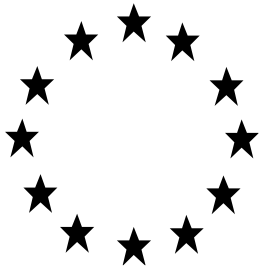
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



epsilon-Momfluorothrin

Product-type 18

(Insecticides, acaricides and products to control other arthropods)

July 2016

UK

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of the new active substance *epsilon*-momfluorothrin as product-type 18 (insecticides, acaricides and products to control other arthropods), carried out in the context of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

On 29 May 2013, the UK competent authority received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 25 September 2013.

On 6 October 2015 the Rapporteur Member State submitted to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report (CAR).

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

1.2. Purpose of the assessment report

The aim of the assessment report is to support the opinion of the Biocidal Products Committee and a decision on the approval of *epsilon*-momfluorothrin for product type 18, and, should it be approved, to facilitate the authorisation of individual biocidal products. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available from the Agency website, shall be taken into account.

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

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

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

The main identification characteristics and the physico-chemical properties of *epsilon*-momfluorothrin are given in Appendix I to this document.

The active substance approval reference specification is outlined in the Confidential Annex. Any new source of the active must be assessed against this specification.

The validation data provided for the monitoring of the parent in air is fully validated. Monitoring methods for body fluids and tissues and food and feed are not required. The validation data provided for the monitoring of residues in soil and water are not complete and further data post approval of the active are required. The following data gaps relating to the product, safety properties, shelf life study, internal pressure and weight loss of can after activation, are also required at product authorisation stage,

2.1.2. Intended Uses and Efficacy

The assessment of the biocidal activity of the active substance demonstrates that it has 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. However, the Applicant has stated that *epsilon*-momfluorothrin acts primarily as a knock-down agent and so will always be used in combination with another pyrethroid active substance to provide the 'kill' effect.

epsilon-Momfluorothrin is an active substance proposed for use as an insecticide in Product Type 18 of the Biocidal Products Regulation. Insecticidal products containing *epsilon*-momfluorothrin are for use in the control of crawling and flying insects.

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

2.1.3. Classification and Labelling

2.1.3.1. Current classification

This harmonised classification was agreed by RAC (15 September 2015).

Table 2.1 Current classification of *epsilon*-momfluorothrin based on CLP Regulation

Pictogram:	
Signal word:	Danger
Classification:	Acute Tox Cat 4, STOT-SE Cat 2 Aquatic classification: acute category 1, chronic category 1.
H-Statements:	H302: Harmful if swallowed H371: May cause damage to the organs (Central Nervous System)

	H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects
Precautionary Statements	P260: Do not breathe vapour/spray P264: Wash contaminated skin thoroughly after handling P270: Do not eat drink or smoke when using this product P273: Avoid release to the environment P301+ P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell P308 + P311: If exposed or concerned: Call a POISON CENTER or doctor/physician P330: Rinse mouth P391: Collect spillage P405: Store locked up P501: Dispose of contents/container to licensed waste disposal company
In line with Article 27 of CLP to avoid unnecessary duplication of hazard statements for labelling purposes where the criteria for H400 applies in addition to H410, H 411, H412 or H413 the appropriate hazard statement for inclusion on the label is H410 together with the associated pictogram and signal word. The appropriate acute M factor is 100 based on the lowest acute toxicity endpoint (LC50 = 0.012 mg a.s./l for rainbow trout). The appropriate chronic M factor is 100 based on the lowest chronic NOEC (*Daphnia magna* NOEC = 0.0005 mg a.s./l) and since the active substance is rapidly degradable.	

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

2.2.1.1.1. *Toxicology hazard summary*

epsilon-Momfluorothrin is an α-cyano synthetic pyrethroid consisting of two main isomers; RTZ: RTE ratio is 9:1. The toxicological batches tested are considered representative of the technical specification. Two representative products containing *epsilon*-momfluorothrin for use as insecticides (PT 18) are being supported; an oil based aerosol (*epsilon*-momfluorothrin /Sumithrin OBA) and a water based aerosol (*epsilon*-momfluorothrin /Sumithrin WBA). The formulations contain 0.1% *epsilon*-momfluorothrin.

Active substance: *epsilon*-momfluorothrin

The potential of *epsilon*-momfluorothrin to cause adverse health effects has been investigated in a standard package of guideline and GLP animal studies.

epsilon-Momfluorothrin is rapidly absorbed (>80%), extensively metabolised and excreted. Based on all available data, an oral absorption value of **100%** will be taken forward to the risk characterisation. The *in vitro* human dermal penetration study conducted with a solvent based formulation containing 1% *epsilon*-momfluorothrin suggests that 6% of the applied dose will be absorbed by this route. The representative products under review are an oil based aerosol and a water based aerosol. A formulation comparison performed by the UK CA suggests that neither product is similar to the tested solution and contains co-formulants that can enhance absorption. Furthermore, the active substance is more dilute in both the OBA and WBA formulations (10-fold less than the tested 1% in ethanol) which has the potential to increase penetration. In accordance with EFSA guidance (EFSA Journal 2012; 10(4):2665) and in the absence of product specific data, a default dermal absorption

value of **75%** is to be used for *epsilon*-momfluorothrin in both the OBA and WBA formulations as both products contains < 5% *epsilon*-momfluorothrin. For the inhalation route, it is assumed, based on the oral data, that *epsilon*-momfluorothrin will be completely absorbed and an inhalation absorption value of **100%** is therefore proposed.

Several studies in a number of laboratory animal species have indicated that *epsilon*-momfluorothrin has low acute toxicity by the inhalation and dermal routes and does not require classification based on LD_{50} or LC_{50} values. *epsilon*-Momfluorothrin is however harmful by the oral route and meets the criteria for classification as Acute Tox Category 4, H302. Neurotoxic effects have been reported in both acute oral and acute oral neurotoxicity studies and in an acute inhalation study. Classification is proposed for STOT-SE2, H371 (see below for consideration of neurotoxicity).

epsilon-Momfluorothrin is not irritating to skin and only mildly irritating to the eye. There is no evidence that it causes respiratory tract irritation. No classification for skin, eye or respiratory irritation is therefore proposed and these local effects will not be considered further in the risk characterisation.

epsilon-Momfluorothrin was negative in the guinea pig maximisation test for skin sensitisation. There is no specific information to determine whether *epsilon*-momfluorothrin induces respiratory sensitisation. However, there is no evidence from the repeat dose inhalation study suggesting that *epsilon*-momfluorothrin may cause respiratory sensitisation. Therefore, no classification for skin or respiratory sensitisation is proposed and these local effects will not be considered further in the risk assessment.

In repeat dose studies with the active substance, effects on body and liver weight are considered to be the most sensitive markers for establishing NOAELs for use in the risk assessment. The repeated-dose toxicity of *epsilon*-momfluorothrin was investigated by the oral route in rats (dietary studies of 90 days and 1 and 2 years duration), mice (dietary study of 18 months duration) and dogs (dietary studies of 90 days and 1 year duration). There were no treatment-related mortalities or overt clinical signs of toxicity in any of the studies. In both the sub-chronic and chronic studies, the rat was more sensitive than the dog; therefore, these studies were chosen to take forward in the risk characterisation. The lowest NOAEL of 11.6 mg/kg bw/d based on decreased body weight gain and an increase in liver weight and identified for parental toxicity from the rat 2 generation oral study has been used for the derivation of both the medium- and long-term AELs.

The repeated-dose toxicity of *epsilon*-momfluorothrin via the dermal route was investigated in rats in a 28-day study. A NOAEL of 1000 mg/kg bw/d was established. No long term studies were carried out given the absence of effects at the limit dose of 1000 mg/kg bw/d in the 28-day study.

The repeated-dose toxicity of *epsilon*-momfluorothrin via the inhalation route was investigated in rats in a 28 day study. No treatment-related deaths occurred but clinical signs of neurotoxicity were observed (tremor, hypersensitivity, tip toe gait, muscular rigidity and ataxic gait) immediately after exposure at 150 and 300 mg/m^3 and had resolved before the following treatment. These effects are therefore considered acute effects for which STOT-SE2 has already been proposed (see below for consideration of neurotoxicity). Increased liver weights were seen in both males and females of the 150 and 300 mg/m^3 groups. At the highest dose, males showed an increase in aspartate aminotransferase and changes in blood chemistry (increased total cholesterol and decreased blood glucose level). In females exposed to 150 and 300 mg/m^3, increased liver weight was accompanied by an increase in total cholesterol and phospholipids. Effects on the liver occurred at dose levels that would merit classification as STOT-RE2, however they are considered adaptive and do not produce significant adverse toxicological effects and so STOT-RE2 is not justified. Based on the genotoxicity testing *in vitro* and *in vivo* *epsilon*-momfluorothrin is considered to be non-genotoxic. *epsilon*-Momfluorothrin gave a marginal positive response in the

chromosomal aberration assay but was negative *in vitro* in the Ames and gene mutation tests and *in vivo* in both the mammalian erythrocyte micronucleus test and the UDS assay. Overall, on a weight of evidence approach the data do not support classification of *epsilon*-momfluorothrin for mutagenicity.

The carcinogenic potential of *epsilon*-momfluorothrin was investigated in rats and mice in guideline oral gavage studies. No increased incidence in tumour formation following treatment with *epsilon*-momfluorothrin was reported in mice. An increased incidence of liver adenoma and carcinoma was reported in the rat at high doses in the carcinogenicity study. However, based on mode of action data and the available literature, it is considered that this mode of action is not relevant to humans and *epsilon*-momfluorothrin is not carcinogenic to humans. Overall the available data do not support classification of *epsilon*-momfluorothrin for carcinogenicity.

The effect of *epsilon*-momfluorothrin on fertility has been investigated in a two generation study in rats. The available data showed no effects on fertility and therefore do not support the classification for this endpoint.

The effects on development have been investigated in guideline studies in both rats and rabbits. In the developmental studies there was no foetal toxicity at the highest doses tested in either species at which maternal toxicity occurred. The LOAEL for maternal toxicity in rats was set on the basis of the occurrence of tremors. In rabbits, a transient decrease in food consumption in dams was the only maternal effect interpreted to be treatment related. Overall, the data do not support the classification of *epsilon*-momfluorothrin for developmental toxicity.

Neurotoxic effects have been reported in the acute oral and acute oral neurotoxicity studies at doses of 200 mg/kg bw and above. Neurotoxic effects were also reported in the acute and 28 day inhalation studies. Whilst these effects fall within the guidance values for STOT-SE1 via the oral route, this classification is not considered appropriate given that lethality was observed at these dose levels and classification for acute oral toxicity has already been proposed. Therefore in accordance with the CLP guidance no classification is proposed for STOT-SE1 via the oral route. In the acute inhalation study, neurotoxic effects were seen at 0.5 mg/l in a small number of animals which is indicative of classification as STOT-SE1 but these were not seen in the next dose group of 1 mg/l. In the 2 mg/l dose group, which falls within the guidance values for STOT-SE2, the majority of animals showed clear signs of neurotoxicity. In addition, *epsilon*-momfluorothrin is a pyrethroid, a class of chemicals known to induce neurotoxic effects. Overall, given the inconsistencies in the data, the absence of a clear dose response and the known neurotoxic potential of pyrethroids, STOT-SE2, H371 is proposed. No route of exposure is specified as the clinical findings reported in the acute oral study appear to indicate that inhalation is not the only route that leads to neurotoxicity.

The immunotoxicity of *epsilon*-momfluorothrin has been investigated in a 28 oral study in rats. There was no evidence of immunotoxicity at the highest dose tested (241 mg/kg bw/d) and the NOAEL for the study was determined to be 81 mg/kg bw/d due to systemic toxicity.

Representative products: *epsilon*-momfluorothrin /Sumithrin OBA and *epsilon*-momfluorothrin /Sumithrin WBA

Acute toxicity studies on the *epsilon*-momfluorothrin/Sumithrin OBA and WBA products indicates that the criteria for classification for acute toxicity by the oral, dermal and inhalation routes are not satisfied.

No skin irritation potential was identified in either *epsilon*-momfluorothrin /Sumithrin OBA or *epsilon*-momfluorothrin / Sumithrin WBA. While *epsilon*-momfluorothrin /Sumithrin OBA

and *epsilon*-momfluorothrin /Sumithrin WBA did not meet the criteria for classification as an eye irritant, the OBA formulation did produce initial eye irritation effects. These should be brought to the user's attention. *epsilon*-Momfluorothrin, *epsilon*-momfluorothrin /Sumithrin OBA and *epsilon*-momfluorothrin / Sumithrin WBA are not irritating to the respiratory tract. No classification for skin, eye or respiratory irritation is therefore warranted.

epsilon-Momfluorothrin /Sumithrin OBA and *epsilon*-momfluorothrin / Sumithrin WBA were found to be negative for skin sensitisation when tested in the guinea pig (Buehler test). There is no specific information to determine whether the products induce respiratory sensitisation. However, there is no evidence from the repeat dose inhalation study suggesting that *epsilon*-momfluorothrin causes respiratory sensitisation and none of the co-formulants in *epsilon*-momfluorothrin /Sumithrin OBA or WBA are classified as respiratory sensitisers. Therefore, no classification for skin or respiratory sensitisation is warranted.

For repeated oral, inhalation and dermal toxicity, genotoxicity, carcinogenicity, reproductive toxicity and neurotoxicity, information on *epsilon*-momfluorothrin has been used to predict the likely health hazards of *epsilon*-momfluorothrin /Sumithrin OBA and *epsilon*-momfluorothrin / Sumithrin WBA. In addition, any available data on the other constituents of the formulation has been considered. No classification is proposed for *epsilon*-momfluorothrin /Sumithrin OBA or *epsilon*-momfluorothrin / Sumithrin WBA for these endpoints.

2.2.1.1.2. *Critical endpoints for AEL/C (Acceptable Exposure Levels/Concentrations) derivation*

The UK CA has proposed the following route-specific systemic AEL values for *epsilon*-momfluorothrin as there are clear differences in the potency of the substance by the inhalation route, oral and dermal route. *epsilon*-Momfluorothrin is most potent by the inhalation route, although only a 28-day study is available by this route of exposure. No effects on carcinogenicity or reproductive toxicity were seen in the oral studies. Effects are less potent by the oral route and no systemic effects were seen by the dermal route up to the limit dose in a 28-day rat study. Therefore inhalation-specific systemic AELs will be derived to be compared with inhalation exposures and oral-specific AELs will be derived to be compared with oral and dermal exposures. Route-specific AELs, where appropriate, reduce the uncertainty created by route-to-route extrapolation.

Inhalation-specific systemic AEL (short-term, medium-term and long-term)

The NOAEC from a 28 day inhalation study in the rat has been used to generate an inhalation-specific systemic AEL. The NOAEC from this study results in the lowest systemic dose from the whole dataset. Transient neurological effects and increased liver weight were the key health effects in determining the NOAEC of 50 mg/m^3 (equivalent to a systemic NOAEL of 9 mg/kg bw/d derived in accordance with the TNsG on Annex I Inclusion (ECHA, 2009, updated 2013)). This is consistent with observations from oral studies across all species and gives the most conservative systemic AEL. In addition, this inhalation study reflects more accurately the proposed spray use of the representative products.

To derive the AEL, an assessment factor of 100-fold has been applied to the systemic NOAEL to account for inter and intra-species differences only. Based on the rapid recovery (by day 3) of clinical signs in the 28 day inhalation study and the absence of significant qualitative or quantitative liver changes with duration of exposure after oral, no additional correction is required to extrapolate from 28 days to medium or long term AELs. The inhalation-specific systemic short-, medium- and long-term AEL for *epsilon*-momfluorothrin is therefore **0.09 mg/kg bw/d** (9/100).

Oral-specific short-term systemic AEL

A short-term AEL (i.e. estimated human exposure ≤ 24h) is based on single dose studies or repeat dose studies demonstrating relevant acute effects. The rat acute oral neurotoxicity study fulfils the criteria and has been used to generate an AEL for acute exposures. At the LOAEL of 200 mg/kg bw, tremors, excess salivation, straub tail and one mortality were reported. The NOAEL was identified as 80 mg/kg bw. To derive the AEL, an assessment factor of 100-fold has been applied to the NOAEL to account for inter and intra-species differences. There is no need for absorption adjustment as oral absorption of *epsilon*-momfluorothrin is >80%. Therefore the oral-specific short-term systemic AEL for *epsilon*-momfluorothrin is therefore **0.8 mg/kg bw/d** (80/100). It is noted that a lower NOAEL of 25 mg/kg bw/d was identified for maternal tremors in the rat oral developmental toxicity study. However, as these effects appeared only during late gestation, they were considered less appropriate for deriving the short-term AEL.

Oral-specific medium-term systemic AEL

A medium term AEL (i.e. estimated human exposure up to 3 months) is based on repeat dose studies demonstrating relevant effects. Considering all the data, the most appropriate study for an oral-specific medium term AEL was the oral 2-generation reproduction study. Adverse effects were observed following treatment with 32 mg/kg bw/d or greater in parental animals and were reported as decreased body weight gain and an increase in liver weight. The NOAEL of 11.6 mg/kg bw/d was identified from this study. To derive the AEL, an assessment factor of 100-fold has been applied to the NOAEL to account for inter and intra-species differences. There is no need for absorption adjustment as oral absorption of *epsilon*-momfluorothrin is > 80%. The oral-specific medium term systemic AEL for *epsilon*-momfluorothrin is therefore **0.12 mg/kg bw/d** (12/100).

Oral-specific long term systemic AEL

Studies with duration of 18 months or longer, 2-generation study, developmental toxicity and 12 month dog studies are examples used to set chronic AELs. Considering all the data, the most appropriate study for the oral-specific long term AEL was the oral 2-generation reproduction study. Adverse effects were observed following treatment with 32 mg/kg bw/d or greater in parental animals and were reported as decreased body weight gain and an increase in liver weight. The NOAEL of 11.6 mg/kg bw/d was identified from this study. To derive the AEL, an assessment factor of 100-fold has been applied to the NOAEL to account for inter and intra-species differences. There is no need for absorption adjustment as oral absorption of *epsilon*-momfluorothrin is > 80%. The oral-specific long term systemic AEL for *epsilon*-momfluorothrin is therefore **0.12 mg/kg bw/d** (12/100).

Thus, the following route-specific systemic AELs are derived:

Inhalation-specific systemic AEL (all durations) = 0.09 mg/kg bw/d
Oral-specific systemic short-term AEL= 0.8 mg/kg bw/d
Oral-specific systemic medium-/long-term AEL= 0.12 mg/kg bw/d

ARfD and ADI

Although an ARfD and ADI are not required for the scenarios assessed in this CAR, they might still be needed at Product Authorisation for different uses/scenarios. Therefore an ARfD of 0.8 mg/kg bw, equivalent to the oral-specific short-term AEL, is derived and an ADI of 0.12 mg/kg bw/d, equivalent to the oral-specific long-term AEL, is established.

