(Z,E)-Tetradeca-9,12-dienyl acetate

Biocide for Use as Attractant

Dossier According to Directive 98/8/EC

Document III-A

Data on the Active Substance

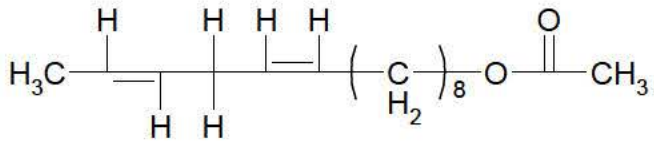
Section A1 Annex Point IIA1	Applicant	
1.1 **Applicant**	Name: Aeroxon Insect Control GmbH Address: Bahnhofstrasse 35, 71332 Waiblingen, Germany [redacted]	
1.2 **Manufacturer of Active Substance** (if different)	[redacted] Location of manufacturing plant: as above	
1.3 **Manufacturer of Product(s) (if different)** **1) Product 1**	"as above point 1.1"	

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	May 2007
Materials and Methods	Acceptable
Conclusion	Agree with applicant's version
Reliability	n.a.
Acceptability	Acceptable
Remarks	-

Section A2 Identity of Active Substance

Subsection (Annex Point)			Official use only
2.1	**Common name (IIA2.1)**	9,12-Tetradecadien-1-ol, acetate, (9Z,12E); (Z,E)-Tetradeca-9,12-dienyl acetate	x
2.2	**Chemical name (IIA2.2)**	Z,E-9,12-Tetradecadien-1-yl acetate	x
2.3	**Manufacturer´s development code number(s) (IIA2.3)**	Not available	
2.4	**CAS No and EC numbers (IIA2.4)**		
2.4.1	**CAS-No**	30507-70-1	
	Isomer 1	-	
	Isomer n	-	
2.4.2	**EC-No**	not available	
	Isomer 1	-	
	Isomer n	-	
2.4.3	**Other**	Not available	
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**		
2.5.1	**Molecular formula**	$C_{16}H_{28}O_2$	
2.5.2	**Structural formula**		
2.5.3	**Molecular mass**	252.4 g/mol	
2.6	**Method of manufacture of the active substance (IIA2.1)**	For information about manufacturing of the active substance please refer to the confidential data section of this dossier.	
2.7	**Specification of the purity of the active substance, as appropriate (IIA2.7)**	For information about the specification of the active substance please refer to the confidential data section of this dossier.	x
2.8	**Identity of impurities and additives, as appropriate (IIA2.8)**	For information about the identity of impurities and additives of the active substance please refer to the confidential data section of this dossier.	
2.8.1	**Isomeric composition**	Not relevant	

Section A2 Identity of Active Substance

2.9	**The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)**	The active substance is a synthetic pheromone.

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	November 2008
Materials and Methods	-
Conclusion	Agree with applicant's version
Reliability	1
Acceptability	Acceptable
Remarks	2.1: Common name: (Z,E)-Tetradeca-9,12-dienyl acetate Common abbreviations: ZE-TDA *Plodia* – pheromone 2.2: Chemical name: IUPAC name: (9Z,12E)-Tetradeca-9,12-dien-1-yl acetate 2.7: Minimum degree of purity of the active substance: 97.7%w/w (Please see also Doc. III-A2.7); Range of purity: 99.0 – 99.34%w/w

Section A2 (2.7/01)
Annex Point IIA2.7

Specification of the purity of the active substance, as appropriate

Official use only

The information supplied in DOC IVA 2.7/01 indicates that the enantiomere of (9Z,12E) 9,12-Tetradecadien-1-ol, acetate, [redacted] and [redacted] can be converted to the peaks of identical retention times under the same conditions as used for the 3-batch analysis described in DOC IIIA 4.1/01 and DOC IVA 4.1/02

The [redacted] is identical to the impurity 3 and the [redacted] is identical to the impurity 5 of the three batch analysis.

The specification of technical (9Z,12E) 9,12-Tetradecadien-1-ol, acetate is supposed with regard t the results of the three batch analysis (refer to Doc IVA 4.1/01):

x

	Parent (9Z,12E) 9,12-Tetradecadien-1-ol, acetate	Impurity 3 [redacted]	Impurity 5 [redacted]
	% w/w		
Batch 262-7/6	99.00	[redacted]	[redacted]
Batch 262-8/6	99.29		
Batch 262-9/6	99.34		
Mean	99.20	[redacted]	[redacted]
SD	0.15	[redacted]	[redacted]
Mean - 5 SD	98.45	-	-
Mean +3 SD	-	[redacted]	[redacted]
t(99%, f=2) = 9.925 Mean - t(p=99%,f) x SD	97.7	-	-
t(95%, f=2) = 4.303 Mean - t(p=95 %,f) x SD	-	[redacted]	[redacted]

P = probability, f = degrees of freedom=n-1

The advice to define the specification for the parent and the impurities in a technical material is related to the determination of parent and impurities in 5 replicates. The factors 5 (probability 99% for the minimum content of the parent) and 3 (probability 95% for the maximum content of impurities) are derived from t-statistic and are usually suitable. However, we suppose an adjustment of the factors to the reduced number of replicates.

In consequence the supposed specification for the parent and the both impurities are:

x

Parent (9Z,12E) 9,12-Tetradecadien-1-ol, acetate	Impurity 3 [redacted]	Impurity 5 [redacted]
% w/w		
> 97.7	[redacted]	[redacted]

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	November 2008
Materials and Methods	Acceptable
Conclusion	Agree with applicant's version with the amendments given below.
Reliability	n.a.
Acceptability	Acceptable
Remarks	Affirmation of the method: Please see Doc. III-A 4.1/01. Minimum degree of purity of ZE-TDA: 97.7%w/w according to Student's t-distribution is accepted.

Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Subsection		Official use only
2.10.1 Human exposure towards active substance		X
2.10.1.1 Production		X
i) Description of process	The active substance is manufactured in the USA and no exposure data for workers in the production of the pheromone are available. The synthetic pheromone is produced from crotyl alcohol and 1,9-decadyiyne as starting materials. During the production process of the formulated product, the active substance is applied in droplets on a card board (130 mm x 90 mm) at an amount of 2.0 mg per card. Production occurs in a closed system.	
ii) Tonnage imported into the EU	[redacted]	
2.10.1.2 Intended use(s)	PT 19 - Attractant	**x**
1. Professional Users		
i) Description of application process	The pheromone is used in traps of a size of 130 mm x 90 mm consisting of carton covered with a sticky glue. A card contains 2 mg of the pheromone, which is slowly released from the card. The trap is fixed to a solid background with a tape on its back. A silicone paper is then removed from the sticky glue on front of the trap for its activation. Male adults of *Plodia interpunctella* are attracted by the pheromone and on contact with the glue will be trapped. Thus, significant exposure to the active substance is considered unlikely to occur.	
ii) Workplace description	Card boards treated with the pheromone are put on the target area to be protected. No exposure during handling occurs.	
iii) Inhalation exposure	A card contains 2 mg of the pheromone, which is slowly released from the card over a period of approximately 6 weeks. Thus, significant exposure to the active substance is considered unlikely to occur.	**x**
iv) Dermal exposure	The product is used in trapping systems. There is no exposure of humans from use of the traps treated with the active substance.	
2. Non-professional Users including the general public	Use in trapping systems	**x**
(i) via inhalational contact	A card contains 2 mg of the pheromone, which is slowly released from the card over a period of approximately 6 weeks. Thus, significant exposure to the active substance is considered unlikely to occur.	
(ii) via skin contact	The product is used in trapping systems. There is no exposure of humans from use of the traps treated with the active substance.	

Section A2.10 Annex Point IIA2.10	Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC	
(iii) via drinking water	The product is used in trapping systems. There is no exposure of water or soil from use or production of the traps treated with the active substance.	
(iv) via food	The product is used in trapping systems. There is no exposure of humans or animals from use or production of the traps treated with the active substance.	
(v) indirect via environment	The product is used in trapping systems. There is no exposure of water or soil from use or production of the traps treated with the active substance.	
2.10.2 Environmental exposure towards active substance		
2.10.2.1 Production	Production of the pheromone outside the EU	
(i) Releases into water	Not applicable	
(ii) Releases into air	Not applicable	
(iii) Waste disposal	Not applicable	
2.10.2.2 Intended use(s)	Indoor or out insecticidal spray or electrical evaporators	x
Affected compartment(s):		
Air	Yes. The pheromone is used in traps of a size of 130 mm x 90 mm consisting of carton covered with a sticky glue The trap is fixed to a solid background with a tape on its back. A silicone paper is then removed from the sticky glue on front of the trap for its activation. Male adults of *Plodia interpunctella* are attracted via the air phase.	
Surface water	No. The product is used in trapping systems. There is no exposure of water or soil from use or production of the traps treated with the active substance.	
Sediment	No. The product is used in trapping systems. There is no exposure of water or soil from use or production of the traps treated with the active substance.	
Soil	No. The product is used in trapping systems. There is no exposure of water or soil from use or production of the traps treated with the active substance.	
Predicted concentration in the affected compartment(s)	Air: The pheromone is used in traps of a size of 130 mm x 90 mm consisting of carton covered with a sticky glue The trap is fixed to a solid background with a tape on its back. A silicone paper is then	x

Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

removed from the sticky glue on front of the trap for its activation. Male adults of *Plodia interpunctella* are attracted via the air phase. Thus, exposure is considered negligible.

Other compartments:

No contamination

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	October 2008
Materials and methods	n.a.
Conclusion	Acceptable with the amendments given below.
Reliability	n.a.
Acceptability	Acceptable with the amendments given below.
Remarks	**2.10.1 Human exposure towards active substance:** The human exposure assessment, in accordance with efficacy and the intended use, as evaluated by the rapporteur member state, is presented in the Annex of this document. 2.10.1.2 The trap is replaced once a week (cf. Doc. III-A.5) **2.10.2 Environmental exposure towards active substance:** 2.10.2.2. Indoor use only. The active substance is used in pheromone traps indoors. The total amount in a single trap is 2 mg which is released from the trap over a period of approximately 1 week. The highest concentration of the pheromone can be expected in air near the traps. Concentrations will decrease with the distance. Thus, concentrations in the air phase above other environmental compartments will be very low and consequently the concentration in water and soil will be negligible. Thus it is unlikely that exposure will exceed natural emission levels and will be below 375 g a.s./ha/year. Because of its limited indoor use, no predicted environmental concentrations were calculated.

Sample table:

Section A2.10 **Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC**

Annex Point IIA2.10

Table A2.10: Workplace exposure / Inhalation exposure (use additional terminology from the TNsGs on Human exposure

Exposure scenario	Workplace operation	PPE	Year(s) of measurement	Number of measurements	Type of measurements	Exposure concentration
Production	Not applicable, pheromone production outside the EU [redacted]					
Formulation	Cleaning not applicable	Not required, no contamination			area, short-term	
Application MG.3./PT.19.	Handling of cards treated with the pheromone. Remove of the silicone paper from the cardboard to activate the trap.	Not required, no contamination				

ANNEX by the Competent Authority:

Intended Use

The intended use of the attractant Lebensmittelmotten-Falle given by the applicant is as follows:

The pheromone ZE-TDA is used in traps of a size of 130 mm x 90 mm consisting of carton covered with a sticky glue. A card contains 2 mg of the pheromone, which is slowly released from the card. The trap is fixed to a solid background with a tape on its back. A silicone paper is then removed from the sticky glue on front of the trap for its activation. Male adults of *Plodia interpunctella* are attracted by the pheromone and on contact with the glue will be trapped.

