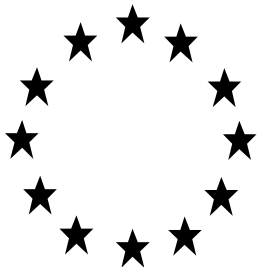
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



d-Allethrin

Product-type 18
(Insecticides, acaricides and products to control other arthropods)

October 2021

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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 biocidal active substance d-allethrin as product-type 18 (insecticides, acaricides and products to control other arthropods), carried out in the context of the work programme for the review of existing active substances provided for in Article 89 of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

d-Allethrin with CAS No. 584-79-2 was notified as an existing substance by Sumitomo Chemical (UK) Plc, United Kingdom. d-Allethrin with CAS No. 231937-89-6 was notified as an existing substance by Endura S.p.A, Italy.
Regulation (EU) No 1062/2014 of 4th of August 2014 lays down the detailed rules for the evaluation of dossier and for the decision-making process.
In accordance with the provisions of Article 6 of that Regulation, Germany was designated as Rapporteur Member State to carry out the assessment on basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for d-Allethrin as an active substance in Product Type 18 was 30 of April 2006.

On 26 April 2006, the German Competent Authority received a dossier for d-allethrin from the applicant Sumitomo and a dossier for d-allethrin from the applicant Endura. It was established that the active substances are chemically identical and the correct CAS No. for the used isomeric composition is 231937-89-6, as CAS No 584-79-2 refers to an isomeric composition without specified ratio of the four isomers. The Rapporteur Member State accepted the dossier from the applicant Sumitomo as complete for the purpose of the evaluation on 30 March 2007. The dossier from the applicant Endura has been accepted by the Rapporteur Member State as complete for the purpose of the evaluation on 26 June 2015 as the applicant needed this time to conduct negotiations on a letter of access for different toxicological studies with vertebrates.

No harmonised classification for d-allethrin is available. Therefore a classification is proposed and a CLH dossier has been submitted to ECHA by the evaluating Competent Authority.

For the implementation of the common principles of Annex VI, the content and conclusions of this document shall be taken into account.

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 d-allethrin for product-type18, 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 web-site shall be taken into account.

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

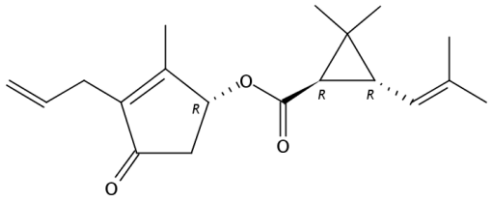
2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

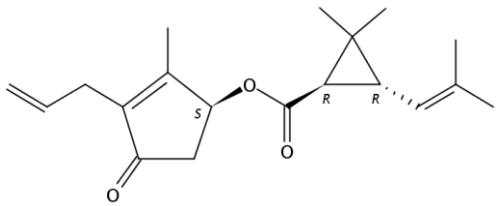
2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Identity

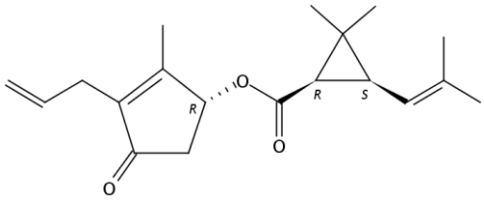
common name	d-Allethrin
Chemical name (IUPAC)	(RS)-3-allyl-2-methyl-4-oxocyclopent-2-enyl-(1R,3RS)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate
CAS no.	231937-89-6
EINECS no.	-
Molecular formula	$C_{19}H_{26}O_3$
Molecular mass	302.41 g/mol
Structural formula	Isomer 1: 1R trans; R or (1R; 1R, 3R): (1R)-3-allyl-2-methyl-4-oxocyclopent-2-en-1-yl-(1R,3R)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate CAS No. 61009-26-5



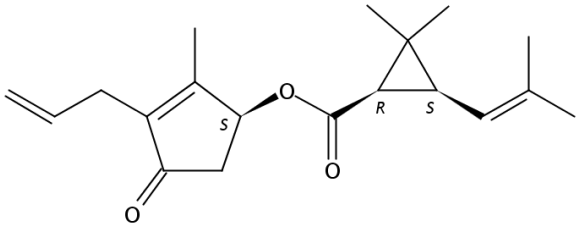
Isomer 2: 1R trans; S or (1S; 1R, 3R): (1S)-3-allyl-2-methyl-4-oxocyclopent-2-en-1-yl-(1R,3R)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate CAS No. 28434-00-6



Isomer 3: 1R cis; R or (1R; 1R, 3S): (1R)-3-allyl-2-methyl-4-oxocyclopent-2-en-1-yl-(1R,3S)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate CAS No. 61009-23-2



Isomer 4: 1R cis; S or (1S; 1R, 3S):
(1S)-3-allyl-2-meth-yl-4-oxocyclopent-2-en-1-yl-(1R,3S)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate
CAS No. 61046-09-1



d-Allethrin is a mixture of four isomers. The substance comprises [1R,trans;1S]-isomer:[1R, trans;1R]-isomer: [1R, cis;1S]-isomer and [1R cis;1R]-isomer at a ratio of 4:4:1:1. All four isomers have a biocidal activity (Rauch, 1974). However the [1R, trans;1S]-isomer is the most biologically active. The possible four further isomers are minor isomers of d-allethrin with contents of <10%. The minimum purity based on the four main isomers is 900 g/kg.

The racemic micture of all 8 stereoisomers is called Allethrin.

Physico-chemical Properties and Method of Analysis of d-Allethrin

d-Allethrin is a mixture of four racemic isomers. It is a pale yellow to yellow brown liquid with a pour point under -50 °C. The boiling point was determined at 281,5 °C (p = 1013 hPa, Siwoloboff). However, with the DSC measurement of one applicant decomposition at 120°C was determined. Based on the used method we assume that the decomposition of the substance was not noticed and reported when the Siwoloboff method was used.

The vapour pressure is determined to 5.95 x 10^{-4} Pa at 20 °C and the water solubility is 2.6 mg/L at 20°C. Based on these values the Henry Laws constant is calculated to be 0.069 Pa m^3 mol^{-1} or respectively 0.00163 Pa m^3 mol^{-1} . (The differences are based on the different values for the vapour pressure) The partition coefficient at 25°C and pH 5.9 is 4.95
The active substance d-Allethrin is determined with GC-FID methods. The method has been validated in terms of specificity, linearity, precision and recovery. The determination of the optical isomer ratio was done by liquid chromatography with UV detection at 230nm and has been validated in terms of specificity, linearity, precision and recovery.
The impurities were also determined with GC-FID or GC-MS methods. (Doc. III-A4.1)

Residue analysis

Discussion of the residue definition:
The analytical methods for residues are able to detect 1 or 2 isomers (diastereomers) depending on the selectivity of the separation technique. No enantioselective methods are used for monitoring. Typically, the quantification is based on the sum of peaks detected. Therefore, we propose to revise the residue definition in "d-allethrin (sum of the isomers)".

Analytical methods are available for determination of d-allethrin (sum of the isomers) in air. Sufficiently validated primary and confirmatory method for determination of d-allethrin residues (sum of the isomers) in drinking water are missing. According to Guidance on information requirements chapter 5.2.3 "Water" an analytical method for drinking water must be submitted, if the active substance falls within the definition of pesticides given in Annex I of the European

Drinking Water Directive. d-Allethrin falls within the definition.
As exposure of surface water via STP and of soil via sewage sludge is possible by the intended use validated primary and confirmatory method for determination of d-allethrin residues (sum of the isomers) in these matrices are needed and have still to be submitted. Relevant exposure of plants and plant products and animal products is unlikely by the intended uses. Therefore, analytical methods are not needed for these matrices.

Air: Based on the proposed uses residues of d-allethrin in air are expected. A sufficiently validated analytical method for determination of d-allethrin (sum of the isomers) in air by GC-ECD is provided. The limit of quantification (LOQ) is 0.62 µg/m³. For confirmatory purposes a sufficiently validated method by GC-MS is presented. In addition a further analytical method for determination of d-allethrin (sum of the isomers) in air by GC-MS is provided. The limit of quantification is 1.5 µg/m³. The included data for confirmatory purposes are insufficient. Chromatograms for the additional fragment ions m/z 107 and 136 at LOQ and 10*LOQ are missing.
A classification of the active substance as "Muta. Cat. 2" was proposed by the eCA. It should be noted, that then the LOQs of both analytical methods in air are not sufficient for monitoring the action limit calculated using the AEL based on TTC for genotoxic substances.

Animal and human body fluids and tissues: The active substance d-allethrin is currently not classified as toxic or very toxic. An analytical method for d-allethrin (sum of the isomers) in blood based on GC-MS is available. The limit of quantification is 1 µg/L. A confirmatory method is not included. A classification of the active substance as "Acute Tox. Cat. 3" is proposed by the eCA. In case of entry into force of the proposed classification a confirmatory method forforfor blood and a sufficiently validated primary and confirmatory method for tissues are required.

Biocidal Product Duracide A:
In addition to the active substance, the biocidal product contains further substances of concern (component 1, component 2; see confidential applicant dossier IIIB2.2/01 and IIIB2.2/02). These components are themselves active substances of biocidal products. The applicant submitted sufficiently validated methods for determination of component 1 in air in the corresponding dossier for this active substance. Sufficiently validated methods for the determination of component 1 in soil, in drinking and surface water are missing and should be provided. For component 2 the applicant submitted sufficiently validated methods for soil, water and air in the corresponding dossier for this active substance.

Biocidal Product Pynamin Forte 40mg Mat:
In addition to the active substance, the biocidal product contains no further substances of concern. Methods for the determination of non-active ingredients were not considered necessary.

Identity, Physico-chemical Properties and Method of Analysis of the Pynamin® Forte40 mg Mat (Sumitomo)

The biocidal product Pynamin® Forte 40 mg Mat is a concentrate with intention to be applied on a mat with 40.8% d-allethrin. Physico-chemical testing on the Pynamin® Forte 40 mg Mat is limited to appearance and storage stability. Further data are required for the product authorisation stage.

The active substance is determined with GC-MS method by using an internal standard. The method was validated by investigating linearity, specificity, precision and recovery.

Identity, Physico-chemical Properties and Method of Analysis of Duracide A (Endura)

Duracide A is a transparent oily amber to light brown liquid with a characteristic odour with 7.7% d- allethrin. The surface tension of the product is 33.3 mN/m at 20°C and a viscosity of 61.1 mm2/s respectively 64.9 mPa*s. The storage stability studies indicated that the product is stable at low temperatures and for 8 weeks at 40°C.
A shelf life must be set at product authorisation stage when the long term storage stability test

is submitted and evaluated.
The determination of the d-allethrin in Duracide A is performed by GC using an internal standard and a flame ionisation detector (FID).
The method was validated by investigating linearity, specificity and precision.

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) mosquitoes (e.g. *Anopheles spp, Aedes spp, Culex spp*) and flies (*Musca domestica*). The evaluation of the data provided in support of the efficacy of the accompanying products, establishes that products containing d-allethrin may be expected to be efficacious.

The product Pynamin Forte 40 mg mat is claimed for non-professional and indoor use (excluding kitchens). The product will be formulated as vapor releasing impregnated mats used in conjunction with an electric heating unit.

The product Duracide A is claimed for professional and non-professional indoor use in domestic households excluding kitchens and in commercial & industrial buildings as a spray application. It will be formulated for use as an aerosol by diluting a liquid concentrate based on Tetramethrin, d-Allethrin and Piperonyl butoxide. However, as the product Duracide A contains more than one active substance, a sufficient efficacy of d-allethrin in a representative product is only demonstrated for the product Pynamin Forte 40 mg mat.

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.

Mode of Action
d-Allethrin is a pyrethroid insecticide. It acts on the sodium channel in the nerve membranes of the invertebrate nervous system causing pronounced repetitive activity and a prolongation of the transient increase in sodium permeability of the nerve membranes. This results in continual nerve impulse transmission leading to tremors and death.

Resistance
Resistance against pyrethroids can occur in relevant pest species. In Europe the main resistance problems have occurred with pests of agricultural significance - among them some species of flies and cockroach populations. Cross-resistance of pest species to other pyrethroids is to be anticipated due to a common mode of action and instances of cross-resistance (or multiple resistance) between pyrethroids and organochlorine insecticides have been reported.

To avoid and fight resistance, management procedures should be planned and conducted (see Doc. II documents).

2.1.3. Classification and Labelling

d-Allethrin is not legally classified according Regulation (EC) No 1272/2008. The participants indicated the current classification and labelling on the basis of Directive 67/548/EEC.

Table 2-1 Current classification of d-allethrin based on Directive 67/548/EEC as given by the participants

	Classification	Wording
Hazard Symbols, Indications of danger		Harmful

	Classification	Wording
	 Xn  N	Dangerous for the environment
R-phrases	R20/22: R50/53:	Harmful by inhalation and if swallowed. Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S-phrases	S2: S36: S60: S61:	Keep out of reach of children Wear suitable protective clothing. This material and/or its container must be disposed of as hazardous waste Avoid release to the environment. Refer to special instructions/Safety data sheet.

Table 2-2 Proposed classification of d-allethrin by the eCA based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Acute Tox. 3 Acute Tox. 4 STOT SE 1 STOT-RE 2 dermal Repr. 2 Aquatic Acute 1 Aquatic Chronic 1	
Hazard statements	 H301 H332 H370 H373 H361d H400 H410	 Toxic if swallowed. Harmful if inhaled. Causes damage to the nervous system after oral and inhalation exposure. May cause damage to the skin through prolonged or repeated exposure. Suspected of damaging the unborn child. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.
M-Factor	100 (acute) 100 (chronic)	

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

	Labelling	Wording
Pictograms	 GHS06	

	Labelling	Wording
	 GHS08  GHS09 Remark: if the hazard pictogram 'GHS06' applies, the hazard pictogram 'GHS07' shall not appear	
Signal Word	Danger	
Hazard statements	H301 H332 H370 H361d H373 H410	Toxic if swallowed. Harmful if inhaled. Causes damage to the nervous system after oral and inhalation exposure. Suspected of damaging the unborn child. May cause damage to the skin through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.
Suppl. Hazard statements	-	-
Precautionary statements	P201 P202 P260 P261 P264 P270 P271 P273 P280 P301+P310 P304+P340 P308+P311 P308+P313 P312 P314 P321 P391 P405 P501	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/ vapours/spray. Avoid breathing dust/fume/gas/mist/ vapours/spray. Wash … thoroughly after handling. Do not eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection. IF SWALLOWED: Immediately call a POISON CENTER/doctor/... IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF exposed or concerned: Call a POISON CENTER/doctor… IF exposed or concerned: Get medical advice/attention. Call a POISON CENTRE/doctor/…if you feel unwell. Get medical advice/attention if you feel unwell. Specific treatment (see … on this label). Collect spillage. Store locked up. Dispose of contents/container to ...

Currently, there is no harmonised classification and labelling entry available for the active substance d-allethrin. The classification and labelling proposed by the eCA is in accordance with Regulation (EC) No. 1272/2008. Based on the lowest ecotoxicological effect values the classification as "H400 - Aquatic Acute 1" and "H410 - Aquatic Chronic 1" is justified (regarding

to Regulation (EC) No. 286/2011). The M-factor of 100 is proposed for both, acute and chronic toxicity (see Doc II, chapter 4.3).
Based on acute toxicity studies, it is proposed to classify d-allethrin with Acute Tox. 3; H301 (Toxic if swallowed), Acute Tox. 4; H332 (Harmful if inhaled) and STOT-SE 1 (Causes damage to the nervous system, oral and inhalation route).
Based on severe inflammatory response in rabbits after repeated dermal application of esbiothrin/d-allethrin, it is proposed to classify d-allethrin with STOT-RE 2 dermal H373 (Causes damage to the skin through prolonged or repeated exposure).
Based on a positive chromosomal aberration and micronucleus test with allethrin *in vivo* as well as positive micronucleus test with allethrin *in vitro*, classification with Muta. 2 (H341) was initially proposed by the eCA. A discussion on the mutagenic potential of d-allethrin based on all available data took place at the BPC WG (V) 2018. It was finally concluded by the majority of the WG that the database is not convincing enough to consider d-allethrin as mutagenic.
In a developmental toxicity study with d-allethrin it cannot be unequivocally demonstrated that the developmental effects are secondary to maternal toxicity. Therefore, classification with Repr. 2; H361d (Suspected of damaging the unborn child) is proposed for d-allethrin.

Classification and Labelling of Pynamin Forte 40 mg mat

Table 2-4 Proposed classification of Pynamin Forte 40 mg mat based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Acute Tox. 3 Acute Tox. 4 Asp. 1 Skin Sens. 1 Repr. 2 STOT SE 1 STOT RE 2 (dermal) Aquatic Acute 1 Aquatic Chronic 1	
Hazard statements	H301 * H332 H304 H317 H361d H370 H373 H400 H410	Toxic if swallowed. Harmful if inhaled. May be fatal if swallowed and enters airways. May cause an allergic skin reaction. Suspected of damaging the unborn child. Causes damage to the nervous system after oral and inhalation exposure. May cause damage to the skin through prolonged or repeated exposure. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.

***** Please note that the biocidal product is the concentrate, which is authorized with the only intention to be applied on the mat. Therefore, the mat is not part of the biocidal product. Thus, that according to Regulation (EU) No 528/2012, Article 19 4 (b), the biocidal product (liquid concentrate) shall not be authorised for making available on the market for use by the general public due to its classification**.**

Table 2-5 Proposed labelling of Pynamin Forte 40 mg mat based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms		

	 GHS07  GHS06 GHS08  GHS09	
Signal Word	Danger	
Hazard statements	H301 H332 H304 H317 H361d H370 H373 H410	Toxic if swallowed. Harmful if inhaled. May be fatal if swallowed and enters airways. May cause an allergic skin reaction. Suspected of damaging the unborn child. Causes damage to the nervous system after oral and inhalation exposure. May cause damage to the skin through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects. Very toxic to aquatic life with long lasting effects.
Suppl. Hazard statements	-	-
Precautionary statements	P101 P102 P201 P202 P260 P264 P270 P273 P280 P302 + P352 P301 + P310 + P330+ + P331 P308 + P311 P361 + P364 P391 P405 P501	If medical advice is needed, have product container or label at hand. Keep out of the reach of children. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapours/spray.Wash … thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of water/… IF SWALLOWED: Immediately call a POISON CENTER/doctor/… Rinse mouth. Do NOT induce vomiting. IF exposed or concerned: Call a POISON CENTER/ doctor/…. Take off immediately all contaminated clothing and wash it before reuse. Collect spillage. Store locked up. Dispose of contents/container to …

Remark:

According to the product label submitted by the applicant the active substance concentrate used for the impregnation of the biocidal product contains also a perfume and a dye. Such components were not listed in the identity according to Doc. IIIB2.1 and have, therefore, not been evaluated for classification and labelling.

Classification and Labelling of Duracide A (concentrate)

Table 2-6 Proposed classification of Duracide A based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Carc. 2 Repr. 2 STOT SE 2 Aquatic Acute 1 Aquatic Chronic 1	
Hazard statements	H351 H361d H371 H400 H410	Suspected of causing cancer. Suspected of damaging the unborn child. May cause damage to the nervous system after oral and inhalation exposure. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects

Remark:
The classification as Repr. 2 and STOT SE 2 is based on the classification proposed for the active substance. The classification as STOT SE 2 and Carc. 2 is based on the classification proposed for another active substance in Duracide A during approval according to Regulation (EU) No 528/2012.
The dilution of the biocidal product assessed for non-professional users (Duracide A - FIK aerosol, 1.29 g Duracide A/100g) does not require classification based on the classification of the active substances. Further classification may result from the toxicological properties of unknown co-formulants.

Table 2-7 Proposed labelling of Duracide A based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	 GHS08  GHS09	
Signal Word	Warning	
Hazard statements	H351 H361d H371 H410	Suspected of causing cancer. Suspected of damaging the unborn child. May cause damage to the nervous system after oral and inhalation exposure. Very toxic to aquatic life with long lasting effects

Suppl. Hazard statements	None	
Precautionary statements	P201	Obtain special instructions before use.
	P202	Do not handle until all safety precautions have been read and understood.
	P260	Do not breathe dust/fume/gas/mist/ vapours/spray. Wash … thoroughly after handling.
	P264	Do not eat, drink or smoke when using this product.
	P270	Avoid release to the environment.
	P273	Wear protective gloves/protective clothing/eye protection/face protection.
	P280	IF exposed or concerned: Call a POISON CENTER/ doctor/...
	P308 + P311	IF exposed or concerned: Get medical advice/attention.
	P308 + P313	Collect spillage.
	P391	Store locked up.
	P405	Dispose of contents/ container to …
	P501	

Remark:
The classification and labelling of the representative b.p. proposed by the eCA is in accordance with Regulation (EC) No. 1272/2008 (2.ATP) at which the M-factor of 100 is used for both categories (acute and chronic aquatic hazard).

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

For the present Assessment Report on d-allethrin, the applicants submitted studies on five different technical substances forming the allethrin series: allethrin, d-allethrin, bioallethrin, esbiothrin and S-bioallethrin. These allethrins differ with regard to their isomeric composition, particularly in the relative content of the [1R, trans; 1S] diastereoisomer which is reported to display the highest insecticidal potential of the 8 allethrin isomers (Rauch *et al*., 1974; WHO, 1989).

The allethrins are classified as type I pyrethroids which lack an alpha-cyano substituent. Neurotoxicity of type I pyrethroids is characterised by fine tremor progressing to whole body tremor and prostration, aggressive sparring, and increased sensitivity to external stimuli (enhanced startle response). These signs, along with enhanced salivation, decreased righting reflex, and hunched posture, were seen in many of the studies conducted with d-allethrin, bioallethrin, esbiothrin and S-bioallethrin. If the [1R, trans; 1S] isomer is more insecticidally active than the other isomers, it could be assumed that neurotoxicity in mammals occurs at lower doses for enriched products. However, this is not always evident from the database of toxicity studies, where similar signs of toxicity were observed at similar doses for d-allethrin, bioallethrin, esbiothrin and S-bioallethrin.

Reported oral acute LD_{50} values in rat were between 310 and 2150 mg/kg for d-allethrin, 375 and 1130 mg for bioallethrin, and 350-500 for esbiothrin. For mice LD_{50} values were between 360 and 730 mg/kg bw for d-allethrin and 96/117 mg/kg bw for esbiothrin. The range for each substance suggests, that mortality from neurotoxicity after oral administration was more dependent on other factors (e.g. solvent) than the type of isomeric mixture. This assumption is supported by similar LOAELs for maternal (neuro)toxicity for d-allethrin and esbiothrin in rat and rabbit developmental studies (rat: 100/125, rabbit: 350/300 mg/kg bw/d d-allethrin/esbiothrin) and comparable oral neurotoxicity of S-bioallethrin in the rat with an LOAEL of 90 mg/kg bw.

The neurotoxic effects were noted during or shortly after each inhalation and oral exposure in acute and repeat-dose toxicity studies and they were considered to represent acute effects. Therefore, d-Allethrin and esbiothrin do warrant classification for specific target organ toxicity following - single exposure (STOT SE).
Following medium- and long-term oral exposure to allethrins, liver toxicity (hepatocellular hypertrophy) associated with changes in liver enzymes and other biochemistry parameters (i.e.

cholesterol, total proteins, albumin), pituitary, thyroid and kidney is the most important endpoint for all isomeric mixtures. Resulting NOAEL/LOAEL intervals of oral 90-d rat studies (NOAEL: 36.6-50 mg/kg bw/d; LOAEL: 126-149 mg/kg bw/d), and one oral 2-mo mouse study (NOAEL: 22 mg/kg bw/d; LOAEL: 229 mg/kg bw/d) using d-allethrin, esbiothrin and S-bioallethrin were partially overlapping. Although the dog was more sensitive to liver toxicity induced by allethrins, the corresponding NOAEL/LOAELs for esbiothrin (28-d: 20/63 mg/kg bw/d, 52-week: 14/70 mg/kg bw/d), d-allethrin (52-week: 20/60 mg/kg bw/d) and bioallethrin (26-week: 6/36 mg/kg bw/d) were comparable. Comparison between d-allethrin and esbiothrin induced chronic liver toxicity in rat and mouse showed less coherent but consistent values.
When taking route-specific absorption rates into account, acute and chronic systemic effects of the allethrins were observed at comparable doses after oral, inhalative and dermal administration. Hence, corresponding data will be included in the bridging concept.
Because of these toxicological similarities, a bridging of toxicity data between the four chemicals appears to be justified. Wherever the NOAEL/LOAEL intervals of the isomer mixtures do not overlap, the lower value will be used within this bridging concept, adhering to the precautionary principle.

Hazard identification and effects assessment

Absorption, Distribution, Excretion, and Metabolism

A detailed review of available toxicity data for bioallethrin, esbiothrin and S-bioallethrin technical concluded similar toxicity profiles (submitted as A6.4.1/02). On this basis, it seems reasonable to propose, that the toxicokinetic properties of d-allethrin and esbiothrin will be similar. In order to limit vertebrate testing, the available data for S-bioallethrin are also used as a basis to estimate dermal absorption of d-allethrin.
Two oral rat studies were performed using (^{14}C)-d-trans-allethrin labelled at its acid or alcohol moiety. Both studies of [redacted] (1991) gave comparable results as reported below. Generally, there were no overt signs of toxicity in any of the treated groups. Several animals were lethargic for 1-2 days after treatment but then returned to normal activity. One dermal absorption study was conducted with (^{14}C)-allethrin.
Information about radioactivity present in bile was not provided since the animals under investigation were not bile cannulated. Taking into account urinary excretion and excretion of metabolites – that are considered to result from hepatic metabolism - in faeces, an oral absorption value of 60 % can be derived from the studies (for detailed information it is refered to Doc II). Tissue distribution was wide but concentrations were low. There were no major differences between sexes. [14C-acid] d-trans-allethrin is eliminated fast from the body and was readily eliminated in urine and faeces of all dose groups within 2-3 days after treatment. Excretion via expired air was very low or was not detectable. Total radiocarbon eliminated in the faeces was slightly higher than that eliminated in the urine and no major differences of excretion were evident between sexes and dose groups. The kinetics of excretion of d-trans-allethrin, as well as the concentration curves in the tissues and organs, indicates that the substance does not accumulate, but is continuously eliminated.
d-trans-allethrin was extensively metabolized independent of dose and sex. All dose groups show comparable patterns of metabolites. Metabolic key reactions include a) oxidation of double bonds into epoxides which are in part hydrated to the corresponding diol, b) oxidation of isobutenyl methyl groups to the corresponding alcohol and carboxy product, c) ester hydrolysis, and d) subsequent conjugations. These pathways resulted in 7 major types of metabolites that, together with unmetabolised allethrin, accounted for 75-97 % of the eliminated radioactive dose: epoxy-allethrin, carboxy-allethrin, allethrolone, hydroxy-chrysanthemate, carboxy-chrysanthemate, esters containing carboxy-chrysanthemate, allethrolone or dihydroxyallethrolone, and conjugates of carboxy-chrysanthemate, allethrolone as well as dihydroxyallethrolone.

Dermal absorption

Dermal absorption was considered to be 25 % (including a skin depot of ~15 %), independent of the concentration applied (0.06-2 %)

However, the applicant Endura did not submit specific information. Thus, default values according to the EFSA Guidance on Dermal Absorption (2012) are applied for the exposure and risk assessment of the reference product Duracide A.

Acute Toxicity

Generally, major effects observed after oral, dermal or inhalation exposure to d-allethrin and/or esbiothrin comprised neurological and behavioural findings (e.g. decrease in spontaneous activity, tremor, muscle fibrillation, salivation and convulsions).

In rats, d-allethrin as well as esbiothrin displayed moderate acute toxicity with typical neurological signs after oral administration. The LD_{50} values obtained after exposure to esbiothrin were lower than after d-allethrin exposure. This may be due to the different isomer content and composition. However, a read-across between d-allethrin, bioallethrin, esbiothrin and S-bioallethrin was established and is also valid for acute toxicity. Furthermore, the toxicity seems to be dependent on the vehicle. The application of more lipophilic vehicles like corn oil led to lower LD_{50} values for d-allethrin or esbiothrin.
In mice, typical neurological signs were also observed after oral administration of d-allethrin or esbiothrin.
The lowest oral LD_{50} value was determined in a study following OECD TG 401 to be 96/117 mg/kg bw (M/F) for esbiothrin in PEG 200.

After dermal exposure, d-allethrin was not acutely toxic to rabbits, rats and mice. Furthermore, no acute toxicity was observed after treatment of rabbits or rats with esbiothrin. For d-allethrin, treatment-related mortality was observed at doses of 2000 (60 % males dead at this dose) and 3000 mg/kg bw (40% females dead at this dose). For esbiothrin, dermal LD_{50} was higher than 2000 mg/kg bw.

The 3-hour inhalation exposure of d-allethrin diluted with kerosene as vehicle resulted in LC_{50} values of 1.65 mg/L in rats or 1.56 and > 1.65 mg/L for male and female mice, respectively. These values correspond to a LC50 (4h estimate) of 1.24 mg/L for rats and a LC50 (4h estimate) of 1.17 mg/L for mice.
Neurological symptoms were reported from concentrations of 1.623 mg/L of undiluted d-allethrin (lowest doses tested) and 0.111 mg/L diluted d-allethrin.

Acute irritation studies (skin and eye) with d-allethrin and esbiothrin did not meet the criteria for classification. Furthermore, no evidence for skin sensitisation was found in studies with both substances.

Proposal for classification/labelling for acute toxicity according to Regulation (EC) No. 1272/2008:
Overall, a classification into Acute Tox. 3; H301 (Toxic if swallowed) and Acute Tox. 4; H332 (Harmful if inhaled) is proposed by the eCA.

Specific target organ toxicity following single exposure (STOT SE)
Acute oral toxicity study with d-allethrin and esbiothrin in rats and mice revealed neurotoxic effects at the following doses: ≥ 80 mg/kg bw ([redacted]., 1979), ≥ 100 mg/kg bw ([redacted], 1989), ≥ 169 mg/kg bw (Anonymous; year not stated); ≥ 200 mg/kg bw ([redacted], 1985), ≥ 300 mg/kg bw ([redacted], 2006; [redacted], 1981; [redacted], 2006).

In dogs (52-week capsule study; [redacted], 1989) tremors, blepharospasms, ataxia, mydriasis, salivation, prostrate position, dyspnea and convulsive seizures were noted from 20 mg/kg bw/d onwards. However, based on the late onset of effects it was decided in BPC WG (III) 2017 to set the NOAEL at 20 mg/kg bw. The NOEAL of 30 mg/kg/bw from the rat oral acute acute neurotoxocity study was finally used as point of departure for the $AEL_{short\text{-}term}$.
At 100 mg/kg bw/d mortalities following severe convulsive seizures and pronounced elevations of the body temperature occurred.

In the 26-week dietary toxicity study in beagle dogs [redacted], 1982) body trembling was noted at 162 mg/kg bw/d). In the 28-day dog study [redacted], 1986), at a dose of 153 mg/kg bw/d, neurotoxic effects manifested clinically in tremor and convulsions.

In a 90-day inhalation toxicity study in rats exposed to d-allethrin ([redacted], 1993) irregular respiration, decreased activity, salivation, or urinary incontinence in the high dose of 0.310 mg/L air were considered acute effects.

In teratogenicity studies in rats with esbiothrin and d-allethrin ([redacted], 1990; [redacted], 1989) tremor, hypersensitivity, body jerks and excess salivation were noted in the dams at 125 or 100 mg/kg bw/d, respectively. In rabbits ([redacted], 1990; [redacted], 1989) tremor, clonic convulsions, decreased motor activity, ataxia, impaired/loss of righting reflex, excess salivation occurred at 300 and 350 mg/kg bw/d esbiothrin and d-allethrin, respectively. The relevant overall maternal NOAEL was 30 mg/kg bw/day, based on neurotoxicity and decreased body weight gain at 100 mg/kg bw/day and above in the rat (d-allethrin).

In an acute neurotoxicity study in rats ([redacted], 1997) hunched posture, body twitches, tremor, reduced motor activity, gait abnormalities and decreased grip strength occurred in females at 90 mg/kg bw. Based on these findings, a NOAEL for neurotoxic effects of 30 mg/kg is set.

The neurotoxic effects were noted during or shortly after each inhalation and oral exposure in acute and repeat-dose toxicity studies and they were considered to represent acute effects.

In accordance to CLP Regulation which states that STOT-SE is defined as "specific, non-lethal target organ toxicity arising from a single exposure to a substance", and includes "all significant health effects that impair function, both reversible and irreversible", the eCA proposes STOT-SE 1, H370 (nervous system, oral and inhalation route), based on animal data showing neurotoxic effects resulting from a single dose below the Guidance value of 300 mg/kg bw or 1 mg/L/4h for Category 1.

Proposal for classification/labelling for specific target organ toxicity following singleexposure (STOT SE) according to Regulation (EC) No. 1272/2008:
STOT-SE 1; H370 Causes damage to the nervous system after oral and inhalation exposure.

Short-term Toxicity
Summary of repeat-dose oral studies in rodents
Subchronic toxicity of d-allethrin in the rat was assessed on the basis of a 90-day oral rat study with S-bioallethrin ([redacted] 1996), a 90-day oral rat study with d-allethrin ([redacted], 2007), which was based on a 28-day range-finding study ([redacted], 2006), and a non-guideline 8-week range-finding feeding study with esbiothrin in mice ([redacted], 1986).
Major toxic effects comprised a decrease in body weight gain, alterations in clinical chemistry and distinct organ toxicity regarding liver, kidney, thyroid and pituitary. Histopathological changes were reported in hepatocytes (hypertrophy and inclusion bodies), in renal proximale tubules (eosinophilic hyaline droplets), pituitary gland cells (hypertrophy, enlarged secretory granules) and the thyroid gland (hypertrophy, colloid depletion) in the 90-day study in rats with S-bioallethrin. These were accompanied by biochemical evidence for compromised liver function (increased serum levels of AST, ALT, and albumin in study by [redacted] (2007)). Alterations in thyroid and pituitary may point to changes in thyroid hormone homeostasis and compensatory pituitary-dependent thyroidotrophic stimulation. The relevant LOAEL in the rat is 149/175 mg/kg bw/d (M/F, 2000 ppm S-bioallethrin). The NOAEL in this study is 36.6 / 42.3 mg/kg bw/d (500 ppm).
In the 90-day oral toxicity study in rats with d-allethrin changes in biochemistry parameters (higher activities of ALT and AST in males, higher protein, albumin and cholesterol concentrations) and an increased liver weight pointed to the liver as a target organ. In the

recovery period these changes were partially reversible. The NOAEL was 50 mg/kg bw/d.
In the 8-week study in mice, which was conducted as a dose-range finding study for the 102-week study, the following changes were noted from 1000 ppm onwards (229 mg/kg bw/d): Increased liver, lower kidney and higher spleen weights, higher activities of AP and ALT and higher values for cholesterol and creatinine. Histopathological examination did not reveal any treatment-related changes. The NOAEL in this study is approx. 30 mg/kg bw/d (100 ppm).

Summary of repeat-dose oral studies in dogs
In the dog, three subchronic oral toxicity studies and one 28-day non-guideline study were evaluated: a 52-week dietary study using esbiothrin ([redacted], 1989), a 52-week capsule study using d-allethrin ([redacted], 1989) and a 26-week dietary study with bioallethrin ([redacted], 1982). Signs of liver toxicity were evident from all three studies and comprised increased liver weight, hepatocellular hypertrophy, increases in AP, AST/ALT, GGT levels and variations in triglycerides, cholesterol and albumin. In the 52-week study ([redacted], 1989) the brownish pigment in the lysosomal bodies of hepatocytes occurred in all dose groups (80-400-2000 ppm; corresponding to 0-2.7/3.2-13.7/16.1-69.9/80.4 in males/females), with increasing incidence. At the two lower dose groups it was suspected by the applicant that the brownish material could be a complex of dietary fat with the test substance. With regard to toxicokinetics, no potential for accumulation of the test substance was noted and residues in fat were very low (0.01 %). The test substances were totally excreted after 2-3 days. These properties are opposed to the suspected accumulation of the test substances in the hepatocytes. Since no morphological alteration of hepatocytes was noted at the two lower dose levels (80 and 400 ppm) this was not considered an adverse effect of the test substance. Increased cholesterol and AP levels were recorded in addition at 2000 ppm. The NOAEL was therefore 400 ppm (13.7 and 16.1 mg/kg bw/d in males and females, respectively).

Acute neurotoxic effects were observed in the 52-week capsule study in dogs ([redacted], 1989; d-allethrin) at 60 mg/kg bw/d. Dogs showed frequently tremors, blepharospasms, ataxia, mydriasis, salivation, prostrate position, dyspnea and convulsive seizures. In the high dose group 10 of 12 animals died (week 1: 200 mg/kg bw/d, 4 mortalities; from week 2: 100 mg/kg bw/d, 6 mortalities) following severe convulsive seizures and pronounced elevations of the body temperature (> 41 °C). Hepatocellular pigment was noted in the liver in groups 2-4 in males and females (6, 20, 60 mg/kg bw/d) and an increased absolute liver weight was recorded in group 5 females (100 mg/kg bw/d). Liver weights of group 5 males were not taken, except for one dog (absolute 177 g), due to unscheduled sacrifice or deaths. InInIn the BPC-WG HH (2017) it was decided to set the NOAEL at 20 mg/kg bw/d.
In the 26-week dietary toxicity study in beagle dogs [redacted], 1982) body trembling was noted in the high dose group of 5000 ppm (162/172 mg/kg bw/d). Throughout the study, a slight reduction was seen in mean body weight gain values for the male dogs treated at 1000 ppm (36.3 / 36.4 mg/kg bw/d) and for both male and female dogs treated at 5000 ppm, when compared with the controls. Slightly lower food consumption was noted in animals of the high dose group. An increase of alkaline phosphatase (AP) was recorded for males at 1000 and for both gender at 5000 ppm, an increase of gamma glutamyl transpeptidase (GGT) and alanine aminotransferase (ALT) for both gender at 5000 ppm. Relative liver weights were increased in dogs at 1000 and 5000 ppm. Hepatocellular hypertrophy (swelling) was observed in dogs with increasing incidence and severity at 1000 and 5000 ppm. A brown, granular pigment was seen in hepatocytes and bile canaliculi. A similar brown pigment was present within tubular epithelial cells of the kidney at 5000 ppm. The exact nature and origin of the pigment in the liver was not revealed by special staining. The NOAEL in this study was 200 ppm (6.1 / 7.2 mg/kg bw/d).
After feeding of dogs with 3200 ppm esbiothrin (63/75 mg/kg bw/d) over 28 days ([redacted], 1986), pigmentation of the liver accompanied by increases in AP and ALT, as well as changes in serum fat and protein levels and body weight were reported. At a dose of 6400 ppm (153/174 mg/kg bw/d), neurotoxic effects manifested clinically in tremor and convulsions, and one death was observed on day 29.

Summary of repeated dose dermal toxicity studies in the rabbit
Subacute dermal toxicity was assessed on the basis of two 3-week dermal toxicity studies in rabbits using esbiothrin ([redacted], 1990) and d-allethrin ([redacted], 1990). Repeated dermal

exposure of rabbits to 1000 mg/kg bw/d undiluted esbiothrin over 3 weeks did not evoke significant systemic effects (lower body weight in males only) but caused progressive inflammation of the skin from 40 mg/kg bw/d onwards. Inflammatory changes of the skin consisted of slight to moderate erythema, slight edema, slight desquamation, slight fissuring at 40 mg/kg bw/d. At 200 mg/kg bw/d some animals had severe edema, moderate desquamation (hyperkeratosis/acanthosis), moderate fissuring of the skin and a microabscess in addition. . At 1000 mg/kg bw/d slight to moderate atonia, blanched treatment sites, necrosis, subcutaneous haemorrhage and pustules (ulceration) were noted in addition to the above mentioned changes. Another 21-day study with repeated dermal exposure of rabbits to d-allethrin in 0.5 % aqueous methylcellulose yielded both local and systemic effects. Local adverse effects seen at doses ≥ 10 mg/kg bw/d comprised a well-defined erythema with or without slight edema. These findings progressed to well-defined or moderate erythema and edema for all animals during week 2. Desquamation of the stratum corneum (sloughing) and fissuring of the skin (cracking) were recorded in the majority of rabbits treated at 300 mg/kg bw/d.
Histopathological changes comprised a continuous granular layer (1/5 M at 3 mg/kg bw/d and among rabbits from 10 mg/kg bw/d and above), a, diffuse acanthosis (in most rabbits at 300 mg/kg bw/d, in two males at 30 mg/kg bw/d and in single male and female rabbit at 10 mg/kg bw/d), a minimal focal acanthosis among rabbits at 30 mg/kg bw/d. At 300 mg/kg bw/d an increased incidence of moderate focal inflammation in the superficial dermis and folliculitis usually with inflammatory cells in follicle lumens and/or vascular congestion was recorded.
Systemic effects were observed at 300 mg/kg bw/d and included raised neutrophil counts in males and reduction of the albumin/globulin ratio in both sexes, which might be secondary to chronic skin irritation. A tendency for reduced bw gain was shown for rabbits treated with 300 mg/kg bw/d, which was significant for females at 2 and 3 weeks. Since skin effects occurred at lower doses than systemic effects, a separate NOAEC/LOAEC for local skin effects and appropriate classification/labelling is suggested. Based on the skin findings it is proposed to classify d-allethrin according to Regulation (EC) No. 1272/2008: STOT RE 2 H373 (May cause damage to the skin through prolonged or repeated exposure).

Summary of repeat-dose inhalation studies in rats
A 90-day inhalation toxicity study performed with rats exposed to d-allethrin ([redacted], 1993) also revealed liver toxicity with corresponding changes in clinical chemistry (increased creatinine and decreased triglyceride levels, increased activities of GGT). Decreased haemoglobin and haematocrit levels were noted in females as well as local irritation (nasal and conjunctival discharge) and irregular respiration, decreased activity, salivation, or urinary incontinence in the high dose of 0.310 mg/L air. The suggested LOAEC of 0.05 mg/L for local effects was based on clinical observations. A systemic LOAEC of 0.310 mg/L was based on effects on clinical chemistry evident in comparison to both air and vehicle controls.

