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

DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR UNION AUTHORISATION APPLICATIONS

(submitted by the applicant)

PESGUARD® GEL

Product type 18

(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine (Clothianidin) & Pyriproxyfen

Case Number in R4BP: BC-HS027052-37

Evaluating Competent Authority: NL

Date: October 2020

1 Table of Contents

1 CONCLUSION

The product *Pesguard®* Gel is a ready to use bait for use by professionals against cockroaches.

The efficacy package provided demonstrates that *Pesguard®* Gel is effective against German cockroaches (*Blattella germanica*), Brown banded cockroaches (*Supella longipalpa*), Oriental cockroaches (*Blatta orientalis*) and American Cockroaches (*Periplaneta americana*) both as nymphs and adults. The gel should be applied as a number of spots of approximately 4 mm diameter (each spot comprising approximately 0.032g of bait).

The information on composition, physical and chemical properties and analytical methods is acceptable. The product contains 0.513% technical clothianidin and 0.507% technical pyriproxyfen, is stable for 2 years at ambient temperatures and is not sensitive to elevated temperatures or humidity. The product should however be protected from frost and stored away from direct sunlight.

With regard to physical and chemical hazards, *Pesguard®* Gel is not classified.

The content of the active substances can be monitored using a validated HPLC-UV method.

Based on the human health risk assessment, no adverse health effects are expected after use of *Pesguard®* Gel in accordance to the intended use.

It can be concluded that the use of *Pesguard®* Gel as proposed presents an acceptable risk to the environment.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
Pesguard® Gel	European Union

Pesguard® Gel was originally referred to by the experimental formulation known as X-7472-14. This was later changed to a "registration code number" [redacted].

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Sumitomo Chemical Agro Europe S.A.S.
	Address	Parc d'Affaires de Crécy 10A Rue de la Voie Lactée 69370 Saint Didier au Mont d'Or France
Pre-submission phase started on	14 December 2015	
Pre-submission phase concluded on	26 January 2016	
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	McLaughlin Gormley King Company (MGK)
Address of manufacturer	7325 Aspen Lane North Minneapolis MN 55428 United States
Location of manufacturing sites	4001 Peavey Road Chaska MN 55318 United States 7325 Aspen Lane North Minneapolis MN 55428 United States

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine (Clothianidin)
Name of manufacturer	Sumitomo Chemical Company, Ltd
Address of manufacturer	27-1, Shinkawa 2-chome Chuo-ku 104-8260 Tokyo Japan
Location of manufacturing sites	Oita Works 2200, Tsurusaki Oita City 870-0106 Oita Japan

Active substance	Pyriproxyfen
Name of manufacturer	Sumitomo Chemical Co. Ltd.
Address of manufacturer	27-1, Shinkawa 2-chome Chuo-ku 104-8260 Tokyo Japan
Location of manufacturing sites	Misawa Works, Aza-Sabishirotaira Oaza-Misawa, 033-0022 Misawa Aomori Japan

2.1.2 Product composition and formulation

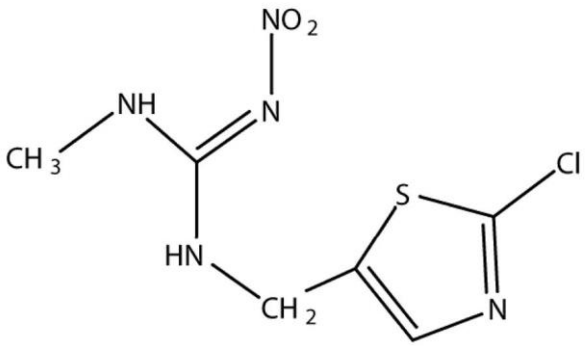
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

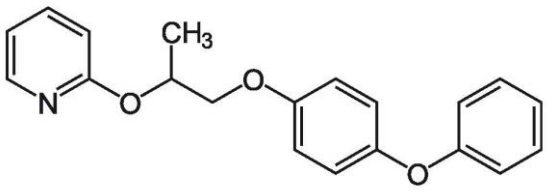
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Clothianidin
IUPAC or EC name	(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine
EC number	433-460-1
CAS number	210880-92-5
Index number in Annex VI of CLP	613-307-00-5
Minimum purity / content	950 g/kg

Structural formula	

Main constituent(s)	
ISO name	Pyriproxyfen
IUPAC or EC name	2-(1-methyl-2-(4-phenoxyphenoxy)ethoxy)pyridine
EC number	429-800-1
CAS number	95737-68-1
Index number in Annex VI of CLP	613-303-00-3
Minimum purity / content	970 g/kg (sum of isomers; racemate)
Structural formula	

2.1.2.2 Candidate(s) for substitution

Clothianidin is considered a candidate for substitution as it fulfils two of the PBT criteria:
- persistent and toxic.

The Assessment Report, however, states "even though the T-criterion as well as the P-, vP-criterion are fulfilled the active substance clothianidin is neither PBT- nor vP/vB-candidate as the B and vB-criteria are not fulfilled.

No specific test for potential endocrine disruption was carried out. However, from the available CMR studies and the repeated dose studies, there is no evidence for endocrine disruption or for CMR effects".

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Clothianidin	3-[(2-chloro-1,3-thiazol-5-yl)methyl]-2-methyl-1-nitroguanidine	Active substance	210880-92-5	433-460-1	0.526 (TGAI) Pure: 0.5%
Pyriproxyfen (Sumilarv)	2-(1-methyl-2-(4-phenoxyphenoxy) ethoxy)pyridine	Active substance	95737-68-1	429-800-1	0.515 (TGAI) Pure: 0.5%
Acetic acid	Ethanoic acid	Non-active substance	64-19-7	200-580-7	0.3
Potassium sorbate	potassium (E,E)-hexa-2,4-dienoate	Non-active substance	24634-61-5	246-376-1	0.5
Refer to the confidential annex for details of the co-formulants					

2.1.2.4 Qualitative and quantitative information on the composition of the biocidal product family[2]

Not applicable.

2.1.2.5 Information on technical equivalence

The active substance manufacturer for clothianidin is Sumitomo Chemical Company Ltd., Sumitomo Chemical Company LTD, Oita Works, 2200 Tsurusaki Oita City, 870-0106 Oita, Japan. This source is equivalent based on the equivalence assessment by ECHA (case BC-WD030793-37).

The active substance manufacturer for Pyriproxyfen is Sumitomo Chemical Company Ltd., Misawa Works, Aza-Sabishirotaira, Oaza-Misawa, Misawa, 033-0022 Aomori, Japan. This is the reference source for Pyriproxyfen.

2.1.2.6 Information on the substance(s) of concern

Acetic acid and potassium sorbate are considered substances of concern for human health and Environment. Please refer to 2.1.2.3 with regard to their content in the formulation. For other information, please refer to the confidential annex.

2.1.2.7 Information on endocrine disrupting properties

An assessment of the endocrine disruption is presented in section "Assessment of effects" for human health aspect and in section "Effects assessment on the environment" for the environmental aspect and/or the confidential annex.
For the active substances clothianidin and pyriproxyfen no ED assessment is required because for active substances which have been approved, the EU assessment should be

followed. The Assessment Reports for clothianidin (2014) and pyriproxyfen (2012) both state that these active substances would not be considered as having endocrine disrupting properties.
For two co-formulants an ED alert was identified. However, for both co-formulants CA NL concludes that we have to await the discussions at EU level. See the confidential annex for more specific information.
In conclusion, based on available information, it is not possible to conclude whether the non-active substance should be considered to have ED properties before the expiration of the legal deadline in the BPR and therefore the process will be concluded at the post-authorisation stage. Once the conclusion regarding ED properties of these co-formulants is available, the applicant must inform the eCA. If needed, the conditions of authorization shall be revised.

2.1.2.8 Type of formulation

RB Bait (ready for use)

2.1.3 Hazard and precautionary statements

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

Classification		
Hazard category	Skin Sens. 1 Aquatic Chronic 1	
Hazard statement	H317: May cause an allergic skin reaction. H410: Very toxic to aquatic life with long lasting effects.	
Labelling		
Hazard Pictogram	 GHS07: exclamation mark	 GHS09: environment
Signal words	Warning	
Hazard statements	H317: May cause an allergic skin reaction. H410: Very toxic to aquatic life with long lasting effects.	
Precautionary statements	P273: Avoid release to the environment. P280: Wear protective gloves. P302+P352: IF ON SKIN: Wash with plenty of water/… P333+P313: If skin irritation or rash occurs: Get medical advice/attention. P391; Collect spillage. P501: Dispose of contents/container to …	

Note	**UFI:** G690-10HC-H00S-64C4 In line with CA document CA-May15-Doc.4.4 all P-statements that are triggered by CLP need to be included. However, if P-statements are triggered, but considered not applicable for the product than they can be omitted. The following P-statements are omitted: - P261, as the product is a gel and the actives or co-formulants are not volatile. - P272 and P362+P364 as the gel is applied by syringe, no contamination of work clothing is anticipated - P321 is also triggered by H317. However, it is indicated that his is highly recommended only in exceptional cases where specific treatment is known and required. This is not applicable for Pesguard Gel.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Professional Use - RTU Bait

Product Type	Product type 18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	*Blattella germanica* – German cockroach – nymphs and adults *Supella longipalpa* – Brown banded cockroach - nymphs and adults *Blatta orientalis* – Oriental cockroach – nymphs and adults *Periplaneta americana* – American cockroach - nymphs and adults
Field of use	Indoor In cracks and crevices, or in concealed locations inaccessible to humans or domestic animals: behind refrigerators, cupboards and shelves, under kitchen appliances, in electrical control boxes, voids and ducting and under bathroom fixtures etc.
Application method(s)	Bait application (RTU)

<table>
<tr><td>Application rate(s) and frequency</td><td>Pesguard® Gel should be applied as a number of spots of approximately 4 mm diameter (each spot comprising approximately 0.032g of bait). In cases of heavy infestation, where larger cockroach species are present (B. orientalis or P. americana), in areas that are particularly dirty or cluttered or where alternative sources of food cannot be entirely eliminated the higher application rate (e.g. 2 instead of 1 spot per m2 in case of a light infestation) should be used.

The maximum number of annual applications is 11.
<table>
<tr><th>Infestation level</th><th>Recommended application rate (number of 4mm diameter spots (approximately 0.032g of bait) per m^2)</th></tr>
<tr><td>Light</td><td>1 – 2</td></tr>
<tr><td>Medium</td><td>3 – 6</td></tr>
<tr><td>Heavy</td><td>6 - 10</td></tr>
</table>
</td></tr>
<tr><td>Category(ies) of users</td><td>Professional</td></tr>
<tr><td>Pack sizes and packaging material</td><td>30g PP syringe
HDPE Screw top cap</td></tr>
</table>

2.1.4.2 Use-specific instructions for use

See the general directions for use

2.1.4.3 Use-specific risk mitigation measures

See the general directions for use

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See the general directions for use

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

See the general directions for use

2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See the general directions for use

2.1.5 General directions for use

2.1.5.1 Instructions for use

Always read the label or leaflet before use and respect all the instructions provided.

Do not expose bait drops to sunlight or heat (i.e radiator).

The pre-filled plastic reservoir containing *Pesguard®* Gel is intended for use with the plunger provided or a specific bait application device common to the pest control industry. Refer to the manufacturer's instructions for directions on the use of the applicator.

Inject the bait into cracks and crevices, void spaces, or in concealed locations inaccessible to humans or domestic animals where insects may live, feed and breed. Such areas are generally warm/damp and dark (behind refrigerators cupboards and shelves, under kitchen appliances, in electrical control boxes, voids and ducting and under bathroom fixtures etc). Inspection or trapping to confirm infestation is recommended prior to treatment. Ensure that any alternative food sources are removed and concentrate the bait placements as individual spots at cockroach activity sites. The product should only be applied to areas inaccessible to children and pets.

Do not apply *Pesguard®* Gel where it will come into contact with water or in areas that are routinely cleaned. Typically, cockroaches will die a few hours after a single feed on *Pesguard®* Gel. In infested premises, dead cockroaches will normally be seen within 24 hours of treatment.

Remove the cap from the nozzle, touch the top to the surface to be treated, and push down on the plunger. Replace the cap on the dispenser after treatment is completed.

The bait will adhere to non-greasy or non-dusty surfaces and will remain pliable and palatable to cockroaches as long as it is visibly present.

Treated areas should be visually inspected after 1–2 weeks. Where initial infestation was heavy a second *Pesguard®* Gel application may be required if the first treatment has been consumed and live cockroaches are still present.

A second visual inspection of bait placements is recommended 2-4 weeks after the initial treatment. Reapply when bait is no longer visibly present, according to the level of infestation (light, medium or heavy). Replace bait before it is completely consumed to keep cockroaches from returning.

Inform the registration holder if the treatment is ineffective.

Spills and residues containing the product need to be removed as chemical waste.

Care should be taken to avoid depositing gel onto exposed surfaces. If gel contacts an exposed surface, remove gel with a paper towel and clean the area with disposable wet wipes.

During follow-up visits, inspect bait placements and re-apply when necessary.

Do not place bait in locations that are routinely washed, as bait will be removed by washing. Do not use this product in or on electrical equipment where a possibility of shock hazard exists. Avoid contact with textiles and clothing, as bait may stain.

2.1.5.2 Risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (glove material

to be specified by the authorisation holder within the product information).

Do not apply bait in areas where repellent insecticides have been used without thoroughly cleaning the surface with disposable wet wipes.
Do not apply repellent insecticides after application of the bait.

Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals.

Avoid placing gel on fabrics or carpets since it may stain some absorbent materials. To prevent staining, exposed bait should be cleaned up immediately with disposable wet wipes.

Cleaning materials must be disposed of to solid waste.

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Likely direct or indirect effects

No adverse effects expected when used as directed.

Description of first aid measures

Skin contact: Remove contaminated clothing immediately and wash skin with soap and water. Get medical attention if irritation persists after washing.

Eye contact: If symptoms occur; rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

Ingestion: If swallowed: If symptoms occur call a POISON CENTRE or a doctor.

If inhaled: not applicable.

Most important symptoms and effects, both acute and delayed

Eyes: May cause temporary eye irritation.

Emergency measures to protect the environment

Avoid release of the product to the environment.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Only pass on empty containers/packaging for recycling.
Disposal of this packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Protect from frost. Store away from direct sunlight.
Shelf life: 2 years.

2.1.6 Other information

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2.1.7 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	30g	Polypropylene	Screw top cap (HDPE with a UV blocker additive)	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Product
Please refer to the reference list contained in Annex 3.1.

Active Substance
A new study ([redacted]) has been conducted to determine the biodegradability of [^{14}C]-Pyriproxyfen in activated sludge based on OECD Method 314B and is contained within both the product dossier and the active substance dossier for Pyriproxyfen.

2.1.8.2 Access to documentation

The applicant is the data holder of the product and active data. A letter of Access is therefore not required.

2.1.8.3 Similar conditions of use

The pre-submission concluded that the product will have similar conditions of use across the Union, in accordance with Article 43(1).

2.2 Assessment of the biocidal product

Pesguard® Gel was originally referred to by the experimental formulation known as [redacted]. This was later changed to a "registration code number" [redacted].

2.2.1 Intended use(s) as applied for by the applicant

Please refer to 2.1.4.1

2.2.2 Physical, chemical and technical properties

Some studies within this section are performed with [redacted], which is a development code for *Pesguard®* Gel. The composition of the formulations is identical.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6303 (Physical State)	[redacted] revision 0 Purity: 0.504% clothianidin; 0.487% pyriproxyfen	Solid	[redacted]
eCA remark The applicant indicated the product is a gelatinous solid, which is a more accurate description than what was reported in the study [redacted]. Photos of the product included in the [redacted] accelerated storage stability confirm that the product is gel-like and could be regarded as a paste. Formally, the GLP claim of this report cannot be accepted as the test item identification is incomplete. A batch number is missing. Although the report states that lot # GLP2953 was used, this is the lab's internal designation for the test item and not that of the manufacturer. As GLP is not a requirement, the eCA considers that the study can be accepted as the study clearly indicated what product was tested and the active substance contents is within the specified range.				
Colour at 20 °C and 101.3 kPa	EPA OPPTS 830.6302 (Color)	[redacted] revision 0 Purity: 0.504% clothianidin; 0.487% pyriproxyfen	Tan	[redacted]
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304 (Odor)	[redacted] revision 0 Purity: 0.504% clothianidin; 0.487% pyriproxyfen	Chicken meal, dog food odour	[redacted]
Acidity / alkalinity	EPA OPPTS 830.7000 (pH)	[redacted] revision 0 Purity: 0.504%	The product pH is 4.88 at 5% in water	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		clothianidin; 0.487% pyriproxyfen		
eCA remark The product is a solid for purposes of the evaluation and is not diluted in water during use. A determination of the pH is therefore not required according to the BPR guidance. The applicant has provided data on a 5% dispersion, which can be considered as supplementary. Normally, a 1% dispersion should be tested – the test at 5% is therefore expected to result in a (slightly) lower pH.				
Relative density / bulk density	EPA OPPTS 830.7300 (Density / Relative Density / Bulk Density)	[redacted] revision 0 Purity: 0.504% clothianidin; 0.487% pyriproxyfen	The product specific gravity at 16.5°C is 1.062 g/cm^3	[redacted]
eCA remark The method used is based on adding the product to a 50mL graduated cylinder, followed by packing/shaking to reduce air bubbles. Therefore, the reported value is probably comparable to a tap density. The study can be accepted considering the product is gel-like. A pour density is not considered necessary. The method used is equivalent to CIPAC MT3 / OECD 109.				
Storage stability test – **accelerated storage**	CIPAC MT 46.3 (storage stability)	Cockroach bait – [redacted] (Lot no.DAT-041415A) 0.5% clothianidin 0.5% pyriproxyfen	The bait was found to be stable after storage at 54°C for 2 weeks in its original packaging (PP syringes). The active ingredient content was quantified using validated analytical method ref. [redacted] with slight modifications. The concentration of both clothianidin and pyriproxyfen remained constant with 1.61% and -0.39% change, respectively.	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			The mean weight change after storage was -0.2%. The product packaging (PP syringe) remained unchanged. The colour of the bait changed slightly but in subsequent efficacy tests using aged bait the bait was found to perform satisfactorily ([redacted]). Based upon the results of this study the bait can be expected to be stable for 2 years.	
	Guideline No. 830-63 17. 830-6320	[redacted] revision 0 Purity: 0.504% clothianidin; 0.492% pyriproxyfen	The bait was found to be stable after storage at 54°C for 2 weeks in glass and in commercial PP syringe (see section 2.1.7 for details). The active ingredient content was quantified using validated analytical method ref. [redacted] respectively. Clothianidin Initial 0.504% 2w 0.492% (-2.4%) in glass	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			2w 0.501% (-0.6%) in syringe Pyriproxyfen Initial 0.489% 2w 0.479% (-2.0%) in glass 2w 0.468% (-4.3%) in syringe The material stored at 54°C became darker in colour. Appearance: Initial: Tan gelatinous solid 2w: Tan gelatinous solid with slight discoloration and darkening in sample material, stored in glass. 2w: Tan gelatinous solid, stored in syringe Evaluation of the containers showed no signs of corrosion.	

eCA remark

The appearance changes during storage at elevated temperatures. Considering the product is a bait, this may affect the palatability of the formulation. The applicant has therefore provided efficacy data ([redacted], evaluated in the efficacy section 2.2.5.5), which shows the product is still efficacious despite the colour change compared to a fresh sample. Therefore, the eCA does not consider limitations of the storage conditions necessary.

In stability studies, the pH is normally reported, but for this non-flowing product, not diluted during use, pH data is not strictly required. It was therefore not included in the stability studies. See also the eCA remark under the entry acidity/alkalinity.

The analytical method used in the study [redacted] is a modified version of the method reported in the analytical method section ([redacted]). The method was modified as the lab did not have identical equipment available. Modifications were reported in detail: a 150mm column was used instead of a 100mm column (both C18), flow rate was lowered from 2 to 1.5mL/min, a lower amount of

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
internal standard was used and the sample concentration was slightly reduced. The modifications are not expected to have a major effect on the selectivity of the method and judging the chromatograms of the validation study, there are no substances that may have retention times shifts which may reduce separation or cause interferences. However, as the ratio between sample and the internal standard was changed (20g sample to 1g IS in 70mL acetone to 10g sample to 0.1g IS in 50mL acetone), the linearity should have been reported, which lowers the reliability of the study. Considering the results are confirmed by the study [redacted], this is considered an acceptable deficiency in this case.				
Storage stability test – **long-term storage at ambient temperature**	Guideline No. 830-6317. 830-6320	[redacted] revision 0 Purity: 0.496% clothianidin; 0.504% pyriproxyfen	Evaluation of the active ingredient content of [redacted] Revision 0 throughout the study shows no signs of degradation at room temperature (the % difference for clothianidin stored in both glass and plastic (PP) syringes was -2.4% and -4.8% after 24 months, and for pyriproxyfen it was -0.4% and -4.6%, respectively). No changes in the appearance of the material were observed. Evaluation of the containers showed no signs of corrosion. The room temperature samples were analysed after 3, 6, 12, and 24 months of storage. At each inspection interval the containers were inspected for any signs of corrosion and weight loss. A physical observation of the test substance in the clear glass containers was made. The room temperature was an average of	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			21.4°C. Humidity was not recorded because the test substance was not being stored in permeable containers. The analytical method used was validated under GLP-2953.	

eCA remark

More detailed information on the active substance content was available:

t	Clothianidin	Change	Pyriproxyfen	Change
0	0.496	n/a	0.504	n/a
3m, glass	0.486	-2.02	0.518	2.78
3m, PP	0.483	-2.62	0.509	0.99
6m, glass	0.500	0.81	0.501	-0.60
6m, PP	0.486	-2.02	0.489	-2.98
12m, glass	0.522	5.24	0.520	3.17
12m, PP	0.487	-1.81	0.475	-5.75
24m, glass	0.484	-2.42	0.502	-0.40
24m, PP	0.472	-4.84	0.481	-4.56

The applicant has indicated the influence of humidity was not tested. Considering the product is gelatinous with a significant water content, the influence of humidity is expected to be negligible.

