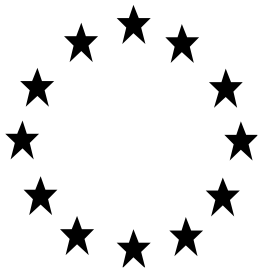
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



Selontra®

Product type PT 14

Cholecalciferol

Case Number in R4BP: BC-LS050091-32

Evaluating Competent Authority: Finland

Date: 17/03/2020
Updated: October 2020

Assessment history

Application type	refMS/ eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
NA-APP	FI	BC-LS050091-32	17.03.2020	Initial assessment	
NA-AAT	FI		October 2020	*Changes in the PAR:* - *The waiver for metal corrosivity test has been corrected*	28

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1 CONCLUSION

The Finnish CA considers the information provided for the intended uses sufficient for the authorisation of Selontra® and proposes the authorisation of the product as a rodenticide against rats and house mice in and around buildings by the professionals and trained professionals. The product and uses are the same as in the active substance evaluation of cholecalciferol.

Selontra® has shown to be effective against mice and rats. The risk for primary and secondary poisoning of non-target animals cannot be excluded, but when used as instructed and applying specific risk mitigation measures, the risk is considered to be acceptable in relation to the benefit of using Selontra® for the rodent control.

One co-formulant, 2-phenylphenol, was identified as a substance of concern for the environment. An analytical method for the analysis of 2-phenolphenyl is set as a post authorization condition.

Cholecalciferol has been identified as a candidate for substitution due to endocrine disrupting properties and because it causes unacceptable risk for primary and secondary poisoning of non-target organisms. Thus, authorization of Selontra® can take place if the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied.

Selontra® is considered to satisfy conditions b and c of Article 5(2). Cholecalciferol is considered an important contribution to the selection of rodenticides as it has a different mode of action compared to anticoagulant rodenticides and alphachloralose. It can be used against rats and mice resistant to anticoagulant rodenticides and it also enables rotation of rodenticides acting by different mechanisms. Effective rodent control is necessary in society and thus not approving Selontra® would have a disproportionate negative impact on society when compared with the risk to the environment arising from the use of the substance. Thus, authorization of Selontra® is proposed for five years according to the Article 19(5).

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	Country (if relevant)
Selontra®, Relpexa, Exittus	Finland (reference member state)
Selontra®, Relpexa	Austria
Selontra®, Relpexa	Bulgaria
Selontra®, Relpexa	Croatia
Selontra®, Relpexa	Cyprus
Selontra®, Relpexa	Czech Republic
Selontra®, Relpexa, Exittus	Denmark
Selontra®, Relpexa	Estonia
Selontra®, Relpexa	France
Selontra®, Relpexa	Germany
Selontra®, Relpexa	Greece
Selontra®, Relpexa	Hungary
Selontra®, Relpexa	Ireland
Selontra®, Relpexa	Italy
Selontra®, Relpexa	Latvia
Selontra®, Relpexa	Lithuania
Selontra®, Relpexa	Netherlands
Selontra®, Relpexa, Exittus	Norway
Selontra®, Relpexa	Poland
Selontra®, Relpexa	Romania
Selontra®, Relpexa	Slovakia
Selontra®, Relpexa	Slovenia
Selontra®, Relpexa	Spain
Selontra®, Relpexa, Exittus	Sweden
Selontra®, Relpexa	Switzerland
Selontra®, Relpexa	United Kingdom

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	BASF OY
	Address	Tammasaarenkatu 3, FI-00180, Helsinki, Finland
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer of the product

Name of manufacturer	BASF Agro B.V. Arnhem (NL) - Freienbach Branch
Address of manufacturer	Huobstrasse 3, 8808 Pfäffikon SZ, Switzerland
Location of manufacturing sites	BASF plc St. Michaels Industrial Estate, Widnes, Cheshire, WA8 8TJ, United Kingdom

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

Active substance	Cholecalciferol
Name of manufacturer	BASF Agro B.V. Arnhem (NL) - Freienbach Branch
Address of manufacturer	Huobstrasse 3, 8808 Pfäffikon SZ, Switzerland
Location of manufacturing sites **Site #1**	Fermenta Biotech Limited Village Takoli P.O. Nagwain Distt. Mandi – 175 121 Himachal Pradesh India
Site #2	Fermenta Biotech Limited Z-109 B & C, SEZ II, Dahej Taluka – Vagara District Bharuch 392 130 Gujarat India

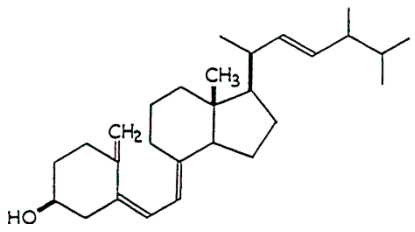
2.1.2 Product composition and formulation

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

Please note that where the product is referred to as BAS 410 05 I in this PAR (i.e. study summaries), this is the internal BASF formulation code for Selontra®.

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	Cholecalciferol, Vitamin D_3
IUPAC or EC name	9,10-secocholesta-5,7,10-trien-3-ol
EC number	200-673-2
CAS number	67-97-0
Index number in Annex VI of CLP	603-180-00-4
Minimum purity / content	97.0%
Structural formula	

2.1.2.2 Candidate(s) for substitution

The active substance in Selontra, cholecalciferol, is a candidate for substitution meeting criteria (a) and (e) of Article 10 (1) of Regulation (EU) No 528/2012, according to the BPC opinion for cholecalciferol adopted on December 13, 2017 (ECHA/BPC/180/2017).

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Cholecalciferol	9,10-secocholesta-5,7,10-trien-3-ol	Active substance	67-97-0	200-673-2	0.075 (0.077 technical active substance at 97% purity)
2-Phenylphenol	2-Phenylphenol	Preservative	90-43-7	201-993-5	0.0496

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Other components of the formulation[1]					

For heterogeneous products, an FAO/WHO tolerance of 25% applies to the active substance content.

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

Not applicable

2.1.2.5 Information on technical equivalence

The second source of cholecalciferol (Fermenta Biotech) has been assessed as technically equivalent by ECHA (Decision number TAP-D-1399859-99-00/F).

2.1.2.6 Information on the substance(s) of concern

No substances of concern for human health are present according to CA-Nov-Doc.5.11 - please see the confidential annex for further details. For the environment, one co-formulant, was identified as a substance of concern according to Guidance on the Biocidal Products Regulation, Vol. IV Environment – Assessment and Evaluation (Parts B+C), V.2.0, October 2017' (BPR vol. IV, Parts B+C).

2.1.2.7 Type of formulation

Ready-to-use bait: paste.

2.1.3 Hazard and precautionary statements

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

The product does not need to be classified. The concentration of the active substance cholecalciferol is below the specific concentration limits as set by the CLP Regulation. The co-formulants do not influence the classification (see Confidential Annex 3.6).

Classification	
Hazard category	Not classified
Hazard statement	Not required
Labelling	
Signal words	Not required
Hazard statements	Not required
Precautionary statements	Not required

[1] Refer to confidential annex

2.1.4 Authorised use(s)

The product Selontra® (0.075% cholecalciferol) is a new product which has not yet been authorised. With this application, first authorisation of the product is applied for with the intended uses detailed in this section and section 2.2.1.

2.1.4.1 Use description

Table 1. Use # 1 – House mice – professionals – indoor

Product Type	PT 14 Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism (including development stage)	*Mus musculus* (house mice), including strains resistant to anticoagulant rodenticides, adults and juveniles.
Field of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	The number of bait points used depends on the pest pressure at the site where the product is to be used: Mice: 20-40 g (1 or 2 units) of bait every 1-2 metres.
Category(ies) of users	Professionals
Pack sizes and packaging material	3- 10 kg in PP or HDPE or PET or PE or LDPE buckets with lids and re-closable pots. 3- 10 kg in PP or HDPE or PET or PE or LDPE lined re-closable container such as a pot, tin or cardboard carton, also tin plated steel tins. Pre-filled PP or PE or LDPE bait boxes overpacked in 3-10 kg in PP or PET or PE re-closable container or re-closable cardboard carton.

2.1.4.2 Use-specific instructions for use

- Bait may only have to be placed for 7 days to achieve control provided that sufficient bait for the size of the infestation is placed on day 1 of the treatment. Inspect baits 1-2 days after the first placement and replace eaten bait. If a bait point is completely consumed, replace with the maximum amount of bait at that bait point. This will ensure optimum control in the shortest time is achieved. Inspect baits regularly (at least weekly) in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Continue placing bait every 7 days until consumption ceases. Note that if an insufficient amount of bait is used at any time of the treatment, this may lead to sub-optimal results.
- Remove the remaining product at the end of treatment period.
- Follow any additional instructions provided by the relevant code of best practice.

2.1.4.3 Use-specific risk mitigation measures

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

- When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

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

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

Table 2. Use # 2 – Rats – professionals – indoor

Product Type	PT 14 Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism (including development stage)	*Rattus rattus* (black or roof rat), adults and juveniles. *Rattus norvegicus* (brown rat), including strains resistant to anticoagulant rodenticides, adults and juveniles.
Field of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	The number of bait points used depends on the pest pressure at the site where the product is to be used: Rats: 100-140 g (5-7 units) of bait every 5-10 metres.
Category(ies) of users	Professionals
Pack sizes and packaging material	3-10 kg in PP or HDPE or PET or PE or LDPE buckets with lids and re-closable pots. 3-10 kg in PP or HDPE or PET or PE or LDPE lined re-closable container such as a pot, tin or cardboard carton, also tin plated steel tins. Pre-filled PP or PE or LDPE bait boxes overpacked in 3-10 kg in PP or PET or PE re-closable container or re-closable cardboard carton.

2.1.4.7 Use-specific instructions for use

- Bait may only have to be placed for 7 days to achieve control provided that sufficient bait for the size of the infestation is placed on day 1 of the treatment. Inspect baits 1-2 days after the first placement and replace eaten bait. If a bait point is completely consumed, replace with the maximum amount of bait at that bait point. This will ensure optimum control in the shortest time is achieved. Inspect baits regularly (at least weekly) in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Continue placing bait every 7 days until consumption ceases. Note that if an insufficient amount of bait is used at any time of the treatment, this may lead to sub-optimal results.
- Remove the remaining product at the end of treatment period.

- Follow any additional instructions provided by the relevant code of best practice.

2.1.4.8 Use-specific risk mitigation measures

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

- When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

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

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

Table 3. Use # 3 – House mice and rats – professionals – outdoor around buildings

Product Type	PT 14 Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism (including development stage)	*Mus musculus* (house mice), including strains resistant to anticoagulant rodenticides, adults and juveniles. *Rattus rattus* (black or roof rat), adults and juveniles. *Rattus norvegicus* (brown rat), including strains resistant to anticoagulant rodenticides, adults and juveniles.
Field of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	The number of bait points used depends on the pest pressure at the site where the product is to be used: Mice: 20-40 g (1 or 2 units) of bait every 1-2 metres. Rats: 100-140 g (5-7 units) of bait every 5-10 metres.
Category(ies) of users	Professionals
Pack sizes and packaging material	3-10 kg in PP or HDPE or PET or PE or LDPE buckets with lids and re-closable pots. 3-10 kg in PP or HDPE or PET or PE or LDPE lined re-closable container such as a pot, tin or cardboard carton, also tin plated steel tins. Pre-filled PP or PE or LDPE bait boxes overpacked in 3- 10 kg in PP or PET or PE re-closable container or re-closable cardboard carton.

2.1.4.12 Use-specific instructions for use

- Bait may only have to be placed for 7 days to achieve control provided that sufficient bait for the size of the infestation is placed on day 1 of the treatment. Inspect baits 1-2 days after the first placement and replace eaten bait. If a bait point is completely consumed, replace with the maximum amount of bait at that bait point. This will ensure optimum control in the shortest time is achieved. Inspect baits regularly (at least weekly) in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Continue placing bait every 7 days until consumption ceases. Note that if an insufficient amount of bait is used at any time of the treatment, this may lead to sub-optimal results.
- Remove the remaining product at the end of treatment period.
- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- Follow any additional instructions provided by the relevant code of best practice.

2.1.4.13 Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

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

- When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

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

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

Table 4. Use # 4 – House mice and rats – trained professionals – indoor

Product Type	PT 14 Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism (including development stage)	*Mus musculus* (house mice), including strains resistant to anticoagulant rodenticides, adults and juveniles. *Rattus rattus* (black or roof rat), adults and juveniles. *Rattus norvegicus* (brown rat), including strains resistant to anticoagulant rodenticides, adults and juveniles.
Field of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations Covered and protected baiting points
Application rate(s) and frequency	The number of bait points used depends on the pest pressure at the site where the product is to be used: Mice: 20-40 g (1 or 2 units) of bait every 1-2 metres. Rats: 100-140 g (5-7 units) of bait every 5- 10 metres. The same amount of bait per baiting point is used for permanently installed baits. However permanent baiting points should only be installed at preferred rodent entry points and nesting sites inside or in the immediate vicinity of buildings.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	3-10 kg in PP or HDPE or PET or PE or LDPE buckets with lids and re-closable pots. 3-10 kg in PP or HDPE or PET or PE or LDPE lined re-closable container such as a pot, tin or cardboard carton, also tin plated steel tins. Pre-filled PP or PE or LDPE bait boxes overpacked in 3- 10 kg in PP or PET or PE re-closable container or re-closable cardboard carton.

2.1.4.17 Use-specific instructions for use

- Bait may only have to be placed for 7 days to achieve control provided that sufficient bait for the size of the infestation is placed on day 1 of the treatment. Inspect baits 1-2 days after the first placement and replace eaten bait. If a bait point is completely consumed, replace with the maximum amount of bait at that bait point. This will ensure optimum control in the shortest time is achieved. Inspect baits regularly (at least weekly) in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Continue placing bait every 7 days until consumption ceases. Note that if an insufficient amount of bait is used at any time of the treatment, this may lead to sub-optimal results.
- Remove the remaining product at the end of treatment period.
- Permanent baiting: where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population.
- Follow any additional instructions provided by the relevant code of best practice.

2.1.4.18 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient.
- The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.

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

- When placing bait points close to water drainage systems, ensure that bait contact with water is avoided.

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

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

Table 5. Use # 5 – House mice and rats – trained professionals – outdoor around buildings

Product Type	PT 14 Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides.
Target organism (including development stage)	*Mus musculus* (house mice), including strains resistant to anticoagulant rodenticides, adults and juveniles. *Rattus rattus* (black or roof rat), adults and juveniles. *Rattus norvegicus* (brown rat), including strains resistant to anticoagulant rodenticides, adults and juveniles.
Field of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations Covered and protected baiting points

Application rate(s) and frequency	The number of bait points used depends on the pest pressure at the site where the product is to be used: Mice: 20-40 g (1 or 2 units) of bait every 1-2 metres. Rats: 100-140 g (5-7 units) of bait every 5- 10 metres. The same amount of bait per baiting point is used for permanently installed baits. However permanent baiting points should only be installed at preferred rodent entry points and nesting sites inside or in the immediate vicinity of buildings.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	3-10 kg in PP or HDPE or PET or PE or LDPE buckets with lids and re-closable pots. 3-10 kg in PP or HDPE or PET or PE or LDPE lined re-closable container such as a pot, tin or cardboard carton, also tin plated steel tins. Pre-filled PP or PE or LDPE bait boxes overpacked in 3-10 kg in PP or PET or PE re-closable container or re-closable cardboard carton.

2.1.4.22 Use-specific instructions for use

- Bait may only have to be placed for 7 days to achieve control provided that sufficient bait for the size of the infestation is placed on day 1 of the treatment. Inspect baits 1-2 days after the first placement and replace eaten bait. If a bait point is completely consumed, replace with the maximum amount of bait at that bait point. This will ensure optimum control in the shortest time is achieved. Inspect baits regularly (at least weekly) in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Continue placing bait every 7 days until consumption ceases. Note that if an insufficient amount of bait is used at any time of the treatment, this may lead to sub-optimal results.
- Protect bait from the atmospheric conditions. Place the baiting points in areas not liable to flooding.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
- Remove the remaining product at the end of treatment period.
- Permanent baiting: where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population.
- Follow any additional instructions provided by the relevant code of best practice.

2.1.4.23 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.

- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not apply this product directly in the burrows.
- Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient.
- The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.

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

- When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

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

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

2.1.5 General directions for use

2.1.5.1 Instructions for use

Professionals and trained professionals

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- Use the higher bait point density and the maximum number of bait units wherever rats or mice have been seen. Be aware of under-baiting – follow the label recommendations for the quantity of bait per bait-point and the frequency of bait-points.
- Use the lower density of bait points in light infestations.

- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
- Try to establish a barrier of bait points between living and feeding areas.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened *(see section 5.3 for the information to be shown on the label)*.
- *[If national policy or legislation requires it]* When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the rodenticide as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.
- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, consider the use of a rodenticide with a different mode of action. Also consider the use of traps as an alternative control measure.

Professionals only

- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Bait stations should be placed in the immediate vicinity of places where rodent activity has been previously observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Remove the remaining bait or the bait stations at the end of the treatment period.

Trained professionals only

- Use the lower density of bait points in light infestations or in permanent baiting by trained professionals.
- The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).

2.1.5.2 Risk mitigation measures

Professionals and trained professionals

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*"
- Dispose dead rodents in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*.
- Do not use in pulsed baiting treatments

Professionals only

- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week). *[Where relevant, specify if more frequent or daily inspection is required].*
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- The product information (i.e. label and/or leaflet) shall clearly show that:
    - the product shall not be supplied to the general public (e.g. "for professionals only").
    - the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
    - users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. label bait stations according to the product recommendations").
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not wash the bait stations with water between applications.
- Do not use bait for permanent baiting or for the prevention of rodent infestation or monitoring of rodent activities.

Trained professionals only

- The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only").
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment *[unless authorised for permanent baiting treatments]*.
- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.

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

- Cholecalciferol causes hypercalcaemia at toxic doses. Treat symptomatically. Treatment would include a low calcium diet, a high salt and fluid intake and avoidance of exposure to sunlight. Monitoring serum calcium levels may aid treatment. Cortisone has been used successfully in some cases.

- First Aid

o If medical advice is needed, have product container or label at hand.
o IF INHALED: Get medical advice/attention if you feel unwell.
o IF ON SKIN: Get medical advice/attention if you feel unwell.
o IF IN EYES: If symptoms occur; rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
o IF SWALLOWED: Rinse mouth. Get immediate medical advice/attention. Contact a veterinary surgeon in case of ingestion by a pet.

- Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre *[insert national phone number]*"

- Hazardous to wildlife.

2.1.5.4 Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose the uneaten bait and the packaging in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*.

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

- Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.

- Store away from food stuffs and animal feeding stuffs and products which may have an odour.

- Store in places prevented from the access of children, birds, pets and farm animals.

- Shelf life: 3 years.

2.1.6 Other information

- Rodent death will occur 2-5 days after ingestion of a lethal amount of bait.

- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.

- This product contains a bittering agent and a dye.

2.1.7 Packaging of the biocidal product

Each bait unit weighs 20 g and is enrobed with a perforated polyolefin film.

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)**
PP or HDPE or PET or PE or LDPE **buckets** with lids and re-closable pots	3-10 kg	PP, HDPE, PET, PE, or LDPE	lids and re-closable pots: PP, HDPE, PET, PE, or LDPE	Professional and trained professional	Yes Container stable after 3 years storage at ambient temperature in the PE bags.
PP or HDPE or PET or PE or LDPE lined re-closable **container** such as a **pot, tin** or cardboard **carton**	3-10 kg	PP, HDPE, PET, PE, LDPE, tin, or cardboard	re-closable container: PP, HDPE, PET, PE, LDPE, tin or cardboard	Professional and trained professional	Yes Container stable after 3 years storage at ambient temperature in the PE bags.
Reclosable tin plated metal pots	3-10 kg	Tin plated metal	re-closable container: tin plated metal	Professional and trained professional	Yes Container stable after 3 years storage at ambient temperature in the PE bags. Taking into account the formulation type (paste), extrapolation to more rigid container acceptable.
Pre-filled PP or PE or LDPE **bait boxes*** overpacked in PP or PET or PE re-closable **container** or re-closable **cardboard carton**	Pre-filled bait box containing 40 g to 140 g bait overpacked in 3-10 kg	PP, PET, PE, LDPE or cardboard	re-closable: PP, PET, PE, LDPE or cardboard carton	Professional and trained professional	Yes Container stable after 3 years storage at ambient temperatures in the PE bags.
* tamper resistant					

PE - Polyethylene
PP - Polypropylene
PET - Polyethylene terephthalate
HDPE - High-density polyethylene
LDPE - Low-density polyethylene
Type of metal: steel, grade MR
Type of plating: tin

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Please refer to the reference list in Annex 3.1 and confidential Annex 3.6.

2.1.8.2 Access to documentation

The applicant is the data holder of the product data and the active substance data.

2.2 Assessment of the biocidal product

2.2.1 Intended use as applied for by the applicant

Product Type	PT 14 Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not applicable for rodenticides.
Target organism (including development stage)	*Mus musculus* (house mice), including strains resistant to anticoagulant rodenticides, adults and juveniles *Rattus rattus* (black or roof rat), adults and juveniles *Rattus norvegicus* (brown rat), including strains resistant to anticoagulant rodenticides), adults and juveniles.
Field of use	Professionals - In and around buildings (rats and mice) Trained professionals – In and around buildings (rats and mice)
Application method(s)	Professionals - Ready-to-use bait to be used in tamper-resistant bait stations Trained professionals - Ready-to-use bait in tamper-resistant bait stations or covered and protected baiting points
Application rate(s) and frequency	The number of bait points used depends on the pest pressure at the site where the product is to be used: Mice: 20 to 40 g (1 or 2 units) of bait every 1-2 metres. Rats: 100-140 g (5-7 units) of bait up to 10 metres apart.
Category(ies) of users	Professionals and trained professionals.
Pack sizes and packaging material	Up to 10 kg in PP or HDPE or PET or PE or LDPE buckets with lids and re-closable pots. Up to 10 kg in PP or HDPE or PET or PE or LDPE lined re-closable container such as a pot, tin or cardboard carton, also lacquered tins. Pre-filled PP or PE or LDPE bait boxes overpacked in up to 10 kg in PP or PET or PE re-closable container or re-closable cardboard carton.

