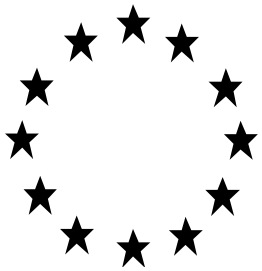
Directive 98/8/EC concerning the placing biocidal products on the market

Inclusion of active substance in Annex I and IA to Directive 98/8/EC

Assessment Report



(Z,E)-Tetradeca-9,12-dienyl acetate
Product-type 19
(Attractant)

Date of SCB vote: 24th September 2010

Annex I and IA – RMS Austria

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of (Z,E)-Tetradeca-9,12-dienyl-acetate (ZE-TDA) as product-type 19 (repellents and attractants), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

ZE-TDA (CAS no. 30507-70-1) was notified as an existing active substance, by Aeroxon Insect Control GmbH (Waiblingen, Germany), hereafter referred to as the applicant, in product-type 19.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 7(1) of that Regulation, Austria was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for ZE-TDA as an active substance in product-type 19 was 30 April 2006, in accordance with 9(2) of Regulation (EC) No 1451/2007.

On 30 April 2006, the Austrian Competent Authority received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 30 October 2006. Evaluation was suspended between 29th October 2007 and 29th June 2008 since data in the field of efficacy were missing.

On 23 February 2009, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 30 March 2009. The competent authority report included a recommendation for the inclusion of Active substance ZE-TDA in Annex I and IA to the Directive for product-type 19.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 06 April 2009. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

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

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

2 Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

On the basis of the final competent authority report, the Commission proposed the inclusion of Active substance name in Annex I and IA to Directive 98/8/EC and consulted the Standing Committee on Biocidal Products on 24th September 2010.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 24th September 2010.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include ZE-TDA in Annex I and IA to Directive 98/8/EC for product-type 19. The aim of the assessment report is to facilitate the authorisation and registration in Member States of individual biocidal products in product-type 19 that contain ZE-TDA. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

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

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

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

The overall conclusion from the evaluation is that it may be expected that there are products containing ZE-TDA for the product-type 19, which will fulfill the requirements laid down in Article 5 of Directive 98/8/EC. This conclusion is however subject to: compliance with the particular requirements in the following sections of this assessment report,

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

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

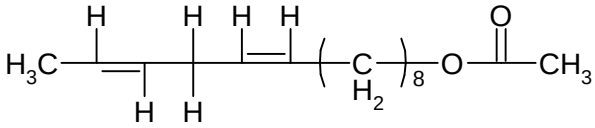
3 http://ec.europa.eu/comm/environment/biocides/index htm

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

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

The active substance (Z,E)-Tetradeca-9,12-dienyl acetate (short: ZE-TDA) is attributed the CAS-No 30507-70-1 (no EINECS and no ELINCS number allocated.). The molecular formula is $C_{16}H_{28}O_2$, and the molecular weight is 252.4 g/mol. The minimum degree of purity is 97.7%w/w.
Structural formula:



The spectral data (UV/VIS, IR, MS and 13-C-NMR spectra) are in good accordance with the assigned molecular structure of (Z,E)-Tetradeca-9,12-dienyl acetate.

The physico–chemical properties are studied for the purified active substance of stated specification (purity: 98.5%w/w ZE-TDA). ZE-TDA is a colourless liquid with no specific odour. Its melting point is -46.7°C and the boiling point is 318°C. The density is 0.8893 kg/L at 20°C. The vapour pressure of the active substance is 0.18 Pa at 20°C, 0.29 Pa at 25°C and 2.2 Pa at 50°C, and the calculated Henry's law constant is 381.76 Pa x m3/mol at 20°C. The water solubility is: 0.140 mg/L (pH: 6.10) and 0.115 mg/L (pH: 7.62) at 10°C; 0.143mg/L (pH: 6.22) and 0.119 mg/L (7.58) at 20°C; 0.150 mg/L (pH: 6.18) and 0.121 mg/L (pH: 7.56) at 30°C.
The active substance ZE-TDA hydrolyses in water at acidic and alkaline pH values (DT50 is 9h and 13h) but does not form any ions. A reversible dissociation of the active substance is therefore impossible.
A preliminary test is employed to determine the approximate solubility of the test substance. Due to the structure of the test substance, ZE-TDA in n-Heptane, p-Xylene, 1,2-Dichloroethane, Methanol or Propan-2-ol, Acetone and Ethyl acetate could be anticipated to be unlimited soluble.
The active substance does not contain any organic solvent, therefore the stability in organic solvents was not tested. The partition coefficient octanol-water is log P_{ow} >6.5 at pH 6.5 and 20°C. The active substance is not considered surface active, because it does not display amphipathic properties.
The active substance displays neither explosive nor oxidizing properties based on its structure. A DSC-measurement on thermal stability showed exothermal decomposition of the active substance at 330 – 450°C. The active substance is not flammable up to 330 – 450°C. The DSC-measurement in a closed glass crucible showed exothermal decomposition in the temperature range of 330 - 450°C with an energy of 374 J/g. ZE-TDA is not considered to be reactive to container material (metal containers).

The characterization of ZE-TDA is performed by using a GC system with FID detection. The method has been validated and is considered suitable to give information on the chemical composition of the technical grade ZE-TDA.
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 required.

The determination of residues in air can be performed by air-sampling (Sorbent Tubes) followed by extraction of the adsorbent with acetone and determination by gas chromatography.
As ZE-TDA is not classified as toxic or very toxic, analytical methods for detection and identification of residues in animal and human body fluids and tissues were not assessed.
An analytical method for the determination of residues of ZE-TDA in/on food or feedstuffs is not required because the active substance is not used in a manner that may cause contamination of food or feedstuffs (see chapter 2.2.2.5 Risk from residues on food and feed-stuff).

2.1.2. Intended Uses and Efficacy

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

The active substance is intended to be used in pheromone traps containing 2 mg of active substance on carton covered with sticky glue. Male adults of *Plodia interpunctella* are attracted via the air phase. The user (general public and professional) should observe the trap once per week and replace it if its surface is covered with trapped moths. 1 trap is needed per 15 m^3 room volume.

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

2.1.3. Classification and Labelling

Current classification according to Directive 67/548/EEC

ZE-TDA is currently not classified according to Annex I of Council Directive 67/548/EEC.

Proposed classification and labelling according to Directive 67/548/EEC and Reg. 1272/2008/EC

Based on the available toxicological studies (acute, sub-chronic, genotoxicity) no classification and labelling is proposed with regard to human health hazard assessment.

Based on limited acute aquatic toxicity data and evidence that ZE-TDA is rapidly biodegradable and may not bioaccumulate no classification and labelling is proposed with regard to environmental hazard assessment.

Also for the representative biocidal product no classification is necessary; the product consists of the active substance glued to cardboard.

2.2. Summary of the Risk Assessment

2.2.1. Risk arising from physico-chemical properties

No unacceptable risk arising from physico-chemical properties could be identified.

2.2.2. Human Health Risk Assessment

2.2.2.1. Hazard identification

For (Z,E)-Tetradeca-9,12-dienyl-acetate (ZE-TDA), no adverse effects were observed within the toxicological studies submitted, that are acute oral and inhalation toxicity tests, a guinea pig maximisation test and the in vitro genotoxicity test battery including bacterial gene mutation, mammalian cytogenicity and mammalian gene mutation tests. Within the skin and eye irritation studies only very minimal, reversible skin and eye reactions were observed.

Repeated dose studies were not especially conducted for ZE-TDA but a sub-chronic rat gavage study was conducted with doses up to 1000 mg/kg bw of a commercial blend of branched acetates with an aliphatic chain length from C10 to C14. Compared to ZE-TDA the tested substance shows similar carbon number and log K_{ow} (~6.5) and the straight chain structure ZE-TDA should be at least as easily metabolised as the related branched structure. The respective subchronic LOAEL of 500 mg/kg bw day is based on increased liver weight without any further evidence of hepatotoxicity and furthermore kidney effects with some characteristics of a male rat specific α2µ-globulin mediated mechanism (not finally proven).

