Product Assessment Report

Lebensmittelmottenfalle

April 2013

Registration no:	AT/2013/R/00003/19
Granting date/entry into force of registration:	8. August 2013
Expiry date of registration:	31st January 2023
Active ingredient:	Z,E-9,12-Tetradecadien-1-yl acetate
Product type:	19

Biocidal product assessment report related to product authorisation under Directive 98/8/EC

Contents

1 General information about the product application

1.1 Applicant

Company Name:	Aeroxon Insect Control GmbH
Address:	Bahnhofstrasse 35
City:	Waiblingen
Postal Code:	71332
Country:	Germany
Telephone:	0049 71511 7155
Fax:	
E-mail address:	Axel.Engelhart@aeroxon.de

1.1.1 Person authorised for communication on behalf of the applicant

Name:	Sascha Otto
Function:	Consultant to Aeroxon
Address:	Hinter den Hoefen 24
City:	Lamstedt
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1.2 Current authorisation holder[1]

Company Name:	No existing authorisation available
Address:	
City:	
Postal Code:	
Country:	
Telephone:	
Fax:	
E-mail address:	
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	

[1] Applies only to existing authorisations

1.3 Proposed authorisation holder

Company Name:	Aeroxon Insect Control GmbH
Address:	Bahnhofstrasse 35
City:	Waiblingen
Postal Code:	71332
Country:	Germany
Telephone:	0049 71511 7155
Fax:	
E-mail address:	Axel.Engelhart@aeroxon.de
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	

1.4 Information about the product application

Application received:	31.01.2013
Application reported complete:	02.04. 2013
Type of application:	Registration
Further information:	No

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	Lebensmittelmotten-Falle
Manufacturer's development code number(s), if appropriate:	No
Product type:	PT 19
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	2 mg Z,E-9,12-Tetradecadien-1-yl-acetat per trap, 97,7% min. purity
Formulation type:	Liquid on a solid carrier
Ready to use product (yes/no):	Yes
Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); If yes: authorisation/registration no. and product name: or	Yes

Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):	

1.5.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	Lebensmittelmotten-Falle is a ready to use trap consisting of a cardboard carrying the pheromone Z,E-9,12-Tetradecadien-1-yl acetate and is partly covered with an adhesive glue. The aim of use is to protect stored food or feedstuff which should be well closed against the Indian meal moth via mating disruption.
Target organisms:	Plodia interpunctella
Category of users:	Non professional users /consumers, professionals
Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	The maximum application rate is determined by the amount of active substance on each trap (2 mg). The recommended application is 1 trap per cupboard or small room, 2 traps for larger rooms. Traps should be inspected at least once a week and replaced after 6 weeks or, if covered with moths.
Potential for release into the environment (yes/no):	no
Potential for contamination of food/feedingstuff (yes/no)	no
Proposed Label:	Lebensmittelmotten-Falle is a ready to use trap consisting of a cardboard carrying the pheromone Z,E-9,12-Tetradecadien-1-yl acetate and is partly covered with an adhesive glue. The recommended application is 1 trap per cupboard or small room, 2 traps for larger rooms. Do not use the product in spaces where un-packaged food or feed is kept. Traps should be inspected at least once a week and replaced after 6 weeks or, if covered with moths. The used product can be disposed in household rubbish.
Use Restrictions:	Lebensmittelmotten-Falle shall not be used in spaces where un-packaged food or feed is kept.

1.5.3 Information on active substance(s)[2]

Active substance chemical name:	Z,E-9,12-Tetradecadien-1-yl acetate	
CAS No:	30507-70-1	
EC No:	Not allocated	
Purity (minimum, g/kg or g/l):	977 g/kg	
Inclusion directive:	2011/11/EU	
Date of inclusion:	1 February 2013	
Is the active substance equivalent to the active substance listed in Annex IA to 98/8/EC (yes/no):	yes	
Manufacturer of active substance(s) used in the biocidal product:		
Company Name:	Bedoukian Research Inc	
Address:	21 Finance Drive	
City:	Danbury	
Postal Code:	CT 06810	
Country:	USA	
Telephone:	+1-203-830-4000	
Fax:	+1-203-830-4010	
E-mail address:	customerservice@bedoukian.com	

1.5.4 Information on the substance(s) of concern[3]

Substance chemical name	not applicable	
CAS No:		
EC No :		
Purity (minimum, g/kg or g/l):		
Typical concentration (minimum and maximum, g/kg, or g/l):		
Relevant toxicological/ecotoxicological information:		
Original ingredient (trade name):		

1.6 Documentation

1.6.1 Data submitted in relation to product application

The applicant Aeroxon Insect Control GmbH (Waiblingen, Germany) is the same as for Annex IA inclusion of ZE-TDA (CAS no. 30507-70-1) in product-type 19. Please find the data in the CAR.

[2] Please insert additional columns as necessary
[3] Please insert additional columns as necessary

Furthermore the applicant submitted new data for the biocidal product (physical and chemical properties , analytical method and efficacy data), which are listed in the reference list in Annex 2: List of studies reviewed. Please find the study summaries for studies which were evaluated for product authorisation in Annex 9: Study summaries of studies reviewed.

1.6.2 Access to documentation

If the applicant has submitted a letter of access to data it should be stated here. It must be clear to which data access is granted.

The applicant Aeroxon Insect Control GmbH (Waiblingen, Germany) is the same as for Annex IA inclusion of ZE-TDA (CAS no. 30507-70-1) in product-type 19.
Furthermore, Aeroxon Insect Control GmbH submitted new data for the use of the biocidal product (physical and chemical properties , analytical method and efficacy data). As the applicant is the owner of the data mentioned above, no letter of access is necessary.

2 Summary of the product assessment

2.1 Identity related issues

The biocidal product is identical to the active substance included in Annex IA (Z,E-9,12-Tetradecadien-1-yl acetate (2 g per trap), purity min. 977 g/kg).

The active substance is identical to the active substance listed in Annex IA of 98/8/EC. The manufacturer of the active substance and the production site of the active substance used are identical to the manufacturer of the active substance and the production site of the active substance included in Annex IA of Directive 98/8/EC. Therefore no check for equivalence is necessary.

There are two different types of Lebensmittelmotten-Falle:

The first type is a 2-dimensional form of the product. The cardboard covered with adhesive glue has a size of 130 mm x 90 mm. It contains 2 mg of the pheromone, which is slowly released from the trap. The trap is fixed to a solid background with a tape on its back. A silicone paper is then removed from the adhesive glue on front of the trap for its activation. As a second option, the activated trap could be re-inserted into a variant of the packaging, which would serve as housing of the trap during service.

The second type is a triangle form of the product. The carton covered with adhesive glue has a size of 274 mm x 55 mm, which is folded two times by the user to form the triangle shape. It contains 2 mg of the pheromon which is slowly released from the trap. The trap is either hung up at the top edge or arranged upright onto a solid ground. For activation a silicone paper is removed from the adhesive glue before folding the trap.

Definition of the biocidal product:

As conclusion of the different options AT considered that the biocidal product according to Article 2(1) a) of Directive 98/8/EC is the active substance Z,E-9,12-Tetradecadien-1-yl acetate only.

Explanation:

The product ”Lebensmittelmotten-Falle” has been analysed based on the definitions for substances, mixtures and articles stated in Regulation (EC) No. 1907/2006 (REACH) and supported by the rules explained in the ”Guidance on requirements for substances in articles” published by the European Chemicals Agency (ECHA).

Article 3(3) of the REACH Regulation defines an article as “an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition”.
Following the definition for an article and the advice of the above mentioned guidance it is obvious that the cardboard has to be regarded as an article. The more difficult question to be evaluated was if the glue has to be regarded as integral part of the cardboard (= article) or if the active substance and the glue have to be regarded as mixture and the cardboard as a carrier for these substances (combination of substances and an article).

For such borderline cases above mentioned guidance document provides support for the final decision:

In step 1 the function of the object has to be identified by looking at the result of using the object and by paying less attention to the quality of the result. It can be said that the object releases a substance to attract/confuse the male Plodia interpunctella. Furthermore, if the moths find the way to the object they are caught by the adhesive surface.

In step 2 the question has to be answered whether the shape/surface/design of the object is more relevant for the identified function than the chemical composition.
As this question cannot be clearly answered by yes or no, it has to be clarified in step 3, if the object contains a substance that can be separated from the object. As this question can be answered with yes (the active substance can be released) the evaluation has to go on by answering the indicative questions which can be found in chapter 2.4 of the mentioned guidance:

Question 4a: If the substance/mixture were to be removed or separated from the object and used independently from it, would the substance/mixture still be capable in principle (though perhaps without convenience or sophistication) of carrying out the function defined under step 1?

Question 4b: Does the object act mainly (i.e. according to the function defined under step 1) as a container or carrier for release or controlled delivery of the substance/mixture or its reaction products?

Question 4c: Is the substance/mixture consumed (i.e. used up e.g. due to a chemical or physical modification) or eliminated (i.e. released from the object) during the use phase of the object, thereby rendering the object useless and leading to the end of its service life?

If these questions can be answered predominantly with yes (i.e. 2 of 3) rather than no, then the object should be regarded as a combination of an article (functioning as a container or a carrier material) and a substance/mixture.

When answering mentioned questions for the active substance and the glue separately following decision can be drawn.

Answer on 4a:	yes, for the active substance yes, for the glue	Both substances can in principle fulfil their functions also independently from the cardboard
Answer on 4b:	yes, for the active substance	the active substance has to be released over a period of time, the cardboard is the carrier for the substance
	no, for the glue	The glue will and should not be separated from the cardboard
Answer on 4c:	yes, for the active substance	At the end of use the active substance has been released from the cardboard, which leads to the end of the service live of the product
	no, for the glue	The glue will remain on the cardboard and will not be consumed during the use phase

Conclusion: The glue (answers predominately ”no”) has to be regarded as an integral part of the article (card board), whereas the active substance (answers predominately ”yes”) has to be regarded as a substance on a carrier. As Article 2 (1) of Directive 98/8/EC defines a biocidal product as an active substance or a preparation (mixture) containing active substance(s), only the active substance is the biocidal product to be considered for the assessment.

2.2 Classification, labelling and packaging

2.2.1 Harmonised classification of the biocidal product

Current classification according to Directive 67/548/EEC:

There is currently no harmonised classification for ZE-TDA in Annex VI of Regulation (EC) No 1272/2008.

Proposed classification and labelling according to Directive 67/548/EEC and Regulation (EC) No 1272/2008.

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.

2.2.2 Labelling of the biocidal product

Please see 2.2.1

Table 2.2.2-1 Proposed classification of the Lebensmittelmotten-Falle according to Directive 67/548/EEC

Classification	as in Directive 67/548/EEC
Class of danger	Not classified
R phrases	None
S phrases	S 2 Keep out of reach of children
Proposed packaging	None

Table 2.2.2-2 Proposed classification of the Lebensmittelmotten-Falle according to Regulation (EC) No 1272/2008

Classification	as in Regulation (EC) No 1272/2008
Class of danger	Not classified
R phrases	None
S phrases	P 102 Keep out of reach of children
Proposed packaging	None

2.2.3 Packaging of the biocidal product

The packing unit consists of 2 traps.

2.3 Physico/chemical properties and analytical methods

2.3.1 Physico-chemical properties

An overview of the physico-chemical properties of the active substances can be found in the CAR[1].

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).

For details please see the CAR, DOC II-A, section 1.3.

As the biocidal product is identical with the active substance, please see above.

2.3.2 Analytical methods

2.3.3 Analysis of active substance as manufactured

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.

2.3.4 Residue analysis

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.

2.3.5 Formulation analysis

A new study (Wilfinger, 2013d), referenced as **Doc III B 4.1/02,** has been submitted by the applicant. The analytical method described by Wilfinger (2013d), was based on the method of Bockhorn (2006) which has already been evaluated for Annex IA inclusion of ZE-TDA and can be found in the respective CAR referenced as **Doc III B 4.1/01**.

The method presented by Wilfinger (2013d) can be summarized as follows:

The complete unit (glue trap) was cut in pieces of about 4.5 x 1.5 cm by scalpel and scissor. Then 50 mL extraction solvent hexane/n-pentane (50/50); v/v) was added into an appropriate Erlenmeyer flask. The flask was closed with an appropriate plug. Then the front protective paper from the first piece was removed by a pair of tweezers, given in the extraction solvent and mixed by about 5 minutes intensive stirring (about 150 rpm/min) to dissolve the glue from the piece and prevent the pieces sticking during the extraction process. The pieces were given consecutively in the Erlenmeyer flask and treated in the same way as described above. Finally, the flask was placed into an ultrasonic bath for two hours. Every 15 minutes the ultrasonic bath was started for two minutes at room temperature. Then about 1 mL of the supernatant of the raw extract (wait for settling down of the cloudiness/turbidness) was transferred into an amber crimp vial and measured by GC/FID.

2.4 Risk assessment for Physico-chemical properties

No new physico-chemical data of (Z,E)-Tetradeca-9,12-dienyl acetate were submitted except storage stability data.
(Z,E)-Tetradeca-9,12-dienyl acetate is not flammable and does not have explosive, oxidising or corrosive properties (please see Doc II A of the CAR, table 5.1-1).
In conclusion, no physico-chemical hazards could be identified for the active substance. Hence no classification is required on the base of physico-chemical properties. No unacceptable risk arising from physico-chemical properties could be identified and no classification and labelling with regard to physico-chemical properties are required.

Concerning long-term storage stability (shelf life), two accelerated storage tests for 12 weeks at a temperature of 35°C were submitted (CIPAC MT 46 GIFAP Monograph 17).

A: Test item: Food Moth Trap "1mg N143 Project 5002", Wilfinger (2013a):

Results:

1. Stability of the commercial packaging material (visual):
BS (before storage): The commercial packaging (white side-seamed pouch pack with double closing seam on the back side) contained one rectangular (about 16.5 cm × 9 cm) glue trap. The packaging was found tightly sealed prior to opening and no damage neither to the commercial packaging nor to the test item was observed.
AS (after storage): No visible damage or deterioration neither to the commercial packaging nor to the test item was observed after storage.

2: Weight change of the commercial packaging material
AS: The change in weight of the entire test item (including packaging) after storage was ≤ 2.72 % of the initial weight.

3. Appearance, colour and odour (visual)
BS: The food moth trap consists of front protective paper, one odourless glue trap with imprinted moth motives and cardboard backing sheet. A red protective strip on the cardboard backing sheet covers a line of adhesive that fixes the trap to its intended place.
AS: No visual differences or any other changes in appearance, colour and odour were observed after storage compared to initial values.

4. Mean content of active ingredient (GC/FID):
BS: 0.95 mg (Z,E)-tetradeca-9,12-dienyl acetate (TDA) per unit.
AS: 0.98 mg (Z,E)-tetradeca-9,12-dienyl acetate (TDA) per unit.

5. Applicability of the glue trap:
BS: The glue traps were found to be mechanically stable during the application, but were not easily and residue-free removable from the solid surface.
AS: The glue traps were found to be mechanically stable during the application, but were not easily and residue-free removable from the solid surface.

6. Catching ability of the glue:
BS: suitable.
AS: suitable.

B: Test item: Food Moth Trap "2 mg N143 Project 5002", Wilfinger (2013b):

Results:

1. Stability of the commercial packaging material (visual):
BS: The commercial packaging (white side-seamed pouch pack with double closing seam on the back side) contained one rectangular (about 16.5 cm × 9 cm) glue trap. The packaging was found tightly sealed prior to opening and no damage neither to the commercial packaging nor to the test item was observed.
AS: No visible damage or deterioration neither to the commercial packaging nor to the test item was observed after storage.

2: Weight change of the commercial packaging material
AS: The change in weight of the entire test item (including packaging) after storage was ≤ 2.67 % of the initial weight.

3. Appearance, colour and odour (visual)
BS: The food moth trap consists of front protective paper, one odourless glue trap with imprinted moth motives and cardboard backing sheet. A red protective strip on the cardboard backing sheet covers a line of adhesive that fixes the trap to its intended place.
AS: No visual differences or any other changes in appearance, colour and odour were observed after storage compared to initial values.