Proposal for Classification/labelling for specific target organ toxicity following repated exposure according to Regulation (EC) No. 1272/2008:
From the 3-week dermal toxicity studies in rabbits with esbiothrin the local LOAEL (skin) was 40 mg/kg bw/d ([redacted], 1990) based on slight to moderate erythema. The dermal effects were of lower severity and increased dose dependently. The other study with d-allethrin ([redacted], 1990) presented inflammation and diffuse acanthosis from 10 mg/kg bw/d with a dose-dependent increase in severity. At 300 mg/kg bw/d increased incidence of moderate focal inflammation in the superficial dermis and folliculitis (usually with inflammatory cells in follicle lumens and/or vascular congestion) was recorded.
Proposal for classification: STOT-RE 2 dermal H373 (May cause damage to the skin through prolonged or repeated exposure).It was noted that the main target organs in repeated dose oral toxicity studies in rats and dogs were the liver and the CNS. Liver toxicity was manifested by increases in organ weight, hepatocellular hypertrophy, and changes in clinical chemistry parameters, i.e. increases in cholesterol, total protein and albumin levels, increased activities of alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma glutamyltransferase (GGT), alkaline phosphatase (AP) with possible secondary effects on the function and regulation of the thyroid and pituitary gland.
As a weight-of-evidence approach, the liver changes were finally considered as adaptive and not adverse. The alterations of biochemical parameters were not observed in an order of magnitude

to consider them as adverse (at least a double to 2-fold increase), although statistically significant. Adverse histopathological lesions such as hyperplasia, degeneration or necrosis were not reported for the liver. Thus, a classification for liver toxicity according to Regulation (EC) No. 1272/2008 is not proposed.

Genotoxicity

Mutagenicity studies with the S-bioallethrin and allethrin under light exposure revealed the formation of mutagenic photodecomposition products (epoxide of cyclopropyl allethrin for S-bioallethrin and allethronyl glyoxylate monohydrate for allethrin).

It is not possible to clarify (1) presence of the photometabolites in the genotoxicity and mutagenicity studies and (2) a possible impact of these photometabolites on the outcome of the mutagenicity and genotoxicity studies. Therefore, the effect of photometabolites was excluded from the evaluation regarding classification and labeling of the a.s. for mutagenicity. However, for the risk assessment mutagenic photometabolites have been taken into account.

The *in vitro* tests with S-bioallethrin, esbiothrin (d-trans-allethrin), bioallethrin and d-allethrin differed from negative (Ames test [esbiothrin, d-allethrin], chromosomal aberrations [d-allethrin], unscheduled DNA synthesis [esbiothrin]), not evaluable (unscheduled DNA synthesis [d-allethrin], Mouse lymphoma assay [d-allethrin and esbiothrin]) to positive (Ames test [photoproducts of S-bioallethrin, bioallethrin]).

The *in vivo* test with esbiothrin did not result in an increase in the number of micronucleated polychromatic erythrocytes. However, the study is of limited reliability.

In contrast to this, a micronucleus and chromosomal aberration study with allethrin (containing the same isomers like d-allethrin and 4 additional stereo isomers) revealed a statistically significant increase in chromosomal aberrations and micronuclei. This finding was supported by a positive micronucleus test *in vitro*. Furthermore, DNA strand breaks, reduced level in superoxide dismutase and catalase, increased levels of reactive oxygen species, lipidperoxidation products and 8-hydroxy-2'-deoxyguanosine were obtained after treatment of mice with allethrin.

The mutagenicity of the active substance was also discussed at BPC WG (V) 2018. According to the minutes the members overall considered that ideally further *in vivo* information would have been useful to address the residual uncertainty. However, such information could not be requested at this stage. Based on the available data and the weight of evidence, the majority of the WG considered the active substances as not mutagenic.

Remark regarding study by Srivastava, 2012 (key study for in vivo genotoxicity):

It should be noted that after BPC WG discussion the publication by Srivastava et al. (2012) has been retracted at the request of the Editor-in-Chief. However, the retraction of this article remains without impact on risk assessment and the proposal for classification and labelling.

Proposal for classification/labelling for germ cell mutagens according to Regulation (EC) No. 1272/2008:

Initially, a classification into category 2; H341 (Suspected of causing genetic effects) is proposed by the eCA.

Remark regarding proposed classification: A discussion on the mutagenic potential of d-allethrin based on all available data took place at the BPC WG (V) 2018. It was finally concluded by the majority of the WG that the database is not convincing enough to consider d-allethrin as mutagenic.

Based on the discussion taken place at the BPC WG no classification is finally proposed by the eCA.

Discussion on photo metabolites

Following the BPC-WG HH (III) 2017 meeting, a first e-consultation was launched in August 2017 to discuss the risk assessment for photodegradation products of substances belonging to the allethrin series. These mutagenic photometabolites are formed following light exposure and identified as (1) the epoxide on cyclopropyl alcohol moiety and (2) allethronyl glyoxylate monohydrate. In course of the debate a request for *in vivo* genotoxicity studies was identified in order to finally conclude on the genotoxic potential of the photometabolites.
Following clarification by the EU Commission and ECHA that a request for new vertebrae studies is not possible at this stage a second e-consultation was launched in December 2017 and continued at BPC-WG HH V 2018.
One applicant submitted an expert statement where the mutagenic potential of photometabolites *in vitro* was supported. In terms of risk assessment the eCA suggested considering the TTC approach as the BPR GD stipulates that […] TTC might be considered for the starting point of risk characterisation as risk management tools to estimate negligible exposure potential […]". The appropriate TTC value for genotoxic compounds is 2.5 x 10^{-6} mg/kg bw/day. Exposure below this value is considered as indication for low probability of risk for human health.

The eCA again introduced the two studies showing the formation of mutagenic photometabolites (Kimmel [1982] and [redacted] [1988, 1984]). One applicant announced that two studies have been conducted in the meanwhile clarifying the formation of mutagenic photometabolites. The BPC WG (V) 2018 agreed that this data has to be submitted and evaluated post meeting in an ad hoc follow-up. In the WebEx meeting conducted in July 2019 a conclusion on both (1) the mutagenicity of photometabolites and (2) risk assessment of photo metabolites was drawn. According to the minutes it was agreed that the photometabolites epoxide and allethronyl glyoxylate monohydrate should be considered mutagenic. The members of the WG further supported the proposed TTC approach applying the value of 2.5 x 10^{-6} mg/kg bw/day for the risk assessment of photometabolites. Furthermore, it was concluded that d-allethrin/esbiothrin was converted in real-life exposure conditions by sunlight to these genotoxic photodegradation products in a yield of approximately 0.5 % (50 % exposure and 1 % formation rate) and that, based on the new available data, glass shields did not inhibit the photodegradation. The members also agreed that no further refinement would be applicable.

For further information on the discussions taken place, it is referred to final minutes of the BPC WG (III) 2017 and BPC WG (V) 2018.

Chronic Toxicity/ Carcinogenicity

Chronic oral administration of d-allethrin ([redacted], 1985; [redacted]., 1989) and esbiothrin ([redacted], 1990) resulted in liver effects in rats and mice. Relative kidney weight was increased in male rats of the high dose group following d-allethrin exposure.
In rats, increased organ weight, histiocyte infiltration (d-allethrin), hepatocyte hypertrophy, focal degeneration and necrosis (esbiothrin) occurred. In the rat study with esbiothrin ([redacted], 1990) biochemical markers of liver toxicity were noted simultaneously: significant increases in liver enzymes, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) in both sexes at 1500 and 4500 ppm, as well as an increase in cholesterol concentration in both sexes at 4500 ppm.
In addition, the oral administration of esbiothrin for 52 and 104 weeks to SD rats ([redacted], 1990) induced slightly lower body weights in females from the 1500 ppm (122.6 mg/kg bw/d) group and in males and females at 4500 ppm (258.7 / 407.7 mg/kg bw/d).

The NOAEL in rats was 125 ppm (6 mg/kg bw/d) with d-allethrin based on increased liver weight, histiocyte infiltration (females only), and phagocytosis of crystals by histiocytes (females only) at 25 mg/kg bw/d d-allethrin ([redacted]., 1985).

The NOAEL in rats receiving esbiothrin was 500 ppm (27/38 mg/kg bw/d) based on increased liver weights, biochemical and histopathological changes ([redacted], 1990). The study was not considered as key study, because the mortality of rats after 104 weeks was higher (51.7 %) than required by OECD 453. Therefore, the study has a reliability of 2, but is considered acceptable.

In mice receiving esbiothrin and d-allethrin, a NOAEL of 42 and 72 mg/kg bw/d, respectively can be derived based on liver toxicity at 214 and 350 mg/kg bw/d. In the mice studies using esbiothrin ([redacted], 1990) and d-allethrin ([redacted], 1989) there is some evidence for liver toxicity (increased weight) but since clinical chemistry and urinalysis was not conducted and haematology only partially, the weight changes do not have a clinical correlate.

In the study with esbiothrin no histopathological changes were observed in the liver, which could be associated with the observation of increased liver weights in males, particularly at 1250 ppm. In the study with d-allethrin centrilobular hypertrophy of hepatocytes were noted and fat deposition was noted at 3000 ppm. Histopathological correlates (hypertrophy of hepatocytes) to an increased organ weight obviously occur only at higher doses.

No increase in neoplastic lesions was observed in rats or mice by feeding with up to 259/214 mg/kg bw/d esbiothrin (rat/mouse) or 102/350 mg/kg bw/d d-allethrin (rat/mouse).

Proposal for classification/labelling for chronic toxicity/carcinogenicity according to Regulation (EC) No. 1272/2008:
None.

Reproduction Toxicity

Developmental toxicity / teratogenicity
In four developmental studies evaluating esbiothrin and d-allethrin in rat and rabbit, the relevant overall maternal NOAEL was 30 mg/kg bw/day, based on neurotoxicity (excess salivation, tremor) and decreased body weight gain at 100 mg/kg bw/day and above in the rat (d-allethrin). No developmental toxicity was observed up to and including 100 mg/kg bw/d (d-allethrin) and 125 mg/kg bw/d (esbiothrin) in rats.

- Increased incidences of rib/rib-vertebrae malformations in rabbits were observed in the teratogenicity study with d-allethrin. As d-allethrin in comparison to esbiothrin contains two further isomers ([1R,cis;1R] and [1R, cis; 1S]) it could be hypothesized that the teratogenic effect is attributed to the additional isomers. However, effects in rabbits were observed at a dose of 350 mg/kg bw/d. Such a high dose was not tested in the rabbit teratogenicity study with esbiothrin. Therefore, the teratogenic effects might be also (or additionally) an effect of the higher dose selected in the study with d-allethrin. Thus, it was not demonstrated that the effects observed are linked to a specific isomer. Furthermore, the incidence of some malformations exceeded the historical control ranges.
- In the study with esbiothrin no developmental toxicity was observed at 300 mg/kg bw/d, the highest dose tested. The corresponding NOAEL in rabbits was 100 mg/kg bw/d.
- In principle, maternal toxicity was similar in the study using d-allethrin ([redacted] 1989) and esbiothrin ([redacted] 1990). In both studies the NOAEL was 100 mg/kg bw/d. The effect level was dependent on dose spacing being 350 mg/kg bw/d in the study using d-allethrin and 300 mg/kg bw in the study using esbiothrin.
- Maternal effects in the study with esbiothrin comprised neurotoxicity (tremors, decreased motor activity, ataxia and impaired righting reflex), mortality (4 out of 20 dams), reduced food consumption and a reduced pregnancy rate in the high dose group. In addition, the number of resorptions and post-implantation loss increased from 100 mg/kg bw/d. However, no abortions were observed.
- Neurotoxic signs were also observed in the high dose group of rabbits receiving d-allethrin (tremors, loss of righting reflex, clonic convulsion and mydriasis). Like in the other rabbits study also mortality occurred in the high dose goup (1/20 dams). Specifically in the study with d-allethrin the maternal clinical signs of toxicity occurred approximately four hours

after intubation and did not persist for more than 1 day at the dose of 350 mg/kg bw/d. The deaths at the top dose occurred after 9-10 days of gestation and only one of the does presented clinical neurotoxic signs prior to death. In addition, the number of resorptions / litter, post-implantation loss and early resorptions were higher in the dams receiving d-allethrin. However, no doe aborted or prematurely delivered a litter during the study. Therefore, no clear maternal toxicity was observed during the study and the effects observed on foetuses are considered to be treatment related. Taken together, in the developmental toxicity study with d-allethrin it can not be unequivocally demonstrated that the developmental effects are secondary to maternal toxicity. Therefore, classification with Repr. 2; H361d Suspected of damaging the unborn child is proposed.

Proposal for classification/labelling for developmental toxicity according to Regulation (EC) No. 1272/2008:
Repr. 2; H361d (Suspected of damaging the unborn child) based on increased incidence of rib and vertebral malformations in the offspring [rabbits].

Fertility
The study with esbiothrin submitted as key study by the applicant was compromised by an infection in does of the P- and pups of the F1-generation, resulting in enhanced mortality of F1 pups in the treated groups during lactation as well as clinical findings in females which cannot be attributed to treatment.
Another study on d-allethrin by [redacted] (1989) is of good quality and will be used as key study instead. In this study, the parental NOAEL was 200 ppm (9 mg/kg bw/d) based on decreased body weight gain, decreased food consumption, increased relative and absolute liver weights, and hepatocellular hypertrophy in the P- and F1-generation in males at 2000 ppm (170 mg/kg bw/d) and in males and females at 6000 ppm (387 mg/kg bw/d). No effects on reproduction and fertility parameters were observed up to the highest dose tested, hence a reproductive NOAEL of 387 mg/kg bw/d (6000 ppm) was derived. The offspring NOAEL of 170 mg/kg bw/d (2000 ppm, maternal intake during lactation) was based on reduced body weight gain of F1 pups at 6000 ppm maternal intake of d-allethrin.

Proposal for classification/labelling for fertility toxicity according to Regulation (EC) No. 1272/2008:
None

Developmental neurotoxicity
From the eCA's perspective d-allethrin and esbiothrin fulfil the criteria triggering a DNT testing. Neurotoxic effects were observed in the vast majority of studies submitted within the dossier. Furthermore, it cannot be excluded that pups are exposed to d-allethrin and esbiothrin during lactation. For reasons of animal welfare it was proposed to set an additional safety factor of 3 to account for the data gap regarding DNT.
In an ad hoc-follow up expert group it was agreed to set an additional assessment factor for uncertainties regarding possible DNT effects. The value of 3 was supported. The additional assessment factor should be applied for the derivation of AELshort-term and ARfD.

Endocrine disrupting properties

Scientific criteria

The following scientific criteria were presented by the EC in an amended version in 2017:

- "From [date of application], an active substance, safener or synergist shall be considered as having endocrine disrupting properties that may cause adverse effect in humans if […] it is a substance that meets all of the following criteria, unless there is evidence demonstrating that the adverse

effects identified are not relevant to to humans:
  - (1) it shows an adverse effect in an intact organism or its progeny, which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
  - (2) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;
  - (3) the adverse effect is a consequence of the endocrine mode of action.
- The identification of an active substance, safener or synergist as having endocrine disrupting properties that may cause adverse effect in humans in accordance with the fifth paragraph shall be based on all of the following points:
  - (1) all available relevant scientific data (*in vivo* studies or adequately validated alternative test systems predictive of adverse effects in humans or animals; as well as *in vivo, in vitro*, or, if applicable, in silico studies informing about endocrine modes of action):
    - (a) scientific data generated in accordance with internationally agreed study protocols, in particular those listed in the Commission Communications in the framework of setting out the data requirements for active substances and plant protection products, in accordance with this Regulation;
    - (b) other scientific data selected applying a systematic review methodology, in particular following guidance on literature data which is listed in the Commission Communications in the framework of setting out the data requirements for active substances and plant protection products, in accordance with this Regulation;
  - (2) an assessment of the available relevant scientific data based on a weight of evidence approach in order to establish whether the criteria set out in the fifth paragraph are fulfilled; in applying the weight of evidence determination,,the assessment of the scientific evidence shall, in particular, consider all of the following factors:
    - (a) both positive and negative results;
    - (b) the relevance of the study designs, for the assessment of adverse effects and of the endocrine mode of action;
    - (c) the quality and consistency of the data, considering the pattern and coherence of the results within and between studies of a similar design and across different species;
    - (d) the route of exposure, toxicokinetic and metabolism studies;
    - (e) the concept of the limit dose, and international guidelines on maximum recommended doses and for assessing confounding effects of excessive toxicity;
  - (3) using a weight of evidence approach, the link between the adverse effect(s) and the endocrine mode of action shall be established based on biological plausibility, which shall be determined in the light of current scientific knowledge and under consideration of internationally agreed guidelines;
  - (4) adverse effects that are non-specific secondary consequences of other toxic effects shall not be considered for the identification of the substance as endocrine disruptor."

The eCA has evaluated the active substance step by step as suggested and has come to the following conclusions:

Considering 1: The reproductive toxicity classification (Repro 2) is based in on a higher tier OECD study where ribs malformations were observed in rabbits. This is supported by ToxRefDB (US EPA) database (see details in DocIIA).

Considering 2: There is no clear evidence for an endocrine mode of action in respective mechanistic studies in vitro. Almost all screening studies for estrogenic, androgenic or progestogenic potential of allethrins were negative and there was no consistent pattern observed regarding any anti-estrogenic and anti-androgenic activity. Overall, several in vitro screen studies suggest that allethrins may have the potential to affect the estrogenic and androgenic pathways, but the available data do not provide evidence for strong interaction. The limited evidence for anti-estrogenic or anti-androgenic effects in several published studies cannot

overrule the acceptable submitted OECD TG fertility studies in vivo ([redacted] 1989 presented in Doc IIA). In this two-generation study with d-allethrin no adverse reproductive findings were observed. No study with allethrins submitted by the applicant showed significant alterations on weight or histology of male/female gonadal organs in any species after oral, inhalation or dermal exposure.

Considering 3: In the 90-day study with S-bioallethrin ([redacted] 1996) alterations in thyroid (hypertrophy, colloid depletion) and pituitary (hypertrophy, enlarged secretory granules) were observed. However, no further information was retrieved from the literature review relating allethrins and thyroid toxicity, and therefore, no plausible link could be drawn between the adverse effects and an endocrine mode of action. Possible anti-androgenic and anti-androgenic effects of allethrin are rather not considered related to developmental toxicity (rib malformation observed in rabbits, [redacted], 1989).

Conclusion 1-3: evaluation of step 1.1-1.3 allethrin **is not an endocrine disruptor.**

Considering 1a) and b): Studies based on OECD guidelines were taken into account as well as published literature obtained by a systematic review. Evaluation was performed in line with current standards (OECD testing guidelines).

Considering 2a) (positive and negative results): The vast majority of studies were negative for any effect based on endocrine mechanisms.

Considering 2b) (relevance): Relevance of the studies summarised in this addendum is considered supplemental as no consistent pattern (in vitro studies) or reproducibility (in vivo studies) of the effects was observed. These differences may be influenced by the testing method, such as solvent type, incubation time, inadequate study design, problematic statistical analyses, different criteria used to asses test performance and interpret the response of each study.

Considering 2c) (consistency): Classification based on the submitted teratogenicity study (Hoberman, 1989) was supported by the article published by [redacted] 2011. Estrogenic, androgenic and progestogenic acitivites by allethrins could be excluded in the vast majority of in vitro studies from literature search. However, study results on possible anti-estrogenic or anti-androgenic effects in vitro or motor activity and/or mAChR densitity in cortex were conflicting.

Considering 2d) (kinetics): Not applicable.

Considering 2e) (limit dose): Not applicable.

Considering 3) (plausibility): There is no plausible link between isolated adverse effects and an endocrine mode of action, since most of the respective studies were negative or revealed conflicting results.-

Considering 4) (secondary effects): Not applicable.

Based on the criteria presented by the European Commission in 2017, d-allethrin was **not considered to be an endocrine disruptor**. However, it should be noted, that this evaluation does not follow the ECHA / EFSA (2018)[1]. Therefore, a final conclusion on the ED properties of d-Allethrin based on the ECHA / EFSA (2018) cannot be drawn.

[1] ECHA / EFSA (2018) Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. https://doi.org/10.2903/j.efsa.2018.5311

Neurotoxicity

An acute neurotoxicity study ([redacted], 1997) revealed acute effects after single dose gavage administration of 90 mg/kg bw (NOAEL 30 mg/kg bw) of S-bioallethrin in rats. Neurotoxic signs observed were tremors, body twitches, reduced activity, hunched posture, gait abnormalities, elevated body temperature and decreased grip strength (statistically significant only for hindlimbs) in females. Male animals did not show any neurotoxic signs.
In a subchronic dietary neurotoxicity study ([redacted], 2000) no neurotoxic effects were observed in rats up to and including 452/550 mg/kg bw/d S-bioallethrin. A decrease in body weight gain and a decreased terminal body weight was noted in male and female rats in the highest dose tested (452/550 mg/kg bw/d). The study is considered not reliable because no neurotoxicity and no liver toxicity was reported.
General toxicity studies have reported clinical observations of neurotoxicity after acute and repeated dosing in rats and dogs after gavage or capsule administration including hunched posture, twitches, ataxia, tremor, convulsions, salivation, hypersensitivity and changes in spontaneous activity. Histopathological examination did not reveal any microscopical changes in the central or peripheral nervous system as far as evaluated. Although clinical observations and neuropathy are important manifestations of neurotoxicity, it has become clear that other signs of nervous system toxicity such as loss of motor co-ordination, sensory deficits, or learning and memory deficits may be equally important (OECD 424, 1997). Changes in the muscarinic cholinergic system and the dopaminergic system as well as behavioural findings have been described in open literature but were not evaluated in any of the acute or repeat-dose studies with esbiothrin, d-allethrin or (S)-)-)-bioallethrin. However, the relevance of these data is unclear, especially as inter-laboratory reproducibility has been limited ([redacted] 1990, 1991; [redacted]., 2003; [redacted], 2003).
Hence, a NOAEL for neurotoxic effects of 30 mg/kg is set, based on the findings in the acute neurotoxicity study.

Proposal for Classification/labelling for repeated dose toxicity according to Regulation (EC) No. 1272/2008:
STOT-SE 1; H370 (Causes damage to the nervous system after oral and inhalation exposure) based on neurotoxic symptoms in acute and repeat-dose studies in rats, rabbits and dogs.

Medical Data

Plant personnel
Medical reports from 2002 to 2004 of workers involved in packing of pyrethroids including d-allethrin at Misawa works of Sumitomo Chemicals Co., Ltd, Japan, did not provide any evidence for occupation-related problems due to exposure to pyrethroids. The possibility of worker's exposure is minimal, because the plant is designed to minimize the opportunity of exposure. Exposure may occur only in packing the products into containers.

Endura S.p.A. is subjected to medical inspections according to the Italian laws in force. From 2001-2004 a total number of 65 workers and from 2005-2008 a total number of 50 workers are checked by a qualified doctor by means of the following controls: medical examination (frequency is usually once in a year and once every six months only for pilot plant, production or maintenance staff); blood, hepatic, renal and urine tests (frequency is usually once in a year and once every six months only for pilot plant, production or maintenance staff); spirometry (frequency is usually once in a year); biological monitoring (frequency is usually once in a year and once every six months only for pilot plant, production or maintenance staff); once every two years: audiometry; once every five years: ergovision.

In reference to the blood analyses and the medical examinations carried out on all employees during the year during the years 2001-2008, all results appears to be in the average. In relation to personal protection equipment, it is agreed that the equipment is suitable to the type of activities and roles existing in the Company. In conclusion, no evidence of anomalies or medical situations to be kept under control was notified and no cases existed in which alterations are strictly related to exposure to substances used in the Ravenna plant.

Direct observations
Examination of 30 volunteers including 10 children exposed to esbiothrin vapours generated using a heated liquidator (Esbiothrin 2.6 % LED) for 45 nights did not show adverse reactions with regard to clinical symptoms, haematology, serum biochemistry and pulmonary function. This is consistent with a review from a UKPID monograph on allethrins (1998) which states that there are no reports on toxicity in humans to allethrins.

Diagnosis of poisoning and proposed treatment
Skin: Decontamination of the skin with soap and water. Subsequently, paresthesia can be treated by lavage of the contaminated skin with oil. Vit. E cream has been found effective for treating paresthesia in experimental and clinical trials.
Systemic treatment: Antagonistic treatment of the ion channel effects. Control of the secondary consequences mediated by neurotransmitters. Ion channel and membrane stabilizing drugs: Tetracaine, lidocaine (although local anesthetics are cardiotoxic), phenobarbitone, phenytoin, valproate (act equally on the pyretroid evoked and normal sodium current), diazepam (against seizures), mephenesin (effective *in vivo* at a dose close to that producing anesthesia), urethane (effective against type I poisoning at doses producing muscle relaxation but effective against type II poisoning at lower doses), methocarbamol (antagonism of motor signs of type I and II pyrethroids), ivermectin (restores the membrane conductance of N. vagus in rats), pentobarbitone (chloride channel agonist, effective against type II motor signs), atropine (against salivation), chlomethiazole (membrane stabilizer).
(Ray and Forshaw (2000). Pyrethroid Insecticides: Poisoning syndromes, synergies, and therapy. Clinical Toxicology, 38(2), 95-101 [Endura], ASB2008-1085)

Summary & Conclusion

Based on acute toxicity studies, it is proposed to classify d-allethrin with Acute Tox. 3; H301 (Toxic if swallowed) and Acute Tox. 4; H332 (Harmful if inhaled).

Based on acute neurotoxic effects noted during or shortly after each inhalation and oral exposure in acute and repeat-dose toxicity studies in rats, mice and dogs, the eCA proposes STOT-SE 1, H370 (Causes damage to the nervous system after oral and inhalation exposure).

Based on severe progressive dermal inflammation of the skin (erythema, edema, desquamation, fissuring, microabscess atonia, blanched treatment sites, necrosis, subcutaneous haemorrhage, pustules, ulceration) in rabbits after repeated dermal application of 1000 mg/kg bw/d esbiothrin and moderate erythema, oedema and moderate focal inflammation in superficial dermis at 300 mg/kg bw/d d-allethrin over 21-days (3 mg/cm^2) it is proposed to classify d-allethrin with STOT-RE 2 dermal H373 (May cause damage to the skin through prolonged or repeated exposure).

Based on an increased incidence of rib and vertebral malformations in the offspring (rabbits), it is proposed to classify d-allethrin with Repr. 2; H361d (Suspected of damaging the unborn child).

Remark on the evaluation of relevance and the toxicological evaluation of the specification by Endura:
Initially, mutagenic properties for d-allethrin was proposed, but the classification as mutagenic category 2 for the active substance was not accepted by the WG members. However, as the WG members decided not to consider d-allethrin as mutagenic, possible genotoxic properties of the impurities needed to be addressed again. The members of an AHFU concluded that ta number of 8 impurities in the proposed reference specification which is based on data of Endura, are considered relevant and are missing in some of the specifications of the studies submitted by Sumitomo for toxicological assessment.
Therefore, in order to demonstrate that the impurities do not have mutagenic properties, an AMES test with a batch containing the relevant impurities was required from Endura. In case of a negative result, genotoxic properties of the impurities would have been excluded and the proposed reference specification would have been covered by the batches used for the

toxicological studies.
However, the test submitted ([redacted], 2020) showed a positive result. In this Ames test an approximately two-fold increase in revertant colonies in comparison to the negative control was observed in bacterial strains TA100 and TA102 (including metabolic activation).
Therefore, it was decided that due to the potential genotoxic properties of the impurities, the tox studies with batches of Sumitomo's test substance could not be used for the evaluation of the proposed reference specification derived from Endura's data. With this decision, it is not possible to identify a safe use regarding the human health risk assessment.

For further information on relevant impuritiesimpuritiesthe evaluation of relevance and the toxicological evaluation of the specification (including the Ames test ([redacted] 2020)), it is referred to DocIIA and the confidential document "Confi_d-Allethrin_relev impurities_comparison tox batches vs spec_BfR_210301_tc".

Exposure assessment

Exposure of Professionals

Not applicable for **Pynamin Forte 40 mg mat** since this biocidal product is intended to be used only by non-professional users.

Duracide A is applied as water or solvent based product to control insects The active substance d-Allethrin and the biocidal product are produced within the EU.

The following scenarios for Duracide A are covered by the exposure assessment in this report

- Spraying of water based Duracide A-EC (scenario 1)
- Spraying of a solvent based Duracide A (scenario 2)
- ULV application of solvent based Duracide A (scenario 3)
- ULV application of water based Duracide A-EC (scenario 4)
- Cold and thermal fogging of solvent based Duracide A (scenario 5)
- Cold and thermal fogging of water based Duracide A-EC (scenario 6)
- Secondary exposure to d-Allethrin (scenario 7)
- Secondary exposure to photometabolites (scenario 8).

In general, respiratory exposure to vapour of the active substance is assessed as negligible due to the low vapour pressure of d-Allethrin (0.0006 Pa at 20 °C). However, as worst case the saturated vapour concentration (SVC) is considered as the theoretical maximum concentration attainable by vapour in every scenario. It is also assumed that all applications (spraying, ULV, fogging) are performed on a daily basis in a season of 160 days per year.

Scenario 1 and 2 are spraying scenarios of different spraying solutions.

For **scenario 1**, spraying of an water based solution, a formulation step of adding an emulsifier to the concentrate Duracide A (7.7 % d-Allethrin) is necessary resulting in the concentrate Duracide A-EC (6.8 % d-Allethrin) prior to dilution. For spraying of Duracide A-EC, mixing and loading, application and post-application phase are required.
Formation of aerosols during preparation, dilution of Duracide A-EC, and cleaning of the spray gun is not expected.
Concerning dermal exposure of the formulation step (adding emulsifier to Duracide A), the mixing phase is assessed with Model 4, Mixing & Loading of the Biocides Human Health Exposure Methodology (October 2015, p. 272) as proposed by the Human Exposure Expert Group opinion No. 1 for small quantities.

During spraying of the water based solution (0.14 % d-Allethrin), droplet aerosols are formed which cause inhalation and dermal exposure. The assessment of potential inhalation and dermal exposure to d-Allethrin is based on Model 1 (Spraying) of the guidance document Biocides Human Health Exposure Methodology (October 2015, p. 204).Since Spraying Model 1 includes a contribution to exposure from mixing and loading, the estimation is valid for mixing & loading and application phase.

During cleaning of equipment (spray gun, ULV equipment, and fogger) (post-application phase in scenarios 1-6) aerosol formation is not expected. To assess the potential dermal exposure the default values (75th percentile) according to the HEAdhoc Recommendation 6 Version 4 (2020, p.44,), with an exposure duration of 5 minutes, are chosen.
In **scenario 2** (spraying of a solvent based Duracide A solution), a formulation step (addition of an emulsifier) is not necessary. Duracide A (7.7 % d-Allethrin) is diluted with kerosene based solvent and then filled into the tank intended to be applied as spray solution (0.12 % d-Allethrin). During spraying of the solvent based solution of Duracide A, droplet aerosols are formed and inhalation and dermal exposure occurs. Inhalation and dermal exposure to the 0.12 % spray solution is estimated using Spraying Model 1 of the Biocides Human Health Exposure Methodology (October 2015, p. 204). Since Spraying Model 1 includes a contribution to exposure from mixing and loading, the estimation is valid for mixing & loading and the application phase.

Scenario 3 and 4 are ULV (ultra low volume) application scenarios of different solutions.

In **scenario 3** ULV application of a solvent based solution of Duracide A is assessed. Therefore, Duracide A (7.7 % d-Allethrin) is loading into the spray tank and diluted with kerosene . Aerosol formation during this working step and cleaning activities is not expected. The dermal exposure is assessed with Mixing & Loading Model 4 of the Biocides Human Health Exposure Methodology (October 2015, p. 272).
Application of ULV (0.385 % d-Allethrin) is performed for 1 hour/day, according the HEAdhoc Recommendation No.6 (2020, p. 36), and agreed at the WG HH III-2017. Fogging and misting Model 2 and 3 of Biocides Human Health Exposure Methodology (October 2015, p. 209), is chosen for calculation of inhalation and dermal exposure during the application phase.
For **scenario 4**, ULV application of water based Duracide A-EC, a formulation step of adding an emulsifier to the concentrate Duracide A (7.7 % d-Allethrin) is necessary resulting in the concentrate Duracide A-EC (6.8 % d-Allethrin) prior to dilution. It is assumed that this step is performed daily. Duracide A-EC (6.8 % d-Allethrin) is loading in the ULV tank and further diluted with water. The dermal exposure is assessed with Mixing & Loading Model 4 of the Biocides Human Health Exposure Methodology (October 2015, p. 272). Application of ULV solution (0.14 % d-Allethrin) is performed for 1 hour/day. Fogging and Misting Model 2 and 3 of the Biocides Human Health Exposure Methodology (October 2015, p. 209), is chosen for calculation of inhalation and dermal exposure during the application phase.

Scenario 5 and 6 are cold and themal fogging scenarios of different fogging solutions.

Scenario 5, fogging of solvent based Duracide A (7.7 % d-Allethrin), includes mixing and loading, application and post-application phase.
During loading of fogging machine aerosol formation is not expected. The dermal exposure is assessed with Mixing & Loading Model 4 of the Biocides Human Health Exposure Methodology (October 2015, p. 272).
During the application phase (cold and thermal fogging of 0.12 % d-Allethrin), droplet aerosols are formed and inhalation and dermal exposure occurs. Inhalation and dermal exposure is estimated using Fogging and Misting Model 2 and 3 of the Biocides Human Health Exposure Methodology (October 2015, p. 209). The model determined inhalation and dermal exposure during thermal fogging at mid level using a fogging machine (without mixing and loadingloading). It is assumed that using a stationary fogger leads to a lower level of inhalation exposure compared to a portable fogger, as the worker leaves the room immediately after starting the fogging machine.
For **scenario 6**, fogging application of water based Duracide A-EC, a formulation step of adding an emulsifier to the concentrate Duracide A (7.7 % d-Allethrin) is necessary resulting in the

concentrate Duracide A-EC (6.8 % d-Allethrin) prior to dilution. Duracide A-EC is loading of the ULV tank and further diluted with water. The dermal exposure is assessed with Mixing & Loading Model 4 of the Biocides Human Health Exposure Methodology (October 2015, p. 272). During cold and thermal fogging of water based Duracide A-EC (0.14 % d-Allethrin), droplet aerosols are formed and inhalation and dermal exposure occurs estimated using Fogging and misting Model 2 and 3 of the Biocides Human Health Exposure Methodology (October 2015, p. 209). It is assumed that using a stationary fogger leads to a lower level of inhalation exposure compared to a portable fogger, as the worker leaves the room immediately after starting the fogging machine.

For **secondary exposure (scenario 7)** it is assumed that there is no (or minimal) inhalation exposure for professional bystanders. Rooms are kept closed during application and re-entry is allowed after a ventilation phase. During this period it is assumed that most of the product is deposited on surfaces and all remaining active substance will be evaporated during the ventilation phase. Therefore, the inhalation exposure of bystanders to aerosols as well as vapour of the active substance d-Allethrin is assessed as **negligible.** However, as worst case the saturated vapour concentration (SVC) of d-Allethrin is considered as the theoretically maximum attainable concentration.A potential dermal exposure of bystanders is expected due to contact to treated surfaces. The contact is estimated to be incidental.

The formation of **photometabolites (scenario 8)** is considered applicable for secondary exposure of professionals if exposure to treated rooms to sunlight or UV-lights cannot be excluded. Pyrethroids (d-Allethrin) are converted by sunlight to photodegradation products in a yield of approximately 1% (according to literature). It is assuming that the degradation rates of the photometabolites are not smaller than its formation rates therefore it has to be concluded that the exposure to the photometabolites is about 1 % of the respective d-allethrin exposure. A further refinement is that the photolysis rate is proportional to the intensity of irradiance from a light source: only 50% of the residues are exposed to window filtered sunlight. This results in 1% formation of photometabolites x 0.5 = 0.5% formation of photometabolites. The described refinement is also assumed in combination with the use of protective gloves.

Exposure of Non-Professionals

Pynamin Forte 40 mg mat
Primary non-professional exposure via the dermal route occurs when a Pynamin Forte 40 mg mat is placed in the evaporator and when it is removed. Inhalation and oral exposure are not expected. The biocidal product is intended to be used by adults only.

Table 2-8 Summary of primary systemic exposure of non-professional users to d-allethrin from Pynamin Forte 40 mg mat.

	Inhalation exposure (mg/kg bw/[d])	Dermal exposure (mg/kg bw/[d])	Oral exposure (mg/kg bw/[d])	All routes (mg/kg bw [/d]
Modelled data				
Acute exposure	Covered by medium-term exposure			
Medium-term exposure				
Adults, use, placing mats	Not applicable	1.0×10^{-2}	Not applicable	1.0×10^{-2}
Adults use, removal of mats	Not applicable	3.5×10^{-3}	Not applicable	3.5×10^{-3}
Adults, total	Not applicable	1.35×10^{-2}	Not applicable	1.35×10^{-2}

Duracide A - FIK aerosol

The biocidal product Duracide A (concentrate) is not intended for non-professional use. Instead, exposure to typical ready-to-use spraying product (Duracide A – FIK aerosol) for non-professional user is assessed. This biocidal product (Duracide A - FIK aerosol) contains 1.29 % of Duracide A. The other non-active components are not known and have not been assessed within this report. The biocidal product contains two other active substances, which are not assessed in this dossier. The final concentration of d-allethrin in this biocidal product is 0.1 % (w/w).

Table 2-9 Summary of primary systemic exposure of non-professional users to d-allethrin from Duracide A - FIK aerosol.

	Inhalation exposure (mg/kg bw/[d])	Dermal exposure (mg/kg bw/[d])	Oral exposure (mg/kg bw/[d])	All routes (mg/kg bw [/d]
Modelled data				
Acute exposure	Covered by medium-term exposure			
Medium-term exposure				
Application, air space spray	3.85×10^{-3}	4.48×10^{-3}	2.77×10^{-4}	8.61×10^{-3}

Secondary Exposure of the General Public

Pynamin Forte 40 mg mat

Secondary exposure of the general public occurs via two scenarios. The first one is exposure during evaporation via inhalation. The second scenario is dermal and for toddlers also oral exposure via residues on surfaces.

Table 2-10 Summary of secondary systemic exposure of the general public to d-allethrin from Pynamin Forte 40 mg mat.

	Inhalation exposure (mg/kg bw/[d])	Dermal exposure (mg/kg bw/[d])	Oral exposure (mg/kg bw/[d])	All routes (mg/kg bw [/d]
Modelled data				
Acute exposure	Covered by medium-term exposure			
Medium-term exposure				
Adults, evaporation during use	6.11×10^{-3}	Not applicable	Not applicable	6.11×10^{-3}
Toddlers, evaporation during use	1.83×10^{-2}	Not applicable	Not applicable	1.83×10^{-2}
Adults, contact to residues	Not applicable	5.46×10^{-3}	Not applicable	5.46×10^{-3}
Toddlers, contact to residues	Not applicable	8.82×10^{-3}	4.23×10^{-3}	1.31×10^{-2}

Duracide A — FIK aerosol

Secondary acute exposure after non-professional use to d-allethrin from Duracide A - FIK aerosol occurs when toddlers and children are present during biocidal product application. It is expected that the professional user takes all measures needed to prevent access of the general public.
Secondary medium-term exposure after non-professional use to d-allethrin from Duracide A - FIK aerosol occurs when adults get in contact to contaminated clothing or other treated surfaces. It is assumed that there is no difference between contaminations resulting from non-professional use or professional use.

Table 2-11 Summary of secondary systemic exposure of the general public to d-allethrin from Duracide A - FIK aerosol.

	Inhalation exposure (mg/kg bw [/d]	Dermal exposure (mg/kg bw [/d])	Oral exposure (mg/kg bw [/d]	All routes (mg/kg bw [/d]
Acute exposure				
Toddlers/Children stay in rooms during application, for adults see primary exposure (Consexpo 4.1)				
Children	1.02×10^{-2}	1.13×10^{-2}	7.82×10^{-4}	2.22×10^{-2}
Toddlers	2.33×10^{-2}	2.69×10^{-2}	1.68×10^{-3}	5.19×10^{-2}

Medium-term exposure				
Toddlers contact to parent's contaminated clothing	-	1.50×10^{-4}	1.20×10^{-4}	2.70×10^{-4}
Toddlers contact to residues on the floor, represents also worst case estimate for children and adults	-	1.23×10^{-2}	4.72×10^{-4}	1.28×10^{-2}

Secondary exposure to photometabolites of the active substance

According to Kimmel et al. (J. Agric. Food Chem., 30, 623-626, 1982) d-allethrin and other related pyrethroids are converted by sunlight to genotoxic photodegradation products. Medium-term exposure to adults and toddlers has been estimated. It is assumed that only residues on surfaces are subject to photodegradation. Thus, primary exposure and inhalation exposure are not included in the exposure estimates for photometabolites.

Table 2-12 Summary of secondary systemic exposure of the general public to the photometabolites from Pynamin Forte 40 mg mat

Exposure scenario	**Exposure (mg/kg bw/[d])**
Medium-term exposure – internal dose	
Tier 1	
Adults (dermal)[1]	5.46×10^{-5}
Toddlers (dermal and oral)[1]	1.31×10^{-4}
Tier 2	
Adults (dermal)[1]	2.73×10^{-5}
Toddlers (dermal and oral)[1]	6.55×10^{-5}

[1] secondary exposure after non-professional use

Table 2-13 Summary of secondary systemic exposure of the general public to the photometabolites from Duracide A – FIK aerosol

Exposure scenario	**Exposure (mg/kg bw/[d])**
Medium-term exposure – internal dose	
Tier 1	
Adults (dermal)[1]	Not assessed separately
Toddlers (dermal and oral)[1]	1.28×10^{-4}
Tier 2	

Adults (dermal)[1]	Not assessed separately
Toddlers (dermal and oral)[1]	6.4 x 10^{-5}

[1] secondary exposure after non-professional use

Exposure via Residues in Food
d-Allethrin is an insecticide used for the control of mosquitoes and other small biting flies for non-professional and professional use.

