Note to the reader:

Please note that CA NL has replaced the former refMS (UK). Below is provided a table specifying the history of the asset.

In 20/07/2016, UK as refMS, authorised the product *EXOSEX SPTab* (*EU-0014018-0000*).

On 13/10/2020, an application was submitted to CA NL for the product *INSECTRAC SPTab*.

Since 31 January 2020, the UK cannot act as the reference Member State as it is no longer an EU Member State. As proposed in the procedure agreed in CG42 (CG-42-2020-08 AP 6.2) and first noted during the 89th CA meeting (CA-Sept20-Doc.7.8) and preliminary agreed in the closed session of the 90th CA-meeting (CA-Dec20.Doc.7.2[1]), NL agreed to take over the role of Reference Member State for this product.

Please note that NL as new refMS did not modify the original PAR. The update of parts of the assessment or SPC would only be performed at the renewal stage of the product.

The amendments made are only related to Annex A (p. 50 – 55). Please find these amendments highlighted in yellow in the PAR.

Application type	**refMS**	**Case / Asset number in the refMS**	**Decision date**	**Assessment carried out (i.e. first authorisation / amendment /renewal)**
SA-APP	UK	EU-0014018-0000	20/07/2016	Assessment report prepared by UK
SA-AAT	UK	BC-JB028328-53	12/12/2016	Correction of error in SPC
SA-AAT	UK	BC-RM028331-36	12/12/2016	Correction of error in SPC
SA-MAC	UK	BC-KV041840-19	05/04/2019	Addition of a single non-active substance has increased the shelf life of the product.
SA-TRS	UK	BC-LJ051127-42	24/05/2019	New authorisation holder
SA-AAT	UK	BC-LX051942-06	04/06/2019	Revised certificate
SA-AAT	UK	BC-WR052009-14	06/06/2019	Revision of certificate and SPC
SA-AAT	UK	BC-EJ052080-58	13/06/2019	Revised certificate

SA-AAT	UK	BC-UG052081-46	13/06/2019	Revised certificate
SA-ADC	UK	BC-KU053178-12	29/08/2019	Change of product name from 'EXOSEX SPTab' to 'INSECTRAC SPTab'
SA-AAT	UK	BC-PE053677-31	03/09/2019	Amended administrative change certificate
SA-RMS	NL	BC-PD062226-47	03/09/2021	Assessment report amended by NL as new refMS

Product Authorisation

EXOSEX® SP_{Tab} Containing [2](9Z,12E)-tetradeca-9,12-dien-1-yl acetate

From Exosect Limited for use in product type 19

UK Competent Authority Product Assessment Report

in accordance with Article 25 (simplified procedure)

Health and Safety Executive
Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS, UK
Tel: +44 (0) 151 951 3868
Fax: +44 (0) 151 951 4889
Email: PA.Biocides@hse.gsi.gov.uk
Website: www.hse.gov.uk/biocides/index.htm

[2] Please note: in accordance with the Corrigendum to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012, concerning the making available on the market and use of biocidal products; the active substance name (Z,E)-Tetradec-9,12-dienyl acetate was changed to (9Z,12E)-tetradeca-9,12-dien-1-yl acetate in April 2019, as part of major change application BC-KV041840-19, submitted 3/8/2018.

1. APPLICANT, ACTIVE INGREDIENT MANUFACTURER, PRODUCT MANUFACTURER/FORMULATOR AND AUTHORISATION HOLDER

1.1 Applicant

Company Name:	International Pheromone Systems Ltd.
Address:	Evolution House, Long Acres Road, Clayhill Industrial Estate, Neston, Cheshire, CH64 3RL
Country:	United Kingdom
Telephone:	+44 (0)151 363 7060
Email:	info@internationalpheromone.co.uk

1.1.1 Authorisation holder

Company Name:	International Pheromone Systems Ltd.
Address:	Evolution House, Long Acres Road, Clayhill Industrial Estate, Neston, Cheshire, CH64 3RL
Country:	United Kingdom
Telephone:	+44 (0)151 363 7060
Email:	info@internationalpheromone.co.uk

1.2 Active Substance Supplier[3]

Name:	Aeroxon Insect Control GmbH
Address:	Bahnhofstraβe 35, D-71332 Waiblingen
Country	Germany
Telephone:	+49 (0) 71 51/17 15 - 0
Fax:	+49 (0) 71 51/17 15 - 30
Email:	

1.2.1 Statement of Technical Equivalence

The manufacturer and manufacturing site for the production of [2](Z,E)-tetradeca-9, 12-dienyl acetate is the same as that evaluated during the active substance approval. Therefore, the UK competent authority believes that there are no issues raised regarding the technical equivalence of the active substance.

1.2.2 Access to documentation

[3] Please note: in accordance with the Corrigendum to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012, concerning the making available on the market and use of biocidal products; the active substance name (Z,E)-Tetradec-9,12-dienyl acetate was changed to (9Z,12E)-tetradeca-9,12-dien-1-yl acetate in April 2019, as part of major change application BC-KV041840-19, submitted 3/8/2018.

The UK competent authority has been provided with a letter of access from Aeroxon Insect Control GmbH which submitted a [3](Z,E)-tetradeca-9, 12-dienyl acetate dossier accepted for active substance approval. This letter dated 29th January 2013 granting Exosect Limited access to the active substance and product documents of the active substance (Z,E)-tetradeca-9, 12-dienyl acetate for the authorisation of their products within European Union (EU).

1.3 Manufacturer/formulator of product

Company Name:	International Pheromone Systems Ltd.
Address:	Evolution House, Long Acres Road, Clayhill Industrial Estate, Neston, Cheshire, CH64 3RL
Country:	United Kingdom
Telephone:	+44 (0)151 363 7060
Email:	info@internationalpheromone.co.uk

1.4 Date of authorisation and authorisation number

Product authorisation granted on: 20th July 2016
Product authorisation expires on: 19th July 2026

Authorisation number: UK-2016-1002

1.5 Amendment history

April 2019 – major change to extend the shelf life of the product to 24 months and change of active substance name

Major change application BC-KV041840-19 was submitted 3/8/2018 to extend the shelf life of the product from 6 to 24 months.

A new coformulant was added to the formulation to achieve this and a 24 month storage stability study was submitted to support the new shelf life.

A shelf life of 6 months was previously supported if the product was stored below 4 ºC. The 24 month storage stability study does not support the 24 month shelf life applied for as part of this major change. However, it does support a shelf life of 6 months, if the product is stored below 25 ºC.

The classification of the product is not affected by the addition of the new co-formulant. The new co-formulant is not a substance of concern at the concentration stated in the Confidential Annex of this PAR.

In addition to the changes requested as part of major change application BC-KV041840-19, the name of the active substance has been changed from (Z,E)-Tetradec-9,12-dienyl acetate

[3] Please note: in accordance with the Corrigendum to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012, concerning the making available on the market and use of biocidal products; the active substance name (Z,E)-Tetradec-9,12-dienyl acetate was changed to (9Z,12E)-tetradeca-9,12-dien-1-yl acetate in April 2019, as part of major change application BC-KV041840-19, submitted 3/8/2018.

to (9Z,12E)-tetradeca-9,12-dien-1-yl acetate. This is in accordance with Corrigendum to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012, concerning the making available on the market and use of biocidal products. All references to (Z,E)-Tetradec-9,12-dienyl acetate within this PAR apply to (9Z,12E)-tetradeca-9,12-dien-1-yl acetate

The following updates have been made to this PAR:

- The conditions of storage have been updated in section 8.1 and 8.2.
- An evaluation of the 24 month storage stability study has been added in section 3.2.2 and Annex A.
- A conclusion regarding the classification of the new formulation has been added to sections 4.1.3 and 5.2.1 of this PAR.
- Details of the formulation change have been added to the Confidential Annex..
- According to the Corrigendum to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012, concerning the making available on the market and use of biocidal products; the active substance name (Z,E)-Tetradec-9,12-dienyl acetate has been changed to (9Z,12E)-tetradeca-9,12-dien-1-yl acetate.

2. GENERAL PRODUCT INFORMATION

2.1 Identity of the Biocidal Product

Table 2.1 Composition of the Biocidal Product

Trade name	**Exosex® SP_{Tab}**			
Active substance	**Minimum Purity (% w/w)**	**CAS No.**	**EC No.**	**Content (% w/w)**
(Z,E) TETRADECA-9, 12-DIENYL ACTETATE	97.7	30507-70-1	250-753-6	1.00
Please refer to R4BP2 for full specification of Exosex® SP_{Tab}: 2013/2676/5576/UK/APP/9433				
Please refer to R4BP3 asset no. UK-0008863-0000				

2.2 Product Type

PT 19

2.3 Procedure for evaluation

Product authorisation

2.4 Classification and Labelling

2.4.1 Proposal by the supplier of the active substance

The supplier of the active substance proposes that (Z,E) TETRADECA-9, 12-DIENYL ACTETATE is not classified according to Annex I of Council Directive 67/548/EEC.

2.4.1.1 Proposal by RMS at Annex I inclusion

The RMS proposed that (Z,E) TETRADECA-9, 12-DIENYL ACTETATE is not classified accordingly to Annex I of Council Directive 67/548/EEC.

2.4.2 Classification and labelling of the biocidal product according to Regulation (EC) 1272/2008

Classification	
Hazard category	None
Hazard statement	None
Labelling	
Signal words	None
Hazard statements	None
Precautionary statements	None
Note	**None**

2.4.2.1 Proposal on the basis of the active substance classification proposed by the active substance supplier

On the basis of the classification proposed by the supplier of the active substance, the Applicant has proposed that the biocidal product does not meet the criteria for classification

2.5 Packaging

Exosex® SP_{Tab} is a 1g wax based compressed powder block, containing 10g/kg (Z,E) TETRADECA-9, 12-DIENYL ACTETATE. It is for use by professional operators only. The product application states that the product is administered into a dispensing unit. The product is supplied in 80mm x 125mm PE/PET Doy bag containing 24x1g tablets.

3 PHYSICOCHEMICAL PROPERTIES

3.1 Physicochemical properties of EXOSEX® SP_{Tab}

The applicant has submitted to the UK competent authority a letter from Aeroxon Insect Control GmbH which grants access to the phys-chem data generated at active substance approval of (Z,E) TETRADECA-9, 12-DIENYL ACTETATE. These data were used to support the methods of analysis of the active substance in the technical material, impurities/residues and formulation analysis. This data is presented in sections 3.3 - 3.4 of this document and the Confidential Annex document.

The following information was provided to determine whether the risk phrases R10, R11, R12 and R65 are required for the product:

Table 3.1 Physico-chemical properties of EXOSEX® SP_{Tab}

Flammability of solids (°C)	**Viscosity**	**Surface Tension**	**Density**

Not highly flammable	Viscosity is not required as the product is a solid formulation	Surface tension is not required as the product is a solid formulation which is not diluted in water	Pour density: 0.34 g/ml Tap density: 0.42 g/ml

The applicant has submitted data for the following endpoints:

Physical state, colour and odour
Density
Accelerated and ambient temperature storage stability

The applicant conducted a flammability study on the formulation. The opinion of the UK competent authority after evaluating a flammability study conducted to Test Method EEC A10 is that the biocidal product is not highly flammable.

The new physicochemical data has been evaluated and is summarised in Annex A of this document.

3.2 Storage stability

The applicant has addressed the storage stability endpoint as follows:

3.2.1 Low temperature storage stability

Table 3.1 Results of 6-month and 12-month stability study at 4°C

Low temperature storage stability	Pre-storage	6-months	12-months
In-house method (6 and 12-months @ 4°C)	10.44 g/kg	9.64 g/kg	8.43 g/kg

3.2.2 Ambient temperature storage stability (please see the Confidential Annex of this PAR for the new formulation)

Table 3.1 Results of 24 month storage stability study at 25°C

Ambient temperature storage stability	Pre-storage	6-months	9-months	24-months
(Z,E)-9,12-tetradecadienyl acetate	10.18 g/kg	9.76 g/kg	8.57 g/kg	7.86 g/kg
Appearance	Yellow tablet, with some flaking of the tablet observed	Acceptable - no change	Acceptable - no change	Acceptable - no change
Packaging stability (Doy sales pack)	-	Acceptable - no change	Acceptable - no change	Acceptable - no change

Based on the data submitted, a shelf life of 6 months can be recommended for the new formulation, due to the active substance falling by 16% after 9 months. In addition, a label recommendation will be required to store the product at temperatures below 25ºC.

3.3 Analytical method for the active substance, impurities and residues

Suitable analytical methods of analysis for the active ingredient were considered in the Competent Authority Report (CAR) at active substance approval and deemed acceptable. This method has been read across to the Product Assessment Report and deemed acceptable to address this data requirement.

Suitable analytical methods of analysis for the impurities in the technical active ingredient were considered in the CAR at active substance approval and deemed acceptable. This method has been read across to the PAR and considered acceptable to address this data requirement.

Residues monitoring methods for soil and water are not required according to TNsG on data requirements (Guidance for Waiving of Data Requirements for Pheromones).

Suitable methods of analysis for the active substance in air were considered in the CAR at active substance approval and deemed acceptable. This method has been read across to the Product Assessment Report and deemed acceptable to address this data requirement.

3.4 Formulation Analysis

The analytical method used to determine the active ingredient in EXOSEX® SP_{Tab} has been fully validated. See the confidential Annex document.

Major change application BC-KV041840-19 was submitted 3/8/2018 to extend the shelf life of the product from 6 to 24 months. A new co-formulant was added to the formulation at a concentration of 0.05% as part of this major change. The Authorisation Holder has therefore submitted specificity data (chromatograms of standards, blank formulation and formulation), which indicates that neither the active substance or internal standard peaks are affect by the addition of the new co-formulant.

