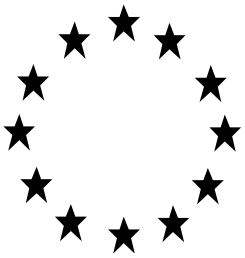
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR SAME BIOCIDAL PRODUCT APPLICATIONS

(submitted by the evaluating Competent Authority)



ADDICT GEL COCKROACH, DINO GEL COCKROACH.

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

Dinotefuran

Case Number in R4BP: BC-FS025918-15

Evaluating Competent Authority:
UK CA – Health and Safety Executive.

Date:/12/2016

TABLE OF CONTENTS

CONCLUSION

1.1. SUMMARY OF DECISIONS AND RESTRICTIONS

It is concluded after evaluation, that sufficient data have been provided to verify the outcome and conclusions, and permit authorisation of the biocidal product subject to the following conditions:

1.1.1. Usage area

User	Application method
Professional	Gel bait RFU in a solvent resistant plastic (eg. Polypropylene, polyethelene) syringe. Application onto dry surfaces (spot treatment) and in cracks and crevices (indoors only) within domestic dwellings and commercial buildings.

1.1.2. Pests and application rate

Authorisation is granted for the control of German and Oriental cockroaches.

Apply in 0.1 g spots (with each spot containing 0.002 g of dinotefuran):
- Apply 2-4 spots per m² for small cockroach species (*B. germanica*)
- Apply 4-8 spots per m² for large cockroach species (*B. orientalis*)

Apply a maximum of 0.8g of product per m^2 for heavy infestations:
-Up to 16 spots when treating a house.
-Up to 72 spots when treating public buildings.
In case of heavy infestation, a second application may be performed after 7 days.

1.1.3. Active substance details

The concentration of the active substance dinotefuran in the biocidal product is 2% w/w. The source is Mitsui Chemicals Agro, Inc. Minimum purity 99.1% w/w.

1.1.4. Comparative assessment and authorisation

The product has been subject to a comparative assessment as dinotefuran is considered a candidate for substitution in accordance with Article 10(1)(d) of EU Regulation 528/2012.

As the outcome of the comparative assessment was not sufficiently conclusive to state that the criteria of Article 23(3) of EU Regulation 528/2012 are met, the product can be **authorised for a period not exceeding 5 years**.

1.2. NECESSARY ISSUES ACCOUNTED FOR IN THE PRODUCT LABEL

FOR USE ONLY BY PROFESSIONAL OPERATORS.

PREVENT ACCESS TO BAITS by children and animals.
DO NOT apply this product in areas easily accessible to children or animals.
DO NOT USE where food, feed or water could become contaminated.
Use only as a spot treatment in areas that will not be accessible, will not be submerged in water and where bait would not be removed by routine cleaning.
Wash hands and exposed skin before meals and after use.
KEEP IN A SAFE PLACE.
DO NOT APPLY IN OR AROUND DRAINS.
To maintain product palatability apply away from sources of heat.
DO NOT contaminate streams, rivers or waterways with the product or used containers.
Store in original container.
FOR INDOOR USE ONLY.
Protect from frost.
Dinotefuran is a nitroguanidine compound included with other insect nicotinic acetylcholine receptor (nAChRs) agonists in the Insect Resistance Action Committee (IRAC) group 4A. Detailed mode of action studies suggest that dinotefuran binds to the acetylcholine receptor site in a mode that differs to the chlorinated neonicotinic molecules included in IRAC group 4A. In common with all insecticides the possibility of the development of a cross resistance or a specific resistance to dinotefuran cannot be discounted.
Strategies to reduce the risk of resistance developing such as recommendations to treat to levels that ensure complete kill of target pest infestations and to use dinotefuran alternately with substances with a different mode of action can be implemented at end-use product approval. Monitoring programs to confirm that target pests remain susceptible to dinotefuran will be implemented upon product approval.

1.3. REQUIREMENT FOR FURTHER INFORMATION

The HPLC-MS/MS monitoring method for water that has been evaluated in the CAR, is validated for only one ion transition. Further validation data for a second transition should be provided by the data owner as a post authorisation condition by 31st December 2017.

2. ASSESSMENT REPORT

2.1. SUMMARY OF THE PRODUCT ASSESSMENT

Please note that authorisation of Addict Gel Cockroach was conducted through the same biocidal product route and is based upon the product Dinotefuran 2% Bait under R4BP3 asset number UK-0011870-0000. Therefore, the below PAR is a replica of that created for Dinotefuran 2% Bait and references the Dinotefuran 2% bait name but the confidential information has been removed. This PAR also covers the product Dino Gel Cockroach, which is an additional trade name of Addict Gel Cockroach.

2.1.1. ADMINISTRATIVE INFORMATION

Product name

Product name	**Country (if relevant)**
Addict Gel Cockroach	United Kingdom
Dino Gel Cockroach	United Kingdom

Authorisation holder

Name and address of the authorisation holder	**Name**	LODI S.A.S.
	Address	Parc d'Activités des Quatre Routes Grand Fougeray 35390 France
Authorisation number	UK-2017-1064	
Date of the authorisation	25-01-2017	
Expiry date of the authorisation	01-03-2021	

Manufacturer(s) of the product

Name of manufacturer	Mitsui Chemicals Agro, Inc. [redacted]
Address of manufacturer	Mitsui Chemicals Agro, Inc., Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chuo-ku, Tokyo, 103-0027, Japan
Location of manufacturing sites	[redacted]

Manufacturer(s) of the active substance(s)

Active substance	Dinotefuran
Name of manufacturer	Mitsui Chemicals Agro, Inc. [redacted]
Address of manufacturer	Mitsui Chemicals Agro, Inc., Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chuo-ku, Tokyo, 103-0027, Japan

Location of manufacturing sites	Mitsui Chemicals Inc./Omuta Works, 30 Asamuta-Machi, Ohmuta Shi, Fukuoka, 836-8610, Japan.

2.1.2. PRODUCT COMPOSITION AND FORMULATION

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes

Identity of the active substance

Main constituent(s)	
ISO name	Dinotefuran
IUPAC or EC name	(*RS*)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine
EC number	605-399-0
CAS number	165252-70-0
Minimum purity / content	99.1 % w/w (991 g/kg)

Candidate(s) for substitution

According to the most recent scientific information available, the active substance in this biocidal product, dinotefuran, is considered a candidate for substitution using the criteria in Article 10(1) of EU Regulation 528/2012, although it is not considered as meeting the exclusion criteria according to Article 5(1). This conclusion is based on section 1.4.4. of the Evaluation of Active Substances Assessment Report for dinotefuran under PT18 and the EU list (dated November 2015): https://circabc.europa.eu/sd/a/419b9650-db4b-4c6e-91d8-fbefa8669715/List_compilation_exclusion_substituion_criteria_version_November%202015.xls, which states that dinotefuran is proposed to be classified as persistent/very persistent (P/vP) and toxic (T) but not bio-accumulative. Therefore dinotefuran can be considered to meet the criteria in Article 10(1)(d), notably it meets two of the criteria for being PBT in accordance with Annex XIII to regulation (EC) No 1907/2006.
Please see section 2.2.8 for details of the comparative assessment.

Qualitative and quantitative information on the composition of the biocidal product

See CONFIDENTIAL ANNEX 3.6. and the original Dinotefuran 2% Bait PAR (R4BP3 asset number UK-0011870-0000).

Information on technical equivalence

The notified source of dinotefuran (Mitsui Chemicals Agro, Inc.) is the same as that in the CAR for active substance approval.
LODI S.A.S. is the applicant for authorisation of the product and a letter of access has been provided by Mitsui Chemicals Agro, Inc. co-signed by LKC UK LTD granting access to both the Dinotefiran 2% Bait product and the dinotefuran active substance (Annex II) dossier. However, the composition details and vertebrate testing facilities have been removed.

Information on the substance(s) of concern

No substances of concern were identified by human health toxicology. The environment assessment revealed that there were four potential SoC's. Three substances initially had

one or more of the classifications Aquatic Acute 1-H400, Aquatic Chronic 1-H410 and Aquatic Chronic 2-H411 whereas, denatonium benzoate had a classification of aquatic Chronic 3-H412. Although the applicant was able to submit evidence that supported a non-classification for the first three, this was not the case for denatonium benzoate and hence, it was the only one out of the potential 4 identified as a SoC by the environmental assessment. Despite all this, its risk can be considered negligible due to its presense being at low levels (0.01% w/w) in the formulation.

Type of formulation

VIII.5.2. Gel [Bait] (ready for use)

2.1.3. AUTHORISED USE(S)

Table 1. Use # 1 – Professional

Product Type	PT-18 (insecticides, acaricides and products to control other arthropods)
Where relevant, an exact description of the authorised use	VII.2 Health protection
Target organism (including development stage)	I.3.4.1 Blattellidae, Blattellid Cockroaches Including: *B. germanica* (German cockroaches) and *B. orientalis* (Oriental cockroaches).
Field of use	IV.1. Indoor use only. IV.1.3 To be used in/at: IV.1.3.1 Industrial/commercial premises IV.1.3.2 households/private areas. IV.1.3.3 Public (e.g. Hospitals, Nursing Homes)
Application method(s)	V.I.6. Bait application V.I.7.1. Open via crack and crevice or spot treatment only
Application rate(s) and frequency	Apply in 0.1 g spots (with each spot containing 0.002 g of dinotefuran): - Apply 2-4 spots per m² for small cockroach species (*B. germanica*) - Apply 4-8 spots per m² for large cockroach species (*B. orientalis*) Apply a maximum of 0.8g of product per m^2 for heavy infestations: -Up to 16 spots when treating a house. -Up to 72 spots when treating public buildings. In case of heavy infestation, a second application may be performed after 7 days.
Category(ies) of users	V.2. Professional
Pack sizes and packaging material	A syringe-style applicator, composed of solvent resistant plastic (eg. Polypropylene, polyethylene): 30g

2.1.4. HAZARD AND PRECAUTIONARY STATEMENTS[1]

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

The non classification of the product is acceptable from a chemistry perspective.

Classification	
Hazard category	Aquatic chronic category 2
Hazard statement	H411 Toxic to aquatic life with long lasting effects
Labelling	
Signal words	Not required
Hazard statements	H411 Toxic to aquatic life with long lasting effects
Precautionary statements	P273: Avoid release to the environment. P391: Collect spilage P501: Dispose of contents/container in accordance with local/regional/national/international regulation (to be specified).
Note	GHS09: environment. **Above information is for the biocidal product**

2.1.5 PACKAGING OF THE BIOCIDAL PRODUCT

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Syringe applicator with a cap and adaptor nozzle.	30 g	solvent resistant plastic (eg. Polypropylene, polyethylene)	Cap and adaptor nozzle	Professional	Yes

[1] For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

2.1.6. DIRECTIONS FOR USE

A. INSTRUCTIONS FOR USE

Use # 1 - Professional

To apply the gel, remove the cap from the nozzle, touch the tip of the nozzle to the surface to be treated and depress plunger slightly. Re-apply according to remaining level of infestation and when bait is no longer visibly present. Replace cap for storage of the product.
Use only as a spot treatment in areas that will not be accessible, will not be submerged in water and where bait would not be removed by routine cleaning.
To maintain product palatability apply away from sources of heat.

Spot treatment method of application:
Remove cap from tip of applicator tube. Place tip at spot where gel is to be applied. Depress plunger until appropriate amount is dispensed. Replace cap when finished dispensing gel.

Cracks and crevices method of application:
Gel bait should be applied directly into cracks and crevices where insects hide. Place the applicator tip directly into cracks and crevices and deposit gel. Bait should be in the void area and not on open or exposed surfaces.

B. PARTICULARS OF LIKELY DIRECT OR INDIRECT EFFECTS, FIRST AID INSTRUCTIONS AND EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT

The following information has been provided by the applicant:

Particulars of likely direct or indirect effects:

ENGINEERING CONTROLS:
Provide general ventilation. The use of closed system or local exhaust ventilation is recommended. Provide safety shower and eye wash station near work area.

First aid instructions:

Ingestion:
Rinse mouth with water. Get medical attention immediately. Induce vomiting as directed by medical personnel. Never give anything by mouth to an unconscious or convulsing person.
Inhalation:
If you feel unwell, remove to fresh air immediately. Get medical attention if cough or other symptoms develop. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.
Skin Contact:
Immediately remove contaminated clothing and shoes. Flush skin and clean off with large amounts of water. Get medical attention if symptoms develop.
Eye Contact:
Immediately flush with plenty of water. Part eyelids with fingers to assure complete flushing. Check for and remove contact lenses if easily possible. Get medical attention if irritant persists.

Emergency measures to protect the environment:

Environmental protection: Do not let this product enter the environment.
Spill control: Scoop or sweep up the spilled product and place it in a disposal container. Use appropriate tools. Whatever cannot be saved for recovery may be burned in an

approved incinerator or disposed in approved waste facility.
Personal precautions: Wear PPE:
Eye/face protection: Safety glasses, goggles.
Skin Protection:
Hand protection: Chemical resistant gloves.
Body Protection: Safety helmet, protective clothing, safety boots.
Respiratory protection: Chemical cartridge respirator.

C. INSTRUCTIONS FOR SAFE DISPOSAL OF THE PRODUCT AND ITS PACKAGING

DO NOT contaminate streams, rivers or waterways with the product or used containers.
P501: Dispose of contents/container in accordance with local/regional/national/international regulation (to be specified).

D. CONDITIONS OF STORAGE AND SHELF-LIFE OF THE PRODUCT UNDER NORMAL CONDITIONS OF STORAGE

Store in original container.
Store in a cool, well ventilated place.
Do NOT store in direct sunlight.
Protect from frost.
A shelf life of 2 years is supported.