For non-professional use the dietary risk assessment has shown that the application of the representative products leads to unacceptable health risks for adults and children. Therefore non-professional use of d-allethrin containing products in food preparation or storage areas e.g. kitchens, has to be excluded. For additional uses it must be verified at product authorization level whether residues in food or feed may occur.

For professional use no dietary risk assessment has been performed for active substance authorization as currently no guidance document is publicly available. At product authorization level a dietary risk assessment has to be performed if products may lead to residues in food or feed.

Risk characterisation

Risk Assessment for Professionals

Not applicable for **Pynamin Forte 40 mg mat** since this biocidal product is intended to be used only by non-professional users.

For the biocidal product **Duracide A** the risk characterisation for systemic effects of d-allethrin is performed with the AEL approach. In this approach total internal body burden is compared to the $AEL_{long\text{-}term}$ of 0.04 mg/kg bw/d. The long-term AEL is taken because repeated exposure at the workplace cannot be excluded for the use of d-allethrin.
The AEL (an internal reference value) is based upon the oral NOAEL of 6 mg/kg bw/day (liver toxicity) from a 123-wk rat study, and the knowledge of 60 % oral absorption rate. By using a (default) assessment factor of 100 and assuming 60% oral absorption an $AEL_{long\text{-}term}$ of 0.04 mg/kg bw/day is derived for long term exposure towards d-allethrin
If the total internal body burden is lower than the reference dose, health risks leading to concern are not anticipated.
For the professional exposure the estimated uptake / reference value is above 100 % and thus for no scenario a safe use is identified.
If risk mitigation measures (wearing of protective gloves (sc. 7 and 8) or wearing of protective coverall and protective gloves (sc. 1-6)) are taken into account (tier 2) for all scenarios, the estimated exposure is below the reference value (for the relation between scenario number and scenario name see table 2-14 below).

Acute irritation studies revealed that d-allethrin is not irritating to the skin or the eyes of rabbits. Nevertheless severe inflammatory response in rabbits is observed after repeated dose 21-day dermal application of d-allethrin.
Therefore a **semiquantitative risk characterisation for local dermal** effects of d-allethrin is performed taking into account the $NOAEC_{local,\ dermal\ effects}$ as well as the in use concentration of d-allethrin in %.
The dermal NOAEC of 0.15% (a no adverse effect concentration) is derived from from a 21-d dermal rabbit study. If the concentration is lower than the reference concentration, health risks leading to concern are not anticipated.
For the application phases of the professional exposure scenarios 1, 2 and 4-7 the estimated in

use concentration / reference value is below 100 %.
In the preparation phases of scenarios 1 and 3-6 the active substance concentration exceeds the $NOAEC_{local, dermal effects}$.
For scenario 3 (ULV application of solvent based solution of Duracide A) the active substance concentration exceeds the $NOAEC_{local, dermal effects in}$ in the mixing and loading, application and post-application phases.
For the post-application phases of the professional exposure scenario 1, 2 and 4-6 the in use concentration / reference value is below 100 %.
Based on these results and conclusions on dermal local health risks in tier 1, a further refinement of the semiquantitative risk characterisation is considered obligatory for scenario 1 and 3-6.
If risk mitigation measures (wearing of protective coverall and protective gloves) are taken into account (tier 2) for the preparation phase or mixing and loading phase of scenario 1, 3-6 as well as for the application and post-application phase of scenario 3, the in use concentration of d-allethrin is considered to be acceptable.
A **secondary exposure to genotoxic photodegradation products of d-allethrin (scenario 8)** is assumed. The risk characterisation of genotoxic photodegradation products of d-allethrin is performed with the TTC approach. In this approach total internal body burden is compared to the TTC value for genotoxic substances of $2.5x10^{-6}$ mg/kg bw/d. In a Tier 1 assessment taking already the use of protective gloves into account (Tier 1b) the potential exposure exceeds the TTC value. Based on a further refinement (refinement of the exposure estimate) and taking risk mitigation measures (wearing of protective gloves) into account the estimated exposure is below the TTC value.

Table 2-14 Overall assessment for the biocidal product Duracide A

Scenario	Conclusion risk assessment systemic effects	Conclusion risk assessment local dermal effects	Overall conclusion	Included RMM
1 - spraying of water based Duracide A-EC	acceptable	acceptable	acceptable	protective coverall, protective gloves
2 - spraying of solvent based Duracide A	acceptable	acceptable	acceptable	protective coverall, protective gloves
3 - ULV application of solvent based Duracide A	acceptable	acceptable	acceptable	protective coverall, protective gloves
4 -ULV Application of water based Duracide A-EC	acceptable	acceptable	acceptable	protective coverall, protective gloves
5 - cold and thermal fogging of solvent based Duracide A	acceptable	acceptable	acceptable	protective coverall, protective gloves
6 -Cold and thermal fogging of water based Duracide A-EC	acceptable	acceptable	acceptable	protective coverall, protective gloves
7 - secondary	acceptable	acceptable	acceptable	protective

exposure to d-allethrin				gloves
8 – secondary exposure to photometabolites	acceptable	-	acceptable	protective gloves
Post application	Secondary systemic exposure of the general public to d-allethrin in Duracide A (concentrate):	General public	Not assessed[1]	Post application[1]
Post application	Secondary systemic exposure of the general public to the photometabolites of Duracide A (concentrate)	General public (children and toddler)	Not assessed[1]	Post application[1]

[1] Secondary exposure and risk assessment of the general public after professional use would have to be considered at product authorisation stage. Based on the current risk assessment for exposure to photometabolites after non-professional use, a risk for the general public is also expected after professional use. Therefore, the professional use of corresponding biocidal products should be restricted to areas that are inaccessible to the general public.

For all considered exposure scenarios, the risk assessment does not indicate a concern taking into account the described protection measures. For detailed description of the required measures please refer to chapter 15.1.2 of the document Doc-II. Regarding all considered scenarios, the risk characterisation is considered to be sufficiently comprehensive and reliable for the purpose of inclusion of d-allethrin in the Union List. It is essential to indicate that the conclusion only applies to the active substance and its photometabolites in the biocidal product (and not to other ingredients).

Safety Measures for Professionals

Risk mitigation measures (RMM), necessary in all scenarios only for dermal exposure reductionfor hands and body (e.g. gloves and coverall). For secondary exposure to photometabolites dermal exposure reduction to hands (e.g. gloves) is needed.
In general, personal protective equipment (PPE) should be replaced by engineering and/or technical and/or procedural measures, if possible. According to the Chemical Agent Directive 98/24/EC, article 6, paragraph 2 – it should be ensured that technical and organisational measures are applied by preference, and that only the remaining risks are mitigated by PPE.

Risk Assessment for Non-Professionals

Pynamin Forte 40 mg mat

Table 2-15 Summary risk assessment for primary systemic exposure of non-professional usersto d-allethrin from Pynamin Forte 40 mg mat

Exposure scenario	ExposureAdults (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure	Covered by medium-term exposure		
Medium-term exposure			
Dermal	**1.35 x 10^{-2}**	0.04	**34**

Duracide A – FIK aerosol

Table 2-16Table 2-17 Summary risk assessment for primary systemic exposure to d-allethrin from Duracide A — FIK aerosol

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AELAELAEL)
Acute exposure	Covered by medium-term exposure		
Medium-term exposure			
Inhalation	3.85 x 10^{-3}	0.04	9.6
Dermal	4.48 x 10^{-3}	0.04	11.2
Oral	2.77 x 10^{-4}	0.04	0.7
Total	8.61 x 10^{-3}	0.04	**21.5**

Risk assessment for the General Public

Pynamin Forte 40 mg mat

Table 2-18 Summary risk assessment for secondary systemic exposure of adults to d-allethrin from Pynamin Forte 40 mg mat

Exposure scenario	Exposure Adults (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure	Covered by medium-term exposure		
Medium-term exposure			
Inhalation during application	6.11 x 10^{-3}	0.04	15
Dermal contact to residues	5.46 x 10^{-333}	0.04	14
Total	**1.16 x 10^{-2}**	0.04	**29**

Table 2-19 Summary risk assessment for secondary systemic exposure of toddlers to d-allethrin from Pynamin Forte 40 mg mat

Exposure scenario	Exposure Toddlers (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure	Covered by medium-term exposure		
Medium-term exposure			
Inhalation during application	1.83x 10^{-2}	0.04	46
Dermal contact to residues	8.82x 10^{-3}	0.04	22
Oral intake of residues	4.23 x 10^{-3}	0.04	11
Total	**3.14 x 10^{-2}**	0.04	**79**

Table 2-20 Summary risk assessment for total primary and secondary systemic exposure of non-professional adults to d-allethrin Pynamin Forte 40 mg mat

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure	Covered by medium-term exposure		
Medium-term exposure			
Primary exposure	1.35 x 10^{-2}	0.04	34
Secondary exposure	16 x 10^{-2}	0.04	29
Total	**2.51 x 10^{-2}**	0.00.044	**63**

Duracide A — FIK aerosol

Table 2-21 Summary risk assessment for secondary exposure of adults to d-allethrin from Duracide A — FIK aerosol

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure	Equivalent to primary exposure		
Medium-term exposure	Refer to exposure of toddlers, representing worst case		

Table 2-22 Summary risk assessment for secondary exposure of children to d-allethrin from Duracide A — FIK aerosol

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure **Stay in rooms during application**			
Inhalation	1.02×10^{-2}	0.06	17
Dermal	1.13×10^{-2}	0.06	19
Oral	7.82×10^{-4}	0.06	1.3
Total	**2.22×10^{-2}**	0.06	**37**
Medium-term exposure **Contact to residues on the floor**	Refer to exposure of toddlers, representing worst case		

Table 2-23 Summary risk assessment for secondary exposure of toddlers to d-allethrin from Duracide A — FIK aerosol

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure **Stay in rooms during application**			
Inhalation	2.33×10^{-2}	0.06	39
Dermal	2.69×10^{-222}	0.06	45
Oral	1.68×10^{-3}	0.06	2.8
Total	**5.19×10^{-2}**	0.06	**87**
Medium-term exposure			
Contact to parent's clothing			
Dermal	1.50×10^{-4}	0.04	0.4
Oral	1.20×10^{-4}	0.04	0.3
Total	**2.70×10^{-4}**	0.04	**0.7**

Contact to residues on the floor			
Dermal	1.23 x 10^{-2}	0.04	31
Oral	4.72 x 10^{-4}	0.04	1.2
Total	**1.28 x 10^{-2}**	0.04	**32**
Total (both medium-term scenarios)	**1.31 x 10^{-2}**	0.4 0404	**33**
Total (all scenarios combined)	**6.5 x 10^{-2}**	0.06	**108**

Table 2-24 Summary risk assessment for total primary and secondary systemic exposure of non-professional adults to d-allethrin from Duracide — FIK aerosol

Exposure scenario	**Exposure (mg/kg bw/[d])**	**AEL (mg/kg bw/[d])**	**Exposure (% of AEL)**
Acute exposure	Covered by medium-term exposure		
Medium-term exposure			
Primary exposure	8.61 x 10^{-3}	0.04	22
Secondary exposure, exposure of toddlers representing worst case for adults	1.31 x 10^{-2} [22]	0.04	33
Total	**2.17 x 10^{-2}**	0.04	**54**

Overall primary and secondary local exposure to d-allethrin from the biocidal product Duracide — FIK aerosol is acceptable in relation to human health.

Photo degradation products of d-allethrin:

Table 2-25 Summary of secondary systemic exposure of the general public to the photometabolites from Pynamin Forte 40 mg mat

Exposure scenario	**Exposure (mg/kg bw/[d])**	**TTC (mg/kg bw/[d])**	**Exposure (% of TTC)**
Medium-term exposure – internal dose			
Tier 1			
Adults (dermal) [1]	5.46 x 10^{-5}	2.5 x 10^{-6}	**2184**

Toddlers (dermal and oral)[1]	1.31 x 10^{-4}	2.5 x 10^{-6}	**5240**
Tier 2			
Adults (dermal) [1]	2.73 x 10^{-5}	2.5 x 10^{-6}	**1092**
Toddlers (dermal and oral)[1]	6.55 x 10^{-5}	2.5 x 10^{-6}	**2620**

[1] secondary exposure after non-professional use

Table 2-26 Summary of secondary systemic exposure of the general public to the photometabolites from Duracide A – FIK aerosol

Exposure scenario	**Exposure (mg/kg bw/[d])**	**TTC (mg/kg bw/[d])**	**Exposure (% of TTC)**
Medium-term exposure – internal dose			
Tier 1			
Adults (dermal) [1]	Not assessed separately	2.5 x 10^{-6}	Not assessed separately
Toddlers (dermal and oral)[1]	1.28 x 10^{-4}	2.5 x 10^{-6}	**5120**
Tier 2			
Adults (dermal)[1]	Not assessed separately	2.5 x 10^{-6}	Not assessed separately
Toddlers (dermal and oral)[1]	6.4 x 10^{-5}	2.5 x 10^{-6}	**2560**

[1] secondary exposure after non-professional use

Referring to the photo degradation products of the active substances, no safe use is identified for non-professionals.

Safety Measures for Non-Professionals

Pynamin Forte 40 mg mat and Duracide A - FIK aerosol

The primary systemic exposure estimates for the active substance are in almost all cases below the systemic AEL. The risk identified for combined secondary acute and medium-term exposure to Duracide – FIK aerosol for children/toddlers can be managed by appropriate risk mitigation measures, reducing contact to the biocidal product (e.g. by prohibiting the presence of children/toddlers during application).. Thus, it is concluded that primary systemic exposure of non-professional users to d-allethrin from both products is acceptable regarding human health. Specific safety measures are not applicable

, if only secondary exposure to the active substance (excl. photodegradation products) is

considered.

Safety Measures for secondary exposure of the General public

Pynamin Forte 40 mg mat and Duracide A - FIK aerosol
The exposure estimates for the active substance are in almost all cases below the systemic AEL. The risk identified for combined secondary acute and medium-term exposure to Duracide – FIK aerosol for children/toddlers can be managed by appropriate risk mitigation measures, reducing contact to the biocidal product (e.g. by prohibiting the presence of children/toddlers during application).Thus, it is concluded that secondary exposure of the general public to d-allethrin from Pynamin Forte 40 mg mat or Duracide A — FIK aerosol is acceptable regarding human health. Further specific safety measures are not applicable, if only secondary exposure to the active substance (excl. photodegradation products) is considered.

Overall primary and secondary exposure

Pynamin Forte 40 mg mat and Duracide A - FIK aerosol
It is likely that non-professional users, who are primarily exposed by handling the biocidal product, are also charged by secondary exposure during evaporation of d-allethrin and via residues.
The combined exposure estimates for primary and secondary exposure of adults are below the systemic AEL. Thus, it is concluded that combined exposure of non-professional adults to d-allethrin from either product is acceptable regarding human health.
Specific safety measures are not applicable, if only primary and secondary exposure to the active substance (excl. photodegradation products) is considered.

Local dermal exposure

No local exposure assessment is performed

Conclusion

Primary exposure and secondary exposure of non-professionals to d-allethrin from Pynamin Forte 40 mg mat or Duracide A - FIK aerosol is acceptable with respect to human health.
The biocidal product Pynamin Forte 40 mg mat is classified as Skin Sens. 1, H317. This hazard can currently not be characterised and assessed quantitatively.
In addition, the biocidal product is classified as Repr. 2 (among others). According to Regulation (EC) No 1272/2008 such products also have to be labelled with P280 (Wear protective gloves/protective clothing/eye protection/face protection.) to prevent dermal exposure. However, the biocidal product is foreseen for non-professional use. The non-professional user is usually not familiar to use any personal protection equipment (PPE). Therefore, it is laid down in Regulation (EU) No 528/2012, annex VI, point 63 that biocidal products should normally not be authorised for non-professional use if PPE is the only measurement to reduce exposure. Anyway, exceptions are possible. In this respect, it should be noted that dermal contact to the biocidal products is short and dermal exposure during use of the biocidal products is low, even under worst case conditions as applied in this exposure assessment. To exclude skin-sensitising properties of this biocidal product further information is required. In addition, the potential of pyrethroids to provoke paresthesia would have to be taken into consideration for the labelling of biocidal products.

The secondary exposure assessments is based on the assumption that evaporators are not used for more than 10 h per day or that persons do not stay in rooms for more than 10 h, where these units are applied. This limitation has to be clearly communicated on a corresponding product label. Alternatively, an acceptable exposure and risk assessment for longer exposure times has to be provided for product authorisation.

It should also be considered that evaporator units are normally connected to sockets accessible to children. An exposure assessment for toddlers opening such an evaporator has not been performed. Worst case, the oral intake of a whole evaporator mat must be expected resulting in a non-acceptable exposure. Therefore, evaporator units for the biocidal product should also be child-resistant.
Referring to the photo degradation products of the active substances, no safe use is identified for the intended non-professional use.
Based on the toxicological properties of pyrethroids, lethal intoxication after the application of such biocidal products containing d-allethrin must be expected for cats and poikilothermic animals. Thus, specific risk mitigation measures for these particular pet species are required at product authorisation stage to prevent exposure.

2.2.2. Environmental Risk Assessment

The assessment of fate and distribution of the a.s. in the environment was based on studies conducted with esbiothrin, bioallethrin, d-allethrin, and d-trans-prallethrin. Esbiothrin is regarded as being equivalent to d-trans-allethrin 75/25, consisting of the [1R, trans: 1R]-isomer:[1R, trans;1S]-isomer at a ratio of 1:3. Bioallethrin comprises the [1R trans;1R]- and [1R trans;1S]-isomers in the ratio 1:1. In an aerobic biodegradation soil simulation study (*cf* chapter 2.2.2.1) it was demonstrated that both enantiomers of esbiothrin/d-trans-allethrin 75/25 show similar degradation behaviour. Thus, the results of studies conducted with bioallethrin have been accepted for the assessment of biodegradation of esbiothrin/d-trans-allethrin 75/25. D-allethrin is a mixture of 4 isomers, containing the [1R, trans: 1R]-, and [1R, trans: 1S]-isomer to 40% each as well as the [1R, cis: 1R]-, and the [1R, cis: 1S]-isomer to 10% each. Finally, d-trans-prallethrin is structurally similar to esbiothrin but substituted by a propynyl- instead of propenyl-group at the 4-oxocyclopent-2-enyl ring. Since physic-chemical properties of d-trans-prallethrin and esbiothrin are highly comparable and the structural difference is not expected to significantly affect fate and behaviour, d-trans-prallethrin was accepted for read-across to esbiothrin.

Hazard identification and effects assessment

Aquatic Compartment

Acute tests with species from three trophic levels are available for both applicants. The effect values for *Daphnia magna* and both tested fish species were in the same range with EC/LC_{50} values between 6.1 µg/L (*Daphnia magna*) and 13 µg/L (*Oncorhynchus mykiss*). Green algae were less sensitive by a factor of 1000 (72h-E_rC_{50} = 2.8 and 6.6 mg/L).
In addition, a 21d-reproduction test with *Daphnia magna* is available for applicant Sumitomo with the test substance esbiothrin, resulting in a NOEC of 2.7 µg/L.
For product authorisation, ENDURA will need a Letter of Access (LoA) to the long-term daphnia study from SUMITOMO or must provide an own long-term daphnia study. For the risk characterisation of the active substance all available effect data on aquatic organisms were considered and the $PNEC_{water}$ was derived based on the NOEC value for daphnia with an assessment factor of 50.

$PNEC_{water}$ = 2.7 µg/L / 50 = **0.054 µg/L**

Sediment

Tests with benthic organisms are not available. Therefore, the $PNEC_{sed}$ has to be derived from the $PNEC_{water}$ using the equilibrium partitioning method (EPM).
Using the $PNEC_{water}$ of 0.054 µg/L, a $K_{susp\text{-}water}$ of 36.025 and a RHO_{susp} of 1150 kg/m³ results in

a $PNEC_{sed}$ of **1.7 µg/kg ww**.

Inhibition of microbial activity (STP)

The company Sumitomo submitted a test conducted according to OECD 209 guideline, from which a NOEC of ≥102.4 mg d-allethrin/L (highest test concentration) was derived. In a second OECD 209 test, submitted by ENDURA, no significant inhibition was found up to the highest test concentration of 994 mg d-allethrin/L as well. According to the Guidance on the Biocidal Products Regulation (2015, Volume IV Environment, Part B Risk Assessment (active substances), chapter 3.4, Infobox 7, p. 127) the NOEC is set equal to the limit of water solubility, if no significant inhibition is observed at the highest test concentration. This NOEC is subsequently used to derive the $PNEC_{microorganisms,STP}$. For the active substance d-allethrin, this agreement leads to a NOEC of 2.6 mg/L based on the information available on water solubility from the applicants (ENDURA: 2.59 mg/L at 20°C, SUMITOMO: 2.62 mg/L at 20°C). Consequentially, this results in a **$PNEC_{microorganisms,STP}$ of 0.26 mg/L.**

Terrestrial Compartment

No effect values for terrestrial organisms are available for d-allethrin. Therefore, the $PNEC_{soil}$ is derived from the $PNEC_{water}$ using the equilibrium partitioning method.
With a $K_{soil-water}$ of 42.35 and a RHO_{soil} of 1700 kg/m³, a **$PNEC_{soil}$ of 1.34 µg/kg ww** is derived from the $PNEC_{water}$ of 0.054 µg/L.

Atmosphere
D-Allethrin is not expected to volatilise in significant quantities due to the low vapour pressure and Henry's law constant. A photodegradation half-life of 1.733 h in air was estimated. Hence, accumulation and long range transport of d-allethrin in the atmosphere is not expected.

Secondary Poisoning
The a.s. d-allethrin exhibits a bioaccumulation potential in fish with an experimental derived BCFfish of 1314 L/kg wet fish. The BCF for earthworm was calculated to be 1070 L/kg wet earthworm, thus bioaccumulation in terrestrial organisms has to be assumed as well.
Therefore, an assessment for secondary poisoning was performed for both the aquatic and the terrestrial food chain using the PNECoral of 4.16 mg/kg food for mammals. No unacceptable risk for fish-eating predators (aquatic food chain) or earthworm-eating predators (terrestrial food chain) could be identified.

Exposure assessment

For environmental exposure estimation of the a.s. d-allethrin representative biocidal products have been assessed:

- **Pynamin® Forte 40 mg** (containing a nominal 40 mg a.s. per mat).

For the life cycle stage "production", no exposure assessment has been performed as the active substance is produced outside the EU. According to the applicant Sumitomo, exposure of the environment during formulation of the biocidal products is not expected due to the controls in place and all waste from the process is disposed of in an approved facility. The applicant's statement is deemed to be plausible to the eCA during active substance evaluation.

No industrial/professional use of the b.p. is foreseen. For the life cycle stage "private or non-professional use", environmental exposure assessment has been performed for the representative product depending on intended use and application. The environmental exposure is assessed applying the Guidance on BPR Vol. IV B, ENV (2015) and the OECD Emission Scenario

Document Number 18 for Insecticides, Acaricides and Products to Control Other Arthropods (PT 18) for Household and Professional Uses (July 2008).

The application of the b.p. Pynamin® 40 mg Forte as insecticide is envisaged for the control of adult biting mosquitoes inside private houses only (except kitchens). The b.p. is formulated as an insecticidal cellulose paper mat containing a nominal concentrate (40 mg a.s.) and is to be applied by diffusion. Due to the proposed non-professional indoor use of the ready-to-use product (RTU) the application mode can be described as diffusor.

The exposure of the a.s. in the life cycle stage "private or non-professional use" of the biocidal product is estimated considering the indoor application steps by non-professionals and subsequent cleaning steps of the floor of the treated room. An overview of the application pattern, the intended use of the b.p. relevant for environmental exposure assessment as well as a detailed description of emission scenarios including the input and output values are given in Doc IIB 8.3, chapter 8.3.1.4.

- **Duracide A**

The product familiy Duracide A is a liquid frame formulation containing 7.7 % w/w of d-allethrin. During active substance approval, an environmental risk assessment is only conducted for d-allethrin. For national authorisation of the Duracide A, a re-evaluation considering all active substances will be required.
The product family consists of three products with different intended uses, application techniques and application rates:

- Duracide A **- Emulsifiable concentrate (EC-product)**
- Duracide A **- As it is (As it is-product)**
- Duracide A **- Ready to use aerosol (RTU-product)**

For the life cycle stage "production", no exposure assessment has been performed as the active substance is produced outside the EU. According to the applicant Endura, exposure of the environment during formulation of the biocidal products is not possible as the whole formulation process occurs in closed systems and all accumulating waste is incinerated by local companies. The applicant's statement is deemed to be plausible to the eCA during active substance evaluation.

For the life cycle stage "professional and private use", an environmental exposure assessment has been performed depending on intended use and application of the b.p. The environmental exposures are assessed applying the Guidance on BPR Vol. IV B, ENV (2015) and the OECD Emission Scenario Document Number 18 for Insecticides, Acaricides and Products to Control Other Arthropods (PT 18) for Household and Professional Uses (July 2008).

The application of the b.p. as insecticide is envisaged for knock down and kill of flying insects such as mosquitoes (*Aedes aegypti* and *Culex quinquefasciatus*) and houseflies (*Musca domestica*). It is intended to be used only indoors by professional (EC- and as it is-product) and non-professional (RTU-product) users either in domestic households or commercial/industrial buildings. All of the above mentioned b.p. are to be applied for air-space treatments. Hence, the application mode can be described as general air-space treatment.

The exposure of the a.s. in the life cycle stage "professional and non-professional use" of the biocidal product Duracide A (EC, As it is- and RTU-product) is estimated considering the mixing and loading step (only for professional users), the indoor application steps by professionals or non-professionals and subsequent cleaning steps of the floor of the treated room. An overview of the application pattern and the intended use of Duracide A (EC, As it is- and RTU-product) relevant for environmental exposure assessment as well as a detailed description of emission scenarios including the input and output values are given in Doc IIB 8.3.

Two general cleaning methods (wet and dry cleaning with emission to waste water or wastes) are described in the OECD ESD No.18. Generally, cleaning steps take place at the same day as the application. It is not expected that residues of neither Pynamin® Forte 40 mg nor Duracide A can be removed by dry cleaning methods. Thus, the exposure pathway of solid waste to municipal landfill is negligible. The wet room cleaning process is relevant for the environmental risk assessment. The emission rates to waste water were used for the exposure assessment taking into account fate and behaviour of a.s. in the environment and the simultaneity of treatments by the houses connected to the STP. Assuming that residues of a.s. removed through wet cleaning may be emitted to waste water, the STP is considered as the primary receiving compartment for a.s. Hence, PECs have been estimated for the aquatic compartment including STP, surface water, and sediment, and for the terrestrial compartment including soil and groundwater.

Exposure assessment of the metabolites in the aquatic compartment
The a.s. underwent no significant hydrolytic degradation in water at environmentally relevant pH-values. A study on photolytic degradation showed the major photodegradates (> 10%) allethrolone and dihydroxy-allethrolone. Anyhow, photolytic degradation in water is assumed to be relevant only in the upper centimeters of natural water bodies. The degradation of the parent compound in STP was estimated to be zero ($k_{STP} = 0 \cdot h^{-1}$) and was not considered for the exposure estimation of the water /sediment phase, respectively. In water/sediment studies several relevant metabolites (dl-ALON, d-c/t-CRA, t-COOH-CA and ωt-COOH-d-t-allethrin) could be identified.

Based on the laboratory testing data and QSAR predictions, the acute toxicity of the metabolites dl-ALON, d-c/t-CRA and t-COOH-CA is relatively low to fish, Daphnia and algae particularly in relation to the parent compound. Regarding ωt-COOH-d-t-allethrin, the lowest QSAR estimated EC_{50} is 0.08 mg/L for invertebrates indicating that this metabolite may be toxic to aquatic organisms, but is less toxic than the parent compound. However, no experimental validation of this result is available. For the environmental risk assessment it is considered appropriate to assume that the aquatic toxicity of this metabolite is equal to that of the parent substance. This approach is potentially conservative but is in line with the effect assessment for other metabolites of pyrethroid active substances (see cyphenothrin, epsilon-momfluorothrin).

In conclusion, it will be assumed that possible risk for the aquatic environment due to the major metabolites is covered by the risk assessment performed for the parent substance.

Metabolites in the terrestrial compartment
Degradation of the active substance in soil leads to formation of the major metabolites t-COOH-CA and dl-ALON. Due to the absence of substance specific data, the environmental exposure assessment for the soil metabolites is based on the worst case assumption of a 100% formation for both metabolites. Then, the environmental concentrations in soil for the metabolites are derived by the PEC_{soil} of the parent compound considering the molecular weight of each metabolite. The simulation model FOCUS PEARL 4.4.4 is used for the refinement of the environmental exposure assessment of d-allethrin and its metabolites (t-COOH-CA, dl-ALON) in the groundwater. For the calculation of $PEC_{groundwater}$ following application scheme is used: Sewage Sludge Application. The application of the sewage sludge is conducted either on arable land or on grassland. In both cases it is assumed that the sewage sludge is incorporated to the soil and the concentration in the soil leachate is determined at a target depth of 1m.

Fate and distribution in the environment

Biodegradation

D-allethrin has been shown to be not readily biodegradable in an OECD 301 F study, resulting in 26 % degradation within 28 days of incubation. Additionally, the active substance is considered

to be not inherently biodegradable based on 53.5 % degradation in a test conducted on d-allethrin according to OECD 302 C (Modified MITI Test (II)).

Water-sediment systems

Data on route and rate of degradation of d-allethrin are available from investigations on the degradation behaviour of [^{14}C]-d-allethrin and [cyclopropyl-1-^{14}C]-d-trans-prallethrin conducted in three water-sediment systems. Due to the use of reverse-phase HPLC, cis- and trans-isomers of d-allethrin could have been determined separately. Read-across between d-trans-prallethrin and d-trans-allethrin was accepted by eCA since both substances are almost identical with respect to their chemical structures and physico-chemical properties.

In both studies, the test substance disappeared rapidly from the water phase, mainly caused by transfer into the sediment. Calculated $DissT_{50}$ for the water layer varied between 1.8 days and 2.8 days for the trans-isomers of d-allethrin as well as d-trans-prallethrin, and between 2.2 and 5.4 days for the cis-isomers of d-allethrin at test temperature. Normalization of dissipation half-lifes to an average EU outdoor temperature of 12°C resulted in $DissT_{50}$ values between 3.4 d and 5.3 days for the trans-isomers of d-allethrin, and between 4.2 and 10.2 days for the cis-isomers, respectively. For d-trans-prallethrin the conversion led to a $DissT_{50}$ of 6.7 days at 12°C. Considering the sum of trans- and cis-isomers a $DissT_{50}$ of 1.8 days and 3.2 days at 20°C (corresponding to 3.4 days and 6.1 days at 12°C) was derived for the water layer, respectively. For the total system, DT_{50} values of 7.1 days and 7.6 days (12°C) have been calculated for d-trans-allethrin. Comparably longer half-lifes have been derived from the study with d-trans-prallethrin. Thus, a DT_{50} of 143.7 days (12°C, modelling value) was calculated for the total system, indicating a long residence time of the substance in the sediment. This was further supported by a $DissT_{50\text{-modelling}}$ of 132.1 days (12°C) for the sediment, which could have been calculated by the eCA.

Also the cis-isomers were found to be more persistent than the trans-isomers of d-allethrin in the whole water-sediment systems. Thus, trigger half-lifes of 27.0 and 35.0 days at 20°C, corresponding to 51.2 and 66.4 days at 12°C, have been delivered by the study conducted with [^{14}C]-d-allethrin. Modelling-half-lifes amounted to 66.4 days and 70.7 days at 12°C.

For the sum of both isomers (d-c/t-allethrin), $DT_{50\text{-trigger}}$ values of 9.7 days and 8.7 days as well as $DT_{50\text{-modelling}}$ values of 14.8 days and 13.8 days have been derived for the total system at an environmental temperature of 12°C. Additionally, dissipation times for the sediment could have been calculated by eCA, considering the decline of measured radioactivity of d-c/t-allethrin after reaching the maximum value. From this, trigger half-lifes of 27.1 days and 38.7 days at 12°C as well as $DT_{50\text{-modelling}}$ values of 27.1 days and 88.0 days at 12°C were determined.

As main transformation products with formation of >10 % of applied radioactivity (AR) d-c/t-CRA (max. 42.3 %, water layer), t-COOH-CA (max. 34.3 %, water layer), and ωt-COOH-d-t-allethrin (max. 15.3%, water layer) were found in the studies. As a [^{14}C]-cyclopropyl labelled allethrin was used in all of the water/sediment studies, radiochemical analysis did not provide information about any metabolites derived from the cyclopentyl side. The first step in the abiotic as well as biotic degradation reaction is the hydrolytic cleavage of the ester link, splitting the molecule into d-c/t-CRA and dl-ALON. Consequently, levels of dl-ALON will be equal to levels of d-c/t-CRA or t-COOH-CA. Non-extractable residues amounted to 11.2 - 22.8% AR at the end of the studies, while ultimate biodegradation was low as indicated by a maximum CO_2 evolution of 33.4 % AR after 61 d.

Soil

The applicant SUMITOMO submitted three studies, investigating the degradation behaviour of d-trans-allethrin and its enantiomers (d-trans-d equivalent to [1R, trans: 1R]-allethrin and d-trans-l-allethrin equivalent to [1R, trans;1S]-allethrin) in soil under aerobic conditions. All studies have been conducted at 25±1°C in the dark, according to EPA Pesticide Assessment Guidelines, Subdivision N, Section 162-1. Two studies have been conducted with bioallethrin which comprises the [1R trans;1R]- and [1R trans;1S]-isomers in the ratio 1:1.

Incubation period was 183 days for the studies using bioallethrin, while tests conducted on d-trans-d and d-trans-l-allethrin lasted only 30 days. Only one soil type, a sandy loam originating from Hanford, Madera County, California, was tested. The organic C content of the soil (0.46 %) was slightly below the OECD 307 requirements (0.5-2.5%). At test temperature, half-life varied

between 19.4 days and 51.8 days in the single test vessels, resulting in $DT_{50modelling}$ values between 54.9 days and 146.6 days when converted to 12°C average EU outdoor temperature. Slowest degradation rates were observed for the individual stereoisomers d-trans-d-allethrin and d-trans-l-allethrin, finding expression in a $DT_{50\text{-}modelling}$ of 129.2 days and 119.6 days at 12°C (average of two replicates), respectively. For PEC estimation of d-trans-allethrin, the geometric mean was calculated from four modelling DT_{50} values, resulting in 103.47 days at 12°C average EU outdoor temperature. Non-extractable residues increased constantly until the end of each study and were found at a maximum of 24.9 % AR (day 122). Mineralisation varied between 4.6 % AR (day 14) and 71.3 % AR (day 183). The degradation products dl-ALON (max. 36.5 % AR), t-COOH-CA (max. 35.1 % AR), and d-t-CRA (max. 9.3 % AR, exceeding 5 % AR on two consecutive sampling dates) have to be considered as major metabolites.
To provide information on the degradation behaviour of the cis-isomer of d-allethrin, an aerobic biodegradation test according to OECD 307 was performed. The study was conducted on three soils (loam, sandy loam, sandy clay loam) using [^{14}C]-d-cis-allethrin. In the sandy clay loam, d-cis-Allethrin was still found to 15.9 % AR at the end of the study. Degradation half-lifes were recalculated by eCA, resulting in $DT_{50\text{-}trigger}$ values of 18.7 days (loam), 20.9 days (sandy loam), and 22.1 days (sandy clay loam) at test temperature (corresponding to 52.9 days, 59.1 days, and 62.5 days at 12°C). Determination of the $DT_{50\text{-}modelling}$ yielded values of 88.0 days, 97.6 days, and 251.0 days at 12°C. Non-extractable residues increased during the incubation period up to a maximum of 23.2 % AR. At the end of the study (120 days) levels of radiolabelled carbon dioxide amounted to 55.2 %, 34.8 % and 49.9 % AR. No relevant metabolites were identified in this study.
Based on all available studies, providing information about aerobic degradation of d-allethrin in soil, a $DT_{50\ modelling}$ of 113.8 days (at 12°C) was determined for PEC estimation by calculating the geometric mean.

Metabolite t-COOH-CA ((1R, 3R)-trans-2,2-dimethyl-3-carboxycyclopropanecarboxylic acid)
In a laboratory study (OECD 307), the rate of aerobic degradation of t-COOH-CA in three soils (two loam soils and one sandy clay loam soil) was investigated. The DT_{50} values for degradation of [acid-^{14}C]-trans-COOH-CA in Aschard loam, France site #2 loam and Norbert sandy clay loam soils were calculated to be 3.6 days, 5.9 days and 10.1 days, respectively, when transformed to a temperature of 12°C.
Mineralisation of the metabolite t-COOH-CA accounted for a maximum of 41.2 % AR for the Aschard loam soil, 50.3 % AR for the France site #2 loam soil and 45.4 % AR for the sandy clay loam soil. Maximum of bound residues amounted to 51 % AR at day 6 for the Aschard loam soil, 43.6 % AR at day 14 for the France site #2 loam soil and 33.0 % AR at day 30 for the Norbert sandy clay loam soil. Information on characteristics of the bound residues is not available.

At WGII-2017 the WG agreed on harmonisation of biodegradation endpoints for the pyrethroid metabolites (t-COOH-CA, d-c/t-CRA). Decisions of the WG regarding the DT_{50} values to be used in PEC calculations are reflected in the LoEP, chapter 4.

Abiotic Degradation

Two hydrolysis studies were submitted by the applicants: ENDURA submitted a hydrolysis study conducted with d-allethrin, but no degradation products had been identified. The other study was performed by Sumitomo with bioallethrin (d-trans-allethrin 50/50). The results of both studies were considered to be suitable for (read across to) d-allethrin. DD-Allethrin is not susceptible to hydrolysis in the pH-range from 4 to 7. At pH 9, the a.s. showed hydrolytic degradation. The hydrolysis half-life was recalculated to reflect an average EU outdoor temperature of 12 °C for fresh water (based on EU TGD (2003), chapter 2.3.6.1). The half-life amounts to 12.2 days at pH 9. The major degradation products of d-allethrin are allethrolone (dl-ALON, 4-hydroxy-3-methyl-2-prop-2-enylcyclopent-2-en-1-one) and two isomeric bicyclic ketones (Compounds 1A and 2A). Hydrolysis is not considered to be a significant degradation route for d-allethrin at environmentally relevant temperatures and pH.
The definitive study on photolysis in water was conducted by SUMITOMO with bioallethrin. The

results were considered to be sufficient to read across to d-allethrin. DD-Allethrin undergoes photodegradation in aqueous media. A degradation rate constant of 0.0142 hours^{-1} and a half-life (DT_{50}) of 48.8 h for a California (USA) winter day was determined. Major degradates (> 10% of the applied radioactivity) were allethrolone (dl-ALON, 4-hydroxy-3-methyl-2-prop-2-enylcyclopent-2-en-1-one) and dihydroxy-allethrolone. Both photodegradation products are not regarded as relevant for a quantitative environmental risk assessment of the water compartment.

d-Allethrin is susceptible to photodegradation in air and the half-life is estimated to be 1.733 h.

Distribution and Mobility

A HPLC test according to OECD 121 performed with d-allethrin was submitted by ENDURA. The chromatography of the test item resulted in two main peaks (resulting in log Koc = 3.34 which is equal to a Koc value of 2209 mL/g and log Koc = 3.53 which is equal to a Koc value of 3373 mL/g). A study on adsorption/desorption of 1R-trans-allethrin (ratio unclear from study report) in four different soils was conducted according to US EPA N 163-1. The results were considered to be suitable for the assessment of d-allethrin. A mean log K_{OC} of 3.148 (equivalent to 1405 mL/g) was derived.

For the environmental risk assessment the Koc of 1405 mL/g is used in the environmental exposure assessment.

Bioaccumulation

Aquatic

Based on the physicochemical properties an approximate estimation of the bioconcentration factor BCF can be calculated. Taking into account the log K_{OW} value of 4.95 (25°, pH 5) the BCF_{fish} amounts to 3217 L*kg$_{wet\ fish}^{-1}$.

In consequence of the log K_{OW} above 3 an experimental study with fish is required. A study on bioaccumulation in aquatic organisms is missing for the active substance d-allethrin. Instead an aquatic bioaccumulation study with the substance [Alc-^{14}C]-d-trans-Etoc (d-trans-prallethrin) is available (delivered by the company Sumitomo). Considering the chemical structure and the isomeric issue, d-trans-prallethrin and d-trans-allethrin are almost identical. As the trans-isomers of d-allethrin representing 80% of the isomeric mixture the read-across relating to the bioaccumulation potential between d-trans-prallethrin and d-allethrin is accepted by eCA.

A dynamic 42-day fish accumulation study was conducted using the most insecticidal active d-trans- isomer of Etoc (prallethrin; (RS)-2-methyl-4-oxo-3-(prop-2-ynyl)-cyclopent-2-enyl (1RS)-cis,trans-2,2-dimethyl-3-(2-methylprop-1-enyl) cyclopropane carboxylate; CAS No. 103065-19-6). According to the applicant the trans-isomer ratio of prallethrin exceeds 75%. The study was conducted according to U.S. EPA-FIFRA Guideline 165-4 which is comparable to OECD 305. The daily bioconcentration factors based on total ^{14}C radioactivity ranged from 787-1160 L*kg$_{wet\ fish}^{-1}$ for whole fish, 81-236 L*kg$_{wet\ fish}^{-1}$ for edible tissue and 2210-3130 L*kg$_{wet\ fish}^{-1}$ for non-edible tissue.

From the point of view of the eCA no actual steady state was reached during the uptake phase as BCF values differ with more than 20% of each other between the intervals. Therefore, the use of the kinetic BCF_K, calculated directly from the kinetic rate constants is proposed. For substances with high lipophilicity (i.e. with log K_{OW} > 3), bioconcentration should be expressed in relation to lipid content in addition to whole body weight. The BCF_K of 987 was therefore recalculated by the eCA taking into account the lipid content of 3.8%. After normalisation to lipid content of 5% and after correction for growth dilution, a BCF_{KgL} value of **1314** L*kg$_{wet\ fish}^{-1}$ was obtained.

