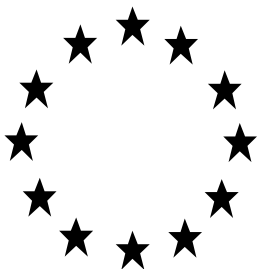
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Clothianidin RB 1

(MaxForce Platin)

Product type 18

Clothianidin, as included in the Union list of approved active substances

Case Number in R4BP: BC-NH027167-40

Evaluating Competent Authority: Belgium

Date: 21/05/2019

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1 CONCLUSION

BE considers that the product Clothianidin RB1/Maxforce Platin, formulated by Bayer S.A.S., with the active substance Clothianidin concentrated at 1 % w/w may be authorized as insecticidal product (PT18) under the following conditions :

- Application rate : 0.1 - 0.3 g /m²
- Application method : A ready to use insecticidal gel bait applied using cartridge and syringe
- Field of use : indoor use by professionals only in public or residential buildings, food handling /storage premises, small scale animal housing (only building, feed handling and storage premises, excluding stables, animal pens and cages where animals are located)

The conclusions of each assessment are summarized below :

The biocidal product is a white gel with blue dots, with weak cereal odour.

Based on the long term storage study at ambient temperature the product is stable during 5 years at 20°C.

The packaging of the biocidal product must be light-proof.

No classification related to physico-chemical risks is necessary.

According to the field tests provided by the Applicant, the product used as a RTU gel bait (fresh/stored 5 years at ambient temperature) is efficacious against :

- Nymph and adult German cockroaches (*Blatella germanica)* :
  - at 0.1 g/m^2 in case of moderate infestation (i.e. when cockroaches are not visible during the day)
  - at 0.2 g/m^2 in case of more severe infestation (i.e. when cockroaches are visible during the day) using 2 spots of 0.1 g/m^2 (i.e. 0.1 g ⇔ 7 mm diameter drop)
- Nymph and adult oriental cockroaches (*Blatta orientalis)* : at 0.2 g/m^2 using 2 spots of 0.1 g/m^2 (i.e. 0.1 g ⇔ 7 mm diameter drop)
- Nymph and adult American cockroaches *(Periplaneta americana*)
  - at 0.2 g/m^2 in case of moderate infestation (i.e. when cockroaches are not visible during the day) using 2 spots of 0.1 g/m^2 (i.e. 0.1 g ⇔ 7 mm diameter drop)
  - at 0.3 g/m2 in case of severe infestation (i.e. when cockroaches are visible during the day) using 3 spots of 0.1 g/m2 (i.e. 0.1 g ⇔ 7 mm diameter drop)-

According to the field tests provided by the Applicant, the product used as a RTU gel bait (fresh) is efficacious against :

Grey silverfishes (*Ctenolepisma longicaudatum*) at 0.1422 g/m² (0.1g ≈ 7 mm diameter drop)

After cMS commenting it was decided that overall shelf life is restricted to 2 years for reasons of ensuring efficacy against all claimed species.

With regard to human toxicology no classification concerning local effects is required. Nevertheless, the biocidal product contains 1,2-benzisothiazolin-3-one and the reaction mass of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1). The additional label element EUH208 to protect already sensitised individuals is triggered by the concentration of C(M)IT/MIT and BIT exceeding one tenth of the specific concentration limit for C(M)IT/MIT and BIT, respectively.

The risk assessment for human health shows that no unacceptable risk is anticipated for the professional user of the biocidal product even if unprotected. However, according to good occupational practice and taking into account the additional label element EUH208 it is recommended that protective gloves are worn.

No unacceptable risk is anticipated for the general public with the intended use of the biocidal product

The product Clothianidin RB 1 requires an environmental classification as "Aquatic Chronic 1 – H410" (Very toxic to aquatic life with long-lasting effects) due to the toxicity and the concentration of the active substance clothianidin.

No unacceptable effect to the environment is expected from the use of the product, neither for the aquatic compartment (STP, water and sediments), nor for the terrestrial compartment. Exposure of the atmosphere is considered to be negligible. No unacceptable risk of secondary poisoning of honeybees following contaminated sludge application is to be expected. No unacceptable risk to the groundwater is expected and the requirements of Directive 98/83/EC and 2006/118/EC are complied with.

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**
MAXFORCE PLATIN	Austria
MAXFORCE PLATIN	Belgium
MAXFORCE PLATIN	Croatia
MAXFORCE PLATIN	Bulgaria
MAXFORCE PLATIN	Slovenia
MAXFORCE PLATIN	France
MAXFORCE PLATIN	Germany
MAXFORCE PLATIN, SOLFAC GEL SCARAFAGGI NF	Italy
MAXFORCE PLATIN	Luxemburg
MAXFORCE PLATIN	Portugal
MAXFORCE PLATIN	Spain
MAXFORCE PLATIN	Switzerland
MAXFORCE PLATIN	United Kingdom
MAXFORCE PLATIN	Ireland
MAXFORCE PLATIN	Netherlands
MAXFORCE PLATIN	Greece
MAXFORCE PLATIN	Denmark
MAXFORCE PLATIN	Norway
MAXFORCE PLATIN	Sweden

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Bayer CropScience SA-NV
	Address	J.E. Mommaertslaan 14 1831 Diegem (Machelen) BELGIUM
Authorisation number		
Date of the authorisation		

Expiry date of the authorisation	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Bayer S.A.S.- Division Crop Science
Address of manufacturer	16 Rue Jean-Marie Leclair 69266 Lyon Cedex 09 France
Location of manufacturing sites	Bayer CropScience France SAS - Site Marle Z.I. Antoine Laurent de Lavoisier F-02250 Marle-sur-Serre France
	Norbert/ Jacobson Co. 3060 Southpark Blvd. 30294 Ellenwood Georgia, USA.

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

Active substance	Clothianidin
Name of manufacturer	Bayer AG (Art. 95 List: BAYER S.A.S)
Address of manufacturer	Alfred-Nobel-Str. 50 40789 Monheim am Rhein Germany
Location of manufacturing sites	Bayer AG ChemPark, 41538 Dormagen Germany

2.1.2 Product (family) composition and formulation

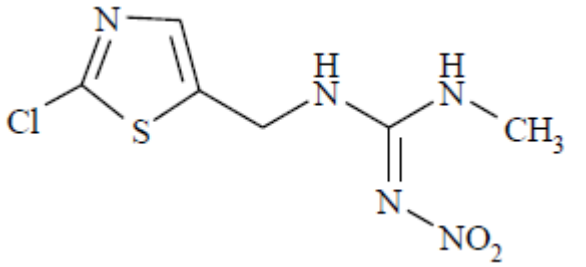
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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	97.5%
Structural formula	

2.1.2.2 Candidate(s) for substitution

According to the BPC opinion for clothianidin this substance is considered to be very persistent (vP) and toxic to aquatic life (T) but not bioaccumulative (B). This opinion states that clothianidin is considered as a candidate for substitution using the criteria in Article 10(1)(d). Clothianidin does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

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

The full composition of the biocidal product, including the non-active ingredients is provided in R4BP and in the Confidential Annex to this PAR.

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Clothiandin	(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine	Active substance	210880-92-5	433-460-1	1.026 (technical content) 1.000 (pure content)
		Non-active substance			

2.1.2.4 Information on technical equivalence

Technical equivalence under Article 54(4) Regulation (EU) No 528/2012 was confirmed for the source of the active substance clothianidin (CAS No 210880-92-5) contained in the biocidal product (decision no: TAP-D-1213732-33-00/F).

2.1.2.5 Information on the substance(s) of concern

Please see the confidential annex for further details.

2.1.2.6 Type of formulation

RB - Bait (ready for use)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Aquatic Chronic cat. 1
Hazard statement	H410 : Very toxic to aquatic life with long lasting effects.
Additional hazard statement	EUH208: Contains 1,2-benzisothiazolin-3-one and 5-chloro-2-methyl-isothiazol-3-one/2-methyl-isothiazol-3-one. May produce an allergic reaction.
Labelling	
Signal words	Warning
Pictogram	GHS09
Hazard statements	H410 : Very toxic to aquatic life with long lasting effects.
Precautionary statements	P273 Avoid release to the environment P391 Collect spillage P501 Dispose contents/container in accordance with all local, national and international regulations
Additional hazard statement	EUH208: Contains 1,2-benzisothiazolin-3-one and 5-chloro-2-methyl-isothiazol-3-one/2-methyl-isothiazol-3-one. May produce an allergic reaction.
Note	EUH208: Contains 1,2-benzisothiazolin-3-one and 5-chloro-2-methyl-isothiazol-3-one/2-methyl-isothiazol-3-one. May produce an allergic reaction.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – – Cockroach and silverfishes – Professional users - Indoor	
Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	*Blattella germanica* (German cockroaches) *Blatta orientalis* (Oriental Cockroaches) *Periplaneta Americana* (American Cockroaches) *Ctenolepisma longicaudatum* (grey silverfishes)
Field of use	A ready to use insecticidal gel bait for the control of cockroach nymphs and adults. For use indoors : • Domestic premises • Food Handling /storage premises • Public buildings • Small Scale Animal Housing i.e. zoos, pet shops, kennels, veterinary practices, laboratory animal houses etc. (only building, feed handling and storage premises, excluding stables, animal pens and cages where animals are located).
Application method(s)	Bait application
Application rate(s) and frequency	Based on the efficacy tests submitted and validated, the product MAXFORCE® PLATIN (RTU gel bait with 1% Clothianidin) can be granted with the following use conditions : 1) Against small cockroaches i.e. nymph and adult German cockroaches (*Blattella germanica*): • at 0.1 g/m^2 (moderate infestation i.e. German cockroaches rarely visible during the day). • at 0.2 g/m^2 (severe infestation i.e. German cockroaches commonly visible during the day) using 2 spots of 0.1 g/m^2 The gel baits must stay in place at least 14 days for optimal efficacy. One month after (taken into account as worst-case in the TOX risk assessment), new fresh gel baits can be reapplied if cockroaches are still visible. 2) Against large cockroaches i.e. nymph and adult oriental cockroaches (*Blatta orientalis*) at 0.2 g/m^2 using 2 spots of 0.1 g/m^2: The gel baits must stay in place at least 4 weeks for optimal efficacy. If cockroaches are still visible, new fresh gel baits can be reapplied. 3) Against nymph and adult American cockroaches (*Periplaneta americana*) at 0.2 g/m^2 or at 0.3 g/m^2 using 2 or 3 spots of 0.1 g/m^2 respectively The gel baits must stay in place at least 12 weeks for optimal efficacy. If cockroaches are still visible, new fresh gel baits can be reapplied.

	4) Against grey silverfishes *Ctenolepisma longicaudatum* at 0.1422 g/m² The gel baits must stay in place at least 8 weeks for optimal efficacy. If silverfishes are still visible, new fresh gel baits can be reapplied. Do not apply more than one time per month.
Category(ies) of users	Professional
Pack sizes and packaging material	cartridge and syringe - Plastic: PE - 10 - 30 g The biocidal product is contained within PE syringes and cartridges 10 to 30g with cap and piston delivered with application cannulas (PP). Sales presentation in blisters or cardboard boxes from 1 to 8 cartridges.

2.1.4.2 Use-specific instructions for use

- please refer to 2,1,5,1 and to 2,1,6

2.1.4.3 Use-specific risk mitigation measures

please refer to 2.1.5.2

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

please refer to 2.1.5.3

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

please refer to 2.1.5.4

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

please refer to 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

The biocidal product (b.p.) is dispensed using a suitable gel applicator. When the treatment has been completed remove the empty cartridge and dispose of safely. If the cartridge is only partially used, remove it from the applicator, seal it with the end cap provided and store as directed.

For maximum effectiveness the b.p. must be placed in and around cockroach harbourages and, if possible, between these areas and food sources. Survey the area to be treated to

identify sites of cockroach infestation e.g. by using traps and/or flush-out aerosols, searching for droppings, cast skins and egg cases etc.

In addition, for an optimal effectiveness, all natural source of food palatable for cockroach must be removed from the infested area to encourage the ingestion of the bait.

The product is to be placed as spot treatment in the vicinity of corners, cracks and crevices (e.g. behind or under equipment and furniture like counters, refrigerators, cookers, sinks, baths etc.), voids, service-ducts, lift shafts, pipework…

The b.p. is particularly valuable in sensitive areas where the use of conventional insecticide formulations is restricted e.g. in the vicinity of electric and electronic equipment etc.

Where immigration of cockroaches has been identified, placement of additional bait in peripheral areas of the site will aid control. Apply the b.p. directly as spots or thin ribbons to surfaces in identified target areas.

It should be placed out of sight and where light intensity is low. Place the bait spots in places inaccessible for children or pets. Avoid application to excessively dusty, damp or greasy locations. Do not apply in areas subjected to wet cleaning. Do not apply to areas that have recently been treated with other insecticides or contaminate the bait with other insecticides.

An effect on the cockroach population can be expected very quickly with dead cockroaches evident within 24 hours of treatment. Maximum levels of control are achieved between six days and 2 months after treatment depending upon the level of infestation and as long as the gel is present.

Where infestations are high, inspect the applied spots of the b.p. once a month and make further applications as required. However do not apply more than one time per month.

For use against silverfish: Place many small drops in areas where silverfish hide and live. These areas may be under/behind base/skirting boards, under wooden facing or other areas that provide cover.

Do not apply in animal pens and cages.

Removal of old baits/gel spots should be done by a professional pest control operator.

INFORM THE REGISTRATION HOLDER IF THE TREATMENT IS INEFFECTIVE

DO NOT APPLY THE PRODUCT ON ABSORBENT SURFACES

DO NOT EXPOSE BAIT DROPS TO SUNLIGHT OR HEAT SOURCES

PROTECT FROM RAIN

READ ALL PRECAUTIONS BEFORE USE

- <u>On the label, the Applicant does mention :</u>
- Before treatment, the professional users must survey the area to be treated to identify sites of cockroach & silverfish infestation e.g. by using traps and/or flush-out aerosols, searching for droppings, cast skins and egg cases etc.
- For maximum effectiveness, the product must be placed in and around cockroach & silverfish harbourages and, if possible, between these areas and food sources. It should be placed out of sight and where light intensity is low.
- Place the bait spots in places inaccessible for children or pets. Avoid application to excessively dusty, damp or greasy locations, and surfaces subject to wet cleaning.

2.1.5.2 Risk mitigation measures

• Avoid application to excessively dusty, damp or greasy locations. Do not apply in areas subjected to wet-cleaning. Pay particular attention to cracks and crevices and other entry points usually used by insects, as well as areas behind or under machinery, kitchen and bathroom equipment or pipework. The product can be placed in voids, service-ducts, lift shafts, electric and electronic equipment, etc."

• Not intended for uses in in stables, pens or cages for animals. Not recommended for use in insectivorous birds and reptiles' facilities.

• Keep out of the reach of children.

•. Wear suitable protective gloves when the product is handled.

• Avoid contact with skin.

• Wash hands and exposed skin before meals and after use.

• Do not apply to surfaces on which food or feed is stored, prepared or eaten.

• Use only in positions inaccessible to children and animals.

• Do not attempt to open or refill cartridges.

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

General advice:

If significant amounts are spilled, the following advice is applicable. Move out of dangerous area. Place and transport victim in stable position (lying sideways). Remove contaminated clothing immediately and dispose of safely.

If necessary take the affected individual to a healthcare center and bring packaging or label whenever possible.

Never leave an affected individual unattended.

Skin contact: Wash off thoroughly with plenty of soap and water, subsequently rinse with water. If skin irritation/sensitization occurs, persists or intensifies seek medical advice.

Eye contact: Immediately flush eyes with plenty of lukewarm water. Check for and remove any contact lenses. Continue to rinse for at least 5 minutes. If symptoms persists, seek medical attention.

Ingestion: Rinse mouth with water. Call a physician or poison control center immediately. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink."

Advice for medical and healthcare personnel: Provide symptomatic and supportive treatment.

When asking for medical advice keep packaging or label at hand and call your local poison control center (for Belgium : 070 245 245)

2.1.5.4 Instructions for safe disposal of the product and its packaging

• Dispose of contents/container in accordance with local regulation.

• Unwanted gel can be removed when freshly applied by sponging with a 5% sodium chloride solution. Sponges/tissues used should be disposed of as solid waste.

• Aged gel can be removed with spatulas and disposed of as solid waste

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

Conditions of storage: Do not allow to freeze. Keep in a safe place. Shelf life at ambient temperature: 2 years (After cMS commenting it was decided that overall shelf life is restricted to 2 years for reasons of ensuring efficacy against all claimed species.)

2.1.6 Other information

- Good sanitation procedures and all other measures that prevent infestations from developing (i.e. non-chemical measures) have to be established.
- Products should always be used in accordance with label recommendations, in terms of dose to be applied and treatment intervals. The effective dose must be applied and no higher or lower doses.
- Treatments should be alternated with products with different modes of action, i.e avoid rotating different neonicotinoids. It is advisable to avoid using Maxforce Platin exclusively and continuously as the sole agent for cockroach control. Maxforce Platin should be used as one component of an integrated pest management program which features gel formulations with different food bases, and products from alternative chemical classes with different application methods
- Levels of effectiveness should be monitored (periodic checks), and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refugia can contribute to the risk of re-infestation.
- In cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product with the same mode of action especially neonicotinoids should be avoided.
- -If signs of resistance begin to appear (as indicated either by control failures or through the test procedure) then every effort should be made to eradicate the population. The measures necessary for eradication will vary in different situations; they may involve a number of procedures using both chemical and non-chemical measures.

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)
cartridge and syringe	10 - 30 g	Plastic: PE	end cap provided (applicator can be re-sealed; piston is delivered	professional	

			with application cannulas, comprised in commercial packs (PP))		

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substances have been submitted in relation to the product application.

The whole list of data submitted by the applicant is included in the annex 3.1.

2.1.8.2 Access to documentation

The applicant has submitted a Letter of Access from Sumitomo Chemical (U.K.), granting access to the evaluating member state competent authority to the data submitted in the active substance dossier for clothianidin PT18.

2.2 ASSESSMENT OF THE BIOCIDAL PRODUCT

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

Table 2. Use # 1 – – Cockroach and silverfishes – Professional users - Indoor	
Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	*Blattella germanica* (German cockroaches) *Blatta orientalis* (Oriental Cockroaches) *Periplaneta Americana* (American Cockroaches) *Ctenolepisma longicaudatum* (grey silverfishes)
Field of use	A ready to use insecticidal gel bait for the control of cockroach nymphs and adults. For use indoors : • Domestic premises • Food Handling /storage premises • Public buildings • Small Scale Animal Housing i.e. zoos, pet shops, kennels, veterinary practices, laboratory animal houses etc. (only building, feed handling and storage premises, excluding stables, animal pens and cages where animals are located).
Application method(s)	Bait application
Application rate(s) and frequency	Based on the efficacy tests submitted and validated, the product MAXFORCE® PLATIN (RTU gel bait with 1% Clothianidin) can be granted with the following use conditions : 1) Against small cockroaches i.e. nymph and adult German cockroaches (*Blattella germanica*): • at 0.1 g/m^2 (moderate infestation i.e. German cockroaches rarely visible during the day). • at 0.2 g/m^2 (severe infestation i.e. German cockroaches commonly visible during the day) using 2 spots of 0.1 g/m^2 The gel baits must stay in place at least 14 days for optimal efficacy. One month after (taken into account as worst-case in the TOX risk assessment), new fresh gel baits can be reapplied if cockroaches are still visible. 2) Against large cockroaches i.e. nymph and adult oriental cockroaches (*Blatta orientalis*) at 0.2 g/m^2 using 2 spots of 0.1 g/m^2: The gel baits must stay in place at least 4 weeks for optimal efficacy. If cockroaches are still visible, new fresh gel baits can be reapplied. 3) Against nymph and adult American cockroaches (*Periplaneta americana*) at 0.2 g/m^2 or at 0.3 g/m^2 using 2 or 3 spots of 0.1 g/m^2 respectively The gel baits must stay in place at least 12 weeks for optimal efficacy. If cockroaches are still visible, new fresh gel baits can be reapplied.

	4) Against grey silverfishes *Ctenolepisma longicaudatum* at 0.1422 g/m² The gel baits must stay in place at least 8 weeks for optimal efficacy. If silverfishes are still visible, new fresh gel baits can be reapplied. Do not apply more than one time per month.
Category(ies) of users	Professional
Pack sizes and packaging material	cartridge and syringe - Plastic: PE - 10 - 30 g The biocidal product is contained within PE syringes and cartridges 10 to 30g with cap and piston delivered with application cannulas (PP). Sales presentation in blisters or cardboard boxes from 1 to 8 cartridges.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Organoleptic 21°C	Clothianidin 0.91%	gel	*Determination of physico-chemical properties and accelerated storage stability test for Clothianidin RB 1% in PE Syringe*, Manka S., 2015/05/06
Colour at 20 °C and 101.3 kPa	Organoleptic 21°C	Clothianidin 0.91%	White gel with blue dots	*Determination of physico-chemical properties and accelerated storage stability test for Clothianidin RB 1% in PE Syringe*, Manka S., 2015/05/06
Odour at 20 °C and 101.3 kPa	Organoleptic 21°C	Clothianidin 0.91%	Weak cereal odor	*Determination of physico-chemical properties and accelerated storage stability test for Clothianidin RB 1% in PE Syringe*, Manka S., 2015/05/06
Acidity / alkalinity	MT 75.3	Clothianidin 0.91%	1% solution: 6.3 The product is very viscous, making impossible determination of pH of the undiluted solution.	*Determination of physico-chemical properties and accelerated storage stability test for Clothianidin RB 1% in PE Syringe*, Manka S., 2015/05/06
Relative density / bulk density	EC440/2008 A.3 (20°C)	Clothianidin 0.91%	Initial:1.18 g/mL	*Determination of physico-chemical*

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		- initial sample - aged sample (60 months)	Aged :1.15 g/mL	*properties and accelerated storage stability* *Determination of physico-chemical properties and accelerated storage stability test for Clothianidin RB 1% in PE Syringe*, Rump E., 2018/03/20 *test for Clothianidin RB 1% in PE Syringe*, Manka S., 2015/05/06
Storage stability test – **accelerated storage**	MT 46.3 2 weeks 54°C Active substance determination HPLC & UV detection (the method is validated, see 2.2.4)	Clothianidin 0.91%	$\underline{\text{Appearance}}_{T0}$: white gel with blue dots and weak cereal odor $\underline{\text{Appearance}}_{T2w}$: beige to light brown gel with blue dots and weak cereal odor $\underline{\text{a.s. concentration}}_{T0}$: 0.91% $\underline{\text{a.s.concentration}}_{T2w}$: 0.94%. The relative variation is 3.3% $\underline{pH}_{T0}$: 6.3 $\underline{pH}_{T2w}$: 6.3 $\underline{\text{Density}}_{T0}$: 1.18 g/mL $\underline{\text{Density}}_{T2w}$: 1.20 g/mL	*Determination of physico-chemical properties and accelerated storage stability test for Clothianidin RB 1% in PE Syringe*, Manka S., 2015/05/06
Storage stability test – **long term storage at ambient temperature**	60 months 20°C	Clothianidin 0.91%	$\underline{\text{Appearance}}_{T0}$: white gel with blue dots and weak cereal odor	*Determination of physico-chemical properties and*

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	Active substance determination HPLC & UV detection (the method is validated, see 2.2.4)		Appearance$_{T60}$: slightly yellowish gel with blue dots and weak cereal odor a.s. concentration$_{T0}$: 0.91% a.s.concentration$_{T60}$: 0.98%. The relative variation is 7.7% pH$_{T0}$: 6.3 pH$_{T60}$: 6.2 Density$_{T0}$: 1.18 g/mL Density$_{T60}$: 1.15 g/mL	*accelerated storage stability test for Clothianidin RB 1% in PE Syringe*, Manka S., 2015/05/06 *Determination of physico-chemical properties and accelerated storage stability test for Clothianidin RB 1 (10g/kg) in PE Syringe, Manka S., 2018/04/23*
Storage stability test – **low temperature stability test for liquids**	1 week 0°C HPLC & UV detection (the method is validated, see 2.2.4)	Clothianidin 0.91%	Appearance$_{T0}$: white gel with blue dots and weak cereal odor Appearance$_{T2w}$: slightly beige gel with blue dots and weak cereal odor a.s. concentration$_{T0}$: 0.91% a.s.concentration$_{T2w}$: 0.92%. The relative variation is 1.1% pH$_{T0}$: 6.3 pH$_{T1w}$: 6.4 Density$_{T0}$: 1.18 g/mL Density$_{T1w}$: 1.18 g/mL	*Determination of physico-chemical properties and accelerated storage stability test for Clothianidin RB 1% in PE Syringe*, Manka S., 2015/05/06