3.5 Risk Characterisation for the physico-chemical properties

(Z,E) TETRADECA-9, 12-DIENYL ACTETATE does not exhibit any hazardous physico-chemical properties. The substance is thermally stable and not highly flammable. It does not show any explosive or oxidising properties.

The product is not highly flammable and is not expected to have any explosive or oxidising properties.

The non-active ingredients of the formulated product are inert materials or other substances not expected to be hazardous, therefore there is no expected risk from the formulated product with regards to the physico-chemical properties.

4 HUMAN HEALTH RISK ASSESSMENT

Table 4.1: Intended uses for Exosex SPTab

MG/PT	Field of use envisaged	Likely concentration at which a.s. will be used
MG03: repellents and attractants Product type PT19.03	Stored product Lepidoptera typically *found in food and feedstuff manufacturing and storage facilities.*	10mg/25m^2/application

4.1 HUMAN EXPOSURE ASSESSMENT

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

The assessment of human exposure to Z,E-9,12 tetradecadienyl acetate (ZE-TDA) in the biocidal product Exosex SPTab follows the recommendations and information presented in the document "Human Exposure to Biocidal Products - Technical Notes for Guidance (June 2007)". The biocidal product "Exosex SPTab" consists of a compressed powder (Entostat™) tablet containing 10mg of the Straight Chain Lepidopteran Pheromone (SCLP) Z,E-9,12 tetradecadienyl acetate (ZE-TDA). Details of the formulation of the powder can be found in the confidential annex.

A human exposure assessment for only the active substance (ZE-TDA) in the biocidal product has been provided as the Entostat™ powder is not considered to be a substance of concern (please see confidential annex for further details).

Table 4.2: Exposure Pathways for Exosex SPTab

Exposure path	Primary (direct) exposure, during use of the b.p.		Secondary (indirect) exposure	
	Professional use	Non-professional Use	Other workers & bystanders in treated facilities	Incidental ingestion of food containing residues of a.s.
Inhalation	Yes	Not applicable	Yes	Negligible
Dermal	Yes	Not applicable	Negligible	Negligible
Oral	Not relevant	Not applicable	Not relevant	Yes

[1] This product is for professional use only and is not for use by non-professionals in the Consumer market.

4.1.2 Professional use pattern – position supplied by the applicant

The use pattern and instructions for the use of Exosex SPTab by professionals are described below.

Removal and application of the Exosex SPTab tablet into the dispenser by professional applicators

Physical form and composition description: A compressed powder (Entostat™) tablet containing 10mg of the Straight Chain Lepidopteran Pheromone (SCLP) Z,E-9,12 tetradecadienyl acetate (ZE-TDA).

Use pattern: The product is for indoor, professional use only and deployed by Pest Control Officers (PCO) who are either external trained professional pest control contractors or in-house trained pest control personnel.

Deployment: Exosex SPTab consists of tablets made of compressed Entostat powder containing moth pheromone, and a deployment kit. Exosex SPTab tablets and the deployment kit are packaged separately. The deployment kit consists of:

- A box containing 24 plastic dispensing units with adhesive pads;
- A box containing 24 tablets; and
- Instructions for use.

The tablet is inserted into a plastic dispensing unit which is secured to walls, pillars, machinery and other suitable surfaces (i.e. not above conveyer belts or where powder may fall into a recipe). Dispensers are deployed in a grid format, 1-2 metres above ground level at a distance of 5m between each tablet.

The deployment instructions are as follows:

- Push tablet firmly into dispenser, leaving approximately 50% of the tablet exposed.
- Remove plastic protection from sticky mounting on back of dispenser.
- Clean surface of substrate and press dispenser, tablet upper-most into position.

Dosage: The recommended dosage is 1 tablet (10mg a.s) per $25m^2$. Tablets are replaced every 60 days to ensure continued performance, with a maximum of 6 applications / yr.

Application areas: Range from $25m^2$ upwards, depending on the facility e.g. largest trial area covered approx. $9000m^2$.

Typical facilities include:

- Bakeries
- Confectionary manufacturers
- Pasta factories
- Cereals processing and packing
- Instant drink production and packing
- Flour mills
- Dried fruit and nuts processing and packing
- Spice processing and packing
- Animal and pet food factories
- Tobacco processing & storage facilities
- Packing and storage facilities for finished goods

The number of dispensing units required would therefore range from 1 unit ($25m^2$) to 360 units ($9000\ m^2$).

UK CA approach to assessing potential inhalation exposure to ZE-TDA

During use, exposure to airborne a.s. may occur through volatilisation from the surface of the tablet. The following tiered approach has been considered for people working in the treated facility.

Tier 1 Assessment – Potential inhalation exposure to ZE-TDA at its saturated vapour concentration (SVC)

(i) As an **extreme worst-case assessment,** it has been conservatively assumed that adults (no assessment of children undertaken as they should not be present in such facilities) are exposed to ZE-TDA at its SVC. The SVC for ZE-TDA can be calculated from its vapour pressure of 0.29 Pa at 25 °C and its molecular weight 252.4

The SVC for ZE-TDA is:

$$\frac{\text{vapour pressure (0.29 Pa) x molecular weight (252.4 g/mol)}}{\text{gas constant (8.31451) x temperature in degrees Kelvin (298 }^{\circ}\text{K)}} = \mathbf{29.5416\ mg/m^3}.$$

Product is to be used in areas where children will not be present therefore, exposure assessment is based on adult working in facilities inhaling vapour given off from dispenser for a 10 hour shift.

Potential inhalation exposure to air saturated with ZE-TDA

Tier 1a: Exposure for 24 hours in a day	
Exposure descriptor	**ZE-TDA**
Saturated vapour concentration (mg/m^3)	29.5
Inhalation rate for adult (m^3/24 hours occupancy)	16
Amount of active substance inhaled over 24 hours (mg)	472
Body weight (kg)	60
Systemic dose of a.s. for 24 hours exposure (mg/kg bw/d)	**7.87**
Systemic dose of a.s. for 10 hours exposure (mg/kg bw/d)	**3.28**

Tier 2 Assessments: Potential inhalation exposure using ConsExpo 4.1,
use of the SVC for the Tier 1 assessments are conservative, as it is extremely unlikely that the SVC will be reached for such a product type given ventilation etc.
As a worst case, inhalation exposure is assessed using ConsExpo based on the product being used indoors (no ventilation) and humans will be exposed for 24 hours in a day during a work shift [Tier 2a]; assessments have also been undertaken for 24 hours exposure with ventilation (using default ventilation rate of 0.6 h^{-1} for a non-specified room (Bremmer and Van Veen 2000) in Tier 2b.
However more realistically, given the product is used in a work environment it is anticipated people would only be exposed to the product during their work shift and so exposure assessments for 10-hours exposure with no ventilation [Tier 2c] and (with ventilation) [Tier 2d] have been undertaken.
In the assessments the default human factor values from the Manual of Technical Agreements (HEEG Opinion on 'Default Human Factor Values for Biocidal Products') have been used: body weight: 60 kg (adult); inhalation rate: 16 m^3/24-hour day (adult). The ConsExpo Output Reports, including other parameters used, are given for 24 & 10 hours exposure (with and without ventilation).

ConsExpo 4.1 report

Tier 2a – 24 hour exposure, no ventilation – Inhalation (point estimates):

Compound

molecular weight	252	g/mol
vapour pressure	0.29	Pascal

General Exposure Data

exposure frequency	260	1/year
body weight	60	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	1	fraction
exposure duration	24	hour
room volume	62.5	m3
ventilation rate	0	1/hr
applied amount	10	milligram
release area	7.54	cm2
application duration	24	hour
mass transfer rate	0.000943	m/s

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	16	m3/day

Output

Inhalation (point estimates)

inhalation mean event concentration :	0.0145	mg/m3
inhalation mean concentration on day of exposure:	0.0145	mg/m3
inhalation air concentration year average :	0.0103	mg/m3/day
inhalation acute (internal) dose :	0.00387	mg/kg

Tier 2b – 24 hour exposure, with ventilation – Inhalation (point estimates):

Compound

molecular weight	252	g/mol
vapour pressure	0.29	Pascal

General Exposure Data

exposure frequency	260	1/day
body weight	60	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	1	fraction
exposure duration	24	hour
room volume	62.5	m3
ventilation rate	0.6	1/hr
applied amount	10	milligram
release area	7.54	cm2
application duration	24	hour
mass transfer rate	0.00094	m/s

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	16	m3/day

Output

Inhalation (point estimates)

inhalation mean event concentration :	0.00187	mg/m3
inhalation mean concentration on day of exposure:	0.00187	mg/m3
inhalation air concentration year average :	0.682	mg/m3/day
inhalation acute (internal) dose :	0.000499	mg/kg

Tier 2c – 10 hour exposure (a work shift), no ventilation – Inhalation (point estimates):

Compound

molecular weight	252	g/mol
vapour pressure	0.29	Pascal

General Exposure Data

exposure frequency	260	1/year
body weight	60	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	1	fraction
exposure duration	10	hour
room volume	62.5	m3
ventilation rate	0	1/hr
applied amount	10	milligram
release area	7.54	cm2
application duration	24	hour
mass transfer rate	0.00094	m/s

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	16	m3/day

Output

Inhalation (point estimates)

inhalation mean event concentration :	0.00604	mg/m3
inhalation mean concentration on day of exposure:	0.00252	mg/m3
inhalation air concentration year average :	0.00179	mg/m3/day
inhalation acute (internal) dose :	0.000671	mg/kg

Tier 2d – 10 hour exposure (a work shift), with ventilation – Inhalation (point estimates):

ConsExpo 4.1 report

Compound

molecular weight	252	g/mol
vapour pressure	0.29	Pascal

General Exposure Data

exposure frequency	260	1/year
body weight	60	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	1	fraction
exposure duration	10	hour
room volume	62.5	m3
ventilation rate	0.6	1/hr
applied amount	10	milligram
release area	7.54	cm2
application duration	24	hour

mass transfer rate	0.00094	m/s

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	16	m3/day

Output

Inhalation (point estimates)

inhalation mean event concentration :	0.00168	mg/m3
inhalation mean concentration on day of exposure:	0.0007	mg/m3
inhalation air concentration year average :	0.000498	mg/m3/day
inhalation acute (internal) dose :	0.000187	mg/kg

Potential inhalation exposure using ConsExpo 4.1

Tier	Scenario	Systemic inhalation exposure (i.e. total acute internal dose) [mg a.s./kg bw/day] * Adult
2a	24 hours/day exposure – no ventilation (indoors)	0.00387
2b	24 hours/day exposure – with ventilation (0.6 $h^{-1)}$ (indoors)	0.000499
2c	10 hours/day exposure – no ventilation (indoors)	0.000671
2d	10 hours/day exposure – with ventilation (0.6 $h^{-1)}$	0.000187
* As only 50% of tablet is left exposed, systemic inhalation exposure will be less than values given in table which can be considered worst case		

UK CA approach to assessing dermal exposure

A quantitative risk assessment focusing on direct dermal exposure has been conducted. The following conservative assumptions have been made:

The transfer efficiency of ZE-TDA from the inert material of the tablet surface to the hands is not well characterised; however, data in the TNsG (Part 2, p. 206) provides a transfer efficiency of 2% for transfer of dried fluid from rough sawn timber and a 3 % transfer efficiency of dried liquid pesticide residues from painted wood. The ZE-TDA could be considered to be impregnating the whole of the tablet and to be locked into the tablet (2% transfer coefficient applies), rather than merely coating the surface of the tablet (3% transfer coefficient applies). However, for the purposes of this assessment, the worst-case transfer coefficient of 3% is used in the exposure calculation.

The greatest potential for dermal exposure would occur when the user removes the product from the packaging and pushes it into the dispenser. For this manipulation, it can be conservatively assumed that the user might contact the tablet with their fingertips. An estimated surface area of 35.7 cm^2 is used to represent the fingertips of one hand [Appendix E-3, ECETOC TRA (2009)2 gives the total area of 5 fingertips of one hand as 35.7 cm^2].

Tablet surface area of 7.54 cm^2

A dermal absorption value of 100 % and body weight of 60 kg

Dermal use scenario is only applicable to adults as the product is for professional use only.

Using the assumptions detailed previously, the worst case dermal exposure associated with applying one tablet (containing 10 mg ZE-TDA) into the dispenser is estimated to be:

10 mg / 7.54 cm^2 x 3 % x 35.7 cm^2 x 100 % / 60 kg = **0.02 mg a.s./kg bw/day**

In order to follow the deployment instructions, it is assumed that it takes 5 minutes to deploy Exosex SPTab according to the recommended grid format. It is also assumed that Exosex SPTab is deployed over the duration of 1 hour per day. This is based on the default durations for "Placing bait" stated for Product Type 19 and Product Type 14 in the Excel use pattern database which is referenced in the document "Human Exposure to Biocidal Products - Technical Notes for Guidance (June 2007)" Over the course of 1 hour per day the number of Exosex SPTab tablets that would be deployed by a professional worker is 12 tablets (60 minutes/5 minutes = 12). This would result in a total estimated dermal exposure to ZE-TDA of:

0.02 mg a.s./kg bw/day x 12 = 0.28 mg a.s./kg bw/day without gloves and 0.028 mg a.s./kg bw/day with gloves.

These exposure estimates must be regarded as conservative based on the above assumptions (particularly the assumption that all a.s. is on the surface of the tablet and thus 3 % is available for transfer to the fingers).