2.1.7 OTHER INFORMATION

None

2.2 ASSESSMENT OF THE BIOCIDAL PRODUCT

2.2.1 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES

'Dinotefuran 2% bait' is a ready for use gel bait (RB) formulation. This was the representative formulation considered in the CAR for active substance approval. The physical and chemical and storage stability data submitted to support the formulation are summarised in table 3.1, these include new studies complying with current, GLP standards and address the concerns identified in the CAR.

Subsection (Annex Point/TNsG)	**Method**	**Purity/ Specification**	**Results**	***UK CA comments***	**GLP (Y/N)**	**Reference**
3.1 Appearance	Visual	'Dinotefuran 2% bait' with bittering agent		*Acceptable.*	Y	Cage, S., 2014. MCW0042
3.1.1 Physical state and nature			paste-like			
3.1.2 Colour			brown			
3.1.3 Odour			No odour			
3.2 Explosive properties	EEC A.14	'Dinotefuran 2% bait'	Not explosive.	*Acceptable.*	Y	Cage, S., 2012. MCW0034
3.3 Oxidising properties	EC A.21	'Dinotefuran 2% bait' with bittering agent	Not oxidising.	*Acceptable.*	Y	Cage, S., 2014 MCW0057
3.4 Flash-point and other indications of flammability or	EEC A.10	'Dinotefuran 2% bait'	No propagation of flame was observed. The product is not classed as flammable.	*Acceptable. Although the test does not*	Y	Cage, S., 2012. MCW0037

Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	*UK CA comments*	GLP (Y/N)	Reference
spontaneous ignition				*include use of a wetted zone, as specified in the CLP Reg., as the flame is not propagated a wetted zone would stop the flame therefore the product is not classified as a flammable solid under CLP.*		
Auto-ignition temperature	A.15		Product did not auto-ignite below 400°C	*Acceptable.*		Cage, S., 2012 MCW0038
3.5 Acidity/Alkalinity	CIPAC MT 75.3	'Dinotefuran 2% bait', Lot 00001 with bittering agent	5.1	*Acceptable. No acidity/alkalinity required as 4<pH<10*	Y	Cage, S., 2014. MCW0042
3.6 Relative density/bulk density	EEC A.3	'Dinotefuran 2% bait', Lot 00001	1.13	*Acceptable.*	Y	Cage, S., 2012. MCW0039

<table>
<tr><th>Subsection (Annex Point/TNsG)</th><th>Method</th><th>Purity/ Specification</th><th>Results</th><th>UK CA comments</th><th>GLP (Y/N)</th><th>Reference</th></tr>
<tr><td>3.7 Storage stability - stability and shelf life

Accelerated storage data
54°C for 14 days</td><td>CIPAC MT 46.3

Visual

Validated HPLC method

CIPAC MT 75.3

visual observations</td><td>‘Dinotefuran 2% bait’, Lot 00004 with bittering agent</td><td>Accelerated storage data:
<table>
<tr><td>Test</td><td>Prior to storage</td><td>After 24 months</td></tr>
<tr><td>Appearance</td><td>Brown paste like formulation. No odour.</td><td>Brown paste like formulation. No odour.</td></tr>
<tr><td>Active content</td><td>2.1% w/w</td><td>2.1% w/w</td></tr>
<tr><td>pH (1% soln)</td><td>5.0</td><td>5.2</td></tr>
<tr><td>Product application</td><td colspan="2">The product was easily and consistently applied from the front, middle and end of the tube before and after storage.</td></tr>
<tr><td>Pack interactions</td><td colspan="2">No evidence of product permeation at each timepoint.</td></tr>
</table></td><td>Acceptable. No loss of active ingredient following storage and pH did not significantly change after storage. No acidity or alkalinity required as 4<pH<10.

No adverse packaging interactions were observed and the syringe did not block and the product could consistently be applied through the commercial packaging following storage.</td><td>Y</td><td>Cage, S., 2014. MCW0058</td></tr>
<tr><td>3.7 Storage stability - stability and shelf life</td><td></td><td>‘Dinotefuran 2% bait’, Lot 00001</td><td>Ambient storage data:
<table>
<tr><td>Test</td><td>Prior to storage</td><td>After 24 months</td></tr>
</table></td><td>Acceptable. No loss of active ingredient following</td><td>Y</td><td>Cage, S., 2014. MCW0042</td></tr>
</table>

<table>
<tr><th>Subsection (Annex Point/TNsG)</th><th>Method</th><th>Purity/ Specification</th><th>Results</th><th>UK CA comments</th><th>GLP (Y/N)</th><th>Reference</th></tr>
<tr><td>Ambient storage data
Samples were stored at room temperature in the dark in translucent plastic syringes (commercial packs)</td><td>Visual

Validated HPLC method

CIPAC MT 75.3

visual observations</td><td>with bittering agent</td><td><table>
<tr><td>Appearance</td><td>Brown paste like formulation. No odour.</td><td>Brown paste like formulation. No odour.</td></tr>
<tr><td>Active content</td><td>2.1% w/w</td><td>2.1% w/w</td></tr>
<tr><td>pH (1% soln)</td><td>5.1</td><td>5.0</td></tr>
<tr><td>Product application</td><td colspan="2">The product was easily and consistently applied from the front, middle and end of the tube before and after storage.</td></tr>
<tr><td>Pack interactions</td><td colspan="2">No evidence of product permeation at each timepoint.</td></tr>
</table></td><td>storage and pH did not significantly change after storage. No acidity or alkalinity required as 4<pH<10.

No adverse packaging interactions were observed and the syringe did not block and the product could consistently be applied through the commercial packaging following storage.</td><td></td><td></td></tr>
<tr><td>3.7 Storage stability - stability and shelf life

Cold temperature storage data
0°C for 7 days</td><td>CIPAC MT39.3</td><td>‘Dinotefuran 2% bait’, Lot 00001</td><td>Cold temperature storage<table>
<tr><td>Test</td><td>Prior to storage</td><td>After storage (temp and length)</td></tr>
<tr><td>Appearance</td><td>Viscous brown gel.</td><td>Viscous brown gel,</td></tr>
</table></td><td>Acceptable. No adverse change to the product appearance occurred on cold temperature</td><td>Y</td><td>Cage, S., 2012. MCW0043</td></tr>
</table>

Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	*UK CA comments*	GLP (Y/N)	Reference
			no separation observed.	*storage. Additionally, the label phrase 'Protect from frost' is to be recommended.*		
3.8 Technical characteristics	-	-	Not relevant to a RB formulation	*Acceptable.*	-	-
3.9 Compatibility with other products	case	-	The formulation is a ready to use bait and is not designed for use with any other products.	*Acceptable.*	-	Waiver
3.10 Surface tension	case	-	Determination of the surface tension of the bait is not required as the formulation is a gel paste. There is also limited exposure.	*Acceptable. In line with the ECHA guidance, surface tension is required for liquid formulations. The product is a solid paste, therefore no surface tension is required.*	-	Waiver
3.11 Viscosity	OECD 114	'Dinotefuran 2% bait', Lot 00001	viscosity at 20°C = 110,000 – 1400000 mPa.s viscosity at 40°C = 56,000 – 300,000 mPa.s	*Acceptable.*	Y	Cage, S., 2012 MCW0040

Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	*UK CA comments*	GLP (Y/N)	Reference
3.12 Particle size distribution	-	-	Not relevant to a RB formulation	*Acceptable.*	-	-

Conclusion on the physical, chemical and technical properties of the product
Dinotefuran 2% bait is a brown ready to use bait formulation containing 2 % w/w of dinotefuran (pure). The pH of a 1 % solution is 5.1. The formulation is not explosive, flammable or oxidising. There was an acceptable retention of the physical and chemical properties on cold temperature and accelerated storage. Ambient storage data demonstrate the formulation is stable for 2 years in polyethylene syringes (commercial packaging).

2.2.2 METHODS FOR DETECTION AND IDENTIFICATION

Analytical method for the active substance in the biocidal product

The dinotefuran content in the biocidal product 'Dinotefuran 2% bait' was determined by an HPLC method using an external standard and UV detection (270 nm). A Synergi Hydro-RP, 4µm, 25 cm x 4.6 mm id column was used at 45°C with a mobile phase of MeOH : 0.01% orthophosphoric acid (20:80 v/v).

Samples were prepared by weighing 1250 mg of 'Dinotefuran 2% bait' and dissolving in 50 mL methanol. 5 mL aliquots were diluted with 15 mL methanol and then made up to 100 mL with purified water. The final sample concentration was 1.25 mg/mL.

A summary of the validation data are outlined in table 2.2.3.

Table 2.2.3: Analytical validation data for the determination of 'dinotefuran' in 'Dinotefuran 2% bait'

Matrix	LOQ	Recovery fortification level (%w/w)	Recoveries % range (mean)	Repeatability % RSD (n)	Linearity	Specificity
Dinotefuran	2.0 % w/w	2.0	99.9 – 101.1 (100.3, n=4) Acceptable SANCO range 97 – 103 %	0.64 (10) Acceptable Horwitz %RSD = 2.41	7.6 – 37.8 mg/L [equiv. to *ca.* 30 - 150% nominal content] n = 5 r = 1.0000	Chromatograms of standards, test item and blank showed no interference at the retention time of interest (7 mins). Confirmation was achieved by DAD analysis.

Conclusion on the methods for identification of the product
The method is satisfactorily validated in accordance with the EU guidance document SANCO/3030/99 rev. 4. According to the implementing regulation 2015/416 there are no relevant impurities associated with dinotefuran, therefore no further consideration is required from a chemistry perspective.

Analytical methods for the monitoring of residues (soil, water, air, body fluids and tissues and food)

An acceptable monitoring method for the determination of residues of dinotefuran in soil is available from the evaluation of the active substance approval. A method was submitted and evaluated for water, but it was considered acceptable for one ion transition only and the following was stated in the CAR: *"Validation data for a second ion transition would be required in order to fully meet the*

requirements. The method is considered suitable as a monitoring method subject to the submission of validation data for a second ion transition."
UK CA therefore require the post-authorisation submission of validation data for the second ion transition by the data owner, by 31st December 2017.

A method is not required for air as the vapour pressure of dinotefuran was estimated to be < 1.7 x 10-6 Pa at 30 °C and no relevant exposure according to application technique is likely to occur, as the product is applied as a paste not as a spray. This case was accepted in the CAR and is applicable to this product authorisation.

Methods for the detection of dinotefuran in matrices of plant and animal origin were not provided. However, the intended use pattern of the product will not result in contact with food or feedstuffs. The product is intended for professional use in cracks and crevices and the label states *'Do not use where food, feed or water could be contaminated'.* Therefore an analytical method to determine residues in food of plant and animal origin is considered unnecessary. This case was accepted in the CAR and is applicable to this product authorisation.

Dinotefuran is not classified as toxic or very toxic and hence a monitoring method for residues in body fluids and tissues is not required.

2.2.3 EFFICACY AGAINST TARGET ORGANISMS

A. FUNCTION AND FIELD OF USE

Dinotefuran 2 % Bait is an insecticide (PT 18).

The product is for use indoors and is applied by spot or crack and crevice treatment where target pests congregate.

The product is intended for use only by professional operators.

B. ORGANISMS TO BE CONTROLLED AND PRODUCTS, ORGANISMS OR OBJECTS TO BE PROTECTED

Dinotefuran 2 % bait is used to control cockroaches, primarily German cockroaches, *Blattella germanica*, and oriental cockroaches, *Blatta orientalis*.

C. EFFECTS ON TARGET ORGANISMS, INCLUDING UNACCEPTABLE SUFFERING

The product is an insecticide bait containing 2.0 % dinotefuran.

The product aims to control the cockroach population.

The product is packaged in a syringe applicator. Typically, 16 - 72 spots of approximately 0.1 g each are placed in areas where cockroaches are observed. This is applied at approximately 0.2 – 0.4 g m-2 for *B. germanica* and 0.4 – 0.8 g m-2 for *B. orientalis*. The product can be reapplied once after 7 days in cases of heavy infestation.

D. MODE OF ACTION, INCLUDING TIME DELAY

The applicant has provided the following description regarding the mode of action of Dinotefuran 2 % Bait:

'Contact and ingestion; Dinotefuran is a neonicotinoid in the nitroguanidine class. It appears that dinotefuran acts as an agonist of insect nicotinic acetylcholine receptors, but it is postulated that dinotefuran affects the nicotinic acetylcholine binding in a mode that differs from other neonicotinoid insecticides.'