Waiving of the chronic, carcinogenicity and reproductive studies was accepted, based on the absence of adverse effects in the acute studies, genotoxicity studies and the sub-chronic study submitted, as well as on considerations of metabolism. In analogy to literature data for the structurally related very long chain (C24 to C34) esters (waxes) (Hargrove et al. 2004), it is expected that ZE-TDA is quickly metabolised by hydrolysis to the acetic acid and the linear C14 alcohol, dehydrogenation and ß-oxidation or glucuronide conjugation. An ample literature review (Veenstra et al. 2009) on long chain alcohols (C6-C22) supports that this category does not show tissue retention or bioaccumulation potential and may enter common lipid biosynthesis pathways, getting indistinguishable from the lipids derived from other sources. Furthermore for this category of long chain alcohols subchronic NOAELs between 200 and 1000 mg/kg bw day are reported and no adverse effects on fertility and development were observed in respective studies. Moreover the alcohol moiety of the pheromone ZE-TDA is closely related to the essential fatty acid linoleic acid that may be consumed in amounts of several grams per day. Finally, ZE-TDA is a member of the so-called group of Straight-Chained Lepidopteran Pheromones (SCLP), and it is accepted that SCLPs are of low toxicity to mammals. Consequently, a guidance document for waiving of data requirements for pheromones for inclusion in Annex I/IA of Directive 98/8/EC was endorsed in March 2005, which built the basis for the waiving arguments within this dossier.

2.2.2.2. Effects assessment

For the purpose of quantitative risk assessment an AEL MEDIUM AND LONG TERM of 1 mg/kg bw day was deduced from the NOAEL of 100 mg/kg bw day for the structurally related branched alkyl (C10-C14) acetates within the sub-chronic feeding study and a standard assessment factor of 100. Considering the data and information summarized above (2.2.2.1) this is considered a sufficiently robust estimate.

2.2.2.3. Exposure assessment

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 2.2.2.3-1).

Table 2.2.2.3-1: 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.

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).

Assessment of exposure during manufacturing of the active substance is not required, since the active substance is produced outside the European Union.

Formulation of the biocidal product takes place in a closed system. ZE-TDA is applied as droplets with a commercially available ink jet on a card board with polyethylene layer. 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 (dermal and/or inhalative) may occur is filling of the pheromone reservoir of the automated production device.

Exposure during or after application is considered to be negligible. As worst case assumption immediate uptake of the total amount of the active substance (2 mg) within a single trap is calculated for adults, children and infants. Inhalation exposure is calculated for exposure to 20 traps for adults, children and infants.

The exposure values relevant for risk characterisation are presented in chapter 2.2.2.4 of this document.

2.2.2.4. Risk characterisation

Risk from exposure during the production of the product (filling, sampling, maintenance, cleaning of the active substance reservoir, see table 1.2.2.4-1) and from use of the product (activating trap and secondary exposure including children and infants, see table 1.2.2.4-2) is acceptable. For precautionary reasons appropriate personal protective equipment should be used within the formulation process. Furthermore for precautionary reasons the "Lebensmittelmotten-Falle" should be kept out of reach of children and infants.

Table 2.2.2.4-1 Production of the biocidal product, risk characterisation

Exposure Scenario: **Task: Charging a reservoir with active substance**		**Estimated Internal Exposure [mg/kg bw/day]**				**Relevant NOAEL [mg/kg b.w/day] & Reference Value**	**AF MOE_{ref}**	**MOE**	**Exposure / AEL**
		Estim. oral uptake	**Estim. inhal. uptake**	**Estim. dermal uptake**	**Estim. total uptake (combined exposure)**				
Tier 1	Exposure estimation via Model 3 for mixing and loading[1] (parameters: 2000ml a.s. /event, 60kg bw (adult, default))	n r.	1.48E-04	0.5929	**0.59**	NOAEL: 100 AEL systemic: 1	100	169	0.593

[1]from „Technical Notes for Guidance on Human Exposure to Biocidal Products" (European Commission, 2002a)

Table 2.2.2.4-2 Indirect exposure as a result of use, risk characterisation

Exposure Scenarios: see below		Estimated Internal Exposure [mg/kg bw/day]				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value	AF MOE_{ref}	MOE	Exposure / AEL
		Estim. oral uptake	Estim. inhal. uptake	Estim. dermal uptake	Estim. total uptake (combined exposure)				
Tier 1	Maximum possible uptake (dermal, oral, and/or inhalative; the whole amount of a.s. contained in one trap is taken up) by an adult (60 kg bw)	0.03			**0.03**	NOAEL: 100 AEL system.: 1	100	3000	0.033
Tier 1	Maximum possible uptake (dermal, oral, and/or inhalative; the whole amount of a.s. contained in one trap is taken up) by a child (15 kg bw)	0.13			**0.13**	NOAEL: 100 AEL system.: 1	100	750	0.133

Table 2.2.2.4-2 Indirect exposure as a result of use, risk characterisation (continued)

Tier 1	Maximum possible uptake (dermal, oral, and/or inhalative; the whole amount of a.s. contained in one trap is taken up) by an infant (10 kg bw)	0.20			**0.20**	NOAEL: 100 AEL system.: 1	100	500	0.200
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) (1 trap; 20 traps)		0.005[1] 0.029[2] 0.1[3] 0.58[4]			NOAEL: 100 AEL system.: 1	100	20000[1] 3448[2] 1000[3] 172[4]	0.005[1] 0.029[2] 0.100[3] 0.580[4]

[1] adult, 1 trap; [2] infant, 1 trap; [3] adult, 20 traps; [4] infant, 20 traps

2.2.2.5. Risk from residues on food and feed-stuff

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. Furthermore in analogy to literature data for the structurally related very long chain (C24 to C34) esters (waxes) (Hargrove et al. 2004), it is expected that ZE-TDA (C16) is easily catabolised by hydrolysis to the free alcohol, dehydrogenation to the acid and further ß-oxidation or glucuronide conjugation and excreted via the kidneys. It is also known that higher alcohols occur either free or bound in plant and animal tissues and free higher alcohols, including Cetyl alcohol (C16H33OH), Stearyl alcohol (C18H37OH) and Oleyl alcohol (C18H35OH) are abundant in fish oil (Berlitz et Grosch 1999). C14 to C24 fatty acids are – bound as esters within phoshpholipids and glycolipids - the major component of cell membranes and a relevant part of our natural diet. Natural intake of the structurally related very long chain (C24 to C34) alcohols, aldehydes, acids and esters (waxes) thereof is estimated to be about 2 g/day as part of our natural diet including cereal grains, bran, germ, leaves, seeds, nuts and unrefined oils (Hargrove et al. 2003). Furthermore an ample literature review (Veenstra et al. 2009) on the structurally related long chain alcohols (C6-C22) supports that this category does not show tissue retention or bioaccumulation potential and may enter common lipid biosynthesis pathways, getting indistinguishable from the lipids derived from other sources. Furthermore for this category of long chain alcohols subchronic NOAELs between 200 and 1000 mg/kg bw day are reported and no adverse effects on fertility and development were observed in respective studies. Moreover the alcohol moiety of the pheromone ZE-TDA is closely related to the essential fatty acid linoleic acid that may be consumed in amounts of several grams per day.

Furthermore on the basis of a conservative AEL of 1 mg/kg bw day derived from a sub-chronic rat study even the risk for immediate uptake of the total amount of the active substance (2 mg) within a single trap is acceptable, also for infants (compare with table 2.2.2.4-2, tier 1: The acceptable daily uptake of 10 mg for infants (body weight 10kg) corresponds to the active substance content of 5 traps (=10mg))

Thus the risk from residues from ZE-TDA on food/feeding stuff is considered to be negligible.

2.2.3. Environmental Risk Assessment

2.2.3.1. Fate and distribution in the environment

Based on model estimations on ready biodegradability, evidence from another SCLP acetate (Straight-Chained Lepidopteran Pheromone) and on its role in intraspecies communication it can be concluded that ZE-TDA will dissipate in environmental compartments due to volatilisation and biodegradation. ZE-TDA is readily biodegradable not fulfilling the 10-d window.

Abiotic degradation due to hydrolysis at pH 7 and photolysis in water was not investigated. However, ZE-TDA is hydrolysed at pH 4 and 9 with DT50 values of 9 and 13 hours. Also from its UV/VIS absorption spectrum its susceptibility for photolytic breakdown can be considered as low.