4. Mean content of active ingredient (GC/FID):
BS: 1.85 mg (Z,E)-tetradeca-9,12-dienyl acetate (TDA) per unit
AS: 1.95 mg (Z,E)-tetradeca-9,12-dienyl acetate (TDA) per unit

5. Applicability of the glue trap:
BS: The glue traps were found to be mechanically stable during the application but were not easily and residue-free removable from the solid surface.
AS: The glue traps were found to be mechanically stable during the application but were not easily and residue-free removable from the solid surface.

5. Catching ability of the glue:
BS: suitable.
AS: suitable.

Summary:

The results of the accelerated storage tests at a temperature of 35°C for 12 weeks indicate that the formulation is stable with regards to the active substance contents and the visual properties of the product.

A long term stability study at 20°C for 4 years, namely “Physico-chemical Properties of the Food Moth Trap (2 mg N143 Project 5002) over 4 Years Storage at 20°C”, study number S12-04233 was initiated in November 2012 and is on-going (Wilfinger (2013c)). The expected date of finalisation is the year 2016, at the moment only a starting date report is available.

It should be noted that results from accelerated studies are overruled by the results from long-term storage stability studies if such studies are available.

In the meantime Austria accepts the accelerated storage tests at a temperature of 35°C for 12 weeks.

In this test there is no indication of losses of the active substance and furthermore, an efficacy test is available: COMPARATIVE TESTING OF AEROXON PHEROMONE TRAPS FOR PHYCITID MOTHS AFTER LONG-TERM STORAGE (Heller, G., 2008). It is indicating that traps, which were stored over up to four years, are still efficient in trapping male Plodia interpunctella (please see DOC III B5_10_2-05 in the CAR).

A further efficacy study (Fox-Smith, E. 2013a) shows sufficient efficacy even containing 1 mg a.s./trap instead of 2 mg. Thus, the evidence of prolonged storage stability is shown indirectly and a storage stability of 4 years accepted. As soon as the long term stability study at 20°C for 4 years is available, the data have to be submitted for verification.

2.5 Effectiveness against target organisms

New data/information submitted for the product or the active substance(s) should be evaluated and the result summarised here.
Generally, in this section a summary of the effect and efficacy of the biocidal product including function, pests controlled, known limitations, potential for resistance, unacceptable suffering of the target organisms and other effects should be made. An assessment on how the efficacy of the product is reflected in the label claim should also be made.

To assess the efficacy of "Lebensmittelmotten-Falle" under close to application test conditions, a study was performed where 10 male and 10 female moths per replicate were introduced into a room with either a test product trap or a control trap attached above a shelf with containers of flaked almonds and breakfast cereals. Moths were allowed to stay in the test room for mating and egg deposition for 7 days. During this period trapped moths were counted. The containers with stored goods were then transferred into a climate chamber for incubation. After 4 weeks the developed offspring was counted. This test was replicated 8 times. The efficacy in trapping male moths was 26% on average. In terms of reduced food infestation with moth larvae, the application of the pheromone-baited traps led to a reduction of food infestation by 58 %.

The different degrees of efficacy and the time course of male catches over the experimental period indicate a combined mechanism. Some of the males were caught on the traps while the remaining males were most probably impaired in their mate finding capabilities.

Further experiments were carried out to compare the efficacy of "Lebensmittelmotten-Falle" to other products on the market and to assess the efficacy of the product after up to four years of storage. Unfortunately, each of these experiments did not comply with modern scientific criteria. Major limits were the absence of replicates, and thus, absence of statistical assessment of the results, non-randomised trap positions in the experimental room, effects of the trap position on catch numbers in some cases, and reciprocal impact of traps. The results indicate, however, that the efficacy of "Lebensmittelmotten-Falle" is most probably comparable to the efficacy of other products on the market, and that the efficacy of the product is therefore most probably maintained for up to four years of storage.

For the efficacy data submitted for the Annex IA inclusion of (Z,E)-Tetradeca-9,12-dienyl acetate please see the CAR.

New data also have been submitted (Heller, G., 2011, Fox-Smith, E. 2013a, Fox-Smith, E. 2013b, Fox-Smith, E. 2013c, Fox-Smith, E. 2013d), please see Annex 2 (list of studies reviewed) and Annex 9 (study summaries of studies reviewed).

The relevant trials conducted with formulations equal to "Lebensmittelmotten-Falle" is summarised in Table 2.5-1 and 2.5-2 below.

The data provided by the applicant demonstrate that the active substance (Z,E) tetradeca-9,12-dienyl acetate used in a pheromone trap may significantly reduce infestation of food stuff with P. interpunctella larvae. The data justify product registration for "Lebensmittelmotten-Falle" under condition that the mode of action submitted by the applicant is revised. It should state mating disruption instead of male trapping.

The label claim has to be adapted according to the experimental data: Lebensmittelmotten-Falle reduces infestation of dried food stuff by P. interpunctella by mating disruption. The emitted pheromone confuses males on their search for females and thereby prevents them from reproducing. If males are found on the traps this indicates potential infestation of the premises. Traps should be exchanged after 6 weeks.

2.5.1 Dose / mode of action / known limitations / resistance

Dose:

Lebensmittelmotten-Falle is a ready to use trap consisting of a cardboard carrying the pheromone Z,E-9,12-Tetradecadien-1-yl acetate and is covered with a layer of adhesive glue. The maximum concentration is determined by the amount of active substance (2 mg) on each trap evaporating during a period of 6 weeks.

Mode of action/Function:

Lebensmittelmotten-Falle is a trap that captures a number of moths by physical means with adhesive glue also. It is based on the active substance (Z,E)-Tetradeca-9,12-dienyl acetate, a sex pheromone naturally produced by the females of Plodia interpunctella, to call males for mating. This mechanism of attraction is disturbed by emitting pheromone in the storage facilities which results in confusing the males and finally in mating disruption.

Using the active substance (Z,E)-Tetradeca-9,12-dienyl acetate in a trap results in males being guided to the trap where they are partly caught or mainly disoriented with respect to females. Mating is disrupted because the males cannot find the females and consequently reproduction is inhibited. No time delay of responses of males is expected and an immediate response within one day has been observed in the reported studies.

The pheromone is not active against eggs and larvae that have already infested the foodstuff. The product is targeting in preventing further spoiling of foodstuff.

Organism(s) to be controlled and products, organisms or objects to be protected

Male adults of the Indian meal moth Plodia interpunctella are attracted by the pheromone. By confusing the male moths they are prevented from finding the female moths. Thus mating is disrupted, reproduction is inhibited and infestation of dried foodstuff is reduced.
Products intended to be protected are dried food and feedstuffs, e.g. nuts, muesli, cookies, chocolate, flour, rice, dried fruits, fodder, etc. that is stored in closed or re-closed package.

Effects on target organisms and efficacy

Male adults of Plodia interpunctella are attracted and confused by the pheromone. Some will be trapped on the glue. Trapped moths will die. Confused and trapped male moths are prevented from finding the females. Mating is disrupted, reproduction is inhibited and infestation of feedstuff is reduced.

Limitations:

Experimental methods were reliable and overall well documented. However, neither the capacity to catch male E. kuehniella , E. cautella and E. elutella nor the capacity to reduce feedstuff infestation

by them has been sufficiently demonstrated. Based on the presented data the product is therefore neither suitable to monitor nor to control E. kuehniella , E. cautella and E. elutella.

Therefore, the results do not permit to register “Lebensmittelmotten-Falle” as biocidal product against E. kuehniella , E. cautella and E. elutella.

Occurrence of resistance

No reduced efficacy or resistance has been reported for P. interpunctella up to now. However, under specific conditions resistance to pheromone treatments has been reported in the literature. Risk factors are long-term application on isolated populations and use of a single pheromone compound out of the species-specific pheromone blend. Under these conditions males are selected to discriminate the full natural pheromone blend against the synthetic one-component lure. Most probably some of these factors will not apply to P. interpunctella. Therefore, it is deemed sufficient if the Applicant provides a literature survey at the next renewal or prolongation of product registration. The survey shall specifically document cases of resistance to pheromone treatment and discuss whether identified risk factors apply to P. interpunctella.

Table B 2.5-1: Efficacy of Lebensmittelmotten-Falle– Plodia interpunctella submitted for the Annex I inclusion

Test substance	Test organism(s)	Test system / concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference
Lebensmittelmotten-Falle Pheromone trap with Z,E-Tetradeca-9,12-dienyl acetate (TDA), Ready to use	Plodia interpunctella, laboratory strain, emerging adult moths from a culture vessel containing pupae and young adults (both sexes)	1 replicate, 60 m³ test chamber, 3 traps per test chamber, Exposure time: 6 days. Traps: 1. LeMoFa [1)] (batch P 134, test item) 2. Salvo Mottenval (reference) 3. Adhesive paper (control)	Simulated use study Room temperature was 20-22 °C, Seasonal photo period	No. of **trapped male moths** (cumulated): 1. LeMoFa [1)] 62 2. Salvo Mottenval 15 3. Control 0	Heller, G. (2005a) **(Section B5.10.2/01)**
Lebensmittelmotten-Falle Pheromone trap with Z,E-Tetradeca-9,12-dienyl acetate (TDA), **Different batches**, Ready to use	Plodia interpunctella, laboratory strain, emerging adult moths from a culture vessel containing pupae and young adults (both sexes)	2 replicates, 60 m³ test chamber, 5 different traps per test chamber, Exposure time: 6 days Traps (different batches): 1. LeMoFa [1)] (Aeroxon P056, test item) 2. LeMoFa (Aeroxon, P051, test item) 3. LeMoFa (Aeroxon, P027, test item) 4. Kapo L4 035 (batch P02.04, reference) 5. Adhesive paper (control)	Room temperature was 20-22 °C, Seasonal photo period	No. of **trapped moths** (cumulated): Mean of 2 replicates 1. Aeroxon P056 18.5 2. Aeroxon, P051 23.5 3. Aeroxon, P027 2.5 4. Kapo L4 035 23 5. Control 0	Heller, G. (2004) **(Section B5.10.2/02)**
Lebensmittelmotten-Falle Pheromone trap with Z,E-Tetradeca-9,12-dienyl acetate (TDA), Ready to use	Plodia interpunctella, laboratory strain, emerging adult moths from a culture vessel containing pupae and young adults (both sexes)	2 replicates, 30 m³ test chamber, 4 different traps per test chamber, Exposure time: 6 days , Traps (in 1 test chamber): 1. LeMoFa (batch Aeroxon Q-012, test item) 2. Celaflor NexaLotte (batch 114A33604C003965, reference) 3. Globol (batch not stated, reference) 4. Adhesive paper (control)	Room temperature was 20-22 °C, Seasonal photo period	No. of **trapped male moths** (cumulated): Mean of 2 replicates 1. Aeroxon Q-012 38.5 2. Celaflor 34.0 3. Globol 8 4. Control 1.5	Heller, G. (2005b) **(Section B5.10.2/03)**

Lebensmittelmotten-Falle Pheromone trap with 2 mg Z,E-Tetradeca-9,12-dienyl acetate (TDA) Ready to use	Plodia interpunctella, laboratory strain, 10 male and 10 female moths per relicate (age: 48±24 h)	8 replicates, 10 male and 10 female adults, 30 m³ test room (4 x 2.7 m²), 1 trap per room, Egg laying medium: almonds and cereals, Exposure time: 7 days, Incubation of medium: 4 weeks, Traps: 1. LeMoFa (test item) 2. Adhesive paper (control)	Temperature: 17.3-30.1°C (test room) and 26.5-34°C (climate chamber), Moisture: 11-56% (test room) and 29-73% (climate chamber), Seasonal photo period	No. of **trapped male moths** (cumulated): Mean of 8 replicates 1. Test item 3.5 2. Control 1.25 Efficacy: 25.7% **Hatched larvae** in food containers: 1. Test item 19.9 2. Control 48.0 Efficacy: 58.6%	Klug, T. 2008 **(Section B5.10.2/04)**
Lebensmittelmotten-Falle Pheromone trap with Z,E-Tetradeca-9,12-dienyl acetate (TDA), **Aged under shelf life conditions,** Ready to use	Plodia interpunctella, laboratory strain, emerging adult moths from a culture vessel, both sexes, about 100-125 adult male moths emerged during the test	3 replicates, 30 m³ test chamber, 4-5 different traps per test chamber, Exposure time: 7 days Traps: 1. LeMoFa (batch PB of 2004, test item) 2. LeMoFa (batch P287 of 2004, test item) 3. LeMoFa (batch Q283 of 2005, test item) 4. LeMoFa (batch R353 of 2006, test item) 5. LeMoFa (batch S256 of 2007, test item) 6. Adhesive paper (control)	Room temperature 23 °C, Seasonal photo period	No. of **trapped moths** (cumulated): Mean of 2-3 replicates 1. PB 21.0 2. P287 28.5 3. Q28 26.0 4. R353 20.0 4. S256 22.0 5. Control 1.3 Each trap caught between 12 and 28% of the estimated number of adult male moths in the test. The total number of 3-4 traps caught on average 70% of the estimated number of available male moths.	Heller, G. (2008) **(Section B5.10.2/05)**

1) Lebensmittelmotten-Falle

Table B 2.5-2: New efficacy data of Lebensmittelmotten-Falle – Plodia interpunctella

Test substance	**Test organism(s)**	**Test system / concentrations applied / exposure time**	**Test conditions**	**Test results: effects, mode of action, resistance**	**Reference**
Lebensmittelmotten-Falle Pheromone trap with Z,E-Tetradeca-9,12-dienyl acetate (TDA), **Trap inside cardboard box** Ready to use	Plodia interpunctella, laboratory strain, larvae, pupae and emerging adults from a culture vessel , both sexes	2 replicates, 30 m³ test chamber, 3 different traps per test chamber: I) LeMoFa [1)] in cardboard box II) LeMoFa III) Control trap Distance between traps: >2m Traps in height of 1.8-2.0m Change of trap position after 1st replicate 7 days exposure time	Room temperature 22 °C, Seasonal photo period	No. of **trapped moths** (cumulated: 1st / 2nd replicate I) 23 / 32 II) 29 / 22 III) 0 / 1 ⇨ No difference between the original trap and the trap covered by a cardboard box.	Heller, G. (2011) **(Section B5.10.2/06)**
Lebensmittelmotten-Falle Pheromone trap with **1 mg** Z,E-Tetradeca-9,12-dienyl acetate (TDA) **Aged for 5 weeks under in-use conditions**	Plodia interpunctella, laboratory strain, 10 male and 10 female moths per replicate, newly emerged, unmated	4 replicates, 10 male and 10 female adult moths, 15 m³ test chamber 1 trap per test chamber Petri dishes with egg laying medium Exposure period: 5 days (for mating, trapping, egg laying) Incubation of medium: 17 days	I) Aging of traps: 18.4 - 21.4°C, dark II) Test chamber: Temperature: 22.4 - 28.0°C Humidity: 16.4% and 23.6% Lighting: diffuse, even lighting; 12:12 light : dark photoperiod III) Incubation of Petri dishes: 26 - 33°C	No. of **trapped moths** (cumulated (mean, n=4): 1. Test item 3.0 2. Control 3.5 **Hatched larvae** in the petri dishes (mean, n=4): 1. Test item 6.0 2. Control 129.3 Efficacy: 95.4%	Fox-Smith, E.., 2013 **(Section B5.10.2/07)**
Lebensmittelmotten-Falle, Pheromone trap with **1 mg** Z,E-Tetradeca-9,12-dienyl acetate (TDA), **Aged for 5 weeks under in-use conditions**	Ephestia kuehniella, laboratory strain, 10 male and 10 female moths per replicate, newly emerged, unmated	4 replicates, 10 male and 10 female adult moths, 15 m³ test chamber 1 trap per test chamber Petri dishes with egg laying medium Exposure period: 5 days (for mating, trapping, egg laying) Incubation of medium: 27 days	I) Aging of traps: 18.4 - 21.4°C, dark II) Test chamber: Temperature: 23.6 - 28.2°C Humidity: 14.2% and 21.5% Lighting: diffuse, even lighting; 12:12 light : dark photoperiod III) Incubation of Petri	No. of **trapped moths** (cumulated, Ø, n=4): 1. Test item 3.5 2. Control 2.8 **Hatched larvae** (Ø, n=4): 1. Test item 1.8 2. Control 5.3 Efficacy: 66.7%	Fox-Smith, E.., 2013 **(Section B5.10.2/08)**