E. EFFICACY DATA

Experimental data on the efficacy of the biocidal product against target organism(s)					
Function and field of use envisaged	**Test substance**	**Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide for control of cockroaches. Professional use in homes and public buildings.	Dinotefuran 2 % Bait without bittering agent	*B. germanica*	Field study. 6 mixed residential and commercial sites tested. Pre-treatment and daily monitoring using sticky traps. Product applied as a spot and crack and crevice treatment according to label at a rate of 0.2 - 0.4 g m^{-2}	Sites 1 – 5 show reduction in population of 98 % after 6 weeks. Site 6 shows 70.8 % after 10 weeks and 98.6 % reduction 4 weeks after reapplication	Heaven, H. (2013)a
	Dinotefuran 2 % Bait without bittering agent	*B. germanica*	Field study. 6 mixed residential and commercial sites tested. Pre-treatment and daily monitoring using sticky traps. Product applied as a spot and crack and crevice treatment according to label at a rate of 0.2 - 0.4 g m^{-2}	All sites show reduction in population of 93.7 – 100 % after 6 weeks.	Heaven, H. (2013)b

	Dinotefuran 2 % Bait without bittering agent	*B. orientalis*	Field study. 4 mixed residential and commercial sites tested. Pre-treatment and daily monitoring using sticky traps. Product applied as a spot and crack and crevice treatment according to label at a rate of 0.4 - 0.8 g m^{-2}	Sites 1, 3 and 4 show reduction in population of > 90 % after 9 weeks. Site 2 shows no significant reduction.	Heaven, H. (2013)c
	Dinotefuran 2 % Bait without bittering agent	*B. orientalis*	Field study. 4 mixed residential and commercial sites tested. Pre-treatment and daily monitoring using sticky traps. Product applied as a spot and crack and crevice treatment according to label at a rate of 0.2 - 0.6 g m^{-2}	Sites 1, 3 and 4 show reduction in population of > 90 % after 9 weeks. Site 2 shows no significant reduction.	Heaven, H. (2013)d
	Dinotefuran 2 % Bait without bittering agent	*B. germanica*	Field study. 1 site tested Pre-treatment and daily monitoring using sticky traps. Product applied at approximately 2 g m^{-2}	89.22 – 96.98 % reduction after a second application.	Koizumi, T. (2010)
	Dinotefuran 2 % Bait without bittering agent	*B. germanica*	Field study. 1 site tested Pre-treatment and daily monitoring using sticky traps. Product applied at approximately 1 g m^{-2}	Reduction in population of: > 80 % after 13 days > 90 % after 20 days 100 % after 55 days	Kosone, K. (2010)

	Dinotefuran 2 % Bait	*B. germanica* *B. orientalis*	Choice / palatability test Alternative food source provided. Fresh, 2 week aged and 2 year aged product tested. Application per replicate: 0.4 g for *B. germanica* 0.8 g for *B. orientalis*	100 % mortality of *B. germanica* after 7 days for the unaged and 2 year aged product and 11 days for the 2 week aged product. 100 % mortality for *B. orientalis* after 16 for fresh and 2 year aged product and 8 days for 2 week aged product.	Kinsey, R. (2014) a
	Dinotefuran 2 % Bait	Adult *B. germanica*	Choice / palatability test Alternative food source provided. Application per replicate: 0.4 g	> 95 % mortality of *B. germanica* after 7 days. 100 % mortality after 12 days.	Kinsey, R. (2013)
	Dinotefuran 2 % Bait	Juvenile *B. germanica*	Choice / palatability test Alternative food source provided. Application per replicate: 0.4 g	> 95 % mortality of *B. germanica* after 6 days. 100 % mortality after 8 days.	Kinsey, R. (2014) b
	Dinotefuran 2 % Bait	Juvenile *B. orientalis*	Choice / palatability test Alternative food source provided. Application per replicate: 0.8 g	> 95 % mortality of *B. germanica* after 13 days	Kinsey, R. (2014) c

	Dinotefuran 2 % Bait	*B. germanica* *B. orientalis*	Choice / palatability test Alternative food source provided. Fresh and 2 week aged product tested. Application per replicate: 0.4 g for *B. germanica* 0.8 g for *B. orientalis*	> 95 % mortality of *B. germanica* after 3 / 7 days and 100% mortality of *B. germanica* after 4 / 10 days for the fresh and 2 week aged product respectively. > 95 % mortality of *B. orientalis* after 3 / 5 days and 100 % mortality of *B. orientalis* after 5 / 10 days for the fresh and 2 week aged product respectively.	Kinsey, R. (2014) d
	Dinotefuran 2 % Bait. without bittering agent	*B. germanica*	Choice / palatability test Alternative food source provided. Application per replicate: 1.0 g No negative controls. Reference product tested as a positive control.	LT_{90}: 2.75 days Mortality > 95 %: 9 days	Kazuma, T. & Minagawa, K. (2010) a
	Dinotefuran 2 % Bait. without bittering agent	*B. germanica*	Choice / palatability test Alternative food source provided. Application per replicate: 1.0 g No negative controls. Reference product tested as a positive control.	LT_{90}: 2.32 days Mortality > 95 %: 4 days	Kazuma, T. & Minagawa, K. (2010) b

	Dinotefuran 2 % Bait. without bittering agent	*P. fuliginosa*	Choice / palatability test Alternative food source provided. Application per replicate: 1.0 g No negative controls. Reference product tested as a positive control.	LT_{90}: 8.97 days Mortality > 95 %: 13 days Mortality 100 %:17 days	Kazuma, T. & Minagawa, K. (2010) c
	Dinotefuran 2 % Bait. without bittering agent	*B. germanica*	Choice / palatability test Alternative food source provided. Application per replicate: 0.2 g No negative controls. Reference product tested as a positive control.	LT_{90}: 2.35 days Mortality > 95 %: 6 days Mortality 100 %:13 days	Nagai, J. (2010)

***Grey rows indicate studies submitted which are considered to be unacceptable.**

Conclusion on the efficacy of the product

The label claim made for Dinotefuran 2 % Bait is
'for the control of cockroaches.'

According to the TNsG, bait products with control claims for use against cockroaches should be supported by laboratory and/or simulated-use data demonstrating mortality and palatability, and field data demonstrating the efficacy of the product when applied according to the use instructions. This should be provided for a small species of cockroach, preferably *B. germanica*, and a large species of cockroach, such as *B. orientalis* or *P. americana*. As stated in the TNsG, these data should demonstrate a population reduction ≥ 80 % within 2 to 10 weeks for field trials and a mortality ≥ 95 % in laboratory trials. Additionally, the TNsG state that, due to the specificity of baits, only species for which efficacy has been demonstrated in field data can be named in the label claim. Therefore the UK CA considers that the data must demonstrate efficacy in field trials against *B. germanica* and *B. orientalis*.

The UK CA considers the methodology in the four studies, Heaven (2013), to be acceptable. The field data in these 4 studies successfully demonstrates that, when applied according to the use instructions and at the requested application rate, the product was effective in controlling the population of both *B. germanica* and *B. orientalis*.

The UK CA considers the methodology used in the field studies, Koizumi (2010) and Kosone (2010) to be acceptable. Although, the product was shown to be efficacious against *B. germanica*, the UK CA does not consider these studies acceptable to support the product at the requested application rate due to the lack of details about the test sites. Additionally, it is unclear how the product in these studies was applied (i.e. as spots and/or in cracks and crevices). It is, therefore, not possible to determine if these studies were carried out according to the use instructions. Therefore, these studies are not considered to be key studies in support of the product's efficacy and label claims but provide additional supporting evidence of the efficacy of the product.

The UK CA considers the methodology used in the laboratory based choice studies, Kinsey (2013 & 2014 a-d) to be acceptable. These studies demonstrate the palatability of the product for both *B. germanica and B. orientalis* and demonstrate > 95 % mortality for both species within 11 and 20 days respectively. This meets the criteria for such studies in

the TNsG. In addition the first study, Kinsey (2014a) demonstrates the maintained palatability of the product after a storage period of 2 years.
The UK CA does not consider the methodology of the remaining studies, Kazuma & Minagawa (2010a, b, c and d) and Nagai (2010) to be acceptable. As these studies do not provide sufficient negative control data, the UK CA does not consider these data to be sufficiently robust and, therefore, considers them only as supplementary evidence in support of the product.

With regard to the presence of a 'bittering agent', the applicant has confirmed that denatonium benzoate is part of the final product formulation. A number of the studies above investigated the product before this 'bittering agent' was added to the formulation. The applicant has confirmed that a number of the laboratory based reports, Kinsey (2014), were conducted with the new formulation including this bittering agent. Additionally, although no field data is provided with the product containing the 'bittering agent', the applicant has also provided a laboratory study report, Kinsey (2014), where both versions of the product are tested. This study shows that the formulation containing denatonium benzoate was more efficacious and, therefore, demonstrates that the presence of this bittering agent has no significant negative impact on the palatability of the product. Therefore, the UK CA accepts that data demonstrating the efficacy of the product without denatonium benzoate is sufficient to demonstrate the efficacy of Dinotefuran 2% Bait.

The UK CA concludes that the data package submitted has provided sufficient data to verify the outcome and conclusion, and permit the authorisation of the product, Dinotefuran 2 % Bait.

The applicant has provided sufficient palatability, mortality and field data to demonstrate the efficacy of the product according to the use instructions.

The UK CA considers that the data have demonstrated that the product is suitable for use at an application rate of 0.2 – 0.4 g m^{-2} for *B. germanica* and 0.4 – 0.8 g m^{-2} for *B. orientalis.*

The UK CA also considers that the data have sufficiently demonstrated the efficacy of the product after a maximum storage period of 2 years in ambient conditions.

F. OCCURRENCE OF RESISTANCE AND RESISTANCE MANAGEMENT

The applicant has provided the following statements regarding the occurrence of resistance to Dinotefuran 2 % Bait and resistance management:

'Dinotefuran is a nitroguanidine compound included with other insect nicotinic acetylcholine receptor (nAChRs) agonists in the Insect Resistance Action Committee (IRAC) group 4A. Detailed mode of action studies suggest that dinotefuran binds to the acetylcholine receptor site in a mode that differs to the chlorinated neonicotinic molecules included in IRAC group 4A. In common with all insecticides the possibility of the development of a cross resistance or a specific resistance to dinotefuran cannot be discounted'

'Strategies to reduce the risk of resistance developing such as recommendations to treat to levels that ensure complete kill of target pest infestations and to use dinotefuran alternately with substances with a different mode of action can be implemented at end-use product approval. Monitoring programs to confirm that target pests remain susceptible to dinotefuran will be implemented upon product approval.'

The UK CA agrees with these statements and notes that the above strategies for resistance management should be referred to on the product label.

G. KNOWN LIMITATIONS

There are no known limitations to consider for Dinotefuran 2 % Bait.

H. EVALUATION OF THE LABEL CLAIMS

The label claim supported by the data is:

'for the control of German and Oriental cockroaches.'

2.2.4 RISK ASSESSMENT FOR HUMAN HEALTH

No new data/information is required for the acute toxicity and irritation endpoints because the product authorisation applied for is identical to the representative product in the active substance approval CAR. However, to refine the dermal absorption values used in the exposure (risk) assessment, the applicant has generated and submitted product-specific data, which has been evaluated and presented below for the purposes of this product authorisation.

A. ASSESSMENT OF EFFECTS ON HUMAN HEALTH

'Dinotefuran 2% bait' is a ready for use gel bait (RB) formulation. This was the representative formulation considered in the CAR for active substance approval. No classification is proposed for human health, as the criteria for classification under Regulation (EC) 1272/2008 are not met.

The applicant has also generated a new OECD 428 in-vitro dermal absorption study, performed with the formulation for which authorisation is sought. The evaluation of this is presented in this section (2.2.5.A).

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Dinotefuran 2% is not corrosive or irritating to the skin.
Justification for the value/conclusion	This was the representative formulation considered in the CAR for active substance approval. Based on the results of the skin irritation data evaluated during the EU Review of the active substance, together with the information available on the co-formulants (SDS supplied by applicant, and Annex VI to CLP Reg 1272/2008), no classification is proposed.
Classification of the product according to CLP and DSD	None proposed

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Dinotefuran 2% is not corrosive or irritating to the eye.
Justification for the value/conclusion	This was the representative formulation considered in the CAR for active substance approval. Based on the results of the acute eye irritation data evaluated during the EU Review of the active substance, together with the information available on the co-formulants (SDS supplied by applicant, and Annex VI to CLP Reg 1272/2008), no classification is proposed.
Classification of the product according to	None proposed

CLP and DSD	

Respiratory tract irritation

No information has been submitted to experimentally assess the potential for respiratory tract irritation as a result of inhalation exposure to the biocidal product. The MSDSs for two co-formulants state that the substances 'may cause respiratory irritation'. However, these co-formulants are present at a low concentration (less than 1 %) in product, are not known to the UK CA to be respiratory sensitisers, and inhalation exposure of humans to these co-formulants will be negligable due to the physical nature of the product (a gel paste); thus, these co-formulants present no realistic concerns in relation to respiratory sensitisation to humans. The product does not meet the classification criteria for either dermal or ocular irritation and it can be predicted that it will not have the capacity to cause respiratory tract irritation.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	The product is not a skin or eye irritant, and it can be predicted that the product is not a respiratory tract irritant. This conclusion is consistent with the available information on the irritant properties of the active ingredient and each of the co-formulants.
Classification of the product according to CLP and DSD	None proposed.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not a skin sensitiser
Justification for the value/conclusion	This was the representative formulation considered in the CAR for active substance approval. Based on the results of the acute skin sensitisation data evaluated during the approval of the active substance, together with the hazard information available on the co-formulants (SDS supplied by applicant, and Annex VI to CLP Reg 1272/2008), no classification is proposed.
Classification of the product according to CLP and DSD	None proposed

Respiratory sensitization (ADS)

The product has not been tested for respiratory sensitisation. Based on the hazard information on the active substance and other co-formulants, there are no known causes of respiratory sensitisation.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	No concerns regarding this endpoint

Justification for the value/conclusion	No hazard triggers from active substance or co-formulants
Classification of the product according to CLP and DSD	None proposed.

Acute toxicity
Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not toxic via oral route.
Justification for the selected value	This was the representative formulation considered in the CAR for active substance approval. Based on the results of the acute oral toxicity data evaluated during the EU review of the active substance, together with the hazard information available on the co-formulants (SDS supplied by applicant, and Annex VI to CLP Reg 1272/2008), no classification is proposed.
Classification of the product according to CLP and DSD	None proposed.

Acute toxicity by inhalation

No data have been provided by the applicant. Based on the waiver provided by the applicant, this is acceptable.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	No value – see waiver below
Justification for the selected value	See waiver below
Classification of the product according to CLP and DSD	None proposed.

Data waiving	
Information requirement	Acute inhalation toxicity
Justification	Dinotefuran has a low vapour pressure (5×10^{-5} Pa at 30°C), so it does not meet the criteria to be considered a volatile substance. Additionally, the active substance is included in ready-to use bait products; not powder form, and not applied in a manner that generates exposure to aerosols, particles or droplets of an inhalable size. Therefore this study is not required.