The following deficiencies of the study were identified and should be taken into account. Only one concentration of test material was tested. At least two concentrations of test substance are recommended according to OECD 305. Furthermore, the total organic carbon content (TOC) was only measured once in the dilution water at the beginning instead of frequently during the study duration and the TOC was with 3 mg/l higher than the recommended limit concentration (2 mg/l) in the test water according to OECD 305. Therefore, reduced bioavailability of the test substance

due to adsorption to organic matter could not be excluded.
According to the applicant the study on bioaccumulation in fish was performed with the most insecticidal active d-trans- isomer of prallethrin, but the precise isomer was not stated. It is assumed that the (1R trans) (1S) isomer was used, which is known as the most insecticidal active isomer of the different isomers of synthetic allethrins. This isomer is contained in d-allethrin with 40%. The other trans-isomer (1R trans) (1R) is also contained with 40%. For the cis-isomers, contained with 20% in the isomeric mixture, no information about the accumulation potential in fish is available.
Therefore, some uncertainty remains referring to the bioaccumulation behaviour of the active substance d-allethrin.
However, the calculated and the measured BCF values are in the same order of magnitude (calculated BCF =3217 $L*kg_{wet\ fish}^{-1}$; measured BCF = 1314 $L*kg_{wet\ fish}^{-1}$) but differ with a factor of 2.5. Based on the result, the active substance d-allethrin indicates a potential for bioaccumulation in the aquatic compartment. However, the B criterion is not fulfilled.

Please note, in an investigation of [redacted] (2015) on bioaccumulation in fish several pyrethroid substances were detected in wild river fish collected in four Iberian rivers. Isomeric characterisation was carried out and the results remarked a general preference of cis isomers in bioaccumulation. The results of this publication should be kept in mind in future in case of renewal of the authorisation procedure. Until then maybe further information might be available on monitoring data regarding pyrethroid substances that should then be taken into account for the environmental risk and hazard assessment.

Terrestric

A $BCF_{earthworm}$ for d-allethrin of **1070** $L*kg_{wet\ earthworm}^{-1}$ was estimated from the log Kow of 4.95 indicating a potential for bioaccumulation in the terrestrial compartment.

2.2.2.4 Risk characterisation

Pynamin 40mg mat (Sumitomo):
For the representative b.p. Pynamin 40mg mat risk quotients are below the trigger value of 1 for the aquatic compartment and the terrestrial compartment including groundwater (considering the FOCUS PEARL refinement). No unacceptable risk was identified for predators in the aquatic or terrestrial food chain (secondary poisoning). Thus, the use of d-allethrin in the b.p. indicates no unacceptable risks for the environment.

Duracide A (Endura):
No unacceptable risk was identified for aquatic microorganisms (STP). The estimated risk quotients for the aquatic compartment (surface water and sediment) are above the trigger value of 1 for all three formulations of Duracide A. For the terrestrial compartment (soil and groundwater) risk quotients are above the trigger value of 1 for the EC formulation and the As-it-is formulation. For the RTU-formulation a risk for the groundwater compartment was estimated as well. For all formulations there was still an unacceptable risk identified after refinement for the groundwater compartment relating to the major metabolites dl-ALON and t-COOH-CA.Thus, the use of the b.p. Duracide A indicates an unacceptable risk for the environment.At the time of the a.s. evaluation only acute aquatic toxicity data are available for the substance d-allethrin from the applicant Endura. Long-term aquatic toxicity data are only available for invertebrates for the active substance esbiothrin from another applicant (read-across between esbiothrin und d-allethrin was accepted by eCA). The $PNEC_{water}$ for the risk assessment of the active substance was based on all available aquatic effect data. For product authorisation, applicant ENDURA will need a Letter of Access to the long-term study with *Daphnia magna* from SUMITOMO or must provide an own long-term daphnia study. If neither a LoA nor an own long-term daphnia study is provided by ENDURA, the $PNEC_{water}$ used for product authorisation has to be based on the available short-term studies (for details see Doc II-A, chapter 4). However, the unacceptable risk to the environment may not be reduced sufficiently by only providing further chronic studies on aquatic organisms. Therefore, for the application of products containing d-allethrin, further data to prove a risk to the environment have to be provided by the applicant for the product

authorisation process.

2.2.2.5 PBT and vPvB assessment

The PBT-and vPvB-Assessment for d-allethrin, including its isomers and transformation products, was performed following to the requirements of the Guidance on the Biocidal Products Regulation (2015, Volume IV Environment, Part B Risk Assessment (active substance), chapter 3.11, pp. 171), according to Annex XIII of the REACH regulation.

(v)P Assessment

P criterion: Half life > 40 d freshwater or >120 d in freshwater sediment or > 120 d in soil

vP criterion: Half life > 60 d water or > 180 d in freshwater sediment or >180 d in soil

Calculation of ready biodegradability of d-allethrin using BioWin v4.10 results in a probability for fast biodegradation of 0.6497 (biodegrades fast) for BioWin 2 and 2.4365 (weeks-months) for BioWin 3, as well as 0.1153 (not readily degradable) for BioWin 6. According to REACH legislation (Guidance on information requirements and chemical safety assessment, Chapter R.11: PBT/vPvB Assessment, Version 3.0, 2017) d-allethrin has to be considered potentially persistent based on these calculations.
D-allethrin has been shown to be neither readily (in a test according to OECD 301 F), nor inherently biodegradable based on a test according to OECD 302 C. Additionally, d-allethrin was found to be hydrolytic stable under environmental pH and temperature conditions (*cf* section 4.1.1.2).
The active substance d-allethrin consists of the [1R,trans;1R] + [1R,trans;1S] + [1R,cis;1R] + [1R,cis;1S]-isomers in an approximate ratio of 4:4:1:1. Information about route and rate of both cis- and trans-isomers of d-allethrin in freshwater is available from a water-sediment study conducted according to OECD guideline 308, using [cyclopropyl-1-^{14}C]-d-allethrin and a second study, conducted according to EPA Pesticide Assessment Guidelines, Subdivision N, Section 162-4, using [cyclopropyl-1-^{14}C]-d-trans-prallethrin. Read-across from d-trans-prallethrin to d-allethrin to (trans-isomer) was based on the high similarity in the chemical structures and in physical-chemical properties and agreed by the majority of participants of the WG-III-2017 Ad-hoc follow-up to ItemItem 6.3/6.4 (Point 2 and 3: Bioaccumulation and Persistence). Due to the high Koc and since the test substance was rapidly transferred into the sediment in both studies. Therefore, the criterion of 120 days (P), and 180 days (vP) for freshwater sediment was applied to evaluate the persistence of isomers of d-allethrin in aquatic systems:

d-trans-allethrin: Based on the study conducted with [cyclopropyl-1-^{14}C]-d-trans-prallethrin, providing a $DT_{50modelling}$ of 143.72 d (12°C) for the total system, and a $DissT_{50}$ of 132.1 days for the sediment supporting a long residence time in this compartment, d-trans-allethrin **is considered to fulfil the P criterion in sediment.**

d-cis-allethrin: based on the available information (modelling half-lifes in total system: 66.4 days (Swiss Lake) and 70.7 days (Calwich Abbey) at 12°C) d-cis-allethrin **does not fulfil the (v)P criterion in sediment.**

For the soil compartment, degradation half-lives of d-trans-allethrin between 19.4 days and 51.8 days at 20°C, corresponding to 54.9 days and 146.6 days at an average EU outdoor temperature of 12°C have been derived from four laboratory soil degradation studies. Only one soil type (California sandy loam) of less Corg content (0.46%), was used in all of the four soil simulation studies, whereas this soil type cannot be considered as worst case regarding degradation. Thus, the worst case DT_{50} of 146.6 d from d-trans-d-allethrin was used for comparison with the P-threshold, leading to the conclusion that the **trans-isomer of d-allethrin is persistent in soil**.

Persistence of the cis-isomer of d-allethrin was evaluated based on a soil simulation study according to OECD 307. Three soils (loam, sandy loam, sandy clay loam) were tested. Degradation half-lives were recalculated by eCA, resulting in $DT_{50\text{-trigger}}$ values of 18.7 days (loam), 20.9 days (sandy loam), and 22.1 days (sandy clay loam) at test temperature (corresponding to 52.9 days, 59.1 days, and 62.6 days at 12°C). $DT_{50\ modelling}$ values amounted to 31.1 days (loam), 34.5 days (sandy loam), and 88.7 days (sandy clay loam) at test temperature. This corresponds to 88.0 days, 97.6 days, and 251.0 days respectively, when standardized to 12°C. Since only three DT_{50} values are available, persistence of the cis-isomers of d-allethrin was evaluated based on the worst-case $DT_{50modelling}$ of 251 days, **leading to the conclusion that the cis-isomer of d-allethrin is very persistent in soil.**

In summary, it has to be concluded that d-allethrin fulfils the vP criterion since

- d-trans-allethrin is considered to fulfil the P criterion in the aquatic compartment and soil
- d-cis-allethrin fulfills the vP criterion in soil and
- both isomers are contained in d-allethrin in relevant fractions.

Metabolites
According to the Guidance on the BPR, Volume IV, Part A, Version 1.1 (November 2014), environmental risk assessment needs to be performed for all major metabolites, e.g. metabolites formed in amounts of ≥ 10% of the active substance at any time of the degradation studies, or appearing at two consecutive sampling points at amounts ≥ 5%, or accounting for ≥ 5% of the active substance at the final time point while the maximum of formation is not yet reached.
Four relevant metabolites have been identified in water-sediment and soil simulation studies: dl-ALON, d-c/t-CRA, t-COOH-CA, and ωt-COOH-d-t-allethrin.

Metabolite dl-ALON (allethrolone, 4-hydroxy-3-methyl-2-prop-2-enylcyclopent-2-en-1-one) – CAS-Nr. 29605-88-7
QSAR calculations on ready biodegradability were done for the metabolite dl-ALON, which was detected at levels between 6.4 % and 36.5 % AR in the soil simulation studies conducted with d-trans-allethrin, when the ^{14}C label is contained in the alcohol moiety of the molecule. Calculation of ready biodegradability of dl-ALON using BioWin v4.10 results in a probability for fast biodegradation of 0.8194 (biodegrades fast) for BioWin 2 and 3.0003 (weeks) for BioWin 3, as well as 0.6482 (readily biodegradable) for BioWin 6. Calculation with EPISuite resulted in a water solubility of 7126.4 mg/L and a Koc of 21.05 L/kg, indicating that dl-ALON is highly bioavailable under the expected concentrations.
According to REACH legislation (Guidance on information requirements and chemical safety assessment, Chapter R.11: PBT/vPvB Assessment, Version 3.0, 2017) dl-ALON cannot be considered to be persistent based on these calculations.
dl-ALON does not fulfil the (v)P criterion.

Metabolite d-c/t-CRA ((1RS)-cis/trans-chrysantemic acid) - CAS-Nr. 4638-92-0
Calculation of ready biodegradability of d-c/t-CRA using BioWin v4.10 results in a probability for fast biodegradation of 0.3869 (does not biodegrade fast) for BioWin 2 and 2.9799 (weeks) for BioWin 3, as well as 0.2788 (not readily biodegradable) for BioWin 6. According to REACH legislation (Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT/vPvB Assessment, Version 3.0, 2017) conclusion on persistency of d-c/t-CRA is not possible based on these calculations only as the results of the BioWin models do not comply. As the results of the BioWin calculations are not unambiguous further indications on biodegradability of d-c/t-CRA are necessary to conclude on its persistency.
The metabolite d-c/t-CRA was detected in two water-sediment simulation studies conducted with [^{14}C]-d-allethrin, and [cyclopropyl-1-^{14}C]-d-trans-prallethrin as well as to minor amounts (max. of 9.3 % at day 122) in the soil simulation study using [acid-^{14}C]-d-trans-allethrin. In the soil simulation study d-t-CRA was detected at two consecutive sampling points with > 5% (system I: 5.6% at day14, and 6.2% at day 30; system II: 5.8% at day 61, 6.2% at day 92, and 9.3% at day 122) decreasing thereafter to 2.7% in system I, and to 3.3% in system II after 6 months. In the water-sediment study with [^{14}C]-d-allethrin, the metabolite reached its maximum at day

14 in both, water (21.7 % AR) and sediment (15.0 % AR) of the Calwich Abbey system. In the Swiss Lake, d-c/t-CRA increased up to 12.4 % AR in the water layer, and up to 5.3 % AR in the sediment at day 30. Thereafter, the metabolite disappeared almost completely from each compartiment until the end of the study, corresponding to a loss of 95% within 47 days (Calwich Abbey) and 97% within 70 days (Swiss Lake) for the total system. Taking into account a conservative DT_{90} of 70 days (considering the dissipation of 97% between day 30 and 100 in the Swiss Lake System) a conservative SFO-DT_{50} can be calculated backward by dividing the DT_{90} by 3.32, resulting in a half-life of 21.1 days at test temperature, which corresponds to 39.8 days at 12°C.
At WG-II-17 it was discussed and agreed to harmonize biodegradation endpoints of pyrethroid metabolites, using data from studies performed on d-allethrin (SUMITOMO, eCA DE), cyphenothrin (SUMITOMO, eCA EL), and imiprothrin (SUMITOMO, eCA UK). For the whole isomeric mixture it was concluded that the worst case value of 52.9 days (at 12 °C) for d-c-CRA should be compared to the freshwater trigger, taking into account the high water solubility of 1016.8 mg/L and a Koc of 121.9 L/kg (EPISuite).(EPISuite). This value was derived from a water/sediment study,, submitted in support of cyphenothrin to the EL CA. Thus, as finally agreed at BPC 35 (June 2020), **the P-criterion is fulfilled for d-c-CRA.** The worst-case DT50 of 35.8 d (12°C), derived for d-t-CRA from the same study, however, does not exceed the freshwater trigger. Based on this, **d-t-CRA does not fulfil the P-criterion.**

Metabolite t-COOH-CA ((1R, 3R)-2,2-dimethyl-3-carboxycyclopropanecarboxylic acid) - CAS-Nr. 1701-82-2
Calculation of ready biodegradability of t-COOH-CA using BioWin v4.10 results in a probability for fast biodegradation of 0.5808 (biodegrades fast) for BioWin 2 and 3.3668 (days - weeks) for BioWin 3, as well as 0.6006 (readily degradable) for BioWin 6. According to REACH legislation (Guidance on information requirements and chemical safety assessment, Chapter R.11: PBT/vPvB Assessment, Version 3.0, 2017) t-COOH-CA cannot be considered to be persistent based on these calculations.
In the laboratory study on aerobic biodegradation of [acid-^{14}C]-d-trans-allethrin in soil the metabolite t-COOH-CA was detected with a maximum amount of 30 % AR at day 61 and of 35.1 % AR at day 91 in System I and II, respectively. In the water-sediment studies (DocIIIA7.1.2.2.2_01 and _02), conducted on [^{14}C]-d-allethrin and [cyclopropyl-1-^{14}C]-d-trans-prallethrin, the maximum concentrations varied between 8.6 % AR (day 30) in the sediment and 34.3 % AR (day 100) in the water layer.
The rate of aerobic degradation of t-COOH-CA in soil was investigated in a laboratory study according to OECD 307 in three soils (2 loam soils, 1 sandy clay loam soil) using labelled test substance. Taking into account the available DT_{50} values (12°C) between 3.6 days and 10.1 days, the metabolite t-COOH-CA has to be considered as not persistent in soil systems.
However, following discussions at WG-II-17 it was agreed that a worst case total system value of 101 days at 12 °C could be used for the aquatic compartment based on a water/sediment study submitted in support of cyphenothrin to the EL CA. Calculation with EPISuite implies that t-COOH-CA is highly water soluble (34012 mg/L) and highly mobile (Koc 33.3 L/kg estimated from MCI). As finally agreed at BPC 35 (June 2020), the DT_{50} of 101 days (12°C) is compared to the freshwater trigger, resulting in the conclusion that **the (v)P criterion is fulfilled for the major metabolite t-COOH-CA.**

Metabolite ωt-COOH-d-t-allethrin
In a strict sense, ωt-COOH-d-t-allethrin is not a metabolite but a transformation product of d-allethrin, whereas the methyl group of the 2-methylprop-1-enyl substructure is probably enzymatically oxidized to the respective carboxylic acid. ωt-COOH-d-t-allethrin was detected in a water-sediment simulation study conducted with [^{14}C]-d-allethrin as well as in soil simulation studies.
Calculation of ready biodegradability of ωt-COOH-d-t-allethrin using BioWin v4.10 results in a probability for fast biodegradation of 0.6974 (biodegrades fast) for BioWin 2 and 2.7348 (weeks-months) for BioWin 3, as well as 0.1434 (not readily biodegradable) for BioWin 6.
According to REACH legislation (Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT/vPvB Assessment, Version 3.0, 2017) ωt-COOH-d-t-allethrin has to be considered as persistent based on these calculations due to the results of the BioWin

models 3 and 6. This result is supported by the finding that solubiltiy of ωt-COOH-d-t-allethrin in water is rather low (but far above the expected environmental concentrations).
Phys.-chem. properties and biodegradation data estimated by QSAR imply that ωt-COOH-d-t-allethrin differs from d-allethrin regarding adsorption potential and water solubility whereas degradation behavior (abiotic & biotic) is predicted to be highly comparable.
The eCA has recalculated half-lifes for ωt-COOH-d-t-allethrin from data of the water-sediment study (DocIIIA7.1.2.2.2_01) by modelling both, parent and transformation product simultaneously. The eCA confirms the results, which have been presented by SUMITOMO for discussion at WG-II-17 ($DT_{50trigger\text{-}total\ system}$ 9.3 d at 12°C for Calwich Abbey and 39.4 d at 12°C for Swiss Lake). The low Koc along with the high water solubility and the observation that ωt-COOH-d-t-allethrin was found mainly in the water phase supports a comparison with the freshwater-trigger, whereupon a substance is classified as persistent with a half-life of >40 days. Considering the $DT_{50\text{-}total\ system}$ of 39.4 d at 12°C derived for the Swiss Lake system, the trigger is almost passed.
In the light of the uncertainties related to the recovery and the possibility that hydrolysis significantly contributed to degradation in the water-sediment system, the calculated half-lives of ωt-COOH-d-t-allethrin might be as unrealistically low as for d-allethrin. In the light of mentioned above, participants of the WG-III-2017 Ad-hoc follow-up to Item 6.3/6.4 (Point 2 and 3: Bioaccumulation and Persistence) agreed that the available data is not sufficient to definitively conclude on the persistency of the metabolite ωt-COOH-d-t-allethrin.
Therefore, ωt-COOH-d-t-allethrin is regarded to potentially fulfil the P-criterion.

(v)B Assessment
B criterion: BCF > 2000
vB criterion: BCF > 5000

Based on an experimental study conducted with the almost chemical identical substance d-trans-prallethrin, a growth-corrected kinetic BCF_{KgL} value of **1314** $L*kg_{wet\ fish}^{-1}$ was obtained.
Therefore, the (v)B criterion is not fulfilled for d-allethrin.

Metabolites
For prediction of the bioaccumulation behaviour of the relevant metabolites built in water/sediment systems, soil and by hydrolysis/photolysis, the BCF_{fish} was calculated using the software BCFBAF v3.01. Taking the calculated BCF_{fish} values between 2.51 - 3.16 $L*kg_{wet\ fish}^{-1}$ into account, the aquatic bioaccumulation potential of the major metabolites can be classified as rather low.
There is no evidence for the relevant metabolites fulfilling the B criterion.

T Assessment
The T criterion is fulfilled, if a NOEC < 0.01 mg/L is derived. A long-term toxicity study with *Daphnia magna* was provided for esbiothrin by the applicant Sumitomo resulting in a NOEC of 2.7 µg/L. As read-across from esbiothrin to d-allethrin is , the T criterion is also fulfilled for d-allethrin.
In addition, the effect values from the available short-term studies for d-allethrin also show the fulfilment of the T criterion. The lowest aquatic acute endpoint of 6.1 µg/L determined for *Daphnia magna* is already lower than the threshold for fulfilling the T criterion (NOEC < 0.01 mg/L).
Therefore, the T criterion is fulfilled for d-allethrin.

Metabolites
Acute aquatic toxicity studies are available for the relevant degradation products d-c/t-CRA and t-COOH-CA.
The following endpoints were obtained for **t-COOH-CA**: 96-h LC_{50} for fish > 94 mg/L, 48-h EC_{50} for daphnia > 92 mg/L and 96-h ErC_{50} for algae was 75 mg/L (cf. final CAR for epsilon-momfluorothrin, May 2016). For the metabolite **d-t-CRA** the concluded endpoints are as follows: 96-h LC_{50} for fish > 1.9 mg/L, 48-h EC_{50} for Daphnia > 1.8 mg/L and 96-h ErC_{50} for

algae > 1.6 mg/L (cf. CAR for empenthrin, November 2017). The acute toxicity of the metabolites d-c/t-CRA and t-COOH-CA is relatively low. The T criterion is considered as not fulfilled.
Furthermore, for all metabolites QSAR estimation was used to predict the toxicity to fish, invertebrates and algae using the software ECOSAR. The lowest calculated E(L)C_{50} for **dl-ALON** is 218 mg/L, which is below the trigger value. Regarding **ωt-COOH-d-t-allethrin**, the lowest QSAR estimated EC_{50} is 0.08 mg/L (Daphnia) indicating that this metabolite may be toxic to aquatic organisms, but the T criterion is not fulfilled.
It could be concluded that the **T criterion is not fulfilled** for the above mentioned metabolites.

Conclusion on the PBT assessment
The vP as well as the T criterion is **fulfilled.** Therefore, based on the available data, the active substance d-allethrin **fulfils two of three PBT criteria** and has to be considered as **Candidate for Substitution.**

Metabolites:
It has to be assumed that the vP-criterion is fulfilledfor the major metabolite t-COOH-CA and the P criterion for the metabolite d-c-CRA. The P-criterion is potentially fulfilled for ωt-COOH-d-t-allethrin. The B and T criterion is not fulfilled for all relevant metabolites. Therefore, it could be reasoned that the degradation products do **not meet the PBT criteria**.

2.2.3. Assessment of endocrine disruptor properties

No specific tests for potential endocrine disruption were carried out. Therefore only an initial assessment of endocrine disrupting properties was performed for the active substance d-allethrin on the basis of the data available to the eCA:

- d-allethrin is not included on the European Commission's strategy priority list of substances for further evaluation.
- d-allethrin does not meet the transitional criterion for Endocrine Disruptors of Regulation (EU) No 528/2012. The criterion for classification as carcinogen category 2 is not fulfilled, but the criterion as toxic for reproduction category 2 is met (see "Classification and Labelling").

In conclusion, at the moment there exists no indication that d-allethrin exhibit endocrine disrupting properties.
Therefore, the active substance shall **not be considered as having endocrine-disrupting properties**.

2.3. Overall conclusions

The outcome of the assessment for d-Allethrin in product-type 18 is specified in the BPC opinion following discussions at the 40th 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.

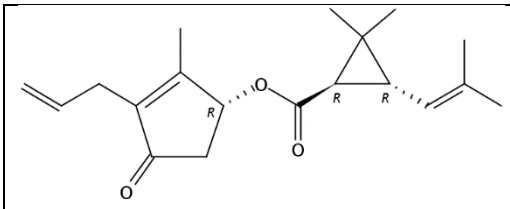
Appendix I: List of endpoints

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

Active substance	d-Allethrin
Product-type	18

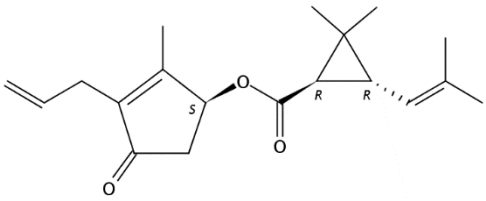
Identity

Chemical name (IUPAC)	(RS)-3-allyl-2-methyl-4-oxocyclopent-2-enyl-(1R,3R;1R,3S)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate
Chemical name (CA)	Cyclopropanecarboxylic acid, 2,2-dimethyl-3-(2-methyl-1-propen-1-yl)- ,2-methyl-4-oxo-3-(2-propen-1-yl)-2-cyclopenten-1-yl ester, (1R) -
CAS No	231937-89-6
EC No	-
Other substance No.	CIPAC: 742
Minimum purity of the active substance as manufactured (g/kg or g/l)	900 g/kg (four main isomers)
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	- Chrysanthemic anhydride; CAS-No.: 14297-82-6 - Allethrolone homologue n. 2; CAS-No.: 54363-26-7 - Allethrin homologue n. 2 CAS-No.: 54363-26-7 - Allethrin Structural Isomer n.4 (1RS)-2-methyl-3-(prop-2-en-1-yl)-4-oxocyclopent-2-en-1-yl-(1R,3R)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate - Dimer of allethrolone n. 1 - Dimer of allethrolone n. 2 - Dimer of allethrolone n. 3 - Dimethylformamide (DMF); CAS-No.: 68-12-2
Molecular formula	$C_{19}H_{26}O_3$
Molecular mass	302.41 g/mol
Structural formula	Isomer 1: 1R trans; R or (1R; 1R, 3R): CAS No. 61009-26-5

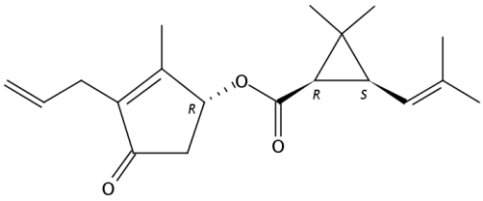


Isomer 2: 1R trans; S or (1S; 1R, 3R):

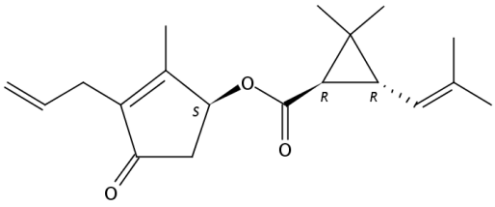
CAS No. 28434-00-6



Isomer 3: 1R cis; R or (1R; 1R, 3S):
CAS No. 61009-23-2



Isomer 4: 1R cis; S or (1S; 1R, 3S):
CAS No. 61046-09-1



Physical and chemical properties

Melting point (state purity)	<-50°C (223 K) (99.5% related to mixture of 8 isomers, Sumitomo) < -50° C, atmospheric pressure (99.1% related to mixture of 8 isomers, Endura)
Boiling point (state purity)	281.5°C (1013 hPa) (> 90% related to mixture of 8 isomers, Sumitomo) no boiling point (99.1% related to mixture of 8 isomers, Endura)
Thermal stability / Temperature of decomposition	Decomposition phenomena at 120°C and 230°C. (99.1% related to mixture of 8 isomers, Endura)

Appearance (state purity)	Yellow to yellow-brown liquid (technical grade AS, Sumitomo and 99.1% related to mixture of 8 isomers, Endura)
Relative density (state purity)	1.01 ± 0.00112 (20°C) (99.5% related to mixture of 8 isomers, Sumitomo) 1.0078 (20°C) 0.9948 (40°C) 98.6) 0.9948 (40°C) (98.6%, Endura)
Surface tension (state temperature and concentration of the test solution)	50...9 mN/m at 20,4 °C (c= *9090% of a saturated Solution*) (99.5%, Sumitomo) 48.3 mN/m at 20° C (c= *90% of a saturated Solution*) (96.8%, Endura)
Vapour pressure (in Pa, state temperature)	5.95×10^{-4} Pa at 20°C 1.32×10^{-3} Pa at 25°C (99.5% related to mixture of 8 isomers, Sumitomo) $< 0.14 \times 10^{-4}$ Pa at 25° C $< 0.30 \times 10^{-4}$ Pa at 40° C (99.1% related to mixture of 8 isomers, Endura)
Henry's law constant (Pa m^3 mol^{-1})	0.069 (Pa·m^3/mol) (calculated, Sumitomo) 1.63×10^{-3} (Pa·m^3/mol) (calculated, Endura)
Solubility in water (g/l or mg/l, state temperature)	<u>pH 5 buffer</u> 20°C: 2.60 ± 0.375 mg/L 10°C: 2.12 ± 0.257 mg/L <u>pH 7 buffer</u> 20°C: 4.39 ± 0.120 mg/L 10°C: 3.89 ± 0.236 mg/ <u>pH 9 buffer:</u> 20°C: 3.30 ± 0.182 mg/L 10°C: 2.11 ± 0.248 mg/L <u>Water</u> 20°C: 2.62 ± 0.318 mg/L 10°C: 3.46 ± 0.494 mg/L (99.5% related to mixture of 8 isomers, Sumitomo) 20°C: 2,585 mg/L (99.1% related to mixture of 8 isomers, Endura)
Solubility in organic solvents (in g/l or mg/l, state temperature)	n-hexane: > 1 kg/L at 25° C methanol: > 1 kg/L at 25° C (99.1% related to mixture of 8 isomers, Endura)
Stability in organic solvents used in biocidal products including relevant breakdown products	Not required since d-Allethrin as manufactured does not include organic solvent. (Sumitomo and Endura)
Partition coefficient (log P_{OW}) (state temperature)	4.95 temperature: 25±1°C pH: 5.83-5.96 (99.5% related to mixture of 8 isomers, Sumitomo) 4.88 at 25°C (98.6%, Endura)

Dissociation constant	d-Allethrin is a covalent, organic molecule that does not dissociate into ionic species. (Sumitomo) It cannot be determined since d-Allethrin has no acidic or basic properties in water in the range pH 4 to 9. (Endura)
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	No absorption maximas > 290 nm (Sumitomo) 1000 µg/mL in methanol : 304 nm : 75.7 L/mol*cm 307 nm: 76.6 L/mol*cm 1000 µg/mL 10% 1 N HCl solution in aqueous solution : 304 nm : 72.6 L/mol*cm 307 nm : 73.2 L/mol*cm 1000 µg/mL 10% 1 N NaOH solution in aqueous solution 304 nm: 85.6 L/mol*cm 307 nm : 85.4 L/mol*cm (99.1% related to mixture of 8 isomers, Endura)
Flammability or flash point	Flash point: >110°C (Sumitomo) Flash point: 138°C (Endura) Flammability: 311°C (Endura)
Explosive properties	The chemical structure of d-allethrin does not contain any chemical groups with explosive properties. (Sumitomo) Not explosive (Endura)
Oxidising properties	Not determined as there are no functional groups which are capable of exhibiting oxidative capacity. (Sumitomo, Endura)
Auto-ignition or relative self ignition temperature	322 ± 8°C for a 0.25 mL sample at 100.52 kPa (Sumitomo)

Classification and proposed labelling

with regard to physical hazards	-
with regard to human health hazards	**Acute Tox. 3**, H301 Toxic if swallowed **Acute Tox. 4**, H332 Harmful if inhaled **STOT-SE 1**, H370 Causes damage to the nervous system after oral and inhalation exposure **STOT-RE 2**, H373 May cause damage to the skin through prolonged or repeated exposure. **Repr.2**, H361d Suspected of damaging the unborn child
with regard to environmental hazards	**Aquatic Acute 1**, H400 Very toxic to aquatic life; M=100 **Aquatic Chronic 1**, H410 Very toxic to aquatic life with long lasting effects; M=100

Chapter 2:Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	**Sumitomo**: The active substance d-Allethrin is determined with GC-FID methods. The determination of the optical isomer ratio was done by liquid chromatography with UV detection at 230nm. **Endura:** The active substance d-Allethrin is determined with GC-FID methods. A two-dimensional achiral/chiral HPLC method with circular dichroism (CD) detection was optimized for the stereochemical resolution and determination of the elution order of the eight stereoisomers of synthetic Allethrin.
Impurities in technical active substance (principle of method)	**Sumitomo**: The impurities were determined with two GC-FID methods which have been validated in terms of recovery and precision. No GC-MS is provided. **Endura**: The identification of impurities in d-Allethrin was performed by means of capillary gas chromatography coupled with a Mass Spectrometer (GC-MS).

Analytical methods for residues

Soil (principle of method and LOQ)	Residue definition: d-allethrin (sum of the isomers) Sumitomo: data gap Endura: data gap
Air (principle of method and LOQ)	Residue definition: d-allethrin (sum of the isomers) Endura: GC-ECD, LOQ 0.62 µg/m³; confirmation included by GC-MS Sumitomo: GC-MS, LOQ 1.5 µg/m³; confirmation insufficient Note: LOQ > limit calculated using the AEL based on TTC for genotoxic substances. Data gap in case of classification as Muta.2
Water (principle of method and LOQ)	Drinking water: residue definition: d-allethrin (sum of the isomers) Sumitomo: data gap Endura: data gap Surface water: residue definition: d-allethrin (sum of the isomers) Sumitomo: data gap Endura: data gap

Body fluids and tissues (principle of method and LOQ)	Not required since not classified as toxic or very toxic additional method for blood: GC-MS, LOQ: 1 µg/L d-allethrin (sum of the isomers), confirmatory method in blood required in case of classification as "acute toxic cat. 3 primary and confirmatory method for d-allethrin (sum of the isomers) in tissues required in case of classification as acute toxic cat. 3
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	No relevant residues expected
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	No relevant residues expected

Chapter 3:Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	60 % based on excretion in urine and metabolite excretion in faeces (some metabolites are considered to result from hepatic metabolism) biliary excretion not investigated (esbiothrin)
Rate and extent of dermal absorption:	Sumitomo: 25 % (10 hours, S-bioallethrin), Conc. of a.s. in vehicle (Isopar M): 0.06, 0.5, 2.0 % w/v (value was agreed at the BPC-WG HH III (2017) Endura: 25/75 % default values according to the EFSA Guidance on Dermal Absorption (2012) At product authorisation stage, formulation specific information would have to be submitted or a re-evaluation of the dermal absorption data in accordance with current EFSA Guidance on Dermal Absorption will be required.
Distribution:	Widely distributed; highest residues in liver, fat, blood, and kidney (0.3 % total residues at day 7) (esbiothrin)
Potential for accumulation:	No evidence for accumulation (esbiothrin)

Rate and extent of excretion:	> 50 % in 24 hours, >90 % within 3 days, via urine: 26-50 % via faeces: 50-71 % (esbiothrin)
Toxicologically significant metabolite(s)	Extensive metabolism, involving ester hydrolysis, epoxidation, epoxide hydrolysis, hydroxylation and conjugation reactions, > 15 metabolites; unmetabolised parent : 3-40 % of dose (esbiothrin) Mutagenic photodecomposition products: epoxide of cyclopropyl allethrin for S-bioallethrin and allethronyl glyoxylate monohydrate for allethrin

Acute toxicity

Rat LD_{50} oral	Oral LD_{50}, mouse, M: 96 mg/kg (esbiothrin, PEG 200) **Acute Tox. 3; H301** Oral LD_{50}, rat, F: 310 mg/kg (d-allethrin, aqueous susp., 10 % Tween-80)
Rat LD_{50} dermal	Dermal LD_{50} rat, M/F: > 2000 mg/kg bw (esbiothrin & d-allethrin non-diluted)
Rat LC_{50} inhalation	Inhalative LC_{50} mouse, M: 1.56 mg/L (d-allethrin,deo-dorised kerosene) This value corresponds to LC_{50} (4h estimate) = 1.17 mg/L **Acute Tox. 4; H332** Inhalative LC_{50} rat, M/F: 1.65 mg/L (d-allethrin, deo-dorised kerosene) This value corresponds to LC_{50} (4h estimate) = 1.24 mg/L

Skin corrosion/irritation	Not irritating (rabbit; d-allethrin & esbiothrin)
Eye irritation	Not irritating (rabbit; d-allethrin & esbiothrin)
Respiratory tract irritation	Conclusive but not sufficient for classification
Skin sensitisation (test method used and result)	Not sensitizing (guinea pig; GPMT, d-allethrin & esbiothrin)
Respiratory sensitisation (test method used and result)	Data lacking

Repeated dose toxicity

Short term

Species / target / critical effect	Rabbit (d-allethrin, dermal): systemic: reduced bw gain, clinical chemistry, haematology local (skin): acanthosis, erythema, inflammation **STOT RE 2; H373**
Relevant oral NOAEL / LOAEL	Data lacking
Relevant dermal NOAEL / LOAEL	21-d rabbit (d-allethrin): systemic: 30/300 mg/kg bw/d dermal: 0.03/0.1 mg/cm^2 (3/10 mg/kg bw/d)
Relevant inhalation NOAEL / LOAEL	Data lacking

Subchronic

Species/ target / critical effect	Rat (d-allethrin, oral & inhalative, S-Bioallethrin, oral): hepatotoxicity and neurotoxicity Dog (esbiothrin, bioallethrin, oral, dietary): hepatotoxicity Dog (d-allethrin, oral, capsule): neurotoxicity
Relevant oral NOAEL / LOAEL	NOAEL/LOAEL for liver effects = 6/36 mg/kg bw/d (Bioallethrin, 26-week study, dog) based on liver toxicity NOAEL for neurotoxic effects = 36/162 mg/kg bw/d
Relevant dermal NOAEL / LOAEL	Data lacking
Relevant inhalation NOAEL / LOAEL	90-d rat (d-allethrin): systemic: 0.050/0.310 mg/L (NOAEL =11.4 mg/kg bw/d) based on liver effects and neurotoxicity local: 0.014/0.050 mg/L (NOAEL =3.3 mg/kg bw/d) based on eye and body surface changes

Long term

Species/ target / critical effect	Rat, mouse (esbiothrin; d-allethrin)
Relevant oral NOAEL / LOAEL	123-wk rat: 6/25 mg/kg bw/d (d-allethrin)
Relevant dermal NOAEL / LOAEL	Data lacking
Relevant inhalation NOAEL / LOAEL	Data lacking

Genotoxicity[1]	CA and MN induction in mice (allethrin)[2] Support by MN induction *in vitro* (allethrin)

[2] Remark regarding study by Srivastava, 2012 (key study for in vivo genotoxicity):
After the BPC WG discussion, the article has been retracted at the request of the Editor-in-Chief. However, the retraction of this article remains without impact on risk assessment or the proposal for classification and labelling.

Carcinogenicity

Species/type of tumour	Rat, mouse: no substance-related tumours (esbiothrin; d-allethrin)
Chronic NOAEL	123-wk rat: 6 mg/kg bw/d (d-allethrin)
Relevant long-term oral NOAEL	123-wk rat: 6 mg/kg bw/d (d-allethrin)
Relevant carcinogenic NOAEL/LOAEL (rat, mouse)	123-wk rat: NOAEL = 102/121 mg/kg bw/d (highest dose tested, d-allethrin) 102/81-wk mouse: NOAEL = 214/350 mg/kg bw/d (highest dose tested, esbiothrin/d-allethrin)

Reproductive toxicity

Developmental toxicity

Species/ Developmental target / critical effect	Rat (esbiothrin, d-allethrin): maternal: reduced bw gain, tremor, hypersensitivity, salivation, 4/20 deaths developmental: no findings Rabbit (d-allethrin): maternal: body weight loss, reduced feed consumption, gastric lesions, 1/20 does: tremor, convulsions, death developmental: vertebrae and rib malformations **Repr. 2; H361d**
Relevant maternal NOAEL	Rat: 30 mg/kg bw/d (d-allethrin) Rat: 25 mgkg bw/d (esbiothrin) Rabbit: 100 mg/kg bw/d (d-allethrin, esbiothrin)
Relevant developmental NOAEL	Rat: 100 mg/kg bw/d (d-allethrin) Rabbit: 100 mg/kg bw/d (d-allethrin)

Fertility

Species/critical effect	Rat (d-allethrin): parental: reduced body weight gain, liver toxicity reproductive: no findings offspring: reduced birth weight, reduced bw gain, hepatocellular hypertrophy
Relevant parental NOAEL	9 mg/kg bw/d (d-allethrin)
Relevant offspring NOAEL	170 mg/kg bw/d (d-allethrin, maternal intake during lactation)
Relevant fertility NOAEL	387 mg/kg bw/d (d-allethrin)

Neurotoxicity

Species/ target/critical effect	Acute neurotoxicity rat (S-bioallethrin): females: hunched posture, tremor, reduced activity, gait abnormalities, decrease in grip strength (hindlimbs) 90-d neurotox rat (S-bioallethrin): no neurotoxic effects observed (not reliable) **STOT SE 1; H370**
Relevant neurotoxicity NOAEL(s)	NOAEL 30 mg/kg bw (acute neurotox rat, S-bioallethrin) The LOAEL of 90 mg/kg bw is lower than the rat oral LD_{50} value (310 mg/kg bw).

Developmental Neurotoxicity

Species/ target/critical effect	Data lacking

Immunotoxicity

Species/ target/critical effect	Data lacking

Developmental Immunotoxicity

Species/ target/critical effect	Data lacking

Medical data

Review on Medical Examination of Factory Workers (Sumitomo)	No findings attributable to pyrethroid exposure.
Health Monitoring of Human Volunteers exposed to esbiothrin 2.6 % LED (Sumitomo)	No findings attributable to esbiothrin exposure.
Medical surveillance data on manufacturing plant personnel (Endura).	No findings attributable to d-trans-allethrin exposure.

Summary

Initially, eCA proposed classification for Muta. 2 (H341). A discussion on the mutagenic potential of d-allethrin based on all available data took place at the BPC WG (V) 2018. It was finally concluded by the majority of the WG that the database is not convincing enough to consider d-allethrin as mutagenic.

The listed reference values were agreed in the BPC WG HH III (2017) and apply.

	Value	Study	Safety factor
AEL_{acute}[1), 43)]	0.06 mg/kg bw	acute neurotoxicity study	300

	(oral absorption 60 %)	rat, acute effects	
$AEL_{medium-term}$[1)]	0.04 mg/kg bw (oral absorption 60 %)	6-mo dog, dietary	100
$AEL_{long-term}$[1)]	0.04 mg/kg bw (oral absorption 60 %)	123-wk rat	100
NOAEC local effects (dermal)	0.15 %	21-d rabbit, dermal	n.a.
ADI (if residues in food or feed)[2)]	0.06 mg/kg bw	123-wk rat	100
ARfD (if residues in food or feed)[2), 43)]	0.1 mg/kg bw	acute neurotoxicity study rats, acute effects	300

[1)] AEL: Systemic (= Internal) Acceptable Exposure Level

[22] Not expected from the applied uses, but cannot be excluded with certainty for further applications under PT 18.

[43)] The eCA proposed to base the $AEL_{short-term}$ on acute neurotoxicity effects observed in the 1-year dog study (Dalgard 1989). However, in the BPC-WG HH 2017 it was decided to base the reference values for acute effects ($AEL_{short-term}$ and ARfD) on the rat acute neurotoxicity study (Broadmeadow 1997). In an ad hoc-follow-up on DNT it was decided to apply an additional assessment factor of 3 for the uncertainties regarding DNT.