Exposure summary

Exposure Scenario	**Systemic dose (mg/kg bw/day)**
Tier 1 Inhalation exposure (people working in the treated facilities for 10 hours)	3.28
Tier 2 Inhalation exposure (people working in the treated facilities for a 10 hour shift with ventilation)	0.000187
Dermal exposure (from PCO/workers touching tablet)	0.28 (without gloves) 0.028 (with gloves)

4.1.3 – Addition of a new coformulant to extend the shelf life of the product

As part of major change application BC-KV041840-19 (submitted 3/8/2018), a new co-formulant was added at 0.05% w/w, to extend the shelf life of the product to 24 months (please see the confidential annex of this PAR for details of the change to the formulation).

According to the Guidance on the Application of the CLP Criteria (version 5.0, July 2017) its final concentration is well below the generic cut-off values triggering the classification of EXOSEX SPTAB for acute oral toxicity, skin and eye irritation and respiratory irritation. Therefore, the overall classification of EXOSEX SPTAB for

Human Health effects remains as in Table 2.4.2 Classification and labelling of the biocidal product according to Regulation (EC) 1272/2008. No classification is required.

4.2 RISK CHARACTERISATION FOR HUMAN HEALTH

Inhalation Exposure

Tier 1

Active substance	AEL (mg/kg bw/day)	Systemic dose (mg/kg bw/day)	% AEL
ZE-TDA	1	7.87	787
ZE-TDA	1	3.28	328

Exposure exceeds AEL therefore a Tier 2 more realistic refined assessment using Consexpo 4.1 has been carried out.

Tier 2

Potential inhalation exposure using ConsExpo 4.1

Tier	Scenario	Systemic inhalation exposure (i.e. total acute internal dose) [mg a.s./kg bw/day] Adult	AEL (mg/kg bw/day)	% AEL
2a	24 hours/day exposure – no ventilation (indoors)	0.00387	1	0.387
2b	24 hours/day exposure – with ventilation (0.6 $h^{-1)}$ (indoors)	0.000499	1	0.0499
2c	10 hours/day exposure – no ventilation (indoors)	0.000671	1	0.0671
2d	10 hours/day exposure – with ventilation (0.6 $h^{-1)}$	0.000187	1	0.0187

Exposure is within AEL and thus is considered acceptable.

Dermal exposure

Using the assumptions detailed previously, the worst case dermal exposure associated with applying one tablet (containing 10 mg ZE-TDA) into the dispenser is estimated to be:

10 mg / 7.54 cm2 x 3 % x 35.7 cm2 x 100 % / 60 kg = **0.02 mg a.s./kg bw/day**

In order to follow the deployment instructions, it is assumed that it takes 5 minutes to deploy Exosex SPTab according to the recommended grid format. It is also assumed that Exosex SPTab is deployed over a duration of 1 hour per day. This is based on the default durations for “Placing bait” stated for Product Type 19 and Product Type 14 in the Excel use pattern database which is referenced in the document “Human Exposure to Biocidal Products - Technical Notes for Guidance (June 2007)” Over the course of 1 hour per day the number of Exosex SPTab tablets that would be deployed by a professional worker is 12 tablets (60 minutes/5 minutes = 12). This would result in a total estimated dermal exposure to ZE-TDA of:

0.02 mg a.s./kg bw/day x 12 = 0.28 mg a.s./kg bw/day without gloves and 0.028 mg a.s./kg bw/day with gloves.

These exposure estimates must be regarded as conservative based on the above assumptions (particularly the assumption that all a.s. is on the surface of the tablet and thus 3 % is available for transfer to the hands).

Comparing 0.28 mg a.s./kg bw/day without gloves to AEL of 1 mg/kg bw/day gives % of AEL of 28. Exposure is therefore considered acceptable.

5. ENVIRONMENTAL RISK ASSESSMENT

5.1 ENVIRONMENTAL EXPOSURE ASSESSMENT

The active substance (Z,E)-tetradeca-9,12-dienyl acetate contained within Exosex SPTab is part of the sex pheromone blend naturally produced by the females of the Indian meal moth, Plodia interpunctella, to call males for mating. The use pattern for Exosex SPTab is directly related to the representative product from the AR of (Z,E)- tetradeca-9,12-dienyl acetate (or ZE-TDA) under PT 19 as an attractant. ZE-TDA is also a member of a group of compounds known as Straight Chain Lepidopteran Pheromones (or SCLP). It is applied to dispenser systems from which the a.s evaporates and confuses the male moths so that either they do not find the females or they are guided into a trap.

The representative product evaluated at active substance approval used a concentration of 2 mg a.s. in a ready to use adhesive trap for general public and professional use, with one trap used per 15 m3 room volume. The maximum frequency of treatment is weekly and the size of area protected can range from cupboards (e.g. 1 m3) to larger storage rooms (e.g. 300 m3). No emissions assessment was carried out in the AR and the Guidance for Waiving of Data Requirements for Pheromones for Inclusion in Annex I/ IA of Directive 98/8/EC, 2005 was cited in that;

One main principle for data requirements in the Guidance is that - in case of outdoor use – exposure levels which are comparable to natural emissions are safe for non-target species and therefore test data on SCLP will only be required if their use will result in environmental contamination exceeding natural environmental levels. According to Guidance this equates to an outdoor application rate of up to 375 g SCLP/ ha/ year.

The further reasoning for the lack of PECs in the ZE-TDA Assessment Report (AR) was that exposure to all environmental compartments would be insignificant – based on the low levels of ZE-TDA in product, the exclusively indoor use pattern and the potential for degradation of a.s.

ZE-TDA is readily biodegradable “failing the 10-day window” in an OECD 301 D study with 71 % degradation after 28 d (but > 50 - < 60 % after 10 d) with a predicted photo-transformation in air by OH-radicals of 2.7 and 3.1 hours (trans and cis-isomers, respectively) and by ozone radicals of 0.7 and 1.1 hours (trans- and cis-isomers).

According to guidance in the draft ESD for PT 19 on attractants (section 3.5) the main emission will be into the air compartment with only a limited fraction which will be transformed into the liquid form. With reference to the indoor use, emissions to indoor air are completely released to the outdoor air compartment during e.g. venting of the room (cf. OECD, 2008).

As ZE-TDA has a reported Log Kow >6.5, vapour pressure of 0.29 Pa at 25 °C and water solubility of only 0.119 mg l-1 the calculated Henry’s constant is 381.76 Pa m3 mol-1 indicating ZE-TDA is considered to be volatile. Hence emissions of a.s are expected to occur solely via the air.

In the absence of any measured ecotoxicological data used to derive a PNEC value the UK CA has chosen to compare the calculated emission from Exosex SPTab in air to the natural environmental levels of SCLP given in the data waiving guidance.

Calculation of indoor emission to air

The current application for Exosex SPTab is for professional use indoors to control stored product moth infestation in food, feedstuff and tobacco manufacturing and storage facilities. The product is supplied as a compressed wax powder tablet with a total weight of 1 g which contains 10 mg of a.s. Each tablet is inserted into a hanging dispenser set up about 1 – 2 m above ground level, spaced every 5 m in a grid format.

As guidance in the draft ESD for PT 19 is more applicable to a fixed number of attractant products in a domestic situation, the UK CA has used the following approach to calculate the indoor emission of ZE-TDA;

Each tablet is expected to last 60 d (2 months) before it should be replaced and is intended to provide airborne pheromone to buildings with a floor area of 25 m2. Assuming a minimum ceiling height of only 2 m as worst case, the internal volume treated by each tablet would be 2 x 25 = 50 m3. Using the maximum rate of loss of 10.06 µg/ h per gram (or tablet) as provided by the applicant gives an emission of;

10.06 µg h-1 x 24 h / 50 m^3 = 4.83 x 10-3 mg m-3 d-1

By way of comparison, the representative product evaluated as part of the active substance approval containing 2 mg a.s. to treat 15 m^3 per week gives an emission of;

2 mg / (15 m^3 x 7 d) = 1.905 x 10-2 mg m-3 d-1

Hence the emission to air from Exosex SPTab is less than that of the representative product evaluated as part of the active substance approval.

Calculation of outdoor emissions to air at 100 m from a point source

As an extreme worst case the UK CA has calculated the outdoor emission when a 9000 m2 room containing a.s. is vented assuming 100 % of the a.s. present in the room is present as vapour and is emitted on venting.

The distance of 100 m from a factory or similar industrial facility was chosen to represent the average distance between the emission source and the border of an industrial site (ECHA guidance on ERA) and can be thought of as a technosphere most likely encompassing a car park and/ or delivery area. In all likelihood a natural environment is unlikely to be found within 100 m of the facility. A 9000 m2 room was chosen as an example of the largest trial area covered in the application.

A 9000 m2 room requires 360 tablets, each tablet contains 10 mg a.s. giving a total of 360 x 10 mg = 3600 mg a.s. A calculation has then been made using the assumptions detailed in section 2.3.8.2 in the draft ECHA Guidance on environmental risk assessment (2013) to calculate Clocalair where;

Clocalair = Elocalair, x Cstdair (equation 40)

Cstdair, the concentration in air at source strength of 1 kg d-1 = 2.78 x 10-4 mg m-3

Elocalair = 3.6 x 10-3 kg

Hence 3.6 x 10-3 kg x 2.78 x 10-4 mg m-3 = 1.00 x 10-6 mg m-3 or 1.00 x 10-9 g m-3

A comparison of this value to the naturally occurring levels of SCLP of 375 g / ha/ year taken from the AR and the Guidance for Waiving of Data Requirements (2005) has then been made;

Assuming year round use 375 g SCLP / 365 = 1.027 g / ha/ day

(1 hectare = 10 000 m^2 and assuming 10 m height gives 100 000 m^3)

So 1.027 g / ha = 1.027 x 10-5 g m-3 day

Hence if the worst case predicted emission did reach the environment, levels of SCLP are predicted to be well below natural levels at a distance of 100 m from the factory.

5.2 RISK CHARACTERISATION FOR THE ENVIRONMENT

UK CA: As there are no PNEC values to base a risk assessment upon the UK CA has calculated indoor emissions to air and shown that the predicted concentration is less than that predicted for the representative product evaluated as part of the active substance approval. The UK CA has also demonstrated that should a worst case emission from the indoor use of Exosex SPTab occur, levels of ZE-TDA at a distance of 100 m from an industrial facility are predicted to be much less than naturally occurring levels (according to the Guidance for Waiving of data requirements for pheromones 2005).

Furthermore any a.s reaching air is predicted to rapidly be degraded by photooxidation with DT50 values of approximately 3 hours or less.

Based on the proposed indoor use pattern for this product no direct release to STP, to surface water and the sediment are anticipated. In addition ZE-TDA will volatise from surface water based on the Henry´s law constant (381.76 Pa m3 mol-1) leading to fast dissipation of the parent compound in addition to being readily biodegradeable.

Hence no risk is predicted to occur in any environmental compartment for this product.

Primary and Secondary Poisoning of Birds and Mammals

As accepted in the AR based on the limited indoor use pattern of this product (Z, E)-tetradeca-9,12-dienyl acetate is not expected to pose a risk from primary or secondary poisoning.

Mixed actives assessment

As Exosex SPTab contains only (Z, E)- tetradeca-9,12-dienyl acetate as its active substance, a mixed actives assessment is not required.

Substances of Concern

There are no substances of concern identified in the formulation for the environment.

Regulatory decision for Exosex SPTab

On the basis of the emissions assessment to air the UK CA considers that the use of Exosex SPTab does not present an unacceptable risk to the environment if applied indoors according to its label instructions for use.

5.2.1 – Addition of a new coformulant to extend the shelf life of the product

As part of major change application BC-KV041840-19 (submitted 3/8/2018), a new co-formulant: was added at 0.05% w/w, to extend the shelf life of the product to 24 months (please see the confidential annex of this PAR for details of the change to the formulation).

According to the Guidance on the Application of the CLP Criteria (version 5.0, July 2017) no classification is required for EXOSEX SPTAB following the addition of this new coformulant.

6 EFFICACY

6.1 FUNCTION

The product is an insect attractant (PT 19).

6.2 ORGANISM(S) TO BE CONTROLLED AND PRODUCTS, ORGANISMS OR OBJECTS TO BE PROTECTED.

Exosex SPTab is used to control:
Plodia interpunctella (Indian meal moth), *Ephestia kuehniella* (Mediterranean flour moth), *E. elutella* (warehouse/cocoa moth), *Cadra cautella* (almond moth) and *C. figuliella* (raisin moth).

6.3 EFFECTS ON TARGET ORGANISMS

Exosex SPTab is a pheromone-based system which is used to control problem infestations of stored product Lepidoptera (moths) commonly found in food and feedstuff manufacturing and storage facilities.

The product acts by mating disruption, with the active substance disrupting the reproductive cycle of the stored product Lepidopteran species.

The product consists of 1 gram cylinders of compressed wax powder containing 10 mg of the active substance. These cylinders, also referred to as tablets, are inserted into the ribbed receptor of a plastic dispensing unit. This is then attached to a suitable vertical support e.g. walls, columns, pillars, machinery, etc. via sticky 'grip lock' strip on the back.

The product is applied at a rate of approximately 1 compressed powder cylinder per 25 m^2 of floor surface i.e. approximately 10 mg active substance 25 m^{-2}. The tablets are claimed to be active for approximately 60 days.

6.4 EVALUATION OF THE LABEL CLAIMS

The following label claims are to be included:

'A pheromone based system for long term control of stored product moths'.