Acute toxicity by dermal route

The acute dermal toxicity from exposure to the biocidal product was investigated experimentally during the EU Review for dinotefuran.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not toxic via dermal route.
Justification for the selected value	This was the representative formulation considered in the CAR for active substance approval. Based on the results of the acute oral toxicity data evaluated during the EU review of the active substance, together with the hazard information available on the co-formulants (SDS supplied by applicant, and Annex VI to CLP Reg 1272/2008), no classification is proposed.
Classification of the product according to CLP and DSD	None proposed.

Information on dermal absorption

The applicant has provided an OECD 428 *in-vitro* dermal absorption study. This study was not considered during the EU Review for dinotefuran, therefore it has been evaluated in the context of the current product application.

Summary table of in vitro studies on dermal absorption					
Method, Guideline, GLP status, Reliability	**Species, Number of skin samples tested per dose, Other relevant information about the study**	**Test substance, Doses**	**Absorption data for each compartment and final absorption value**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 428, EC No. 440/2008, Method B.45	Human split-thickness, n =5 (3 donors) cells. Exposure was for 8 h, when there was a 1st skin wash. 2nd skin wash at 24 h	Dinotefuran 2% gel, synonyms Roachdown Gel and New GOK1. 50% dilution (1:1 in water) Application 0.1 mg dinotefuran / cm^2	Receptor Fluid (0-24h) = 0.07% Tape strips 3 to 15 = 0.30% Skin residue < 0.01% **Dermal absorption =** 0.37% ± 0.06% rounded to **0.4%** Standard Deviation not included, in accordance with EFSA Guidance on Dermal absorption EFSA Journal 2012;10(4):2665))	Receptor chamber wash was not conducted, however, noting overall recoveries were acceptable (96-102%), most receptor fluid values were below LOQ for the entire 24 t time-course and no adherence of test item to donor chamber was seen, this omission is not considered to be critical. The eMS	Laboratory Reference # D80138 Hassler, 2014

Summary table of in vitro studies on dermal absorption					
Method, Guideline, GLP status, Reliability	**Species, Number of skin samples tested per dose, Other relevant information about the study**	**Test substance, Doses**	**Absorption data for each compartment and final absorption value**	**Remarks** *(e.g. major deviations)*	**Reference**
				agrees with not including 2nd skin wash in "absorbed" fraction	

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	dinotefuran	-	-
Value(s)*	0.4% for concentrate and for 50% dilution	-	-
Justification for the selected value(s)	Experimental data on the formulation for which authorisation is being sought	-	-

** please include the concentration range(s) the values are applicable for, if relevant*

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

No substances of concern that require evaluation have been identified (no classification of the product required for human health).

Available toxicological data relating to a mixture

Not relevant to this application.

Other

Not relevant to this application.

B. EXPOSURE ASSESSMENT

Table 2.2.5.B.1 Intended uses of Dinotefuran 2 % Bait

Product type	Field of use envisaged	Concentration of product and active substance in the in-use formulation
18	Dinotefuran 2 % bait is a ready to use gel applied indoors by professionals against cockroaches (professional application: spot treatment and crack and crevice application of gel at an application rate of 0.2 - 0.8 g product m^{-2}).	Dinotefuran 2 % bait used directly, contains 2 % w/w (20 g/kg) dinotefuran.

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product. The main paths of human exposure are outlined in Table 2.2.5.B.2.

Table 2.2.5.B.2 Main paths of human exposure to the active substance from the use of Dinotefuran 2 % bait

Summary table: relevant paths of human exposure				
Exposure path	**Professional use**	**Non-professional (amateur) use**	**General public[a]**	**Via the environment**
Dermal	Yes: through handling the gel and application (spot treatment and crack and crevice application)	No	Yes: through contact with the applied gel or dislodged residue	No
Oral	No	No	Yes: through contact with the applied gel or dislodged residue	No
Inhalation	No	No	Yes: through working or living in the building post application	No
[a] People other than those applying the product				

List of scenarios:

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Handling & Applying gel	Primary exposure	Professional
2.	Dermal exposure to dislodged gel	Secondary exposure	Bystanders
3	Oral exposure to dislodged gel	Secondary exposure	Bystanders
4	Inhalation exposure to occupant of premises	Secondary exposure	Bystanders

In line with the TNsG on Human Exposure to Biocidal Products (2002), the UK CA has carried out for this product, Dinotefuran 2 % bait and it's specified uses, an exposure assessment for human health based on a tiered approach. The UK has started each exposure assessment using worst-case assumptions (e.g. assuming no personal protective equipment is worn). If the risks to human health following exposure to dinotefuran were considered to be acceptable following comparison of the predicted systemic dose with the appropriate NOAEL/NOAEC from animal studies, then no further refinement of the exposure scenario was carried out. If an unacceptable risk is identified for a particular exposure scenario, then a further refinement of the exposure/risk assessment was carried out using additional parameters (e.g. additional PPE etc.).

A dermal absorption value of 0.4% has been used based on information taken from the toxicology section of this PAR (section 2.2.5.A).

Industrial exposure

No industrial applications have been applied for.

Professional exposure

Scenario 1

Professional exposure: Application of Dinotefuran 2 % bait using spot treatment and crack and crevice application

The product is supplied in a ready-to-use applicator tube with plunger and so is not diluted before use. This is an industry standard size disposable syringe which contains a total of 30 g product. The syringe has an adaptor nozzle that is attached before use; this nozzle is very narrow to allow for dispensing of small amounts (0.1 g) of gel. Different nozzles would provide different sized spots of gel. To apply dinotefuran 2 % bait, the cap would be removed from the tip of the applicator tube, the tip would be placed where gel is to be applied and the plunger depressed in order to dispense the gel. After the gel has been applied, the cap would be replaced. The gel bait would be applied directly into cracks and crevices where insects hide. The bait should be in the void area and not on open or exposed surfaces.

Dinotefuran 2 % bait should be applied in 0.1 g spots in cracks and crevices. The gel should be applied at a rate of 0.2 g to 0.4 g per m^2; 0.2 g/m^2 for small cockroach species and 0.4 g/m^2 for large cockroach species. A maximum application rate of 0.8 g/m^2 can be used for heavy infestations. Numerous small application spots are preferable to large application spots. Professionals would typically use the syringe in a trigger operated applicator (caulking gun) and the operator would usually control the size of the spots, however the syringe is supplied with a narrow gauge pointed nozzle to facilitate placement of small spots. Professional operators recognise that bead application is wasteful and not as efficient as small spot treatment. In cases of heavy infestations, a second application may be performed after 7 days.

An applied spot of gel is 0.1 g in weight (equivalent to 1 mm in size) and the applicator tube and plunger system allow for controlled applications of small volumes of gel. The Applicant informs us that uncontrolled releases of higher quantities than this are unlikely. A spot of gel (weighing 0.1 g) contains 2 % dinotefuran, so each spot would contain 0.1 x (2/100) = 0.002 g (2 mg) of active substance.

The Applicant has informed that a worker could apply the treatment once per hour during an average 8 hour day. It is also assumed that a worker could potentially be exposed to a spot of product each time it is used. Therefore the worker could potentially transfer a spot of gel to their hands 8 times a day. The daily exposure to dinotefuran would therefore be: 8 x 2 = 16 mg a.s./ day

The tier 1 assessment reflects the worst-case exposure scenario and so no PPE has been used. In the tier 2 assessment, gloves have been accounted for with a penetration factor of 10 % because protective gloves can be expected to have a 90 % protection factor from challenges by a liquid (Section 4.2.9.9 MOTA version 4).

For an adult operator, bodyweight = 60 kg (ECETOC, 2001 and ECB, 2003) and a dermal penetration of 0.4 %, the systemic dose to dinotefuran for tier 1 would be:

$$\frac{\text{Daily exposure (mg a.s./day)} \times \text{Glove penetration (\%)} \times \text{Dermal penetration (\%)}}{\text{Bodyweight (kg)}}$$

$$= \frac{16 \times (100/100) \times (0.4/100)}{60}$$

= **0.001 mg a.s./ kg / day**

The values calculated for both tier 1 and tier 2 are shown in Table 2.2.5.B.3 as follows:

Table 2.2.5.B.3 Professional application of Dinotefuran 2 % bait using spot treatment and crack and crevice application

Professional user, spot treatment and crack and crevice application. PPE = none. Dermal absorption = 0.4 %.		
Exposure Descriptor	**Tier 1**	**Tier 2**
Amount of product in a single gel spot (g)	0.1	0.1
Concentration of dinotefuran (% w/w)	2 %	2 %
Active ingredient per gel spot (mg a.s.)	2	2
Number of treatments per day	8	8
Daily dermal exposure (mg a.s./day)	16	16
Body weight (kg)	60	60
Glove penetration (%)	100 %	10 %
Dermal penetration (%)	0.4 %	0.4 %
Systemic dose (mg a.s./kg/day)	**0.001**	**0.0001**

Summary of primary exposure assessments for professional uses of Dinotefuran 2 % bait

Summary table: estimated exposure from professional uses					
Exposure Scenario		**Estimated Internal Exposure**			
		estimated oral uptake (mg a.s./kg bw/day)	**estimated inhalation uptake (mg a.s./kg bw/day)**	**estimated dermal uptake (mg a.s./kg bw/ day)**	**estimated total uptake (mg a.s./kg bw/day)**
Spot treatment and crack and crevice application					
Tier 1 (no PPE)	Professional applying dinotefuran 2 % bait as a spot or crack and crevice treatment. (long-term).	NA	NA	0.001	0.001
Tier 2 (gloves)		NA	NA	0.0001	0.0001

Non-professional exposure

No non-professional applications have been applied for.

Exposure of the general public (Secondary Exposure)

Scenario [2] Non-professional dermal exposure to dislodged gel

Given that the product is used in cracks/crevices/voids and not on open or exposed surfaces then one could consider secondary exposure to the gel bait to be relatively unlikely. However, it is still necessary to assess exposure/risk to the gel and so reverse reference calculations have been carried out for completeness.

It is proposed that occupants of treated premises could be dermally exposed to the gel should they be in contact with applied gel or gel that has become dislodged from treated areas. This scenario is considered to be a short-term dermal exposure.

Gel bait should be applied into cracks and crevices where insects hide; it should be placed in the void area and not on open or exposed surfaces. The label includes the statement "USE ONLY in positions inaccessible to children and animals".

These potential dermal exposures have been calculated by determining the amount of gel a person would have to be exposed to in order to achieve the AEL of Dinotefuran 2 % bait. This has been calculated for an adult, child and an infant, as follows:

The concentration of dinotefuran in the product is 2 % and the acute AEL is 1.75 mg a.s./kg bw/day. A bodyweight of 60 kg for an adult, 34.4 kg for a child and 10 kg for an infant has been used in accordance with ECETOC, 2001

Therefore the amount of gel that a person would need to be dermally exposed to in order to reach the AEL would be:

$$\frac{\text{(AEL (mg a.s./kg/day) x Bodyweight (kg)) / Dermal Absorption (\%)}}{\text{Concentration of Dinotefuran in product (\%)}}$$

Therefore for an adult:

$$= \frac{(1.75 \times 60) / (0.4/100)}{(2/100)}$$

= **1312500 mg product / day**

The gel is applied in spots, each of 0.1 g in size, so this amount of product would equate to: (1312500 / 1000) / 0.1 = **13125 spots of gel per day**.

Table 2.2.5.B.4 shows the amount of product and number of spots required to reach the AOEL for adults, children and infants.

Table 2.2.5.B.4 Non-professional dermal exposure to dislodged gel

	Dermal exposure to Dinotefuran 2 % gel		
	Adult	**Child**	**Infant**
	Adult dermally exposed to dislodged gel	Child dermally exposed to dislodged gel	Infant dermally exposed to dislodged gel
Concentration Dinotefuran (% w/w)	2 %	2 %	2 %
AEL (mg a.s./kg bw/day)	1.75	1.75	1.75
Body weight (kg)	60	34.4	10
Dermal absorption (%)	0.4 %	0.4 %	0.4 %
Amount of gel dermally exposed to reach AEL (mg product /day)	**1312500**	**752500**	**218750**
Amount of gel in a single gel spot (g)	0.1	0.1	0.1
Number of gel spots dermally exposed to	**13125**	**7525**	**2187.5**

Scenario [3] Non-professional oral exposure to gel

If infants came into contact with dislodged or applied gel, they could contaminate their hands and ingest the gel. The gel bait will contain a bittering agent that could discourage ingestion. This is a short-term oral exposure scenario.

This potential oral exposure has been calculated by determining the amount of gel an infant would have to ingest in order to achieve the AEL of Dinotefuran 2 % bait. This has only been calculated for an infant, as follows:

The concentration of dinotefuran in the product is 2 % and the acute AEL is 1.75 mg a.s./kg/day. A bodyweight of 10 kg for an infant has been used in accordance with ECETOC, 2001 and absorption via the oral route is assumed to be 100 %.

Therefore the amount of gel that an infant would need to ingest in order to reach the AEL would be:

$$\frac{\text{(AEL (mg a.s./kg/day) x Bodyweight (kg)) / Oral Absorption (\%)}}{\text{Concentration of Dinotefuran in product (\%)}}$$

$$= \frac{(1.75 \times 10) / (100/100)}{(2/100)}$$

= 875 mg product / day

The gel is applied in spots, each of 0.1 g in size, so this amount of product would equate to: (875 / 1000) / 0.1 = 8.8 spots of gel per day.
Table 2.2.5.B.5 shows the amount of product and number of spots required for an infant to reach the AEL by ingestion.