The acceptable intended use is given in table 2.10-1.

Table 2.10-1: Acceptable intended use of the attractant Lebensmittelmotten-Falle

MG (main group)		2
PT (product type)		PT 19
Formulation	**Type**	Ready to use adhesive trap
	Conc. of a.s.	2 mg of the pheromone per trap
Field of use envisaged		Use in adhesive traps
Likely amount at which the a.s. will be used	**Method**	The trap is fixed to a solid background. A silicone paper is then removed from the sticky glue on front of the trap for its activation. Male adults of *Plodia interpunctella* are attracted via the air phase.
	Applied amount of product	1 trap per 15 m^3 room volume
	Number treatments /year	52 times per year The trap should be observed once per week and replaced if its surface is covered with trapped moths.
	Typical size of application area	The size of the protected area typically ranges from that for cupboards (e.g. 1m^3) to that for larger storage rooms (e.g. 300 m^3).
	g a.s./m^3	Not known
User		General public and professional user

Human Exposure Assessment

Preliminary note: The references to key studies are highlighted bold throughout this chapter.

The guidance documents contain only sparse information concerning attractants and repellents not applied directly on human skin. Although no specific guidance is available for the assessment of human exposure to the active substance (Z,E)-Tetradeca-9,12-dienyl acetate (ZE-TDA) during or after use of "Lebensmittelmotten-Falle" as moth attractant, the assessment of human exposure follows the recommendations of "Technical Notes for Guidance on Human Exposure to Biocidal Products" (European Commission, 2002a) and "Human Exposure to Biocidal Products User guidance version 1" (European Commission, 2002b).
The applicant's proposed assessment is presented in Doc. III-A 2.10, Doc III-B 6.6 and Doc. IV Request for general information. Industry generated experimental data or field studies to quantify human exposure to ZE-TDA from its use in "Lebensmittelmotten-Falle" are not available for this assessment.

A tiered approach is followed for exposure estimation. In tier 1 the maximum theoretically possible exposure is calculated (conservative assumptions, realistic worst case), considering validated toxicological parameters (e.g. dermal absorption). If this exposure assessment produces an unacceptable outcome in risk assessment, a tier 2 assessment is performed (i.e. refinement of the exposure studies/models, considering specific data like for example time budgets, transfer factors and the effects of exposure reduction measures, e.g. personal protective equipment). In case the predicted exposure from tier 2 should still represent a risk, a third tier would be necessary considering surveys or studies with the actual product or with a surrogate.

Identification of the oral, dermal and inhalation absorption of the active substance

Oral absorption:	100%	(default)
Dermal absorption:	100%	(default)
Inhalation absorption:	100%	(default)

For detailed information on absorption via the different exposure routes, please see Doc. II-A, chapter 3.1.

Identification of main paths of human exposure towards active substance from its use in biocidal product

Human exposure towards the active substance from its use in the biocidal product can take place via different "routes of exposure", i.e. via inhalation, dermal contact and/or ingestion (see table 1).
Exposure estimates indicate that exposure towards the active ingredient during application of the biocidal product "Lebensmittelmotten-Falle" will be negligible.

Table 2.10-2: Main paths of human exposure to ZE-TDA

Exposure path	**Production of a.s. and b.p. (Industrial use)**		**Primary (direct) exposure, during use of the b.p.**		**Secondary (indirect) exposure**
	a.s.[1]	**b.p.**	**Industrial use / Professional use**	**General public**	**Incidental contact after application (General public)[2]**
Inhalation	Not relevant	Negligible	Negligible	Negligible	Negligible
Dermal	Not relevant	Yes	Negligible	Negligible	Negligible
Oral	Not relevant	Not relevant	Not relevant	Not relevant	Negligible

[1] As ZE-TDA is produced outside the European Union, no data on exposure to the active substance during its production are required.
[2] Accidental ingestion and skin contact by infants/children were identified as the only relevant exposure routes.

Detailed information on the assessment of human exposure towards the active substance from its use in biocidal product is given in the following chapters.

Human exposure during manufacturing of the active substance

Assessment of exposure during manufacturing of the active substance is not required, since the active substance ZE-TDA is produced outside the European Union; European monitoring data are not available.

Human exposure during manufacturing of the formulated product

The moth trap "Lebensmittelmotten-Falle" is prepared in a closed system and in a dedicated production area. ZE-TDA is applied as droplets [redacted] on a card board with polyethylene layer (2 mg active substance per trap; card board area: 130 mm x 90 mm). The droplets of active substance are immediately covered with a layer of glue and wrapped in silicon paper covers.

The main step in production where human exposure may occur is filling of the pheromone reservoir of the automated production device, a 2 litre vessel.

A reservoir with the maximal capacity of 2000 mL is charged with the active substance from a 5 L container at a task duration of 5 to 15 min. The amount of active substance charged is adapted to the actual production output of each purchase order. During one year the reservoir is charged up to 20 times in varying intervals and varying amounts of active substance. (Doc. IV-A 2.10)

Further steps in the process during which human exposure may occur are sampling for quality control, maintenance work and cleaning activities. They are considered to be negligible in comparison to the filling and loading process.

Inhalation exposure

Exposure during filling is assessed using Model 3 "Mixing and loading" (TNsG on Human Exposure (2002a), part 2).

Tier 1: The exposure model indicates that exposure by inhalation may amount to 0.005 mg per kg a.s. handled (machine reservoir, 75th%). For the task of charging 2000 mL of a.s., the inhalative systemic uptake results in **1.5 x 10^{-4} mg a.s./kg bw/day**. The detailed calculation is presented in table 2.

Table 2: Inhalation exposure to ZE-TDA during manufacturing of the formulated product

Parameters	**Values**	**Reference**
Density of active substance	0.8893 g/ml	Doc. III-A 3; Study A 3.1.3
Max. amount of active substance per task	2000 mL	(Doc. IV-A 2.10)
	1.7786 kg	Calculated
Default value for potential inhalation exposure (75th percentile)	0.005 mg a.s./kg a. s./day	Model 3 for mixing and loading (EUROPOEM, (TNsG on Human Exposure (2002a), part 2)
Inhalative systemic uptake per day per person	0.005 x 1.7786 = $8.89 \cdot 10^{-3}$ mg/day	Calculated
Body weight of adult	60 kg	Default (TNsG on Human Exposure (2002a), part 2)
Inhalative systemic uptake per kg bw per day	$8.89 \cdot 10^{-3}$ / 60 = 1.5 x 10^{-4} mg a.s./kg bw/day	Calculated

In all, inhalation exposure during manufacturing of the formulated product is considered negligible. Even a worst-case estimation (chronic inhalation by adult exposed to volatilised product) via the ideal gas law, considering the saturation concentration of ZE-TDA in air (18.3 mg/m³), an inhalation volume of 1.25 m³/h, exposure to 1% of the saturation concentration (ventilation) and a working day of 8 hours, would result in a maximum inhalative systemic uptake of 0.031 mg/kg bw/day, which is below the respective acceptable exposure level.

Dermal exposure

The same scenario as described for the inhalation exposure is also applied for the estimation of dermal exposure during filling (Model 3 "Mixing and loading", TNsG Human Exp. (2002), part 2).

Tier 1: The exposure model indicates that dermal exposure may amount to 20 mg per kg a.s. handled (machine reservoir, 75th%). For the task of charging 2000 mL of a.s., the dermal systemic uptake results in **0.6 mg a.s./kg bw/day**. Detailed calculation is presented in table 3.

Table 3: Dermal exposure to ZE-TDA during manufacturing of the formulated product

Parameters	**Values**	**Reference**
Density of active substance	0.8893 g/ml	Doc. III-A 3; Study A 3.1.3
Amount of active substance per task	2000 mL	(Doc. IV-A 2.10)
	1.7786 kg	Calculated
Default value for potential dermal exposure (75th percentile)	20 mg a.s./kg a. s./day	Model 3 for mixing and loading (EUROPOEM, (TNsG on Human Exposure (2002a), part 2)
Dermal systemic uptake per day per person	20 x 1.7786 = 35.6 mg/day	Calculated
Body weight of adult	60 kg	Default (TNsG on Human Exposure (2002a), part 2)
Dermal systemic uptake per kg bw per day	35.6 / 60 = 0.6 mg a.s./kg bw/day	Calculated

Oral exposure

Based on the fact that manufacturing of the biocidal product Lebensmittelmotten-Falle is done by professional workers ingestion of ZE-TDA is assumed to be **not relevant**.

Total primary human exposure during formulation of the biocidal product

Total exposure to the active substance during formulation of the biocidal product Lebensmittelmotten-Falle can be derived as follows:

Table 4: Total primary human exposure during manufacturing of the formulated product

Exposure Scenario: Task: Charging a reservoir with active substance (Mixing and loading, model 3)		**Estimated Internal Exposure [mg/kg bw/day]**			
		Oral uptake	**Inhalation uptake**	**Dermal uptake**	**Total uptake (combined exposure)**
Tier 1	Exposure estimation using Model 3 for mixing and loading (parameters: 1 L a.s. / day; bodyweight: 60kg (adult, default))	n.r.[1]	1.5 x 10^{-4} [2]	0.6	0.6

[1] not relevant
[2] negligible

HUMAN EXPOSURE DURING APPLICATION OF THE FORMULATED PRODUCT (PRIMARY EXPOSURE)

There are no industry generated experimental data available for the exposure of humans to ZE-TDA when used in biocidal products as attractants. The estimation of exposure is therefore based on modelling and follows the recommendations given in the TNsG on Human Exposure (2002a) as far as information is available. Exposure during application of "Lebensmittelmotten-Falle" by professionals or by the general public is considered to be the same.
Detailed information on the intended use is given in Doc. II-A, chapter 3.

Inhalation exposure: Non-professional use

A single trap of "Lebensmittelmotten-Falle" contains 2 mg active substance, which is covered by a layer of glue. Due to the slow diffusion of ZE-TDA through this protective layer only small amounts of the active ingredient are released. Considering the short time necessary for the activation of "Lebensmittelmotten-Falle" (which is removing the silicone paper from the sticky glue covering the trap) primary inhalation exposure during application is considered to be **negligible**.

Worst case consideration: Assuming a release of the total amount of the active substance (2 mg) at once, inhalative uptake of 100% of the active substance and a body weight of 60 kg (adult, default), inhalative systemic exposure comes up to 0.03 mg/kg bw/event, which is well below the respective acceptable exposure level (See Doc. II-A chapter 3.9)

Dermal exposure: Non-professional use

The layer of glue covering the active substance prevents direct dermal contact with the active substance. ZE-TDA diffuses slowly through the protective film and will be distributed within this film. Therefore, contact with glue will also result in an exposure with the pheromone.
Considering small amounts of uptake due to low concentrations within the glue layer, and a small exposed area (exposure only to finger tips or small areas of the hand), dermal exposure can be assumed as **negligible**.