6.5 NEW DATA

New studies for the product Exosex SPTab are as follows:

Stored product Lepidoptera

[redacted]. Evaluation of the impact of the Exosex SPTab auto-confusion system on stored-product Lepidoptera populations in a UK organic produce warehouse. Report No. [redacted].

[redacted] investigated the efficacy of Exosex SPTab against *E. kuehniella* and *P. interpunctella.*

The study was a field trial conducted in the UK in 2008 and 2009. The trial location was an organic produce warehouse with a ground area of approximately 1000 m^2, and the test area consisted of 3 large rows of stacked pallet cages divided by access pathways.

The study report stated that, due to over-winter temperatures in the warehouse, the moth population showed clear seasonality. For this reason, monitoring had historically been conducted from the middle of April through to the end of October. Therefore, in the first (pre-treatment) phase of the study, the moth population was monitored for a period of 196 days during the same period i.e. 18/4/08 – 31/10/08. The applicant has indicated to the UK CA that, when conducting field trials in commercial sites, it's not always possible to collect trap catch data at the same time intervals. This was the case with this field trial, where monitoring was conducted on an approximately weekly basis.

Monitoring was conducted by means of 27 pheromone baited adult male monitoring traps placed directly on racking at a height of approximately 1.2 m above ground level.

The second (treatment) phase was conducted in 2009 over the same time period as the first phase, and at the same time of year (29/4/09 – 27/10/09). A total of 40 dispensers (each containing 10.0 mg active substance) were placed in the warehouse in a grid pattern (approximately 5 x 5 m) to give an overall distribution of approximately 1 tablet 25.0 m^{-2}. For each dispenser, the initial tablets were replaced after 58 days, the replacement tablets themselves replaced 67 days later, and these tablets replaced 56 days later.

During the treatment phase, the same number of monitoring traps was used as in the first phase, and these were placed in the same locations as in the first phase. Monitoring was again conducted on an approximately weekly basis.
The test report stated that no other insecticidal treatments were carried out at the location during the pre-treatment and treatment phases.

The results for the pre-treatment phase acted as a baseline control against which the efficacy of the treatment could be measured. The results for the pre-treatment phase

showed that no adult moths were caught at the first 2 monitoring times, nor at the final 2 points. The results also showed 2 distinct peaks of 174 moths (30/6/08) and 225 (4/8/08). This was indicative of 2 generations of moths emerging. The data for the pre-treatment phase as a whole showed counts in the range 0 – 225 moths, with a total count of 941.

The pre-treatment results were also expressed as 'Total Daily Counts' (TDC). As stated above, it's not always possible to collect trap catch data at the same time intervals. Therefore, TDC's are used to eliminate any differences in comparative trap count numbers attributed to differences in the periods between trap count recording dates.

For each monitoring period, the TDC is calculated by dividing the total trap count during that period, by the number of days in the period. For example, during the 7 day period between pre-treatment monitoring points 8 (13/6/08) and 9 (20/6/08), the total trap catch was 65-moths. The TDC for this monitoring period was, therefore, 65/7 = 9.29. For the pre-treatment period as a whole, the TDC were in the range 0.00 – 22.5, with a mean TDC of 0.18.

The results for the treatment phase showed that no adult moths were caught at the first 5 monitoring times, nor at the final 4 points. A peak of 23 moths was recorded on 7/7/09, comparing favourably with the peak of 225 during the pre-treatment phase. Unlike the pre-treatment phase, no subsequent peak was recorded after this point.

The data for the treatment phase as a whole showed counts in the range 0 – 23 moths, with a total count of 101. The TDC were in the range 0.00 – 3.29, and a mean of 0.02.

The percentage reduction in the population during the treatment phase, compared with the pre-treatment phase, was calculated using the following formula:
% reduction = ((B-A)/A) X 100.
where:

A = total adult male moths captured during the pre-treatment phase.
B = total adult male moths captured during the treatment phase.
The percentage reduction was, therefore, ((101-941)/941) x 100 = 89.3 %. This large reduction in the population size was reflected in the mean TDC's for the pre-treatment and treatment periods of 0.18 and 0.02, respectively.

[redacted]. Evaluation of the impact of the Exosex SPTab auto-confusion system on stored-product Lepidopteran populations in a spice processing plant in the Netherlands. Report No. [redacted].

[redacted] investigated the efficacy of Exosex SPTab against *P. interpunctella.*

The study was a field trial conducted in the Netherlands in 2007 and 2008. The trial location was the single floor processing and storage area of a spice processing plant, with a ground area of approximately 1730 m^2.

The study was conducted in 2 phases i.e. pre-treatment and treatment. In the first (pre-treatment) phase of the study, the moth population was monitored on a monthly basis for a period of 367 days between 24/2/07 and 26/2/08. Monitoring was

conducted by means of 7 pheromone baited adult male monitoring traps placed in key locations at a height of approximately 1 – 2 m above ground level.

The second (treatment) phase was conducted over 366 days between 27/2/08 and 27/2/09. A total of 69 dispensers (each containing 10.0 mg active substance) were placed in the processing plant in a grid pattern (approximately 5 x 5 m) to give an overall distribution of approximately 1 tablet 25.0 m^{-2}. For each dispenser, the initial tablets were replaced after 60 days, with the tablets subsequently replaced at 60 day intervals.

During the treatment phase, the same number of monitoring traps was used as in the first phase, and these were placed in the same locations as in the first phase.
The test report stated that no other insecticidal treatments were carried out at the location during the pre-treatment and treatment phases. The only control measures that were taken consisted of general cleaning and removal of infested materials.
During both phases, a warehouse adjoining the processing plant was used as an untreated control. The warehouse was separated from the plant by a plastic covered doorway.

Although an untreated control was conducted, the results for the pre-treatment phase also acted as a baseline control against which the efficacy of the treatment could be measured.

The results for the pre-treatment phase in the processing plant showed monthly counts in the range 0 – 51 moths, with a total count of 134. The TDC were in the range 0.00 – 1.34, and a mean of 0.05.

The results for the treatment phase in the processing plant showed monthly counts in the range 0 – 5 moths, with a total count of 14. The TDC were in the range 0.00 – 0.17, and a mean of 0.01. The total number of moths, and the TDC, were lower than those for the untreated area, where the treatment data showed monthly counts in the range 0 – 32, a total of 117, TDC in the range 0.00 – 1.07, and a mean of 0.05.
For the processing plant, the percentage reduction in the population during the treatment phase, compared with the pre-treatment phase, was calculated using the same formula as that used in Pease, (2012a).
The percentage reduction was, therefore, ((14-134)/134) x 100 = 89.6 %. This large reduction in the population size was reflected in the mean TDC's for the pre-treatment and treatment periods of 0.05 and 0.01, respectively.
The mean numbers of moths captured in the pre-treatment phase were 17.86 (treatment area) and 31.00 (untreated area).
The mean numbers of moths captured in the treatment phase were 2.00 (treatment area) and 16.43 (untreated area).

The Henderson-Tilton formula (Henderson & Tilton, 1955) was used to compare the adult moth captures in the processing plant and the untreated warehouse.
This formula is as follows:

$$\text{Corrected \%} = \left(1 - \frac{\text{mean n in C before treatment} * \text{mean n in T after treatment}}{\text{mean n in C after treatment} * \text{mean n in T before treatment}} \right) * 100$$

where:
C = untreated control area.
T = treated area.
Thus, the corrected % reduction was (1-(31.00 x 2.00)/16.43 x 17.8)) x 100

= 78.9 %.

[redacted]. Evaluation of the impact of the Exosex SPTab auto-confusion system on stored-product Lepidopteran populations in a German bakery. Report No. [redacted]

Milanesi, (2011a) investigated the efficacy of Exosex SPTab against *E. kuehniella* and *P. interpunctella.*

The study was a field trial conducted in Germany in 2007 - 2009. The trial location was a large open plan room on the third floor of a commercial bakery, with a ground area of approximately 500 m^2.

The study was conducted in 2 phases i.e. pre-treatment and treatment. In the first (pre-treatment) phase of the study, the moth population was monitored on a monthly basis for a period of 2 years between January 2007 and December 2008. Monitoring was conducted by means of 2 pheromone baited adult male monitoring traps placed in key locations at a height of approximately 1 – 2 m above ground level.

The second (treatment) phase was conducted over approximately 1 year between January and December 2009. A total of 21 dispensers (each containing 10.0 mg active substance) were placed in the test area to give an overall distribution of approximately 1 tablet 24.0 m^{-2}. For each dispenser, the initial tablets were replaced after 60 days, with the tablets subsequently replaced at 60 day intervals. During the treatment phase, the same number of monitoring traps was used as in the first phase, and these were placed in the same locations as in the first phase.
The test report stated that no other insecticidal treatments were carried out at the location during the pre-treatment and treatment phases. The only control measures that were taken consisted of general cleaning and removal of infested materials. During both phases, the first floor of the bakery was used as an untreated control. The results for the pre-treatment phase in the treated and untreated areas were expressed as ranges, and these showed predominantly 'medium pressure' (11 - 50 captures per month) in the treated area and predominantly 'high pressure' (> 50 captures per month) in the untreated area.

The results for the treatment phase were expressed as actual counts. Those for the treated area showed a mean monthly count of 18.4 moths (range 3 – 46), and a total count of 442. The TDC were in the range 0.14 – 2.69, and a mean of 0.97. The mean and total number of moths, and the TDC, were lower than those for the untreated area, where the treatment data showed a mean monthly count of 115.3 moths (range 17 – 235), a total of 1384, TDC in the range 0.63 – 11.19, and a mean of 4.78.

The reduction in the population in the treated area was compared with that in the untreated area, and the percentage reduction calculated using the following formula:
% reduction = ((B-A)/A) X 100.
where:

A = mean monthly count in the untreated area.
B = mean monthly count in the treated area.
The percentage reduction was, therefore, ((18.4-115.3)/115.3) x 100 = 84.0 %. This large reduction in the population size was reflected in the mean TDC's for the treated and untreated areas of 0.97 and 4.78, respectively.

• [redacted]. **Evaluation of the impact of the Exosex SPTab auto-confusion system on stored-product Lepidopteran populations in a UK chocolate factory warehouse. Report No.** [redacted] investigated the efficacy of Exosex SPTab against *C. cautella.*
The study was a field trial conducted in the UK between 2006 and 2009. The trial location was a chocolate factory warehouse with a ground area of approximately 2000 m^2.

The study was conducted in 2 phases i.e. pre-treatment and treatment. In the first (pre-treatment) phase of the study, the moth population was monitored on a monthly basis for a period of 1 year between September 2006 and August 2007. Monitoring was conducted by means of 8 pheromone baited adult male monitoring traps placed throughout the factory at a height of approximately 1 - 2 m above ground level.
In the second (treatment) phase, the moth population was monitored on a monthly basis between September 2007 and March 2009. A total of 72 dispensers (each containing 10.0 mg active substance) were placed in the factory in a grid pattern (approximately 5 x 5 m) to give an overall distribution of approximately 1 tablet 28.0 m^{-2}. For each dispenser, the initial tablets were replaced after 60 days, and the tablets thereafter replaced at 60 day intervals.

During the treatment phase, the same number of monitoring traps was used as in the first phase, and these were placed in the same locations as in the first phase.
The test report stated that pest control practices at the test location consisted of spot spraying with an aerosol sprayer in conjunction with general line cleaning and 12 month complete shutdown cleaning.

The results for the pre-treatment phase acted as a baseline control against which the efficacy of the treatment could be measured. The results for the pre-treatment period showed monthly adult total counts in the range 18 – 143 moths, with a total count of 893. The TDC were in the range 0.64 – 5.11, and a mean of 0.31.

The data for the first year of treatment (September 2007 - August 2008) showed monthly counts in the range 12 – 166, a total count of 644, TDC in the range 0.43 – 5.93, and a mean of 0.22.

In the first 2 months of the treatment period the monthly count increased to 166 and then decreased to 32 i.e. below pre-treatment levels, over the following 2 months. This was different from the same period of the pre-treatment phase, where a monthly count of 127 was recorded in December 2006. As the product had, at this point, been active for 2.5 months, a period corresponding to a full moth life cycle, the observed reduction in this period, compared to the pre-treatment phase, is likely to have been due to the action of the product.

The data for year 2 showed monthly counts in the range 0 – 69, a total of 201, TDC in the range 0.00 – 2.46, and a mean of 0.13. During this period (September 2008 – March 2009), the moth counts were generally lower than in year 1, with counts of 0 recorded in the final 2 months of the trial (February & March 2009).

The percentage reduction in the population has been based on a comparison between the mean TDC for year 2 (September 2008 – March 2009) and the mean TDC for the same period during the pre-treatment period i.e September 2006 - March 2007. The mean TDC for the period September 2006 – March 2007 was 0.44, and a comparison of this value with that for year 2 (0.13) therefore shows a 70.5 % reduction in the *C. cautella* population.

[redacted]. Evaluation of the impact of the Exosex SPTab auto-confusion system on stored-product Lepidopteran populations in a UK flour mill. Report No. [redacted] investigated the efficacy of Exosex SPTab against *E. kuehniella.*
The study was a field trial conducted in the UK in 2008 and 2009. The trial location was 2 large rooms in a 2 storeyed flour mill containing milling and processing lines, with a ground area of approximately 4200 m^2.