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Waived	-	Not applicable as the packaging is light-proof.	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waived	-	Not applicable because according to the label instructions the biocidal product has to be stored cool, dry and protected from frost in closed, original containers.	-
Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material	Visual inspection	PE syringe: Clothianidin 0.91%	After storage at 54°C, 2w: Test Item in sound condition, sealed and without leakages After storage at 20°C, 24m: Test Item in sound condition, sealed and without leakages	*Determination of physico-chemical properties and accelerated storage stability* *test for Clothianidin RB 1% in PE Syringe*, Manka S., 2015/05/06
Wettability	Waived	-	The biocidal product is a gel	-
Suspensibility, spontaneity and dispersion stability	Waived	-	The biocidal product is a gel	-
Wet sieve analysis and dry sieve test	Waived	-	The biocidal product is a gel	-
Emulsifiability, re-emulsifiability and emulsion stability	Waived	-	The biocidal product is a ready-to-use gel	-
Disintegration time	Waived	-	The biocidal product is a gel	-
Particle size distribution, content of dust/fines, attrition, friability	Waived	-	The biocidal product is a gel	-
Persistent foaming	Waived	-	The biocidal product is a ready-to-use gel	-
Flowability/Pourability/Dustability	Waived	-	The biocidal product is a ready-to-use gel	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Burning rate — smoke generators	Waived	-	The biocidal product is not a smoke generator	-
Burning completeness — smoke generators	Waived	-	The biocidal product is not a smoke generator	-
Composition of smoke — smoke generators	Waived	-	The biocidal product is not a smoke generator	-
Spraying pattern — aerosols	Waived	-	The biocidal product is not an aerosol	-
Physical compatibility	Waived	-	The biocidal product is not intended to be used with other products including other biocidal products. Therefore no information is submitted about its compatibility with other products.	-
Chemical compatibility	Waived	-	The biocidal product is not intended to be used with other products including other biocidal products. Therefore no information is submitted about its compatibility with other products.	-
Degree of dissolution and dilution stability	Waived	-	The biocidal product is a gel	-
Surface tension	Waived	-	The biocidal product is a gel	-
Viscosity	MT 192 (OECD 114)	Clothianidin 0.91% - Initial sample - Aged sample after 60 months	At 20°C, initial sample: 20 s^{-1}: 21574 mPa 40 s^{-1}: 13724 mPa 60 s^{-1}: 10608 mPa 80 s^{-1}: 8853 mPa	*Determination of physico-chemical properties and accelerated storage stability*

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			100 s^{-1}: 7693 mPa <u>At 20°C, aged sample:</u> 20 s^{-1}: 28617 mPa 40 s^{-1}: 17311 mPa 60 s^{-1}: 12916 mPa 80 s^{-1}: 10508 mPa 100 s^{-1}: 9041 mPa <u>At 40°C, aged sample</u>: 20 s^{-1}: 16563 mPa 40 s^{-1}: 10161 mPa 60 s^{-1}: 7552 mPa 80 s^{-1}: 6183 mPa 100 s^{-1}: 5292 mPa	*test for Clothianidin RB 1% in PE Syringe*, Manka S., 2015/05/06 *Determination of physico-chemical properties and accelerated storage stability* *test for Clothianidin RB 1% in PE Syringe*, Rump E., 2018/03/20
Loss on drying	Analogous to CIPAC MT 75.3	Clothianidin 0.91%	47.7 %	*Determination of physico-chemical properties and accelerated storage stability* *test for Clothianidin RB 1% in PE Syringe*, Manka S., 2015/05/06

Conclusion on the physical, chemical and technical properties of the product
The biocidal product is a white gel with blue dots, with weak cereal odor. The pH is 6.3 and the density is 1.18 g/mL.

The concentration of active substance is 1 % w/w according to the applicant and 0.91% w/w in the analysed sample. Since the variation between these two concentrations is <15%, the value of 1% w/w, as claimed by the applicant, is accepted.

The product is stable during 2 weeks at 54°C and 60 months at 20°C, regarding the active substance composition, appearance, pH and density. The same characteristics are stable during a storage of 1 week at zero degrees. The packaging of the biocidal product must be light-proof.

The dynamic viscosity at 20°C is 21574 mPa at the shearing rate of 20 s^{-1}; and 7693 mPa at 100 s^{-1} shearing rate; at 40°C is 16560 mPa at the shearing rate of 20 s^{-1}; and 5290 mPa at 100 s^{-1} shearing rate.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	European Commission Regulation (EC) No. 440/2008, A. 14. Explosive properties OECD 113: Screening test for thermal stability and stability in air	Clothianidin 0.91%	No explosive properties	*Explosive Properties A.14*, Dornhagen J., 2013/06/18
Flammable gases	Waived	-	The biocidal product is a gel	-
Flammable aerosols	Waived	-	The biocidal product is not an aerosol	-
Oxidising gases	Waived	-	The biocidal product is a gel	-
Gases under pressure	Waived	-	The biocidal product is a gel	-
Flammable liquids	ASTM D93: Standard Test Methods for Flash Point by Pensky-Martens Closed Cup Tester Regulation 440/2008 (EC) consolidated version, Annex A.9. "Flash Point"	Clothianidin 0.91%	Flash point : No flash point was observed before the test item began to boil (98 - 101 °C)	*Flash Point A.9 of Clothianidin RB 1%*, Brux A., 2013/06/03

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Flammable solids	Waived	-	The biocidal product is a gel	-
Self-reactive substances and mixtures	Waived	-	There are no ingredients with explosive or self-reactive properties present in the biocidal product.	-
Pyrophoric liquids	Waived	-	Based on experience in handling and use and the chemical structure of product contents, pyrophoric properties are not to be expected.	-
Pyrophoric solids	Waived	-	The biocidal product is a gel	-
Self-heating substances and mixtures	Waived	-	Based on experience in handling and use and the chemical structure of product contents, self-heating behaviour is not expected.	-
Substances and mixtures which in contact with water emit flammable gases	Waived	-	The biocidal product contains water. Therefore an emission of flammable gases is not expected when the preparation comes in contact with water.	-
Oxidising liquids	European Commission Regulation (EC) No. 440/2008, A.21. Oxidising properties (liquids)	Clothianidin 0.91%	No oxidising properties	*Oxidising Properties (Liquids) A.21*, Dornhagen J., 2013/06/18
Oxidising solids	Waived	-	The biocidal product is a gel	-
Organic peroxides	Waived	-	Based on the chemical structure of product contents, organic peroxide behaviour is not expected.	-
Corrosive to metals	Waived	-	No free sodium hydroxide is present in the biocidal product; all of it is consumed in the reaction of organic acids.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Auto-ignition temperatures of products (liquids and gases)	European Commission Regulation (EC) No. 440/2008, A. 15. auto-ignition temperature (liquids and gases)	Clothianidin 0.91%	The auto-ignition temperature is 465°C.	*Auto-ignition temperature (Liquids and Gases) A.15*, Dornhagen J., 2013/06/18
Relative self-ignition temperature for solids	Waived	-	The biocidal product is a gel	-
Dust explosion hazard	Waived	-	The biocidal product is a gel	-

Conclusion on the physical hazards and respective characteristics of the product
The biocidal product has no explosive, flammable or oxidising properties. The auto-ignition temperature is 465°C.

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		
a.s. Clothianidin	HPLC with UV detection (270 nm)	3 fortifications per concentration level (70%, 100%, 130%) 0.12 mg/ml clothianidin 0.16 mg/ml clothianidin 0.20 mg/ml clothianidin 0.24 mg/ml clothianidin 0.28 mg/ml clothianidin 0.32 mg/ml clothianidin	r = 1 (in the range clothianidin: 0.1202 – 0.3205 mg/ml)	Specific: interference from other substances <3% of total peak area	70% level: 95.21 – 98.23 100% level: 96.26 – 97.89 130% level: 91.75 – 98.14	97	2.06	-	*MV071 BSC: HPLC - Determination of Clothianidin in Clothianidin RB 1%*, Manka S., 2013/02/08 *Validation of Method MV071: BCS: HPLC – determination of Clothianidin in Clothianidin RB 1%*, Manka S., 2013/02/18

Analytical methods for the determination of active substance residues in relevant environmental media (soil, air and water), in animal and human body fluids and tissues, as well as in/on food or feedstuffs, were not submitted for the biocidal product since this point is covered by the data set of the active substance Clothianidin.

Conclusion on the methods for detection and identification of the product
Clothianidin can be determined using HPLC method with UV detection. The identity of the analyte is confirmed by comparison and matching of the retention times. The standard regression is linear. The method is repeatable. The recovery rates range between 95.21-98.23% and has a mean of 97%. Repeated injection of the samples resulted in a relative standard deviation of 2.06%.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

FUNCTION

According to the label submitted by the applicant :

The product ***MAXFORCE PLATIN*** is a ready to use insecticidal gel bait for the control of cockroaches (nymphs and adults) and of silverfishes, dispensed using a suitable gel applicator as spots or thin ribbons to surfaces in identified target areas. It contains 1% clothianidin in a foodstuffs matrix particularly palatable to cockroaches.

FIELD OF USE

PT 18 "Insecticides, acaricides and products to control other arthropods"

The product ***MAXFORCE PLATIN*** is intended to be used indoor by professionals only :

- in public or residential buildings : continuously occupied areas including hospitals, hotels, public baths, municipal buildings, churches, halls, community centers, airports, train and bus stations, cinemas, etc…
- in food handling / storage premises : processing (food manufacture, kitchens, slaughterhouses, etc.), storage (food retailers, warehouses, raw material stores, silos except where grain is stored, etc…) and preparation (restaurants, commercial kitchens, etc.)
- in animal housing : zoos, pet shops, kennels, veterinary practices, laboratory animal houses etc. (only building, feed handling and storage premises, excluding stables, animal pens and cages where animals are located).

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

OBJECTS TO BE PROTECTED

To protect livestock & poultry houses and domestic premises.

ORGANISMS TO BE CONTROLLED

According to the use claimed by the applicant :

- Cockroaches (nymphs and adults)
  - Blattella germanica (German cockroaches)
  - Blatta orientalis (Oriental Cockroaches)
  - Periplaneta Americana (American Cockroaches)
- *Ctenolepisma longicaudatum* (grey silverfishes)

2.2.5.3 Effects on target organisms, including unacceptable suffering

Clothianidin has a systemic insecticidal (killing) effect by contact and ingestion on the target organisms.

2.2.5.4 Mode of action, including time delay

Clothianidin belongs to the chemical class of insecticides known as neonicotinoids.

Clothianidin is a nicotinic acetylcholine receptor (nAChR) agonist (IRAC Class 4A).

It's an "axonal" active substance (along the nerve fiber – not at the nerve gap like fipronil and indoxacarb), acting agonistically on insect nicotinic acetylcholine (major excitatory neurotransmitter in the insect central nervous system) receptors located in the central nervous system at the postsynaptic membrane, over stimulates nerve, opening the voltage sensitive Na+ channels. Bind to the acetylcholine site on nAChRs, it's causing a range of symptoms from hyper-excitation to lethargy and paralysis.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
FUNCTION	**FILED OF USE ENVISAGED**	**TEST SUBSTANCE**	**TEST ORGANISMS**	**TEST METHOD**	**TEST SYSTEM / CONCENTRATIONS APPLIED / EXPOSURE TIME**	**TEST RESULTS : EFFECTS**	**REFERENCE**
Insecticide	PT18 RTU gel bait	***Clothianidin 1 RB*** batch 2012-004896 (1% Clothianidin) ⇔ ***MAXFORCE® PLATIN***	***Blattella germanica*** *(adults 5♀+5♂ ; 10 middle nymphs)*	***Palatability Lab test*** The target organisms were introduced in a cardboard container (60 cm wide and 52 cm deep) containing a drinking station, a feeding source and harborage. One day later, the test-product was placed in the container. The competitive food remained in the area until	**Comparison of the efficacy of unstressed and stressed bait.** With an untreated control. Dosage : 200 mg product in a cardboard container (60 cm wide and 52 cm deep) => 0.2 g / 0.312 m^2 = 0.641 g/m^2 in a Petri dish Temperature : +24 – 26 °C Rel. humidity : ambient Light regime : Not reported 4 replicates Mortality % recorded after 1, 2, 3, 6, 10 and 13 days.	With product stored at ambient temperature (+22°C ±2°C) for two weeks : Mortality $_{Adults\text{-}3\ days}$ = 98 % Mortality $_{Nymphs\text{-}3\ days}$ = 98 % Mortality $_{Mix\text{-}3\ days}$ = 98 % With product stored at +54°C for two weeks : Mortality $_{Adults\text{-}3\ days}$ = 95 % Mortality $_{Nymphs\text{-}3\ days}$ = 88 %* Mortality $_{Mix\text{-}3\ days}$ = 92 % Untreated control : Mortality $_{Adults\text{-}3\ days}$ = 0 % Mortality $_{Nymphs\text{-}3\ days}$ = 5 % Mortality $_{Mix\text{-}3\ days}$ = 3 % ***MAXFORCE® PLATIN*** (stored at ambient temperature for two weeks or stored at 54°C for two weeks) is effective to control adult and middle nymph German cockroaches using 0.641 g PB/m^2 (6.41 mg Clothianidin/m^2) within 3 days. * Note from the Applicant : Cockroach nymphs have the habit of being less mobile that adults. In fact first	*Evaluation of Clothianidin 1 RB after two weeks storage at 54°C against susceptible cockroaches (Blattella germanica)* Guenther Nentwig – Nov. 2012 Réf. M-451267-03-1 **Reliability 1**

				the end of the trial.		instars L1 almost never leave the harborage to search for food, every life cycle stage will increase their radius of activity. In consequence, the efficacy on nymphs appears to be lower but this effect is not due to robustness or physiological difference but based on the reduced foraging activity. This is normal cockroach behaviour.	
Insecticide	PT18 RTU gel bait	***Clothianidin 1 RB*** ⇔ ***MAXFORCE® PLATIN*** Batch 2013-000912 : produced 15.03.2013 under ambient conditions (Stored for 4 years at ambient temperature). Batch EMGE000962 : fresh commercial batch. Negative control	***Blattella germanica*** *(adults 5♀+5♂* and 5 middle nymphs) ***Blatta orientalis*** *(adults 5♀+5♂* and 5 middle nymphs) ***Periplaneta americana*** *(*American cockroach) *(adults 5♀+5♂* and 5 middle nymphs)	***Palatability Lab test*** The target organisms were introduced in a cardboard container (56 cm wide and 37 cm deep) containing a drinking station, a feeding source and harborage. One day later, the test-product was placed in the container. The competitive food remained in the area until the end of the trial.	This trial should demonstrate the performance and efficacy of Maxforce Platin (Clothianidin RB 1) after storage for 4 years in the final packaging against three commercially important target cockroach species. Plastic container (37 cm x 56 cm) with drinking station, harborage and feeding source. <u>Dosage :</u> 200 mg product in a cardboard container (56 cm wide and 37 cm deep) => 0.2 g / 0.2072 m^2 = 0.9652 g/m^2 in a Petri dish <u>Temperature</u> : *+24 – 26°C* <u>Rel. humidity</u> : not controlled <u>Light regime</u> : illumination from 4.00 until 16.00 Mortality recorded after 1, 2, 3, 6, 10 & 13 days (extended to 16 & 20 days for *Periplaneta Americana)*	***Blattella germanica*** <u>Fresh product :</u> Mortality $_{Adults\text{-}10\ days}$ = 100 % Mortality $_{Nymphs\text{-}10\ days}$ = 80 % Mortality $_{Mix\text{-}10\ days}$ = 90 % <u>Stored at ambient temperature for 4 years :</u> Mortality $_{Adults\text{-}10\ days}$ = 100 % Mortality $_{Nymphs\text{-}10\ days}$ = 83 % Mortality $_{Mix\text{-}10\ days}$ = 92 % ***Blatta orientalis*** <u>Fresh product :</u> Mortality $_{Adults\text{-}10\ days}$ = 100 % Mortality $_{Nymphs\text{-}10\ days}$ = 80 % Mortality $_{Mix\text{-}10\ days}$ = 90 % <u>Stored at ambient temperature for 4 years :</u> Mortality $_{Adults\text{-}10\ days}$ = 100 % Mortality $_{Nymphs\text{-}10\ days}$ = 90 % Mortality $_{Mix\text{-}10\ days}$ = 95 % ***Periplaneta Americana*** <u>Fresh product :</u> Mortality $_{Adults\text{-}13\ days}$ = 81 % Mortality $_{Nymphs\text{-}13\ days}$ = 67 % Mortality $_{Mix\text{-}13\ days}$ = 74 % <u>Stored at ambient temperature for 4 years :</u>	*Maxforce Platin (Clothianidin RB 1): comparison of fresh and aged samples against three cockroach species.* G. Michel – May 2017 Réf. M-589095-01-1 **Supportive information**

						Mortality $_{\text{Adults-13 days}}$ = 97 % Mortality $_{\text{Nymphs-13 days}}$ = 60 % Mortality $_{\text{Mix-13 days}}$ = 78 % Clothianidin RB 1 can be stored safely under ambient conditions for at least 4 years without loss of palatability and efficacy of the product inside. However, a difference in palatability is observed btw adults & nymphs (with results not acceptable according to the pass criteria mentioned in the ECHA EFF guidance).	
Insecticide	PT18 RTU gel bait	***MAXFORCE® PLATIN*** (***Clothianidin 1 RB*** - batch 2012-004896 with 1% Clothianidin) Contained in 30g cartridge - Fresh - Stored for two years at ambient temperature	***Blattella germanica*** *(adults 5♀+5♂ ; 10 middle nymphs)* Introduced in the container one day before adding the BP With drinking station + feeding source + harborage	***Palatability Lab test*** The target organisms were introduced in a cardboard container (49 cm wide and 59 cm deep) containing a drinking station, a feeding source and harborage. One day later, the test-product was placed in the container. The competitive food remained in the area until	With an untreated control. <u>Dosage :</u> 200 mg product in a cardboard container (49 cm wide and 59 cm deep) => 0.2 g / 0.2891 m^2 = 0.6918 g/m^2 in a Petri dish. <u>Temperature</u> : *+24 – 26 °C* <u>Rel. humidity</u> : *Not reported* <u>Light regime</u> : from 4.00 until 16.00 3 replicates Mortality % recorded after 1, 2, 3, 6, 10 and 13 days.	<u>Fresh product :</u> Mortality $_{\text{Adults-1 day}}$ = 97 % Mortality $_{\text{Nymphs-6 days}}$ = 100 % <u>Stored for two years at ambient temperature:</u> Mortality $_{\text{Adults-1 day}}$ = 97 % Mortality $_{\text{Nymphs-6 days}}$ = 97 % ***MAXFORCE® PLATIN*** is palatable for control nymph and adult German cockroaches, regardless the storage time of the product (fresh & 2 years at ambient temperature). ***MAXFORCE® PLATIN*** is effective to control nymph and adult German cockroaches using 0.6918 g PB/m^2 (6.918 mg Clothianidin/m^2) within 1 day and 6 days respectively.	*Palatability and efficacy in simulated use trials of Maxforce Platin after two years of ambient storage* V. Gutsmann – August 2015 Réf. M-531535-01-1 **Supportive information**

				the end of the trial.			
Insecticide	PT18 RTU gel bait	***MAXFORCE® PLATIN*** (***Clothianidin 1 RB*** - batch 2012-004896 with 1% Clothianidin) - Fresh - Stored for two years at ambient temperature	***Blatella germanica*** ***Periplaneta americana*** ***Blatta orientalis*** *(adults 5♀+5♂* and 10 middle nymphs for each specie) Introduced in the container one day before adding the BP With drinking station + feeding source + harborage	***Palatability Lab test*** The target organisms were introduced in a cardboard container (49 cm wide and 59 cm deep) containing a drinking station, a feeding source and harborage. One day later, the test-product was placed in the container. The competitive food remained in the area until the end of the trial.	With an untreated control. Dosage : 0.2 g / 0.2891 m^2 = 0.6918 g/m^2 in a Petri dish Temperature : *+24 – 26 °C* Rel. humidity : *Not reported* Light regime : from 4.00 until 16.00 3 replicates Mortality % recorded after 1, 2, 3, 6, 10 and 13 days.	***Blatella germanica*** *FRESH* $Mortality_{Adults}$ = 97 % - 2 days $Mortality_{Nymphs}$ = 100 % - 6 days *STRESSED* $Mortality_{Adults}$ = 100 % - 2 days $Mortality_{Nymphs}$ = 100 % - 6 days ***Periplaneta americana*** *FRESH* $Mortality_{Adults}$ = 100 % - 2 days $Mortality_{Nymphs}$ = 97 % - 6 days *STRESSED* $Mortality_{Adults}$ = 97 % - 6 days $Mortality_{Nymphs}$ = 97 % - 10 days ***Blatta orientalis*** *FRESH* $Mortality_{Adults}$ = 97 % - 2 days $Mortality_{Nymphs}$ = 97 % - 6 days *STRESSED* $Mortality_{Adults}$ = 97 % - 2 days $Mortality_{Nymphs}$ = 97 % - 6 days ***MAXFORCE® PLATIN*** is palatable for control nymph and adult German, American and Oriental cockroaches, regardless the storage time of the product (fresh & 2 years at ambient temperature). *FRESH PRODUCT* *No difference of palatability between the 3 species.* => Using 0.6918 g PB/m^2 (6.918 mg Clothianidin/m^2), fresh ***MAXFORCE® PLATIN*** is	*Maxforce Platin (Clothianidin RB 1): comparison of fresh and stress tested samples against three cockroach species* V. Gutsmann – June 2015 Réf. M-525136-02-1 **Reliability 1**

<table>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>effective to control adult German, American & Oriental cockroaches within 2 days and effective to control German, American & Oriental nymph cockroaches within 6 days.

<u>STRESSED PRODUCT</u>
No difference of palatability between German & Oriental cockroaches
=> Using 0.6918 g PB/m^2 (6.918 mg Clothianidin/m^2), stressed MAXFORCE® PLATIN is effective to control adult German & Oriental cockroaches within 2 days and effective to control nymph German & Oriental cockroaches within 6 days.

Periplaneta Americana seems to be the most robust species => Using 0.6918 g PB/m^2 (6.918 mg Clothianidin/m^2), stressed MAXFORCE® PLATIN is effective to control adult American cockroaches within 6 days and effective to control nymph American cockroaches within 10 days.</td><td></td></tr>
<tr><td>Insecticide</td><td>PT18
RTU gel bait</td><td>Clothianidin 1 RB
⇔
MAXFORCE® PLATIN

<u>Batch 2013-000912 :</u>
produced in Feb 2013 under ambient conditions (Stored for 5 years at ambient temperature).</td><td>Blattella germanica (adults 5♀+5♂ and 5 middle nymphs)

Blatta orientalis
(adults 5♀+5♂ and 5 middle nymphs)

Periplaneta americana
(American cockroach)
(adults 5♀+5♂ and 5 middle nymphs)</td><td>Palatability Lab test

The target organisms were introduced in a cardboard container (56 cm wide and 37 cm deep) containing a drinking station, a feeding source and harborage.</td><td>This trial should demonstrate the performance and efficacy of Maxforce Platin (Clothianidin RB 1) after storage for 5 years in the final packaging against three commercially important target cockroach species.

Plastic container (37 cm x 56 cm) with drinking station (vial with water), harborage and feeding source (dry dog food).