ZE-TDA is decomposed in the atmosphere by photooxidation by OH-radicals with estimated half-lives of 2.7 and 3.1 hours (trans and cis-isomers, respectively) and by ozone radicals with half-lives of 0.7 and 1.1 hours (trans- and cis-isomers). Besides the different isomers of the active substance, metabolites characterised by hydroperoxy and furan moieties can be formed. Because of degradation and physico-chemical properties no abiotic effects on the atmospheric environment are likely.

No information regarding distribution in environmental compartments was available. Regarding accumulation model calculations with different QSARs based on the log K_{ow} (>6.5) results are contradictory. In addition these predictions do not take into account metabolism in aquatic organisms. It is reasonable to assume that based on the chemical similarities between wax esters and ZE-TDA that its metabolism and conversion will follow the same pattern. As wax esters are an important energy (storage) source/substrate for aquatic marine organisms and an important component of the marine food chain it is unlikely that ZE-TDA will bioaccumulate and biomagnify in marine biota.

2.2.3.2. Effects assessment

The active substance, ZE-TDA is a sex pheromone, which is released by female moths to attract male adults of the species *Plodia interpunctella*. The pheromone itself does not have any adverse effects on the target organisms but modifies its behaviour.

The active substance interferes with the receptor molecule of the olfactory organs located on the antennae of the males of *Plodia interpunctella* and a couple of related pest species (e.g. *Ephestia*). This reaction is very specific and limited to a defined group of species.

No ecotoxicity studies on ZE-TDA were performed. The submitted SAR estimation suggested high aquatic toxicity, however, the reliability of these values is limited. Public available literature suggests that SCLP are potentially toxic to aquatic organisms. It seems that invertebrates and algae are especially susceptible to these effects. Whether these effects may arise from physical interactions/ impairments on the tested organisms could not be fully evaluated due to a lack of information.

Acute toxicity to terrestrial mammals is considered to be low.

ZE-TDA is not listed in the Commission staff working document on implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706)[1]. Furthermore there is no substance property or information indicating concern (cf. molecular structure, information on reproductive toxicity).

2.2.3.3. PBT assessment

Persistence:

There are no indications that ZE-TDA is persistent in environmental compartments. Data on ready biodegradability show that ZE-TDA is rapidly biodegradable.

The P-criterion is not met.

Bioaccumulation:

Log $BCF_{fish} \geq 2.8$

The B-criterion is probably met though it is unlikely that ZE-TDA will bioaccumulate in aquatic species (cf. Doc. II-A, section 4.1.4).

Toxicity:

Based on a weight of evidence approach it is unlikely that the chronic NOEC of ZE-TDA is <0.01 mg/L (cf. Doc. II-A, section 4.2.1).

No specific tests for potential endocrine disruption and carcinogenicity were carried out. However as described in section 1.2.3.2 there no substance property or information indicating concern. From the available genotoxicity studies, the subchronic study and the literature review on potential fertility and developmental effects of long chain alcohols and from knowledge of metabolism there is no concern for endocrine disruption or for CMR effects (see Doc. II-A section 3). The T-criterion is therefore not met.

Conclusion: ZE-TDA does not meet the PBT criteria.

2.2.3.4. Exposure assessment

Environmental exposure via manufacturing of the biocidal product is assumed to be negligible (cf. Doc. II-B) based on the production process.

The active substance is used in pheromone traps that capture moths by physical means with sticky glue indoors. The total amount in a single trap is 2 mg. ZE-TDA is released by diffusion through the glue layer from the trap. The trap is renewed every week resulting in 52 times per year that represents a reasonable worst number of replacement-events.

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1999:0706:FIN:EN:PDF

Exposure to all environmental compartments is considered to be insignificant. Therefore no calculation of the predicted environmental concentrations (PECs) according to the Technical Guidance Document on Risk Assessment (European Commission, 2003) is provided.

2.2.3.5. Risk characterisation

As the exposure of the aquatic and terrestrial compartment during manufacture of the biocidal product and indoor usage is negligible, for these compartments a risk characterisation is not performed. Also no predictable risk for the air compartment could be identified based on the exposure and physico-chemical properties. These are also reasons why no unacceptable effects on surface and groundwater as such and for the abstraction of drinking water are likely.

2.2.4. List of endpoints

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

3. PROPOSAL FOR THE ENVISAGED DECISION

3.1. Background to the proposed decision

On the basis of the proposed and supported uses and the evaluation conducted as summarised in chapter 2.1 – 2.3 of this document, it can be concluded that (Z,E)-Tetradeca-9,12-dienyl acetate fulfils the requirements laid down in Article 5(1) (b), (c), and (d) of Directive 98/8/EC under the conditions listed in 3.2.2. (Z,E)-Tetradeca-9,12-dienyl acetate is proposed to be included in Annex I and IA of the Directive.

3.2. Proposed decision regarding inclusion of (Z,E)-Tetradeca-9,12-dienyl acetate in Annex I and IA

Common name: (Z,E)-Tetradeca-9,12-dienyl acetate

CAS No.: 30507-70-1

EC No.: Not available

The active substance as manufactured shall have a minimum purity of 97.7% (w/w).

Product Type: Attractant (Product Type 19).

Specific Provisions

When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment.

(1) Residues in food/feedstuff: ZE-TDA should only be applied where food and feed-stuff is stored in closed or re-closed package

(2) Justification: No residue studies for ZE-TDA are available for food and feedstuff.

The representative product evaluated for Annex IA inclusion of the active substance is a pheromone trap containing 2 mg of active substance.

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

No comprehensive environmental risk assessment was carried out since only indoor use was considered and exposure to all environmental compartments is considered to be insignificant.

3.4. Requirement for further information

None

3.5. Proposal for the expiry date of the inclusion

Ten years after inclusion into Annex I and IA.

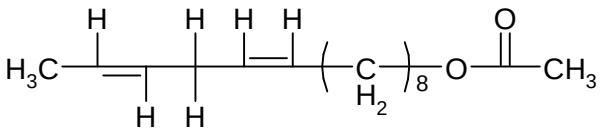
APPENDIX I: LIST OF ENDPOINTS

Chapter 1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling

Active substance (ISO Common Name)	(Z,E)-Tetradeca-9,12-dienyl acetate
Function (e.g. fungicide)	Attractant (pheromone for trapping system)

Rapporteur Member State	Austria

Identity (Annex IIA, point II.)

Chemical name (IUPAC)	(9Z,12E)-Tetradeca-9,12-dien-1-yl acetate
Chemical name (CAS)	9,12-Tetradecadien-1-ol, acetate, (9Z,12E)-
CAS No	30507-70-1
EC No	Not allocated
Other substance No.	None
Minimum purity of the active substance as manufactured (g/kg or g/l)	977 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	Confidential information
Molecular formula	$C_{16}H_{28}O_2$
Molecular mass	252.4 g/mol
Structural formula	

Physical and chemical properties (Annex IIA, point III, unless otherwise indicated)

Melting point (state purity)	- 46.7°C at 1013.3 hPa (purity 98.5 g/kg)
Boiling point (state purity)	318°C at 1013.3 hPa (purity 98.5 g/kg)
Temperature of decomposition	Exothermal decomposition in the temperature range 330 – 450°C with an energy of 374 J/g
Appearance (state purity)	Colourless liquid of no specific odour (purity 98.5 g/kg)
Density (state purity)	0.8893 kg/L at 20°C (purity 98.5 g/kg)
Surface tension	The active substance is not considered surface active, because it does not display amphipathic properties.
Vapour pressure (in Pa, state temperature)	0.18 Pa (20°C), 0.29 Pa (25°C) and 2.2 Pa (50°C)
Henry's law constant (Pa m^3 mol^{-1})	381.76 Pa m³/mol (20°C; calculated)
Solubility in water (g/l or mg/l, state temperature)	pH 5: (not determined, hydrolysis)
	pH 9: (not determined, hydrolysis)
	0.140 mg/L (10°C; pH 6.10) 0.115 mg/L (10°C; pH 7.62) 0.143 mg/L (20°C; pH 6.22) **0.119 mg/L (20°C; pH 7.58)** 0.150 mg/L (30°C; pH 6.18) 0.121 mg/L (30°C; pH 7.56)
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	Due to the structure of the test substance, the solubility of ZE-TDA in n-Heptane, p-Xylene, 1,2-Dichloroethane, Methanol or Propan-2-ol, Acetone and Ethyl acetate could be anticipated to be unlimited soluble
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	The a.s. as manufactured does not include any organic solvent
Partition coefficient (log P_{OW}) (state temperature)	pH 5: (not determined)
	pH 9: (not determined, hydrolysis)
	>6.5 (20°C; pH 6.5) log P_{ow} was not determined at pH 4 and pH 9 because the active substance is rapidly hydrolysed in both media.
Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	Not determined pH4 and 9: not stable
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	The active substance ZE-TDA does rapidly hydrolyse in water at acidic and alkaline pH values but does not form any ions. A reversible dissociation of the active substance is therefore impossible.
UV/VIS absorption (max.) (if absorption >290 nm state ε at wavelength)	No peak maxima at wavelengths ≥290 nm
Photostability (DT_{50}) (aqueous, sunlight, state pH) (point VII.7.6.2.2)	Not determined
Quantum yield of direct phototransformation in water at □ >290 nm (point VII.7.6.2.2)	Not determined