Worst case consideration: Assuming the loss of protective function of the glue layer as a very conservative approach, a dermal uptake of the total amount of the active substance on one single trap (2 mg a.s., transfer factor 100%) and a body weight of 60 kg (adult, default), dermal systemic exposure comes up to 0.03 mg/kg bw/event, which is well below the respective acceptable exposure level (See Doc. II-A chapter 3.9).

Oral exposure: Non-professional use

Oral exposure not expected to occur during the application of the biocidal product and is therefore considered as **not relevant**.

Worst case consideration: Even an oral uptake of the total amount of the active substance on one single trap (2 mg a.s.), considering a body weight of 60 kg (adult, default), oral systemic exposure comes up to 0.03 mg/kg bw/event, which is well below the respective acceptable exposure level (See Doc. II-A chapter 3.9).

Total primary human exposure during application of the product

Exposure of non-professional users to ZE-TDA during use of the biocidal product "Lebensmittelmotten-Falle" is summarised in table 5 below.

Table 5: Overview of primary exposure results for ZE-TDA used in the biocidal product "Lebensmittelmotten-Falle"

Exposure Scenario: Application of the biocidal product		**Estimated Internal Exposure [mg/kg bw/day]**			
		Oral uptake	**Inhalation uptake**	**Dermal uptake**	**Total uptake (combined exposure)**
Tier 1	Activation of product (Removal of paper from glue)	Not relevant	Negligible	Negligible	n.a.[1]

[1] n.a.: not applicable

Secondary exposure as a result of use of the active substance in the biocidal product

Inhalation exposure

Inhalation exposure is considered to be **negligible** for secondary exposure due to the low amount of active substance contained in a single trap (2 mg) and the slow release of this substance:
Assuming linear release of 2 mg active substance (corresponding to 1 trap) over one week, 0.29 mg active substance will be emitted per day. Expecting the whole daily release being inhaled by an adult (60 kg; default) or an infant (10 kg; default) this results in 0.005 mg/bw kg/day for an adult and in 0.029 mg/kg bw/day for an infant.
(Analogous: Linear release of active substance from 20 traps for protection of ca. 300 m³ room volume: 0.1 mg/bw kg/day for an adult and in 0.58 mg/kg bw/day for an infant.)

Worst case consideration: Even the uptake of the total amount of active substance in a single trap at once (2 mg a.s.) by inhalation by an adult or infant at a single day would be below the respective acceptable exposure level (See Doc. II-A chapter 3.9). (Adult: 0.03 mg/kg bw/day; infant: 0.2 mg/kg bw/day)

Dermal and oral exposure

Secondary dermal exposure for adults is considered negligible for the same reasons as for primary dermal exposure. ZE-TDA is covered by a layer of glue preventing direct dermal contact and the applied amount of active substance per trap is low (2 mg/trap). Oral exposure is expected to be not relevant for adults, because ZE-TDA is fixed on a solid background and can't be ingested by accident without considering misuse.

A possible scenario for dermal and oral exposure was only identified for children (Acute secondary dermal and oral exposure of a child):
An unattended child finds a trap (single, exceptional event). Due to the normal behaviour of children to investigate objects, dermal exposure may occur via touching the glue layer and oral exposure may occur via hand-to mouth transfer or chewing the card board.

Tier 1: (Worst case consideration) A child takes up the whole amount of a.s. contained in a trap (i.e. 2 mg ZE-TDA); 100% dermal and oral absorption; body weight of 15 kg (default); This would result in a total amount of **0.13 mg/kg bw/event** via dermal and oral exposure routes.

Summary of secondary exposure estimates

All secondary exposure scenarios are summarised in table 6 below. Under normal use conditions, secondary exposure is considered negligible.

Table 6: Summary of secondary exposure to ZE-TDA used in the b.p. "Lebensmittelmotten-Falle"

Exposure Scenarios: see below		**Estimated Internal Exposure [mg/kg bw/day]**		
		Oral uptake	**Inhal. Uptake**	**Dermal uptake**
Tier 1	Maximum possible uptake (dermal, oral, and/or inhalative; the whole amount of active substance contained in one trap is taken up) by an adult (60 kg bw), a child (15 kg bw) or an infant (10 kg bw)	Adult: 0.03[1,2] (negligible) Child: 0.13[1,2] Infant: 0.2[1,2]		
Tier 2	Inhalation exposure, linear release of 2 mg a.s., the whole daily release is inhaled by an adult (60 kg; default) or an infant (10 kg; default)		Adult: 0.005 mg/bw kg/day[3] Infant: 0.029 mg/kg bw/day[3]	

[1] Combined exposure (max. total) for exposure to 1 trap

[2] This represents a worst case assumption. Under normal use conditions, secondary exposure is considered negligible.

[3] Analogous: Linear release of active substance from 20 traps for protection of ca. 300 m³ room volume; The estimated internal exposure amounts to 0.1 mg/bw kg/day (adult) and in 0.58 mg/kg bw/day (infant).

Purity/Specification:	**Official use only**
Some studies were performed with z,e 9,12- tetradecadien-1-yl acetate, technical grade, instead of purified grade. The melting and the boiling point should be performed with purified active. A material of a higher purity would lead to higher melting point (-46.7°C) or a lower boiling point (318°C) Nevertheless, at any temperature of the intended use the physical state of the active will be that of a liquid. An impurity of higher volatility in the technical grade material may result in a higher vapour pressure. The application site to the area of the intended use is the gas phase. The biocide is neither sprayed nor spread. Therefore, the concentration in the air may be overestimated by using this higher vapour pressure. These higher concentrations in air were used for the calculation of risk to man and environment and present a worse case of exposition. The results of water solubility may be too high but the observed water solubility is very low and the application site is a non aqueous formulation (card coated with the active). Therefore, the Henry constant does not indicate the process of volatilisation of the active from the application system. In consequence, the use of technical grade material instead of purified active seems to be acceptable.	**x**

Section A3	**Physical and Chemical Properties of Active Substance**							
Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.1 Melting point, boiling point, relative density (IIA3.1)								
3.1.1 Melting point								
Melting pt. 1	EEC A.1. (OECD 102)	Batch no. 2005320-0022, identity confirmed by GLC, purity: 98.5 %	**Result:** - 46.7 °C **pressure:** 1013.3 hPa		Y	1	Smeykal, 2006	x

Section A3	Physical and Chemical Properties of Active Substance							
Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.1.2 Boiling point								
Boiling pt. 1	EEC A.2. (OECD 103)	Batch no. 2005320-0022, identity confirmed by GLC, purity: 98.5 %	**Result:** 318 °C **pressure:** 1013.3 hPa		Y	1	Smeykal, 2006	x
3.1.3 Bulk density/ relative density								
Bulk/rel. density 1	EEC A.3. (OECD 109)	Batch no. 2005320-0022, identity confirmed by GLC, purity: 98.5 %	Relative density: 0.8893 kg/L at 20 °C		Y	1	Wilfinger, 2006a	x

Section A3	Physical and Chemical Properties of Active Substance							
Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.2 Vapour pressure (IIA3.2)								
Vapour pressure 1	EEC A.4. (OECD 104, dynamic method)	Batch no. 2005320-0022, identity confirmed by GLC, purity: 98.5 %	The Antoine constants from the regression of the data from the dynamic method were used to calculate the vapour pressure **temperature:** 20°C **result:** 0.18 Pa **temperature:** 25°C **result:** 0.29 Pa **temperature:** 50°C **result:** 2.3 Pa		Y	1	Smeykal, 2006	x
3.2.1 Henry´s Law Constant (Pt. I-A3.2)	Calculation from vapour pressure and water solubility		**Calculated,** **result**: 381.76 Pa m³/mole		N	1	May, 2006	x

Section A3	Physical and Chemical Properties of Active Substance							
Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.3 Appearance (IIA3.3)								
3.3.1 Physical state	Visual determination	Batch no. 2005320-0022, identity confirmed by GLC, purity: 98.5 %	Liquid		Y	1	Wilfinger, 2006a	x
3.3.2 Colour	Visual determination		Colourless					
3.3.3 Odour	Olfactory determination		No specific odour					
3.4 Absorption spectra (IIA3.4)								
UV/VIS	OECD 101	Batch no. 2005320-0022, identity confirmed by GLC, purity: 98.5 %	UV/VIS, IR, MS and 13-C-NMR with interpretation of the spectral data which are in good accordance to the assigned molecular structure.		Y	1	Wilfinger, 2006b	x
IR	IR spectro meter							
NMR	Carbon-13 method							
MS	LC/MS-MS							

Section A3	Physical and Chemical Properties of Active Substance							
Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.5 Solubility in water (IIA3.5)								
Water solubility 1	EEC A.6. (OECD 105)	Batch no. 2005320-0022, identity confirmed by GLC, purity: 98.5 %	Using the column elution method the water solubility of the test item at different temperatures was found to be: **temperature:** 10°C **pH:** 6.10 / 7.62 **Result:** 0.140 / 0.115 mg/L **temperature:** 20°C **pH:** 6.22 / 7.58 **result:** 0.143 / 0.119 mg/L **temperature:** 30°C **pH:** 6.18 / 7.56 **result:** 0.150 / 0.121 mg/L	Please refer to the additional justification for acidic and alkaline pH range, data point 3.5	Y	1	Wilfinger, 2006c	x
3.6 Dissociation constant (-)				Please refer to the separately provided justification for data point 3.6.				x

Section A3	Physical and Chemical Properties of Active Substance							
Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA3.1)				Please refer to the separately provided justification for data point 3.7.				x
3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2)				Please refer to the separately provided justification for data point 3.8.				x
3.9 Partition coefficient n-octanol/water (IIA3.6)								x
log Pow 1	EEC A.8. (OECD 117, HPLC method)	Batch no. 2005320-0022, identity confirmed by GLC, purity: 98.5 %	**Result:** log p_{ow} > 6.5 **temperature:** 20 °C **pH:** 6.5	Please refer to the additional justification for acidic and alkaline pH range, data point 3.9.	Y	1	Wilfinger, 2006d	
3.10 Thermal stability, identity of relevant breakdown products (IIA3.7)	OECD 113	Batch no. 2005320-0022, identity confirmed by GLC, purity: 98.5 %	The DSC-measurement in a closed glass crucible showed an exothermal decomposition in the temperature range 330 – 450 °C with an energy of 374 J/g (< 500 J/g		Y	1	Smeykal, 2006	x

Section A3	Physical and Chemical Properties of Active Substance							
Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
			indicates no explosive properties).					
3.11 Flammability, including auto-flammability and identity of combustion products (IIA3.8)				Please refer to the separately provided justification for data point 3.11.				x
3.12 Flash-point (IIA3.9)								x
Flash-point 1				Please refer to the separately provided justification for data point 3.12.				
3.13 Surface tension (IIA3.10)								x
Surface tension 1				Please refer to the separately provided justification for data point 3.13.				
3.14 Viscosity (-)				Please refer to the separately provided justification for data point 3.14.				x
3.15 Explosive properties (IIA3.11)			Please refer to study submitted in 3.10: The DSC-measurement in a closed glass crucible showed an	Please refer to the separately provided justification for data point 3.15.	Y	1	Smeykal, 2006	x

Section A3	Physical and Chemical Properties of Active Substance							
Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
			exothermal decomposition in the temperature range 330 – 450 °C with an energy of 374 J/g (< 500 J/g indicates no explosive properties).					
3.16 Oxidizing properties (IIA3.12)				Please refer to the separately provided justification for data point 3.16.				x
3.17 Reactivity towards container material (IIA3.13)				Please refer to the separately provided justification for data point 3.17.				x

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date May 2008

Materials and methods

Purity/Specification: The argumentation is not accepted. However, the technical grade material (purity 98.5%) is considered sufficiently pure for the phys-chem tests.