<u>Dosage :</u></td><td>Blattella germanica

% Mortality (total adults & nymphs)
<table><tr><th></th><th>3 d</th><th>6 d</th><th>10 d</th><th>13 d</th></tr><tr><td>Untreated</td><td>0</td><td>7</td><td>10</td><td>-</td></tr><tr><td>Fresh product</td><td>83</td><td>92</td><td>100</td><td>-</td></tr><tr><td>5y-aged product</td><td>75</td><td>92</td><td>100</td><td>-</td></tr></table>
Blatta orientalis

% Mortality (total adults & nymphs)
<table><tr><th></th><th>3 d</th><th>6 d</th><th>10 d</th><th>13 d</th></tr><tr><td>Untreated</td><td>0</td><td>0</td><td>0</td><td>0</td></tr></table></td><td>Maxforce Platin (Clothianidin RB 1): comparison of fresh and 5 year old samples against three cockroach species (28/08/2018)

Réf. M-633234-01-1

Reliability 1
Key study</td></tr>
</table>

		Batch EMGE001226 : fresh commercial batch produced in Feb 2018 Negative control		One day later, the test-product was placed in the container. The competitive food remained in the area until the end of the trial.	200 mg product in a cardboard container (56 cm wide and 37 cm deep) => 0.2 g / 0.2072 m^2 = 0.9652 g/m^2 in a Petri dish Temperature : *+24 – 26°C* Rel. humidity : not controlled Light regime : illumination from 4.00 until 16.00 Mortality recorded after 1, 2, 3, 6, 10 & 13 days (extended to 16 & 20 days for *Periplaneta Americana)* 3 replicates	<table><tr><td>**Fresh product**</td><td>80</td><td>98</td><td>98</td><td>98</td></tr><tr><td>**5y-aged product**</td><td>82</td><td>95</td><td>98</td><td>100</td></tr></table> ***Periplaneta Americana*** <table><tr><td colspan="5">% Mortality (total adults & nymphs)</td></tr><tr><td></td><td>**3 d**</td><td>**6 d**</td><td>**10 d**</td><td>**13 d**</td></tr><tr><td>**Untreated**</td><td>0</td><td>0</td><td>0</td><td>0</td></tr><tr><td>**Fresh product**</td><td>78</td><td>95</td><td>98</td><td>98</td></tr><tr><td>**5y-aged product**</td><td>68</td><td>90</td><td>92</td><td>95</td></tr></table> The product ***MAXFORCE® PLATIN*** can be stored safely under ambient conditions for 5 years without loss of palatability and efficacy of the product inside.	
Insecticide	PT18 RTU gel bait	***Clothianidin 1 RB*** batch 2012-004896 (1% Clothianidin) ⇔ ***MAXFORCE® PLATIN***	***Blattella germanica*** *(adults 5♀+5♂)*	***Lab no-choice test*** The target organisms were introduced in a cardboard container (20 cm wide and 20 cm deep) without drinking station, feeding source or harborage Three days later, the test-product was placed in	With an untreated control Dosage : 200 mg product in a plastic container (20 cm wide and 20 cm deep) => 0.2 g / 0.04 m^2 = 5 g/m^2 in a Petri dish Temperature : *Not reported* Rel. humidity : *Not reported* Light regime : *Not reported* 3 replicates Mortality % recorded after 30', 60', 90', 2h, 3h, 4h, 6h, 8h and 24h	Mortality $♂_{6h}$ = 100 % Mortality $♀_{8h}$ = 100 % ***MAXFORCE® PLATIN*** is effective to control adult German cockroaches using 5 g PB/m^2 within 8h. Female German cockroaches seem to be more robust than males.	*Evaluation of the fastness of action of Clothianidin 1 RB* *versus different gels against susceptible cockroaches (Blattella germanica)* Guenther Nentwig – Dec. 2012 Réf. M-451276-02-1 (#2) **Reliability 3** Test performed without drink/food

				the container.			& Test conditions not reported
Insecticide	PT18 RTU gel bait	***Clothianidin 1 RB*** batch 2012-004896 (1% Clothianidin) ⇔ ***MAXFORCE® PLATIN*** Stored for 12 months at ambient temperature	***Blatta orientalis*** (adults and middle nymphs)	**Field Trial** Four trial sites : 2 restaurants, 1 public house and 1 "plant room" basement, reflecting the range of situations in which Oriental cockroaches commonly occur in the UK. Adhesive insect monitors were used to measure trends in infestation levels	<u>Dosage :</u> 2x 0.1 g PB beads/$m^2$of floor area Typical UK field conditions (from Feb to Sept. 2013) No replicates and no untreated control sites i.e. with pests as cockroaches, it's not appropriate to leave infestations untreated. In this trial, efficacy is established by the presence of dead cockroaches after treatment and by comparison of pre-treatment and post-treatment catches of cockroaches on monitors	<u>After 4 weeks :</u> at 0.2 g/m^2: 82% reduction <u>After 12 weeks :</u> at 0.2 g/m^2: 90% reduction **MAXFORCE® PLATIN** is effective to control adult and nymph Oriental cockroaches using 2 spots of 0.1 g PB/m^2 (1.00 mg Clothianidin/m^2) within 4 weeks.	*UK Field Trials with Clothianidin 1% RB and Maxforce Prime for control of the Oriental Cockroach (Blatta orientalis)* Clive J Boase – Dec. 2013 Réf. M-475046-01-1 (#4) **Reliability 1** **Key study**
Insecticide	PT18 RTU gel bait	***Clothianidin 1 RB*** batch 2012-004896 (1% Clothianidin) ⇔ ***MAXFORCE® PLATIN*** Applied using *BaitGun*	***Blattella germanica***	**Field Trial**	0.05 – 0.1 – 0.2 g/m^2 With 10 replicates /application rate <u>Temperature</u> : *+16 – 24 °C* <u>Rel. humidity</u> : *47 - 62%* <u>Light regime</u> : Not reported	<u>After 8 weeks :</u> at 0.2 g/m^2: 85.8 % reduction Please note that an application rate of 0.1 g/m^2 is not sufficient to achieve more than 80% reduction of the cockroach population. However, the Applicant has provided some justification to explain such bad results i.e. external infestation did occur.	*Field Trial of Performance of Cockroach Gel Bait Clothianidin 1%w/w (0.2g/m2, 0.1g/m2 and 0.05g/m2) against German Cockroaches*

					Sydney has a sub-tropical climate. The period of this trial was February to May (which is the end of Summer to early Autumn). The weather is hot to warm and humid in this period.		P.F. Miller – June 2013 Réf. M-499912-02-1 (#9) **Reliability 3** Please note that this efficacy test has been performed a second time (please see below test #8).
Insecticide	PT18 RTU gel bait	***Clothianidin 1 RB*** batch 2012-004896 (1% Clothianidin) ⇔ ***MAXFORCE® PLATIN*** Stored for 12 months at ambient temperature	***Blattella germanica*** Note from the Applicant : A natural field population represents a natural mix of life cycle stages. A precise age of cockroaches cannot be determined. As general information, normal cockroach populations contain app. 40% adults and 60 % nymphs.	**Field Trial** Method in accordance with French registration standard Methodology C.E.B. N°249 AXA Monitoring Roach traps (from LODI group) are used as a monitoring device and placed overnight in each apartment. An apartment is considered	Trial sites : multi-family public housing Dosages according to the infestation level : 28 apartments (including 4 untreated controls apartments). # Untreated control (4 apartments) # 0.05 g/m² (8 apartments with up to 62 cockroaches trapped overnight – very low rate for maintenance use) # 0.1 g/m² (8 apartments with up to 60 cockroaches trapped overnight – low rate for moderate infestations) # 0.2 g/m² (8 apartments with more than 60 cockroaches trapped overnight – high rate for severe infestations)	<u>After 2 weeks :</u> at 0.05 g/m² : 88.2% reduction at 0.1 g/m² : 91.7% reduction at 0.2 g/m²: 93.1% reduction ***MAXFORCE® PLATIN*** is effective to control nymph & adult German cockroaches using : - 0.05 g PB/m² (0.5 mg Clothianidin/m²) within 2 weeks for maintenance use - 0.1 g PB/m² (1.00 mg Clothianidin/m²) within 2 weeks for moderate infestations - 0.2 g PB/m² (2.00 mg Clothianidin/m²) within 2 weeks for severe infestations	*Field testing of the efficacy of insecticidal gel baits to control German cockroaches* B. Serrano - July 2013 Report Ref. 1561-EU/1212R Réf. M-497862-01-1 (#8) **Reliability 1** **Key study**

				as a testable unit with a minimum pre-count of 16-20 cockroaches. Baits applied using *BaitGun*. The product was applied in a manner consistent to the proposed label and in accordance with the preferred insect's locations i.e. under the fridge, under the kitchen sink, under the oven & water-heater and on all cracks & crevices.	Level of infestation monitored by sticky traps – but results not reported Temperature : *+20 – 25 °C (with floor heating)* Rel. humidity : *55 - 75%* Light regime : Not reported Trials conducted from Feb to June 2013 in Bayonne (South-West of France)		
Insecticide	PT18 RTU gel bait	***Clothianidin 1 RB*** batch 2012-004896 (1% Clothianidin) ⇔ ***MAXFORCE® PLATIN***	***Periplaneta americana*** (American cockroach) ***Periplaneta australasiae***	**Field Trial**	Product applied in the kitchen and bathroom/laundry 0.1 – 0.2 – 0.3 g/m^2 With 8 replicates /application rate	**At 0.1 g/m^2 :** 19.20% reduction after 2 weeks 57.10% reduction after 6 weeks 90.16% reduction after 12 weeks	*Field Trial of Performance of Cockroach Gel Bait Clothianidin 1%w/w (0.3g/m2, 0.2g/m2 and*

		Stored for 12 months at ambient temperature	(Australian cockroach) (adults and middle nymphs - mix))* * The species ratio of the treatments groups above is mentioned to be 2/3 of *P. americana* and 1/3 of *P.australasiae*. => The targeted species is representing the majority and gets reliably killed. Furthermore, both species have similar nutritional needs and habits.		Temperature : *+21 – 32 °C* Rel. humidity : *63 - 69%* Light regime : Not reported *Cairns has a tropical climate. The period of this trial was February to May, which represents the end of the wet season (Summer) to the start of the dry season early Autumn. It is very humid and warm all through this period and a very good environment for American and Australian Cockroach.* Level of infestation monitored by sticky traps before and after treatment.	**At 0.2 g/m² :** 83.1% reduction after 2 weeks 76.89% reduction after 6 weeks 93.44% reduction after 12 weeks **At 0.3 g/m² :** 55.59% reduction after 2 weeks 97.16% reduction after 6 weeks 95.22% reduction after 12 weeks A high population reduction for *P. americana* in the negative control sites (on average between 16.1 and 21.2% reduction) has been reported & could be justified as followed to be acceptable : First of all, we consider that the level of efficacy in relation to negative control is validated in the lab palatability test (V. Gutsmann – June 2015, Réf. M-525136-01-1 (#11)), where negative control and other influencing conditions can be controlled. Field conditions are indeed very difficult to standardise. In field conditions, we consider that control populations do only indicate qualitatively that roaches are still present but their numbers should not be used to calculate treatment success. In addition, the populations of large cockroaches such as *P. americana* do fluctuate much more that for instance populations of German cockroach. American roaches are more mobile, can even fly and move in an out premises more than German roaches that are living and breeding purely inside the infested premises. Since some control sites were very close to the treated sites, an effect on negative control population is always possible. Furthermore, the selected sites are domestic properties, and hygiene sanitation levels can be affected by the owners and could play a role on the cockroach behaviour.	*0.1g.m2) against a Mixed Population of American and Australian Cockroach* P.F. Miller – June 2013 Réf. M-499919-01-1 (#10) **Reliability 2**

						We feel that the population reduction have been calculated according to guidelines, and achieved (and exceeded) the necessary thresholds. Based on the scientific reasoning above on fluctuation of controls due to biology of these target species, we believe that this field trial was conducted well and supports a label claim against *Periplaneta americana*. The treatment with ***MAXFORCE® PLATIN*** does result in excellent reduction of the total American cockroach population after the end of the usual observation period of 12 weeks using 0.2 g PB/m^2 (2 mg Clothianidin/m^2) or 0.3 g PB/m^2 (3 mg Clothianidin/m^2). This is exceeding the threshold of the guidelines which specify a reduction of >80% after treatment. As the conclusion, the BE eCA does still maintain and support the validation of the use of ***MAXFORCE PLATIN*** against *Periplaneta americana*.	
Insecticide	PT18 RTU gel bait	***Clothianidin 1 RB*** batch 2012-004896 (1% Clothianidin) ⇔ ***MAXFORCE® PLATIN***	***Lepisma saccharina***	**Field Trial** In a single family dwelling. Test-product applied by small drops of 60 mg (via a baitgun) in areas where insects were thought to be foraging and hiding i.e below floor boards, behind silicone seams and	12.8 g / 90 m^2 = 0.1422 g/m^2 Reporting of any sightings of silverfish.	Only scores ++/- Clothianidin 1 RB, batch 2012-004896 (with 1% Clothianidin) seems to be effective to control silverfishes using 0.1422 g PB/m^2 within 1-2 weeks and up to 28 weeks.	*Control of an infestation with silverfish (Lepisma saccharina) in a single family dwelling with Clothianidin RB 1* V. Gutsmann – June 2014 Réf. M-490293-01-1 (#7) **Reliability 4** Only scores ++/-

				near wooden panels serving as blinds in the kitchen area.			
Insecticide	PT18 RTU gel bait	***Clothianidin 1 RB*** batch EMGE00874 (1% Clothianidin) ⇔ ***MAXFORCE® PLATIN***	*Ctenolepisma longicaudatum* (grey silverfish)*) the most common silverfish species in buildings in the Netherlands.	**Field Trial** Four suitable test sites (residential houses) with a long history of having silverfish were found for the trial. All four of the test sites are semi-detached houses in the Netherlands in a housing estate where a large number of the inhabitants also have had or still have problems caused by the presence of silverfish in their houses.	0.1422 g/m^2 using the BaitGun Test performed in June, July, August & September 2017 Level of infestation monitored by glass "pitfall" traps before and after treatment & by visual inspection (in order to find the best areas to apply the test-product). Treatment applied in 3 of the test locations and the 4th location was used as control, into likely hiding places of silverfish.	<u>After 7 days :</u> 80% reduction of the visible silverfish population (with a majority of dead insects) and 85% reduction in trap catches. <u>After 63 days :</u> 100% reduction of the visible silverfish population (with a majority of dead insects) and 93% reduction in trap catches. Since there is neither guideline for the evaluation of PT18 products against silverfishes nor formal agreement about the e-consultation launched by DE in July 2017, the BE eCA is of the opinion to consider this study as valid : ***MAXFORCE® PLATIN*** is then effective to control silverfishes using 0.1422 g PB/m^2 (1.422 mg Clothianidin/m^2) within 7 to 63 days. According to a document provided by the Applicant (Dr V. Gutsmann – 2015 – "*Description of Lepismatidae appearance and behaviour - consequences for evaluating treatment success*" ref. M-538863-01-1), all three species Silverfish (*Lepisma saccharina*), oven fish (*Thermobia domestica*) and grey fish (*Ctenolepisma longicaudata*) (belonging to the family of Lepismatidae and to the order of Zygentoma) are very similar in behaviour and food preferences. Therefore, as a consequence, data obtained with one species could be bridged to the above mentioned three target species.	*Field efficacy of a bait containing 1% Chlothianidin against the grey silverfish (Ctenolepisma longicaudatum) in houses* M.D. Brooks - January 2018 Ref. M-609824-01-1 (#14) **Reliability 1**

				Before the start of the trial samples of silverfish were taken from each of the test locations to verify the species found. In all four houses the presence ofthe grey silverfish was determined. **Trial overview:** Day -14 : pre-count and activity inspection Day -7 : pre-count and activity inspection Day 0 : pre-count and activity inspection and bait application Day 7 : activity inspection			

				and bait point inspection Day 21 : activity inspection and bait point inspection Day 49 : activity inspection and bait point inspection Day 63 : final activity inspection			

Conclusion on the efficacy of the product

According to the field tests provided by the Applicant & considering the requirements from the PT18 EFF guidance (i.e. population reduction has to exceed 80%), the product ***MAXFORCE® PLATIN*** (1% Clothianidin) used as a RTU gel bait (fresh/stored up to 5 years at ambient temperature) is efficacious against :

1) Against small cockroaches i.e. nymph and adult German cockroaches (*Blattella germanica*) for indoor use :

• at 0.1 g/m^2 (moderate infestation i.e. German cockroaches rarely visible during the day).

• at 0.2 g/m^2 (severe infestation i.e. German cockroaches commonly visible during the day) using 2 spots of 0.1 g/m^2

The gel baits must stay in place at least 14 days for optimal efficacy. One month after (taken into account as worst-case in the TOX risk assessment), new fresh gel baits can be reapplied if cockroaches are still visible.

2) Against large cockroaches i.e. nymph and adult oriental cockroaches (*Blatta orientalis*) at 0.2 g/m^2 using 2 spots of 0.1 g/m^2 for indoor use :

The gel baits must stay in place at least 4 weeks for optimal efficacy. If cockroaches are still visible, new fresh gel baits can be reapplied.

3) Against nymph and adult American cockroaches (*Periplaneta americana*) at 0.2 g/m^2 or at 0.3 g/m^2 using 2 or 3 spots of 0.1 g/m^2 respectively

The gel baits must stay in place at least 12 weeks for optimal efficacy. If cockroaches are still visible, new fresh gel baits can be reapplied.

According to the field tests provided by the Applicant, the product ***MAXFORCE® PLATIN*** (1% Clothianidin) used as a RTU gel bait (fresh) is efficacious against :

Ctenolepisma longicaudatum (grey silverfishes) at 0.1422 g/m² (0.1g ≈ 7 mm diameter drop)

The gel baits must stay in place at least 63 days for optimal efficacy. If silverfishes are still visible, new fresh gel baits can be reapplied.

2.2.5.6 Occurrence of resistance and resistance management

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

According to the nformation found in the Doc I rev.11 from 2014 about clothianidin :

The potential resistance of target insects to clothianidin could be of concern and, as such, resistance management measures should be included in the authorisation of products.

These could include (but should not be restricted to) the following factors:

- Good sanitation procedures and all other measures that prevent infestations from developing (i.e. non-chemical measures) have to be established.
- Products should always be used in accordance with label recommendations, in terms of dose to be applied and treatment intervals. The effective dose must be applied and no higher or lower doses.
- Treatments should be alternated with products with different modes of action, i.e avoid rotating different neonicotinoids.
- Levels of effectiveness should be monitored (periodic checks), and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refugia can contribute to the risk of re-infestation.
- In cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product with the same mode of action especially neonicotinoids should be avoided.
- If signs of resistance begin to appear (as indicated either by control failures or through the test procedure) then every effort should be made to eradicate the population. The measures necessary for eradication will vary in different situations; they may involve a number of procedures using both chemical and non-chemical measures.

2.2.5.7 Known limitations

Considering the maintenance usage, the RMS is of the opinion that this use may be considered as a preventive treatment. Since the potential resistance of target insects to clothianidin could be of concern, the rMS is of the opinion to restrict the use of the product in areas where a cockroach infestation is well identified. The maintenance usage is then not acceptable and has to be removed from the label claims.

Before treatment, the professional users must survey the area to be treated to identify sites of cockroach infestation e.g. by using traps and/or flush-out aerosols, searching for droppings, cast skins and egg cases etc.

The RMS is also of the opinion to remove the word "rapid" mentioned in the sentence "is used indoor for the rapid control of cockroaches" because an insecticidal activity within 2 weeks does not reflect a rapid action.

2.2.5.8 Evaluation of the label claims

Based on the efficacy tests submitted and validated, the product ***MAXFORCE® PLATIN*** (RTU gel bait with 1% Clothianidin) can be granted with the following use conditions :

1) Against small cockroaches i.e. nymph and adult German cockroaches (*Blattella germanica*) for indoor use :

• at 0.1 g/m^2 (moderate infestation i.e. German cockroaches rarely visible during the day).

• at 0.2 g/m^2 (severe infestation i.e. German cockroaches commonly visible during the day) using 2 spots of 0.1 g/m^2

The gel baits must stay in place at least 14 days for optimal efficacy. One month after (taken into account as worst-case in the TOX risk assessment), new fresh gel baits can be reapplied if cockroaches are still visible.

2) Against large cockroaches i.e. nymph and adult oriental cockroaches (*Blatta orientalis*) at 0.2 g/m^2 using 2 spots of 0.1 g/m^2 for indoor use :

The gel baits must stay in place at least 4 weeks for optimal efficacy. If cockroaches are still visible, new fresh gel baits can be reapplied.

3) Against nymph and adult American cockroaches (*Periplaneta americana*) at 0.2 g/m^2 or at 0.3 g/m^2 using 2 or 3 spots of 0.1 g/m^2 respectively

The gel baits must stay in place at least 12 weeks for optimal efficacy. If cockroaches are still visible, new fresh gel baits can be reapplied.

According to the field tests provided by the Applicant, the product ***MAXFORCE® PLATIN*** (1% Clothianidin) used as a RTU gel bait (fresh product only) is efficacious against :

Ctenolepisma longicaudatum (grey silverfishes) at 0.1422 g/m² (0.1g ≈ 7 mm diameter drop).

The gel baits must stay in place at least 63 days for optimal efficacy. If silverfishes are still visible, new fresh gel baits can be reapplied.

The time between 2 applications can be shorter depending on the consumption of the bait or on its degree of degradation. However, the time between 2 applications can't be shorter than 4 weeks according to the TOX Risk Assessment.

So, the proposed label claims can be accepted if, on the label, the Applicant does mention :

- Before treatment, the professional users must survey the area to be treated to identify sites of cockroach infestation e.g. by using traps and/or flush-out aerosols, searching for droppings, cast skins and egg cases etc.
- For maximum effectiveness, all natural source of food palatable for cockroaches must be removed from the infested area to encourage the ingestion of the bait.
- For maximum effectiveness, the product must be placed in and around cockroach harborages.
- The bait should be placed out of sight
- Do not expose bait drops to sunlight or heat (i.e. heater, water heater, …).
- Place the bait spots in places inaccessible for children or pets. Avoid application to excessively dusty, damp or greasy locations, and surfaces subject to wet cleaning.

- The word "rapid" mentioned in the sentence "is used indoor for the *rapid* control of cockroaches" should be removed.

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

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

2.2.6 Risk assessment for human health

The toxicological properties of the active substance clothianidin are summarised in the CA report (AR Germany, 2014).

Acute oral and dermal toxicity tests as well as tests for skin and eye irritation and skin sensitisation have been conducted with the test product referred to as BES0600 Insecticide = Clothianidin RB 1 = MaxForce Platin.

According to the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP) the biocidal product MaxForce Platin is not to be classified for Acute Toxicity, Skin/Eye Irritation/Corrosion, Skin sensitisation, or any other endpoint.

2.2.6.1 Assessment of effects on Human Health

(I) Skin corrosion and irritation

(Cfr IUCLID Section 8.1)

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**
Skin irritation in vivo, OECD 404, GLP: yes, RL 1	Rabbit, New Zealand White, 3 females	BES0600 Insecticide, batch No 2012-004896 unchanged (no vehicle), semi occlusive, 4 h	Mean score (24, 48, 72h) per animal: Erythema : 0, 0, 0 Edema: 0, 0, 0	Erythema score (1h): 0 (3/3 animals) Edema score (1h): 0 (3/3 animals) There was no dermal irritation observed at any treated dose site during the study.	See Confidential PAR for more details

No human data is available for skin corrosion/irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation

Value/conclusion	Not irritating to skin
Justification for the value/conclusion	According to the skin irritation study (OECD Guideline 404) performed with the biocidal product, Clothianidin RB1/MaxForce Platin showed no irritating effect to the skin of rabbits.
Classification of the product according to CLP	Not classified.

(II) Eye Irritation

(Cfr IUCLID Section 8.2)

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**
Eye Irritation *in vivo*, OECD 405, GLP: yes, RL 1	Rabbit, New Zealand White, 3 females	BES0600 Insecticide, batch No 2012-004896, unchanged (no vehicle)	Mean scores per animal (24, 48, 72h): Cornea: 0, 0, 0 Iris: 0, 0, 0 Conjuctivae: 0, 0, 0 Chemosis: 0, 0, 0	Cornea (1h): 0 (3/3 animals) Iris (1h): 0 (3/3 animals) Conjuctivae (1h): 1 (3/3 animals) Chemosis (1h): 1 (1/3 animals) Discharge (1h): 1 (2/3 animals) All conjunctivae reactions were totally reversible within 24h.	See Confidential PAR for more details

No human data is available for serious eye damage/irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating to eye
Justification for the value/conclusion	According to the eye irritation study (OECD Guideline 405) performed with the biocidal product, Clothianidin RB1/MaxForce Platin showed no irritating effect to the eye of rabbits.
Classification of the product according to CLP	Not classified.

(III) Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the conclusion	No data on respiratory tract irritation is available for the biocidal product. Toxicological properties and classification of the biocidal product Clothianidin RB1/MaxForce Platin was deduced from the respective properties of the active substance clothianidin and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP and DSD	No classification for respiratory tract irritation is necessary.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	The toxicity of the active substance (clothianidin) and the co-formulants is known. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Data of the a.s. clothianidin were evaluated by the Rapporteur Member State (RMS) Germany and published as Assessment Report (AR Germany, 2014). Neither clothianidin nor any co-formulant is classified for STOT-SE 3, H335 – May cause respiratory irritation. Therefore, the biocidal product Clothianidin RB1/MaxForce Platin does not need to be classified for respiratory tract irritation.