Ready to use			dishes: 26 - 33°C		
Lebensmittelmotten-Falle, Pheromone trap with **1 mg** Z,E-Tetradeca-9,12-dienyl acetate (TDA), **Aged for 5 weeks under in-use conditions** Ready to use	Ephestia cautella, laboratory strain, 10 male and 10 female moths per replicate, newly emerged, unmated	4 replicates, 10 male and 10 female adult moths, 15 m³ test chamber 1 trap per test chamber Petri dishes with egg laying medium Exposure period: 5 days (for mating, trapping, egg laying) Incubation of medium: up to 24 days	I) Aging of traps: 18.4 - 21.4°C, dark II) Test chamber: Temperature: 23.6 - 28.0°C Humidity: 17.1% and 26.8% Lighting: diffuse, even lighting; 12:12 light : dark photoperiod III) Incubation of Petri dishes: 26 - 33°C	No. of **trapped moths** (cumulated, Ø, n=4): 1. Test item 3.0 2. Control 1.0 **Hatched larvae** (mean, n=4): 1. Test item 2.5 2. Control 8.8 Efficacy: 71.4%	Fox-Smith, E.., 2013 **(Section B5.10.2/09)**
Lebensmittelmotten-Falle, Pheromone trap with **1 mg** Z,E-Tetradeca-9,12-dienyl acetate (TDA), **Aged for 5 weeks under in-use conditions** Ready to use	Ephestia elutella, laboratory strain, 10 male and 10 female moths per replicate, newly emerged, unmated	4 replicates, 10 male and 10 female adult moths, 15 m³ test chamber 1 trap per test chamber Petri dishes with egg laying medium Exposure period: 5 days (for mating, trapping, egg laying) Incubation of medium: up to 23 days	I) Aging of traps: 18.4 - 21.4°C, dark II) Test chamber: Temperature: 22.3 - 28.3°C Humidity: 14.2% and 34.8% Lighting: diffuse, even lighting; 12:12 light : dark photoperiod III) Incubation of Petri dishes: 26 - 33°C	No. of **trapped moths** (cumulated, Ø, n=4): 1. Test item 1.5 2. Control 0.5 **Hatched larvae** (Ø, n=4): 1. Test item 1.5 2. Control 4.8 Efficacy: 68.4%	Fox-Smith, E.., 2013 **(Section B5.10.2/10)**

1) Lebensmittelmotten-Falle

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

The pheromone traps used contain 2 mg of active substance on a carton covered with a adhesive glue. The constant pheromone emission causes that male adults of Plodia interpunctella are impaired to locate and fertilize females. The user (general public and professional) should observe the trap once per week and replace it if its surface is covered with trapped moths. The trap is used indoors only, in rooms or cupboards were well packaged food or feedstuff is stored.
The ready to use traps have a card board size of 130 mm x 90 mm (2- dimensional forms) or of 274 mm x 55 mm for the (triangle form). The card board consists of a carton covered with a adhesive glue and 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 adhesive glue on front of the trap activation of the pheromone.

Tabel 2.6.1-1 Intended use authorised by the Austrian CA

MG/PT	**Field of use envisaged**	**Likely concentration at which a.s. will be used**
MG: 3, PT19	Lebensmittelmotten-Falle contains the pheromone as active component. The traps consist of a cardboard of a size of 130 mm x 90 mm or 274 mm x 55 mm carrying a small amount of the pheromone and are covered with a layer of adhesive glue. When the pheromone trap is activated the pheromone is continuously released for about 6 weeks. The constant pheromone emission will impair the ability of Plodia interpunctella (Indian meal moth) males to locate and fertilize females. Mating is disrupted and infestation rates of dried feeding stuff will be reduced.	The maximum concentration is determined by the amount of Z,E-9,12-Tetradecadien-1-yl acetate (2 mg) on each trap evaporating during a period of 6 weeks.

2.6.2 Assessment of exposure to humans and the environment

No new exposure studies have been submitted.

2.7 Risk assessment for human health

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

No new studies on human health have been submitted. The toxicology of the active substance was examined extensively according to standard requirements. The results of this toxicological assessment can be found in the CAR.

2.7.1.2 Toxicology of the substance(s) of concern

The biocidal product does not contain a substance of concern in the definition of Directive 98/8/EC.

2.7.1.3 Toxicology of the biocidal product

As the biocidal product is identical with the active ingredient, please see above.

The biocidal product contains the active substance Z,E-9,12-Tetradecadien-1-yl acetate (min. purity: 977 g/kg) at an amount of 2 mg per trap.

2.7.1.4 Exposure of professional, non-professional users and the general public users

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).

Human exposure towards the active substance/the biocidal product can take place via different “routes of exposure”, i.e. via inhalation, dermal contact and/or ingestion. Exposure estimates indicate that exposure towards the active ingredient/the biocidal product Lebensmittelmotten-Falle will be negligible.

Table 2.7.2.1-1: Main paths of human exposure to ZE-TDA

Exposure path	Production of Lebensmittelmotten-Falle	Primary (direct) exposure, during use of the b.p.		Secondary (indirect) exposure
	b.p.	Industrial use / Professional use	General public	Incidental contact after application (General public)[2]
Inhalation	Negligible	Negligible	Negligible	Negligible
Dermal	Yes	Negligible	Negligible	Negligible
Oral	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.

Formulation of Lebensmittelmotten-Falle 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 only 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.

For details of the results of the exposure calculations for ZE-TDA please see Doc II-B of the CAR.

2.7.1.5 Exposure of non-professional users and the general public

For details of the results of the exposure calculations for the ZE-TDA please see Doc II-B of the CAR.

2.7.1.6 Exposure to residues in food

No relevant food and feed stuff exposure is to be expected since “Lebensmittelmotten-Falle” contains only 2 mg of ZE-TDA shall not be used in spaces where un-packaged food or feed is kept. For details of the exposure for the ZE-TDA please see Doc II-C of the CAR.

2.7.2 Risk Characterisation

2.7.2.1 Risk for Professional Users at Production of Lebensmittelmotten-Falle

Based on the risk assessment of the active substance, a risk for professional users resulting from the intended use is unlikely. Regarding occupational safety, there are no objections against the intended use.

Risk from exposure during the production of the product (filling, sampling, maintenance, cleaning of the active substance reservoir, see table 2.7.3.1-1) is acceptable.

Table 2.7.3.1-1 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)

2.7.2.2 Risk for professionals, non-professional users and the general public using Lebensmittelmottenfalle

Risk from exposure from use of Lebensmittelmotten-Falle (activating trap and secondary exposure including children and infants, see table 2.7.3.1-2) is acceptable. However for precautionary reasons the "Lebensmittelmotten-Falle" should be kept out of the reach of children and infants.

Table 2.7.3.1-2 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	0.13			**0.13**	NOAEL: 100 AEL system.:	100	750	0.133

	whole amount of a.s. contained in one trap is taken up) by a child (15 kg bw)				1			
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

2.7.2.3 Risk for consumers via residues

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) 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. 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.

Furthermore on the basis of an AEL of 1 mg/kg bw day derived from a sub-chronic rat study (with a structurally related mixture of acetates with C10 to C14 alykyl groups) 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. 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.

2.8 Risk assessment for the environment

No new studies have been submitted and the product applied for authorisation is identical to the active ingredient discussed in the CAR. The intended use and the exposure to the environment is the same as discussed in the CAR. So please see the CAR for further information.

ZE-TDA will dissipate in environmental compartments due to volatilisation and biodegradation. ZE-TDA is readily biodegradable not fulfilling the 10-d window. ZE-TDA is hydrolysed at pH 4 and 9 with DT_{50} values of 9 and 13 hours.

Because of degradation and physico-chemical properties no abiotic effects on the atmospheric environment are likely.

Based on the chemical similarities between wax esters and ZE-TDA it is reasonable to assume 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.

No ecotoxicity studies on ZE-TDA were performed. Acute toxicity to terrestrial mammals is considered to be low.

ZE-TDA is not in discussion to be an endocrine disruptor and there is no substance property or information indicating concern.

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

As the exposure of the aquatic and terrestrial compartment during manufacture of Lebensmittelmotten-Falle 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.

2.9 Measures to protect man, animals and the environment

The information summarised here covers the requirements as described in the TNsG on Data Requirements, common core data for the product, section 8, points 8.1 to 8.8

8.1		**Recommended methods and precautions concerning handling, use, storage, transport or fire (IIA8.1)**
8.1.0	**Methods and precautions concerning placing on the market**	No specific precautions necessary if used correctly.
8.1.1	**Methods and precautions concerning handling and use**	No specific precautions apart from the usual ones for chemical products are necessary to reduce emissions.
8.1.2	**Methods and precautions concerning storage**	**Conditions for safe storage, including any incompatibilities** Requirements to be met by storerooms and containers: Store only in unopened original containers. Information about storage in one common storage facility: Store away from foodstuffs. Further information about storage conditions: Store in cool, dry conditions in well-sealed containers. Specific end use(s): No further relevant information available
8.1.3	**Methods and precautions concerning transport**	**UN-Number** ADR, AND, IMDG, IATA Void **UN proper shipping name** ADR, AND, IMDG, IATA Void **Transport hazard class(es)** ADR, IMDG Class Void No hazardous good ADN/R Class Void **IATA** Class Void Not restricted **Packing group** ADR, IMDG, IATA Void **Environmental hazards** Marine pollutant No **Special precautions to users** Not applicable **Transport in bulk according to**

	Annex II of MARPOL73/78 and the IBC Code	Not applicable
	Transport/Additional information the	Not dangerous according to above specifications
8.1.4	**Methods and precautions concerning fire**	**Extinguishing media** Suitable extinguishing agents: Use fire fighting measures that suit the environment **Advice for firefighters** Protective equipment: Wear self-contained breathing apparatus. Do not inhale explosion gases or combustion gases
8.2		**In case of fire, nature of reaction products, combustion gases, etc. (IIB8.2)**
8.2.1	**Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available**	**Description of first aid measures** General information: Instantly remove any clothing spoiled by the product. After inhalation: Inhalation leading to adverse effects is very unlikely. After skin contact: Instantly wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor. After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor. After swallowing: Swallowing leading to adverse effects is very unlikely. Information for doctor: Most important symptoms and effects, both acute and delayed: No further relevant information available. Indication of any immediate medical attention and special treatment needed: No further relevant information available.
8.2.2	**Emergency measures to protect the environment**	**Environmental precautions** Do not allow to enter drainage system, surface or ground water.
8.3	**Procedures, if any, for cleaning application equipment (IIB8.3)**	Not required.
8.4	**Identity of relevant combustion products in cases of fire (IIB8.4)**	No specific precautions beyond the usual ones for un-substituted hydrocarbon products are necessary. Toxic combustion products are not expected.

8.5	**Procedures for waste management of the biocidal product and its packaging and where relevant, treated waste material for industry, professional users and the general public (non-professional users), e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration (IIB-VIII.8.5)**	**Waste treatment methods** Recommendation: The waste code numbers mentioned are recommendations based on the probable use of the product. A used product can be disposed of in household rubbish. Uncleaned packaging: Recommendation: Dispose of packaging according to regulations on the disposal of packaging.
8.6	**Possibility of destruction or decontamination following release in or on the following: (a) Air; (b) Water, including drinking water; (c) Soil (IIB8.6)**	Not required. ZE-TDA is not toxic or harmful to the environment.
8.6.1	**Possibility of destruction or decontamination following release in the air**	ZE-TDA is instable in air. Release into air is very limited due to small amount handled in Europe.
8.6.2	**Possibility of destruction or decontamination following release in water, including drinking water**	Do not allow undiluted ZE-TDA or large quantities of it to reach ground water, water bodies or sewage system.
8.6.3	**Possibility of destruction or decontamination following release in or on soil**	ZE-TDA is not persistent in soil. Release into soil is very limited due to the small amount handled in Europe.
8.7	**Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms (IIB8.7)**	Not relevant. ZE-TDA has a species specific but non-toxic action. The use of the product precludes exposure to non-target organisms.

8.8	**Specify any repellents or poison control measures included in the preparation that are present to prevent action against non-target organisms (IIB8.8)**	No repellents or poison control measures included in the preparation.
8.5	**Procedures for waste management of the biocidal product and its packaging and where relevant, treated waste material for industry, professional users and the general public (non-professional users), e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration (IIB-VIII.8.5)**	**Waste treatment methods** Recommendation: The waste code numbers mentioned are recommendations based on the probable use of the product. A used product can be disposed of in household rubbish. Uncleaned packaging: Recommendation: Dispose of packaging according to regulations on the disposal of packaging.
8.6	**Possibility of destruction or decontamination following release in or on the following: (a) Air; (b) Water, including drinking water; (c) Soil (IIB8.6)**	Not required. ZE-TDA is not toxic or harmful to the environment.
8.6.1	**Possibility of destruction or decontamination following release in the air**	

The instructions for use must contain the following indications:

- **ZE-TDA shall not be used in spaces where un-packaged food or feed is kept.**

Justification:

- **No residue studies for ZE-TDA are available for food and feedstuff.**

3 Proposal for decision

3.1 Decision for granting an registration

As laid down in the Austrian registration decision directed to the Applicant.

3.2 Limits/restrictions of registration

No.	(A) **Limitations/restrictions of registration** Member States shall ensure that registrations are subject to the following conditions:	**(B) Original "Elements to be taken into account by Member States when authorising products" as described in the Assessment Report of (Z,E)-Tetradeca-9,12-dienyl acetate accompanying the Annex IA inclusion directive 2011/11/EU**	**(C) Elements maintained or changed with justification**
(1)	Registration is only possible for traps containing a maximum of 2 mg of (Z,E)-Tetradeca-9,12-dienyl acetate for indoor use. Justification: If this is not fulfilled, only authorisation is possible.	The maximum amount of (Z,E)-Tetradeca-9,12-dienyl acetate is 2 mg per trap. The representative product evaluated for Annex IA inclusion of the active substance is a pheromone trap containing 2 mg of active substance.	Element maintained. See (A).
(2)	ZE-TDA should only be applied where food and feed-stuff is stored in closed or re-closed package. Justification: No residue studies for (Z,E)-Tetradeca-9,12-dienyl acetate are available for food and feedstuff.	Labels should indicate that biocidal products containing (Z,E)-tetradeca-9,12-dienyl acetate are not to be used in spaces where un-packaged food or feed is kept.	Element maintained. See (A).

Annex:

1. **Summary of product characteristics**
2. **List of studies reviewed**
3. **Analytical methods residues – active substance**
4. **Toxicology and metabolism –active substance**
5. **Toxicology – biocidal product**
6. **Safety for professional operators**
7. **Safety for non-professional operators and the general public**
8. **Residue behaviour**
9. **Study summaries of studies reviewed**

Annex 1: Summary of product characteristics

(a) Product trade name: Lebensmittelmotten-Falle

(b) (i) Qualitative and quantitative information on the composition of the biocidal product

NB: This information is confidential and should not be disclosed to third parties

Active substance(s)				Contents				
Common name	**IUPAC name**	**CAS number**	**EC number**	**Concentration**	**Unit[1]**	**w/w (%)**	**Minimum purity (% w/w)**	**Same source as for Annex IA inclusion**
(Z,E)-Tetradeca-9,12-dienyl acetate	(9Z,12E)-Tetradeca-9,12-dien-1-yl acetate	30507-70-1	Not allocated	2	mg/trap	---	97.7 % w/w	☒ yes ☐ no
Add rows as necessary								

Co-formulants					Contents				
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Concentration**	**Unit**	**w/w (%)**	**Classification**	**Substance of concern**
									☐ yes ☒ no
Add rows as necessary									

Sum	**n.a.**		**n.a.**

1 g/l, g/kg, other. For biological products, the concentration should state the number of activity units/units of potency (as appropriate) per defined unit of formulation (e.g. per gramme or per litre).

(b) (ii) Is the product identical to the representative product, assessed for the purpose of the Annex IA inclusion?

☒ **yes** ☐ **no** ☐ **unknown**

If not, briefly describe the difference.

The product is identical with the active substance included in Annex IA.

(b) (iii) Does the biocidal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?