In stability studies, the pH is normally reported, but for this non-flowing product, not diluted during use, pH data is not strictly required. It was therefore not included in the stability studies. See also the eCA remark under the entry acidity/alkalinity.

Pesguard® Gel has a shelf-life of 2 years in PP syringes, the proposed commercial packaging. Palatability data with fresh and aged samples is evaluated in the efficacy section. Both aged samples after accelerated (2 weeks at 54°C) and real-time storage (2 years) were tested.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **low temperature stability test for liquids**	-	-	The label states, "Protect from frost", therefore, no further testing is required.	-
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Guideline No. 830-63 17. 830-6320	[redacted] revision 0 Purity: 0.496% clothianidin; 0.504% pyriproxyfen	The product was found to be stable for 2 years when stored in both glass jars and plastic (PP) 30cc syringes. The packaging is semi-transparent and stored under ambient light, which is not representative for direct sunlight. Therefore, the storage conditions include the condition that the product is to be stored away from direct sunlight.	[redacted]
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Guideline No. 830-63 17. 830-6320	[redacted] revision 0 Purity: 0.496% clothianidin; 0.504% pyriproxyfen	Evaluation of the active ingredient content of [redacted] Revision 0 throughout the study shows no signs of degradation at room temperature. The room temperature was an average of 21.4°C. Humidity was not recorded because the test substance was not being stored in permeable containers.	[redacted]
eCA remark The applicant has indicated the influence of humidity was not tested. Considering the product is gelatinous with a significant water content, the influence of humidity is expected to be negligible.				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
The active substance was proven to be stable at accelerated conditions (2 weeks at 54°C).				
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Guideline No. 830-63 17. 830-6320	[redacted] revision 0 Purity: 0.496% clothianidin; 0.504% pyriproxyfen	Evaluation of the active ingredient content of [redacted] Revision 0 throughout the study shows no signs of degradation at room temperature. No changes in the appearance of the material were observed. Evaluation of the PP containers showed no signs of corrosion.	[redacted]
Wettability	-	-	Not relevant. The product is a gelatinous solid and will not be mixed with water.	-
Suspensibility, spontaneity and dispersion stability	-	-	Not relevant. The product is a gelatinous solid and will not be mixed with water before use. This endpoint only needs to be addressed for products that form suspensions upon use.	-
Wet sieve analysis and dry sieve test	-	-	Not relevant. The product is a gelatinous solid. This data requirement is only valid for wettable powders, suspension concentrates, water dispersible granules, aqueous capsule suspensions, dispersible concentrates, suspo-emulsions, water soluble granules and water-soluble powders.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not relevant. The product is a gelatinous solid. This data	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			requirement is only valid for emulsifiable products.	
Disintegration time	-	-	Not relevant. The product is a gelatinous solid. This data requirement is only relevant to water dispersible solids.	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not relevant. The product is a gelatinous solid. This data requirement is only valid for powders and granules.	-
Persistent foaming	-	-	Not relevant. The product is a gelatinous solid. This data requirement is only valid for products that are applied in water.	-
Flowability/Pourability/Dustability	-	-	Not relevant. The product is a gelatinous solid. Flowability and Dustability are only valid for granular materials. Pourability is only valid for suspension concentrates, capsule suspensions or suspo-emulsions.	-
Burning rate — smoke generators	-	-	Not relevant. The product is a gelatinous solid. The product will not generate smoke.	-
Burning completeness — smoke generators	-	-	Not relevant. The product is a gelatinous solid. The product will not generate smoke.	-
Composition of smoke — smoke generators	-	-	Not relevant. The product is a gelatinous solid. The product will not generate smoke.	-
Spraying pattern — aerosols	-	-	Not relevant. The product is a	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			gelatinous solid. The product is not an aerosol.	
Physical compatibility	-	-	Not relevant. The product is not intended to be used in conjunction with any other biocidal products.	-
Chemical compatibility	-	-	Not relevant. The product is not intended to be used in conjunction with any other biocidal products.	-
Degree of dissolution and dilution stability	-	-	Not applicable. The product is not diluted before use.	-
Surface tension	-	-	Not relevant. The product is a gelatinous solid.	-
Viscosity	-	-	Not relevant. The product is a gelatinous solid.	-

Conclusion on the physical, chemical and technical properties of the product

The physical chemistry data confirm that the product is a gelatinous solid which is tan in colour with a chicken meal, dog food odour. The product has a pH of 4.88 at 5% in water and a specific gravity of 1.062 g/cm^3 at 16.5°C. The bait was shown to be stable following storage at ambient temperature for 2 years in PP. Packaging material is semi-transparent and should therefore be protected from direct sunlight.
The product is not heat sensitive (stable for 2 weeks at 54°C), but low temperature stability was not investigated. Therefore, storage conditions should indicate the product should be protected from frost.

Storage conditions: Protect from frost. The product is to be stored away from direct sunlight. Shelf-life 2 years.

2.2.3 Physical hazards and respective characteristics

For purposes of classification and labelling, the product is assessed as a solid. Although the product contains water, it does not flow, even when heated to 50°C.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	EPA OPPTS 830.6316 (Explodability)	[redacted] revision 0 Purity: 0.504% clothianidin; 0.487% pyriproxyfen	Non-explosive	[redacted]
			In addition, based on a review of the product co-formulants, as none of them are classified as explosive, the product does not require to be classified as an explosive according to Regulation (EC) 1272/2008.	[redacted]
eCA remark The study [redacted] does not contain information on what basis the product is not considered explosive. Test method EPA OPPTS 830.6316 is not described within the test report. Therefore, the study is not acceptable. The product does not contain any potentially explosive compounds: none of the co-formulants or the active substances are classified and based on the information available, the functional groups relating to explosive properties, as defined in appendix 6 of the UN manual of tests and criteria, do not seem to be present in the formulation, with one exception: clothianidin. As this substance was considered not explosive as part of the substance evaluation, it is not expected that clothianidin does not need to be considered further for assessment of the explosive properties of the product. Based on the above, the eCA considers that the product does not need to be classified as an explosive in the sense of Regulation (EC) 1272/2008.				
Flammable gases	-	-	Not applicable to a solid product.	-
Flammable aerosols	-	-	Not applicable to a solid product.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Oxidising gases	-	-	Not applicable to a solid product.	-
Gases under pressure	-	-	Not applicable to a solid product.	-
Flammable liquids	-	-	Not applicable to a solid product.	-
Flammable solids	EPA OPPTS 830.6315 (Flammability)	[redacted] revision 0 Purity: 0.504% clothianidin; 0.487% pyriproxyfen	Non-flammable	[redacted]
eCA remark The study was performed in a comparable way to EC A10 and the UN test method. Therefore, the study is considered acceptable. It allows the conclusion the formulation does not need to be classified as a flammable solid. As it is possible to debate whether a gel may be a liquid instead, the eCA considers that the outcome of the flammability study is as may be expected based on the composition of the product. Although the product contains minor (<<1%) amounts of flammable constituents, the product is not expected to have a flashpoint below its boiling point.				
Self-reactive substances and mixtures	-	-	None of the components of the product are classified as self-reacting substances. Experience in the use of the product does not indicate that the product will self-react.	-
Pyrophoric liquids	-	-	Not applicable to a gelatinous solid product.	-
Pyrophoric solids	-	-	None of the components of the product are classified as pyrophoric. Experience in the use of the product does not indicate that the product will be pyrophoric.	-
Self-heating substances and mixtures	-	-	For purposes of classification and labelling, the product is considered to be a solid as it is a gelatinous	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			solid which does not flow, even when heated to 50°C. Classification as a self-heating substance should be considered. The gelatinous mass does not have a large surface and is therefore not expected to be liable to self-heating. Considering its unique physical state, low surface area and composition, the product does not need to be classified as self-heating.	
Substances and mixtures which in contact with water emit flammable gases	-	-	None of the components of the product are known to emit flammable gases when in contact with water. Experience in the use of the product does not indicate that the product will emit flammable gas when in contact with water. The product itself also contains water.	-
Oxidising liquids	-	-	Not applicable to a gelatinous solid product.	-
Oxidising solids	EPA OPPTS 830.6314 (Oxidising or Reducing Action)	[redacted] revision 0 Purity: 0.504% clothianidin; 0.487% pyriproxyfen	No oxidising properties	[redacted]
			In addition, based on a review of the product co-formulants, as none of them are classified as potentially oxidising compounds,	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the product does not required to be classified as oxidising according to Regulation (EC) 1272/2008.	
eCA remark The study does not contain information on what basis the product is not considered oxidising. Test method EPA OPPTS 830.6314 is not described within the test report. Therefore, the study is not acceptable. However, the product does not contain any potentially oxidising compounds: none of the co-formulants or the active substances are classified and based on the information available, the functional groups relating to oxidising properties, as defined in appendix 6 of the UN manual of tests and criteria, do not seem to be present in the formulation. The eCA considers that the product does not need to be classified as oxidising in the sense of Regulation (EC) 1272/2008.				
Organic peroxides	-	-	Following a review of the components of the product it can be concluded that the product does not contain any organic peroxides.	-
Corrosive to metals	-	-	The product is considered a solid for the purposes of classification and labelling, for which no appropriate test method is available. The product is a gelatinous gel which does not flow, even when heated to approximately 50°C. It is therefore not possible to test the product using the existing UN test method as this method is intended for liquids. The eCA therefore accepts that a study is not required.	-
Auto-ignition temperatures of products (liquids and gases)	-	-	Not applicable to a solid product.	-
Relative self-ignition	-	-	The recommended test method for	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
temperature for solids			determining relative self-ignition temperature according to Guidance on the BPR: Volume I Parts A+B+C, Version 2.0 May 2018, is UN Test N.4, as described in Section 33.3.1.6 of the UN-MTC. Section 33.3.1.6.3 makes clear that this procedure is applicable only to powders and granules. Therefore, no suitable method is available for determining the relative self-ignition temperature of a gelatinous solid and the study can be waived on the grounds that it is not technically feasible.	
eCA remark The justification is acceptable to the eCA, although it is noted that no full information is available on the individual constituents. Also considering the composition of the product, the major components are not expected to have an auto-ignition temperature of potential concern. The main constituent is water and as the product is a bait, it contains a significant amount of foodstuffs, which do not self-ignite.				
Dust explosion hazard	-	-	Not applicable to a gelatinous solid product.	-

Conclusion on the physical hazards and respective characteristics of the product
Following a review of the components of the product it can be concluded that the product is not explosive, flammable or oxidising. The product does not require classification under Regulation (EC) No 1272/2008 for physical hazards.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Clothianidin	HPLC-UV	0.5% 5 replicates	0.0050-1.00 mg/ml; r^2 = 0.9998938; 8 points	No interference	98.2 – 100.2[A]	99.0%	0.78, [A]	N/A	[redacted]
Pyriproxyfen	HPLC-UV	0.5% 5 replicates	0.0050-1.25 mg/ml; r^2 = 0.9999835; 8 points	No interference	96.5 – 98.1[A]	97.5%, [A]	0.69, [A]	N/A	[redacted]
Methods for substances of concern The substances of concern present in the formulation cannot be formed during storage. Therefore, no analytical methods are required.									

[A] Calculated by the eCA

eCA remark

The analytical method provided is based on reversed phase HPLC-UV with internal standardisation (dibutyl phthalate), equipped with a C-18 column and detection at 290nm. The mobile phases are acetonitrile and water, used in a gradient. Sample preparation involves dissolving in acetone, centrifugation, sonication and filtration prior to analysis.

As the accuracy was determined based on 5 replicates, it is possible to calculate a %RSD from the recovery experiments, which is then used to evaluate system precision. The %RSD (~0.8%) determined this way meets the Horwitz criterion (maximum %RSD at 1% target analyte is 2.68% according to SANCO/3030/99 revision 4). It is noted by the eCA that the range nor individual recoveries were reported. Therefore, the eCA has recalculated the individual recoveries and %RSD from the raw data included in the report.

Specificity was addressed using the appropriate chromatograms. Linearity graphs were forced through zero, which is formally not allowed. However, judging the plots, the effect is expected to be minor and therefore accepted as a minor deficiency by the eCA (slope for clothianidin: y = 7871610x; slope pyriproxyfen: y = 3342658x).

The method is considered adequately validated to determine the active substance content in the formulation *Pesguard®* Gel.

Conclusion on the methods for detection and identification of the product

A method of analysis employing HPLC-UV is provided for the determination of the active substances, clothianidin and pyriproxyfen, in the product. The method is fully validated in accordance with SANCO/3030/99 rev. 4 11/07/00.

Methods of analysis for the determination of clothianidin in soil, water, air and food/feed of plant origin have previously been evaluated at EU level and accepted for inclusion to Annex I of Directive 98/8/EC. Methods for monitoring residues in body fluids and tissues, and food/feed of animal origin are not necessary, as the intended uses will not result in significant residues when the label instructions are followed (store away from food, beverages and pet food).

Methods of analysis for the determination of pyriproxyfen residues in soil, water and air have previously been evaluated at EU level and accepted for inclusion to Annex I of Directive 98/8/EC. Methods for monitoring residues in body fluids and tissues, and food/feed of plant and animal origin are not necessary, as the intended uses will not result in significant residues when the label instructions are followed (store away from food, beverages and pet food).

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The product *Pesguard®* Gel is an insecticide (PT18) containing 0.5% clothianidin (neonicotinoid) and 0.5% pyriproxyfen (insect growth regulator) for use by professionals against cockroaches.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

Organisms to be controlled: For the control of German cockroaches (*Blattella germanica*), Brown banded cockroaches (*Supella longipalpa*), Oriental cockroaches (*Blatta orientalis*) and American Cockroaches (*Periplaneta americana*) both as nymphs and adults.

Products/Organisms to be protected: General hygiene.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Ingestion of *Pesguard®* Gel results in knockdown and mortality.

2.2.5.4 Mode of action, including time delay

Clothianidin belongs to the chemical class of insecticides known as neonicotinoids or chloronicotinyls, which interfere with the nicotinic acetylcholine receptors at the post-synaptic membrane. The compound acts agonistically on insect nicotinic acetylcholine receptors located in the central nervous system. Clothianidin has an insecticidal effect by contact and ingestion (systemic insecticide).

Pyriproxyfen is an insect growth regulator and acts as a juvenile hormone analogue (or mimic), interrupting the insect morphogenesis. It prevents (depending upon the time of application) egg hatching, metamorphosis of larvae into pupae, and pupae into adults.

The time delay for efficacy to begin depends on the developmental stage of the cockroaches at the time of application. Initial activity normally takes approximately 24 hours, as clothianidin is a slow acting contact and ingestion active substance, and the visual effects of pyriproxyfen only become apparent when a growth-stage change occurs in a treated insect (or failure to change, leading to death).

2.2.5.5 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
PT18 Pesguard® Professional Cockroach Gel Bait	[redacted] (identical to *Pesguard®* Professional Cockroach Gel Bait) containing 0.5% w/w clothianidin + 0.5% w/w pyriproxyfen	**American Cockroach** (*Periplaneta americana*), **Brown-Banded cockroach** (*Supella longipalpa*). Laboratory cultured adult males	Laboratory choice trial - Cockroach gel baits tested in the study: 1) [redacted] cockroach gel bait (0.50% clothianidin + 0.50% pyriproxyfen) 2) control: only rat chow - Test method: arena choice-test bioassay (alternative food: rat chow) - 20 cockroaches per replicate. - 5 replicates per treatment per species Arena surface: (58.4 x 40.6 x 22.9 cm =2374.2 cm^2 = 0.23 m^2 floor area) Dosage: 0.3 ± 0.03 g This application amount was selected (high label rate) to ensure that a sufficient amount of bait was available at the start of the study to meet the consumption needs of all the cockroaches. Preliminary work indicated that provisioning a lower amount of bait would result in insufficient food acquisition by the cockroaches, leading to uncontrolled experimental variation due to food availability, competition and cannibalism. Environmental conditions P. americana: 21-24 °C, 64-78% RH Environmental conditions S.longipalpa: 22-25 °C, 51-60% RH	**Table 1:** Efficacy of cockroach baits against American cockroaches (*Periplaneta americana*) exposed to three different bait treatments (average± standard error, n = 5). Values in bold indicate where mortality exceeded 90%. [redacted] (0.5% clothianidin + 0.5% pyriproxyfen) **Day 1:** Alive 40.0±8.2; Knockdown 9.0±2.9; Moribund 44.0±5.1; Dead 7.0 ± 5.8 **Day 2:** Alive 20.0±5.5; Knockdown 11.0±2.9; Moribund 41.0±5.6; Dead 28.0 ± 5.6 **Day 3:** Alive 14.0±4.3; Knockdown 6.0±2.9; Moribund 23.0±4.4; Dead 57.0 ± 5.1 **Day 4:** Alive 8.0±3.4; Knockdown 9.0±2.4; Moribund 11.0±2.4; Dead 72.0 ± 3.4 **Day 5:** Alive 5.0±1.6; Knockdown 5.0±2.2; Moribund 10.0±2.2; Dead 80.0 ± 5.2 **Day 6:** Alive 4.0±2.9; Knockdown 4.0±1.9; Moribund 9.0±2.9; Dead 83.0 ± 6.4 **Day 7:** Alive 3.0±2.0; Knockdown 3.0±2.0; Moribund 6.0±1.9; Dead 88.0 ± 5.6 **Day 8:** Alive 1.0±1.0; Knockdown 4.0±4.0; Moribund 4.0±1.9; Dead **91.0 ± 4.8** Untreated **Day 1:** Alive 100.0±0.0; Knockdown 0.0±0.0; Moribund 0.0±0.0; Dead 0.0±0.0 **Day 2:** Alive 100.0±0.0; Knockdown 0.0±0.0; Moribund 0.0±0.0; Dead 0.0±0.0 **Day 3:** Alive 99.0±1.0; Knockdown 0.0±0.0; Moribund 0.0±0.0; Dead 1.0±1.0 **Day 4:** Alive 97.0±2.0; Knockdown 2.0±2.0; Moribund 0.0±0.0; Dead 1.0±1.0 **Day 5:** Alive 96.0±2.0; Knockdown 1.0±1.0; Moribund 0.0±0.0; Dead 3.0±1.2 **Day 6:** Alive 93.0±1.2; Knockdown 3.0±1.2; Moribund 1.0±1.0; Dead 3.0±1.2 **Day 7:** Alive 94.0±1.0; Knockdown 2.0±1.2; Moribund 0.0±0.0; Dead 4.0±1.0 **Day 8:** Alive 95.0±1.6; Knockdown 0.0±0.0; Moribund 1.0±1.0; Dead 4.0±1.0 **Day 9:** Alive 95.0±1.6; Knockdown 0.0±0.0; Moribund 0.0±0.0; Dead 5.0±1.6 **Day 10:** Alive 95.0±1.6; Knockdown 0.0±0.0; Moribund 0.0±0.0; Dead 5.0±1.6 **Day 11:** Alive 95.0±1.6; Knockdown 0.0±0.0; Moribund 0.0±0.0; Dead 5.0±1.6 **Day 12:** Alive 95.0±1.6; Knockdown 0.0±0.0; Moribund 0.0±0.0; Dead 5.0±1.6 Efficacy of [redacted] was demonstrated with 91% mortality within eight days in American cockroaches. **Table 2**: Efficacy of cockroach baits against brown banded cockroaches (*Supella longipalpa*) exposed to three different bait treatments (average± standard error, n = 5). Values in bold indicate where mortality exceeded 90%. [redacted] (0.5% clothianidin + 0.5% pyriproxyfen) **Day 1:** Alive 7.0±2.5; Knocked-down 1.0±1.0; Moribund 0.0±0.0; Dead **92.0±3.0** **Day 2:** Alive 3.0±2.0; Knocked-down 0.0±0.0; Moribund 1.0±1.0; Dead **96.0±2.9**	[redacted]

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

3	3.0±2.0	0.0±0.0	1.0±1.0	**96.0±2.9**
4	2.0±1.2	0.0±0.0	0.0±0.0	**98.0±1.2**
5	0.0±0.0	0.0±0.0	0.0±0.0	***100.0±0.0***
6	0.0±0.0	0.0±0.0	0.0±0.0	***100.0±0.0***
7	0.0±0.0	0.0±0.0	0.0±0.0	***100.0±0.0***

Figures in italics have been added, as they were omitted from the original report.

Day	Untreated (only rat chow)			
	Alive	Knocked-down	Moribund	Dead
1	99.0±1.0	0.0±0.0	0.0±0.0	1.0±1.0
2	97.0±2.0	1.0±1.0	0.0±0.0	2.0±2.0
3	94.0±1.9	0.0±0.0	0.0±0.0	6.0±1.9
4	92.0±2.0	0.0±0.0	0.0±0.0	8.0±2.0
5	92.0±2.0	0.0±0.0	0.0±0.0	8.0±2.0
6	91.0±1.9	0.0±0.0	0.0±0.0	9.0±1.9
7	91.0±1.9	0.0±0.0	0.0±0.0	9.0±1.9

Efficacy of [redacted] was demonstrated with 92% mortality within one day in Brown banded cockroaches.

PT18
OU812 gel bait matrix incorporating 0.5% pyriproxyfen

0.5% w/w pyriproxyfen (identical to the pyriproxyfen content in *Pesguard®* Professional Cockroach Gel Bait)

German cockroach (*Blattella germanica*)

Laboratory trial/ screening study

Test design:
a) 25 cockroaches, 4-week old immature male and 25 4-week old immature female cockroaches representing the approximate upper limit of the reproductive output of a single ootheca, were used per replicate

b) 5 replicates per treatment

c) 7 treatments
1. OU812 Matrix containing 0.50% w/w pyriproxyfen
Aim: to assess the morphological abnormalities induced by dietary exposure to pyriproxyfen in cockroach bait.