2.2.1.2. Exposure assessment and risk characterisation

The active substance and representative products are manufactured outside the EU. As there is no direct contact with technical *epsilon*-momfluorothrin or related products within

the EU during its manufacture, the exposure from their manufacture has not been addressed.

Exposure assessments have been carried out on one of the representative products, *epsilon*-momfluorothrin /Sumithrin WBA as this was the worst case (see Doc IIB for details) and could be applied to the second product, *epsilon*-momfluorothrin /Sumithrin OBA. The exposure scenarios considered for the representative product were confined to non-professionals and the general public as the representative products are intended for use by non-professionals in households for the control of insects.

Table 2.2 Main paths of human exposure to the active substance from the use of *epsilon*-momfluorothrin/Sumithrin WBA or *epsilon*-momfluorothrin/Sumithrin OBA

Exposure path	Professional use	Non-professional use	General public[a]	Via the environment
Dermal	Not applied for	Yes: through handling the insecticide and application (space spraying, targeted spot or crack & crevice treatment)	Yes: through contact with residues of the product after settling on surfaces or contact with treated areas.	No
Oral	Not applied for	Yes: after spray application particles that are too large to be inhaled may be swallowed.	Yes: through hand to mouth contact after dermal exposure.	No
Inhalation	Not applied for	Yes: during spray application of the product.	Yes: through living or working in the building post application.	No
[a] People other than those applying the product				

Primary and secondary exposure assessments for the scenarios were initially assessed against the preliminary AEL (0.09 mg/kg bw/d). Where there was an unacceptable level of *epsilon*-momfluorothrin exposure via the representative product, refinement of the risk assessment was completed by comparison of route specific exposure levels with relevant refined AELs.

Primary Exposure

Professional users

The representative products are for non-professional use only and therefore human health scenarios for professionals have not been evaluated.

Non-Professional users

Primary exposure scenarios for non-professional users with *epsilon*-momfluorothrin /Sumithrin WBA and OBA have been modelled and the WBA formulation has been used as the worst case scenario (see Doc IIB for details). The exposure values were calculated and are presented (Table 2.4). The estimated systemic exposures have then been compared with the relevant route-specific AEL values and the sum of the percentages of the route-specific exposure/AEL ratios have been calculated.

Table 2.3 Primary exposure values and risk characterisation following exposure to the active substance in the products *epsilon*-momfluorothrin/Sumithrin WBA or OBA (a risk envelope approach) using the relevant route-specific AELs

Exposure Scenario		Estimated Internal Exposure				Inhalation exposure as percentage of inhalation –specific AEL (0.09 mg/kg bw/d)	Total dermal and oral exposure as percentage of the oral-specific AELs (short-term 0.8 mg/kg bw/d; medium/long-term 0.12 mg/kg bw/d	Total risk (from inhalation, oral and dermal exposure) as sum of the percentages of the route-specific AELs	Acceptable (Y/N)
		Oral uptake (mg/kg bw/day)	Inhalation uptake (mg/kg bw/day)	Dermal uptake (mg/kg bw/ day)	Total dermal and oral uptake (mg/kg bw/day)				
Air space spray application : Exposure to person actually applying the product & exposed for short duration afterwards [Consumer Spraying and Dusting Model 1,TnSG 2002, Part 2, p194)]									
Adult	Non-professional spraying *epsilon*-momfluorothrin/ Sumithrin WBA (0.1% *epsilon*-momfluorothrin) into the air indoors to control flying insects- **short term duration**	NA	0.00012	0.00504	0.00504	0.13%	0.63%	0.76%	Y
Air space spray application: Exposure to person actually applying the product & then exposed via inhalation to droplets in the air dispersing 4 hours after application [ConsExpo 4.1)]									
Adult (Tier 1)	Non-professional spraying *epsilon*-momfluorothrin/Sumithrin WBA (0.1% *epsilon*-momfluorothrin) into the air indoors to control flying insects- **short term duration**	0.000249	0.000245	0.00056	0.000809	0.27%	0.10%	0.38%	Y
Adult (Tier 2)		0.000125	0.000123	0.00056	0.000685	0.14%	0.09%	0.23%	Y
Air surface spray application for crack & crevice / spot treatment : Exposure to person actually applying the product & exposed for short duration afterwards									

[Consumer Spraying and Dusting Model 2,TnSG 2002, Part 2, p197)]									
Adult	Non-professional spraying *epsilon*-momfluorothrin/Sumithrin WBA (0.1% *epsilon*-momfluorothrin) into cracks and crevices/targeted spot application indoors to control crawling insects-**short term duration**	NA	0.000087	0.0096	0.0096	0.1%	1.2%	1.3%	Y
Air surface spray application for crack & crevice / spot treatment : Exposure to person actually applying the product & then exposed via inhalation to droplets in the air dispersing 4 hours after application [ConsExpo 4.1]									
Adult (Tier 1)	Non-professional spraying *epsilon*-momfluorothrin/Sumithrin WBA (0.1% *epsilon*-momfluorothrin) into cracks and crevices/targeted spot application indoors to control crawling insects-**short term duration**	0.000124	0.000245	0.000417	0.000541	0.27%	0.07%	0.34%	Y
Adult (Tier 2)		0.000115	0.000123	0.000417	0.000532	0.14%	0.07%	0.21%	Y

Exposure Scenario	**Estimated Internal Exposure**				**Inhalation exposure as percentage of inhalation –specific AEL (0.09 mg/kg bw/d)**	**Total dermal and oral exposure as percentage of the oral-specific AELs (short-term 0.8 mg/kg bw/d; medium/long-term 0.12 mg/kg bw/d**	**Total risk (from inhalation, oral and dermal exposure) as sum of the percentages of the route-specific AELs**	**Acceptable (Y/N)**
	Oral uptake (mg/kg bw/day)	**Inhalation uptake (mg/kg bw/day)**	**Dermal uptake (mg/kg bw/ day)**	**Total dermal and oral uptake (mg/kg bw/day)**				

Air space spray application : Exposure to person actually applying the product & exposed for short duration afterwards [Consumer Spraying and Dusting Model 1,TnSG 2002, Part 2, p194)]									
Adult	Non-professional spraying *epsilon*-momfluorothrin/ Sumithrin WBA (0.1% *epsilon*-momfluorothrin) into the air indoors to control flying insects- **short term duration**	NA	0.00012	0.00504	0.00504	0.13%	0.63%	0.76%	Y
Air space spray application: Exposure to person actually applying the product & then exposed via inhalation to droplets in the air dispersing 4 hours after application [ConsExpo 4.1)]									
Adult (Tier 1)	Non-professional spraying *epsilon*-momfluorothrin/Sumithrin WBA (0.1% *epsilon*-momfluorothrin) into the air indoors to control flying insects- **short term duration**	0.000249	0.000245	0.00056	0.000809	0.27%	0.10%	0.38%	Y
Adult (Tier 2)		0.000125	0.000123	0.00056	0.000685	0.14%	0.09%	0.23%	Y
Air surface spray application for crack & crevice / spot treatment : Exposure to person actually applying the product & exposed for short duration afterwards [Consumer Spraying and Dusting Model 2,TnSG 2002, Part 2, p197)]									
Adult	Non-professional spraying *epsilon*-momfluorothrin/Sumithrin WBA (0.1% *epsilon*-momfluorothrin) into cracks and crevices/targeted spot application indoors to control crawling insects- **short term duration**	NA	0.000087	0.0096	0.0096	0.1%	1.2%	1.3%	Y
Air surface spray application for crack & crevice / spot treatment : Exposure to person actually applying the product & then exposed via inhalation to droplets in the air dispersing 4 hours after application [ConsExpo 4.1]									

Adult (Tier 1)	Non-professional spraying *epsilon*-momfluorothrin/Sumithrin WBA (0.1% *epsilon*-momfluorothrin) into cracks and crevices/targeted spot application indoors to control crawling insects- **short term duration**	0.000124	0.000245	0.000417	0.000541	0.27%	0.07%	0.34%	Y
Adult (Tier 2)		0.000115	0.000123	0.000417	0.000532	0.14%	0.07%	0.21%	Y

The systemic exposures in all scenarios do not exceed the route-specific AELs and the total risks are acceptable. Therefore, acceptable risks have been identified in all the primary scenarios.

Secondary exposure

Secondary exposure scenarios were determined by the UK CA and a summary of the exposures is provided below (full details at Doc IIB). The estimated systemic exposures have then been compared with the relevant route-specific AEL values and the sum of the percentages of the route-specific exposure/AEL ratios have been calculated.

Table 2.4 Secondary exposure values and risk characterisation following exposure to the active substance in the products *epsilon*-momfluorothrin / Sumithrin WBA or OBA (a risk envelope approach) using the relevant route-specific AELs

Exposure Scenario	Estimated Internal Exposures				Inhalation exposure as percentage of inhalation – specific AEL (0.09 mg/kg bw/d)	Total dermal and oral exposure as percentage of the oral-specific AELs (short-term 0.8 mg/kg bw/d; medium/ long-term 0.12 mg/kg bw/d	Total risk (from inhalation, oral and dermal exposure) as sum of the percentages of the route-specific AELs	Acceptable (Y/N)
	Oral uptake (mg/kg bw)	Inhalation uptake (mg/kg bw)	Dermal uptake (mg/kg bw)	Total dermal and oral uptake (mg/kg bw)				
Bystanders who might be in the room during application of space spray or enter the room post application and are exposed via inhalation to droplets in the air dispersing 4 hours after application- short term duration								
Adult (Tier 1)	0.000249	0.000245	NA	0.000249	0.27%	0.03%	0.3%	Y
Adult (Tier 2)	0.000125	0.000123	NA	0.000125	0.14%	0.02%	0.15%	Y
Toddler (Tier 1)	0.0015	0.00148	NA	0.0015	1.64%	0.19%	1.83%	Y
Toddler (Tier 2)	0.000754	0.000742	NA	0.000754	0.8%	0.09%	0.89%	Y
Infant (Tier 1)	0.00125	0.00124	NA	0.00125	1.4%	0.16	1.6%	Y
Infant (Tier 2)	0.000628	0.000618	NA	0.000628	0.7%	0.08%	0.78%	Y
Bystanders who might be in the room during application of surface spray (crack & crevice/spot treatment) or enter the room post application and are exposed via inhalation to droplets in the air dispersing 4 hours after application- short term								

duration								
Adult (Tier 1)	0.00037	0.000367	NA	0.00037	0.41%	0.05%	0.46%	Y
Adult (Tier 2)	0.000124	0.000245	NA	0.000124	0.27%	0.02%	0.29%	Y
Toddler (Tier 1)	0.00224	0.00222	NA	0.00224	2.57%	0.28%	2.85%	Y
Toddler (Tier 2)	0.000696	0.000272	NA	0.000696	0.3%	0.09%	0.39%	Y
Infant (Tier 1)	0.00187	0.00185	NA	0.00187	2.06%	0.23%	2.29%	Y
Infant (Tier 2)	0.00058	0.000227	NA	0.00058	0.25%	0.07%	0.32%	Y
Crawling across treated floor after air space spray application- medium term duration								
Toddler	0.0101	NA	0.0756	0.0857	NA	71%	71%	Y
Infant	0.0126	NA	0.0945	0.107	NA	89%	89%	Y
Crawling across treated floor after crack and crevice application- medium term duration								
Toddler	0.0084	NA	0.0643	0.0728	NA	61%	61%	Y
Infant	0.0105	NA	0.0804	0.0909	NA	76%	76%	Y
Crawling across treated floor after targeted spot application- medium term duration								
Toddler	0.00151	NA	0.0113	0.0129	NA	11%	11%	Y
Infant	0.00189	NA	0.0142	0.0161	NA	13%	13%	Y
Secondary inhalation exposure to product in treated environment (volatilised residues)- long term duration								
Adult	NA	0.000010	NA	NA	0.01%	NA	0.01%	Y
Child	NA	0.000020	NA	NA	0.02%	NA	0.02%	Y
Toddler	NA	0.000031	NA	NA	0.03%	NA	0.03%	Y
Infant	NA	0.000026	NA	NA	0.03%	NA	0.03%	Y

The exposure values for the secondary scenarios presented are all acceptable. Therefore, acceptable risks have been identified in all the secondary scenarios.

Combined exposure

Combined exposures have been determined for those scenarios where combination is realistically expected.
It is considered that the situations where combined exposure (exposure that could arise from a number of tasks that could be performed in a single day) could occur are: for the adult/child space spraying application and then, on the same day staying in the treated room after application and being exposed to volatilised active substance residues from the product; for the adult/child surface spraying application and then, on the same day staying

in the treated room and being exposed to volatilised active substance residues from the product; toddler/infant bystander exposure from being present in the room during spray application and remaining in the room after application and then, on same day crawling across treated floor and being exposed to volatilised active substance residues from the product.

Additional combined exposure for the primary scenarios have been included as it was agreed by the WG, after trilateral discussions with member states, that it is possible that one person may treat both types of target pest i.e. air space and cracks and crevices/spot treatment on the same day.

The systemic exposures estimated for these combined scenarios have then been compared with the relevant route-specific AEL values and the sum of the percentages of the route-specific exposure/AEL ratios have been calculated.

Table 2.5 Combined exposures (primary and secondary) and risk characterisation to *epsilon*-momfluorothrin in the products *epsilon*-momfluorothrin /Sumithrin WBA and OBA (within risk envelope) using the relevant route-specific AELs

Exposure group	Primary exposure (air space or surface spray)		Secondary exposure					Total oral and dermal exposure from primary and secondary scenarios (mg/kg bw/d)	Total inhalation exposure from primary and secondary scenarios (mg/kg bw/d)	Total dermal and oral exposure as percentage of the oral-specific AELs (short-term 0.8 mg/kg bw/d; medium/long-term 0.12 mg/kg bw/d	Total inhalation exposure as percentage of inhalation – specific AEL (0.09 mg/kg bw/d)	Total risk (from inhalation, oral and dermal exposure) as sum of the percentages of the route-specific AELs	Acceptable (Y/N)
			Bystander		Crawling		Inhalation						
	Oral and dermal exposure (mg/kg bw/d)	Inhalation exposure (mg/kg bw/d)	Oral and dermal exposure (mg/kg bw/d)	Inhalation exposure (mg/kg bw/d)	Oral and dermal exposure (mg/kg bw/d)	Inhalation exposure (mg/kg bw/d)	Inhalation exposure (mg/kg bw/d)						
Air space spraying – short-term scenarios													
Adult	0.00504	0.00012	-	-	-	-	-	0.00504	0.00012	0.63%	0.13%	0.76%	Y
Adult (Tier 1)	0.000809	0.000245	-	-	-	-	0.00001	0.000809	0.000255	0.10%	0.28%	0.38%	Y
Adult (Tier 2)	0.000181*	0.000123*	-	-	-	-	0.00001	0.000181	0.000133	0.02%	0.15%	0.17%	Y
Toddler (Tier 1)	-	-	0.0015	0.000148	0.0857	NA	0.00003	0.0872	0.000178	10.90%	0.20%	11.1%	Y
Toddle	-	-	0.000	0.0007	0.085	NA	0.0000	0.0864	0.0007	10.8%	0.86%	11.7%	Y

rs (Tier 2)			754	42	7		3	54	72				
Infants (Tier 1)	-	-	0.00125	0.00124	0.107	NA	0.000026	0.10825	0.001266	13.53%	1.41%	14.9%	Y
Infants	-	-	0.000628	0.000618	0.107	NA	0.000026	0.107628	0.000644	13.4%	0.71%	14.2%	Y
Surface spray (cracks & crevices) -													
Adult	0.0096	0.000087	-	-	-	-	-	0.0096	0.000087	1.3% (short-term)	0.1% (short-term)	1.3%	Y
Adult (Tier 1)	0.000541	0.000245	-	-	-	-	0.00001	0.000541	0.000255	0.07%	0.28%	0.35%	Y
Adult (Tier 2)	0.000532*	0.000045*	-	-	-	-	0.00001	0.000532	0.000046	0.07% (short-term)	0.05% (short-term)	0.13%	Y
Toddlers (Tier 1)	-	-	0.00224	0.00222	0.0728	NA	0.00003	0.07504	0.00225	62.53% (medium-term)	2.50% (long-term)	65.03%	Y
Toddlers (Tier 2)	-	-	0.000696	0.000272	0.0728	NA	0.00003	0.07349	0.000302	61.3% (medium-term)	0.34 % (long-term)	61.58%	Y
Infants (Tier 1)	-	-	0.00187	0.00185	0.0909	NA	0.000026	0.09277	0.001876	77.31% (medium-term)	2.08% (long-term)	79.39%	Y
Infants	-	-	0.000058	0.000227	0.0909	NA	0.000026	0.09148	0.000254	76.23% (medium-term)	0.28% (long-term)	76.51%	Y
Surface spray (spot treatment)													
Adult	0.0096	0.000087	-	-	-	-	-	0.0096	0.000087	1.2% (short-	0.1% (short-	1.3%	Y

										term)	term)		
Adult (Tier 1	0.000541	0.000245	-	-	-	-	0.00001	0.000541	0.000255	0.07%	0.28%	0.35%	
Adult (Tier 2)	0.000532*	0.000045*	-	-	-	-	0.00001	0.000532	0.000046	0.07% (short-term)	0.05% (short-term)	0.13%	Y
Toddlers (Tier 1)	-	-	0.00224	0.00222	0.0129	NA	0.00003	0.01514	0.00225	12.62% (medium-term)	2.50% (long-term)	15.12%	
Toddlers	-	-	0.000696	0.000272	0.0129	NA	0.00003	0.01359	0.000302	11.33% (medium-term)	0.34% (long-term)	11.67%	Y
Infants (Tier 1)	-	-	0.00187	0.00185	0.0161	NA	0.000026	0.01797	0.001876	14.98% (medium-term)	2.08% (long-term)	17.06%	
Infants (Tier 2)	-	-	0.00058	0.000227	0.0161	NA	0.000026	0.01668	0.000254	13.9% (medium-term)	0.28% (long-term)	14.18%	Y

* Bystander exposure not included as primary exposure accounts for 4h exposure after spraying

Combined exposure levels were acceptable for adults, children, toddlers and infants. Overall, acceptable risks are identified for all combined exposure scenarios.

2.2.1.3. Conclusions of the risk characterisation

2.2.1.3.1. ***Primary exposure***

Professional users

This is not required as the representative products *epsilon*-momfluorothrin /Sumithrin WBA and OBA are not intended for professional use.

Non-Professional users

Primary exposure for *epsilon*-momfluorothrin /Sumithrin WBA has been evaluated for non-professionals using the product as an air space or surface spray for the control of insects. These exposure estimates are also applicable to *epsilon*-momfluorothrin /Sumithrin OBA, using a risk envelope approach. The exposure scenarios for adults applying the product showed that the exposure values were all below the relevant route-specific AEL. Therefore acceptable risks have been identified for all the primary exposure scenarios.