Table 2.2.5.B.5 Non-professional oral exposure to dislodged gel (infant only)

	Oral exposure to Dinotefuran 2 % gel
Scenario	Infant eats gel
Concentration Dinotefuran gel (% w/w)	2 %
AEL (mg a.s./kg bw/day)	1.75
NOAEL (mg a.s./kg bw/day)	125
Safety factor	100
Body weight (infant) (kg)	10
Absorption of a.s. via ingestion (%)	100 %
Amount of gel to be ingested to achieve AOEL (mg product/day)	875
Amount of gel in a single gel spot (g)	0.1
Number of gel spots ingested	8.8

Scenario [4] Non-professional inhalation exposure to the occupants of the premises

Occupants of treated premises could be exposed to vapours volatilised from the gel on treated surfaces. Adults, children and infants could inhale the vapours of dinotefuran 2 % gel when in enclosed unventilated spaces. This would be a long-term exposure scenario and in a worst-case situation, occupiers could be exposed to air saturated with these vapours for 24 hours a day.

The assumptions and constants used for this scenario are summarised in the following Table.

Table 2.2.5.B.6 Assumptions and constants used for exposure estimation from saturated vapour concentration of dinotefuran

Parameter	**Value**	**Reference**
Vapour Pressure of dinotefuran at 25 ^{o}C (Pa)	5.00E-05	
Molecular Weight of dinotefuran (g/mol)	202.20	
Gas Constant	8.31451	
Temperature (Kelvin)	298	(25 ^{o}C)
Adult Inhalation Rate (m^3/day)	15.20	Exposure Factors Sourcebook for European Populations. European Centre for Ecotoxicology and Toxicology of Chemicals, Brussels, Belgium, Technical Report No 79 (2001).
Child Inhalation Rate (m^3/day)	14.00	
Infant Inhalation rate (m^3/day)	4.50	
Adult Body Weight (kg)	60.0	
Child Body Weight (kg)	34.4	
Infant Body Weight (kg)	10.0	

The saturated vapour concentration of dinotefuran is as follows:

SVC (g/m^3) = $\frac{\text{Vapour pressure (Pa) x Molecular weight}}{\text{Gas constant x Temperature (Kelvin)}}$

= $\frac{\text{5.00E-05 x 202.20}}{\text{8.31451 x 298}}$

= 4.08E-06 g/m^3

= **0.004080 mg/m^3**

Using inhalation rates and body weights as shown in Table 2.2.5.B.6, the estimates of the daily exposure to dinotefuran are as follows:

Table 2.2.5.B.7 Non-professionals: daily systemic exposure to dinotefuran through secondary inhalation

Exposure descriptor	**Adult**	**Child**	**Infant**
Saturated vapour concentration of dinotefuran (mg/m^3)	0.004080	0.004080	0.004080
Daily inhalation exposure (mg/day)	0.062021	0.057125	0.018362
Daily systemic exposure to dinotefuran (mg a.s./kg/day)	**0.001034**	**0.001661**	**0.001836**

Professional exposure via inhalation has not been assessed separately. The exposure to the SVC has been calculated and found to be acceptable. The exposure to professionals via inhalation will not be more than the SVC above and so is also acceptable.

SUMMARY OF SECONDARY EXPOSURE

Exposure Scenario	**Estimated Internal Exposures**			
	estimated oral uptake (mg a.s./kg bw/day)	**estimated inhalation uptake (mg a.s./kg bw/day)**	**estimated dermal uptake (mg a.s./kg bw/day)**	**estimated total uptake (mg a.s./kg bw/day)**
Secondary inhalation exposure to occupants of premises (long-term)				
Adult	NA	0.001034	NA	0.001034
Child	NA	0.001661	NA	0.001661
Infant	NA	0.001836	NA	0.001836
Exposure Scenario	**Amount of gel required to reach AEL (mg product / day)**		**Number of gel spots required to reach AEL**	
Secondary dermal exposure to dislodged or applied gel (Acute)				

Adult	1312500	13125
Child	752500	7525
Infant	218750	2187.5
Secondary oral exposure to dislodged or applied gel (Acute)		
Infant	875	8.8

C. RISK CHARACTERISATION FOR HUMAN HEALTH

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	Rabbit developmental study	175 mg/kg bw	100 (10 intra-species x 10 inter-species)	NONE (100% oral abs)	1.75
AELmedium-term	52-week dog	22 mg/kg bw/day	100 (10 intra-species x 10 inter-species)	NONE (100% oral abs)	0.22
AELlong-term	52-week dog	22 mg/kg bw/day	100 (10 intra-species x 10 inter-species)	NONE (100% oral abs)	0.22
ARfD	Rabbit developmental study	175 mg/kg bw	100 (10 intra-species x 10 inter-species)	NONE (100% oral abs)	1.75
ADI	52-week dog	22 mg/kg bw/day	100 (10 intra-species x 10 inter-species)	NONE (100% oral abs)	0.22

[1] Background and reason for assessment factor.

Risk for industrial users

No industrial applications have been submitted.

Risk for professional users

Systemic effects

Summary of primary exposure assessment for professional users of Dinotefuran 2 % Bait

Exposure Scenario		Estimated internal exposure				Long-term AEL systemic (mg a.s./kg bw/day)	Systemic exposure / AEL ratio
		Estimated oral uptake (mg a.s./kg bw/day)	Estimated inhalation uptake (mg a.s./kg bw/day)	Estimated dermal uptake (mg a.s./kg bw/ day)	Estimated total uptake (mg a.s./kg bw/day)		
Professional applying dinotefuran 2 % bait as a spot or crack and crevice treatment, long-term exposure assumed	Tier 1 (no PPE)	NA	NA	0.001	0.001	0.22	0.0045
	Tier 2 (gloves, 10 % penetration)	NA	NA	0.0001	0.0001	0.22	0.00045

Conclusion

One professional exposure scenario has been identified, which is the application of Dinotefuran 2 % Bait using spot treatment and crack and crevice application. The risks are considered to be acceptable at the tier 1 exposure assessment, which assumes that no PPE is used; at this level the systemic exposure/AEL ratio is 0.0045.

Since the exposure to the SVC has been calculated and found to be acceptable. The exposure to professionals via inhalation will not be more than the SVC and so will also be acceptable.

Risk for non-professional users

No non-professional applications have been applied for.

Risk for the general public (Secondary Exposure)

Systemic effects

Summary of secondary exposure assessment for non-professional dermal exposure to dislodged Dinotefuran 2 % Bait

	Adult	Child	Infant
Number of spots of Dinotefuran 2 % Bait in dermal contact required to achieve acute systemic AEL by dermal contact	13125	7525	2187.5

Summary of secondary exposure assessment for non-professional (infant) oral exposure to dislodged Dinotefuran 2 % Bait

	Infant
Number of spots of Dinotefuran 2 % Bait to be ingested to achieve acute systemic AEL	8.8

Summary of secondary exposure assessment for non-professional inhalation exposure to Dinotefuran 2 % Bait

Exposure Scenario	**Estimated internal exposure**				**Long-term AEL systemic (mg a.s./kg bw/day)**	**Systemic exposure/ AEL ratio**
	Estimated oral uptake (mg a.s./kg bw/day)	**Estimated inhalation uptake (mg a.s./kg bw/day)**	**Estimated dermal uptake (mg a.s./kg bw/ day)**	**Estimated total uptake (mg a.s./kg bw/day)**		
Adult	NA	0.001034	NA	0.001034	0.22	0.005
Child	NA	0.001661	NA	0.001661	0.22	0.008
Infant	NA	0.001836	NA	0.001836	0.22	0.008

Conclusion (Secondary Exposure)

The risks are considered to be acceptable for occupants of treated premises, who could be exposed to vapours from Dinotefuran 2 % Bait after its application; the systemic exposure/AEL ratios are 0.005 - 0.008 for these scenarios.

The other secondary exposure scenarios are considered using the reverse reference method to calculate the number of spots of Dinotefuran 2 % Bait that an individual could come in contact with that would result in the acute systemic AEL being achieved.

Firstly, it is proposed that occupants of treated premises could potentially be dermally exposed to the bait should they be in contact with applied gel or gel that has become dislodged from treated areas; for adults, children and infants, respectively, contact with 13125, 7525 and 2187.5 spots of Dinotefuran 2 % Bait could result in the systemic AEL being achieved.

Secondly, if infants came into contact with dislodged or applied gel, they could contaminate their hands and ingest the gel; the ingestion of 8.8 spots of Dinotefuran 2 % Bait would result in the systemic AEL being achieved.

As a further risk mitigation measure with regard to the oral route of exposure, a bittering agent (denatonium benzoate) will be included in the Dinotefuran 2 % Bait formulation. This will be included at 0.01 %. It should be noted that some children under 3-4 years old may not be able to taste denatonium benzoate due to their sense of taste not yet having developed sufficiently; also, some older people do not develop the ability to taste denatonium benzoate. The ability to taste - or not to taste - the bittering agent is a reflection of the diverse nature of the human population. Its inclusion will deter some but

not necessarily all individuals (e.g. in particular some children) from ingesting the product [Review by W. Klein-Schwartz of Maryland Poison Centre, Baltimore (Vet Hum Toxicol, 1991 Dec 33(6): 545-7); Study by Berning CK, Griffith JF and Wild JE (Fundam Toxicol, 1982 Jan-Feb; 2(1): 44-8].

Because the secondary exposure scenarios considered using the reverse reference method indicate that contact with, or the consumption of, a relatively low number of spots of Dinotefuran 2 % bait by infants would result in the acute systemic AEL being achieved, it is recommended that the product is labelled with the following phrases:

PREVENT ACCESS TO BAITS by children and animals

KEEP IN A SAFE PLACE

Eight spots is the maximum amount of product that could be applied in a square metre. However since this product should be applied in cracks and crevices where insects hide, in the void areas and not on open surfaces; the product should not be in places that are easily accessible. If the product is applied as per the instructions on the label, it would seem unlikely that the exposure level would be achieved.

2.2.5 RISK ASSESSMENT FOR ANIMAL HEALTH

Based on the product's authorised pattern of use, an assessment for animal health is not required.

2.2.6 RISK ASSESSMENT FOR THE ENVIRONMENT

A. ASSESSMENT OF THE EFFECTS ON THE ENVIRONMENT

No new data are provided for this product. All PNECs have been taken directly from the active substance approval CAR, and the product is the same as the representative product in the CAR.

PNEC	**Value**
STP	100 mg/L
Water	0.254 µg/L
Soil	0.00176 mg/kg wet wt (measured) 1.71×10^4 mg/kg wet wt determined by EPM

Further Ecotoxicological studies

No additional data on the product is available.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No additional data on the product is available.

Supervised trials to assess risks to non-target organisms under field conditions

No additional data on the product is available.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No additional data on the product is available.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

N/A

Foreseeable routes of entry into the environment on the basis of the use envisaged

Please refer to section Fate and distribution in exposed environmental compartments.

Further studies on fate and behaviour in the environment (ADS)

No new environmental fate & behaviour or leaching data on the a.s. (dinotefuran) or product specific data are available as they have not been considered necessary. All agreed endpoints have been taken from the Final PT18 CAR as this product is identical to the representative product assessed at EU level.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

N/A

Aquatic toxicity

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

Species	Time-scale	Endpoint	Toxicity
Fish			
Oncorhynchus mykiss	94 d	NOEC	10.1mg/l
	96 h	LC_{50}	>100 mg/l
Invertebrates			
Chironomus riparius (water	27 d	NOEC	2.54 µg/l

spiked study)	48 h	LC_{50}	72.1 µg/l
Algae			
Pseudokirchneriella subcapitata	96 h	NOE_rC	100 mg/l
	96 h	E_rC_{50}	>100 mg/l
Microorganisms			
Activated sewage sludge respiration inhibition	3 h	NOEC	1000 mg/l
Aquatic plants			
Lemna gibba	7 d	NOEC	110 mg/l
	7 d	EC_{50}	>110 mg/l

Conclusion used in Risk Assessment – Acute aquatic toxicity	
Value/conclusion	$PNEC_{water}$ = 2.54/10 = 0.254 µg/L
Justification for the value/conclusion	Same as in the CAR

Measured aquatic bioconcentration

No studies were submitted to address the bioconcentration potential of dinotefuran in the aquatic compartment on the basis that bioconcentration testing with aquatic organisms is unnecessary as the log K_{ow} is -0.64 at pH 7 (and 25 °C).

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

N/A

B. EXPOSURE ASSESSMENT

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Indoor loose gel bait as spot treatment into cracks & crevices plus other "hard-to-clean" areas
ESD(s) used	Emission Scenario Document for Product Type 18: Insecticides, acaricides and products to control other arthropods for household and professional uses, July 2008
Approach	Scenario 1: Realistic worst case consumption
Distribution in the	Calculated based on TGD 200, PT18 ESD and SimpleTreat

environment	modelling (for STP behaviour)
Groundwater simulation	Porewater calculations were first undertaken in line with TGD 2003 (equation 67) as a basic screening approach. As acceptable levels (ie. <<0.1 µg l^{-1}) were predicted using this highly conservative approach, higher tier (FOCUS PEARL 4.4.4) models were not considered necessary.
Confidential Annexes	NO
Life cycle steps assessed	Scenario 1: Production: No (manufactured outside of EU) Formulation: No (formulated outside of EU) Use: Yes Service life: Yes (product losses from indoor scenario by regular wet cleaning as leaching is not relevant)
Remarks	Dinotefuran 2% Bait is the representative product used in the EU evaluation of dinotefuran as a new a.s. in the EU. All uses were considered acceptable at EU level and this product application seeks authorisation of those same uses.