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	EPA OPPTS OPPTS 830.6303 (Physical State)	0.075% cholecalciferol	Semi-solid paste	Kroehl, T. (2013)
Colour at 20 °C and 101.3 kPa	EPA OPPTS 830.6302 (Color)	0.075% cholecalciferol	Grey-green	Kroehl, T. (2013)
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304 (Odor)	0.075% cholecalciferol	Faintly sweet	Kroehl, T. (2013)
Acidity / alkalinity	EPA OPPTS 830.7000 (pH) and CIPAC MT 75.3	0.075% cholecalciferol	1% dilution: pH 6.7.	Kroehl, T. (2013)
Relative density / bulk density	-	-	Not applicable. It is not technically feasible to determine the bulk density for a ready-to-use bait (RB) type product which has the consistency of a paste. The available CIPAC methods (MT33, MT 159 and MT 169) are applicable only to powders and granules.	-
Storage stability test – **accelerated storage**	CIPAC MT 46.3 (storage stability) Test conditions: two weeks at 54 °C in a thermostatically controlled oven. Packaging: glass bottles. Parameters tested: chemical assay of cholecalciferol and physical properties (condition, physical state, colour, odour, pH value, caking) before and after storage.	0.075% cholecalciferol	Active substance content before and after storage: Initial: 714 ppm (-4.8% deviation to declared content) 2 weeks: 672 ppm (-5.9% deviation to the content before storage). Therefore no significant decrease in active substance content was observed following the 14 day storage period at 54°C. No significant variation in the technical characteristics of the product was observed following the 14 day storage period at 54°C. Based upon the results of this study the bait can be considered to be stable for 2 years (extrapolated).	Kroehl, T. (2013)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **long term storage at ambient temperature**	CLI Technical Monograph No. 17 Test conditions: Three years (156 weeks) at 25 °C in a thermostatically controlled cabinet. Packaging: polyethylene bag, packed in a polypropylene bucket. Parameters tested: chemical assay of cholecalciferol and physical properties (condition, physical state, colour, odour, pH value, weight change, caking, packaging resistance) before and after storage.	0.075% cholecalciferol	Active substance content before and after storage: Initial: 766 ppm 26 weeks: 769 ppm 52 weeks: 772 ppm 104 weeks: 769 ppm 156 weeks: 781 ppm Denatonium benzoate (aversive agent): Initial: 9.3 mg/kg 26 weeks: 9.4 mg/kg 52 weeks: 9.1 mg/kg 104 weeks: 9.2 mg/kg 156 weeks: 9.0 mg/kg Therefore, no significant decrease in active substance or denatonium benzoate content was observed following the 156 week storage period at 25°C. Appearance: Initial: semi-solid grey-green paste, faintly sweet smell, no caking. 156 weeks: semi-solid grey-green paste, faintly sweet smell, no caking. pH value pH of pure water: Initial: 5.8 (24 °C) 26 weeks: 5.8 (24 °C) 52 weeks: 5.8 (23 °C) 104 weeks: 5.7 (23 °C) 156 weeks: 5.7 (23 °C) pH at 1.0 % in pure water: Initial: 6.5 (22 °C) 26 weeks: 6.6 (23 °C) 52 weeks: 6.5 (23 °C) 104 weeks: 6.3 (23 °C)	Kroehl, T. (2018)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			156 weeks: 6.5 (24 °C) The product shows no significant change in pH on storage. Weight change of unopened container: Initial: 3444.84 g 156 weeks: 3443.27 g Weight change < 0.1 %. Resistance of the packaging material to its content: Initial: Bait unit, PE-bag and PP-bucket in good condition; seals intact, no corrosion and no other influence of the product on the original container was observed 156 weeks: As initial Conclusion: No significant variation in the physical properties (appearance, pH, weight change, caking, packaging resistance) of the product was observed following the 156 week storage period at 25°C. Based upon the results of this study the bait can be considered to be stable for at least 3 years.	
Storage stability test – **low temperature stability test for liquids**	-	-	Not applicable. The product is not a liquid.	-
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	Not applicable as the packaging precludes light.	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	Not applicable as the packaging precludes moisture. Effects of temperature have been addressed in the accelerated storage stability study above.	-
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	Reactivity towards the container material has been addressed in the long term storage stability study above.	-
Wettability	-	-	Not applicable as the product is a semi-solid paste.	-
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable as the product is a semi-solid paste.	-
Wet sieve analysis and dry sieve test	-	-	Not applicable as the product is a semi-solid paste.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable as the product is a semi-solid paste.	-
Disintegration time	-	-	Not applicable as the product is a semi-solid paste.	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not applicable as the product is a semi-solid paste.	-
Persistent foaming	-	-	Not applicable as the product is a semi-solid paste.	-
Flowability/Pourability/Dustability	-	-	Not applicable as the product is a semi-solid paste.	-
Burning rate — smoke generators	-	-	Not applicable as the product is not a smoke generator.	-
Burning completeness — smoke generators	-	-	Not applicable as the product is not a smoke generator.	-
Composition of smoke — smoke generators	-	-	Not applicable as the product is not a smoke generator.	-
Spraying pattern — aerosols	-	-	Not applicable as the product is not an aerosol.	-
Physical compatibility	-	-	Not applicable as the product is not intended to be used with other products.	-
Chemical compatibility	-	-	Not applicable as the product is not intended to be used with other products.	-
Degree of dissolution and dilution stability	-	-	Not applicable as the product is not intended to be dissolved.	-
Surface tension	-	-	Not applicable as the product is not intended to be dissolved	-
Viscosity	-	-	Not applicable as viscosity is not relevant for solid/paste RB products.	-

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

Selontra® is a green-grey semi-solid paste with a faintly sweet odour and a pH of 6.7 in a 1% aqueous solution. The product has been demonstrated to be stable in studies at 54°C for 14 days (in glass bottle) and at 25°C for 3 years (in PE bag), with no significant loss of active substance or denatonium benzoate. The packaging of the product remained free from any corrosion or degradation for the duration of the studies and the shelf life of the product is at least 3 years. The storage stability studies considering the stability of packaging can be extrapolated from PE to the other packaging materials (PP, HDPE, PET, LDPE and steel plated with tin) as only rigid containers are used and the formulation type of the product is a paste.

The physical, chemical and technical properties are acceptable.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	-	-	Neither the active substance nor any of the co-formulants are classified as explosive indicating that the product will not possess explosive properties.	-
Flammable gases	-	-	Not applicable. The product is not a gas.	-
Flammable aerosols	-	-	Not applicable. The product is not an aerosol.	-
Oxidising gases	-	-	Not applicable. The product is not a gas.	-
Gases under pressure	-	-	Not applicable. The product is not a gas.	-
Flammable liquids	-	-	Not applicable. The product is not a liquid.	-
Flammable solids	-	-	Not applicable. Neither the active substance nor any of the co-formulants are classified as flammable indicating that the product will not possess flammable properties.	-
Self-reactive substances and mixtures	-	-	Not applicable. Neither the active substance nor any of the co-formulants are classified as self-reactive indicating that the product will not possess self-reactive properties.	-
Pyrophoric liquids	-	-	Not applicable. The product is not a liquid.	-
Pyrophoric solids	-	-	Not applicable. Neither the active substance nor any of the co-formulants are classified as pyrophoric solids indicating that the product will not possess pyrophoric properties.	-
Self-heating substances and mixtures	-	-	Not applicable. Neither the active substance nor any of the co-formulants are classified as self-heating substances indicating that the product will not possess self-heating properties.	-
Substances and mixtures which in contact with water emit flammable gases	-	-	Not applicable. Neither the active substance nor any of the co-formulants emit flammable gases in contact with water.	-
Oxidising liquids	-	-	Not applicable. The product is not a liquid.	-
Oxidising solids	-	-	Not applicable. Neither the active substance nor any of the co-formulants are classified as oxidising indicating that the product will not possess oxidising properties.	-
Organic peroxides	-	-	Not applicable. Neither the active substance nor any of the co-formulants are organic peroxides.	-
Corrosive to metals	-	-	Not applicable. The product is a solid for which an appropriate test method is not available. Therefore, the product cannot be tested and classified according to CLP	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			criteria for corrosivity to metals. (updated October 2020) ~~Neither the active substance nor any of the co-formulants are corrosive to metals~~.	
Auto-ignition temperatures of products (liquids and gases)	-	-	Not applicable. The product is neither a liquid nor a gas.	-
Relative self-ignition temperature for solids	-	-	Not applicable. Neither the active substance nor any of the co-formulants are classified as self-igniting indicating that the product will not be self-igniting.	-
Dust explosion hazard	-	-	Not applicable as the product is a semi-solid paste bait.	-

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

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ)**	**Reference**
					Range	Mean	RSD		
Cholecalciferol	HPLC-DAD	55, 100, 145% nominal (n = 18)	37 – 318 µg/mL corresponding 183 – 1590 mg/kg 24.4 – 212% of nominal (n = 6) correlation coefficient (r) of 1.000 slope = 7.4915, intercept = 21.3707	No interferences observed. Blank formulation was analysed and also UV-spectra were compared in standard solution chromatograms and in formulation chromatograms.	95.1 – 96.9	96.0	0.7	5 mg/kg	Weller, D. (2013)
Pre-cholecalciferol Isomeric form of cholecalciferol forming reversibly in solution Correction factor for pre-cholecalciferol: 2.27 *) validation data measured for cholecalciferol, the peak area being corrected with the correcting factor	HPLC-DAD	*)	*)	No interferences observed. Blank formulation was analysed and also UV-spectra were compared in standard solution chromatograms and in formulation chromatograms.	Repeatability 6 samples, 3 injections each mean: 46.88 mg/kg sd: 0.8399 %RSD: 1.79 Accuracy, precision (*			--	Weller, D (2013)
Cholecalciferol	HPLC-MS	50, 100, 150% nominal (n = 18)	20 – 160 µg/L corresponding 200-1600 mg/kg	No interferences observed. Blank formulation was analysed.	93.3 – 102.8	97.1	2.1	60 mg/kg	Klink, D. (2014)

			26.7 – 213% of nominal (n = 6) correlation coefficient (r) of 0.9997 (slope = 4.056 x 10^{-3}, intercept = 1.373 x 10^{-2}).						
Denatonium benzoate	UHPLC-(QqQ)MS	10, 100, 200% nominal (n=9)	0.798 – 23.940 µg/L corresponding 0.8-24 mg/kg 8 – 240% of nominal (n=6), correlation coefficient (r) of 0.99995 (slope = 7.253 x 10^{-2}, intercept = 1.784 x 10^{-2})	No interferences observed. Blank formulation was analysed.	96.8-102.9	100.5	2.0 Note: In study report %RSD of 2.1 is reported. However, correct value is 2.0 %RSD.	0.8 mg/kg	Klink, D. (2015)

Conclusion on the methods for detection and identification of the product

Methods of analysis employing both HPLC-DAD and HPLC-MS are provided for the determination of the active substance, cholecalciferol, in the product. In addition, a method for the determination of the aversive agent denatonium benzoate in the product by UHPLC-MS is also provided. The methods are fully validated in accordance with SANCO/3030/99 rev. 4 11/07/00. All the methods are proven to be linear, specific, repeatable and precise to analyse cholecalciferol and aversive agent denatonium benzoate in the biocidal product.

The biocidal product, Selontra®, consists of the active substance cholecalciferol and co-formulants. One of the co-formulants, 2-phenylphenol, is identified as a substance of concern for the environment and therefore an analytical method for the analysis of 2-phenylphenol in the biocidal product Selontra® is needed. This requirement will be set as a post authorization condition for the product authorization of Selontra®. The analytical method for the analysis of 2-phenylphenol in soil is presented in the assessment report of 2-phenylphenol (2015), for which the applicant has a Letter of Access. Analytical methods for other compartments are not considered necessary. The other co-formulants are not toxicologically or ecotoxicologically relevant at the levels presented in the formulation (i.e. no classification of the product is appropriate), therefore analytical methods to monitor these components in soil, water, air, animal and human body fluids and tissues and treated food or feedings stuffs are not scientifically justified. Analytical methods for monitoring the active substance cholecalciferol in different compartments are reported in the assessment report of the active substance (2018).

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Selontra® is a rodenticide (PT 14) containing 750 ppm (w/w) cholecalciferol intended for use in and around buildings for the control of rodent pests by professionals and trained professionals.

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

Selontra® is for the control of:

Rattus norvegicus (Norway rat, brown rat)

Rattus rattus (Ship rat, roof rat, black rat)

Mus musculus (House mouse).

for the purpose of the protection of public health, including:

- Prevention of infestations of rodents known to transmit of disease;
- Prevention of the contamination of food and feeding stuffs and other materials, with urine, faeces and rodent hairs, at all stages of their production, storage and use;
- Protection of buildings and structures including pipes, cables and overall integrity;
- Protection of livestock, wild and domestic;
- Social abhorrence and stigma;
- Legal requirements.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Cessation of feeding (within 1-2 days after ingestion) and mortality (within 2-5 days after uptake of a lethal dose), in both rats and mice (including those strains resistant to anticoagulants).

2.2.5.4 Mode of action, including time delay

Cholecalciferol causes hypercalcaemia, the mobilisation of calcium from the bone matrix to the plasma and the subsequent deposition in the soft tissues, e.g. kidney and lungs, ultimately causing death. Time to death is generally 2 to 5 days after ingestion of a lethal dose as the toxicant is slow-acting, bait shyness does not generally occur, as bait acceptance is excellent. Once a rodent consumes a lethal dose, food intake ceases generally within 1-2 days.

2.2.5.5 Efficacy data

Note: some mouse study reports used the scientific name *Mus domesticus,* which is reflected in the following tables. The scientific name is now internationally recognised as *Mus musculus domesticus*.

In all efficacy studies Selontra® (internal BASF formulation code 410 05 I) is the test substance.

Efficacy against *Rattus norvegicus* (Norway rat / brown rat)

14 efficacy studies are provided for Selontra® against *R. norvegicus* (3 no-choice tests, 6 choice tests (of which 2 are on aged bait) and 5 field tests) which are summarised below. Laboratory studies were conducted with laboratory strains and wild strains. Of the lab trials, 6 trials were conducted with anticoagulant resistant[2] (first generation anticoagulants and difenacoum & bromadiolone) or tolerant[3] (difenacoum & bromadiolone) strains.

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol	Norway rat (*Rattus norvegicus*) Hampshire strain (L120Q) (difenacoum and bromadiolone tolerant)	**3-Day No-choice feeding test:** 10 male and 10 female rats were caged singly, in suitable cages under ambient conditions. There was a 3-day acclimatisation period prior to testing where ground laboratory (control) diet plus tap water was provided *ad libitum*, followed by a 1-day pre-test take period (where the control diet take was measured), followed by a 3-day no-choice test period, where the soft block paste bait treatment and tap water were offered. A 14 days' post-treatment observation period followed, where the control diet plus tap water were offered. Bait take, difference in body weight (from start of test) and mortality were measured. Ambient: (21°C ± 2°C temperature, 55% ± 10% relative humidity, 12:12 hours light:dark) were maintained during the study. 21 day post treatment observation period fed laboratory diet, plus tap water, *ad libitum.*	**Body weight, bait take, mortality: Hampshire strain (L120Q) male (*R. norvegicus*)** **No.** / **Initial b.wt. (g)** / **Pre-test take (g)** / **Test - daily take (g)**: **Day 1**, **Day 2**, **Day 3** / **Total test** / **mg/kg ingested** / **Final b.wt. (g)** / **Days to death** 1	297	26.0	19.9	3.4	0.0	23.3	58.8	275	3 2	241	19.4	15.8	2.7	0.0	18.5	57.6	215	3 3	308	23.7	22.0	5.8	0.0	27.8	67.7	289	3 4	294	27.0	0.0	24.1	3.3	27.4	69.9	280	3 5	291	26.1	21.0	5.0	0.0	26.0	67.0	277	3 6	282	24.4	19.5	5.3	0.0	24.8	66.0	257	3 7	246	22.4	10.8	15.0	1.3	27.1	82.6	233	3 8	291	23.5	20.9	5.1	0.0	26.0	67.0	268	3 9	283	24.0	21.1	6.7	0.0	17.8	73.7	250	3 10	302	26.5	21.1	8.7	0.0	29.8	74.0	301	2 **Mean**	**284**	**24.3**	**17.2**	**8.2**	**0.5**	**25.9**	**68.4**	**265**	**2.9** **Body weight, bait take, mortality: Hampshire strain (L120Q) female (*R. norvegicus*)** **No.** / **Initial b.wt. (g)** / **Pre-test take (g)** / **Test - daily take (g)**: **Day 1**, **Day 2**, **Day 3** / **Total test** / **mg/kg ingested** / **Final b.wt. (g)** / **Days to death** 1	170	13.8	15.4	3.5	0.0	18.9	83.4	157	3 2	183	18.7	15.7	2.8	0.0	18.5	75.8	176	2 3	164	15.2	0.0	14.3	3.1	17.4	79.6	154	3 4	169	17.2	14.7	4.5	0.0	19.2	85.2	161	3	[redacted] (2013a)

2 "Berkshire" rats are also homozygous for the L120Q mutation and are even more resistant to difenacoum and bromadiolone than "Hampshire" rats. "Berkshire" resistance is conferred not only by the presence of the L120Q mutation but also an additional level of resistance provided by enhanced clearance of the rodenticides by special enzymes (metabolic resistance). Practically no control, i.e. complete failure, would be expected if difenacoum or bromadiolone baits were used against infestations of "Berkshire" rats. Hence they are classed in these reports as bromadiolone and difenacoum resistant.

3 "Hampshire" rats are homozygous for the L120Q mutation and are resistant to the first generation anticoagulants and have a level of resistance to the second generation anticoagulants difenacoum and bromadiolone. Practically a low level of control would be expected if difenacoum or bromadiolone baits were used against infestations of "Hampshire" rats. Hence they are classed in these reports as bromadiolone and difenacoum tolerant.

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference

5	185	19.4	19.4	2.1	0.0	21.5	87.2	172	3
6	174	15.6	14.9	2.4	0.0	17.3	74.6	158	3
7	170	16.1	13.9	4.7	0.0	18.6	82.1	156	3
8	171	17.9	14.5	4.0	0.0	18.5	81.1	165	3
9	160	18.7	17.6	1.6	0.0	19.2	90.0	156	3
10	160	17.2	16.5	0.0	0.0	16.5	77.3	154	3
Mean	**171**	**17.0**	**14.3**	**4.0**	**0.3**	**18.6**	**81.6**	**161**	**2.9**

Selontra®

A soft block paste bait containing 750ppm cholecalciferol

Norway rat (*Rattus norvegicus*)

Berkshire strain (L120Q) (difenacoum and bromadiolone resistant)

3-Day No-choice feeding test:

10 male and 10 female rats were caged singly, in suitable cages under ambient conditions. There was a 3-day acclimatisation period prior to testing where ground laboratory (control) diet plus tap water was provided *ad libitum*, followed by a 1-day pre-test take period (where the control diet take was measured), followed by a 3-day no-choice test period, where the soft block paste bait treatment and tap water were offered. A 14 days post-treatment observation period followed, where the control diet plus tap water were offered. Bait take, difference in body weight (from start of test) and mortality were measured.