2. Dog chow
Aim: to measure the background frequency of morphological abnormalities under a standard balanced feeding regimes used successfully in MGK's cockroach rearing program.

3. OU812 Matrix (placebo)
Aim: to assess developmental impact and abnormalities associated with continuous dietary exposure to the placebo matrix of the

Table 1. Morphological and developmental stage distribution of cockroaches alive at the 98-day termination of the study.

Treatment	Percentage (SEM) of individuals per category					
	Normal Nymphs (live)	Normal adult ♂ (live)	Normal adult ♀ (live)	Abnormal Nymphs (live)	Abnormal adult ♂ (live)	Abnormal adult ♀ (live)
Treatment 1: 0.50% pyriproxyfen	0.0 b (0.0)	0.4 d (0.4)	0.0 e (0.0)	72.0 a (4.6)	0.0 c (0.0)	1.6 c (0.8)
Treatment 2: Dog chow	1.6 b (1.2)	35.6 a (1.7)	37.6 a (2.9)	0.0 c (0.0)	5.2 bc (2.4)	1.6 c (1.2)
Treatment 3: Placebo	48.4 a (4.3)	14.0 bc (3.2)	12.0 cd (3.3)	0.0 c (0.0)	4.0 bc (1.1)	3.2 c (1.2)
Treatment 4: 0.10% PYR frass in placebo	31.6 a (8.6)	13.2 c (3.8)	17.2 bc (3.4)	0.0 c (0.0)	5.2 bc (1.4)	6.0 bc (2.4)
Treatment 5: 1.0% PYR frass in placebo	36.4 a (9.3)	6.8 cd (1.5)	2.8 de (0.5)	0.0 c (0.0)	16.0 a (1.8)	18.8 a (4.5)
Treatment 6: 10.0% PYR frass in placebo	0.0 b (0.0)	0.0 d (0.0)	0.0 e (0.0)	33.6 b (10.1)	11.2 ab (3.1)	14.0 ab (3.7)
Treatment 7: 10.0% PL	30.8 a (7.0)	24.0 b (4.4)	22.8 b (2.5)	0.0 c (0.0)	3.6 bc (1.3)	2.0 c (1.6)

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
			cockroach bait. 4. OU812 Matrix incorporating cockroach faeces/frass (0.10% w/w) collected from adult male cockroaches fed only with OU812 Matrix with 0.50% w/w pyriproxyfen separately. Aim: to assess the morphological and developmental impact associated with low level coprophagy of frass pellets deposited by cockroaches consuming 0.50% w/w pyriproxyfen containing bait product. 5. OU812 Matrix incorporating cockroach faeces/frass (1.0% w/w) collected from adult male cockroaches fed only with OU812 Matrix with 0.50% w/w pyriproxyfen separately. Aim: to assess the morphological and developmental impact associated with an intermediate level of coprophagy of frass pellets deposited by cockroaches consuming 0.50% w/w pyriproxyfen containing bait product. 6. OU812 Matrix incorporating cockroach faeces/frass (10.0% w/w) collected from adult male cockroaches fed only with OU812 Matrix with 0.50% w/w pyriproxyfen separately. Aim: to assess the morphological and developmental impact associated with a high level of coprophagy of frass pellets deposited by cockroaches consuming 0.50% w/w pyriproxyfen containing bait product. 7. OU812 Matrix incorporating cockroach faeces (10.0% w/w) collected from adult male cockroaches fed only with OU812 Placebo Matrix separately. Aim: to assess the morphological and developmental impact associated with a high level of coprophagy of frass pellets deposited by cockroaches consuming the no treatment (placebo) bait product. cockroaches consuming the bait product. d) 1 cockroach species	frass in placebo Different letters within a column indicate significant differences (Tukey's HSD; $P < 0.05$). (SEM) = (Standard error of the mean) The consumption of frass containing pyriproxyfen has a significant morphological and developmental impact both on nymphs and adult cockroaches alive. **Table 2.** Morphological and developmental stage distribution of cockroaches that died during the 98-day duration of the study.	[redacted]

Treatment	Percentage (SEM) individuals per category					
	Normal Nymphs (dead)	Normal adult ♂ (dead)	Normal adult ♀ (dead)	Abnormal Nymphs (dead)	Abnormal adult ♂ (dead)	Abnormal adult ♀ (dead)
Treatment 1: 0.50% pyriproxyfen	8.8 a (7.3)	0.0 a (0.0)	0.8 a (0.8)	6.8 a (3.4)	1.2 ab (0.8)	8.4 ab (3.0)
Treatment 2: Dog chow	9.2 a (3.6)	2.0 a (1.6)	4.4 a (2.1)	0.4 a (0.4)	1.2 ab (0.8)	1.2 b (1.2)
Treatment 3: Placebo	6.4 a (2.7)	2.4 a (0.4)	5.6 a (2.0)	1.6 a (0.8)	0.4 b (0.4)	2.0 b (1.1)
Treatment 4: 0.10% PYR frass in placebo	5.6 a (1.6)	5.6 a (4.2)	2.0 a (1.1)	6.4 a (2.5)	3.2 ab (1.5)	4.8 b (1.0)
Treatment 5: 1.0% PYR frass in placebo	8.4 a (6.9)	0.4 a (0.4)	0.4 a (0.4)	4.4 a (1.5)	2.4 ab (1.0)	3.2 b (1.6)
Treatment 6: 10.0% PYR frass in placebo	7.2 a (5.3)	0.0 a (0.0)	0.4 a (0.4)	14.0 a (7.3)	5.6 a (2.4)	14.0 a (3.9)

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

e)Arena surface: (33cmx19cmx10.8cm = 6.771,6 cm^2 = 0.68 m^2 floor area)

f) Dosage: 0.75g per arena

Treatment						
Treatment 7: 10.0% PL frass in placebo	5.2 a (1.2)	3.6 a (2.6)	2.0 a (1.1)	1.6 a (0.8)	0.4 b (0.4)	4.0 b (1.7)

Different letters within a column indicate significant differences (Tukey's HSD; $P < 0.05$).
(SEM) = (Standard error of the mean)

The consumption of frass containing pyriproxyfen has a significant morphological and developmental impact both on dead nymphs and adult cockroaches.

Table 3. Emergence of adult cockroaches (combined category of live, dead, male, female, normal and abnormal phenotypes).

Treatment	% Total Adult Eclosion
Treatment 1: 0.50% pyriproxyfen (PYR)	12.4 c
Treatment 2: Dog chow	88.8 a
Treatment 3: Placebo (PL)	43.6 b
Treatment 4: 0.10% PYR frass in placebo	57.2 b
Treatment 5: 1.0% PYR frass in placebo	50.8 b
Treatment 6: 10.0% PYR frass in placebo	45.2 b
Treatment 7: 10.0% PL frass in placebo	62.4 b

Different letters within a column indicate significant differences (Tukey's HSD; $P < 0.05$).

Table 4. Frequency of abnormal phenotype in adult cockroaches (combined category of live, dead male, female abnormal phenotype).

Treatment	% Abnormal Adult Phenotype
Treatment 1: 0.50% pyriproxyfen	11.2 c
Treatment 2: Dog chow	9.2 c
Treatment 3: Placebo	9.6 c
Treatment 4: 0.10% PYR frass in placebo	19.2 c
Treatment 5: 1.0% PYR frass in placebo	40.4 ab
Treatment 6: 10.0% PYR frass in placebo	44.8 a
Treatment 7: 10.0% PL frass in placebo	10.0 c

Different letters within a column indicate significant differences (Tukey's HSD; $P < 0.05$).

Table 5. Frequency of abnormal phenotype in immature cockroaches (combined category of live, dead abnormal phenotype).

Treatment	% Abnormal Immature Phenotype
Treatment 1: 0.50% pyriproxyfen	78.8 a
Treatment 2: Dog chow	0.4 c
Treatment 3: Placebo	1.6 c
Treatment 4: 0.10% PYR frass in placebo	6.4 c
Treatment 5: 1.0% PYR frass in placebo	4.4 c

[redacted]

Experimental data on the efficacy of the biocidal product against target organism(s)

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method, Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><td>Treatment 6: 10.0% PYR frass in placebo</td><td>47.6 b</td></tr>
<tr><td>Treatment 7: 10.0% PL frass in placebo</td><td>1.6 c</td></tr>
</table>
Different letters within a column indicate significant differences (Tukey's HSD; $P < 0.05$).

Table 6. Normalized frequency of abnormal phenotype development in German cockroaches exposed to various dietary regimes.
<table>
<tr><th>Treatment</th><th>% Abnormal Phenotype</th></tr>
<tr><td>Treatment 1: 0.50% pyriproxyfen</td><td>98.7 a</td></tr>
<tr><td>Treatment 2: Dog chow</td><td>10.6 c</td></tr>
<tr><td>Treatment 3: Placebo</td><td>12.0 c</td></tr>
<tr><td>Treatment 4: 0.10% PYR frass in placebo</td><td>27.1 bc</td></tr>
<tr><td>Treatment 5: 1.0% PYR frass in placebo</td><td>48.9 b</td></tr>
<tr><td>Treatment 6: 10.0% PYR frass in placebo</td><td>99.6 a</td></tr>
<tr><td>Treatment 7: 10.0% PL frass in placebo</td><td>12.2 c</td></tr>
</table>
Different letters within a column indicate significant differences (Tukey's HSD; $P < 0.05$).

[redacted] satisfied the requirements of the TNsG, demonstrating that in the 98 day study, pyriproxyfen ingestion lead to only 0.4% cockroaches developing into normal adult males (and 0.0% into normal adult females), whilst all the other cockroaches either died or developed abnormally (not developing to the next instar or becoming sterile).
</td><td></td></tr>
<tr><td>PT18
Pesguard® Professional Cockroach Gel Bait</td><td>[redacted] (identical to Pesguard® Professional Cockroach Gel Bait) containing 0.5% w/w clothianidin + 0.5% w/w pyriproxyfen</td><td>German cockroach (Blattella germanica)</td><td>Laboratory choice trial
a) Cockroach gel baits tested in the study:
- [redacted] cockroach gel bait (0.50% clothianidin + 0.50% pyriproxyfen)

Dog chow was the alternative food
b) Test method: arena choice-test bioassay (alternative food: dog chow)
c) Experimental design: completely randomized block design
d) Replications: 6 (50 adult male cockroaches per arena or 300 cockroaches per treatment), which mimics a high infestation of 74 cockroaches in 0.09m^2)

Arena surface: 33 cm x 19 cm x 10.8 cm clear plastic shoe boxes =627 cm^2 = 0.63 m^2 floor arena

Dosage rate: The applied bait amount (0.04 g of bait per spot) corresponds to a label rate of 12 bait placements of 0.48 g bait per placement which is the recommended low</td><td>
Table 1. Efficacy of cockroach baits deployed in a choice test environment (average % mortality ± SEM). Values in bold indicate mortality ≥ 90%.
<table>
<tr><th></th><th colspan="2">Average % Mortality ± SEM</th></tr>
<tr><th>Day</th><th>[redacted] + Dog chow</th><th>Dog chow + Dog chow</th></tr>
<tr><td>1</td><td>9.0 ± 2.57</td><td>0.0 ± 0.0</td></tr>
<tr><td>2</td><td>50.3 ± 3.52</td><td>0.3 ± 0.33</td></tr>
<tr><td>3</td><td>79.3 ± 4.02</td><td>0.3 ± 0.33</td></tr>
<tr><td>4</td><td>95.0 ± 1.69</td><td>0.3 ± 0.33</td></tr>
<tr><td>5</td><td>98.7 ± 0.67</td><td>0.3 ± 0.33</td></tr>
<tr><td>6</td><td>99.0 ± 0.68</td><td>0.3 ± 0.33</td></tr>
</table>
SEM = Standard error of the mean

German cockroaches fed rapidly on cockroach bait in the study. Cockroaches exhibited a significant preference towards cockroach bait over dog chow. There was no positional effect associated with randomized bait placements shown by the similar consumption observed in the control (dog chow only) treatment.
Mortality: During the course of the study, the untreated control mortality remained low (0.30% at the termination of the study on day 14). The experimental cockroach bait [redacted] provided a very fast overall efficacy against German cockroaches. Mortality reached 95% on day 4 for cockroaches exposed to [redacted]
</td><td>[redacted]</td></tr>
</table>

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
			application rate for heavy infestations. This bait application amount was selected to provide sufficient amount of bait for at least a single initial feeding bout on the bait for all cockroaches present in the arena. Provisioning a lower amount of bait would result in insufficient food acquisition by the cockroaches, leading to uncontrolled experimental variation due to food availability, competition and cannibalism. Environmental conditions: 25 °C, 60% RH nd 11:13 (L:D) regime.		
PT18 Clothianidin/Nylar	Cockroach bait – [redacted] (containing 0.5% w/w clothianidin and 0.5% w/w pyriproxyfen) identical to *Pesguard®* Professional Cockroach Gel Bait.	**German cockroach** (*Blattella germanica*) Laboratory strain (Sumitomo), originally sourced in 1997 from the Vector Control Research Unit of University of Science Malaysia (USM).	Laboratory choice trial Test design: - 100 male (1-2w old) cockroaches per replicate. - 5 replicates per treatment per species - 2 treatments: a) [redacted] (fresh sample) b) [redacted] (aged sample) - Arena surface: (35 x 26 x 10 cm = 9100 cm^2 = 0.91 m^2 floor area) - Dosage: 1g of bait - Alternative food: 1 g of mouse pellet •Mortality in the treatment replicates was corrected for the natural mortality using Control A, as follows: Corrected Mortality (%) = [(M – Mc) / (100 – Mc)] × 100 M was percentage mortality for treatment replicates, while Mc was percentage mortality observed in Control A replicate •Amount of food (or bait) consumed by cockroaches in treatment replicates were adjusted for moisture loss using following formula: Amount consumed =(Total weight loss in treatment × final weight in Control B) / Initial weight in Control B Environmental conditions: 24-28 °C, 40-80% RH.	**Table 1**: Consumption of cockroach bait and mouse pellet (=control) [redacted] Clothianidin/Nylar 0.5% w/w/0.5% w/w — Fresh sample: Bait 0.307g (100%); Mouse pellet 0.000g (0%); **Total food consumed 0.307g** [redacted] Clothianidin/Nylar 0.5% w/w/0.5% w/w — Aged sample: Bait 0.329g (99%); Mouse pellet 0.002g (1%); **Total food consumed 0.331g** Control A Mouse Pellets (Challenge Diet) — N/A: Bait N/A; Mouse pellet 1.184g (100%); **Total food consumed 1.184g** Aged samples were those previously stored at 54°C for 2 weeks prior to the experiment. Fresh samples were kept under ambient room conditions until the experiment. Amount consumed (average of 5 replicates) was the amount of bait (food) consumed (in grams) after 7 days of exposure. Amount consumed is adjusted for moisture loss. When the mouse pellet (the feed used to breed German cockroaches in EHTC) was placed in the same tray alongside with the [redacted] as the challenge diet, German cockroaches preferred to feed on the [redacted] (100% and 99% of total consumption), indicating the high palatability of the [redacted], both for fresh and aged samples **Table 2**: Moisture Loss of the Bait and Food (Control B) [redacted] Fresh sample: Before 1.002g; After 0.593g; Weight Loss** 0.409g (41%) [redacted] Aged sample: Before 1.072g; After 0.638g; Weight Loss** 0.435g (41%) Mouse Pellets (Challenge Diet) N/A: Before 1.143g; After 1.158g; Weight Loss** 0.015g (-1%) *Mean of 5 replicates	[redacted]

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
				Positive values indicate loss of water from the bait or food (mouse pallet).Negative values indicate either no water loss, or the bait or food (mouse pallet) had gained weight by absorbing moisture from the air **Table 3: Accumulative mortality Sample / Sample condition / Mortality (%) at various days after treatment*: 0.25 / 1 / 2 / 3 / 4 / 5 / 6 / 7 [redacted] Fresh sample: 77 / 96 / 99 / 100 / 100 / 100 / 100 / 100 [redacted] Aged sample: 78 / 97 / 100 / 100 / 100 / 100 / 100 / 100 Control A Mouse Pellets (Challenge Diet) N/A: 0 / 0 / 0 / 0 / 0 / 0 / 0 / 0 *Values were accumulative kills (mortality), which include dead and moribund cockroaches Efficacy of both fresh and artificially aged bait was demonstrated at >95% mortality after 1 day at an application rate of 1 g per arena of 0.09 m^2.	
PT18 Pesguard® Professional Cockroach Gel Bait	*Pesguard® Gel* (containing 0.5% w/w clothianidin and 0.5% w/w pyriproxyfen) identical to Pesguard® Professional Cockroach Gel Bait.	**German cockroach** (*Blattella germanica*) and **Oriental cockroach** (*Blatta orientalis*)	Field trial in a multi-family public accommodation (German cockroach) or restaurants/bakeries etc. (oriental cockroach). In Bayonne (64 area- France). Test design: - The sticky traps were placed overnight at each test site -A site was viable if it had a minimum pre-count of 16-20 German cockroaches and/or 10 oriental cockroaches. - Two pre-counts were made at Day - 14 and Day - 7: the mean of these values gave the pre-treatment infestation level. - 5 untreated sites - 15 treatment sites divided into three groups of five: Low (maintenance) dose Medium (light infestation) dose and High (heavy infestation) dose - 1 treatment: [redacted] - 2 cockroach species -Dosage: The number of 4 mm diameters spots (approximatively 0.032 g of bait) applied per m^2 in relation to the infestation level: Low: 1 – 2 spots Medium: 3 - 6 spots High: 6 -10 spots	**Table 1**: *B. germanica*, cockroach populations numbers after treatment -10.5 days / +1 day / +7 days / +14 days / +30 days / +60 days / +70 days Test product - Low dose: 52.4 / 54.0 / 9.4 / 6.6 / 2.2 / 4.6 / 2.2 Test product - Medium dose: 64.0 / 61.6 / 9.6 / 6.4 / 2.0 / 7.4 / 3.6 Test product - High dose: 103.6 / 105.2 / 14.2 / 7.8 / 17.2 / 18.2 / 11.6 Untreated: 46.6 / 50.6 / 48 / 50.8 / 50.8 / 48.2 / 48.8 **Table 2**: Percentages of reduction of *Blattella germanica*' populations after treatment +1 day / +7 days / +14 days / +30 days / +60 days / +70 days Test product - Low dose: -4,3 / 82,7 / 88,2 / 96,2 / 91,9 / 96,1 Test product - Medium dose: 3,9 / 84,8 / 90,3 / 97,3 / 89,3 / 95 Test product - High dose: 1,2 / 85,7 / 92,3 / 86 / 85,4 / 90,9 Untreated: -11,8 / -1,9 / -8,8 / -10,3 / -6,7 / -9,8 For low dose treatment >90% population reduction was found after 30 days. For Medium and high dose treatment >90% population reduction was found after 14 days. **Table 3**: *B. orientalis*, cockroach populations numbers after treatment -10.5 days / +1 day / +7 days / +14 days / +30 days / +60 days / +70 days Test product - Low dose: 12.2 / 12.0 / 2.4 / 1.2 / 0.2 / 1.4 / 0.6	[redacted]

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
			-Application: Bait was applied under the fridge, under the kitchen sink, under the oven and the water-heater and on all cracks and crevices that can be a harbourage for cockroaches. - The number of trapped cockroaches were counted, (instar, adult males and females). -Assessments were carried out 1, 7, 14, 30, 60 and 70 days after treatment. The trial was conducted from August to November 2015	Test product - Medium dose 22.8 22.6 4.4 0.6 0.8 1.2 1.0 Test product - High dose 27.4 25.8 2.4 1.2 1.0 1.0 0.4 Untreated 11.2 11.2 10.8 11.8 11 11.4 10.8 **Table 4:** Percentages of reduction of *Blatta orientalis'* populations after treatment | | **+1 day** | **+7 days** | **+14 days** | **+30 days** | **+60 days** | **+70 days** | | Test product - Low dose | -1,9 | 83,1 | 91,9 | 98,8 | 90,4 | 96 | | Test product - Medium dose | -1,3 | 81,2 | 97,6 | 96,7 | 94,7 | 95,9 | | Test product - High dose | 6,2 | 91,8 | 95,9 | 96,7 | 96,2 | 98,6 | | Untreated | 2 | 5,3 | -8,9 | 1,3 | -3,7 | 3,1 | For high dose treatment >90% population reduction was found after 7 days. For low and Medium dose treatment >90% population reduction was found after 14 days.	
PT18 Pesguard® Professional Cockroach Gel Bait	Cockroach bait – [redacted] (containing 0.5% w/w clothianidin and 0.5% w/w pyriproxyfen) identical to *Pesguard®* Professional Cockroach Gel Bait. Fresh + artificially aged bait	**American cockroach** (*Periplaneta americana*)	... Laboratory choice trial Test design: - 20 adult male cockroaches per replicate. - 5 replicates per treatment per species - 2 treatments: a) [redacted] (fresh sample) b) [redacted] (aged sample) -Arena surface: (35 x 26 x 10 cm = 9100 cm^2 = 0.91 m^2 floor area) Dosage: 1g of bait Alternative food: 2g of mouse pellet Mortality in the treatment replicates was corrected for the natural mortality using Control A, as follows: Corrected Mortality (%) = [(M – Mc) / (100 – Mc)] × 100 M was percentage mortality for treatment replicates, while Mc was percentage mortality	**Table 1:** Consumption of cockroach bait and mouse pellet | **Sample** | **Sample Condition[1]** | **Bait &mouse pellets** | **Amount consumed[2]** | | [redacted] | Fresh sample | Bait | 0.592 g (100%) | | | | Mouse pellets | 0.000 g (0%) | | | | Total food consumed | **0.592 g** | | | Aged sample | Bait | 0.613 g (100%) | | | | Mouse pellets | 0.000 g (0%) | | | | Total food consumed | **0.613 g** | | Control A Mouse pellets (Normal Roach diet) | N/A | Bait | N/A | | | | Mouse pellets | 2.390 g (100%) | | | | Total food consumed | **2.390 g** | [1]Aged samples were those previously stored at 54°C for 2 weeks prior to the experiment. Fresh samples were kept under ambient room conditions until the experiment [2]Amount consumed (average of 5 replicates) was the amount of bait (food) consumed (in grams) after 14 days of exposure. Amount consumed is adjusted for loss of moisture. When the mouse pellets (the feed used to breed American cockroaches in EHTC) were placed in the same tray alongside the [redacted], American cockroaches preferred to feed on the [redacted] (100% of total consumption), indicating the high palatability of	[redacted]

Experimental data on the efficacy of the biocidal product against target organism(s)

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method, Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>observed in Control A replicate
•Amount of food (or bait) consumed by cockroaches in treatment replicates were adjusted for moisture loss using following formula:
Amount consumed =(Total weight loss in treatment × final weight in Control B) / Initial weight in Control B

Environmental conditions: 24-28 °C, 40-80% RH.</td><td>the [redacted], both for fresh and ages samples.