The study was conducted in 2 phases i.e. pre-treatment and treatment. In the first (pre-treatment) phase of the study, the moth population was monitored on a monthly basis for a period of 10 months between 11/2/08 and 4/12/08. Monitoring was conducted by means of 8 pheromone baited adult male monitoring traps placed in key locations at a height of approximately 1 – 2 m above ground level.
The second (treatment) phase was conducted over 10 months between 6/2/09 and 30/11/09. A total of 168 dispensers (each containing 10.0 mg active substance) were placed in the processing plant in a grid pattern (approximately 5 x 5 m) to give an overall distribution of approximately 1 tablet 25.0 m^{-2}. For each dispenser, the initial tablets were replaced after 61 days, with the tablets subsequently replaced at intervals of 58, 63, 58, 61 and 59 days.

During the treatment phase, the same number of monitoring traps was used as in the first phase, and these were placed in the same locations as in the first phase. The test report stated that the control measures against the pest species consisted of deep cleaning and a treatment programme of weekly residual spray applications using alpha-cypermethrin and permethrin.

During both phases, 3 separate areas of the mill were used as an untreated control. These areas were separated from the test area by at least a corridor and a door. Although an untreated control was conducted, the results for the pre-treatment phase also acted as a baseline control against which the efficacy of the treatment could be measured.

The results for the pre-treatment phase in the treated area showed monthly counts in the range 11 – 215 moths, with a total count of 960. The TDC were in the range 0.05 – 0.96, and a mean of 0.36.

The results for the treatment phase in the treated area showed monthly counts in the range 0 – 92 moths, with a total count of 241. The TDC were in the range 0.00 – 0.43, and a mean of 0.09. The total number of moths was higher than that for the untreated area, where the treatment data showed monthly counts in the range 0 – 75 and a total of 221. The mean TDC was, however, lower than that for the untreated area, where the mean was 0.22 (range 0.00 – 0.93).

For the treated area, the percentage reduction in the population during the treatment phase, compared with the pre-treatment phase, was calculated using the following formula:

% reduction = ((B-A)/A) X 100.
where:

A = total adult male moths captured during the pre-treatment phase.

B = total adult male moths captured during the treatment phase.

The percentage reduction was, therefore, ((241-960)/960) x 100 = 74.9 %.
The mean numbers of moths captured in the pre-treatment phase were 120.00 (treatment area) and 71.67 (untreated area).
The mean numbers of moths captured in the treatment phase were 30.13 (treatment area) and 73.67 (untreated area).
The Henderson-Tilton formula (Henderson & Tilton, 1955) was used to compare the adult moth captures in the processing plant and the untreated warehouse.
This formula is as follows:

$$\text{Corrected \%} = \left(1 - \frac{\text{mean n in C before treatment} * \text{mean n in T after treatment}}{\text{mean n in C after treatment} * \text{mean n in T before treatment}}\right) * 100$$

where:
C = untreated control area.
T = treated area.
Thus, the corrected % reduction was (1-(71.67 x 30.13)/73.67 x 120.00)) x 100 = 75.6 %.

[redacted]. Evaluation of the impact of the Exosex SPTab auto-confusion system on stored-product Lepidopteran populations in a German beverage production facility. Report No. [redacted]

[redacted] investigated the efficacy of Exosex SPTab against *E. kuehniella.*

The study was a field trial conducted in Germany between 2008 and 2010. The trial location was a large area located on the ground floor of a beverage production facility, used for the processing and packing of a variety of powdered instant drinks, with a ground area of approximately 7200 m^2.

The study was conducted in 2 phases i.e. pre-treatment and treatment. In the first (pre-treatment) phase of the study, the moth population was monitored on a monthly basis for a period of 1 year between February 2008 and January 2009. Monitoring was conducted by means of 9 pheromone baited adult male monitoring traps placed throughout the factory at a height of approximately 1 - 2 m above ground level.
In the second (treatment) phase, the moth population was monitored on a monthly basis between February 2009 and January 2010. A total of 192 dispensers (each containing 10.0 mg active substance) were placed in the factory in a grid pattern (approximately 5 x 5 m) to give an overall distribution of approximately 1 tablet 37.0 m^{-2}. For each dispenser, the initial tablets were replaced after 57 days, and the tablets then replaced at intervals of 66, 60, 64, 55 and 58 days.

During the treatment phase, the same number of monitoring traps was used as in the first phase, and these were placed in the same locations as in the first phase.
The test report stated that pest control practices at the test location during the pre-treatment phase consisted of general daily cleaning, together with ULV treatments. The latter were carried out when the moth counts indicated 'medium pressure' (11 – 40 captures per month). In addition, a routine fogging treatment was carried out during the Christmas shutdown, irrespective of the level of infestation recorded.

The same measures were taken during the treatment phase, except that no ULV treatments were carried out.

The results for the pre-treatment phase acted as a baseline control against which the efficacy of the treatment could be measured.

The results were expressed as ranges, and showed that, during the pre-treatment period, 'medium pressure' (11 – 40 captures) was recorded on 16 occasions, 'low pressure' (< 10 captures) on 72 occasions, and 'no captures on 20 occasions. During the treatment period, 'medium pressure' was recorded on 2 occasions, 'low pressure' on 79 occasions, and 'no captures' on 27 occasions.

The study report did not include any data on percentage reduction in population.

[redacted]. Evaluation of the impact of the Exosex SPTab auto-confusion system on stored-product Lepidopteran populations in a Belgian tobacco warehouse. Report No. [redacted]

[redacted] investigated the efficacy of Exosex SPTab against *E. elutella.*
The study was a field trial conducted in Belgium in 2008 and 2009. The trial location was a contained section of a tobacco warehouse, consisting of large blocks of stacked pallet cages with minimal access, and with a ground area of 8666 m^2.
The study was conducted in 2 phases i.e. pre-treatment and treatment. In the first (pre-treatment) phase of the study, the moth population was monitored on a weekly basis for a period of approximately 6 months between 28/4/08 and 3/11/08.

Monitoring was conducted by means of 24 pheromone baited adult male monitoring traps placed throughout the test area at a height of approximately 1.8 – 2.0 m above ground level.

In the second (treatment) phase, the moth population was monitored on a weekly basis for approximately 6 months between 27/4/09 and 2/11/09. A total of 332 dispensers (each containing 10.0 mg active substance) were placed in the factory in a grid pattern (approximately 5 x 5 m) to give an overall distribution of 1 tablet 26.1 m^{-2}. For each dispenser, the initial tablets were replaced after 59 days, and the replacement tablets themselves replaced after a further 61 days.

During the treatment phase, the same number of monitoring traps was used as in the first phase, and these were placed in the same locations as in the first phase.

The test report stated that pest control practices at the test location during the pre-treatment phase consisted of general fogging of the warehouse, using permethrin, in response to sustained high catches over a 2 week period, and, at the end of the season, routine fogging of sections of the warehouse where moth activity had been recorded during the season. In addition to the end of season treatment, 2 fogging treatments were carried out in weeks 24 and 35, in response to high levels of moth capture.

Control measures similar to the above were also taken during the treatment phase, except that 1 fogging treatment was carried out in week 35, in response to high moth captures.

The study report did not include any data on percentage reduction in population. The UK CA does not, however, consider this to be an issue. The criteria for permethrin treatments remained the same throughout both phases of the test, two treatments with permethrin were required during the pre-treatment phase, due to sustained high catches, whilst only one was required in the treatment phase.

As the two phases are not directly comparable, due to the difference in the number of permethrin treatments conducted in each phase, the UK CA considers that calculating a percentage reduction would not be fully representative of the data. The results for the pre-treatment phase acted as a baseline control against which the efficacy of the treatment could be measured.

The results for the pre-treatment period showed weekly counts in the range 0 – 92 moths, a mean weekly count of 14.2, and a total count of 398.

The results for the treatment period showed weekly counts in the range 0 – 34 moths, a mean weekly count of 6.3, and a total count of 177.

[redacted]. Evaluation of the impact of the Exosex SPTab auto-confusion system on stored-product Lepidopteran populations in a Spanish bakery. Report No. [redacted]

[redacted] investigated the efficacy of Exosex SPTab against *E. kuehniella.*

The study was a field trial conducted in Spain in 2008 and 2009. The trial location consisted of 2 units. Each unit contained flour storage areas containing silos, and processing areas with production lines and ovens, and the units were separated by a roll-up door that was kept open. The treated area had a ground area of approximately 2000 m^2.

The study was conducted in 2 phases i.e. pre-treatment and treatment. In the first (pre-treatment) phase of the study, the moth population was monitored on a monthly basis for a period of 1 year between January and December 2008. Monitoring was conducted by means of 4 pheromone baited adult male monitoring traps placed throughout the factory at a height of approximately 1 - 2 m above ground level.

In the second (treatment) phase, the moth population was monitored on a monthly basis between January and December 2009. A total of 72 dispensers (each containing 10.0 mg active substance) were placed in the treatment area to give an overall distribution of approximately 1 tablet 28.0 m^{-2}. For each dispenser, the initial tablets were replaced after 57 days, and the tablets then replaced at intervals of 63, 62, 57, 63 and 59 days.

During the treatment phase, the same number of monitoring traps was used as in the first phase, and these were placed in the same locations as in the first phase. The test report stated that pest control practices at the test location during the pre-treatment phase consisted of ULV spray applications in conjunction with general cleaning. A total of 9 ULV treatments were carried out, when the moth counts indicated 'medium pressure' (11 – 40 captures per month). The same measures were taken during the treatment phase, except that a total of 7 ULV treatments were carried out using deltamethrin and tetramethrin.

The results for the pre-treatment phase acted as a baseline control against which the efficacy of the treatment could be measured.

The results were expressed as ranges. The pre-treatment phase involved 48 monitoring time points i.e. 12 monthly counts for each of the 4 traps. The results showed that no captures were recorded on 2 occasions, 'low pressure' (1 - 25 captures) on 0 occasions, 'medium pressure' (26-100 captures) on 2

occasions, and 'high pressure' (> 100 captures) on 40 occasions. On the remaining 4 occasions, no data were collected.

The treatment period also involved 48 monitoring time points. The results showed that no captures were recorded on 15 occasions, 'low pressure' on 8 occasions, 'medium pressure' on 12 occasions, and 'high pressure' on 6 occasions. On the remaining 7 occasions, no data were collected.

The study report did not include any data on percentage reduction in population. A tabulated summary of the studies can be found in Annex C of this document.

6.6 DISCUSSION

The Technical Notes for Guidance (TNsG) for PT19 does not include guidance on pheromone-based attractants. As there is no guidance, the UK CA considers that good science should apply, and has evaluated the data package on this basis.

In the study by [redacted], the UK CA considers the field test methodology used to be acceptable.

In the study, Exosex SPTab was applied at approximately10.0 mg active substance 25.0 m^{-2} i.e. the requested application rate for the product. The tablets were replaced after 58, 67 and 56 days, giving a mean replacement period of 60.3 days, which was in line with the product directions for use which states that the tablets should be replaced every 60 days.

The moth species targeted in the field trial – *E. kuehniella* and *P. interpunctella* – are 2 of the claimed target species for the product.

In the field trial, no insecticidal treatments were carried out at the warehouse during the pre-treatment and treatment periods.

Given the level of reduction achieved in the *E. kuehniella* and *P. interpunctella* populations over the 196 day treatment period (89.3 %), compared with the pre-treatment levels, the UK CA considers the results as demonstrating the efficacy of Exosex SPTab as a moth attractant/mating disruptor when applied at an application rate of approximately 10.0 mg active substance per 25.0 m^2 floor area and over a period of 60 days per tablet.

In the study by [redacted], the UK CA considers the field test methodology used to be acceptable.

In the study, Exosex SPTab was applied at approximately 10.0 mg active substance 25.0 m^{-2} i.e. the requested application rate for the product. The tablets were replaced at 60 day intervals, which was in line with the product directions for use.

The moth species targeted in the field trial – *P. interpunctella* – is 1 of the claimed target species for the product.

In the trial study, no insecticidal treatments were carried out at the processing plant during the pre-treatment and treatment periods. Although the plant was subjected to general cleaning, the UK CA does not consider this as compromising the results.

Given that the trial was conducted outside the UK, the UK CA asked the applicant to provide a reasoned case as to why the environmental conditions during the trial are relevant to the UK situation.

In response, the applicant has provided the following:

'Exosect Ltd wish to submit the following reasoned case for the acceptance of efficacy data generated in facilities outside the UK (Germany, Netherlands, Belgium and Spain).

Exosex SPTab is intended only for indoor use in commercial facilities such as bakeries, confectionary manufactures, flour mills, pasta factories, processing and packing of cereals, spices, dried fruit and nuts, instant drink production and packing, animal /pet food factories, tobacco processing & storage facilities, packing and storage facilities for finished goods.

Whilst variations in climatic conditions in different geographical locations may influence the efficacy of some pest control products when used outdoors, this is not normally the case for the indoor applications.

The environmental conditions typically found inside the aforementioned types of facilities are closely monitored and controlled in order to maintain the optimum conditions for manufacturing and storage of raw materials & finished products. It is also important to maintain acceptable & comfortable conditions for workers. Such environmental controls are common practice in commercial facilities across the EU. In order to further support this case, a summary of the average maximum & minimum climatic temperatures found at all the field trial locations has been included and is shown in Figure 1 & Table 1.

The climatic temperature data illustrates that the average max / min temperatures do not significantly vary between the UK sites and the majority of the EU sites (except Barcelona, where temperatures are notably elevated). However, any extreme fluctuations in external temperatures would be compensated for by appropriately moderating the internal factories conditions.

Given that the trial data clearly shows a very good level of efficacy across a range of indoor application areas in controlled environments, within a variety of geographical locations it can be concluded that efficacy data generated outside of the UK is directly comparable & relevant to UK situation and should be considered suitable to support registration of Exosex SPTab for use against all five target organisms'.

