS Report number HT 04/111. 21/05/04 GLP, Not Published	Y	SYN
IIIB2 3.4(01)	Jackson, W.A.	2004	Auto-ignition temperature– A12690A. Syngenta PHS Report number HT 04/110. 21/05/04 GLP, Not Published	Y	SYN
IIIB2 3.5(01)	Wochner, F.	2004	A12690A: pH(1%), pH(undiluted) and density. Syngenta Crop Protection Münchwilen AG, Report No. 111887, 15/03/2004 GLP, Not Published	Y	SYN
IIIB2 3.6(01)	Wochner, F.	2004	A12690A: pH(1%), pH(undiluted) and density. Syngenta Crop Protection Münchwilen AG, Report No. 111887, 15/03/2004 GLP, Not Published	Y	SYN
IIIB2 3.6(02)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN
IIIB2 3.7(01)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN
IIIB2 3.7(02)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN

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IIIB2 3.7(03)	Mullee, D.M., Bartlett, A.J.	1996	DEMAND 10CS: Determination of long term storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/008, 04/05/1996 GLP, Not Published	Y	SYN
IIIB2 3.7(04)	Lumsden, A.M.	1998	ICON 10CS (lambda-cyhalothrin): Determination of long term storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/047, 07/08/1998 GLP, Not Published	Y	SYN
IIIB2 3.8(01)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN
IIIB2 3.8(02)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN
IIIB2 3.8(03)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN
IIIB2 3.8(04)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN
IIIB2 3.10.1(01)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN
IIIB2 3.10.2(01)	Lumsden, A.M. Bartlett, A.J.	1996	ICON 10CS: Determination of accelerated storage stability and physico-chemical characteristics. SafePharm Laboratories Ltd Report No. 560/046, 19/08/1996 GLP, Not Published	Y	SYN
IIIB2 4.1(01)	Fox, D. Swanson, M.	1993	The Weight Percent Determination of Lambda-Cyhalothrin in Microcapsule Formulations By Capillary Gas Chromatography (WRC-92-156) Zeneca Ag Products, Richmond, United States TMR0457A, 02.03.1993 not GLP, not published Syngenta File N PP321/1890	Y	SYN
IIIB2 4.1(02)	Garton, P.K.	1998	The Determination of Lambda-cyhalothrin in Karate and Warrior Microcapsule Formulations by Capillary Gas Chromatography. Method Addendum for WRC 92-156	Y	SYN

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			Zeneca Ag Products, Richmond, United States TMR0457A, 10.03.1998 not GLP, not published Syngenta File N PP321/1891		
IIIB2 4.1(03)	Zhang, J. and Garton P.K.	1999	The Determination of *Lambda*-Cyhalothrin in Formulations by Gas Chromatography (WRC-99-070) Zeneca Ag Products, Richmond, United States AMW00038-01A, 04.29.1999 not GLP, not published Syngenta File N Not stated	Y	SYN
IIIB2 4.1(04)	Johnson, N.	2005a	Analytical Method SF-121/1 Lambda Cyhalothrin CS (100) in Formulation A12690A by GC Analytical & Product Chemistry Department, Syngenta Crop Protection Inc., Greensboro, NC 27419 U.S.A. not GLP, not published Syngenta File N Not stated	Y	SYN
IIIB2 4.1(05)	Johnson, N.	2005b	A12690A: Validation of analytical method SF-121/1 Final report Analytical & Product Chemistry Department, Syngenta Crop Protection Inc., Greensboro, NC 27419 U.S.A. not GLP, not published Syngenta File N Not stated	Y	SYN
IIIB2 5.10.2(01)	Le Quesne, L.	2002	Field trial study to determine the efficacy of Demand CS vs *Lasius niger* (the garden or black ant), Sorex Limited Product Development Laboratory report no. LR 058/02, 7 October, 2002 non GLP, not published	Y	SYN
IIIB2 5.10.2(02)	Le Quesne, L.	2002	Field trial study to determine the efficacy of Demand CS vs *Lasius niger* (the garden or black ant), Sorex Limited Product Development Laboratory report no. LR 059/02, 9 October, 2002 non GLP, not published	Y	SYN
IIIB2 5.10.2(03)	Le Quesne, L.	2002	Field trial study to determine the efficacy of Demand CS vs *Lasius niger* (the garden or black ant). Sorex Limited Product Development Laboratory report no. LR 060/02, 9 October, 2002 non GLP, not published	Y	SYN
IIIB2 5.10.2(04)	Le Quesne, L.	2002	Field trial study to determine the efficacy of Demand CS vs *Lasius niger* (the garden or black ant). Sorex Limited Product Development Laboratory report no. LR 061/02, 9 October, 2002 non GLP, not published	Y	SYN