3.1.1 Melting point, 3.1.2 Boiling point: Reference: This corresponds to Study A 3.1.1/01

3.1.3 Relative density: Results: This is not a relative density, but a density.
Reference: This corresponds to Study A 3.1.3

3.2 Vapour pressure: Results: vp(50°C)= 2.2 Pa; Reference: This corresponds to Study A 3.1.1/01

3.2.1 Henry´s Law Constant: Method: Is calculated from vapour pressure (20°C) and water solubility (20°C, pH 7.58). Reference: This corresponds to Study A3.2.1

3.3 Appearance: Reference: This corresponds to Study A 3.1.3

3.4 Absorption spectra:

UV/VIS: The UV/VIS indicate significant absorption <210 nm . Furthermore, no peak maxima at wavelengths ≥290 nm can be found. Reference: This corresponds to Study A 3.4

3.5 Solubility in water: Reference: This corresponds to Study A 3.5

3.6 Dissociation constant: Justification, see Doc. III- A3.6

3.7 Solubility in organic solvents, including the effect of temperature on solubility: Justification, see Doc. III-A 3.7

3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products: Justification, see Doc. III-A 3.8

3.9 Partition coefficient n-octanol/water: Reference: This corresponds to Study A 3.9; Justification, see Doc. III-A 3.9

3.10 Thermal stability, identity of relevant breakdown products: Reference: This corresponds to Study A 3.1.1/01

3.11 Flammability, including auto-flammability and identity of combustion products: Justification, see Doc. III-A 3.11

3.12 Flash-point: Justification, see Doc. III-A 3.12

3.13 Surface tension: Justification, see Doc. III-A 3.13

3.14 Viscosity: Justification, see Doc. III-A 3.14

3.15 Explosive properties: Justification, see Doc. III-A 3.15; Reference: This corresponds to Study A 3.1.1/01

3.16 Oxidising properties: Justification, see Doc. III-A 3.16

3.17 Reactivity towards container material: Justification, see Doc. III-A 3.17

Conclusion Agree with applicant's version

Reliability 1

Acceptability Acceptable

Remarks -

Section A3.5 **Annex Point IIA3.5**	**(Sub)heading: Solubility in water, water solubility in acidic and alkaline pH range**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [X]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	The water solubility was not determined in the acidic and alkaline pH range (pH 4 and pH 9) because the active substance is rapidly hydrolyzed in both media.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	June 2008	
Evaluation of applicant's justification	Agree with the applicant's version	
Conclusion	Agree with the applicant's version	
Remarks	-	

Section A3.6 Annex Point IIA3.6	(Sub)heading: Dissociation constant (IIIA3.6)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [X]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	In chemistry and biochemistry, dissociation means the propensity of a larger object to separate (dissociate) reversibly into smaller components, as when a complex falls apart into its component molecules. The dissociation of salts by solvation in a solvent like water means the separation of the anions and cations. The dissociation of acids in a solution means the split-off of a proton H^+. Dissociation is an equilibrium process, meaning that splitting and recombination takes place at the same time. Z,E-9,12-Tetradecadien-1-yl acetate does rapidly hydrolyse in water at different pH values but does not form any ions. Therefore a recombination of the molecule parts does not occur. A reversible dissociation of the active substance is therefore impossible.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	June 2008	
Evaluation of applicant's justification	Agree with the applicant's version	
Conclusion	Agree with the applicant's version	
Remarks	-	

Section A3.7 Annex Point IIIA3.7	(Sub)heading: Solubility in organic solvents, including the effect of temperature on solubility (IIIA3.7)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [X]	**Other justification [X]**	
Detailed justification:	The solubility of a test substance in organic solvents has to be determined with the CIPAC MT 181. The solubility is determined by adding measured volumes of a solvent to a known mass of the test substance until complete dissolution is observed. A preliminary test is employed to determine the approximate solubility of the test substance. The results of the preliminary test are used to select the most appropriate mass of test substance for the test. The preferable solvents are n-heptane, p-xylene, 1,2-dichloroethane, methanol or propan-2-ol, acetone and ethyl acetate. Due to the structure of the test substance, the solubility of Z,E-9,12-Tetradecadien-1-yl acetate in all solvents could be anticipated to be unlimited miscible. In addition, the active substance is used at a total amounts of 10 kg per year in Europe. Specific data on solubility and stability in organic solvents are not required. The active is rapidly hydrolyzed under alkaline and acidic conditions. The log p_{ow} is > 6.5 at neutral pH.	
Undertaking of intended data submission [ ]		

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2008
Evaluation of applicant's justification	Agree with the applicant's version
Conclusion	Agree with the applicant's version
Remarks	-

Section A3.8 Annex Point IIIA3.8	(Sub)heading: Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.8)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	[redacted] Specific data on solubility and stability in organic solvents are not required. The active is rapidly hydrolyzed under alkaline and acidic conditions. The log p_{ow} is > 6.5 at neutral pH.	X
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	June 2008	
Evaluation of applicant's justification	Agree with the applicant's version, with the amendments given below.	
Conclusion	Agree with the applicant's version, with the amendments given below.	
Remarks	The active substance as manufactured does not include any organic solvent.	

Section A3.9 **Annex Point IIA3.9**	**(Sub)heading: Partition coefficient n-octanol/water (IIA3.9)**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [X]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	The partition coefficient n-octanol/water was not determined in the acidic and alkaline pH range (pH 4 and pH 9) because the active substance is rapidly hydrolyzed in both media.	X
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	June 2008	
Evaluation of applicant's justification	Agree with the applicant's version	
Conclusion	Agree with the applicant's version	
Remarks	For log P_{ow} at pH 6.5, please see Doc. III-A.3 subsection 3.9.	

Section A3.11 **Annex Point IIA3.8**	**(Sub)heading: Flammability, including auto-flammability and identity of combustion products (IIA3.8)**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [X]**	
Detailed justification:	[redacted] DSC measurement on thermal stability showed exothermal decomposition of the active substance at 330 – 450 °C. Specific data on flammability are therefore not required.	X
	During the production process of the formulated product, the active is applied in droplets on a card board (130 mm x 90 mm) at an amount of 2.0 mg per card.	X
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	June 2008	
Evaluation of applicant's justification	Agree with the applicant's version.	
Conclusion	Agree with the applicant's version.	
Remarks	Reference: Study A 3.1.1/01 The production process takes place at room temperature.	

Section A3.12 Annex Point IIA3.12	(Sub)heading: Flash-point (IIA3.12)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [X]**	
Detailed justification:	[redacted] DSC measurement on thermal stability showed exothermal decomposition of the active substance at 330 – 450 °C. Specific data on flammability or flash point are therefore not required.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	June 2008	
Evaluation of applicant's justification	According to Dir 67/548/EEC, a substance is classified "flammable" if its flash point is equal or greater than 21°C and less than or equal to 55°C. The result of the DSC measurement does not support that the flash point is less than or equal to 55°C.	
Conclusion	Agree with the applicant's version.	
Remarks	Reference: Study A 3.1.1/01	

Section A3.13 Annex Point IIA3.13	(Sub)heading: Surface tension (IIA3.13)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	Surfactants are wetting agents that lower the surface tension of a liquid, allowing easier spreading, and lower the interfacial tension between two liquids. Surfactants are usually organic compounds that are amphipathic, meaning they contain both hydrophobic groups (their "tails") and hydrophilic groups (their "heads"). Therefore, they are typically sparingly soluble in both organic solvents and water. Surfactants reduce the surface tension of water by adsorbing at the liquid-gas interface. They also reduce the interfacial tension between oil and water by adsorbing at the liquid-liquid interface. Many surfactants can also assemble in the bulk solution into aggregates that are known as micelles. The concentration at which surfactants begin to form micelles is known as the critical micelle concentration or CMC. When micelles form in water, their tails form a core that is like an oil droplet, and their (ionic) heads form an outer shell that maintains favorable contact with water. When surfactants assemble in oil, the aggregate is referred to as a reverse micelle. In a reverse micelle, the heads are in the core and the tails maintain favorable contact with oil. Surfactants are also often classified into three primary groups; anionic, cationic and non-ionic. Z,E-9,12-Tetradecadien-1-yl acetate has a very low water solubility of about 0.15 mg/L at neutral pH values. Therefore, the requirements of a surface active substance concerning the amphipathic character is not fulfilled. [redacted]The substance is applied in droplets on a card board to produce the final formulated product and thus the substance will not get in contact with surface waters. Thus, the determination of the surface tension is not applicable.	
Undertaking of intended data submission [ ]		

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2008
Evaluation of applicant's justification	Agree with the applicant's version
Conclusion	Agree with the applicant's version
Remarks	-

Section A3.14 Annex Point IIIA3.14	(Sub)heading: Viscosity (IIA3.14)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	[redacted] The liquid active substance is applied as droplets from an automated dispenser onto the cardboard of the trapping system. For that, the formulation is a ready for use product and the user is not able to handle the active substance itself.	X
Undertaking of intended data submission [ ]		

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2008
Evaluation of applicant's justification	Agree with the applicant's version.
Conclusion	Agree with the applicant's version
Remarks	The justification is accepted in the view of the fact that the substance is not expected to be viscous as it is applied as droplets from an automated ink jet printer and therefore has to display a certain flowability. In addition, this end point is not listed in the TNsG on data requirements (Addendum Guidance for Waiving of Data Requirements for Pheromones) as required or conditionally required.

Section A3.15 Annex Point IIA3.15	(Sub)heading: Explosive properties (IIA3.15)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [X]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	[redacted] The DSC-measurement in a closed glass crucible showed an exothermal decomposition in the temperature range 330 – 450 °C with an energy of 374 J/g (< 500 J/g indicates no explosive properties). During the production process of the formulated product, the active is applied in droplets on a card board (130 mm x 90 mm) at an amount of 2.0 mg per card.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	June 2008	
Evaluation of applicant's justification	Agree with the applicant's version	
Conclusion	Agree with the applicant's version	
Remarks	According to the UN Manual of Tests and Criteria, Appendix 6, paragraph 3.3, the acceptance procedure for Class 1 explosives needs not be applied if a formulation has an energy of decomposition of less than 500 J/g. Moreover, there are no structural alerts for explosive properties.	