The UK CA agrees with the applicant that the climatic temperature data illustrates that the average max/min temperatures do not vary significantly between the UK sites and other EU locations. The UK CA considers the applicant's reasoned case to be acceptable.

Given the level of reduction achieved in the *P. interpunctella* population over the 366 day treatment period (78.9 %), compared with the pre-treatment levels, the UK CA considers the results as demonstrating the efficacy of Exosex SPTab as a moth attractant/mating disruptor when applied at an application rate of approximately

10.0 mg active substance per 25.0 m^2 floor area and over a period of 60 days per tablet.

In the study by [redacted], the UK CA considers the field test methodology used to be acceptable.

In the study, Exosex SPTab was applied at approximately
10.0 mg active substance 24.0 m^{-2} i.e. above the requested application rate for the product.

The tablets were replaced at 60 day intervals, which was in line with the product directions for use.

The moth species targeted in the field trial – *E. kuehniella* and *P. interpunctella* – are 2 of the claimed target species for the product.

In the trial, no insecticidal treatments were carried out at the processing plant during the pre-treatment and treatment periods. Although the plant was subjected to general cleaning, the UK CA does not consider this as compromising the results.

As described previously for [redacted], the UK CA considers the applicant's reasoned case regarding the climatic conditions to be acceptable.

Given the level of reduction achieved in the *P. interpunctella* population in the treated area over the 1 year treatment period (84.0 %), compared with the level in the untreated area, the UK CA considers the results as demonstrating the efficacy of Exosex SPTab as a moth attractant/mating disruptor when applied at an application rate of approximately 10.0 mg active substance per 25.0 m^2 floor area and over a period of 60 days per tablet.

In the study by [redacted], the UK CA considers the field test methodology used to be acceptable.

In the study, Exosex SPTab was applied at approximately
10.0 mg active substance 28.0 m^{-2} i.e. below the requested application rate for the product.

The tablets were replaced at 60 day intervals, which was in line with the product directions for use.

The moth species targeted in the field trial – *C. cautella* – is 1 of the claimed target species for the product.

As stated in Section 6.5, pest control practices at the test location consisted of spot spraying with an aerosol sprayer in conjunction with general line cleaning and 12 month complete shutdown cleaning. At the UK CA's request, the applicant has provided the following information by way of explanation/clarification.
'Line cleaning
This term is factory terminology for area segregation according to production activity (e.g. packing line, wrapping line etc.). The test area was a packing conveyor belt line, where individual items were moved along a conveyor belt and placed in boxes. The term line cleaning refers to general sweeping and cleaning activities around the working area to remove build-up of spilled food fragments, dust, wrapping materials and other detritus.

Shut-down cleaning
This is the term used for cessation of production activity, shut-down of machinery and a much more extensive and thorough cleaning process often involving internal components of machinery, removal of panels to cable ducting etc. The term is used interchangeably in the pest control industry with that of deep cleaning.

Spot treatments
Spot treatment is the terminology used for small, localised treatment of an item rather than broad treatment of an area such as a space spray or fogging method treatment. In this particular case the company were working with open food produce and had a zero pesticide use policy. The spot treatment in this case was a simple household aerosol spray used upon incidental sighting of all insect species, cockroaches, flies and adult moth used by the inspector on routine 4 weekly inspections of the areas patrolled.

Frequency of use
Line cleaning was conducted as a routine task on a weekly, bi-weekly or monthly cycle depending on the activity of the given manufacturing area according to necessity.

Shut-down cleaning was conducted once per year over the Christmas period only. This was due to the 24/7 continual operating conveyor system.

Spot treatment was conducted in this particular area on a 4 weekly cycle at the same time as monitoring trap counting was conducted'.

As the UK CA needs to be satisfied that the above procedures did not negatively affect the trial results, the applicant has provided the following reasoned case.

'Measure of efficacy is a direct comparison of pest population size measured before (pre-treatment) and after (post-treatment) introduction of the test item in question and over a period long enough to include and compare any seasonal variation in pest numbers pre and post treatment. So long as all other activities that may affect the pest population are conducted in the same manner in both the pre-treatment and post-treatment period and results are measured over the full cycle of the pest there are no other factors other than the test item that can be responsible for a reduction in pest population and hence proof of its efficacy.

In the case of this trial these conditions were fully met. Also both line cleaning and spot treatment were insignificant factors in the control of this particular pest and were reported here for completeness. Shut-down cleaning was a significant factor but happened at exactly the same time in both pre-treatment and post-treatment periods (one week over Christmas holiday) and according to same methodology in both'.

The UK CA accepts the applicant's reasoned case and is satisfied that the cleaning procedures and the short, small scale spot treatments did not affect the trial results. Given the level of reduction achieved in the *C. cautella* population over the 18 month treatment period (70.5 %), compared with the pre-treatment levels, the UK CA considers the results as demonstrating the efficacy of Exosex SPTab as a moth attractant/mating disruptor when applied at an application rate of approximately 10.0 mg active substance per 25.0 m^2 floor area and over a period of 60 days per tablet.

In the study by [redacted], the UK CA considers the field test methodology used to be acceptable.

In the study, Exosex SPTab was applied at approximately 10.0 mg active substance 25.0 m^{-2} i.e. the requested application rate for the product. The tablets were replaced after 58, 63, 58, 61 and 59 days, giving a mean replacement period of 59.8 days, which was in line with the product directions for use.

The moth species targeted in the field trial – *E. kuehniella* – is 1 of the claimed target species for the product.

As stated in Section 6.5, the control measures against the pest species consisted of deep cleaning and a treatment programme of weekly residual spray applications using alpha-cypermethrin and permethrin.

At the UK CA's request, the applicant has provided the following information by way of explanation/clarification.

'*Deep cleaning*
The deep cleaning practices at this site were continual. The test areas in question were very large, covering two floors of a flour mill processing building and containing several different pieces of equipment. These pieces of equipment would be shut down, one at a time according to a rota and cleaned thoroughly.

Residual spraying

Residual spraying would take place on the shutdown piece of equipment only during cleaning as part of the cleaning process. The remainder of the area was in full working order so no full area treatment was possible due to exposed food produce'.

As the UK CA needs to be satisfied that the above procedures did not negatively affect the trial results, the applicant has provided the following reasoned case.

'Most importantly all practices were maintained the same throughout pre-treatment and post-treatment monitoring periods to ensure any reductions in pest population were attributable to the test item only.

Secondly due to the scale of the test area and duration of the study, the residual treatment and cleaning can be deemed insignificant in terms of the reduction of the pest population monitored over the whole test area. Data clearly shows that combined cleaning and residual treatment of machinery at best maintained the population at the same levels over the whole site from year to year. This was confirmed by the catch data for trap 1, where no cleaning was possible in the area. Also within this study it was possible to find an area completely isolated from the pheromone treatment to use as an untreated control. Monitoring of this area showed no differences in pest population size over the pre-treatment and post-treatment years confirming pest pressure was equal in both periods in the absence of the test-item. Pest pressure was reduced by >50 % in the presence of the test item'.

The UK CA accepts the applicant's reasoned case and is satisfied that the deep cleaning and localised residual spraying of equipment did not affect the trial results. Given the level of reduction achieved in the *C. cautella* population over the 18 month treatment period (75.6 %), compared with the pre-treatment levels, the UK CA

considers the results as demonstrating the efficacy of Exosex SPTab as a moth attractant/mating disruptor when applied at an application rate of approximately 10.0 mg active substance per 25.0 m^2 floor area and over a period of 60 days per tablet.

In the study by [redacted], the UK CA considers the field test methodology used to be acceptable.

In the study, Exosex SPTab was applied at approximately 10.0 mg active substance 37.0 m^{-2} i.e. below the requested application rate for the product.

The tablets were replaced after 66, 60, 64, 55 and 58 days, giving a mean replacement period of 60.6 days, which was in line with the product directions for use.

The moth species targeted in the field trial – *E. kuehniella* – is 1 of the claimed target species for the product.

As described previously for [redacted], the UK CA considers the applicant's reasoned case regarding the climatic conditions to be acceptable.

As stated in Section 6.5, the control measures against the pest species consisted of a series of ULV treatments, together with a routine fogging treatment carried out during the Christmas shutdown.

At the UK CA's request, the applicant has provided the following information by way of explanation/clarification.

'Cleaning
Cleaning practices were conducted continually on a rota system throughout the entire area.

General fogging
Conducted annually, on a single occasion during factory shutdown at Christmas.

Residual Insecticide Treatments
Conducted on individual machinery items. At this site residual treatments were triggered by pest population monitoring counts exceeding threshold numbers in the areas in close proximity to the monitored areas'.

As the UK CA needs to be satisfied that the above procedures did not negatively affect the trial results, the applicant has provided the following reasoned case.

'As above it was ensured that all practices were maintained the same in both pre-treatment and post-treatment monitoring periods. The test site was very large and effect was measured over the whole site to minimise influence of individual differences in localised small areas. The test duration was for a whole year, the same as the pre-treatment period to minimise seasonal effects on change in population. For these reasons any differences in pest numbers could be attributed only to the presence of the test item.

The effect of the test item is clearly shown by the number of insecticide treatments required as a result of pest numbers exceeding acceptable thresholds. In the pre-treatment year, numbers exceeded critical limits on 6 occasions and 6 residual insecticide treatments were required. For the same area during the in-life phase of the study, pest numbers were maintained below the threshold and no insecticide treatments were required for the entire test period in the presence of the test item'.

The UK CA accepts the applicant's reasoned case and is satisfied that the deep cleaning, fogging, and spraying of equipment did not affect the trial results.

Although the trial results were expressed as ranges of counts, rather than specific numbers, the UK CA considers the levels of infestation seen in the treatment phase, compared with those pre-treatment phase, as being indicative of the efficacy of the product.

In the study by [redacted], the UK CA considers the field test methodology used to be acceptable.

In the study, Exosex SPTab was applied at a rate of
10.0 mg active substance 26.1 m^{-2} i.e. slightly below the requested application rate for the product.

The tablets were replaced after 59 and 61 days, giving a mean replacement period of 60 days, which was in line with the product directions for use.

The moth species targeted in the field trial – *E. elutella* – is 1 of the claimed target species for the product.

As described previously for [redacted], the UK CA considers the applicant's reasoned case regarding the climatic conditions to be acceptable.

As stated in Section 6.5, the control measures against the pest species consisted of a series of fogging treatments. As the UK CA needs to be satisfied that these procedures did not negatively affect the trial results, the applicant has provided the following reasoned case.

'In this study the conditions under which population changes might occur are more complex and a clearly scientifically reasoned case more difficult to put forward.

The warehouse in question was of a very large scale and subject to the conditions of seasonal temperature change. This is helpful in demonstrating the efficacy of the test item. In the pre-treatment year, two very clear peaks in pest numbers can be seen, corresponding to first and second generation of the pest. These numbers were high and breached the threshold which triggered two corresponding fogging treatments. During the treatment year, despite similar temperatures the numbers were clearly reduced in the presence of the test item to the extent where only 1 fogging treatment was required. The peaks in numbers were markedly reduced in the presence of the test item. The reduction appeared less significant in view of the fact that fogging treatments were reduced from two to only one per year. However, numbers were far in excess of the threshold in the pre-treatment year, whilst only just in breach during the treatment year.

Due to changes in the type of produce stored in the warehouse between the years, the susceptibility to pest pressure in the year of the test was far greater than in the

pre-treatment year. The variety of tobacco stored in the test year being far more susceptible to infestation and subsequent population increase than the previous year. This difference in activities could not be anticipated at the start of the trial and is indirect evidence of higher level of control than can be shown directly in monitoring trap catch results. This point was noted by the warehouse pest control manager as significant proof of efficacy not possible to show in scientifically within the report'.

The UK CA accepts the applicant's reasoned case and is satisfied that the fogging treatments did not affect the trial results.

Given the level of reduction achieved in the *E. elutella* population over the 6 month treatment period (55.5 %), compared with the pre-treatment levels, the UK CA considers the results as demonstrating the efficacy of Exosex SPTab as a moth attractant/mating disruptor when applied at an application rate of approximately 10.0 mg active substance per 25.0 m^2 floor area and over a period of 60 days per tablet.

In the study by [redacted], the UK CA considers the field test methodology used to be acceptable.
In the study, Exosex SPTab was applied at approximately
10.0 mg active substance 28.0 m^{-2} i.e. below the requested application rate for the product.

The tablets were replaced after 57, 63, 62, 57, 63 and 59 days, giving a mean replacement period of 60.2 days, which was in line with the product directions for use which states that the tablets should be replaced every 60 days.

The moth species targeted in the field trial – *E. kuehniella* – is 1 of the claimed target species for the product.

As described previously for [redacted], the UK CA considers the applicant's reasoned case regarding the climatic conditions to be acceptable.

As stated in Section 6.5, the control measures against the pest species consisted of 9 ULV treatments during the pre-treatment phase and 7 ULV treatments during the treatment phase. As the UK CA needs to be satisfied that these procedures did not negatively affect the trial results, the applicant has provided the following reasoned case.

'As with previous studies the ULV treatments were triggered by numbers exceeding threshold of 25-moths in a sampling period. In this case it is not so much the reduction in insecticide treatments that provide proof of efficacy. The large reduction in pest population in the presence of the test item is clearly evident when compared with the pre-treatment period.

This was a very heavily infested site where pest numbers exceeded >100 / trap in every trap on every sampling occasion (40 in total) between February and November in the pre-treatment period.