Ambient: (21°C ± 2°C temperature, 55% ± 10% relative humidity, 12:12 hours light: dark) were maintained during the study. 21-day post treatment observation period fed laboratory diet, plus tap water, *ad libitum.*

Body weight, bait take, mortality: Berkshire strain (L120Q) male (*R. norvegicus*)

No.	Initial b.wt. (g)	Pre-test take (g)	Test - daily take (g)			Total test	mg/kg ingested	Final b.wt. (g)	Days to death
			Day 1	Day 2	Day 3				
1	289	26.6	20.7	0.8	0.0	21.5	55.8	269	3
2	267	26.6	18.4	6.1	0.0	24.5	68.8	251	3
3	259	25.5	16.9	0.9	0.0	17.8	51.5	232	3
4	236	24.8	18.5	2.0	0.0	20.5	65.1	212	3
5	255	28.8	21.5	6.3	0.0	27.8	81.8	242	3
6	275	25.2	25.7	3.1	0.0	28.8	78.5	261	2
7	245	23.6	21.7	4.1	0.0	25.8	79.0	225	3
8	250	21.3	18.8	6.4	0.0	25.2	75.6	233	3
9	264	23.4	23.0	8.3	0.0	31.3	88.9	249	3
10	225	22.8	19.2	4.9	0.0	24.1	80.3	216	3
Mean	**257**	**24.9**	**20.4**	**4.3**	**0.0**	**24.7**	**72.5**	**239**	**2.9**

Body weight, bait take, mortality: Berkshire strain (L120Q) female (*R. norvegicus*)

No.	Initial b.wt. (g)	Pre-test take (g)	Test - daily take (g)			Total test	mg/kg ingested	Final b.wt. (g)	Days to death
			Day 1	Day 2	Day 3				
1	168	18.1	14.3	2.3	0.0	16.6	74.1	155	3
2	179	16.8	14.9	1.4	0.0	16.3	68.3	168	2
3	188	19.3	13.6	1.4	0.0	15.0	59.8	167	3
4	184	17.1	10.0	7.4	0.0	17.4	70.9	162	3
5	176	18.0	10.2	3.1	0.0	13.3	56.7	150	3
6	190	22.2	12.0	1.3	0.0	13.3	52.5	175	3
7	171	19.2	14.7	2.5	0.0	17.2	75.4	172	3
8	248	15.5	14.7	6.3	0.0	21.0	63.5	226	3
9	156	19.1	14.6	1.4	0.0	16.0	76.9	138	3
10	174	19.3	14.1	3.0	0.0	17.1	73.7	150	3

[redacted] (2013b)

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference

Mean	**183**	**18.5**	**13.3**	**3.0**	**0.0**	**16.3**	**67.2**	**166**	**2.9**	

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol	Norway rat (*Rattus norvegicus*) Welsh strain (Y139S) (1st generation anticoagulant resistant).	**3-Day No-choice feeding test:** 10 male and 10 female rats were caged singly, in suitable cages under ambient conditions. There was a 3-day acclimatisation period prior to testing where ground laboratory (control) diet plus tap water was provided *ad libitum*, followed by a 1-day pre-test take period (where the control diet take was measured), followed by a 3-day no-choice test period, where the soft block paste bait treatment and tap water were offered. A 14 days post-treatment observation period followed, where the control diet plus tap water were offered. Bait take, difference in body weight (from start of test) and mortality were measured. Ambient: (21°C ± 2°C temperature, 55% ± 10% relative humidity, 12:12 hours light: dark) were maintained during the study. 21-day post treatment observation period fed laboratory diet, plus tap water, *ad libitum.*	**Body weight, bait take, mortality: Welsh strain (Y139S) male (*R. norvegicus*)**	[redacted] (2013c)

No.	Initial b.wt. (g)	Pre-test take (g)	Test - daily take (g)			Total test	mg/kg ingested	Final b.wt. (g)	Days to death
			Day 1	Day 2	Day 3				
1	249	20.8	20.7	3.3	0.0	24.0	72.29	239	3
2	237	21.0	12.6	12.3	0.0	24.9	78.80	210	3
3	274	23.0	16.7	4.2	0.0	20.9	57.21	245	3
4	245	16.5	12.5	0.9	0.0	13.4	41.02	221	3
5	244	20.8	15.8	3.9	0.0	19.7	60.55	221	3
6	280	22.9	14.6	1.1	0.0	15.7	42.05	250	3
7	287	25.0	17.6	3.0	0.0	20.6	53.83	263	3
8	281	25.5	18.0	9.3	0.0	27.3	72.86	264	3
9	284	24.2	20.5	2.5	0.0	23.0	60.74	257	3
10	287	23.5	16.6	5.2	0.0	21.8	56.97	264	3
Mean	**267**	**22.3**	**16.6**	**4.6**	**0.0**	**21.1**	**59.63**	**243**	**3.0**

Body weight, bait take, mortality: Welsh strain (Y139S) female (*R. norvegicus*)

No.	Initial b.wt. (g)	Pre-test take (g)	Test - daily take (g)			Total test	mg/kg ingested	Final b.wt. (g)	Days to death
			Day 1	Day 2	Day 3				
1	252	17.0	20.4	5.0	0.0	25.4	75.60	229	3
2	240	12.9	18.3	9.0	0.0	27.3	85.31	213	3
3	199	4.8	13.2	5.9	0.0	19.1	71.98	175	3
4	241	17.0	17.5	7.2	2.0	26.7	83.09	230	3
5	232	11.1	14.4	4.9	0.0	19.3	62.39	207	3
6	235	19.2	17.7	11.9	0.0	29.6	94.47	215	3
7	204	17.4	16.1	3.9	0.0	20.0	73.53	183	3
8	192	12.9	13.3	4.0	0.0	17.3	67.58	178	3
9	224	15.9	18.2	8.5	0.0	26.7	89.40	207	3
10	195	15.7	16.3	2.7	0.0	19.0	73.08	172	3
Mean	**221**	**14.4**	**16.5**	**6.3**	**0.2**	**23.0**	**77.64**	**201**	**3.0**

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol	Norway rat (*Rattus norvegicus*) Wistar strain, laboratory cultured (anticoagulant susceptible)	**4-Day Choice feeding cage study:** 10 male and, 10 female rats (170-250g body weight) were weighed and individually caged in polypropylene cages 38cm(l) x 25cm(w) x 20cm(h) with stainless steel wire mesh lids and bases over a tray containing a paper liner. There was a 3-day acclimatisation period prior to testing where ground laboratory (control) diet was presented in two identical feeding dishes (placed symmetrically in the cage) plus tap water provided *ad libitum*. 24 hours prior to test baiting, the feed dishes were replaced with two identical dishes each containing 50g of control diet. Consumption of the control diet was recorded to the nearest 0.1g (the "pre-test diet intake") and statistical analysis (unpaired T-test – p=0.05) conducted to establish if there was a significant difference between the positions of feed dishes. A 4-day test period followed; 50g each of the bait treatment and the control diet were placed in the separate feed dishes (position rotated each day). After each 24 hour period, spillages were retrieved, returned to the dish and any extraneous matter removed. The feed dishes were weighed to provide a value for each 24 hour bait/control diet take. Test bait and control diet were replaced daily. Mice were observed daily. Tap water was provided *ad libitum* during the study period. A 10 day post baiting observation period followed, where control diet and tap water were provided *ad libitum*. After the 4 day choice feeding period, the daily test bait and control diet takes were summed and a palatability ratio calculated. $PR = \frac{\text{Total TB}}{\text{Total CD}}$	**Bait and control diet uptake during 4-day choice test (male rats)** **No. / Body wt (g) Initial / Total Test take (g) / Total Control take (g) / PR (T/C) / Body wt (g) Day 4 / Body wt (g) Final / Days to death** 1 / 242 / 20.4 / 6.9 / 2.96 / - / 238 / 2 2 / 227 / 13.2 / 7.7 / 1.71 / - / 218 / 2 3 / 231 / 17.3 / 7.9 / 2.19 / - / 224 / 2 4 / 237 / 18.0 / 12.3 / 1.46 / - / 223 / 3 5 / 239 / 17.9 / 9.3 / 1.92 / - / 227 / 2 6 / 238 / 17.8 / 8.4 / 2.12 / - / 226 / 2 7 / 222 / 16.6 / 8.8 / 1.89 / - / 221 / 2 8 / 235 / 16.0 / 14.9 / 1.07 / - / 227 / 2 9 / 210 / 14.2 / 11.8 / 1.20 / - / 194 / 2 10 / 233 / 20.3 / 8.1 / 2.51 / - / 228 / 2 **Total** / **-** / **171.7** / **96.1** / **19.04** / **-** / **-** / **-** **Mean** / **231** / **17.2** / **9.6** / **1.90** / **-** / **223** / **2.1** Total test take (g) = 171.7, Total control take (g) = 96.1, Palatability Ratio (T/C) = 1.79 (range 1.07-2.96), % Acceptance = 64.1, Mean mg/kg body weight ingested = 55.5 (range 43.6-65.3), Total deaths = 10, Mean days to death = 2.1 (range 2-3). **Bait and control diet uptake during 4-day choice test (female rats)** **No. / Body wt (g) Initial / Total Test take (g) / Total Control take (g) / PR (T/C) / Body wt (g) Day 4 / Body wt (g) Final / Days to death** 1 / 175 / 14.0 / 7.4 / 1.89 / - / 174 / 3 2 / 171 / 16.0 / 6.1 / 2.62 / - / 174 / 3 3 / 171 / 14.1 / 8.9 / 1.58 / - / 177 / 2 4 / 176 / 18.1 / 10.5 / 1.72 / - / 175 / 2 5 / 172 / 21.9 / 5.5 / 3.98 / - / 172 / 2 6 / 188 / 13.8 / 10.2 / 1.35 / - / 188 / 3	[redacted] (2013h)

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
		PR = palatability ratio, TB = consumption of test bait (g), CD = consumption of control diet (g).		

7	176	8.3	12.2	0.68	-	154	3
8	176	12.7	7.3	1.74	-	158	3
9	185	15.5	5.6	2.77	-	172	3
10	173	9.8	12.5	0.78	-	153	3
Total	**-**	**144.2**	**86.2**	**19.13**	**-**	**-**	**-**
Mean	**176**	**14.4**	**8.6**	**1.91**	**-**	**170**	**2.7**

Total test take (g) = 144.2, Total control take (g) = 86.2, Palatability Ratio (T/C) = 1.67 (range 0.68-3.98), % Acceptance = 62.6, Mean mg/kg body weight ingested = 61.5 (range 35.4-95.5), Total deaths = 10, Mean days to death = 2.7 (range 2-3).

Selontra®

A soft block paste bait containing 750ppm cholecalciferol.

Norway rat, (*Rattus norvegicus*)

Hampshire strain (L120Q) (difenacoum and bromadiolone tolerant)

4-Day Choice feeding cage study:

Choice feeding (palatability) and rat activity within the trial site following baiting, and by calculation of pre-treatment versus post-treatment census feed uptake and the tracking census, percentage survival rate post-baiting, plus rat mortality during the study period (based on dead rats found).

After the 4d choice feeding period, the individual daily test bait and control diet takes were summed and the individual palatability ratio calculated. Individual Palatability Ratio= Total individual test bait take/ total individual control diet take.

The individual takes were then further summed to give the total test bait and control diet takes. The (group) palatability ratio was calculated. Palatability ratio = Total test bait take / Total control diet take.

Throughout the choice feeding period the rats were observed at least once a day. At the conclusion of the choice feeding period, the rats were maintained for a further 10d .The rats were observed at least once a day and any toxic signs and mortality recorded. The bodyweight at death was recorded. Any rats exhibiting severe signs of cholecalciferol toxicity, such that death was expected were culled and recorded as dead on that day.

Post monitoring of test organisms: At the conclusion of the choice feeding period, the rats were maintained for a further 10d with food and tap water *ad libitum*. At the end of the 10d any survivors were destroyed and their body weight recorded

Table 1: Full protocol palatability feeding study against 10 male Hampshire strain (L120Q) rats (T=test, C= Control)

Animal No.	Initial b.wt. (g)	Pre-test take (g)		Test - daily take (g)							
		A	B	Day 1 T	Day 1 C	Day 2 T	Day 2 C	Day 3 T	Day 3 C	Day 4 T	Day 4 C
1	399	12.1	13.7	23.7	1.1	5.6	5.6	0.0	1.3	0.0	0.0
2	416	13.6	9.8	18.39	7.8	4.9	4.4	0.0	0.0	0.0	0.0
3	423	8.6	12.3	21.9	1.1	7.8	2.1	0.0	0.0	0.0	0.0
4	375	13.9	10	17.6	1.6	4.7	5.8	0.0	0.0	0.0	0.0
5	385	10	14.3	18	3.5	6.7	2.5	0.0	0.0	0.0	0.0
6	372	14.6	7.4	19.9	5	4.1	2	0.0	0.0	0.0	0.0
7	404	10.1	12.4	17.2	5.8	3.2	3.1	0.0	0.0	0.0	0.0
8	398	12	9.2	17.6	5.5	7.6	4.1	0.0	0.0	0.0	0.0
9	405	13.2	10	21.6	3.2	11.3	0.2	0.0	0.0	0.0	0.0
10	375	7.2	13.8	20.3	0.8	6.8	4.2	0.0	0.0	0.0	0.0
Mean	**395**	**11.5**	**11.3**	**19.7**	**3.5**	**6.2**	**3.4**	**0.0**	**1.3**	**0.0**	**0.0**
Ratio			1.02		5.56		1.84		0.1		0.0

Cont. table 1

Animal No. and sex	Total test	Total control	P.R. T/C	Final b.wt. (g)	Days to death	Total Test	Total Control	mg/kg ingested
1	29.3	8	3.66	343	4	29.3	8	55.1
2	23.8	12.2	1.95	345	4	23.8	12.2	42.9
3	29.7	3.2	9.28	339	4	29.7	3.2	52.7
4	22.3	7.4	3.01	310	4	22.3	7.4	44.6
5	24.7	6	4.12	330	4	24.7	6	48.1
6	24	7	3.43	298	4	24	7	48.4
7	20.4	8.9	2.29	330	4	20.4	8.9	37.9
8	25.2	9.6	2.63	346	4	25.2	9.6	47.5
9	32.9	3.4	9.68	377	3	32.9	3.4	60.9
10	26.9	5	5.38	317	4	26.9	5	53.9

[redacted] (2013l)

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference

Mean	**25.9**	**7.1**	**4.54**	**334**	**3.9**	**25.9**	**7.07**	**49.2**
Ratio		3.67						

Total test intake, g = 259.2
Total control take, g= 70.7
Palatability Ratio, T/C= 3.67
Range palatability ratios= 1.95 to 9.68
% Acceptance= 78.6
Mean mg/kg ingested = 49.2g
Total death = 10; Mean time to death = 3.9 days (range days = 3 to 4)

Table 2: Full protocol palatability feeding study against 10 female Hampshire strain (L120Q) rats (T=test, C= Control)

		Pre-test take (g)		Test - daily take (g)					
No.	**Initial b.wt. (g)**	**A**	**B**	**Day 1 T**	**Day 1 C**	**Day 2 T**	**Day 2 C**	**Day 3 T**	**Day 3 C**
1	245	6.5	6.2	18.4	1.4	3.4	1.5	0.0	0.0
2	250	10.1	8.8	18	0.7	4.6	1.5	0.0	0.0
3	227	8.9	2.9	15.7	0.8	2.4	1.2	0.0	0.0
4	233	5.9	8.9	16.5	1.7	0.0	0.0	0.0	0.0
5	244	7	7.2	16.7	0.6	3.3	1.7	0.0	0.0
6	238	7.9	6.3	20	0.1	1.5	1.6	0.0	0.0
7	246	4.8	10.3	13	1.9	0	3.3	0.0	0.0
8	248	10.3	7.2	21	0.1	1.4	0.7	0.0	0.0
9	269	6.3	10.4	16.7	0.8	0.6	1.3	0.0	0.0
10	250	15.1	11.6	26.4	0.3	6.5	1.6	0.0	0.0
Mean	**245**	**8.3**	**8**	**18.2**	**0.8**	**2.4**	**1.4**	**0.0**	**0.0**
Ratio			1.04		21.70		1.65		

Cont. table 2

Animal No. and sex	Total test	Total control	P.R. T/C	Final b.wt. (g)	Days to death	Total Test	Total Control	mg/kg ingested
1	21.8	2.9	7.52	215	3	21.8	2.9	66.7
2	22.6	2.2	10.27	230	3	22.6	2.2	67.8
3	18.1	2.0	9.05	204	3	18.1	2.0	59.8
4	16.5	1.7	9.71	198	3	16.5	1.7	53.1
5	20	2.3	8.7	217	3	20	2.3	61.5
6	21.5	1.7	12.65	222	2	21.5	1.7	67.8
7	13	5.2	2.5	222	3	13	5.2	39.6
8	22.4	0.8	28	218	3	22.4	0.8	67.7
9	17.3	2.1	8.24	224	3	17.3	2.1	48.2
10	32.9	1.9	17.32	225	3	32.9	1.9	98.7
Mean	**20.6**	**2.3**	**11.39**	**218**	**2.9**	**20.6**	**2.28**	**63.1**
Ratio		9.04						

Total test intake = 206.1
Total control take, g= 22.8

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
			Palatability Ratio, T/C= 9.04 Range palatability ratios= 2.50 to 28.00 % Acceptance= 90.0 Mean mg/kg ingested = 63.1g Total death = 10 Mean time to death = 2.9 days (range days = 2 to 3)	
Selontra® A soft block paste bait containing 750ppm cholecalciferol.	Norway rat, (*Rattus norvegicus*) Berkshire strain (L120Q) (difenacoum and bromadiolone resistant)	**4-Day Choice feeding cage study:** Choice feeding (palatability)and rat activity within the trial site following baiting, and by calculation of pre-treatment versus post-treatment census feed uptake and the tracking census, percentage survival rate post-baiting, plus rat mortality during the study period (based on dead rats found). After the 4d choice feeding period, the individual daily test bait and control diet takes were summed and the individual palatability ratio calculated. Individual Palatability Ratio= Total individual test bait take/ total individual control diet take. The individual takes were then further summed to give the total test bait and control diet takes. The (group) palatability ratio was calculated. Palatability ratio = Total test bait take / Total control diet take. Throughout the choice feeding period the rats were observed at least once a day. At the conclusion of the choice feeding period, the rats were maintained for a further 10d .The rats were observed at least once a day and any toxic signs and mortality recorded. The bodyweight at death was recorded. Any rats exhibiting severe signs of cholecalciferol toxicity, such that death was expected were culled and recorded as dead on that day. At the conclusion of the choice feeding period, the rats were maintained for a further 10d with food and tap water *ad libitum.* At the end of the 10d any survivors were destroyed and their body weight recorded.	**Table 1:** Full protocol palatability feeding study against 10 male Berkshire (L120Q) rats (T=test, C=Control) **Animal No.** / **Initial b.wt. (g)** / **Pre-test take (g)** A / B / **Test - daily take (g)** Day 1 Test / Day 1 Control / Day 2 Test / Day 2 Control / Day 3 Test / Day 3 Control 1 246 10 11 16.8 0.9 3 5.4 0.0 0.0 2 304 13.1 11.5 11.1 10.4 0.0 5.5 0.0 0.0 3 303 11.2 14.6 16.5 4.9 0.8 2.4 0.0 0.0 4 290 10.7 11.3 18.3 2.9 1.6 3.6 0.0 0.0 5 291 13.3 11.1 17.4 4.7 2.4 5.7 0.0 0.0 6 238 10.8 7.6 20.3 0.3 3.7 4.7 0.6 0.0 7 278 7.5 15 14.3 5.4 0.9 3.6 0.0 0.0 8 243 9.1 7.7 14.0 4 0.7 3.9 0.0 0.0 9 284 9.8 13.7 14.0 6.8 0.0 2.3 0.0 0.0 10 289 10.3 12.2 17.8 3.3 0.0 8.8 0.0 0.0 **Mean** **277** **10.6** **11.6** **16.1** **4.4** **1.3** **4.6** **0.1** **0.0** Ratio 0.91 3.68 0.29 Cont. Table 1: **Animal No.** / **Total test** / **Total Control** / **P.R. T/C** / **Final b.wt. (g)** / **Days to death** / **Total Test** / **Total Control** / **mg/kg ingested** 1 19.8 6.3 3.14 232 3 19.8 6.3 60.4 2 11.1 15.9 0.7 263 4 11.1 15.9 27.4 3 17.3 7.3 2.37 280 3 17.3 7.3 42.8 4 19.9 6.5 3.06 275 3 19.9 6.5 51.5 5 19.8 10.4 1.9 274 3 19.8 10.4 51 6 24.6 5 4.92 224 3 24.6 5 77.5 7 15.2 9 1.69 260 3 15.2 9 41	[redacted] (2013n)

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference

8	14.7	7.9	1.86	233	3	14.7	7.9	45.4
9	14	9.1	1.54	263	3	14	9.1	37
10	17.8	12.1	1.47	277	3	17.8	12.1	46.2
Mean	**17.4**	**9**	**2.27**	**258**	**3.1**	**17.4**	**9**	**48**
Ratio		1.95						

Total test intake g = 174.2; Total control take, g = 89.5
Palatability Ratio, T/C= 1.95; Range palatability ratios= 0.70 to 4.92; % Acceptance= 66.1
Mean mg/kg ingested = 48.0
Total deaths = 10; Mean time to death = 3.1 days (range days = 3 to 4)

Table 2: Full protocol palatability feeding study against 10 female Berkshire (L120Q) rats (T=test, C=Control)

Animal No.	Initial b.wt. (g)	Pre-test take (g)		Test - daily take (g)					
		A	B	Day 1 Test	Day 1 Control	Day 2 Test	Day 2 Control	Day 3 Test	Day 3 Control
1	187	6.2	4.6	6.9	7.5	1.6	6.3	0.0	0.0
2	197	6.4	5.5	13.9	1.6	1	8.7	0.0	0.0
3	211	4.7	8.7	9.3	5.2	0	6.1	0.0	0.0
4	188	5.9	7.0	12.7	1	3.5	6	0.0	0.0
5	189	5.4	6.8	12.3	0.6	1.4	5.5	0.0	0.0
6	181	9.5	6.9	11.5	3.1	1.9	2	0.0	0.0
7	198	4.4	8.8	19.3	0.7	0.4	9.8	0.0	1.0
8	192	7.3	9.0	16.1	1.7	0	7	0.0	0.0
9	204	8	6.5	15.5	1.7	0.8	9.1	0.0	0.0
10	173	6.2	6.3	10.7	2.7	0.6	7.4	0.0	0.0
Mean	**192**	**6.4**	**7**	**12.8**	**2.6**	**1.1**	**6.8**	**0.0**	**0.1**
Ratio			0.91		4.97		0.16		0.0

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance	**Test organism(s)**	**Test method, Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**

Cont. table 2:

Animal No.	Total test	Total Control	P.R. T/C	Final b.wt. (g)	Days to death	Total Test	Total Control	mg/kg ingested
1	8.5	13.8	0.62	162	4	8.5	13.8	34.1
2	14.9	10.3	1.45	170	4	14.9	10.3	56.7
3	9.3	11.3	0.82	199	3	9.3	11.3	33.1
4	16.2	7	2.31	175	3	16.2	7	64.6
5	13.7	6.1	2.25	181	3	13.7	6.1	54.4
6	13.4	5.1	2.63	176	3	13.4	5.1	55.5
7	19.7	11.5	1.71	173	4	19.7	11.5	74.6
8	16.1	8.7	1.85	186	3	16.1	8.7	62.9
9	16.3	10.8	1.51	179	4	16.3	10.8	59.9
10	11.3	10.1	1.12	160	3	11.3	10.1	49
Mean	**13.9**	**9.5**		**176**	**3.4**	**13.9**	**9.5**	**54.5**
Ratio		1.47						