Section A3.16 Annex Point IIA3.16	(Sub)heading: Oxidizing properties (IIA3.16)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [X]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	[redacted] The DSC-measurement in a closed glass crucible showed an exothermal decomposition in the temperature range 330 – 450 °C with an energy of 374 J/g (< 500 J/g indicates no explosive properties. From the structure of the active it is concluded that the substance does not reveal any oxidizing properties. The substance is a long chained carbon containing oxygen as acetate group only, which does not build any free oxygen in contact with other substances.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	June 2008	
Evaluation of applicant's justification	Agree with the applicant's version	
Conclusion	Agree with the applicant's version	
Remarks	-	

Section A3.17 Annex Point IIA3.17	(Sub)heading: Reactivity towards container material (IIA3.17)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	[redacted] The non-corrosive substance has been imported in metal containers of 5 kg contents for many years. Reactivity towards the container material has never been reported.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	June 2008	
Evaluation of applicant's justification	The applicant's version is accepted.	
Conclusion	The applicant's version is accepted.	
Remarks	-	

Section A4 (4.1/01)

Annex Point IIA4.1

Analytical Methods for Detection and Identification of the Active Substance and its Impurities

Three batch analysis of Z,E-9,12-Tetradecadien-1-yl acetate (TDA), technical

			Official use only
		1 REFERENCE	
1.1	**Reference**	Bockhorn, A. (2006a), Three Batches Analysis of z,e-9,12-Tetradecadien-1-yl-acetate (TDA), testing facility: SOFIA-GmbH, Berlin, Germany, published: no, report No. 262-10-12/06, (Dates of work: not stated)	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Aeroxon Insect Control GmbH	
1.2.2	Companies with letter of access	Not applicable	
1.2.3	Criteria for data protection	New data, not yet submitted to any MS.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No	
2.2	**GLP**	No	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**		
3.1.1	Enrichment	Under the assumption that the signal response using a flame ionisation detector (FID) is proportional to the mass of each compound the relative peak areas can be taken directly for the quantification of each of the separated compounds. Under the same chromatographic conditions a mass spectrometric analysis was performed to identify the unknown impurities. Even if no exact identification of the impurity succeeds, the kind of compound or the chemical class can be defined by its mass spectrum. An absolute quantification using GC-FID was performed using two standard substances. Finally a total combustion was done to evaluate if any inorganic residues/impurities occur.	x
3.1.2	Cleanup	No clean up	
3.2	**Detection**		

Section A4 (4.1/01)

Annex Point IIA4.1

Analytical Methods for Detection and Identification of the Active Substance and its Impurities

Three batch analysis of Z,E-9,12-Tetradecadien-1-yl acetate (TDA), technical

3.2.1	Separation method	a) Screening analysis using gas chromatography and flame ionisation detector (GCFID) and two capillaries of different stationary phases: GC-Parameter: Instrument: HP5890 A Series II (Agilent) Autosampler: CTC-Combi PAL Carrier gas: Hydrogen 5.0, 8 PSI Injection temperature: 220°C Oven temperature: 100°C (1min.)-10°C/min.- 160°C- 25°C/min.- 240°C (15min.) Split-Injection. 1/20; injection volume: 1 µL 1. ZB-Wax (Phenomenex) Column: ZB-Wax (Phenomenex) 30 m x 0.25 mm i.d. x 0.25 µm film 2. DB-210 (J&W) Column: DB 210 (J&W) 30 m x 0.32 mm i.d. x 0.25 µm film b) The mass spectrometric analysis: GC-Parameter: Instrument: MSD 5971 and GC HP5890 A Series II (Agilent) Autosampler: CTC-Combi PAL Column: ZB-Wax (Phenomenex) 30 m x 0.25 mm i.d. x 0.25 µm film Carrier gas: Hydrogen 5.0, 8 PSI Inj. Temp.: 220°C Det. Temp.: 280°C Oven-Progr.Temp.: 70°C (1min.)-10°C/min.- 150°C- 25°C/min.- 230°C (3min.) Splitless-Inj. 1; Inj.Vol.: 1 µL c) Mineralisation Total combustion is performed for 6h at 450°C. Oven: Nabertherm L5/11S, Germany Balance: Explorer 210, Ohaus, Switzerland
3.2.2	Detector	a) Flame ionisation detector (FID): Detector temperature: 280°C b) Mass spectrometric parameters: m/z 50-300, cyclic scans per second: 1,7 solvent delay 6.0 min, Detector temperature: 280°C
3.2.3	Standard(s)	Z,E-9,12-Tetradecadien-1-yl-acetate (TDA): Batch 262-7/6 Batch 262-8/6 Batch 262-9/6 No external standard
3.2.4	Interfering substance(s)	Not applicable

3.3 Linearity

Section A4 (4.1/01)

Annex Point IIA4.1

Analytical Methods for Detection and Identification of the Active Substance and its Impurities

Three batch analysis of Z,E-9,12-Tetradecadien-1-yl acetate (TDA), technical

3.3.1	Calibration range	Not applicable
3.3.2	Number of measurements	Not applicable
3.3.3	Linearity	Not applicable
3.4	**Specifity: interfering substances**	Not applicable
3.5	**Recovery rates at different levels**	Not applicable
3.5.1	Relative standard deviation	Not applicable
3.6	**Limit of determination**	Not applicable
3.7	**Precision**	
3.7.1	Repeatability	RSD 0.15% Z,E-9,12-Tetradecadien-1-ylacetate; RSD 26.88% Impurity 3 [redacted] RSD 74.92% Impurity 5 [redacted]
3.7.2	Independent laboratory validation	Not applicable

Section A4 (4.1/01)

Annex Point IIA4.1

Analytical Methods for Detection and Identification of the Active Substance and its Impurities

Three batch analysis of Z,E-9,12-Tetradecadien-1-yl acetate (TDA), technical

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

The aim of this study was the characterization of technical Z,E-9,12-Tetradecadien-1-ylacetate, followed by verification and identification of residues above 1 g/kg (0.1%). Under the assumption that the signal response using a flame ionisation detector (FID) is proportional to the mass of each compound, the relative peak areas can be taken directly for the quantification of each of the separated compounds. Under the same chromatographic conditions a mass spectrometric analysis was performed to identify the unknown impurities. Even if no exact identification of the impurity succeeds, the kind of compound or the chemical class can be defined by its mass spectrum. An absolute quantification using GC-FID was performed using two standard substances. Finally a total combustion was done to evaluate if any inorganic residues/impurities occur.

4.2 Conclusion

The following dissipation was found:

99.21% Z,E-9,12-Tetradecadien-1-ylacetate
[redacted] Impurity 3 [redacted]
Impurity 5

The determination of Z,E-9,12-Tetradecadien-1-ylacetate in technical Z,E-9,12-Tetradecadien-1-ylacetate is valid with regard to SANCO 3030/99 rev.4 because the RSD of the repeated determination was less than 1.34% and the detector response was of sufficient linearity as indicated in Doc IV 4.1/02.

Impurity 3: The molecular mass and fragmentation indicate the [redacted] The determination of the [redacted] is performed with a valid analytical method (refer to Doc IVA 4.1/02).

Impurity 5: The compound is identified as [redacted] by comparison to quality control data of the manufacturing process and co-chromatography during validation of the analytical method (refer to Doc IV A 4.1/02).

No residues after mineralisation were measured and no visible residues could be found. The limit of quantification is 0.1%. This is 1 g/kg of the technical product.

x

4.2.1 Reliability: 1

4.2.2 Deficiencies: No

Section A4 (4.1/01)

Annex Point IIA4.1

Analytical Methods for Detection and Identification of the Active Substance and its Impurities

Three batch analysis of Z,E-9,12-Tetradecadien-1-yl acetate (TDA), technical

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	November 2008
Materials and methods	The applicant states that due to the circumstance that a real limited amount of technical active is prepared normally no more than once per year it was not possible to get a standard of sufficient quality independently prepared from the manufacturing site of the technical active. The hypothesis that the mass of ZE-TDA and impurities is proportional to peak response of FID, sum 100%, was confirmed by using material from Sigma (85%) whose content of ZE-TDA was uncertified (one-point calibration). Therefore, the peak response in comparison to TDME peak (also from uncertified material) was used as a second anchor to prove reliability of the estimation by relative peak response in FID. In addition no residues after mineralisation were measured and no visible residues could be found.
Conclusion	Please refer to Doc III-A 2.7 for characterisation of technical (Z,E)-Tetradeca-9,12-dienyl acetate and verification and identification of impurities above 1 g/kg.
Reliability	2
Acceptability	Acceptable
Remarks	Several impurities were detected. However, only “impurity 3” and “impurity 5” are on hand at concentrations above 1 g/kg (0.1%). Please also refer to Doc. III-A 4.1/01 confidential.

Section A4 (4.1/02)
Annex Point IIA4.1

Analytical Methods for Detection and Identification of the Active Substance and its Impurities

Three batch analysis of Z,E-9,12-Tetradecadien-1-yl acetate (TDA), technical

Official use only

1 REFERENCE

1.1	**Reference**	Bockhorn, A. (2006b), Determination of two impurities in the three Batches Analysis of z,e-9,12-Tetradecadien-1-yl-acetate (TDA), testing facility: SOFIA-GmbH, Berlin, Germany, published: no, report No. 1201-40-41/06, (Dates of work: not stated)
1.2	**Data protection**	Yes
1.2.1	Data owner	Aeroxon Insect Control GmbH
1.2.2	Companies with letter of access	Not applicable
1.2.3	Criteria for data protection	New data, not yet submitted to any MS

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	SANCO 3030/99 rev.4
2.2	**GLP**	No
2.3	**Deviations**	No

3 MATERIALS AND METHODS

3.1 Preliminary treatment

3.1.1 Enrichment

For Z,E-9,12-Tetradecadien-1-yl acetate (TDA) and [redacted] (impurity 3):

[redacted] the quantification is performed by the detector response of z,e-9,12-Tetradecadien-1-yl-acetate.

10 mg of technical z,e-9,12-Tetradecadien-1-yl-acetate (EZ-TDA) are dissolved in 10 ml heptane as stock solution. Concentrations from 0.1 µg/ml to 30 µg/ml of EZ-TDA are obtained by dilution of this stock solution. Tetradecanoic acid methylester (TDME) is used as an internal standard and injection standard at 100 µg/ml at each calibration point.

[redacted]

FID response and m/z 94 of GC/MS response is used for quantification.

For [redacted] (impurity 5):

10 mg of [redacted] is dissolved in 10 ml heptane as stock solution. Concentrations from 0.1 µg/ml to 100 µg/ml of [redacted] are obtained by dilution of this stock solution. Tetradecanoic acid methylester (TDME) is used as an internal standard and injection standard at 100 µg/ml at each calibration point. The concentration level of the technical z,e-9,12-Tetradecadien-1-yl-acetate for fortification is 1 g/L in heptane.