[54)] The eCA proposed an $AEC_{medium-term}$ for dermal effects observed in the 21-d rabbit study. However, it was decided in the BPC WG HH 2017 to apply a NOAEC (%) instead.

Photometabolites

In an ad hoc follow-up in July 2019 it was agreed that the photometabolites epoxide and allethronyl glyoxylate monohydrate should be considered mutagenic. The members of the WG further supported the proposed TTC approach applying the value of 2.5 x 10^{-6} mg/kg bw/day for the risk assessment of photometabolites.

The following TTC values should be used for all reference values:

	Value	**Study**	**Safety factor**
AEL_{acute}[1)] $AEL_{medium-term}$[1)] $AEL_{long-term}$[1)] ADI (if residues in food or feed)[2)] ARfD (if residues in	0.0000025 mg/kg bw/d	TTC for genotocic substances (0.15 µg/d, 60 kg bw)	n.a.

food or fffeed)[2)]			

[1)] AEL: Systemic (= Internal) Acceptable Exposure Level
[2)] Not expected from the applied uses, but cannot be excluded with certainty for further applications under PT 18.

MRLs

Relevant commodities	No relevant residues expected (as use in food preparation or storage areas is excluded)

Reference value for groundwater

According to BPR Annex VI, point 68	-

Dermal absorption

Study (*in vitro/vivo*), species tested	Data lacking (see information on a.s.)
Formulation (formulation type and including concentration(s) tested, vehicle)	Data lacking (see information on a.s.)
Dermal absorption values used in risk assessment	Data lacking (see information on a.s.)

Acceptable exposure scenarios (including method of calculation)

Formulation of biocidal product	Not assessed by the rapporteur under the requirements of the BPD.
Intended uses	Duracide A (7.7 % d-Allethrin) Duracide A-EC (6.8 % d-Allethrin) Spraying solvent based Duracide A (0.12 % d-Allethrin) ULV application solvent based Duracide A (0.385 % d-Allethrin) Fogging solvent based Duracide A (0.12 % d-Allethrin) Spraying, ULV application, and Fogging water based Duracide A-EC (0.14 % d-Allethrin)
Industrial users	-

Professional users Spraying of water based Duracide A-EC (scenario 1) Spraying of solvent based emulsion Duracide A (scenario 2) ULV application of solvent based Duracide A (scenario 3) ULV application of water based Duracide A-EC (scenario (scenario 4) Fogging of solvent based Duracide A (scenario 5) Fogging of water based Duracide A-EC (scenario 6)	All scenarios acceptable in Tier 2 (with PPE) Exposure calculation according Biocides Human health Exposure Methodology, 2015, BPC Ad hoc Working Group on Human Exposure (HEAdhoc) - Recommendation no. 6 - Human Exposure Methods and models to assess exposure to biocidal products in different product types Version 4, 2020, and Human Exposure Expert Group (HEEG) opinion No. 1 - on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale - Agreed at TM I2008.
Secondary exposure	Secondary exposure to allethrin **(scenario 7)** Secondary exposure to photometabolites **(scenario 8**)
Non professional users	No acceptable use identified due to exposure to genotoxic photometabolites
Exposure via residue in food	No acceptable use identified for non-professional use. For professional use no dietary risk assessment has been performed for active substance authorization as currently no guidance document is publicly available.

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)	ENDURA: **d-allethrin:** pH 4 (50°C): stable pH 7 (50°C): stable pH 9 (50°C): stable SUMITOMO: **bioallethrin** pH 5 (25°C): stable pH 7 (25°C): stable pH 9 (25°C): DT_{50} 4.3 d / calculation to reflect EU outdoor temperature of 12°C: 12.2
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	SUMITOMO **d-trans-allethrin/esbiothrin:** Photolysis in aqueous media**:** Degradation rate: 0.0142 d^{-1} DT_{50} : 48.8 h for a California (USA) winter day **Metabolites:** dl-ALON (allethrolone): 9.75 % after 120 hours dihydroxy-allethrolone: 34.85 % after 120 hours
Readily biodegradable (yes/no)	Not readily biodegradable
Inherent biodegradable (yes/no)	-
Biodegradation in freshwater	-
Biodegradation in seawater	No exposure
Non-extractable residues (water / sediment systems)	SUMITOMO **[cyclopropyl-1-^{14}C]-d-allethrin:** max. 22.8% of applied radioactivity after 61 days **[cyclopropyl-1-^{14}C]-d-trans-prallethrin:** 15.2% of applied radioactivity after 91 days

Distribution in water / sediment systems (active substance)	**Degradation and dissipation half-lifes given at test-temperature correspond to trigger-values. Values at 12°C represent modelling half-lifes.** SUMITOMO **[cyclopropyl-1-^{14}C]-d- allethrin:** Calwich Abbey (system I) *d-trans-allethrin:* Total System: DT_{50} = 4.0 d (20°C), 7.6 d (12°C) Water Layer: $DissT_{50}$ = 1.8 d (20°C), 3.4 d (12°C) *d-cis-allethrin:* Total System: DT_{50} = 27.0 d (20°C), 70.7 d (12°C) Water Layer: $DissT_{50}$ = 2.2 d (20°C), 9.5 d (12°C) *d-c/t-allethrin*:* Total System: DT_{50} = 5.1 d (20°C), 14.8 d (12°C) Water Layer: $DissT_{50}$ = 1.8 d (20°C), 4.2 d (12°C) Sediment: $DissT_{50}$ = 14.3 d (20°C), 27.1 d (12°C) Mineralization: 33.4% (day 61) residues of a. s. (% of applied): Water layer: 64.6%-0% (day 0-day 30) Sediment: max 30.3%-1.7% (day 2-day 61) Swiss Lake (system II) *d-trans-allethrin:* Total System: DT_{50} = 3.7 d (20°C), 7.1 d (12°C) Water Layer: $DissT_{50}$ = 2.8 d (20°C), 5.3 d (12°C) *d-cis-allethrin:* Total System: DT_{50} = 35.0 d (20°C), 66.4 d (12°C) Water Layer: $DissT_{50}$ = 5.4 d (20°C), 17.3 d (12°C) *d-c/t-allethrin*:* Total System: DT_{50} = 4.6 d (20°C), 13.8 d (12°C) Water Layer: $DissT_{50}$ = 3.2 d (20°C), 6.1 d (12°C) Sediment: $DissT_{50}$ = 20.4 d (20°C), 88.0 d (12°C) Mineralization: 13.5% (day 100) residues of a. s. (% of applied): Water layer: 61.2%-0% (day 0-day 30) Sediment: max 15.6%-0% (day 2-day 100)

*sum of cis- and trans-isomers

[cyclopropyl-1-^{14}C]-d-trans-prallethrin

Total System: $DT_{50\text{-modelling}}$ = 45.8 d (25°C), 143.7 d (12°C)

Water Layer: $DissT_{50}$ = 2.4 d (25°C), 6.7 d (12°C)
Sediment: $DissT_{50}$ = 46.7 d (25°C), 132.1 d (12°C)
Mineralization: 28.2% (day 91)
residues of a. s. (% of applied):
Water layer: 50.2%-0% (day 0-day 30)

Sediment: max 58.2%-18.3% (day 7-day 91)

Distribution in water / sediment systems (metabolites)	SUMITOMO **[cyclopropyl-1-^{14}C]-d-allethrin:** **Metabolites ≥10 %** d-c/t-CRA: max 36.7% (day14, system I) and 17.7% (day 30, system II) of applied radioactivity; DT_{50} for PECsw: 52.9 d (12°C) from a study performed on cyphenothrin (SUMITOMO) t-COOH-CA: max 36.1% (day 30, system I) and 49.5% (day 100, system II) of applied radioactivity; DT_{50} for PECsw: 101.0 d (12°C) from a study performed on cyphenothrin (SUMITOMO) ωt-COOH-d-t-allethrin: max 9.5% (day 7, system I) and 16.6% (day 7, system II) of applied radioactivity no DT50 available for PEC-calculations dl-ALON: as d-c/t-CRA -> not detected due to label position; no DT50 available for PEC-calculations **Metabolites ≥5 % at two consecutive sampling points** **-** **Metabolites ≥5 % at final time point, maximum not reached** - **[cyclopropyl-1-^{14}C]-d-trans-prallethrin** **Metabolites ≥10 %** d-t-CRA: max 51.7% of applied radioactivity at day14 t-COOH-CA: max 31.1% of applied radioactivity at day 60 **Metabolites ≥5 % at two consecutive sampling points** **-** **Metabolites ≥5 % at final time point, maximum not reached** **-**

Route and rate of degradation in soil

Mineralization (aerobic)	SUMITOMO **[alc-^{14}C]-d-trans-allethrin:** sandy loam, max. 71.3% of applied radioactivity after 183 days at 20°C **[acid-^{14}C]-d-trans-allethrin:** sandy loam, max. 41.4% of applied radioactivity after 183 days at 20°C **[alc-^{14}C]-d-trans-d-allethrin:** sandy loam, max. 19.0% of applied radioactivity after 30 days at 20°C **[alc-^{14}C]-d-trans-l-allethrin:** sandy loam, max. 10.7% of applied radioactivity after 30 days at 20°C **(1R)-cis-[cyclopropyl-1-^{14}C]-allethrin:** loam, max. 55.2 % of applied radioactivity after 120 days at 25°C, sandy loam, max. 34.8% of applied radioactivity after 120 days at 25°C, sandy clay loam, max. 49.9% of applied radioactivity after 120 days at 25°C **Metabolite [acid-^{14}C]t-COOH-CA** Aschard loam: 41.2% of applied radioactivity after 14 days at 20°C France site #2 loam: 50.3% of applied radioactivity after 30 days at 20°C Norbert sandy clay loam: 45.4% of applied radioactivity after 30 days at 20°C

Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): SUMITOMO **[alc-^{14}C]-d-trans-allethrin:** sandy loam System I: DT_{50} = 20.5 d (FOMC), r^2 0.942 System II: DT_{50} = 20.0 d (FOMC), r^2 0.991 **[acid-^{14}C]-d-trans-allethrin:** sandy loam System I: DT_{50} = 19.4 d (SFO), r^2 0.997 System II: DT_{50} = 31.7 d (SFO), r^2 0.965 **[alc-^{14}C]-d-trans-d-allethrin:** sandy loam System I: DT_{50} = 51.8 d (SFO), r^2 0.990 System II: DT_{50} = 39.5 d (SFO), r^2 0.949 **[alc-^{14}C]-d-trans-l-allethrin:** sandy loam System I: DT_{50} = 40.4 d (SFO), r^2 0.970 System II: DT_{50} = 44.1 d (SFO), r^2 0.996 DT_{50lab} (25°C, aerobic): SUMITOMO **(1R)-cis-[cyclopropyl-1-^{14}C]-allethrin:** Loam: DT_{50} = 18.7 d (FOMC), r^2 0.990 Sandy loam: DT_{50} = 20.9 d (FOMC), r^2 0.990 Sandy clay loam: DT_{50} = 22.1 d (FOMC), r^2 0.993 DT_{50} modelling (12°C): SUMITOMO **[alc-^{14}C]-d-trans-allethrin:** sandy loam DT_{50} = 102.6 d (FOMC) **[acid-^{14}C]-d-trans-allethrin:** sandy loam DT_{50} = 72.3 d (SFO) **[alc-^{14}C]-d-trans-d-allethrin:** sandy loam DT_{50} = 129.2 d (SFO) **[alc-^{14}C]-d-trans-l-allethrin:** sandy loam DT_{50} = 119.6 d (SFO) **(1R)-cis-[cyclopropyl-1-^{14}C]-allethrin:** Loam: DT_{50} = 88.0 d (FOMC) Sandy loam: DT_{50} = 97.6 d (FOMC) Sandy clay loam: DT_{50} = 251.0 d (DFOP) **Geomean DT_{50} modelling, n=7: 113.8 d (12°C)** **<u>Metabolite [acid-^{14}C]t-COOH-CA</u>** Aschard loam: DT_{50} = 1.9 d (SFO, 20°C), r^2 0.981 France site #2 loam: DT_{50} = 3.1 d (SFO, 20°C), r^2 0.985 Norbert sandy clay loam: DT_{50} = 5.3 d (SFO, 20°C), r^2 0.971 **DT_{50} used for PEC: 1163 d (12°C)** from a study performed on d-trans-tetramethrin (SUMITOMO)

DT_{90lab} (20°C, aerobic):	DT_{90lab} (20°C, aerobic): SUMITOMO **[alc-^{14}C]-d-trans-allethrin:** sandy loam System I: DT_{90} = 122.2 d (FOMC), r^2 0.942 System II: DT_{90} = 118.7 d (FOMC), r^2 0.991 **[acid-^{14}C]-d-trans-allethrin:** sandy loam System I: DT_{90} = 64.4 d (SFO), r^2 0.997 System II: DT_{90} = 105.4 d (SFO), r^2 0.965 **[alc-^{14}C]-d-trans-d-allethrin:** sandy loam System I: DT_{90} = 172.2 d (SFO), r^2 0.990 System II: DT_{90} = 131.3 d (SFO), r^2 0.949 **[alc-^{14}C]-d-trans-l-allethrin:** sandy loam System I: DT_{90} = 134.1 d (SFO), r^2 0.970 System II: DT_{90} = 146.6 d (SFO), r^2 0.996 DT_{90lab} (25°C, aerobic): SUMITOMO **(1R)-cis-[cyclopropyl-1-^{14}C]-allethrin:** Loam: DT_{50} = 103.1 d (FOMC), r^2 0.990 Sandy loam: DT_{50} = 114.6 d (FOMC), r^2 0.990 Sandy clay loam: DT_{50} = 190.2 d (FOMC), r^2 0.993 **<u>Metabolite [acid-^{14}C]t-COOH-CA</u>** Aschard loam: DT_{90} = 6.3 d (SFO), r^2 0.981 France site #2 loam: DT_{90} = 10.3 d (SFO), r^2 0.985 Norbert sandy clay loam: DT_{90} = 17.6 d (SFO), r^2 0.971
DT_{50lab} (10°C, aerobic):	Not available
DT_{50lab} (20°C, anaerobic):	Not available
degradation in the saturated zone:	Not available
Field studies (state location, range or median with number of measurements)	-
DT_{50f}:	Not available
DT_{90f}:	Not available
Anaerobic degradation	Not available
Soil photolysis	Not available

Non-extractable residues (Soil laboratory studies)	SUMITOMO **[alc-^{14}C]-d-trans-allethrin:** max. 21.9% of applied radioactivity after 122 days **[acid-^{14}C]-d-trans-allethrin:** max. 24.9% of applied radioactivity after 122 days **[alc-^{14}C]-d-trans-d-allethrin:** max. 11.3% of applied radioactivity after 30 days **[alc-^{14}C]-d-trans-l-allethrin:** max. 12.9% of applied radioactivity after 30 days **(1R)-cis-[cyclopropyl-1-^{14}C]-allethrin:** loam, max. 23.2 % of applied radioactivity after 120 days, sandy loam, max. 22.1% of applied radioactivity after 120 days, sandy clay loam, max. 18.9% of applied radioactivity after 120 days **<u>Metabolite [acid-^{14}C]t-COOH-CA</u>** Aschard loam: 51.0% of applied radioactivity at day 6 France site #2 loam: 43.6% of applied radioactivity at day 14 Norbert sandy clay loam: 33.0% of applied radioactivity after 30 days
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	SUMITOMO **Metabolites ≥10 %** <u>dl-ALON:</u> 6.4% (day 30)-36.5% (day 7) of applied radioactivity no DT50 available for PEC-calculations <u>t-COOH-CA:</u> 30.0% (day 61)-35.1% (day 91) of applied radioactivity **Metabolites ≥5 % at two consecutive sampling points** <u>d-t-CRA: max.</u> 9.3% of applied radioactivity at day 122 (system I: 5.6% at day14, and 6.2% at day 30; system II: 5.8% at day 61, 6.2% at day 92, and 9.3% at day 122) no DT50 available for PEC-calculations **Metabolites ≥5 % at final time point, maximum not reached** -
Soil accumulation and plateau concentration	-

Adsorption/desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	SUMITOMO: **1R-trans-allethrin (ratio 1R-trans-1R to 1R-trans-1S unclear from study report):** *K_a :* 4.087 – 25.94 mL/g (4 soils) *K_d :* 8.827 – 36.95 mL/g (4 soils) *K_{aoc} :* 1134 - 1718 mL/g (4 soils) *K_{doc} :* 1592 - 3212 mL/g (4 soils) K_{aoc} (arithmetic mean): 1405 mL/g **Metabolites:** dl-ALON: 21.05 (QSAR estimation) t-COOH-CA: 2.24 (QSAR estimation)

Fate and behaviour in air

Direct photolysis in air	-
Quantum yield of direct photolysis	-
Photo-oxidative degradation in air	Theoretical estimation according to Atkinson, using US EPA AOPWIN, version 1.91. DT_{50}: 1.733 h 24-hours-mean concentration: 5×10^5 OH radicals/cm³
Volatilization	No data supplied, not required

Reference value for groundwater

According to BPR Annex VI, point 68	-

Chapter 5: Effects on Non-target Species

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

Species	Time-scale	Endpoint	Toxicity
Fish			
SUMITOMO: *Oncorhynchus mykiss*	96 h	Mortality	LC_{50} = 13 µg/L (study performed with esbiothrin)
ENDURA: *Danio rerio*	96 h	Mortality	LC_{50} =7.08 µg/L
Invertebrates			
SUMITOMO: *Daphnia magna*	48 h	Immobility	EC_{50} = 8.3 µg/L (study performed with esbiothrin)
ENDURA: *Daphnia magna*	48 h	Immobility	EC_{50} = 6.1 µg/L

SUMITOMO: *Daphnia magna*	**21 d**	**Reproduction**	**NOEC = 2.7 µg/L** (study performed with esbiothrin)
Algae			
SUMITOMO: *Pseudokirchneriella subcapitata*	72 h	Growth inhibition	E_rC_{50} = 6.6 mg/L NOE_rC = 1.1 mg/L
ENDURA: *Scenedesmus subspicatus*	72 h	Growth inhibition	E_rC_{50} = 2.8 mg/L NOE_rC = 0.32 mg/L
Microorganisms			
Activated sludge (SUMITOMO)	3 h (static)	Respiration inhibition	NOEC: ≥102.4 mg/L
Activated sludge (ENDURA)	3 h (static)	Respiration inhibition	NOEC: ≥ 994 mg/L

Effects on earthworms or other soil non-target organisms

Acute toxicity to ……..	n.a.
Reproductive toxicity to ……	-

Effects on soil micro-organisms

Nitrogen mineralization	n.a.
Carbon mineralization	n.a.

Effects on terrestrial vertebrates

Acute toxicity to mammals	n.a.
Acute toxicity to birds	n.a.
Dietary toxicity to birds	n.a.
Reproductive toxicity to birds	n.a.

Effects on honeybees

Acute oral toxicity	n.a.
Acute contact toxicity	n.a.

Effects on other beneficial arthropods

Acute oral toxicity	n.a.
Acute contact toxicity	n.a.
Acute toxicity to ……..	-

Bioconcentration

Bioconcentration factor (BCF)	Calculated BCF_{fish} = 3217 $L*kg_{wet\ fish}^{-1}$ Calculated $BCF_{earthworm}$ = 1070 $L*kg_{wet\ earthworm}^{-1}$ Measured (growth corrected, lipid normalized) $BCF_{KgL,fish}$ = **1314** $L*kg_{wet\ fish}^{-1}$ (test substance: d-trans-prallethrin = d-trans-ETOC, read-across to d-allethrin accepted)
Depration time (DT_{50})	T ½ for clearance related to total radioactive residues: 1.24 ± 0.19
Depration time (DT_{90})	Time to reach 90% of steady state related to total radioactivity: 4.11 ± 0.62 days
Level of metabolites (%) in organisms accounting for > 10 % of residues	No information available

Chapter 6: Other End Points

-

Appendix II: List of Intended Uses

Summary of intended uses

Object and/or situation a)	Product name	Organisms Controlled c)	Formulation		Application			Applied amount per treatment			Remarks
			Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	number min max	interval between applications (min)	g a.s./L min max	Water L/m3 min…max	g a.s./m2 min ….max	
Vaporising mat placed on a vaporising heating unit indoors (without kitchens)	Pynamin Forte 40mg Mat	Adult biting mosquitos including *Aedes spp. Culex* and other small biting/harmful flying insects (e.g. midges)	Vaporising Mat	40 mg per mat	Electric device	Max. 10 h/day	Usage over 150 day is considered as worst case	One mat is effective over 10 h for an average 35 m³ room (highest vaporisation rates at 4.15 mg/h after 2-4 h, reducing to 3.255 mg/h after 8 h.			
Spraying of aqueous emulsion indoor by professional users	Duracide A	Mosquitos (*Aedes aegypti* and *Culex quinquefasciatus*) and Houseflies (*Musca domestica*).	Emulsifi-able Concentrate (EC)	68 g/kg	Spraying pumps, ULV, thermal or cold fogging	Up to 160 days per year		1.02-1.36	0.03-0.1 L emulsion /100 m³	0.031 - 0.136	The EC product is obtained after dilution of 88 parts of Duracide A to 100, by adding the emulsifier SOITEM 107bis or equivalent. 15-20 g of this EC product are further diluted into 1 L of water
Spraying of solvent based solution indoor by professional users	Duracide A	Mosquitos (*Aedes aegypti* and *Culex quinquefasciatus*) and	As it is	77 g/kg	Spraying pumps, ULV, thermal or cold fogging,	Up to 160 days per year		*Spraying pumps: 1.155 (solvent);* *ULV: 2.57-3.85 (solvent);*	Spraying pumps: 0.03 - 0.1 L solution/ 100 m^3;	Spraying pumps: 0.035 - 0.116; ULV: 0.0129 -	Duracide A can be diluted with a suitable solvent (kerosene based) and then applied through

		Houseflies (*Musca domestica*).			Air space application			*Thermo and cold fogging: 0.385-1.155 (solvent)*	ULV: 0.005 - 0.03 L solution/ 100 m^3; Thermo and cold fogging: 0.03 - 0.1 L solution/ 100 m^3	0.116; Thermo and cold fogging: 0.0116 - 0.116	spraying pumps, ULV, cold- or thermo-fogging devices. Recommended product dilutions are: 1) Spraying pumps: 15 g of Duracide A in 1 L of solvent; 2) ULV: 10 g of Duracide A in 0.2-0.3 L of solvent; 3) Thermo and cold fogging: 10-15 g of Duracide A in 1-2 L of solvent.
Manual spraying indoor by non-professional users	Duracide A	Mosquitoes (*Aedes aegypti* and *Culex quinquefasciatus*) and Houseflies (*Musca domestica*).	Ready to use aerosol	0.1%	Manual spraying	3-6 sec as spraying time for each application in typical 30 m^3 rooms				0.01 - 0.03 (3-9 g of product sprayed for each application)	

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

Appendix III: List of studies

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

Reference list, by Author

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE).	Doc II	N/A	1989	Ventilation for acceptable Indoor Air Quality (ASHRAE 62-1989). Atlanta GA.	N	N/A
Anonymous	A 3.4/01	Pynamin Forte (d-Allethrin)	Not specified	Spectral data of Pynamin Forte technical grade (UV, IR, NMR and MS) Sumitomo Chemical Co., Ltd. Sumitomo reference number KP-30-0016 Non-GLP, Unpublished	Y	SCC
Anonymous	A 3.3.1/01 A 3.3.2/01 A 3.3.3/01 A 3.12/01 A 3.14/01 (filed under	Pynamin Forte (d-Allethrin)	1984	Technical report: Physical and chemical properties of Pynamin ® and Pynamin ® Forte technical material. 11 April 1984 Sumitomo Chemical Co., Ltd. Osaka, Japan. Sumitomo reference number KP-40-0017 Non-GLP, unpublished	Y	SCC

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
	A 3.3.1/01)					
Anonymous	A 6.1.1/03	Pynamin Forte (d-Allethrin)	-	Toxicity of Pynamin Forte (III) Acute oral and subcutaneous toxicity in mice. Sumitomo Chemical Co., Ltd. Sumitomo reference number KT-70-0004 Non-GLP, Unpublished	Y	SCC
Anonymous	A 6.1.2/03	Pynamin Forte (d-Allethrin)	-	Acute dermal toxicity of Pynamin Forte and Pynamin Sumitomo Chemical Company, Ltd. Sumitomo reference number KT-70-0005 Non-GLP, Unpublished	Y	SCC
Anonymous	A 6.1.1/06 IUCLID summary only	Pynamin Forte (d-Allethrin)	-	Acute oral, subcutaneous and intraperitoneal toxicity of Pynamin Forte in mice. Sumitomo Chemical Co., Ltd. Japan Sumitomo reference number KT-70-0003 Non-GLP Unpublished	Y	SCC
Anonymous	A 6.4.1/03	Bioallethrin, Esbiothrin and Esbiol	-	Comparison of the three Roussel Uclaf technical products in the d-trans-allethrin series (bioallethrin, esbiothrin and esbiol) in terms of the chemical specifications and toxicological properties	Y	SCC
Anonymous	Doc II	Pynamin Forte 40mg Mat (d-Allethrin)	N/A	Vaporisation test of Pynamin Forte 40mg Mat. Household and Public Hygiene Chemicals Division. Sumitomo Chemical Co. Ltd. Report number KF-20-0031. Unpublished.	Y	SCC
Anonymous	Doc II	Pynamin Forte	N/A	The test procedure to measure the aerial concentration of active ingredient evaporated from mat formulation containing Pynamin Forte in the	Y	SCC

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
		(d-Allethrin)		closed room. Household and Public Hygiene Chemicals Division. Sumitomo Chemical Co. Ltd. Report number KF-80-0051. Unpublished.		
Anonymous	Doc II	Pynamin Forte (d-Allethrin)	N/A	Aerial concentration of pynamin forte evaporated from heated mat (3553.tif). Household and Public Hygiene Chemicals Division. Sumitomo Chemical Co. Ltd. Report number not stated.	Y	SCC
Anonymous	Doc II	d-Allethrin	N/A	Deposit of d-allethrin on the floor, wall and ceiling of the test chamber during mat use. Household and Public Hygiene Chemicals Division. Sumitomo Chemical Co. Ltd. Unpublished report number KF-90-0122	Y	SCC
Anonymous	A 3.4/01	Pynamin Forte (d-Allethrin)	Not specified	Spectral data of Pynamin Forte technical grade (UV, IR, NMR and MS) Sumitomo Chemical Co., Ltd. Sumitomo reference number KP-30-0016 Non-GLP, Unpublished	Y	SCC
Anonymous	A 3.3.1/01 A 3.3.2/01 A 3.3.3/01 A 3.12/01 A 3.14/01 (filed under	Pynamin Forte (d-Allethrin)	1984	Technical report: Physical and chemical properties of Pynamin ® and Pynamin ® Forte technical material. 11 April 1984 Sumitomo Chemical Co., Ltd. Osaka, Japan. Sumitomo reference number KP-40-0017 Non-GLP, unpublished	Y	SCC

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	A 3.3.1/01)					
Anonymous	A 6.1.1/03	Pynamin Forte (d-Allethrin)	-	Toxicity of Pynamin Forte (III) Acute oral and subcutaneous toxicity in mice. Sumitomo Chemical Co., Ltd. Sumitomo reference number KT-70-0004 Non-GLP, Unpublished	Y	SCC
Anonymous	A 6.1.2/03	Pynamin Forte (d-Allethrin)	-	Acute dermal toxicity of Pynamin Forte and Pynamin Sumitomo Chemical Company, Ltd. Sumitomo reference number KT-70-0005 Non-GLP, Unpublished	Y	SCC
Anonymous	A 6.1.1/06 IUCLID summary only	Pynamin Forte (d-Allethrin)	-	Acute oral, subcutaneous and intraperitoneal toxicity of Pynamin Forte in mice. Sumitomo Chemical Co., Ltd. Japan Sumitomo reference number KT-70-0003 Non-GLP Unpublished	Y	SCC
Anonymous	A 6.4.1/03	Bioallethrin, Esbiothrin and Esbiol	-	Comparison of the three Roussel Uclaf technical products in the d-trans-allethrin series (bioallethrin, esbiothrin and esbiol) in terms of the chemical specifications and toxicological properties	Y	SCC
Anonymous			2006	Memorandum: Allethrins: HED chapter of reregistration eligibility decision document (RED). United States Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances. Washington, D. C. 20460, Dec. 20, 2006	N	Public
Anonymous	A 6.1.1/03		-	Toxicity of Pynamin Forte (III) Acute oral and subcutaneous toxicity in mice. Sumitomo Chemical Co., Ltd.	Y	SCC

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
				Sumitomo reference number KT-70-0004 Non-GLP, Unpublished		
Anonymous	A 6.1.2/03		-	Acute dermal toxicity of Pynamin Forte and Pynamin Sumitomo Chemical Company, Ltd. Sumitomo reference number KT-70-0005 Non-GLP, Unpublished	Y	SCC
Anonymous	A 6.1.1/05 IUCLID summary only		-	Acute oral, subcutaneous and intraperitoneal toxicity of Pynamin Forte in mice. Sumitomo Chemical Co., Ltd. Japan Sumitomo reference number KT-70-0003 Non-GLP Unpublished	Y	SCC
Anonymous	A 6.4.1/03		-	Comparison of the three Roussel Uclaf technical products in the d-trans-allethrin series (bioallethrin, esbiothrin and esbiol) in terms of the chemical specifications and toxicological properties	Y	SCC
Anonymous	B 6.6/02		N/A	Deposit of Pynamin Forte on the floor, wall and ceiling of the test chamber during mat use. Household and Public Hygiene Chemicals Division. Sumitomo Chemical Co. Ltd. Report number KF-90-0122. Unpublished.	Y	SCC
Anonymous	A 3.4	Pynamin Forte (d-Allethrin)	Not specified	Spectral data of Pynamin Forte technical grade (UV, IR, NMR and MS) Sumitomo Chemical Co., Ltd. Sumitomo reference number KP-30-0016 Non-GLP, Unpublished	Y	SCC
Anonymous	A 3.3.1/01	Pynamin Forte	1984	Technical report: Physical and chemical properties of Pynamin ® and Pynamin ® Forte technical material.	Y	SCC

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
	A 3.3.2/01 A 3.3.3/01 A 3.12 A 3.14 (filed under A 3.3.1/01)	(d-Allethrin)		11 April 1984 Sumitomo Chemical Co., Ltd. Osaka, Japan. Sumitomo reference number KP-40-0017 Non-GLP, unpublished		
Atkinson, R.	Doc II	N/A	1985	Kinetics and mechanisms of the gas-phase reactions of the hydroxyl radical with organic compounds under atmospheric conditions. Chem. Rev. 85, 69-201. Published.	N	N/A
[redacted]	A 6.1.1/04	Esbiothrin	1985	Acute oral toxicity study in the rat. Centre de Recherches, Roussel Uclaf, France. Reference number RU.EBT.84323/A GLP, Unpublished	Y	SCC
[redacted]	A 7.5.3.1.2/01 (IUCLID only)	Pynamin Forte (d-Allethrin)	1978	Eight-day dietary LC50 - Bobwhite quail, Pynamin Forte. 31 July 1978 Wildlife International Ltd. Report number 163-102, Sumitomo reference number KT-81-0022 Non-GLP, Unpublished	Y	SCC
Bright A.A.S.	A 3.7	d-Allethrin	1999	Solubility in organic solvents 21 May 1999 AgrEvo UK Ltd. Chesterfield Park. UK	Y	SCC

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
				Report number CHR/98/060. Study identification 98062601A. Sumitomo reference number C001909 GLP, Unpublished		
Bright A.A.S	A 3.13/01	Esbiol	1999	Surface tension, Esbiol technical 21 May 1999 AgrEvo UK Ltd. Chesterfield Park. UK Report number CHR/98/058. Study identification 98062601H. Sumitomo reference number C001907 GLP, Unpublished	Y	SCC
[redacted]	A 6.9/02		1997	ESBIOL: Rat Acute Oral Neurotoxicity Study. 26 November 1997. Huntingdon Life Sciences Ltd. GLP, unpublished	Y	SCC
Brouwer, D. H., Kroese, R., Van Hemmen, J.J.	Doc II	N/A	1999	Transfer of contaminants from surface to hands: Experimental assessment of linearity of the exposure process, adherence to the skin, and area exposed during fixed procedure and repeated contact with surfaces contaminated with a powder. Department of Chemical Exposure Assessment, TNO Nutrition and Food Reasearch Institute, The Netherlands. Applied Occupational and Environmental Hygiene. Volume 14: 231-239. Published.	N	N/A
Burwood C.E.	A 3.10 A 3.4/02 A 3.11 A 3.12 A 3.14	d-Allethrin	2006	D-Allethrin: Evaluation of physico-chemical properties. 13 October 2006. Covance Laboratories Ltd. Harrogate, UK. Report	Y	SCC

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
	(filed under A 3.10)			number 2282/017-D2149 GLP, Unpublished		
Cantalamessa F.	DocII	Pyrethroids	1993	Acute toxicity of two pyrethroids, permethrin, and cypermethrin in neonatal and adult rats. Arch Toxicol. 1993;67(7):510-3. Published	N	N/A
Chari S., Shepler K and Ruzo L.O.	A 7.1.1.1.2/01	[Alc-^{14}C]-d-trans-Allethrin 50/50 (bioallethrin)	1990	Sunlight Photodegradation of [Alc-^{14}C]-d-trans-Allethrin in a Buffered Aqueous Solution at pH 5. 19 April 1990 Pharmacology and Toxicology Research Laboratory, 4123-B, Lakeside Drive, Richmond, California 94806. PTRL Report Number 197W-1. Sumitomo reference number KM-01-0006. GLP, Unpublished	Y	SCC
[redacted]	A6.6.2		2004	Allethrin chromosome aberrations in Chinese hamster ovary cells in vitro. Research Toxicology Centre S.p.A., Report N° 9425. GLP/unpublished.	Y	Endura
[redacted]	A6.6.3		2004	Allethrin mutation in L5178Y TK± mouse lymphoma cells (Fluctuation method). Research Toxicology Centre S.p.A., Report N° 9424. GLP/unpublished.	Y	Endura
[redacted]	A 7.4.1.1	d-Allethrin	2006	Acute Toxicity of D-Allethrin to Zebra Fish (Danio rerio), Determined Under Flow-through Exposure. ChemService S.r.l. Testing Laboratory, Via Fratelli Beltrami 15, 20026 Novate Milanese (MI), Italy, Study No.CH-E-003/2006	Y	Endura

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
				GLP,unpublished		
[redacted]	A 7.4.1.2	d-Allethrin	2006	Acute Toxicity of d-allethrin to Daphnia magna, in a 48 hour immobilization test. ChemService S.r.l. Testing Laboratory, Via Fratelli Beltrami 15, 20026 Novate Milanese (MI), Italy, Study No.CH-E-004/2006 GLP,unpublished	Y	Endura
[redacted]	A6.5/03		1989	Chronic Toxicity of Pynamin Forte in Dogs. 14 March 1989. Hazelton Laboratories America, Inc. HLA Study No. 343-207 GLP, unpublished	Y	SCC
Di Blasi	A3.17		2006	Reactivity towards Container Material, Endura S.p.A., NO GLP, (unpublished).	Y	Endura
Dykes J.	A 7.1.3	^{14}C-1R-trans-Allethrin	1990	"Soil/sediment adsorption-desorption with ^{14}C-Allethrin" 26 December 1990 Analytical Bio-chemical Laboratories, Inc. 7200 East ABC Lane, P.O. Box 1097, Columbia, Missouri 65205. ABC report number 38539. Sumitomo reference number A97529. GLP, Unpublished	Y	SCC
EC	Doc II	N/A	2002	Technical Notes for Guidance. Human Exposure to Biocidal Products. Guidance on Exposure Estimation. Report was prepared under contract B4-3040/2000/291079/MAR/E2 for the European Commission, DG Environment. June 2002.	N	N/A
EC	Doc II-4, Chapter 4		2006	Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate	--	--

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
				Studies on Pesticides in EU Registration, Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp		
ECB	B 6.5		2000	Distillates (petroleum), hydrotreated light IUCLID Dataset European Commission – European Chemicals Bureau Published www.ECB,jrt.it White Spirits IPCS International Programme on Chemical Safety, Health and Safety Guide No. 103 Published www.inchem.org	N	ECB
ECB.	Doc II	N/A	2003	Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC, Commission Regulation 1488/94 and Directive 98/8/EC. European Chemicals Bureau - Institute for Health and Consumer Protection.	N	N/A
ECHA	Doc II-4, Chapter 4	--	2013	Guidance on information requirements, Guidance on Regulation (EU) No 528/2012 concerning the Making Available on the Market and Use of Biocidal Products (BPR), Version 1.0	-	-
ECHA	Doc II-4, Chapter 4	--	2015	Guidance on the Biocidal Products Regulation, Volume IV Environment – Part B Risk Assessment (active substances), Version 1.0	-	--
ECHA	Doc II-4, Chapter 4	--	2012	Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT/vPvB Assessment, Version 2.0	-	--

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
ECHA	Doc II B 8.3	N/A	2013	Manual of Technical Agreements (MOTA), v.6	N	N/A
ECHA	Doc II B 8.3	N/A	2015	Technical Agreements for Biocides, v1.0	N	N/A
ECHA	Doc II-4, Chapter 4	--	2011	Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures	-	--
[redacted]	A 6.3.2	Pynamin Forte (d-Allethrin)	1990	Twenty-one day dermal toxicity study in rabbits with Pynamin Forte. 26 March 1990 Huntingdon Research Centre Ltd. UK. HRC report number SMO 329/891585. Sumitomo reference number KT-01-0099. GLP, Unpublished	Y	SCC
Enayati A.A. *et al.*	A 5.7/01	Pyrethroids	2003	Molecular evidence for a kdr-like pyrethroid resistance mechanism in the malaria vector mosquito *Anopheles stephensi*. The Royal Entomological Society. Medical and Veterinary Entomology (2003) 17, 138-144.	N	N/A
EPPO	A 5.7/02	N/A	2003	Resistance risk analysis. PP 1/213(2) 2003 OEPP/EPPO Bulletin 33, 37-63.	N	N/A
Eriksson, P.; Fredriksson A.	A 6.9		1991	Neurotoxic effects of two different pyrethroids, bioallethrin and deltamethrin, on immature and adult mice: changes in behavioral and muscarinic receptor variables. In: Toxicology and Applied Pharmacology. 108:78-85	N	Public
Eriksson, P.; Nordberg, A.	A 6.9		1990	Effects of Two Pyrethroids, Bioallethrin and Deltamethrin, on Subpopulations of Muscarinic and Nicotinic	N	Public

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				Receptors in the Neonatal Mouse Brain. In: Toxicology and Applied Pharmacology. 102: 456-463		
Estigoy L., Sheplar K., Ruzo L.O.	A 7.1.1.1.1	[Alc-14C]-d-trans-allethrin 50/50 (bioallethrin)	1990	Hydrolysis of [Alc-14C]-d-trans-allethrin at pH 5, 7 and 9. 19 April 1990 Pharmacology and Toxicology Research Laboratory, 4123-B, Lakeside Drive, Richmond, California 94806. PTRL Report number 196-W-1. Sumitomo reference number KM-01-0007 GLP, Unpublished	Y	SCC
[redacted]	A 6.9	N/A	2006	General statement of Neurotoxicity for Pyrethroids. 20 February 2006 Sumitomo Chemical Report number QAT-0081 Data review, unpublished	Y	SCC
Fujita T.	A 2.7 A 2.8 (filed under A 2.7)	Pynamin Forte (d-Allethrin)	2001	Analysis results of recent batches of Pynamin Forte. 28 December 2001 Environmental Health Division, Sumitomo Chemical Company. Non-GLP, Unpublished	Y	SCC
Furuta R	A 4.1	Pynamin Forte (d-Allethrin)	1989	Analytical methods to verify certified limits of Pynamin Forte technical grade 27 February 1989 Biochemistry and Toxicology Laboratory, Sumitomo Chemical C., Ltd. Sumitomo reference number KA-90-0044 Non-GLP, Unpublished	Y	SCC

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Furuta R.	A 3.1.3/01	Pynamin Forte (d-Allethrin)	1988	Specific gravity of Pynamin Forte 29 September 1988 Sumitomo Chemical Co., Ltd. Laboratory of biochemistry and toxicology. Sumitomo reference number KP-80-0047 Non-GLP, Unpubished	Y	SCC
Garofani S.	A4.2/02		2006c	d-Allethrin (technical grade): Validation of the Analytical Method for the determination of the content of d-Allethrin in air. Chemservice S.r.l., Draft Interim Report No. CH 011/2006. GLP, (unpublished).	Y	Endura
Garofani S.	A4.2/03		2006d	Validation of the Analytical Method for the determination of the content of D-allethrin in water samples from the aquatic ecotoxicological studies. Chemservice S.r.l., Study No. CH-012/2006. GLP, (unpublished).	Y	Endura
Garofani S.	A3.1.1/ A3.1.2 A3.4/01 A3.4/02 A3.9		2006a	d-Allethrin. (pure active substance): Determination of the physico-chemical properties, ChemService S.r.l., Draft Interim No. CH-009/2006, GLP, (unpublished).	Y	Endura
Garofani S.	A3.3.3 A3.12 A3.14 A3.15		2006b	d-Allethrin. (pure active substance): Determination of the physico-chemical properties, ChemService S.r.l., Draft , GLP, (unpublished).Interim No. CH-010/2006	Y	Endura
[redacted]	A.6.1.5		1989	Skin sensitisation study of Esbiothrin, Lot No. 7N1418B3 (95.7% a.i.) in guinea pigs (Closed Patch Technique). 24 May 1989 Hazleton Laboratories America, Inc, Madison.	Y	SCC