In the presence of the test item this threshold was only exceeded on 6 occasions with reduced insecticide applications also. There were 14 monitoring instances where adults moth catches <25 and below the threshold for insecticide treatments during the year of the trial compared to 4 which occurred only in the winter month of December in the pre-treatment period.

All other conditions and practices were maintained the same in both pre-treatment and treatment periods and comparative reduction in both pest numbers and numbers of insecticide treatments as described provides reason why insecticide treatments did not compromise the trial results'.

Although the trial results were expressed as ranges of counts, rather than specific numbers, the UK CA considers the levels of infestation seen in the treatment phase, compared with those pre-treatment phase, as being indicative of the efficacy of the product.

6.7 CONCLUSIONS

In the studies by [redacted], the product was applied at an application rate in line with the requested application rate of approximately 1 tablet 25.0 m^{-2}, with the tablets being replaced after a period of 60 days i.e. in line with the product directions for use.

During [redacted], no insecticidal treatments were conducted during the pre-treatment and treatment phases. In the studies by [redacted], although various insecticidal treatments were carried out during these trials, these tended to be relatively infrequent in relation to the length of the trials, and tended to be relatively small-scale and localised. For these reasons, together with
the fact that where treatments were conducted the pattern and timing of the treatments tended to be the same during the pre-treatment and treatment periods, the UK CA is satisfied that these treatments did not affect the results from the trials.

In the study by [redacted], the product was applied at a lower rate than in the other studies i.e. 1 tablet 37.0 m^{-2}, with the tablets being replaced after 60 days.

The UK CA considers the field trial data package as a whole as supporting the use pattern and label claim for Exosex SPTab i.e. as a moth attractant/mating disruptor when applied at an application rate of approximately 1 tablet
(10.0 mg active substance) 25.0 m^{-2} floor area and over a period of 60 days per tablet.

6.7.1 Addition of a new coformulant to extend the shelf life of the product

As part of major change application BC-KV041840-19 (submitted 3/8/2018), a new co-formulant was added at 0.05% w/w, to extend the shelf life of the product to 24 months (please see the confidential annex of this PAR for details of the change to the formulation).

The new coformulant and associated changes to the formulation do not affect the above conclusion regarding the efficacy of the product.

7. Eligibility for the simplified authorisation procedure

Following evaluation, the product Exosex® SP_{Tab} has been shown to meet the conditions required for simplified authorisation as defined in Article 25 of 528/2012, i.e.:

1. The active substance [4](Z,E)TETRADECA-9,12-DIENYL ACTETATE appears in Annex I of 528/2012 with no restrictions applied.
2. The biocidal product contains no substances of concern.
3. The biocidal product does not contain any nanomaterials.
4. The use pattern and associated label claims of the biocidal product have been judged sufficiently effective.
5. The handling of the biocidal product as part of its intended use does not require any PPE.

8. DECISION

8.1 Summary of decisions and restrictions.

It is concluded that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the authorisation of the product Exosex® SP_{Tab} under Article 25 of 528/2012 according to the following conditions:

1. Professional use only

2. For use indoors only.

3. For use as a moth attractant/mating disruptor when applied at an application rate of 1 tablet (10.0 mg active substance) 25.0 m^{-2} floor area and over a period of 60 days per tablet.

4. The maximum level of the active ingredient [5](Z,E) TETRADECA-9, 12-DIENYL ACTETATE in the product is 1.0 %.

5. The source of the active ingredient is Aeroxon Insect Control GmbH, Bahnhofstraβe 35, D-71332 Waiblingen. Germany, minimum purity of 97.7%.

6. The shelf life is 6 months when stored below 25ºC.

7. Directions for use

Exosex SPTab consists of tablets made of compressed Entostat powder containing moth pheromone, and a deployment kit. Exosex SPTab tablets and the deployment kit are packaged separately. The deployment kit consists of:

- A box containing 24 plastic dispensing units with adhesive pads;
- A box containing 24 tablets; and
- Instructions for use.

[4] Please note: in accordance with the Corrigendum to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012, concerning the making available on the market and use of biocidal products; the active substance name (Z,E)-Tetradec-9,12-dienyl acetate was changed to (9Z,12E)-tetradeca-9,12-dien-1-yl acetate in April 2019, as part of major change application BC-KV041840-19, submitted 3/8/2018.

[5] Please note: in accordance with the Corrigendum to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012, concerning the making available on the market and use of biocidal products; the active substance name (Z,E)-Tetradec-9,12-dienyl acetate was changed to (9Z,12E)-tetradeca-9,12-dien-1-yl acetate in April 2019, as part of major change application BC-KV041840-19, submitted 3/8/2018.

The tablet is inserted into a plastic dispensing unit which is secured to walls, pillars, machinery and other suitable surfaces (i.e. not above conveyer belts or where powder may fall into a recipe). Dispensers are deployed 1-2 metres above ground level at a rate of 1 tablet 25.0 m^{-2} floor area.

The deployment instructions are as follows:

- Push tablet firmly into dispenser, leaving approximately 50% of the tablet exposed.
- Remove plastic protection from sticky mounting on back of dispenser.
- Clean surface of substrate and press dispenser, tablet upper-most into position.

Applied at an application rate of 1 tablet (10.0 mg active substance) 25.0 m^{-2} floor area and over a period of 60 days per tablet.

Store unopened below 25ºC.
Use within 6 months.
Once opened, use immediately.

8.2 Necessary Issues Accounted for in the Product Label

- Keep out of reach of children.
- Do not eat, drink or smoke when using this product.
- FOR USE ONLY BY PROFESSIONAL OPERATORS
- The (COSHH) Control of Substances Hazardous to Health Regulations 2002 may apply to the use of this product at work.
- DO NOT USE in locations where food, feed or water could become contaminated.
- This material and its container must be disposed of in a safe way.
- FOR INDOOR USE ONLY.
- WASH HANDS AND EXPOSED SKIN before meals and after use.
- KEEP IN A SAFE PLACE.
- Do not apply directly to tobacco.
- Store unopened below 25ºC.
- Use within 6 months.
- Once opened, use immediately.

UK Competent Authority
Date: June 2016

ANNEX A. PHYSIOCHEMICAL PROPERTIES

Table A1. Summary of physicochemical properties of Exosex® SP_{Tab}

1. Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reference
3.1 Appearance	Appearance	Exosex Sp tab	Compressed powder cylinder Opaque yellow in colour with a unique plasticine odour	-	Y	[redacted]
3.1.1 Physical state and nature						
3.1.2 Colour						
3.1.3 Odour						
3.2 Explosive properties	Not tested	-	**Applicant's statement**: The active substance did not display any explosive properties. The co-formulants are not explosive.	The active was not found to be explosive in the active substance approval evaluation. None –of the co-formulants are classified as explosive. The BP is not, therefore, expected to be explosive.	-	-
3.3 Oxidising properties	.Not tested	-	**Applicant's statement**: The formulation does not contain any components that have oxidative properties and furthermore there are no structural indications of oxidizing potential. (Ref: Doc III B2, confidential data). Furthermore, the active substance does not display any oxidative properties. (Ref: Doc III A3.16. This data is citable by means of a letter of access).	The active was not found to be oxidising in the active substance approval evaluation and none of the co-formulants are classified as	-	-

1. Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reference
				oxidising. The BP is not, therefore, expected to be oxidising.		
3.4 Flash-point and other indications of flammability or spontaneous ignition	Not tested	-	**Applicant's statements:** **Auto flammability (auto-ignition)** A study for auto-flammability of the product is considered to be scientifically unjustified because the product does not contain any components that are classed as auto-flammable. (Ref: Doc III B2, confidential data) **Flammability in contact with water** The determination of the flammability of the product when in contact with water is considered to be scientifically unjustified because the formulation does not contain any components which are reactive with water. (Ref: Doc III B2, confidential data) **Pyrophoric properties** A study to determine the pyrophoric properties of the product is considered to be scientifically unjustified as the formulation does not contain any components that are classed as pyrophoric. (Ref: Doc III B2, confidential data) The applicant also provided data	The active was not found to be flammable in the active substance approval evaluation. None of the co – formulants are classified as flammable or auto-flammable. The BP is not, therefore, expected to be flammable.	-	-

<table>
<tr><th>1. Subsection (Annex Point/TNsG)</th><th>Method</th><th>Purity/ Specification</th><th>Results</th><th>Remarks/ Justification</th><th>GLP (Y/N)</th><th>Reference</th></tr>
<tr><td></td><td>EEC A10</td><td>Exosex SPtab</td><td>Not highly flammable</td><td></td><td>Y</td><td>[redacted]</td></tr>
<tr><td>3.5 Acidity/Alkalinity</td><td>Not tested</td><td></td><td>Applicant's statement: Exosex SPTab is a ready-to use solid, wax product which is insoluble in water. pH determination is therefore not technically feasible.</td><td>The applicant's justification for the non-submission of data is accepted.</td><td>-</td><td>-</td></tr>
<tr><td>3.6 Relative density/bulk density</td><td>CIPAC MT 186</td><td>Exo 2</td><td>pour density: 0.34 g/ml

tap density: 0.42 g/ml</td><td>The data generated on 'Exo 2' can be used to support 'Exosex SP tab'</td><td></td><td>[redacted]</td></tr>
<tr><td>3.7 Storage stability - stability and shelf life

To be stored at 4ºC</td><td>In house</td><td>Exosex Sp tab</td><td>BP stored in the LDPE/PET bags at 4ºC

<table><tr><th>Test</th><th>Prior to storage</th><th>After 6 months at storage at 4ºC</th></tr><tr><td>Active content</td><td>10.44 g/kg</td><td>9.64 g/kg</td></tr><tr><td>Appearance</td><td>Uniform solid opaque yellow wax block

Some flakes were observed on</td><td>No change</td></tr></table></td><td>The product is a pheromone and hence it is stored at a low temperature.

The product is stable when stored at 4 ºC for six months (this is the label recommendation) .</td><td>Y</td><td>[redacted]</td></tr>
</table>

<table>
<tr><th>1. Subsection (Annex Point/TNsG)</th><th>Method</th><th>Purity/ Specification</th><th>Results</th><th>Remarks/ Justification</th><th>GLP (Y/N)</th><th>Reference</th></tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>
<table>
<tr><td></td><td>bottom and side of bag</td><td></td></tr>
<tr><td>Packaging</td><td>Stable pack</td><td>No change</td></tr>
<tr><td>Evaporation rate</td><td>see 3.8</td><td>Not determined</td></tr>
</table>
<table>
<tr><th>Test</th><th>Prior to storage</th><th>After 12 months at storage at 4ºC</th></tr>
<tr><td>Active content</td><td>10.44 g/kg</td><td>8.43 g/kg</td></tr>
<tr><td>Appearance</td><td>Uniform solid opaque yellow wax block

Some flakes were observed on bottom and side of bag</td><td>No change</td></tr>
<tr><td>Packaging</td><td>Stable pack</td><td>No change</td></tr>
<tr><td>Evaporation rate</td><td>See 3.8</td><td>Not determined</td></tr>
</table>
Ambient storage in LDPE/PET bag
</td>
<td>The active has degraded by over 10 % after 12 months. The shelf life is 6 months at 4ºC.

The small flakes observed around side and bottom of the bag is not regarded as significant.

The evaporation rate after storage has not been assessed – see 3.3</td>
<td>Y</td>
<td>[redacted]</td>
</tr>
</table>

<table>
<tr><th>1. Subsection (Annex Point/TNsG)</th><th>Method</th><th>Purity/ Specification</th><th>Results</th><th>Remarks/ Justification</th><th>GLP (Y/N)</th><th>Reference</th></tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>
<table>
<tr><th>Test</th><th>Prior to storage</th><th>After 6 months at ambient temp</th></tr>
<tr><td>Active content</td><td>9.54 g/kg</td><td>7.10 g/kg</td></tr>
<tr><td>Appearance</td><td>Uniform solid opaque yellow wax block

Some flakes were observed on bottom and side of bag</td><td>No change</td></tr>
<tr><td>Packaging</td><td>Stable pack</td><td>No change</td></tr>
<tr><td>Evaporation rate</td><td>See 3.8</td><td>Not determined</td></tr>
</table>
<table>
<tr><th>Test</th><th>Prior to storage</th><th>After 3 months at ambient temp</th></tr>
<tr><td>Active content</td><td>10.56 /kg</td><td>8.97g/kg</td></tr>
</table>
With regards to the stability of the dispenser used with the biocidal product, this is not directly relevant to the stability of the BP and
</td>
<td>The BP is not stable on storage at ambient temperature for 6 months. Given the nature of the active this is as expected.

These further data were provided to support the claim on the label that once the BP is removed from cold temperature storage it has to be used within 2 weeks. These</td>
<td>N</td>
<td>[redacted]</td>
</tr>
</table>

1. Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reference
			its packaging. However, the applicant (HSE internal reference TRIM 2013/330255) has stated the following: *The product is intended for indoor use only. Due to the lack of exposure to direct sunlight or effects of weathering the High Impact Polystyrene (HIP) is not expected to nor has it been seen degrade.* *The product is a modular system. The initial purchase includes the PDU packs. Subsequent applications (every 60 days) however, only require the tablets to be replaced as the existing PDU's are refilled & continue to be used. This is a cost effective approach for both the customer & Exosect as a supplier.* *Additionally, Exosex SPTab has been approved & marketed since 2009 and during this time customer experience has shown that the PDU's are very stable & durable, only needing to be replaced if they become accidentally damaged.* *Similar HIP hanging dispensers have also been used successfully outside for agricultural pheromone tablets where they are subject to continual weathering & UV exposure and no instability has been observed.*	data show that after 3 months ambient storage the active is degraded by 15 %. Hence it is not stable. There is no data to support the label claim. The active content was determined using the method outlined in 3.2.2.		