Table 2: Moisture Loss of the Bait and Food (Control B)
<table>
<tr><th rowspan="2">Sample</th><th rowspan="2">Sample Condition</th><th colspan="3">Weight of Bait /Food[1]</th></tr>
<tr><th>Before</th><th>After</th><th>Weight Loss[2]</th></tr>
<tr><td rowspan="2">[redacted]</td><td>Fresh sample</td><td>2.036 g</td><td>1.284g</td><td>0.752 g</td></tr>
<tr><td>Aged sample</td><td>2.035 g</td><td>1.299 g</td><td>0.736 g</td></tr>
<tr><td>Control A Mouse pellets (Normal Roach diet)</td><td>N/A</td><td>2.108g</td><td>2.230g</td><td>-0.122g</td></tr>
</table>
[1] Average of 5 replicates
[2] Positive values indicate loss of water from the bait or food (mouse pellets). Negative values indicate either no water loss, or the bait or food (mouse pellets) had gained weight by absorbing moisture from the air

Table 3: Accumulative mortality
<table>
<tr><th rowspan="2">Sample</th><th rowspan="2">Sample Condition</th><th colspan="15">Mortality at various days (%)[1]</th></tr>
<tr><th>0.25</th><th>1</th><th>2</th><th>3</th><th>4</th><th>5</th><th>6</th><th>7</th><th>8</th><th>9</th><th>10</th><th>11</th><th>12</th><th>13</th><th>14</th></tr>
<tr><td rowspan="2">[redacted]</td><td>Fresh sample</td><td>0</td><td>24</td><td>47</td><td>61</td><td>68</td><td>77</td><td>80</td><td>82</td><td>88</td><td>93</td><td>93</td><td>94</td><td>94</td><td>95</td><td>99</td></tr>
<tr><td>Aged sample</td><td>0</td><td>39</td><td>57</td><td>70</td><td>72</td><td>77</td><td>80</td><td>85</td><td>86</td><td>88</td><td>88</td><td>92</td><td>92</td><td>95</td><td>95</td></tr>
<tr><td>Control A Mouse pellets (Normal Roach diet)</td><td>N/A</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
</table>
[1] Values were accumulative kills (mortality) of 5 replicates, which include dead and moribund cockroaches.

Efficacy of [redacted] against American cockroach was demonstrated, achieving >90% mortality within 9 day after exposure to the fresh bait, and 11 days to the aged bait.</td><td></td></tr>
<tr><td>PT18
Pesguard® Gel Bait</td><td>Pesguard® Gel Bait containing 0.5% w/w clothianidin + 0.5% w/w pyriproxyfen</td><td>American cockroach (Periplaneta americana) and brown-banded cockroaches (Supella longipalpa)</td><td>Field trial in a multi-family public accommodation or restaurants/bakeries etc. in Bayonne (64 area-France)

Test design:
- 5 sticky traps were placed overnight at each test site
-A site was viable if it had a minimum pre-count of 16-20 American cockroaches or 10 brown-banded cockroaches.
- Two pre-counts were made at Day - 14 and</td><td>Table 2 - Reduction (%) of Periplaneta americana populations numbers after treatment
<table>
<tr><th></th><th>+7 days</th><th>+14 days</th><th>+30 days</th><th>+90 days</th></tr>
<tr><td>Test product</td><td>26.6</td><td>96.0</td><td>88.9</td><td>92.5</td></tr>
<tr><td>Untreated</td><td>2.2</td><td>30.8</td><td>-13</td><td>-4.0</td></tr>
</table>
Table 2 - Reduction (%) of Supella longipalpa populations numbers after treatment
<table>
<tr><th>+7 days</th><th>+14 days</th><th>+30 days</th><th>+90 days</th></tr>
</table></td><td>[redacted]</td></tr>
</table>

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
			Day - 7 : the mean of these values gave the pre-treatment infestation level. - 5 untreated sites - 5 treatment sites - 1 treatment: *Pesguard®* Gel - 2 cockroach species -Dosage: The number of 5 mm diameter spots (approximatively 0.05 g of bait) applied per m² in relation to the infestation level: •American cockroaches: 2 to 6 spots per m² •Brown-banded cockroaches: 1 to 2 spots per m² -Application: Bait was applied under the fridge, under the kitchen sink, under the oven and the water-heater and on all cracks and crevices that can be a harbourage for cockroaches. -Assessments: 7, 14, 30 and 90 days after treatment. -The results were given by a % reduction at each assessment: % reduction = ((Pi-Pn)/P1) x 100 Where Pi is the pre-trapping infestation level (mean of the -14 days and -7 days assessments), and Pn is the insects trapped at assessment number "n". The same assessments are conducted in the untreated (control) locations. Date of testing: September 2016 to January 2017. Brown banded cockroach: multi-family public accommodation buildings. The heating for the entire building is under floor heating which is controlled by the apartment office and not by the individual residents. American cockroach: in food storage rooms of restaurants, bakeries and butcheris	**Test product** 2.9 91.7 96.7 81.1 **Untreated** 10.2 -1.8 -8.5 -9.0 *Pesguard®* gel demonstrated a good control of the American and brown-banded cockroaches with > 90% population reduction at 14 days after treatment up to 30 days after treatment for *S. longipalpa* and up to 90 days after treatment for *P. americana*.	
PT18 Pesguard® Gel Bait	*Pesguard®* Gel Bait containing 0.5 % w/w	**German cockroach** (*Blattella*	. Field trial in a multi-family public accommodation in Bayonne (64 area-France) Test design:	**Table 1**- Reduction (%) of cockroach population numbers after treatment **+7 days** **+30 days** **+60 days** **+90 days** **+120 days**	[redacted]

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
	clothianidin + 0.5% w/w pyriproxyfen	*germanica*)	- 5 sticky traps were placed overnight at each test site -A site was viable if it had a minimum pre-count of 16-20 German cockroaches. - Two pre-counts were made at Day - 14 and Day - 7: the mean of these values gave the pre-treatment infestation level. - 5 untreated sites - 5 treatment sites treated with *Pesguard®* Gel bait -Dosage *Pesguard®* gel: The number of 5 mm diameter spots (approximatively 0.05 g of bait) applied per m² in relation to the infestation level: Light: 3-6 spots per m², i.e 27 and 34 spots in the 10 m² treated (2 apartments) Heavy: 6-10 spots per m², i.e. 50 to 52 in the 10 m² treated (3 apartments) -Application: Bait was applied under the fridge, under the kitchen sink, under the oven and the water-heater and on all cracks and crevices that can be a harbourage for cockroaches. -Assessments: 7, 30, 60, 90 and 120 days after treatment. -The results were given by a % reduction at each assessment: % reduction = ((Pi-Pn)/P1) x 100 Where Pi is the pre-trapping infestation level (mean of the -14 days and -7 days assessments), and Pn is the insects trapped at assessment number "n". The same assessments were conducted in the untreated (control) locations. Date of testing: August to October 2016. The heating for the entire building is under floor heating which is controlled by the apartment office and not by the individual residents.	**_Pesguard®_ gel bait**: 83.7 / 93.6 / 97.7 / 94.7 / 71.3 **Untreated**: -13.5 / -2.8 / -6.8 / -19.1 / -5.4 *Pesguard®* gel bait demonstrated efficacy against German cockroaches with >90% at 30 days after treatment up to 90 days after treatment. The efficacy dropped to 71.3% reduction of the cockroach population at 120 days after treatment	
PT18 Pesguard® Gel Bait	*Pesguard®* Gel Bait containing 0.5% w/w clothianidin + 0.5% w/w	**American cockroach** (*Periplaneta americana*) and **Oriental**	Laboratory choice trial Test design: - 30 cockroaches per replicate (10 adult male, 10 adult (non-gravid) female and 10 advanced/mature stage (4-5th instar)	Table: Summary of mortality data at test end points of 12 days for German cockroaches and 20 days for American and Oriental cockroaches	[redacted]

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
	pyriproxyfen Fresh and 3 years old product	**cockroach** (*Blatta orientalis*) and **German cockroach** (*Blattella germanica*)	nymphs). - 4 replicates per treatment per species - 3 treatments: a) *Pesguard®* gel b) *Pesguard®* gel, aged for +3 years d) Control -Arena: 38 x 27 x 28 cm Dosage: 1g of bait for German Cockroaches 2 g of bait for America Cockroaches and Oriental cockroaches. Alternative food source: bran pellets and a water source Trial duration: 20 days for America Cockroaches and Oriental cockroaches. 12 days for German cockroaches. Environmental conditions: -12:12 light dark regime -temp: 23-30 °C -relative humidity: 25-54% RH	<table><tr><td></td><td>*Pesguard®* gel (fresh)</td><td>*Pesguard®* gel (3 year aged)</td><td>Control</td></tr><tr><td>*Blattella germanica* (12 days)</td><td>100.0</td><td>100.0</td><td>4.7</td></tr><tr><td>*Periplaneta Americana* (20 days)</td><td>95.3</td><td>99.3</td><td>0.0</td></tr><tr><td>*Blatta orientalis* (20 days)</td><td>100.0</td><td>98.7</td><td>13.3</td></tr></table> Efficacy of the test formulation was demonstrated, achieving >95% mortality after exposure to the bait, both for fresh and 3-year aged sample.	

Conclusion on the efficacy of the product

The efficacy package provided demonstrates that *Pesguard®* Gel is effective against German cockroaches (*Blattella germanica*), Brown banded cockroaches (*Supella longipalpa*), Oriental cockroaches (*Blatta orientalis*) and American Cockroaches (*Periplaneta americana*) both as nymphs and adults.

2.2.5.6 Occurrence of resistance and resistance management

Pyriproxyfen

Pyriproxyfen is a juvenile hormone analogue (or mimic) and an Insect Growth Regulator (IGR). It prevents juvenile-sensitive insect stages (larvae/nymphs) from developing into adults and therefore rendering them unable to reproduce.

Insect Growth Regulators (IGRs) have a unique mode of action, separate from most other chemical insecticides. They are quite selective in their mode of action and potentially act only on the target species.

Several features of insect growth regulators (IGRs) make them attractive as alternatives to broad-spectrum insecticides. Because they are more selective, they are less harmful to the environment and more compatible with pest management systems that include biological controls.

Although they are rarely fatal for adult insects, IGRs can prevent reproduction, egg-hatch, and moulting from one stage to the next. Many IGR products are mixed with other insecticides that kill adult insects, therefore reducing the population of existing adults, whilst also preventing any immature stages and eggs from developing into adults.

Another advantage of IGRs is their low toxicity to vertebrates (i.e. people, pets or other animals).

Due to their unique mode of action, biochemical insect growth regulators have played an important role in integrated pest management systems and as an effective resistance management tool.

Insects have demonstrated a propensity to develop resistance to insecticides. Broad-spectrum insecticides that are used routinely will eventually lose their effectiveness due to resistance. Intelligent and strategic use of IGRs should reduce the likelihood of resistance developing.

There are indications that there is a possibility of development of resistance to IGRs in species specific to biocidal uses (as has been seen in crop protection). However, within the PT18 biocide use, the risk is not considered very high.

Clothianidin

Clothianidin belongs to the neonicotinoid chemical class.

Resistance and cross-resistance against neonicotinoids (chloronicotinyls like thiamethoxam, acetamiprid and imidacloprid), a group of insecticides acting agonistically on insect nicotinic acetylcholine receptors (nAChRs) can occur in relevant susceptible pests in Europe, particularly cockroaches[1,2,3].

Insect resistance has developed to the neonicotinoids in a number of species, most notably those of the orders Hemiptera (aphids, whiteflies, and plant hoppers) and Coleoptera (beetles), but are also active against some Lepidopteran species. The neonicotinoids are broad-spectrum insecticides; they are considered less harmful to the environment (as nicotinoids occur in a wide range of plant species). They are also of low toxicity to vertebrates (i.e. people, companion animals or other animals).

Resistance to the neonicotinoids has been confirmed in several insect species important in crop protection, such as *Aphis gossypii*. Whilst target site resistance has been confirmed in some species, such as *Bemisia tabaci*, (tobacco whitefly) and *Myzus*

persicae (Peach-potato aphid) the mechanisms for resistance remain unelucidated in others, such as *Leptinotarsa decemlineata*.

In general, precautions should be taken to reduce the possibility of insects developing resistance to neonicotinoid insecticides.

[1] Wen, Z. and J.G. Scott. (1997). Cross-Resistance to Imidacloprid in strains of german cockroach (Blattella germanica) and House Fly (Musca domestica). *Pesticide Science*, 49 367-371.

[2] Fardisi,M.,Gondhalekar, A.D., Scharf, M.E. (2017). Development of Diagnostic Insecticide Concentrations and Assessment of Insecticide Susceptibility in German Cockroach (Dictyoptera: Blattellidae) Field Strains Collected From Public Housing. *Journal of Economic Entomology*, 110(3), 2017, 1210–1217

[3] Ko AE, Bieman DN, Schal C, Silverman J (2016) Insecticide resistance and diminished secondary kill performance of bait formulations against German cockroaches (Dictyoptera: Blattellidae). *Pest Management Science* 72: 1778–1784

Resistance management

As part of the resistance management associated with IGRs (such as pyriproxyfen), IRAC (the Insecticide Resistance Action Committee) has recommended that for non-crop protection uses (such as the PT18 uses) IGRs should be used in mixture or co-formulation with insecticides with other modes of action. Similarly, with the recent occurrence in the USA of bed bug resistance to the neonicotinoid group of chemistry, and data from the above mentioned studies[1,2,3] mixture or co-formulation with other modes of action would also seem prudent. This is especially important, as populations of cockroaches are already resistant to other insecticide modes of action. *Pesguard®* Gel bait combines two of the most effective non-pyrethroid modes of action, so it can be considered that this product fits well with the recommendations of IRAC. As part of the biocide authorisation of pyriproxyfen, one of the recommendations was: 'To prevent resistance the label should recommend alternation of the product with products containing an active substance with a different mode of action'. *Pesguard®* Gel bait achieves this within a co-formulated product with clothianidin.

Sumitomo has a resistance monitoring scheme in place for their biocidal products, monitoring feedback from customers and literature publications, for their biocidal products and monitoring of resistance to *Pesguard®* Gel bait will be carried out, once product authorisation is granted.

2.2.5.7 Known limitations

No limitations on efficacy have been found when the product is used according to the use instructions.

2.2.5.8 Evaluation of the label claims

LABEL

Pesguard® Gel is effective against German cockroaches (*Blattella germanica*), Brown banded cockroaches (*Supella longipalpa*), Oriental cockroaches (*Blatta orientalis*) and American Cockroaches (*Periplaneta americana*) both as nymphs and as adults.

<u>Use instructions</u>

The pre-filled plastic reservoir containing *Pesguard®* Gel is intended for use with the plunger provided or bait application devices common to the pest control industry. Refer to the manufacturer's instructions for directions on the use of the applicator. Inject the bait into cracks and crevices, void spaces, and other locations where insects may live, feed and breed. Such areas are generally warm/damp and dark (e.g. behind or under furniture or equipment) and inspection or trapping to confirm infestation is recommended prior to treatment. Ensure that any alternative food sources are removed and concentrate the bait placements as individual spots at cockroach activity sites (only in areas inaccessible to children and pets).
Do not apply *Pesguard®* Gel where it will come into contact with water or in areas that are routinely cleaned. Typically, cockroaches will die a few hours after a single feed on *Pesguard®* Gel. In infested premises, dead cockroaches will normally be seen within 24 hours of treatment.
Treated areas should be re-inspected after 1–2 weeks. Where initial infestation was heavy a second *Pesguard®* Gel application may be required if the first treatment has been consumed and live cockroaches are still present.
Remove the cap from the nozzle, touch the top to the surface to be treated, and push down on the plunger. Replace the cap on the dispenser after treatment is completed.
The bait will adhere to non-greasy or non-dusty surfaces and will remain pliable and palatable to roaches as long as it is visibly present.
A visual inspection of bait placements is recommended 2-4 weeks after the initial treatment. Reapply when bait is no longer visibly present, according to the level of infestation. Replace bait before it is completely consumed to keep cockroaches from returning.

Rate of application
Pesguard® Gel should be applied as a number of spots of approximately 4mm diameter (each spot comprising approximately 0.032g of bait). In cases of heavy infestation, where larger cockroaches are present, in areas that are particularly dirty or cluttered or where alternative sources of food cannot be entirely eliminated the higher application rate should be used.

Infestation level	**Recommended application rate [number of 4mm diameter spots (approximately 0.032g of bait) per m^2]**
Low	1 - 2
Medium	3 - 6
High	6 - 10

Efficacy against *Blatella germanica*

To demonstrate efficacy against *Blatella germanica*, three laboratory tests and two field tests were provided. Furthermore, a laboratory study with only pyriproxyfen as an active substance was provided to demonstrate the efficacy of the IGR active substance in the product to be authorized. No simulated use test is provided. However, the efficacy guidance states that simulated use tests can be waived if a robust field trial is provided. The eCA considers the field tests results sufficient to be able to waive the simulated use trial.

In the first laboratory test (arena/choice test, [redacted]) 95% mortality was demonstrated after 4 days at an application rate of 12 bait placements of 0.50 g bait *per* placement which is the recommended low application rate for heavy infestations. In the second laboratory test (arena/choice test, [redacted]) efficacy of both fresh and artificially aged bait was demonstrated at >95% mortality after 1 day at an application rate of 1 g per arena of 0.09 m^2. In the third laboratory test (palatability test,

[redacted]) efficacy of both fresh and +3 years aged bait was demonstrated at 100% mortality after 12 days.

In the first field test ([redacted]) efficacy of the product was tested at three infestation levels and the claimed application rates for those levels. Low (1-2 spots per m2 (0.032 g of bait per spot)), medium (3-6 spots per m^2) and high (6-10 spots per m^2). For low infestation treatment >90% population reduction was found after 30 days. For medium and high infestation treatment >90% population reduction was found after 14 days. In the second field study ([redacted]) >90% population reduction was observed after 30 days for all infestation levels and the corresponding claimed application rates.

Evaluation of IGR study

In the laboratory study with only pyriproxyfen ([redacted]) developmental abnormalities in nymphs were demonstrated by dietary exposure to pyriproxyfen in immature German cockroaches. The bait product containing pyriproxyfen at 0.5% w/w was the most effective in controlling cockroaches by completely preventing the development of the normal phenotype in adult cockroaches. As an abnormal phenotype is indicative of reproductive inhibition in German cockroaches this result shows this product to be highly effective in controlling reproductive potential of the cockroaches.

The development of abnormal immature phenotype was not significantly different among control treatments (2, 3 and 7) and the two feeding regimes containing 0.1 and 1.0% w/w pyriproxyfen frass (6.4 and 4.4% abnormal nymphal phenotype, treatment 4 and 5, respectively, P>0.05, Tukey's HSD All-Pairwise Comparisons Test). However, consumption of a diet consisting of 10.0% w/w pyriproxyfen frass, treatment 6, provided a significant increase (14%) in the frequency of abnormal nymphal phenotypes (47.6%) which was significantly different from other treatments (P<0.05, Tukey's HSD All-Pairwise Comparisons Test).

Therefore, increasing the dose of pyriproxyfen containing frass in the bait (Treatment 5) resulted in a significant increase in the frequency of abnormal phenotype development over the control treatments (P<0.05, Tukey's HSD All-Pairwise Comparisons Test). From a field control perspective these results are even more important considering that one of the most difficult aspects of cockroach control is the high reproductive potential of the target species.

Based on all the provided efficacy data it can be concluded that *Pesguard®* Gel is effective at application rates of 1-2, 3-6 and 6-10 spots of 0.032 g/m^2 against light, medium and heavy infestations of *Blatella germanica*.

According to the efficacy guidance a lab test is required in which 95% of the insects do not develop to the next instar. For this product family only one such test is provided with *Blatella germanica* and not with the other target species. However, this product family is not based solely on an IGR but on a combination of Pyriproxfen and Clothianidin, which is not an IGR. The combination of the two active substances is sufficient to reduce the population >80%, either by just killing or by preventing developing to the next instar. Therefore, the eCA does not consider it necessary to show that at least 95% does not develop in the next instar to authorise this product family.

Efficacy against *Supella longipalpa*

To demonstrate efficacy against *Supella longipalpa*, one laboratory test and one field test were provided. No simulated use test is provided. However, the efficacy guidance states

that simulated use tests can be waived if a robust field trial is provided. The eCA considers the field tests results sufficient to be able to waive the simulated use trial.

In the laboratory test (arena/choice test, [redacted]) 92% mortality was demonstrated after 1 day at an application rate of 0.3 ± 0.03 g (approx. 9-10 spots of 0.032 g/m^2) which is the recommended high application rate for heavy infestations. This application amount was selected to ensure that sufficient amount of bait was available at the start of the study to meet the consumption needs of all the cockroaches. Preliminary work indicated that provisioning a lower amount of bait would result in insufficient food acquisition by the cockroaches, leading to uncontrolled experimental variation due to food availability, competition and cannibalism.