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
				Reference number QDT-0032 ESTC TIBY 89 HZLA A1 US3093 GLP, Unpublished.		
Gottschild, D, Storzer, W., Wilkening, A.	Doc II	N/A	1993	Criteria for assessment of plant protection products in the registration of BBA, 65-67. Published.	N	N/A
Grützner I.	A 7.1.1.2.1	Pynamin Forte (d-Allethrin)	2002	Ready biodegradability of Pynamin Forte in a manometric respirometry test. 9 January 2002 RCC Ltd. Switzerland. Report number 820563. Sumitomo reference number KM-0019 GLP, Unpublished	Y	SCC
[redacted]	A 7.4.1.4	Pynamin Forte (d-Allethrin)	2001	Toxicity of Pynamin Forte to Activated Sludge in a Respiration Inhibition Test. 29 October 2001 RCC Ltd, Environmental Chemistry & Pharmanalytics Division, CH-4452, Itengen/Switzerland. Report number 820462. Sumitomo reference number KW-0008. GLP, Unpublished	Y	SCC
Guidicelli J.C.	A 3.3.1/02 A 3.3.2/02 A 3.3.3/02 (filed under	Esbiol	1991	Physical and chemical properties of Esbiol ® technical. 15 March 1991 Roussel Uclaf, Paris, France. Study number STE-058-A-03-2/63. Sumitomo reference number A98527 GLP, unpublished	Y	SCC

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
	A 3.3.1/02)					
[redacted]	A 7.4.1.1/02	Esbiothrin	1993	The Acute Toxicity of Esbiothrin to Rainbow Trout (*Oncorhynchus mykiss*). 18 August 1993. Safepharm Laboratories Limited, P.O. Box No. 45, Derby, DE1 2BT UK. Report number 154/1615. Doc No REFG93-28, Sumitomo reference number A98445 GLP, Unpublished	Y	SCC
[redacted]	A 7.4.1.2/02	Esbiothrin	1993	The Acute Toxicity of Esbiothrin to *Daphnia magna*. 18 August 1993 Safepharm Laboratories Limited, P.O. Box No. 45, Derby, DE1 2BT. UK. Report number 154/1614. Document number G93-28. Sumitomo reference number A98445 GLP, Unpublished	Y	SCC
[redacted]	A 6.1.2/02	Pynamin Forte (d-Allethrin)	1981	Acute dermal toxicity of Pynamin Forte® in rabbits. 15 February 1981 Sumitomo Chemical Company, Ltd. Hyogo, Japan. Document code KT-00--0036 GLP, Unpublished	Y	SCC
[redacted]	A 6.1.4/03 IUCLID summary only	Pynamin Forte (d-Allethrin)	1980	Primary eye and skin irritation tests of Pynamin Forte® technical in rabbits 21 September 1980 Research department, pesticides division, Sumitomo Chemical Co., Ltd. Japan. Sumitomo reference number KT-10-0040 Non-GLP, Unpublished	Y	SCC

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Hemant D.	A4.3		2006	Development and validation of analytical method for active ingredient analysis of d-Allethrin by HPLC. Jai Research Foundation, Dept. of Toxicology, Valvada – 396 108, Dist. Valsad, Gujarat, India., Study No. 5835. GLP/unpublished.	Y	Endura
[redacted]	A 6.3.2/02		1990	21-Day Dermal Toxicity Study with Esbiothrin in Rabbits. Hazelton Laboratories, America Report number HLA 6298-102 GLP, Unpublished	Y	SCC
Herrera A. and Laborda E.	A 6.6.1/03		1988	Mutagenic activity in synthetic pyrethroids in Salmonella typhimurium Mutagenesis, vol. 3, no. 6, pp. 509-514 (1988) Non-GLP, Published	N	N/A
[redacted]	A 6.1.1./01	Pynamin Forte (d-Allethrin)	1989	Acute oral toxicity study of Pynamin Forte in rats. 15 February 1989 Sumitomo Chemical Co., Ltd. Japan Study number 1646. Sumitomo reference number KT-90-0079 GLP, Unpublished	Y	SCC
[redacted]	A 6.1.2/01	Pynamin Forte (d-Allethrin)	1989	Acute dermal toxicity study of Pynamin Forte in rabbits. 15 February 1989 Sumitomo Chemical Co., Ltd. Japan Study number 1705. Sumitomo reference number KT-90-0080. GLP, Unpublished	Y	SCC
Hoberg J.R.	A 7.4.1.3	Pynamin Forte	2002	Pynamin Forte toxicity to the freshwater green alga, Pseudokirchneriella subcapitata. 22 November 2002	Y	SCC

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
		(d-Allethrin)		Springborn smithers Laboratories, 790 Main Street, Wareham, massachusetts 02571-1075. Report number 13048.6336. Sumitomo reference number KW-0011 GLP, Unpublished		
[redacted]	A 6.8.2/02	Pynamin Forte (d-Allethrin)	1989	Reproductive effects of Pynamin Forte administered orally in feed to Crl:COBS® CD® (SD)BR rats for two generations. 29 March 1989 Argus Research Laboratories, Inc 905 Sheehy Drive Horsham, PA 19044. Report number Argus 1119-002, Sumitomo reference number KT-91-0087 GLP, Unpublished	Y	SCC
[redacted]	A 6.8.1/01		1989	Teratology study in rats with Pynamin Forte. 17 July 1989 Argus Research Laboratories Inc. Report number Argus 1119-004. Sumitomo reference number KT-91-0094 GLP, Unpublished	Y	SCC
[redacted]	A 6.8.1/02		1989	Teratology study in rabbits with Pynamin Forte. 17 July 1989 Argus research Laboratory Inc. Report number Argus 1119-006. Sumitomo reference number KT-91-0097 GLP, Unpublished.	Y	SCC
[redacted]	A 6.8.1/04		1990	Developmental Toxicity (Embryo-fetal Toxicity and Teratogenic Potential) Study of Esbiothrin Technical Administered Orally via Stomach Tube to New Zealand White Rabbits. 31 August 1990	Y	SCC

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
				Argus Research Laboratories Inc. Study number 718-002 GLP, Unpublished		
Hoffman M.J.	A 3.1.2	Pynamin Forte (d-Allethrin)	1989	Determination of boiling point/boiling range of Pynamin Forte. 30 May 1989 Hazleton Laboratories America Inc. Madison, Wisconsin, USA. Report number HLA 6001-309, Sumitomo reference number KP-91-0053 GLP, Unpublished	Y	SCC
Hour T.-C., Chen L. and Lin J.-K.	A 6.6.1/04		1998	Comparative investigation on the mutagenicities of organophosphate, phthalimide, pyrethroid and carbamate insecticides by the Ames and lactam tests. Mutagenesis, vol. 13, no. 2, pp. 157-166 (1998) Non-GLP, Published	N	N/A
Inglesfield C	A 7.5.1.2	Cypermethrin	1984	Toxicity of the Pyrethroid Insecticides Cypermethrin and WL85871 to the Earthworm, *Eisenia foetida* Savigny Shell Research Limited, Sittingbourne Research Centre, Sittingbourne, Kent, UK. Published.	N	N/A
IPCS EHC	A 7.4.3.2 A 7.5.4.1 A6.2 A6.11	Allethrins	1989	IPCS, International Programme on Chemical Safety, *Environmental Health Criteria 87, Allethrins.* World Health Organization, Geneva 1989	N	public
IPCS HSG	A 7.4.3.2	Allethrins	1989	IPCS, International Programme on Chemical Safety, Health and Safety Guide No. 24 *Allethrins. Health and Safety Guide*	N	public

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
				World Health Organization, Geneva 1989		
IPCS International Programme on Chemical Safety	Doc II	Allethrins	1989	Allethrins: Health and Safety Guide No. 24	N	N/A
IPCS International Programme on Chemical Safety	Doc II	Allethrins	1989	Allethrins: Environmental Health Criteria No. 87.	N	N/A
IRAC	A 5.7/03	N/A	2005	Insecticide Resistance Action Committee – Mode of Action v.4.2.1 (2005). www.irac-online.org	N	N/A
Isobe N., Matsuo M. and Miyamoto J.	A 7.1.1.1.2 /02	Allethrin	1984	Novel Photoproducts of Allethrin. Laboratory of Biochemistry and Toxicology, Sumitomo Chemical Co., Ltd. Tetrahedron Letters, vol. 25, no. 8, pp. 861-864 (1984)	N	SCC
[redacted]	A 7.1.1.1.2 /03	Allethrin	1988	Identification of a mutagen in photooxidation products of allethrin. Biochemistry and Toxicology Laboratory, Sumitomo Chemical Co., Ltd., Japan Sumitomo reference number KT-80-0084 Non-GLP	Y	SCC
Jassen, J.E.	Doc II	N/A	1989	Ventilation for Acceptable Indoor Air Quality. ASHRAE Journal. Published.	N	N/A
[redacted]	A 6.1.3/03 IUCLID summary only	Pynamin Forte (d-Allethrin)	-	Acute inhalation toxicity of Pynamin Forte and Pynamin in mice and rats. Research department, pesticides division, Sumitomo Chemical Co., Ltd. Japan. Sumitomo reference number KT-70-0010 Non-GLP, Unpublished	Y	SCC

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[redacted]	A 6.1.1/05 IUCLID summary only	Pynamin Forte (d-Allethrin)	-	Toxicity of Pynamin Forte (I). Acute oral and subcutaneous toxicity in rats. Sumitomo Chemical Co., Ltd. Japan Sumitomo reference number KT-70-0002 Non-GLP, Unpublished	Y	SCC
[redacted]	A 6.4.1/02 IUCLID summary only	Pynamin Forte (d-Allethrin)	-	90-Day subacute toxicity study of Pynamin Forte on rats Sumitomo Chemical Co., Ltd. Japan. Sumitomo reference number KT-70-0006 Non-GLP, Unpublished	Y	SCC
Kaman R.A.	A 7.1.2/01	d-*trans*-Prallethrin	1999	Aerobic Aquatic Soil Metabolism Study of [cyclopropyl-1-^{14}C]-d-*trans*-Prallethrin. Environmental and Metabolic Fate, Ricerca Inc., Painesville, USA. Report number 7434-98-0013-EF-001 GLP, Unpublished	Y	SCC
[redacted]	A 6.1.3/01	Pynamin Forte (d-Allethrin)	1989	Acute inhalation toxicity study of Pynamin Forte in rats. 15 February 1989 Sumitomo Chemical Co., Ltd Japan. Study number 1651. Sumitomo reference number KT-90-0082 GLP, Unpublished	Y	SCC
[redacted]	A 6.4.3	Pynamin Forte (d-Allethrin)	1993	Three month inhalation toxicity study of Pynamin Forte in rats. 18 March 1993 Sumitomo Chemical Co., Ltd. Japan. Study number 2596. Sumitomo reference number KT-30-0123	Y	SCC

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				GLP, Unpublished		
Khambay B.P.S.	A 5.7/04	Pyrethroids	2002	Pyrethroid Insecticides. Pesticide Outlook, pg 49-54. April 2002. The Royal Society of Chemistry 2002.	N	N/A
Kimmel E.C., Casida J.E. and Ruzo L.O.	A 6.6.1/02	Allethrin and Terallethrin	1982	Identification of Mutagenic Photoproducts of the Pyrethroids Allethrin and Terallethrin Journal of Agricultural and Food Chemistry, vol. 30, no. 4, pp.623-626 (1982) Non-GLP, Published	N	N/A
[redacted]	A 6.6.2	Pynamin Forte (d-Allethrin)	1989	In vitro chromosomal aberration test of Pynamin Forte in Chinese hamster ovary cells (CHO-K1). 21 April 1989 Sumitomo Chemical Co., Ltd. Japan. Study number 1729. Sumitomo reference number KT-90-0088	Y	SCC
[redacted]	A 6.6.3/02	Pynamin Forte (d-Allethrin)	1989	In vitro unscheduled DNA synthesis (USD) assay of Pynamin Forte in rat hepatocytes. 12 May 1989 Sumitomo Chemical Co., Ltd. Japan Study number 1553. Sumitomo reference number KT-90-0089 GLP, Unpublished	Y	SCC
[redacted]	A 6.6.1		1989	Reverse mutation test of Pynamin Forte in Salmonella typhimurium and Escherichia coli. 13 February 1989 Sumitomo Chemical Co., Ltd. Study number 1725. Sumitomo reference number KT-90-0083. GLP, Unpublished	Y	SCC
[redacted]	A		1981	Acute inhalation toxicity of Pynamin Forte® in rats	Y	SCC

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[redacted]	6.1.3/02 IUCLID summary only			and mice. 7 July 1981 Research department, pesticides division, Sumitomo Chemical Co., Ltd. Osaka, Japan. Sumitomo reference number. KT-10-0041 GLP, Unpublished		
[redacted]	A 6.1.4/02		1990	Primary eye irritation study in rabbits with esbiothrin technical. Stillmeadow, Inc., Texas. Reference number 7551-90 (unpublished). 28 December 1990. GLP; Unpublished	Y	SCC
Leng G, Ranft U, Sugiri D, Hadnagy W, Berger-Preiss E, Idel H.	A6.12.4	2003	Pyrethroids used indoors--biological monitoring of exposure to pyrethroids following an indoor pest control operation. Int. J. Hyg. Environ. Health. 206(2):85-92		N	Public
Lentz N.R.	A3.1.1	Pynamin Forte (d-Allethrin)	2008	Pynamin Forte PAI – Determination of the Melting/Freezing Temperature Following OECD Guideline 102 and the Official Journal of the European Communities L383A, Method A.1. 4 August 2008 Springborn Smithers Laboratories, Massachusetts, USA. Study no. 13048.6557. GLP, Unpublished	Y	SCC
Lentz N.R.	A3.1.3/02	Pynamin Forte (d-Allethrin)	2008	Pynamin Forte PAI – Determination of the Density of a Test Substance Following OECD Guideline 109 and the Official Journal of the European Communities L383A, Method A.3. 4 August 2008	Y	SCC

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				Springborn Smithers Laboratories, Massachusetts, USA. Study no. 13048.6558. GLP, Unpublished		
Lentz N.R.	A 3.5/02	Pynamin Forte (d-Allethrin)	2008	Pynamin Forte PAI – Determination of the Water Solubility of a Test Substance Following OECD Guideline 105 and the Official Journal of the European Communities, L383A, Method A.6. 20 August 2008. Springborn Smithers Laboratories, Massachusetts, USA. Study no. 13048.6555 GLP, Unpublished	Y	SCC
Lentz N.R.	A3.13/02	Pynamin Forte (d-Allethrin)	2008	Pynamin Forte PAI – Determination of Surface Tension Using a Ring Tensiometer Following OECD Guideline 115 and the Official Journal of the European Communities L383A, Method A.5. 4 August 2008 Springborn Smithers Laboratories, Massachusetts, USA. Study no. 13048.6556. GLP, Unpublished	Y	SCC
[redacted]	A 6.8.1/03	Esbiothrin	1990	Developmental Toxicity (Embryo-fetal Toxicity and Teratogenic Potential) Study of Esbiothrin Technical Administered Orally via Gavage to Crl:CD®BR VAF/Plus® Presumed Pregnant Rats. 31 August 1990 Argus Research Laboratories Inc. Study number 718-001 GLP, Unpublished	Y	SCC

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[redacted]	A 5.3	Pynamin Forte (d-Allethrin)	1985	LD50 values of S-4068SF and other pyrethroids against housefly, mosquito and cockroach by topical application. November 1985 Pesticides laboratory, Takarazuka Research Center , Sumitomo Chemical Co., Ltd Hyogo, Japan. Report Number FFE-50-0022	Y	SCC
Manson P and Scholey A	A 7.4.1.2/01	Pynamin Forte (d-Allethrin)	2007	d-Allethrin: Acute Toxicity to *Daphnia magna*. 9 March 2007 Covance Laboratories Limited, Harrogate, North Yorkshire, UK. Report number 2282/033-D2149 GLP, Unpublished	Y	SCC
Matoba Y, Inoue A, Takimoto Y.	Doc II	Prallethrin	2004	Clarifying Behaviour of Prallethrin Evaporated from an Electric Vaporizer on the Floor and Estimating Associated Dermal Exposure. Environmental Health Science Laboratory. Sumitomo Chemical Company. J.Pestic. Sci., **29**(4), 313-321. Published.	N	N/A
Matoba, Y, Takimoto, Y., Kato, T.	Doc II	d-Phenothrin and d-Tetramethrin	1988	Indoor Behaviour and Risk Assessment Following Residual Spraying of d-Phenothrin and d-Tetramethin. American Industrial Hygiene Association Journal. 59:191-199. Published.	N	N/A
Matoba, Y., Hirota, T., Ohnishi, J., Murai, N., Matsuo, M.	Doc II		199An indoor simulation of the behavior of insecticides supplied by an electric vaporizer. Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd. Chemosphere Vol 28. No 3 pp435-451. Published.		N	N/A

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Matsunaga, M.	Doc II	Pynamin Forte (d-Allethrin)	1986	Measurement of aerial concentration of Pynamin Forte during Pynamin Forte 40 mg mat use. Household and Public Hygiene Chemicals Division. Sumitomo Chemical Co. Ltd. Report number KF-60-0065. Unpublished.	Y	SCC
Matsuoka A., Hayashi M. and Ishidate Jr. M.	A 6.6.2/02	Allethrin and other compounds	1979	Chromosomal aberration tests on 29 chemicals combined with S9 mix in vitro. Mutation Research, vol. 66, pp. 277-290 (1979) Non-GLP, Published	N	N/A
[redacted]	A 6.7/02		1989	Pynamin Forte: Potential tumorigenic effects in prolonged dietary administration to mice. 17 March 1989 Report number SMO 247/881028. Sumitomo reference number KT-91-0086 GLP, Unpublished	Y	SCC
[redacted]	A 6.9/02	S-bioallethrin	2000	AE F147006 (S-Bioallethrin) Rat 90-day neurotoxicity study. 6 July 2000. Aventis CropScience UK Limited Report number TOX/00/254-103 GLP, unpublished	Y	SCC
[redacted]	A 6.4.1/01		1996	S-bioallethrin (Esbiol) Code: RU 16121. Rat 90-day dietary repeat dose study. 3 April 1996 AgrEvo UK Limited. Report number TOX/95/254-5. Study reference number TOX 94423. GLP, Unpublished	Y	SCC
[redacted]	A 6.1.1/02		1981	Acute oral toxicity of Pynamin Forte in rats. 2 September 1981 Sumitomo Chemical Co., Ltd. Hyogo, Japan.	Y	SCC

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				Sumitomo reference number KT-10-0042 GLP, Unpublished		
Moriya M., Ohta T., Watanabe K., Miyazawa T., Kato K. and Shirasu Y.	A 6.6.1/05		1983	Further mutagenicity studies on pesticides in bacterial reversion assay systems. Mutation Research, vol. 116, pp. 185-216 (1983) Non-GLP, Published	N	N/A
[redacted]	A 6.1.4/01 A 6.1.4/02 (filed under A 6.1.4/01)	Pynamin Forte (d-Allethrin)	1988	Primary eye and skin irritation test with Pynamin ® Forte in rabbits. 18 November 1988 Sumitomo Chemical Co., Ltd. Japan. Study number 1537. Sumitomo reference number KT-80-0078 GLP, Unpublished	Y	SCC
[redacted]	A 6.1.5	Pynamin Forte (d-Allethrin)	1989	Skin sensitisation test with Pynamin Forte in guinea pigs 15 February 1989 Sumitomo Chemical Co., Ltd. Japan Study number 1556. Sumitomo reference number KT-90-0081 GLP, Unpublished	Y	SCC
Nisar, R.	A 6.6.1/06	d-Allethrin	2020	d-Allethrin: Bacterial reverse mutation assay Covance Laboratories Ltd., Report N° 8423327 GLP/unpublished	Y	Endura
OECD	Doc II	N/A	1993	OECD/GD(92)172. The rate of photochemical transformation of gaseous organic compounds in air under tropospheric conditions – Environmental Monograph No 61. Paris 1993.	N	N/A

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OECD	Doc II B 8.3	N/A	2008	OECD Series on Emission Scenario Documents, Number 18 Emission Scenario Document for insecticides, acaricides and products to control other athropods for household and professional uses	N	N/A
[redacted]	A6.1.1		2006	Acute Oral Toxicity Study of d-allethrin in Rats. Jai Research Foundation, Dept. of Toxicology, Valvada – 396 108, Dist. Valsad, Gujarat, India., Study No. 6018. GLP/unpublished.	Y	Endura
[redacted]	A6.1.2		2006	Acute Dermal Toxicity Study of d-allethrin in Rats. Jai Research Foundation, Dept. of Toxicology, Valvada – 396 108, Dist. Valsad, Gujarat, India., Study No. 6019. GLP/unpublished.	Y	Endura
[redacted]	A6.1.3		2006	Acute Inhalation Toxicity Study of d-allethrin in Rats. Jai Research Foundation, Dept. of Toxicology, Valvada – 396 108, Dist. Valsad, Gujarat, India., Study No. 6021. GLP/unpublished.	Y	Endura
[redacted]	A6.1.5		2006	Skin Sensitization Study of d-Allethrin in Guinea Pigs (Guinea Pig Maximization Test). Jai Research Foundation, Dept. of Toxicology, Valvada – 396 108, Dist. Valsad, Gujarat, India., Study No. 6020. GLP/unpublished.	Y	Endura
[redacted]	B6.1.1		2006	Acute Oral toxicity study of Duracide A in rats. Jai Research Foundation, Study N° 6035 GLP, Unpublished	Y	Endura
[redacted]	B6.1.2		2006	Acute Dermal toxicity study of Duracide A in rats. Jai Research Foundation, Study N° 6036 GLP, Unpublished	Y	Endura
[redacted]	B6.1.3		2006	Acute Inhalation Toxicity study of Duracide A in rats.	Y	Endura

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				Jai Research Foundation, Study N° 6040 GLP, Unpublished		
[redacted]	B6.2.1		2006	Acute Dermal Irritation study of Duracide A in rabbits. Jai Research Foundation, Study N° 6037 GLP, Unpublished	Y	Endura
[redacted]	B6.2.2		2006	Acute Eye Irritation study of Duracide A in rabbits. Jai Research Foundation, Study N° 6038 GLP, Unpublished	Y	Endura
[redacted]	B6.3		2006	Skin Sensitization Study of Duracide A in Guinea Pigs (Buehler Test). Jai Research Foundation, Study N° 6039 GLP, Unpublished	Y	Endura
[redacted]	A 6.9		2003	Critical Analysis of Potential Body Temperature Confounders on Neurochemical Endpoints Caused by Direct Dosing and Maternal Separation in Neonatal Mice: a Study of Bioallethrin and Deltamethrin Interactions with Temperature on Brain Muscarinic Receptors. In: Journal of Applied Toxicology. 23: 9-18	N	Public
[redacted]	A 6.5/02		1989	Toxicity study in Beagle dogs by repeated oral administration in diet for 52 weeks. 6 September 1989 Centre International de Toxicologie. Study Number 2181 TCS GLP, Unpublished. Including the following range finder study report. Petra D. 1987. Dose range finding in Dogs by repeated oral administration for 28 days. 7 January 1987 Centre International de Toxicologie. Study Number	Y	SCC

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				2180 TSC GLP, Unpublished.		
Proctor K.L. and Lentz N.R.	A 3.2/02	Pynamin Forte (d-Allethrin)	2009	Determination of the Vapour Pressure of Pynamin Forte PAI Following OECD Guideline 104 and the Official Journal of the European Communities, L383A, Method A.4 21 April 2009 Springborn Smithers Laboratories, Massachusetts, USA. Study no. 13048.6559 GLP, unpublished	Y	SCC
PSD	A 5.7/05	N/A	2004	Resistance risk analysis and use of resistance management strategies. Efficacy October 2004. www.pesticides.gov.uk.	N	N/A
Ramesh A., Ravi P. E.	A4.2/04		2004	Negative Ion Chemical Ionization-Gas Chromatographic-Mass Spectrometric Determination of Residues of Different Pyrethroid Insecticides in Whole Blood and Serum, Journal of Analytical Toxicology, Vol. 28, November/December 2004, (published).	N	Public
Rauch, F., Lhoste, J., Martel, J.			1974	Insecticidal properties of some allethrin isomers used in coil formulations against mosquitoes. In: Pesticide Science. 5: 651-656.	N	Public
Ray, D. E.; Verschoyle, R. D.; Muhammad, B. Y.	A 6.9		2002	Reproducibility of developmental neurotoxicity produced by pyrethroids and DDT in neonatal mice. In: Toxicologist. 66: 131	N	Public
Ray, D.E. & Forshaw P.J.	A6.12.5		2000	Pyrethroid Insecticides: Poisoning Syndromes, Synergies, and Therapy. Journal of toxicology. Clinical toxicology, {J-Toxicol-Clin-Toxicol}, 38 (2): 95-101	N	Public

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Reis, K. H.	A 7.1.1.2.2 /01 & 02	d-Allethrin	2007	Inherent biodegradability of d-Allethrin in a modified MITI test (II), Ibacon, Study N° 29101169, October, 25, 20006/February 19, 2007, GLP, unpublished	Y	Endura
Richold M., Edgar D.H., Ransome S.J., Bosworth H.J. and Banks.	A 6.6.3/01	Esbiothrin	1985	An assessment of the mutagenic potential of Esbiothrin using an in vitro mammalian cell test system. 1 February 1985 Huntingdon Research Centre, UK Report number RSL 649/84422. Sumitomo reference number A95112. GLP, Unpublished	Y	SCC
Ross *et al.*	Doc II	N/A	1990	Measuring potential dermal transfer of surface pesticide residue generated from indoor fogger use: an interim report. Food and Agriculture, Worker Health and Safety Branch, California. Chemosphere, Vol 20, Nos. 3/4, pp 349-360. Published.	N	N/A
Ross *et al.*	Doc II	N/A	1991	Measuring potential dermal transfer of surface pesticide residue generated from indoor fogger use: Using the CDFA roller method: Interim report II. Food and Agriculture, Worker Health and Safety Branch, California. Chemosphere, Vol 22, Nos. 9-10, pp 975-984. Published.	N	N/A
[redacted]	A 6.2/01		1991	Absorption, Distribution, Elimination and Metabolism of [^{14}C-alcohol]-d-trans-allethrin in the rat. 16 May 1991 Pharmacology and Toxicology Research Laboratory-West, Inc. Richmond. USA.	Y	SCC

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				Report number 418E/219W. Sumitomo reference number KM-11-0009 GLP, Unpublished		
[redacted]	A 6.2/02		1991	Absorption, Distribution, Elimination and Metabolism of [^{14}C-acid]-d-trans-allethrin in the rat. 16 May 1991 Pharmacology and Toxicology Research Laboratory-West, Inc. Richmond. USA. Report number 417E/215W. Sumitomo reference number A95010 GLP, Unpublished	Y	SCC
Ruzo, L.O., Gaughan, L.C., Casida J.E.	Doc II	S-Bioallethrin	1980	Pyrethroid Photochemistry: S-Bioallethrin Journal of Agricultural and Food Chemistry, vol. 28, pp. 246-249. Published.	N	N/A
Ryoichi K, Satoru N	A 7.1.1.2.2		1993	Biotic degradation test of S-41311AI by activated sludge. 22 October 1993 Sumitomo Chemical Company, Ltd report BDG92002/BDG93001 GLP, Unpublished	Y	SCC
Saito S.	A 3.5/01	Pynamin Forte (d-Allethrin)	1989	Water solubility of Pynamin Forte. 18 May 1989 Sumitomo Chemical Co., Ltd. Japan Study number WSL8901. Sumitomo reference number KP-90-0051 GLP, Unpublished	Y	SCC
Saito S.	A 3.9	Pynamin Forte	1989	Partition coefficient (n-octanol/water) of Pynamin Forte 18 May 1989	Y	SCC

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		(d-Allethrin)		Sumitomo Chemical Co., Ltd. Japan Study number PAR8901. Sumitomo reference number KP-90-0052 GLP, Unpublished		
[redacted]	A6.6.1		2006	Bacterial reverse mutation test of d-Allethrin using Salmonella typhimurium. Jai Research Foundation, Dept. of Toxicology, Valvada – 396 108, Dist. Valsad, Gujarat, India., Study No. 5751. GLP/unpublished.	Y	Endura
[redacted]	A 6.7/01 A 6.5/01 (filed under A 6.7/01)		1985	Chronic toxicity and oncogenicity study of Pynamin Forte ® in rats 15 May 1985 Daiyu-Kai Institute of Medical Science, Japan. Project number 8010 & 8011. Sumitomo reference number KT-51-0058. GLP, Unpublished	Y	SCC
[redacted]	A 6.8.2/01	Esbiothrin	1988	Two-generational reproduction toxicity study in rats. 27 July 1989 Centre International de Toxicologie. Study number 1690 RSR. Sumitomo reference number A95122. GLP, Unpublished	Y	SCC
Savron L,	A6.12.1		2006	Safety, Environment and quality department. Ravenna Plant Medical Data. Unpublished	Y	Endura

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Sayers L.E.	A 7.4.3.4	Esbiothrin	2009	Esbiothrin – Full Life-Cycle Toxicity Test with Water Fleas, *Daphnia magna*, Under Static-Renewal Conditions. 10 March 2009 Springborn Smithers Laboratories, Massachusetts, U.S.A. Study No. 13048.6576 GLP, Unpublished	Y	SCC
Schick, M.	A 7.1.2.2.2 /01	d-Allethrin	2012	[^{14}C]d-Allethrin: Degradation in Water Sediment Systems Under Aerobic Conditions, PTRL West, Inc. 625-B Alfred Nobel Drive Hercules, CA 94547, PTRL West Study Number 2031W; PTRL West Report Number 2031W-1, GLP, unpublished	Y	SCC
Schick, M.	A 7.2.1/04	d-cis-Allethrin	2011	Aerobic Degradation of [^{14}C]d-cis-Allethrin in Three Soils, PTRL West, Inc Study Number 2029W, GLP, unpublished	Y	SCC
Schmidt J M	A 7.2.1/01	d-trans-Allethrin	1992a	Aerobic Soil Metabolism Study of [Alc-^{14}C]-d-trans-Allethrin. 26 May 1992 ABC Laboratories, Inc., Columbia, U.S.A. Final Report no. 38485 GLP, Unpublished	Y	SCC
Schmidt J M	A 7.2.1/02	d-trans-Allethrin	1992b	Aerobic Soil Metabolism Study of [Acid-^{14}C]-d-trans-Allethrin. 18 May 1992, ABC Laboratories, Inc., Columbia, U.S.A. Final Report no. 38484 GLP, Unpublished	Y	SCC
Semann T.M.	A 3.2/01	Pynamin Forte	1989	Vapour pressure determination of Pynamin Forte.	Y	SCC

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		(d-Allethrin)		30 May 1989 Hazleton Laboratories America, Inc Madison, Wisconsin. USA Report number HLA 6001-269. Sumitomo reference number KP-91-0056. GLP, Unpublished		
Seyfried B.	A 7.1.1.2.1 /02	Allethrin	2002	Ready biodegradability of Allethrin in a manometric respirometry test, RCC Ltd, Study N° 842118, GLP, unpublished	Y	Endura
Seyfried B.	A 7.4.1.3	Allethrin	2002	Toxicity of Allethrin to Scenedesmus subspicatus in a 72-hour algal growth inhibition test. RCC Ltd, Report No. 842115 GLP, unpublished	Y	Endura
Seyfried B.	A 7.4.1.4/02	Allethrin	2002	Toxicity of Allethrin to activated sludge in a respiratory inhibition test. RCC Ltd, Study N° 842117, GLP, unpublished	Y	Endura
Shafer T.J., Meyer D.A. and Crofton K.M	A 6.9		2005	Developmental neurotoxicity of pyrethroid insecticides: Critical review and future research needs	N	
Shepler. K	A 7.2.1/05	t-COOH-CA	2011	Aerobic Degradation of [acid-^{14}C]*t*-COOH-CA in Three Soils, PTRL West, Inc. Study Number KM0026, GLP, unpublished	Y	SCC
Shono F.	A 6.12.1		2005	Review on medical examination of factory workers exposed to pyrethroids 21 November 2005 Sumitomo Chemical Co., Ltd Report number SVT-0009 Unpublished	Y	SCC

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[redacted]	A 6.7/03	Esbiothrin	1990	Combined Chronic Toxicity/Oncogenicity Study by Repeated Dietary Administration to Rats (104 weeks). 9 March 1990 Centre International de Toxicologie GLP, Unpublished	Y	SCC
[redacted]	A 6.7/04	Esbiothrin	1990	102-Week Dietary Carcinogenicity Study in Mice. 11 April 1990 Centre International de Toxicologie GLP, Unpublished	Y	SCC
[redacted]	A 6.5/04		1982	6-Month Dietary Toxicity Study in Dogs. 14 September 1982. International Research and Development Corporation. Ref: IRDC.BA.406.034/A1 GLP, unpublished	Y	SCC
Sumida, K., Saito, K., Ooe, N., Isobe, N., Kaneko, H. & Nakatsuka I.	A6.10/02		2001	Evaluation of in vitro methods for detecting the effects of various chemicals on the human progesterone receptor, with a focus on pyrethroid insecticides. Toxicology Letters 118: 147–155.	N	Public
Takada Y.	A 5.7/06	Pyrethroids	1992	Can a New Pyrethroid Kill kdr-type Houseflies? Sumitomo Chemical's, Takarazuka Research Center, 4-2-1 Hyogo, Japan. XIX International Congress of Entomology 1992.	N	N/A

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[redacted]	A 7.4.1.1/01	Pynamin Forte (d-Allethrin)	1984	The acute toxicity of Pynamin Forte to Carp (*Cyprinus carpio*). July 1984 Sumitomo Chemical Co., Ltd. Japan. Report number F-84104. Sumitomo reference number KW-30-0001 Non-GLP, Unpublished	Y	SCC
[redacted]	A 6.2/03		1998	C-allethrin: Dermal absorption in the rat. 23 July 1998 Covance Laboratories Ltd. UK Report number 194/179-D1141. Study reference number TOX 96291. GLP, Unpublished	Y	SCC
[redacted]	B 6.2* B 6.4		1998	^{14}C-allethrin: Dermal absorption in the rat. 23 July 1998 Covance Laboratories Ltd. UK Report number 194/179-D1141. Study reference number TOX 96291. GLP, Unpublished	Y	SCC
[redacted]	A6.4.1/01		2006	D-Allethrin: Repeated dose 28-day range finding oral toxicity study in rats. Department of Toxicology, Jai Research Foundation, Study N° 5762, October 18, 2006 (unpublished).	Y	Endura
[redacted]	A6.4.1.1		2007	D-Allethrin: Repeated dose 90-days oral toxicity study in rats. ai Research Foundation, Dept. of Toxicology, Valvada – 396 108, Dist. Valsad, Gujarat, India., Study No. 5762. GLP/unpublished.	Y	Endura
Tognucci A.	A 7.1.1.1.1	d-allethrin	2002	Hydrolysis determination of Allethrin at different pH values. RCC Ltd, Study N° 842216, July 6 2002 (unpublished)	Y	Endura

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Tognucci A.	A 7.1.3	d-allethrin	2002	Estimation of the Adsorption Coefficient of Allethrin on soil using High Performance Liquid Chromatography (HPLC). RCC Ltd, Study N° 842119, July 16 2002 (unpublished)	Y	Endura
Tsuji, R., Kobayashi, K., Ikeda, M., Yoshioka, T. Yamada T., Seki, T., Okuno, Y., Nakatsuka, I., Tsuruo, Y. & Kishioka, S	A6.10/01		2002	Lack of Changes in Brain Muscarinic Receptor and Motor Activity of Mice after Neonatal Inhalation Exposure to d-Allethrin. J. Appl. Toxicol. 22: 423–429	N	Public
Tsuzuki, M. Ohnishi, N, Takimoto, Y.	Doc II	Pynamin Forte (d-Allethrin)	1998	Indoor air concentration of pynamin forte evaporated from liquid electric vaporiser. Environmental Health Science Laboratory. Sumitomo Chemical Co. Ltd. Report number ER-RD-9838. Company reference number KF-0142. Unpublished.	Y	SCC
UKPID	A 6.12.1 A 6.12.8		1998	Monograph: Allethrin. National Poisons Information (Birmingham Centre) http://www.intox.org/databank/documents/chemical/allethrn/ukpid31.htm	N	Public
US EPA.	Doc II	N/A	1992	Dermal exposure assessment: Principles and Applications, Report number EPA 600/8-91/011B. USEPA Exposure Assessment Group, Office of Health and Environmental Assessment, Office of Research and Development, Washington DC, USA.	N	N/A

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US EPA.	Doc II	N/A	1994	Methodologies for Assessing Residential Exposure to Pesticides, EPA 736-5-94-0001.	N	N/A
US EPA.	Doc II	N/A	1998	Hazard evaluation division, Standard Evaluation Procedure, Inhalation Toxicity Testing. US EPA-540/09-88-101.	N	N/A
US EPA.	Doc II	Prallethrin	2000	Prallethrin [(*RS*)-2-methyl-4-oxo-3-(2-propynyl) cyclopent-2-enyl (1*RS*)-cis, trans-chrysanthemate]; Pesticide Tolerance. The Federal Register, June 26 2000, **65** (123) page iv.	N	N/A
Vaccaro, J. T *et al*.	Doc II	Chlorpyrifos	1991	Evaluation of dislodgeable residues and absorbed doses of chlorpyrifos to crawling infants following indoor broadcast applications of a chlorpyrifos based emulsifiable concentrate., The Dow Company, Indianapolis. August 28, 1991.	N	N/A
[redacted]	A 6.6.4	Esbiothrin	1984	Esbiothrin, detection of a mutagenic potency micronucleus test in the mouse. Centre de Recherches, Roussel Uclaf, France. 21 March 1984 Study number RU-EBT-84.603/A GLP, Unpublished	Y	SCC
Vaughan, V.C., Mackay, R.J., Nelson, W.E.	Doc II	N/A	1975	In *Textbook of Pediatrics* 10th Ed. Saunders, Philadelphia, London, Toronto, pp. 1876. Published.	N	N/A
[redacted]	A6.1.4.1		2006	Acute Dermal Irritation Study of d-Allethrin in Rabbits. Jai Research Foundation, Dept. of Toxicology, Valvada – 396 108, Dist. Valsad, Gujarat, India., Study No. 5760. GLP/unpublished.	Y	Endura
[redacted]	A6.1.4.2		2006	Acute Eye Irritation Study of d-Allethrin in Rabbits. Jai Research Foundation, Dept. of Toxicology,	Y	Endura

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				Valvada – 396 108, Dist. Valsad, Gujarat, India., Study No. 5761. GLP/unpublished.		
Wheeler J.P.	Doc II	N/A	2003	Amateur Exposure to Pesticides Resulting from use of Liquid and Mat Insecticide Evaporator devices. A thesis submitted to the University of Manchester for the degree of Master of Science in the Faculty of Medicine, Dentistry, Nursing and Pharmacy. Centre for Occupational and Environmental Health. July 2003. Further information on the conditions under which disclosures and exploitation may take place is available from the Head of the Department of Centre of Occupational and Environmental Health.	N	N/A
WHO	A 5.7/07	N/A	1998	Test Procedures for Insecticide Resistance Monitoring in Malaria Vectors, Bio-Efficacy and Persistence of Insecticides on Treated Surfaces. Report of the WHO Informal Consultation. WHO, Geneva, Switzerland 28-30 September 1998.	N	N/A
WHO	Doc II	N/A	1999	WHO Pesticide Evaluation Scheme (WHOPES). Safe and effective use of household insecticide products. Guide for the production of educational and training materials. WHO/CDS/CPC/WHOPES/99.1.1999.	N	N/A
WHO	Doc II	d-Allethrin	2002	WHO Specifications and Evaluations for Public Health Pesticides. d-Allethrin - (*RS*)-3-allyl-2-methyl-4-oxocyclopent-2-enyl (1*R*)-*cis*, *trans*-chrysanthemate. WHO Geneva 2002	N	N/A
WHO	Doc II	Allethrins	1989	Environmental Health Criteria 87: Allethrins World Health Organisation , Geneva 1989	N	N/A
WHO	A 5.7/07	N/A	1998	Test Procedures for Insecticide Resistance Monitoring in Malaria Vectors, Bio-Efficacy and Persistence of Insecticides on Treated Surfaces.	N	N/A

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				Report of the WHO Informal Consultation. WHO, Geneva, Switzerland 28-30 September 1998.		
WHO	A 7.5.3.1.1 A 7.5.3.1.2 A6.3.1 A6.3.2 A6.3.3 A6.4.1/02 A6.4.2 A6.4.3 A6.5 A6.7.1 A6.7.2 A6.8.1 A6.8.2	d-Allethrin	2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN World Health Organization, Geneva, 2002	N	public
WHO (EHC 87, 1989)	A 6.5		1989	International Programme on Chemical Safety: Environmental health criteria 87: Allethrins. Published under the joint sponsorship of the United Nations Environment Programme, the International Labour Organisation, and the World Health Organization. World Health Organisation, Geneva, 1989 http://www.inchem.org/documents/ehc/ehs/ehc87.htm	N	
WHO	A 6.3.1		2002	Specifications and evaluations for public health pesticides: d-Allethrin. World Health Organisation, Geneva, 2002 http://www.who.int/whopes/quality/en/dAllethrin_spec_eval_March_04.pdf	N	

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Williams P.T.	Doc II	N/A	2005	Waste Treatment and Disposal. John Wiley & Sons Ltd. ISBN 0-470-84913-4. Published.	N	N/A
Wimbush J. and Corfield L.	A 4.2		2006	Pynamin Forte (d-allethrin): Validation of an analytical method for the determination of residues in air. 7 April 2006 Covance Laboratories Ltd, Harrogate UK. Report number 2282/016-D2149 UK, GLP, Unpublished	Y	SCC
Worgan J.P., Franklin C.A.(Eds).	Doc II	N/A	2005	Occupational Residential Exposure Assessment for Pesticides. John Wiley & Sons. Published.	N	N/A
Yoshimura J., Mikami N. and Matsuo M.	A 7.2.1/03	d-trans-Allethrin	1993	Aerobic Soil Metabolism Study of ^{14}C-*d-trans-d*- and ^{14}C-*d-trans-l*-Allethrin Isomers. 17 February 1993 Sumitomo Chemical Co., Ltd. Project ID SOI89002, report number KM-00-0014 GLP, Unpublished	Y	SCC