Physical and chemical properties (continued) (Annex IIA, point III, unless otherwise indicated)

Flammability	Not flammable up to 330 – 450°C (exothermal decomposition of the active substance)
Explosive properties	Not explosive; 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)

Classification and proposed labelling (Annex IIA, point IX)

with regard to physical/chemical data	None
with regard to toxicological data	None
with regard to fate and behaviour data	None
with regard to ecotoxicological data	None

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	GC/FID method
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	GC/FID method

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	Not required according to TNsG on data requirements (Guidance for Waiving of Data Requirements for Pheromones)
Air (principle of method and LOQ) (Annex IIA, point 4.2)	GC/FID method; LOQ = 3.39 µg/m3
Water (principle of method and LOQ) (Annex IIA, point 4.2)	Not required according to TNsG on data requirements (Guidance for Waiving of Data Requirements for Pheromones)
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	Not required according to TNsG on data requirements
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not required according to TNsG on data requirements
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not required according to TNsG on data requirements

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals (Annex IIA, point 6.2)

Rate and extent of oral absorption:	Not determined, therefore assumed to be 100%. Literature supports an oral uptake rate > 90% for the structurally related fatty alcohol Hexadecanol. (Assumption: in GI ZE-TDA is hydrolysed to acetic acid and the C14 alcohol; however the degree of hydrolysis is not supported by data).
Rate and extent of dermal absorption:	Not determined, therefore assumed to be 100%
Distribution:	Not determined
Potential for accumulation:	No accumulation assumed. The structurally related long chain alcohols (C6-C22) doe not show tissue retention or bioaccumulation.
Rate and extent of excretion:	It may be assumed that the ester ZE-TDA is hydrolysed chemically or enzymatically to the corresponding acetic acid and alcohol. The alcohol then is oxidised by alcohol dehydrogenases to finally form the corresponding acid, which is degraded by β-oxidation to carbon dioxide like other fatty acids or by conjugation with glucuronide and excreted via the kidneys.
Toxicologically significant metabolite	None

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral	>2000 mg/kg bw
Rat LD_{50} dermal	Assumed to be very low
Rat LC_{50} inhalation	>5.2 mg/L
Skin irritation	Non-irritant
Eye irritation	Non-irritant
Skin sensitization (test method used and result)	No skin sensitizer (GPMT)

Repeated dose toxicity (Annex IIA, point 6.3)

	Sub-chronic: Substance tested: Isomeric mixture of acetates with generic structure CH_3COOR, where R is a branched alkyl group having carbon numbers predominantly in the range of C10 – C14 with C13 as main constituent.
Species/ target / critical effect	Sub-chronic: Rat / liver and kidney / increased organ/body weight ratio
Lowest relevant oral NOAEL / LOAEL	Sub-chronic: NOAEL: 100 mg/kg bw day (isomeric mixture) LOAEL: 500 mg/kg bw day (isomeric mixture)
Lowest relevant dermal NOAEL / LOAEL	Not determined
Lowest relevant inhalation NOAEL / LOAEL	Not determined

Genotoxicity (Annex IIA, point 6.6)	Negative within a bacterial mutagenicity assay and an in vitro cytogenicity test with human peripheral lymphocytes and in vitro gene mutation test (Mouse lymphoma L5178 cells/TK Locus)

Carcinogenicity (Annex IIA, point 6.4)

Species/type of tumour	Not determined.
lowest dose with tumours	Not determined

Reproductive toxicity (Annex IIA, point 6.8)

Species/ Reproduction target / critical effect	Not determined
Lowest relevant reproductive NOAEL / LOAEL	Not determined
Species/Developmental target / critical effect	Not determined
Lowest relevant developmental NOAEL / LOAEL	Not determined

Neurotoxicity / Delayed neurotoxicity (Annex IIIA, point VI.1)

Species/ target/critical effect	Not required
Lowest relevant developmental NOAEL / LOAEL	Not required

Other toxicological studies (Annex IIIA, VI/XI)

.....	None

Medical data (Annex IIA, point 6.9)

.....	No adverse effects known.

Summary (Annex IIA, point 6.10)

	Value	Study	Safety factor
AEL long term	1 mg/kg bw day	sub-chronic rat	100
AEL medium term	1 mg/kg bw day	sub-chronic rat	100
AEL short term	1 mg/kg bw day	sub-chronic rat	100
Drinking water limit	0.1 µg/L		

Acceptable exposure scenarios (including method of calculation)

Professionals (formulation of the b.p.)	Inhalation exposure: 1.5×10^{-4} mg a.s./kg bw/day (negligible) (Model 3 ”Mixing and loading”, TNsG on Human Exposure (2002a), part 2)

	Dermal exposure: 0.6 mg a.s./kg bw/day (Model 3 "Mixing and loading", TNsG on Human Exposure (2002a), part 2) Oral exposure: not relevant
Professionals and Non-professionals (application of the b.p.)	Inhalation exposure: negligible Dermal exposure: negligible Oral exposure: not relevant
Indirect exposure as a result of use	Inhalation exposure: negligible Dermal and oral exposure: negligible under normal use conditions; 0.13 mg/kg bw/event (worst case, child takes up the whole amount of a.s. contained in a single trap either by the oral or dermal route; 15 kg bw, 100% absorption)

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water (Annex IIA, point 7.6, IIIA, point XII.2.1, 2.2)

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH_4_: unstable, rapid hydrolysis
	pH_9_: unstable, rapid hydrolysis
	pH_6.5_: not determined
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Not determined
Readily biodegradable (yes/no)	Yes, but failing the 10-d window
Biodegradation in seawater	Not determined
Non-extractable residues	Not determined
Distribution in water / sediment systems (active substance)	Not determined
Distribution in water / sediment systems (metabolites)	Not determined

Route and rate of degradation in soil (Annex IIIA, point VII.4, XII.1.1, XII.1.4; Annex VI, para. 85)

Mineralization (aerobic)	Not determined
Laboratory studies (range or median, with number of measurements, with regression coefficient)	SCLP acetate (gossyplure) Dissipation, DT50 = 1d (32°C)
Field studies (state location, range or median with number of measurements)	Not determined
Anaerobic degradation	Not determined
Soil photolysis	Not determined
Non-extractable residues	Not determined
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	Not determined
Soil accumulation and plateau concentration	Not determined

Adsorption/desorption (Annex IIA, point XII.7.7; Annex IIIA, point XII.1.2)

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	Not determined

Fate and behaviour in air (Annex IIIA, point VII.3, VII.5)

Direct photolysis in air	Not determined
Quantum yield of direct photolysis	Not determined
Photo-oxidative degradation in air	DT50 approx. 3 hours by OH-radicals DT50 approx. 1 hour by ozone radicals
Volatilization	Volatile, Henry's law constant: 381.76 Pa m^3/mole

Monitoring data, if available (Annex VI, para. 44)

Soil (indicate location and type of study)	Not available
Surface water (indicate location and type of study)	Not available
Ground water (indicate location and type of study)	Not available
Air (indicate location and type of study)	Not available

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)
(Annex IIA, point 8.2, Annex IIIA, point 10.2)

Species	Time-scale	Endpoint	Toxicity
Fish			
No study performed			
Invertebrates			
No study performed			
Algae			
No study performed			
Microorganisms			
No study performed	-	-	-

Effects on earthworms or other soil non-target organisms

Acute toxicity to …….. (Annex IIIA, point XIII.3.2)	Not available
Reproductive toxicity to …… (Annex IIIA, point XIII.3.2)	Not available