In the field test ([redacted]) efficacy of the product was tested with 5 mm diameter spots (approximatively 0.05 g of bait) per m² in relation to the infestation level, that in this case was 1 to 2 spots per m² (0.05-0.10 g of bait). Results showed that for low infestation treatment, 96.7% population reduction was found after 30 days. Moreover, after 90 days 81.1% population reduction was still found.

Based on the provided efficacy data it can be concluded *Pesguard®* Gel is effective against infestations of *Supella longipalpa*.

Efficacy against *Periplaneta americana*

To demonstrate efficacy against *Periplaneta americana*, three laboratory tests and one field test were provided. No simulated use test is provided. However, the efficacy guidance states that simulated use tests can be waived if a robust field trial is provided. The eCA considers the field tests results sufficient to be able to waive the simulated use trial.

In the first laboratory test (arena/choice test, [redacted]) 91% mortality was demonstrated after 8 days at an application rate of 0.3 ± 0.03 g (approx. 9-10 spots of 0.032 g/m^2) which is the recommended high application rate for heavy infestations. This application amount was selected to ensure a sufficient amount of bait was available at the start of the study to meet the consumption needs of all the cockroaches. Preliminary work indicated that provisioning a lower amount of bait would result in insufficient food acquisition by the cockroaches, leading to uncontrolled experimental variation due to food availability, competition and cannibalism.

In the second laboratory test (laboratory/choice test, [redacted]) efficacy of both fresh and artificially aged bait was demonstrated at 95% mortality after 13 days day at an application rate of 1 g per arena of 0.09 m^2 with a palatability of 100% for both fresh and artificially aged product. In the third laboratory test (palatability test, [redacted]) efficacy of both fresh and +3 years aged bait was demonstrated at >95% mortality after 20 days.

In the field test ([redacted]) efficacy of the product was tested with 5 mm diameter spots (approximatively 0.05 g of bait) per m² in relation to the infestation level, that in this case was 2 to 6 spots per m² (0.10-0.3 g of bait which corresponds to a medium-high label rate of 3-9 spots of 0.032g). Results showed that for low infestation treatment 92.5% population reduction was found after 90 days.

Based on the provided efficacy data it can be concluded *Pesguard®* Gel is effective against infestations of *Periplana americana*.

Efficacy against *Blatta orientalis*

To demonstrate efficacy against *Blatta orientalis*, one laboratory test and one field test were provided. No simulated use test is provided. However, the efficacy guidance states that simulated use tests can be waived if a robust field trial is provided. The eCA considers the field tests results sufficient to be able to waive the simulated use trial.

In the field test ([redacted]) efficacy of the product was tested at three infestation levels and the claimed application rates for those levels; Low (1-2 spots per m^2 (0.032 g of bait per spot)), medium (3-6 spots per m^2) and high (6-10 spots per m^2). For low and medium infestation treatment >90% population reduction was found after 14 days and lasted until the end of the observation period (70 days). For high infestation treatment >90% population reduction was found after 7 days up to 70 days.

In the laboratory test (palatability test, [redacted]) efficacy of both fresh and +3 years aged bait was demonstrated at >95% mortality after 20 days.

Based on the provided efficacy data it can be concluded *Pesguard®* Gel is effective against infestations of *Blatta orientalis*.

Shelf-life

For two cockroach species (*Blatella germanica* and *Periplaneta Americana*), efficacy and palatability of artificially aged bait was demonstrated in efficacy studies [redacted] and [redacted]. Also, for three cockroach species (*Blatella germanica, Periplaneta Americana* and *Blatta orientalis*) efficacy and palatability was demonstrated for 3-year old bait ([redacted]).
For the other claimed cockroach species (*Supella longipalpa*), no data on palatability/efficacy of the aged bait was provided. As the product contains a preservative, the claimed shelf-life of 2 years is acceptable for all claimed target species in line with the Technical Agreements for Biocides (section D.7 Shelf life of PT18 bait products).

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The product is not intended to be used with other biocidal products.

2.2.6 Risk assessment for human health

Studies for acute oral and dermal toxicity, skin and eye corrosion/irritation and skin sensitisation were provided in which [redacted] was tested. *Pesguard®* Gel was originally referred to by the experimental formulation known as [redacted]. This was later changed to a "registration code number" [redacted]. In other words, [redacted] (containing 0.5% w/w clothianidin and 0.5% w/w pyriproxyfen) is identical to *Pesguard®* Gel.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
EPA OPPTS 870.2500 (Acute Dermal Irritation) OECD Guideline 404 (Acute Dermal Irritation / Corrosion)	Rabbits, New Zealand White, 3 Females	0.5 ml, 4 h exposure	Not irritating (0 at all timepoints)	None	[redacted]

No human data are available.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The product does not require classification for skin irritation according to Regulation (EC) No 1272/2008.
Justification for the value/conclusion	A primary skin irritation test was conducted with rabbits to determine the potential for [redacted] to produce irritation after a single topical application. 0.5 ml of the test substance was applied to the skin of three healthy rabbits for 4 hours. Following exposure, dermal irritation was evaluated by the method of Draize *et al*. No skin irritation was observed in two animals during the study. Within 30-60 minutes of patch removal, one treated site exhibited very slight erythema. The overall incidence and severity of irritation decreased with time. The affected animal was free of dermal

	irritation by 24 hours. Note: study was conducted as required by the US EPA to support the registration at EPA.
Classification of the product according to CLP and DSD	Not classified

Eye irritation

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
EPA OPPTS 870.2400 (Acute Eye Irritation) OECD Guideline 405 (Acute Eye Irritation / Corrosion)	Rabbits, New Zealand White, 3 Females	0.1 ml/animal	All scores for cornea, iris and conjunctivae were 0 at 24h, 48h and 72h. Not irritating to eyes	None	[redacted]

No human data are available.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The product does not require classification for eye irritation according to Regulation (EC) No 1272/2008.
Justification for the value/conclusion	A primary eye irritation test was conducted with rabbits to determine the potential for [redacted] to produce irritation from a single instillation via the ocular route. A volume of 0.1 ml of the test substance was instilled into the right eye of three healthy rabbits. The left eye remained untreated and served as a control. Ocular irritation was evaluated by the method of Draize et al. No corneal opacity or iritis was observed in any treated eye during this study. One hour after test substance instillation, minimal conjunctivitis was noted for all three treated eyes. The overall incidence and severity of irritation decreased thereafter. All animals were free of ocular irritation by 48 hours. Note: study was conducted as required by the US EPA to support the registration at EPA.
Classification of the product according to	Not classified

CLP and DSD	

Respiratory tract irritation

Data waiving	
Information requirement	Respiratory tract irritation
Justification	Based on the calculation method described in Annex I of Regulation 1272/2008/EC, no classification for respiratory tract irritation is warranted for *Pesguard®* Gel. Furthermore, exposure to humans *via* inhalation is very unlikely given that the product is a gelatinous solid. Details of the product composition are presented in Section 2. There are no components of the product classified for respiratory tract irritation or acute respiration toxicity. A study is not required, nor considered an appropriate use of animals.

Skin sensitisation

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
EPA OPPTS 870.2600 (Skin Sensitisation) OECD Guideline 406 (Skin Sensitisation)	Guinea pig; Hartley; 10 ♀ and 10 ♂	0.45 ml applied neat, 6h exposure, topical application	The product is considered to be a skin sensitiser.	None	[redacted]

No human data are available.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Skin sensitiser
Justification for the value/conclusion	A dermal sensitisation test was conducted with guinea pigs to determine the potential for [redacted] to produce sensitisation after repeated topical applications. The neat test substance was topically applied to twenty healthy test guinea pigs, once each week for a three-week induction period. Twenty-eight days after the first induction dose, a challenge dose of the test substance at its highest non-irritating concentration (HNIC, determined in the preliminary irritation screen to be 100%) was applied to a naive site on each guinea pig. A naive control group (ten animals) was maintained under the same environmental conditions and treated with the test substance at challenge only. Approximately 24 and 48 hours after each induction and challenge dose, the animals were scored for erythema. Based on the results of this study, the test substance is considered to be a contact sensitiser. The positive response observed in the historical positive control validation study with alpha-Hexylcinnamaldehyde, ≥95% (HCA) validates the test system used in this study. Note: study was conducted as required by the US EPA to support the registration at EPA. Note eCA: Based on the positive Buehler study, *Pesguard®* Gel is classified with H317.
Classification of the product according to CLP and DSD	Skin Sens. 1; H317: May cause an allergic skin reaction.

Respiratory sensitisation (ADS)

No data are available on humans.

Data waiving	
Information requirement	Respiratory sensitisation
Justification	Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for respiratory sensitisation by calculation. Section 3.4.3 of the Regulation states that classification of a product for sensitising effects is necessary if it contains at least one ingredient has been classified as a respiratory sensitiser and is present at or above the appropriate generic concentration limit as shown in Table 3.4.5 and for individuals who are already sensitised to the substance or mixture refer to Table 3.4.6. Details of the product composition are presented in Section 2. There are no components of the product classified for respiratory sensitisation. The product does not therefore require classification for respiratory sensitisation. A study is not required, nor considered an appropriate use of animals.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	The product does not require classification for respiratory sensitisation according to Regulation (EC) No 1272/2008. Note: study was conducted as required by the US EPA to support the registration at EPA.
Justification for the value/conclusion	Refer to the table above.
Classification of the product according to CLP and DSD	Not classified

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels Type of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
EPA OPPTS 870.1100 (Acute Oral Toxicity); OECD Guideline 425 (Acute Oral Toxicity: Up-and-Down Procedure); GLP; Reliability 1	Rat, Sprague-Dawley, Female; limit test, 3 animals	5000 mg/kg bw in diet	There were no signs of toxicity. The only observation was reduced faecal volume.	>5000 mg/kg bw	None	[redacted]

No data are available on humans.

Value used in the Risk Assessment – Acute oral toxicity	
Value	>5000 mg/kg bw
Justification for the selected value	Limit dose showed no signs of toxicity. Note: study was conducted as required by the US EPA to support the registration at EPA.
Classification of the product according to CLP and DSD	Not classified

Acute toxicity by inhalation

No data are available.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	The product does not require classification for acute inhalation toxicity according to Regulation (EC) No 1272/2008.
Justification for the selected value	Based on the calculation method described in Annex I of Regulation 1272/2008/EC, no classification for acute inhalation toxicity is warranted for *Pesguard®* Gel. Furthermore, exposure to humans via inhalation is very unlikely given that the product is a gelatinous solid.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	-
Justification	Based on the calculation method described in Annex I of Regulation 1272/2008/EC, no classification for acute inhalation toxicity is warranted for *Pesguard®* Gel. Furthermore, exposure to humans via inhalation is very unlikely given that the product is a gelatinous solid. A study on acute toxicity by inhalation is therefore not considered necessary.

Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
EPA OPPTS 870.1200 (Acute Dermal Toxicity); OECD Guideline 402 (Acute Dermal Toxicity); GLP; Reliability 1	Rat, Sprague-Dawley, Male/Female; limit test, 10 animals (5♂; 5♀)	5000 mg/kg bw limit test; test area 38 cm^2	There were no signs of toxicity. Irritation was noted for two dose sites on Day 1 and the animals all gained weight.	>5000 mg/kg bw	None	[redacted]

No data are available on humans.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	>5000 mg/kg bw
Justification for the selected value	Limit dose showed no signs of toxicity. Note: study was conducted as required by the US EPA to support the registration at EPA.
Classification of the product according to CLP and DSD	Not classified

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	Clothianidin	Pyriproxyfen
Value(s)	50%	40%
Justification for the selected value(s)	The value used is the default value used in the absence of data on dermal absorption for water-based formulations containing ≤5%.*	The value used is the default value used in the absence of data on dermal absorption for formulations containing ≤5% and that dermal absorption is not expected to exceed oral absorption.**

**Dermal absorption value was changed during the commenting phase to 50%, default for water-based formulations containing ≤5% EFSA Journal 2017;15(6):4873.*

*** Dermal absorption value for pyriproxyfen were selected in accordance with the EFSA Panel on Plant Protection Products and their Residues (PPR) Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665. [30 pp.])*

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

In line with CA document "CA-Nov14-Doc.5.11 - SoC guidance_final.doc", acetic acid is identified as a SoC as SCOEL values for this substance are available. The Scientific Committee on Occupational Exposure Limits (SCOEL, June 2012) has recommended an 8-hour TWA of 10 ppm (25 mg/m^3) and STEL (15 min) of 20 ppm (50 mg/m^3) for acetic acid.

Additionally, Substance potassium sorbate is included in the Union List (Regulation (EU) No 528/2012) for PT 8 and as the potassium sorbate is present >0.1 %, the substance complies with the triggers for substance of concern (add 2 of the SoCs guidance).

Exposure these identified SoCs is of no concern when using the product. For more detailed discussion, please be referred to the confidential annex of this PAR (section 3.6).

Available toxicological data relating to a mixture

Not applicable

Others

Endocrine disruption activity of active substances
For the active substances clothianidin and pyriproxyfen no ED assessment is required because for active substances which have been approved, the EU assessment should be followed. The Assessment Reports for clothianidin (2014) and pyriproxyfen (2012) both state that these active substances would not be considered as having endocrine disrupting properties.

Endocrine disruption activity of non-active substances
The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders).
According to the Endocrine disruption criteria a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

a) it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;
c) the adverse effect is a consequence of the endocrine mode of action.

From this criteria ED screening was performed by CA NL.
For two co-formulants an ED alert was identified, however, for these co-formulant CA NL concludes that we have to await the discussions at EU level. See the confidential annex for more specific information.

In conclusion, based on available information, it is not possible to conclude whether the non-active substance should be considered to have ED properties before the expiration of the legal deadline in the BPR and therefore the process will be concluded at the post-authorisation stage. Once the conclusion regarding ED properties of these co-formulants is available, the applicant must inform the eCA. If needed, the conditions of authorization shall be revised.

2.2.6.2 Exposure assessment

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	No	n.a.	n.a.	Negligible	Negligible	n.a.
Dermal	n.a.	Yes	n.a.	n.a.	Negligible	Yes	n.a.
Oral	n.a.	No	n.a.	n.a.	No	Yes (toddler)	No

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.	Application	Primary exposure – dermal contact with product during application	Professional
2.	Indirect exposure	Secondary exposure – oral exposure to a bead of product due to hand-to-mouth transfer (infants and toddlers only)	bystanders

Pesguard® Gel containing 0.05 g/kg clothianidin and 0.05 g/kg pyriproxyfen is intended to be used as bait for the control of cockroaches. The formulation is a gel commercialised in a ready to use container for use with bait applicator gun common to the pest control industry.

Industrial exposure

Not Applicable.

Professional exposure

Pesguard® Gel may be used as a spot or crack and crevice treatment to control cockroaches in non-food/non-feed areas (i.e. rubbish rooms, lavatories, floor drains [to sewers], entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets and storage [after canning or bottling]). Food/feed areas (*i.e.* areas for receiving storage, packing (canning, bottling, wrapping, and boxing), storage of prepared edible waste, and enclosed processing systems [mills, dairies, edible oils, and syrups], serving areas). For Household Use (*i.e.* in closets, basements, attics, recreation rooms, living areas, kitchens, bathrooms, dining rooms, pantries, food storage shelving, waste receptacles, *etc.*). Domestic premises (*i.e.* food handling areas [i.e. for food processing, storage and preparation], food manufacturing premises, commercial kitchens, restaurants, food stores, supermarkets, retail outlets *etc.*). Public Buildings such as hotels, restaurants and other food handling establishments, hospitals, nursing homes, health care facilities, motels, hotels, schools, day care centres, correctional facilities, zoos, theatres, etc.). Commercial and Industrial premises (*i.e.* apartments, military installations, garages, laboratories, factories, warehouses, food processing and meat packing plants, food storage areas, shops, pet shops, workshops, aircraft, vehicles, railway stock, boats, ships, computer and electronic equipment facilities, sub-surface utility systems [steam/ electric/ gas/ data cable tunnels, drainage systems and sanitary sewers] that are not storm or runoff drainage systems, *etc*.).

The pre-filled plastic reservoir containing *Pesguard® Gel* is intended for use with a bait application gun common to the pest control industry. The cap is removed from the dispenser nozzle, the nozzle tip is placed on the surface to be treated and the plunger pushed down. Following application, the cap is replaced on the dispenser. Once the container is empty it is disposed of following the label instructions, no cleaning operations are necessary.

The bait will adhere to non-greasy or non-dusty surfaces and will remain pliable and palatable to roaches as long as it is visibly present. A visual inspection of bait placements is recommended 2-4 weeks after the initial treatment.

Description of Scenario 1

It is unlikely that significant amounts of *Pesguard® Gel* will come into contact with the professional applicator. The risk of inhaling volatilised clothianidin or pyriproxyfen is assumed to be negligible considering the low vapour pressure of both clothianidin and pyriproxyfen (1.3×10^{-10} Pa at 25°C and $<1.33 \times 10^{-5}$ Pa at 22.81°C). Thus, levels of inhalation and dermal exposure to clothianidin and pyriproxyfen for professional applicators under these conditions are expected to be very low or even negligible. However, as a precautionary approach a reverse reference scenario can be used.

The margin of safety has been calculated taking into account the AEL and dermal absorption.

Exposure is assumed to result from dermal contact with the product. The product may be applied throughout the working week, and as cockroaches are not appearing seasonal, the professional exposure needs to be compared to the $AEL_{long\text{-}term}$.

Given the sensitising potential of *Pesguard® Gel*, impermeable gloves should be worn when handling and using the product application equipment.

	Parameters	Value
Tier 1	Application Concentration	Clothianidin: 0.5% Pyriproxyfen: 0.5%
	Dermal absorption	Clothianidin: 50% Pyriproxyfen: 40%
	Oral absorption	Clothianidin: 100% Pyriproxyfen: 40%
	Body weight*	Adult: 60 kg
Tier 2	PPE: Protective gloves**	90%

* HEEG Opinion no. 17: Default human factor values for use in exposure assessments for biocidal products.
** HEEG Opinion no. 9. Default protection factors for protective clothing and gloves. TM I 2010, Ispra 27/01/2010

Calculations for Scenario 1

Tier 1 (No PPE)
Clothianidin
With a default dermal absorption of 50%, the amount of product which could be present on the unprotected skin to reach the long-term AEL of 0.1 mg/kg bw/d for Clothianidin can be calculated as follows:

AEL (mg/kg/d)	x	adult body weight (kg)	÷	dermal penetration %	÷	concentration in bait %	=	mg
0.1		60		50		0.5		2400

The applicant indicates that a 4 mm bead could weigh 0.032 g or 32 mg. The bead would thus be:
32/4 = 8 mg/mm.

The 2400 mg on unprotected skin required to reach the AEL could thus be a bead of

2400/8 = 300 mm (30 cm) spread on the skin.

Pyriproxyfen
With a dermal absorption of 40%, the amount of product which could be present on the unprotected skin to reach the AEL of 0.04 mg/kg bw/d of Pyriproxyfen can be calculated as follows:

AEL (mg/kg/d)	x	adult body weight (kg)	÷	dermal penetration %	÷	concentration in bait %	=	mg
0.04		60		40		0.5		1200

The applicant indicates that a 4 mm bead could weigh 0.032 g or 32 mg. The bead would thus be:
32/4 = 8 mg/mm.

The 1200 mg on unprotected skin required to reach the AEL could thus be a bead of 1200/8 = 150 mm (15 cm) spread on the skin.

Estimates of professional exposure without the use of PPE are considered to be protectively low. However, since *Pesguard® Gel* is classified as a skin sensitiser an exposure assessment assuming PPE is worn has been carried out.

Tier 2 (With PPE [gloves])
Clothianidin
Given the dermal sensitisation hazard of *Pesguard® Gel*, suitable protective gloves should be worn when handling the product application equipment. If it is considered that the penetration of Clothianidin through protective gloves is 10%, the operator would need to get **24000 mg** (or 24 g) of biocidal product on the outside of the gloves and this would need to remain on the surface until the active had migrated through the gel and penetrated the glove.

This would mean a bead of 3000 mm (300 cm) would be required spread on the outer surface of the gloves to reach the AEL.

Pyriproxyfen
Given the dermal sensitisation hazard of *Pesguard® Gel*, suitable protective gloves should be worn when handling the product application equipment. If it is considered that the penetration of Pyriproxyfen through protective gloves is 10%, the operator would need to get **12000 mg** (or 12 g) of biocidal product on the outside of the gloves and this would need to remain on the surface until the active had migrated through the gel and penetrated the glove.

This would mean a bead of 1500 mm (150 cm) would be required spread on the outer surface of the gloves to reach the AEL.

Non-professional exposure

Pesguard® Gel is not for use by non-professionals.

Exposure of the general public

Scenario 2

Description of Scenario 2
As an infant or toddler could be exposed by poking their fingertips into treated areas (i.e. cracks, crevices) followed by oral intake, exposure via hand-to-mouth transfer cannot fully be excluded. Therefore, a reverse reference scenario is included for accidental exposure. In a very worst-case exposure scenario for hand-to-mouth exposure, as an infant (6 monts-1 year old) picks up a bead of product, and the full amount of the product is orally absorption (i.e. 100% oral absorption. Considering the lower dermal absorption values (i.e. 50% for clothianidin 40% for pyriproxyfen), dermal exposure by dermal contact or via hand-to-mouth behaviour, which consists of 90% dermal exposure and 10% of the dermal exposure considered for oral exposure, is therefore covered by this scenario for all age groups. The risk of inhaling dried residues of clothianidin or pyriproxyfen is considered to be negligible considering the low vapour pressure of clothianidin and pyriproxyfen (1.3×10^{-10} Pa at 25°C and $<1.33 \times 10^{-5}$ Pa at 22.81°C, respectively). The nature of the product composition (adherent gel) and its high moisture content also contributes to maintain the product pliable and not drying out too quickly. The risk of an infant and a toddler is assessed using a reverse reference approach, to assess how may beads of product could be orally exposed to before exceeding the AELshort-term. One bead of product is 32 mg.