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A 2.7 A 2.8 (filed under A 2.7)	Fujita T.	Pynamin Forte (d-Allethrin)	2001	Analysis results of recent batches of Pynamin Forte. 28 December 2001 Environmental Health Division, Sumitomo Chemical Company. Non-GLP, Unpublished	Y	SCC
A 3.1.1	Lentz N.R.	Pynamin Forte (d-Allethrin)	2008	Pynamin Forte PAI – Determination of the Melting/Freezing Temperature Following OECD Guideline 102 and the Official Journal of the European Communities L383A, Method A.1. 4 August 2008 Springborn Smithers Laboratories, Massachusetts, USA. Study no. 13048.6557. GLP, Unpublished	Y	SCC
A 3.1.2	Hoffman M.J.	Pynamin Forte (d-Allethrin)	1989	Determination of boiling point/boiling range of Pynamin Forte. 30 May 1989 Hazleton Laboratories America Inc. Madison, Wisconsin, USA. Report number HLA 6001-309, Sumitomo reference number KP-91-0053 GLP, Unpublished	Y	SCC
A 3.1.3/01	Furuta R.	Pynamin Forte (d-Allethrin)	1988	Specific gravity of Pynamin Forte 29 September 1988 Sumitomo Chemical Co., Ltd. Laboratory of biochemistry and toxicology. Sumitomo reference number KP-80-0047	Y	SCC

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				Non-GLP, Unpubished		
A 3.1.3/02	Lentz N.R.	Pynamin Forte (d-Allethrin)	2008	Pynamin Forte PAI – Determination of the Density of a Test Substance Following OECD Guideline 109 and the Official Journal of the European Communities L383A, Method A.3. 4 August 2008 Springborn Smithers Laboratories, Massachusetts, USA. Study no. 13048.6558. GLP, Unpublished	Y	SCC
A 3.10 A 3.4/02 A 3.11 A 3.12 A 3.14 (filed under A 3.10)	Burwood C.E.	d-Allethrin	2006	D-Allethrin: Evaluation of physico-chemical properties. 13 October 2006. Covance Laboratories Ltd. Harrogate, UK. Report number 2282/017-D2149 GLP, Unpublished	Y	SCC
A 3.13	Bright A.A.S	Esbiol	1999	Surface tension, Esbiol technical 21 May 1999 AgrEvo UK Ltd. Chesterfield Park. UK Report number CHR/98/058. Study identification 98062601H. Sumitomo reference number C001907 GLP, Unpublished	Y	SCC
A 3.13/02	Lentz N.R.	Pynamin Forte (d-Allethrin)	2008	Pynamin Forte PAI – Determination of Surface Tension Using a Ring Tensiometer Following OECD Guideline 115 and the Official Journal of the European Communities L383A, Method A.5.	Y	SCC

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				4 August 2008 Springborn Smithers Laboratories, Massachusetts, USA. Study no. 13048.6556. GLP, Unpublished		
A 3.2/01	Semann T.M.	Pynamin Forte (d-Allethrin)	1989	Vapour pressure determination of Pynamin Forte. 30 May 1989 Hazleton Laboratories America, Inc Madison, Wisconsin. USA Report number HLA 6001-269. Sumitomo reference number KP-91-0056. GLP, Unpublished	Y	SCC
A 3.2/02	Proctor K.L. and Lentz N.R.	Pynamin Forte (d-Allethrin)	2009	Determination of the Vapour Pressure of Pynamin Forte PAI Following OECD Guideline 104 and the Official Journal of the European Communities, L383A, Method A.4 21 April 2009 Springborn Smithers Laboratories, Massachusetts, USA. Study no. 13048.6559 GLP, unpublished	Y	SCC
A 3.3.1/01 A 3.3.2/01 A 3.3.3/01 A 3.12/01 A 3.14/01 (filed under	Anonymous	Pynamin Forte (d-Allethrin)	1984	Technical report: Physical and chemical properties of Pynamin ® and Pynamin ® Forte technical material. 11 April 1984 Sumitomo Chemical Co., Ltd. Osaka, Japan. Sumitomo reference number KP-40-0017 Non-GLP, unpublished	Y	SCC

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A 3.3.1/01)						
A 3.3.1/02 A 3.3.2/02 A 3.3.3/02 (filed under A 3.3.1/02)	Guidicelli J.C.	Esbiol	1991	Physical and chemical properties of Esbiol ® technical. 15 March 1991 Roussel Uclaf, Paris, France. Study number STE-058-A-03-2/63. Sumitomo reference number A98527 GLP, unpublished	Y	SCC
A 3.4	Anonymous	Pynamin Forte (d-Allethrin)	Not specified	Spectral data of Pynamin Forte technical grade (UV, IR, NMR and MS) Sumitomo Chemical Co., Ltd. Sumitomo reference number KP-30-0016 Non-GLP, Unpublished	Y	SCC
A 3.5/01	Saito S.	Pynamin Forte (d-Allethrin)	1989	Water solubility of Pynamin Forte. 18 May 1989 Sumitomo Chemical Co., Ltd. Japan Study number WSL8901. Sumitomo reference number KP-90-0051 GLP, Unpublished	Y	SCC
A 3.5/02	Lentz N.R.	Pynamin Forte (d-Allethrin)	2008	Pynamin Forte PAI – Determination of the Water Solubility of a Test Substance Following OECD Guideline 105 and the Official Journal of the European Communities, L383A, Method A.6. 20 August 2008. Springborn Smithers Laboratories, Massachusetts, USA.	Y	SCC

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				Study no. 13048.6555 GLP, Unpublished		
A 3.7	Bright A.A.S.	d-Allethrin	1999	Solubility in organic solvents 21 May 1999 AgrEvo UK Ltd. Chesterfield Park. UK Report number CHR/98/060. Study identification 98062601A. Sumitomo reference number C001909 GLP, Unpublished	Y	SCC
A 3.9	Saito S.	Pynamin Forte (d-Allethrin)	1989	Partition coefficient (n-octanol/water) of Pynamin Forte 18 May 1989 Sumitomo Chemical Co., Ltd. Japan Study number PAR8901. Sumitomo reference number KP-90-0052 GLP, Unpublished	Y	SCC
A 4.1	Furuta R	Pynamin Forte (d-Allethrin)	1989	Analytical methods to verify certified limits of Pynamin Forte technical grade 27 February 1989 Biochemistry and Toxicology Laboratory, Sumitomo Chemical C., Ltd. Sumitomo reference number KA-90-0044 Non-GLP, Unpublished	Y	SCC
A 4.2	Wimbush J. and Corfield L.	Pynamin Forte (d-Allethrin)	2006	Pynamin Forte (d-allethrin): Validation of an analytical method for the determination of residues in air. 7 April 2006 Covance Laboratories Ltd, Harrogate UK. Report number 2282/016-D2149 UK,	Y	SCC

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				GLP, Unpublished		
A 4.2	Wimbush J. and Corfield L.		2006	Pynamin Forte (d-allethrin): Validation of an analytical method for the determination of residues in air. 7 April 2006 Covance Laboratories Ltd, Harrogate UK. Report number 2282/016-D2149 UK, GLP, Unpublished	Y	SCC
A 4.2/04	Ramesh A., Ravi P. E.		2004	Negative Ion Chemical Ionization-Gas Chromatographic-Mass Spectrometric Determination of Residues of Different Pyrethroid Insecticides in Whole Blood and Serum, Journal of Analytical Toxicology, Vol. 28, November/December 2004, (published).	N	Public
A 5.3	Makita M. and Shinjo G.	Pynamin Forte (d-Allethrin)	1985	LD50 values of S-4068SF and other pyrethroids against housefly, mosquito and cockroach by topical application. November 1985 Pesticides laboratory, Takarazuka Research Center , Sumitomo Chemical Co., Ltd Hyogo, Japan. Report Number FFE-50-0022	Y	SCC
A 5.7/01	Enayati A.A. *et al.*	Pyrethroids	2003	Molecular evidence for a kdr-like pyrethroid resistance mechanism in the malaria vector mosquito *Anopheles stephensi*. The Royal Entomological Society. Medical and Veterinary Entomology (2003) 17, 138-144.	N	N/A
A 5.7/02	EPPO	N/A	2003	Resistance risk analysis. PP 1/213(2) 2003 OEPP/EPPO Bulletin 33, 37-63.	N	N/A

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A 5.7/03	IRAC	N/A	2005	Insecticide Resistance Action Committee – Mode of Action Classification v.4.2.1 (2005). www.irac-online.org	N	N/A
A 5.7/04	Khambay B.P.S.	Pyrethroids	2002	Pyrethroid Insecticides. Pesticide Outlook, pg 49-54. April 2002. The Royal Society of Chemistry 2002.	N	N/A
A 5.7/05	PSD	N/A	2004	Resistance risk analysis and use of resistance management strategies. Efficacy Guideline 606. PSD. October 2004. www.pesticides.gov.uk.	N	N/A
A 5.7/06	Takada Y.	Pyrethroids	1992	Can a New Pyrethroid Kill kdr-type Houseflies? Sumitomo Chemical's, Takarazuka Research Center, 4-2-1 Hyogo, Japan. XIX International Congress of Entomology 1992.	N	N/A
A 5.7/07	WHO	N/A	1998	Test Procedures for Insecticide Resistance Monitoring in Malaria Vectors, Bio-Efficacy and Persistence of Insecticides on Treated Surfaces. Report of the WHO Informal Consultation. WHO, Geneva, Switzerland 28-30 September 1998.	N	N/A
A 6.1.1./01	[redacted]	Pynamin Forte (d-Allethrin)	1989	Acute oral toxicity study of Pynamin Forte in rats. 15 February 1989 Sumitomo Chemical Co., Ltd. Japan Study number 1646. Sumitomo reference number KT-90-0079 GLP, Unpublished	Y	SCC
A 6.1.1/02	[redacted]	Pynamin Forte (d-Allethrin)	1981	Acute oral toxicity of Pynamin Forte in rats. 2 September 1981 Sumitomo Chemical Co., Ltd. Hyogo, Japan. Sumitomo reference number KT-10-0042	Y	SCC

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				GLP, Unpublished		
A 6.1.1/03	Anonymous	Pynamin Forte (d-Allethrin)	-	Toxicity of Pynamin Forte (III) Acute oral and subcutaneous toxicity in mice. Sumitomo Chemical Co., Ltd. Sumitomo reference number KT-70-0004 Non-GLP, Unpublished	Y	SCC
A 6.1.1/04	[redacted]	Esbiothrin	1985	Acute oral toxicity study in the rat. Centre de Recherches, Roussel Uclaf, France. Reference number RU.EBT.84323/A GLP, Unpublished	Y	SCC
A 6.1.1/04 IUCLID summary only	[redacted]		-	Toxicity of Pynamin Forte (I). Acute oral and subcutaneous toxicity in rats. Sumitomo Chemical Co., Ltd. Japan Sumitomo reference number KT-70-0002 Non-GLP, Unpublished	Y	SCC
A 6.1.1/05 IUCLID summary only	Anonymous		-	Acute oral, subcutaneous and intraperitoneal toxicity of Pynamin Forte in mice. Sumitomo Chemical Co., Ltd. Japan Sumitomo reference number KT-70-0003 Non-GLP Unpublished	Y	SCC
A 6.1.1/05 IUCLID summary only	[redacted]	Pynamin Forte (d-Allethrin)	-	Toxicity of Pynamin Forte (I). Acute oral and subcutaneous toxicity in rats. Sumitomo Chemical Co., Ltd. Japan Sumitomo reference number KT-70-0002 Non-GLP, Unpublished	Y	SCC
A 6.1.2/01	[redacted]	Pynamin Forte (d-Allethrin)	1989	Acute dermal toxicity study of Pynamin Forte in rabbits. 15 February 1989 Sumitomo Chemical Co., Ltd. Japan	Y	SCC

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				Study number 1705. Sumitomo reference number KT-90-0080. GLP, Unpublished		
A 6.1.2/02	[redacted]	Pynamin Forte (d-Allethrin)	1981	Acute dermal toxicity of Pynamin Forte® in rabbits. 15 February 1981 Sumitomo Chemical Company, Ltd. Hyogo, Japan. Document code KT-1--0040 GLP, Unpublished	Y	SCC
A 6.1.2/03	Anonymous	Pynamin Forte (d-Allethrin)	-	Acute dermal toxicity of Pynamin Forte and Pynamin Sumitomo Chemical Company, Ltd. Sumitomo reference number KT-70-0005 Non-GLP, Unpublished	Y	SCC
A 6.1.3/01	[redacted]	Pynamin Forte (d-Allethrin)	1989	Acute inhalation toxicity study of Pynamin Forte in rats. 15 February 1989 Sumitomo Chemical Co., Ltd Japan. Study number 1651. Sumitomo reference number KT-90-0082 GLP, Unpublished	Y	SCC
A 6.1.3/02 IUCLID summary only	[redacted]		1981	Acute inhalation toxicity of Pynamin Forte® in rats and mice. 7 July 1981 Research department, pesticides division, Sumitomo Chemical Co., Ltd. Osaka, Japan. Sumitomo reference number. KT-10-0041 GLP, Unpublished	Y	SCC
A 6.1.3/03	[redacted]	Pynamin Forte	-	Acute inhalation toxicity of Pynamin Forte and Pynamin in mice and rats.	Y	SCC

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IUCLID summary only		(d-Allethrin)		Research department, pesticides division, Sumitomo Chemical Co., Ltd. Japan. Sumitomo reference number KT-70-0010 Non-GLP, Unpublished		
A 6.1.4/01 A 6.1.4/02 (filed under A 6.1.4/01)	[redacted]	Pynamin Forte (d-Allethrin)	1988	Primary eye and skin irritation test with Pynamin ® Forte in rabbits. 18 November 1988 Sumitomo Chemical Co., Ltd. Japan. Study number 1537. Sumitomo reference number KT-80-0078 GLP, Unpublished	Y	SCC
A 6.1.4/03 IUCLID summary only	[redacted]	Pynamin Forte (d-Allethrin)	1980	Primary eye and skin irritation tests of Pynamin Forte® technical in rabbits 21 September 1980 Research department, pesticides division, Sumitomo Chemical Co., Ltd. Japan. Sumitomo reference number KT-10-0040 Non-GLP, Unpublished	Y	SCC
A 6.1.5	[redacted]	Pynamin Forte (d-Allethrin)	1989	Skin sensitisation test with Pynamin Forte in guinea pigs 15 February 1989 Sumitomo Chemical Co., Ltd. Japan Study number 1556. Sumitomo reference number KT-90-0081 GLP, Unpublished	Y	SCC
A 6.10/01	Tsuji, R., Kobayashi, K., Ikeda, M., Yoshioka, T. Yamada T., Seki, T., Okuno,		2002	Lack of Changes in Brain Muscarinic Receptor and Motor Activity of Mice after Neonatal Inhalation Exposure to d-Allethrin. J. Appl. Toxicol. 22: 423–429	N	Public

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	Y., Nakatsuka, I., Tsuruo, Y. & Kishioka, S					
A 6.10/02	Sumida, K., Saito, K., Ooe, N., Isobe, N., Kaneko, H. & Nakatsuka I.		2001	Evaluation of in vitro methods for detecting the effects of various chemicals on the human progesterone receptor, with a focus on pyrethroid insecticides. Toxicology Letters 118: 147–155.	N	Public
A 6.11	IPCS EHC		1989	IPCS, International Programme on Chemical Safety, Environmental Health Criteria 87, Allethrins. World Health Organization, Geneva 1989	N	Public
A 6.12.1	Shono F.	N/A	2005	Review on medical examination of factory workers exposed to pyrethroids 21 November 2005 Sumitomo Chemical Co., Ltd Report number SVT-0009 Unpublished	Y	SCC
A 6.12.1 A 6.12.8	UKPID		1998	Monograph: Allethrin. National Poisons Information Service (Birmingham Centre) http://www.intox.org/databank/documents/chemical/allethrn/ukpid31.htm	N	
A 6.12.4	Leng G, Ranft U, Sugiri D, Hadnagy W, Berger-Preiss E, Idel H.		2003	Pyrethroids used indoors--biological monitoring of exposure to pyrethroids following an indoor pest control operation. Int. J. Hyg. Environ. Health. 206(2):85-92	N	Public
A 6.12.5	Ray, D.E. & Forshaw P.J.		2000	Pyrethroid Insecticides: Poisoning Syndromes, Synergies, and Therapy. Journal of toxicology. Clinical toxicology, {J-Toxicol-Clin-Toxicol}, 38 (2): 95-101	N	Public

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A 6	IPCS EHC		1989	IPCS, International Programme on Chemical Safety, Environmental Health Criteria 87, Allethrins. World Health Organization, Geneva 1989	N	Public
A 6.2/01	[redacted]		1991	Absorption, Distribution, Elimination and Metabolism of [^{14}C-alcohol]-d-trans-allethrin in the rat. 16 May 1991 Pharmacology and Toxicology Research Laboratory-West, Inc. Richmond. USA. Report number 418E/219W. Sumitomo reference number KM-11-0009 GLP, Unpublished	Y	SCC
A 6.2/02	[redacted]		1991	Absorption, Distribution, Elimination and Metabolism of [^{14}C-acid]-d-trans-allethrin in the rat. 16 May 1991 Pharmacology and Toxicology Research Laboratory-West, Inc. Richmond. USA. Report number 417E/215W. Sumitomo reference number A95010 GLP, Unpublished	Y	SCC
A 6.2/03	[redacted]		1998	C-allethrin: Dermal absorption in the rat. 23 July 1998 Covance Laboratories Ltd. UK Report number 194/179-D1141. Study reference number TOX 96291. GLP, Unpublished	Y	SCC
A 6.3.1	WHO		2002	Specifications and evaluations for public health pesticides: d-Allethrin. World Health Organisation, Geneva, 2002 http://www.who.int/whopes/quality/en/	N	

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				dAllethrin_spec_eval_March_04.pdf		
A 6.3.1	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.3.2	[redacted]	Pynamin Forte (d-Allethrin)	1990	Twenty-one day dermal toxicity study in rabbits with Pynamin Forte. 26 March 1990 Huntingdon Research Centre Ltd. UK. HRC report number SMO 329/891585. Sumitomo reference number KT-01-0099. GLP, Unpublished	Y	SCC
A 6.3.2	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.3.2/02	[redacted]	Esbiothrin	1990	21-Day Dermal Toxicity Study with Esbiothrin in Rabbits. Hazelton Laboratories, America Report number HLA 6298-102 GLP, Unpublished	Y	SCC
A 6.3.3	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.4.1/01	[redacted]		1996	S-bioallethrin (Esbiol) Code: RU 16121. Rat 90-day dietary repeat dose study. 3 April 1996 AgrEvo UK Limited. Report number TOX/95/254-5. Study reference number TOX 94423. GLP, Unpublished	Y	SCC

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A 6.4.1/02 IUCLID summary only	[redacted]	Pynamin Forte (d-Allethrin)	-	90-Day subacute toxicity study of Pynamin Forte on rats Sumitomo Chemical Co., Ltd. Japan. Sumitomo reference number KT-70-0006 Non-GLP, Unpublished	Y	SCC
A 6.4.1/02	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.4.1/03	Anonymous	Bioallethrin, Esbiothrin and Esbiol	-	Comparison of the three Roussel Uclaf technical products in the d-trans-allethrin series (bioallethrin, esbiothrin and esbiol) in terms of the chemical specifications and toxicological properties	Y	SCC
A 6.4.2	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.4.3	[redacted]	Pynamin Forte (d-Allethrin)	1993	Three month inhalation toxicity study of Pynamin Forte in rats. 18 March 1993 Sumitomo Chemical Co., Ltd. Japan. Study number 2596. Sumitomo reference number KT-30-0123 GLP, Unpublished	Y	SCC
A 6.4.3	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.5	WHO (EHC 87, 1989)		1989	International Programme on Chemical Safety: Environmental health criteria 87: Allethrins. Published under the joint sponsorship of the United Nations Environment Programme, the International	N	

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				Labour Organisation, and the World Health Organization. World Health Organisation, Geneva, 1989 http://www.inchem.org/documents/ehc/ehs/ehc87.htm		
A 6.5	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.5/02	[redacted]		1989	Toxicity study in Beagle dogs by repeated oral administration in diet for 52 weeks. 6 September 1989 Centre International de Toxicologie. Study Number 2181 TCS GLP, Unpublished. Including the following range finder study report. Petra D. 1987. Dose range finding in Dogs by repeated oral administration for 28 days. 7 January 1987 Centre International de Toxicologie. Study Number 2180 TSC GLP, Unpublished.	Y	SCC
A 6.5/03	[redacted]		1989	Chronic Toxicity of Pynamin Forte in Dogs. 14 March 1989. Hazelton Laboratories America, Inc. HLA Study No. 343-207 GLP, unpublished	Y	SCC
A 6.5/04	[redacted]		1982	6-Month Dietary Toxicity Study in Dogs. 14 September 1982. International Research and Development Corporation. Ref: IRDC.BA.406.034/A1 GLP, unpublished	Y	SCC
A 6.6.1	Kogiso S.		1989	Reverse mutation test of Pynamin Forte in	Y	SCC

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				Salmonella typhimurium and Escherichia coli. 13 February 1989 Sumitomo Chemical Co., Ltd. Study number 1725. Sumitomo reference number KT-90-0083. GLP, Unpublished		
A 6.6.1/02	Kimmel E.C., Casida J.E. and Ruzo L.O.	Allethrin and Terallethrin	1982	Identification of Mutagenic Photoproducts of the Pyrethroids Allethrin and Terallethrin Journal of Agricultural and Food Chemistry, vol. 30, no. 4, pp.623-626 (1982) Non-GLP, Published	N	N/A
A 6.6.1/03	Herrera A. and Laborda E.	Allethrin, Resmethrin, Permethrin and Fenvalerate	1988	Mutagenic activity in synthetic pyrethroids in *Salmonella typhimurium* Mutagenesis, vol. 3, no. 6, pp. 509-514 (1988) Non-GLP, Published	N	N/A
A 6.6.1/04	Hour T.-C., Chen L. and Lin J.-K.	Allethrin and other pesticides	1998	Comparative investigation on the mutagenicities of organophosphate, phthalimide, pyrethroid and carbamate insecticides by the Ames and lactam tests. Mutagenesis, vol. 13, no. 2, pp. 157-166 (1998) Non-GLP, Published	N	N/A
A 6.6.1/05	Moriya M., Ohta T., Watanabe K., Miyazawa T., Kato K. and Shirasu Y.		1983	Further mutagenicity studies on pesticides in bacterial reversion assay systems. Mutation Research, vol. 116, pp. 185-216 (1983) Non-GLP, Published	N	N/A
A 6.6.2/01	[redacted]		1989	In vitro chromosomal aberration test of Pynamin Forte in Chinese hamster ovary cells (CHO-K1).	Y	SCC

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				21 April 1989 Sumitomo Chemical Co., Ltd. Japan. Study number 1729. Sumitomo reference number KT-90-0088		
A 6.6.2/02	Matsuoka A., Hayashi M. and Ishidate Jr. M.	Allethrin and other compounds	1979	Chromosomal aberration tests on 29 chemicals combined with S9 mix in vitro. Mutation Research, vol. 66, pp. 277-290 (1979) Non-GLP, Published	N	N/A
A 6.6.3/01	Richold M., Edgar D.H., Ransome S.J., Bosworth H.J. and Banks.	Esbiothrin	1985	An assessment of the mutagenic potential of Esbiothrin using an in vitro mammalian cell test system. 1 February 1985 Huntingdon Research Centre, UK Report number RSL 649/84422. Sumitomo reference number A95112. GLP, Unpublished	Y	SCC
A 6.6.3/02	[redacted]	Pynamin Forte (d-Allethrin)	1989	In vitro unscheduled DNA synthesis (USD) assay of Pynamin Forte in rat hepatocytes. 12 May 1989 Sumitomo Chemical Co., Ltd. Japan Study number 1553. Sumitomo reference number KT-90-0089 GLP, Unpublished	Y	SCC
A 6.6.4	[redacted]	Esbiothrin	1984	Esbiothrin, detection of a mutagenic potency micronucleus test in the mouse. Centre de Recherches, Roussel Uclaf, France. 21 March 1984 Study number RU-EBT-84.603/A GLP, Unpublished	Y	SCC

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A 6.6.7 , (filed under A 7.1.1.1.2/ 03	Isobe N., Mihara M., Suzuki H., Matsuo M. and Miyamoto J.		1988	Identification of a mutagen in photooxidation products of allethrin. Biochemistry and Toxicology Laboratory, Sumitomo Chemical Co., Ltd., Japan Sumitomo reference number KT-80-0084 Non-GLP	Y	SCC
A 6.7.1	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.7.2	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.7/01 A 6.5/01 (filed under A 6.7/01)	[redacted]		1985	Chronic toxicity and oncogenicity study of Pynamin Forte ® in rats 15 May 1985 Daiyu-Kai Institute of Medical Science, Japan. Project number 8010 & 8011. Sumitomo reference number KT-51-0058. GLP, Unpublished	Y	SCC
A 6.7/02	[redacted]		1989	Pynamin Forte: Potential tumorigenic effects in prolonged dietary administration to mice. 17 March 1989 Report number SMO 247/881028. Sumitomo reference number KT-91-0086 GLP, Unpublished	Y	SCC

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A 6.7/03	[redacted]	Esbiothrin	1990	Combined Chronic Toxicity/Oncogenicity Study by Repeated Dietary Administration to Rats (104 weeks). 9 March 1990 Centre International de Toxicologie GLP, Unpublished	Y	SCC
A 6.7/04	[redacted]	Esbiothrin	1990	102-Week Dietary Carcinogenicity Study in Mice. 11 April 1990 Centre International de Toxicologie GLP, Unpublished	Y	SCC
A 6.8.1	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.8.1/01	[redacted]		1989	Teratology study in rats with Pynamin Forte. 17 July 1989 Argus Research Laboratories Inc. Report number Argus 1119-004. Sumitomo reference number KT-91-0094 GLP, Unpublished	Y	SCC
A 6.8.1/02	[redacted]		1989	Teratology study in rabbits with Pynamin Forte. 17 July 1989 Argus research Laboratory Inc. Report number Argus 1119-006. Sumitomo reference number KT-91-0097 GLP, Unpublished.	Y	SCC
A 6.8.1/03	[redacted]	Esbiothrin	1990	Developmental Toxicity (Embryo-fetal Toxicity and Teratogenic Potential) Study of Esbiothrin Technical Administered Orally via Gavage to Crl:CD®BR VAF/Plus® Presumed Pregnant Rats.	Y	SCC

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				31 August 1990 Argus Research Laboratories Inc. Study number 718-001 GLP, Unpublished		
A 6.8.1/04	[redacted]		1990	Developmental Toxicity (Embryo-fetal Toxicity and Teratogenic Potential) Study of Esbiothrin Technical Administered Orally via Stomach Tube to New Zealand White Rabbits. 31 August 1990 Argus Research Laboratories Inc. Study number 718-002 GLP, Unpublished	Y	SCC
A 6.8.2	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.8.2/01	[redacted]	Esbiothrin	1988	Two-generational reproduction toxicity study in rats. 27 July 1989 Centre International de Toxicologie. Study number 1690 RSR. Sumitomo reference number A95122. GLP, Unpublished	Y	SCC
A 6.8.2/02	[redacted]	Pynamin Forte (d-Allethrin)	1989	Reproductive effects of Pynamin Forte administered orally in feed to Crl:COBS® CD® (SD)BR rats for two generations. 29 March 1989 Argus Research Laboratories, Inc 905 Sheehy Drive Horsham, PA 19044. Report number Argus 1119-002, Sumitomo reference number KT-91-0087 GLP, Unpublished	Y	SCC

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A 6.9	Eriksson, P.; Fredriksson A.		1991	Neurotoxic effects of two different pyrethroids, bioallethrin and deltamethrin, on immature and adult mice: changes in behavioral and muscarinic receptor variables. In: Toxicology and Applied Pharmacology. 108:78-85	N	Public
A 6.9	Fujita T.	N/A	2006	General statement of Neurotoxicity for Pyrethroids. 20 February 2006 Sumitomo Chemical Report number QAT-0081 Data review, unpublished	Y	SCC
A 6.9	Pauluhn, J.; Schmuck G.		2003	Critical Analysis of Potential Body Temperature Confounders on Neurochemical Endpoints Caused by Direct Dosing and Maternal Separation in Neonatal Mice: a Study of Bioallethrin and Deltamethrin Interactions with Temperature on Brain Muscarinic Receptors. In: Journal of Applied Toxicology. 23: 9-18	N	Public
A 6.9	Ray, D. E.; Verschoyle, R. D.; Muhammad, B. Y.		2002	Reproducibility of developmental neurotoxicity produced by pyrethroids and DDT in neonatal mice. In: Toxicologist. 66: 131	N	Public
A 6.9	Shafer T.J., Meyer D.A. and Crofton K.M		2005	Developmental neurotoxicity of pyrethroid insecticides: Critical review and future research needs	N	
A 6.9/02	[redacted]		1997	ESBIOL: Rat Acute Oral Neurotoxicity Study. 26 November 1997. Huntingdon Life Sciences Ltd. GLP, unpublished	Y	SCC
A 6.9/02	[redacted]	S-bioallethrin	2000	AE F147006 (S-Bioallethrin) Rat 90-day neurotoxicity study. 6 July 2000. Aventis CropScience UK Limited Report number TOX/00/254-103	Y	SCC

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				GLP, unpublished		
A 7.1.1.1.1	Estigoy L., Sheplar K., Ruzo L.O.	[Alc-14C]-d-trans-allethrin 50/50 (bioallethrin)	1990	Hydrolysis of [Alc-14C]-d-trans-allethrin at pH 5, 7 and 9. 19 April 1990 Pharmacology and Toxicology Research Laboratory, 4123-B, Lakeside Drive, Richmond, California 94806. PTRL Report number 196-W-1. Sumitomo reference number KM-01-0007 GLP, Unpublished	Y	SCC
A 7.1.1.1.2/ 01	Chari S., Shepler K and Ruzo L.O.	[Alc-^{14}C]-d-trans-Allethrin 50/50 (bioallethrin)	1990	Sunlight Photodegradation of [Alc-^{14}C]-d-trans-Allethrin in a Buffered Aqueous Solution at pH 5. 19 April 1990 Pharmacology and Toxicology Research Laboratory, 4123-B, Lakeside Drive, Richmond, California 94806. PTRL Report Number 197W-1. Sumitomo reference number KM-01-0006. GLP, Unpublished	Y	SCC
A 7.1.1.1.2/ 02	Isobe N., Matsuo M. and Miyamoto J.	Allethrin	1984	Novel Photoproducts of Allethrin. Laboratory of Biochemistry and Toxicology, Sumitomo Chemical Co., Ltd. Tetrahedron Letters, vol. 25, no. 8, pp. 861-864 (1984)	N	SCC
A 7.1.1.1.2/ 03	Isobe N., Mihara M., Suzuki H., Matsuo M. and Miyamoto J.	Allethrin	1988	Identification of a mutagen in photooxidation products of allethrin. Biochemistry and Toxicology Laboratory, Sumitomo Chemical Co., Ltd., Japan Sumitomo reference number KT-80-0084 Non-GLP	Y	SCC

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A 7.1.1.2.1	Grützner I.	Pynamin Forte (d-Allethrin)	2002	Ready biodegradability of Pynamin Forte in a manometric respirometry test. 9 January 2002 RCC Ltd. Switzerland. Report number 820563. Sumitomo reference number KM-0019 GLP, Unpublished	Y	SCC
A 7.1.1.2.2	Ryoichi K, Satoru N	Imiprothrin	1993	Biotic degradation test of S-41311AI by activated sludge. 22 October 1993 Sumitomo Chemical Company, Ltd report BDG92002/BDG93001 GLP, Unpublished	Y	SCC
A 7.1.2.2.2/01	Schick, M.	d-Allethrin	2012	[^{14}C]d-Allethrin: Degradation in Water Sediment Systems Under Aerobic Conditions, PTRL West, Inc. 625-B Alfred Nobel Drive Hercules, CA 94547, PTRL West Study Number 2031W; PTRL West Report Number 2031W-1, GLP, unpublished	Y	SCC
A 7.1.2/01	Kaman R.A.	d-*trans*-Prallethrin	1999	Aerobic Aquatic Soil Metabolism Study of [cyclopropyl-1-^{14}C]-d-*trans*-Prallethrin. Environmental and Metabolic Fate, Ricerca Inc., Painesville, USA. Report number 7434-98-0013-EF-001 GLP, Unpublished	Y	SCC
A 7.1.3	Dykes J.	^{14}C-1R-trans-Allethrin	1990	"Soil/sediment adsorption-desorption with ^{14}C-Allethrin" 26 December 1990	Y	SCC

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				Analytical Bio-chemical Laboratories, Inc. 7200 East ABC Lane, P.O. Box 1097, Columbia, Missouri 65205. ABC report number 38539. Sumitomo reference number A97529. GLP, Unpublished		
A 7.2.1/01	Schmidt J M	d-trans-Allethrin	1992a	Aerobic Soil Metabolism Study of [Alc-^{14}C]-d-trans-Allethrin. 26 May 1992 ABC Laboratories, Inc., Columbia, U.S.A. Final Report no. 38485 GLP, Unpublished	Y	SCC
A 7.2.1/02	Schmidt J M	d-trans-Allethrin	1992b	Aerobic Soil Metabolism Study of [Acid-^{14}C]-d-trans-Allethrin. 18 May 1992, ABC Laboratories, Inc., Columbia, U.S.A. Final Report no. 38484 GLP, Unpublished	Y	SCC
A 7.2.1/03	Yoshimura J., Mikami N. and Matsuo M.	d-trans-Allethrin	1993	Aerobic Soil Metabolism Study of ^{14}C-*d-trans-d*- and ^{14}C-*d-trans-l*-Allethrin Isomers. 17 February 1993 Sumitomo Chemical Co., Ltd. Project ID SOI89002, report number KM-00-0014 GLP, Unpublished	Y	SCC
A 7.2.1/04	Schick, M.	d-cis-Allethrin	2011	Aerobic Degradation of [^{14}C]d-cis-Allethrin in Three Soils, PTRL West, Inc Study Number 2029W, GLP, unpublished	Y	SCC
A 7.2.1/05	Shepler. K	t-COOH-CA	2011	Aerobic Degradation of [acid-^{14}C]*t*-COOH-CA in Three Soils,	Y	SCC

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				PTRL West, Inc. Study Number KM0026, GLP, unpublished		
A 7.4.1.1/01	[redacted]	Pynamin Forte (d-Allethrin)	1984	The acute toxicity of Pynamin Forte to Carp (*Cyprinus carpio*). July 1984 Sumitomo Chemical Co., Ltd. Japan. Report number F-84104. Sumitomo reference number KW-30-0001 Non-GLP, Unpublished	Y	SCC
A 7.4.1.1/02	[redacted]	Esbiothrin	1993	The Acute Toxicity of Esbiothrin to Rainbow Trout (*Oncorhynchus mykiss*). 18 August 1993. Safepharm Laboratories Limited, P.O. Box No. 45, Derby, DE1 2BT UK. Report number 154/1615. Doc No REFG93-28, Sumitomo reference number A98445 GLP, Unpublished	Y	SCC
A 7.4.1.2/01	Manson P and Scholey A	Pynamin Forte (d-Allethrin)	2007	d-Allethrin: Acute Toxicity to *Daphnia magna*. 9 March 2007 Covance Laboratories Limited, Harrogate, North Yorkshire, UK. Report number 2282/033-D2149 GLP, Unpublished	Y	SCC
A 7.4.1.2/02	Handley J.W., Sewell I.G. and Bartlett A.J.	Esbiothrin	1993	The Acute Toxicity of Esbiothrin to *Daphnia magna*. 18 August 1993 Safepharm Laboratories Limited, P.O. Box No. 45, Derby, DE1 2BT. UK. Report number 154/1614. Document number G93-28. Sumitomo reference number A98445 GLP, Unpublished	Y	SCC

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A 7.4.1.3	Hoberg J.R.	Pynamin Forte (d-Allethrin)	2002	Pynamin Forte toxicity to the freshwater green alga, Pseudokirchneriella subcapitata. 22 November 2002 Springborn smithers Laboratories, 790 Main Street, Wareham, massachusetts 02571-1075. Report number 13048.6336. Sumitomo reference number KW-0011 GLP, Unpublished	Y	SCC
A 7.4.1.4	Grützner I.	Pynamin Forte (d-Allethrin)	2001	Toxicity of Pynamin Forte to Activated Sludge in a Respiration Inhibition Test. 29 October 2001 RCC Ltd, Environmental Chemistry & Pharmanalytics Division, CH-4452, Itengen/Switzerland. Report number 820462. Sumitomo reference number KW-0008. GLP, Unpublished	Y	SCC
A 7.4.3.2 A 7.5.4.1	IPCS EHC	Allethrins	1989	IPCS, International Programme on Chemical Safety, *Environmental Health Criteria 87, Allethrins.* World Health Organization, Geneva 1989	N	public
A 7.4.3.2	IPCS HSG	Allethrins	1989	IPCS, International Programme on Chemical Safety, Health and Safety Guide No. 24 *Allethrins. Health and Safety Guide* World Health Organization, Geneva 1989	N	public

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A 7.4.3.4	Sayers L.E.	Esbiothrin	2009	Esbiothrin – Full Life-Cycle Toxicity Test with Water Fleas, *Daphnia magna*, Under Static-Renewal Conditions. 10 March 2009 Springborn Smithers Laboratories, Massachusetts, U.S.A. Study No. 13048.6576 GLP, Unpublished	Y	SCC
A 7.5.1.2	Inglesfield C	Cypermethrin	1984	Toxicity of the Pyrethroid Insecticides Cypermethrin and WL85871 to the Earthworm, *Eisenia foetida* Savigny Shell Research Limited, Sittingbourne Research Centre, Sittingbourne, Kent, UK. Published.	N	N/A
A 7.5.3.1.1 A 7.5.3.1.2	WHO	d-Allethrin	2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN World Health Organization, Geneva, 2002	N	public
A 7.5.3.1.2/01 (IUCLID only)	[redacted]	Pynamin Forte (d-Allethrin)	1978	Eight-day dietary LC50 - Bobwhite quail, Pynamin Forte. 31 July 1978 Wildlife International Ltd. Report number 163-102, Sumitomo reference number KT-81-0022 Non-GLP, Unpublished	Y	SCC
B 6.2* B 6.4	[redacted]		1998	^{14}C-allethrin: Dermal absorption in the rat. 23 July 1998 Covance Laboratories Ltd. UK Report number 194/179-D1141. Study reference number TOX 96291.	Y	SCC

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				GLP, Unpublished		
B 6.5	ECB		2000	Distillates (petroleum), hydrotreated light IUCLID Dataset European Commission – European Chemicals Bureau Published www.ECB,jrt.it White Spirits IPCS International Programme on Chemical Safety, Health and Safety Guide No. 103 Published www.inchem.org	N	ECB
B 6.6/01	Matsunaga, M.		1986	Measurement of aerial concentration of Pynamin Forte during Pynamin Forte 40 mg mat use. Household and Public Hygiene Chemicals Division. Sumitomo Chemical Co. Ltd. Report number KF-60-0065. Unpublished.	Y	SCC
B 6.6/02	Anonymous		N/A	Deposit of Pynamin Forte on the floor, wall and ceiling of the test chamber during mat use. Household and Public Hygiene Chemicals Division. Sumitomo Chemical Co. Ltd. Report number KF-90-0122. Unpublished.	Y	SCC
Doc I	Anonymous		2006	Memorandum: Allethrins: HED chapter of reregistration eligibility decision document (RED). United States Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances. Washington, D. C. 20460, Dec. 20, 2006	N	Public
Doc I	Rauch, F., Lhoste, J., Martel, J.		1974	Insecticidal properties of some allethrin isomers used in coil formulations against mosquitoes. In:	N	Public

Section No / Reference No	Author(s)	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
				Pesticide Science. 5: 651-656.		
Doc II	American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE).	N/A	1989	Ventilation for acceptable Indoor Air Quality (ASHRAE 62-1989). Atlanta GA.	N	N/A
Doc II	Anonymous	Pynamin Forte 40mg Mat (d-Allethrin)	N/A	Vaporisation test of Pynamin Forte 40mg Mat. Household and Public Hygiene Chemicals Division. Sumitomo Chemical Co. Ltd. Report number KF-20-0031. Unpublished.	Y	SCC
Doc II	Anonymous	Pynamin Forte (d-Allethrin)	N/A	The test procedure to measure the aerial concentration of active ingredient evaporated from mat formulation containing Pynamin Forte in the closed room. Household and Public Hygiene Chemicals Division. Sumitomo Chemical Co. Ltd. Report number KF-80-0051. Unpublished.	Y	SCC
Doc II	Anonymous	Pynamin Forte (d-Allethrin)	N/A	Aerial concentration of pynamin forte evaporated from heated mat (3553.tif). Household and Public Hygiene Chemicals Division. Sumitomo Chemical Co. Ltd. Report number not stated.	Y	SCC
Doc II	Anonymous	d-Allethrin	N/A	Deposit of d-allethrin on the floor, wall and ceiling of the test chamber during mat use. Household and Public Hygiene Chemicals Division. Sumitomo Chemical Co. Ltd. Unpublished report number KF-90-0122	Y	SCC
Doc II	Atkinson, R.	N/A	1985	Kinetics and mechanisms of the gas-phase reactions of the hydroxyl radical with organic	N	N/A

Section No / Reference No	Author(s)	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
				compounds under atmospheric conditions. Chem. Rev. 85, 69-201. Published.		
Doc II	Brouwer, D. H., Kroese, R., Van Hemmen, J.J.	N/A	1999	Transfer of contaminants from surface to hands: Experimental assessment of linearity of the exposure process, adherence to the skin, and area exposed during fixed procedure and repeated contact with surfaces contaminated with a powder. Department of Chemical Exposure Assessment, TNO Nutrition and Food Reasearch Institute, The Netherlands. Applied Occupational and Environmental Hygiene. Volume 14: 231-239. Published.	N	N/A
Doc II	EC	N/A	2002	Technical Notes for Guidance. Human Exposure to Biocidal Products. Guidance on Exposure Estimation. Report was prepared under contract B4-3040/2000/291079/MAR/E2 for the European Commission, DG Environment. June 2002.	N	N/A
Doc II	ECB.	N/A	2003	Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC, Commission Regulation 1488/94 and Directive 98/8/EC. European Chemicals Bureau - Institute for Health and Consumer Protection.	N	N/A
Doc II	Gottschild, D, Storzer, W., Wilkening, A.	N/A	1993	Criteria for assessment of plant protection products in the registration of BBA, 65-67. Published.	N	N/A
Doc II	IPCS International Programme on Chemical Safety	Allethrins	1989	Allethrins: Health and Safety Guide No. 24	N	N/A