☐ **yes** ☒ **no**

If yes, does the product comply with Directive 2001/18/EC?

☐ **yes** ☐ **no**

A copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes where provided for by Part B of the above-mentioned Directive was provided.

(c) Manufacturer(s) of the active substance(s) (name(s) and address(es) including location of plant(s))[2]

Name of the active substance: (Z,E)-Tetradeca-9,12-dienyl acetate

Manufacturer

Company Name: Bedoukian Research Inc
Address: 21 Finance Drive
City: Danbury Postal Code: CT 06810 Country: USA
Telephone: +1-203-830-4000 Fax: +1-203-830-4010
E-Mail: customerservice@bedoukian.com

Intra-Community VAT number or, for non EU companies, company registration number:

Manufacturing site(s) (if different)

Company Name:
Address:
City: Postal Code: Country:
Telephone: Fax: E-Mail:

Intra-Community VAT number or, for non EU companies, company registration number:

(d) Formulator(s) of the biocidal product (name(s) and address(es) including location of plant(s))[2]

Formulator
Company Name: Aeroxon Insect Control GmbH
Address: Bahnhofstrasse 35
City: Waiblingen Postal Code: 71332 Country: Germany
Telephone: 0049 71511 7155 Fax: E-Mail: Axel.Engelhart@aeroxon.de

Intra-Community VAT number or, for non EU companies, company registration number:

Formulation site(s) (if different)

Company Name:
Address:
City: Postal Code: Country:
Telephone: Fax: E-Mail:

Intra-Community VAT number or, for non EU companies, company registration number:

2 All sites involved in the manufacturing process of each active substance and of the product must be listed.

Physical state and nature of the biocidal product:

(e) Type of formulation: liquid (Select from pre-defined list)

(f) Ready-to-use product: ☐no ☒ yes

Classification and labelling statements of the biocidal product:

(g) Product classification: not classified

(h) Risk and Safety Phrases: no risk and safety phrases

(i) Product classification according to GHS: not classified

(j) Hazard statement according to GHS: no hazard statements

(k) Intended uses and efficacy:

(l)	PT: 19
(m)	Target harmful organisms: Plodia interpunctella
(n)	Development stage of target organisms: Adults
(o)	Function/mode of action: Mating disruption
(p)	Field of use: Indoors, in rooms or cupboards were food or feedstuff (well packaged) is stored
(q)	Application aim: Protection of food or feedstuff from pests (Indian meal moths)
(r)	User category Non professional users / consumers and professionals
(s)	Application method[3]: Ready to use product

(Repeat box as necessary)

Directions for use[4]:

(t) Manner and area of use[5]:

Lebensmittelmotten-Falle is a glue trap, used indoors, in food storage facilities, to protect stored food or feedstuff (which should be well closed) against the Indian meal moth via mating disruption.

Conditions of use[6]: 1 trap per cupboard or small room, 2 traps for larger rooms

3 Indicate how the product will be applied (e.g. brush, spray, dipping, bait, etc). Where the product is to be used by more than one user category, indicate the application method(s) intended for each user category.
4 Provide in the following sections the information as it is proposed to appear on the product label or appropriate product literature.
5 Indicate information on the target organisms, the mode of action, the field of use, the application aim, the user category and the application method. All efficacy claims should be reflected.
6 Include the details of the directions for use. This should be expressed in terms of amount of product per unit area or a length of application (e.g. dip for 3 minutes). For aerosols and sprays a discharge rate should be included. If the product is a concentrate, indicate the dilution rate(s) here (e.g. dilute 1 part of product with x parts of water).

(u) Instructions for safe use of the product:[7]
Traps should be inspected at least once a week and replaced after 6 weeks or, if covered with moths.

(v) Particulars of likely direct or indirect adverse effects and first aid instructions. Description of first aid measures

After inhalation: Inhalation leading to adverse effects is very unlikely.

After skin contact: Instantly wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.

After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.

After swallowing: Swallowing leading to adverse effects is very unlikely.

Information for doctor:

Most important symptoms and effects, both acute and delayed: No further relevant information available.

Indication of any immediate medical attention and special treatment needed: No further relevant information available.

(w) Instructions for safe disposal of the product and its packaging

The used product can be disposed in household rubbish.

(x) Conditions of storage and shelf-life of the product under normal conditions of storage

Store only in unopened original containers in cool, dry conditions.

(y) Additional information: -

7 Where appropriate, indicate here the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by man or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during use, storage and transport (e.g. personal protective clothing and equipment, measures for protection against fire, covering of furniture, removal of food and feedingstuff and directions to prevent animals from being exposed).

Annex 2: List of studies reviewed

List of new data[8] submitted in support of the evaluation of the active substance

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
No new data have been submitted in support of the evaluation of the active substance									

8 Data which have not been already submitted for the purpose of the Annex IA inclusion.

List of <u>new data</u> submitted in support of the evaluation of the biocidal product

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
B3.7/02	B3.7/02	Wilfinger, W.	2013a	Physico-chemical Properties of the Food Moth Trap "1mg N143 Projekt 5002" before and after Accelerated Storage at 35 °C for 12 Weeks- starting date report- Eurofins Agroscience Services EcoChem GmbH Aeroxon Insect Control Report-no. S12-04232 GLP: yes, GEP: yes Published: no Submitted in: B3.1/01	**Aeroxon**	☐	☒	☒	☐
B3.7/03	B3.7/03	Wilfinger, W.	2013b	Physico-chemical Properties of the Food Moth Trap "2mg N143 Projekt 5002" before and after Accelerated Storage at 35 °C for 12 Weeks-starting date report Eurofins Agroscience Services EcoChem GmbH Aeroxon Insect Control Report-no. S12-04234 GLP: yes Published: no Submitted in: B3.1/02	**Aeroxon**	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
B3.7/04	B3.7/04	Wilfinger, W.	2013c	Physico-chemical Properties of the Food Moth Trap "2 mg N143 Projekt 5002" over 4 Years Storage at 20°C-starting date report Eurofins Agroscience Services EcoChem GmbH Aeroxon Insect Control Report-no. S12-04233 GLP: yes Published: no	Aeroxon	☐	☒	☒	☐
B4.1/02	B4.1/02	Wilfinger, W	2013d	METHOD SET UP AND VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF THE CONTENT OF ACTIVE INGREDIENT (Z,E)-TETRADECA-9,12-DIENYL ACETATE (TDA) IN FOOD MOTH TRAPS Eurofins Agroscience Services EcoChem GmbH Aeroxon Insect Control Report-no. S12-04228 GLP: yes Published: no	Aeroxon	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
B5.10.2/06	B5.10.2/06	Heller, G.	2011	HAS THE USAGE OF A PROTECTIVE CARDBOARD BOX AN INFLUENCE ON THE TRAPPING EFFICACY OF THE AEROXON PHEROMONE TRAP FOR PHYCITID MOTHS? Aeroxon Insect Control Aeroxon Insect Control Report-no. Ingelheim_110518 GLP/GEP: no Published: no	Aeroxon	☐	☒	☒	☐
B5.10.2/07	B5.10.2/07	Fox-Smith, E.	2013a	SIMULATED USE TRIAL TO DETERMINE THE EFFICACY OF LEBENSMITTELMOTTENFALLE (PHEROMONE MOTH TRAP) AGAINST PLODIA INTERPUNCTELLA i2L Research Ltd., Cardiff UK Aeroxon Insect Control Report-no. 12/158A GLP/GEP: no Published: no	Aeroxon	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
B5.10.2/08	B5.10.2/08	Fox-Smith, E.	2013b	SIMULATED USE TRIAL TO DETERMINE THE EFFICACY OF LEBENSMITTELMOTTENFALLE (PHEROMONE MOTH TRAP) AGAINST EPHESTIA KUEHNIELLA i2L Research Ltd., Cardiff UK Aeroxon Insect Control Report-no. 12/158B GLP/GEP: no Published: no	Aeroxon	☐	☒	☒	☐
B5.10.2/09	B5.10.2/09	Fox-Smith, E.	2013c	SIMULATED USE TRIAL TO DETERMINE THE EFFICACY OF LEBENSMITTELMOTTENFALLE (PHEROMONE MOTH TRAP) AGAINST EPHESTIA CAUTELLA i2L Research Ltd., Cardiff UK Aeroxon Insect Control Report-no. 12/158C GLP/GEP: no Published: no	Aeroxon	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
B5.10.2/10	B5.10.2/10	Fox-Smith, E.	2013d	SIMULATED USE TRIAL TO DETERMINE THE EFFICACY OF LEBENSMITTELMOTTENFALLE (PHEROMONE MOTH TRAP) AGAINST EPHESTIA ELUTELLA i2L Research Ltd., Cardiff UK Aeroxon Insect Control Report-no. 12/158D GLP/GEP: no Published: no	Aeroxon	☐	☒	☒	☐
B5.11/01	B5.11/01	Haynes, K.F.; Gaston, L.K.; Mistrot Pope, M.; Baker, T.C.	1984	POTENTIAL FOR EVOLUTION OF RESISTANCE TO PHEROMONES University of California, Riverside, California 92521 Report-no. n/a GLP/GEP: no Published: no		☐	☒	☐	☒
Add rows as necessary									

Annex 3: Analytical methods residues – active substance

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

Date: April 2013

Matrix, action levels, relevant residue and reference

matrix	limit	relevant residue	reference or comment
plant products food of animal origin soil drinking water surface water air body fluids / tissues	For all matrices not attributed except for air		

Methods suitable for the determination of residues (monitoring methods)

Methods for products of plant origin

reference	matrix	LOQ (mg/kg)	principle	comment	owner
Not required according to TNsG on data requirements under the condition that the stored food and feedstuff is kept closed.					

Methods for foodstuffs of animal origin

reference	matrix	LOQ (mg/kg)	principle	comment	owner
Not required according to TNsG on data requirements under the condition that the stored food and feedstuff is kept closed.					

Methods for soil

reference	LOQ (mg/kg)	principle	comment	owner
Not required according to TNsG on data requirements (Guidance document for waiving of data requirements for pheromones for inclusion in Annex IA of Directive 98/8/EC)				

Methods for drinking water and surface water

reference	matrix	LOQ (µg/l)	principle	comment	owner
Not required according to TNsG on data requirements (Guidance document for waiving of data requirements for pheromones for inclusion in Annex IA of Directive 98/8/EC)					

Methods for air

reference	LOQ (µg/m3)	principle	comment	owner
Bockhorn, A. (2006b) **Doc. III-A 4.2/01**	3.39	GC/FID method		Aeroxon Insect Control GmbH

Methods for body fluids/tissue

reference	matrix	LOQ (mg/kg)	principle	comment	owner
Not required according to TNsG on data requirements					

Annex 4: Toxicology and metabolism –active substance

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

Threshold Limits and other Values for Human Health Risk Assessment

Date: April 2013

Summary			
	Value	Study	SF
AEL long-term	1 mg/kg bw day	Sub-chronic study with structurally related substance: isomeric mixture of acetates with C10 to C14 alkyl groups	100
AEL medium-term	See as above	See asabove	See as above
AEL acute	-	-	-

Inhalative absorption	100% (assumption, because of no data)
Oral absorption	100% (assumption, because of no data)

Dermal absorption: 100% (assumption, because of no data)

Classification	
with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	No classification
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	No classification

Annex 5: Toxicology – biocidal product

Lebensmittelmotten-Falle

Date: April 2013

General information	
Formulation Type	Liquid on solid carrier
Active substance(s) (incl. content)	(Z,E)-Tetradeca-9,12-dienyl acetate, 2 mg/trap
Category	non-professional users / consumers, professionals

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)	
Rat LD50 oral (OECD 420)	>2000 mg/kg bw
Rat LD50 dermal (OECD 402)	Assumed to be very low
Rat LC50 inhalation (OECD 403)	>5.2 mg/L
Skin irritation (OECD 404)	Non-irritant
Eye irritation (OECD 405)	Non-irritant
Skin sensitisation (OECD 429; LLNA)	No skin sensitizer (GPMT)

Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)	
Short-term toxicity studies	
Toxicological data on active substance(s)	See Annex 4
Toxicological data on non-active substance(s)	not applicable
Further toxicological information	See assessment report active substance

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Directive 1999/45/EC	No classification
Regulation 1272/2008/EC	No classification

Annex 6: Safety for professional operators

Lebensmittelmotten-Falle

Date: April 2013

Exposure assessment

Exposure scenarios for intended uses (Annex IIIB, point 6.6)

Primary exposure during production of Lebensmittelmotten-Falle

Component	**CAS**	**Potential Dermal Total [mg/day]**	**Potential Dermal Total [mg/kg/d]**	**Actual Dermal Total [mg/day]**	**Actual Dermal Total [mg/kg/d]**	**Inhalation Exposure [mg/kg/d]**	**Model**
(Z,E)-Tetradeca-9,12-dienyl acetate	30507-70-1				0.593	$1.48x10^{-4}$	Model 3 for mixing and loading (EUROPOEM, (TNsG on Human Exposure (2002a), part 2)

Risk assessment

Component	CAS	AEL [mg/kg/d]	Absorption		Inhal ext [mg/kg/d]			Derm ext [mg/kg/d]			RCR ges
			inh	**derm**	**Act. Expo**	**RW**	**RCR**	**Act. Expo**	**RW**	**RCR**	
(Z,E)-Tetradeca-9,12-dienyl acetate	**30507-70-1**	**1**	**100**	**100**	**$1.48x10^{-4}$**			**0.593**			**0.593**

The risk assessment for the substance(s) of concern has to be carried out in almost the same manner.
The product does not contain substances of concern.

Annex 7: Safety for non-professional operators and the general public

Lebensmittelmotten-Falle

Date: April 2013

General information	
Formulation Type	Liquid on solid carrier
Active substance(s) (incl. content)	(Z,E)-Tetradeca-9,12-dienyl acetate, 2 mg/trap
Category	non-professional users / consumers, professionals
Authorisation number	AT/2013/R/00003/19

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

Data base for exposure estimation	
according to	Appendix: Toxicology and metabolism – active substance/CAR

Exposure scenarios for intended uses (Annex IIIB, point 6.6)	
Primary exposure	See Annex 2.7 to PAR
Secondary exposure, acute	See Annex 2.7 to PAR
Secondary exposure, chronic	See Annex 2.7 to PAR

Conclusion:
Exposure of professionals, non-professionals and the consumers to the biocidal product containing 2 mg as active substance per trap is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

Details for the exposure estimates: See Annex 2.7 to PAR

Annex 8: Residue behaviour

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

Date: April 2013

Intended Use (critical application): Lebensmittelmotten-Falle is a glue trap, used indoors, in food storage facilities, to protect stored food or feedstuff (which should be well closed) against the Indian meal moth via mating disruption. The maximum concentration on each trap is 2 mg (Z,E)-Tetradeca-9,12-dienyl acetate which is evaporating during a period of 6 weeks.

Active substance(s):	(Z,E)-Tetradeca-9,12-dienyl acetate
Formulation of biocidal product:	Z,E)-Tetradeca-9,12-dienyl acetate is a liquid applied to a card board partly covered with a adhesive glue.
Place of treatment, numbers and frequency of treatment:	It is used indoors, in food storage facilities, to protect stored food or feedstuff (which should be well closed) against the Indian Meal moth. The maximum concentration on each trap is 2 mg (Z,E)-Tetradeca-9,12-dienyl acetate which is evaporating during a period of 6 weeks. The ready-to-use product is used in rooms or cupboards were food or feedstuff is stored. 1 trap per cupboard should be taken for a small room, 2 traps for larger rooms. Traps should be inspected at least once a week and replaced after 6 weeks or, if covered with moths.

The intended use descriptions of the (Z,E)-Tetradeca-9,12-dienyl acetate-containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The product is to be used for protection of stored and well packaged food against the Indian meal moth. No further data are required concerning the residue behaviour.