Emission estimation
Scenario [1]

Dinotefuran 2% bait (containing 2.0% w/w a.s.) is a ready to use gel applied indoors by professionals against crawling insects e.g. cockroaches. It is provided to the end user ready-to-use in a syringe style applicator tube as a spot, crack and crevice treatment. Gels are applied in areas characterised by high insect infestation. These areas include voids, cracks and crevices, in legs of equipment, along plumbing and cable runs, in electric boards and on ventilation openings. Due to the inaccessible nature of the treatment areas, gel is often applied in situations where applications using sprays cannot be conducted (e.g. institutional kitchens, hospitals, pharmaceutical laboratories and schools). In addition, the nature of the target application areas is such that gels are protected from cleaning processes. A summary of the use scenario is found below :

Product Type	Method of Application	Application Rate
PT 18.01 Professional user	Dinotefuran 2% bait: containing 2% active ingredient. No other substances are used for dilution as the product is supplied ready-to-use in a syringe style applicator tube. Spot treatment method of application: Remove cap from tip of applicator tube. Place tip at spot where gel bait is to be applied. Depress plunger until appropriate amount is dispensed. Replace cap when finished application.	Spot treatment: Apply gel bait in a 0.1 g spot. Approximately 0.2 g gel bait per m^2 for small cockroach species and 0.4 g gel bait per m^2 for large cockroach species is recommended. Up to 0.8 g per m^2 may be used for heavy infestations. Numerous small application spots are preferable to fewer larger application spots. Cracks and crevices: Apply gel

	Cracks and crevices method of application: Gel bait should be applied directly into cracks and crevices where insects hide. Remove cap from tip of applicator tube. Place tip directly into cracks and crevices and deposit gel bait. Gel bait should be in void areas and not on open or exposed surfaces. Replace cap when finished application.	bait in a 0.1 g spot. Approximately 0.2 to 0.4 g gel bait per m^2 is recommended for small and large cockroach species, respectively. Up to 0.8 g gel bait per m^2 may be used for heavy infestations. Numerous small application spots are preferable to fewer larger application spots.

The full emissions assessment from indoor wet cleaning of "hard to clean" areas is presented within Doc II-B of the Final dinotefuran CAR under PT18. This application is identical to the representative product that was considered acceptable at EU level so most of the evaluation has not been repeated again.

Input Parameters for calculating local emissions	**Data/Endpoint**
Local population in catchment of STP (-)	10,000
Daily wastewater flow per inhabitant (l d^{-1} eq^{-1})	200
Effluent discharge rate of STP (l d^{-1})	2×10^6
Size of targeted treatment area within each domestic dwelling (m²) *	2.0
Size of targeted treatment area within each larger building (m²) *	9.3
Number of potential houses treated per catchment (-)	4000 (indoor)
Number of potential large buildings treated per catchment (-) *	300 (indoor)
Simultaneity Factor (%) based upon weekly treatment indoors	2.75 (indoor)
$F_{simultaneity}$ for weekly indoor re-application (worst case use pattern)	0.0275
Maximum % exposed to cleaning – gel bait (crack and crevice & spot treatment)*	3
Cleaning efficacy (F_{CE}) : crack, crevice and spot treatment to difficult to access areas*	0.03
Fraction to water at STP (derived by SimpleTreat in EUSES 2.1.2)	>0.996
Fraction to sewage sludge at STP (derived by SimpleTreat in EUSES 2.1.2)	3.91×10^{-3}
Fraction to air at STP (derived by SimpleTreat in EUSES 2.1.2)	1.65×10^{-9}
Sludge rate: rate of sewage sludge production at STP (kg d^{-1})	710

** Input values from conclusions of TM-IV-2009, TM-I-2010 and TM-II-2010*

Calculations for Scenario [1]

The full emissions assessment from indoor wet cleaning of "hard to clean" areas is presented within Doc II-B of the Final dinotefuran CAR under PT18. This application is

identical to the representative product that was considered acceptable at EU level so most of the evaluation has not been repeated again.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	Y	Y	NR	NR	Y	N	Y	Y	Y - Biota

Input parameters for calculating the fate and distribution of dinotefuran in the environment	**Value**
Solubility in water	39.83 g l^{-1} (20 ºC, unbuffered)
Partition co-efficient (log K_{ow})	-0.64 (25 ºC and pH 7)
Vapour pressure *	5.0 x 10^{-5} Pa (at 25 ºC) <1.7 x 10^{-6} Pa (at 30 ºC)
Density	1.40 g cm^{-3}
Surface tension	72 mN m^{-1} (at 20.2 °C)
Molecular weight	202.2 g mol^{-1}
Koc	31.4 L kg^{-1}
Readily biodegradable	No
Aquatic degradation (total system) DT_{50} First order degradation rate constant k	112 d (12 °C) 0.0062 d^{-1}
Aerobic soil degradation DT_{50} First order degradation rate constant k	19.2 d (12 °C) 0.036 d^{-1}

** Although vapour pressure at 20 °C could not be determined, crude calculation in line with equations in the TGD (based upon values at 25 °C) gives rise to a Henry's law constant of 2.54E-7 Pa m^3 mol^{-1} and a Log Henry's constant of -6.60.*

Input parameters for calculating the fate and distribution of major metabolites DN and MNG in the environment	**DN**	**MNG**
Molecular weight (in g mol^{-1})	157.22	**118.1**

Solubility in water (in g l^{-1} at 25 °C) *	99.5	1000
Partition co-efficient (log K_{ow}) *	-0.18	-1.17
Vapour pressure in Pa (at 25 °C) *	0.65	16.9
Koc (in L kg^{-1}) : MCI method * Koc (in L kg^{-1}) : Kow method *	45.0 4.44	24.1 2.70
Readily biodegradable *	No	No
Aquatic degradation (total system) DT_{50} (in d at 12 °C) First order degradation rate constant k (in d^{-1})	199 0.0035	- -
Aerobic soil degradation DT_{50} (in d at 12 °C) First order degradation rate constant k (in d^{-1})	- -	137 0.0051

** All indicated endpoints have been determined by US-EPA EPISuite v4.11 modelling in the absence of actual supporting data (based on reasoned arguments due to restricted indoor use pattern of representative product and the likelihood of limited emissions to aquatic and terrestrial compartments). QSAR values have been derived using SMILES notations of N=C(NC)NCC1CCOC1 for DN and NC(NC)=NN(=O)(=O) for MNG but if extension of use for a.s. is sought leading to an increase in emissions, then predicted values should be replaced by measured ones*

Calculated fate and distribution in the STP	
Compartment	Percentage [%]
	Scenario 1
Air	1.65E-7
Water	99.6
Sludge	0.391
Degraded in STP	0

Calculated PEC values

STP – resultant local emissions	**PEC_{STP} (in mg L^{-1})**
Domestic housing : normal treatment	2.64×10^{-5}
Larger buildings : normal treatment	9.14×10^{-6}
Total (housing + large buildings) : normal treatment	3.55×10^{-5}
Domestic housing : heavy treatment	5.30×10^{-5}
Larger buildings : heavy treatment	1.84×10^{-5}
Total (housing + large buildings) : heavy treatment	7.14×10^{-5}

Surface waters – resultant local emissions	**PEC_{water} (in mg L^{-1})**
Domestic housing : normal treatment	2.64×10^{-6}
Larger buildings : normal treatment	9.14×10^{-7}
Total (housing + large buildings) : normal treatment	3.55×10^{-6}
Domestic housing : heavy treatment	5.30×10^{-6}
Larger buildings : heavy treatment	1.84×10^{-6}
Total (housing + large buildings) : heavy treatment	7.14×10^{-6}

Sediment – resultant local emissions : not presented as they will be derived from surface water PECs using EPM. However, as $PNEC_{sediment}$ will be derived by the same approach, the risks posed to sediment will be identical to those posed to surface waters.

Soil (Ecosystem) – resultant local emissions	PEC_{soil} (mg kg^{-1} wwt)
Housing – normal rate	2.61×10^{-7}
Larger buildings – normal rate	9.07×10^{-8}
Housing and buildings – normal rate	3.52×10^{-7}
Housing – heavy rate	5.25×10^{-7}
Larger buildings – heavy rate	1.82×10^{-7}
Housing and buildings – heavy rate	7.08×10^{-7}

Primary and secondary poisoning

Primary poisoning

Due to the intended use of the product (indoors by syringe applicator into otherwise inaccessible cracks and crevices) the risk of exposure to birds and mammals is considered to be negligible and a primary poisoning assessment is considered not to be applicable.

Secondary poisoning

The first step in an assessment of secondary poisoning risk is to consider whether a chemical has the potential to bioaccumulate. The potential for bioaccumulation can be estimated from the value of the n-Octanol/water partition coefficient, log K_{ow}. It is accepted that values of log K_{ow} greater than or equal to 3 indicate that the substance may bioaccumulate (TGD). Since dinotefuran has a log K_{ow} of -0.64, the compound displays little potential for bioaccumulation and therefore no further consideration of this pathway is necessary.

C. RISK CHARACTERISATION FOR THE ENVIRONMENT

Atmosphere

Conclusion: No predicted environmental concentrations of dinotefuran [or its metabolites] have been produced as these are expected to be negligible based on its low vapour pressure (5.0×10^{-5} Pa at 25 °C), limited indoor use pattern and formulation type (gel bait). Therefore, Dinotefuran 2 % Bait is not considered to be a concern for the air compartment when applied in accordance with the proposed use pattern.

Sewage treatment plant (STP)

Scenario	PEC/PNEC
Domestic housing : indoor normal treatment	2.64×10^{-7}
Larger buildings : indoor normal treatment	9.14×10^{-8}
Combined housing & buildings : indoor normal treatment	3.55×10^{-7}

Domestic housing : indoor heavy treatment	5.30×10^{-7}
Larger buildings : indoor heavy treatment	1.84×10^{-7}
Combined housing & buildings : indoor heavy treatment	7.14×10^{-7}

Conclusion: Application of Dinotefuran 2% bait in accordance with the intended use pattern does not pose unacceptable risk to STP micro-organisms as all PEC:PNEC values are << 1.

Aquatic compartment

Scenario	**PEC/PNEC**
Domestic housing : indoor normal treatment	1.03×10^{-2}
Larger buildings : indoor normal treatment	3.60×10^{-3}
Combined housing & buildings : indoor normal treatment	1.40×10^{-2}
Domestic housing : indoor heavy treatment	2.09×10^{-2}
Larger buildings : indoor heavy treatment	7.24×10^{-3}
Combined housing & buildings : indoor heavy treatment	2.81×10^{-2}

Conclusion: Application of Dinotefuran 2% bait in accordance with the intended use pattern does not pose unacceptable risk to aquatic organisms in surface waters as all PEC:PNEC values are <<1.

Terrestrial compartment

Scenario	**PEC/PNEC**
Domestic housing : indoor normal treatment	1.53×10^{-3}
Larger buildings : indoor normal treatment	5.30×10^{-4}
Combined housing & buildings : indoor normal treatment	2.06×10^{-3}
Domestic housing : indoor heavy treatment	3.07×10^{-3}
Larger buildings : indoor heavy treatment	1.06×10^{-3}
Combined housing & buildings : indoor heavy treatment	4.14×10^{-3}

Conclusion: Application of Dinotefuran 2% bait in accordance with the intended use pattern does not pose unacceptable risk to soil organisms as all PEC:PNEC values are <<1.

Groundwater

Predicted concentrations of dinotefuran in local soil have been used to crudely indicate groundwater levels (in line with the TGD for risk assessment). Whilst this approach would be simplistic and takes no account of soil characterisation, transformation or dilution in deeper soil layers, it does suggest a "worst case" porewater concentration of 0.000265 µg l^{-1}. This concentration in porewater of non-specific "agricultural soil" falls significantly below the current quality standard (0.1 µg l^{-1}) set by the EU Drinking Water Directive (98/83/EC) and indicates that risks from contamination of groundwater would be acceptable.

If it were assumed as an "extreme worst case" assessment that degradation resulted in equivalent levels of MNG (major soil metabolite) to those predicted in soil for dinotefuran, then risks to porewater from formation of the metabolite would also fall significantly below the current quality standard (0.1 µg l^{-1}) from the EU Drinking Water Directive (98/83/EC). Calculated porewater levels of 0.000211 µg l^{-1} were determined for the major metabolite, based upon emission from the limited indoor use patterns of Dinotefuran 2% Bait.

Mixture toxicity

The product contains only one a.s. so there is no need to perform a "multiple active" assessment. However, the presence of any relevant "Substances of Concern" in the formulation is considered as follows for any contribution they may give to overall environmental risk.

Screening step

Screening Step 1: Identification of the concerned environmental compartments

According to the online EChA C&L Inventory, 4 compounds within the product formulation have the potential to be classified as "Substances of Concern" based upon reported entries on existing Material Safety Data Sheets for materials currently in the marketplace.

In relation to the first potential SoC*, 4551 entries state that the material should not be classified for environmental effects whilst the following additional classifications have been allocated in different entries: H410 (43 entries) and H411 (2 entries). As supporting evidence, the applicant has submitted an MSDS from its supplier indicating that the material is not classified for the environment and so it should not be considered as an SoC.

In relation to the second potential SoC*, 1674 entries state that the material should not be classified for environmental effects whilst the following additional classifications have been allocated in different entries : H400 (15 entries), H411 (2 entries) and H412 (403 entries). The applicant has submitted an MSDS from its supplier indicating that the material is not classified for the environment and so it should not be considered as an SoC.

In relation to the third potential SoC*, 1368 entries state that the material should not be classified for environmental effects whilst the following additional classifications have been allocated in different entries: H400+H410 (1 entry) and H411 (3 entries). The applicant has submitted an MSDS from its supplier indicating that the material is not classified for the environment and so it should not be considered as an SoC.

In relation to denatonium benzoate, 1419 entries state that the material should be classified as H412 with 165 entries indicating that it should be unclassified for environmental effects. As supporting evidence, the applicant has submitted an MSDS from

* For more information see the original Dinotefuran 2% Bait PAR.

its supplier indicating that H412 is appropriate. Therefore, denatonium benzoate should be considered as an SoC.