Effects on soil micro-organisms (Annex IIA, point 7.4)

Nitrogen mineralization	Not available
Carbon mineralization	Not available

Effects on terrestrial vertebrates

Acute toxicity to mammals (rats) (Annex IIIA, point XIII.3.3)	LD50 >2000 mg/kg, oral exposure LC50 >5.2 mg/L, inhalation exposure
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	Not available
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	Not available
Reproductive toxicity to birds (Annex IIIA, point XIII.1.3)	Not available

Effects on honeybees (Annex IIIA, point XIII.3.1)

Acute oral toxicity	Not available
Acute contact toxicity	Not available

Effects on other beneficial arthropods (Annex IIIA, point XIII.3.1)

Acute oral toxicity	Not available
Acute contact toxicity	Not available
Acute toxicity to ……..	-

Bioconcentration (Annex IIA, point 7.5)

Bioconcentration factor (BCF)	Log BCF_{fish}: 4.7 (TGD estimation, "modified Connell equation") Log BCF_{fish}: 2.84 (BCFWIN v2.17)
Depration time (DT_{50}) (DT_{90})	Not determined
Level of metabolites (%) in organisms accounting for >10 % of residues	Not determined

Chapter 6: Other End Points

None

APPENDIX II: LIST OF INTENDED USES

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 Appendix II-1.

Table Appendix II-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

APPENDIX III: LIST OF STUDIES

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

Reference list: listed by section point

Section point/ reference number	**Year**	**Title** **Testing Facility** **Owner / Source (where different from owner)** **Report No** **GLP or GEP status (where relevant)** **Published or not**	**Data protection claimed** **yes/no**	**Owner**
A 2.7/01	2006	Analytical conditions for P6050-99 Bedoukian Indian Meal Moth Technical Pheromone z,e-9,12-tetradecadienyl acetate Report No.: No GLP: n.a. Unpublished	yes	AEROXON INSECT CONTROL
A 2.8/01	2006	Assignment of z,z-9,12-tetradecadienyl acetate structure to impurity number 3 Report No.: not indicated GLP: n.a. Unpublished	yes	AEROXON INSECT CONTROL
A 2.8/02	2006	Certificate of analysis; Bedoukian Research Inc.; Report No.: not indicated GLP: No Unpublished	yes	AEROXON INSECT CONTROL
A 2.10	2008	(Z,E)-9,12-Tetradecadien-1-yl acetate (Plodia) (PT 19) – Nachforderungen; Company statement dating from 13th November 2008; GLP: n.a. Unpublished	n.a.	AEROXON INSECT CONTROL
A 3.1.1/01	2006	Z,E-9,12-tetradecadien-1-yl acetate - thermal stability (OECD 113), melting point a.1. (OECD 102), Boiling point a.2. (OECD 103), Vapour pressure a.4 (OECD 104)" Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany Aeroxon Insect Control, Waiblingen, Germany Report-no.: 20051129.01 GLP: yes Published: no	yes	AEROXON INSECT CONTROL

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 3.1.3	2006	Relative Density of z,e-9,12-Tetradecadien-1-yl acetate GAB Biotechnologie GmbH & GAB Analytik GmbH; Niefern- Öschelbronn Aeroxon Insect Control, Waiblingen, Germany Study code:20051432/01-PCRD GLP: yes Published: no	yes	AEROXON INSECT CONTROL
A 3.2.1	2006	z,e-9,12-Tetradecadien-1-yl acetate Doc IV –A, Point 3.2.1 Henry´s Law Constant GAB Consulting GmbH Aeroxon Insect Control, Waiblingen, Germany Report number:180332-IVA-030201-01 GLP: no	yes	AEROXON INSECT CONTROL
A 3.4	2006	UV/VIS absorption Spectrum, Infrared absorption Spectrum, 13 C- NMR Spectrum and Spectrum of z,e-9,12-Tetradecadien-1-yl acetate GAB Biotechnologie GmbH & GAB Analytik GmbH; Niefern- Öschelbronn Aeroxon Insect Control, Waiblingen, Germany Study code:20051432/01- PCSD GLP: yes	yes	AEROXON INSECT CONTROL
A 3.5	2006	Water solubility of z,e-9,12-Tetradecadien-1-yl acetate GAB Biotechnologie GmbH & GAB Analytik GmbH; Niefern- Öschelbronn Aeroxon Insect Control, Waiblingen, Germany Study code:20051432/01- PCSB GLP: yes	yes	AEROXON INSECT CONTROL
A 3.9	2006	Partition coefficient of z,e-9,12-Tetradecadien-1-yl acetate (hplc method) GAB Biotechnologie GmbH & GAB Analytik GmbH; Niefern- Öschelbronn Aeroxon Insect Control, Waiblingen, Germany Study code:20051432/01- PCPC GLP: yes	yes	AEROXON INSECT CONTROL
A 4.1/01	2006	Three Batches Analysis of z,e-9,12-Tetradecadien-1-yl-acetate (TDA) SOFIA-GmbH, Berlin, Germany Aeroxon Insect Control, Waiblingen, Germany Report-no. 262-10-12/06 GLP: no Published: no	yes	AEROXON INSECT CONTROL
A 4.1/02	2006	Determination of two impurities in the three Batches Analysis of z,e-9,12-Tetradecadien-1-yl-acetate (TDA) SOFIA-GmbH, Berlin, Germany Aeroxon Insect Control, Waiblingen, Germany Report-no. 1201-40-41/06 GLP: no Published: no	yes	AEROXON INSECT CONTROL

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 4.2/01	2006	Validation of an Analytical Method for the Determination of z,e-9,12-Tetradecadien-1-yl-acetate (TDA) in Air SOFIA-GmbH, Berlin, Germany Aeroxon Insect Control, Waiblingen, Germany Report-no. 262-7-9/06 GLP: no Published: no	yes	AEROXON INSECT CONTROL
A 5.3.1/01	2005	Comparative Testing of two Commercial Pheromone Traps for Phycitid Moths with Plodia interpunctella (HÜBNER 1810 - 1813) Aeroxon Insect Control Aeroxon Insect Control, Waiblingen, Germany Report-no. not available GLP: no Published: no	yes	AEROXON INSECT CONTROL
A 5.3.1/02	1995	Production and release of (Z,E)-9,12-tetradecadienal by sex pheromone glands of females of Plodia interpunctella (Lepidoptera: Pyralidae) - J. chem. ecol., 1995, Vol. 21, No. 6, 787 - 799 Report-no. GLP: no Published: yes	no	-
A 5.3.2/01	1980	Anemotactic response threshold of the indial meal moth, Plodia interpunctella (Häbnmer) (Lepidoptera: Pyralidae), to its sex pheromone - J. chem. ecol., 1980, Vol. 6, No. 5 Report-no. not available GLP: no Published: yes	no	-
A 5.4.1/01	2007	Evaluation of long-term mating disruption of Ephestia kuehniella and Plodia interpunctella (Lepidoptera: Pyralidae) in Indoor Storage Facilities by Pjheromone Traps and Monitoring of Relative Aerial Concentrations of Pheromone - J. econ. entom., 2007, Vol. 100, No. 3 Report-no. not available GLP: no Published: yes	no	-
A 5.7/01	1984	Potential for evolution of resistance to pheromones - - Report-no. GLP: no Published: no	no	-