	Parameters	Value
Tier 1	Concentration active per bead of 32 g product	Clothianidin: 0.16 mg Pyriproxyfen: 0.16 mg
	Oral absorption	Clothianidin: 100% Pyriproxyfen: 40%
	Body weight*	Infant: 8 kg Toddler: 10 kg

* HEEG Opinion: Default human factor values for use in exposure assessments for biocidal products.

Calculations for Scenario 2

Summary table: systemic exposure from non-professional uses				
Exposure descriptor	**Clothianidin**		**Pyriproxyfen**	
	Infant	Toddler	Infant	Toddler
Maximal systemic exposure via oral route (AEL short-term)	0.25 mg/kg bw/day		0.12 mg/kg bw/day	
Maximal intake dose (mg) AEL x bw x correction factor oral absorption	0.25 x 8 x 1 = 2 mg	0.25 x 10 x 1 = 2.5 mg	0.12 × 8 x 2.5 = 2.4 mg	0.12 × 10 x 2.5 = 3 mg

Concentration active in one bead	32 mg x 0.5% = 0.16 mg		32 mg x 0.5% = 0.16 mg	
Number of beads of product that can be consumed before exceeding the AEL short-term:	2/0.16 = 12.5	2.5/0.16 = 15.6	2.4/0.16 = 15	3/0.16 = 18.8

Further information and considerations on scenario 1
No further information or considerations are required for this scenario as estimated levels of exposure using precautionary assumptions demonstrate acceptable margins of safety for clothianidin and pyriproxyfen.

Combined scenarios
The product contains two active substances, the combined effect should be considered. As the exposure scenarios are both based on reverse reference calculations, they cannot be evaluated by summing up the risk indices (as would be in accordance with mixture toxicity evaluation as included in BPR guidance).

However, based on the reverse reference calculation for the protected (gloves, due to sensitising properties of product) professional user can be exposure to 12 g - 24 g (pyriproxyfen and clothianidin, respectively) of product on the outside of the gloves and this would need to remain on the surface until the actives had migrated through the paste and penetrated the glove.
As the included photograph (Figure 2.2.6.3/01) representing 4 g of a paste product shows quit a lot of product, it is considered that a professional operator would be unlikely to get this amount of a paste formulation on their gloves during the application of the gel bait by dispensing gun. Therefore, it is concluded that no adverse effects are expected to the combined exposure to both actives substances when applying *Pesguard®* Gel.

Based on the reverse reference scenario for infant and toddlers. Considering the worst-case outcome of the assessment (for infants), an infant can consume 12.5 - 15 (clothianidin and pyriproxyfen, respectively) beads of product before exceeding the AELshort-term. Considering the intended use, The product is applied by injecting the bait into cracks and crevices, void spaces and other locations where insects may live, feed and breed, exposure of the entire surface area of the hand is considered unlikely. Such areas are generally warm/damp and dark (e.g. behind or under furniture or equipment) and not easily accessible. Furthermore, in the intended use is indicated that product should only be applied to areas inaccessible to children and pets. Considering the outcome of the calculations and the intended use, no adverse effects are expected after the combined exposure to both active substances for infants or toddlers by indirect exposure due to use of *Pesguard®* Gel.

Monitoring data
Not required as estimated levels of exposure using precautionary assumptions demonstrate acceptable margin of safety for clothianidin and pyriproxyfen.

Dietary exposure
No food, drinking water or livestock exposure is foreseen as the product should not be applied to areas where food utensils or food preparation surfaces may become contaminated and should only be applied to areas inaccessible to pets.

The following sentences are included in the instruction of use:

- Ensure that any alternative food sources are removed and concentrate the bait placements as individual spots at cockroach activity sites (only in areas inaccessible to children and pets).
- Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals. Moreover, the following sentences are included in the risk mitigation measures:

Considering these instructions and risk mitigation measures, dietary exposure is foreseen to be negligible.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

No food or livestock exposure is foreseen as the product should not be applied to areas where food utensils or food preparation surfaces may become contaminated and should only be applied to areas inaccessible to pets.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Pesguard® Gel is not for use by non-professionals.

Exposure associated with production, formulation and disposal of the biocidal product

Production and formulation are addressed under other EU legislation (*e.g.* Directive 98/24/EC) and not repeated under Regulation 528/2012 (this principle was agreed at Biocides Technical Meeting TMI06).

As the product is applied directly from the container and disposed of once empty, there is no cleaning operation to consider.

Aggregated exposure

Not applicable.

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation of clothianidin

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
Professional user					
OEL	-	-	-	-	-
Non- professional user					
$AEL_{short-term}$	Pharmacology study, mouse	25 mg/kg	100	n.a.	0.25 mg/kg bw
$AEL_{medium-term}$	90-day dog, supported by 90-day rat and embryotoxicity rabbit	20 mg/kg bw/day	100	n.a.	0.2 mg/kg bw/day
$AEL_{long-term}$	2-year rat, supported by 2-	9.7 mg/kg bw/day	100	n.a.	0.1 mg/kg bw/day

	gen. rat				
ARfD*	Pharmacology study, mouse	25 mg/kg	100	n.a.	0.25 mg/kg bw
ADI*	2-year rat, supported by 2-gen. rat	9.7 mg/kg bw/day	100	n.a.	0.1 mg/kg bw/day

[1] Please explain background and reason for assessment factor.

* The ADI an ARfD are not relevant for this product risk characterisation, as no product residues are expected in food or feed.

Reference values to be used in Risk Characterisation of pyriproxyfen

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
Professional user					
$AEL_{medium/long-term}$	1-year dog	10 mg/kg bw/day	100	40%	0.04 mg/kg bw/day
$AEL_{short-term}$	28-day rat	30 mg/kg bw/day	100	40%	0.12 mg/kg bw
Non- professional user					
$AEL_{secondary\ exposure}$	1-year dog	10 mg/kg bw/day	100	40%	0.04 mg/kg bw/day
$AEL_{medium/long-term}$	-	-	-	-	-
ARfD	-	-	-	-	-
ADI	-	-	-	-	-

[1] Please explain background and reason for assessment factor.

Risk for industrial users

Not applicable.

Risk for professional users

The risk associated with direct use of the product *Pesguard®* Gel is considered to be very low or even negligible. Given the dermal sensitisation hazard of *Pesguard® Gel* professional users are required to wear suitable protective gloves when handling the product.

However, as a precautionary approach using a reverse reference scenario and considering an operator wearing gloves, it was demonstrated that a bead of 3000 mm of clothianidin or 1500 mm pyriproxyfen spread on the gloves could lead to predicted exposure at the AEL, which although applicator guns can be messy tools, is unlikely for a trained professional operator following good hygiene practice.

If it is considered that the penetration of clothianidin and pyriproxyfen through protective gloves is 10%, the operator would need to get about 12 g - 24 g (pyriproxyfen and clothianidin, respectively) of product on the outside of the gloves and this would need to remain on the surface until the actives had migrated through the paste and penetrated the glove.

The following photograph represents what 4 g of a paste product looks like (using toothpaste as the representative product).

Figure 2.2.6.3/01

This appears to be quite a lot of product and it is considered that a professional operator would be unlikely to get this amount of a paste formulation on their gloves during the application of the gel bait.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

As the only scenario considered to result in exposure to professional users has been estimated using a reverse reference calculation no combined exposure assessment is possible. However, given the large MoS presented for Scenario 1 it is considered that combined exposure presents a very low risk with large MoS to the adult.

Risk for non-professional users

Pesguard® Gel is not for use by non-professionals.

Risk for the general public

Pesguard® Gel is applied by injecting the bait into cracks and crevices, void spaces and other locations where insects may live, feed and breed. Such areas are generally warm/damp and dark (e.g. behind or under furniture or equipment) The product should only be applied to areas inaccessible to children and pets. However, as an infant or toddler could be exposed by poking their fingertips into treated areas (i.e. cracks, crevices) followed by oral intake, exposure via hand-to-mouth transfer cannot fully be excluded. Therefore, a reverse reference scenario is included for accidental exposure. In a very worst-case exposure scenario for hand-to-mouth exposure, as an infant (6 monts-1 year old) picks up a bead of product, and the full amount of the product is orally absorption (i.e. 100% oral absorption. Considering the lower dermal absorption values (i.e. 50% for clothianidin 40% for pyriproxyfen), dermal exposure by dermal contact or via hand-to-mouth behaviour, which consists of 90% dermal exposure and 10% of the dermal exposure considered for oral exposure, is therefore covered by this scenario for all age groups.

The risk of inhaling dried residues of clothianidin or pyriproxyfen is assumed to be negligible considering the low vapour pressure of clothianidin and pyriproxyfen (1.3×10^{-10} Pa at 25°C and $<1.33 \times 10^{-5}$ Pa at 22.81°C, respectively). The nature of the product composition (adherent gel) and its highly moisture content also contribute to maintain the product pliable and not drying out too quickly.

The risk of an infant and a toddler is assessed using a reverse reference approach, to assess how may beads of product could be orally exposed to before exceeding the AELshort-term.

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Margin of Safety	Acceptable (yes/no)
Clothianidin					
Scenario 2 (Infant)	1	9.7	0.1	Number of beads of product that can be consumed before exceeding the AEL short-term: 12.5	Yes
Scenario 2 (toddler)	1	9.7	0.1	Number of beads of product that can be consumed before exceeding the AEL short-term: 15.6	Yes
Pyriproxyfen					
Scenario 2 (Infant)	1	10	0.04	Number of beads of product that can be consumed before exceeding the AEL short-term: 15	Yes
Scenario 2 (toddler)	1	10	0.04	Number of beads of product that can be consumed before exceeding the AEL short-term: 18.8	Yes

Local Effects

The product is classified as sensitising (H317: May cause an allergic skin reaction). Therefore, risk characterisation for local effects is presented in the table below.

Local effects

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM &PPE**	**Conclusion on risk**
Primary exposure										
High	H317-Skin sensitisation	-	18	Professional user	Applying and inspecting (visually) the baits	Skin	When applying the product Frequency: 1 time every 1-2 week, Duration: few minutes , Recommended application rate (number of 4mm diameter spots (approximately 0.032g of bait) per m2) is dependent on infestation level: 1-2 spots per m2 for light, 3-6 spots per m2 for medium and 6-10 spots per m2 for heavy infestation.	Exposure below or similar to brief contact with RMM and PPE.	All measures to eliminate exposure as much as possible, such as: **Personal protective equipment:** Gloves **The following P-statements are included in the label:** P280: Wear protective gloves P302+P352 IF ON SKIN: Wash with plenty of water/... P333+313: If skin irritation or rash occurs: Get medical advice/attention Packaging minimising risk for exposure: syringe with	Acceptable: Negligible exposure P-statements related to H317 on the label

									plunger	
Secondary exposure										
High	H317-Skin sensitisation	-	18	General public	N/A	Skin	Touching treated surfaces or via hand-to-mouth transfer (infant or toddler)	Exposure below or similar to an infant or toddler exposed by poking their fingertips into treated areas (i.e. cracks, crevices) followed by oral intake through hand-to-mouth transfer	All measures to eliminate exposure as much as possible, such as: Labelling, instructions for use: *Do not apply bait to areas where food utensils or food preparation surfaces may become contaminated. *Care should be taken to avoid depositing gel onto exposed surfaces. If gel contacts an exposed surface, remove gel and wash exposed surfaces. *Do not place treatments in locations where routine cleansing operations may transfer diluted bait to food or food preparation surfaces. *Do not treat food preparation surfaces.	Acceptable: Negligible exposure Labelling, instructions for use: *Bait should be inaccessible or removed from exposed surfaces

Conclusion

The AEL is neither reached nor exceeded by the estimated exposures. The local risk is considered acceptable in the view of negligible exposure. *Pesguard® Gel* application demonstrates acceptable margins of safety (MoS).

Risk for consumers via residues in food

No food, drinking water or livestock exposure is foreseen as the product should not be applied to areas where food utensils or food preparation surfaces may become contaminated and should only be applied to areas inaccessible to pets.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

The product contains two active substances, the combined effect should be considered. As the exposure scenarios are both based on reverse reference calculations, they cannot be evaluation by summing up the risk indices (as would be in accordance to mixture toxicity evaluation as included in BPR guidance).

However, based on the reverse reference calculation for the protected (gloves, due to sensitising properties of product) professional user can be exposure to 12 g - 24 g (pyriproxyfen and clothianidin, respectively) of product on the outside of the gloves and this would need to remain on the surface until the actives had migrated through the paste and penetrated the glove.
As the included photograph (Figure 2.2.6.3/01) representing 4 g of a paste product shows, and considering that the product is applied by dispensing gun and while wearing gloves, it is concluded that no adverse effects are expected to the combined exposure to both actives substances when applying *Pesguard®* Gel.

Based on the reverse reference scenario for infant and toddlers. Considering the worst-case outcome of the assessment (for infants), an infant can consume 12.5 - 15 (clothianidin and pyriproxyfen, respectively) beads of product before exceeding the AELshort-term. The product is applied by injecting the bait into cracks and crevices, void spaces and other locations where insects may live, feed and breed, exposure of the entire surface area of the hand is considered unlikely. Such areas are generally warm/damp and dark (e.g. behind or under furniture or equipment) and not easily accessible. Furthermore, in the intended use is indicated that product should only be applied to areas inaccessible to children and pets. Considering the outcome of the calculations and the intended use, no adverse effects are expected after the combined exposure to both active substances for infants or toddlers by indirect exposure due to use of *Pesguard®* Gel.

2.2.7 Risk assessment for animal health

No food or livestock exposure is foreseen as the product is not intended to be applied to areas where food utensils or food preparation surfaces may become contaminated and should only be applied to areas inaccessible to pets.

2.2.8 Risk assessment for the environment

Pesguard® Gel (containing 0.5% w/w clothianidin and 0.5% w/w pyriproxyfen) is a ready to use gel product for the control of cockroaches. Spots of gel bait are injected into cracks and crevices where the insects may live. Each spot consists of approximately 0.032 g bait and 1-2 spots per m^2 are applied for maintenance treatments up to a maximum of 6-10 spots per m^2 for heavy infestations.

Both clothianidin and pyriproxyfen have been assessed under the EU Review programme and details of the evaluations are included in the respective Assessment Reports[1,2]. A new study ([redacted]) was submitted in which the biodegradation

1 Assessment Report – Clothianidin, Product Type 18 (Insecticides, Acaricides and Products to control other Arthropods), June 2014

of [^{14}C]-pyriproxyfen under aerobic conditions in activated sludge was determined according to OECD 314B. This study is not included in the Assessment Report of pyriproxyfen (2012). The study is considered reliable and the results of the study are used in the exposure assessment performed for Pesguard Gel.

No other new data are submitted over and above those evaluated under the EU reviews for the active substances.

The uses evaluated in the Assessment Reports differ to those proposed for *Pesguard® Gel*. Although both clothianidin and pyriproxyfen were evaluated as PT18, use in animal houses was considered; therefore, a new environmental risk assessment has been performed for the proposed use.

[2] Assessment Report – Pyriproxyfen, Product type 18 (Insecticides, acaricides and products to control other arthropods), 21 September 2012

2.2.8.1 Effects assessment on the environment

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

The PNECs agreed for clothianidin and pyriproxyfen under their EU reviews and detailed in their respective Assessment Reports are presented in Table 2.2.8.1-1. No further ecotoxicology data are submitted.

Table 2.2.8.1-1: Agreed PNECs for clothianidin and pyriproxyfen

PNEC	Clothianidin (from AR, 2014)	Pyriproxyfen (from AR, 2012)
$PNEC_{STP}$	100 mg a.s./L	10 mg a.s./L
$PNEC_{aquatic, freshwater}$	0.08 µg a.s./L	3 ng a.s./L (continuous exposure)
$PNEC_{sediment, freshwater}$	0.34 µg a.s./kg wwt	1.4 µg a.s./kg wwt
$PNEC_{terrestrial}$	1.8 µg a.s./kg wwt	1.1 µg a.s./kg wwt
$PNEC_{oral, birds}$	-*	19 mg a.s./kg diet
$PNEC_{oral, mammals}$	-*	6.7 mg a.s./kg diet
$PNEC_{Bee}$	14.6 µg a.s./kg nectar/pollen**	***

*The log Kow of clothianidin is low (<1) with low estimated BCFs in fish (0.78 L/kg) and earthworms (0.9 L/kg). The risk of bioaccumulation was therefore assessed as low in the Assessment Report and a quantitative assessment was not performed. The change in use pattern does not alter this conclusion.

** Clothianidin has shown to be highly toxic to Bees both by oral and contact exposure. The 48-hour LD50 for oral toxicity was 0.0038 µg/Bee. Currently, there is no assessment concept available how to derive a PNEC for Bees. As clothianidin is a systemic insecticide, it is taken up from soil by plants and exposure to Bees via nectar and pollen is possible. Therefore, as a first step, the effect value has to be recalculated into a concentration in pollen/nectar. The data from the oral exposure test can be transformed to mg a.s./kg nectar/pollen using the information given in the publication included in . There, it is stated that a dose of 0.016 µg a.s./Bee is equivalent to 615 µg a.s./kg sucrose solution. From this it can be concluded that the LD50 of 0.0038 µg a.s./Bee was equivalent to 146 µg a.s./kg sucrose = 146 µg a.s./kg nectar/pollen.

As a first approach, an assessment factor of 10 is applied to derive the $PNEC_{Bee}$, resulting in a $PNEC_{Bee}$ of 14.6 µg a.s./kg nectar/pollen.

*** Exposure of Bees and other beneficial arthropods is considered insignificant. Therefore, a PNECadd,terrestrial was not calculated in the Assessment Report of pyriproxyfen.

A number of metabolites were considered relevant in both the soil and aquatic metabolism studies with clothianidin and pyriproxyfen. For clothianidin the metabolites MNG and TZNG were detected in soil metabolism studies at respective maxima of 10.7% and 9.1% AR and the metabolite TMG was detected in sediment in the sediment/water study at a maximum of 22.9% AR.
No risk characterisation is performed for the metabolites of clothianidin as their ecotoxicity was found to be far below the effect value of the parent (please refer to Table 2.2.8.1-2 for the PNECs of the metabolites).

For pyriproxyfen the metabolites 4-OH-Pyr (water 4.8% AR, sediment 14.8% AR), PYPAC (water 23.6% AR, sediment 7.6% AR) and DPH-Pyr (water 11.8% AR, sediment 4.3% AR) were detected in the sediment/water study. The metabolites 4-OH-Pyr and PYPAC were also detected in the soil metabolism study at respective maxima of 6.3% AR and 8.6% AR.
The relevant ecotoxicological metabolites of pyriproxyfen in water are 4-OH-Pyr, PYPAC and DPH-Pyr.
4'-OH-Pyriproxyfen was the only major (>10%) metabolite in sediment. No toxicity data for this metabolite are available, for the risk it is assumed that 4'-OH-Pyriproxyfen has the same characteristics as the parent. For that matter a combined assessment was performed using a combined degradation rate in the STP resulting in combined PECs for the receiving compartments. In laboratory incubated soil, the maximum level of the main degradation product PYPAC in any of the investigated soils exceeded 5% AR at two consecutive time points in soil.

The PNECs for the metabolites of clothianidin and pyriproxyfen are given in Table 2.2.8.1-2.

Table 2.2.8.1-2: PNECs for the metabolites of clothianidin and pyriproxyfen

PNEC	**Metabolites of Clothianidin (from AR, 2014)**		
	MNG (soil)	**TZNG (soil)**	**TMG (sediment)**
$PNEC_{freshwater}$	0.100 mg/L*	0.057 mg/L*	0.05 mg/L*
$PNEC_{sediment}$	0.124 mg/kg wwt**	0.387 mg/kg wwt**	0.34 µg/kg wwt‡
$PNEC_{terrestrial}$	0.0042 mg a.s./kg wwt^{+}	0.0083 mg a.s./kg wwt^{+}	1.8 µg/kg wwt^{++}
PNEC	**Metabolites of Pyriproxyfen (from AR, 2012)**		
	4-OH-Pyr* **	**PYPAC**	**DPH-Pyr**
$PNEC_{aquatic, freshwater}$	0.27 µg/L	30 µg/L	5.1 µg/L
$PNEC_{sediment, freshwater}$	0.015 mg/kg wwt	-	-
$PNEC_{terrestrial}$	-	14.5 µg/kg wwt	114 µg/kg wwt

*PNECs not calculated in AR, so calculated using AF of 1000 and acute endpoints in AR for acute studies with fish, Daphnia and algae for each metabolite
** PNECs in sediment and terrestrial not detailed in the AR. PNECs have therefore been calculated using the equilibrium partitioning method and assuming Koc-values for MNG of 21 mL/g, TZNG of 276 mL/g, PYPAC of 20.7 mL/g and DPH-Pyr of 1110 ml/g.
*** These PNECs were not used. For the risk assessment pyriproxyfen and 4-OH-Pyr was combined
‡PNEC not given in AR. *Chironomus* endpoint is from a spiked water study and no Koc for TMG is available. Therefore worst-case assumption of equivalent toxicity to the parent was made.
$^{+}$PNEC not given in AR. Calculated based on data summarised in CAR using AF of 50 (2 long-term end-points, earthworms and soil micro-organisms)
$^{++}$In AR PNEC for clothianidin is considered to apply

Endocrine disruption (ED) activity of non- active substances (ENV)

The toxicological endocrine disruption assessment with respect to human health is presented in the ED section of human toxicology. This section describes the ED screening for environmentally related issues (see below).