Section No / Reference No	Author(s)	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Doc II	IPCS International Programme on Chemical Safety	Allethrins	1989	Allethrins: Environmental Health Criteria No. 87.	N	N/A
Doc II	IPCS EHC		1989	IPCS, International Programme on Chemical Safety, Environmental Health Criteria 87, Allethrins. World Health Organization, Geneva 1989 http://www.inchem.org/documents/ehc/ehc/ehc87.htm#SectionNumber:6.1 (last requested March 9th 2018)	N	Public
Doc II	Jassen, J.E.	N/A	1989	Ventilation for Acceptable Indoor Air Quality. ASHRAE Journal. Published.	N	N/A
Doc II	Matoba Y, Inoue A, Takimoto Y.	Prallethrin	2004	Clarifying Behaviour of Prallethrin Evaporated from an Electric Vaporizer on the Floor and Estimating Associated Dermal Exposure. Environmental Health Science Laboratory. Sumitomo Chemical Company. J.Pestic. Sci., **29**(4), 313-321. Published.	N	N/A
Doc II	Matoba, Y, Takimoto, Y., Kato, T.	d-Phenothrin and d-Tetramethrin	1988	Indoor Behaviour and Risk Assessment Following Residual Spraying of d-Phenothrin and d-Tetramethin. American Industrial Hygiene Association Journal. 59:191-199. Published.	N	N/A
Doc II	Matoba, Y., Hirota, T., Ohnishi, J., Murai, N., Matsuo, M.		1994	An indoor simulation of the behavior of insecticides supplied by an electric vaporizer. Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd. Chemosphere Vol 28. No 3 pp435-451. Published.	N	N/A
Doc II	Matsunaga, M.	Pynamin Forte	1986	Measurement of aerial concentration of Pynamin Forte during Pynamin Forte 40 mg mat use.	Y	SCC

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		(d-Allethrin)		Household and Public Hygiene Chemicals Division. Sumitomo Chemical Co. Ltd. Report number KF-60-0065. Unpublished.		
Doc II	OECD	N/A	1993	OECD/GD(92)172. The rate of photochemical transformation of gaseous organic compounds in air under tropospheric conditions – Environmental Monograph No 61. Paris 1993.	N	N/A
Doc II	Ross *et al.*	N/A	1990	Measuring potential dermal transfer of surface pesticide residue generated from indoor fogger use: an interim report. Food and Agriculture, Worker Health and Safety Branch, California. Chemosphere, Vol 20, Nos. 3/4, pp 349-360. Published.	N	N/A
Doc II	Ross *et al.*	N/A	1991	Measuring potential dermal transfer of surface pesticide residue generated from indoor fogger use: Using the CDFA roller method: Interim report II. Food and Agriculture, Worker Health and Safety Branch, California. Chemosphere, Vol 22, Nos. 9-10, pp 975-984. Published.	N	N/A
Doc II	Ruzo, L.O., Gaughan, L.C., Casida J.E.	S-Bioallethrin	1980	Pyrethroid Photochemistry: S-Bioallethrin Journal of Agricultural and Food Chemistry, vol. 28, pp. 246-249. Published.	N	N/A
Doc II	Tsuzuki, M. Ohnishi, N, Takimoto, Y.	Pynamin Forte (d-Allethrin)	1998	Indoor air concentration of pynamin forte evaporated from liquid electric vaporiser. Environmental Health Science Laboratory. Sumitomo Chemical Co. Ltd. Report number ER-RD-9838. Company reference number KF-0142. Unpublished.	Y	SCC
Doc II	US EPA.	N/A	1992	Dermal exposure assessment: Principles and Applications, Report number EPA 600/8-91/011B.	N	N/A

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				USEPA Exposure Assessment Group, Office of Health and Environmental Assessment, Office of Research and Development, Washington DC, USA.		
Doc II	US EPA.	N/A	1994	Methodologies for Assessing Residential Exposure to Pesticides, EPA 736-5-94-0001.	N	N/A
Doc II	US EPA.	N/A	1998	Hazard evaluation division, Standard Evaluation Procedure, Inhalation Toxicity Testing. US EPA-540/09-88-101.	N	N/A
Doc II	US EPA.	Prallethrin	2000	Prallethrin [(*RS*)-2-methyl-4-oxo-3-(2-propynyl) cyclopent-2-enyl (1*RS*)-cis, trans-chrysanthemate]; Pesticide Tolerance. The Federal Register, June 26 2000, **65** (123) page iv.	N	N/A
Doc II	US EPA	allethrins	2009	Reregistration eligibility decision for allethrins https://archive.epa.gov/pesticides/reregistration/web/pdf/allethrins-amended-red.pdf (website requested on March 9th 2018)	N	Public
Doc II	Vaccaro, J. T *et al*.	Chlorpyrifos	1991	Evaluation of dislodgeable residues and absorbed doses of chlorpyrifos to crawling infants following indoor broadcast applications of a chlorpyrifos based emulsifiable concentrate., The Dow Company, Indianapolis. August 28, 1991.	N	N/A
Doc II	Vaughan, V.C., Mackay, R.J., Nelson, W.E.	N/A	1975	In *Textbook of Pediatrics* 10th Ed. Saunders, Philadelphia, London, Toronto, pp. 1876. Published.	N	N/A
Doc II	Wheeler J.P.	N/A	2003	Amateur Exposure to Pesticides Resulting from use of Liquid and Mat Insecticide Evaporator devices. A thesis submitted to the University of Manchester for the degree of Master of Science in the Faculty of Medicine, Dentistry, Nursing and Pharmacy. Centre	N	N/A

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				for Occupational and Environmental Health. July 2003. Further information on the conditions under which disclosures and exploitation may take place is available from the Head of the Department of Centre of Occupational and Environmental Health.		
Doc II	WHO	N/A	1999	WHO Pesticide Evaluation Scheme (WHOPES). Safe and effective use of household insecticide products. Guide for the production of educational and training materials. WHO/CDS/CPC/WHOPES/99.1.1999.	N	N/A
Doc II	WHO	d-Allethrin	2002	WHO Specifications and Evaluations for Public Health Pesticides. d-Allethrin - (*RS*)-3-allyl-2-methyl-4-oxocyclopent-2-enyl (1*R*)-*cis*, *trans*-chrysanthemate. WHO Geneva 2002	N	N/A
Doc II	WHO	Allethrins	1989	Environmental Health Criteria 87: Allethrins World Health Organisation , Geneva 1989	N	N/A
Doc II	Williams P.T.	N/A	2005	Waste Treatment and Disposal. John Wiley & Sons Ltd. ISBN 0-470-84913-4. Published.	N	N/A
Doc II	Worgan J.P., Franklin C.A.(Eds).	N/A	2005	Occupational Residential Exposure Assessment for Pesticides. John Wiley & Sons. Published.	N	N/A
Doc II B 8.3	ECHA	N/A	2013	Manual of Technical Agreements (MOTA), v.6	N	N/A
Doc II B 8.3	ECHA	N/A	2015	Technical Agreements for Biocides, v1.0	N	N/A
Doc II B 8.3	OECD	N/A	2008	OECD Series on Emission Scenario Documents, Number 18 Emission Scenario Document for insecticides, acaricides and products to control other athropods for household and professional uses	N	N/A

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Doc II-4, Chapter 4	EC		2006	Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp	--	--
Doc II-4, Chapter 4	ECHA	--	2013	Guidance on information requirements, Guidance on Regulation (EU) No 528/2012 concerning the Making Available on the Market and Use of Biocidal Products (BPR), Version 1.0	-	-
Doc II-4, Chapter 4	ECHA	--	2015	Guidance on the Biocidal Products Regulation, Volume IV Environment – Part B Risk Assessment (active substances), Version 1.0	-	--
Doc II-4, Chapter 4	ECHA	--	2012	Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT/vPvB Assessment, Version 2.0	-	--
Doc II-4, Chapter 4	ECHA	--	2011	Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures	-	--

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Section No / Reference No	Author(s)	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A 3.1.1	Garofani S.		2006a	d-Allethrin. (pure active substance): Determination of the physico-chemical properties, ChemService S.r.l., Draft Interim No. CH-009/2006, GLP,	Y	Endura

Section No / Reference No	Author(s)	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
				(unpublished).		
A 3.1.2	Garofani S.		2006a	d-Allethrin. (pure active substance): Determination of the physico-chemical properties, ChemService S.r.l., Draft , GLP, (unpublished).Interim No. CH-009/2006	Y	Endura
A 3.12	Garofani S.		2006b	d-Allethrin. (pure active substance): Determination of the physico-chemical properties, ChemService S.r.l., Draft , GLP, (unpublished).Interim No. CH-010/2006	Y	Endura
A 3.14	Garofani S.		2006b	d-Allethrin. (pure active substance): Determination of the physico-chemical properties, ChemService S.r.l., Draft , GLP, (unpublished).Interim No. CH-010/2006	Y	Endura
A 3.15	Garofani S.		2006b	d-Allethrin. (pure active substance): Determination of the physico-chemical properties, ChemService S.r.l., Draft , GLP, (unpublished).Interim No. CH-010/2006	Y	Endura
A 3.17	Di Blasi		2006	Reactivity towards Container Material, Endura S.p.A., NO GLP, (unpublished).	Y	Endura
A 3.3.3	Garofani S.		2006b	d-Allethrin. (pure active substance): Determination of the physico-chemical properties, ChemService S.r.l., Draft , GLP, (unpublished).Interim No. CH-010/2006	Y	Endura
A 3.4/01	Garofani S.		2006a	d-Allethrin. (pure active substance): Determination of the physico-chemical properties, ChemService S.r.l., Draft , GLP, (unpublished).Interim No. CH-009/2006	Y	Endura
A 3.4/02	Garofani S.		2006a	d-Allethrin. (pure active substance): Determination of the physico-chemical properties, ChemService S.r.l., Draft , GLP, (unpublished).Interim No. CH-009/2006	Y	Endura

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A 3.9	Garofani S.		2006a	d-Allethrin. (pure active substance): Determination of the physico-chemical properties, ChemService S.r.l., Draft , GLP, (unpublished).Interim No. CH-009/2006	Y	Endura
A 4.2/02	Garofani S.		2006c	d-Allethrin (technical grade): Validation of the Analytical Method for the determination of the content of d-Allethrin in air. Chemservice S.r.l., Draft Interim Report No. CH 011/2006. GLP, (unpublished).	Y	Endura
A 4.2/03	Garofani S.		2006d	Validation of the Analytical Method for the determination of the content of D-allethrin in water samples from the aquatic ecotoxicological studies. Chemservice S.r.l., Study No. CH-012/2006. GLP, (unpublished).	Y	Endura
A 4.2/04	Ramesh A., Ravi P. E.		2004	Negative Ion Chemical Ionization-Gas Chromatographic-Mass Spectrometric Determination of Residues of Different Pyrethroid Insecticides in Whole Blood and Serum, Journal of Analytical Toxicology, Vol. 28, November/December 2004, (published).	N	Public
A 4.3	Hemant D.		2006	Development and validation of analytical method for active ingredient analysis of d-Allethrin by HPLC. Jai Research Foundation, Dept. of Toxicology, Valvada – 396 108, Dist. Valsad, Gujarat, India., Study No. 5835. GLP/unpublished.	Y	Endura
A 5.7/01	Enayati A.A. *et al.*	Pyrethroids	2003	Molecular evidence for a kdr-like pyrethroid resistance mechanism in the malaria vector mosquito *Anopheles stephensi*. The Royal Entomological Society. Medical and Veterinary Entomology (2003) 17, 138-144.	N	N/A

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A 5.7/01	Enayati A.A. *et al.*	Pyrethroids	2003	Molecular evidence for a kdr-like pyrethroid resistance mechanism in the malaria vector mosquito *Anopheles stephensi*. The Royal Entomological Society. Medical and Veterinary Entomology (2003) 17, 138-144.	N	N/A
A 5.7/02	EPPO	N/A	2003	Resistance risk analysis. PP 1/213(2) 2003 OEPP/EPPO Bulletin 33, 37-63.	N	N/A
A 5.7/03	IRAC	N/A	2005	Insecticide Resistance Action Committee – Mode of Action Classification v.4.2.1 (2005). www.irac-online.org	N	N/A
A 5.7/04	Khambay B.P.S.	Pyrethroids	2002	Pyrethroid Insecticides. Pesticide Outlook, pg 49-54. April 2002. The Royal Society of Chemistry 2002.	N	N/A
A 5.7/05	PSD	N/A	2004	Resistance risk analysis and use of resistance management strategies. Efficacy Guideline 606. PSD. October 2004. www.pesticides.gov.uk.	N	N/A
A 5.7/06	Takada Y.	Pyrethroids	1992	Can a New Pyrethroid Kill kdr-type Houseflies? Sumitomo Chemical's, Takarazuka Research Center, 4-2-1 Hyogo, Japan. XIX International Congress of Entomology 1992.	N	N/A
A 5.7/07	WHO	N/A	1998	Test Procedures for Insecticide Resistance Monitoring in Malaria Vectors, Bio-Efficacy and Persistence of Insecticides on Treated Surfaces. Report of the WHO Informal Consultation. WHO, Geneva, Switzerland 28-30 September 1998.	N	N/A
A 6.1.1	[redacted]		2006	Acute Oral Toxicity Study of d-allethrin in Rats. Jai Research Foundation, Dept. of Toxicology, Valvada – 396 108, Dist. Valsad, Gujarat, India., Study No. 6018. GLP/unpublished.	Y	Endura

Section No / Reference No	Author(s)	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A 6.1.2	[redacted]		2006	Acute Dermal Toxicity Study of d-allethrin in Rats. Jai Research Foundation, Dept. of Toxicology, Valvada – 396 108, Dist. Valsad, Gujarat, India., Study No. 6019. GLP/unpublished.	Y	Endura
A 6.1.3	[redacted]		2006	Acute Inhalation Toxicity Study of d-allethrin in Rats. Jai Research Foundation, Dept. of Toxicology, Valvada – 396 108, Dist. Valsad, Gujarat, India., Study No. 6021. GLP/unpublished.	Y	Endura
A 6.1.4.1	[redacted]		2006	Acute Dermal Irritation Study of d-Allethrin in Rabbits. Jai Research Foundation, Dept. of Toxicology, Valvada – 396 108, Dist. Valsad, Gujarat, India., Study No. 5760. GLP/unpublished.	Y	Endura
A 6.1.4.2	[redacted]		2006	Acute Eye Irritation Study of d-Allethrin in Rabbits. Jai Research Foundation, Dept. of Toxicology, Valvada – 396 108, Dist. Valsad, Gujarat, India., Study No. 5761. GLP/unpublished.	Y	Endura
A 6.1.5	[redacted]		2006	Skin Sensitization Study of d-Allethrin in Guinea Pigs (Guinea Pig Maximization Test). Jai Research Foundation, Dept. of Toxicology, Valvada – 396 108, Dist. Valsad, Gujarat, India., Study No. 6020. GLP/unpublished.	Y	Endura
A 6.10/01	Tsuji, R., Kobayashi, K., Ikeda, M., Yoshioka, T. Yamada T., Seki, T., Okuno, Y., Nakatsuka, I., Tsuruo, Y. & Kishioka, S		2002	Lack of Changes in Brain Muscarinic Receptor and Motor Activity of Mice after Neonatal Inhalation Exposure to d-Allethrin. J. Appl. Toxicol. 22: 423–429	N	Public
A 6.10/02	Sumida, K., Saito, K., Ooe, N., Isobe,		2001	Evaluation of in vitro methods for detecting the effects of various chemicals on the human	N	Public

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	N., Kaneko, H. & Nakatsuka I.			progesterone receptor, with a focus on pyrethroid insecticides. Toxicology Letters 118: 147–155.		
A 6.11	IPCS EHC		1989	IPCS, International Programme on Chemical Safety, Environmental Health Criteria 87, Allethrins. World Health Organization, Geneva 1989	N	Public
A 6.12.1 A 6.12.8	UKPID		1998	Monograph: Allethrin. National Poisons Information Service (Birmingham Centre) http://www.intox.org/databank/documents/chemical/allethrn/ukpid31.htm	N	Public
A 6.12.1	Savron L,		2006	Safety, Environment and quality department. Ravenna Plant Medical Data. Unpublished	Y	Endura
A 6.12.4	Leng G, Ranft U, Sugiri D, Hadnagy W, Berger-Preiss E, Idel H.		2003	Pyrethroids used indoors--biological monitoring of exposure to pyrethroids following an indoor pest control operation. Int. J. Hyg. Environ. Health. 206(2):85-92	N	Public
A 6.12.5	Ray, D.E. & Forshaw P.J.		2000	Pyrethroid Insecticides: Poisoning Syndromes, Synergies, and Therapy. Journal of toxicology. Clinical toxicology, {J-Toxicol-Clin-Toxicol}, 38 (2): 95-101	N	Public
A 6.2	IPCS EHC		1989	IPCS, International Programme on Chemical Safety, Environmental Health Criteria 87, Allethrins. World Health Organization, Geneva 1989	N	Public
A 6.2/01	[redacted]		1991	Absorption, Distribution, Elimination and Metabolism of [^{14}C-alcohol]-d-trans-allethrin in the rat. 16 May 1991 Pharmacology and Toxicology Research Laboratory-West, Inc. Richmond. USA. Report number 418E/219W. Sumitomo reference number KM-11-0009	Y	SCC

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				GLP, Unpublished		
A 6.3.1	WHO		2002	Specifications and evaluations for public health pesticides: d-Allethrin. World Health Organisation, Geneva, 2002 http://www.who.int/whopes/quality/en/dAllethrin_spec_eval_March_04.pdf	N	Public
A 6.3.1	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.3.2	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.3.3	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.4.1.1	[redacted]		2007	D-Allethrin: Repeated dose 90-days oral toxicity study in rats. ai Research Foundation, Dept. of Toxicology, Valvada – 396 108, Dist. Valsad, Gujarat, India., Study No. 5762. GLP/unpublished.	Y	Endura
A 6.4.1/01	[redacted]		2006	D-Allethrin: Repeated dose 28-day range finding oral toxicity study in rats. Department of Toxicology, Jai Research Foundation, Study N° 5762, October 18, 2006 (unpublished).	Y	Endura
A 6.4.1/02	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.4.2	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.4.3	[redacted]	Pynamin Forte	1993	Three month inhalation toxicity study of Pynamin Forte in rats.	Y	SCC

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		(d-Allethrin)		18 March 1993 Sumitomo Chemical Co., Ltd. Japan. Study number 2596. Sumitomo reference number KT-30-0123 GLP, Unpublished		
A 6.4.3	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.5	WHO (EHC 87, 1989)		1989	International Programme on Chemical Safety: Environmental health criteria 87: Allethrins. Published under the joint sponsorship of the United Nations Environment Programme, the International Labour Organisation, and the World Health Organization. World Health Organisation, Geneva, 1989 http://www.inchem.org/documents/ehc/ehs/ehc87.htm	N	
A 6.5	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.5/02	[redacted]	Esbiothrin	1989	Toxicity study in beagle dogs by repeated oral administration in diet for 52 weeks. 6 September 1989 Centre International de Toxicologie. Report number 2181 TCC. Sumitomo reference number A95121/C003952. GLP, Unpublished	Y	SCC
A 6.6.1	Satheesh V.K.		2006	Bacterial reverse mutation test of d-Allethrin using Salmonella typhimurium. Jai Research Foundation, Dept. of Toxicology, Valvada – 396 108, Dist.	Y	Endura

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				Valsad, Gujarat, India., Study No. 5751. GLP/unpublished.		
A 6.6.1/02	Kimmel E.C., Casida J.E. and Ruzo L.O.	Allethrin and Terallethrin	1982	Identification of Mutagenic Photoproducts of the Pyrethroids Allethrin and Terallethrin Journal of Agricultural and Food Chemistry, vol. 30, no. 4, pp.623-626 (1982) Non-GLP, Published	N	N/A
A 6.6.1/02	Kimmel E.C., Casida J.E. and Ruzo L.O.	Allethrin and Terallethrin	1982	Identification of Mutagenic Photoproducts of the Pyrethroids Allethrin and Terallethrin Journal of Agricultural and Food Chemistry, vol. 30, no. 4, pp.623-626 (1982) Non-GLP, Published	N	N/A
A 6.6.1/02	Kimmel E.C., Casida J.E. and Ruzo L.O.		1982	Identification of Mutagenic Photoproducts of the Pyrethroids Allethrin and Terallethrin Journal of Agricultural and Food Chemistry, vol. 30, no. 4, pp.623-626 (1982) Non-GLP, Published	N	N/A
A 6.6.1/03	Herrera A. and Laborda E.	Allethrin, Resmethrin, Permethrin and Fenvalerate	1988	Mutagenic activity in synthetic pyrethroids in *Salmonella typhimurium* Mutagenesis, vol. 3, no. 6, pp. 509-514 (1988) Non-GLP, Published	N	N/A
A 6.6.1/03	Herrera A. and Laborda E.	Allethrin, Resmethrin, Permethrin and Fenvalerate	1988	Mutagenic activity in synthetic pyrethroids in *Salmonella typhimurium* Mutagenesis, vol. 3, no. 6, pp. 509-514 (1988) Non-GLP, Published	N	N/A
A 6.6.1/03	Herrera A. and Laborda E.		1988	Mutagenic activity in synthetic pyrethroids in Salmonella typhimurium	N	N/A

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				Mutagenesis, vol. 3, no. 6, pp. 509-514 (1988) Non-GLP, Published		
A 6.6.1/04	Hour T.-C., Chen L. and Lin J.-K.	Allethrin and other pesticides	1998	Comparative investigation on the mutagenicities of organophosphate, phthalimide, pyrethroid and carbamate insecticides by the Ames and lactam tests. Mutagenesis, vol. 13, no. 2, pp. 157-166 (1998) Non-GLP, Published	N	N/A
A 6.6.1/04	Hour T.-C., Chen L. and Lin J.-K.	Allethrin and other pesticides	1998	Comparative investigation on the mutagenicities of organophosphate, phthalimide, pyrethroid and carbamate insecticides by the Ames and lactam tests. Mutagenesis, vol. 13, no. 2, pp. 157-166 (1998) Non-GLP, Published	N	N/A
A 6.6.1/04	Hour T.-C., Chen L. and Lin J.-K.		1998	Comparative investigation on the mutagenicities of organophosphate, phthalimide, pyrethroid and carbamate insecticides by the Ames and lactam tests. Mutagenesis, vol. 13, no. 2, pp. 157-166 (1998) Non-GLP, Published	N	N/A
A 6.6.1/05	Moriya M., Ohta T., Watanabe K., Miyazawa T., Kato K. and Shirasu Y.	Allethrin and other pesticides	1983	Further mutagenicity studies on pesticides in bacterial reversion assay systems. Mutation Research, vol. 116, pp. 185-216 (1983) Non-GLP, Published	N	N/A
A 6.6.1/05	Moriya M., Ohta T., Watanabe K., Miyazawa T., Kato K. and Shirasu Y.	Allethrin and other pesticides	1983	Further mutagenicity studies on pesticides in bacterial reversion assay systems. Mutation Research, vol. 116, pp. 185-216 (1983) Non-GLP, Published	N	N/A
A 6.6.1/05	Moriya M., Ohta T., Watanabe K., Miyazawa T., Kato K. and Shirasu Y.		1983	Further mutagenicity studies on pesticides in bacterial reversion assay systems. Mutation Research, vol. 116, pp. 185-216 (1983) Non-GLP, Published	N	N/A

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A 6.6.1/06	Nisar, R.	d-Allethrin	2020	d-Allethrin: Bacterial reverse mutation assay Covance Laboratories Ltd., Report N° 8423327 GLP/unpublished	Y	Endura
A 6.6.2	[redacted]		2004	Allethrin chromosome aberrations in Chinese hamster ovary cells in vitro. Research Toxicology Centre S.p.A., Report N° 9425. GLP/unpublished.	Y	Endura
A 6.6.2/02	Matsuoka A., Hayashi M. and Ishidate Jr. M.	Allethrin and other compounds	1979	Chromosomal aberration tests on 29 chemicals combined with S9 mix in vitro. Mutation Research, vol. 66, pp. 277-290 (1979) Non-GLP, Published	N	N/A
A 6.6.2/02	Matsuoka A., Hayashi M. and Ishidate Jr. M.	Allethrin and other compounds	1979	Chromosomal aberration tests on 29 chemicals combined with S9 mix in vitro. Mutation Research, vol. 66, pp. 277-290 (1979) Non-GLP, Published	N	N/A
A 6.6.2/02	Matsuoka A., Hayashi M. and Ishidate Jr. M.		1979	Chromosomal aberration tests on 29 chemicals combined with S9 mix in vitro. Mutation Research, vol. 66, pp. 277-290 (1979) Non-GLP, Published	N	N/A
A 6.6.3	[redacted]		2004	Allethrin mutation in L5178Y TK± mouse lymphoma cells (Fluctuation method). Research Toxicology Centre S.p.A., Report N° 9424. GLP/unpublished.	Y	Endura
A 6.7.1	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.7.2	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public

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A 6.7/03	[redacted]	Esbiothrin	1990	Combined Chronic Toxicity/Oncogenicity Study by Repeated Dietary Administration to Rats (104 weeks). 9 March 1990 Centre International de Toxicologie GLP, Unpublished	Y	SCC
A 6.7/04	[redacted]	Esbiothrin	1990	102-Week Dietary Carcinogenicity Study in Mice. 11 April 1990 Centre International de Toxicologie GLP, Unpublished	Y	SCC
A 6.8.1	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.8.1/03	[redacted]	Esbiothrin	1990	Developmental Toxicity (Embryo-fetal Toxicity and Teratogenic Potential) Study of Esbiothrin Technical Administered Orally via Gavage to Crl:CD®BR VAF/Plus® Presumed Pregnant Rats. 31 August 1990 Argus Research Laboratories Inc. Study number 718-001 GLP, Unpublished	Y	SCC
A 6.8.1/03	[redacted]	Esbiothrin	1990	Developmental Toxicity (Embryo-fetal Toxicity and Teratogenic Potential) Study of Esbiothrin Technical Administered Orally via Gavage to Crl:CD®BR VAF/Plus® Presumed Pregnant Rats. 31 August 1990 Argus Research Laboratories Inc. Study number 718-001 GLP, Unpublished	Y	SCC
A 6.8.1/04	[redacted]		1990	Developmental Toxicity (Embryo-fetal Toxicity and Teratogenic Potential) Study of Esbiothrin Technical Administered Orally via Stomach Tube to New	Y	SCC

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				Zealand White Rabbits. 31 August 1990 Argus Research Laboratories Inc. Study number 718-002 GLP, Unpublished		
A 6.8.2	WHO		2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN. World Health Organization, Geneva, 2002	N	Public
A 6.8.2/01	[redacted]	Esbiothrin	1988	Two-generational reproduction toxicity study in rats. 27 July 1989 Centre International de Toxicologie. Study number 1690 RSR. Sumitomo reference number A95122. GLP, Unpublished	Y	SCC
A 6.9	Eriksson, P.; Fredriksson A.		1991	Neurotoxic effects of two different pyrethroids, bioallethrin and deltamethrin, on immature and adult mice: changes in behavioral and muscarinic receptor variables. In: Toxicology and Applied Pharmacology. 108:78-85	N	Public
A 6.9	Eriksson, P.; Nordberg, A.		1990	Effects of Two Pyrethroids, Bioallethrin and Deltamethrin, on Subpopulations of Muscarinic and Nicotinic Receptors in the Neonatal Mouse Brain. In: Toxicology and Applied Pharmacology. 102: 456-463	N	Public
A 6.9	Pauluhn, J.; Schmuck G.		2003	Critical Analysis of Potential Body Temperature Confounders on Neurochemical Endpoints Caused by Direct Dosing and Maternal Separation in Neonatal Mice: a Study of Bioallethrin and Deltamethrin Interactions with Temperature on Brain Muscarinic Receptors. In: Journal of Applied	N	Public

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				Toxicology. 23: 9-18		
A 6.9	Ray, D. E.; Verschoyle, R. D.; Muhammad, B. Y.		2002	Reproducibility of developmental neurotoxicity produced by pyrethroids and DDT in neonatal mice. In: Toxicologist. 66: 131	N	Public
A 6.9	Shafer T.J., Meyer D.A. and Crofton K.M		2005	Developmental neurotoxicity of pyrethroid insecticides: Critical review and future research needs	N	
A 7.1.1.1.1	Tognucci A.	d-allethrin	2002	Hydrolysis determination of Allethrin at different pH values. RCC Ltd, Study N° 842216, July 6 2002 (unpublished)	Y	Endura
A 7.1.1.2.1/ 02	Seyfried B.	Allethrin	2002	Ready biodegradability of Allethrin in a manometric respirometry test, RCC Ltd, Study N° 842118, GLP, unpublished	Y	Endura
A 7.1.1.2.2/ 01 & 02	Reis, K. H.	d-Allethrin	2007	Inherent biodegradability of d-Allethrin in a modified MITI test (II), Ibacon, Study N° 29101169, October, 25, 20006/February 19, 2007, GLP, unpublished	Y	Endura
A 7.1.3	Tognucci A.	d-allethrin	2002	Estimation of the Adsorption Coefficient of Allethrin on soil using High Performance Liquid Chromatography (HPLC). RCC Ltd, Study N° 842119, July 16 2002 (unpublished)	Y	Endura
A 7.4.1.1	[redacted]	d-Allethrin	2006	Acute Toxicity of D-Allethrin to Zebra Fish (Danio rerio), Determined Under Flow-through Exposure. ChemService S.r.l. Testing Laboratory, Via Fratelli Beltrami 15, 20026 Novate Milanese (MI), Italy, Study No.CH-E-003/2006 GLP,unpublished	Y	Endura
A 7.4.1.2	Croce V.	d-Allethrin	2006	Acute Toxicity of d-allethrin to Daphnia magna, in a 48 hour immobilization test.	Y	Endura

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				ChemService S.r.l. Testing Laboratory, Via Fratelli Beltrami 15, 20026 Novate Milanese (MI), Italy, Study No.CH-E-004/2006 GLP,unpublished		
A 7.4.1.3	Seyfried B.	Allethrin	2002	Toxicity of Allethrin to Scenedesmus subspicatus in a 72-hour algal growth inhibition test. RCC Ltd, Report No. 842115 GLP, unpublished	Y	Endura
A 7.4.1.4/02	Seyfried B.	Allethrin	2002	Toxicity of Allethrin to activated sludge in a respiratory inhibition test. RCC Ltd, Study N° 842117, GLP, unpublished	Y	Endura
A 7.4.3.2 A 7.5.4.1	IPCS EHC	Allethrins	1989	IPCS, International Programme on Chemical Safety, *Environmental Health Criteria 87, Allethrins.* World Health Organization, Geneva 1989	N	public
A 7.4.3.2	IPCS HSG	Allethrins	1989	IPCS, International Programme on Chemical Safety, Health and Safety Guide No. 24 *Allethrins. Health and Safety Guide* World Health Organization, Geneva 1989	N	public
A 7.5.1.2	Inglesfield C	Cypermethrin	1984	Toxicity of the Pyrethroid Insecticides Cypermethrin and WL85871 to the Earthworm, *Eisenia foetida* Savigny Shell Research Limited, Sittingbourne Research Centre, Sittingbourne, Kent, UK. Published.	N	N/A
A 7.5.3.1.1 A 7.5.3.1.2	WHO	d-Allethrin	2002	WHO SPECIFICATIONS AND EVALUATIONS FOR PUBLIC HEALTH PESTICIDES, d-ALLETHRIN World Health Organization, Geneva, 2002	N	public
B 6.1.1	[redacted]		2006	Acute Oral toxicity study of Duracide A in rats.	Y	Endura

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				Jai Research Foundation, Study N° 6035 GLP, Unpublished		
B 6.1.2	[redacted]		2006	Acute Dermal toxicity study of Duracide A in rats. Jai Research Foundation, Study N° 6036 GLP, Unpublished	Y	Endura
B 6.1.3	[redacted]		2006	Acute Inhalation Toxicity study of Duracide A in rats. Jai Research Foundation, Study N° 6040 GLP, Unpublished	Y	Endura
B 6.2.1	[redacted]		2006	Acute Dermal Irritation study of Duracide A in rabbits. Jai Research Foundation, Study N° 6037 GLP, Unpublished	Y	Endura
B 6.2.2	[redacted]		2006	Acute Eye Irritation study of Duracide A in rabbits. Jai Research Foundation, Study N° 6038 GLP, Unpublished	Y	Endura
B 6.3	[redacted]		2006	Skin Sensitization Study of Duracide A in Guinea Pigs (Buehler Test). Jai Research Foundation, Study N° 6039 GLP, Unpublished	Y	Endura
B 6.5	ECB		2000	Distillates (petroleum), hydrotreated light	N	ECB

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				IUCLID Dataset European Commission – European Chemicals Bureau Published www.ECB,jrt.it White Spirits IPCS International Programme on Chemical Safety, Health and Safety Guide No. 103 Published www.inchem.org		
Doc I	Anonymous		2006	Memorandum: Allethrins: HED chapter of reregistration eligibility decision document (RED). United States Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances. Washington, D. C. 20460, Dec. 20, 2006	N	Public
Doc I	Rauch, F., Lhoste, J., Martel, J.		1974	Insecticidal properties of some allethrin isomers used in coil formulations against mosquitoes. In: Pesticide Science. 5: 651-656.	N	Public
Doc II	American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE).	N/A	1989	Ventilation for acceptable Indoor Air Quality (ASHRAE 62-1989). Atlanta GA.	N	N/A
Doc II	Atkinson, R.	N/A	1985	Kinetics and mechanisms of the gas-phase reactions of the hydroxyl radical with organic compounds under atmospheric conditions. Chem. Rev. 85, 69-201. Published.	N	N/A
Doc II	Brouwer, D. H., Kroese, R., Van Hemmen, J.J.	N/A	1999	Transfer of contaminants from surface to hands: Experimental assessment of linearity of the exposure process, adherence to the skin, and area	N	N/A

Section No / Reference No	Author(s)	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
				exposed during fixed procedure and repeated contact with surfaces contaminated with a powder. Department of Chemical Exposure Assessment, TNO Nutrition and Food Reasearch Institute, The Netherlands. Applied Occupational and Environmental Hygiene. Volume 14: 231-239. Published.		
Doc II B8.2	EC	N/A	2015	Biocides Human health Exposure Methodology	N	N/A
Doc II B8.2	Human Exposure Expert Group (HEEG)	N/A	2008	HEEG opinion No. 1 - on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale - Agreed at TM I08	N	N/A
Doc II B8.2	BPC Ad hoc Working Group on Human Exposure (HEAdhoc)	N/A	2020	Recommendation no. 6 - Human Exposure Methods and models to assess exposure to biocidal products in different product types Version 4	N	N/A
Doc II	EC	N/A	2002	Technical Notes for Guidance. Human Exposure to Biocidal Products. Guidance on Exposure Estimation. Report was prepared under contract B4-3040/2000/291079/MAR/E2 for the European Commission, DG Environment. June 2002.	N	N/A
Doc II	ECB.	N/A	2003	Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC, Commission Regulation 1488/94 and Directive 98/8/EC. European Chemicals Bureau - Institute for Health and Consumer Protection.	N	N/A
Doc II	Gottschild, D, Storzer, W., Wilkening, A.	N/A	1993	Criteria for assessment of plant protection products in the registration of BBA, 65-67. Published.	N	N/A

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Doc II	IPCS International Programme on Chemical Safety	Allethrins	1989	Allethrins: Health and Safety Guide No. 24	N	N/A
Doc II	IPCS International Programme on Chemical Safety	Allethrins	1989	Allethrins: Environmental Health Criteria No. 87.	N	N/A
Doc II	Jassen, J.E.	N/A	1989	Ventilation for Acceptable Indoor Air Quality. ASHRAE Journal. Published.	N	N/A
Doc II	Matoba Y, Inoue A, Takimoto Y.	Prallethrin	2004	Clarifying Behaviour of Prallethrin Evaporated from an Electric Vaporizer on the Floor and Estimating Associated Dermal Exposure. Environmental Health Science Laboratory. Sumitomo Chemical Company. J.Pestic. Sci., **29**(4), 313-321. Published.	N	N/A
Doc II	Matoba, Y, Takimoto, Y., Kato, T.	d-Phenothrin and d-Tetramethrin	1988	Indoor Behaviour and Risk Assessment Following Residual Spraying of d-Phenothrin and d-Tetramethin. American Industrial Hygiene Association Journal. 59:191-199. Published.	N	N/A
Doc II	Matoba, Y., Hirota, T., Ohnishi, J., Murai, N., Matsuo, M.		1994	An indoor simulation of the behavior of insecticides supplied by an electric vaporizer. Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd. Chemosphere Vol 28. No 3 pp435-451. Published.	N	N/A
Doc II	OECD	N/A	1993	OECD/GD(92)172. The rate of photochemical transformation of gaseous organic compounds in air under tropospheric conditions – Environmental Monograph No 61. Paris 1993.	N	N/A
Doc II	Ross *et al.*	N/A	1990	Measuring potential dermal transfer of surface pesticide residue generated from indoor fogger	N	N/A

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				use: an interim report. Food and Agriculture, Worker Health and Safety Branch, California. Chemosphere, Vol 20, Nos. 3/4, pp 349-360. Published.		
Doc II	Ross *et al.*	N/A	1991	Measuring potential dermal transfer of surface pesticide residue generated from indoor fogger use: Using the CDFA roller method: Interim report II. Food and Agriculture, Worker Health and Safety Branch, California. Chemosphere, Vol 22, Nos. 9-10, pp 975-984. Published.	N	N/A
Doc II	Ruzo, L.O., Gaughan, L.C., Casida J.E.	S-Bioallethrin	1980	Pyrethroid Photochemistry: S-Bioallethrin Journal of Agricultural and Food Chemistry, vol. 28, pp. 246-249. Published.	N	N/A
Doc II	US EPA.	N/A	1992	Dermal exposure assessment: Principles and Applications, Report number EPA 600/8-91/011B. USEPA Exposure Assessment Group, Office of Health and Environmental Assessment, Office of Research and Development, Washington DC, USA.	N	N/A
Doc II	US EPA.	N/A	1994	Methodologies for Assessing Residential Exposure to Pesticides, EPA 736-5-94-0001.	N	N/A
Doc II	US EPA.	N/A	1998	Hazard evaluation division, Standard Evaluation Procedure, Inhalation Toxicity Testing. US EPA-540/09-88-101.	N	N/A
Doc II	US EPA.	Prallethrin	2000	Prallethrin [(*RS*)-2-methyl-4-oxo-3-(2-propynyl) cyclopent-2-enyl (1*RS*)-cis, trans-chrysanthemate]; Pesticide Tolerance. The Federal Register, June 26 2000, **65** (123) page iv.	N	N/A
Doc II	Vaccaro, J. T *et al*.	Chlorpyrifos	1991	Evaluation of dislodgeable residues and absorbed doses of chlorpyrifos to crawling infants following indoor broadcast applications of a chlorpyrifos	N	N/A

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				based emulsifiable concentrate., The Dow Company, Indianapolis. August 28, 1991.		
Doc II	Vaughan, V.C., Mackay, R.J., Nelson, W.E.	N/A	1975	In *Textbook of Pediatrics* 10th Ed. Saunders, Philadelphia, London, Toronto, pp. 1876. Published.	N	N/A
Doc II	Wheeler J.P.	N/A	2003	Amateur Exposure to Pesticides Resulting from use of Liquid and Mat Insecticide Evaporator devices. A thesis submitted to the University of Manchester for the degree of Master of Science in the Faculty of Medicine, Dentistry, Nursing and Pharmacy. Centre for Occupational and Environmental Health. July 2003. Further information on the conditions under which disclosures and exploitation may take place is available from the Head of the Department of Centre of Occupational and Environmental Health.	N	N/A
Doc II	WHO	N/A	1999	WHO Pesticide Evaluation Scheme (WHOPES). Safe and effective use of household insecticide products. Guide for the production of educational and training materials. WHO/CDS/CPC/WHOPES/99.1.1999.	N	N/A
Doc II	WHO	d-Allethrin	2002	WHO Specifications and Evaluations for Public Health Pesticides. d-Allethrin - (*RS*)-3-allyl-2-methyl-4-oxocyclopent-2-enyl (1*R*)-*cis*, *trans*-chrysanthemate. WHO Geneva 2002	N	N/A
Doc II	WHO	Allethrins	1989	Environmental Health Criteria 87: Allethrins World Health Organisation , Geneva 1989	N	N/A
Doc II	Williams P.T.	N/A	2005	Waste Treatment and Disposal. John Wiley & Sons Ltd. ISBN 0-470-84913-4. Published.	N	N/A

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Doc II	Worgan J.P., Franklin C.A.(Eds).	N/A	2005	Occupational Residential Exposure Assessment for Pesticides. John Wiley & Sons. Published.	N	N/A
Doc II B 8.3	ECHA	N/A	2013	Manual of Technical Agreements (MOTA), v.6	N	N/A
Doc II B 8.3	ECHA	N/A	2015	Technical Agreements for Biocides, v1.0	N	N/A
Doc II B 8.3	OECD	N/A	2008	OECD Series on Emission Scenario Documents, Number 18 Emission Scenario Document for insecticides, acaricides and products to control other athropods for household and professional uses	N	N/A
Doc II-4, Chapter 4	EC		2006	Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp	--	--
Doc II-4, Chapter 4	ECHA	--	2013	Guidance on information requirements, Guidance on Regulation (EU) No 528/2012 concerning the Making Available on the Market and Use of Biocidal Products (BPR), Version 1.0	-	-
Doc II-4, Chapter 4	ECHA	--	2015	Guidance on the Biocidal Products Regulation, Volume IV Environment – Part B Risk Assessment (active substances), Version 1.0	-	--
Doc II-4, Chapter 4	ECHA	--	2012	Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT/vPvB Assessment, Version 2.0	-	--
Doc II-4, Chapter 4	ECHA	--	2011	Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of	-	--

Section No / Reference No	Author(s)	Test Material	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
				substances and mixtures		