(IV) Skin sensitization

(Cfr IUCLID Section 8.3)

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**
LLNA, OECD 429, GLP: yes, RL 1	mouse, CBA:J, female, 5 / group	BES0600 Insecticide, batch No 2012-004896 Vehicle: 1% Pluronic L92 surfactant in distilled water, 10%, 5%, 2.5% (w/w), topical application to the dorsum of each ear for 3 consecutive days Positive control: hexylcinnamicaldehyde, purity 96.2% (The undiluted test item or 25% and 50% dilutions in the vehicle were too viscous to be applied properly. Therefore, 10% (w/w) was the highest concentration tested.)	All tested dose levels (2.5, 5, 10% (w/w)) induced a stimulation index less than 3.0. Thus, the EC3 was not calculated. The stimulation index (SI) was calculated as 0.93, 1.24, 0.94 for the dose levels 2.5%, 5%, 10%, respectively. Positive control: SI 3.05% at 25% (w/w) (Irritation: As no edema and erythema formation was noted at the concentration of 10% (w/w), this concentration was chosen as the highest concentration in the main study.)	Deviation: ear thickness and bw not determined in preliminary experiment Neither edema nor erythema were observed. Thus, the test item is not excessively irritant at 10%	See Confidential PAR for more details

No human data is available for skin sensitisation.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitising.
Justification for the value/conclusion	According to a skin sensitisation study (OECD Guideline 429), the biocidal product Clothianidin RB 1/MaxForce Platin showed no sensitising effect as test material concentrations of 2.5, 5, and 10% (w/w) revealed SI values < 3%.

	In addition, because the more concentrated biocidal product could not be tested because of too viscous to apply, the toxicity of the active substance (clothianidin) and the co-formulants is reviewed. Thus, toxicological properties and classification of the biocidal product was in addition deduced from the respective properties of the a.s. and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Data of the a.s. clothianidin were evaluated by the Rapporteur Member State (RMS) Germany and published as Assessment Report (AR Germany, 2014). The biocidal product contains 1,2-benzisothiazolin-3-one and the reaction mass of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1). The additional label element EUH208 is triggered by the concentration of C(M)IT/MIT and BIT exceeding one tenth of the specific concentration limit for C(M)IT/MIT and BIT, respectively.
Classification of the product according to CLP and DSD	No classification for skin sensitisation is warranted. But: special labelling requirements to protect already sensitized individuals is required. EUH208: Contains 1,2-Benzisothiazolin-3-one and the reaction mass of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.

(V) Respiratory sensitization (ADS)

(Cfr IUCLID Section 8.4)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to the respiratory tract.
Justification for the value/conclusion	No data on respiratory sensitisation is available for the biocidal product. Toxicological properties and classification of the biocidal product Clothianidin RB1/MaxForce Platin was deduced from the respective properties of the active substance clothianidin and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP and DSD	No classification for respiratory sensitisation is necessary.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	The toxicity of the active substance (clothianidin) and the co-formulants is known. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). The biocidal product Clothianidin RB1/MaxForce Platin is not classified for skin sensitisation based on the results of a LLNA study. In the biocidal product neither clothianidin nor any of the co-formulants is classified for respiratory sensitisation. Therefore, the biocidal product Clothianidin RB1/MaxForce Platin does not need to be classified for respiratory sensitisation.

(VI) Acute toxicity

a. Acute toxicity by oral route

(Cfr IUCLID Section 8.5.1)

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**
Acute Oral Toxicity: Up-and-Down Procedure, OECD 425, GLP: yes, RL 1	rat, Sprague-Dawley, 3 female	BES0600 Insecticide, batch No 2012-004896 5000 mg/kg bw, Gavage, 50% in water: 60-80% too viscous to be administered properly	no test item related mortality and no clinical signs, no effect on body weight	>5000 mg/kg bw	-	See Confidential PAR for more details

No human data is available for acute oral toxicity.

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not harmful.
Justification for the selected value	According to an acute oral toxicity study (OECD Guideline 425), the oral LD_{50} of the tested biocidal product Clothianidin RB1/MaxForce Platin exceeds 5000 mg/kg bw.
Classification of the product according to CLP and DSD	Not classified.

b. Acute toxicity by inhalation

(Cfr IUCLID Section 8.5.2)

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not harmful.
Justification for the selected value	No data on acute inhalation toxicity is available for the biocidal product. Toxicological properties and classification of the biocidal product Clothianidin RB1/MaxForce Platin was deduced from the respective properties of the active substance clothianidin and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP and DSD	Not classified.

No human data is available for acute inhalation toxicity.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	The toxicity of the active substance clothianidin and the co-formulants is known. Thus, toxicological properties and classification of the biocidal product Clothianidin RB1/MaxForce Platin can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Data of the a.s. clothianidin were evaluated by the Rapporteur Member State (RMS) Germany (AR Germany, 2014). Clothianidin is not classified for acute inhalation toxicity. The co-formulant Bitrex Anhydrous (denatonium benzoate) is classified for Acute Tox 4; H332 according to CLP. A specific concentration limit is not specified for Bitrex Anhydrous in Annex VI of Regulation (EC) No 1272/2008, so that the generic concentration limit of the CLP applies: All components classified for acute toxicity in Categories 1-3 at a concentration < 0.1% and in Category 4 at a concentration < 1% do not need to be considered for classification purposes of a mixture. The concentration of Bitrex Anhydrous is below 1% and, therefore, does not need to be considered. Therefore, no classification and labelling of the biocidal product Clothianidin RB1/MaxForce Platin is warranted with respect to acute inhalation toxicity according to the provisions of the CLP regulation.

c. *Acute toxicity by dermal route*

(Cfr IUCLID Section 8.5.3)

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**
Standard acute method, limit test, OECD 402, GLP: yes, RL 1	rat, Sprague-Dawley, male / female, 5 / group	BES0600 Insecticide, batch No 2012-004896, unchanged (no vehicle), 5000 mg/kg bw, approximately 10% of body surface	No mortality, No effects on body weight, Clinical signs: Erythema occurred in 3 animals (1 male, 2 females) reversible by day 7. No further clinical findings were observed.	> 5000 mg/kg bw	-	See Confidential PAR for more details

No human data is available for acute dermal toxicity

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not harmful.
Justification for the selected value	According to an acute dermal toxicity study (OECD Guideline 402), the dermal LD_{50} of the tested biocidal product Clothianidin RB1/MaxForce Platin exceeds 5000 mg/kg bw.
Classification of the product according to CLP and DSD	Not classified.

(VII)Information on dermal absorption

A study or other data on the potential dermal absorption of clothianidin from the biocidal product Clothianidin RB1/MaxForce Platin is not available. For this reason, the dermal absorption data reported in the assessment report on clothianidin (AR Germany, 2014) has been used by the applicant in order to assess the dermal absorption.

Within the assessment report for clothianidin (Product Type 18) a value of 2% dermal absorption is proposed based on an *in vivo* study in rhesus monkeys for another biocidal product which was already been accepted for PT8. Concerning the PT18 formulation/use this value covers in use concentrations of the spray liquid/bait gel in the range of 8.7 – 26 g/L. Thus the concentration of 10 g clothianidin per kg (11 g/L calculated with ρ=1.1 g/mL) present in the Clothianidin RB1/MaxForce Platin gel formulation is well covered by this range. Therefore, it is considered by the applicant not necessary to submit a new study, and considered to be a reasonable approach to consider 2% as well for the clothianidin gel formulation of the biocidal product Clothianidin RB1/MaxForce Platin.

However, the BE RMS has some reservation to use a dermal absorption of 2% for the following reasons: The 2% dermal absorption is applicable for a formulation tested in the frame of PT8. This dermal absorption was then used for a formulation (not the same) in the frame of PT18, and should be used again for another formulation. Nevertheless, we agree that the 2% value covers the in use concentration. In addition, the Clothianidin RB1/MaxForce Platin gel formulation is also water-based and the co-formulants are not expected to increase dermal penetration of the a.s. clothianidin. {information removed, see Confidential PAR for more details}The Clothianidin RB1/MaxForce Platin gel formulation is not irritating to the skin (also the initial scoring is zero), and is not skin sensitizing.

According to the Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665), a default value of 75% should be used for products or in use dilutions containing ≤ 5% active substance.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Clothianidin
Value(s)*	75%
Justification for the selected value(s)	No test data on the formulation. Default value, according to the Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665)

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

It is concluded that the biocidal product does not contain a substance of concern that needs to be considered for the purpose of human health risk assessment.

Regarding the Clothianidin 1% Gel formulation it is noted that the product contains some substances that are classified regarding human health effects. Classification mainly refers to local effects, i.e. skin corrosion, skin irritation, skin sensitisation and eye damage/irritation. Nevertheless, due to the overall very low content of these substances within the formulation only one substance triggers potential classification of the product as far as the concentration of the substance within the formulation is concerned, i.e. {information removed, see Confidential PAR for more details}
No corrosivity potential is therefore expected for the product.
Results of the acute toxicity studies done with the Clothianidin RB1/MaxForce Platin formulation confirm that the product is not corrosive nor is it irritating to skin. Thus no classification of the biocidal product concerning human health is required.

The biocidal product contains 1,2-benzisothiazolin-3-one and the reaction mass of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1). Results of the skin sensitisation study done with the Clothianidin RB1/MaxForce Platin formulation confirm that the product is not a skin sensitizer.However, the additional label element EUH208 to protect already sensitized individuals is triggered by the concentration of C(M)IT/MIT and BIT exceeding one tenth of the specific concentration limit for C(M)IT/MIT and BIT, respectively.

Therefore, it is concluded that the biocidal product Clothianidin RB1/MaxForce Platin gel does not contain a substance of concern that needs to be considered for the purpose of human health risk assessment.

(IX) Available toxicological data relating to a mixture

Toxicological data relating to a mixture that a substance(s) of concern is a component of, are not required.

(X) Other

Germ Cell Mutagenicity, Carcinogenicity and Reproductive Toxicity

Neither clothianidin nor any of the co-formulants is classified for germ cell mutagenicity, carcinogenicity and reproductive toxicity.

Thus, the biocidal product does not need to be classified for germ cell mutagenicity, carcinogenicity or reproductive toxicity.

Aspiration hazard

Neither the a.s. clothianidin nor any co-formulant is classified for aspiration hazard.

Thus, the biocidal product does need to be classified for aspiration toxicity.

Specific Target Organ Toxicity – Single Exposure (STOT-SE)

No classification of clothianidin with respect to specific target organ toxicity – single exposure (STOT-SE) is proposed. No co-formulant is classified for STOT-SE effects.

Therefore, the biocidal product does not need to be classified with respect to STOT-SE effects.

Specific Target Organ Toxicity – Repeated Exposure (STOT-RE)

Neither the a.s. clothianidin nor any co-formulant is classified for STOT-RE effects.

Therefore, the biocidal product does not need to be classified with respect to STOT-RE effects.

Food and feedingstuffs studies

The biocidal product, Clothianidin RB1/MaxForce Platin, is not intended for direct application to foods or feedingstuff or to surfaces and areas where foods or feedingstuff are prepared or stored. Hence, exposure of food and feedingstuff to the Clothianidin RB1/MaxForce Platin can be excluded when applied according to the recommended uses and label instructions for use (controlled placement: place in places inaccessible for children or animals; do not apply to surfaces on which food or feed is stored, prepared or eaten; do not apply in animal pens and cages). Additional food or feedingstuff studies are not required.

ED properties

A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the ED properties of the substances in Clothianidin RB1/MaxForce Platin:

1. Assessment of the ED properties of the active substances in Clothianidin RB1/MaxForce Platin:

- According to point 2.1.1 of the final CA document, the assessment of ED properties of the active substances that have already been evaluated and approved will be coordinated at EU level. Hence, the rMS should not evaluate the ED properties of these substances nor request additional data on the ED properties in the context of product authorisation procedures. As Clothianidin is not part of the list1 of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review.

- Therefore, BE eCA considers that there are no concerns regarding ED properties of Clothianidin.

2. Assessment of the ED properties of non-active substances (co-formulants) in Clothianidin RB1/MaxForce Platin:

- After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex - ED assessment), none of the co-formulants are subject to an on-going evaluation or a decision regarding their ED properties. Based on the available information, BE eCA considers that there is no concern regarding the ED properties of these co-formulants.

Overall conclusion on the biocidal product regarding ED properties:
Based on the existing knowledge and the data provided by the applicant, there is no indication of concern regarding the ED properties of the substances used in the biocidal product/product family Clothianidin RB1/MaxForce Platin.

If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product/family authorisation will be revised.

Other test(s) related to the exposure to humans

The biocidal product, Clothianidin RB1/MaxForce Platin, is an insecticide used by professionals. Other test(s) related to the exposure to humans are not available and are not necessary for the proposed biocidal use pattern. Exposure estimates and risk characterisations are provided in the human risk assessment. The risk characterisation showed no concern when Clothianidin RB1/MaxForce Platin is handled and applied as intended (controlled placement: place in places inaccessible for children or animals; do not apply to surfaces on which food or feed is stored,

prepared or eaten; do not apply in animal pens and cages) or when people are indirect exposed to residues of the biocidal product. Therefore, no other test related to the exposure to humans is necessary.

2.2.6.2 Exposure assessment

The biocidal product, Clothianidin RB1/MaxForce Platin, is an insecticidal bait developed for the control of cockroach nymphs and adults as well as for the control of silverfish. It contains the active substance clothianidin (10 g/kg). The product is formulated as a ready to use gel and packed in cartridges/syringes (containing 10 to 30 g of the product) that are designed for the controlled placement of the bait.

The PT 18 biocidal product is intended for professional uses only and is applied as spot treatment by dispersion through a "gage needle" in identified target areas in e.g. kitchens, slaughterhouses, warehouses, restaurants hospitals etc.

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 [b)]	**Professional use**	**Non-professional use**	**Industrial use [b)]**	**Professional use**	**General public**	**Via food [a)]**
Inhalation	No	No	n.a.	No	n.a.	No [c)]	No
Dermal	No	Yes	n.a.	No	n.a.	Yes	No
Oral	No	No	n.a.	No	n.a.	Yes	No

n.a.: not applicable

[a)]: Considering the intended use application of bait spots to control cockroaches and silverfish and the formulation as a gel which ensures a controlled placement of the product exposure via food can be excluded.

[b)]: As already outlined in the assessment report for clothianidin: The exposure during the formulation of the biocidal product is not under the requirements of the BPD. However, it is assumed that the production is performed in conformity with national and European occupational safety and health regulations.

[c)]: Due to the very low vapour pressure (vapour pressure of 3.8×10^{-11} Pa at 20°C) and its gel formulation, the risk of inhalation exposure to vapour can be regarded as negligible. Nevertheless inhalation exposure to volatilised clothianidin will be assessed following the tier one approach outlined in HEEG opinion 13.

(I) 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 – placing of the bait spots	Professionals
2.	Post application	Primary exposure – removal of an empty cartridge	Professionals
3.	Removal of bait spots	Secondary exposure – house owner (adult) removes bait spots	General public
4.	Accidental exposure	Secondary exposure – a toddler (10 kg) gets accidentally access to a spot and ingests corresponding amount of product of bait	General public (toddler)
5.	Exposure to volatilised clothianidin (vapour)	Secondary exposure – following application of the product an infant, child or adult inhales volatilised clothianidin	General public

The assessment of the biocidal product has been undertaken using a tiered approach. In the first instance exposure scenarios have been assessed using worst-case assumptions (e.g. no personal protective equipment is used). Where the risks to human health and companion animals following exposure to clothianidin were considered to be acceptable the exposure scenario was not refined further. If an unacceptable risk was identified for a particular exposure scenario, then the assessment was refined further (e.g. by additional PPE).

Concerning the exposure assessment for the biocidal product reference is made to the EU evaluation of the active substance imidacloprid with one of the representative formulations, i.e. Imidacloprid Gel 2.15%, essentially referring to the same type of formulation. In addition, the intended use and type of application is the same. Thus it is considered to be a reasonable approach to follow the same procedures as considered for the EU evaluation of representative formulation Imidacloprid Gel 2.15%.

(II) Industrial exposure

The exposure during the formulation of the biocidal product is not under the requirements of the BPR. Otherwise the product is not used in an industrial way.

(III) Professional exposure

Primary exposure

Due to the ready to use formulation no mixing and loading is required. With respect to exposure during application it was considered that the operator could come into contact with the formulation when sealing partially used cartridges, with the end cap provided by the manufacturer, and/or when removing the end cap. Furthermore it was concluded that though no cleaning of the application equipment is required the operator might come into contact with the product when removing an empty cartridge.

Scenario [1] Primary exposure – Application – Placing of the bait spots by the professional operator

Description of Scenario [1]: Primary exposure – Application – Placing of the bait spots by the professional operator

When assessing dermal exposure to Clothianidin Gel 1% / MaxForce Platin the special application pattern of the product – spot application using the syringe or cartridge together with suitable gel applicator – has to be taken into account. The spot application together with the gel formulation reduces dermal exposure to the operator via splashes or drift during application. Under normal use conditions operator exposure to Clothianidin Gel 1% / MaxForce Platin via the dermal route is unlikely to occur during placing the gel spots.

However, there might be a risk for hand exposure when sealing partially used cartridges, with the end cap provided by the manufacturer, and/or when removing the end cap.

For the representative formulation {information removed, see Confidential PAR for more details} being evaluated on EU level it was agreed that the end cap be handled five times for sealing and opening the cartridge (e.g. due to treatment at different locations). Hence the same procedure is followed in this evaluation.

Concerning dermal exposure it was assumed that each time when sealing or opening the cartridge a string of 0.5 cm of the gel will be transferred to the hand. Thus it was concluded that about 0.004 cm^3 of gel might be transferred to the hand during sealing or opening the cartridge considering a diameter of 1 mm of the gel string (inner diameter of the "gage needle"). This corresponds to 0.005 g gel per sealing and opening (= value of 0.00444 g rounded to the upper end) when taking into account the specific weight of Clothianidin Gel 1% / MaxForce Platin of 1.11 g/cm^3, or to 0.05 g gel per day for the assumed 5 times sealing and 5 times opening.

Considering the concentration of clothianidin of 10 mg/g, a default dermal absorption of 75% and a body weight of 60 kg the corresponding systemic exposure of the professional operator when applying the product without the use of personal protective equipment is calculated using the following formula:

$$S = AS \times CA \times DA \div BW$$

Where:

S = Systemic exposure [mg/kg bw]

AS = Amount of product present on skin [g]

CA = Concentration of the active substance [mg/g]

DA = dermal absorption [fraction]

BW = Body weight [kg]

Due to both the non-volatile nature of clothianidin (Vp 3.8 x 10^{-11} Pa at 20°C) and the gel formulation it can be considered that inhalation exposure to *Clothianidin Gel 1% / MaxForce Platin* will not occur in all phases of application. The inhalation exposure is therefore assessed as negligible through all phases of application. This conclusion is further confirmed by the results obtained for scenario 5 "Exposure to volatilised clothianidin".

	Parameters	Value
Tier 1	Concentration of clothianidin	10 mg/g
	Amount of product present on skin	0.05 g
	Dermal absorption	0.75
	Body weight	60 kg

Calculations for scenario [1]: Primary exposure – Application – Placing of the bait spots by the professional operator

S = AS x CA x DA ÷ BW
= 0.05 g x 10 mg/g x 0.75 / 60
= 0.00625 mg/kg bw/d

Summary table: estimated exposure from professional use - Application					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1]	1 / no PPE	-	0.00625	-	0.00625

Scenario [2] Primary exposure – Post Application – Removal of an empty cartridge by the professional operator

Description of Scenario [2]: Primary exposure – Post Application – Removal of an empty cartrigde by the professional operator
Concerning removal of an empty cartridge the EU evaluation for Imidacloprid GL 2.15 assumed that potentially the amount of product equivalent to one sealing event could be transferred to the skin. Thus the same approach is followed in this evaluation. Referring to scenario [1] the amount of gel being transferred to the skin during one sealing/opening event is assumed to be 0.005 g gel. Considering the concentration of clothianidin of 10 mg/g, a default dermal absorption of 75% and a body weight of 60 kg the corresponding systemic exposure of the professional operator when applying the product without the use of personal protective equipment is calculated using the following formula: S = AS x CA x DA ÷ BW Where: S = Systemic exposure [mg/kg bw] AS = Amount of product present on skin [g] CA = Concentration of the active substance [mg/g] DA = dermal absorption [fraction] BW = Body weight [kg] Due to both the non-volatile nature of clothianidin (Vp 3.8 x 10^{-11} Pa at 20°C) and the gel formulation it can be considered that inhalation exposure to *Clothianidin Gel 1% / MaxForce Platin* will not occur in all phases of application. The inhalation exposure is therefore assessed as negligible through all phases of application. This conclusion is further confirmed by the results obtained for scenario 5 "Exposure to volatilised clothianidin".

	Parameters	Value
Tier 1	Concentration of clothianidin	10 mg/g
	Amount of product present on skin	0.005 g
	Dermal absorption	0.75
	Body weight	60 kg

Calculations for scenario [2]: Primary exposure – Post Application – Removal of an empty cartridge by the professional operator

S = AS x CA x DA ÷ BW
= 0.005 g x 10 mg/g x 0.75 / 60
= 0.000625 mg/kg bw/d

Summary table: estimated exposure from professional use – Post Application					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2]	1 / no PPE	-	0.000625	-	0.000625

Combined scenarios

For the professional operator a combined exposure from placing the bait spots (scenario 1) and removal of an empty cartridge (scenario 2) can be assumed. The overall combined exposure is 0.006875 mg/kg bw (= 0.00625 mg/kg bw from placing the bait spots + 0.000625 mg/kg bw from removing an empty cartridge).

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenarios [1,2]	-	0.006	-	0.006

In conclusion:

Summary table: estimated primary exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1]	1 / no PPE	-	0.00625	-	0.00625
Scenario [2]	1 / no PPE	-	0.000625	-	0.000625
Scenarios [1,2]	1 / no PPE	-	0.006875	-	0.006875

(IV) Non-professional exposure

Not relevant. The biocidal product Clothianidin RB1/MaxForce Platin is intended for professional use only.

(V) Exposure of the general public

Removal of old baits/gel spots is the task of the professional pest control operator. Nevertheless, it is assumed that the house owner could be exposed to the biocidal product Clothianidin RB1/MaxForce Platin during the removal of bait spots. Thus, scenario [3] was included. Additionally, it was assumed that a toddler could get access to a gel spot and ingests the corresponding amount of gel accidentally. For several reasons that is considered to be an unlikely/unrealistic scenario [4]:

- The label clearly informs the professional operator that the product has to be placed out of reach of children.

- {information removed, See Confidential PAR for more details}. Accordingly, it is not expected that a toddler would remove significant amounts of gel even if by accident access to a gel spot is given.

- As a further risk mitigation measure the product contains the bittering agent Bitrex.

Thus the scenario [4] has to be regarded as rather theoretical but nevertheless will be taken into account.

Furthermore, following recommendations given in HEEG opinion 13 inhalation exposure to volatilized clothianidin is assessed, scenario [5], following the tier one approach. Though due to the very low vapour pressure of 3.8×10^{-11} Pa (at 20°C) and the gel formulation this route of exposure can already be regarded as negligible.