Annex 9: Study summaries of studies reviewed

Section B4 (4.1/02) Analytical Methods for Detection and Identification

Annex Point IIB IV.4.1

Z,E-9,12-TETRADECADIEN-1-YL ACETATE, Dispenser

Analytical method: Concentrations of the active substance(s) in the biocidal product

Official use only

1 REFERENCE

1.1	**Reference**	Wilfinger, W. (2013), Method set up and validation of the analytical method for determination of the content of the active ingredient (Z,E)-tetradeca-9,12-dienyl acetate (TDA) in Food Moth Trap, testing facility: Eurofins Agroscience Services, EcoChem GmbH, Niefern-Öschelbronn, Germany, published: no, report No. S12-04228, (Dates of work: 27 October 2012 – January 2013).
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	Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its entry into Annex I/IA / authorisation

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	No
2.2	**GLP**	Yes
2.3	**Deviations**	Not applicable

3 MATERIALS AND METHODS

3.1	**Preliminary treatment**	
3.1.1	Enrichment	The complete unit (glue trap) was cut in pieces of about 4.5 x 1.5 cm by scalpel and scissor. Then 50 mL extraction solvent hexane/n-pentane (50/50); v/v) were added into an appropriate Erlenmeyer flask. The flask was closed with an appropriate plug. Then the front protective paper from the first piece was removed by a pair of tweezers, given in the extraction solvent and mixed by about 5 minutes intensive stirring (about 150 rpm/min) to dissolve the glue from the piece and prevent the pieces sticking during the extraction process. The pieces were given in the same was as described above. Finally, the flask was placed into an ultrasonic bath for two hours. Every 15 minutes the ultrasonic bath was started for two minutes at room temperature. Then about 1 mL of the supernatant of the raw extract (wait for settling down of the cloudiness/turbidness) was transferred into an amber crimp vial and measured by GC/FID. The analytical method was based on a method supplied by the sponsor (see 4.1/01, SOFIA GmbH, report no. 408-11-13/06). The analytical concentrations of the test item in the samples were determined after extraction of the sample in hexane/n-pentane (50/50; v/v).
3.1.2	Cleanup	No further clean up
3.2	**Detection**	
3.2.1	Separation method	GC-FID Column : DB-5 MS, length 30 m, i.d. 0.25 mm, 0.25µm film thickness Carrier gas: Helium 5.0

Section B4 (4.1/02) Analytical Methods for Detection and Identification

Annex Point IIB IV.4.1

Z,E-9,12-TETRADECADIEN-1-YL ACETATE, Dispenser

Analytical method: Concentrations of the active substance(s) in the biocidal product

Injection temperature: 220°C

Detector temperature: 280°C

Oven temperature:

Temp. [0°C]	Time [min]	Rate [0°C/min]	Final Temp. [0°C]
100	1	10	160
160	1	25	240 (15 min)

Flow:

helium: 1.2 mL/min

helium + air: 380 mL/min

helium + hydrogen: 30 mL/min

Purge flow: 20 mL/min

Split flow: 5 mL/min

Injection volume: 1 µl

Retention time of (Z,E)-tetradeca-9,12-dienyl acetate (TDA): about 13.1 min

3.2.2	Detector	Flame ionisation detector (FID)
3.2.3	Standard(s)	-
3.2.4	Interfering substance(s)	Not observed
3.3	**Linearity**	
3.3.1	Calibration range	y = 2252.933 x – 26.176
3.3.2	Number of measurements	5
3.3.3	Linearity	For the calibration of (Z,E)-tetradeca-9,12-dienyl acetate (TDA) a calibration curve of 1. degree was calculated from standards injections from 1.0 mg/L to 100.00 mg/L of (Z,E)-tetradeca-9,12-dienyl acetate (TDA) (1 µL injection volume). The linear correlation coefficient for the calibration range was found to be 1.0000.
3.4	**Specifity: interfering substances**	(Z,E)-tetradeca-9,12-dienyl acetate (TDA) was identified by retention time through comparison with a certified reference item. The retention time of (Z,E)-tetradeca-9,12-dienyl acetate (TDA) in the reference item matched the retention time of (Z,E)-tetradeca-9,12-dienyl acetate (TDA) in the sample. The interferences by other substances present in the preparation was determined by analyzing the blank formulation (supplied by the sponsor).
3.5	**Recovery rates at different levels**	The mean recovery for (Z,E)-tetradeca-9,12-dienyl acetate (TDA) in the preparation was found to be 105%. (2 different concentrations, each with 5 independent samples). The criteria given in SANCO/3030/99 rev.4. are fulfilled (proposed acceptable mean % recovery for the concentration range 0.01-0.1 % active (nominal) is 90-110 %).
3.5.1	Relative standard	The mean relative standard deviation (RSD) was found to be 3.2%.

Section B4 (4.1/02) Analytical Methods for Detection and Identification

Annex Point IIB IV.4.1

Z,E-9,12-TETRADECADIEN-1-YL ACETATE, Dispenser

Analytical method: Concentrations of the active substance(s) in the biocidal product

	deviation	
3.6	**Limit of determination**	Limit of determination: not stated The Limit of Quantification (LOQ) for (Z,E)-tetradeca-9,12-dienyl acetate (TDA) in the preparation was 0.4 mg/unit (lowest measured recovery determination).
3.7	**Precision**	
3.7.1	Repeatability	The relative standard deviation (RSD) for the whole procedure of sample preparation and measurement of five independent weighed units of the test item was found to be 3.2%. The determined relative standard deviation of 3.2% for the complete analytical procedure fulfils the criteria given in SANCO/3030/99 rev. 4 (proposed acceptable RSD for the concentration range 0.01% (Z,E)-tetradeca-9,12-dienyl acetate (TDA) is 5.36% (Horwitz equation).
3.7.2	Independent laboratory validation	Not required for the determination of the active substances in the formulation

Section B4 (4.1/02) **Analytical Methods for Detection and Identification**

Annex Point IIB IV.4.1 Z,E-9,12-TETRADECADIEN-1-YL ACETATE, Dispenser

Analytical method: Concentrations of the active substance(s) in the biocidal product

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

Equipment

- normal laboratory glassware and instrumentation
- HP Gas Chromatograph 5890 Series 2 with FID Detector (Hewlett Packard, Germany)
- Autosampler Chromtech Analytics Liquid Sampler A200SE (Chromtech, Germany)
- Column: DB-5 MS, length 30 m, i.d. 0.25 mm, 0.25 µm film thickness (Agilent J&W, Germany)

Reagents and solvents

n-Hexane (PROLABO 26185.297, Germany)

n-Pentane (PROLABO 24575.320, Germany)

Hexane/n-pentane (50/50; v/v) was used for all standard and sample solutions

Test item

(I) Name: Food moth trap

Batch code: 1mg N143 Projekt 5002

(II) Name: Food moth trap

Batch code: 2mg N143 Projekt 5002

Blank formulation

Name: Lebensmittelmotten-Falle (sticky lure trap)

Batch number of sponsor: S-267_A

Reference item

Name: Z,E-9,12-Tetradecadien-1-yl acetate

Lot No.: 2011060-0028

Method principle

GC/FID analysis

4.2 Conclusion

The analytical method for the determination of the active ingredient (Z,E)-tetradeca-9,12-dienyl acetate (TDA) in Food Moth Traps was validated with respect to specificity, linearity of detector response, precision, accuracy and non-analyte interference of the analytical system following SANCO/3030/99 rev 4. dated 11/07/2000. The analytical system showed a sufficient specificity for analysing (Z,E)-tetradeca-9,12-dienyl acetate (TDA) in Food Moth Traps as outlined in SANCO/3030/99 rev. 4.

4.2.1 Reliability 1

4.2.2 Deficiencies No

Section B4 (4.1/02) Analytical Methods for Detection and Identification

Annex Point IIB IV.4.1

Z,E-9,12-TETRADECADIEN-1-YL ACETATE, Dispenser

Analytical method: Concentrations of the active substance(s) in the biocidal product

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	March 2013
Materials and methods	Agree with the applicant´s version
Conclusion	Agree with the applicant´s version
Reliability	1
Acceptability	Acceptable
Remarks	-

Section B5 Effectiveness against target organisms and intended uses

Subsection (Annex Point)			Official use only
5.1	**Product type(s) and field(s) of use envisaged (IIB5.1)**		
5.1.1	**Product type(s)**		
	MG01: Disinfectants, general biocidal products	Not relevant	
	MG02: Preservatives	Not relevant	
	MG03: Pest control	PT19, Repellents and attractants Use in traps	
	MG04: Other biocidal products	Not relevant	
	Further specification	Not relevant	
5.1.2	**Overall use pattern**	Lebensmittelmotten-Falle is a trap that captures moths by physical means with sticky glue. The biocidal active substance Z,E-Tetradeca-9,12-dienyl acetate (TDA) attracts males of Plodia interpunctella, Ephestia kuehniella, Ephestia cautella and Ephestia elutella and disturbs the reproduction of these pest species.	X
5.2	**Method of application including description of system used (IIB5.2)**	The Lebensmittelmotten-Falle consists of a cardboard carrying the pheromone, which is covered with 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. For the trap itself three different models exist: I) Two dimensional form (used for efficacy trial unless stated otherwise) II) Two dimensional, identical with trap no. I, but inserted into a cardboard box with wholes large enough to allow moths to be caught inside III) Three dimensional, triangle form, trapping area is larger (than in model I and II, but content of a.i. is identical Male adults of Plodia interpunctella, Ephestia kuehniella, Ephestia cautella and Ephestia elutella are attracted by the pheromone and on contact with the glue will be trapped.	x
5.3	**Application rate and if appropriate, the final concentration of the biocidal product and active substance in the system in which the preparation is to be used, e.g. cooling water, surface water, water used for heating purposes (IIB5.3)**	Traps containing the active substance are fixed in rooms or cupboards were food or feedstuff is stored. For cupboards and small rooms one trap is sufficient. For larger storerooms more traps may be required, depending on local circumstances. Each trap contains 2 mg Z,E-9,12-Tetradecadien-1-yl acetate. Under conditions of use a concentration gradient of the pheromone will be found in air. Thus, a final concentration cannot be stated.	X

Section B5 Effectiveness against target organisms and intended uses

5.4	**Number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals (IIB5.4)**	Application: preventive and upon infestation. Traps should be inspected at least once a week and replaced after 6 weeks or, if covered with moths. There is no geographical variation of application rates within the community. No waiting period.	
5.5	**Function (IIB5.5)**	PT19 Attractant (III.2.7)	
5.6	**Pest organism(s) to be controlled and products, organisms or objects to be protected (IIB5.6)**		
5.6.1	**Pest organism(s) to be controlled**	Pyraloidea (I.3.12.3) Plodia interpunctella, Ephestia kuehniella, Ephestia cautella and Ephestia elutella	X
5.6.2	**Products, organisms or objects to be protected**	Food protection (VII.1) Dried food and feedstuffs, e.g. nuts, muesli, cookies, chocolate, flour, rice, dried fruits, fodder, etc. Indoor use (IV.1) To de used at commercial premises (IV 1.3.1), households/ private areas (IV 1.3.2) and public areas (IV 1.3.3).	
5.7	**Effects on target organisms (IIB5.7)**	The pheromone is used in traps consisting of cardboard covered with sticky glue. Male adults of Plodia interpunctella, Ephestia kuehniella, Ephestia cautella and Ephestia elutella are attracted by the pheromone and on contact with the glue will be trapped. Trapped moths will die. By preventing the male moths from finding the females the mating is disrupted, reproduction is inhibited and control of the whole population is achieved.	X
5.8	**Mode of action (including time delay) in so far as not covered by section A5.4 (IIB5.8)**	Attractant (III.2.7) Can control entire population (III.3.3) Residual activity (effective for 6 weeks) (III.4.2) 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, Ephestia kuehniella, Ephestia cautella and Ephestia elutella. The product evaporates this pheromone, attracts male moths and prevents them from finding the female moths. There is no time delay for the attractive effect on male moths. The results of mating disruption are effective with the next generation.	X
5.9	**User: industrial, professsional, general public (non-professional)**		X

Section B5 Effectiveness against target organisms and intended uses

	(IIB5.9)	
	1. Industrial	No industrial use is intended.
	2. Professional	Not intended.
	3. General public	Intended
5.10	**Efficacy data: The proposed label claims for the product and efficacy data to support these claims, including any available standard protocols used, laboratory tests, or field trials, where appropriate (IIB5.10)**	
5.10.1	**Proposed label claims for the product**	Controls Plodia interpunctella, Ephestia kuehniella, Ephestia cautella and Ephestia elutella. Residual activity (III.4.2) (6 weeks after activation of the trap)
5.10.2	**Efficacy data**	Refer to **B5.10.2-01** to **B5.10.2-10**
5.11	**Any other known limitations on efficacy including resistance (IIB5.10)**	
5.11.1	**Use-related restrictions**	The use of Lebensmittelmotten-Falle is limited to indoors.
5.11.2	**Prevention of the development of resistance**	Development of resistance is neither expected nor known.
5.11.3	**Concomitant use with other (biocidal) products**	The Lebensmittelmotten-Falle is not used in direct contact with other biocidal products.

Section B5 Efficacy Data

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	5.3.2013
Comments	5.1.2: Efficient reduction of egg laying (development of larvae in the exposed feedstuff) was shown for Plodia interpunctella only. Thus, all other species have to be removed from product labels, intended used, overall use pattern etc. The overall use pattern has to modified to: The traps will help detecting Plodia interpunctella infestations. The pheromone acts as mating disruption agent. It confuses male moths on their search for females and inhibits mating. A high proportion of females remain unfertilised. A 5.2: Mention P. interpunctella only, see above. 5.3: *Since the applicant doesn't provide room size ranges for the application of 1* or 2 traps, the CA concludes based on the experimental data provided in B5_10_2-04.doc that 1 trap should be recommended for storage facilities of up to 25 m^3, two traps may be required in larger storage rooms. Final concentration: to be based on full evaporation of 2 mg substance in a small storage room, i.e. 10 m^3. 5.6.1: Based on the submitted experimental reports all species except P. interpunctella have to be removed from the list, see 5.1.2 5.7/5.8: All experimental data submitted so far show that mating disruption by confusing males through high pheromone concentration is the main mode of action. Trap catches serve monitoring purposes, but may fail to detect infestation at a very early point in time. 5.9: Adapt statement to 5.6.2; Industrial use is to be included since commercial premises and public areas are explicitly mentioned at point 5.6.2 5.10.1: The label claim has to be adapted according to the experimental data: Lebensmittelmottenfalle reduces infestation of dried food stuff by P. interpunctella through mating disruption. The emitted pheromone confuses males on their search for females and thereby prevents them from reproducing. If males are found on the traps this indicates potential infestation of the premises. Traps should be exchanged after 6 weeks. 5.11.2: The use of only one single compound of the full P. interpunctella sex pheromone blend entails a risk of resistance development. Under continuous application males will be selected to discriminate the single compounds against the full blend. This applies in particular to isolated populations. However, isolated populations are not to be expected in typical households, open public and open industrial areas. Any risk will be limited to highly specific food storage facilities that are either geographically isolated through distance or climatic conditions. It is expected that these are continuously monitored such that resistance would be readily detected. It is therefore deemed sufficient if the applicant submits a brief literature survey when applying for an extension of the product registration period. The survey will have to summarize recent results in resistance development to pheromone treatments.