Although denatonium benzoate should be considered in the assessment, its contribution to overall risk of the formulation can be considered negligible. The bittering agent is present at low levels (0.01% w/w) when considered in relation to that of dinotefuran (2% w/w) so may be discounted from additional assessment as the concentration of this SoC in the formulation is 200-fold lower than the a.s. under consideration. Additionally, the active substance appears to be significantly more toxic (classification H400 + H410) than the Substance of Concern (H412).

For these reasons, it has not been considered necessary to carry out an additional assessment for this SoC compound, given the negligible additional risk it poses. It is evident that risks arising from application of the product will be driven solely due to the presence of dinotefuran.

Conclusion: Although an environmental SoC may be present (denatonium benzoate), it is present at 1/200th the concentration of a.s. and has much lower (eco)toxicity. Whilst it should not be ignored, the potential risks from denatonium benzoate will be several orders of magnitude lower than the a.s. and there seems no added value in calculating emissions – in reality, risks will be driven solely by the a.s.

Aggregated exposure (combined for relevant emission sources)

Dinotefuran is a new active substance under BPR with limited use only as an indoor gel bait against cockroaches (PT 18). This product represents the first authorisation for an insecticidal product within the EU.

Aggregated exposure assessment has not been considered.

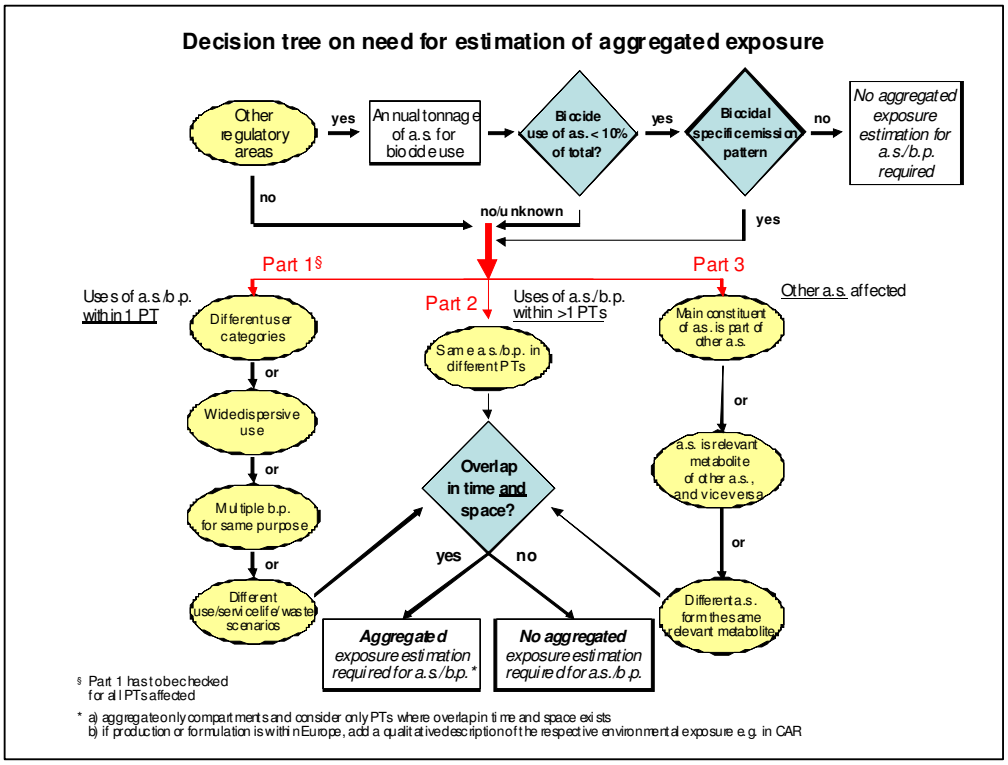


Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product
The risks for environmental exposure associated with the intended use of Dinotefuran 2% Bait as a professional indoor use product applied at a maximum application rate of 0.8 g product per m^2 are acceptable; all PEC:PNEC values for STP, surface water and soil are < 1. Furthermore, predicted levels reaching porewater fall significantly below the trigger level for drinking water (0.1 µg l^{-1}). Although the product contains an SoC, denatonium benzoate, it is present in the gel bait at concentrations which are 200 times lower than those of the active substance. In addition, its toxic effects (H412) are much lower compared to the a.s. (H400 + H410) and therefore will only provide a negligible contribution to overall risks. As environmental risks posed by the a.s. itself are all << 1 (based on PEC:PNEC values), calculation of denatonium benzoate emissions have not been undertaken. Environmental risks posed by the product have therefore been driven only by dinotefuran. The product assessment for Dinotefuran 2% Bait under the limited indoor use pattern has been carried out in line with current guidance and EU-agreed modelling. Uses are identical to those outlined for the representative product in the EU evaluation of dinotefuran as a new a.s. under BPD/R and acceptable risks are clearly demonstrated to all environmental compartments.

Authorisation may be granted for an indoor crack /crevice and spot treatment applied only by professional operators in domestic dwellings and commercial buildings.

2.2.7 MEASURES TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

Please refer to section 2.1.6.

2.2.8 SUBSTITUTION/EXCLUSION CRITERIA AND COMPARATIVE ASSESSMENT

A. BACKGROUND

According to the most recent scientific information available, the active substance in this biocidal product, dinotefuran, is considered a candidate for substitution using the criteria in Article 10(1) of EU Regulation 528/2012, although it is not considered as meeting the exclusion criteria according to Article 5(1). This conclusion is based on section 1.4.4. of the Evaluation of Active Substances Assessment Report for dinotefuran under PT18 and the EU list (dated November 2015): https://circabc.europa.eu/sd/a/419b9650-db4b-4c6e-91d8-fbefa8669715/List_compilation_exclusion_substituion_criteria_version_November%202015.xls, which states that dinotefuran is proposed to be classified as persistent/very persistent (P/vP) and toxic (T) but not bio-accumulative. Therefore, dinotefuran can be considered to meet the criteria in Article 10(1)(d), notably it meets two of the criteria for being PBT in accordance with Annex XIII to regulation (EC) No 1907/2006.
Under Article 23(1) of Regulation 528/2012, Member States evaluating biocidal products containing an active substance that is a candidate for substitution in accordance with Article 10(1) are required to perform a comparative assessment. The UK CA has therefore used the approach in the most recent EU guidance[2] on the comparative assessment of the biocidal product.
In line with this Note for Guidance, the UK CA began the comparative assessment with the screening phase (Annex 1.1 of guidance document) to identify whether the diversity of the active substances – mode of action combination in authorised biocidal products is adequate.

B. SCREENING PHASE OF COMPARATIVE ASSESSMENT

Intended use of the biocidal product and properties of active substance.
Article 23(3) and the Note for Guidance identify that the comparative assessment should address the uses specified in the application of the biocidal product, as the requirement for a comparative assessment is product specific.

Table 1: Intended uses of the biocidal product.

Product Type	PT-18 (insecticides, acaricides and products to control other

[2] Notes for guidance: Comparative assessment of biocidal products – consolidated version of CA Sept13-Doc.5.1.f & CA-Dec13-Doc5.1.k-Final

	arthropods)
Where relevant, an exact description of the authorised use	VII.2 Health protection
Target organism (including development stage)	I.3.4.1 Blattellidae, Blattellid Cockroaches Including: *B. germanica* (German cockroaches) and *B. orientalis* (Oriental cockroaches).
Field of use	IV.1. Indoor use only. IV.1.3 To be used in: IV.1.3.1 Industrial/commercial premises IV.1.3.2 households/private areas. IV.1.3.3 Public (e.g. Hospitals, Nursing Homes)
Application method(s)	V.I.6. Bait application V.I.7.1. Open via crack and crevice or spot treatment only
Function/mode of action	III.1 Mode of exposure: III.1.1. Ingestion (bait) III.1.3. Contact III.2 Type of effect: III.2.8 Other: agonist of insect nicotinic acetylcholine receptors. It appears that its mechanism differs from other neonicotinoid insecticides.
Category(ies) of users	V.2. Professional
Formulation type:	VIII.5.2 Gel bait (RFU)

As shown in table 1, the biocidal product is a ready for use, gel bait formulation intended for use by professionals users inside domestic, commercial and public buildings. It is intended to control cockroaches, including the *B. germanica* and *B. orientalis* species. The active substance dinotefuran is an insecticide (PT18) which acts on organisms by contact and ingestion. According to information provided by the Insecticide Resistance Action Committee (IRAC), an international scientific committee with an overview of the global position of insecticide resistance, the mode of action of dinotefuran belongs to Insecticide Main Group 4A (Nicotinic acetylcholine receptor (NACHR) competitive Modulators – Neonicotinoids).

Chemical diversity of the active substances – screening phase results.
According to the information available from the ECHA database in October 2015, there were 168 biocidal products authorised for Product type 18 (Insecticides) under the Biocidal Products Directive and Biocidal Products Regulation (including Mutual Recognitions and same biocidal product authorisations). With this being the first product containing dinotefuran as its active ingredient, these 168 products contain one of the following twelve active substances:

- Abamectin
- Aluminium phosphide releasing phosphine
- *Bacillus thuringiensis* sub-species *israelerisis* Serotype H14, Strain AM65-52
- Carbon dioxide
- Fipronil
- Imidacloprid
- Indoxacarb
- Magnesium phosphide releasing phosphine
- Metofluthrin

- Nitrogen
- Spinosad
- Sulphuryl fluoride

During the EU-wide screening process the UK identified five authorised lead PT18 products (i.e. not including mutual recognitions) containing one of the above stated active substances with a similar target pest; cockroaches. Of these products, two are based on spinosad, one based on indoxacarb, one other nitrogen and the final abamectin.

The nitrogen containing product is for indoor use as a fumigant and so is very different to the spot/crack and crevice application method intended for dinotefuran 2% bait. A minimum nitrogen concentration needs to be achieved within a purpose built sealed enclosure and, applied within specific application parameters by trained professionals. In contrast, Dinotefuran 2% Bait is applied in 0.1g spots without the need for similar application requirements. In addition to this, the user of the nitrogen based product is restricted to 'specialised professional', whereas Dinotefuran 2% Bait can be used by any professional operator. Against this background, the nitrogen product was not judged as a suitable direct replacement for Dinotefuran 2% Bait.

The remaining four products were all gel bait RFU with a mixture of professional and non-professional users. The abamectin containing baits, which were authorised in the Netherlands with no current mutual recognition application in the UK, is for indoor use by non-professionals only. The abamectin Baits' instruction for use states; "If 3 months after the start of the treatment the infestation continues, a professional pest controller should be contacted". Therefore, the description of the intended user and use of abamectin Baits conclusively describes that it is a product to be used before professional help is required and hence is not considered a possible replacement for Dinotefuran 2% Bait which is for professional use only.

One of the spinosad containing products that was mutually recognised in the UK, is eligible for both non-professional and professional use however, it's usage area is restricted to animal production facilities and hence was not considered as a possible replacement for Dinoterfuran 2% Bait where use areas include domestic dwellings and commercial buildings.

The two products that remained were a spinosad product that was authorised in France, with no current mutual recognition application in the UK (domain of use not clear), and a product containing indoxacarb authorised in the UK.

The Insecticide Resistance Action Committee (IRAC), class each of the actives in the following mode of action groups:

Table 2: Mode of action for the three comparable PT18 insecticidal substances in authorised biocidal products

Active substance	Main group and primary site of action	Chemical sub-group [exemplifying active ingredient]
Spinosad	Main Group 5 (Nicotinic acetylcholine receptor (nAChR) allosteric activators)	Sub-group N/A [Spinosyns]

Indoxacarb	Main Group 22 (Voltage-dependent sodium channel blockers)	Sub-group A [Indoxacarb]
Dinotefuran	Main Group 4 (Nicotinic acetylcholine receptor (nAChR) competitive modulators)	Sub-group A [Neonicotinoids]

Table 2 shows that all three active substances are in different mode of action groups but despite this, all three actives act upon an insect's nervous system.
Where dinotefuran acts as an agonist at the nAChRs in the insects, spinosad activates nAChRs (by acting at a site distinct from the target site of the neonicotinoids) causing constitutive function. Therefore, although the active ingredients both act on the same enzyme, mode of action and the end outcome are different. Spinosad is also a candidate for substitution itself as it also meets the criteria in Article 10(1)(d) of EU Regulation 528/2012 for being PBT in accordance with Annex XIII to regulation (EC) N 1907/2006. Its conclusion in section 2.2.2.3 of the active substance approval Assessment Report and and the EU list (dated November 2015): https://circabc.europa.eu/sd/a/419b9650-db4b-4c6e-91d8-fbefa8669715/List_compilation_exclusion_substituion_criteria_version_November%202015.xls states that it is considered persistent (P) (sediment) and toxic (T) hence, it can be considered less of an environmental risk compared to dinotefuran which is vP and T. Although indoxacarb acts on a different enzyme to dinotefuran, the end outcome for both is a hindrance of the nervous system. Indoxacarb is not a candidate for substitution itself and would therefore be a more suitable substitute for dinotefuran.

C. UK CA CONCLUSIONS ON COMPARATIVE ASSESSMENT

Taking into account the available information summarised here, the UK CA considers that if dinotefuran were substituted, the chemical diversity would be inadequate for the given PT/use/target organism/mode of action combination. In addition to this, of the three actives mentions product availability is limited to 3 in total. As such to ensure that retail competition encourages affordable prices, we believe that restricting this limited product number encompassing these three actives any further could have a negative economic impact. Therefore, the UK CA concludes that in line with Article 23(3)(a) and (b) of the BPR, the Note for Guidance and since dinotefuran does not meet the exclusion criteria as outlined in Article 5(1) of the BPR, it is valid to conduct no further investigation at this point. According to section 4 of the Note for Guidance, if the outcome of the comparative assessment is not sufficiently conclusive to state that the criteria of Article 23(3) of EU Regulation 528/2012 are met, the product can be authorised for a period not exceeding 5 years. As such the UK CA considers that the comparative assessment for Dinotefuran 2% Bait application can be finalised at the screening stage and the application taken forward to product authorisation in accordance with Article 23(6) of the BPR.