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 6.1.1/01	2006a	Acute Oral Toxicity Study of Z,E-9,12-Tetradecadien-1-Yl Acetate in Cd Rats LPT Lab. of Pharmacology and Toxicology KG, Hamburg, Germany Aeroxon Insect Control, Waiblingen, Germany Report-no. 19780/06 GLP: yes Published: no	yes	AEROXON INSECT CONTROL
A 6.1.2/01	1982	Monographs on Fragrance Raw Materials - Report-no. 1982 GLP: no Published: no	no	-
A 6.1.3/01	2006b	Acute Inhalation Toxicity Study of Z,E-9,12-Tetradecadien-1-Yl Acetate in Rats LPT Lab. of Pharmacology and Toxicology KG, Hamburg, Germany Aeroxon Insect Control, Waiblingen, Germany Report-no. 19781/06 GLP: yes Published: no	yes	AEROXON INSECT CONTROL
A 6.1.4/01	2006c	Acute Dermal Irritation / Corrosion Test (Patch Test) of Z,E-9,12-Tetradecadien-1-Yl Acetate in Rabbits LPT Lab. of Pharmacology and Toxicology KG, Hamburg, Germany Aeroxon Insect Control, Waiblingen, Germany Report-no. 19782/06 GLP: yes Published: no	yes	AEROXON INSECT CONTROL
A 6.1.4/02	2006d	Acute Eye Irritation / Corrosion Test of Z,E-9,12-Tetradecadien-1-Yl Acetate in Rabbits LPT Lab. of Pharmacology and Toxicology KG, Hamburg, Germany Aeroxon Insect Control, Waiblingen, Germany Report-no. 19783/06 GLP: yes Published: no	yes	AEROXON INSECT CONTROL
A 6.1.5/01	2006	Examination of Z,E-9,12-Tetradecadien-1-Yl Acetate in Guinea Pigs According To Magnusson And Kligman (Maximisation Test) LPT Lab. of Pharmacology and Toxicology KG, Hamburg, Germany Aeroxon Insect Control, Waiblingen, Germany Report-no. 19784/06 GLP: yes Published: no	yes	AEROXON INSECT CONTROL

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 6.2/01	1964	A comparison of the metabolism of cis, cis-linoleic, trans, trans-linoleic, and a mixture of cis,trans- and trans,cis-linoleic acids in the rat. - Report-no. GLP: no Published: J Lipid Res, 5, 473-6	no	-
A 6.2/02	2001	Isomerization increases the postprandial oxidation of linoleic acid but not alpha-linolenic acid in men. - Report-no. GLP: no Published: J Lipid Res, 42, 995-7	no	-
A 6.3.1/01	1990	Subchronic toxicity evaluation of tridecyl acetate in rats - Report-no. 14 GLP: no Published: Fundamental and applied Toxicology 14, 104 - 112.	no	-
A 6.3.1/01	1992	Exposure, fate and potential residues in food of applied lepidopteran pheromones. In: Insect pheromones and other behaviour-modifying chemicals: application and regulation, R.L. Ridgeway, M.Inscoe and H. Arn (eds.). - Report-no. 51 GLP: no Published: no	no	-
A 6.3.1/02	1988	Biorational control of crop pest by mating disruption; residue analyses of Z-9-dodecen-1-yl acetate and Z-11-tetradecenyl-1-yl acetate in grapes". In: Biotechnology for Crop Protection, P.Hedin, J.J. Menn and R.Hollingworth (eds.) - Report-no. 379 GLP: no Published: no	no	-
A 6.3.3/01	1990	Subchronic toxicity evaluation of tridecyl acetate in rats - Report-no. 14 GLP: no Published: Fundamental and applied Toxicology 14, 104 - 112. Submitted in: K IIA + IIIA 6.3.1/01	no	-

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 6.3.3/02	1990	Specific Paper on the Four Notified Pheromones On the Attractants and Repellents a.i. List Biocide Directive 98/8/EC, p. 10 - Report-no. GLP: no Published: no	no	-
A 6.3.3/01	1976	Role of insect sex pheromone in mating behaviour. I. Theoreticalconsideration on release and diffusion of sex pheromone in the air. - Report-no. 11 GLP: no Published: no	no	-
A 6.4.1/01	1990	Subchronic toxicity evaluation of tridecyl acetate in rats - Report-no. 14 GLP: no Published: Fundamental and applied Toxicology 14, 104 - 112. Submitted in: K IIA + IIIA 6.3.1/01	no	-
A 6.4.1/01	1992	Exposure, fate and potential residues in food of applied lepidopteran pheromones. In: Insect pheromones and other behaviour-modifying chemicals: application and regulation, R.L. Ridgeway, M.Inscoe and H. Arn (eds.). - Report-no. 51 GLP: no Published: no Submitted in: K IIA + IIIA 6.3.1/01	no	-
A 6.4.1/02	1988	“Biorational control of crop pest by mating disruption; residue analyses of Z-9-dodecen-1-yl acetate and Z-11-tetradecenyl-1-yl acetate in grapes". in: Biotechnology for Crop Protection, P.Hedin, J.J. Menn and R.Hollingworth (eds.) - Report-no. 379 GLP: no Published: no Submitted in: K IIA + IIIA 6.3.1/02	no	-

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 6.4.3/01	1990	Subchronic toxicity evaluation of tridecyl acetate in rats - Report-no. 14 GLP: no Published: Fundamental and applied Toxicology 14, 104 - 112. Submitted in: K IIA + IIIA 6.3.1/01	no	-
A 6.4.3/01	1976	Role of insect sex pheromone in mating behaviour. I. Theoreticalconsideration on release and diffusion of sex pheromone in the air. - Report-no. 11 GLP: no Published: no Submitted in: K IIA + IIIA 6.3.3/01	no	-
A 6.4.3/02	1990	Specific Paper on the Four Notified Pheromones On the Attractants and Repellents a.i. List Biocide Directive 98/8/EC, p. 10 - Report-no. GLP: no Published: no Submitted in: K IIA + IIIA 6.3.3/02	no	-
A 6.5/01	1990	Subchronic toxicity evaluation of tridecyl acetate in rats - Report-no. 14 GLP: no Published: Fundamental and applied Toxicology 14, 104 - 112. Submitted in: K IIA + IIIA 6.3.1/01	no	-
A 6.6.1/01	2006e	Mutagenicity Study of Z,E-9,12-Tetradecadien-1-Yl Acetate in The Salmonella Typhimurium Reverse Mutation Assay (In Vitro) LPT Lab. of Pharmacology and Toxicology KG, Hamburg, Germany Aeroxon Insect Control, Waiblingen, Germany Report-no. 19785/06 GLP: no Published: no	yes	AEROXON INSECT CONTROL
A 6.6.2/01	2006f	In Vitro Assessment of The Clastogenic Activity of Z,E-9,12-Tetradecadien-1-Yl Acetate in Cultured Human Peripheral Lymphocytes LPT Lab. of Pharmacology and Toxicology KG, Hamburg, Germany Aeroxon Insect Control, Waiblingen, Germany Report-no. 19786/06 GLP: no Published: no	yes	AEROXON INSECT CONTROL

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 6.6.3/01	2006	Mutagenicity study of Z,e-9,12-tetradecadien-1-yl acetate in the mouse lymphoma Forward mutation assay LPT Lab. of Pharmacology and Toxicology KG, Hamburg, Germany Aeroxon Insect Control, Waiblingen, Germany Report-no. 19787/06 GLP: yes Published: no	yes	AEROXON INSECT CONTROL
A 6.7/01	1990	Subchronic toxicity evaluation of tridecyl acetate in rats - Report-no. 14 GLP: no Published: Fundamental and applied Toxicology 14, 104 - 112. Submitted in: K IIA + IIIA 6.3.1/01	no	-
A 6.8.1/01	1990	Developmental toxicology of industrial alcohols: a summary of 13 alcohols administered by inhalation to rats. - Report-no. 6 GLP: no Published: Toxicology and Industrial Health 6: 3/4 373-387	no	-
A 6.8.2/01	1990	Subchronic toxicity evaluation of tridecyl acetate in rats - Report-no. 14 GLP: no Published: Fundamental and applied Toxicology 14, 104 - 112. Submitted in: K IIA + IIIA 6.3.1/01	no	-
A 6.8.2/02	1990	Developmental toxicology of industrial alcohols: a summary of 13 alcohols administered by inhalation to rats. - Report-no. 6 GLP: no Published: Toxicology and Industrial Health 6: 3/4 373-387 Submitted in: K IIA + IIIA 6.8.1/01	no	-
A7.1.1.2.1/01	2009	Assessment of the Ready Biodegradability of Z,E-9,12-Tetradecadienyl Acetate (ZE-TDA) with the Closed Bottle Test. Testing facility: eurofins-GAB GmbH, Niefern-Öschelbronn, Germany, unpublished report No. S09-02939	yes	AEROXON INSECT CONTROL

Section point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
A 7.3.1	2006	ZE-TDA - Estimation of the photochemical oxidative degradation Report-no. 180332-A3-070301-01	yes	AEROXON INSECT CONTROL.