Section A4 (4.1/02)

Annex Point IIA4.1

Analytical Methods for Detection and Identification of the Active Substance and its Impurities

Three batch analysis of Z,E-9,12-Tetradecadien-1-yl acetate (TDA), technical

FID response and m/z 94 of GC/MS response is used for quantification versus the external standard of [redacted]

3.1.2 Cleanup — No clean up

3.2 Detection

3.2.1 Separation method

a) Instrumental parameters for GC-FID measurement:

Separation column: ZB-Wax (Phenomenex)

GC-Parameter:

Instrument: HP5890 A Series II (Agilent)

Autosampler: CTC-Combi PAL

Column: ZB-Wax (Phenomenex) 30 m x 0,25 mm i.d. x 0,25 µm film

Carrier gas: Hydrogen 5.0, 8 PSI

Injection temperature: 220°C

Detector temperature: 280°C

Oven temperature: 100°C (1min)-10°C/min- 160°C- 25°C/min-240°C (15min)

Splitless-Injection (0.5min); injection volume: 1 µl

b) Instrumental parameters for GC-MS measurement:

Separation column: ZB-Wax (Phenomenex)

GC-Parameter:

Instrument: MSD 5971 and GC HP5890 A Series II (Agilent)

Autosampler: CTC-Combi PAL

Column: ZB-Wax (Phenomenex) 30 m x 0,25 mm i.d. x 0,25 µm film

Carrier gas: Helium 5.0, 8 PSI

Inj. Temp.: 220°C

Det. Temp.: 280°C

Oven-Progr. Temp.: 70°C (1min)-10°C/min- 150°C- 25°C/min-230°C (3min)

Splitless-Inj. (0.5min); Inj.Vol.: 1 µl

Mass spectrometric parameters:

m/z 50-300,

solvent delay 6.0 min

3.2.2 Detector

a) Flame ionisation detector (FID):

Detector temperature: 280°C

b) Mass spectrometric parameters:

m/z 50-300, selected ion monitoring, dwell time 0.05 sec/amu, solvent delay 6.0 min, Detector temperature 280°C

3.2.3 Standard(s)

References	LOT Number	Name	SOFIA-No	Purity [%]
Matrix	2006277-0009	z,e-9,12-Tetradecadien-1-yl-acetate	1201-40/06	98.8

Section A4 (4.1/02)

Annex Point IIA4.1

Analytical Methods for Detection and Identification of the Active Substance and its Impurities

Three batch analysis of Z,E-9,12-Tetradecadien-1-yl acetate (TDA), technical

(3) Standard for quantification of impurity 3	[redacted]	[redacted]	[redacted]	98.8
Standard for quantification of impurity 5	[redacted]	[redacted]	[redacted]	92
Internal Standard	70301-026 (Aldrich)	Tetradecanoic acid methyl ester		99

3.2.4 Interfering substance(s)

Not applicable since a matrix Z,E-9,12-Tetradecadien-1-yl acetate (TDA) without [redacted] (impurity 3) and [redacted] (impurity 5) is not available

3.3 Linearity

3.3.1 Calibration range

For Z,E-9,12-Tetradecadien-1-yl acetate (TDA) and [redacted] (impurity 3):
0.1 – 30 µg/L for GC/FID and GC/MS

For [redacted] (impurity 5):
0.1 – 100 µg/L for GC/FID
0.05 – 10 µg/L and GC/MS

3.3.2 Number of measurements

For Z,E-9,12-Tetradecadien-1-yl acetate (TDA) and [redacted] (impurity 3):
6 concentrations with 3 replicates for GC/FID and GC/MS

For [redacted] (impurity 5):
7 concentrations with 3 replicates for GC/FID and
6 concentrations with 3 replicates for GC/MS

3.3.3 Linearity

For Z,E-9,12-Tetradecadien-1-yl acetate (TDA) and [redacted] (impurity 3):
Response = 0.0117 + 0.534 x concentration, r^2= 1, GC/FID
Response = 0.100 + 1.11 x concentration, r^2= 1, GC/MS

For [redacted] (impurity 5):
Response = 0.0101 + 0.446 x concentration, r^2= 1, GC/FID
Response = 0.0379 + 4.02 x concentration, r^2= 1, GC/MS

Section A4 (4.1/02)

Annex Point IIA4.1

Analytical Methods for Detection and Identification of the Active Substance and its Impurities

Three batch analysis of Z,E-9,12-Tetradecadien-1-yl acetate (TDA), technical

3.4 Specifity: interfering substances

For Z,E-9,12-Tetradecadien-1-yl acetate (TDA) and [redacted] (impurity 3):
The FID chromatograms in combination with MS chromatograms (retention times) and the mass response at m/z [redacted] guarantee the identity of the analyte.

For [redacted] (impurity 5):
The FID chromatograms in combination with MS chromatograms (retention times) and the mass response at m/z [redacted] guarantee the identity of the analyte.

Representative chromatograms are delivered within the report.

3.5 Recovery rates at different levels

For Z,E-9,12-Tetradecadien-1-yl acetate (TDA) and [redacted] (impurity 3):

100 mg/L technical (4.8 g impurity 3/kg), Mean recovery (n=5) 100%
120 mg/L technical (4.8 g impurity 3/kg), Mean recovery (n=5) 104%
200 mg/L technical (4.8 g impurity 3/kg), Mean recovery (n=5) 99.9%
for GC/FID

100 mg/L technical (6.0 g impurity 3/kg), Mean recovery (n=5) 100%
120 mg/L technical (6.0 g impurity 3/kg), Mean recovery (n=5) 102%
200 mg/L technical (6.0 g impurity 3/kg), Mean recovery (n=5) 104%
for GC/MS

For [redacted] (impurity 5):

100 mg/L technical (0.3 g impurity 5/kg), Mean recovery (n=5) 100%
Fortification level 1 (0.3 g impurity 5/kg), Mean recovery (n=5) 98.7%
Fortification level 2 (3 g impurity 5/kg), Mean recovery (n=5) 109%
for GC/FID

100 mg/L technical (0.46 g impurity 5/kg), Mean recovery (n=5) 100%
Fortification level 1 (0.3 g impurity 5/kg), Mean recovery (n=5) 98.7%
Fortification level 2 (3 g impurity 5/kg), Mean recovery (n=5) 96.6%
for GC/MS

3.5.1 Relative standard deviation

For Z,E-9,12-Tetradecadien-1-yl acetate (TDA) and [redacted] (impurity 3):

100 mg/L technical (4.9 g impurity 3/kg), RSD (n=5) 1.5%
120 mg/L technical (4.9 g impurity 3/kg), RSD (n=5) 9.2%
200 mg/L technical (4.9 g impurity 3/kg), RSD (n=5) 2.4%
for GC/FID

100 mg/L technical (4.9 g impurity 3/kg), RSD (n=5) 4.2%
120 mg/L technical (4.9 g impurity 3/kg), RSD (n=5) 7.6%
200 mg/L technical (4.9 g impurity 3/kg), RSD (n=5) 4.9%
for GC/MS

For [redacted] (impurity 5):

100 mg/L technical (0.3 g impurity 5/kg), RSD (n=5) 14.5%
Fortification level 1(0.3 g impurity 5/kg), RSD (n=5) 15.3%
Fortification level 2 (3 g impurity 5/kg), RSD (n=5) 3.5%
for GC/FID

Section A4 (4.1/02)
Annex Point IIA4.1

Analytical Methods for Detection and Identification of the Active Substance and its Impurities

Three batch analysis of Z,E-9,12-Tetradecadien-1-yl acetate (TDA), technical

		100 mg/L technical (0.46 g impurity 5/kg), RSD (n=5) 18.9% Fortification level 1 (0.3 g impurity 5/kg), RSD (n=5) 19.7% Fortification level 2 (3 g impurity 5/kg), RSD (n=5) 9.0% for GC/FID
3.6	**Limit of determination**	For [redacted] (impurity 3): For GC/FID, the LOQ is 0.1 g/kg (1/5 of impurity 3) because 1/5 increasing detector response is established to be within 70 – 125% recovery an acceptable RSD of 9.2%. For GC/MS, the LOQ is 0.1 g/kg (1/5 of impurity 3) because 1/5 increasing detector response is established to be within 70 – 125% recovery and a RSD of 7.6%. For [redacted] (impurity 5): For GC/FID, the LOQ is 0.3 g/kg because of recovery within 70 – 125% and acceptable RSD of 14.5%. For GC/MS, the LOQ is 0.3 g/kg because of recovery within 70 – 125% and acceptable RSD of 18.9%.
3.7	**Precision**	
3.7.1	Repeatability	For [redacted] (impurity 3): For GC/FID, RSD of 9.2%. For GC/MS, RSD of 7.6%. For [redacted] (impurity 5): For GC/FID, RSD of 14.5%. For GC/MS, RSD of 18.9%.
3.7.2	Independent laboratory validation	Not applicable

Section A4 (4.1/02)

Annex Point IIA4.1

Analytical Methods for Detection and Identification of the Active Substance and its Impurities

Three batch analysis of Z,E-9,12-Tetradecadien-1-yl acetate (TDA), technical

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

The aim of this study was the validation of the analytical method for impurity 3 [redacted] and impurity 5 [redacted] which were identified during characterisation of technical Z,E-9,12-Tetradecadien-1-ylacetate at a level of less than 1 g/kg (0.1%) (refer to Doc IV A 4.1.-01). The validation for [redacted] was based on the variation of in weighing because a synthetic reference was not available. Reference for quantification was the detector response of [redacted]. The validation of [redacted] was based on standard addition of a reference standard which was also used for quantification.

The analytical determinations were done by GC/FID and confirmed by GC/MS (m/z 94).

4.2 Conclusion

Both methods are valid with regard to linearity, accuracy and specifity. The validation of impurity 3 [redacted] was performed reading SANCO 3030/99 rev.4. The LOQ could be established at 1 g/kg.

The validation of impurity 5 [redacted] was performed reading SANCO 3030/99 rev.4. The LOQ could be established at 0.3 g/kg.

The validation confirms that the content of the impurities 3 and 5 which were evaluated during the Batch analysis (refer to Doc IV A 4.1.-01) are reliable.

4.2.1 Reliability: 1

4.2.2 Deficiencies: No

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	September 2008
Materials and methods	Acceptable
Conclusion	Agree with applicant's version
Reliability	2 (Please see also Doc. III-A.4.1/01)
Acceptability	Acceptable
Remarks	Several impurities were detected. However, only "impurity 3" and "impurity 5" are on hand at concentrations above 1 g/kg (0.1%). (Please see also Doc. III-A.4.1/01) Please also refer to Doc. III-A 4.1/02 confidential.