As also discussed in Section 2.2.6.1 (Endocrine disruption activity of non-active substances) ED criteria became applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders). The product *Pesguard® Gel* contains the active substances clothianidin and pyriproxyfen, as well as various co-formulants. For the active substances clothianidin and pyriproxyfen no ED assessment is required because for active substances which have been approved, the EU assessment should be followed. The Assessment Reports for clothianidin (2014) and pyriproxyfen (2012) both state that these active substances would not be considered as having endocrine disrupting properties.

There are indications of endocrine disruption for two co-formulants (see Section 2.2.6.1). For these co-formulants CA NL concludes to await the discussions at EU level. See the confidential annex for more specific information.

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

Not relevant.

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

The product is intended for use indoors therefore there will be no direct exposure of the environment. However, according to the ESD for PT18 there could be exposure of the STP via waste-water after wet washing of the treated area and subsequent exposure of surface water and agricultural land after spreading of sewage sludge.

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

Summary table on further studies on fate and behaviour in the environment

Method, Guideline, GLP status, Reliability	Compartment	Duration	Temp [°C]	concentration	Half-life, DT_{50} [d]	Remarks	Reference
OECD Method 314B, GLP, reliability 1	Activated Sludge	28 days	22 ± 2°C in the dark	0.01 mg/L solution of [pyridyl-2,6-^{14}C] pyriproxyfen	0.0529 days in biotic sludge 149 days in abiotic sludge	See below	IUCLID 10.2

Conclusion used in Risk Assessment – Further studies on fate and behaviour in the environment	
Value/conclusion	[pyridyl-2,6-^{14}C]Pyriproxyfen in the biotic sludge system underwent primary biodegradation to ten transformation products and a polar region and underwent significant ultimate biodegradation (conversion to $^{14}CO_2$) by 63.1% AR over the course of the 28-day study. The overall material balance averaged 95.0% AR in the biotic and 111.9% AR in the abiotic solution. No significant degradation occurred in the abiotic sludge. The calculated half-life of the parent [pyridyl-2,6-^{14}C]pyriproxyfen was determined to be approximately 0.0529 days in the biotic sludge and 149 days in the abiotic sludge.
Justification for the value/conclusion	The biodegradation of [pyridyl-2,6-^{14}C]pyriproxyfen was studied at a concentration of approximately 0.01 mg/L and a temperature of 22 ± 2ºC for 28 days in activated sludge. Activated sludge samples were analyzed at time zero, and 0.167 (4 hours), 1, 2, 3, 7, 14, 21 and 28 days after dosing to determine primary and ultimate biodegradation. At each sampling interval, the aqueous sludge samples were extracted and analyzed by liquid scintillation counting (LSC) and high performance liquid chromatography with radiochemical detection (HPLC/RAM) to evaluate primary degradation. Analysis of 14CO2 trapping solutions was made to evaluate ultimate biodegradation. Dissolved organic carbon (DOC) measurements were also made to evaluate ultimate biodegradation of the reference substance. [pyridyl-2,6-^{14}C]Pyriproxyfen underwent both primary and ultimate biodegradation over the course of the 28-day study. Mass balance of the biotic sludge system ranged from 88.5 to 100.9% of the applied radioactivity (% AR). Mass balance of the abiotic sludge system ranged from 104.3 to 116.6% AR. Ultimate biodegradation (conversion to CO2) occurred at 63.1 and 1.1% AR in the biotic and abiotic activated sludge test solutions, respectively. Three regions of radioactivity and a polar region were observed in the HPLC analyses of the biotic sludge in addition to the parent peak and are summarized in the table below. No single peak >10% AR was measured in the region marked as 'others'. No single peak was greater than 8% AR in the polar region of the representative samples (Day 1 and 14) by the HPLC analysis using a Hydro-RP column for the separation of small polar molecules.

Sample Day	% Degradation in the Biotic Sludge Solution (% of AR)					
	Pyriproxyfen	Polars	PYPAC	DPH-Pyr	4'-OH-Pyr	Others*
0	92.7	ND	ND	ND	ND	ND
0.167	10.4	8	8	5.9	22.9	31.8
1	2.5	19.6	4.8	8.1	4.7	36.3
3	ND	18.7	ND	4.3	5.4	28.8
7	1.5	32.9	ND	ND	2.2	11.1
14	ND	33.5	ND	ND	ND	8.8
21	ND	25.8	2.9	ND	2.9	7.7
28	ND	20.4	ND	ND	ND	17.3

* No single peak ≥10% AR was measured in the region designated 'others'
ND = Not Detected or <0.1 % AR.

Sample Day	% Degradation in the Abiotic Sludge Solution (% of AR)					
	Pyriproxyfen	Polars	PAPAC	DPH-Pyr	4'-OH-Pyr	Others
0	116.5	ND	ND	ND	ND	ND
0.167	116.6	ND	ND	ND	ND	ND
1	114	ND	ND	ND	ND	ND
3	112.5	ND	ND	ND	ND	ND
7	112	ND	ND	ND	ND	ND
14	106	3.6	ND	ND	ND	1.7
21	103.6	ND	ND	ND	ND	1.2
28	103	ND	ND	ND	ND	ND

ND = Not Detected or <0.1 % AR.

No major regions of radioactivity were observed in the HPLC analyses of the abiotic sludge in addition to the parent peak. The DT50 and DT90 values were calculated with the non-linear kinetic software, CAKE using the SFO model. The overall primary biodegradation half-life after 28 days in the biotic sludge was calculated to be 0.0529 days. The elimination rate constant, ke, was 13.1 days-1.

The DT90 value for the biotic system was 0.176 days. No significant degradation occurred in the abiotic sludge. The half-life after 28 days in the abiotic sludge was calculated to be 149 days. The elimination rate constant, ke, was 0.00467 days-1. The DT90 value for the abiotic system was determined to be 494 days. The kinetic values are presented below:

Test Matrix	DT_{50} (Days)	DT_{90} (Days)	Rate Constant (k, day^{-1})	χ^2	r^2
Biotic Activated Sludge	0.0529	0.176	13.1	6.14	0.9992
Abiotic (sterile) Sludge	149	494	0.00467	0.947	0.9361

The DOC depletion in the ethylene glycol reference control was 97.6% by Day 1, thus exceeding the "pass" criteria of the test (reaching 70% or greater DOC depletion within 14 days). This rapid degradation of the reference substance confirmed the presence of an acceptable microbial community and confirmed system integrity.
The eCA has the following comments:
The sludge biodegradability test with ^{14}C labelled pyriproxyfen was conducted according to the OECD314B guideline "Biodegradation in activated sludge". The results are reliable and show very fast degradation of the test item.

Some minor remarks on the study and report

	- The concentration of sludge was 3000 mg/L (24 g of dry weight solid equivalents in 8L) within the limits of 2500-4000 mg/L subscribed in OECD 314B guidance. - More measurements the first day and direct after addition of the test substance are recommended for rapid degrading compounds. - One metabolite, 4'-OH-Pyr, is above the 10% Good recoveries were obtained, average 95.0% AR and 111.9% AR for the biotic and abiotic test. Degradation rate constant was determined with software CAKE and the DT50 of 0.0529 day was obtained via SFO fit for the biotic test. Very fast degradation was best fitted with an SFO fit. A combined degradation rate and DT50 for pyriproxyfen and 4-OH-Pyr was derived and set at 0.107/h at 20°C (DT_{50} is 0.27 d)

Leaching behaviour (ADS)

Leaching tests are not relevant to the proposed use under PT18.

Testing for distribution and dissipation in soil (ADS)

No further data on distribution and dissipation in soil are submitted.

Testing for distribution and dissipation in water and sediment (ADS)

No further data on distribution and dissipation in water and sediment are submitted.

Testing for distribution and dissipation in air (ADS)

No further data on distribution and dissipation in air are submitted.

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)

Not relevant.

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)

The product is not intended to be sprayed outside and a large scale formation of dust will not occur. Clothianidin is, however, a neonicotinoid and therefore potential exposure of Bees has been considered via the soil route. Emission to soil is included due to STP-sludge application.

As clothianidin is a systemic insecticide, it is taken up from soil by plants and exposure to Bees via nectar and pollen is possible, as stated in the Assessment Report for

Clothianidin[3]. There is currently no harmonized scenario available and therefore the assessment has been based on a comparison of the $PNEC_{Bee}$ and the highest PEC_{soil}. As a worst-case approach, it was assumed that the concentration in nectar and pollen is equivalent to the concentration in soil, i.e. a 100% uptake of clothianidin from soil by plants and a 100% transfer in nectar and pollen occurs.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	Crack and crevice treatment – heavy infestation (worst-case)
ESD(s) used	OECD emission scenario document (ESD) for insecticides, acaricides and products to control other arthropods for household and professional uses, 17 July 2008 Technical Agreements for Biocides. European Chemicals Agency, Report no. ECHA-17-R-19-EN, Helsinki, Finland, August 2017.
Approach	Exposure calculated using the worst-case assumption for heavy infestation, i.e. 10 spots per m^2, each spot comprising of approximately 0.032 g bait.
Distribution in the environment	Calculated based on Guidance for BPR IV/B (2017) and SimpleTreat 4.0 with 3.1 setting
Groundwater simulation	None performed as $PEC_{porewater}$ calculated using the equilibrium partitioning method and guidance from AHEE 2019 metabolites in groundwater are <0.1 µg/L
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	None

3 Assessment Report – Clothianidin, Product Type 18 (Insecticides, Acaricides and Products to control other Arthropods), October 2014

Emission estimation

Worst-case assessment for crack and crevice treatment (heavy infestation)

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Heavy infestation			
Application rate of biocidal product	0.032	g per spot	S
Concentration of active substance in the product	0.5	% w/w	S
Number of applications per day per building	1	d^{-1}	D The default for houses is 1. The default for large buildings is 3. For the latter, a value of 1 was used in this assessment, although this should be 3. One could argue that the 10 spots per m^2 already suggests a worst-case value and that an additional 3 applications is overly conservative, but since the 3 application per day per building is EU agreed, this value should be used. An increase from 1 to 3 would results in a 50% increase of the overall emission for this product (houses + large buildings). This increase is not expected to change the outcome of this assessment (see final RQ table).
Number of gel points per meter	10	Spots/m^2	S
Fraction emitted to air	0	-	D
Fraction emitted to applicator	0	-	D
Fraction emitted to treated surface	1	-	D
Area treated with product (house)	2	m^2	D Targeted spot application
Area treated with product (larger building)	9.3	m^2	D* Crack and crevice/ spot
Cleaning efficiency (F_{CE})	0.03	-	D

S= set; D =default;* Based on ECHA WG-II-2018 Item 7.3e: Generic treatment areas assigned to each specific pest (follow up of WG-I-2018)

Calculations for the worst-case assessment for crack and crevice treatment (heavy infestation)

Based on the above assumptions the calculated release to wastewater for each household is 0.096 mg/d and for each large building is 0.446 mg/d.

According to the ESD each STP catchment consists of 10,000 individuals each producing 200 litres of wastewater per day in 4000 households and 300 larger buildings.

As a worst-case it was assumed that 3 to 11 applications per year would be made and thus a simultaneity factor of 0.815% was used to account for simultaneous daily use. Taking these assumptions into account results in the following daily emission of wastewater to the STP.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission (Elocal$_{compartment}$) [kg/d] (each active)**	**Remarks**
STP	4.22E-06	-

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
Crack and crevice heavy infestation	Yes*	Yes*	No	No	Yes	No	Yes*	Yes*	No

*indirect exposure

Clothianidin - Input parameters for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	249.7	g/mol	All inputs taken from the Assessment report for clothianidin (October 2014)
Melting point	176.8	°C	
Vapour pressure (at 20°C)	3.8E-11	Pa	
Water solubility (at 20°C and pH 4)	304	mg/L	
Log Octanol/water partition coefficient (pH 7)	0.905	Log 10	
Organic carbon/water partition coefficient (Koc)	160	L/kg (arithmetic)	
Biodegradability	Not Readily biodegradable		
DT_{50} for biodegradation in surface water and sediment	145.3	d (worst-case at whole system DT50 at 12ºC)	
DT_{50} for hydrolysis in surface water	stable	-	
DT_{50} for photolysis in surface water	23.4	d (at latitude 50°N)	
DT_{50} for degradation in soil	429.8	d (geomean field DT50 at 12ºC)	
DT_{50} for degradation in air (24-hours-mean-day concentration of $5x10^5$ OH radical cm^{-3})	2.8	hr	

Pyriproxyfen - Input parameters for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	321.37	g/mol	All inputs taken from the Assessment report for pyriproxyfen (September 2012)
Melting point	48-50	°C	
Boiling point	318	°C	
Vapour pressure (at 22.81°C)	1.33E-5	Pa	
Water solubility (at 20°C and pH 7)	0.101	mg/L	
Log Octanol/water partition coefficient (pH 7)	4.86	Log 10	
Organic carbon/water partition coefficient (Koc)	21175	L/kg (mean)	
Biodegradability	Not Readily biodegradable		
DT_{50} for biodegradation in surface water	12.3	d (geomean at 12ºC)	
DT_{50} for biodegradation in sediment	34.2	d (geomean at 20ºC)	
DT_{50} for hydrolysis in surface water	Stable	-	
DT_{50} for photolysis in surface water	5	d	
DT_{50} for degradation in soil	14.8	d (geomean at 12ºC)	
DT_{50} for degradation in air 24-hours-mean-day concentration of $5x10^5$ OH radical cm^{-3}	0.307	d	

Rate constant for biodegradation in STP	0.107	h-1	Inputs taken from [redacted] (OECD 314B study)

Metabolites of Pyriproxyfen - Input parameters for calculating the fate and distribution in the environment					
Input	**Value**			**Unit**	**Remarks**
	4'-OH-Pyr#	**DPH-Pyr**	**PYPAC**		
Molecular weight	337.4	245.3	167.2	g/mol	All inputs taken from the Assessment report for pyriproxyfen (September 2012)
Vapour pressure (at 25°C)	1.05E-7	1.77E-4	7.77E-2	Pa	
Water Solubility (at 25°C)*	1.4	-¤	65000	mg/L	
Henry's law constant (at 25°C)	-	-	2.0E-4	Pa m^3 mol^{-1}	
Organic carbon/water partition coefficient (Koc)	2598	9620*	20.7	L/kg (mean)	
DT_{50} for biodegradation in surface water$	5.9	n.d.	51	d (geomean at 12ºC)	
DT_{50} for biodegradation in sediment	24.9	n.d.	25.5	d (geomean at 20ºC)	
DT_{50} for biodegradation in soil$	65.4	n.d.	12.9	d (at 12ºC)	

\# For comparison purposes only. 4'-OH-Pyr was combined with the parent in the risk assessment.
* Obtained from Document IIB of the CAR.
¤ No experimentally determined value is available. Value of the parent used in the CAR.
$ Obtained from Document IIA of the CAR.

Metabolites in STP and subsequent aquatic environment

As discussed in Section 2.2.8.1 further studies on fate and behaviour, an OECD 314B study on biodegradation in activated sludge of the active substance pyriproxyfen was conducted.

In the study, three metabolites were found: 4-OH-Pyr, DPH-Pyr and PYPAC. The transformation goes via 4-OH-pyriproxyfen into DPH-PYR and eventually into PYPAC. Considering that pyriproxyfen and hydroxypyriproxyfen (4-OH-Pyr) have the same fate and toxicological properties, the half-life was derived for the sum of the parent and the metabolite.

Combined Pyriproxyfen and 4-OH-Pyr - Input parameter for calculating the fate and distribution in the environment			
Value		**Unit**	**Remarks**
Rate constant for biodegradation in STP	0.107	h-1 (20°C)	Inputs taken from [redacted] (OECD 314B study)

Calculated fate and distribution in the STP			
Compartment	**Percentage [%]**		**Remarks**
	Clothianidin	**Combined Pyriproxyfen and 4-OH-PYR***	
Air	3.86E-11	0.05 (0.004)	Calculated with SimpleTreat
Water	98.0	21.98 (2.65)	
Sludge	1.96	64.24 (51.10)	
Degraded in STP	0	13.72 (46.28)	

* Breakdown in the STP is calculated using Simple Treat 4.0 with 3.1 settings using the input data, half-life value, temperature. Values between brackets is the resulting distribution based on the OECD 314B test.

The first metabolite of concern is consequently DPH-Pyr.
For the calculation of the metabolite PECs in surface water, it is assumed that the entire fraction of pyriproxyfen that is degraded in the STP (13.72%) results in the formation of DPH-Pyr, i.e.:

$$Elocal_{water\_TP} = Elocal_{water\_Parent} * F_{STP\ degraded} * f_{ij} * \frac{Mass_{molar_{TP}}}{Mass_{molar_{Parent}}}$$

Symbol	Description	Unit
$Elocal_{water\_TP}$	local emission rate of transformation product	[kg d^{-1}]
$Elocal_{water\_Parent}$	local emission rate of parent substance	[kg d^{-1}]
$F_{STP,\ degraded}$	fraction of parent substance degraded in STP	[-]
f_{ij}	formation fraction of transformation product set to 1 as first tier worst case.	[-]
$Mass_{molarTP}$	molecular mass of transformation product	[g mol^{-1}]
$Mass_{molarParent}$	molecular mass of parent substance	[g mol^{-1}]

Since no information is available on the distribution between water, sediment and sludge, it is assumed that all mass goes to water (effluent STP). The amount of metabolite was derived from the parent's release (4.22 mg/d) according to aforementioned equation.
The metabolite concentrations in the effluent (PEC_{STP}) were calculated by applying a volume of 2000 m^3/d. The PEC for surface water was derived by applying the dilution factor of ten and corrected for sorption onto suspended matter. DPH-Pyr and PYPAC were considered in the risk assessment. No sediment PECs are calculated, because both PECs and PNECs for the metabolites are based on equilibrium partitioning, which would result in similar PEC/PNEC ratios for the water and sediment compartment.

The study on degradation in soil (Section 2.2.8.1) indicates that the metabolites 4'-OH-Pyr, DPH-Pyr, and PYPAC are formed in soil. For the calculation of the PEC values of the metabolites in soil, it is assumed that the applied STP sludge only contains the parent pyriproxyfen and no metabolites. In addition, the metabolites are less hydrophobic than the parent and therefore are less likely to settle in the sludge. Hence, the metabolite formation in soil is considered to be more important than the metabolite formation in the STP sludge for metabolite levels in soil.

For the calculation of the PEC values of the metabolites in soil, AHEE 2019 guidance was implemented using the concentration in sludge of the parent as starting point multiplied

with the molar weight ratio and formation fraction. As a worst-case approach formation fraction is set at 1.

Concentrations in groundwater have been calculated in accordance with the guidance and the parameters used are stated elsewhere in the PAR.

Calculated PEC values

Sewage treatment plant (STP)

	PEC_{STP}
	[mg/L]
Clothianidin	2.07E-06
Pyriproxyfen including 4-OH-PYR	4.64E-07

Aquatic compartment

	PEC_{water}	**PEC_{sed}**
	[mg/L]	[mg/kg_{wwt}]
Clothianidin	2.07E-07	8.81E-07
Pyriproxyfen including 4OH-PYR	4.50E-08	2.07E-05

Terrestrial compartment

PEC_{soil} after 10 sludge applications is based on the degradation rate of clothianidin in soil (DT_{50}=429.8d) and the leaching rate on agricultural soils (k=0.00048), which leads to an accumulation factor (Facc) of 0.47. $PEC_{initial}$ is the concentration in soil after a single sludge application. The long-term soil concentrations after 10 years of sludge application are presented as the initial concentration (immediately after the last sludge application) and as the TWA concentration (30 days after the last sludge application). Because the PNEC is based on studies with a single exposure, the TWA PEC is not used in further calculations.

	$PEC_{initial\_0}$	**PEC_{soil_10} after 10 sludge applications $PEC_{initial}$**	**PEC_{soil_10} after 10 sludge applications PEC_{TWA30d}**
	[mg/kg wwt]	[mg/kg wwt]	[mg/kg wwt]
Clothianidin	1.54E-07	**2.88E-07**	2.79E-07
Pyriproxyfen including 4'-OH-PYR	4.91E-06	**4.91E-06**	4.91E-06

Non target arthropods (Bees)

In line with the CAR for Clothianidin[4], as clothianidin is a systemic insecticide and has been shown to be highly toxic to Bees, a risk assessment for Bees was performed. As currently no harmonized scenario is available, the assessment was based on a comparison of the $PNEC_{Bee}$ and the PEC_{soil}. As a worst-case approach, it was assumed that the concentration in nectar and pollen is equivalent to the concentration in soil, i.e. a 100% uptake of clothianidin from soil by plants and a 100% transfer in nectar and pollen occurs. For the assessment, the highest PEC_{soil} value was used.

	PEC_{Bee}
	[mg/kg wwt]
Clothianidin	2.88E-07*
Pyriproxyfen	n/a

*Based on PECsoil after 10 sludge applications.

Groundwater

	PEC_{GW}
	[µg/L]
Clothianidin	9.49E-05
Pyriproxyfen including 4'-OH-PYR	7.05E-06

PECs for the metabolites of pyriproxyfen in the various compartments have been calculated by adjusting the relevant PEC for the parent compound for the maximum observed fraction formed in the relevant compartment in the environmental fate studies and the molecular weight ratio of parent and metabolite:

PEC metabolite = PEC parent * Fij * (molecular weight metabolite/molecular weight parent).

Summary table of calculated PEC values for the metabolites of pyriproxyfen		
	PYPAC	**DPH-Pyr**
PECwater (mg/L)	1.51E-08	2.18E-08
PECsoil (mg/kg wwt)	3.89E-06	3.34E-05
PECgw (µg/L)	7.71E-03	1.69E-03

Primary and secondary poisoning

Primary poisoning

Primary poisoning is not expected for the intended use. Hence the product meets the standards for the risk to birds and mammals.