2.2.1.3.2. ***Secondary exposure***

Secondary exposure to *epsilon*-momfluorothrin in the product *epsilon*-momfluorothrin /Sumithrin WBA was evaluated. These exposure estimates are also applicable to *epsilon*-momfluorothrin /Sumithrin OBA, using a risk envelope approach. The estimated exposures posed an acceptable risk to all the exposed groups.

Overall, acceptable risks were identified for secondary exposure scenarios.

Although exposure to *epsilon*-momfluorothrin in Sumithrin OBA and WBA products has been shown to pose an acceptable risk to humans, the method of application i.e. spraying in households has the potential to land on food or feeding stuffs; therefore, the UK CA proposes that the product label contains the following phrases:

- Do not use directly on food and/or feedstuff nor on surfaces upon which food and/or feedstuff are prepared, stored or consumed.

- Before use, food, feedstuff, food and feedstuff preparing equipment, eating utensils and water storage tanks should be covered.

2.2.1.3.3. ***Combined exposure***

After completion of combined exposure assessment and comparison with the relevant route-specific AELs, there were no unacceptable risks posed to the exposure groups used in the modelling scenarios.

2.2.1.4. Risk assessment for animal health

For use in private areas, it can be expected that domestic animals (companion animals) may be exposed to *epsilon*-momfluorothrin during or after non-professional use of the biocidal product. As a worst-case, it can be assumed that the hazard assessment performed for human health would cover the risk for companion animals. According to the ECHA Technical Agreements for Biocides (TAB, September 2015), the risk to companion animals (pets) should be considered at the member state level at the product authorisation

stage. As such this has not been considered any further under EU legislation for the authorisation of *epsilon*-momfluorothrin.

2.2.2. Environmental Risk Assessment

2.2.2.1. Fate and distribution in the environment

The representative products *epsilon*-momfluorothrin / Sumithrin WBA and OBA contain a mixture of *epsilon*-momfluorothrin RTZ and *epsilon*-momfluorothrin RTE in the ratio of 9: 1 respectively so where endpoints are presented for the RTZ isomer these have been used in the risk assessment. Values for the minor (RTE) isomer have been given as supporting data, following the route adopted for Metofluthrin (PT 19 final CAR June 2010). The structures and position of [^{14}C] radiolabels are shown for *epsilon*-momfluorothrin RTZ and *epsilon*-momfluorothrin RTE in the following figures. As a number of common breakdown products have been identified in degradation studies and the degradation schemes themselves appear relatively complex, it is proposed to refer to the compounds using a set of agreed abbreviations as shown in the following figures.

Figure 2.1 Radiolabelled [^{14}C] *epsilon*-momfluorothrin RTZ and degradation products

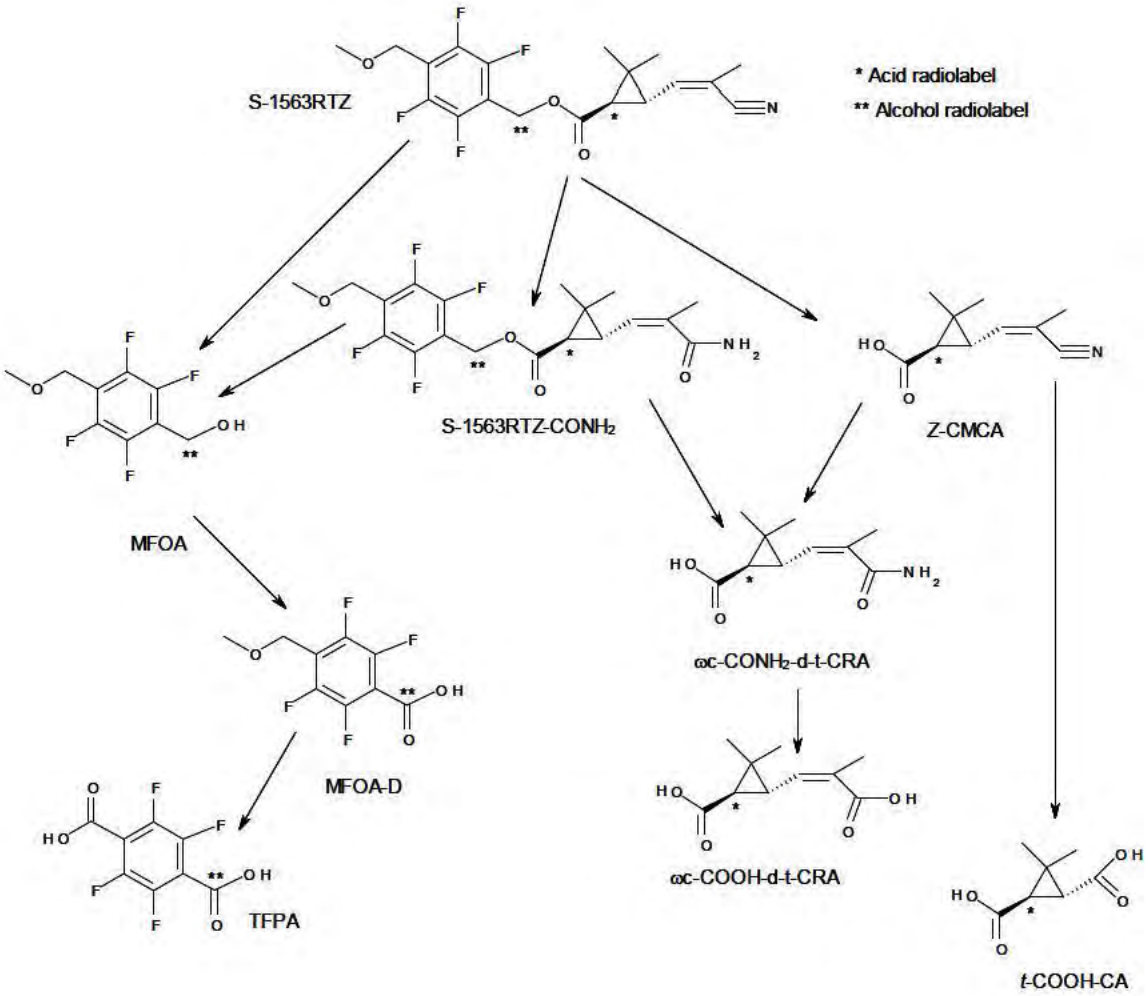
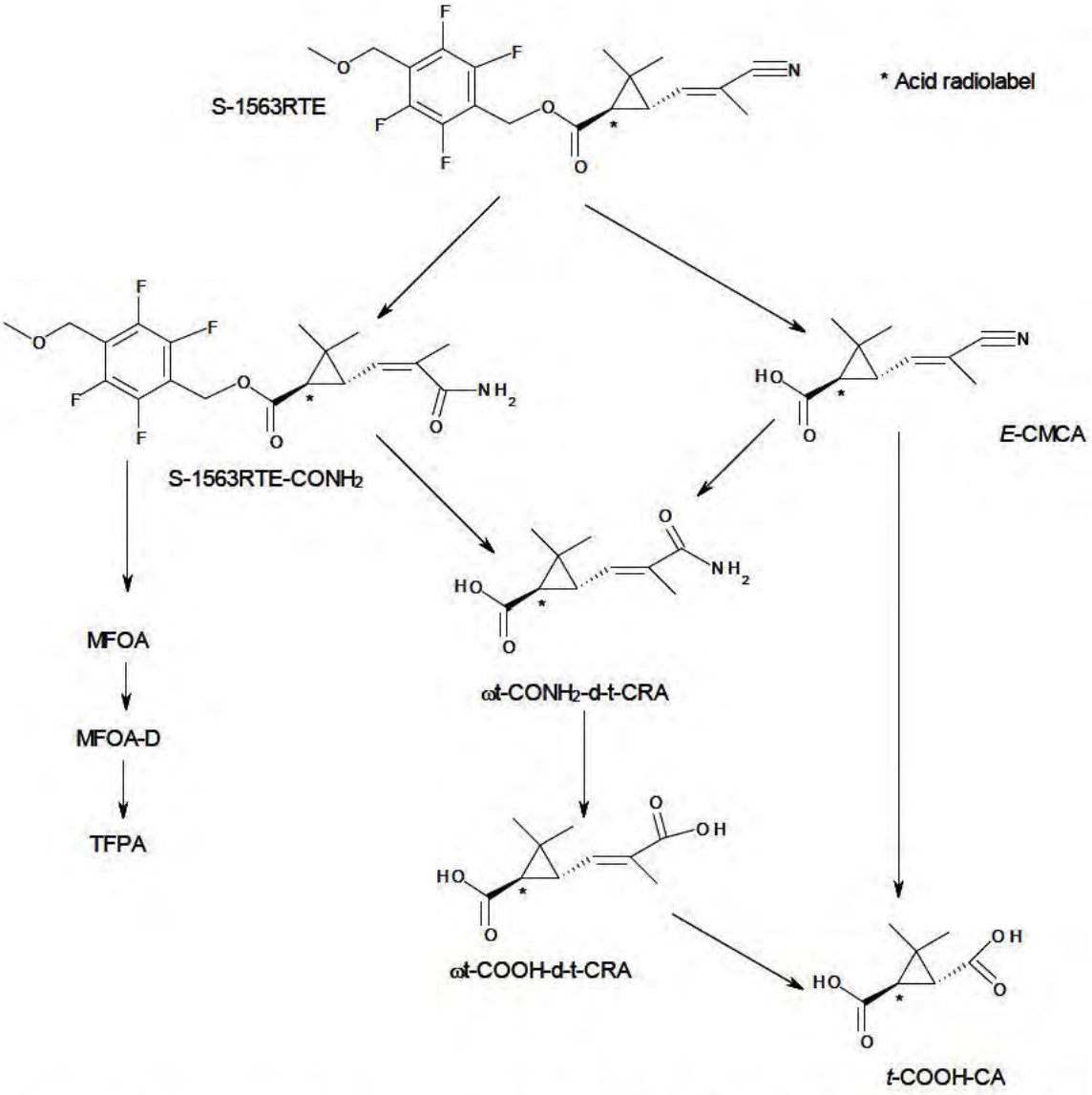


Figure 2.2 Radiolabelled [^{14}C] *epsilon*-momfluorothrin RTE and degradation products



epsilon-Momfluorothrin has been shown to be hydrolytically stable between pH 4 - 7 with a predicted DT_{50} of > 1 year (corrected to 12 °C). However, at elevated pH 9 hydrolytic cleavage of the ester was observed to give alcohol MFOA and carboxylic acid *Z*-CMCA (both at > 90 %). Further degradation of these metabolites was not observed and extrapolation of the degradation rate to 12°C gave a DT_{50} for *epsilon*-momfluorothrin at pH 9 of 35.5 – 36.0 days. Although significant hydrolysis was demonstrated at pH 9, it is still unknown as to which point above pH 7 hydrolysis starts to become a significant pathway and depending on the local pH of surface waters hydrolysis could be a major degradation pathway for *epsilon*-momfluorothrin. However as MFOA and *Z*-CMCA are both formed in the water/ sediment study the UK CA considers the behaviour in these systems will be more representative of natural environmental conditions.

Under constant irradiation at pH 7 in buffer, metabolites MFOA and *Z*-CMCA were again identified and a seasonal DT_{50} value of approximately 32 days was predicted at 40 °N from the available data (after adjustment for natural sunlight). The turbidity of surface waters and the non-professional use pattern proposed for the representative products make it

difficult to accurately predict the influence of photolysis in such systems on an EU-wide basis but in Northern European scenarios (similar to UK conditions at 50 – 58 °N), it is likely that photolysis will only have a relatively minor impact on removal of *epsilon*-momfluorothrin from the aquatic compartment.

Based on the data provided, *epsilon*-momfluorothrin was not shown to be readily biodegradable with 0 % degradation based on CO_2 evolution. However a water / sediment study using two test systems showed rapid degradation of *epsilon*-momfluorothrin with < 4 % AR remaining after 8 days incubation giving a DT_{50} of 3.2 days (corrected to 12°C). Significant amounts of CO_2 and bound residues were observed with a range of 15.0 – 43.0 % AR total system (CO_2) and 12.2 - 28.5 % AR total system (bound). This indicates that *epsilon*-momfluorothrin will be subject to significant levels of degradation in the aquatic environment. A number of major metabolites were formed in this study, (MFOA, MFOA-D, TFPA, *Z*-CMCA and ωc-$CONH_2$-d-t-CRA) and as DT_{50} values were either > 40 days in the water/ sediment system (at 12 °C) or could not be calculated it has to be assumed that these metabolites fulfil the persistence P (and potentially vP) criteria as laid out in Annex XIII of REACH.

The fate of *epsilon*-momfluorothrin in air was investigated using the quantitative structure activity relationship estimation method (AOPWIN v.1.70; 1995 and corrected in line with defaults taken from the draft ECHA guidance on Environmental risk assessment 2013) which considers the reaction with the daily air concentrations of hydroxyl (OH^-) radicals. A maximum estimated half-life of 0.68 days was predicted but, as the active substance is not considered to be volatile as indicated by the reported vapour pressure of 2.5×10^{-7} Pa (at 20 ºC), the air compartment is not considered further in the exposure assessment.
An aerobic soil degradation study in four soils was carried out and the rapid degradation of *epsilon*-momfluorothrin was observed with a geometric mean value of 5.77 days (corrected to 12 °C). Four major metabolites were identified and DT_{50} values (at 12 °C) were calculated as follows, MFOA-D (DT_{50} 73.2 days), TFPA (DT_{50} 125 days), Z-CMCA (DT_{50} 31.9 days) and ωc-$CONH_2$-d-t-CRA (DT_{50} 84.8 days). Again significant amounts of CO_2 and bound residues were observed up to 58.4 % AR total system (CO_2) and 58.1 % AR total system (bound), indicating that *epsilon*-momfluorothrin will be subject to significant levels of degradation in the terrestrial environment.

The adsorption and desorption of *epsilon*-momfluorothrin has been studied in a batch equilibrium study, using four soil types and one sediment. K_{oc} values ranged from 1033 - 4344 L kg^{-1} were obtained giving an arithmetic mean of 1748, indicating high adsorption to soil.

Furthermore as *epsilon*-momfluorothrin has been shown to degrade rapidly in soil the UK CA has concluded that accumulation of *epsilon*-momfluorothrin in soil is extremely unlikely to occur.

A QSAR approach using EPISUITE (v 4.11 US EPA) was taken with respect to the major degradation products identified in the preceding sections.

2.2.2.2. Effects assessment

The assessment factors (AF) used to define the PNECs for the environmental compartments of concern have been taken from the Technical Guidance Document on Risk Assessment (TGD) in support of Commission Directive 93/67/EEC (new notified substances), Commission Regulation (EC) No. 1499/94 (existing substances) and Directive 98/8/EC (biocidal products) (EC, 2003).

A 3 h respiration inhibition test, carried out according to OECD guideline 209, was submitted to assess the effects of *epsilon*-momfluorothrin on sewage treatment plant microorganisms.

There was no significant inhibition of oxygen consumption at 1000 mg/L *epsilon*-momfluorothrin, the highest concentration tested. However, given that the test item was tested at above the limit of solubility (lowest aqueous solubility of the RTE and RTZ isomers = 0.607 mg a.s. l-1), no solvent was used and unsuspended particles were noted at above 1 mg/L, the UK CA considers it more appropriate to define the NOEC/ER10/ER50 as greater than the limit of solubility. Therefore a NOEC/EC10 > 0.607 mg a.s. l-1 is used to derive the PNECmicroorganisms of > 0.0607 mg l-1 for use in the risk assessment.

epsilon-Momfluorothrin has been shown to be acutely toxic to aquatic organisms with the most sensitive endpoint reported for the fish (rainbow trout; *Oncorhynchus mykiss*) with a 96 h LC_{50} of 1.2 µg l^{-1}. The lowest chronic toxicity endpoint comes from the 21-d *Daphnia magna* study, with a NOEC = 0.5 µg l^{-1}. Given that chronic toxicity data is available on 3 taxonomic groups but it is not clear that an appropriately sensitive fish species was tested, an assessment factor of 50 is appropriate and the $PNEC_{water}$ is 1 x 10^{-5} mg a.s. l^{-1}.

A chronic spiked sediment study was supplied which suggested that sediment dwellers were not as sensitive to *epsilon*-momfluorothrin as the pelagic invertebrates with a NOEC of 0.035 mg a.s. kg^{-1} dwt sediment. The TGD states that, when long-term toxicity test data are available for benthic organisms the $PNEC_{sed}$ is calculated using assessment factors for long-term tests and this result should prevail in the risk assessment (see Section 3.5.4 of the TGD). Therefore, according to the TGD, the $PNEC_{sed}$ for *epsilon*-momfluorothrin can be derived using the 0.035 mg a.s. kg^{-1} dwt sediment. The TGD recommends an assessment factor (AF) of 100 is applied where only a single sediment NOEC/EC_{10} is available, hence the $PNEC_{sediment}$ is 3.5 x 10^{-4} mg a.s. kg^{-1} dwt sediment. Using a default conversion factor the $PNEC_{sediment}$ = 7.61 x 10^{-5} mg a.s. kg^{-1} wwt.

Studies on the toxicity of *epsilon*-momfluorothrin to earthworms, rove beetles and terrestrial plants were submitted. The TGD (part II page 116) states that the PNEC soil is calculated via an assessment factor when toxicity data are available for a producer, a consumer and/or a decomposer. In this instance data are available for all three groups however the plant toxicity study was only given a reliability score of 3. Based on the lowest NOEC (0.01 mg kg^{-1} dry weight soil with *Aleochara*) from long-term studies of two trophic levels (i.e. soil dwelling organisms and microorganisms) and using an Assessment Factor of 50 (Table 20, TGD), the PNECsoil = 2 x 10^{-4} mg kg^{-1} dwt or 1.77 x 10^{-4} mg kg^{-1} wwt. Given *epsilon*-momfluorothrin is rapidly degraded in soil, a TWA PNECsoil = 3.04 x 10^{-5} mg kg^{-1} dwt or 2.69 x 10^{-5} mg kg^{-1} wwt has also been determined.

Acute, short-term and reproductive studies were provided to assess the toxicity of *epsilon*-momfluorothrin to birds. The TGD states that, secondary poisoning effects on bird and mammal populations rarely become manifest in short-term studies. For this reason, results from long-term studies are strongly preferred. Using the lowest chronic NOEC of 500 mg a.s. kg^{-1} diet and an assessment factor of 30 (TGD, Part II, Table 23), the $PNEC_{oral\ bird}$ is 16.7 mg a.s. kg^{-1} diet. The PNEC oral is also required in terms of dose (this is required for the consumption of insects route of exposure). The $PNED_{oral\ bird}$ = 2.14 mg a.s. kg^{-1} d^{-1}. For mammals the NOEC of 200 mg a.s. kg^{-1} diet is used from the two-generation reproductive toxicity study. Using an assessment factor of 30 this equates to a $PNEC_{oral\ mammal}$ of 6.7 mg a.s. kg^{-1} diet. In terms of daily dose the $PNED_{oral\ mammal}$ = 0.39 mg a.s. kg^{-1} d^{-1}.