Author(s)	Year	Title, Reference	Data protection claimed yes/no	Owner
Benson A A and Lee R F	1972	Wax esters**:** major marine metabolic energy sources. Biochem J. 128(1): 10P.	no	
Berlitz, Grosch	1999	Food Chemistry Springer, ISBN 3-540-64692-2	no	
Cronin, M.T.D., Worth A.P.	2008	(Q)SARs for predicting effects relating to reproductive toxicity. QSAR & Combinational Science 27: 91-100.	no	
Doi A.M., Hill G., Seely J., Hailey J.R., Kissling G., Bucher J.R.	2007	$\acute{\alpha}_{2\mu}$-Globulin Nephropathy and renal tumors in national toxicology program studies Toxicologic Pathology 35, 533-540	no	
Friedberg	1976	Plasma Transport forms of ingested fatty alcohols in the rat Lipids 11(8), 587-593	no	-
Goto, G., Masuoka, Y., and Hiraga, K.	1974	Photooxidation of the sex pheromone (Z,E)-9,12-tetradecadienyl-1-acetate. Chem. Lett. 1275.	no	
Guoni-Berthold, Berthold HK	2002	Policosanol: clinical pharmacology and therapeutic significance of a new lipid-lowering agent. Am Heart J 143, 356-365	no	
Hard G.C., Rodgers I.I., Baetcke K.P., Richards W.L., McGaughy R.E., Valcovic L.R.	1993	Hazard evaluation of chemicals that cause accumulation of $\acute{\alpha}_{2\mu}$-globulin, hyaline droplet nephropathy, and tuble neoplasia in the kidneys of male rats. Environmental Health Perspectives 99, 313-349	no	
Hargrove James L., Greenspan Phillip, Hartle Diane K.	2004	Nutritional Significance and Metabolism of Very Long Chain Fatty Alcohols and Acids from Dietary Waxes Exp Biol Med. 229/3, 215-26.	no	-
Henson, R.D.	1977	Environmental Fate of Gossyplure. Environmental Entomology, Volume 6, Number 6, pp. 821-822(2)	no	
Minich D.M. Vonk R.J., Verkade H.J.	1997	Intestinal absorption of essential fatty acids under physiological and essential fatty acid-deficient conditions. Journal of Lipid Research 38, 1709-1721	no	-
Nordøy ES	1995	Do minke whales (Balaenoptera acutorostrata) digest wax esters? Br J Nutr. 1995 Nov;74(5):717-22.	no	
Place AR	1992	Comparative aspects of lipid digestion and absorption: physiological correlates of wax ester digestion. Am J Physiol 263, R464-R471	no	
Rahn C. H., Sand D. M., Schlenk H.	1973	Wax Esters in Fish. Metabolism of Dietary Palmityl Palmitate in the Gourami (*Trichogaster cosby*) Vol. 103 No. 10, pp. 1441-1447	no	
Rosa, E., Baratab, C, Damásiob, J.., Boscha PM, and Guerreroa, A.	2006	Aquatic ecotoxicity of a pheromonal antagonist in Daphnia magna and Desmodesmus subspicatus, Aquatic Toxicology, 79, 3, pp. 296-303	no	

Author(s)	Year	Title, Reference	Data protection claimed yes/no	Owner
Sandersona H., Belangerb S.E., Fiskc P.R., Schäfersd C., Veenstrae G., Nielsenf A.M., Kasaig Y., Willingh A., Dyerb S.D., Stantona K., Sedlaka R.	2009	An overview of hazard and risk assessment of the OECD high production volume chemical category—Long chain alcohols [C6–C22] (LCOH), , Ecotoxicology and Environmental Safety Volume 72, Issue 4, 973-979	no	
Sargent, R.R. Gatten and R.J. Henderson J.R.	1981	Marine Wax Esters**.** Pure and Appl. Chemistry, 53, pp. 867-871	no	
Shani A., Klug J. T.	1980b	Sex pheromone of Egyptian cotton leafworm (Spodoptera littoralis) Journal of Chemical Ecology , 6(5) 1561-1573	no	
Shani A., Klug J.T.	1980a	Photooxidation of (Z,E)-9,11-tetradecadienyl acetate, the main component of the sex pheromone of the female egyptian cotton leafworm. Tetrahedron letters, 21, pp:1563-1564	no	
Tong, W., Fang, W.D., Hong, H., Xie, Q., Perkins, R. and Sheehan, D.M.	2004	Receptor-mediated toxicity: QSARs for estrogen receptor binding and priority setting of potential estrogenic endocrine disruptors. In: Cronin, M.T.D. and Livingstone D.J. (Eds) Predicting Chemical Toxicity and Fate. CRC Press Boca Raton FL pp.285-314.	no	
USEPA	1996	Estimating Toxicity of Industrial chemicals to aquatic organisms using structure-activity relationships, Edit. Clements, http://www.epa.gov/oppt/newchems/tools/sarman.pdf	no	
Veenstra G., Webb C., Sanderson H., Belandger S.E., Fisk P., Nielsen A., Kasay Y., Willing A., Dyer S., Penney D., Certa H., Stanton K., Sedlak R.	2009	Human health risk assessment of long chain alcohols. Exotoxicology and Environmental Safety 72, 1016-1030	no	-
Weatherston I., Minks A.K.	1995	Regulation of semiochemicals — global aspects. Integrated Pest Management Reviews, 1, pp:1-13.	no	
Weatherston I., Stuart, R.	2002	Regulatory issues in the commercial development of pheromones and other semiochemicals. IOBC wprs Bulletin Vol 25(9) pp.1-10	no	
WHO	2003	Diet, Nutrition and the prevention of chronic diseases. WHO Technical Report Series 916. Report of a joint FAO/WHO expert consultation. ISBN 92 4 120916 X	no	
William **B.** RizzoS, Debra A. Craft, Andrea **L.** Dammann, and Mary W. Phillips	1987	Fatty Alcohol Metabolism in Cultured Human Fibroblasts The Journal of biological chemistry. 262/36, 17412-17419.	no	

APPENDIX IV-1: STANDARD TERMS AND ABBREVIATIONS

Note: The technical terms “active ingredient” and “active substance” are equivalent

Stand. Term / Abbreviation	Explanation
A	ampere
Ach	acetylcholine
AchE	acetylcholinesterase
ADI	acceptable daily intake
ADME	administration distribution metabolism and excretion
ADP	adenosine diphosphate
AE	acid equivalent
AF	assessment factor
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD_{50}	approximate median lethal dose, 50%
ALT	alanine aminotransferase (SGPT)
Ann.	Annex
AOEL	acceptable operator exposure level
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BAF	bioaccumulation factor
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point
BP	Biocidal Product
BPD	Biocidal Products Directive

Stand. Term / Abbreviation	Explanation
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathy
BSP	bromosulfophthalein
Bt	*Bacillus thuringiensis*
Bti	*Bacillus thuringiensis israelensis*
Btk	*Bacillus thuringiensis kurstaki*
Btt	*Bacillus thuringiensis tenebrionis*
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10^{-2})
°C	degrees Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DANN
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
d	day(s)
DES	diethylstilboestrol
DIS	draft international standard *(ISO)*

Stand. Term / Abbreviation	Explanation
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days post inoculation
DRP	detailed review paper *(OECD)*
DSC	Differential scanning calorimetry
$DT_{50(lab)}$	period required for 50 percent dissipation (under laboratory conditions) (define method of estimation)
$DT_{90(field)}$	period required for 90 percent dissipation (under field conditions) (define method of estimation)
dw	dry weight
DWQG	drinking water quality guidelines
ε	decadic molar extinction coefficient
E_bC_{50}	median effective concentration, biomass
E_rC_{50}	median effective concentration, growth rate
EC_{50}	median effective concentration
ECD	electron capture detector
ED_{50}	median effective dose
EDI	estimated daily intake
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EN	European norm
EPMA	electron probe micro-analysis
ERL	extraneous residue limit
ESPE46/51	evaluation system for pesticides
EUSES	European Union system for the evaluation of substances
F	field
F_0	parental generation
F_1	filial generation, first
F_2	filial generation, second
FBS	full base set
FELS	fish early-life stage
FIA	fluorescence immuno-assay
FID	flame ionisation detector
F_{mol}	fractional equivalent of the metabolite´s molecular weight compared to the active substance
FOB	functional observation battery
f_{oc}	organic carbon factor (compartment dependent)
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram(s)
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GMM	genetically modified micro-organism
GMO	genetically modified organism
GPC	gel-permeation chromatography
GPS	global positioning system
GSH	glutathione