Total test intake = 139.4
Total control take, g= 94.7
Palatability Ratio, T/C= 1.47
Range palatability ratios= 0.62 to 2.63
% Acceptance= 59.5
Mean mg/kg ingested = 54.5
Total death = 10
Mean time to death = 3.4 days (range days = 3 to 4)

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol.	Norway rat, (*Rattus norvegicus*) Welsh strain (Y139S) (1st generation anticoagulant resistant)	**4-Day Choice feeding cage study:** Choice feeding (palatability) and rat activity within the trial site following baiting, and by calculation of pre-treatment versus post-treatment census feed uptake and the tracking census, percentage survival rate post-baiting, plus rat mortality during the study period (based on dead rats found). After the 4d choice feeding period, the individual daily test bait and control diet takes were summed and the individual palatability ratio calculated. Individual Palatability Ratio= Total individual test bait take/ total individual control diet take. The individual takes were then further summed to give the total test bait and control diet takes. The (group) palatability ratio was calculated. Palatability ratio = Total test bait take / Total control diet take. Throughout the choice feeding period the rats were observed at least once a day. At the conclusion of the choice feeding period, the rats were maintained for a further 10d .The rats were observed at least once a day and any toxic signs and mortality recorded. The bodyweight at death was recorded. Any rats exhibiting severe signs of cholecalciferol toxicity, such that death was expected were culled and recorded as dead on that day. At the conclusion of the choice feeding period, the rats were maintained for a further 10d with food and tap water *ad libitum*. At the end of the 10d any survivors were destroyed and their body weight recorded.	**Table 1:** Full protocol palatability feeding study against 10 male Welsh (Y139S) rats (T=test, C=control) **Animal No.** | **Initial b.wt. (g)** | **Pre-test take (g)** A | B | **Test - daily take (g)** Day 1 Test | Day 1 C | Day 2 T | Day 2 Cl | Day 3 T | Day 3 C | Day 4 T | Day 4 C 1 | 338 | 9.3 | 13 | 15 | 6.6 | 0.3 | 10.8 | 0 | 0.7 | 0 | 0 2 | 315 | 10.1 | 11.6 | 17.5 | 2.2 | 3.7 | 6 | 0 | 0 | 0 | 0 3 | 327 | 10 | 9.2 | 23.7 | 1.6 | 4.2 | 3.2 | 0 | 2 | 0 | 0 4 | 324 | 12.4 | 8.3 | 18.7 | 2.7 | 1.9 | 6.4 | 0 | 0 | 0 | 0 5 | 337 | 12 | 10.8 | 16.4 | 4.8 | 0.5 | 9.4 | 0 | 0 | 0 | 0 6 | 337 | 14 | 7.4 | 4.1 | 17 | 0 | 17.2 | 0 | 8.9 | 0 | 0 7 | 325 | 9.2 | 10.8 | 22.8 | 2.3 | 3.5 | 5.1 | 0 | 0 | 0 | 0 8 | 307 | 12.1 | 6 | 17.2 | 7.2 | 3.8 | 4.1 | 0 | 0 | 0 | 0 9 | 313 | 10 | 11.3 | 18.5 | 1.8 | 5.5 | 3.6 | 0 | 0.7 | 0 | 0 10 | 303 | 9.9 | 12.5 | 16.2 | 4.6 | 0 | 9.6 | 0 | 0 | 0 | 0 **Mean** | **323** | **10.9** | **10.1** | **17** | **5.1** | **2.3** | **7.5** | **0** | **1.2** | **0** | **0** Ratio | | | 1.08 | | 3.35 | | 0.31 | | 0 | | Cont. Table 1: **Animal No.** | **Total test** | **Total Control** | **P.R. T/C** | **Final b.wt. (g)** | **Days to death** | **TOTAL T** | **TOTAL C** | **mg/kg ingested** 1 | 15.3 | 18.1 | 0.85 | 296 | 3 | 15.3 | 18.1 | 33.9 2 | 21.2 | 8.2 | 2.59 | 289 | 3 | 21.2 | 8.2 | 50.5 3 | 27.9 | 6.8 | 4.1 | 304 | 3 | 27.9 | 6.8 | 64 4 | 20.6 | 9.1 | 2.26 | 284 | 3 | 20.6 | 9.1 | 47.7 5 | 16.9 | 14.2 | 1.19 | 293 | 3 | 16.9 | 14.2 | 37.6 6 | 4.1 | 43.1 | 0.1 | 360 | survived | 4.1 | 43.1 | 9.1	[redacted] (2013m)

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance	**Test organism(s)**	**Test method, Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**

7	26.3	7.4	3.55	301	3	26.3	7.4	60.7
8	21	11.3	1.86	276	3	21	11.3	51.3
9	24	6.1	3.93	283	3	24	6.1	57.5
10	16.2	14.2	1.14	271	3	16.2	14.2	40.1
Mean	**19.4**	**13.9**	**2.16**	**296**		**19.4**	**13.9**	**45.2**
Ratio		1.4						

Total test intake = 193.5
Total control take, g= 138.5
Palatability Ratio, T/C= 1.40
Range palatability ratios= 0.10 to 4.10
% Acceptance= 58.3
Mean mg/kg ingested = 45.2
Total death = 9
Mean time to death = 3 days (range days = 3 to 3)

Table 2: Full protocol palatability feeding study against 10 female Welsh (Y139S) rats (T=test, C=control)

Animal No.	Initial b.wt. (g)	Pre-test take (g)		Test - daily take (g)					
		A	B	Day 1 T	Day 1 C	Day 2 T	Day 2 C	Day 3 T	Day 3 C
1	208	10.2	9.3	18.9	0.5	5.6	3.1	0.5	0.0
2	190	3.1	10	17.1	0.7	1.5	3.7	0.0	0.3
3	206	12.5	9.7	18.9	0.6	5.3	4	0.0	0.0
4	202	8.4	8.0	17.1	2.8	8.3	3.2	0.0	0.0
5	221	7.6	5.4	20.4	0.9	8.7	1	0.0	0.0
6	190	6.5	6.6	15.3	3.5	7.7	1.4	0.0	0.0
7	206	8.0	5.7	15.8	1.1	5.6	3.8	0.0	0.0
8	212	4.9	7.0	19.4	1.1	5.4	2.2	0.0	0.0
9	190	8.8	6.0	17	1.8	5.3	2	0.0	0.0
10	202	10.1	11.1	17.5	4.6	0.6	6.4	0.0	0.0
Mean	**203**	**8.0**	**7.9**	**17.7**	**1.8**	**5.4**	**3.1**	**0.1**	**0.3**
Ratio			1.02		10.08		1.75		1.67

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance	**Test organism(s)**	**Test method, Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**

Cont. Table 2:

Animal No.	Total t	Total C	P.R. T/C	Final b.wt. (g)	Days to death	Total T	Total C	mg/kg ingested
1	25	3.6	6.94	205	2	25	3.6	90.1
2	18.6	4.7	3.96	172	3	18.6	4.7	73.4
3	24.2	4.6	5.26	205	2	24.2	4.6	88.1
4	25.4	6	4.23	197	2	25.4	6	94.3
5	29.1	1.9	15.32	201	3	29.1	1.9	98.8
6	23	4.9	4.69	185	2	23	4.9	90.9
7	21.4	4.9	4.37	193	2	21.4	4.9	77.9
8	24.8	3.3	7.52	186	3	24.8	3.3	87.7
9	22.3	3.8	5.87	176	3	22.3	3.8	88
10	18.1	11.0	1.65	198	2	18.1	11	67.2
Me**an**	**23.2**	**4.9**		**192**	**2.4**	**23.2**	**4.9**	**85.6**
Ratio								

Total test intake = 231.9
Total control take, g= 48.7
Palatability Ratio, T/C= 4.76
Range palatability ratios= 1.65 to 15.32
% Acceptance= 82.6
Mean mg/kg ingested = 85.6
Total death = 10
Mean time to death = 2.4 days (range days = 2 to 3)

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol.	Norway rat, (*Rattus norvegicus*): Wild population located on a stud (horse) farm, Ellesmere, Shropshire, UK. (resistance status unknown)	**Field trial:** The field trial was conducted in a stable block including feed storage and inaccessible areas. No rodenticide treatments were applied for 10 days prior to testing. 40 census feed points and 40 tracking patches were used (distributed throughout the trial area). 39 test bait points were used for the actual bait testing. The field test was conducted in four phases: (a) Pre-trial survey: Assessing the infestation and selecting locations for tracking patches and census/bait points, which were then marked on a sketch map of the site. (b) Pre-treatment census: Tracking patches and census feed points were positioned, 4 days later, 200g of whole wheat (control diet) was placed in each of the 40 census diet trays and tracking patches freshly coated in silver sand. Each day for 4 days, the control diet in each tray was weighed to the nearest 1.0g and replenished. Marks on tracking patches were recorded to give an index: 0 = no tracks, 1 = 1-5 prints, 2 = 6 prints - 25% of patch tracked, 3 = 25% - 95% of patch tracked, 4 = >95% of patch tracked. At end of census period all diet trays were removed. (c) Treatment (7 days; 7 day gap post treatment): Treatment was conducted using soft block bait (BAS 410 05 I) & surplus baiting technique. The 39 bait trays were filled with approx. 150g (9 soft blocks) of bait approx. 5-10m apart. Amount consumed was recorded after 24 hrs then at intervals ≤72 hrs, for 7 day treatment period, and tracking patches were assessed and re-coated. At end of the treatment period, all bait was removed, and tracking patches evaluated.	**Pre-Treatment Census results** **Pre-census diet / Tracking indices** **Day** | **Diet take (g)** | **Activity points** | **Score** | **Active patches** 1 | 1149 | 30/40 | 81 | 34/40 2 | 929 | 26/40 | 88 | 34/40 3 | 1071 | 21/40 | 83 | 34/40 4 | 1504 | 24/40 | 85 | 33/40 **Total** | **4653** | **101/160** | **337** | **135/160** **Mean** | **1163** | **25/40** | **84** | **34/40** **Treatment results** **Treatment bait / Tracking indices** **Day** | **Bait take (g)** | **Activity points** | **Score** | **Active patches** 1 | 400 | 20/39 | 99 | 38/40 2 | 156 | 20/39 | 53 | 22/40 3 | 16 | 6/39 | 38 | 15/40 4 | 242 | 7/39 | 26 | 11/40 5-7 | 13 | 5/39 | 4 | 2/40 **Total** | **827** | **58/195** | **220** | **88/160** **Mean** | **165** | **12/39** | **44** | **18/40** **Post-Treatment Census results** **Post-census diet / Tracking indices** **Day** | **Diet take (g)** | **Activity points** | **Score** | **Active patches** 1 | 0 | 0/40 | 0 | 0/40 2 | 7 | 1/40 | 3 | 2/40 3 | 55 | 1/40 | 0 | 0/40 4 | 0 | 0/40 | 2 | 2/40 **Total** | **62** | **2/160** | **5** | **4/160** **Mean** | **16** | **0.5/40** | **1** | **1/40** **Percentage reduction in population – post treatment** | **Diet census** | **Tracking indices**	Hughes, C.S. (2013i)

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

<table>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test method, Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td>(d) Post-treatment census period (4 days). 7days after treated bait had been removed, the 40 census diet trays were placed in their original positions, filled with 200g of control diet, and feeding/activity monitored, the same as for the pre-treatment census phase. At end of day 4, all feed was removed.</td><td>
<table>
<tr><th rowspan="2">Total bait take</th><th colspan="2">Diet take</th><th colspan="2">Score</th></tr>
<tr><th>Day 4</th><th>Day 1-4</th><th>Day 4</th><th>Day 1-4</th></tr>
<tr><td>827g</td><td>99%</td><td>99%</td><td>99%</td><td>99%</td></tr>
</table>
% reduction = (pre-treatment index – mean post treatment index) x 100/pre-treatment index.
</td><td></td></tr>
<tr><td>Selontra®
A soft block paste bait containing 750ppm cholecalciferol.</td><td>Norway rat, (Rattus norvegicus):

Wild population located on a dairy farm, Ellesmere, Shropshire, UK.

(resistance status unknown)</td><td>Field trial:

The field trial was conducted in and around the farm buildings, including feed storage and inaccessible areas. No rodenticide treatments were applied for 10 days prior to testing. 49 census feed points (plastic bait trays 120 x 180mm) and 49 tracking patches (either 120 x 180 mm, or 200 x 200 mm covered in silver sand) were used (distributed throughout the trial area). 56 test bait points were used for the actual bait testing.

The field test was conducted in four phases:
(a) Pre-trial survey: Assessing the infestation and selecting locations for tracking patches and census/bait points, which were then marked on a sketch map of the site.

(b) Pre-treatment census: Tracking patches and census feed points were positioned, 4 days later, 200g of whole wheat (control diet) was placed in each of the 40 census diet trays and tracking patches freshly coated in silver sand. Each day for 4 days, the control diet in each tray was weighed to the nearest 1.0g and replenished. Marks on tracking patches were recorded to give an index: 0 = no tracks, 1 = 1-5 prints, 2 = 6 prints - 25% of patch tracked, 3 = 25% - 95% of patch tracked, 4 = >95% of patch tracked. At end of census period all diet trays were removed.

(c) Treatment (7 days; 7 day gap post treatment): Treatment was conducted using soft block bait (BAS 410 05 I) & surplus baiting technique. The 39 bait trays were filled with approx. 150g (9 soft blocks) of bait approx. 5-10m apart. Amount consumed was recorded after 24 hrs then at intervals ≤72 hrs, for 7 day treatment period, and tracking patches were assessed and re-coated. At end of the treatment period, all bait was removed, and tracking patches evaluated.</td><td>
Pre-Treatment Census results
<table>
<tr><th rowspan="2">Day</th><th colspan="2">Pre-census diet</th><th colspan="2">Tracking indices</th></tr>
<tr><th>Diet take (g)</th><th>Activity points</th><th>Score</th><th>Active patches</th></tr>
<tr><td>1</td><td>830</td><td>29/49</td><td>78</td><td>35/49</td></tr>
<tr><td>2</td><td>1342</td><td>28/49</td><td>80</td><td>33/49</td></tr>
<tr><td>3</td><td>1598</td><td>24/49</td><td>86</td><td>32/49</td></tr>
<tr><td>4</td><td>2271</td><td>31/49</td><td>85</td><td>32/49</td></tr>
<tr><td>Total</td><td>6041</td><td>112/196</td><td>329</td><td>132/196</td></tr>
<tr><td>Mean</td><td>1510</td><td>28/49</td><td>82</td><td>33/49</td></tr>
</table>
Treatment results
<table>
<tr><th rowspan="2">Day</th><th colspan="2">Treatment bait</th><th colspan="2">Tracking indices</th></tr>
<tr><th>Bait take (g)</th><th>Activity points</th><th>Score</th><th>Active patches</th></tr>
<tr><td>1</td><td>725</td><td>26/56</td><td>77</td><td>31/49</td></tr>
<tr><td>2</td><td>293</td><td>22/56</td><td>49</td><td>20/49</td></tr>
<tr><td>3</td><td>195</td><td>22/56</td><td>42</td><td>21/49</td></tr>
<tr><td>4</td><td>126</td><td>19/56</td><td>21</td><td>15/49</td></tr>
<tr><td>5-7</td><td>574</td><td>15/56</td><td>23</td><td>12/49</td></tr>
<tr><td>Total</td><td>1913</td><td>104/280</td><td>212</td><td>99/245</td></tr>
<tr><td>Mean</td><td>383</td><td>21/56</td><td>42</td><td>20/49</td></tr>
</table>
Post-Treatment Census results
<table>
<tr><th rowspan="2">Day</th><th colspan="2">Post-census diet</th><th colspan="2">Tracking indices</th></tr>
<tr><th>Diet take (g)</th><th>Activity points</th><th>Score</th><th>Active patches</th></tr>
<tr><td>1</td><td>153</td><td>5/49</td><td>4</td><td>2/49</td></tr>
<tr><td>2</td><td>58</td><td>3/49</td><td>3</td><td>3/49</td></tr>
<tr><td>3</td><td>58</td><td>3/49</td><td>4</td><td>3/49</td></tr>
<tr><td>4</td><td>73</td><td>4/49</td><td>4</td><td>3/49</td></tr>
<tr><td>Total</td><td>342</td><td>15/196</td><td>15</td><td>11/196</td></tr>
<tr><td>Mean</td><td>86</td><td>4/49</td><td>4</td><td>3/49</td></tr>
</table>
Percentage reduction in population – post treatment
<table>
<tr><th rowspan="2">Total bait take</th><th colspan="2">Diet census
Diet take</th><th colspan="2">Tracking indices
Score</th></tr>
<tr><th>Day 4</th><th>Day 1-4</th><th>Day 4</th><th>Day 1-4</th></tr>
<tr><td>1913g</td><td>96%</td><td>94%</td><td>95%</td><td>95%</td></tr>
</table>
</td><td>Hughes, C.S. (2013j)</td></tr>
</table>

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

<table>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test method, Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td>(d) Post-treatment census period (4 days). 7days after treated bait had been removed, the 40 census diet trays were placed in their original positions, filled with 200g of control diet, and feeding/activity monitored, the same as for the pre-treatment census phase. At end of day 4, all feed was removed.</td><td>% reduction = (pre-treatment index – mean post treatment index) x 100/pre-treatment index.</td><td></td></tr>
<tr><td>Selontra®
A soft block paste bait containing 750ppm cholecalciferol.</td><td>Norway rat, (Rattus norvegicus):

Wild population located on a dairy farm, Warendorf district, Germany.

(resistance status unknown)</td><td>Field trial:

Study conditions: Ambient (as encountered in and around agricultural buildings in January-March). The field trial was conducted in and around dairy farm buildings. 27 census feed points (bait stations) [25 bait points – different locations to census points] (at >1m distance) and 16 tracking patches were distributed in the trial area.

The field test was conducted in four phases: (a) Implementation of trial: Assessing infestation, based on droppings, mouse damage, feeding and footprints. Locations of census points, tracking patches and bait points were marked on a site map.

(b) Pre-treatment census (4 days; 7 day gap): Census feed points/tracking patches were positioned. For 4 days, whole wheat was placed in each of the 27 census diet trays and tracking patches freshly coated. Every day, the residual census feed take at each census point was measured and the feed replenished as necessary. Tracking activity was monitored, marks on tracking patches were recorded to provide an index, using the following scale: 0 = no tracks, 1 = 1-5 footprints, 2 = 6 footprints to 25% of the patch tracked, 3 = 25% to 95% of the patch tracked, 4 = greater than 95% of the patch tracked. Tracking patches were left in the same positions during treatment and post treatment census. At the end of census, all feed points were removed and a 7-day ‘lag’ period followed prior to baiting.