Acute aquatic toxicity studies were provided for the metabolites MFOA, MFOA-D and TFPA, indicating low toxicity. However, these studies were not conducted to GLP. Acute aquatic toxicity endpoints for these metabolites have also been estimated using QSARs. In addition QSAR estimates have been provided for the metabolites Z-CMCA and ωc-CONH2- d-t-CRA. The non-GLP study and QSAR results indicate low toxicity for all metabolites. On the basis of this dataset the UK CA considers that quantitative PNEC values for the metabolites Z-CMCA and ωc-CONH2- d-t-CRA cannot be accurately defined. Therefore, as a reasonable worst-case PNEC values for the parent are used to characterise the toxicity of Z-CMCA and ωc-CONH2- d-t-CRA in relevant compartments. For MFOA-D, TFPA and MFOA it is considered

appropriate to use the lower of the endpoints from the non-GLP aquatic organism toxicity studies or ECOSAR predictions to characterise the toxicity of these metabolites. PNECwater values for MFOA-D, TFPA and MFOA have been derived using the lowest acute toxicity endpoint and an Assessment Factor of 1000 (given data is available for 3 trophic levels). PNECsoil and PNECsed values for MFOA-D, TFPA and MFOA have been derived using the equilibrium partitioning method.

2.2.2.3. PBT and POP assessment

PBT assessment

According to the TGD In line with Annex III Annex III of Regulation (EC) No 1907/2006 (REACH), the Persistent, Bioaccumulative and Toxic (PBT) assessment is considered to be different from the local and regional assessment approaches, as it seeks to protect ecosystems where risks are more difficult to estimate. Under the Biocidal Products Regulation (BPR), any active substance that is found to be either a PBT or very Persistent very Bioaccumulative (vPvB) substance shall not be Approved unless a specific derogation applies. Any active substance which now has been demonstrated to trigger any two of the P or B or T criteria must be considered as a "candidate for substitution".

Persistence
Based upon results from an OECD 301B ready biodegradation study where 0 % degradation was determined after 28 d, the P criterion cannot automatically be discounted (as outlined in screening criteria taken from Chapter R11 – PBT Assessment of the ECHA (REACH) Guidance on information requirements and chemical safety assessment).

Data have been presented that show that *epsilon*-momfluorothrin rapidly degrades in the aquatic environment with a worst-case DT_{50} value of 3.21 d at a normalised temperature of 12 °C under aerobic conditions in two sediment/ water systems. An aerobic degradation study in 4 soil types was also presented where a DT_{50} of 5.77 d (at 12 °C) was obtained. Therefore, *epsilon*-momfluorothrin does not fulfil the criteria for a persistent compound according to Chapter R11 of ECHA Guidance (where the P criterion is defined as being where $T_{½}$ > 40 d in freshwater and/or > 120 d in freshwater sediment and/ or > 120 d in soil). The *epsilon*-momfluorothrin major metabolites can be considered against the persistence criteria using the DT_{50} values generated from the submitted *in vitro* degradation studies (soil and water/ sediment) as well as *in silico* screening using EPISUITE v 4.11 (provided by the applicant). Taking the measured DT_{50} values (normalised to 12 °C), as summarised below;

Table 2.6 Metabolite degradation rates in aquatic and terrestrial compartments at

12 °C

Compound	Water/ Sediment DT_{50}	Aerobic Soil DT_{50}	Persistence
epsilon-momfluorothrin RTZ	3.21	5.77	Not persistent
MFOA	49.9	-	P
MFOA-D	> 1000	73.2	vP
TFPA	> 1000	125	vP
Z-CMCA	87.6	31.9	vP
ωc-CONH2-d-t-CRA	96.3	84.8	vP

Where P refers to persistent and vP refers to very persistent

As insufficient data were provided to calculate a DT_{50} for MFOA-D and TFPA in the water / sediment systems a default of >1000 days has been assigned and it has to be assumed that both metabolites fall into the category of very persistent (vP). Taking the persistence screening results provided by the applicant using EPISUITE v 4.11, the following results are obtained;

Table 2.7 EPISUITE 4.11 modelling of metabolites

Source	MFOA	MFOA-D	TFPA	Z-CMCA	ωc-CONH2-d-t CRA
Biowin2	0.0000	0.0000	0.0000	0.9825	0.8605
Biowin3	1.2274 > months	1.1244 > months	1.2210 > months	2.8732 weeks	2.8616 weeks
Biowin6	0.0000	0.0000	0.0000	0.2587	0.2848
Ready biodegradability	No	No	No	Yes	Yes
Screening criteria	P (or vP) fulfilled if BIOWIN2 < 0.5 and BIOWIN3 < 2.25 OR BIOWIN6 < 0.5 and BIOWIN3 < 2.25				
Conclusion	P (or vP) fulfilled	P (or vP) fulfilled	P (or vP) fulfilled	P not fulfilled	P not fulfilled

Where the values for BIOWIN2 and BIOWIN6 relate to the probably of fast degradation (with 1 most likely to have fast degradation) and the values for BIOWIN3 predict the timeframe required for biodegradation to occur.
In summary, although *epsilon*-momfluorothrin is not persistent, it must be considered that all of the major metabolites fulfil the P (and potentially vP) criteria.

Bioaccumulation

epsilon-Momfluorothrin - A substance is considered to have the potential to fulfil the criterion of bioaccumulation when the log Kow exceeds 4.5 (according to the TGD). The maximum log Kow of *epsilon*-momfluorothrin is for the RTZ isomer and is 2.99 at (25 °C) (Document IIIA3, Section 3.9). The value for the RTE isomer is lower at 2.88 at 25 °C.

Additionally a fish bioconcentration study determined a whole fish steady-state bioconcentration factor of 612 L/kg (steady state) or 784 L/kg (kinetic). Therefore, as the BCF is < 2000 (trigger according to TGD), *epsilon*-momfluorothrin does not fulfil the criterion. It must also be noted that because [^{14}C]*epsilon*-momfluorothrin was extensively metabolised and was not detected in fish after Day 1 of the exposure phase, BCF values were based on total radioactive residues.

MFOA - The predicted log Kow is 1.659 using EPISUITE Kowwin (version 1.68). The bioaccumulation criterion is therefore not met.

MFOA-D - The predicted log Kow is 1.358 using EPISUITE Kowwin (version 1.68). The bioaccumulation criterion is therefore not met.

ωc-CONH2- d-t-CRA - The predicted log Kow is 1.001 using EPISUITE Kowwin (version 1.68). The bioaccumulation criterion is therefore not met.
TFPA - The predicted log Kow is 0.357 using EPISUITE Kowwin (version 1.68). The bioaccumulation criterion is therefore not met.

Z-CMCA - The predicted log Kow is 2.017 using EPISUITE Kowwin (version 1.68). The bioaccumulation criterion is therefore not met.

In summary, neither *epsilon*-momfluorothrin or its metabolites meet the criterion for bioaccumulation.

Toxic

epsilon-Momfluorothrin - According to the most sensitive chronic toxicity endpoint is the 21 d NOEC = 0.5 µg a.s. l^{-1} for *Daphnia magna*, which is also below the toxicity trigger of < 0.1 mg l^{-1}. Therefore, the toxic criterion is fulfilled according to the TGD.

MFOA - The lowest predicted acute toxicity endpoint for fish, *Daphnia magna* or green algae using ECOSAR (version 1.11) is the EC50 = 40.2 mg l^{-1} for green algae. This value exceeds the toxicity criterion of < 0.1 mg l^{-1}. There is uncertainty regarding this QSAR estimate but it is considered sufficient to conclude on whether the toxicity criterion of the PBT assessment is met. It is also supported by the non-GLP studies, with a lowest EC_{50} > 93 mg l^{-1}. The toxic criterion is therefore not met.

MFOA-D - The lowest predicted acute toxicity endpoint for fish, *Daphnia magna* or green algae using ECOSAR (version 1.1) is the EC50 = 2303 mg l^{-1} for green algae. It is also supported by the non-GLP studies, with a lowest EC_{50} = 75 mg l^{-1}. The toxic criterion is therefore not met.

ωc-CONH2- d-t-CRA - The lowest predicted acute toxicity endpoint for fish, *Daphnia magna* or green algae using ECOSAR (version 1.1) is the EC50 = 4.08 mg l^{-1} for green algae. The toxic criterion is therefore not met.

TFPA - The lowest predicted acute toxicity endpoint for fish, *Daphnia magna* or green algae using ECOSAR (version 1.1) is the EC50 = 11000 mg l^{-1} for green algae. It is also supported by the non-GLP studies, with a lowest EC_{50} >110 mg l^{-1}. The toxic criterion is therefore not met.

Z-CMCA - The lowest predicted acute toxicity endpoint for fish, *Daphnia magna* or green algae using ECOSAR (version 1.1) is the EC50 = 14.3 mg l^{-1} for green algae. The toxic criterion is therefore not met.

In summary, for *epsilon*-momfluorothrin the toxicity criterion is met. The toxic criterion is not met for the metabolites.

POP assessment

Under the Biocidal Products Regulation (BPR), an assessment is needed to demonstrate that a substance does not fulfil selection criteria under the United Nations Environment Programme – Persistent Organic Pollutants convention (UNEP-POPs) to limit emissions to the environment of those chemicals with high potential for persistence, bioaccumulation, long-range transport, and adverse effects on human health and the environment.
The criteria for a substance being a persistent organic pollutant (POP) are 'P', 'B' and having the potential for long range transport. In addition, high toxicity can breach the 'B' criterion, in which case a substance will be a persistent organic pollutant if it is 'P', demonstrates the potential for long range transport, and is either 'B' or 'T'.

epsilon-Momfluorothrin has been identified as triggering the 'T' criteria, but is not considered to require the 'P' or 'B' criterion. Theoretically, *epsilon*-momfluorothrin will not pose a possible risk for long-range transport on the basis of an estimated atmospheric half-life of 16.4 h (assuming a 24 h day and an OH radical concentration of 5.0E+5 OH-/ cm^3 when estimated using the AOPWIN v 1.92 QSAR modelling tool). This conclusion is further supported by the compound's very low vapour pressure (2.48 x 10^{-7} Pa at 20 °C), low predicted Henry's Law constant plus limited environmental exposure from current non-professional use patterns.

Given the above, *epsilon*-momfluorothrin does not meet the criteria for being a persistent organic pollutant.

2.2.2.4. Exposure assessment

The environmental exposure assessment for *epsilon*-momfluorothrin has been performed by the UK CA, using all available information. This has been taken from submitted studies from the Applicant and the Organisation for Economic Co-operation and Development (OECD) 5th Draft Emission Scenario Document (ESD) on "Insecticides, acaricides and products to control arthropods (PT 18) for household and professional use" (OECD, 2008). Information and guidance was also taken from part II of the Technical Guidance Document on risk assessment (TGD; EC, 2003) and the ECHA Guidance on Environmental Risk Assessment (ERA)- Active Substance (draft) version 1.1 August 2013. Information and decisions taken at TM-I-2011 (regarding a combined simultaneity assessment), TM-I-2008 (regarding use the use of a water/ sediment derived DT_{50}) along with refinement of the treated perimeter area as detailed in the ESD have been taken into account in this emissions assessment.

The representative products are both aerosols: *epsilon*-momfluorothrin / Sumithrin OBA (Oil-based Aerosol) and *epsilon*-momfluorothrin / Sumithrin WBA (Water-based Aerosol). As the *epsilon*-momfluorothrin content (0.1 % w/ w *epsilon*-momfluorothrin and 0.2 % *d*-phenothrin (Sumithrin)) is identical for both products and worst-case assumptions have been considered when addressing exposure, the majority of the environmental exposure assessment will be the same for both products. As only *epsilon*-momfluorothrin WBA is to be used for a space spray application the risk assessment will be based on the proposed uses of this product. However any identified risks will apply equally to *epsilon*-momfluorothrin OBA for all uses other than space spray. No product specific data on the environmental fate has been provided and none is required. The exposure and risk has only been presented for *epsilon*-momfluorothrin only, for product authorisation the possible additive and/ or synergistic effect of Sumithrin (and any Substances of Concern) will need to be considered.

The proposed domestic uses of product are as follows;

- Indoor for the control of crawling or flying insects (e.g. cockroaches, ants, flies or mosquitoes).

- Outdoor for the control of crawling insects (e.g. cockroaches and ants).

Table 2.8 PEC input assumptions for assessment of emissions from representative products (*epsilon*-momfluorothrin / Sumithrin OBA or WBA)

Input/ Parameter (units)	Data/ Endpoint
Number of houses in catchment of STP (-) Indoor / Outdoor	4000 / 2500
Effluent discharge rate of STP (l d^{-1})	2 x 10^6
Number of applications (-) Crack and Crevice / Space spray / Outdoor	1 / 4 / 1
Cleaning efficiency (-) Crack and crevice / Space spray	0.03 / 1
Perimeter application width of spray application- Default (foundation height / ground width) (m)	0.5 / 0.5
Simultaneity Factor (%)- Default Crack and crevice / Space spray	0.0275 / 0.055
Simultaneity Factor (%)- Refined Combined assessment[#] Indoor crack & crevice / Indoor Space spray / Outdoor spray	0.0069/ 0.0138 / 0.0138
Cleaning efficacy (F_{CE}) : crack, crevice and spot treatment to difficult to access areas	0.03
Fraction to water at STP *	77.8
Fraction to sewage sludge at STP *	17.4
Fraction to air at STP *	9.93 x 10^{-5}
Sludge rate : rate of sewage sludge production at STP (kg d^{-1})	710

* Derived by SimpleTreat 3.1; [#] Refinement agreed at TM-I-2011

Releases into the environment can take place from processes at any stage of the life-cycle of a substance. However, based on the Applicant's envisaged fields of use for *epsilon*-momfluorothrin, the following have been considered to present the worst-case scenarios in terms of predicted environmental concentrations (PEC):

Indoor use

Emissions from a space spray application or as a spot treatment in difficult to access areas (crack and crevice treatment) as a result of wet cleaning resulting in:

- Direct exposure to the sewage treatment plant (STP) compartment via drains with,
  - i. indirect exposure to surface waters (including sediment) via STP effluent,
  - ii. indirect exposure to soil compartment (including groundwater) via STP sludge application to land and
  - iii. indirect exposure to biota via surface waters (bioconcentration in fish leading to secondary poisoning of fish-eating birds).

As detailed in the ESD, in the case of air space treatment there is no direct application on material, and the insecticide particles are suspended in the air with 96 % falling to the floor during the day and subject to wet cleaning. In the case of the crack and crevice application these are likely to be to areas not prone to frequent wet cleaning.

Further to the above assumptions, the indirect environmental exposure via domestic waste disposal to landfill (as a result of disposal of used packaging plus waste product and dry cleaning such as vacuuming of treated areas) has not been considered in this exposure assessment. This is because this route of exposure is less likely to be of concern when

compared to the direct exposure via the STP compartment. In addition, the effect of its dilution with other wastes, biodegradation of the active substance (a.s.) and the significant containment measures at landfill sites according to European Union (EU) waste regulations (EU Directive 99/31/EC) further reduce any potential concerns.

Outdoor use

Emissions from the treatment of

- Direct exposure to the sewage treatment plant (STP) compartment via drains from urban use with,
  i. indirect exposure to surface waters (including sediment) via STP effluent,
  ii. indirect exposure to soil compartment (including groundwater) via STP sludge application to land and
  iii. indirect exposure to biota via surface waters (bioconcentration in fish leading to secondary poisoning of fish-eating birds).
- Direct exposure to the soil from rural application
  i. direct exposure to soil from spray drift, deposition of droplets and wash off from a rain event
  ii. indirect exposure to groundwater from the soil

For urban applications of *epsilon*-momfluorothrin it is assumed that emissions will fall to a non permeable surface and that releases of insecticide will be washed with rainwater to drainage leading to STP. Conversely for rural application releases the assumption is that releases will end up on unpaved soil.

As stated in the ESD for PT 18; *Under outdoor conditions the use of an aerosol to control flying insects is highly localised and has a limited time of action due to the dilution in the air compartment. Therefore there is no specific scenario developed for this application and it is considered that the treatment of flying insects will be covered by the indoor space spray application assessment.*

In addition to the three scenarios already described a combined assessment taking into account all three scenarios was also included. In the case of *epsilon*-momfluorothrin if Indoor and Outdoor uses are split 50 : 50 and the two indoor uses are further split 50 : 50 this would give the following $F_{simultaneity}$;

Indoor: Crack and crevice: 25 % of default F_{sim} of 2.75 % gives a weighted F_{sim} of 0.688 %
Indoor: Space Spray: 25 % of default F_{sim} of 5.5 % gives a weighted F_{sim} of 1.38 %
Outdoor: Spray crawling insects: 50 % of default F_{sim} of 2.75 % gives a weighted F_{sim} of 1.38 %

The UK CA has also taken into acount the fact that although no degradation was observed in the ready biodegradation study, rapid degradation was observed in both soil degradation and the water/ sediment study. As agreed at TM-I-08 and noted in the Manual of Technical Agreements MOTA 2013 (6th draft) the DT_{50} from a water/ sediment study can be considered as an alternative to a STP simulation test and the worst case total system degradation rate can be used as a worst case STP degradation rate (in this case DT_{50} of 3.21 days at 12 ºC).

An assessment of metabolites has not been made as any formed at STP will be present at lower concentrations than *epsilon*-momfluorothrin hence the resulting PEC / PNEC ratios will also be < 1, indicating acceptable risk at STP to micro-organisms from exposure to *epsilon*-momfluorothrin derived metabolites.

Values for major metabolites in the aquatic compartment were calculated taking into account the maximum amount formed in water from the water/ sediment study, adjusted for molecular weight.

Calculation of a value for the PEC in sediment has been performed using the Equilibrium Partitioning Method (EPM) to modify PEC values determined in surface waters using appropriate equations outlined in the TGD for risk assessment.

Although substances with a Koc value < 500 are not thought to absorb to sediment according to the ECHA guidance on ERA notes (Infobox 13) $PEC_{sediment}$ values for all metabolites identified as major in sediment from the water / sediment study have been calculated. As measured data are unavailable for the metabolites the highest K_{oc} prediction and Henry's law constant calculation have been taken from the EPISUITE 4.11 analysis as detailed in Document II-B Table 3.3.4).

As outlined in Section 3.3.3.2 of Document II-B, no predicted environmental concentrations of *epsilon*-momfluorothrin (or its metabolites) in air have been presented as these are expected to be negligible based on its low vapour pressure (2.48×10^{-7} Pa at 20 °C), and proposed non-professional uses.

Application of *epsilon*-momfluorothrin to soil can be considered as direct exposure coming from an outdoor rural application or coming indirectly from the application of sludge to land. In the case of an outdoor rural application a soil depth of 50 cm has been assumed for a rural garden.