Section A4 (4.2/01)
Annex Point IIA4.2

Analytical Methods for Detection and Identification of the Active Substance in Air

Official use only

1 REFERENCE

1.1	**Reference**	Bockhorn, A. (2006b): Validation of an analytical method for the determination of z,e-9,12-Tetradecadien-1-yl-acetate (TDA) in air; testing facility: SOFIA-GmbH, Berlin, Germany, published: no, report No. 262-7-9/06, (Dates of work: not stated)
1.2	**Data protection**	Yes
1.2.1	Data owner	Aeroxon Insect Control GmbH
1.2.2	Companies with letter of access	Not applicable
1.2.3	Criteria for data protection	New data, not yet submitted to any MS

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes SANCO/825/00 rev. 7
2.2	**GLP**	No
2.3	**Deviations**	No

3 MATERIALS AND METHODS

3.1	**Preliminary treatment**	
3.1.1	Enrichment	Tenax TA 35/60, 8 x 100 mm, 100/50 mg, Supelco 20832-U, was used as adsorbent. Sampling was performed with 2 L/min at 37°C and 85% relative humidity over a period of 360 min. The upper layer of the adsorbent is put into a 10 ml screw capped vial, 5 mL acetone and 5 µL of internal standard (TDME, 10 mg/mL) are added. The vial is closed and put into an ultrasonic bath for 10 minutes. This extract is measured by GC-FID. The method was confirmed by GC/MS.
3.1.2	Cleanup	No further clean up
3.2	**Detection**	

Section A4 (4.2/01) Analytical Methods for Detection and Identification of the Active Substance in Air

Annex Point IIA4.2

3.2.1	Separation method	GC-FID Column: ZB-Wax (Phenomenex) 30 m x 0.25 mm i.d. x 0.25 µm film Carrier gas: Hydrogen 5.0, 6.5 PSI Injection temperature: 220°C Oven temperature: 100°C (1min)-10°C/min- 160°C- 25°C/min-240°C (15min) Splitless-Injection, split open after 30 sec (1/20) injection volume: 1 µL GC-MS Column: ZB-Wax (Phenomenex) 30 m x 0.25 mm i.d. x 0.25 µm film Carrier gas: Helium 5.0, constant flow 0.6 mL/min (EPC) Injection temperature: 220°C Detector temperature: 280°C Oven temperature: 70°C (1min)-10°C/min- 230°C (3min) Splitless-Injection, after 30sec (1/20); injection volume: 1 µL
3.2.2	Detector	Flame ionisation detector: detector temperature: 280°C Mass Spectrometry: Selected ion monitoring, 100 msec/ion: TDME m/z 74,1; 87,1; 143,1; TDA: m/z 95,0; 135,1; 192,1; 252,2; Solvent delay: 12 min; temperature transfer line: 280°C
3.2.3	Standard(s)	[redacted] TDA: SIGMA: Z,E-9,12-TETRADECADIEN-1-YL ACETATE (TDA), purity: 85%, order no: T-0893, Lot 31K3796
3.2.4	Interfering substance(s)	No
3.3	**Linearity**	
3.3.1	Calibration range	0 – 24.4 mg/L
3.3.2	Number of measurements	6
3.3.3	Linearity	$r^2 = 0.998$

Section A4 (4.2/01)
Annex Point IIA4.2

Analytical Methods for Detection and Identification of the Active Substance in Air

3.4 Specifity: interfering substances

No interference was observed

3.5 Recovery rates at different levels

Fort. [µg/m³]	Recovery [%]	[%]	
Blank	n.c. n.c. n.c. n.c. n.c.	Mean Std. Dev. RSD	n.c. n.c. n.c.
3.39	76.7 76.6 81.2 88.6 77.1	Mean: Std. Dev.: RSD:	80.0 4.6 5.7
8.47	114.3 103.8 98.7 107.0 103.3	Mean: Std. Dev.: RSD:	105.4 5.2 4.9
33.9	100.4 102.3 124.1 124.7 87.9	Mean: Std. Dev.: RSD:	107.9 14.3 13.3
84.7	113.6 117.8 111.5 112.2 71.6	Mean: Std. Dev.: RSD:	105.4 17.0 16.1
169	105.8 102.2 102.0 91.0 98.1	Mean: Std. Dev.: RSD:	99.8 5.0 5.1

n.c.: not calculated

Blank value is less than 30% of the lowest fortification point (0,02 / 0.39 x 100% = 5%)

3.5.1 Relative standard deviation

See 3.5

3.6 Limit of determination

LOQ = 3.39 µg/m³

3.7 Precision

3.7.1 Repeatability

see 3.5.1

3.7.2 Independent laboratory validation

No

Section A4 (4.2/01)
Annex Point IIA4.2

Analytical Methods for Detection and Identification of the Active Substance in Air

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

Tenax TA 35/60, 8 x 100 mm, 100/50 mg, Supelco 20832-U, was used as adsorbent. Sampling was performed with 2 L/min at 37°C and 85% relative humidity over a period of 360 min.

The upper layer of the adsorbent is put into a 10 ml screw capped vial, 5 ml acetone and 5 µL of internal standard ([redacted], 10 mg/mL) are added. The vial is closed and put into an ultrasonic bath for 10minutes.

This extract is measured by GC-FID. The method was confirmed by GC/MS.

4.2 Conclusion

The method allows the determination of 3.39 µg/m^3 to 169 µg/m^3 of active substance in air.
Result: No significant breakthrough up to 100 µg/tube (169 µg/m^3)was observed.
The tubes should be stored at room temperature in the dark. The analysis should be performed within 14 days after sampling.

4.2.1 Reliability: 1

4.2.2 Deficiencies: No

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	September 2008
Materials and methods	Acceptable
Conclusion	Agree with applicant's version
Reliability	1
Acceptability	Acceptable
Remarks	-

Section A4 (4.2/03) **Annex Point IIA4.2**	**Analytical Methods for Detection and Identification** of Z,E-9,12-Tetradecadien-1-yl acetate in a) water, sediment and soil b) animal and human body fluids and tissues	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	a) **water, sediment and soil** [redacted] During the production process of the formulated product, the active is applied in droplets on a card board (130 mm x 90 mm) at an amount of 2.0 mg per card. Production occurs in a closed system. The product is used by applying the card board to wardrobes, storage rooms and other in-door uses. The volatile pheromone is released from the card and attracts male moth species. Volatility lasts for about one month, depending on climatic conditions. Afterwards, the traps can be disposed with general waste disposal systems. There is no exposure of water or soil from use or production of the traps treated with the active substance. Thus, it is concluded that specific studies on analytical methods for determination of the active substance in water, sediment and soil are not required, also with regard to the very low quantities used. b) **animal and human body fluids and tissues** [redacted] During the production process of the formulated product, the active is applied in droplets on a card board (130 mm x 90 mm) at an amount of 2.0 mg per card. Production occurs in a closed system. The product is used by applying the card board to wardrobes, storage rooms and other in-door uses. The volatile pheromone is released from the card and attracts male moth species. Volatility lasts for about one month, depending on climatic conditions. Afterwards, the traps can be disposed with general waste disposal systems. There is no exposure of humans or animals to residues from use or production of the traps treated with the active substance. Thus, it is concluded that specific studies on analytical methods for determination of the active substance in animals and humans body fluids and tissues are not required, also with regard to the very low quantities used. Furthermore the active substance is not classified being “toxic” or “very toxic”.	X X
Undertaking of intended data submission [ ]	No	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	December 2008
Evaluation of applicant's justification	a) water, sediment and soil According to "Guidance for Waiving of Data Requirements for Pheromones", analytical methods for determination of the active substance in water, sediment and soil are not necessarily required. In case that classification according to Council Directive 67/548/EEC will be proposed, information on analytical methods might be requested. However, it is likely that ZE-TDA is (bio)degraded in environmental compartments. Based on supportive data on another SCLP from the same chemical class as ZE-TDA, dissipation is rapid, based on volatilization and degradation in soil and somewhat slower in water. The same degradation route is also plausible for ZE-TDA yielding its alcohol by hydrolysis, tetradecadienol. b) animal and human body fluids and tissues Regarding the exposure assessment, please see Doc. III-A-2.10.
Conclusion	Agree with applicant's version.
Remarks	According to your comments on the draft-CAR dating from 22.01.2009, use in wardrobes is not intended.

Section A4 (4.3) **Annex Point IIA4.3**	**Analytical Methods for Detection and Identification** Z,E-9,12-Tetradecadien-1-yl acetate residues in/on food or feedstuffs and other products where relevant	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Z,E-9,12-Tetradecadien-1-yl acetate will not be used in contact to food or feeding stuff. Therefore, Z,E-9,12-Tetradecadien-1-yl acetate will not occur in food or feeding stuff and is not a relevant residue in food or feeding stuff.	X
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	August 2008	
Evaluation of applicant's justification	Agree with applicant's version.	
Conclusion	According to the applicant, the "Lebensmittelmotten-Falle" is used in cupboards and rooms to protect food and feed by preventing and reducing infestations with moths. However, no relevant food and feed stuff exposure is to be expected since the "Lebensmittelmotten-Falle" contains only 2 mg of ZE-TDA and should only be applied where food and feed-stuff is stored in closed or re-closed package. Thus the risk from residues from ZE-TDA on food/feeding stuff is considered to be negligible.	
Remarks	-	

Section A5 Effectiveness against target organisms and intended uses

Subsection (Annex Point)			Official use only
5.1	**Function (IIA5.1)**	PT 19 Attractant	Y
5.2	**Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)**		
5.2.1	**Organism(s) to be controlled (IIA5.2)**	Male adults of the Indian meal moth *Plodia interpunctella* are attracted by the pheromone. By trapping the male moths, the reproduction is inhibited and control of the whole population is intended.	see comment
5.2.2	**Products, organisms or objects to be protected (IIA5.2)**	Dried food and feedstuffs, e.g. nuts, muesli, cookies, chocolate, flour, rice, dried fruits, fodder, etc.	Y
5.3	**Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)**		
5.3.1	**Effects on target organisms (IIA5.3)**	The active substance Z,E-9,12-Tetradecadien-1-yl acetate is a natural sex pheromone, which is released by female moths to attract male adults of the species *Plodia interpunctella* (Teal et al., 1995). The pheromone does not have any adverse effects on the target organisms. A study demonstrating the efficacy of the active substance is summarised in the below.	see comment
5.3.2	**Likely concentrations at which the A.S. will be used (IIA5.3)**		N
	PT19	Under conditions of use, the active substance is released into air by diffusion through the carrier material. This process is mainly influenced by temperature and cannot be controlled. However, a constant, steady release from the trap is intended and required to be effective. Males typically trace the female moths by following a concentration gradient of an attractant in a plume of a (natural or artificial) point source. Mankin et al. (1980) found threshold concentrations for male *Plodia interpunctella* in air of 1.34×10^{6} and 1.65×10^{4} molecules/cm³ at 23 and 34°C respectively. This corresponds to 0.56 and 6.916×10^{-3} ng/m³.	N, see comment
5.4	**Mode of action (including time delay) (IIA5.4)**		
5.4.1	**Mode of action**	The active substance Z,E-9,12-Tetradecadien-1-yl acetate is a natural sex pheromone which is released by female moths to attract male	see comment

Section A5		Effectiveness against target organisms and intended uses	
		adults of the species *Plodia interpunctella*. The pheromone does not have any adverse effects on the target organisms. Ryne et al (2007) also described a mating disruption by confusing when the active substance is emitted from a dispenser at high amounts of 2-3 mg/day, as males did not find the females anymore. However the main effect of the product supported by Aeroxon Insect Control GmbH is the attraction of males to a trap, thus preventing them from mating females.	
5.4.2	**Time delay**	No time delay of responses of males is expected.	Y
5.5	**Field of use envisaged (IIA5.5)**		
	MG01: Disinfectants, general biocidal products	Not relevant	Y
	MG02: Preservatives	Not relevant	Y
	MG03: Pest control	PT19, Repellents and attractants Use in traps	Y
	MG04: Other biocidal products	Not relevant	Y
	Further specification	Not required	Y
5.6	**User (IIA5.6)**		
	Industrial	No industrial use of the active substance is intended.	Y
	Professional	The active substance Z,E-9,12-Tetradecadien-1-yl acetate is used in traps in which the target organisms are retained by physical means. The traps are used in places where food or feedstuffs are stored.	Y
	General public	The active substance Z,E-9,12-Tetradecadien-1-yl acetate is used in traps in which the target organisms are retained by physical means. The traps are used in places where food or feedstuffs are stored.	Y
5.7	**Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)**		
5.7.1	**Development of resistance**	The active substance Z,E-9,12-Tetradecadien-1-yl acetate plays a key role for reproductive performance of natural populations of *Plodia interpunctella*. This chemical communication system has been developed in the evolution of this species and is part of its biology. A development of resistance would thus lead to an interruption of the mating process and consequently in a break down of natural population. As males which are not sensitive to the active substance would not be able to mate, a passing on of such a defect is improbable and a development of resistance is therefore not expected.	see comment

Section A5		Effectiveness against target organisms and intended uses	
		Haynes et *al*. (1984) found no indications for a development of resistance in males of *Pectinophora gossypiella*, collected from natural populations which have been exposed to artificially applied pheromones over several years. The trapping system has already been in commercial use for many years. No reduced efficacy or resistance has been reported up to now.	
5.7.2	**Management strategies**	Not required	Y
5.8	**Likely tonnage to be placed on the market per year (IIA5.8)**	The total amount yearly placed onto the European market is about 10 kg.	