(c) Treatment period (21 days; 7 day gap post treatment): The treatment was carried out using the soft block bait (BAS 410 05 I). The 25 bait boxes were filled with approx. 150g of treated bait (9 soft blocks) placed >1m apart. Quantities consumed were recorded every 24 hours for the first 4 days, then 2-3 times per week for the remainder of the test period, replenished as necessary. At each visit, tracking patches were</td><td>
Survival rates of rats: based on feed, sensor & tracking census
<table>
<tr><th>census day</th><th>1</th><th>2</th><th>3</th><th>4</th><th>Total</th></tr>
<tr><td colspan="6">census feed uptake (27 bait points)</td></tr>
<tr><td>Pre-baiting (g)</td><td>1055</td><td>1405</td><td>1557</td><td>1607</td><td>5624</td></tr>
<tr><td>Post-baiting (g)</td><td>27</td><td>26</td><td>41</td><td>49</td><td>143</td></tr>
<tr><td>% survival rate (feed uptake)</td><td>3</td><td>2</td><td>3</td><td>3</td><td>3</td></tr>
<tr><td colspan="6">tracking activity (16 tracking patches)</td></tr>
<tr><td>Pre-baiting (activity index)</td><td>56</td><td>55</td><td>56</td><td>55</td><td>222</td></tr>
<tr><td>Post-baiting (activity index)</td><td>7</td><td>6</td><td>8</td><td>7</td><td>28</td></tr>
<tr><td>% survival rate (activity)</td><td>13</td><td>11</td><td>14</td><td>13</td><td>13</td></tr>
</table>
Consumption (g) during baiting phase & number of dead rats in test area
<table>
<tr><th>Day of trial</th><th>1</th><th>2</th><th>3</th><th>4</th><th>6</th><th>8</th><th>11</th><th>13</th><th>16</th><th>18</th><th>21</th><th>Total</th></tr>
<tr><td>Uptake (g)</td><td>333</td><td>442</td><td>200</td><td>286</td><td>38</td><td>107</td><td>65</td><td>9</td><td>5</td><td>0</td><td>0</td><td>1485</td></tr>
<tr><td>Uptake/24hr (g)</td><td>333</td><td>442</td><td>200</td><td>286</td><td>19</td><td>54</td><td>22</td><td>5</td><td>2</td><td>0</td><td>0</td><td>-</td></tr>
<tr><td>dead rats</td><td>0</td><td>0</td><td>0</td><td>1</td><td>2</td><td>4</td><td>1</td><td>0</td><td>0</td><td>0</td><td>0</td><td>8</td></tr>
</table>
Number of bait points with feeding activity during baiting phase
<table>
<tr><th>Day of trial</th><th>1</th><th>2</th><th>3</th><th>4</th><th>6</th><th>8</th><th>11</th><th>13</th><th>16</th><th>18</th><th>21</th></tr>
<tr><td>Feed sites</td><td>11</td><td>11</td><td>12</td><td>6</td><td>4</td><td>3</td><td>3</td><td>2</td><td>1</td><td>0</td><td>0</td></tr>
<tr><td>No. empty bait points</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Total No. of bait points</td><td>25</td><td>25</td><td>25</td><td>25</td><td>25</td><td>25</td><td>25</td><td>25</td><td>25</td><td>25</td><td>25</td></tr>
</table>
Tracking activity during the baiting period
<table>
<tr><th>Day of trial</th><th>1</th><th>2</th><th>3</th><th>4</th><th>6</th><th>8</th><th>11</th><th>13</th><th>16</th><th>18</th><th>21</th></tr>
</table>
</td><td>Klemann, N. (2013b)</td></tr>
</table>

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance	**Test organism(s)**	**Test method, Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		assessed and re-coated, plus searches for dead mice and non-targets. At the end of the treatment period, all bait was removed and tracking patches evaluated to provide an activity index. A 7-day lag period followed before post-census baiting began. (d) Post-treatment census period (4 days): Seven days after the treated bait was removed, the 27 census diet trays were placed in their original positions, filled with whole wheat and feeding/tracking activities monitored. At the end of day 4, all census feed was removed.	**Activity index (sum)*** 36 36 34 27 24 18 13 7 6 6 6 *based on 16 tracking patches	

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol.	Norway rat, (*Rattus norvegicus*) Wild population, Ken Probert Timber, Oswestry, Shropshire (UK). (resistance status unknown)	**Field trial:** The field test was conducted in five phases: (a) Pre-trial survey: Assessing the infestation, based on holes, droppings, rat damage, feeding and footprints. Locations of census diet, tracking patches and bait points were then marked on a sketch of the site. (b) Pre-treatment census: Wooden bait trays and tracking patches lightly coated with horticultural silver sand were placed in position following the pre-trial survey. At the same time, provisional positions for the 750ppm Cholecalciferol Soft Block bait placements were evaluated. At no time were census diets, tracking patches or 750ppm Cholecalciferol Soft Block bait placements located on the same spot as each other, though for practical reasons their position sometimes had to be close together in protected places where there were signs of rat activity. Four days later, 200g of whole wheat was placed on each census diet tray, and the tracking patches freshly coated in silver sand. On each of the following 4 days, the residual wheat in each tray was inspected, weighed to the nearest 1.0g on a portable electronic balance and, where measurable take had occurred, replenished to an amount sufficient to provide surplus until the next visit 24 hours later. The amount of whole wheat taken by the rats was recorded along with a visual presence of a complete (C), partial (P) or no (N) take. Marks on the tracking patches were recorded to provide an index, using the following scale: 0 = no tracks, 1 = 1-5 footprints, 2 = 6 footprints to 25% of the patch tracked, 3 = 25% to 95% of the patch tracked, 4 = greater than 95% of the patch tracked. The tracking patches were left in the same positions for use during treatment and the post treatment census. At the end of the census all diet trays were removed. (c) Pre-treatment lag period: The pre-treatment census was followed by a pre-treatment lag period. The duration of this period was always 10 days. During this period no census diet or bait was available on site and	**Table 1:** Pre-Treatment Census results **Day** | **Pre-census diet: Diet take (g)** | **Pre-census diet: Activity points** | **Tracking indices: Score** | **Tracking indices: Active patches** 1 | 656 | 23/32 | 42 | 24/32 2 | 647 | 23/32 | 53 | 26/32 3 | 465 | 22/32 | 57 | 23/32 4 | 555 | 28/32 | 58 | 23/32 Total | 2323 | 96/128 | 210 | 96/128 **Mean** | **581** | **24/32** | **53** | **24/32** **Table 2:** Treatment results **Day** | **Treatment bait: Bait take (g)** | **Treatment bait: Activity points** | **Tracking indices: Score** | **Tracking indices: Active patches** 1 | 431 | 24/36 | 50 | 25/32 2 | 171 | 11/36 | 23 | 13/32 3 | 19 | 3/36 | 5 | 5/32 4 | 0 | 0/36 | 1 | 1/32 5 | 0 | 0/36 | 1 | 1/32 6 | 0 | 0/36 | 1 | 1/32 7 | 13 | 2/36 | 0 | 0/32 Total | 634 | 40/252 | 210 | 46/224 **Mean** | **91** | **6/36** | **30** | **7/32** **Table 3:** Post-Treatment Census results **Day** | **Post-census diet: Diet take (g)** | **Post-census diet: Activity points** | **Tracking indices: Score** | **Tracking indices: Active patches** 1 | 0 | 0/32 | 0 | 0/32 2 | 0 | 0/32 | 0 | 0/32 3 | 0 | 0/32 | 0 | 0/32 4 | 0 | 0/32 | 0 | 0/32 Total | 0 | 0/128 | 0 | 0/128 **Mean** | **0** | **0/32** | **0** | **0/32** **Table 4:** Estimates of population reduction achieved with 750ppm Cholecalciferol soft block rodenticide bait (BAS 410 05 I) **Total bait take** | **Diet census: Diet take** Day 4 | Day 1-4 | **Diet census: Active points** Day 4 | Day 1-4 | **Tracking indices: Score** Day 4 | Day 1-4 | **Tracking indices: Active sites** Day 4 | Day 1-4 634g | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% % reduction = (pre-treatment census– mean post treatment census) x 100/pre-treatment census.	Hughes, C.S. (2013o)

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance	**Test organism(s)**	**Test method, Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		no observations were made on the infestations. The site was visited on day 7 of the lag period to lay treatment bait trays, in their pre-identified locations, for the 750ppm Cholecalciferol Soft Block bait (d) Treatment period (7 days; 7 day gap post treatment). The treatment was carried out on 750ppm Cholecalciferol Soft Block rodenticide bait (BAS 410 05 I) using a conventional surplus baiting technique. The bait trays, each containing approximately 150g of the bait, were laid in protected situations sited strategically ca. 5 - 10 m apart throughout the infested areas. A total of 36 bait points were laid at the site. The following days the baits were checked visually for takes, weighed to the nearest 1.0g, and replenished to an amount sufficient to avoid any subsequent complete bait takes. Similar observations and recordings were made for 7 days, with no more than 72 hours between visits. After the day 7 recordings the bait trays and bait were removed from the site. At each visit during the treatment period activity on the tracking patches was recorded and each freshly coated with tracking powder, as during the pre-treatment census. Searches for any non-target animals were also made at each visit. (e) Post-treatment Lag Period: The treatment period was followed by a 7 day lag period to enable any remaining rats a reasonable time in which to die, or recover, from any dose of rodenticide they may have ingested before beginning the post-treatment census (f) Post-treatment census period. The census diet trays were placed in their original positions, filled with 200g of whole wheat and feeding activities monitored the same as for the pre-treatment census phase. At the end of the fourth day, all census feed was removed.		

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol.	Norway rat, (*Rattus norvegicus*). Wild population Ken Probert Timber, Oswestry, Shropshire (UK). (resistance status unknown)	**Field trial:** The site was a retail business in an industrial area situated close to the centre of Oswestry. The site was chosen as representative of an urban infestation. The building was constructed of timber, tin sheeting, block and steel. **Pre-trial survey** The trial site was systematically surveyed for evidence of infestation, such as holes, droppings, footprints, and signs of damage or feeding. Rats that were observed were visually identified as *Rattus norvegicus.* **Pre-treatment census** Wooden bait trays (120 x 180 mm) and tracking patches (ca. 100 x 200 mm) lightly coated with horticultural silver sand were placed in position following the pre-trial survey. At the same time, provisional positions for the Selontra rodent bait placements were evaluated. At no time were census diets, tracking patches or Selontra rodent bait placements located on the same spot as each other, though for practical reasons their positions sometimes had to be close together in protected places where there were signs of rat activity. Four days later, 200g of whole wheat was placed on each census diet tray, and the tracking patches were freshly coated. On each of the following four days the residual wheat in each tray was inspected, weighed to the nearest 1.0 g on a portable electronic balance and, where a measurable take had occurred, replenished to an amount sufficient to provide a surplus until the next visit, 24 h later. The amount taken by the rats was recorded and also a visual observation of the presence of a complete, partial or no take ("C", "P", or "N", respectively). Marks on the tracking patches were recorded on an arbitrary scale, erased, and the patches re- coated. The scale was as follows: 0 = no tracks 1 = from I to 5 footprints	The Selontra rodent bait treatment resulted in a significant reduction of rat activity by day 6 of the treatment period. All the indices of treatment success based on the census diet and tracking data indicated 100% control. This degree of control is considered to be excellent for a subacute toxicant such as cholecalciferol. The results show that in an urban area, against *R. norvegicus*, that at 5 blocks per bait point, Selontra rodent bait (BAS 410 05 I) is an efficacious rodenticide bait. **TABLE 1.** Ken Probert Timber, Shropshire: Summary of Results Using Selontra (BAS 410 05 I) **1A.** Pre-treatment census **Day** / **Pre-Treatment Census Period**: **Total Census Diet Take, g** / **Total Census Tracking Score** 1: 500 / 48 2: 568 / 61 3: 589 / 60 4: 672 / 60 Total: 2329 / 229 **Mean**: **582** / **57** **1B.** Treatment **Day** / **Bait Treatment Period**: **Total Bait Take, g** / **Total Tracking Score** 1: 232 / 78 2: 225 / 8 3: 46 / 6 4: 0 / 0 5: 0 / 0 6: 0 / 0 **Total**: **503** / **92** **1C**. Post-treatment census **Day** / **Post-Treatment Census Period**: **Total Census Diet Take, g** / **Total Census Tracking Score** 1: 0 / 0 2: 0 / 0 3: 0 / 0 4: 0 / 0 Total: 0 / 0 **Mean**: **0** / **0**	Hughes (2018b)

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
		2 = from 6 footprints to 25% of the patch tracked 3 = from 25% to 95% of the patch tracked 4 = more than 95% of the patch covered with tracks The tracking patches were left in position to be utilized again during the Selontra rodent bait treatment and the post-treatment census. The pre-census results indicated the presence of what is considered to be considered a medium level of infestation for an urban environment. **Pre- Treatment Lag Period** The pre-treatment census was followed by a pre-treatment lag period. The duration of this lag period was 10 days. During this period no census diet or bait was available on site and no observations were made on the infestations. The site was visited on day 7 of the lag period to lay treatment bait trays, in their pre identified locations, for the Selontra rodent bait. **Treatment period** The treatment was carried out on Selontra rodent bait (BAS 410 05 I) using a conventional surplus baiting technique. The bait trays, each containing 5 blocks (approximately 100g) of the bait, were laid in protected situations sited strategically ca. 5 - 10 m apart throughout the infested areas. A total of 38 bait points were laid at the site. The following day the baits was checked visually for takes, any takes weighed to the nearest 1.0g, and replenished to an amount sufficient to avoid any subsequent complete bait takes. Similar observations and recordings were made for 6 days, with no more than 72 hours between visits. After 6 days, the bait trays and bait were removed from the site and the treatment period terminated. At each visit during the treatment period, activity on the tracking patches was recorded and each patch freshly coated with tracking powder, as during the pre-treatment census. Searches for any non-target animals were also made at each visit. **Post- Treatment Lag Period** The treatment period was followed by a 7 day lag period to enable any remaining rats a reasonable time in which	**TABLE 2**. Ken Probert Timber, Shropshire: Estimates of Population Reduction Achieved With Selontra (BAS 410 05 I). **Bait Take g** / **Percent Reduction In Population** **Census Diet Take** / **Tracking Score** Day 4 / Day 1-4 / Day 4 / Day 1-4 582 / 100 / 100 / 100 / 100 Percent reduction = (pre-treatment census - mean post-treatment census) x 100 / pre-treatment census.	

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance	**Test organism(s)**	**Test method, Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		to die, or recover, from any dose of rodenticide they may have ingested before beginning the post-treatment census. **Post-treatment census** The census diet trays were returned to their original positions. The post-treatment census was conducted in exactly the same way as the pre-treatment census.		

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol. Post 24-months storage at ambient conditions (aged bait)	Norway rat (*Rattus norvegicus*) Wistar strain, laboratory cultured (anticoagulant susceptible)	**Choice feeding cage study (aged bait):** The application was offering the test substance (A soft block rodenticide bait containing 750ppm cholecalciferol (BAS 410 05 I)) with choice for 4-days. Pre-test period: There was a 3-day acclimatisation period prior to testing where ground laboratory (control) diet was presented in two identical feeding dishes (placed symmetrically in the cage) plus tap water was provided ad libitum. 24 hours prior to test baiting, the feed dishes were replaced with two identical dishes each containing 50g of control diet. Consumption of the control diet was recorded to the nearest 0.1g, and statistical analysis (unpaired T-test – p=0.05) conducted to establish if there was a significant difference between the positions of the two feed dishes. This consumption value represented the pre-test diet take. Choice test: A 4-day test period followed, where 50g each of the bait treatment and the control diet were placed in the separate feed dishes (the position rotated each day for the 4-day test period). After each 24 hour period, any spillage was retrieved and returned to the dish, whilst any extraneous matter was removed. The feed dishes were then weighed to provide a value for each 24 hour bait/control diet take. Test bait and control diet were replaced daily with fresh material in clean dishes. Rats were also observed at least once a day. Tap water was provided ad libitum during the study period. This was followed by a 10 day post baiting observation period, where control diet and tap water were provided *ad libitum*. Delivery method: Oral ingestion and dosage rate as taken. Adjuvants/vehicle/carrier: Not applicable, formulated product offered.	**Table 1:** Full Protocol Palatability feeding study against male and female rats - Fresh (0 months storage) Selontra Rodenticide bait (T=test, C=Control) **No / Sex / Initial B.Wt (g) / Pre-test take A / Pre-test take B / Daily Take (g) Day 1 T / Day 1 C / Day 2 T / Day 2 C / Day 3 T / Day 3 C** 1 M 241 7.4 19.7 13.6 9.9 0.0 0.5 2 M 246 18.8 8.7 21.0 7.6 0.0 1.6 3 M 244 11.5 16.9 22.6 8.0 0.0 4.3 4 M 253 14.3 13.9 19.4 6.1 0.0 0.3 5 M 243 8.7 15.9 16.2 7.3 2.7 8.6 6 F 187 8.0 6.6 15.2 2.5 0.0 4.5 0.0 0.2 7 F 190 12.4 4.9 14.8 4.3 0.0 1.0 0.0 0.3 8 F 195 7.4 9.4 19.3 2.0 3.1 3.8 9 F 208 7.8 15.5 20.8 3.0 0.0 4.9 10 F 198 7.5 10.3 12.6 5.7 0.0 2.3 0.0 0.5 TOTAL 103.8 121.8 175.5 56.4 5.8 31.8 0.0 1.0 MEAN 221 10.4 12.2 17.6 5.6 0.6 3.2 0.0 0.3 **RATIO** **0.85** **3.11** **0.18** **0.00** Cont. Table 1: **No / Sex / TOTAL T / TOTAL C / p.r T/C / B.Wt (g) Final / Days to Death / mg/kg ingested** 1 M 13.6 10.4 1.31 230 2 42.3 2 M 21.0 9.2 2.28 240 2 64.0 3 M 22.6 12.3 1.84 244 2 69.5 4 M 19.4 6.4 3.03 232 2 57.5 5 M 18.9 15.9 1.19 231 2 58.3 6 F 15.2 7.2 2.11 164 3 61.0 7 F 14.8 5.6 2.64 168 3 58.4 8 F 22.4 5.8 3.86 186 2 86.2 9 F 20.8 7.9 2.63 202 2 75.0 10 F 12.6 8.5 1.48 179 3 47.7 TOTAL 181.3 89.2 22.38 MEAN **18.1** **8.92** **2.24** **208** **2.3** **62.0** **RATIO** **2.03**	[redacted] (2015b)

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference

Total test take = 181.3
Total control take, g=89.2
PALATABILITY RATIO, *T/C*=2.03
Range Palatability ratios=1.19 to 3.86
%ACCEPTANCE= 67.0
Mean mg/kg ingested= 62.0
Total deaths= 10
Mean time to death, days= 2.3
Range days= 2 to 3

Table 2: Full protocol palatability feeding study against male and female Wistar Rats: 24 Month Stored Selontra bait

			Pre-test take		Daily Take (g)							
No	**Sex**	**Initial B.Wt (g)**	**A**	**B**	**Day 1 T**	**Day 1 C**	**Day 2 T**	**Day 2 C**	**Day 3 T**	**Day 3 C**	**Day 4 T**	**Day 4 C**
1	M	232	10.3	9.5	17.5	7.5	0.0	4.0				
2	M	216	6.2	11.2	13.2	2.0	0.0	4.3				
3	M	244	11.2	11.1	18.0	3.7	0.4	5.3				
4	M	230	7.0	12.0	15.1	3.8	0.0	5.8	0.0	0.0		
5	M	231	10.1	9.3	11.1	8.6	0.0	3.8	0.0	0.0		
6	F	197	10.2	5.3	17.9	0.3	1.6	2.3	0.0	0.0		
7	F	205	6.3	10.3	13.7	1.7	3.1	3.0	0.0	0.0		
8	F	178	10.3	6.6	17.3	0.7	4.6	3.4	0.0	0.0	0.0	0.1
9	F	175	7.5	10.9	16.1	0.6	1.5	2.8	0.0	0.0		
10	F	196	11.2	7.1	10.7	2.9	4.3	4.9	0.0	0.0		
TOTAL			90.3	93.3	150.6	31.8	15.5	39.6	0.0	0.0	0.0	0.1
MEAN		210	**9.0**	**9.3**	**15.1**	**3.2**	**1.6**	**4.0**	**0.0**	**0.0**	**0.0**	**0.1**
RATIO				**0.97**		**4.74**		**0.39**				**0.00**

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference

Cont. Table 2

No	Sex	TOTAL T	TOTAL C	P.r. T/C	B.Wt, g FINAL	Days to Death	mg/kg ingested
1	M	17.5	11.5	1.52	230	2	56.6
2	M	13.2	6.3	2.10	201	2	45.8
3	M	18.4	9.0	2.04	241	2	56.6
4	M	15.1	9.6	1.57	225	3	49.2
5	M	11.1	12.4	0.90	221	3	36.0
6	F	19.5	2.6	7.50	190	3	74.2
7	F	16.8	4.7	3.57	195	3	61.5
8	F	21.9	4.2	5.21	166	4	92.3
9	F	17.6	3.4	5.18	168	3	75.4
10	F	15.0	7.8	1.92	175	3	57.4
TOTAL		166.1	71.5	31.52			
MEAN		**16.6**	**7.15**	**3.15**	**201**	**2.8**	**60.5**
RATIO			**2.32**				

Total test take=166.1
Total control take, g =71.5
PALATABILITY RATIO, *T/C*=2.32
Range Palatability ratios=0.90 to 7.50
%ACCEPTANCE= 69.9
Mean mg/kg ingested= 60.5
Total deaths=10
Mean time to death, days=2.8
Range days=2to4

Table 3: Anova on Selontra Bait fresh and Post 24 month Storage against male and female Wistar Rats
Comparisons for TEST (Y)
Tukey Pairwise Comparisons: Response = TEST (Y), TERM = CODE
Grouping information using the Tukey Methods and 95% Confidence

CODE	N	Mean	Grouping
B	**10**	**17.4688**	**A**
A	**10**	**17.2712**	**A**

Means that do not share a letter are significantly different
Tukey Simultaneous Tests for differences of Means

Difference (Code)	Difference (Means)	SE	Simultaneous 95% CI	T-Value	Adjusted P val
B-A	0.20	1.31	(-2.56, 2.96)	0.15	0.882

Individual confidence level = 95%
Tukey Simultaneous 95% CIs

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol. Post 36-months storage at ambient conditions (aged bait)	Norway rat, (*Rattus norvegicus*) Wistar Strain, laboratory cultured (anticoagulant susceptible)	**Choice feeding cage study (aged bait):** The choice feeding (palatability) test consisted of a 3-day acclimatisation period which included a 24h pre-test diet take assessment; a 4-day choice feeding period; and a 14-day post-treatment observation period. The choice feeding period compared the amount of test bait eaten, with the amount of control diet, ground laboratory diet, eaten. A group of 5 male and 5 female rats were weighed and individually caged in polypropylene cages 40.0 x 25.0 x 20.0 cm (l x w x h) with stainless steel wire mesh lid and base, over a tray containing a paper liner. The rats were acclimatised to test conditions for three days prior to the choice feeding period. Two identical glass feeding dishes, designed to minimise spillage and nesting, were placed symmetrically in each cage. Ground laboratory diet was provided *ad libitum* in each feeding dish. Tap water was also available *ad libitum*. The feeding dishes were removed 24 h prior to the feeding period and replaced with two identical feeding dishes each containing 50.0 g of ground laboratory diet. The consumption of diet from each of these feeding dishes was recorded, to the nearest 0.1 g, after 24 h; this represents pre-test diet take. For the 4-day choice feeding period, the rats were offered the choice of the test bait or the control diet, ground laboratory diet. Each of the amounts offered was in excess of the rat's daily food requirement. The test bait and control diet, each weighed to the nearest 0.1 g, were offered in identical feeding dishes, symmetrically placed. On the first day, for animals 1 to 5 the test bait feeding dish was placed at the front of the cage and the control diet feeding dish to the rear of the cage, and for rats 6 to 10 the positions of the test bait and control diet feeding dishes were reversed. The position of each dish was alternated daily to eliminate preferred feeding positions. After 24 h, and each day thereafter, any spillage was retrieved and returned to the appropriate feeding dish and any extraneous matter, e.g. faeces, removed. Test bait and control diet were weighed to the nearest 0.1 g. The amount eaten was calculated by	**TEST: Selontra BAS 410 05 I (750 mg/kg)** **CONTROL: ssniff rat and mouse maintenance diet 1536** **FORMULATION: soft block** **REASON FOR TEST: Efficacy post 36-months stored** Animal bx. no: Wistar Han received 23.03.16; No. used 10	[redacted] (2016b)

No:	m/f	Initial b.wt., g	Pre-test take		Daily take, g							
					Day 1	Day 1	Day 2	Day 2	Day 3	Day 3	Day 4	Day 4
			A	B	T	C	T	C	T	C	T	C
1	m	267	6.5	22.1	23.7	4.6	0.0	0.0	0.0	1.9	0.0	0.0
2	m	272	15.8	13.9	24.4	2.9	0.0	0.7	0.0	0.0	0.0	0.0
3	m	261	12.8	17.7	15.9	12.0	0.0	0.0	0.0	0.0	0.0	0.0
4	m	264	9.7	20.2	18.7	6.8	0.0	2.6	0.0	0.1	0.0	0.0
5	m	255	16.5	13.2	20.1	4.1	1.5	3.5	0.0	0.1	0.0	0.0
6	f	202	13.2	5.6	16.9	2.5	3.0	3.8	0.0	0.1	0.0	0.0
7	f	205	11.0	7.8	16.8	4.7	0.8	3.4	0.1	0.1	0.0	0.0
8	f	215	14.5	8.0	17.7	2.3	0.0	3.6	0.3	0.1	0.0	0.0
9	f	216	6.7	13.6	16.5	3.9	4.0	2.7	0.0	0.2	0.0	0.0
10	f	215	17.7	6.9	17.4	4.2	1.9	0.9	0.0	0.1	0.0	0.0
Total			**124.4**	**129.0**	**188.1**	**48.0**	**11.2**	**21.2**	**0.4**	**2.7**	**0.0**	**0.0**
Mean		**237**	**12.4**	**12.9**	**18.8**	**4.8**	**1.1**	**2.1**	**0.0**	**0.3**	**0.0**	**0.0**
Ratio				**0.96**		**3.92**		**0.53**		**0.15**		**-**

Cont.