3. ANNEXES

3.1 LIST OF STUDIES FOR THE BIOCIDAL PRODUCT

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Yes/No)	Owner
3.1/01	Takahashi, N., Shiraki, A., Tobinaga, M.	2010	Pest control bait product "New GOK1": data on setting of specifications and test methods, Experiment Building, Research & Development Dept., Osaka Kasei Co., Ltd., 2-6-11, Nakashima, Nishiyodogawa-ku, Osaka City, Osaka 555-0041, Japan no report no. Not GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
3.2/01	Takahashi, N., Shiraki, A., Tobinaga, M.	2010	Pest control bait product "New GOK1": data on setting of specifications and test methods, Experiment Building, Research & Development Dept., Osaka Kasei Co., Ltd., 2-6-11, Nakashima, Nishiyodogawa-ku, Osaka City, Osaka 555-0041, Japan no report no. Not GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
3.3/01	Cage, S.	2012	Dinotefuran 2% bait relative density Huntingdon Life Sciences Ltd, Eye, Suffolk, IP23 7PX, United Kingdom MCW0039 GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
3.4.1/01	Cage, S.	2014	Dinotefuran 2% Bait: two year storage stability Huntingdon Life Sciences Ltd, Eye, Suffolk, IP23 7PX, UK MCW0042 GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
3.4.1/02	Cage, S.	2014	Dinotefuran 2% bait containing bittering agent: accelerated storage stability Huntingdon Life Sciences, Eye, Suffolk, IP23 7PX, UK MCW0058 GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Yes/No)	Owner
3.4.1/03	Cage, S.	2012	Dinotefuran 2% bait accelerated storage stability + Amendment 1 Huntingdon Life Sciences Ltd, Eye, Suffolk, IP23 7PX, United Kingdom MCW0041 GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
3.4.1/04	Cage, S.	2012	Dinotefuran 2% bait low temperature stability Huntingdon Life Sciences Ltd, Eye, Suffolk, IP23 7PX, United Kingdom MCW0043 GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
3.4.1/05	Takahashi, N., Shiraki, A., Tobinaga, M.	2010	Pest control bait product "New GOK1": stability data Experiment Building, Research & Development Dept., Osaka Kasei, Co., Ltd. 2-6-11, Nakashima, Nishiyodogawa-ku, Osaka City, Osaka 555-0041, Japan no report no. Not GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
3.4.1/06	Takahashi, N., Shiraki, A., Tobinaga, M.	2010	Pest control bait product "New GOK1": stability data Experiment Building, Research & Development Dept., Osaka Kasei, Co., Ltd. 2-6-11, Nakashima, Nishiyodogawa-ku, Osaka City, Osaka 555-0041, Japan no report no. Not GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
3.4.1/07	Takahashi, N., Shiraki, A., Tobinaga, M.	2010	Pest control bait product "New GOK1": stability data Experiment Building, Research & Development Dept., Osaka Kasei, Co., Ltd. 2-6-11, Nakashima, Nishiyodogawa-ku, Osaka City, Osaka 555-0041, Japan no report no. Not GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Yes/No)	Owner
3.4.1/08	Takahashi, N., Shiraki, A., Tobinaga, M.	2010	Pest control bait product "New GOK1": stability data Experiment Building, Research & Development Dept., Osaka Kasei, Co., Ltd. 2-6-11, Nakashima, Nishiyodogawa-ku, Osaka City, Osaka 555-0041, Japan no report no. Not GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
3.9/01	Cage, S.	2012	Dinotefuran 2% bait viscosity Huntingdon Life Sciences Ltd, Eye, Suffolk, IP23 7PX, United Kingdom MCW0040 GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
4.1/01	Cage, S.	2012	Dinotefuran 2% bait explosive properties Huntingdon Life Sciences Ltd., Eye, Suffolk, IP23 7PX, United Kingdom MCW0034 GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
4.2/01	Cage, S.	2012	Dinotefuran 2% bait flammability (solids) Huntingdon Life Sciences Ltd, Eye, Suffolk, IP23 7PX, United Kingdom MCW0037 GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
4.4/01	Cage, S.	2014	Dinotefuran 2% bait containing bittering agent: oxidising properties Huntingdon Life Sciences, Eye, Suffolk, IP23 7PX, UK MCW0057 GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
4.4/02	Cage, S.	2012	Dinotefuran 2% bait oxidising properties Huntingdon Life Sciences Ltd., Eye, Suffolk, IP23 7PX, United Kingdom MCW0036 GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Yes/No)	Owner
4.17.1/01	Cage, S.	2012	Dinotefuran 2% bait auto-ignition temperature (liquids and gases) Huntingdon Life Sciences Ltd, Eye, Suffolk, IP23 7PX, United Kingdom MCW0038 GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
5/01	Cage, S.	2012	Dinotefuran 2% bait method validation Huntingdon Life Sciences Ltd., Eye, Suffolk, IP23 7PX ,United Kingdom MCW0035 GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
6/01	Anonymous	2014	Dinotefuran 2% bait overview of efficacy data for cockroaches LKC Switzerland Ltd, Hauptstrasse 10, 4414 Füllinsdorf, Switzerland no report no. Not GLP unpublished	N	Y	Mitsui Chemicals Agro, Inc.
6.7/01	Heaven, H.	2013	Field trial to determine the efficacy of dinotefuran 2% bait against German cockroaches, Blattella germanica i2L Research Ltd, Capital Business Park, Wentloog, Cardiff CF3 2PX, UK 12/001 Not GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
6.7/02	Heaven, H.	2013	Field trial to determine the efficacy of dinotefuran 2% bait against German cockroaches, Blattella germanica i2L Research Ltd, Capital Business Park, Wentloog, Cardiff CF3 2PX, UK 13/089 Not GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
6.7/03	Heaven, H.	2013	Field trial to determine the efficacy of dinotefuran 2% bait against Oriental cockroaches, Blatta orientalis i2L Research Ltd, Capital Business Park, Wentloog, Cardiff CF3 2PX, UK 12/002 Not GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Yes/No)	Owner
6.7/04	Heaven, H.	2013	Field trial to determine the efficacy of dinotefuran 2% bait against Oriental cockroaches, Blatta orientalis i2L Research Ltd, Capital Business Park, Wentloog, Cardiff CF3 2PX, UK 13/088 Not GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
6.7/05	Kinsey, R.	2014	Laboratory bioassay to determine the efficacy of a dinotefuran 2% gel bait with a bittering agent against juvenile and adult Oriental cockroaches, Blatta orientalis. i2L Research Ltd, Capital Business Park, Wentloog, Cardiff CF3 2PX, UK 12/007 GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
6.7/06	Kinsey, R.	2013	Laboratory bioassay to determine the palatability of a denatonium benzoate spiked Dinotefuran 2% gel bait against German cockroaches, Blattella germanica i2L Research Ltd, Capital Business Park, Wentloog, Cardiff CF3 2PX, UK 13/274 Not GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
6.7/07	Kinsey, R.	2014	Laboratory bioassay to determine the efficacy of a dinotefuran 2% gel bait with a bittering agent against juvenile German cockroaches, Blattella germanica i2L Research Ltd, Capital Business Park, Wentloog, Cardiff CF3 2PX, UK 14/020 Not GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
6.7/08	Kinsey, R.	2014	Laboratory bioassay to determine the efficacy of a dinotefuran 2% gel bait with a bittering agent against juvenile and adult Oriental cockroaches, Blatta orientalis i2L Research Ltd, Capital Business Park, Wentloog, Cardiff CF3 2PX, UK 14/019 Not GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Yes/No)	Owner
6.7/09	Kazuma, T., Minagawa, K.	2010	Dinotefuran bait product and reference product: ad libitum feeding study against German cockroach Japan Environment Sanitation Center, East Branch Office, Environmental Biology Department 18-EB-911-033 Not GLP unpublished	N	Y	Mitsui Chemicals Agro, Inc.
6.7/10	Kazuma, T., Minagawa, K.	2010	Dinotefuran bait product and reference product: ad libitum feeding study against German cockroach (strain that shows dietary aversion to sucrose) Japan Environment Sanitation Center, East Branch Office, Environmental Biology Department 18-EB-911-034 Not GLP unpublished	N	Y	Mitsui Chemicals Agro, Inc.
6.7/11	Kazuma, T., Minagawa, K.	2010	Dinotefuran bait product and reference product: ad libitum feeding study against Smokybrown cockroaches Japan Environment Sanitation Center, East Branch Office, Environmental Biology Department 18-EB-911-032 Not GLP unpublished	N	Y	Mitsui Chemicals Agro, Inc.
6.7/12	Nagai, J.	2010	Dinotefuran bait product: ad libitum feeding study against German cockroach Mitsui Chemicals Agro, Inc., Agricultural Research Insitute no report no. Not GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
6.7/13	Koizumi,T.	2010	Dinotefuran bait product: field efficacy study against German cockroach Japan Environmental Sanitation Center, East Branch Office, Environmental Biology Department 18-EB-911-035 Not GLP unpublished	N	Y	Mitsui Chemicals Agro, Inc.

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Yes/No)	Owner
6.7/14	Kosone, K., Ito, M.	2010	Field efficacy study of dinotefuran bait against German cockroaches Yokohama City Institute of Health, Japan no report no. Not GLP unpublished	N	Y	Mitsui Chemicals Agro, Inc.
6.7/15	Kinsey, R.	2014	GLP Laboratory bioassay to determine the palatability of a dinotefuran 2% gel bait with a bittering agent against German cockroaches, Blattella germanica, and Oriental cockroaches, Blatta orientalis i2L Research Ltd, Capital Business Park, Wentloog, Cardiff CF3 2PX, UK 14/018 GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
8.1/01	Confidential to NA-APP authorisation holder	2010	Acute dermal irritation/corrosion test (patch test) of New GOK 1 in rabbits Address confidential to NA-APP authorisation holder. GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
8.2/01	Confidential to NA-APP authorisation holder	2010	Acute eye irritation/corrosion test of New GOK 1 in rabbits Address confidential to NA-APP authorisation holder. GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
8.3/01	Confidential to NA-APP authorisation holder	2010	Skin sensitisation test of New GOK 1 in guinea pigs-according to the E.V. Buehler method + Amendment-1 Address confidential to NA-APP authorisation holder. GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
8.5.1/01	Confidential to NA-APP authorisation holder	2010	Acute oral toxicity of New GOK1 to the rat - limit test Address confidential to NA-APP authorisation holder. GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key study (Y/N)	Data Protection Claimed (Yes/No)	Owner
8.5.1/02	Confidential to NA-APP authorisation holder	2010	Acute oral toxicity of New GOK1 to the mouse - limit test + Amendment 1 Address confidential to NA-APP authorisation holder. GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
8.5.3/01	Confidential to NA-APP authorisation holder	2009	Acute dermal toxicity test with New GOK1 in the rat - limit test + Amendment 1 Address confidential to NA-APP authorisation holder. GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
8.5.3/02	Confidential to NA-APP authorisation holder	2009	Acute dermal toxicity test with New GOK1 in the Mouse - Limit Test + Amendment 1 Address confidential to NA-APP authorisation holder. GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.
8.6/01	Hassler, S.	2014	Dinotefuran: percutaneous penetration of 14-C dinotefuran formulated as Dinotefuran 2% gel through human split-thickness skin membranes (in vitro) Harlan Laboratories Ltd,. Zelgliweg 1, 4452 Itingen, Switzerland D80138 GLP unpublished	Y	Y	Mitsui Chemicals Agro, Inc.

3.2 OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS

Please see the human health exposure section and the exposure to the environment section of this PAR.

3.3 NEW INFORMATION ON THE ACTIVE SUBSTANCE

No active substance data were required as a condition of the active substance approval, and none have been provided by the applicant to support this product application for Dinotefuran 2% Bait.

3.4 RESIDUE BEHAVIOUR

Dinotefuran is not classified as toxic or very toxic and hence, a monitoring method for residues in body fluids and tissues is not required.

3.5 SUMMARIES OF THE EFFICACY STUDIES

Please see section 3.1 above and the efficacy section of this PAR which summarises these data.

3.6 CONFIDENTIAL ANNEX

3.6.1 PRODUCT COMPOSITION AND FORMULATION

NB: This information is confidential and should not be disclosed to third parties. For the full composition please see the Dinotefuran 2% Bait PAR.

A. QUALITATIVE AND QUANTITATIVE INFORMATION ON THE COMPOSITION OF THE BIOCIDAL PRODUCT

Component	IUPAC name	CAS No.	Function	Content (% w/w)
Dinotefuran, pure	(*RS*)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine	165252-70-0	Active substance	2.00
Denatonium benzoate	phenylmethyl-[2- [(2,6-dimethylphenyl)amino]-2-oxoethyl]-diethylammonium benzoate	3734-33-6	bittering agent	0.01
Confidential ingredients of Addict Gel Cockroach	-	-	-	97.99

3.6.2 INFORMATION ON THE SUBSTANCE(S) OF CONCERN

No substances of concern were identified by human health toxicology. The environment assessment revealed that there were four potential SoC's. Three of which initially had one or more of the classifications Aquatic Acute 1-H400, Aquatic Chronic 1-H410 and Aquatic Chronic 2-H411 whereas, denatonium benzoate had a classification of aquatic Chronic 3-H412. Although the applicant was able to submit evidence that supported a non-classification for the first three, this was not the case for denatonium benzoate and hence, it was the only one out of the potential 4 identified as a SoC by the environmental assessment. Despite all this, its risk can be considered negligible due to its presense being at low levels (0.01% w/w) in the formulation.

3.7 OTHER

None