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IIIB2 5.10.2(05)	Le Quesne, L.	2002	Field trial study to determine the efficacy of Demand CS vs *Lasius niger* (the garden or black ant). Sorex Limited Product Development Laboratory report no. LR 062/02, 9 October, 2002 non GLP, not published	Y	SYN
IIIB2 5.10.2(06)	Le Quesne, L.	2002	A study to determine the efficacy of fresh and aged residual deposits of Demand CS vs the black ant *Lasius niger*. Sorex Limited Product Development Laboratory report no. LR 057/02, 1 October, 2002 non GLP, not published	Y	SYN
IIIB2 5.10.2(07)	Anon	-	Demand CS: Activity on flies Syngenta Crop Protection, Date not stated non GLP, not published	Y	SYN
IIIB2 5.10.2(08)	Serano, B.	2003	Measurement in the laboratory and under practice conditions of the efficacy of a proprietary insecticide product intended to control flies on livestock premises housing domestic production animals, Laboratoire T.E.C. report no. 861OXY/0603R, December, 2003 non GLP, not published	Y	NOV
IIIB2 5.10.2(9)	Williams, N.G.	1994	Bioefficacy evaluation: Demand 10cs against blatta orientalis (oriental cockroach). Zeneca Agrochemicals test reference no. IJ/94/0033, 26 June 1994, non GLP, not published	Y	SYN
IIIB2 5.10.2(10)	Wege, P.J.	2000	Demand 10CS: Efficacy against incidental pests, Syngenta Crop Protection report number TMJ 4380 B, February 2000 non GLP, not published	Y	SYN
IIIB2 5.10.2(11)	Hoppé, M.A.	2002	*Lambda*-cyhalothrin residual space spray project: (3), Control of *Aedes aegypti* and *Blattella germanica* with low rate residual deposits of Icon CS. Syngenta Crop Protection report number TMJ 4733 B, May 2002 non GLP, not published	Y	SYN
IIIB2 6.1.1(01)		1996	Lambda-Cyhalothrin: Acute Oral Toxicity to the Rat of a 100g/l CS Formulation	Y	SYN
IIIB2 6.1.2(01)		1996c	Lambda-Cyhalothrin: Acute Dermal Toxicity to the Rat of a 100g/l CS Formulation	Y	SYN
IIIB2 6.1.3(01)		1992	Lambda-Cyhalothrin: 4-hour inhalation toxicity in the Rat of a 100g/l CS Formulation	Y	SYN

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IIIB2 6.2(01)		1996e	Lambda-Cyhalothrin: Skin Irritation to the Rabbit of a 100g/l CS Formulation	Y	SYN
IIIB2 6.2(02)		1996a	Lambda-Cyhalothrin: Eye Irritation to the Rabbit of a 100g/l CS Formulation	Y	SYN
IIIB2 6.3(01)		1996b	Lambda-Cyhalothrin: Skin Sensitisation to the Guinea Pig of a 100g/l Cs Formulation	Y	SYN
IIIB2 6.4(01)		1997	*Lambda*-cyhalothrin 100g/L CS Formulation: In Vitro Absorption of Lambda-cyhalothrin Through Human Epidermis	Y	SYN
IIIB2 6.7(01)		2005	Induction of micronuclei by lambda-cyhalothrin in Wistar rat bone marrow and gut epithelial cells	N	PD
IIIB2 7.7.1.1 (01)	Kent, S.J. and Shillabeer, R.	1998	Lambda-cyhalothrin: Acute toxicity to *Daphnia magna* of a 100 g l-1 CS formulation Brixham Environmental Laboratory, BL6219/B, 05.1998 GLP, not published	Y	SYN
IIIB2 7.8.2 (01)	Thompson, H.M.	1997	Lambda-Cyhalothrin: Acute contact and oral toxicity to honey bees (*Apis mellifera*) of a 100 g/l CS formulation. Central Science Laboratory, EL8800, 12.1997 GLP, not published	Y	SYN