Section B5 Efficacy Data

Evaluation by Competent Authorities	
	General considerations regarding the experimental desing used in studies B5_10.2_7/8/9/10 Compared to the study B5_10.2_04 infestation rates of test substrates under control treatment were extremely low. A number of factors may have contributed: - Viability of tested females - The tested species have different feeding preferences. One substrate for all, as used in the experiments, may just not work. A selection of natural oviposition substrates might be a better choice, see study B5_10.2_04. - Traps were positioned 20 cm above ground. This may be far below preferred flight levels. - Have the chambers with control treatments ever been exposed to the pheromone*? Simple aeration doesn't help to decontaminate them. The* pheromone may stick to the plastic surfaces and evaporate over time, see Ryne et al. 2007, Journal of Economic Entomology, 100, 1017-1025, with mating disruption under control treatment as a consequence.
Summary and conclusion	The studies submitted justify registration of the product Aeroxon *"Lebensmittelmottenfalle" to control* Plodia interpunctella via mating disruption. The submitted data do not show efficacy for any of the other species.
	COMMENTS FROM …
Date	
Comments	
Summary and conclusion	

Table B5-1: Summary table of data on the method of application including description of system used

Serial number	Product type	Substance(s) used for dilution	Concentration of diluent(s)	Other substance(s) added	Application technique	Remarks
(1)	PT19	Not relevant	Not relevant	Not relevant	Trap is ready to be used after removal of a silicone paper covering the sticky glue.	-

Table B5-2: Summary table of data on the number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals

Serial number	Product type	Application type	Number and timing of application	Waiting periods	Information on recommended variations of the application rate in different locations	Remarks
(1)	PT19	Ready to use product, trap	Trap should be replaced after 6 weeks, or when it is covered with moths.	Not required	Not required	

Table B5-3: Summary of intended uses[1]

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Remarks
				Type	Conc. of as	Method kind	Rate Number min max	Interval between applications	
Indoors, In rooms or cupboards were food or feedstuff is stored.	AT	Lebensmittelmotten-Falle	Plodia interpunctella, Ephestia kuehniella, Ephestia cautella, Ephestia elutella	Ready-to-use	2mg Z,E-9,12-Tetradecadien-1-yl acetate per trap; 0.286 g a.s./kg glue (two dimensional traps, I and II) 0.190 g a.s./kg glue (three dimensional trap, III)	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.	1 trap per cupboard or small room, 2 traps for larger rooms	Up to 6 weeks	Traps should be inspected at least once a week and replaced after 6 weeks or, if covered with moths

[1] adapted from: EU (1998a): European Commission: Guidelines and criteria for the preparation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EC (Article 5.3 and 8,2). Document 1663/VI/94 Rev 8, 22 April 1998

Section B5.10.2/06 Efficacy Data
Annex Point IIB5.10 (Plodia interpunctella)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Heller, G., 2011, HAS THE USAGE OF A PROTECTIVE CARDBOARD BOX AN INFLUENCE ON THE TRAPPING EFFICACY OF THE AEROXON PHEROMONE TRAP FOR PHYCITID MOTHS?, Aeroxon., Ingelheim, Germany, report no. Ingelheim_110518, 18.05.2011	X
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	Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its authorisation	
1.3	**Guideline study**	No guidelines available	
1.4	**Deviations**	Not applicable	
		2 METHOD	
2.1	**Test Substance (Biocidal Product)**	Aeroxon trap in a protective cardboard box Corresponding to the specification given in Section 2, but with the addition of a cardboard box	
2.1.1	Trade name/ proposed trade name	Aeroxon trap in a protective cardboard box	
2.1.2	Composition of Product tested	The composition of the product is given in the confidential section of the dossier.	
2.1.3	Physical state and nature	Physical trap, a sticky glue covered carton containing the active substance. Inserted into a cardboard box with wholes large enough to allow moths to be hatched inside	
2.1.4	Monitoring of active substance concentration	No	
2.1.5	Method of analysis	Not relevant	
2.2	**Reference substance**	Lebensmittelmottenfalle (Aeroxon trap without cardboard box)	
2.2.1	Method of analysis for reference substance	Not relevant	
2.3	**Testing procedure**		
2.3.1	Test population / inoculum / test organism	Plodia interpunctella Laboratory cultures, originating from Detia Freyberg GmbH, larvae, pupae and emerging adults , both sexes	
2.3.2	Test system	Test chamber: 30 m³ Release of moths: Placing of opened culture vessel into test chamber	
2.3.3	Application of TS	Three different traps per test chamber:	

		I) Pheromone trap: Aeroxon trap in a protective cardboard box II) Pheromone trap Aeroxon trap, freely exposed (usual application) III) Control trap: adhesive card without pheromone Traps in a height of 1.8 - 2.0 m. Distance between traps at least 2m. Traps were introduced on day 3 after introduction of culture vessel. Changing of trap positions after repetition 1.
2.3.4	Test conditions	Temperature: 22°C Lighting: natural photoperiod according to the annual season
2.3.5	Duration of the test / Exposure time	Moths remained in the test rooms with the test item for 7 days.
2.3.6	Number of replicates performed	2 replicates
2.3.7	Controls	Control traps were identical to the pheromone traps without cardboard box (same size and coated with the same insect glue), but without pheromone. 2 control replicates
2.4	**Examination**	
2.4.1	Effect investigated	Attraction of the trap.
2.4.2	Method for recording / scoring of the effect	Counting the number of moths sticking to the traps during the 7 days exposure period
2.4.3	Intervals of examination	Counting of trapped moths on day 1 to 7 after introduction of traps. Differences in cumulative trapping results between the 3 different traps were calculated.
2.4.4	Statistics	None
2.4.5	Post monitoring of the test organism	Not applicable
	3 RESULTS	
3.1	**Efficacy**	
3.1.1	Dose/Efficacy curve	A dose/efficacy curve is not applicable, since no different doses were tested.
3.1.2	Begin and duration of effects	Moths were trapped during the whole exposure period (day 1 to 7) in both pheromone traps. No or nearly no moths were caught in blank trap. No significant difference in trapping results between the two models of pheromone traps.
3.1.3	Observed effects in the post monitoring phase	Not relevant
3.2	**Effects against organisms or**	No adverse effects observed

	objects to be protected	
3.3	**Other effects**	None
3.4	**Efficacy of the reference substance**	Not relevant
3.5	**Tabular and/or graphical presentation of the summarised results**	See **Tables B5.10.2/01-02**
3.6	**Efficacy limiting factors**	
3.6.1	Occurrences of resistances	No resistance observed.
3.6.2	Other limiting factors	None

4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS

4.1	**Reasons for laboratory testing**	The test was performed indoors in test rooms. A comparison of a free trap and a trap covered by a cardboard box was intended.
4.2	**Intended actual scale of biocide application**	The tested scale is comparable to the intended use: Test rooms had the size of a small kitchen or a pantry.
4.3	**Relevance compared to field conditions**	
4.3.1	Application method	The application method in this study is equal to the intended use.
4.3.2	Test organism	The tested species is the main target species of the product.
4.3.3	Observed effect	The number of caught moths was determined. A comparison of a free trap and a trap covered by a cardboard box was intended.
4.4	**Relevance for read-across**	No

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	In 2 replicates, mixed sex larvae, pupae and adult moths were released into a test room from a culture vessel. Three days later three traps (pheromone trap with and without cardboard covering and a control trap) were introduced into the test room. For 7 days, trapped moths were counted.
5.2	**Reliability**	Reliable.
5.3	**Assessment of efficacy, data analysis and interpretation**	No difference in trapping results between the two pheromone trap was found.
5.4	**Conclusion**	The test system is targeted at identifying a possible difference between

		covered and non-covered pheromone traps. Test results indicate that no significant difference can be expected.
5.5	**Proposed efficacy specification**	Control of Plodia interpunctella with different pheromone trap models

Section B5.10.2/06 Efficacy Data

Annex Point IIB5.10 (Plodia interpunctella)

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	5.3.2013
Comments	1.1: The experimental design has been commented earlier. Even the experimental report concluded that position effects affected results, e.g. B5_10.2_03. Performing experiments with only 2 replicates under these conditions *doesn't* produce reliable data, as it is again noted in the experimental report that position effects affected the results. 5.4 The similar catch numbers reported in this study (see 1.1) give only a very rough indication that both trap types work equally efficiently. However, efficacy data provided so far indicate that mate disruption is the main mode of action (B5_10_2-07.doc). Under these conditions the exact shape of a trap is irrelevant as long as the active substance is dispensed.
Summary and conclusion	Both trap types can be used a pheromone dispenser to control Plodia interpunctella.
	COMMENTS FROM …
Date	
Comments	
Summary and conclusion	

Table B5.10.2/01. Cumulative number of trapped P. interpunctella- 1st repetition

Trap	Position	No. of trapped moths	[%]
Protected pheromone trap	1	23	44.2
Exposed pheromone trap	3	29 (2f)	55.8
Blank trap	2	0	0
Σ (all traps)		**52**	**100**

Table B5.10.2/02. Cumulative number of trapped P. interpunctella-2nd repetition

Trap	Position	No. of trapped moths	[%]
Protected pheromone trap	3	32 (1f)	58.2
Exposed pheromone trap	1	22	40.0
Blank trap	2	1	1.8
Σ (all traps)		**55**	**100**

Section B5.10.2/07 Efficacy Data
Annex Point IIB5.10 (Plodia interpunctella)

Official use only

1 REFERENCE

1.1	**Reference**	Fox-Smith, E.., 2013, SIMULATED USE TRIAL TO DETERMINE THE EFFICACY OF LEBENSMITTELMOTTENFALLE (PHEROMONE MOTH TRAP) AGAINST PLODIA INTERPUNCTELLA, i2LResearch Ltd., Cardiff, UK, report no. 12/158A, 16.01.2013
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	Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its authorisation
1.3	**Guideline study**	No guidelines available
1.4	**Deviations**	Not relevant

2 METHOD

2.1	**Test Substance (Biocidal Product)**	Lebensmittelmotten-Falle Corresponding to the specification given in Section 2
2.1.1	Trade name/ proposed trade name	Lebensmittelmotten-Falle
2.1.2	Composition of Product tested	The composition of the product is given in the confidential section of the dossier with the exception of content of active ingredient: The tested trap contains only 1 mg of Z,E-9,12-Tetradecadien -1-yl acetate. The reduced content of a.i. per trap (1 mg instead of 2 mg) is used as a worst case to simulate a trap at the end of its shelf life. Lot/Batch numbers: 1 mg N143 Projekt 5002
2.1.3	Physical state and nature	Physical trap, a sticky glue covered carton containing the active substance. Aged for 5 weeks, i.e. the wrapping and the protective sticky layer were both removed from the traps to simulate the efficacy at the end of the claimed use period of 6 weeks.
2.1.4	Monitoring of active substance concentration	No
2.1.5	Method of analysis	Not relevant
2.2	**Reference substance**	No
2.2.1	Method of analysis for reference substance	Not relevant
2.3	**Testing procedure**	
2.3.1	Test population / inoculum / test organism	Plodia interpunctella Laboratory cultures 10 newly emerged unmated male and female moths, each

Section B5.10.2/07 Efficacy Data
Annex Point IIB5.10 (Plodia interpunctella)

2.3.2	Test system	Test chambers: 15 m³ (2.5m × 2.5m × 2.5m) constructed out of clear polythene plastic Egg laying medium: Two 9 cm diameter Petri dishes, each containing approximately 15 g of rearing medium, containing flour, sugar, glycerol, wheat germ oil, water and yeast placed in the centre of the test chamber at approximately 1 m from the floor. Release of moths: males at one end of test chamber, unmated females at the other end.
2.3.3	Application of TS	One aged pheromone trap per test chamber. The trap was then set up vertically, 20cm off the floor in the centre of the test chamber.
2.3.4	Test conditions	I) Aging of traps after activation: 18.4 - 21.4°C, dark II) Test chamber: Ventilation: 2 - 3 times a day opening the door to simulate the opening of a storage room Temperature: 22.4 - 28.0°C Humidity: 16.4% and 23.6% Lighting: diffuse, even lighting; 12:12 light:dark photoperiod III) Incubation of rearing medium: 26 - 33°C
2.3.5	Duration of the test / Exposure time	Moths remained in the test rooms with the test item for 5 days. After that, Petri dishes with laid eggs were transferred into a climate chamber for incubation of eggs for 4 weeks or until signs of eggs or larvae were visible.
2.3.6	Number of replicates performed	4 replicates
2.3.7	Controls	Yes, control traps were identical to the test item traps (same size and coated with the same insect glue), but without pheromone. 4 control replicates
2.4	**Examination**	
2.4.1	Effect investigated	Attraction of the trap, egg production, developed offspring.
2.4.2	Method for recording / scoring of the effect	Counting the number of moths sticking to the traps during the 5 days exposure period, Identifying male moths after 5 days trapping period, Visual assessment of the egg laying medium using a binocular and forceps, Counting the number of larvae after an incubation period of 17 days
2.4.3	Intervals of examination	Counting of trapped moths on day 1 to 5 after introduction. Counting the number of larvae and visual assessment of egg laying medium: day 17.
2.4.4	Statistics	The total number of male moths caught per replicate and the number of larvae found in the petri dishes were subjected to an analysis of variance with treatment as a factor. Prior to analysis data were checked to ensure that the assumptions of the statistical model held and transformed where necessary. Tukey-Kramer tests were used to distinguish between means.
2.4.5	Post monitoring of	Not applicable

	the test organism		
		3 RESULTS	
3.1	**Efficacy**		
3.1.1	Dose/Efficacy curve	A dose/efficacy curve is not applicable, since no different doses were tested.	
3.1.2	Begin and duration of effects	Male moths were trapped during the whole exposure period (day 1 to 5). Larvae were visible from day 11 onwards. No difference in trapping results between blank and pheromone trap. Percentage reduction in larvae (Abbott): 95.4%	
3.1.3	Observed effects in the post monitoring phase	Not relevant	
3.2	**Effects against organisms or objects to be protected**	No adverse effects observed	
3.3	**Other effects**	None	
3.4	**Efficacy of the reference substance**	Not relevant	
3.5	**Tabular and/or graphical presentation of the summarised results**	See **Table B5.10.2/01-02**	
3.6	**Efficacy limiting factors**		
3.6.1	Occurrences of resistances	No resistance observed.	
3.6.2	Other limiting factors	None	
		4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1	**Reasons for laboratory testing**	The test was performed indoors in test rooms, which are comparable to the intended conditions of use.	X
4.2	**Intended actual scale of biocide application**	The tested scale is comparable to the intended use: Test rooms had the size of a small kitchen or a pantry.	
4.3	**Relevance compared to field conditions**		
4.3.1	Application method	The application method in this study is equal to the intended use.	
4.3.2	Test organism	The tested species is the main target species of the product. Test organisms were introduced into the test in a defined number (thus allowing a statistical evaluation) and with a ratio between males and	

		females which can be expected under natural conditions (thus the test product had to compete with the natural pheromone sources of the females in a similar way as under typical conditions of use).	
4.3.3	Observed effect	The number of caught moths and the number of larvae was determined. Trapping of the moths and deterring the male moths are the intended effects, which should result in a reduction of the developing new population. This could be shown with this study.	X
4.4	**Relevance for read-across**	No	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	In 4 replicates, 10 male and 10 female adult moths were released into a test room containing petri dishes with egg laying medium and either a test item trap or a control trap. Moths were allowed to stay in the test room for mating and egg laying for 5 days. The number of moths trapped was assessed daily for a total of 5 days and the number of male moths caught after 5 days was assessed under a microscope once the trap was removed from the chamber. After 5 days the petri dishes with egg laying medium were transferred into a climate chamber for incubation. After 17 days the developed offspring was counted.	X
5.2	**Reliability**	Reliable.	
5.3	**Assessment of efficacy, data analysis and interpretation**	No difference in trapping results between blank and pheromone trap was found. Percentage reduction in larvae (Abbott) in test chambers with pheromone trap compared to those with blank trap was 95.4%.	
5.4	**Conclusion**	The test system represents the intended conditions of use. The high number of catches with the blank trap can be explained by the proximity of the trap (blank trap or pheromone trap) to the egg laying medium. Test results indicate that a good control of the Plodia interpunctella can be achieved. The product is effective against Plodia interpunctella.	
5.5	**Proposed efficacy specification**	Control of Plodia interpunctella, confirmation of efficacy at the end of shelf life, confirmation of efficacy at the end of in-use period	

Section B5.10.2/07 **Efficacy Data**
Annex Point IIB5.10 (Plodia interpunctella)
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	5.3.2013
Comments	3.1.2: Numbers of male moths caught on the pheromone treated traps were almost identical with the numbers caught on control traps. The number of larvae developing under pheromone treatment was significantly lower compared to the number of larvae developing under control treatment as confirmed by statistical testing. 4.3.3: Deterring males is certainly not the purpose of a sex pheromone trap or sex pheromone dispenser. We guess that the applicant wanted to refer to disruption of mate finding under pheromone treatment. 4.1-5.5: Overall, the reported experiment is well designed, except for a lack of calendar dates (when have the experiments been performed) results are well documented in B_5.10.2_08_dossier.pdf. But see B5.doc for a general discussion of experimental conditions. The statistical test results reflect a significant efficacy of the pheromone trap in disrupting mating of Plodia interpunctella as evidenced by significantly reduced infestation rates, see 3.1.2. However, numbers reported on larvae developing in the control treatment are three times exactly 100 or 200 – a very rare coincidence. Please provide the original protocol sheets as fax or PDF. Male catches under pheromone treatment were almost identical to the control treatment.
Summary and conclusion	Experimental methods were reliable (but see general discussion in B5.doc) and overall well documented. Under condition that the original protocol sheets are available, these data show good efficacy of the pheromone to reduce P. interpunctella infestations. The lack of efficacy in catching male P. interpunctella indicates that the main mode of action of the product is disruption of the male ’s ability to locate females.
	COMMENTS FROM …
Date	
Comments	
Summary and conclusion	