No:	TOTAL T	TOTAL C	p. r. T/C	Final b.wt., g	Days to death	mg/kg ingested
1	23.7	6.5	3.65	251	3	66.5
2	24.4	3.6	6.78	260	2	67.3
3	15.9	12.0	1.33	242	2	45.7
4	18.7	9.5	1.97	252	3	53.1
5	21.6	7.7	2.81	250	3	63.7
6	19.9	6.4	3.11	190	3	73.8
7	17.7	8.2	2.16	192	3	64.7
8	18.0	6.0	3.00	200	3	62.8
9	20.5	6.8	3.01	197	3	71.1
10	19.3	5.2	3.71	209	3	67.5
TOTAL	**199.7**	**71.9**				
MEAN	**20.0**	**7.2**		**224**	**2.8**	**63.6**
RATIO			**2.78**			

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance	**Test organism(s)**	**Test method, Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		subtraction, this represents the "take". Test bait and control diet were replaced daily with fresh material in clean feeding dishes to eliminate marking effects. Throughout the choice feeding period, the rats were observed at least once a day. After the 4-day choice feeding period, the individual daily test bait and control diet takes were summed and the individual palatability ratio calculated. Individual Palatability Ratio = Total individual test bait take/ Total individual control diet take The individual takes were then further summed to give the total test bait and control diet takes. The (group) palatability ratio was calculated. Palatability Ratio = Total test bait take /Total control diet take At the conclusion of the choice feeding period, the rats were maintained for a further 14-day period with food and tap water available *ad libitum.* The rats were observed at least once a day and any toxic signs and mortality recorded. The bodyweight at death was recorded. Any rats exhibiting severe signs of cholecalciferol toxicity, such that death was expected were culled and recorded as dead on that day. At the end of the 14-day post-treatment observation period, any survivors were culled and their body weight recorded.		

Efficacy against *Rattus rattus* (black rat / roof rat)

3 efficacy studies are provided for Selontra® against *R. rattus* (1 choice test (on aged bait) and 2 field tests) which are summarised below.

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol.	Black or roof rat, (*Rattus rattus*) Wild population located in a henhouse, Isere, France.	**Field trial:** The test included the following phases: two pre-treatment census phases to evaluate the acceptance of tamper-resistant bait stations separated by a 3 days lag phase (the first on wooden trays in tunnels and the second in rat tamper-resistant bait stations), pre-treatment lag phase (5 days), treatment census, post-treatment lag phase (3 days), post-treatment census in tamper-resistant bait stations. This technique involved the evaluation of the food/bait consumption before, during and after treatment. In order to complete this technique, a specific assessment of Black rat activity with tracking patches was undertaken. The Black rat infestation present in the site was determined by dividing the daily feed/bait consumed during the plateau in the pre-treatment period by half the average daily feed intake of a Black rat (10 g). The mean pre-census diet takes indicated that the site had approximately 47 Black rats present Throughout the pre-census period tracking patches (ca. 100 x 200 mm) lightly coated with horticultural silver sand were placed in position following the pre-trial survey. At no time were census diets, tracking patches or SELONTRA (BAS 410 05 I) bait placements located on the same spot as each other, though for practical reasons their positions were sometimes close together, where there were signs of Black rat activity. Marks on the tracking patches were recorded daily along with the census diet take. The scale was as follows 0 = no tracks 1 = from 1 to 5 footprints 2 = from 6 footprints to 25% of the patch tracked 3 = from 25% to 95% of the patch tracked 4 = more than 95% of the patch covered with tracks. After the recording the patches were re-coated or smoothed over.	**Table 1:** Summary of results from pre-treatment to post-treatment in the site.	Guicherd (2018a)

Trial Phase	Date	Day	Mean Daily Consumption (g)
1st Pre-baiting period	09/04/2018	D0	/
	10/04/2018	D1	0
	11/04/2018	D2	5
	12/04/2018	D3	25
	13/04/2018	D4	85
	15/04/2018	D5	143
	16/04/2018	D6	145
	17/04/2018	D7	325
	18/04/2018	D8	240
	19/04/2018	D9	315
	20/04/2018	D10	425
	21/04/2018	D11	510
	22/04/2018	D12	500
	23/04/2018	D13	530
Lag phase	23 to 26 APR 2018		/
2nd Pre-baiting period	26/04/2018	D17	0
	27/04/2018	D18	45
	30/04/2018	D21	45
	02/05/2018	D23	87,5
	03/05/2018	D24	380
	04/05/2018	D25	390
	05/05/2018	D26	380
	06/05/2018	D27	425
	07/05/2018	D28	450
	08/05/2018	D29	465
	09/05/2018	D30	495
Lag phase	09 to 14 MAY 2018		/
Baiting	14/05/2018	D35	/
	15/05/2018	D36	410
	16/05/2018	D37	520
	17/05/2018	D38	170
	18/05/2018	D39	70
	19/05/2018	D40	0
	20/05/2018	D41	0
	21/05/2018	D42	0
	22/05/2018	D43	0
Lag phase	22 to 25 MAY 2018		/
Post-Baiting	25/05/2018	D46	/
	26/05/2018	D47	0
	28/05/2018	D49	0
	30/05/2018	D51	0

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance	**Test organism(s)**	**Test method, Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		The tracking patches were left in position to be utilised again during the treatment period and the post-treatment census. A total of eight tamper-resistant bait stations were necessary to ensure a global perimeter covering and corresponding to the rodent area activity in the test site. These were positioned throughout the site where high levels of rodent activity were identified and where children and non-target animals had very limited access. During the pre and post-treatment censuses these tamper-resistant bait stations contained oats (150g), which was weighed and replenished at each assessment. The stations were emptied of oats when the bait was placed. In order to evaluate the acceptance of the tamper-resistant bait stations by the Black rats, there were two pre-treatment census phases: The first (from D0, 09 April 2018 to D13, 23 APR 2018) placing the oats on wooden trays (approx. 120 x 180) mm with a wooden rim to prevent spilage) and the second phase (from D17, 26 April 2018 to D30, 09 May 2018) placing oats in the tamper-resistant bait stations. These two pre-census phases were separated by a 3-day lag phase (from 23 to 26 April 2018) with the sponsor's agreement. The objective of the two phases was to establish that there was no significant difference in the amount of pre-treatment census diet consumed in both phases. If the take from the second phase was equal to that of the first phase then this would confirm that the Black rats were acclimated to the tamper-resistant bait stations. The consumption of oats was slightly different between the two pre-treatment census phases but most likely due to habituation of Black rats between wooden trays and tamper-resistant bait station. However, insufficiently different to not use the tamper-resistant bait stations for the test treatment. The SELONTRA (BAS 410 05 I) rodenticide bait was placed into eight lockable tamper-resistant bait stations, located in the high rodent activity areas. The position of each tamper-resistant bait station was entered on the study site map. The tamper-resistant bait stations were located 5 to 10 metres apart.	**Table 2**: Summary of Black rat dead bodies collected in the site along the trial. Trial Phase / Date / Day / Dead Bodies *1st Pre-baiting period*: 09/04/2018 D0 /; 10/04/2018 D1 0; 11/04/2018 D2 0; 12/04/2018 D3 0; 13/04/2018 D4 0; 15/04/2018 D5 0; 16/04/2018 D6 0; 17/04/2018 D7 0; 18/04/2018 D8 0; 19/04/2018 D9 0; 20/04/2018 D10 0; 21/04/2018 D11 0; 22/04/2018 D12 0; 23/04/2018 D13 0 *Lag phase*: 23 to 26 APR 2018 / *2nd Pre-baiting period*: 26/04/2018 D17 0; 27/04/2018 D18 0; 30/04/2018 D21 0; 02/05/2018 D23 0; 03/05/2018 D24 0; 04/05/2018 D25 0; 05/05/2018 D26 0; 06/05/2018 D27 0; 07/05/2018 D28 0; 08/05/2018 D29 0; 09/05/2018 D30 0 *Lag phase*: 09 to 14 MAY 2018 / *Baiting*: 14/05/2018 D35 /; 15/05/2018 D36 0; 16/05/2018 D37 0; 17/05/2018 D38 2; 18/05/2018 D39 0; 19/05/2018 D40 0; 20/05/2018 D41 2; 21/05/2018 D42 0; 22/05/2018 D43 1 *Lag phase*: 22 to 25 MAY 2018 / *Post-Baiting*: 25/05/2018 D46 /; 26/05/2018 D47 0; 28/05/2018 D49 0; 30/05/2018 D51 0 TOTAL 5	

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
		The tamper-resistant bait stations were positioned where children and non-target animals had very limited access. Any possible contact of the bait with food or waterways was avoided. Seven blocks (approximately 140g) of SELONTRA (BAS 410 05 I) rodenticide bait were placed into each tamper-resistant bait station. The tamper-resistant bait stations were monitored every 2 days or every day in the high consumption period (day 0 of treatment until a clear decreasing of consumption of the bait). If in a tamper-resistant bait station all of the bait was consumed, then the assessments for that bait station were conducted daily rather than every two days. The bait treatment continued until there was no further bait take. During all the study, no moisture or degradation of the bait occurred, indicating that all weighings were representative of a consumption and not a loss or a weight gain due to an outside element. Following the removal of the SELONTRA (BAS 410 05 I) rodenticide bait and tamper- resistant bait stations from the site there was a 3-day lag period when no disturbance took place. Following the completion of the post-treatment lag phase the post-treatment census stations (tamper-resistant bait stations) were re-filled with 150 g of the same reference food (oats) as for the pre-census and returned to their original positions. Census diet take was recorded as in the pre-treatment census. At the same time daily tracking activity was recorded as in the pre-treatment census. Assessments were conducted throughout the duration of the trial at intervals of every 1-4 days. During each assessment the food/bait at each station was weighed and replenished if necessary, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying Black rats around the sites.	**Table 3:** Summary of tracking patch results from pre-treatment to post-treatment in the site. 0 = no tracks 1 = from 1 to 5 footprints 2 = from 6 footprints to 25% of the patch tracked 3 = from 25% to 95% of the patch tracked 4 = more than 95% of the patch covered with tracks Therefore, SELONTRA (BAS 410 05 I) demonstrated 100% control of the *Rattus rattus* infestation.	

Trial Phase	Date	Day	Tracking Patch 1	Tracking Patch 2	Tracking Patch 3	Tracking Patch 4	Total score per day
First Pre-baiting	09/04/2018	D0	4	1	3	2	10
	10/04/2018	D1	1	3	4	0	8
	11/04/2018	D2	1	3	1	4	9
	12/04/2018	D3	0	0	1	1	2
	13/04/2018	D4	3	2	4	1	10
	15/04/2018	D5	0	0	2	2	4
	16/04/2018	D6	4	1	3	4	12
	17/04/2018	D7	0	4	3	0	7
	18/04/2018	D8	3	4	1	3	11
	19/04/2018	D9	0	2	4	3	9
	20/04/2018	D10	3	0	4	1	8
	21/04/2018	D11	0	4	3	0	7
	22/04/2018	D12	3	1	3	2	9
	23/04/2018	D13	3	2	4	3	12
Lag phase	23 to 26 APR 2018		/	/	/	/	/
Second Pre-baiting	26/04/2018	D17	2	3	1	1	7
	27/04/2018	D18	1	2	2	2	7
	30/04/2018	D21	1	3	1	4	9
	02/05/2018	D23	4	1	0	0	5
	03/05/2018	D24	0	4	4	0	8
	04/05/2018	D25	2	1	1	4	8
	05/05/2018	D26	1	3	0	0	4
	06/05/2018	D27	3	4	3	1	11
	07/05/2018	D28	1	4	2	3	10
	08/05/2018	D29	4	1	1	2	8
	09/05/2018	D30	4	3	1	3	11
Lag phase	09 to 14 MAY 2018		/	/	/	/	/
Baiting	14/05/2018	D35	2	4	2	3	11
	15/05/2018	D36	4	4	1	1	10
	16/05/2018	D37	1	4	3	3	11
	17/05/2018	D38	2	0	1	3	6
	18/05/2018	D39	1	1	0	2	4
	19/05/2018	D40	0	0	0	0	0
	20/05/2018	D41	0	0	0	0	0
	21/05/2018	D42	0	0	0	0	0
	22/05/2018	D43	0	0	0	0	0
Lag phase	22 to 25 MAY 2018						/
Post-Baiting	25/05/2018	D46	0	0	0	0	0
	26/05/2018	D47	0	0	0	0	0
	28/05/2018	D49	0	0	0	0	0
	30/05/2018	D51	0	0	0	0	0

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol.	Black or roof rat, (*Rattus rattus*) Wild population in an agricultural building in Essertines en Donzy (Loire department) near Lyon city (South East of France).	**Field trial:** The chosen treated site had at least 38 Black rats feeding per day. The site had minimal human and domestic disturbance. No rodenticides had been used at the site for at least 3 months prior to the start of the trial. Five blocks (approximately 100 g) of the Selontra (BAS 410 05 I) rodenticide bait were placed inside commercially available lockable rat tamper-resistant bait stations. These stations were positioned in areas with high Black rat activity at a distance of approximately 5 to 10 m apart. The tamper-resistant bait stations were located out of reach of children and non-target animals. The site was a farm with a barn and two grain silos. The bait treatment phase (see Table 1) commenced once the consumption in the pre-treatment census with tamper-resistant bait stations, was considered to be stable (consumption stable over 3 days and was equivalent to that of the pre-census on wooden trays). Throughout the trial, tracking patches (ca. 100 x 200 mm) lightly coated with horticultural silver sand were placed in position following the pre-trial survey. At no time were census diets, tracking patches or SELONTRA (BAS 410 05 I) bait placements located on the same spot as each other, though for practical reasons their positions were sometimes close together, where there were signs of Black rat activity. Marks on the tracking patches were recorded daily along with the census diet take. The scale was as follows: 0 = no tracks 1 = from 1 to 5 footprints 2 = from 6 footprints to 25% of the patch tracked 3 = from 25% to 95% of the patch tracked 4 = more than 95% of the patch covered with tracks After the recording the patches were re-coated or smoothed over.	**Table 1:** Summary of results from pre-treatment to post-treatment in the site. Trial Phase / Date / Day / Mean Daily Consumption (g) ***1st Pre-baiting period*** 06/06/2018 D0 / 08/06/2018 D2 0 11/06/2018 D5 0 13/06/2018 D7 10 15/06/2018 D9 10 18/06/2018 D12 8 19/06/2018 D13 5 20/06/2018 D14 10 21/06/2018 D15 40 22/06/2018 D16 45 23/06/2018 D17 95 25/06/2018 D19 115 26/06/2018 D20 355 27/06/2018 D21 400 28/06/2018 D22 390 29/06/2018 D23 400 30/06/2018 D24 390 01/07/2018 D25 390 02/07/2018 D26 400 03/07/2018 D27 370 ***Lag phase*** / / ***2nd Pre-baiting period*** 07/07/2018 D31 / 09/07/2018 D33 10 10/07/2018 D34 35 11/07/2018 D35 53 12/07/2018 D36 120 13/07/2018 D37 160 14/07/2018 D38 205 16/07/2018 D40 248 17/07/2018 D41 355 18/07/2018 D42 385 19/07/2018 D43 395 ***Lag phase*** / / ***Baiting*** 23/07/2018 D47 / 24/07/2018 D48 92 25/07/2018 D49 316 26/07/2018 D50 106 27/07/2018 D51 21 28/07/2018 D52 0 29/07/2018 D53 0 30/07/2018 D54 0 01/08/2018 D56 0 ***Lag phase*** / / ***Post-Baiting*** 04/08/2018 D59 / 06/08/2018 D61 0 08/08/2018 D63 0 10/08/2018 D65 0	Guicherd (2018b)

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance	**Test organism(s)**	**Test method, Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		The tracking patches were left in position to be utilised again during the treatment period and the post-treatment census. All tamper-resistant bait stations were located as a function of rat abundance. At the site, the rodent runways, nest areas and sources of food/water were identified. A total of ten tamper-resistant bait stations and five tracking patches were necessary to ensure a global perimeter covering and corresponding to the rodent's area of activity in the test site. They were positioned throughout the test site where a high level of rodent activity existed. In order to evaluate the acceptance of the tamper-resistant bait stations by the Black rats, there were two pre-treatment census phases: The first (from D0, 06 June2018 to D27, 03 JUL 2018) placing oats on wooden trays (approx. 120 x 180) mm with a wooden rim to prevent spillage) and the second phase (from D31, 07 July 2018 to D43, 19 July 2018) placing oats in the tamper-resistant bait stations. The wooden trays and bait station were placed in identical positions. These two pre-census phases were separated by a 4-day lag phase (from 03 July to 07 July 2018) with the sponsor's agreement. Each wooden/tray tamper-resistant bait station was loaded with 100 g of oats and the position of each station included on the site map. These stations were covered or positioned to prevent access by non-target species such as birds. The objective of the two phases was to establish that there was no significant difference in the amount of pre-treatment census diet consumed in both phases. If the take from the second phase was equal to that of the first phase then this would confirm that the Black rats were acclimated to the tamper-resistant bait stations. The consumption of oats was slightly different between the two pre-treatment census phases but most likely due to habituation of Black rats between wooden trays and tamper-resistant bait station. However, this	**Table 2:** Summary of Black rat dead bodies collected in the site along the trial. Trial Phase / Date / Day / Dead Bodies *1st Pre-baiting period*: 06/06/2018 D0 /; 08/06/2018 D2 0; 11/06/2018 D5 0; 13/06/2018 D7 0; 15/06/2018 D9 0; 18/06/2018 D12 0; 19/06/2018 D13 0; 20/06/2018 D14 0; 21/06/2018 D15 0; 22/06/2018 D16 0; 23/06/2018 D17 0; 25/06/2018 D19 0; 26/06/2018 D20 0; 27/06/2018 D21 0; 28/06/2018 D22 0; 29/06/2018 D23 0; 30/06/2018 D24 0; 01/07/2018 D25 0; 02/07/2018 D26 0; 03/07/2018 D27 0 *Lag phase*: / *2nd Pre-baiting period*: 07/07/2018 D31 0; 09/07/2018 D33 0; 10/07/2018 D34 0; 11/07/2018 D35 0; 12/07/2018 D36 0; 13/07/2018 D37 0; 14/07/2018 D38 0; 16/07/2018 D40 0; 17/07/2018 D41 0; 18/07/2018 D42 0; 19/07/2018 D43 0 *Lag phase*: / *Baiting*: 23/07/2018 D47 /; 24/07/2018 D48 0; 25/07/2018 D49 0; 26/07/2018 D50 0; 27/07/2018 D51 1; 28/07/2018 D52 0; 29/07/2018 D53 0; 30/07/2018 D54 0; 01/08/2018 D56 0 *Lag phase*: / *Post-Baiting*: 04/08/2018 D59 /; 06/08/2018 D61 0; 08/08/2018 D63 0; 10/08/2018 D65 0 TOTAL 1	

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
		difference was insufficient to change the test treatment from the tamper-resistant bait stations. Pre-treatment Lag Phase (from 19 to 23 July 2018): The study site was not disturbed for four days to minimise any possible effects of pre- conditioning. No pre-census diet or bait was present. Treatment Census (from D47, 23 July 2018 to D56, 01 August 2018): The Selontra (BAS 410 05 I) rodenticide bait was placed into ten lockable tamper- resistant bait stations, located in the high rodent activity areas. The position of each tamper- resistant bait station was entered on the study site map. The tamper-resistant bait stations were located 5 to 10 metres apart. The tamper-resistant bait stations were positioned where children and non-target animals had very limited access. Any possible contact of the bait with food or waterways was avoided. Five blocks (approximately 100g) of Selontra (BAS 410 05 I) rodenticide bait were placed into each tamper-resistant bait station. The tamper-resistant bait stations were monitored every 2 days or every day in the high consumption period (day 0 of treatment until a clear decreasing of consumption of the bait). If in a tamper-resistant bait station all of the bait was consumed, then the assessments for that bait station were conducted daily rather than every two days. The bait treatment continued until there was no further bait take. During all the study, no moisture or degradation of the bait occurred, indicating that all weighings were representative of a consumption and not a loss or a weight gain due to an outside element. Post-treatment Lag Phase (From 01 to 04 August 2018): Following the removal of the Selontra (BAS 410 05 I) rodenticide bait and tamper-resistant bait stations from the site there was a lag period when no disturbance took place.	**Table 3:** Summary of tracking patch results from pre-treatment to post-treatment in the site. Therefore, SELONTRA (BAS 410 05 I) demonstrated 100% control of the *Rattus rattus* infestation.	