The application of *epsilon*-momfluorothrin to soil can also be made via the application of sewage sludge to land from indoor and outdoor urban uses.

The levels of major metabolites in soil were determined from the maximum level observed in the aerobic soil degradation study and the DT_{50} values from the same study were used to calculate a $PEClocal_{soil}$ ecosystem value.

It should be noted that PEC_{soil} values for grassland and arable land have also been calculated however these will only be used for groundwater assessment.

A crude prediction of the levels of *epsilon*-momfluorothrin in groundwater using the equation from the ECHA guidance on ERA showed that levels below the current quality standard set at 0.1 µg l^{-1} by the EU Drinking Water Directive (98/83/EC) for *epsilon*-momfluorothrin are expected for the indoor and outdoor urban uses of *epsilon*-momfluorothrin. A similar calculation for the outdoor rural use of *epsilon*-momfluorothrin predicts a level of 0.0381µg l^{-1}, which is below the drinking water directive limit.

As the porewater calculation is a simplistic approach which fails to take account of either degradation or dilution in deeper soil levels, the UK CA has chosen to use the FOCUS ground water model of PEARL 4.4.4 to make a more comprehensive prediction of groundwater concentrations for *epsilon*-momfluorothrin and associated metabolites.

A number of worst case default assumptions for the metabolites were used in the modelling, such as a formation fraction for each of 1 and the lowest predicted K_{oc} from QSAR modelling (EPISIUTE 4.11 provided by the applicant) and the representative crops of alfalfa for grassland and cereal and maize to represent arable were chosen.

Note- The application rate calculation was based on a spray application amount of 1.12 g

b.p. per second- this value has since been reduced by the applicant to 0.41 g b.p. per second (an acceptable level of efficacy is shown at this reduced rate (Heaven, 2012)). So the calculation given in Doc IIB represents an extreme worst case.

Predicted levels of *epsilon*-momfluorothrin and associated metabolites were found to be below 0.1 µg l^{-1} (highest value 0.019851 µg l^{-1} at Jokioinen for TFPA applied to alfalfa) indicating that the risk of contamination to groundwater by *epsilon*-momfluorothrin and associated metabolites will be acceptable.

Secondary Poisoning- terrestrial

As described the exposure of soil to *epsilon*-momfluorothrin could result from either the direct exposure from an outdoor rural use, or indirectly via the application of sewage sludge from indoor and outdoor urban uses. The calculation of $C_{earthworm}$, which corresponds to $PEC_{oral\ predator}$ has been made for both of these situations;

Secondary Poisoning- aquatic

The level of *epsilon*-momfluorothrin in fish has also been determined for the indoor and outdoor urban uses where emissions are considered to enter surface water via STP.

2.2.2.5. Risk characterisation

2.2.2.5.1. ***Risk to the aquatic compartment (including sediment)***

Risks to local STP

The following table presents the risk characterisation (PEC: PNEC) values for *epsilon*-momfluorothrin at local STP as a result of the indoor and outdoor urban domestic use of the insecticidal product *epsilon*-momfluorothrin OBA or WBA.

Table 2.9 Risk characterisation (PEC: PNEC) values for *epsilon*-momfluorothrin OBA or WBA

Scenario	PEC (mg l^{-1})	PNEC (mg l^{-1})	PEC: PNEC
Indoor space spray	1.88×10^{-3}	> 0.0607	3.10×10^{-2}
Indoor crack and crevice	4.28×10^{-6}		7.06×10^{-5}
Outdoor urban	1.25×10^{-3}		2.07×10^{-2}
*Combined scenarios	1.10×10^{-3}		1.81×10^{-2}

* Where 'combined scenarios' refers to the refinement agreed at TM-I-2011 where a weighted F_{sim} was applied to each scenario.

From the data presented, PEC / PNEC ratios are all < 1 indicating that the indoor and outdoor urban application of *epsilon*-momfluorothrin OBA and WBA do not pose an unacceptable risk to local STP micro-organisms.

An assessment of metabolites has not been made as any formed at STP will be present at lower concentrations than *epsilon*-momfluorothrin hence the resulting PEC / PNEC ratios will also be < 1, indicating acceptable risk at STP to micro-organisms from exposure to *epsilon*-

momfluorothrin derived metabolites.

Risks to the aquatic compartment (surface waters)

The following table presents the risk characterisation (PEC: PNEC) values for *epsilon*-momfluorothrin in surface waters as a result of the indoor and outdoor urban domestic use of the insecticidal product *epsilon*-momfluorothrin OBA or WBA.

Table 2.10 Risk characterisation (PEC: PNEC) values for *epsilon*-momfluorothrin OBA or WBA in surface waters

Scenario	PEC (mg l^{-1})	PNEC (mg l^{-1})	PEC: PNEC
Indoor space spray	1.87×10^{-4}	1.0×10^{-5}	18.8
Indoor crack and crevice	4.27×10^{-7}		4.27×10^{-2}
Outdoor urban	1.25×10^{-4}		12.5
*Combined scenarios	1.09×10^{-4}		10.9

* Where 'combined scenarios' refers to the refinement agreed at TM-I-2011 where a weighted F_{sim} was applied to each scenario.

From data presented the application of *epsilon*-momfluorothrin WBA in the indoor space spray scenario, outdoor urban and the combined scenarios have given PEC/ PNEC ratios > 1, indicating a potential risk to aquatic organisms in surface water.

Use of *epsilon*-momfluorothrin WBA or OBA in the indoor crack and crevice gives a PEC / PNEC ratio < 1 indicating an acceptable risk to aquatic organisms in surface waters.
The additional exposure route whereby the run off from an outdoor urban use could enter surface water via a storm drain (calculated $PEC_{surface\ water}$ of 1.61×10^{-4} mg l^{-1}), would pose an unacceptable risk to surface water with a PEC/ PNEC of 16.1.

The risk from *epsilon*-momfluorothrin derived metabolites has been calculated from the non- degraded value of *epsilon*-momfluorothrin for the most conservative estimates.

Table 2.11 Risk characterisation (PEC: PNEC) in surface water for *epsilon*-momfluorothrin metabolites MFOA and MFOA-D

	MFOA			MFOA-D		
Compound	PEC (mg l^{-1})	PNEC (mg l^{-1})	PEC: PNEC	PEC (mg l^{-1})	PNEC (mg l^{-1})	PEC: PNEC
Indoor space spray	2.72×10^{-5}	0.0402	6.75×10^{-4}	7.08×10^{-5}	> 0.110	6.44×10^{-4}
Indoor crack and crevice	6.19×10^{-8}		1.54×10^{-6}	1.61×10^{-7}		1.47×10^{-6}
Outdoor urban	1.18×10^{-5}		4.51×10^{-4}	4.72×10^{-5}		4.29×10^{-4}
*Combined scenarios	1.59×10^{-5}		3.94×10^{-4}	4.13×10^{-5}		3.76×10^{-4}

* Where 'combined scenarios' refers to the refinement agreed at TM-I-2011 where

a weighted F_{sim} was applied to each scenario.

Table 2.12 Risk characterisation (PEC: PNEC) in surface water for *epsilon*-momfluorothrin metabolites TFPA and *Z*-CMCA

	TFPA			Z-CMCA		
Compound	**PEC (mg l^{-1})**	**PNEC (mg l^{-1})**	**PEC: PNEC**	**PEC (mg l^{-1})**	**PNEC (mg l^{-1})**	**PEC: PNEC**
Indoor space spray	6.14×10^{-5}	0.075	8.19×10^{-4}	5.50×10^{-5}	1.0×10^{-5}	5.50
Indoor crack and crevice	1.40×10^{-7}		1.87×10^{-6}	1.25×10^{-7}		1.25×10^{-2}
Outdoor urban	4.10×10^{-5}		5.46×10^{-4}	3.67×10^{-5}		3.67
*Combined scenarios	3.59×10^{-5}		4.78×10^{-4}	3.21×10^{-5}		3.21

* Where 'combined scenarios' refers to the refinement agreed at TM-I-2011 where a weighted F_{sim} was applied to each scenario.

Table 2.13 Risk characterisation (PEC: PNEC) in surface water for *epsilon*-momfluorothrin metabolite ωc-$CONH_2$-d-t-CRA

	ωc-$CONH_2$-d-t-CRA		
Compound	**PEC (mg l^{-1})**	**PNEC (mg l^{-1})**	**PEC: PNEC**
Indoor space spray	1.54×10^{-5}	5.0×10^{-6}	1.54
Indoor crack and crevice	3.52×10^{-8}		3.52×10^{-3}
Outdoor urban	1.03×10^{-5}		1.03
*Combined scenarios	9.02×10^{-6}		0.902

* Where 'combined scenarios' refers to the refinement agreed at TM-I-2011 where a weighted F_{sim} was applied to each scenario.

The preceding tables demonstrate that risks are predicted to the aquatic environment for Z-CMCA and ωc-$CONH_2$-d-t-CRA for the space spray, outdoor urban and combined application scenario (Z-CMCA only). Acceptable levels of risk are predicted for metabolites MFOA, MFOAD TFPA and for all metabolites when an indoor crack and crevice use is considered.

Risk to the sediment compartment

The following table presents the risk characterisation (PEC: PNEC) values for *epsilon*-momfluorothrin in sediment as a result of the indoor and outdoor urban domestic use of the insecticidal product *epsilon*-momfluorothrin OBA or WBA. The following risks have been assessed using the corresponding values for wet sediment.

Table 2.14 Risk characterisation (PEC: PNEC) values for *epsilon*-momfluorothrin OBA or WBA in sediment

Scenario	PEC (mg kg $^{-1}$ wwt)	PNEC (mg kg^{-1} wwt)	PEC: PNEC
Indoor space spray	7.27×10^{-3}	7.61×10^{-5}	95.5
Indoor crack and crevice	1.66×10^{-5}		0.218
Outdoor urban	4.85×10^{-3}		63.7
*Combined scenarios	4.25×10^{-3}		55.8

* Where 'combined scenarios' refers to the refinement agreed at TM-I-2011 where a weighted F_{sim} was applied to each scenario.

A risk to the sediment compartment has been identified for all scenarios, except in the case of an indoor crack and crevice application.

Table 2.15 Risk characterisation (PEC: PNEC) values for MFOA and MFOA-D in sediment

	MFOA			MFOA-D		
Compound	PEC (mg kg $^{-1}$ wwt)	PNEC (mg kg^{-1} wwt)	PEC: PNEC	PEC (mg kg $^{-1}$ wwt)	PNEC (mg kg^{-1} wwt)	PEC: PNEC
Indoor space spray	5.24×10^{-4}	0.137	3.83×10^{-3}	1.35×10^{-3}	0.308	4.38×10^{-3}
Indoor crack and crevice	1.19×10^{-6}		8.72×10^{-6}	3.07×10^{-6}		9.97×10^{-6}
Outdoor urban	3.50×10^{-4}		2.55×10^{-3}	8.99×10^{-4}		2.92×10^{-3}
*Combined scenarios	3.06×10^{-4}		2.24×10^{-3}	7.87×10^{-4}		2.56×10^{-3}

* Where 'combined scenarios' refers to the refinement agreed at TM-I-2011 where a weighted F_{sim} was applied to each scenario.

Table 2.16 Risk characterisation (PEC: PNEC) values for TFPA and *Z*-CMCA in sediment

	TFPA			Z-CMCA		
Compound	**PEC (mg kg $^{-1}$ wwt)**	**PNEC (mg kg^{-1} wwt)**	**PEC: PNEC**	**PEC (mg kg $^{-1}$ wwt)**	**PNEC (mg kg^{-1} wwt)**	**PEC: PNEC**
Indoor space spray	6.51×10^{-4}	1.02	6.39×10^{-4}	9.87×10^{-4}	7.61×10^{-5}	13.0
Indoor crack and crevice	1.48×10^{-6}		1.46×10^{-6}	2.25×10^{-6}		2.96×10^{-2}
Outdoor urban	4.35×10^{-4}		4.26×10^{-4}	6.59×10^{-4}		8.66
*Combined scenarios	3.80×10^{-4}		3.73×10^{-4}	5.77×10^{-4}		7.58

* Where 'combined scenarios' refers to the refinement agreed at TM-I-2011 where a weighted F_{sim} was applied to each scenario.

Unacceptable risks to the sediment compartment are predicted for *Z*-CMCA from the indoor space spray, outdoor urban and combined scenario applications of *epsilon*-momfluorothrin. Acceptable risks to sediment were predicted for MFOA, MFOAD and TFPA for all proposed uses.

2.2.2.5.2. *Risk to the terrestrial environment*

Risk to Local (in situ) soil

For the outdoor use direct application to soil is not intended, but exposure to the soil compartment might occur *via* spray drift and run off during the application and *via* the wash-off during a rain event. The risk to soil from the outdoor rural use of *epsilon*-momfluorothrin OBA or WBA is presented in the following table.

Table 2.17 Risk characterisation (PEC: PNEC) values for *epsilon*-momfluorothrin and metabolites from the direct emission to soil in an outdoor rural scenario

Compound	**PEC (mg kg^{-1} wwt)**	**PNEC (mg kg^{-1} wwt)**	**PEC: PNEC**
epsilon-momfluorothrin	2.12×10^{-3}	2.69×10^{-5}	78.8
MFOA-D	1.01×10^{-3}	0.193	5.22×10^{-3}
TFPA	2.56×10^{-4}	0.794	3.22×10^{-4}
Z-CMCA	5.23×10^{-4}	1.77×10^{-4}	2.95
ωc-CONH2-d-t-CRA	1.12×10^{-4}	1.77×10^{-4}	6.32×10^{-1}

Risks have been identified to soil, from *epsilon*-momfluorothrin and Z-CMCA from the use of *epsilon*-momfluorothrin OBA and WBA in an outdoor rural setting.

Risk to Soil from Applied Sewage Sludge

The risk to soil from the application of sewage sludge from an STP via the indoor uses and outdoor urban use of *epsilon*-momfluorothrin OBA or WBA are presented in the following tables.

Table 2.18 Risk characterisation (PEC: PNEC) values for *epsilon*-momfluorothrin OBA or WBA application of sewage sludge to local soil (terrestrial ecosystem)

Scenario	PEC (mg l^{-1})	PNEC (mg kg^{-1} wwt)	PEC: PNEC
Indoor space spray	4.70×10^{-4}	2.69×10^{-5}	17.5
Indoor crack and crevice	1.07×10^{-6}		3.98×10^{-2}
Outdoor urban	3.14×10^{-4}		11.7
*Combined scenarios	2.75×10^{-4}		10.2

* Where 'combined scenarios' refers to the refinement agreed at TM-I-2011 where a weighted F_{sim} was applied to each scenario.

From the data presented in the preceding tables a risk to soil organisms via the application of sewage sludge has been identified for indoor space spray applications, outdoor urban and combined scenario use of *epsilon*-momfluorothrin. Applications of *epsilon*-momfluorothrin WBA and OBA used in an indoor crack and crevice does not pose an unacceptable risk to terrestrial organisms in local soils.

PEC values for *epsilon*-momfluorothrin derived metabolites have been calculated based on soil levels of *epsilon*-momfluorothrin and are presented below for the following scenarios;

Table 2.19 Risk characterisation (PEC: PNEC) values for MFOA-D and TFPA resulting from the application of sewage sludge to local soil (terrestrial ecosystem)

	MFOA-D			TFPA		
Scenario	**PEC (mg l^{-1})**	**PNEC (mg l^{-1})**	**PEC: PNEC**	**PEC (mg l^{-1})**	**PNEC (mg l^{-1})**	**PEC: PNEC**
Indoor space spray	7.43×10^{-4}	0.193	3.85×10^{-3}	2.23×10^{-4}	0.794	2.81×10^{-4}
Indoor crack and crevice	1.69×10^{-6}		8.78×10^{-6}	5.08×10^{-7}		6.40×10^{-7}
Outdoor urban	4.96×10^{-4}		2.57×10^{-3}	1.49×10^{-4}		1.87×10^{-4}
*Combined scenarios	4.34×10^{-4}		2.25×10^{-3}	1.30×10^{-4}		1.64×10^{-4}

* Where 'combined scenarios' refers to the refinement agreed at TM-I-2011 where

a weighted F_{sim} was applied to each scenario.

Table 2.20 Risk characterisation (PEC: PNEC) values *Z*-CMCA and ωc-$CONH_2$-d-t-CRA resulting from the application of sewage sludge to local soil (terrestrial ecosystem)

	Z-CMCA			ωc-$CONH_2$-d-t-CRA		
Scenario	**PEC (mg l^{-1})**	**PNEC (mg l^{-1})**	**PEC: PNEC**	**PEC (mg l^{-1})**	**PNEC (mg l^{-1})**	**PEC: PNEC**
Indoor space spray	3.16×10^{-4}	1.77×10^{-4}	1.78	8.58×10^{-5}	1.77×10^{-4}	0.485
Indoor crack and crevice	7.19×10^{-7}		4.06×10^{-3}	1.96×10^{-7}		1.10×10^{-3}
Outdoor urban	2.10×10^{-4}		1.19	5.72×10^{-5}		0.323
*Combined scenarios	1.84×10^{-4}		1.04	5.00×10^{-5}		0.283

* Where 'combined scenarios' refers to the refinement agreed at TM-I-2011 where a weighted F_{sim} was applied to each scenario.

Acceptable risks to soil are predicted from the application of sewage sludge, for all scenarios and all metabolites except *Z*-CMCA (for which only an indoor crack and crevice use can be considered to be acceptable).

2.2.2.5.3. *Risks to groundwater*

The mean K_{OC} value of 1748 $L.kg^{-1}$ determined from an adsorption / desorption study in a number of soils suggests that *epsilon*-momfluorothrin may be immobile in soil and so therefore indirect exposure of groundwater (and even surface waters via run-off from fields) is unlikely.

Using the relatively simple equations in the ECHA guidance on ERA as a screening tool, calculations of concentration in porewater have been made for indoor and outdoor applications of *epsilon*-momfluorothrin. For indoor and outdoor urban uses, values less than the 0.1 µg l^{-1} current quality standard set by the EU Drinking Water Directive (98/83/EC) were obtained indicating that the risk of contamination to groundwater from *epsilon*-momfluorothrin is low. When a similar screening assessment for the outdoor application in a rural area was performed, a value of 0.0381 µg l^{-1} was obtained.

To more fully assess the risks potentially posed to groundwater from *epsilon*-momfluorothrin and associated metabolites, a more comprehensive assessment was made using PEARL 4.4.4 which takes into account both degradation and dilution into soil of metabolites and *epsilon*-momfluorothrin. The worst case scenario of the outdoor rural application of *epsilon*-momfluorothrin was modelled and a number of worst case default values were assumed for the metabolites, such as a formation fraction of 1 for each compound and the lowest predicted K_{oc} from QSAR modelling (EPISIUTE 4.11 provided by the applicant). (This application rate was based on the original spray application amount of 1.12 g b.p. per second- this value has since been reduced by the applicant to 0.41 g b.p. per second- so can be considered to be a very worst case situation. An acceptable level of efficacy is shown at the reduced rate (Heaven, 2012)).