Scenario [3] Secondary exposure – Acute phase - house owner (adult) removes bait spots

Description of Scenario [3] Secondary exposure – Acute phase - house owner (adult) removes bait spots

It is assumed that the house owner can remove bait spots. As no guidance is available to assess the corresponding exposure a worst case default approach was used assuming that a whole apartment of 100 m² was treated at the maximum application rate and the total amount of product is removed by the house owner. {information removed, See Confidential PAR for more details} therefore a lower dislodgeability can be expected for the dried gel. As was agreed for the same type of formulation in the CAR imidacloprid (Germany, 2011), and as also for Clothianidin RB1/MaxForce Platin the baits are solid and only handled for a very short time it is reasonable to assume the same dislodgeable fraction (df) , i.e. the amount transferred to the skin, of 1 % (agreed that the default values from the Guidance for Human Health Risk Assessment, Volume II, Part B, 2013 are too worst case, and agree with the value of 1% also agreed and used in CAR imidacloprid for the same type of formulation). Considering the maximum recommended treatment rate of 0.3 g Biocidal product/m² the amount of product removed by the house owner is calculated using the following formula:

$$AR = SA \times TR$$

Where:

AR = Amount product removed [g]
SA = Size of the apartment [m²]
TR = Treatment rate [g product/m²]

Accordingly, considering a dislodgeable fraction of 1%, the concentration of clothianidin of 10 mg/g, a default dermal absorption of 75% and a body weight of 60 kg the corresponding systemic exposure of the house owner removing the bait spots is calculated using the following formula:

$$S = AR \times DF \times CA \times DA \div BW$$

Where:

S = Systemic exposure [mg/kg bw]
AR = Amount product removed [g]
DF = Dislodgeable fraction
CA = Concentration of the active substance [mg/g]
DA = dermal absorption [fraction]
BW = Body weight [kg]

	Parameters	Value
Tier 1	Concentration of clothianidin	10 mg/g
	Dislodgeable fraction	1%
	Treatment rate	0.3 g/m²
	Treatment area (apartment size)	100 m²
	Dermal absorption	0.75
	Body weight	60 kg

Calculations for scenario [3] Secondary exposure – Acute phase - house owner (adult) removes bait spots

AR = SA x TR
= 100 m^2 x 0.3 g/m^2
= 30 g

S = AR x CA x DA ÷ BW
= 30 g x 0.01 x 10 mg/g x 0.75 / 60 kg
= 0.0375 mg/kg bw/d

Summary table: estimated exposure for general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [3]	1/ no PPE	-	0.0375	-	0.0375

Scenario [4] Secondary exposure – Acute phase-Accidental ingestion of a bait spot by a toddler

Description of Scenario [4] Secondary exposure – Acute phase-Accidental ingestion of a bait spot by a toddler
It is assumed that a toddler could get access to a gel spot and ingests the corresponding amount of gel accidentally. For several reasons this is considered to be an unlikely/unrealistic scenario: - The label clearly informs the professional operator that the product has to be placed out of reach of children. - {information removed, See Confidential PAR for more details} Accordingly, it is not expected that a toddler is able to remove significant amounts of gel even if by accident access to a gel spot is given. - As a further risk mitigation measure the product contains the bittering agent Bitrex. Considering the maximum amount of product present in one spot of 0.1 g product, the concentration of clothianidin of 10 mg/g, an oral absorption of 100% and a body weight of 10 kg the corresponding systemic exposure of the toddler is calculated using the following formula: S = AR x CA x OA ÷ BW Where: S = Sytemic exposure [mg/kg bw] AR = Amount product removed [g] CA = Concentration of the active substance [mg/g] OA = dermal absorption [fraction] BW = Body weight [kg]

	Parameters	Value
Tier 1	Concentration of clothianidin	10 mg/g
	Amount of removed product	0.1 g
	Oral absorption	1
	Body weight	10 kg

Calculations for scenario [4] Secondary exposure – Acute phase-Accidental ingestion of a bait spot by a toddler

S = AR x CA x OA ÷ BW
= 0.1 g x 10 mg/g x 1 / 10
= 0.1 mg/kg bw/d

Summary table: estimated exposure for general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [4]	1/ no PPE	-	-	0.1	0.1

Scenario [5] Secondary exposure – Chronic phase - Inhalation exposure to volatilised active substance

Description of Scenario [5] Secondary exposure – Chronic phase - Inhalation exposure to volatilised active substance
Secondary exposure to volatilised clothianidin is estimated following in a tier one approach the recommendations given in HEEG Opinion 13 (HEEG opinion on Assessment of Inhalation Exposure of Volatilised Biocide Active Substance) though we conclude that due to the very low vapour pressure (vapour pressure of 3.8 x 10^{-11} Pa at 20°C) of clothianidin and its gel formulation, the risk of inhalation exposure to vapour can be regarded as negligible. Following recommendations given in HEEG opinion 13 exposure to volatilised active substance is calculated using the following formula: $Expo = SVC[\mathrm{mg/m^3}] \cdot \frac{ir[\mathrm{m^3/24\ h}]}{bw[\mathrm{kg}]} = 0.41 \cdot \frac{mw \cdot vp \cdot ir}{bw}$ [mg/kg bw/d] $\frac{Expo}{AEL} = \frac{0.41 \cdot mw[\mathrm{g/mol}] \cdot vp[\mathrm{Pa}] \cdot ir[\mathrm{m^3/24\ h}]}{AEL[mg/kg] \cdot bw[\mathrm{kg}]}$ Where *mw* and *vp* denote the molecular weight (in g/mol) and the vapour pressure (in Pa). Where *ir* and *bw* denote the long-term infant inhalation rate (in m^3/24h) and the infant body weight (in kg). The default values for an infant are taken from the most recent Guidance: ECHA, Biocides Human Health Exposure methodology, 2015. It is concluded that if the resulting value is below ≤ 1 the risk for inhalation exposure to volatilised active substance can be regarded as negligible. If the inhalation risk for the infant is negligible then the inhalation risk for the child and for the adult can also be considered to be negligible.

	Parameters	Value
Tier 1	Vapour pressure (vp)	3.8 x 10^{-11} Pa (20°C)
	Molecular weight (mw)	249.7 g/mol
	Infant inhalation rate (ir)	5.4 m^3/24h
	Infant body weight (bw)	8 kg
	Inhalation absorption	100

Calculations for scenario [5] Secondary exposure – Chronic phase - Inhalation exposure to volatilised active substance

Exposure = 0.41 x 249.7 x 3.8x10^{-11} x 5.4 / 8
= 2.6 x 10^{-9} mg/kg bw/d

Summary table: estimated exposure for general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [5]	1 / no PPE	2.6 x 10^{-9}	-	-	2.6 x 10^{-9}

In conclusion:

	Summary table: estimated secondary exposure for the general public					
Exposure scenario	**Tier/ PPE**	**Exposed population**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [3]	1 / no PPE	adult	-	0.0375	-	0.0375
Scenario [4]	1 / no PPE	toddler	-	-	0.1	0.1
Scenario [5]	1 / no PPE	whole population	≤ 2.6×10^{-9}	-	-	≤ 2.6×10^{-9}

Combined scenarios

Concerning exposure of the general public, it can be concluded that with the intended use of the biocidal product Clothianidin RB1/MaxForce Platin a combination of the exposure scenarios is not relevant.

(VI) Monitoring data

No further information on surveys or studies with the biocidal product or with a surrogate is submitted.

(VII)Dietary exposure

Considering the type of formulation, a gel, and its intended use , the controlled placement of gel spots in insects hiding places but inaccessible for children and animals, not in pens and cages, not on surfaces on which food or feed is stored, prepared or eaten, a contamination of food/feed can reasonable be excluded.

Hence it is concluded that for the biocidal product Clothianidin RB1/MaxForce Platin dietary exposure is not relevant.

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s) [2]**
1.	Plant protection products (Clothianidin was approved until 31/01/2019 under PPP regulation. The renewal of approval was not supported by the main applicant. So the active substance should be withdrawn from EU PPP market after this date)	Insecticide in agriculture	ADI: 0.097 mg/ kg bw/d ARfD: 0.1 mg/ kg bw/d AOEL: 0.1 mg/ kg bw/d MRL in fruits, plants, and products of animal origin from 0.01 to 1.5 mg/kg

[1] e.g. plant protection products, veterinary use, food or feed additives

[2] e.g. MRLs. Use footnotes for references.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not relevant.

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

Not relevant.

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

Not relevant.

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

Exposure associated with the production and formulation of the biocidal product is not addressed and is not considered to be relevant as it is covered by other pieces of legislation such as the REACH regulation (Regulation (EC) No. 1907/2006).

(IX) Aggregated exposure

Aggregated exposure from biocidal uses of the product is not relevant as exposure towards the active substance occurs in a timely and spatially manner. Where relevant, combined exposure scenarios have been addressed accordingly.

(X) Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
1.	Professionals	1 / no PPE	0.00625
2.	Professionals	1 / no PPE	0.000625
1.+ 2.	Professionals	1 / no PPE	0.006875
3.	General public	1 / no PPE	0.0375
4.	General public	1 / no PPE	0.1
5.	General public	1 / no PPE	$\leq 2.6 \times 10^{-9}$

2.2.6.3 Risk characterisation for human health

The reference values to be used in the risk characterisation as proposed in the assessment report of clothianidin (PT 18): Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products; Evaluation of active substances; Assessment Report; Clothianidin; October 2014. Online available at: http://dissemination.echa.europa.eu/Biocides/factsheet?id=0015-18

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (mg/kg bw/d)	AF[1]	Correction for oral absorption (%)	Value (mg/kg bw/d)
AELshort-term	Pharmacological study in mice	25	100	100	0.25
AELmedium-term	Oral, 90-d dog, supported by 90-d rat and embryotoxicity study in rabbit	20	100	100	0.2
AELlong-term	Oral, 2 year study in rat, supported by 2-generation study in rat	10	100	100	0.1
ARfD	Pharmacological study in mice	25	100	100	0.25
ADI	Oral, 2 year study in rat, supported by 2-generation study in rat	10	100	100	0.1

[1] Default assessment factors of 10 for intra-species variability and 10 for inter-individual variability.

Maximum residue limits or equivalent

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRLs	Reg. (EC) No 396/2005, Commission Regulation (EU) 2016/156, SANCO/10533/05	MRL in fruits, plants, and products of animal origin	From 0.01 to 1.5 mg/kg
ADI	06/41/EC		0.097 mg/kg bw/d
ARfD	06/41/EC		0.1 mg/kg bw
AOEL	06/41/EC		0.1 mg/kg bw/d

Specific reference value for groundwater

No specific reference value for groundwater was established. Thus, the European standard value of 0.1 µg/L for the maximum admissible concentration of pesticides in drinking water (Council Directive 98/83/EC) does apply.

(I) Risk for industrial users

The exposure during the formulation of the biocidal product is not under the requirements of the BPR. Otherwise the product is not used in an industrial way.

(II) Risk for professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1] Application Placing bait spots	1	10	0.1	0.00625	6.25	Yes
[2] Post Application Removal of empty cartridge	1	10	0.1	0.000625	0.63	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1, 2] Placing bait spots and removal of empty cartridge	1	10	0.1	0.006875	6.88	Yes

Local effects

The active substance clothianidin is not classified concerning effects that could be relevant in terms of local effects. Thus it is concluded that no further assessment considering local effects that might be triggered by the active substance is required.

Furthermore, as indicated the formulation does not contain a substance of concern which could trigger a local effect assessment. In addition, the acute studies performed with the biocidal product did not trigger any classification in this context.

It also has to be taken into consideration that the risk for the professional user to come into contact with the biocidal product is low due to the use of cartridges, a suitable gel applicator and the physical form, a gel.

Nevertheless, the biocidal product contains 1,2-benzisothiazolin-3-one and the reaction mass of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1). The additional label element EUH208 to protect already sensitised individuals is triggered by the concentration of C(M)IT/MIT and BIT exceeding one tenth of the specific concentration limit for C(M)IT/MIT and BIT, respectively.

As a further risk mitigation measure the label recommends to use protective gloves when handling the biocidal product.

Conclusion

The estimated systemic exposure of the professional operator to the active substance clothianidin assuming a reasonable combination of exposure scenarios, i.e. application of the product (scenario 1) and removal of an empty cartridge (scenario 2) again is below the relevant reference value even when considering the tier one approach which assumes that no personal protective is worn.

In conclusion, based on the results no unacceptable risk is anticipated for the professional user of the biocidal product Clothianidin RB1/MaxForce Platin even if unprotected. However, according to good occupational practice and taking into account the additional label element EUH208 it is recommended that protective gloves are worn.

(III) Risk for non-professional users

Not relevant. The biocidal product is intended for professional use only.

(IV) Risk for the general public

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[3] Removal bait spots by house owner	1	25	0.25	0.0375	15	Yes
[4] accidental ingestion of bait spot by toddler	1	25	0.25	0.1	40	Yes
[5] inhalation of volatilised a.s.	1	10	0.1	$\leq 2.6 \times 10^{-9}$	2.6×10^{-6}	Yes

Combined scenarios

Concerning exposure of the general public, it can be concluded that with the intended use of the biocidal product Clothianidin RB1/MaxForce Platin a combination of the exposure scenarios is not relevant.

Local effects

The active substance clothianidin is not classified concerning effects that could be relevant in terms of local effects. Thus it is concluded that no further assessment considering local effects that might be triggered by the active substance is required.

Furthermore, as indicated the formulation does not contain a substance of concern which could trigger a local effect assessment. In addition, the acute studies performed with the biocidal product did not trigger any classification in this context.

It also has to be taken into consideration that if used as intended the risk for the general public to come into contact with the product is very low.

Nevertheless, the biocidal product contains 1,2-benzisothiazolin-3-one and the reaction mass of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1). An allergic reaction can be triggered in already sensitised individuals. This could happen from contact from the dried biocidal product.

Therefore, as a further risk mitigation measure the instructions for use mention that removal of old baits/gel spots should be done by a professional pest control operator.

Accordingly, concerning local effects no unacceptable risk is anticipated for the general public with the intended use of the biocidal product Clothianidin RB1/MaxForce Platin.

Conclusion

The estimated systemic exposures of the general public to clothianidin is always below the relevant reference value even when considering a house owner removing bait spots or a child ingesting the amount present in one gel spot. In this context it has to be taken into account that as risk mitigation the product contains Bitrex.

In conclusion, based on the results no unacceptable risk is anticipated for the general public with the intended use of the biocidal product.

(V) Risk for consumers via residues in food

Considering the type of formulation, a gel, and its intended use , the controlled placement of gel spots in insects hiding places but inaccessible for children and animals, not in pens and

cages, not on surfaces on which food or feed is stored, prepared or eaten, a contamination of food/feed can reasonable be excluded.

Hence it is concluded that for the biocidal product Clothianidin RB1/MaxForce Platin dietary exposure is not relevant.

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

No substances of concern were identified. Therefore exposure to several active substances or substances of concern within the product is not relevant.

2.2.7 Risk assessment for animal health

Animal exposure to the active substance clothianidin can be excluded when applied according to the recommended use described in the label instructions, as the biocidal product Clothianidin RB1/MaxForce Platin is not intended to be applied to animal pens and cages, or on areas accessible to animals. Therefore no unacceptable risk to animal health is foreseen.

2.2.8 Risk assessment for the environment

The following assessment covers the formulated product Maxforce Platin, a gel bait used as insecticide for controlling nymphs and adults cockroach as well as silverfish (Product Type 18). The product contain one active substance, clothianidin, at a concentration of 1.026%[1] (Please refer to Table 3.6–1 in Confidential annex).

2.2.8.1 Effects assessment on the environment

All data used for the effect assessment of Clothianidin RB 1 are based on the available information on the active substance clothianidin, such as they are presented in its CAR for Product Type 18 (2014).

No new data relevant for the environmental evaluation, neither on the products, nor on the active substances, have been submitted by the applicant.

An overview of the physico-chemical characteristics and ecotoxicity data of the active substances, taken from the EU CAR for PT 18, is summarized below.

Environmental fate and behavior of the active substance

Biodegradation

The key results of the biodegradation studies are summarized in the table below:

Summary of the key results of the biodegradation studies of clothianidin in the different environmental compartments.

Environmental compartment	Distribution (%)	
Water (aerobic)	Clothianidin TMG	18.7 1.3
Sediments (aerobic)	Clothianidin TMG	37.3 22.9
Water-sediment (anaerobic)	Clothianidin TMG	- < 5
Manure (anaerobic)	Clothianidin TMG	35 58
Soil (aerobic)	Clothianidin MNG TZNG TZMU NTG	14.8 10.7 9.1 < 10 < 10

[1] Please note that 1.026% correspond to the technical content of Clothianidin in the formulated product and was used as a worst-case concentration. However the actual content of Clothianidin in formulated product is 1.00% (1.026 % w/w technical-grade Clothianidin with 97.5 % minimum purity = 1.00% w/w pure Clothianidin)

Environmental compartment	DT_{50} (days at 12°C)	
Water (aerobic)	Clothianidin	58.4–94.4
Entire system (aerobic)	Clothianidin	145.3–109.2
Water (anaerobic)	Clothianidin	7.6
Entire system (anaerobic)	Clothianidin	40
Manure (anaerobic)	Clothianidin TMG	25.4–59.9 259.2–375.5
Soil (aerobic – lab)	Clothianidin MNG TZNG	518 156–205 118–211
Soil (aerobic – field)	Clothianidin	429.8

Clothianidin was not readily biodegradable. Moreover it is considered to be persistent in both aerobic and anaerobic water-sediment systems. Clothianidin also showed a limited anaerobic metabolism in manure and TMG, its main metabolite, is considered very persistent.

Soil field dissipation studies confirmed the insignificant primary degradation and the high persistency of clothianidin in soil. Please note that with a DT_{90} value of more than one year in soil field tests ($DT_{90\ (12°C)}$ = 1284.7 d, geometric mean , n = 8), clothianidin fulfils the criteria for exclusion from Annex I.

Abiotic Degradation and distribution

The key results of the abiotic degradation studies and the associated physicochemical parameters are summarized in the table below:

Summary of the key results of the abiotic degradation studies and the associated physicochemical parameters of clothianidin:

Parameter	Result	Metabolites
Hydrolysis	Stable at pH 4 to 7, slow degradation at pH 9	CTNU, TZMU and ACT•HCl
Photolysis[1]	DT_{50} = 3.3 hours	TZMU, methylguanidine, HMIO, formamide and methylurea
Adsoprtion/desorption	KaOC = 160 L/kg KdOC = 188 L/kg	MNG : KaOC = 21 L/kg TZNG : KaOC = 276 L/kg
Degradation in air	DT_{50} = 2.81 h (4.1 hours considering a global 24-hours mean concentration)	-
Vapour pressure (20°C)	3.8 x 10-11 Pa	

Henry's law constant (20°C)	2.9 x 10-11 Pa x m³/mol	

[1] Transferability of the laboratory degradation rates to environmental conditions being rather limited and unclear, no degradation by phototransformation was taken into account for the environmental exposure assessment concerning surface water.

Due to its physicochemical characteristics (vapour pressure and Henry's law constant), no substantial volatilisation of clothianidin is expected. Moreover no accumulation of clothianidin in the air followed by wet or dry deposition is to be expected.

The results of both adsorption and desorption process indicate that the parent compound and its major metabolites are stable in soil and have medium to very high potential for leaching. However in lysimeter studies where clothianidin was used as plant protection product (application by spray and seed treatment), the parent compound did not occurred in the leachates. Though they remained below 0.1 µg/L, MNG and its metabolite NTG, as well as some other undermined metabolites, were detected in leachates. Clothianidin and its metabolites (TZNG, MNG, NTG) could also be detected in 20-30 cm deep soil layers. The majority of radioactivity was identified in the top soil samples and 37-55 % of applied radioactivity that could not be recovered was attributed to losses by mineralisation.

Ecotoxicity data

Clothianidin

Ecotoxicity endpoints used to calculate the Predicted Non Effect Concentrations (PNEC) for clothianidin and its metabolites are summarized in Table 2.2.8–1 and Table 2.2.8–2, respectively. All data are available in the CAR (Document II-A.4 Environmental effects assessment). Table 2.2.8–3 summarizes the PNEC for the different compartments.

Table 2.2.8–1 Summary of the ecotoxicological studies used to derive the Predicted Non Effect Concentrations for clothianidin.

Group	Test type	Endpoint	Test substance	Toxicity value
Sewage Treatment Plant				
Aerobic activated sludge (respiration inhibition)	Chronic	NOEC (3h)[1]	Clothianidin	> 1,000 mg/L
Aquatic compartment				
Aquatic invertebrate – sediment-dwelling organism	Chronic	EC_{10} (28 d)	Clothianidin	0.0004 mg/L
Terrestrial compartment				
Soil-dwelling arthropod (*Poecilus cupreus*)	Chronic	NOEC (77 d)	Clothianidin	0.02 mg a.s./kg dw soil
Honeybees, contact	Acute	LD_{50} (48 h)	Clothianidin	0.0038 µg a.s./bee

[1] Water solubility of 327 mg/L is lower than the highest test concentration.

$PNEC_{water}$ was derived from the laboratory chronic test on *Chironomus riparius* with spiked water. PNEC for benthic organisms was calculated from $PNEC_{water}$ by using the equilibrium partitioning method, though the current Biocidal Products Regulation (BPR, 2015) recommend to perform a sediment spiked test when the substance is likely to accumulate in the sediment as it is the case for clothianidin.

$PNEC_{soil}$ was thus derived from the laboratory chronic test on the larvae of the carabid beetle *Poecilus cupreus*.

Clothianidin has shown to be highly toxic to bees after both oral and contact exposure. As the substance is a systemic insecticide, it is taken up from soil by plant roots and exposure to bees via nectar and pollen might be possible. A PNEC was thus derived for bees from the acute contact endpoint.

The log Pow value of clothianidin was 0.7 (at 25°C, unbuffered), which is below the trigger value of 3, suggesting a low risk for bioaccumulation and secondary poisoning via ingestion of contaminated food by birds and mammals. The BCF for fish was calculated to be 0.78 L/kg and the BCF for earthworm was estimated to be 0.9 L/kg.
As the use of the active substance in an indoor insecticide make the exposure of wild fauna unlikely, especially as there is a low risk for bioaccumulation and secondary poisoning, the oral chronic toxicity to terrestrial vertebrates was not further considered in the risk assessment.

The physico-chemical properties of the active substance do not suggest that it may pose a risk to the atmospheric environment. Therefore no PNEC was calculated for air compartment.

Clothianidin metabolites

Some metabolites of clothianidin has been showed to be persistent in soil and sediment. They have therefore also been taken into account in the risk assessment of the active substance. As no PNEC have been calculated in the CAR, calculations have been performed below.

Table 2.2.8–2 Summary of the ecotoxicological studies used to derive the Predicted Non Effect Concentrations for metabolites of clothianidin.

Group	Test type	Endpoint	Test substance	Toxicity value
Aquatic compartment				
Fish	Acute	LC_{50} (96h)	TMG	> 110 mg/L
Aquatic invertebrate – pelagic organism	Acute	EC_{50} (48h)	TMG	100 mg/L
Aquatic invertebrate – sediment-dwelling organism	Chronic	EC_{10} (28 d)	TMG	> 0.05 mg/L
Algae	Chronic	NOE_rC (72 h)	TMG	3.13 mg/L
Terrestrial compartment - Soil				
Earthworm	Acute	LC_{50} (14 d)	MNG	> 1000 mg a.s./kg dw soil
			TZGN	970 mg a.s./kg dw soil

Soil-dwelling arthropod (*Folsomia candida*)	Chronic	NOEC (28 d)	MNG	≥ 1000 mg a.s./kg dw soil
			TZGN	1 mg a.s./kg dw soil
Soil microorganisms (inhibition of microbial activity, N-mineralisation)	**Chronic**	**NOEC (28 d)**	**MNG**	**0.24 mg a.s./kg dw soil**
			TZNG	**0.47 mg a.s./kg dw soil**

[1] Endpoint from EFSA (2015). Conclusion on the peer review of the pesticide risk assessment for bees for the active substance clothianidin considering all uses other than seed treatments and granules, EFSA Journal, 13(8):4210

In bold, endpoints used to calculate the Predicted Non Effect Concentrations (PNEC).

As clothianidin was not readily biodegradable and was considered to be persistent in aquatic systems, no respiration inhibition test was performed with aerobic activated sludge to measure toxicity to clothianidin metabolites.

In water-sediment system, TMG was detected in sediments in high amount (22.9%). Three acute test (fish, Daphnia and algae) were performed with TMG, as well as a chronic test with Chironomus riparius. This last test provided the lowest endpoint for the aquatic compartment (EC10 > 0.05 mg/L). No degradation test was performed with TMG in sediment. Its persistency in this medium is thus unknown, as it is unclear if the degradation process occurring in manure – where DT50 are available – could also be applied in sediment. However as Chironomus riparius is shown to be the most sensitive organism to both TMG and its parent and as TMG endpoint is 125 higher than clothianidin endpoint, the risk related to TMG was assumed to be covered by the risk related to clothianidin. Therefore, no specific risk assessment has been performed for TMG in sediment.