Section A5 Effectiveness against target organisms and intended uses

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 16.9.2008

Materials and methods

The experiment described in Table "Section 5.3: Summary …" (see below) based on B5.10.2-01.pdf does not provide sufficient evidence for the efficacy of the active substance (Z,E)-Tetradeca-9,12-dienyl-acetate. The methods used in this case and in other experiments (B5.10.2-02.pdf; B5.10.2-03.pdf; B5.10.2-05.pdf) do not comply with basic criteria for scientific experiments:
(a) Within each experiment, trap positions were not randomly assigned. At least in one case, the applicant observed effects of the trap position (B5.10.2-03.pdf).
(b) Experiments were conducted without replicates or at maximum two replicates. Beyond principal objections against experiments without replicates, statistical testing for significance of the results is impossible without sufficient numbers of replicates.
(c) The attraction of males caught in traps baited with the a.s. was chosen as criterion for efficacy. In most insects males may mate more than once if not several times. Few remaining males might fecundate most of the female population. Thus, in trapping systems targeting males the criterion for efficacy must be a reduction in the number of offspring or a reduction of infestation of the protected goods. For the reasons detailed in (a)-(c), the CA does not consider the above referenced data for decisions on inclusion of the a.s.

Public access literature provides ample evidence for the attractiveness of the a.s. to male *Plodia interpunctella*. Furthermore, the applicant provided on request of the CA additional data (Doc IV-B 5_10_2-04.pdf; GPL standard) showing that the number of offspring in dried food may be reduced by 58.6% after application of 2 mg of the active substance per sticky trap in rooms of 15 m^3. "Muesli" and flaked almonds were used as oviposition substrate for the females. The decisions of the CA are based on these experimental data amended with information from public access literature.

Detailed comments:

5.2.1 should state: … By trapping relevant numbers of male moths, reproduction of the population may be reduced.

5.3.1 As stated above, evidence for the efficacy of the a.s. in only given in DOC IV-B 5_19_2-04.pdf).

5.3.2 The applicant should have stated the concentration at which the a.s. will be used. Instead, the applicant refers to threshold concentration at which male *P. interpunctella* still respond to female emitted pheromone, which is interesting but does not provide the data required to carry out risk assessments within the framework of Dir 98/8 EU.

To unfold its effect, the a.s. evaporates from a dispenser trap. The actual concentration of the a.s. highly depends on temperature and aeration of localities where traps are placed. The CA assumes that the a.s. evaporates from the trap within a period of one week, which corresponds to the test period in all experiments reported by the applicant. The only valid demonstration of efficacy was carried out in a room of 15 m^3 at a dosage of 2 mg/trap. The CA therefore assumes that 2 mg/week/15 m^3 room is an adequate estimate of concentrations and application rates of the active substance. This corresponds to $5x10^6$ application units per year in the EU according to the applicant´s estimate of the total amount put on the market per year.

5.4.1 The a.s. is a female emitted sex pheromone in *P. interpunctella*. Under natural conditions, males follow the odour gradient to the source to locate mates. In many species the sensitivity of the sensory apparatus and the male behavioural response are exploited to catch males for monitoring or control purposes, or to

Section A5 Effectiveness against target organisms and intended uses

disrupt mating by an elevated pheromone concentration both in the open field and indoors. Both strategies may be effective, and in some cases it may remain elusive which or whether a combination of both leads to the intended effect against pest populations.

The applicant argues that the main effect of the biocidal product is attraction to the trap. However, this view is not supported by data. The submitted results rather indicate a combined effect of mating disruption and trap catches. On average, only 35% of the males were caught in traps in the course of the relevant experiment documented in Doc IV-B 5_10_2-04.pdf, corresponding to a calculated trap efficacy of 25.7%. In contrast, the efficacy in terms of reduced numbers of offspring was 58.7% in the same experimental system. In most moth species, males may mate more than once. Thus, it is not plausible to assume a reduction of offspring by almost 60% resulting from catches of only 35% of the males. This view is furthermore supported by the fact that male catches were about evenly distributed through the experimental period of one week. Thus, almost 100% of the males were available to fecundate females during the first experimental night. Mating occurs in *P. interpunctella* already during the first scotophase after hatching (Mohandass et al. 2007). When introduced into the experiment, moths were at least 24h, and on average 48h old and unmated (Doc IV-B 5_10_2-04.pdf).

The applicant argues that in a study demonstrating the efficacy of mating disruption in *P. Interpunctella*, pheromone concentrations were high (Ryne et al. 2007). However, the dose used in the referenced study (2-3 mg/100 m^3/day) is similar to the concentration the CA has to assume for the experiments carried out by the applicant as stated above (2 mg/15 m^3/week).

The CA therefore concludes that the mechanism by which the a.s. achieves efficacy most probably is a combination of attraction to the traps and mating disruption by an elevated pheromone concentration in the test facilities.

5.7.1 As any other trait of living organisms, chemical communication is under constant evolutionary process. Thus, pheromone systems may evolve and change over time, leading to pheromone dialects or strains within one species using different pheromone blends (e.g. Roelofs et al. 2002). Haynes & Baker (1988) discussed the potential of resistance to pheromone based pest control strategies and provided additional references. The natural sex pheromone of *P. interpunctella* is composed of a blend (Svensson 2002 and references therein). The heritability of the blend composition is comparatively low and leaves a potential for the evolution of resistance against mating disruption (Svensson 2002). Factors increasing the potential for resistance may be

(a) an isolated population under permanent treatment, and
(b) the use of only one component of the natural pheromone blend in control strategies.

Tabata et al. (2007) report a recent case of resistance to pheromone based control strategies after 10 years of permanent treatment. The efficacy of mating disruption was re-established by use of the full pheromone blend instead of the previously used single compound.

It is agreed that so far resistance against pheromone based control strategies has not been observed in *P. interpunctella*. However, both the applicant and the authorities should be aware that chemical communication in insects is to a certain extent flexible and open to adaptation to new conditions. Resistance to pheromone based control strategies is therefore a relevant issue and needs to be addressed on a regular basis. This includes a periodic check of the scientific literature, an assessment of the prevalent modes of use of the biocidal products containing the a.s., and a survey among the professional users of the biocidal product focused on efficacy.

Section A5 Effectiveness against target organisms and intended uses

Conclusion	The applicant provided data demonstrating the efficacy of the a.s. to reduce infestation rates of stored dried food products by *P. interpunctella.* The a.s., (Z,E)-Tetradeca-9,12-dienyl-acetate, is evaporated from a dispenser material and perceived by males of the species. It is not established whether attraction to pheromone baited traps or disorientation of the males due to a high pheromone concentration leads to the documented effect. However, this uncertainty is limited to physiological processes of the target pest, it does not affect risk assessment. For risk assessment, an emission of 2 mg a.s. per 15 m^3 and week is assumed. The evolution of resistance to the application of the pheromone needs to be assessed on a regular basis. It is suggested that (i) at least every 10 years a report covering the recent scientific literature on pheromone treatment of insect pests and the evolution of resistance will be submitted by the applicant. The report should briefly evaluate recent findings and provide an estimate as to whether the probability of a development of resistance has increased or not. (ii) At least every ten years a report should additionally determine the most important areas of application (households, industrial, storage facilities with enclosed populations) deducted from sales data, and carry out a survey among relevant numbers of actual and previous users of biocidal products which contain the active substance. The aim of this survey will be to detect any potential resistance in terms of transient of permanent reduction of efficacy of the a.s.
Reliability	2 = reliable with restrictions
Acceptability	The submitted study is acceptable and justifies Annex 1 inclusion of the active substance (Z,E)-Tetradeca-9,12-dienyl-acetate.
Remarks	

Section 5.3: Summary table of experimental data on the effectiveness of the active substance against target organisms at different fields of use envisaged, where applicable

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*)
Attractant	PT19	Aeroxon Belgium, batch P 134, (sticky trap containing the a.s.)	*Plodia interpunctella*, laboratory strain, pupae and emerging adults	Sticky traps are placed in distances of 3.5 to 4.5 m in a room of 60 m³. Test species were introduced into the test room. Number of trapped moths were determined daily for 7 days	Three different traps were used: 1. Aeroxon (test item) 2. Salvo Mottenval (reference) 3. Adhesive paper (control) Room temperature was 20-22°C, Seasonal photo period (January / February)	Cumulated number of moths trapped within 7 days: Variant — No. trapped moths 1. Aeroxon — 62 2. Salvo Mottenval — 15 3. Control — 0	Heller, G. (2005)
Attractant/ mating disruptant	PT 19	Sticky trap containing the a.s.	*Plodia interpunctella*, adults, 48h old on average	Sticky traps were placed into a room of 15 m^3. Storage containers with dried food were placed on shelves. Ten virgin males and females were allowed to move in the room. The number of trapped moths and the number of offspring in the food containers was determined after 7 days of exposure.	Aeroxon sticky traps with 2 mg of a.s. per trap; one trap per room; control experiments with sticky traps without a.s. were carried out simultaneously in separate rooms.	35% of the male moths introduced into the experimental chambers were caught on pheromone-baited traps compared to 12.5% on control traps; the infestation of food items was reduced by 58.6% under pheromone treatment. Male moth catches were about evenly distributed throughout the period of exposure. The results indicate a combined mode of action: (i) attraction of the males to the traps; (ii) disruption of mate finding by an elevated pheromone concentration in the test facilities. Resistance has not been observed in the experiment.	Klug, Thomas (2008)

*) References: Heller, G. (2005), Comparative Testing of two Commercial Pheromone Traps for Phycitid Moths with *Plodia interpunctella* (HÜBNER 1810 - 1813)
Further efficacy data is presented in document IIIB, 5.10.2; Klug, T. (2008): Determination of efficacy of Lebensmittelmotten-Falle, a sticky lure trap with a sexual pheromone, against Indian meal moth (*Plodia interpunctella*); Doc IV B 5_10_2-04.pdf.