Trial Phase	Date	Day	Tracking Patch 1	Tracking Patch 2	Tracking Patch 3	Tracking Patch 4	Tracking Patch 5	Total score per day
First Pre-baiting	06/06/2018	D0	/	/	/	/	/	/
	08/06/2018	D2	2	3	1	2	2	10
	11/06/2018	D5	3	0	4	4	1	12
	13/06/2018	D7	4	1	0	0	3	8
	15/06/2018	D9	1	0	2	2	4	9
	18/06/2018	D12	2	3	0	2	4	11
	19/06/2018	D13	3	0	4	3	0	10
	20/06/2018	D14	1	2	4	4	0	11
	21/06/2018	D15	0	3	4	0	3	10
	22/06/2018	D16	0	3	1	3	4	11
	23/06/2018	D17	4	1	1	3	2	11
	25/06/2018	D19	2	0	1	1	4	8
	26/06/2018	D20	0	3	1	1	4	9
	27/06/2018	D21	4	0	3	3	4	14
	28/06/2018	D22	3	2	1	2	3	11
	29/06/2018	D23	1	3	3	3	2	12
	30/06/2018	D24	4	3	2	1	0	10
	01/07/2018	D25	3	4	3	0	2	12
	02/07/2018	D26	3	1	2	0	1	7
	03/07/2018	D27	2	3	3	1	3	12
Lag phase			/	/		/	/	/
Second Pre-baiting	07/07/2018	D31	/	/	/	/	/	/
	09/07/2018	D33	2	4	3	0	3	12
	10/07/2018	D34	3	1	3	4	3	14
	11/07/2018	D35	1	3	2	0	2	8
	12/07/2018	D36	2	0	0	4	3	9
	13/07/2018	D37	0	2	2	1	2	7
	14/07/2018	D38	0	2	2	1	1	6
	16/07/2018	D40	1	0	3	3	0	7
	17/07/2018	D41	2	2	3	4	3	14
	18/07/2018	D42	4	0	2	3	1	10
	19/07/2018	D43	3	3	0	1	3	10
Lag phase			/	/	/	/	/	/
Baiting	23/07/2018	D47	/	/	/	/	/	/
	24/07/2018	D48	2	0	1	0	2	5
	25/07/2018	D49	4	1	4	1	3	13
	26/07/2018	D50	0	2	1	1	1	5
	27/07/2018	D51	0	0	0	1	1	2
	28/07/2018	D52	0	0	0	0	0	0
	29/07/2018	D53	0	0	0	0	0	0
	30/07/2018	D54	0	0	0	0	0	0
	01/08/2018	D56	0	0	0	0	0	0
Lag phase								/
Post-Baiting	04/08/2018	D59	0	0	0	0	0	0
	06/08/2018	D61	0	0	0	0	0	0
	08/08/2018	D63	0	0	0	0	0	0
	10/08/2018	D65	0	0	0	0	0	0

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance	**Test organism(s)**	**Test method, Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		Post-treatment Census (from D59, 04 August 2018 to D65, 10 August 2018): Following the completion of the post-treatment lag phase the post-treatment census stations (tamper-resistant bait stations) were re-filled with 100 g of the same reference food (oats) as for the pre-census and returned to their original positions. Census diet take was recorded as in the pre- treatment census. At the same time daily tracking activity was recorded as in the pre-treatment census. Assessments were conducted throughout the duration of the trial at intervals of every 1-4 days. During each assessment the food/bait at each station was weighed and replenished if necessary, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying Black rats around the sites. The efficacy of the treatment was calculated taking into account the pre and post-census diet takes and tracking scores = ((daily intake in pre-baiting plateau – daily intake in post-baiting)/daily intake in pre-baiting plateau) * 100		

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol. Post 36-months storage at ambient conditions (3 years shelf life)	Black or roof rat, (*Rattus rattus*) Wild derived	**Choice feeding cage study (aged bait):** The choice feeding (palatability) test consisted of an acclimatisation period of 7 days, a 3 day pre-census period, a choice feeding test period and a 14 day observation period. The test period continued for 10 days. At the end of the test period, if there were any surviving rats, then a 14 day observation period would follow. Three test pens (each measuring 69 x 60 x 58 cm, L x W x H and consisting of white polypropylene) were connected by stainless-steel tunnels. All pens contained bedding, pen 1 contained a shelter, pen 3 contained the feeding bowls. Control diet and water was available ad libitum throughout the study. Ambient conditions were 21 ± 2°C, relative humidity 55 ± 10%, under a 12h light, 12h dark light cycle. After the 7 days, the pre-census diet was the same control diet presented in the same position as for the acclimatisation period. The diet was weighed to the nearest 0.1g. After 24h, the diet was re-weighed to the nearest 0.1g. The amount of diet ingested was calculated by subtraction, this represents pre-test diet take. The amount of diet ingested was recorded for three consecutive 24h periods. The choice feeding test period followed immediately after the pre-census period. One bowl with test bait was placed in pen 3. It contained 7 soft blocks of Selontra ® rodent bait (BAS 410 05 I) threaded on wire (approximately 140 g) and securely attached to the feed container. As the baiting regime was that of "surplus baiting" any significant bait take was replenished on a daily basis. Another bowl filled with approximately 140 g ground laboratory diet was placed in pen 3 and any significant take was replenished daily. The control diet and the bait were weighed to the nearest 0.l g. After a period of 24h, and every 24 hours for 10 days the control diet and the bait were re-weighed to the nearest 0.l g. The amounts of control diet and bait ingested were calculated by subtraction.	**TABLE 1. Pre-Census Diet Take** Take Pre-Census Diet, g Day / Males / Females 1 / 78.3 / 54.6 2 / 63.4 / 56.6 3 / 76.l / 51.2 **Mean** / **72.6** / **54.1** **TABLE 2. Test Period With Selontra® rodent bait (BAS 410 05 I)** Males: Bait Take, g / Control Take, g / Palatability Ratio Females: Bait Take, g / Control Take, g / Palatability Ratio 1: 39.4 / 50.0 / 0.79 — 33.4 / 19.3 / 1.73 2: 0.4 / 22.0 / n/a — 10.0 / 8.7 / n/a 3: 0.1 / 0.5 / n/a — 0.1 / 2.7 / n/a 4: 0.1 / 4.1 / n/a — 0.1 / 0.3 / n/a 5: 0.0 / 6.6 / n/a — 0.0 / 0.5 / n/a 6: 0.2 / 11.4 / n/a — 0.2 / 0.8 / n/a 7: 0.0 / 16.7 / n/a — - / - / - 8: 0.1 / 16.2 / n/a — - / - / - 9: 0.2 / 17.7 / n/a — - / - / - 10: 0.1 / 16.1 / n/a — - / - / - **TOTAL**: **40.8** / **161.3** / - — **43.8** / **32.3** / - **MEAN**: - / - / **0.79*** — - / - / **1.73*** *One day	[redacted] (2018)

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
		On the first day of the baiting test period, control diet and bait take recordings were used to calculate the corresponding palatability ratio at that point. Palatability Ratio = Day 1. Total Test bait take / Day 1. Control diet take Dead and moribund rats were searched for at least once a day, but not to the extent that the integrity of the trial was compromised. The bodyweight, and were possible sex, at death and days to death were recorded. Any rats exhibiting severe signs of cholecalciferol toxicity, such that death was expected, were culled and recorded as dead on that day. At the end of the 14-day post-treatment observation period, any survivors were sexed, culled and their bodyweight recorded.	**Table 3. Rat mortality** **Day** / **Number of deaths** (Males / Females) 1: 0 / 0 2: 2 / 1 3: 0 / 1 4: 0 / 1 5: 1 / 0 6: 0 / 2 7: 0 / 0 8: 0 / 0 9: 0 / 0 10: 0 / 0 11: 1 / 0 **Total Deaths**: 4 / 5 **Total Survivors**: **1** / **0** **Mean days to death**: **5.0** / **4.2** **Range days to death**: **2-11** / **2-6** Table 4. Bodyweights of dead/culled rats **Bodyweights (g)** / **Number of deaths** (Males / Females) 60-79.9: 0 / 2 80-99.9: 1 / 2 100-119.9: 1 / 2 120-139.9: 1 / 0 140-159.9: 0 / 0 160-179.9: 0 / 2 180-199.9: 1 / 0 200-219.9: 0 / 0 ≥220: 0 / 0 **TOTAL**: **4** / **5** Selontra® rodent bait (BAS 410 05 I) achieved 90% mortality by Day 24, including a two-week post treatment observation period. The only surviving rat exhibited symptoms of cholecalciferol toxicity. The test indicated that the Selontra® rodent bait (BAS 410 05 I) post 36-months storage at ambient conditions is a palatable and efficacious rodenticide formulation against *Rattus rattus*. The stored bait should be well accepted in the field by *Rattus rattus*.	

Efficacy against *Mus musculus* (house mouse)

12 efficacy studies are provided for Selontra® against *M. musculus* (6 choice tests (of which 2 are on aged bait) and 5 field tests) which are summarised below. Laboratory studies were conducted with laboratory strains and wild strains. Of the lab trials, 3 trials were conducted with an anticoagulant resistant strain (bromadiolone resistant).

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol	House mouse, (*Mus domesticus*) Wild derived (resistance status unknown)	**Choice feeding cage study (surplus baiting method):** The pen contained bedding, harbourages with food (control diet) and water available *ad libitum*, for the study period. Standard laboratory (control) diet, presented in a single container in centre of pen. The test consisted of four phases; (a) A 1 month acclimatisation period, where control diet was presented in the pen. (b) A 3 day pre-census period, where the control diet, plus container (approx. 2kg) was accurately weighed to the nearest 1g. After each 24 hours the container was re-weighed (to the nearest 1g) The amount of diet ingested was calculated by subtraction (representing the 'pre-test diet take'). (c) A choice feeding test period (up to a period of 7 days, with zero bait take or 100% mortality, whichever was the sooner). Four test bait points, along pen walls, each consisting 3 soft blocks (approx. 51g per bait point) secured on an aluminium tray. Any bait take replenished daily. Control diet remained in centre of pen, weighed daily as for the census period. Amount of control diet and bait ingested calculated, mice observed. Day 1, control diet and bait take weights used to calculate the palatability ratio (PR) for day 1. $PR = \frac{\text{Total TB}}{\text{Total CD}}$ PR = palatability ratio, TB = consumption of test bait (g), CD = consumption of control diet (g) Dead mice searched for daily. Body weight at death, days to death and sex were recorded.	**Pre-Census (control) diet take** **Day** / **Pre-Census diet take (g)** 1: 86 2: 115 3: 121 **Mean**: **107** Mean test take = 107g, range 86-121g (approx. 2mice, based on 5g/mouse intake) **Choice feeding test period using soft block bait (BAS 410 05 I), take (g)** **Day** / **Daily bait take (g)** T1 T2 T3 T4 / **Total bait take (g)** / **Control diet take (g)** / **Palatability Ratio** 1: 22 26 30 29	107	2	53.5 2: 11 8 6 10	35	15 | 3: 0 0 0 0	0	7 | 4: 0 0 0 0	0	4 | 5: 0 0 0 0	0	0 | **Total**: **33 34 36 39**	**142**	**28** | **Mouse mortality** **Day** / **No. of deaths** 1: 0 2: 1 3: 15 4: 9 5: 3 Total deaths = 28, Survivors = 0, Mean days to death = 3.5 (range 2-5 days)	[redacted] (2013e)

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
		(d) A 10 day post-test observation period. Any survivors were sexed, culled and weighed. NOTE: An estimation of size of the population was calculated (21 individuals), assuming mice ingest 5g diet per day. Following test, 28 dead bodies were found – 4 male, 24 female, mixed age	**Body weight of culled/dead mice** **Body weight (g) / No. Male mice / No. Female mice** 5-9: 0 / 0 10-12: 0 / 2 13-15: 2 / 1 16-18: 0 / 5 19-21: 2 / 11 22-24: 0 / 0 25-27: 0 / 4 28-30: 0 / 1 **Total: 4 / 24**	

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol	House mouse, (*Mus domesticus*) Wild derived (resistance status unknown)	**Choice feeding cage study (surplus baiting method):** The pen contained bedding, harbourages with food (control diet) and water available *ad libitum*, for the study period. Standard laboratory (control) diet, presented in a single container in centre of pen. The test consisted of four phases; (a) A 1 month acclimatisation period, where control diet was presented in the pen. (b) A 3 day pre-census period, where the control diet, plus container (approx. 2kg) was accurately weighed to the nearest 1g. After each 24 hours the container was re-weighed (to the nearest 1g) The amount of diet ingested was calculated by subtraction (representing the 'pre-test diet take'). (c) A choice feeding test period (up to a period of 7 days, with zero bait take or 100% mortality, whichever was the sooner). Four test bait points, along pen walls, each consisting 3 soft blocks (approx. 51g per bait point) secured on an aluminium tray. Any bait take replenished daily. Control diet remained in centre of pen, weighed daily as for the census period. Amount of control diet and bait ingested calculated, mice observed. Day 1, control diet and bait take weights used to calculate the palatability ratio (PR) for day 1. $PR = \frac{\text{Total TB}}{\text{Total CD}}$ PR = palatability ratio, TB = consumption of test bait (g), CD = consumption of control diet (g) Dead mice searched for daily. Body weight at death, days to death and sex were recorded. (d) A 10 day post-test observation period. Any survivors were sexed, culled and weighed. NOTE: An estimation of size of the population was calculated (38 individuals), assuming mice ingest 5g diet per day. Following test, 43 dead bodies were found – 19 male, 24 female, mixed age.	**Pre-Census (control) diet take** **Day** / **Pre-Census diet take (g)** 1: 177 2: 215 3: 176 **Mean**: **189** Mean test take = 189g, range 176-215g (approx. 38mice, based on 5g/mouse intake) **Choice feeding test period using soft block bait (BAS 410 05 I), take (g)** **Day** / **Daily bait take (g)** T1 T2 T3 T4 / **Total bait take (g)** / **Control diet take (g)** / **Palatability Ratio** 1: 41 55 50 48 — 194 — 12 — 16.1 2: 3 5 15 21 — 44 — 27 — 3: 0 1 1 1 — 3 — 18 — 4: 10 0 0 0 — 10 — 8 — 5: 0 0 0 0 — 0 — 0 — **Total**: **54** **61** **66** **70** — **251** — **68** — **Mouse mortality** **Day** / **No. of deaths** 1: 0 2: 0 3: 31 4: 6 5: 6 Total deaths = 43, Survivors = 0, Mean days to death = 3.4 (range 2-5 days) **Body weight of dead mice** **Body weight (g)** / **No. Male mice** / **No. Female mice** 5-9: 0 — 0 10-12: 0 — 0 13-15: 2 — 2 16-18: 12 — 9 19-21: 4 — 3 22-24: 1 — 5 25-27: 0 — 1 28-30: 0 — 2 31+: 0 — 2 **Total**: **19** — **24**	[redacted] (2013f)

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol.	House mouse, (*Mus domesticus*) CD1 strain (anticoagulant susceptible)	**4-Day Choice feeding cage study:** Study conditions: 10 male and, 10 female mice (20-30g body weight) were weighed and individually caged in polypropylene cages 30cm(l) x 20cm(w) x 20cm(h) with stainless steel wire mesh lids and bases over a tray containing a paper liner. There was a 3-day acclimatisation period prior to testing where ground laboratory (control) diet was presented in two identical feeding dishes (placed symmetrically in the cage) plus tap water provided *ad libitum*. 24 hours prior to test baiting, the feed dishes were replaced with two identical dishes each containing 25g of control diet. Consumption of the control diet was recorded to the nearest 0.1g (the "pre-test diet intake") and statistical analysis (unpaired T-test – p=0.05) conducted to establish if there was a significant difference between the positions of feed dishes. A 4-day test period followed; 25g each of the bait treatment and the control diet were placed in the separate feed dishes (position rotated each day). After each 24 hour period, spillages were retrieved, returned to the dish and any extraneous matter removed. The feed dishes were weighed to provide a value for each 24 hour bait/control diet take. Test bait and control diet were replaced daily. Mice were observed daily. Tap water was provided *ad libitum* during the study period. A 10 day post baiting observation period followed, where control diet and tap water were provided *ad libitum*. After the 4 day choice feeding period, the daily test bait and control diet takes were summed and a palatability ratio calculated. $PR = \frac{\text{Total TB}}{\text{Total CD}}$ PR = palatability ratio, TB = consumption of test bait (g), CD = consumption of control diet (g).	**Bait and control diet uptake during 4-day choice test (male mice)** **No. / Body wt (g) Initial / Total Test take (g) / Total Control take (g) / PR (T/C) / Body wt (g) Day 4 / Body wt (g) Final / Days to death** 1 / 27.0 / 2.1 / 23.0 / 0.09 / 27.8 / 24.5 / 5 2 / 25.4 / 0.0 / 24.0 / 0.00 / 24.8 / 29.0 / - 3 / 27.4 / 2.1 / 14.0 / 0.15 /	22.1 / 3 4 / 24.1 / 2.0 / 14.2 / 0.14 / 19.7 / 19.7 / 4 5 / 25.3 / 3.2 / 12.7 / 0.25 /	22.6 / 3 6 / 28.3 / 3.0 / 4.7 / 0.64 /	22.2 / 3 7 / 25.3 / 2.1 / 11.6 / 0.18 /	21.6 / 3 8 / 27.8 / 2.0 / 2.7 / 0.74 /	22.0 / 3 9 / 25.7 / 2.2 / 11.2 / 0.20 /	23.2 / 3 10 / 26.2 / 3.1 / 11.4 / 0.27 /	23.3 / 3 **Total / - / 21.8 / 129.5 / 2.66 / 72.3 / - / -** **Mean / 26.3 / 2.2 / 13.0 / 0.27 / 24.1 / 23.0 / 3.3** Total test take (g) = 21.8, Total control take (g) = 129.5, Palatability Ratio (T/C) = 0.17 (range 0.00-0.74), % Acceptance = 14.4, Mean mg/kg body weight ingested = 62.2 (range 0.0-94.5), Total deaths = 9, Mean days to death = 3.3 (range 3-5). **Bait and control diet uptake during 4-day choice test (female mice)** **No. / Body wt (g) Initial / Total Test take (g) / Total Control take (g) / PR (T/C) / Body wt (g) Day 4 / Body wt (g) Final / Days to death** 1 / 24.2 / 2.1 / 7.2 / 0.29 /	19.9 / 3 2 / 25.0 / 2.7 / 6.5 / 0.42 /	20.8 / 3 3 / 25.6 / 2.1 / 19.4 / 0.11 / 22.7 / 22.5 / 4 4 / 24.0 / 2.1 / 11.0 / 0.19 / 19.6 / 19.6 / 4 5 / 24.7 / 3.3 / 7.0 / 0.47 /	21.0 / 2 6 / 24.0 / 2.6 / 11.5 / 0.23 /	20.3 / 3 7 / 23.3 / 2.6 / 8.6 / 0.30 / 18.2 / 17.2 / 5 8 / 23.0 / 2.1 / 3.9 / 0.54 /	17.3 / 3 9 / 23.4 / 2.1 / 7.1 / 0.30 /	18.1 / 3 10 / 26.1 / 3.1 / 15.1 / 0.21 / 24.6 / 24.6 / 4 **Total / - / 24.8 / 97.3 / 3.05 / 85.1 / - / -** **Mean / 24.3 / 2.5 / 9.7 / 0.30 / 21.3 / 20.1 / 3.4** Total test take (g) = 24.8, Total control take (g) = 97.3, Palatability Ratio (T/C) = 0.25 (range 0.11-0.54), % Acceptance = 20.3, Mean mg/kg body weight ingested = 76.3 (range 61-5-100.2), Total deaths = 10, Mean days to death = 3.4 (range 2-5).	[redacted] (2013g)