Table B5.10.2/01. Mean number of Indian meal moths (Plodia interpunctella) caught on two types of sticky trap after a 5 day experimental period (means ± standard errors, n=4)

Treatment	Mean number of male moths caught after 5 days	Mean number of female moths caught after 5 days	Mean number of total moths caught after 5 days
Blank trap	3.5 (± 0.5)	3 (± 0.6)	6.5 (± 1.0)
Pheromone trap	3 (± 0.9)	1.3 (± 0.5)	4.3 (± 1.2)

Table B5.10.2/02. Mean number and percentage reduction in Indian meal moth larvae (Plodia interpunctella) in rearing medium after a 17 day incubation period (Abbott corrected means ± standard errors, n=4)

Treatment	Mean number of larvae found	Percentage reduction in larvae
Blank trap	129.3 (± 44.2)	N/a
Pheromone trap	6 (± 1.2)	95.4 (± 0.9)

Section B5.10.2/08 Efficacy Data
Annex Point IIB5.10 (Ephestia kuehniella)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Fox-Smith, E.., 2013, SIMULATED USE TRIAL TO DETERMINE THE EFFICACY OF LEBENSMITTELMOTTENFALLE (PHEROMONE MOTH TRAP) AGAINST Ephestia kuehniella, i2LResearch Ltd., Cardiff, UK, report no. 12/158B, 16.01.2013	
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	Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its authorisation	
1.3	**Guideline study**	No guidelines available	
1.4	**Deviations**	Not relevant	
		2 METHOD	
2.1	**Test Substance (Biocidal Product)**	Lebensmittelmotten-Falle Corresponding to the specification given in Section 2	
2.1.1	Trade name/ proposed trade name	Lebensmittelmotten-Falle	
2.1.2	Composition of Product tested	The composition of the tested product is given in the confidential section of the dossier with the exception of content of active ingredient: The tested trap contains only 1 mg of Z,E-9,12-Tetradecadien -1-yl acetate. The reduced content of a.i. per trap (1 mg instead of 2 mg) is used as a worst case to simulate a trap at the end of its shelf life. Lot/Batch numbers: 1 mg N143 Projekt 5002	
2.1.3	Physical state and nature	Physical trap, sticky glue covered cardboard containing the active substance. Aged for 5 weeks, i.e. the wrapping and the protective sticky layer were both removed from the traps to simulate the efficacy at the end of the claimed use period of 6 weeks.	
2.1.4	Monitoring of active substance concentration	No	
2.1.5	Method of analysis	Not relevant	
2.2	**Reference substance**	No	
2.2.1	Method of analysis for reference substance	Not relevant	
2.3	**Testing procedure**		
2.3.1	Test population / inoculum / test organism	Ephestia kuehniella Laboratory cultures 10 newly emerged unmated male and female moths, each	
2.3.2	Test system	Test chambers: 15 m³ (2.5m × 2.5m × 2.5m) constructed out of clear	

		polythene plastic Egg laying medium: Two 9 cm diameter Petri dishes, each containing approximately 15 g of rearing medium, containing flour, sugar, glycerol, wheat germ oil, water and yeast placed in the centre of the test chamber at approximately 1 m from the floor. Release of moths: males at one end of test chamber, unmated females at the other end.
2.3.3	Application of TS	One aged pheromone trap per test chamber. The trap was then set up vertically, 20cm off the floor in the centre of the test chamber.
2.3.4	Test conditions	I) Aging of traps: 18.4 - 21.4°C, dark II) Test chamber: Ventilation: 2 - 3 times a day opening the door to simulate the opening of a storage room Temperature: 23.6 - 28.2°C Humidity: 14.2% and 21.5% Lighting: diffuse, even lighting; 12:12 light:dark photoperiod III) Incubation of rearing medium: 26 - 33°C
2.3.5	Duration of the test / Exposure time	Moths remained in the test rooms with the test item for 5 days. After that, Petri dishes with laid eggs were transferred into a climate chamber for incubation of eggs for 4 weeks or until signs of eggs or larvae were visible.
2.3.6	Number of replicates performed	4 replicates
2.3.7	Controls	Yes, control traps were identical to the test item traps (same size and coated with the same insect glue), but without pheromone. 4 control replicates
2.4	**Examination**	
2.4.1	Effect investigated	Attraction of the trap, egg production, developed offspring.
2.4.2	Method for recording / scoring of the effect	Counting the number of moths sticking to the traps during the 5 days exposure period, Identifying male moths after 5 days trapping period, Visual assessment of the egg laying medium using a binocular and forceps, Counting the number of larvae after an incubation period of 27 days
2.4.3	Intervals of examination	Counting of trapped moths on day 1 to 5 after introduction. Counting the number of larvae and visual assessment of egg laying medium: day 27.
2.4.4	Statistics	The total number of male moths caught per replicate and the number of larvae found in the petri dishes were subjected to an analysis of variance with treatment as a factor. Prior to analysis data were checked to ensure that the assumptions of the statistical model held and transformed where necessary. Tukey-Kramer tests were used to distinguish between means.
2.4.5	Post monitoring of the test organism	Not applicable

Section B5.10.2/08 Efficacy Data
Annex Point IIB5.10 (Ephestia kuehniella)

3 RESULTS

3.1	**Efficacy**	
3.1.1	Dose/Efficacy curve	A dose/efficacy curve is not applicable, since no different doses were tested.
3.1.2	Begin and duration of effects	Male moths were trapped during the whole exposure period (day 1 to 5). Larvae were visible from day 14 onwards. No difference in trapping results between blank and pheromone trap. Percentage reduction in larvae (Abbott): 66.7%
3.1.3	Observed effects in the post monitoring phase	Not relevant
3.2	**Effects against organisms or objects to be protected**	No adverse effects observed
3.3	**Other effects**	None
3.4	**Efficacy of the reference substance**	Not relevant
3.5	**Tabular and/or graphical presentation of the summarised results**	See **Tables B5.10.2/01-02**
3.6	**Efficacy limiting factors**	
3.6.1	Occurrences of resistances	No resistance observed.
3.6.2	Other limiting factors	None

4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS

4.1	**Reasons for laboratory testing**	The test was performed indoors in test rooms, which are comparable to the intended conditions of use.
4.2	**Intended actual scale of biocide application**	The tested scale is comparable to the intended use: Test rooms had the size of a small kitchen or a pantry.
4.3	**Relevance compared to field conditions**	
4.3.1	Application method	The application method in this study is equal to the intended use.
4.3.2	Test organism	The tested species is one of the target species of the product. Test organisms were introduced into the test in a defined number (thus allowing a statistical evaluation) and with a ratio between males and females which can be expected under natural conditions (thus the test

		product had to compete with the natural pheromone sources of the females in a similar way as under typical conditions of use).
4.3.3	Observed effect	The number of caught moths and the number of larvae was determined. Trapping of the moths and deterring the male moths are the intended effects, which should result in a reduction of the developing new population. This could be shown with this study.
4.4	**Relevance for read-across**	No

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	In 4 replicates, 10 male and 10 female adult moths were released into a test room containing petri dishes with egg laying medium and either a test item trap or a control trap. Moths were allowed to stay in the test room for mating and egg laying for 5 days. The number of moths trapped was assessed daily for a total of 5 days and the number of male moths caught after 5 days was assessed under a microscope once the trap was removed from the chamber. After 5 days the petri dishes with egg laying medium were transferred into a climate chamber for incubation. After 27 days the developed offspring was counted.
5.2	**Reliability**	Reliable.
5.3	**Assessment of efficacy, data analysis and interpretation**	No difference in trapping results between blank and pheromone trap was found. Percentage reduction in larvae (Abbott) in test chambers with pheromone trap compared to those with blank trap was 66.7%.
5.4	**Conclusion**	The test system represents the intended conditions of use. The high number of catches with the blank trap can be explained by the proximity of the trap (blank trap or pheromone trap) to the egg laying medium. Test results indicate that a considerable reduction of Ephestia kuehniella larvae can be achieved. The product is effective in reducing Ephestia kuehniella larvae.
5.5	**Proposed efficacy specification**	Control of Ephestia kuehniella, confirmation of efficacy at the end of shelf life, confirmation of efficacy at the end of in-use period

Section B5.10.2/08 **Efficacy Data**
Annex Point IIB5.10 (Ephestia kuehniella)

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 5.3.2023

Comments

3.1.2: Both results, i.e. numbers of male moths caught on the pheromone treated traps compared to control traps and numbers of larvae developing under pheromone treatment compared to the number of larvae developing under control treatment, are not significant as demonstrated by statistical testing.

4.3.3: Deterring males is certainly not the purpose of a sex pheromone trap or sex pheromone dispenser. We guess that the applicant wanted to refer to disruption of mate finding under pheromone treatment.

4.1-5.4: Overall, the reported experiment is well designed, except for a lack of calendar dates (when have the experiments been performed) results are well documented in B_5.10.2_08_dossier.pdf. But see B5.doc for a general discussion of experimental conditions. However, the results are not conclusive for a number of reasons. The number of larvae that developed in the untreated control substrate is extremely low. Ten females have been introduced into the experimental chambers. Assuming they are healthy and viable each of them would lay up to hundreds of viable eggs. However, even under the control treatment, i.e. without pheromone treatment, between 2 and 9 larvae were found. No matter what the reason is (the CA could only speculate at this point), low infestation rates under the control treatment almost certainly prevent a proof of efficacy.

The statistical test results reflect unpredictable results of product application as documented in the raw data. In only one case application of the product lead to substantial decrease in feedstuff infestation, while there was no or a mild effect in the remaining replicates. A less than 50 % probability that a given product item might work is deemed insufficient for product registration against Ephestia kuehniella. Male catches under pheromone treatment were almost identical to the control treatment.

The applicant argued that the number of catches on traps without pheromone treatment (controls) were due to the proximity of the traps to the egg laying substrate. Alternative hypotheses/considerations: (i) Test chambers were made of *polyethylene plastic, thus without "natural" substrate to rest on. Traps were* accepted instead. (ii) In a field situation any pheromone trap would have to compete with natural odour sources, i.e. females sitting on or close to feeding substrates. Attractive objects in the vicinity of a trap therefore correspond to real life. Avoiding these circumstances would rather shed doubt on the reliability of the experimental settings.

Summary and conclusion

Experimental methods were reliable (but see general discussion in B5.doc) and overall well documented. However, neither the capacity to catch male E. kuehniella nor the capacity to reduce feedstuff infestation has been sufficiently demonstrated. Based on the presented data the product is therefore neither suitable to monitor nor to control E. kuehniella. Therefore, the results do not *permit to register "Lebensmittelmotten-Falle" as biocidal product against* E. kuehniella.

COMMENTS FROM …

Section B5.10.2/08 Efficacy Data
Annex Point IIB5.10 (Ephestia kuehniella)

Date
Comments
Summary and conclusion

Table B5.10.2/01. Mean number of Indian meal moths (Ephestia kuehniella) caught on two types of sticky trap after a 5 day experimental period (means ± standard errors, n=4)

Treatment	Mean number of male moths caught after 5 days	Mean number of female moths caught after 5 days	Mean number of total moths caught after 5 days
Blank trap	2.8 (± 0.6)	2.8 (± 0.9)	5.5 (± 1.4)
Pheromone trap	3.5 (± 0.6)	1.0 (± 0.0)	4.5 (± 0.6)

Table B5.10.2/02. Mean number and percentage reduction in Mediterranean Flour moth larvae (Ephestia kuehniella) in rearing medium after a 27 day incubation period (Abbott corrected means ± standard errors, n=4)

Treatment	Mean number of larvae found	Percentage reduction in larvae
Blank trap	5.3 (± 1.5)	N/a
Pheromone trap	1.8 (± 0.9)	66.7 (± 16.3)

Section B5.10.2/09 Efficacy Data
Annex Point IIB5.10 (Ephestia cautella)

Official use only

1 REFERENCE

1.1	**Reference**	Fox-Smith, E., 2013, SIMULATED USE TRIAL TO DETERMINE THE EFFICACY OF LEBENSMITTELMOTTENFALLE (PHEROMONE MOTH TRAP) AGAINST EPHESTIA CAUTELLA, i2LResearch Ltd., Cardiff, UK, report no. 12/158C, 16.01.2013
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	Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its authorisation
1.3	**Guideline study**	No guidelines available
1.4	**Deviations**	Not relevant

2 METHOD

2.1	**Test Substance (Biocidal Product)**	Lebensmittelmotten-Falle Corresponding to the specification given in Section 2
2.1.1	Trade name/ proposed trade name	Lebensmittelmotten-Falle
2.1.2	Composition of Product tested	The composition of the product is given in the confidential section of the dossier with the exception of content of active ingredient: The tested trap contains only 1 mg of Z,E-9,12-Tetradecadien -1-yl acetate. The reduced content of a.i. per trap (1 mg instead of 2 mg) is used as a worst case to simulate a trap at the end of its shelf life. Lot/Batch numbers: 1 mg N143 Projekt 5002
2.1.3	Physical state and nature	Physical trap, a sticky glue covered cardboard containing the active substance. Aged for 5 weeks, i.e. the wrapping and the protective sticky layer were both removed from the traps to simulate the efficacy at the end of the claimed use period of 6 weeks.
2.1.4	Monitoring of active substance concentration	No
2.1.5	Method of analysis	Not relevant
2.2	**Reference substance**	No
2.2.1	Method of analysis for reference substance	Not relevant
2.3	**Testing procedure**	
2.3.1	Test population / inoculum / test organism	Ephestia cautella Laboratory cultures 10 newly emerged unmated male and female moths, each
2.3.2	Test system	Test chambers: 15 m³ (2.5m × 2.5m × 2.5m) constructed out of clear

		polythene plastic Egg laying medium: Two 9 cm diameter Petri dishes, each containing approximately 15 g of rearing medium, containing flour, sugar, glycerol, wheat germ oil, water and yeast placed in the centre of the test chamber at approximately 1 m from the floor. Release of moths: males at one end of test chamber, unmated females at the other end.
2.3.3	Application of TS	One aged pheromone trap per test chamber. The trap was then set up vertically, 20cm off the floor in the centre of the test chamber.
2.3.4	Test conditions	I) Aging of traps: 18.4 - 21.4°C, dark II) Test chamber: Ventilation: 2 - 3 times a day opening the door to simulate the opening of a storage room Temperature: 23.6 - 28.0°C Humidity: 17.1% and 26.8% Lighting: diffuse, even lighting; 12:12 light:dark photoperiod III) Incubation of rearing medium: 26 - 33°C
2.3.5	Duration of the test / Exposure time	Moths remained in the test rooms with the test item for 5 days. After that, Petri dishes with laid eggs were transferred into a climate chamber for incubation of eggs for 4 weeks or until signs of eggs or larvae were visible.
2.3.6	Number of replicates performed	4 replicates
2.3.7	Controls	Yes, control traps were identical to the test item traps (same size and coated with the same insect glue), but without pheromone. 4 control replicates
2.4	**Examination**	
2.4.1	Effect investigated	Attraction of the trap, egg production, developed offspring.
2.4.2	Method for recording / scoring of the effect	Counting the number of moths sticking to the traps during the 5 days exposure period, Identifying male moths after 5 days trapping period, Visual assessment of the egg laying medium using a binocular and forceps, Counting the number of larvae after an incubation period of 16-24 days
2.4.3	Intervals of examination	Counting of trapped moths on day 1 to 5 after introduction. Counting the number of larvae and visual assessment of egg laying medium: day 16-24.
2.4.4	Statistics	The total number of male moths caught per replicate and the number of larvae found in the petri dishes were subjected to an analysis of variance with treatment as a factor. Prior to analysis data were checked to ensure that the assumptions of the statistical model held and transformed where necessary. Tukey-Kramer tests were used to distinguish between means.
2.4.5	Post monitoring of the test organism	Not applicable