Predicted levels of *epsilon*-momfluorothrin and associated metabolites were found to be below 0.1 µg l^{-1} (highest value 0.019851 µg l^{-1} for alfalfa at Jokionen and TFPA), indicating an acceptable level of risk to groundwater from *epsilon*-momfluorothrin and associated metabolites.

2.2.2.5.4. *Risks to non-target biota (secondary poisoning)*

Assessment of Secondary Poisoning via the Terrestrial food chain

Table 2.21 Secondary poisoning risk for *epsilon*-momfluorothrin OBA and WBA resulting from the direct exposure of soil from an outdoor rural use

	Scenario	$PEC_{oral\ predator}$ as $C_{earthworm}$ (mg $kg_{wetworm}^{-1}$)	PNEC (mg kg^{-1} wwt)	PEC: PNEC
Acute	Birds	3.59×10^{-3}	16.7	2.15×10^{-4}
	Mammals	3.59×10^{-3}	6.7	5.36×10^{-4}
Short term	Birds	4.94×10^{-3}	16.7	2.96×10^{-4}
	Mammals	4.94×10^{-3}	6.7	7.38×10^{-4}

Table 2.22 Risk characterisation (PEC: PNEC) values to earthworm eating birds and mammals from indoor or outdoor urban *epsilon*-momfluorothrin OBA or WBA application

Scenario		$PEC_{oral\ predator}$ $C_{earthworm}$ (mg $kg_{wetworm}^{-1}$)	PNEC (mg kg^{-1} wwt)	PEC: PNEC
Indoor space spray	Birds	2.19×10^{-4}	16.7	1.31×10^{-5}
Indoor space spray	Mammals	2.19×10^{-4}	6.7	3.27×10^{-5}
Indoor crack and crevice	Birds	5.00×10^{-7}	16.7	2.99×10^{-8}
Indoor crack and crevice	Mammals	5.00×10^{-7}	6.7	7.46×10^{-8}
Outdoor urban	Birds	1.46×10^{-4}	16.7	8.75×10^{-6}
Outdoor urban	Mammals	1.46×10^{-4}	6.7	2.18×10^{-5}
*Combined scenarios	Birds	1.28×10^{-4}	16.7	7.66×10^{-6}
*Combined scenarios	Mammals	1.28×10^{-4}	6.7	1.91×10^{-5}

* Where 'combined scenarios' refers to the refinement agreed at TM-I-2011 where a weighted F_{sim} was applied to each scenario.

An acceptable risk to birds and mammals from the consumption of contaminated earthworms is predicted from the indoor and outdoor urban uses of *epsilon*-momfluorothrin OBA and WBA.

The risk to earthworm-eating birds and mammals has also been assessed taking into account reasonable worst-case consumption rates.

Table 2.23 Secondary poisoning risk for *epsilon*-momfluorothrin OBA and WBA resulting from the direct exposure of soil from an outdoor rural use (dose approach)

	Scenario	$PEC_{oral\ predator}$ as $C_{earthworm}$ (mg $kg_{wetworm}^{-1}$)	ETE (mg kg^{-1} d^{-1})	PNED (mg kg^{-1} d^{-1})	ETE: PNED
Acute	Birds	3.59×10^{-3}	3.77×10^{-3}	2.14	1.76×10^{-3}
	Mammals	3.59×10^{-3}	4.60×10^{-3}	0.39	1.18×10^{-2}
Short term	Birds	4.94×10^{-3}	5.19×10^{-3}	2.14	2.43×10^{-3}
	Mammals	4.94×10^{-3}	6.33×10^{-3}	0.39	1.62×10^{-2}

Table 2.24 Secondary poisoning risk for *epsilon*-momfluorothrin OBA and WBA resulting from the application of sewage sludge from STP (indoor uses and outdoor urban use) – dose approach

Scenario		$PEC_{oral\ predator}$ as $C_{earthworm}$ (mg $kg_{wetworm}^{-1}$)	ETE (mg kg^{-1} d^{-1})	PNED (mg kg^{-1} d^{-1})	ETE: PNED
Indoor space spray	Birds	2.19×10^{-4}	2.30×10^{-4}	2.14	1.08×10^{-4}
Indoor space spray	Mammals	2.19×10^{-4}	2.81×10^{-4}	0.39	7.20×10^{-4}
Indoor crack and crevice	Birds	5.00×10^{-7}	5.25×10^{-7}	2.14	2.45×10^{-7}
Indoor crack and crevice	Mammals	5.00×10^{-7}	6.39×10^{-7}	0.39	1.64×10^{-6}
Outdoor urban	Birds	1.46×10^{-4}	1.53×10^{-4}	2.14	7.17×10^{-5}
Outdoor urban	Mammals	1.46×10^{-4}	1.87×10^{-4}	0.39	4.80×10^{-4}
*Combined scenarios	Birds	1.28×10^{-4}	1.34×10^{-4}	2.14	6.28×10^{-5}
*Combined scenarios	Mammals	1.28×10^{-4}	1.64×10^{-4}	0.39	4.20×10^{-4}

* Where combined scenarios refers to the refinement agreed at TM-I-2011 for *Lambda*-cyhalothrin where a weighted F_{sim} was applied to each scenario

Acceptable risks to birds and mammals from the consumption of contaminated earthworms can be predicted from the indoor and outdoor uses of *epsilon*-momfluorothrin OBA and WBA.

Consideration of the risk to birds and mammals from consumption of treated insects is also required.

Table 2.25 Risk to birds and mammals from consumption of treated insects

	Indicator species	ETE (mg kg^{-1} d^{-1})	PNED (mg kg^{-1} d^{-1})	ETE: PNED

Acute	Hedgehog	2.97×10^{-10}	0.39	7.62×10^{-10}
Short-term	Hedgehog	1.41×10^{-10}	0.39	3.62×10^{-10}
Acute	Badger	2.97×10^{-10}	0.39	7.62×10^{-10}
Short-term	Badger	1.41×10^{-10}	0.39	3.62×10^{-10}
Acute	Blackbird	7.26×10^{-10}	2.14	3.39×10^{-10}
Short-term	Blackbird	3.45×10^{-10}	2.14	1.61×10^{-10}
Acute	Magpie	3.30×10^{-10}	2.14	1.54×10^{-10}
Short-term	Magpie	1.57×10^{-10}	2.14	7.33×10^{-11}

Acceptable risks to birds and mammals from the consumption of treated insects can be predicted from the indoor and outdoor urban uses of *epsilon*-momfluorothrin OBA and WBA.

Assessment of Secondary Poisoning via the Aquatic food chain

Table 2.26 Risk characterisation (PEC: PNEC) values to fish eating birds and mammals from indoor or outdoor urban *epsilon*-momfluorothrin OBA or WBA application

Scenario		**$PEC_{oral\ predator}$ (mg kg $_{wet\ fish}^{-1}$)**	**PNEC (mg kg^{-1} wwt)**	**PEC: PNEC**
Indoor space spray	Birds	1.47×10^{-1}	16.7	8.80×10^{-3}
Indoor space spray	Mammals	1.47×10^{-1}	6.7	2.19×10^{-2}
Indoor crack and crevice	Birds	3.35×10^{-4}	16.7	2.01×10^{-3}
Indoor crack and crevice	Mammals	3.35×10^{-4}	6.7	5.00×10^{-3}
Outdoor urban	Birds	9.80×10^{-2}	16.7	5.87×10^{-3}
Outdoor urban	Mammals	9.80×10^{-2}	6.7	1.46×10^{-2}
*Combined scenarios	Birds	8.58×10^{-2}	16.7	5.14×10^{-3}
*Combined scenarios	Mammals	8.58×10^{-2}	6.7	1.28×10^{-2}

* Where 'combined scenarios' refers to the refinement agreed at TM-I-2011 where a weighted F_{sim} was applied to each scenario.

An acceptable risk to birds and mammals from the consumption of fish is predicted for the indoor and outdoor urban uses of *epsilon*-momfluorothrin OBA and WBA.

In addition the risk to fish-eating birds and mammals has also been considered taking into account reasonable worst-case fish consumption rates.

Table 2.27 Secondary poisoning risk for *epsilon*-momfluorothrin OBA and WBA resulting from the application of sewage sludge from STP (indoor uses and outdoor urban use) – dose approach

Scenario		$PEC_{oral\ predator}$ (mg kg $_{wet\ fish}^{-1}$)	ETE (mg kg^{-1} d^{-1})	PNED (mg kg^{-1} d^{-1})	ETE: PNED
Indoor space spray	Birds	1.47×10^{-1}	1.54×10^{-1}	2.14	7.21×10^{-2}
Indoor space spray	Mammals	1.47×10^{-1}	1.88×10^{-1}	0.39	4.82×10^{-1}
Indoor crack and crevice	Birds	3.35×10^{-4}	3.52×10^{-4}	2.14	1.64×10^{-4}
Indoor crack and crevice	Mammals	3.35×10^{-4}	4.29×10^{-4}	0.39	1.10×10^{-3}
Outdoor urban	Birds	9.80×10^{-2}	1.03×10^{-1}	2.14	4.81×10^{-2}
Outdoor urban	Mammals	9.80×10^{-2}	1.25×10^{-1}	0.39	3.22×10^{-1}
*Combined scenarios	Birds	8.58×10^{-2}	9.01×10^{-2}	2.14	4.21×10^{-2}
*Combined scenarios	Mammals	8.58×10^{-2}	1.10×10^{-1}	0.39	2.82×10^{-1}

* Where combined scenarios refers to the refinement agreed at TM-I-2011 for *Lambda*-cyhalothrin where a weighted F_{sim} was applied to each scenario

Acceptable risks to birds and mammals from the consumption of contaminated fish can be predicted for the indoor and outdoor urban uses of *epsilon*-momfluorothrin OBA and WBA.

2.2.3. Human health and environmental risk assessment

For human health no unacceptable risks are identified for primary, secondary or combined exposure scenarios.

Acceptable risks are identified for all environmental compartments following use of products containing *epsilon*-momfluorothrin indoors for crack and crevice treatment at intervals of less than once per week, in areas not subject to frequent wet cleaning.

Unacceptable risks to surface water, sediment and soil are identified following use of products containing *epsilon*-momfluorothrin indoors as an air space spray and as an outdoor surface spray.

2.2.4. Assessment of endocrine disruptor properties

In the sub-acute and sub-chronic studies in rats, mice and dogs, the only endocrine effect was an increase in adrenal weight after exposure by inhalation for 28 days in both sexes of the rat. As the effect was not replicated in other species, via different routes or in longer term studies, this is not a significant effect.

In the carcinogenicity studies, there were histopathological changes reported in the thyroid of male rats but this finding was secondary to the increase in liver weight and hepatic hypertrophy. In the reproductive studies, there were no effects on fertility and therefore *epsilon*-momfluorothrin does not impact on reproductive endocrine organs.

To conclude, a review of all the available toxicology data on *epsilon*-momfluorothrin suggests that the active substance is not an endocrine disruptor.

2.3. Overall conclusions

The outcome of the assessment for *epsilon*-momfluorothrin in product-type 18 is specified in the BPC opinion following discussions at the sixteenth meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2.4. List of endpoints

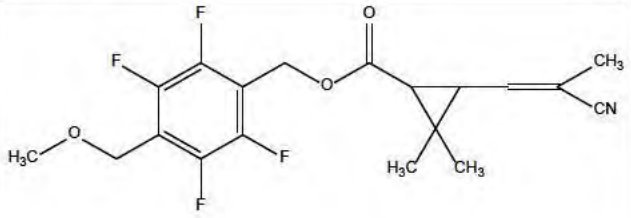
The most important endpoints, as identified during the evaluation process, are listed in Appendix I.

Appendix I: List of endpoints

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

Active substance (ISO Name)	*epsilon*-momfluorothrin (S-1563)
Product-type	18
Applicant	Sumitomo Chemical (UK) PLC

Identity

Chemical name (IUPAC)	**All isomers**: 2,3,5,6-tetrafluoro-4-(methoxymethyl)benzyl (*EZ*)-(1*RS*,3*RS*;1*SR*,3*SR*)-3-(2-cyanoprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate **RTZ isomer**: 2,3,5,6-Tetrafluoro-4-(methoxymethyl)benzyl *(Z)-(1*R,*3*R)-3-(2-cyanoprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate
Chemical name (CA)	**All isomers**: 2,3,5,6-tetrafluoro-4-(methoxymethyl)benzyl (*EZ*)-(1*RS*,3*RS*;1*SR*,3*SR*)-3-(2-cyanoprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate **RTZ isomer**: 2,3,5,6-Tetrafluoro-4-(methoxymethyl)benzyl *(Z)-(1*R,*3*R)-3-(2-cyanoprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate
CAS No	**All isomers**: 609346-29-4 **RTZ isomer**: 1065124-65-3
EC No	None
Other substance No.	None
Minimum purity of the active substance as manufactured (g/kg or g/l)	All isomers: Min. 930 g/kg RTZ isomer: Min. 825 g/kg This needs to be confirmed (see confidential annex).
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None
Molecular formula	$C_{19}H_{19}F_4NO_3$
Molecular mass	385.35
Structural formula	

Physical and chemical properties

Melting point (state purity)	63.95°C to 73.30°C (99.9%)
Boiling point (state purity)	No boiling point observed.
Thermal stability / Temperature of decomposition	Decomposition onset at 326.21 °C
Appearance (state purity)	White powdery solid (99.8%)
Relative density (state purity)	1.3432 at 19.7°C (99.9%)
Surface tension (state temperature and concentration of the test solution)	62.9 mN/m (19.9°C)
Vapour pressure (in Pa, state temperature)	2.5×10^{-7} (20°C) 1.4×10^{-6} (25°C)
Henry's law constant (Pa m^3 mol^{-1})	1.02×10^{-4} (20°C)
Solubility in water (g/l or mg/l, state temperature)	0.933 ± 0.0916 mg/L at 20°C The pH dependence on the water solubility is not required as the active has no readily ionisable groups. The temperature dependence on the water solubility is still to be addressed.
Solubility in organic solvents (in g/l or mg/l, state temperature)	Solubility at 20°C Solvent (g/L) n-heptane: < 10 n-octanol: < 10 Acetone: > 250 1,2-dichloroethane: > 250 Ethyl acetate: > 250 p-xylene: > 250 Methanol: 67-80 The temperature dependence on the solubility in organic solvents has not been addressed.
Stability in organic solvents used in biocidal products including relevant breakdown products	As the TGAI as manufactured is not delivered in an organic solvent then this annex point does not need to be addressed.
Partition coefficient (log P_{OW}) (state temperature)	*epsilon*-momfluorothrin RTZ, Log Pow = 2.99 (25°C) *epsilon*-momfluorothrin RTE, Log Pow = 2.88 (25°C) As the active has no readily ionisable groups the effects of pH on the partition coefficient is not required.
Dissociation constant	No dissociation observed.

UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Absorbance maxima: Acidic conditions: 218.80 nm, ε = 22717.50 271.86 nm, ε = 1863.56 Neutral conditions: 218.73 nm, ε = 22003.18 271.84 nm, ε = 1774.12 Basic conditions: 218.38 nm, ε = 17440.56 234.40 nm, ε = 14865.32 No absorbance at or above 290 nm.
Flammability or flash point	The active is not highly flammable
Explosive properties	The active is not explosive
Oxidising properties	The active is not oxidising
Reactivity towards container material	No reactivity towards the container material observed during 1 years storage

Classification and proposed labelling

with regard to physical hazards	None
with regard to human health hazards	H302, H371
with regard to environmental hazards	H410

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 confidential annex

Analytical methods for residues

Soil (principle of method and LOQ)	GC-MS/MS LOQ = 0.01 mg/kg (*epsilon*-momfluorothrin) The method determines the parent only. The fate assessment indicates that the parent is not a suitable marker for soil and further data are required.
Air (principle of method and LOQ)	GC-MS/MS LOQ = 0.2 µg/m^3 (*epsilon*-momfluorothrin)

Water (principle of method and LOQ)	GC-MS/MS LOQ = 0.05 µg/L (*epsilon*-momfluorothrin)
Body fluids and tissues (principle of method and LOQ)	The active is not classified as toxic or very toxic and hence a method is not required.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	The intended uses are not for use in food preparation or food contact areas and hence methods are not required.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	

Chapter 3:Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	In the rat: *epsilon*-momfluorothrin is extensively absorbed after oral administration (>80%)
Rate and extent of dermal absorption*:	A dermal absorption value of 6% was derived from a study on 1% *epsilon*-momfluorothrin in ethanol
Distribution:	*epsilon*-momfluorothrin and/or its metabolites are widely distributed around the body.
Potential for accumulation:	*epsilon*-momfluorothrin does not have the potential for bioaccumulation.
Rate and extent of excretion:	In the rat, *epsilon*-momfluorothrin is rapidly excreted in the urine, faeces and bile (>85%).
Toxicologically significant metabolite(s)	None

* the dermal absorption value is applicable for the active substance and might not be usable in product authorization

Acute toxicity

Rat LD_{50} oral	Rat: >2000 mg/kg bw in males; 300-2000 mg/kg bw in females
Rat LD_{50} dermal	Rat: >2000 mg/kg bw
Rat LC_{50} inhalation	Rat: >2000 mg/m^3

Skin corrosion/irritation	Not classified
Eye irritation	Not classified
Respiratory tract irritation	Not classified
Skin sensitisation (test method used	Negative in a guinea-pig maximisation test

and result)	

Repeated dose toxicity

1) Species/ target / critical effect	Rat Short term: tremors, excess salivation, straub tail and mortality Medium/long term: ↓ body weight gain, ↑ liver weight
Lowest relevant oral NOAEL / LOAEL (short term)	80 mg/kg bw/d (acute neurotoxicity rat study)
Lowest relevant oral NOAEL / LOAEL (medium/long term)	11.6 mg/kg bw/d (2-generation rat study)

2) Species/target/ critical effect	Rat Lowest relevant (oral): ↓b ↑liver weight Dermal: No effects at the highest dose tested Inhalation: Neurotoxic effects (tremor, ataxic gait, hypersensitivity, tip toe gait, muscular rigidity), ↑liv changes
Lowest relevant oral NOAEL / LOAEL	11.6 mg/kg bw/d (2 generation rat study)
Lowest relevant dermal NOAEL / LOAEL	1000 mg/kg bw/d (28 day rat study)
Lowest relevant inhalation NOAEL / LOAEL	9 mg/kg bw/d (28 day rat inhalation study)

Genotoxicity	Not genotoxic

Carcinogenicity

Species/type of tumour	Rat: Liver carcinomas and adenomas (not considered relevant to humans based on mode of action being similar to that of phenobarbitone) Mouse: no tumours
lowest dose with tumours	Rat: 154 mg/kg bw/d Mouse: > 639 mg/kg bw/d

Reproductive toxicity

Species/ Reproduction target / critical effect	Rat Fertility: No treatment related effects on fertility Parental: : ↓bod weight Offspring: ↓body

	↓thymus and spleen weights
Lowest relevant reproductive NOAEL / LOAEL	Fertility: 95.2 mg/kg bw/d (2 generation rat study) Parental: 11.6 mg/kg bw/d (2 generation rat study) Offspring: 14.7 mg/kg bw/d (2 generation rat study)
Species/Developmental target / critical effect	Rat Maternal: Tremor Developmental: No treatment related effects on development
Lowest relevant developmental NOAEL / LOAEL	Maternal: 25 mg/kg bw/d Developmental: 75 mg/kg bw/d.