As stated previously, the main metabolites of clothianidin formed in soil were MNG (10.7%) and TZGN (9.1%). Although TMG can also extensively be formed in anaerobic conditions (up to 58%), it was not considered to be relevant for Maxforce Platin assessment as it is unclear that degradation process of clothianidin in manure could be applied to soil.
An acute toxicity test with earthworm and a chronic study with Folsomia candida showed a low toxicity of MNG and TZNG. However the test on the inhibition of soil microbial activity (C-mineralisation) showed a toxicity to MNG and TZNG (NOEC = 0.24 and 0.47 mg a.s./kg dw soil, respectively) which was in the range of clothianidin toxicity (0.5 mg a.s./kg dw soil). These endpoints were therefore used to derive a PNECsoil with an assessment factor of 50 (Please refer to Table 2.2.8–3). Please note that the lowest endpoint of clothianidin for soil organisms was provided by a test on Poecilus cupreus but such test was not provided for MNG and TZNG. The toxicity of soil metabolites might therefore be underestimated, especially for TZNG which is structurally close to its parent.

As highlighted previously, clothianidin is a systemic insecticide which it is taken up from soil by plant roots. An acute oral test with bees was provided for TMG (LD50 > 151 µg/bee), but this metabolite was not considered to be relevant for Maxforce Platin assessment.
However according to the EFSA conclusion on the peer review of clothianidin risk assessment for bees2, the major plant metabolites of clothianidin (i.e. which exceeds 10% of total

[2] EFSA (2015). Conclusion on the peer review of the pesticide risk assessment for bees for the active substance clothianidin considering all uses other than seed treatments and granules, EFSA Journal, 13(8):4210

radioactive residues or 0.01 mg/kg in the plant metabolism studies) after soil spray and incorporation at 20cm depth are TZMU and TZNG. According to EFSA report, the residue concentrations of these metabolites following an application rate of 90g clothianidin per hectare were below 0.001 mg/kg. However this application rate is much higher than what is applied through sewage sludge following Maxforce Platin use. Therefore the secondary poisoning of bees was not considered to be relevant for clothianidin metabolites.

Table 2.2.8–3 Predicted Non Effect Concentrations of clothianidin and its metabolites according to the environmental compartment

PNEC by compartment	Unit	Clothianidin	MNG	TZNG	TMG
$PNEC_{STP\ micro\text{-}organisms}$	mg/L	100.0	-	-	-
$PNEC_{water}$	mg/L	8.00×10^{-5}	-	-	-
$PNEC_{sediment}$[1]	mg/kg wwt	3.40×10^{-4}	-	-	-
$PNEC_{soil}$[2]	mg/kg wwt	1.80×10^{-3}	4.24×10^{-3}	8.29×10^{-3}	1.80×10^{-3}
$PNEC_{bees}$	mg/kg nectar or pollen	1.46×10^{-2}	-	-	

1 PNEC for sediment were calculated via the equilibrium partitioning method.

[2] PNEC for TMG is available in the CAR of clothianidin for PT 18 (2014)

No further information is available on the active substances or on the products.

(I) 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

According to the Classification & Labelling Inventory of ECHA3 (C&L Inventory), clothianidin (CAS 210880-92-5) has a harmonized classification for ecotoxicity and is classified as "Aquatic Acute 1 – H400" (Very toxic to aquatic life) and "Aquatic Chronic 1 – H410" (Very toxic to aquatic life with long-lasting effects).

The active substance in the formulated product is the same as evaluated in the CAR, therefore no new data is required. Based on the concentrations of clothianidin in the formulated product (1.026 %), on its lowest acute and chronic endpoints (0.029 mg/L and 0.0004 mg/L for Chironomus riparius, respectively), as well as its persistence in aquatic systems (water and sediments), the active substance is considered as being Aquatic Acute 1" and "Aquatic Chronic 1", both with a M-factor of 10 and 100, respectively.

Based on the available data, only clothianidin is considered to be relevant for classification of the formulated product (Please refer to Confidential Annex for additional information on the co-formulants). According to the Guidance on the Application of the CLP Criteria[4] , the classification of a product is based on summation of the classification of its components.

Firstly, all components classified as Acute 1 are considered. If the sum of the concentrations (in %) of these components multiplied by their corresponding M-factors is greater than 25 %,

3 https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/37717

4 ECHA (2015). Guidance on the Application of the CLP Criteria - Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures, Version 4.1

the whole mixture is classified as Acute 1. For Clothianidin RB 1, the calculation provide the following result: (1.026 × 10) = 10.26.

Based on clothianidin toxicity and concentration, the formulated product Clothianidin RB 1 has therefore no Acute Aquatic classification.

Then all components classified as Chronic 1 are considered according to the same reasoning. The calculation provide the following result for the formulated product: (1.026 × 100) = 102.6.

Clothianidin RB 1 should thus classed as Aquatic chronic 1 based on clothianidin toxicity and concentration.

Conclusion on the environmental classification and labelling of the product
The formulated product Clothianidin RB 1 requires an environmental classification as "Aquatic Chronic 1 – H410" (Very toxic to aquatic life with long-lasting effects) due to the toxicity and the concentration of the active substance clothianidin.

(II) Further Ecotoxicological studies

ED properties

A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the ED properties of the substances in Clothianidin RB1/MaxForce Platin:

1. Assessment of the ED properties of the active substances in Clothianidin RB1/MaxForce Platin:

- According to point 2.1.1 of the final CA document, the assessment of ED properties of the active substances that have already been evaluated and approved will be coordinated at EU level. Hence, the rMS should not evaluate the ED properties of these substances nor request additional data on the ED properties in the context of product authorisation procedures. As Clothianidin is not part of the list1 of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review.

- Therefore, BE eCA considers that there are no concerns regarding ED properties of Clothianidin.

2. Assessment of the ED properties of non-active substances (co-formulants) in Clothianidin RB1/MaxForce Platin:

- After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex - ED assessment), none of the co-formulants are subject to an on-going evaluation or a decision regarding their ED properties. Based on the available information, BE eCA considers that there is no concern regarding the ED properties of these co-formulants.

Overall conclusion on the biocidal product regarding ED properties:
Based on the existing knowledge and the data provided by the applicant, there is no indication of concern regarding the ED properties of the substances used in the biocidal product/product family Clothianidin RB1/MaxForce Platin.

If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product/family authorisation will be revised.

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

No further data is available.

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

No further data is available.

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

According to the label, the product should be placed in locations inaccessible to children or pets. Moreover it is restricted to indoor use. Therefore, no further data was provided.

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

Not relevant.

(VII) Foreseeable routes of entry into the environment on the basis of the use envisaged

According to the intended uses of the product, the main emission pathway to the environment is assumed to be the waste water. Indeed although wet cleaning of treated areas should be avoided, if these surfaces are wet cleaned, the waste cleaning water is disposed to the drain, leading to the release of the product to the local waste water treatment plant. There, it is assumed that waste water is emitted to the surface water after treatment. Fresh water and fresh water sediments could thus be exposed to the active substance. The soil can be then exposed through sludge application, leading to an emission to groundwater. Emissions to air are considered to be negligible. More information are available below in Section 2.2.3 Fate and distribution in exposed environmental compartments.

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

No further data is available.

(IX) Leaching behaviour (ADS)

No further data is available.

(X) Testing for distribution and dissipation in soil (ADS)

For details, please refer to the CAR of clothianidin (Document II-A and III-A). No new data, neither on the products, nor on the active substances, have been submitted by the applicant.

Conclusion used in Risk Assessment –Distribution and dissipation in soil	
Value/conclusion	Clothianidin is not considered to be biodegradable (DT_{50} = 983 days at 12ºC, n=9). Four metabolites were detected in soil: MNG (10.7%), TZNG (9.1%) as well as TZMU and NTG (minor metabolites). The DT_{50} of metabolites in soil at 12°C were determined to be 156-205 days and 118–211days for MNG and TZNG, respectively. The soil DT_{50} value used for PEC calculation was 429,8 days at 12°C (geometric mean value of field dissipation studies, n = 8). Clothianidin was found to be stable during both adsorption and desorption, with a K_{aOC} value of 160 L/kg (mean, n=5) and a K_{dOC} value of 188 L/kg (mean, n=5). The major soil metabolites MNG and TZNG had a K_{aOC} value of 21 L/kg and 276 l/kg. Clothianidin was not detected in leachates of lysimeter studies but MNG and its metabolite NTG, as well as some other undermined metabolites, were detected although their concentrations were below 0.1 µg/L. Clothianidin and its metabolites (TZNG, MNG, NTG) could also be detected in 20-30 cm deep soil layers. However 37-55 % of applied radioactivity that could not be recovered was attributed to losses by mineralisation.

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

For details, please refer to the CAR of clothianidin (Document II-A and III-A). No new data, neither on the products, nor on the active substances, have been submitted by the applicant.

Conclusion used in Risk Assessment –distribution and dissipation in water and sediment	
Value/conclusion	Clothianidin only slowly degraded at pH 9, giving some minor transformation products: CTNU, TZMU and ACT•HCl. Under experimental conditions, clothianidin was rapidly photolysed in water (DT_{50} of 3.3 hours) in TZMU, MG, HMIO, FA and MU. However as the degradation rates under environmental conditions is

	unclear, no degradation by phototransformation was taken into account for the environmental exposure assessment to avoid overestimating the degradation potential of clothianidin. Clothianidin was not readily biodegradable in both aerobic and anaerobic water-sediment systems. DT_{50} in water (12°C) was estimated to be 58.4-94.4 days. However clothianidin was rapidly translocated from the water phase into the sediment (DT_{50} = 7.6 days at 12°C). DT_{50} for entire system (12°C) was estimated to be 145.3-109.2 days in aerobic water-sediment systems and about 40 days in anaerobic water-sediment systems. Metabolism of clothianidin in the water phase was insignificant and ultimate biodegradation is negligible, both in aerobic and anaerobic systems. Therefore clothianidin is considered to be persistent in both aerobic and anaerobic water-sediment systems as well as aquatic systems in general. However TMG was detected to be the main degradation product in sediments (22.9% of applied radioactivity). No further metabolites were detected in significant amounts. Anaerobic degradation of clothianidin investigated in manure showed that TMG was also the only identified metabolite (up to 58 % of the applied radioactivity). TMG seems thus to be the main metabolite of the anaerobic degradation of clothianidin. Its DT_{50} values was determined to be 259.2-375.5 days (12°C) while DT_{50} values for clothianidin for anaerobic degradation was calculated to be 25.4-59.9 days (12°C).

(XII)Testing for distribution and dissipation in air (ADS)

For details, please refer to the CAR of clothianidin (Document II-A and III-A). No new data, neither on the products, nor on the active substances, have been submitted by the applicant.

Conclusion used in Risk Assessment –distribution and dissipation in air	
Value/conclusion	No substantial volatilisation of clothianidin is expected. The DT_{50} of clothianidin in the troposphere was estimated to be 4.1 hours (24-hours mean concentration). Therefore, no accumulation in the air is expected.

(XIII) 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.

(XIV) 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)

Not relevant

2.2.8.2 Exposure assessment

The environmental exposure assessment has been performed in accordance with the Emission Scenario Document for Product Type 18 (insecticides, acaricides and products to control other arthropods)5 as well as the Guidance on the Biocidal Products Regulation (ECHA, 2015)6 and the EUSES Background report (EC 2004)7, and is based on information relating to the Intended Use (Chapter 3 of this document). The environmental exposure assessment was conducted for the local scale only. The emission estimations have been calculated for the formulated product Clothianidin RB 1 only.

In the Emission Scenario Document for Product Type 18 (ESD for PT 18), the main emission pathway to the environment for an indoor application of the gel bait is assumed to be the waste water. Based on the physico-chemical properties of the active substance, it is expected that the emissions will primarily affect the aquatic compartment.

(I) General information on Clothianidin RB 1

Assessed PT	**PT 18 – Insecticides, acaricides and products to control other arthropods**
Use of the product	**Indoor use : gel application** The biocidal product is dispensed using a suitable gel applicator. When the treatment has been completed, remove the empty cartridge and dispose of safely. If the cartridge is only partially used, remove it from the applicator, seal it with the end cap provided and store as directed. <u>For use against cockroach:</u> For maximum effectiveness the product must be placed in and around cockroach harbourages and, if possible, between these areas and food sources. Survey the area to be treated to identify sites of cockroach infestation (e.g. by using traps and/or flush-out aerosols, searching for droppings, cast skins and egg cases etc.) The product is to be placed as spot treatment in the vicinity of corners, cracks and crevices (e.g. behind or under equipment and furniture like counters, refrigerators, cookers, sinks, baths etc.), voids, service-ducts, lift shafts, pipework… Where immigration of cockroaches has been identified, placement of additional bait in peripheral areas of the site will aid control. Apply the product directly as spots or thin ribbons to surfaces in identified target areas. It should be placed out of sight and where light intensity is low, in places inaccessible for children or pets. Avoid application to excessively dusty, damp or greasy locations, and surfaces subject to wet cleaning. Do not apply to areas that have recently been treated

5 OECD Environment, Health and Safety Publications (2008). OECD Series on Emission Scenario Documents Number 18 - Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses. ENV/JM/MONO(2008)14.

6 ECHA (2015) Guidance on Biocidal Products Regulation: Volume IV Environment Part B Risk Assessment (active substances), Version 1.0. European Chemicals Agency, Helsinki, Finland. Available via https://echa.europa.eu/

7 EC (2004) European Union System for the Evaluation of Substances 2.0 (EUSES 2.0). Prepared for the European Chemicals Bureau by the National Institute of Public Health and the Environment (RIVM), Bilthoven, The Netherlands (RIVM Report no. 601900005). Available via http://ecb.jrc.ec.europa.eu/euses/.

	with other insecticides or contaminate the bait with other insecticides. Do not apply to surfaces on which food or feed is stored, prepared or eaten. Where infestations are high, inspect the applied spots of the product regularly and make further applications as required. <u>Application rates for small cockroach species</u>: Maintenance programs (quarterly application): *1 spots x 0.05 g (5 mm diameter) per m² = 0.05 g/m²* Moderate infestations (cockroaches rarely visible during the day, or retreatments): *1 spots x 0.1 g (7 mm diameter) per m² = 0.1 g/m²* High infestation (cockroaches commonly visible during the day): *2 spots x 0.1 g (7 mm diameter) per m² = 0.2 g/m²* <u>Application rates for large cockroach species</u> Moderate infestations (cockroaches rarely visible during the day, or retreatments): *2 spots x 0.1 g (7 mm diameter) per m² = 0.2 g/m²* High infestations (cockroaches commonly visible during the day): *3 spots x 0.1 g (7 mm diameter) per m² = 0.3 g/m²* Note that a thin ribbon, equating to one spot, can alternatively be applied. <u>For use against silverfish</u>: Place many small drops of 2mm diameter each, , totaling between 0.1 and 0.2 g/m² (i.e. 1 or 2 spots of 0.1 g/m²), in areas where silverfish hide and live (e.g. under/behind/base of skirting boards, under wooden facing or other areas that provide cover).
Assessed scenarios	Scenario 1: House Scenario 2: Larger buildings
ESD(s) used	OECD Series on emission scenario number 18: Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional use
Approach	Scenario 1 : Average consumption Scenario 2 : Average consumption
Distribution in the environment	Based on Guidance on - Biocidal Products Regulation - Volume IV Environment - Part B Risk Assessment (active substances) – Version 1.0, April 2015 - OECD Series on emission scenario number 18 : Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional use

Groundwater simulation	EUSES
Confidential Annexes	NO
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	-

(II) Emission estimation

The emission estimations are based on an indoor spot application of the gel bait by professional users both in house and in larger buildings. They are based on the maximum application rate advised by the label and on the annual waste-water amount discharged by a sewage treatment plant (STP) as local point source.

According to the ESD for PT 18, the releases to the environment following the use of insecticides applied indoor can be divided in three steps : during the mixing/loading step, during the application step and finally during the cleaning step. Clothianidin RB 1 is provided in ready-to-use cartridge, therefore no emission is expected during the preparation step of gels. Moreover due to its gel formulation, only negligible releases to the environment are expected during the application of the product. Therefore emissions to the environment mainly takes place during the cleaning step, especially through wet cleaning methods that lead to releases to waste water. Hence the sewage treatment plants (STP) is considered to be the first receiving compartment, followed by surface water, soil and finally groundwater (through sludge application).

Two typical buildings have been defined by ESD for PT 18: a small building that would represent the private house and a larger building that could cover public and professional building.

Scenario 1: Private house

For better efficacy of gel bait insecticide, all the building should be treated at the same time. The formulated products should be applied at a rate of 1-3 spots per square meter, depending on species and severity of infestation in the facility. The worst-case situation assumes a curative treatment with a high infestation level, where the number of points per square meter was set to 3.

The formulated product is applied in protected areas where there is normally no cleaning. Nevertheless, it was considered that releases might be possible, for example, from cockroaches faeces that could be deposited in areas available to cleaning events[8]. Moreover it is not excluded that a fraction of the applied product could be directly eliminated through cleaning event. According to the Technical Meeting on emission estimation for insecticides for household and professional uses, the default treated surface area to be used is 130m² for a standard house. However the wet cleaning zone leading to a release to the STP is 38.5 m² only (TM I 2010)9. Moreover Clothianidin RB 1 is used according to targeted applications. Therefore a refined and more realistic surface of 2 m² can also be used when the formulated product is intended to be used for spot or crack and crevice treatment (TM II 2010)10. Emission estimations have thus been calculated from wet cleaning after both normal surface application (Tier I) and spot application (Tier II).

8 Please note that this scenario has been agreed to be not relevant during the 2nd PT18 EG meeting (2017). However this agreement was not available at the time of the dossier submission.

9 ECHA (2017). Emission estimation for insecticides for household and professional uses (TM I 2010), Technical Agreements for Biocides, p.43, Augustus 2017.

10 ECHA (2017). Emission estimation for insecticides for households and professional uses: targeted applications (TM II 2010), Technical Agreements for Biocides, p.55, Augustus 2018.

Two type of cleaning event are considered: 100% of the surfaces are cleaned by vacuum/broom and the clothes of the applicator are disposable or 100% of the surfaces are washable and the clothes of the applicator are washed.

In the last case, which is applicable to the formulated product Clothianidin RB 1, the efficiency of the cleaning was taken into account as this factor may reduce significantly releases to the environment. It has been considered that the product was applied in crack and crevices, where maximum 3% is exposed to cleaning due to the gel formulation (ESD for PT 18, Table 3.3–8).

Indeed the formulated product is intended to be used in cracks and crevices and other entry points usually used by insects, as well as areas behind or under machinery, kitchen and bathroom equipment or pipework,… (please refer to the SPC).

Please, note that due to the formulation of the product, no emission to air is expected. Therefore, emission to the applicator and to the treated surface are expected according to the following equations:

Emission from applicator during cleaning step:

$$E_{applicator} = E_{appli,\ applicator} \times F_{applicator\ ww}$$

Emission from treated surface during cleaning step (surface treatment):

$$E_{treated\ house\ 1} = N_{appli,\ house} \times N_{appli,\ day} \times N_{point} \times Q_{prod,\ point} \times F_{as} \times AREA_{wet,tier1} \times F_{appli,\ treated} \times F_{ww} \times F_{CE} \times 10^{-3}$$

Emission from treated surface during cleaning step (spot treatment):

$$E_{treated\ house\ 2} = N_{appli,\ house} \times N_{appli,\ day} \times N_{point} \times Q_{prod,\ point} \times F_{as} \times AREA_{wet,tier2} \times F_{appli,\ treated} \times F_{ww} \times F_{CE} \times 10^{-3}$$

Parameters used for calculations and results are available in the table below.

Table 2.2.8–4 Local emission from treated surface during the cleaning step

Local emission from treated surface during cleaning step – Private house				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Applicator				
Emission to the applicator during application step	$E_{appli,\ applicator}$	0	kg/d	Default
Fraction emitted to wastewater from applicator after the application	$F_{applicator\ ww}$	1	/	Default
Treated surface				

Number of applications per building	$N_{appli,\ house}$	1	/	Default
Maximum number of applications per day	$N_{appli,\ day}$	1	d^{-1}	Default
Maximum number of gel points per square meter	N_{point}	3	Point/ m²	Default
Quantity of commercial applied per point of gel	$Q_{prod,\ point}$	0.10	g/point	Data from applicant
Fraction of active substance in the commercial product	F_{as}	1.026×10^{-2}	/	Data from applicant
Wet cleaning zone– surface treatment	$AREA_{wet,tier1}$	38.5	m²	TAB[1]
Wet cleaning zone – spot applications	$AREA_{wet,tier2}$	2	m²	TAB[1]
Fraction emitted to treated surfaces during application	$F_{appli,\ treated}$	1	/	Default
Fraction emitted to waste water during the cleaning step	F_{ww}	1	/	Default
Cleaning efficiency - surface	F_{CE}	0.03	/	ESD for PT 18 Table 3.3–8
Output	**Nomenclature**	**Value**	**Unit**	**Remarks**
Emission to air during the cleaning step	E_{air}	0	kg/d	Default
Emission from the applicator to waste water during the cleaning step	$E_{applicator}$	0	kg/d	Output
Emission from treated surface to waste water during the cleaning step – Tier 1	$E_{treated\ house\ 1}$	3.56×10^{-6}	kg/d	Output
Emission from treated surface to waste water during the cleaning step – Tier 2	$E_{treated\ house\ 2}$	1.85×10^{-7}	kg/d	Output

[1] Conclusions of Technical meetings for environment are gathered in the Technical Agreements for Biocides (TAB) published by ECHA (Latest version : Augustus 2018).

Scenario 2: Larger buildings

Once again, a worst-case situation assuming a curative treatment with a high infestation level, where the number of points per square meter was set to 3, was supposed.

It was be considered that releases to the environment might be possible, for example, from cockroaches faeces that could be deposited in areas subject to cleaning events[11]. Moreover it is not excluded that a fraction of the applied product could be directly eliminated through cleaning event. According TM I 2010, the default treated surface area to be used is 609m² for a commercial or public building. However the wet cleaning zone leading to a release to the STP is 180 m² only. Moreover as Clothianidin RB 1 is used according to targeted applications, a refined and more realistic surface of 9.3 m² can also be used (TM II 2010). Emission estimations have thus been calculated from wet cleaning after both normal surface application (Tier I) and spot application (Tier II).

It was supposed that 100% of the surfaces are washable and the clothes of the applicator are washed. As previously, the efficiency of the cleaning was taken into account: it has been considered that maximum 3% of the applied product is exposed to cleaning (ESD for PT 18, Table 3.3–8).

Please, note that due to the formulation of the product, no emission to air is expected. Therefore, emission to the applicator and to the treated surface are expected according to the following equations:

Emission from applicator during cleaning step:

$$E_{applicator} = E_{appli,\ applicator} \times F_{applicator\ ww}$$

Emission from treated surface during cleaning step (surface treatment – Tier 1):

$$E_{treated\ building\ 1} = N_{appli,\ building} \times N_{appli,\ day} \times N_{point} \times Q_{prod,\ point} \times F_{as} \times AREA_{wet,tier1} \times F_{appli,\ treated} \times F_{ww} \times F_{CE} \times 10^{-3}$$

Emission from treated surface during cleaning step (spot treatment – Tier 2):

$$E_{treated\ building\ 2} = N_{appli,\ building} \times N_{appli,\ day} \times N_{point} \times Q_{prod,\ point} \times F_{as} \times AREA_{wet,tier2} \times F_{appli,\ treated} \times F_{ww} \times F_{CE} \times 10^{-3}$$

Parameters used for calculations and results are available in the table below.

Table 2.2.8–5 Local emission from treated surface during cleaning step

Local emission from treated surface during cleaning step – Larger buildings				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Applicator				
Fraction emitted to wastewater from applicator after the application	$F_{applicator\ ww}$	1	/	Default

[11] Please note that this scenario has been agreed to be not relevant during the 2nd PT18 EG meeting (2017). However this agreement was not available at the time of the dossier submission.