<table>
<tr><th>1. Subsection (Annex Point/TNsG)</th><th>Method</th><th>Purity/ Specification</th><th>Results</th><th>Remarks/ Justification</th><th>GLP (Y/N)</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>For the dispenser it is considered the experience in use of the applicant is sufficient to address its stability. No further consideration is required.

Ambient storage stability data (25˚C) on the new formulation in heat-sealed “non-resealable” Doy sales pack

New formulation contains 0.05% tert-Butylhydroquinone / 2-tert-butylbenzene-1,4-diol (Carnauba wax carrier reduced by 0.05%) which has been added to aid the retention of the active substance in the product. The addition of this co-formulant is deemed very unlikely to affect the physical properties of the formulation.

<table><tr><th>Test</th><th>Prior to storage</th><th>After 3 months at storage at 25ºC</th></tr><tr><td>Active content</td><td>10.18 g/kg</td><td>10.48 g/kg</td></tr><tr><td>Appearance</td><td>Uniform solid opaque yellow tablet

Some flakes were observed</td><td>No change</td></tr></table></td><td>Based on the data submitted, a shelf life of 6 months can be recommended for the new formulation, due to the active substance falling by 16% after 9 months. In addition, a label recommendation will be required to store the product at temperatures below 25ºC.</td><td>Y</td><td>[redacted]</td></tr>
</table>

<table>
<tr><th>1. Subsection (Annex Point/TNsG)</th><th>Method</th><th>Purity/ Specification</th><th>Results</th><th>Remarks/ Justification</th><th>GLP (Y/N)</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Packaging</td><td>Clear sealed plastic stand up pouch with no pack / product interaction</td><td>No change</td></tr>
<tr><td>Evaporation rate</td><td>see 3.8</td><td>Not determined</td></tr>
</table>
<table>
<tr><th>Test</th><th>Prior to storage</th><th>After 6 months at storage at 25ºC</th></tr>
<tr><td>Active content</td><td>10.18 g/kg</td><td>9.76 g/kg</td></tr>
<tr><td>Appearance</td><td>Uniform solid opaque yellow tablet

Some flakes were observed</td><td>No change</td></tr>
<tr><td>Packaging</td><td>Clear sealed plastic stand up pouch with no pack /</td><td>No change</td></tr>
</table>
</td><td></td><td></td><td></td></tr>
</table>

<table>
<tr><th>1. Subsection (Annex Point/TNsG)</th><th>Method</th><th>Purity/ Specification</th><th>Results</th><th>Remarks/ Justification</th><th>GLP (Y/N)</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>product interaction</td><td></td></tr>
<tr><td>Evaporation rate</td><td>see 3.8</td><td>Not determined</td></tr>
</table>
<table>
<tr><th>Test</th><th>Prior to storage</th><th>After 9 months at storage at 25ºC</th></tr>
<tr><td>Active content</td><td>10.18 g/kg</td><td>8.57 g/kg</td></tr>
<tr><td>Appearance</td><td>Uniform solid opaque yellow tablet

Some flakes were observed</td><td>No change</td></tr>
<tr><td>Packaging</td><td>Clear sealed plastic stand up pouch with no pack / product interaction</td><td>No change</td></tr>
<tr><td>Evaporation rate</td><td>see 3.8</td><td>Not determined</td></tr>
</table>
</td><td></td><td></td><td></td></tr>
</table>

<table>
<tr><th>1. Subsection (Annex Point/TNsG)</th><th>Method</th><th>Purity/ Specification</th><th>Results</th><th>Remarks/ Justification</th><th>GLP (Y/N)</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><th>Test</th><th>Prior to storage</th><th>After 12 months at storage at 25ºC</th></tr>
<tr><td>Active content</td><td>10.18 g/kg</td><td>8.96 g/kg</td></tr>
<tr><td>Appearance</td><td>Uniform solid opaque yellow tablet

Some flakes were observed</td><td>No change</td></tr>
<tr><td>Packaging</td><td>Clear sealed plastic stand up pouch with no pack / product interaction</td><td>No change</td></tr>
<tr><td>Evaporation rate</td><td>see 3.8</td><td>Not determined</td></tr>
</table>

<table>
<tr><th>Test</th><th>Prior to storage</th><th>After 18 months at storage at 25ºC</th></tr>
<tr><td>Active content</td><td>10.18 g/kg</td><td>8.7 g/kg</td></tr>
</table>
</td><td></td><td></td><td></td></tr>
</table>

<table>
<tr><th>1. Subsection (Annex Point/TNsG)</th><th>Method</th><th>Purity/ Specification</th><th>Results</th><th>Remarks/ Justification</th><th>GLP (Y/N)</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Appearance</td><td>Uniform solid opaque yellow tablet

Some flakes were observed</td><td>No change</td></tr>
<tr><td>Packaging</td><td>Clear sealed plastic stand up pouch with no pack / product interaction</td><td>No change</td></tr>
<tr><td>Evaporation rate</td><td>see 3.8</td><td>Not determined</td></tr>
</table>
<table>
<tr><th>Test</th><th>Prior to storage</th><th>After 24 months at storage at 25ºC</th></tr>
<tr><td>Active content</td><td>10.18 g/kg</td><td>7.86 g/kg</td></tr>
<tr><td>Appearance</td><td>Uniform solid opaque yellow tablet</td><td>No change</td></tr>
</table>
</td><td></td><td></td><td></td></tr>
</table>

<table>
<tr><th>1. Subsection (Annex Point/TNsG)</th><th>Method</th><th>Purity/ Specification</th><th>Results</th><th>Remarks/ Justification</th><th>GLP (Y/N)</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>Some flakes were observed</td><td></td></tr>
<tr><td>Packaging</td><td>Clear sealed plastic stand up pouch with no pack / product interaction</td><td>No change</td></tr>
<tr><td>Evaporation rate</td><td>see 3.8</td><td>Not determined</td></tr>
</table>
</td><td></td><td></td><td></td></tr>
<tr><td>3.8 Technical characteristics

Evaporation rate</td><td>In house method</td><td>Exosex Sp tab</td><td>Hangers with tablets placed in a wind tunnel at 22ºC with a fan speed of 0.35 m/s. The rate of loss of the active was determined over a 91 day period. The rate loss of the active (µg/h) is shown in the table below:
<table>
<tr><th>Day</th><th>RoL µg/h</th></tr>
<tr><td>0</td><td>10.06</td></tr>
<tr><td>7</td><td>8.56</td></tr>
<tr><td>14</td><td>7.29</td></tr>
<tr><td>30</td><td>5.05</td></tr>
<tr><td>60</td><td>2.53</td></tr>
<tr><td>90</td><td>1.27</td></tr>
</table>
</td><td>The active content was determined using the method outlined in 3.2.2.</td><td>N</td><td>[redacted]</td></tr>
<tr><td>Tablet integrity</td><td>Not tested</td><td>-</td><td>Applicant's statement:</td><td>The applicant's justification is accepted. The determination of the tablet integrity would</td><td>-</td><td>-</td></tr>
</table>

			The determination of the attrition and friability of the tablets is not considered appropriate for this product. The tablets are designed to be inherently friable in order to effectively deliver the pheromone and would not withstand the CIPAC test. **The production process for Exosex SPTab tablets involves cold powder compaction, where a nominal 1g of pheromone / Entostat powder formulation is pressed from a mould.** The Entostat powder acts as the delivery system for the pheromone and as the name suggests "Entostat" powder exhibits electrostatic properties. Even through very slight movement, it develops an electrostatic charge. Insects similarly develop an electrostatic charge as they fly through air or walk across surfaces. When placed in contact with insects, the powder adheres to them and can be passed from one insect to another through direct contact. The major component of the tablet is the Entostat powder (99%), which consists mainly of carnauba wax. Due to the nature of this component, the compression required during production to form a sufficiently compact tablet may vary according to ambient humidity & temperature. It is therefore essential that the tablet is sufficiently robust so as to remain intact during transport & use, but not overly	not be suitable for this product. The storage data show that the compressed solid remains intact prior to and after storage.		

1. Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reference
			compacted which may result in a significant reduction in the availability of the active powder to the target pest when approached and touched. As each tablet batch is manufactured, the first few tablets out of the mould are visually and manually assessed for integrity & the powder compression adjusted accordingly. The tablet should not be cracked & should be hard enough to be pushed into the dispenser without breaking down. The tablet is considered to be soft enough if it is shown to leave a medium 'chalk like' mark when drawn across a canvas type material. The tablets are again visually checked during the packing of the product The packaging of the product has been specially designed to prevent damage of the product during transport. The suitability of the packaging was tested by dispatching trial packs to Scotland where the product was inspected for damage & returned to Exosect Ltd for a final damage assessment. To date there have been no reports of customers receiving damaged product packaging or goods.			
Tablet homogeneity	In house method	Exosex SP tab	QC data of the active content of five batches of tables was provided:	The QC data show that the active content from batch to batch is uniform.	N	Summary of data

1. Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reference
			Batch / **Amount of active (g/kg)** W3236 / 10.72 W3226 / 11.02 W2920 / 10.71 W2291 / 10.69 W2232 / 9.50			
3.9 Compatibility with other products	Not tested	-	-	The product is not intended to be combined or mixed with other biocidal products.	-	-
3.10 Surface tension	-	-	-	Not relevant to a RTU solid		
3.11 Viscosity	-	-	-	Not relevant to a RTU solid		
3.12 Particle size distribution	Laser diffraction	Exosex SP tab	X10: 4.9 µm X50: 14.8 µm X90: 28.3 µm	The powder is compressed into a cylinder tablet for use and hence these data are not directly relevant.	N	Summary of data provided by applicant on the laser diffraction of the powder. Owing to the data not being relevant then no further consideration is required.

ANNEX B. TABLE OF RESULTS FOR EFFICACY

Table B1: Summary of results for Efficacy of Exosex® SP_{Tab}

Test substance	Test organism(s)	Test system / concentrations applied / exposure time	Test results: effects, mode of action, resistance	Reference
Exosex SPTab	*E. kuehniella* *P. interpunctella*	Field trial conducted at an organic produce warehouse in the UK. 1 year pre-treatment phase and 1 year treatment phase. Approximately 1 tablet 25.0 m^{-2}.	Reduction in population of 89.3 %, compared with pre-treatment levels.	[redacted]
Exosex SPTab	*P. interpunctella*	Field trial conducted at a spice processing plant in the Netherlands. 367 day pre-treatment phase and 366 day treatment phase. Approximately 1 tablet 25.0 m^{-2}.	Reduction in population of 78.9 %, compared with pre-treatment levels.	[redacted]
Exosex SPTab	*E. kuehniella* *P. interpunctella*	Field trial conducted at a bakery in Germany. 2 year pre-treatment phase and 1 year treatment phase. Approximately 1 tablet 24.0 m^{-2}.	Reduction in population of 84.0 %, compared with pre-treatment levels.	[redacted]
Exosex SPTab	*C. cautella*	Field trial conducted at a chocolate factory warehouse in the UK. 1 year pre-treatment phase and 6 month treatment phase. Approximately 1 tablet 28.0 m^{-2}.	Reduction in population of 70.5 %, compared with pre-treatment levels.	[redacted]

Test substance	Test organism(s)	Test system / concentrations applied / exposure time	Test results: effects, mode of action, resistance	Reference
Exosex SPTab	*E. kuehniella*	Field trial conducted at a flour mill in the UK. 10 month pre-treatment phase and 10 month treatment phase. Approximately 1 tablet 25.0 m^{-2}.	Reduction in population of 75.6 %, compared with pre-treatment levels.	[redacted]
Exosex SPTab	*E. kuenniella*	Field trial conducted at a beverage production facility in Germany. 1 year pre-treatment phase and 11 month treatment phase. Approximately 1 tablet 37.0 m^{-2}.	No data on percentage reduction.	[redacted]
Exosex SPTab	*E. elutella*	Field trial conducted at a tobacco warehouse in Belgium. 6 month pre-treatment phase and 6 month treatment phase. 1 tablet 26.1 m^{-2}.	<u>Pre-treatment period</u> Weekly counts in the range 0 – 92 moths. Mean weekly count of 14.2. Total count of 398. <u>Treatment period</u> Weekly counts in the range 0 – 34 moths. Mean weekly count of 6.3. Total count of 177.	[redacted]
Exosex SPTab	*E. kuehniella*	Field trial conducted at a bakery in Spain. 1 year pre-treatment phase and 1 year treatment phase. Approximately 1 tablet 28.0 m^{-2}.	No data on percentage reduction.	[redacted]

ANNEX C. REFERENCE LIST

Author(s)	Year	Title	Source	Report No. & Company Study No.	Report Date	Data Protection Claimed	Owner
RMS Austria	2010	Inclusion Of Active Substance in Annex I and IA to Directive 98/8/EC Assessment Report (Z,E)-Tetradeca-9,12-Dienyl Acetate Product-Type 19 (Attractant) Published	Publically available via CIRCABC website https://circabc.europa.eu/sd/a/18fabcde-3455-472c-919f-f4eb746e0186/Post%20SC%20assessment%20report%20ZE-TDA%20PT19.pdf	2010/09/24	N	Public	RMS Austria
[redacted]	2010	Method Validation Study For Exosex SPTab Formulation.	[redacted]	[redacted]	2010/03/25	Yes	Exosect Ltd
[redacted]	2012	Residual Ageing And Rate Of Loss Profiling Of Exosex SPTab	[redacted]	[redacted]	2012/26/10	Yes	Exosect Ltd