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	Rat: Death, tremor, increased salivation and Straub tail.
Lowest relevant neurotoxicity NOAEL	80 mg/kg bw

Immunotoxicity

Species/ target/critical effect	Rat: 241 mg/kg bw/d (highest dose tested)

Medical data

None

	Value	Study	Safety factor
Summary			
ADI	0.12 mg/kg bw/d	2-generation reproduction study	100
ARfD	0.8 mg/kg bw	Acute neurotoxicity study	100
Inhalation-specific systemic AEL(system c, all durations)	0.09 mg/kg bw/d	28 day inhalation study	100
Oral-specific systemic AEL(short term)	0.8 mg/kg bw/d	Acute neurotoxicity study	100
Oral-specific systemic AEL(medium/ long term)	0.12 mg/kg bw/d	2-generation reproduction study	100
Reference value for dermal absorption	6%	1% *epsilon*-momfluorothrin in ethanol	

Summary	Value	Study	Safety factor
Non-professional user			
ADI (acceptable daily intake, external long-term reference dose)	Not required - not used in food or feed	N/A	N/A
AOEL-S (Operator Exposure)	0.09 mg/kg bw/d	28 day inhalation study	100
ARfD (acute reference dose)	0.8 mg/kg bw	Acute neurotoxicity study	100

Acceptable exposure scenarios (including method of calculation)	
Professional users	N/A
Production of active substance:	N/A
Formulation of biocidal product	N/A
Intended uses	N/A
Secondary exposure	N/A
Non-professional users	Non-professional adult air space and surface spray for control of insects
Indirect exposure as a result of use	Adults, toddlers and infants

Combined exposure

After completion of combined exposure assessment there were no unacceptable risks posed to the exposure groups used in the modelling scenarios.

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water	
Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH_4_: >1 year at 12°C (*epsilon*-momfluorothrin RTZ and RTE) No degradation products detected at 50°C pH_7_: > 1year at 12°C (*epsilon*-momfluorothrin RTZ only) MFOA and *Z*-CMCA observed pH_9_: DT_{50} 35.5 days (*epsilon*-momfluorothrin RTZ only) MFOA and *Z*-CMCA observed
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	DT_{50} = 17.6 d extrapolated for "seasonal" natural sunlight at 40 °N (or 14.5 d at 30 - 50 °N) including photoisomerisation.

	DT_{50} = 31.7 d extrapolated for "seasonal" natural sunlight at 40 °N (or 25.9 d at 30 - 50 °N) for the sum of the 8 isomers. Major metabolites for *epsilon*-momfluorothrin RTZ were MFOA (average 26.6 % AR) and Z-CMCA (average 38.8 % AR) and for *epsilon*-momfluorothrin RTE was *E*-CMCA (average 30.9 % AR), with no other degradates present above 4 % AR.
Readily biodegradable (yes/no)	No
Biodegradation in seawater	No data provided
Non-extractable residues	12.2 to 28.5 % total system bound residues were observed
Distribution in water / sediment systems (active substance)	Under aerobic conditions at 20 °C rapid dissipation of *epsilon*-momfluorothrin RTZ and RTE were observed in both water / sediment systems. Dissipation T_{50} values ranged from 0.344 days to 1.1 days at 20°C. Following dissipation from the aqueous phase to the sediment rapid degradation of *epsilon*-momfluorothrin RTZ and RTE was observed with DT_{50} (worst case normalised to 12 °C) of 3.21 d (RTZ) and 2.77 d (RTE). Degradation increased over the study to give 15.0 to 43.0 % AR total system CO_2.
Distribution in water / sediment systems (metabolites)	A number of major metabolites were formed both in the water and sediment phases of the study. The following DT_{50} values are corrected for 12°C, and where a value could not be calculated a default value of 1000 days has been assigned. From *epsilon*-momfluorothrin RTZ [alc^{14}C] was formed MFOA (DT_{50} 49.9 d, maximum 24.9 % AR in water and 12.4 % in sediment), MFOA-D (DT_{50} >1000 d, maximum 61.1 % AR in water and 30.0 % in sediment), and TFPA (DT_{50} >1000 d, maximum level of 53.0 % AR in water and 14.5 % in sediment). Metabolites derived from *epsilon*-momfluorothrin RTZ [acid^{14}C] were *Z*-CMCA (DT_{50} 87.6 d maximum level of 63.1 % AR in water and 29.2 % in sediment), ωc-$CONH_2$-d-t-CRA (DT_{50} 96.3 d, maximum levels of 16.1 % AR in water). The major metabolites derived from *epsilon*-momfluorothrin RTE [acid^{14}C] were *epsilon*-momfluorothrinRTE-$CONH_2$ (DT_{50} 15.3 d, maximum level of 6.0 % AR in water), *E*-CMCA (DT_{50} 71.5 d, maximum level of 52.5 % AR in water and 23.3 % in sediment), ωt-$CONH_2$-d-t-CRA (DT_{50} >1000 d, (maximum

	level of 22.5 % AR in water), and t-COOH-CA (DT_{50} >1000 d, maximum levels 20.6 % AR in water and 9.6 % in sediment).

Route and rate of degradation in soil	
Degradation (aerobic)	41.1 to 58.4 % as CO_2 at study end (*epsilon*-momfluorothrin RTZ) Bound residues 2.4 – 58.1 % AR (alc^{14}C – acid^{14}C)
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): 3.04 d (*epsilon*-momfluorothrin RTZ) 2.95 d (*epsilon*-momfluorothrin RTE) Range 2.08 - 4.07 days χ^2 5.6 - 12.3 (n=4) (*epsilon*-momfluorothrin RTZ) Range 1.48 - 5.31 days χ^2 8.2 – 11.4 (n=4) (*epsilon*-momfluorothrin RTE)
	DT_{90lab} (20°C, aerobic): 10.1 d (*epsilon*-momfluorothrin RTZ) 9.82 d (*epsilon*-momfluorothrin RTE) Range 6.90 - 13.5 days (n=4) (*epsilon*-momfluorothrin RTZ) Range 4.92 - 17.6 days (n=4) (*epsilon*-momfluorothrin RTE)
	DT_{50lab} (12°C, aerobic): 5.77 d (*epsilon*-momfluorothrin RTZ) 5.59 d (*epsilon*-momfluorothrin RTE)
	DT_{50lab} (20°C, anaerobic): Not available
	Major degradates for the [alc-^{14}C]RTZ isomer were carboxylic acid MFOA-D with a DT_{50} (at 12°C) of 73.2 days (maximum 76.8 % AR at day 14) and TFPA with a DT_{50} (at 12°C) of 125 days (maximum 19.5 % AR at day 63). For the [acid-^{14}C]RTZ isomer the major degradates were *Z*-CMCA with a worst case DT_{50} (at 12°C) of 31.9 days (maximum 53.0 % AR at day 14) and ωc-$CONH_2$-d-t-CRA with a worst case DT_{50} (at 12°C) of 84.8 days (maximum 10.3 % AR at day 30). The major observed degradates from the [acid^{14}C] RTE isomer were *E*-CMCA with a worst case DT_{50} (at 12°C) of 8.74 days (maximum 14.1 % AR at day 3), ωt-$CONH_2$-d-t-CRA with DT_{50} (at 12°C) of 8.53 days (maximum 16.4 % AR at day 7), ωt-COOH-d-t-CRA with DT_{50} (at 12°C) of 22.9 days (maximum 12.1 % AR at day 7, n=1) and t-COOH with a DT_{50} (at 12°C) of 37.9 days

	(maximum 11.9 % AR at day 7).
Field studies (state location, range or median with number of measurements)	Not available
Anaerobic degradation	Not available
Soil photolysis	No data provided
Non-extractable residues	No data provided
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	No data provided
Soil accumulation and plateau concentration	

Adsorption/desorption	
Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	Ka: 4.85 – 42.5; Kd: 9.03 – 53.5 Ka_{oc}: 1033 – 4344; Kd_{oc}: 1085– 6219 Arithmetic Mean (n=5): 1748 l kg^{-1} 2484 l kg^{-1} No dependence

Fate and behaviour in air

Direct photolysis in air	DT_{50} = 0.68 d (estimated by QSAR)
Quantum yield of direct photolysis	Not determined
Photo-oxidative degradation in air	Latitude: ..... Season: ..... DT_{50} .....
Volatilization	See Document II-B, Section 3.3.2, Vapour pressure

Monitoring data, if available	
Soil (indicate location and type of study)	No monitoring data available
Surface water (indicate location and type of study)	No monitoring data available
Ground water (indicate location and type of study)	No monitoring data available
Air (indicate location and type of study)	No monitoring data available

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group): *epsilon*-momfluorothrin

Species	Time-scale	Endpoint	Toxicity mg/l
Fish			
Oncorhynchus mykiss	96 h	LC_{50}	0.0012
Pimephales promelas	96 h	LC_{50}	0.0097
Lepomis macrochirus	96 h	LC_{50}	0.0029
Pimephales promelas	28 d	NOEC	0.0031
Invertebrates			
Daphnia magna	48 h	EC_{50}	0.0078
Daphnia magna	21 d	NOEC	0.0005
Algae/macrophytes			
Pseudokirchneriella subcapitata	72 h	E_rC_{50} NOE_rC E_yC_{50}	> 4.8 0.33 3.9
Lemna gibba	7 d	E_rC_{50} NOE_rC E_yC_{50}	> 2.5 2.5 > 2.5
Sediment organisms			
Chironomus dilutus	49 d	EC_{50} NOEC	0.15 0.035
Micro-organisms			
Activated sludge	3 h	NOEC/EC_{10} EC_{50}	> 1 > 1

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

Species	Time-scale	Endpoint	Toxicity mg/l
MFOA-D			
Pimephales promelas	96 h	LC_{50}	>120
Daphnia magna	48 h	EC_{50}	>120
Pseudokirchneriella subcapitata	72 h	EC_{50}	>110
TFPA			
Pimephales promelas	96 h	LC_{50}	>99
Daphnia magna	48 h	EC_{50}	>95

Pseudokirchneriella subcapitata	72 h	EC_{50}	75
MFOA			
Pimephales promelas	96 h	LC_{50}	>95
Daphnia magna	48 h	EC_{50}	>93
Green algae*	72 h	EC_{50}	40.2*

*Endpoint generated from ECOSAR model used as lower than equivalent study endpoint

Effects on earthworms or other soil non-target organisms: *epsilon*-momfluorothrin

Acute toxicity to earthworms	*Eisenia fetida* 14 d LC_{50} = 97.6 mg a.s./kg dwt NOEC = 15.6 mg a.s./kg dwt
Reproductive toxicity to rove beetle	*Aleochara bilineata* 28 d NOEC = 0.01 mg a.s./kg dwt

Effects on soil micro-organisms

Nitrogen mineralization	28 d NOEC = 1000 mg a.s./kg dwt
Carbon mineralization	28 d NOEC = 1000 mg a.s./kg dwt

Effects on terrestrial vertebrates

Acute toxicity to birds	*Colinus virginianus* LD_{50} > 2250 mg a.s./kg bw *Poephila guttata* LD_{50} > 2250 mg a.s./kg bw
Dietary toxicity to birds	*Anas platyrhynchus* 5 d LC_{50} > 1935 mg a.s./kg bw/d *Colinus virginianus* 5 dLC_{50} > 1039 mg a.s./kg bw/d
Reproductive toxicity to birds	*Anas platyrhynchus* 21 week NOEC = 64.7 mg a.s./kg bw/d *Colinus virginianus* 20 week NOEC = 77 mg a.s./kg bw/d

Effects on honeybees

Acute oral toxicity	*Apis mellifera* 48 h LD50 > 5.08 µg a.s./bee
Acute contact toxicity	*Apis mellifera*

	48 h LD50 = 0.21 µg a.s./bee

Effects on terrestrial plants

Phytotoxicity, growth and seedling emergence (tested as *epsilon*-momfluorothrin/Sumithrin WBA)	21 d NOEC < 500 kg product/ha

Bioconcentration

Bioconcentration factor (BCF)	*Lepomis macrochirus* Steady-state BCF (whole fish) = 612 L/kg (based on total ^{14}C as *epsilon*-momfluorothrin was not detected in fish after the first day of the uptake phase)
Depuration rate	0.059-0.071/day
Level of metabolites (%) in organisms accounting for > 10 % of residues	TFPA and MFOA-D

Chapter 6: Other End Points

None

Appendix II: List of Intended Uses

epsilon-momfluorothrin has been evaluated for its intended use as an insecticide (PT 18). The product is intended for use by non-professionals.

Product Type: PT 18	Insecticide Product Type 18.
Concentration used	Concentration of *epsilon*-momfluorothrin is 0.10 % w/w.
Target organism	Flying and crawling insects.
Categories of user	Non-professional.
Packaging	Supplied as an aerosol.
Type of application	Applied as a direct spray and directed crack and crevice spray.
Storage	Store in a well-ventilated place. Keep cool. Store locked up. Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F. Dispose of contents/container to a licensed waste disposal company.

Data supporting *epsilon*-momfluorothrin for its use against the intended target organisms have demonstrated sufficient efficacy for active substance approval to be recommended.

To date, there are no known resistance issues when using *epsilon*-momfluorothrin against the target organisms. Please see Doc IIA, Section 2.5 for further information.

Appendix III: List of Studies

Active substance

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Y/N)	Owner
IIIA3.1.1/1		2011a	S-1563PAI: Determination of melting/boiling point. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.1.1/2		2011b	S-1563RTZ: Determination of melting/boiling point. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.1.1/3		2011c	S-1563RTE: Determination of melting/boiling point. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.1.2/1		2012a	S-1563PAI: Determination of relative density. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.1.2/2		2012b	S-1563TGAI: Determination of relative density. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.2/1		2011d	S-1563: Evaluation of vapour pressure. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.2/2		2011	S-1563RTZ: Evaluation of vapour pressure. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.2/3		2011e	S-1563RTE: Evaluation of vapour pressure. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.2.1/1		2012c	S-1563PAI: Calculation of Henry's Law constant. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.2.1/2		2012e	S-1563RTZ: Calculation of Henry's Law constant. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.2.1/3		2012d	S-1563RTE: Calculation of Henry's Law constant. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.3.1/1		2012f	S-1563PAI: Determination of physical state, colour and odour. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.3.1/2		2012g	S-1563TGAI: Determination of Physical State, colour and odour. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Y/N)	Owner
IIIA3.3.2/1		2012f	S-1563PAI: Determination of physical state, colour and odour. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.3.2/2		2012g	S-1563TGAI: Determination of Physical State, colour and odour. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.3.3/1		2012f	S-1563PAI: Determination of physical state, colour and odour. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.3.3/2		2012g	S-1563TGAI: Determination of Physical State, colour and odour. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.4/1		2011f	S-1563TGAI: Determination of the ultra-violet/visible spectrum. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.4/2		2011g	S-1563RTZ: Determination of the ultra-violet/visible spectrum. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.4/3		2011h	S-1563RTE: Determination of the ultra-violet/visible spectrum. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.4/4		2012h	S-1563PAI: Evaluation of spectroscopic Properties. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.5/1		2010a	S-1563: Development and validation of an analytical method, and evaluation of the water solubility. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.5/2		2010b	S-1563RTZ: Development and validation of an analytical method, and evaluation of the water solubility. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.5/3		2010c	S-1563RTE: Development and validation of an analytical method, and evaluation of the water solubility. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.6		2011a	S-1563RTZ: Evaluation of dissociation constant. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.7		2011a	S-1563TGAI: Determination of solvent solubility. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Y/N)	Owner
IIIA3.9/1		2011b	S-1563RTZ: Determination of octanol:water partition coefficient. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.9/2		2011c	S-1563RTE: Determination of octanol:water partition coefficient. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.10		2012i	S-1563TGAI: Determination of thermal stability. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.11		2012j	S-1563TGAI: Determination of flammability and auto-flammability. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.13		2011b	S-1563TGAI: Determination of surface tension. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.15		2012k	S-1563TGAI: Assessment of explosive properties. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA3.16		2011c	S-1563TGAI: Assessment of oxidising properties. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA4.1.1		2011	Enforcement analytical methods of S-1563 technical material – Amendment No. 1. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA4.1.2		2011	Enforcement analytical methods of S-1563 technical material – Amendment No. 1. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA4.2.1		2011a	Development and validation of an analytical method for the determination of S-1563 in soil. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA4.2.2		2011b	Development and validation of an analytical Method for the determination of S-1563 in air. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
|IIIA4.2.3		2011	Development and validation of an analytical method for the determination of S-1563 in drinking and in surface water. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA5.3.1/1		2011a	Characteristic of insecticidal activity of S-1563 Technical grade. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Y/N)	Owner
IIIA5.3.1/2		2011b	The efficacy evaluation of isomers of S-1563. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA5.3.1/3		2012	Laboratory bioassay to determine the efficacy of aerosol products against mosquitoes, *Aedes albopictus*, bed bugs, *Cimex lectularius* and black ants, *Lasius niger*, applied as direct sprays. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.1.1		2010a	Acute oral toxicity study of S-1563 in rats. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.1.2		2010b	Acute dermal toxicity study of S-1563 in rats. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.1.3		2010c	Acute inhalation toxicity study of S-1563 in rats. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.1.4e		2011a	Eye irritation test of S-1563 in rabbits. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.1.4s		2011b	Skin irritation test of S-1563 in rabbits. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.1.5		2010	Skin sensitization test of S-1563 in guinea pigs (Maximization test). GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.2/1		2012	S-1563 – *In Vitro* absorption from a 1% S-1563 formulation through human epidermis using [^{14}C]-S-1563. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.2/2		2010	Amended Final Report 1: The Disposition and metabolism of S-1563RTZ and S-1563RTE in rats (a single administration) - English translation 2012. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.2/3		2009	Metabolism of S-1563RTZ in rats - distribution, metabolism and excretion in rats after repeated oral administration – English translation 2012. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.2/4		2012	*In vitro* metabolism of S-1563RTE and S-1563RTZ in rat and human liver microsome. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co Ltd.
IIIA6.3.1		2008	S-1563: 2-week oral (capsule) toxicity study in the beagle dog. Not GLP	Y	Y	Sumitomo Chemical Co., Ltd.