Stand. Term / Abbreviation	Explanation
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value)
ha	hectare(s)
Hb	haemoglobin
HC5	concentration which will be harmless to at least 95 % of the species present with a given level of confidence (usually 95 %)
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionisation detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H_S	Shannon-Weaver index
Ht	haematocrit
HUSS	human and use safety standard
I	indoor
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilisation concentration or median inhibitory concentration 1
ICM	integrated crop management
ID	ionisation detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation

Stand. Term / Abbreviation	Explanation
INT	2-p-iodophenyl-3-p-nitrophenyl-5-phenyltetrazoliumchloride testing method
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
IUCLID	International Uniform Chemical Information Database
iv	intravenous
IVF	*in vitro* fertilisation
k *(in combination)*	kilo
k	rate constant for biodegradation
K	Kelvin
Ka	acid dissociation constant
Kb	base dissociation constant
K_{ads}	adsorption constant
K_{des}	apparent desorption coefficient
kg	kilogram
K_H	Henry´s Law constant (in atmosphere per cubic metre per mole)
K_{oc}	organic carbon adsorption coefficient
K_{om}	organic matter adsorption coefficient
K_{ow}	octanol-water partition coefficient
Kp	solid-water partition coefficient
kPa	kilopascal(s)
l, L	litre
LAN	local area network
LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry
LC_{50}	lethal concentration, median
LCA	life cycle analysis
LC-MS-MS	liquid chromatography with tandem mass spectrometry

Stand. Term / Abbreviation	Explanation
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
ln	natural logarithm
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
log	logarithm to the base 10
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar
µm	micrometer (micron)
MAC	maximum allowable concentration
MAK	maximum allowable concentration
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
MIC	minimum inhibitory concentration
min	minute(s)
MKC	minimum killing concentration
mL	millilitre
MLD	median lethal dose
MLT	minimum lethal time

Stand. Term / Abbreviation	Explanation
mm	millimetre
MMAD	mass median aerodynamic diameter
mo	month(s)
MOE	margin of exposure
mol	mole(s)
MOS	margin of safety
Mp	melting point
MRE	maximum residue expected
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MT	material test
MW	molecular weight
n.a.	not applicable
n-	normal (defining isomeric configuration)
N	number of observations
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometre
NMR	nuclear magnetic resonance
no, n°	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOE_rC	no observed effect concentration, growth rate
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection

Stand. Term / Abbreviation	Explanation
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OEL	occupational exposure limit
OH	hydroxide
OJ	Official Journal
OM	organic matter content
Pa	pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the acid dissociation constant
pKb	negative logarithm (to the base 10) of the base dissociation constant
PNEC	predicted no effect concentration (compartment to be added as subscript)

Stand. Term / Abbreviation	Explanation
po	by mouth
POP	persistent organic pollutants
ppb	parts per billion (10^{-9})
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PPP	plant protection product
ppq	parts per quadrillion ($10^{-24)}$
ppt	parts per trillion (10^{-12})
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	product type
PT(CEN)	project team CEN
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QA	quality assurance
QAU	quality assurance unit
(Q)SAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RA	risk assessment
RBC	red blood cell
REI	restricted entry interval
RENI	Registry Nomenclature Information System
Rf	retardation factor
RfD	reference dose
RH	relative humidity
RL_{50}	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rpm	revolutions per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
S	solubility

Stand. Term / Abbreviation	Explanation
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SCAS	semi-continous activated sludge
SCTER	smallest chronic toxicity exposure ratio (TER)
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
S/L	short term to long term ratio
SMEs	small and medium sized enterprises
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
ssp	subspecies
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STER	smallest toxicity exposure ratio (TER)
STMR	supervised trials median residue
STP	sewage treatment plant
t	tonne(s) (metric ton)
$t_{½}$	half-life (define method of estimation)
T_3	tri-iodothyroxine
T_4	thyroxine
T_{25}	tumorigenic dose that causes tumours in 25 % of the test animals
TADI	temporary acceptable daily intake
TBC	tightly bound capacity

Stand. Term / Abbreviation	Explanation
TCD	thermal conductivity detector
TG	technical guideline, technical group
TGD	Technical guidance document
TID	thermionic detector, alkali flame detector
TDR	time domain reflectrometry
TER	toxicity exposure ratio
TER_I	toxicity exposure ratio for initial exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TNsG	technical notes for guidance
TOC	total organic carbon
Tremcard	transport emergency card
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)
TTC	2,3,5-triphenylterazoliumchloride testing method
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UR	unit risk
UV	ultraviolet
UVC	unknown or variable composition,

Stand. Term / Abbreviation	**Explanation**
	complex reaction products
UVCB	undefined or variable composition, complex reaction products in biological material
v/v	volume ratio (volume per volume)
vis	visible
WBC	white blood cell
Wk	week
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
Yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

APPENDIX IV-2: ABBREVIATIONS OF ORGANISATION AND PUBLICATIONS

Abbreviation	Explanation
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
BBA	German Federal Agency of Agriculture and Forestry
CA(S)	Chemical Abstracts (System)
CAB	Centre for Agriculture and Biosciences International
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Food
CE	Council of Europe
CEC	Commission of the European Communities
CEFIC	European Chemical Industry Council
CEN	European Committee for Normalisation
CEPE	European Committee for Paints and Inks
CIPAC	Collaborative International Pesticides Analytical Council Ltd
CMA	Chemicals Manufacturers Association
COREPER	Comite des Representants Permanents
COST	European Co-operation in the field of Scientific and Technical Research
DG	Directorate General
DIN	German Institute for Standardisation

Abbreviation	Explanation
EC	European Commission
ECB	European Chemicals Bureau
ECCO	European Commission Co-ordination
ECDIN	Environmental Chemicals Data and Information Network of the European Communities
ECDIS	European Environmental Chemicals Data and Information System
ECE	Economic Commission for Europe
ECETOC	European Chemical Industry Ecology and Toxicology Centre
EDEXIM	European Database on Export and Import of Dangerous Chemicals
EEC	European Economic Community
EHC	Environmental Health Criteria
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMIC	Environmental Mutagens Information Centre
EPA	Environmental Protection Agency
EPAS	European Producers of Antimicrobial Substances
EPFP	European Producers of Formulated Preservatives
EPO	European Patent Office
EPPO	European and Mediterranean Plant Protection Organization
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union
EUPHIDS	European Pesticide Hazard Information and Decision Support System
EUROPOEM	European Predictive Operator Exposure Model
EWMP	European Wood Preservation Manufacturers
FAO	Food and Agriculture Organization

Abbreviation	Explanation
	of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and Trade
GAW	Global Atmosphere Watch
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (now known as GCPF)
GCOS	Global Climate Observing System
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GEDD	Global Environmental Data Directory
GEMS	Global Environmental Monitoring System
GRIN	Germplasm Resources Information Network
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
ICBP	International Council for Bird Preservation
ICCA	International Council of Chemical Associations
ICES	International Council for the Exploration of the Seas
ILO	International Labour Organization
IMO	International Maritime Organisation
IOBC	International Organization for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee
ISCO	International Soil Conservation Organization
ISO	International Organization for Standardisation

Abbreviation	Explanation
IUPAC	International Union of Pure and Applied Chemistry
JECFA FAO/WHO	Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
JMP	Joint Meeting on Pesticides (WHO/FAO)
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
MITI	Ministry of International Trade and Industry, Japan
NATO	North Atlantic Treaty Organization
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Center for Toxicological Research (USA)
NGO	non-governmental organisation
NTP	National Toxicology Program (USA)
OECD	Organization for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
OPPTS	Office of Prevention, Pesticides and Toxic Substances (US EPA)
OSPAR	Oslo Paris Convention (Convention for the Protection of the Marine Environment of the North-East Atlantic)
PAN	Pesticide Action Network
RIVM	Netherlands National Institute of Public Health and Environmental Protection
RNN	Re-registration Notification Network
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SETAC	Society of Environmental Toxicology and Chemistry

Abbreviation	Explanation
SI	Système International d'Unitès
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UBA	German Environmental Protection Agency
UN	United Nations
UNEP	United Nations Environment Programme
WFP	World Food Programme
WHO	World Health Organization
WPRS	West Palearctic Regional Section
WTO	World Trade Organization
WWF	World Wildlife Fund