Emission to the applicator during application step	$E_{appli,\ applicator}$	0	kg/d	Default
Treated surface				
Number of applications per building	$N_{appli,\ building}$	1	/	Default
Maximum number of applications per day	$N_{appli,\ day}$	1	d^{-1}	Default
Maximum number of gel points per square meter	N_{point}	3	Point/ m²	Default
Quantity of commercial applied per point of gel	$Q_{prod,\ point}$	0.10	g/point	Data from applicant
Fraction of active substance in the commercial product	F_{as}	1.026×10^{-2}	/	Data from applicant
Wet cleaning zone– surface treatment	$AREA_{wet,tier1}$	180	m²	TAB[1]
Wet cleaning zone – spot applications	$AREA_{wet,tier2}$	9.3	m²	TAB[1]
Fraction emitted to treated surfaces during application	$F_{appli\ treated}$	1	/	Default
Fraction emitted to waste water during the cleaning step	F_{ww}	1	/	Default
Cleaning efficiency - surface	F_{CE}	0.03	/	ESD for PT 18 Table 3.3–8
Output	**Nomenclature**	**Value**	**Unit**	**Remarks**
Emission to air during the cleaning step	E_{air}	0	kg/d	Default
Emission from the applicator to waste water during the cleaning step	$E_{applicator}$	0	kg/d	Output
Emission from treated surface to waste water during the cleaning step – Tier 1	$E_{treated\ building\ 1}$	1.66×10^{-5}	kg/d	Output
Emission from treated surface to waste water during the cleaning step – Tier 2	$E_{treated\ building\ 2}$	$8,59 \times 10^{-7}$	kg/d	Output

1 Conclusions of Technical meetings for environment are gathered in the Technical Agreements for Biocides (TAB) published by ECHA (Latest version : Augustus 2018).

Simultaneous use of the formulated product

The use of insecticides over the year depends on the pest pressure but during outbreak periods, pest control operators use products at the same time in private and public or

commercial buildings. To take into account this diffuse emission, it was considered that releases are collected in the same STP, which acts as a unique point source. It is therefore necessary to determine how many houses connected to the STP are simultaneously treated.

According to the ESD of PT 18, it is assumed that 4,000 houses and 300 larger buildings (public and commercial) are connected to a local STP having a 10,000 equivalent habitant capacity. A simultaneity factor (Fsimultaneity) can be calculated based on the results of a French survey on the frequency of insecticide uses (Please refer to Table 2.2.8–6) according to the following equation:

$$F_{simultaneity} = \frac{\sum \text{Number of positive answers} \times \% \text{ of house treated per day}}{100}$$

Where it was considered that if the frequency of treatment is one time per day, with 100% of the houses treated the same day. Based on the same reasoning for a weekly use, then the frequency of use on a daily basis is 1/7 = 0.143 or 14.3%.

Table 2.2.8–6 Results on the survey on frequency of insecticide uses from the Conservatoire National des Arts et Métiers

Frequency	Number of positive answers (%)	% of house treated per day
One time per day	2,77	100
One time per week	9,51	14,3
One time per month	17,74	3,22
Three to eleven time per year	32,15	1,9
One to two times per year	37,82	0,54

According to the applicant, in some case of very high infestation, a re-treatment may be needed after one month. Therefore it was assumed that a treatment was applied every month (worst-case situation). The simultaneity factor was therefore:

$$F_{simultaneity} = \frac{3.22\,x\,17.74+1.9\,x\,32.15+0.54\,x\,37.82}{100} = 1.39\ \%$$

The local emission to waste water was calculated as:

Total local emission to waste water

$$E_{local\ ww} = (E_{treated\ house\ ww} \times N_{house} + E_{treated\ building\ ww} \times N_{buildings}) \times F_{simultaneity}$$

Please note that, as no emission to air and no emission from the applicator are expected due to the formulation of the product, these parameters has not been taken into account in the above equation. Parameters used for calculations are available in Table 2.2.8–7 and result is available in Table 2.2.8–8.

Table 2.2.8–7 Input parameter for calculating the local emission to the sewage treatment plant

Input parameter for calculating the local emission to waste water

Input	Nomenclature	Value	Unit	Remarks
Number of privates houses per local area	$N_{appli,\ building}$	4000	/	Default
Number of buildings per local area	$N_{appli,\ day}$	300	/	Default
Emission to waste water from treated private houses – Tier 1	$E_{treated\ house\ ww}$	3.56×10^{-6}	kg/d	Table 2.2.8–4
Emission to waste water from treated private houses – Tier 2	$E_{treated\ house\ ww}$	1.85×10^{-7}	kg/d	Table 2.2.8–4
Emission to waste water from larger treated buildings – Tier 1	$E_{treated\ building\ ww\ 1}$	1.66×10^{-5}	kg/d	Table 2.2.8–5
Emission to waste water from larger treated buildings – Tier 2	$E_{treated\ building\ ww\ 2}$	8.59×10^{-7}	kg/d	Table 2.2.8–5
Simultaneity factor	$F_{simultaneity}$	1.39×10^{-2}	/	Default

Table 2.2.8–8 Resulting local waste water emission to the sewage treatment plant

Resulting local waste water emission to the sewage treatment plant			
Compartment	**Nomenclature**	**Local emission [kg/d]**	**Remarks**
Waste water – Tier 1	$Elocal_{ww\ 1}$	2.66×10^{-4}	
Waste water – Tier 2	$Elocal_{ww\ 2}$	1.38×10^{-5}	

(III) Calculated PEC values

PEC in air

In the ESD for PT 18 it is stated that depending on the formulation of the product and the physico-chemical characteristics of the active substance, there will be some potential for direct emissions to the air.

Based on the physico-chemical properties of the active substances (low vapour pressure and Henry's Law Constant, please refer to environmental fate and behaviour above) and on the product formulation (gel bait), the emission to air during the application and the cleaning of the product can be considered to be negligible. Moreover given the short half-life of clothianidin in the troposphere due to phototransformation (2.81 h), an accumulation in the air is not to be expected. Therefore negligible amounts of clothianidin are expected in air.

PEC in STP

Predicted environmental concentration (PEC) in the STP is determined after the elimination processes took place, i.e. degradation, volatilization and sedimentation of the active substance. It equals the concentrations in STP effluent and are calculated according to the following the equation (parameters used for calculations are available in Table 2.2.8–9):

$$PEC_{STP} = Elocal_{ww} \times EFFLUENT_{STP} \times F_{water}$$

Table 2.2.8–9 Input parameters for calculating the predicted environmental concentrations of clothianidin in the sewage treatment plant following Clothianidin RB 1 use

Input parameters for calculating the PEC_{STP}				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Concentration in waste water influent – Tier 1	$Elocal_{ww\ 1}$	2.66×10^{-4}	kg/d	Table 2.2.8–8
Concentration in waste water influent – Tier 2	$Elocal_{ww\ 2}$	1.38×10^{-5}	kg/d	Table 2.2.8–8
Fraction remaining in water phase after elimination processes in STP	F_{water}	0.98	%	EUSES calculation
Amount of influent per day in the STP	EFFLUENT	$2x10^6$	L/d	Default value

The results of the calculation are available in Table 2.2.8–13.

PEC in surface water

According to the Intended Use, no direct exposure to surface water is expected. Only indirect exposure via STP is possible. PEC in surface water was calculated according to the following equation (parameters used for calculations are available in Table 2.2.8–10):

$$\mathrm{PECwater} = \frac{\mathrm{Clocaleffluent}}{[1 + (\mathrm{Kp,susp} \bullet \mathrm{SS} \bullet 10^{-6})] \bullet \mathrm{DF}} = \frac{\mathrm{PEC_{STP}}}{[1 + (\mathrm{Kp,susp} \bullet \mathrm{SS} \bullet 10^{-6})] \bullet \mathrm{DF}}$$

Please note that the concentrations in STP effluent (Clocaleffluent) are equal to PECSTP, which are available in Table 2.2.8–13.

Table 2.2.8–10 Input parameters for calculating the predicted environmental concentrations of clothianidin in surface water following Maxforce Platin use

Input parameters for calculating the PEC_{water}				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Concentration in STP effluent	PEC_{STP}	Table 2.2.8–13	mg/L	
Solid-water partitioning coefficient in suspended matter	$K_{p,\ susp}$	16	L/kg	Calculated, see below
Amount of suspended solid in receiving water	SS	15	mg/L	Default
Dilution factor after discharge	DF	10		Default

The Partitioning coefficient between solid and water in suspended matter is calculated by multiplying Koc by the weight fraction of organic carbon in suspended solids (Focsusp = 0.1 by default). The results of the calculation are available in Table 2.2.8–13.

PEC in sediment

The concentration in the solid phase of the sediment is derived from the concentrations in surface water according to equilibrium partition method. PEC in sediment was thus calculated according to the following equation (parameters used for calculations are available in Table 2.2.8–11):

$$\mathrm{PECsed} = \frac{\mathrm{Ksusp-water}}{\mathrm{RHOsusp}} \bullet \mathrm{PECwater} \bullet 1000$$

Table 2.2.8–11 Input parameters for calculating the predicted environmental concentrations of clothianidin in the sediment of freshwater

Input parameters for calculating the PEC_{sed}				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Suspended matter-water partitioning coefficient	$K_{susp\text{-}water}$	4.90	m^3/m^3	EUSES calculation
Density of suspended solid	RHO_{susp}	1,150	kg/m^3	Default
PEC in surface water	PEC_{water}	Table 2.2.8–13	mg/L	

The results of the calculation are available in Table 2.2.8–13.

PEC in soil

PEClocal in soil is normally determined by direct and indirect exposure. According to the Indented Use, direct emissions to the soil compartment is considered as not relevant. The indirect exposure is due to sludge application and described as follows in the BPR (ECHA, 2015): the concentrations in soil is calculated as the average concentration in agricultural soil over a certain time-period after 10 yearly applications of sludge and receiving continuous aerial deposition from a nearby point source over the same period. For terrestrial ecosystem, the concentration is averaged over 30 days while for human indirect exposure, a period of 180 days is used for a worst case approach. Two different soil types are distinguished in this last scenario: arable land and grassland.

Aerial deposition are not assumed to be relevant due to the physico-chemical characteristics of the active substances (please refer to PEC in air above). It is assumed that removal is due to leaching, degradation and volatilization. Calculations have been performed with EUSES. Results available in Table 2.2.8–14.

PEC in groundwater

Predicted environmental concentrations in groundwater are derived from concentrations in pore water of an agricultural area where sludge has been applied yearly during the last 10 years (BPR, 2015). As biodegradation of the active substances during storage of sludge as well as transformation and dilution in deeper soil layers are not taken into account, it can be considered as a worst-case scenario.

Direct emissions to groundwater are not considered as relevant according to the Intended Use but indirect emissions resulting from the soil compartment have been calculated with EUSES and are available in Table 2.2.8–14.

PEC of metabolites

PECs of clothianidin metabolites (MNG and TZNG) have been calculated for the relevant compartment, i.e. soil and groundwater.

In the absence of further physico-chemical data, PECs have been calculated by adjusting the relevant PEC of the parent compound to the percentage formed in the relevant compartment (Please refer to "Environmental fate and behaviour" section) and the difference in molecular weight according to the following equation (Please refer to Table 2.2.8–12):

$$\text{PEC metabolite, compartment} = \text{PEC parent, compartment} \times \text{F compartment} \times \frac{\text{M metabolite}}{\text{M parent}}$$

Please note that metabolites concentrations in groundwater were derived from PECgw of clothianidin adjusted to the fraction of metabolites formed in soil.

Table 2.2.8–12 Input parameters for calculating PEC values of clothianidin metabolites MNG and TZNG in soil.

Input parameters for calculating PEC values of clothianidin metabolites in soil				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
PEC of clothianidin in soil (30 days) –Tier 1	$PEC_{clothianidin, soil1}$	1.94×10^{-5}	mg/kg_{wwt}	Table 2.2.8–13
PEC of clothianidin in soil (30 days) –Tier 2	$PEC_{clothianidin, soil2}$	1.01×10^{-6}	mg/kg_{wwt}	Table 2.2.8–13
PEC of clothianidin in soil (agricultural soil) –Tier 1	$PEC_{clothianidin, agric.1}$	1.70×10^{-5}	mg/kg_{wwt}	Table 2.2.8–14
PEC of clothianidin in soil (agricultural soil) –Tier 2	$PEC_{clothianidin, agric.2}$	8.82×10^{-7}	mg/kg_{wwt}	Table 2.2.8–14
PEC of clothianidin in soil (grassland) –Tier 1	$PEC_{clothianidin, grass.1}$	5.59×10^{-6}	mg/kg_{wwt}	Table 2.2.8–14
PEC of clothianidin in soil (grassland) –Tier 2	$PEC_{clothianidin, grass.2}$	2.90×10^{-7}	mg/kg_{wwt}	Table 2.2.8–14

PEC of clothianidin in groundwater –Tier 1	$PEC_{clothianidin, gw1}$	5.78×10^{-6}	mg/kg_{wwt}	Table 2.2.8–14
PEC of clothianidin in groundwater –Tier 2	$PEC_{clothianidin, gw2}$	3.00×10^{-7}	mg/kg_{wwt}	Table 2.2.8–14
Fraction of MNG formed in soil	$F_{MNG, soil}$	0.107	%	
Fraction of TZNG formed in soil	$F_{TZNG, soil}$	0.091	%	
Molecular mass of MNG	M_{MNG}	118.1	g/mol	
Molecular mass of TZNG	M_{TZNG}	235.65	g/mol	
Molecular mass of clothianidin	$M_{clothianidin}$	249.7	g/mol	

Results are available in Table 2.2.8–15.

Summary of the calculated PEC values

Table 2.2.8–13 Summary table on the predicted environmental concentrations of clothianidin following Clothianidin RB 1 use

Summary table on PEC values of CLOTHIANIDIN							
Scenario	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil} 30 days**	**PEC_{soil} 180 days agriculture**	**PEC_{soil} 180 days grassland**	**PEC_{GW}**
	mg/m^3	mg/l	mg/kg_{wwt}	mg/kg_{wwt}	mg/kg_{wwt}	mg/kg_{wwt}	mg/l
Surface treatment – Tier 1	1.31×10^{-4}	1.30×10^{-5}	5.56×10^{-5}	1.94×10^{-5}	1.70×10^{-5}	5.59×10^{-6}	5.78×10^{-6}
Spot treatment – Tier 2	6.77×10^{-6}	6.77×10^{-7}	2.88×10^{-6}	1.01×10^{-6}	8.82×10^{-7}	2.90×10^{-7}	3.00×10^{-7}

Table 2.2.8–14 Summary table on the predicted environmental concentrations of clothianidin metabolites MNG and TZNG following Clothianidin RB 1 use

Summary table on PEC values of clothianidin metabolites MNG and TZNG				
Scenario	**PEC_{soil} 30 days**	**PEC_{soil} 180 days agriculture**	**PEC_{soil} 180 days grassland**	**PEC_{GW}**
	mg/kg_{wwt}	mg/kg_{wwt}	mg/kg_{wwt}	mg/l
MNG (Tier 1)	9.82×10^{-7}	8.60×10^{-7}	2.83×10^{-7}	2.93×10^{-7}
MNG (Tier 2)	5.11×10^{-8}	4.46×10^{-8}	1.47×10^{-8}	1.52×10^{-8}
TZNG (Tier 1)	1.67×10^{-6}	1.46×10^{-6}	4.80×10^{-7}	4.96×10^{-7}
TZNG (Tier 2)	8.67×10^{-8}	7.57×10^{-8}	2.49×10^{-8}	2.58×10^{-8}

(IV) Primary and secondary poisoning

Primary poisoning

Not relevant.

Secondary poisoning

Chemicals showing bioaccumulation or biomagnification potential may pose a threat due to exposure of organisms higher in the food chain, e.g. top predators, because of secondary poisoning. The oral intake via fish and worms is therefore assessed for mammals and birds for each substance showing a log Pow value over the trigger value of 3. As clothianidin exhibits a low Pow (0.7), a low bioaccumulation potential is expected both for fish (calculated BCFfish = 0.78) and earthworm (BCFearthworm = 0.9). Furthermore, no other indicators point to an intrinsic potential for bioconcentration – e.g. surface tension is 79.6 mN/m, which is above the trigger value of 50 mN/m. Consequently, there is no need for assessing biomagnification via the aquatic or the terrestrial food chain.

Nevertheless, secondary poisoning of bees after sewage sludge application was considered to be relevant due to the high toxicity of clothianidin to honeybees and because the active substance is a systemic insecticide that can be taken up from soil by plant roots. 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 (Please, refer to the CAR). For the assessment, the PEC in grassland agricultural soil (averaged in 180 days) were used to estimate the risk to bees. Calculations have been performed with EUSES. Results available in Table 2.2.8–14.

2.2.8.3 Risk characterisation

Clothianidin RB 1 is used by professional workers as a gel bait insecticide against cockroach and silverfish. In the ESD for PT 18, it is assumed that most of the insecticide applied as a gel bait ends up in a sewage treatment plant. The risk assessment for each environmental compartment is determined by dividing its PEC by the appropriate PNEC. Please note that all PNEC values are available in Table 2.2.8–3 of this document. PEC values are available in Table 2.2.8–13 and Table 2.2.8–14 above.

(I) Atmosphere

Based on the physico-chemical properties of the active substance and on the Intended Use, the emission to air during and after the application of the product can be considered as negligible (see above, "PEC in air"). Moreover on the basis of the short atmospheric lifetime, clothianidin is not expected to display adverse abiotic effects on the atmospheric environment (please refer to the CAR of the active substance).

Conclusion:

Only negligible exposure to the atmosphere is expected and no threat to the atmosphere is expected.

(II) Sewage treatment plant (STP)

The sewage treatment plants is considered as the main receiving compartment according to ESD for PT18.

The risk assessment for STP is determined by dividing the PECSTP by the PNECSTP micro-organisms (please, refer to Table 2.2.8–15). If the result of this ratio is below 1, an acceptable risk to micro-organisms of sewage treatment plants can be concluded.

Table 2.2.8–15 Summary table of the PEC/PNEC values of clothianidin for the sewage treatment plant

Summary table on calculated PEC/PNEC values for sewage treatment plant	
Scenario	**$PEC/PNEC_{STP}$**
Surface treatment – Tier 1	1.31×10^{-6}
Spot treatment – Tier 2	6.77×10^{-8}

Conclusion:

No unacceptable effect to the aquatic micro-organisms of the STP is expected.

(III) Aquatic compartment

The risk assessment is performed for fresh water and sediment-dwelling organisms and is determined by dividing the PECwater (or PECsed) by the PNECwater (or the PNECsed). Where the result of this ratio is below the trigger of 1, an acceptable risk to aquatic organisms can be concluded (please, refer to Table 2.2.8–16). Please note that for the sediment compartment, the risk assessment was performed by summing the PEC/PNEC ratio of the active substance and its degradation product TMG.

Table 2.2.8–16 Summary table of the PEC/PNEC values of clothianidin and its metabolites for the aquatic compartment. Value in bold are over the trigger of 1.

Summary table on calculated PEC/PNEC values for aquatic compartment		
Scenario	**$PEC/PNEC_{water}$**	**$PEC/PNEC_{sed}$**
Surface treatment – Tier 1	1.63×10^{-1}	1.63×10^{-1}
Spot treatment – Tier 2	8.46×10^{-3}	8.46×10^{-3}

The results for sediment-dwelling organisms is equal to the results for pelagic organisms since both PECsed and PNECsed were calculated from the PECwater and PNECwater, respectively, by using equilibrium partitioning method and not measured data.

Clothianidin is considered to be persistent in both aerobic and anaerobic water-sediment systems, with slow to no degradation in the water phase. Moreover the active substance was

rapidly translocated from the water phase into the sediment, where is mainly degraded in TMG (please note that the degradation rate of TMG in sediment in unknown). Clothianidin is highly toxic to sediment-dwelling organisms. However, the value is below the trigger of 1 for both pelagic and sediment-dwelling organisms for surface treatment as well as for spot treatment..

Conclusion:

Unacceptable effect to the aquatic compartment is not expected, neither for sediment-dwelling organisms, nor for pelagic organisms.

(IV) Terrestrial compartment

The risk to terrestrial compartment is assessed by dividing the PECsoil (averaged over 30 days) by the PNECsoil.

Please note that the risk assessment was performed by summing the PEC/PNEC ratio of the active substance and its degradation products MNG and TZNG. If the result of this ratio is below 1, an acceptable risk to terrestrial organisms can be concluded (please, refer to Table 2.2.8–17). Please note that as soil contamination takes place through application of sludge from the STP in agricultural area.

Table 2.2.8–17 Summary table of the PEC/PNEC values of clothianidin and its metabolites for the soil compartment

Summary table on calculated PEC/PNEC values for terrestrial compartment				
Crack and crevice scenario	**PEC/PNEC$_{soil}$ clothianidin**	**PEC/PNEC$_{soil}$ MNG**	**PEC/PNEC$_{soil}$ TZNG**	**PEC/PNEC$_{soil}$ Sum**
Surface treatment – Tier 1	1.08×10^{-2}	2.32×10^{-4}	2.01×10^{-4}	9.88×10^{-3}
Spot treatment – Tier 2	5.61×10^{-4}	1.21×10^{-5}	1.05×10^{-5}	5.84×10^{-4}

Clothianidin was considered to be persistent in soil as well as its main metabolites MNG and TZNG, though their half-lives are less than one year (118 to 211 days). Clothianidin and its metabolites could also be detected in 20-30 cm deep soil layers. Although clothianidin showed a high toxicity to P. cupreus larvae, no ratio is over the trigger value of 1. Therefore the active substance and its degradation products are not expected to display adverse effects on the soil compartment.

Conclusion:

No unacceptable effect to the soil compartment is expected.

(V) Groundwater

Although clothianidin and TZNG were less mobile in soil (KOC = 160 L/kg and 276 L/kg, respectively) than MNG (KOC = 21L/kg), all compounds were detected in 20-30 cm deep soil layers after application by spray and as seed treatment. However the active substance was not detected in the leachates of lysimeter studies, leading to unlikely leakage in groundwater.

EUSES calculations showed that the potential groundwater concentrations of clothianidin and its metabolites did not exceed the threshold value of 0.1 µg/L provided by the BPR (Annex VI, point 68) and the Directive 98/83/EC. Moreover the sum of the PEC_{gw} for these compounds is 6.57 x 10^{-6} mg/L at Tier 1 and 3.41 x 10^{-7} mg/L after refinement, which is below the threshold value of 0.5 µg/L provided by the BPR and the Directive 98/83/EC for a mixture toxicity, leading to an acceptable risk for drinking water and groundwater compartment.

Conclusion:

No unacceptable risk to the groundwater is expected and the requirements of Directive 98/83/EC and 2006/118/EC12 are complied with.

(VI) Primary and secondary poisoning

Primary poisoning

Not relevant.

Secondary poisoning

The log Pow value of clothianidin was below the trigger value of 3, suggesting a low risk of bioaccumulation and secondary poisoning via ingestion of contaminated food by predators. Furthermore, no other indicators point to an intrinsic potential for bioconcentration – e.g. surface tension is 79.6 mN/m, which is above the trigger value of 50 mN/m.

The risk bees is assessed by dividing the PECsoil of clothianidin (averaged over 180 days) for grassland and agricultural soil by the PNECbees. If the result of this ratio is below 1, an acceptable risk to honeybees can be concluded (please, refer to Table 2.2.8–18).

Table 2.2.8–18 Summary table on secondary poisoning assessment due to clothianidin

Summary table on calculated PEC/PNEC values for secondary poisoning of honeybees		
Crack and crevice scenario	**PEC/PNEC grassland**	**PEC/PNEC agricultural soil**
Surface treatment – Tier 1	1.16 x 10^{-3}	3.83 x 10^{-4}
Crack & crevices – Tier 2	4.90 x 10^{-4}	1.61 x 10^{-4}

A risk cannot be excluded for bees at Tier 1. After refinement, the PEC/PNEC value is below the trigger for agricultural soil but it equals 1 in grassland. However the scenario, assuming that all clothianidin in soil is absorbed by plant and translocated to nectar and pollen, without degradation, is unrealistically worst case. Moreover the ratio is not greater but equals to the trigger. Therefore the risk to honeybees is considered to be acceptable.

12Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration, OJL372, 27.12.2006.

Conclusion:

No unacceptable risk of secondary poisoning of birds and mammals trough the ingestion of contaminated terrestrial or aquatic animals is expected. Moreover no unacceptable risk to honeybees trough contact or ingestion of contaminated nectar and pollen is expected.

(VII) Mixture toxicity

Although Clothianidin RB 1 contains only one active substance, several co-formulants of clothianidin could be of concern for the environment based on their classification. Therefore a risk assessment regarding the mixture toxicity has been performed according to the Transitional Guidance on mixture toxicity assessment13.

Screening step

Screening Step 1: Identification of the concerned environmental compartments

For all scenarios, emission to air is considered to be negligible (Please refer to the risk characterisation for atmosphere above). No direct or indirect exposure (e.g. via waste water and STP) to surface water is expected: it was clearly stated in the Instruction for Use that the formulated product must not be applied in area subjected to wet-cleaning (Please refer to the SPC under 2.1.4 and 2.1.5 : "Do not apply in areas not subjected to wet-cleaning"). Exposure to soil is therefore also not expected.