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Y/N)	Owner
			Unpublished			
IIIA6.3.2		2012	A 28-day repeat dose dermal toxicity study of S-1563 in rats. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.3.3/1		2011	Four-week repeated inhalation toxicity study of S-1563 in rats. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.3.3/2		2012	S-1563 - A 28-day oral (dietary) Immunotoxicity study in male Wistar Han rats. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.4.1/1		2010	S-1563: 13-week repeated dose oral (feeding) toxicity study in the Wistar rat followed by a 6-week recovery period. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.4.1/2		2011	S-1563: 13-week repeated dose oral (capsule) toxicity study in the beagle dog followed by a 6-week recovery period, and all subsequent amendments. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.5/1		2011	S-1563: 52-week chronic toxicity (feeding) study in the Wistar rat. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.5/2		2012	S-1563: 52-week repeated dose oral (capsule) toxicity study in the Beagle dog. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.6.1		2009	Reverse mutation test of S-1563 in bacterial systems. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.6.2		2009b	*In vitro* Chromosomal aberration test on S-1563 in Chinese Hamster Lung cells (CHL/IU). GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.6.3		2011	Gene mutation assay in Chinese Hamster V79 cells *in vitro* (V79/HPRT) with S-1563. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.6.4		2010	Micronucleus test on S-1563 in rats. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.6.5		2010	*In vivo* Unscheduled DNA synthesis (UDS) assay with S-1563 in rat hepatocytes. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.7/1		2012a	S-1563: 104-week Oncogenicity (feeding) study in the Wistar rat.	Y	Y	Sumitomo Chemical

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Y/N)	Owner
			GLP Unpublished			Co., Ltd.
IIIA6.7/2		2012b	S-1563: 78-Week Oncogenicity (feeding) study in the CD-1 mouse. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.8.1/1		2012	S-1563: Study on the effect of oral administration of S-1563 on embryo-fetal development in rats. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.8.1/2		2012	Study for effects on embryofoetal development of S-1264 administered orally to rabbits. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.8.2		2012	S-1563: Two-generation reproduction toxicity study in the Han Wistar rat. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.9/1		2012	S-1563: Acute oral neurotoxicity study in rats. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA6.9/2		2011	S-1653 13 week neurotoxicity (feeding) study in rats. GLP Unpublished	Y	Y	Sumitomo Chemical Co Ltd.
IIIA6.10/1		2012a	Study for Mode of Action analysis for effects of S-1563 on male mouse liver -Time course analysis. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co Ltd.
IIIA6.10/2		2012b	Study for Mode of Action analysis for effects of S-1563 on male mouse liver - Dose response and reversibility-. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co Ltd.
IIIA6.10/3		2012c	Study for Mode of Action analysis for effects of S-1563 on female mouse liver – Time course, dose Response and reversibility -. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co Ltd.
IIIA6.10/4		2012a	Study for Mode of Action analysis for tumour formation of S-1563 on rat liver (1) -Time course analysis in male rats. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co Ltd.
IIIA6.10/5		2012b	Study for Mode of Action analysis for tumor formation of S-1563 on rat liver (2) - Analysis for Time course, dose response and reversibility in male rats. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co Ltd.
IIIA6.10/6		2012c	Study for Mode of Action analysis for tumor	Y	Y	Sumitomo

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Y/N)	Owner
			formation of S-1563 on rat liver (3) -Time course analysis at high dose of S-1563 in male rats. Not GLP Unpublished			Chemical Co Ltd.
IIIA6.10/7		2012d	Study for Mode of Action analysis for tumor formation of S-1563 on rat liver (4) – The 2nd study for dose response analysis in male rats. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co Ltd.
IIIA6.10/8		2012e	Study for Mode of Action analysis for tumor formation of S-1563 on rat liver (5) - Analysis for time course and dose response in female rats. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co Ltd.
IIIA6.10/9		2012f	Study for Mode of Action analysis for effects of S-1563 on thyroid gland in male rats. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co Ltd.
IIIA6.10/10		2012g	Study for Mode of Action analysis for tumor formation of S-1563 in rat liver (6): - *In Vitro* Evaluation for role of nuclear receptor CAR in S-1563- and its metabolite Z-CMCA-induced CYP2B1/2 mRNA expression of cultured rat hepatocytes. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co Ltd.
IIIA6.10/11		2013	Comparison of the effects of S-1563 and its metabolite Z-CMCA on replicative DNA synthesis and CYP2B induction in cultured rat and human hepatocytes. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co Ltd.
IIIA6.10/12		2013	Document for EU evaluation: An evaluation of the Human Relevance of S-1563-induced liver tumours in rats based on Mode of Action. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co Ltd.
IIIA7.1.1.1.1		2011	Hydrolysis of [^{14}C]S-1563 in buffered aqueous solutions. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.1.1.1.2		2012	Photodegradation of [^{14}C]S-1563 in aqueous solution buffered at pH 4 by artificial light. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.1.1.2.1		2010	S-1563: Determining the ready biodegradability. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.1.2.2.2		2011	[^{14}C]S-1563: Degradation in water sediment systems under aerobic conditions.	Y	Y	Sumitomo Chemical

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Y/N)	Owner
			GLP Unpublished			Co., Ltd.
IIIA7.1.3/1		2012b	Soil adsorption/desorption of [^{14}C]S-1563 by the Batch Equilibrium Method. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.1.3/2		2011	Estimation of the adsorption coefficient (K_{OC}) of S-1563RTZ and S-1563RTE using high performance liquid chromatography. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.2.2.1		2012	Aerobic soil metabolism of [^{14}C]S-1563 in four soils. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.3.1		2011	Stability of S-1563 in air. GLP Not applicable Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.4.1.1/1		2011a	S-1563 - Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Flow-Through Conditions, Following OPPTS Draft Guideline 850.1075, OECD Guideline #203 and The Official Journal of the European Communities L383A, Method C.1. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.4.1.1/2		2011b	S-1563 - Acute Toxicity to Fathead Minnow (*Pimephales promelas*) Under Flow-Through Conditions, Following OPPTS Draft Guideline 850.1075, OECD Guideline #203 and The Official Journal of the European Communities L383A, Method C.1. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.4.1.1/3		2011c	S-1563 - Acute Toxicity to Bluegill Sunfish (*Lepomis macrochirus*) Under Flow-Through Conditions, Following OPPTS Draft Guideline 850.1075, OECD Guideline #203 and The Official Journal of the European Communities L383A, Method C.1. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.4.1.2		2011d	S-1563 - Acute Toxicity to Water Fleas (*Daphnia magna*) Under Flow-Through Conditions, Following OECD Guideline #202, OPPTS Draft Guideline 850.1010 and The Official Journal of the European Communities L383A, Method C.2. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.4.1.3		2011	S-1563 - 96-Hour Toxicity Test with the Freshwater Green Alga, *Pseudokirchneriella subcapitata*, Following OPPTS Draft Guideline 850.5400, the Official Journal of the European Union Commission Regulation (EC)	Y	Y	Sumitomo Chemical Co., Ltd.

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			No 761/2009 Annex IV Method C.3 and OECD Guideline #201. GLP Unpublished			
IIIA7.4.1.4		2010	S-1563: Activated sludge respiration inhibition test. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.4.3.2		2012	S-1563 – Early Life-Stage Toxicity Test with Fathead Minnow, *Pimephales promelas*, Following OECD Guideline #210 and OPPTS Draft Guideline 850.1400. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.4.3.3.1		2012	Flow-Through Bioconcentration and Metabolism Study of [^{14}C]S-1563 with Bluegill Sunfish (*Lepomis macrochirus*). GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.4.3.4		2012	S-1563 - Full Life cycle Toxicity Test with Water Fleas (*Daphnia magna*) Under Flow-Through Conditions, Following OPPTS Draft Guideline 850.1300, OECD Guideline #211 and The Official Journal of the European Communities L383A, Method C.20. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.4.3.5.1		2012	S-1563 – Toxicity Test with Sediment-Dwelling Midges (*Chironomus dilutus)* Under Static Conditions, Following OECD Guideline 218. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.4.3.5.2		2011b	S-1563 - 7-day Toxicity Test With Duckweed (*Lemna gibba*), Following OECD Guideline 221 and OPPTS Draft Guideline 850.4400. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.5.1.1		2010	S-1563: Determination of Effects on Soil Microflora Activity. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.5.1.2		2010	S-1563 - Acute Toxicity of S-1563 on Earthworms, *Eisenia fetida* Using an Artificial Soil Test. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.5.3.1.1/1		2010a	S-1563: An acute oral toxicity study with the Northern Bobwhite. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.5.3.1.1/2		2010b	S-1563: An Acute Oral Toxicity Study with the Zebra Finch (*Poephila guttata*). GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.

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IIIA7.5.3.1.2/1		2011a	S-1563: A dietary LC_{50} study with the Mallard. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.5.3.1.2/2		2011b	S-1563: A dietary LC_{50} study with the Northern bobwhite. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.5.3.1.3/1		2012a	S-1563: A Reproduction Study with the Northern Bobwhite. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.5.3.1.3/2		2012b	S-1563: A Reproduction Study with the Mallard. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.5.4.1/1		2010	S-1563 - Acute oral and contact toxicity to the honeybee, *Apis mellifera* L. in the laboratory. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA7.5.4.1/2		2010	S-1563: A laboratory study conducted on quartz sand to evaluate the effects on the rove beetle, *Aleochara bilineata* Gyll. (Coleoptera, Staphylinidae). GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIIA8	Anon.	2012	Safety Data Sheet S-1563 TG Report Date: Nov. 26, 2012 SDS No.TE0535C Published	Y	N	Sumitomo Chemical Co., Ltd.
IIIA9	Anon.	2012	Safety Data Sheet S-1563 TG Report Date: Nov. 26, 2012 SDS No.TE0535C Published	Y	N	Sumitomo Chemical Co., Ltd.

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IIB1.3/1 (3.1.1)		2012a	S-1563 / Sumithrin WBA (EU): Determination of physical state, colour and odour. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/2 (3.1.2)		2012a	S-1563 / Sumithrin WBA (EU): Determination of physical state, colour and odour. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.

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IIB1.3/3 (3.1.3)		2012a	S-1563 / Sumithrin WBA (EU): Determination of physical state, colour and odour. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/4 (3.2)		2012b	S-1563 / Sumithrin WBA (EU): Assessment of explosive properties GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/5 (3.3)		2012c	S-1563 / Sumithrin WBA (EU): Assessment of oxidising properties. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/6 (3.4/1)		2012d	S-1563 / Sumithrin WBA (EU): Determination of Flash Point. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/7 (3.4/2)		2012e	S-1563 / Sumithrin WBA (EU): Determination of auto-ignition temperature. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/8 (3.4/3)		2012	Aerosol flammability testing and internal pressure measurement on a sample of S-1563/Sumithrin WBA (EU). GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/9 (3.5)		2012f	S-1563 / Sumithrin WBA (EU): Determination of pH. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/10 (3.6)		2012g	S-1563 / Sumithrin WBA (EU): Determination of relative density. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/11 (3.7)		2013	S-1563 / Sumithrin WBA (EU): Determination of Accelerated Storage Stability GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/12 (3.8)		2012h	S-1563 / Sumithrin WBA (EU): Determination of technical characteristics. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/13 (3.1.1)		2012a	S-1563 / Sumithrin OBA (EU): Determination of physical state, colour and odour. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Yes/No)	Owner
IIB1.3/14 (3.1.2)		2012a	S-1563 / Sumithrin OBA (EU): Determination of physical state, colour and odour. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/15 (3.1.3)		2012a	S-1563 / Sumithrin OBA (EU): Determination of physical state, colour and odour. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/16 (3.2)		2012b	S-1563 / Sumithrin OBA (EU): Assessment of explosive properties GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/17 (3.3)		2012c	S-1563 / Sumithrin OBA (EU): Assessment of oxidising properties. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/18 (3.4/1)		2012d	S-1563 / Sumithrin OBA (EU): Determination of flash point. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/19 (3.4/2)		2012e	S-1563 / Sumithrin OBA (EU): Determination of auto-ignition temperature. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/20 (3.4/3)		2012	Aerosol flammability testing and internal pressure measurement on a sample of S-1563/Sumithrin OBA (EU). GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/21 (3.6)		2012f	S-1563 / Sumithrin OBA (EU): Determination of relative density. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/22(3.7)		2013	S-1563 / Sumithrin OBA (EU): Determination of Accelerated Storage Stability GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.3/23 (3.8)		2012g	S-1563 / Sumithrin OBA (EU): Determination of technical characteristics. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.4 (Foot note 1)		2013	Assessment Report *d*-Phenothrin Product-type 18 (Insecticides, acaricides and products to control other arthropods), March 2013. Not published	N	N	Public

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Yes/No)	Owner
IIB1.4.1/1 (4.1)		2012i	S-1563 / Sumithrin WBA (EU): Analytical Method Development and Validation. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB1.4.1/2 (4.1)		2012	S-1563 / Sumithrin OBA (EU): Analytical Method Development and Validation. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB2.3/1 (5.10/1)		2012a	Evaluation of a spray containing S-1563 (water based aerosol) for knockdown and kill of crawling venomous arthropods (scorpions, spiders & centipedes). Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB2.3/2 (5.10/2)		2012b	Evaluation of a spray containing S-1563 (water based aerosol) for knockdown and kill of caged flies and mosquitoes. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB2.3/3 (B5.10/3)		2012c	Evaluation of a spray containing S-1563 (water based aerosol) for knockdown and kill of caged stinging hymenopterans (yellow jackets, hornets, and paper wasps). Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB2.3/4 (5.10/4)		2012	Evaluation of a spray containing S-1563 (water based aerosol) for knockdown and kill of caged paper wasps, *Polistes dominulus* in the laboratory. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB2.3/5 (5.10/5)		2012	Laboratory bioassay to determine the efficacy of aerosol products against mosquitoes (*Aedes albopictus*), bed bugs (*Cimex lectularius*) and black ants (*Lasius niger*), applied as direct sprays. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB2.3/6 (5.10/6)		2012d	Evaluation of a spray containing S-1563 (water based aerosol) for knockdown and kill of ants and cockroaches. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB2.3/7 (5.10/7)		2012e	Evaluation of SUM and SUM/S-1563 (WBA) as fast-acting space sprays against flying insects in a 6x6x6 foot	Y	Y	Sumitomo Chemical Co., Ltd.

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			Peet Grady chamber. Not GLP Unpublished			
IIB2.3/8 (5.10/1)		2012	Laboratory bioassay to determine the efficacy of aerosol products against mosquitoes (*Aedes albopictus*), bed bugs (*Cimex lectularius*) and black ants (*Lasius niger*), applied as direct sprays. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB2.3/9 (5.10/2)		2012a	Evaluation of a spray containing S-1563 (oil based aerosol) for knockdown and kill of ants and cockroaches. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB2.3/10 (5.10/3)		2012b	Evaluation of a spray containing S-1563 (oil based aerosol) for knockdown and kill of caged flies and mosquitoes. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB2.3/11 (5.10/4)		2012c	Evaluation of a spray containing S-1563 (oil based aerosol) for knockdown and kill of caged stinging hymenopterans (Yellow jackets, hornets, and Paper wasps). Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB2.3/12 (5.10/5)		2012	Evaluation of a spray containing S-1563 (oil based aerosol) for knockdown and kill of caged paper wasps, *Polistes dominulus* in the laboratory. Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB2.3/13 (5.10/6)		2012d	Evaluation of a spray containing S-1563 (oil based aerosol) for knockdown and kill of crawling venomous arthropods (scorpions, spiders & centipedes). Not GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB3.2.3.1/1 (Foot note 2)	European Commission	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2. Italy, April 2003. Not GLP Published	N	N	Public

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IIB3.2.3.1/2 (Foot note 3)	European Commission	2007	Technical Notes for Guidance (TNsG) – Human Exposure to Biocidal Products (2007). Not GLP Published	N	N	Public
IIB3.2.3.1.1/3 (Foot note 4)	Bremmer *et al.*	2006	Pest Control Products Fact Sheet, RIVM report no.: 320005002/2006. Not GLP Published	N	N	NA
IIB3.2.3.1.1/4 (Foot note 5)	ECETOC	2012	ECETOC Targeted Risk assessment version 3: Background and Rationale for the improvements. Technical Report No. 114 ISSN-0773-8072-114. Not GLP Published	N	N	Public
IIB3.2.3.1.1/5 (Foot note 6)	ECETOC	2001	ECETOC (2001): Exposure factors sourcebook for European populations (with focus on UK data). Not GLP Published	N	N	Public
IIB3.2.3.1.1/6 (Foot note 7)	ECHA	2010	ECHA Guidance on information requirements and chemical safety assessment; Chapter R.15: Consumer exposure estimation, Version 2, April 2010. Not GLP Published	N	N	Public
IIB3.2.4.1 (Foot note 9)	OECD	2008	OECD Environment Directorate; Joint Meeting Of The Chemicals Committee And The Working Party On Chemicals, Pesticides And Biotechnology (2008). Emission Scenario Document for Insecticides, acaricides and products to control other arthropods (PT 18) for household and professional uses. 30 June, 2008. OECD Environment, Health and Safety Publications. Series on Emission Scenario. No. 18. Not GLP Published	N	N	Public
IIB3.3.1 (Footnote 10)	OECD	2008	OECD ESD for PT18 (2008): Series on Emission Scenario Documents Number 18 , Emissions Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses ENV/JM/MONO(2008)14).	N	N	Public
IIB3.3.2 (Foot note 11)	European Commission	2003	Technical Guidance Document on Risk assessment (Part II), European Commission, Italy 2003.	N	N	Public

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IIB4.2/1 (6.1.1)		2012a	Acute oral toxicity study of S-1563/ Sumithrin WBA (USA) bulk formulation in rats. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB4.2/2 (6.1.2)		2012b	Acute dermal toxicity study of S-1563/Sumithrin WBA (USA) bulk formulation in rats. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB4.2/3 (6.1.3)		2012	S-1563/Sumithrin WBA (USA): toxicity study by inhalation administration to rats for 1 week. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB4.2/4 (6.1.1)		2012a	Acute oral toxicity study of S-1563/Sumithrin OBA (EU) bulk formulation in rats. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB4.2/5 (6.1.2)		2012b	Acute dermal toxicity study of S-1563/Sumithrni OBA (EU) bulk formulation in rats. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB4.2/6 (6.1.3)		2012	Acute inhalation toxicity study of S-1563/Sumithrni OBA (EU) in rats. GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB4.3/1 (6.3)		2012c	A skin sensitization study of S-1563/Sumithrin WBA (USA) bulk formulation in guinea pigs (Buehler test). GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.
IIB4.3/2 (6.3)		2012c	A skin sensitization study of S-1563/Sumithrin OBA (EU) bulk formulation in guinea pigs (Buehler Test). GLP Unpublished	Y	Y	Sumitomo Chemical Co., Ltd.