Secondary poisoning

[4] Assessment Report Clothianidin, Product-type 18 (Insecticides, Acaricides and Products to control other Arthropods), October 2014, Germany

The risk of bioaccumulation and subsequently secondary poisoning for clothianidin is considered to be negligible based on the low Log Kow (0.905) and calculated BCFs (BCF fish 0.78 L/kg wwt and BCF earthworm 0.9 L/kg wwt).
Concentrations in fish and earthworms were calculated for pyriproxyfen. $PEC_{oral,predator}$ for the aquatic environment was based on a measured BCF of 581 L/kg wet fish, the biomagnification factor (BMF = 2) for compounds with a log K_{ow} between 4.5 and 5, and the PEC water (3.42E-08 mg/L). The PEC for worm-eating birds and mammals was based on a BCF of 870 L/kg wwt calculated from the active substance's log Kow, the PECsoil TWA 30d (2.51E-6 mg/kgwwt), and an equilibrium partitioning-derived concentration in porewater (6.72E-06 mg/L).
The $PEC_{oral, predator}$ in earthworms and fish for pyriproxyfen are given below.

Summary table of residues in Fish and Earthworms for pyriproxyfen	
	$PEC_{oral, predator}$
	[mg/kg wwt]
Fish	5.23E-05
Earthworms	5.51E-03

2.2.8.3 Risk characterisation

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Clothianidin	<0.001
Pyriproxyfen	<0.001

Conclusion: The PEC/PNEC ratios for both active substances are significantly below one demonstrating an acceptable risk to STP microorganisms for both compounds.

Aquatic compartment

Summary table on calculated PEC/PNEC values				
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
Clothianidin	3.00E-03	3.00E-03	n/a	n/a
Pyriproxyfen including 4'-OH-Pyr	0.015	0.015	n/a	n/a

n/a – not applicable.

PEC/PNEC ratios have also been calculated for the major metabolites of pyriproxyfen (detected at >10%) in the water and/or sediment phases in the environmental fate studies). The PEC/PNEC ratios are given below.

Summary table on calculated PEC/PNEC values for the metabolites of pyriproxyfen				
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
PYPAC	<0.001	n/a	n/a	n/a
DPH-Pyr	<0.001	n/a	n/a	n/a

n/a – not applicable

Conclusion: PEC/PNEC ratios for clothianidin, pyriproxyfen and metabolites of pyriproxyfen are below 1 demonstrating an acceptable risk to the aquatic compartment.

Terrestrial compartment

Calculated PEC/PNEC values	
	PEC/PNEC $_{soil}$
Clothianidin	<0.001
Pyriproxyfen including 4'-OH-Pyr	0.004

Calculated PEC/PNEC values	
	PEC/PNEC $_{soil}$
PYPAC	<0.001
DPH-Pyr	<0001

Non target arthropods (Bees)

The highest PEC_{soil} value was used to assess the risk of clothianidin to Bees. Pyriproxyfen is not a relevant substance for NTA assessment. The highest PEC_{soil} value is 4.68E-06 mg/kg wet wt soil. This corresponds to 4.68E-03 µg/kg wet wt. As described in the section *Calculated PEC values* this value was directly compared to the $PNEC_{Bee}$ ($PNEC_{Bee}$ of 14.6 µg a.s./kg nectar/pollen).

The calculated PEC/PNEC values for bees are below one (<0.001), therefore, it can be concluded that sewage sludge application contaminated with clothianidin to agricultural land will pose no risk to Bees exposed to clothianidin *via* nectar and pollen.

Conclusion: The soil PEC/PNEC ratios for both active substances are below one demonstrating an acceptable risk to soil organisms for both compounds. The risk of clothianidin to Bees is acceptable.

Groundwater

The PECgw for clothianidin and pyriproxyfen and metabolites DPH-pyr and PYPAC are 9.49E-05 µg/L and 6.72E-06 µg/L, 1.69E-03 and 7.71E-03 µg/L, respectively. All are significantly below the threshold of 0.1 µg/L and thus the risk to groundwater is considered to be low.

Primary and secondary poisoning

Primary poisoning

It is expected that birds and mammals are not directly exposed to (residues of) *Pesguard®* Gel as the product is used indoor and the secondary exposure is only possible in case the STP sludge is spread on agricultural soil as a fertilizer.

Secondary poisoning

Summary table on secondary poisoning for pyriproxyfen		
Scenario	**$PEC_{oral,\ predator}$ (mg/kg wwt)**	**PEC/PNEC**
fish-eating birds	5.23E-05	< 0.001
fish-eating mammals	5.23E-05	< 0.001
worm-eating bird	5.51E-03	< 0.001
worm-eating mammals	5.51E-03	< 0.001

Conclusion: The risk of bioaccumulation and subsequently secondary poisoning for clothianidin is considered to be negligible based on the low Log K_{ow} (<1) and calculated BCFs (also <1). PEC/PNECs for pyriproxyfen are significantly below 1 demonstrating an acceptable risk for secondary poisoning of birds and mammals.

Mixture toxicity

The product contains two active substances and therefore a mixture toxicity assessment according to the Transitional Guidance on mixture toxicity assessment for biocidal products for the environment (ECHA 2014) is required.

Screening step

Screening Step 1: Identification of the concerned environmental compartments

It is possible that all compartments for which PECs have been calculated may be exposed to both active substances.

Screening Step 2: Identification of relevant substances

The only substances within the product that fulfil the criteria given in Section 3.2.2 of the ECHA guidance are the active substances clothianidin and pyriproxyfen, both present in the formulation at a concentration of 0.5% w/w.

Screening Step 3: Screen on synergistic interactions

Clothianidin and pyriproxyfen are different classes of chemicals having differing modes of action. Clothianidin is a neonicotinoid insecticide and acts agonistically on insect

nicotinic acetylcholine receptors located in the central nervous system. Whereas pyriproxyfen is an insect growth regulator and acts as a juvenile hormone analogue (or mimic), interrupting the insect morphogenesis. It prevents (depending upon the time of application) egg hatching, metamorphosis of larvae into pupae, and pupae into adult.

Based on the differing modes of action synergism is considered unlikely and no synergistic effects have been reported. Neither substance fulfils any of the criteria given in Section 3.2.3 of the ECHA guidance. Synergistic effects are therefore considered unlikely.

Screening step	
	Significant exposure of environmental compartments? (Y/N) Y
	Number of relevant substances >1? (Y/N) Y
	Indication for synergistic effects for the product or its constituents in the literature? (Y/N) N

Tiered approach

Large amounts of data are available for both active substances. The datasets are not identical therefore the ECHA guidance recommends that a Tier 2 assessment is performed for all compartments. However, the assessment scheme proposed in the ECHA guidance was adapted in order to target the higher tier risk assessment towards any compartments which may be of concern and an initial conservative Tier 1 assessment has been performed for all compartments.

Tier 1. PEC/PNEC summation

	Tier 1				
Compartment	**RQ clothianidin**	**RQ pyriproxyfen**	**RQ product**	**Acceptable risk for the environment? (Y/N)**	**Remarks**
Surface water	3.00E-03	1.5E-02	1.8E-02	Y	
Sediment	3.00E-03	1.5E-02	1.8E-02	Y	Equilibrium partitioning method used to define PNEC for both active substances
STP	<0.001	<0.001	<0.001	Y	
Soil	<0.001	0.004	0.004	Y	
Bees	<0.001	-	<0.001	Y	Clothianidin only, Bees are not exposed to pyriproxyfen
Groundwater	< 0.001	< 0.001	< 0.001	Y	
Secondary poisoning of birds and mammals	-	< 0.001	< 0.001	Y	Only pyriproxyfen relevant for secondary

					poisoning assessment.

Conclusion: Based on the conservative Tier 1 assessment above, an acceptable risk is identified for all compartments, for bees and for secondary poisoning of birds and mammals.

Aggregated exposure (combined for relevant emission sources)

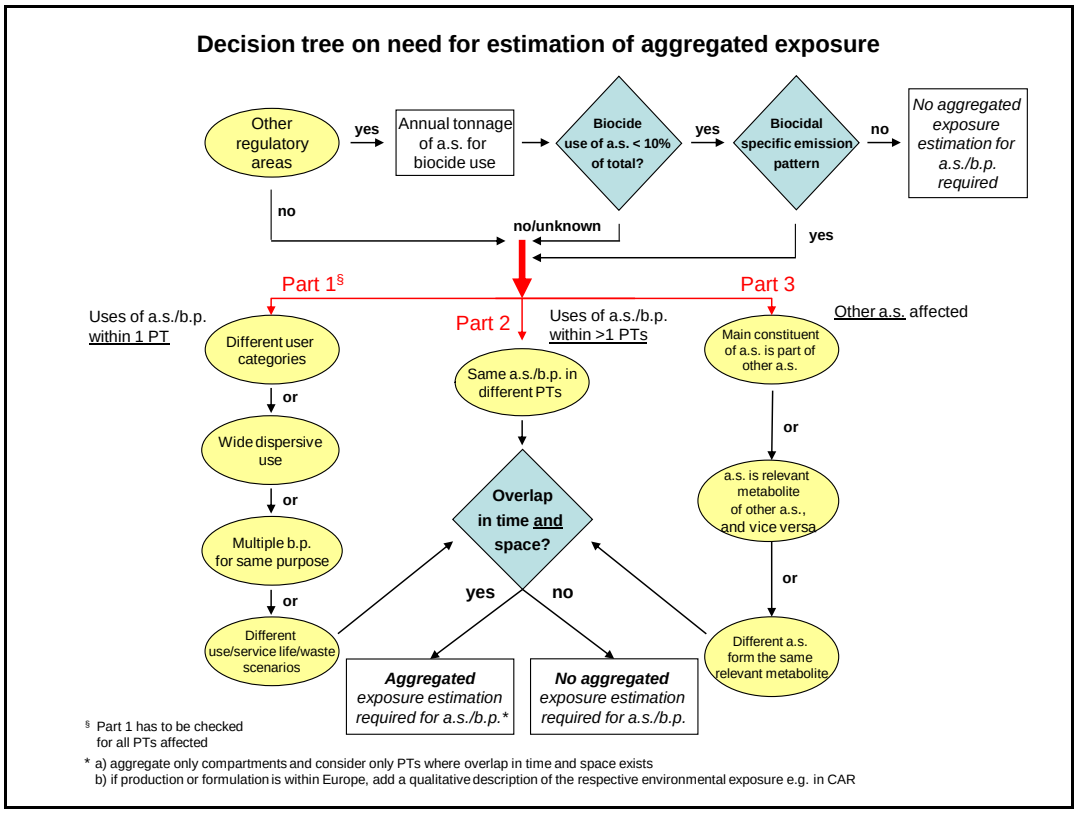

Figure 1: Decision tree on the need for estimation of aggregated exposure

Description:

Clothianidin and pyriproxyfen are also authorized according to the Regulation No. 1107/2009 concerning the placing of plant protection products on the market. Clothianidin and pyriproxyfen are mainly used in biocidal products in the EU. These products are used in different areas, therefore there is no overlapping use of the products.

Decision steps:

Other regulatory areas(?): Yes

Biocide use of a.s. < 10 %? No

Different user categories(?):Yes

Overlap in time and space(?): No

Conclusion: No aggregated exposure estimation required

Conclusion: No aggregated exposure estimation required based on the decision tree analysis.

Overall conclusion on the risk assessment for the environment of the product
Based on the above assessment it can be concluded that the use of *Pesguard®* Gel as proposed presents an acceptable risk to the environment.

2.2.9 Measures to protect man, animals and the environment

Please refer to summary of the product assessment (SPC) and to the relevant sections of the assessment report.

2.2.10 Assessment of a combination of biocidal products

Not relevant as Pesguard® Gel is not intended to be used with other products therefore no combined assessment is necessary.

2.2.11 Comparative assessment

2.2.11.1 Background

Under Article 23(1) of Regulation 528/2012 Member States evaluating biocidal products containing an active substance that is a candidate for substitution (CfS) in accordance with Article 10(1) are required to perform a comparative assessment.

Pesguard gel contains the candidate for substitution Clothianidin in combination with Pyriproxyfen (which is not a candidate for substitution).

The approach in the most recently endorsed EU guidance on the comparative assessment of the biocidal product was used. In line with this Note for Guidance, the comparative assessment was begun with the screening phase (Annex 7.1 of guidance document) to identify whether the diversity of the active substances - mode of action combination in authorised biocidal products, is adequate.

2.2.11.2 Screening phase of comparative assessment

The first step in comparative assessment is to perform an assessment of the existing chemical diversity in authorised biocidal products to minimise the occurrence of resistance.

2.2.11.2.1 Intended use of the biocidal product and properties of active substances

Article 23(3) and the Note for Guidance focus the comparative assessment on 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 arthropods.
Where relevant, an exact description	Insecticide

of the authorised use	
Target organism (including, where relevant) development stage)	• German cockroach *(Blattella germanica)*- • Brown banded cockroach *(Supella longipalpa)* • American cockroach *(Periplaneta americana)* • Oriental cockroach *(Blatta orientalis)* Developmental stages: Adults/nymphs
Field(s) of use	Indoor
Application method(s)	Bait application (RTU)
Category(ies) of users	Professional

As shown in table 1, the biocidal product Pesguard gel, containing Clothianidin and Pyriproxyfen, is intended for use as a bait to control 4 cockroach species by professional users indoors.

2.2.11.2.2 Chemical diversity of the active substances - mode of action combination in authorised biocidal products

The IRAC (Insecticide Resistance Action Committee) has provided information on the potential for resistance; which has also been derived from experience with plant protection products.

As a general rule (CA-May15-Doc.4.3.a-Final) three different and independent active substance/mode of action combinations are needed to consider that diversity is adequate.
To check whether three or more of these combinations are already authorized Pesguard gel is compared with other authorized products in PT18 against cockroaches. According to the information available to the NL CA via the ECHA website, there are 66 biocidal products against cockroaches (as of November 11th 2019) authorised in the EU under Product Type 18 (Insecticides, acaricides and products to control other arthropods) of the Biocidal Products Directive and Biocidal Products Regulation (including Mutual Recognitions and Same Product authorisations).
These products are based on 17 different active substances with 6 different modes of action (based on the IRAC classification of Mode of Action).
However, when specifying further for products against Brown banded Cockroaches (*Supella longipalpa*) for use indoor by professionals only 13 products are authorised, based on 5 different active substances with 2 different Modes of Action.

Pesguard gel contains 2 active substances. The mode of action of Clothianidin is one of the 2 MoA which are already authorised (see table 2). However, Pyriproxyfen has a different mode of action and as such, Pesguard gel provided the third active substance/mode of action combination needed for adequate diversity of biocidal products against a target species.

Table 2: Mode of action for PT18 insecticidal active substances in biocidal products authorised for Professionals against Brown banded cockroaches.

Active substance	**List**	**Mode of action (IRAC)**
Imidacloprid / **Clothianidin**	*4.a. Neonicotinoid*.	**Nicotinic acetylcholine receptor (NACHR)competitive modulator** Bind to the acetylcholine site on nAChRs, causing a range of symptoms from hyperexcitation to lethargy and paralysis. Acetylcholine is the major excitatory

		neurotransmitter in the insect central nervous system.
Fipronil	*2.b. Phenylpyrazoles*	**GABA gated chloride channel blockers** Block the GABA-activated chloride channel, causing hyperexcitation and convulsions. GABA is the major inhibitory neurotransmitter in insects.
Pyriproxyfen	*7.c. Pyriproxyfen*	**Juvenile hormone Mimics** Applied in the pre-metamorphic instar, these compounds disrupt and prevent metamorphosis.

The specified use for Pesguard gel in this application is Cockroach bait for professional use.
In addition to Imidacloprid and Fipronil, it can be seen that Clothianidin in combination with Pyriproxyfen is a key alternative active substance combination, providing a non-phenylpyrazoles, partly non-neonicotinoid choice of alternative for use as Cockroach bait against e.g Brown banded Cockroaches for Professionals to avoid resistance.

Therefore, the NL CA concludes that there is not an adequate chemical diversity and in line with Article 23(3)(b) and according to the Note for Guidance no further investigation is needed at this point. As such, the comparative assessment for Pesguard gel can be finalised at the screening stage and the application taken forward to product authorisation in accordance with Article 23(6) of BPR.

3 Annexes

3.1 List of studies for the biocidal product

Author	Year	Title	Testing laboratory	Report no.	Legal entity owner	Report date	Endpoint names	GLP	Published/ Unpublished	Data Protection Claimed
[redacted]	[redacted]	Bio-efficacy evaluation of cockroach gel baits against male American cockroaches (Choice test method)	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Efficacy data to support these claims.006 [redacted]	No	Unpublished	Yes
[redacted]	[redacted]	[redacted] Primary Skin Irritation in Rabbits	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Skin irritation / corrosion [redacted]	Yes	Unpublished	Yes
[redacted]	[redacted]	[redacted] Primary Eye Irritation in Rabbits	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Eye irritation [redacted]	No	Unpublished	Yes
[redacted]	[redacted]	[redacted]: Dermal Sensitization Test in Guinea Pigs - Buehler Method	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Skin sensitisation [redacted]	Yes	Unpublished	Yes
[redacted]	[redacted]	[redacted] Acute Oral Toxicity - Up-And-Down Procedure In Rats	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Acute toxicity: oral [redacted]	No	Unpublished	Yes
[redacted]	[redacted]	[redacted]: Acute Dermal Toxicity in Rats	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Acute toxicity: dermal [redacted]	No	Unpublished	Yes

Author	Year	Title	Testing laboratory	Report no.	Legal entity owner	Report date	Endpoint names	GLP	Published/ Unpublished	Data Protection Claimed
[redacted]	[redacted]	Laboratory bioassay to determine the efficacy of X [redacted] against brown banded and American cockroaches	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Efficacy data to support these claims.001 (Supella longipalpa and Periplaneta americana), Hostetler (2015) TNsG PT18	Yes	Unpublished	Yes
[redacted]	[redacted]	Product Chemistry and Characterization of [redacted]	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Acidity, alkalinity _ Jeffries D.A. (2015)	Yes	Unpublished	Yes
[redacted]	[redacted]	Analytical Support for [redacted]	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Methods of detection and identification_Jeffries D.A. (2016)	Yes	Unpublished	Yes
[redacted]	[redacted]	Product Chemistry and Characterization of [redacted]	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Appearance (at 20°C and 101.3 kPa) _ Jeffries D.A. (2015) Relative density (liquids) and bulk, tap density (solids) _ Jeffries D.A. (2015) Explosives (4.1) _ Jeffries D.A. (2015) Flammability solids (4.7)_ Jeffries D.A. (2015) Oxidising solids (4.14)_ Jeffries D.A. (2015)	No	Unpublished	Yes
[redacted]	[redacted]	Accelerated Storage Stability Study of Cockroach Bait Sample ([redacted])	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Storage stability tests (Mahidon M., 2015)	No	Unpublished	Yes

Author	Year	Title	Testing laboratory	Report no.	Legal entity owner	Report date	Endpoint names	GLP	Published/ Unpublished	Data Protection Claimed
[redacted]	[redacted]	Determination of the Biodegradability of [14C]Pyriproxyfen in Activated Sludge Based on OECD Method 314B	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Additional information on environmental fate and behaviour_McLaughlin S.P. (2015)	Yes	Unpublished	Yes
[redacted]	[redacted]	Bio-efficacy evaluation of cockroach gel baits against German cockroaches (Choice test method)	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Efficacy data to support these claims.004 (Blattella germanica), Serit (2015) TNsG PT18	No	Unpublished	Yes
[redacted]	[redacted]	Field trial investigating the efficacy of an Insecticidal bait treatment to control German and Oriental cockroaches	[redacted]	[redacted]	Sumitomo Chemical (UK) Plc	[redacted]	Efficacy data to support these claims.004 Field trial (Blattella germanica and Blatta orientalis) Serrano (2015)_TNsG PT18	No	Unpublished	Yes
[redacted]	[redacted]	Developmental abnormalities induced by pyriproxyfen containing cockroach bait in nymphal German cockroaches, Blattella germanica	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Efficacy data to support these claims.002 (Blattella germanica), Suranyi (2015a)_TNsG PT18	No	Unpublished	Yes
[redacted]	[redacted]	Laboratory efficacy evaluation of [redacted] against German cockroaches, Blattella germanica	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Efficacy data to support these claims.003 (Blattella germanica), Suranyi (2015b)_TNsG PT18	No	Unpublished	Yes
[redacted]	[redacted]	Field trial investigating the efficacy of an insecticidal bait treatment to control American and brown-banded cockroaches	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Efficacy data to support these claims.007_Field Study_Supella longipalapa and Peripalneta Americana_Serrano (2017a)_TNsG PT18	No	Unpublished	Yes

Author	Year	Title	Testing laboratory	Report no.	Legal entity owner	Report date	Endpoint names	GLP	Published/ Unpublished	Data Protection Claimed
[redacted]	[redacted]	Field trial investigating the efficacy of an insecticidal bait treatment to control German cockroaches	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Efficacy data to support these claims.008_Field Blattella germanica_Serrano (2017b)_TNsG PT18	No	Unpublished	Yes
[redacted]	[redacted]	Laboratory bioassay to determine the palatability and efficacy of an insecticidal bait against cockroach species	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]		No	Unpublished	Yes
[redacted]	[redacted]	Storage Stability Evaluation of [redacted]	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Storage stability tests-accelerated	Yes	Unpublished	Yes
[redacted]	[redacted]	Storage Stability Evaluation of [redacted]	[redacted]	[redacted]	Sumitomo Chemical (U.K.) Plc	[redacted]	Storage stability tests _ long-term	Yes	Unpublished	Yes

3.2 Output tables from exposure assessment tools

3.3 New information on the active substance

The proposed PAR and IUCLID includes a new study assessing biodegradability of pyriproxyfen in activated sludge (OECD 314B). A study summary and the study report are contained within both the product IUCLID dossier and the active substance IUCLID dossier for Pyriproxyfen.

3.4 Residue behaviour

Not applicable.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

Please refer to IUCLID Section 6.7 and section 2.2.5.5 of the PAR.