Section B5.10.2/09 Efficacy Data
Annex Point IIB5.10 (Ephestia cautella)

		3 RESULTS	
3.1	**Efficacy**		
3.1.1	Dose/Efficacy curve	A dose/efficacy curve is not applicable, since no different doses were tested.	
3.1.2	Begin and duration of effects	Male moths were trapped during the whole exposure period (day 1 to 5). Larvae were visible from day 13 onwards. No difference in trapping results between blank and pheromone trap. Percentage reduction in larvae (Abbott): 71.4%	X
3.1.3	Observed effects in the post monitoring phase	Not relevant	
3.2	**Effects against organisms or objects to be protected**	No adverse effects observed	
3.3	**Other effects**	None	
3.4	**Efficacy of the reference substance**	Not relevant	
3.5	**Tabular and/or graphical presentation of the summarised results**	See **Table B5.10.2/01-02**	
3.6	**Efficacy limiting factors**		
3.6.1	Occurrences of resistances	No resistance observed.	
3.6.2	Other limiting factors	None	
		4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1	**Reasons for laboratory testing**	The test was performed indoors in test rooms, which are comparable to the intended conditions of use.	X
4.2	**Intended actual scale of biocide application**	The tested scale is comparable to the intended use: Test rooms had the size of a small kitchen or a pantry.	
4.3	**Relevance compared to field conditions**		
4.3.1	Application method	The application method in this study is equal to the intended use.	
4.3.2	Test organism	The tested species is one of the target species of the product. Test organisms were introduced into the test in a defined number (thus allowing a statistical evaluation) and with a ratio between males and females which can be expected under natural conditions (thus the test	

		product had to compete with the natural pheromone sources of the females in a similar way as under typical conditions of use).	
4.3.3	Observed effect	The number of caught moths and the number of larvae was determined. Trapping of the moths and deterring the male moths are the intended effects, which should result in a reduction of the developing new population. This could be shown with this study.	
4.4	**Relevance for read-across**	No	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	In 4 replicates, 10 male and 10 female adult moths were released into a test room containing petri dishes with egg laying medium and either a test item trap or a control trap. Moths were allowed to stay in the test room for mating and egg laying for 5 days. The number of moths trapped was assessed daily for a total of 5 days and the number of male moths caught after 5 days was assessed under a microscope once the trap was removed from the chamber. After 5 days the petri dishes with egg laying medium were transferred into a climate chamber for incubation. After up to-24 days the developed offspring was counted.	
5.2	**Reliability**	Reliable.	X
5.3	**Assessment of efficacy, data analysis and interpretation**	No difference in trapping results between blank and pheromone trap was found. Percentage reduction in larvae (Abbott) in test chambers with pheromone trap compared to those with blank trap was 71.4%.	
5.4	**Conclusion**	71.4	
5.5	**Proposed efficacy specification**	Control of Ephestia cautella, confirmation of efficacy at the end of shelf life, confirmation of efficacy at the end of in-use period	

Section B5.10.2/09 Efficacy Data

Annex Point IIB5.10 (Ephestia cautella)

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	5.3.2013
Comments	3.1.2: Both results, i.e. numbers of male moths caught on the pheromone treated traps compared to control traps and numbers of larvae developing under pheromone treatment compared to the number of larvae developing under control treatment, are not significant as demonstrated by statistical testing. 4.1/5.1: Overall, the reported experiment is well designed, except for a lack of calendar dates (when have the experiments been performed) results are well documented in B_5.10.2_09_dossier.pdf. However, it seems that either the low number of replicates or experimental inconsistencies prevented the results from being statistically significant; see statistics section in the experimental report. The statistical data reflect unpredictable results of product application as documented in the raw data. In two cases application of the product lead to substantial decreases in feedstuff infestation, while there was no effect at all in two other replicates. A 50 % probability that a given product item might work is deemed insufficient for product registration against Ephestia cautella. Similarly male catches under pheromone treatment were not significantly different to the control treatment.
Summary and conclusion	Experimental methods were reliable (but see discussion in B5.doc) and overall well documented. However, neither the capacity to catch male E. cautella nor the capacity to reduce feedstuff infestation has been sufficiently demonstrated. Based on the presented data the product is therefore neither suitable to monitor nor to control E. cautella. Therefore, the results do not permit to register *"Lebensmittel*motten-*Falle" as biocidal product against* E. cautella.
	COMMENTS FROM …
Date	
Comments	
Summary and conclusion	

Table B5.10.2/01. Mean number of Ephestia cautella caught on two types of sticky trap after a 5 day experimental period (means ± standard errors, n=4)

Treatment	Mean number of male moths caught after 5 days	Mean number of female moths caught after 5 days	Mean number of total moths caught after 5 days
Blank trap	1.0 (± 0.7)	0.5 (± 0.5)	1.5 (± 1.2)
Pheromone trap	3.0 (± 0.7)	1.3 (± 0.5)	4.3 (± 0.6)

Table B5.10.2/02. Mean number and percentage reduction in Ephestia cautella larvae in rearing medium after a 24 day incubation period (Abbott corrected means ± standard errors, n=4)

Treatment	Mean number of larvae found	Percentage reduction in larvae
Blank trap	8.8 (± 4.0)	N/a
Pheromone trap	2.5 (± 0.6)	71.4 (± 7.4)

Section B5.10.2/10 Efficacy Data
Annex Point IIB5.10 (Ephestia elutella)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Fox-Smith, E.., 2013, SIMULATED USE TRIAL TO DETERMINE THE EFFICACY OF LEBENSMITTELMOTTENFALLE (PHEROMONE MOTH TRAP) AGAINST EPHESTIA ELUTELLA i2LResearch Ltd., Cardiff, UK, report no. 12/158D, 16.01 2013	
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	Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its authorisation	
1.3	**Guideline study**	No guidelines available	
1.4	**Deviations**	Not relevant	
		2 METHOD	
2.1	**Test Substance (Biocidal Product)**	Lebensmittelmotten-Falle Corresponding to the specification given in Section 2	
2.1.1	Trade name/ proposed trade name	Lebensmittelmotten-Falle	
2.1.2	Composition of Product tested	The composition of the product is given in the confidential section of the dossier with the exception of content of active ingredient: The tested trap contains only 1 mg of Z,E-9,12-Tetradecadien -1-yl acetate. The reduced content of a.i. per trap (1 mg instead of 2 mg) is used as a worst case to simulate a trap at the end of its shelf life. Lot/Batch numbers: 1 mg N143 Projekt 5002	X
2.1.3	Physical state and nature	Physical trap, a sticky glue covered carton containing the active substance. Aged for 5 weeks, i.e. the wrapping and the protective sticky layer were both removed from the traps to simulate the efficacy at the end of the claimed use period of 6 weeks.	
2.1.4	Monitoring of active substance concentration	No	
2.1.5	Method of analysis	Not relevant	
2.2	**Reference substance**	No	
2.2.1	Method of analysis for reference substance	Not relevant	
2.3	**Testing procedure**		
2.3.1	Test population / inoculum / test organism	Ephestia elutella Laboratory cultures 10 newly emerged unmated male and female moths, each	
2.3.2	Test system	Test chambers: 15 m³ (2.5m × 2.5m × 2.5m) constructed out of clear	

		polythene plastic Egg laying medium: Two 9 cm diameter Petri dishes, each containing approximately 15 g of rearing medium, containing flour, sugar, glycerol, wheat germ oil, water and yeast placed in the centre of the test chamber at approximately 1 m from the floor. Release of moths: males at one end of test chamber, unmated females at the other end.
2.3.3	Application of TS	One aged pheromone trap per test chamber. The trap was then set up vertically, 20cm off the floor in the centre of the test chamber.
2.3.4	Test conditions	I) Aging of traps: 18.4 - 21.4°C, dark II) Test chamber: Ventilation: 2 - 3 times a day opening the door to simulate the opening of a storage room Temperature: 22.3 - 28.3°C Humidity: 14.2% and 34.8% Lighting: diffuse, even lighting; 12:12 light:dark photoperiod III) Incubation of rearing medium: 26 - 33°C
2.3.5	Duration of the test / Exposure time	Moths remained in the test rooms with the test item for 5 days. After that, Petri dishes with laid eggs were transferred into a climate chamber for incubation of eggs for 4 weeks or until signs of eggs or larvae were visible.
2.3.6	Number of replicates performed	4 replicates
2.3.7	Controls	Yes, control traps were identical to the test item traps (same size and coated with the same insect glue), but without pheromone. 4 control replicates
2.4	**Examination**	
2.4.1	Effect investigated	Attraction of the trap, egg production, developed offspring.
2.4.2	Method for recording / scoring of the effect	Counting the number of moths sticking to the traps during the 5 days exposure period, Identifying male moths after 5 days trapping period, Visual assessment of the egg laying medium using a binocular and forceps, Counting the number of larvae after an incubation period of 17 days
2.4.3	Intervals of examination	Counting of trapped moths on day 1 to 5 after introduction. Counting the number of larvae and visual assessment of egg laying medium: day 17-23.
2.4.4	Statistics	The total number of male moths caught per replicate and the number of larvae found in the petri dishes were subjected to an analysis of variance with treatment as a factor. Prior to analysis data were checked to ensure that the assumptions of the statistical model held and transformed where necessary. Tukey-Kramer tests were used to distinguish between means.
2.4.5	Post monitoring of the test organism	Not applicable

Section B5.10.2/10 Efficacy Data
Annex Point IIB5.10 (Ephestia elutella)

		3 RESULTS	
3.1	**Efficacy**		
3.1.1	Dose/Efficacy curve	A dose/efficacy curve is not applicable, since no different doses were tested.	
3.1.2	Begin and duration of effects	Male moths were trapped during the whole exposure period (day 1 to 5). Larvae were visible from day 17 onwards. No difference in trapping results between blank and pheromone trap. Percentage reduction in larvae (Abbott): 68.4%	
3.1.3	Observed effects in the post monitoring phase	Not relevant	
3.2	**Effects against organisms or objects to be protected**	No adverse effects observed	
3.3	**Other effects**	None	
3.4	**Efficacy of the reference substance**	Not relevant	
3.5	**Tabular and/or graphical presentation of the summarised results**	See **Table B5.10.2/01-02**	
3.6	**Efficacy limiting factors**		
3.6.1	Occurrences of resistances	No resistance observed.	
3.6.2	Other limiting factors	None	
		4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS	
4.1	**Reasons for laboratory testing**	The test was performed indoors in test rooms, which are comparable to the intended conditions of use.	X
4.2	**Intended actual scale of biocide application**	The tested scale is comparable to the intended use: Test rooms had the size of a small kitchen or a pantry.	
4.3	**Relevance compared to field conditions**		
4.3.1	Application method	The application method in this study is equal to the intended use.	
4.3.2	Test organism	The tested species is one of the target species of the product. Test organisms were introduced into the test in a defined number (thus allowing a statistical evaluation) and with a ratio between males and females which can be expected under natural conditions (thus the test	

		product had to compete with the natural pheromone sources of the females in a similar way as under typical conditions of use).	
4.3.3	Observed effect	The number of caught moths and the number of larvae was determined. Trapping of the moths and deterring the male moths are the intended effects, which should result in a reduction of the developing new population. This could be shown with this study.	X
4.4	**Relevance for read-across**	No	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	In 4 replicates, 10 male and 10 female adult moths were released into a test room containing petri dishes with egg laying medium and either a test item trap or a control trap. Moths were allowed to stay in the test room for mating and egg laying for 5 days. The number of moths trapped was assessed daily for a total of 5 days and the number of male moths caught after 5 days was assessed under a microscope once the trap was removed from the chamber. After 5 days the petri dishes with egg laying medium were transferred into a climate chamber for incubation. After 17-23 days the developed offspring was counted.	X
5.2	**Reliability**	Reliable.	
5.3	**Assessment of efficacy, data analysis and interpretation**	No difference in trapping results between blank and pheromone trap was found. Percentage reduction in larvae (Abbott) in test chambers with pheromone trap compared to those with blank trap was 68.4%.	
5.4	**Conclusion**	The test system represents the intended conditions of use. The high number of catches with the blank trap can be explained by the proximity of the trap (blank trap or pheromone trap) to the egg laying medium. Test results indicate that a considerable reduction of the Ephestia elutella larvae can be achieved. The product is effective in reduction of Ephestia elutella larvae.	X
5.5	**Proposed efficacy specification**	Control of Ephestia elutella, confirmation of efficacy at the end of shelf life, confirmation of efficacy at the end of in-use period	

Section B5.10.2/10 Efficacy Data
Annex Point IIB5.10 (Ephestia elutella)

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 5.3.2023

Comments

2.1.2: Provide information on all ingredients.

3.1.2: Both results, i.e. numbers of male moths caught on the pheromone treated traps compared to control traps and numbers of larvae developing under pheromone treatment compared to the number of larvae developing under control treatment, are not significant as demonstrated by statistical testing ($P > 0.05$).

4.3.3: Deterring males is certainly not the purpose of a sex pheromone trap or sex pheromone dispenser. We guess that the applicant wanted to refer to *"*disruption of mate finding*"* under pheromone treatment.

4.1-5.4: Overall, the reported experiment is well designed, except for a lack of calendar dates (when have the experiments been performed) results are well documented in B_5.10.2_08_dossier.pdf. But see B5.doc for a general discussion of experimental conditions. However, the results are not conclusive for a number of reasons. The number of larvae that developed in the untreated control substrate is extremely low. Ten females have been introduced into each experimental chamber. Assuming they are healthy and viable, each female would lay up to several hundreds of viable eggs after mating. However, even under the control treatment, i.e. without pheromone, between 2 and 8 larvae were found, i.e. less than one per female. No matter what the reason is (the CA could only speculate at this point), low infestation rates under the control treatment almost certainly prevent a proof of efficacy.

The statistical test results reflect the very low infestation rates under control treatments. Total numbers of larvae found in the egg laying substrate are only slightly different on a per experiment basis resulting in a non-significant p-value, see 3.1.2. Male catches under pheromone treatment were almost identical to the control treatment.

The applicant argued that the high number of catches on traps without pheromone treatment (controls) were due to the proximity of the traps to the egg laying substrate. First, this must be a copy-paste mistake since extremely few males were caught in both treatments. But even if true alternative hypotheses/considerations would be: (i) Test chambers were made of polyethylene *plastic, thus without "natural" substrate to rest on. Traps were accepted instead*. (ii) In a field situation any pheromone trap would have to compete with natural odour sources, i.e. females sitting on or close to feeding substrates. Attractive objects in the vicinity of a trap therefore correspond to real life. Avoiding these circumstances would rather shed doubt on the reliability of the experimental settings.

Summary and conclusion

Experimental methods were reliable (but see general discussion in B5.doc) and overall well documented. However, neither the capacity to catch male E. elutella nor the capacity to reduce feedstuff infestation has been sufficiently demonstrated. Based on the presented data the product is therefore neither suitable to monitor nor to control E. elutella. Therefore, the results do not permit to register *"Leb*ensmittelmotten-*Falle" as biocidal product against* E. elutella.

Section B5.10.2/10 Efficacy Data
Annex Point IIB5.10 (Ephestia elutella)

	COMMENTS FROM …
Date	
Comments	
Summary and conclusion	

Table B5.10.2/01. Mean number of Ephestia elutella caught on two types of sticky trap after a 5 day experimental period (means ± standard errors, n=4)

Treatment	Mean number of male moths caught after 5 days	Mean number of female moths caught after 5 days	Mean number of total moths caught after 5 days
Blank trap	0.5 (± 0.3)	0.8 (± 0.3)	1.3 (± 0.3)
Pheromone trap	1.5 (± 1.2)	0.0 (± 0.0)	1.5 (± 1.2)

Table B5.10.2/02. Mean number of larvae found and percentage reduction of Ephestia elutella compared to "Blank trap" treatment in rearing medium after a 17 day incubation period (Abbott corrected means ± standard errors, n=4)

Treatment	Mean number of larvae found	Percentage reduction in larvae
Blank trap	4.8 (± 1.4)	N/a
Pheromone trap	1.5 (± 0.6)	68.4 (± 13.6)