Screening Step 2: Identification of relevant substances

Not relevant (see above).

Screening Step 3: Screen on synergistic interactions

No literature data have been submitted about synergistic interactions between formulated product components. However none of these substances is part of the Appendix 3 of the Transitional Guidance on mixture toxicity assessment (ECHA, 2014). Given the composition of the formulated products (Please refer to Table 3.6–1 in Confidential annex), no synergistic interactions is expected between the assessed components.

Screening step	
N	Significant exposure of environmental compartments? (Y/N)
N	Number of relevant substances >1? (Y/N)
N	Indication for synergistic effects for the product or its constituents in the literature? (Y/N)
	No synergistic interactions is expected between the assessed components

13 ECHA (2014), Transitional Guidance on the Biocidal Products Regulation - Transitional Guidance on mixture toxicity assessment for biocidal products for the environment, European Chemicals Agency, Helsinki, Finland. Available via https://echa.europa.eu/

Tiered approach

As the toxicity of formulated product Clothianidin RB 1 is only evaluated based on the toxicity of the active substance clothianidin as well as the toxicity of its metabolites and as no synergistic interactions is expected between the components of the product, no further assessment is needed.

Conclusion:
No unacceptable risk is expected from the formulated product Clothianidin RB 1.

(VIII) Aggregated exposure (combined for relevant emission sources)

According to the BPR (Article 19, point 2)14, the evaluation shall take into account the cumulative effects as well as the synergistic effects of the biocidal product or of its components. This refers to the environmental risk assessment of the substances which are contained in different products of the same Product Type (PT) or of different PTs. A decision tree on the need for estimation of aggregated exposure (Figure 1 below) was available in the BPR to determine when such exposure is needed.
Please note that no guidance on aggregated assessment has been agreed upon. The methodology needs to be further developed and harmonised at EU-level. The assessment was therefore performed for information.

Clothianidin is not regulated by REACH15 but the substance is regulated by EFSA16 as plant protection product (Please refer to Figure 1). However tonnage data being confidential, it is not possible to determine if the biocide use represent less than 10% of the total annual tonnage. Therefore it has been checked if clothianidin was used in others PT.
Clothianidin is notified for inclusion in the EU list of active substances approved for use in biocidal products as PT 18 and PT 8. In their respective CAR, the following uses are considered:

- PT 18 (2014): Spraying/paint-on formulation for controlling flies in livestock and poultry stables. Please note that Alba (mixture of clothianidin and muscalure), a formulated product having this use, is currently under review.

14 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L167, 27.6.2012, p. 166.

15 https://www.echa.europa.eu/web/guest/registration-dossier/-/registered-dossier/9181/1

16 http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=1154

- PT 8 (2008) : Wood treatment against beetles and termites by spraying/brushing, dipping or vacuum pressure treatment. Industrial and professional use only.

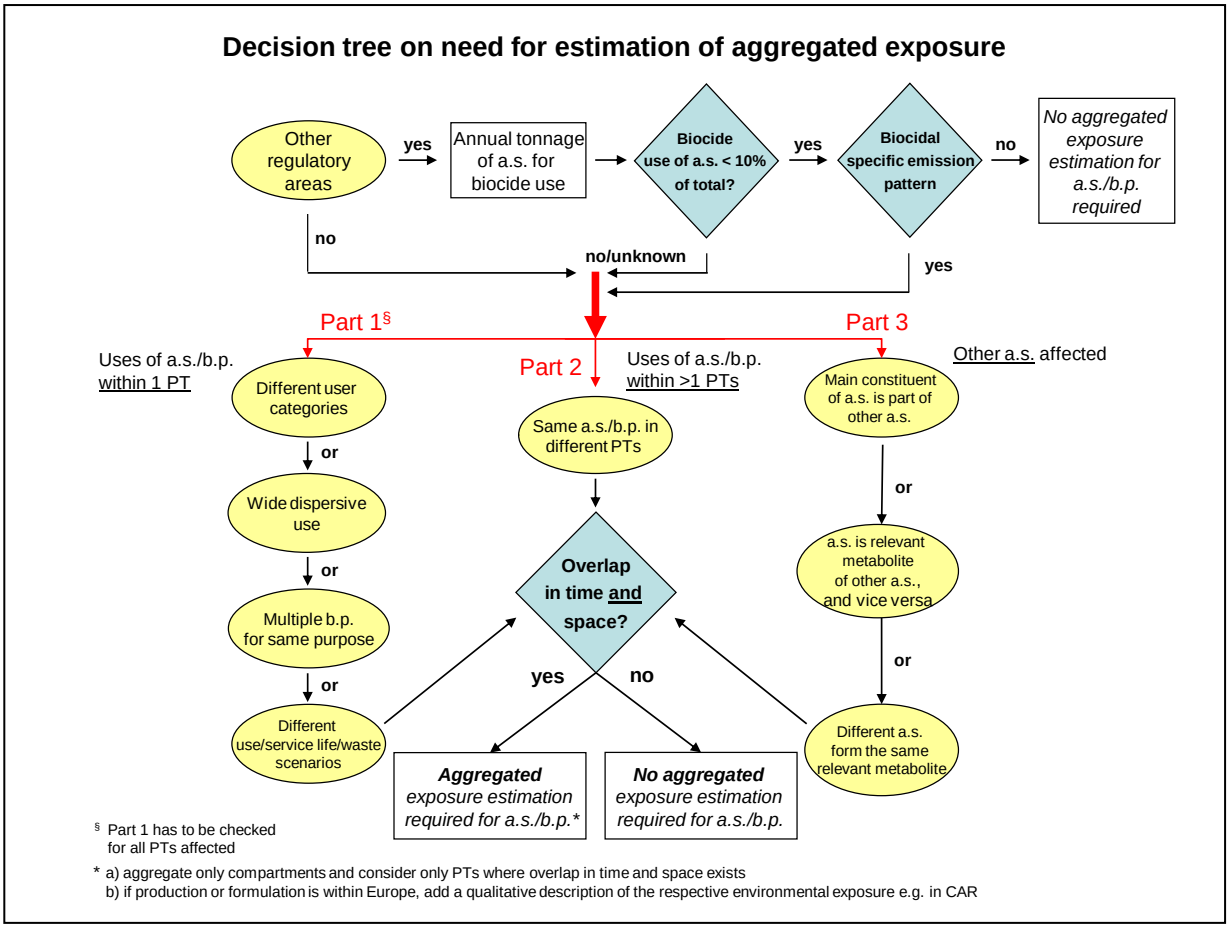


Figure 1: Decision tree on the need for estimation of aggregated exposure

Regarding to the use of clothianidin as wood treatment (PT 8), it is stated in the CAR that there might be unacceptable risk to the aquatic and terrestrial compartment. Therefore mitigation measures should be required to prevent any losses to the environment: all wastes from dipping treatment must be collected, contained and recycled or disposed of as hazardous waste so that there is no drain connections to storm drains or STPs. Moreover the storage places must have impermeable, sealed grounds to prevent penetration of the leachate run-off to soil and they should be roofed to avoid exposure to rainfall. In addition pre-treated timber cannot be used for outdoor constructions except if appropriate mitigation measures (to be defined) are used. Therefore and in the absence of additional data, it was considered that no emission to the environment should be expected from the use of clothianidin as PT 8.

Regarding to the use of clothianidin as an indoor insecticide for controlling flies in livestock and poultry stables (PT 18), releases via contaminated manure are the main path of entry of the formulated product into the environment. A fraction of the insecticide used in animal housing could also be discharged with waste water to the STP after cleaning events. In RMS's opinion, these uses might lead to an overlap in space and time of the contamination of both the aquatic and the soil compartment. Consequently the aggregated exposure assessment according to the BPR is relevant for clothianidin and its metabolites.

However according to the overall conclusion of the CAR (2014), the application of clothianidin in poultry stables connected to an STP pose a risk to surface water and sediment.

Consequently the labelling should exclude the application of product in poultry stables, unless it is clearly demonstrated at the stage of product authorisation that no risks to the environment will occur. Therefore, in the absence of further data, emission to the aquatic compartment or to soil via contaminated sludge is considered unlikely. Regarding the emission to agricultural soil via contaminated manure application, a risk was expected for all animal categories except for beef cattle and poultry from laying hens battery (belt drying). Therefore, in the absence of further data, the aggregate exposure assessment was only performed for the soil compartment and these categories demonstrating a safe use. It thus was assumed that the same agricultural soil was exposed to both sludge contaminated by Clothianidin RB 1 and manure contaminated by the insecticide for controlling flies in stables.

The PECs from the formulated product used for controlling flies in livestock were calculated with the ESD for PT 18 (Please, refer to the CAR[17]). Please note that no PEC have been calculated for clothianidin metabolites in the CAR, except for TMG in soil. The PEC values and PEC/PNEC ratio for clothianidin used as insecticide for controlling flies in livestock stables are provided in Table 2.2.8–19 (arable land) and Table 2.2.8–20 (grassland). Please note that given the physico-characteristics of clothianidin, the exposure to air is considered to be negligible.

Table 2.2.8–19 PEC/PNEC ratio of clothianidin and its metabolites used as insecticide for controlling flies in livestock stables for arable land (CAR, 2014).

Environmental compartment		**PEC** [µg/L] or [mg/kg$_{wwt}$]	**PNEC** [µg/L] or [mg/kg$_{wwt}$]	**PEC/PNEC**
CLOTHIANIDIN				
Soil	Spraying	1.76×10^{-4}	1.80×10^{-3}	9.78×10^{-2}
	Painting	1.23×10^{-4}	1.80×10^{-3}	6.83×10^{-2}
Groundwater		4.69×10^{-5}	-	-
TMG				
Soil	Spraying	1.60×10^{-4}	1.80×10^{-3}	8.89×10^{-2}
	Painting	1.12×10^{-4}	1.80×10^{-3}	6.22×10^{-2}

Table 2.2.8–20 PEC/PNEC ratio of clothianidin and its metabolites used as insecticide for controlling flies in livestock stables for grassland (CAR, 2014).

Environmental compartment		**PEC** [µg/L] or [mg/kg$_{wwt}$]	**PNEC** [µg/L] or [mg/kg$_{wwt}$]	**PEC/PNEC**
CLOTHIANIDIN				
Soil	Spraying	6.21×10^{-4}	1.80×10^{-3}	3.45×10^{-1}
	Painting	4.35×10^{-4}	1.80×10^{-3}	2.42×10^{-1}

17 Table 8-18 of DocII, Table Annex DocIIB-8.3 3g and Table Annex DocIIB-8.3 3h in confidential annexes

Groundwater		1.78×10^{-5}	-	-
TMG				
Soil	Spraying	6.40×10^{-4}	1.80×10^{-3}	3.56×10^{-1}
	Painting	4.48×10^{-4}	1.80×10^{-3}	2.49×10^{-1}

The aggregated exposure of clothianidin was performed by summing the PEC/PNEC values of both PT 18 products (i.e. Clothianidin RB 1 and the insecticide for controlling flies in livestock stables) either for arable land or for grassland. The aggregated exposure was therefore performed according to the following equations:

$$Aggregated\ exposure\ (arable\ land) = \frac{\text{PEC}}{\text{PNEC}}\ \text{Clothianidin RB 1} + \frac{\text{PEC}}{\text{PNEC}}\ \text{livestock stable insecticide in arable land}$$

Or

$$Aggregated\ exposure\ (grassland) = \frac{\text{PEC}}{\text{PNEC}}\ \text{Clothianidin RB 1} + \frac{\text{PEC}}{\text{PNEC}}\ \text{livestock stable insecticide in grassland}$$

The aggregated exposure for is provided in Table 2.2.8–21. For clarity reason, only results with refined data of Tier 2 calculations are presented here

Table 2.2.8–21 Aggregated exposure of clothianidin and its metabolites. Values in bold are over the trigger of 1.

Summary table on calculated ∑ PEC/PNEC values for clothianidin and its metabolites			
Scenario	**Soil**	**Groundwater**	**Secondary poisoning Honeybees**
Arable land - Spraying	1.87×10^{-1}	4.72×10^{-5}	1.00×10^{-1}
Arable land - Painting	1.31×10^{-1}		
Grassland - Spraying	7.02×10^{-1}	1.81×10^{-5}	4.20×10^{-1}
Grassland - Painting	4.92×10^{-1}		

After refinement of the scenarios, the aggregated exposure did not show unacceptable risk for clothianidin and its metabolites.

Conclusion:

No unacceptable effect to the environment is expected from the aggregated exposure of formulated products containing clothianidin.

Overall conclusion on the risk assessment for the environment of the product
No unacceptable effect to the environment is expected from the use of Clothianidin RB 1, neither for the aquatic compartment (STP, water and sediments), nor for the terrestrial compartment. Exposure of the atmosphere is considered to be negligible. No unacceptable

risk of secondary poisoning of honeybees following contaminated sludge application is to be expected. No unacceptable risk to the groundwater is expected and the requirements of Directive 98/83/EC and 2006/118/EC are complied with.

2.2.9 Measures to protect man, animals and the environment

Risk mitigation measures :

- • Avoid application to excessively dusty, damp or greasy locations. Do not apply in areas not subjected to wet-cleaning.
- • Not intended for uses in in stables, pens or cages for animals . Not recommended for use in insectivorous birds and reptiles' facilities.
- • Keep out of the reach of children.
- Wear suitable protective gloves when the product is handled.
- • Avoid contact with skin.
- • Wash hands and exposed skin before meals and after use.
- • Do not apply to surfaces on which food r feed is stored, prepared or eaten.
- • Use only in positions inaccessible to children and animals.
- • Do not attempt to open or refill cartridges.

First aid measures :

- **General advice**: If significant amounts are spilled, the following advice is applicable. Move out of dangerous area. Place and transport victim in stable position (lying - sideways). Remove contaminated clothing immediately and dispose of safely.
  If necessary take the affected individual to a healthcare centre and bring packaging or label whenever possible.
- **Skin contact**: Wash off thoroughly with plenty of soap and water, subsequently rinse with water. If skin irritation/sensitization occurs, persists or intensifies seek medical advice.
- **Eye contact**: : Immediately flush eyes with plenty of lukewarm water. Check for and remove any contact lenses. Continue to rinse for at least 5 minutes. If symptoms persists, seek medical attention
- **Ingestion**: Rinse mouth with water. Call a physician or poison control center immediately. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink."

Advice for medical and healthcare personnel: Provide symptomatic and supportive treatment.

When asking for medical advice keep packaging or label at hand and call your local poison control center (for Belgium : 070 245 245)

Instructions for safe disposal of the product and its packaging

- Dispose of contents/container in accordance with local regulation.
- Unwanted gel can be removed when freshly applied by sponging with a 5% sodium chloride solution. Sponges/tissues used should be disposed of as solid waste.
- Aged gel can be removed with spatulas and disposed of as solid waste

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

- Conditions of storage: Do not allow to freeze. Keep in a safe place.
- Shelf life at ambient temperature: 2 years (After cMS commenting it was decided that overall shelf life is restricted to 2 years for reasons of ensuring efficacy against all claimed species.)

2.2.10 Assessment of a combination of biocidal products

Not relevant.

2.2.11 Comparative assessment

According to the BPC opinion for clothianidin this substance is considered to be very persistent (vP) and toxic to aquatic life (T) but not bioaccumulative (B) in accordance with the criteria laid down in Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council. This BPC opinion states that clothianidin is considered as a candidate for substitution using the criteria in Article 10(1)(d). Clothianidin does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Therefore, in line with Article 23 (1) of Regulation (EU) 528/2012 a comparative assessment for the product Clothianidin RB1 has been conducted (see "Comparative Assessment Report for Clothianidin RB1" for details).

As the outcome of the comparative assessment showed that the product Clothianidin RB1 cannot be considered an outlier and therefore there is not a possibility for substitution, the product can be **authorised for a period not exceeding 5 years.**

3 ANNEXES

3.1 LIST OF STUDIES FOR THE BIOCIDAL PRODUCT

Author(s)	Year	Title	Testing Company	Report No. / Company Study No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Boase, C.J.	2013	UK Field Trials with Clothianidin 1% RB and Maxforce Prime for control of the Oriental Cockroach (Blatta orientalis)	The Pest Management Consultancy, Haverhill, Suffolk, UK	M-475046-01-1	No	No	Yes	Bayer CropScience AG	6.7
Brooks, M.D	2018	Field efficacy of a bait containing 1% Chlothianidin against the grey silverfish (Ctenolepisma longicaudatum Escherish) in houses		MoES06566/ M-609824-01-1		No	Yes	Bayer CropScience AG	6.7
Brux, A.	2013b	Flash Point A.9. of Clothianidin RB 1%	BioGenius GmbH, Bergisch Gladbach, Germany	M-455461-01-1	Yes	No	Yes	Bayer CropScience AG	4.2
Dornhagen, J.	2013a	Explosive Properties A.14	Siemens AG Prozess-Sicherheit, Frankfurt am Main, Germany	M-458149-01-1	Yes	No	Yes	Bayer CropScience AG	4.1
Dornhagen, J.	2013b	Oxidising Properties (Liquids) A.21	Siemens AG Prozess-Sicherheit, Frankfurt am Main, Germany	M-453152-01-1	Yes	No	Yes	Bayer CropScience AG	4.4

Author(s)	Year	Title	Testing Company	Report No. / Company Study No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Dornhagen, J.	2013c	Auto-ignition Temperature (Liquids and Gases) A.15	Siemens AG Prozess-Sicherheit, Frankfurt am Main, Germany	M-458149-01-1	Yes	No	Yes	Bayer CropScience AG	4.17.1
Gutsmann, V	2015a	Maxforce Platin (Clothianidin RB 1): comparison of fresh and stress tested samples against three cockroach species	BCS AG-R&D-ES-I, Bayer CropScience, Monheim, Germany	BES06212 / M-525136-02-1	No	No	Yes	Bayer CropScience	6.7
Gutsmann, V	2015b	Description of Lepismatidae appearance and behaviour - consequences for evaluating treatment success	not applicable	M-538863-01-1	No	No	Yes	Bayer CropScience	6.7
Gutsmann, V	2015b	Palatability and efficacy in simulated use trials of Maxforce Platin after two years of ambient storage		M-531535-01-1		No	Yes	Bayer CropScience	6.7
Gutsmann, V.	2014	Control of an infestation with silverfish (Lepisma saccharina) in a single family dwelling with Clothianidin RB 1	Bayer CropScience	Mo ES 06073 / M-490293-01-1	No	No	Yes	Bayer CropScience	6.7

Author(s)	Year	Title	Testing Company	Report No. / Company Study No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Gutsmann, V.	2018	Maxforce Platin (Clothianidin RB 1): comparison of fresh and 5 years old samples against three cockroaches species		M-633234-01-1		No	Yes	Bayer CropScience	6.7
Gutsmann, V	2018	Position paper- Dosing strategies for cockroach baits		MoES06571/ M-614672-01-1		No	Yes	Bayer CropScience	6.7
Manka, S.	2013	BCS: HPLC - Determination of Clothianidine in Clothianidine RB 1%	BioGenius GmbH, Bergisch Gladbach, Germany	M-449616-01-1	No	No	Yes	Bayer CropScience	5
Manka, S.	2015	Determination of physico-chemical properties and accelerated storage stability test for Clothianidin RB 1% in PE Syringe	BioGenius GmbH, Bergisch Gladbach, Germany	Mo4624	Yes	No	Yes	Bayer CropScience	3.1-3.3; 3.4.1; 3.9
Manka, S.	2016	Determination of physico-chemical properties and accelerated storage stability test for Clothianidin RB 1 (10g/kg) in PE Syringe	BioGenius GmbH, Bergisch Gladbach, Germany	M-454510-03-1	Yes	No	Yes	Bayer CropScience	Submitted during stop the clock phase, 3.1-3.3; 3.4.1; 3.9

Author(s)	Year	Title	Testing Company	Report No. / Company Study No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Manka, S.	2018	*Determination of physico-chemical properties and accelerated storage stability* *test for Clothianidin RB 1 (10g/kg) in PE Syringe*	BioGenius GmbH, Bergisch Gladbach, Germany	-	Yes	No	Yes	Bayer CropScience	Submitted during stop the clock phase, 3.1-3.3; 3.4.1 and 3.9
See Confidential PAR for more details	2013a	Primary Skin Irritation Study in Rabbits	See Confidential PAR for more details	35411 / M-445821-02-1	Yes	No	Yes	Bayer CropScience	8.1.1
See Confidential PAR for more details	2013b	Primary Eye Irritation Study in Rabbits	See Confidential PAR for more details	35410 / M-445819-02-1	Yes	No	Yes	Bayer CropScience	8.1.2
See Confidential PAR for more details	2013c	Local Lymph Node Assay (LLNA) in Mice	See Confidential PAR for more details	35412 / M-445822-02-1	Yes	No	Yes	Bayer CropScience	8.3.1
See Confidential PAR for more details	2013d	Acute Oral Toxicity Up And Down Procedure In Rats	See Confidential PAR for more details	35408 / M-445815-02-1	Yes	No	Yes	Bayer CropScience	8.5.1

Author(s)	Year	Title	Testing Company	Report No. / Company Study No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
See Confidential PAR for more details	2013e	Acute Dermal Toxicity Study in Rats	See Confidential PAR for more details	35409 / M-445818-02-1	Yes	No	Yes	Bayer CropScience	8.5.3
Michel, G	2017	Maxforce Platin (Clothianidin RB 1): comparison of fresh and aged samples against three cockroaches species.		Reference M-589095-01-1		No	Yes	Bayer CropScience	6.7
Miller, P.F. & Peters, B.	2013a	Field Trial of Performance of Cockroach Gel Bait Clothianidin 1%w/w (0.2 g/m2, 0.1 g/m2 and 0.05 g/m2) against German Cockroaches	Faculty of Science, University of Technology, Sydney, Australia	R13-1976 / M-499912-02-1	No	No	Yes	Bayer S.A.S. / Environmental Science	6.7

Author(s)	Year	Title	Testing Company	Report No. / Company Study No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Miller, P.F. & Peters, B.	2013b	Field Trial of Performance of Cockroach Gel Bait Clothianidin (0.3 g/m2, 0.2 g/m2 and 0.1 g/m2) against a Mixed Population of American and Australian Cockroach	Faculty of Science, University of Technology, Sydney, Australia	R13-1980 / M-499919-01-1	No	No	Yes	Bayer S.A.S. / Environmental Science	6.7
Nentwig, G.	2012a	10ESP600 (600-12-07): Evaluation of the fastness of action of Clothianidin 1 RB versus different gels against susceptible cockroaches (Blattella germanica)	BCS AG-ES-I-Product Development White	NE- NE-SH121204 / M-451276-03-1	No	No	Yes	Bayer CropScience	6.7
Nentwig, G.	2012b	08ESP600 (BES 600-12-05): Evaluation of Clothianidin 1 RB after two weeks storage at 54°C against susceptible cockroaches (Blattella germanica)	BCS AG-ES-I-Product Development White	NE-SH121111 / M-451267-02-1	No	No	Yes	Bayer CropScience	6.7

Author(s)	Year	Title	Testing Company	Report No. / Company Study No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Reid, B.L.	2013	Product Performance: Laboratory and Field Efficacy Testing for BES0600 Insecticide	not applicable	M-453208-01-1	No	No	Yes	Bayer CropScience	6.7
Rump, E.	2014	Position Paper - Clothianidin RB 1: Bait use at maintenance rates and resistance	not applicable	277/2014-ER / M-488804-01-1	No	No	Yes	Bayer S.A.S. / Environmental Science	6.7
Rump E.	2018	Determination of physico-chemical properties and accelerated storage stability test for Clothianidin RB 1% in PE Syringe	BioGenius GmbH, Bergisch Gladbach, Germany	-	Yes	No	Yes	Bayer CropScience	
Serrano, B.	2013	Field testing of the efficacy of insecticidal gel baits to control German cockroaches	T.E.C. Laboratory, Anglet, France	1561-EU/1212R / M-497862-01-1	No	No	Yes	Bayer CropScience	6.7

3.2 OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS

The exposure assessment was not performed with exposure assessment tools providing typical output tables. Therefore, such tables are not provided here.

3.3 NEW INFORMATION ON THE ACTIVE SUBSTANCE

No new information is provided on the active substance.

3.4 RESIDUE BEHAVIOUR

No new information is provided about residue behaviour.

3.5 SUMMARIES OF THE EFFICACY STUDIES (B.5.10.1-XX)

Please refer to the summaries found under ***2.2.5.5. efficacy data.***

3.6 CONFIDENTIAL ANNEX

3.7 OTHER

Not relevant.