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol	House mouse, (*Mus domesticus*) Wild derived (Bromadiolone resistant strain (Y139C))	**Choice feeding cage study:** Choice feeding pen study (surplus baiting method): The pen contained bedding, harbourages with food (control diet) and water available *ad libitum*, for the study period. Standard laboratory (control) diet, presented in a single container in centre of pen. The test consisted of four phases; (a) A 1 month acclimatisation period, where control diet was presented in the pen. (b) A 3 day pre-census period, where the control diet, plus container (approx. 2kg) was accurately weighed to the nearest 1g. After each 24 hours the container was re-weighed (to the nearest 1g) The amount of diet ingested was calculated by subtraction (representing the 'pre-test diet take'). (c) A choice feeding test period (up to a period of 7 days, with zero bait take or 100% mortality, whichever was the sooner). Four test bait points, along pen walls, each consisting 3 soft blocks (approx. 51g per bait point) secured on an aluminium tray. Any bait take replenished daily. Control diet remained in centre of pen, weighed daily as for the census period. Amount of control diet and bait ingested calculated, mice observed. Day 1, control diet and bait take weights used to calculate the palatability ratio (PR) for day 1. $PR = \frac{\text{Total TB}}{\text{Total CD}}$ PR = palatability ratio, TB = consumption of test bait (g), CD = consumption of control diet (g) Dead mice searched for daily. Body weight at death, days to death and sex were recorded. (d) A 10-day post-test observation period. Any survivors were sexed, culled and weighed.	**Pre-Census (control) diet take** Day / Pre-Census diet take (g) 1 / 135 2 / 157 3 / 177 Mean / 156 Mean test take = 156g, range 135-177g (approx. 31 mice, based on 5g/mouse intake) **Choice feeding test period using soft block bait (BAS 410 05 I), take (g)** **Day** / **Daily bait take (g)** T1 / T2 / T3 / T4 / **Total bait take** / **Control diet take** / **Palatability Ratio** 1 / 39 / 19 / 37 / 30 / 125g / 5g / 24.9 2 / 8 / 11 / 7 / 17 / 43g / 24g / 3 / 0 / 0 / 0 / 0 / 0g / 13g / 4 / 0 / 0 / 0 / 0 / 0g / 8g / Total / 47 / 30 / 44 / 47 / 168g / 50g / **Mouse mortality** **Day** / **No. of deaths** 1 / 0 2 / 0 3 / 23 4 / 10 Total deaths = 33, Survivors = 0, Mean days to death = 3.3 (range 2-4 days)	[redacted] (2013d)

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
		NOTE: An estimation of size of the population was calculated (31 individuals), assuming mice ingest 5g diet per day. Following test, 33 dead bodies were found – 12 male, 21 female, mixed age.	**Body weight of culled/dead mice**	

Body weight (g)	No. Male mice	No. Female mice
5-9	0	0
10-12	0	1
13-15	1	4
16-18	1	3
19-21	4	6
22-24	4	3
25-27	2	1
28-30	0	1
31+	0	2
Total	**12**	**21**

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol.	House mouse, (*Mus musculus domesticus*) Wild population located on a pig farm, Warendorf district, Germany. (resistance status unknown)	**Field trial:** Study conditions: Ambient (as encountered in and around agricultural buildings in January-March). The field trial was conducted in and around pig farm buildings. 34 census feed points (bait stations) [34 bait points – different locations to census points] (at 1-2m distance) and 20 tracking patches (10 x 10 cm covered in silver sand) were distributed in the trial area. The field test was conducted in four phases: (a) Implementation of trial: Assessing infestation, based on droppings, mouse damage, feeding and footprints. Locations of census points, tracking patches and bait points were marked on a site map. (b) Pre-treatment census (4 days; 7 day gap): Census feed points/tracking patches were positioned. For 4 days, whole wheat was placed in each of the 34 census diet trays and tracking patches freshly coated. Every day, the residual census feed take at each census point was measured and the feed replenished as necessary. Tracking activity was monitored, marks on tracking patches were recorded to provide an index, using the following scale: 0 = no tracks, 1 = 1-5 footprints, 2 = 6 footprints to 25% of the patch tracked, 3 = 25% to 95% of the patch tracked, 4 = greater than 95% of the patch tracked. Tracking patches were left in the same positions during treatment and post treatment census. At the end of census, all feed points were removed and a 7-day 'lag' period followed prior to baiting. (c) Treatment period (21 days; 7 day gap post treatment): The treatment was carried out using the soft block bait (BAS 410 05 I). The 34 bait boxes were filled with approx. 40g of treated bait (2 soft blocks) placed approx. 1-2m apart. Quantities consumed were recorded every 24 hours for the first 4 days, then 2-3 times per week for the remainder of the test period, replenished as necessary. At each visit, tracking patches were assessed and re-coated, plus searches for dead mice and non-targets. At the end of the treatment period, all bait was removed and tracking patches evaluated to provide an activity index. A 7-day lag period followed before post-census baiting began.	**Survival rates of mice: based on feed, sensor & tracking census** ***census day*** / ***1*** / ***2*** / ***3*** / ***4*** / ***Total*** ***census feed uptake (34 bait points)*** Pre-baiting (g): 250 / 315 / 317 / 311 / 1193 Post-baiting (g): 26 / 21 / 27 / 26 / 100 **% survival rate (*feed uptake*)**: **10** / **7** / **9** / **8** / **8** ***tracking activity (20 tracking patches)*** Pre-baiting (activity index): 56 / 55 / 56 / 55 / 222 Post-baiting (activity index): 7 / 6 / 8 / 7 / 28 **% survival rate (*activity*)**: **13** / **11** / **14** / **13** / **13** **Consumption (g) during baiting phase & number of dead mice in test area** **Day of trial**: **1** / **2** / **3** / **4** / **6** / **8** / **11** / **13** / **16** / **18** / **21** / **Total** **Uptake (g)**: 46 / 78 / 81 / 39 / 35 / 30 / 29 / 46 / 21 / 8 / 16 / **429g** **Uptake/24hr (g)**: 46 / 78 / 81 / 39 / 18 / 15 / 10 / 23 / 7 / 4 / 5 / **-** **dead mice**: 0 / 0 / 0 / 1 / 2 / 2 / 0 / 2 / 3 / 0 / 0 / **10** **Number of bait points with feeding activity during baiting phase** **Day of trial**: **1** / **2** / **3** / **4** / **6** / **8** / **11** / **13** / **16** / **18** / **21** **Feed sites**: 6 / 12 / 7 / 6 / 6 / 5 / 3 / 4 / 2 / 3 / 5 **No. empty bait points**: 0 / 0 / 0 / 0 / 0 / 0 / 0 / 0 / 0 / 0 / 0 **Total No. of bait points**: 34 / 34 / 34 / 34 / 34 / 34 / 34 / 34 / 34 / 34 / 34 **Tracking activity during the baiting period** **Day of trial**: **1** / **2** / **3** / **4** / **6** / **8** / **11** / **13** / **16** / **18** / **21** **Activity index (sum)***: 42 / 39 / 37 / 27 / 23 / 18 / 17 / 13 / 9 / 8 / 7 *based on 20 tracking patches	Klemann, N. (2013a)

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance	**Test organism(s)**	**Test method, Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		(d) Post-treatment census period (4 days): Seven days after the treated bait was removed, the 34 census diet trays were placed in their original positions, filled with whole wheat and feeding/tracking activities monitored. At the end of day 4, all census feed was removed.		

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

<table>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test method, Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr>
<td>Selontra®
A soft block paste bait containing 750ppm cholecalciferol.</td>
<td>House mouse, (Mus musculus domesticus)

Wild population located at a storage unit facility in Oswestry, Shropshire (UK)

(resistance status unknown)</td>
<td>Field trial:

(a) Pre-trial survey: Assessing the infestation, based on holes, droppings, damage, feeding and footprints. Locations of census diet, tracking patches and bait points were then marked on a sketch of the site.

(b) Pre-treatment census: Wooden bait trays and tracking patches lightly coated with horticultural silver sand were placed in position following the pre-trial survey. At the same time, provisional positions for the 750ppm Cholecalciferol Soft Block bait placements were evaluated. At no time were census diets, tracking patches or 750ppm Cholecalciferol Soft Block bait placements located on the same spot as each other, though for practical reasons their position sometimes had to be close together in protected places where there were signs of mouse activity.

Four days later, 30g of whole wheat was placed on each census diet tray, and tracking patches freshly coated in silver sand. On each of the following 4 days, the residual wheat in each tray was inspected, weighed to the nearest 1.0g on a portable electronic balance and, where measurable take had occurred, replenished to an amount sufficient to provide surplus until the next visit 24 hours later. The amount of whole wheat taken by the mice was recorded along with a visual presence of a complete (C), partial (P) or no (N) take. Marks on the tracking patches were recorded to provide an index, using the following scale: 0 = no tracks, 1 = 1-5 footprints, 2 = 6 footprints to 25% of the patch tracked, 3 = 25% to 95% of the patch tracked, 4 = greater than 95% of the patch tracked. The tracking patches were left in the same positions for use during treatment and the post treatment census. At the end of the census all diet trays were removed.

(c) Pre-treatment lag period: The pre-treatment census was followed by a pre-treatment lag period. The duration of this period was 10 days. During this period no census diet or bait was available on site and no observations were made on the infestations. The site was visited on day 7 of the lag period to lay treatment bait trays, in their pre identified locations, for the 750ppm Cholecalciferol Soft Block bait</td>
<td>
Table 1: Pre-Treatment Census results
<table>
<tr><th rowspan="2">Day</th><th>Pre-census diet</th><th>Tracking indices</th></tr>
<tr><th>Diet take (g)</th><th>Score</th></tr>
<tr><td>1</td><td>88</td><td>96</td></tr>
<tr><td>2</td><td>88</td><td>83</td></tr>
<tr><td>3</td><td>93</td><td>89</td></tr>
<tr><td>4</td><td>94</td><td>92</td></tr>
<tr><td>Total</td><td>363</td><td>360</td></tr>
<tr><td>Mean</td><td>91</td><td>90</td></tr>
</table>
Table 2: Treatment results
<table>
<tr><th rowspan="2">Day</th><th>Treatment bait</th><th>Tracking indices</th></tr>
<tr><th>Bait take (g)</th><th>Score</th></tr>
<tr><td>1</td><td>22</td><td>103</td></tr>
<tr><td>2</td><td>82</td><td>40</td></tr>
<tr><td>3</td><td>29</td><td>20</td></tr>
<tr><td>4</td><td>0</td><td>0</td></tr>
<tr><td>5</td><td>0</td><td>7</td></tr>
<tr><td>6</td><td>2</td><td>5</td></tr>
<tr><td>7</td><td>0</td><td>3</td></tr>
<tr><td>Total</td><td>135</td><td>178</td></tr>
<tr><td>Mean</td><td>19</td><td>25</td></tr>
</table>
Table 3: Post-Treatment Census results
<table>
<tr><th rowspan="2">Day</th><th>Post-census diet</th><th>Tracking indices</th></tr>
<tr><th>Diet take (g)</th><th>Score</th></tr>
<tr><td>1</td><td>0</td><td>0</td></tr>
<tr><td>2</td><td>0</td><td>2</td></tr>
<tr><td>3</td><td>0</td><td>3</td></tr>
<tr><td>4</td><td>0</td><td>0</td></tr>
<tr><td>Total</td><td>0</td><td>5</td></tr>
<tr><td>Mean</td><td>0</td><td>1</td></tr>
</table>
</td>
<td>Hughes, C.S. (2014b)</td>
</tr>
</table>

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
		(d) Treatment period (7 days; 7 day gap post treatment). The treatment was carried out on 750ppm Cholecalciferol Soft Block rodenticide bait using a conventional surplus baiting technique. The bait trays, each containing approximately 35g of the bait, were laid in protected situations sited strategically ca. 1 - 2 m apart throughout the infested areas. A total of 53 bait points were laid at the site. The following days the baits were checked visually for takes, weighed to the nearest 1.0g, and replenished to an amount sufficient to avoid any subsequent complete bait takes. Similar observations and recordings were made for 7 days, with no more than 72 hours between visits. After the day 7 recordings the bait trays and bait were removed from the site. At each visit during the treatment period activity on the tracking patches was recorded and each freshly coated with tracking powder, as during the pre-treatment census. Searches for any non-target animals were also made at each visit. (e) Post-treatment Lag Period: The treatment period was followed by a 7 day lag period to enable any remaining mice a reasonable time in which to die, or recover, from any dose of rodenticide they may have ingested before beginning the post-treatment census (f) Post-treatment census period. The census diet trays were placed in their original positions. The post-treatment census was conducted in exactly the same way as the pre-treatment census.	**Table 4:** Estimates of population reduction achieved with 750ppm Cholecalciferol soft block rodenticide bait (BAS 410 05 I) **Total bait take (g)** / **Percent reduction in population** / **Diet census take** / **Tracking indices score** Day 4 | Day 1-4 | Day 4 | Day 1-4 135 | 100% | 100% | 99% | 99% % reduction = (pre-treatment index– mean post treatment index) x 100/pre-treatment index	

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol.	House mouse, (*Mus musculus domesticus*) Wild population located in a farm in Oswestry, Shropshire (UK) (resistance status unknown)	**Field trial:** The field test was conducted in five phases: (a) Pre-trial survey: Assessing the infestation, based on holes, droppings, damage, feeding and footprints. Locations of census diet, tracking patches and bait points were then marked on a sketch of the site. (b) Pre-treatment census: Wooden bait trays (75 x 90mm) and tracking patches (ca. 100 x 200 mm) lightly coated with horticultural silver sand were placed in position following the pre-trial survey. At the same time, provisional positions for the 750ppm Cholecalciferol Soft Block bait placements were evaluated. At no time were census diets, tracking patches or 750ppm Cholecalciferol Soft Block bait placements located on the same spot as each other, though for practical reasons their position sometimes had to be close together in protected places where signs of mouse activity were. Four days later, 30g of whole wheat was placed on each of the census diet trays, and tracking patches freshly coated in silver sand. On each of the following 4 days, the residual wheat in each tray was inspected, weighed to the nearest 1.0g on a portable electronic balance and, where measurable take had occurred, replenished to an amount sufficient to provide surplus until the next visit 24 hours later. The amount of whole wheat taken by the mice was recorded along with a visual presence of a complete (C), partial (P) or no (N) take. Marks on the tracking patches were recorded to provide an index, using the following scale: 0 = no tracks, 1 = 1-5 footprints, 2 = 6 footprints to 25% of the patch tracked, 3 = 25% to 95% of the patch tracked, 4 = greater than 95% of the patch tracked. The tracking patches were left in the same positions for use during treatment and the post treatment census. At the end of the census all diet trays were removed. (c) Pre-treatment lag period: The pre-treatment census was followed by a pre-treatment lag period. The duration of this period was 10 days. During this period no census diet or bait was available on site and no observations were made on the infestations. The site was visited on day 7 of the lag period to lay treatment	**Table 1:** Pre-Treatment Census results **Day** | **Pre-census diet** (**Diet take (g)**) | **Tracking indices** (**Score**) 1: 99 / 40 2: 121 / 53 3: 115 / 49 4: 145 / 59 Total: 480 / 201 **Mean: 120 / 50** **Table 2:** Treatment results **Day** | **Treatment bait** (**Bait take (g)**) | **Tracking indices** (**Score**) 1: 135 / 80 2: 20 / 4 3: 27 / 7 4: 0 / 0 5: 10 / 5 6: 0 / 0 7: 4 / 2 Total: 196 / 98 **Mean: 28 / 14** **Table 3:** Post-Treatment Census results **Day** | **Post-census diet** (**Diet take (g)**) | **Tracking indices** (**Score**) 1: 10 / 5 2: 6 / 7 3: 9 / 3 4: 11 / 4 Total: 39 / 19 **Mean: 9 / 5**	Hughes, C.S. (2014c)

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
		bait trays, in their pre identified locations, for the 750ppm Cholecalciferol Soft Block bait. (d) Treatment period (7 days; 7 day gap post treatment). The treatment was carried out on 750ppm Cholecalciferol Soft Block rodenticide bait (BAS 410 05 I) using a conventional surplus baiting technique. The bait trays, each containing approximately 35g of the bait, were laid in protected situations sited strategically ca. 1 - 2 m apart throughout the infested areas. A total of 53 bait points were laid at the site. The following days the baits were checked visually for takes, weighed to the nearest 1.0g, and replenished to an amount sufficient to avoid any subsequent complete bait takes. Similar observations and recordings were made for 7 days, with no more than 72hours between visits. After the day 7 recordings the bait trays and bait were removed from the site. At each visit during the treatment period activity on the tracking patches was recorded and each freshly coated with tracking powder, as during the pre-treatment census. Searches for any non-target animals were also made at each visit. (e) Post-treatment Lag Period: The treatment period was followed by a 7 day lag period to enable any remaining mice a reasonable time in which to die, or recover, from any dose of rodenticide they may have ingested before beginning the post-treatment census. (f) Post-treatment census period. The census diet trays were placed in their original positions. The post-treatment census was conducted in exactly the same way as the pre-treatment census.	**Table 4:** Estimates of population reduction achieved with 750ppm Cholecalciferol soft block rodenticide bait (BAS 410 05 I) **Total bait take** / **Percent reduction in population** **Diet census take**: Day 4: 94%; Day 1-4: 93% **Tracking indices score**: Day 4: 93%; Day 1-4: 92% (196g) % reduction = (pre-treatment index– mean post treatment index) x 100/pre-treatment index	

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol.	House mouse, (*Mus musculus domesticus*) Wild population located in a farm in Oswestry, Shropshire, UK. (resistance status unknown)	**Field trial:** The field trial used the reduced replenishment baiting regime with the conventional surplus baiting technique for the control of the target organism *Mus domesticus*. The field test was conducted in a series of phases: a pre-trial survey, Pre-treatment census, a 10 d pre-treatment lag period, 9 day treatment period followed by a 7 day post lag period and final post treatment census. (a) Pre-trial survey: The trial site was systematically surveyed for evidence of infestation, such as holes, droppings, footprints, and signs of damage or feeding. Mice that were observed were visually identified as *Mus domesticus.* Sketch plans of the site were prepared on which the positions of the census diet and tracking patches and bait points were marked. (b) Pre-treatment census: Wooden bait trays (75 x 90 mm) and tracking patches (approximately 100 x 100 mm) lightly coated with horticultural silver sand were placed in position following the pre-trial survey. At the same time, provisional positions for the 750 ppm cholecalciferol soft block bait placements were evaluated. At no time were census diets, tracking patches or 750 ppm Cholecalciferol soft block bait placements located on the same spot as each other, though for practical reasons their positions sometimes had to be close together in protected places where there were signs of mouse activity. Four days later, 30 g of whole wheat was placed on each census diet tray, and the tracking patches were freshly coated. On each of the following four days the residual wheat in each tray was inspected, weighed to the nearest 1.0g on a portable electronic balance and, where a measurable intake had occurred, replenished to an amount sufficient to provide a surplus until the next visit, 24 h later. The amount taken by the mice was recorded and also a visual observation of the presence of a complete, partial or no take ("C", "P", "N", respectively). Marks on the tracking patches were recorded on an arbitrary scale, erased, and the patches re-coated. The scale was as follows: 0= no tracks 1= from 1 to 5 footprints	**Table 1A:** Pre-treatment Census results **Pre-Census Diet** / **Tracking Indices** **Day** / Diet Take, g / Score 1 / 277 / 69 2 / 210 / 65 3 / 256 / 61 4 / 271 / 67 **TOTAL** / **1014** / **262** **MEAN** / **254** / **66** **Table 1B:** Treatment Results **Treatment Bait** Day / Bait Take, g 1 -7 / 237 8 -9 / 0 **TOTAL** / **237** **MEAN PER DAY** / **26** **Table 1C:** Post-treatment Census Results **Post Census Diet** / **Tracking Indices** **Day** / Diet Take, g / Score 1 / 0 / 0 2 / 0 / 0 3 / 9 / 0 4 / 13 / 0 **TOTAL** / **22** / **0** **MEAN** / **6** / 0 **Table 2:** Estimates of population reduction achieved with Selontra Rodenticide Bait Using the reduced replenishment Baiting regime **Percentage Reduction in Population** **Total Bait Take, (g)** / **Diet Census Take** / **Tracking Indices score** Day 4 / Day 1 -4 / Day 4 / Day 1 -4 **237** / **98** / **98** / **100** / **100** Percent reduction = (pre-treatment index - mean post-treatment index) x 100/pre-treatment index	Hughes, C.S. (2014d)

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance	**Test organism(s)**	**Test method, Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		2=from 6 footprints to 25% of the patch tracked 3= from 25% to 95% of the patch tracked 4= more than 95% of the patch covered with tracks The tracking patches were left in position to be utilised again during the 750 ppm cholecalciferol soft block bait treatment and the post-treatment census. The pre-census results indicated the presence of what is considered to be a medium level of infestation in a rural agricultural environment. (c) Pre-treatment Lag period: The pre-treatment census was followed by a pre-treatment lag period. The duration of this lag period was 10 days. During this period no census diet or bait was available on site and no observations were made on the infestations. The site was visited on Day 7 of the lag period to lay treatment bait trays, in their pre identified locations, for the 750 ppm cholecalciferol soft block bait. (d) Treatment Period: Selontra Bait, using the reduced replenishment baiting regime with the conventional surplus baiting technique. Mouse bait boxes, each containing approximately 35-40 g (2 soft blocks) of the bait, were laid in protected situations sited strategically approximately 1-2 m apart throughout the infested areas. A total of 57 bait points were laid at the site, giving total bait laid out of approximately 2.2 Kg. The site was visited frequently with no more than 72 hours between replenishment and the baits were checked visually for takes at each visit. For the purpose of this trial bait takes were not recorded and bait was not replenished until Day 8 when the bait was then replenished to the original amount laid (2 soft blocks per bait point). After the Day 9 recordings the bait boxes and bait were removed from the site. Tracking scores were not recorded during the treatment period. Searches for any non-target animals were made at each visit. (e) Post-treatment Lag Period: The treatment period was followed by a 7 day lag period to enable any remaining mice a reasonable time in which to die, or recover, from any dose of rodenticide they may have ingested before beginning the post-treatment census.		

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance	**Test organism(s)**	**Test method, Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		(f) Post-treatment Census: The census diet trays were returned to their original positions. The post-treatment census was conducted in exactly the same way as the pre-treatment census.		

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol.	House mouse, (*Mus musculus*) Wild population in a hotel in London, UK. (resistance status unknown)	**Field trial:** The site was an historic hotel in London, a large structure (spread over 100,000 sq. feet) The basement has a solid concrete floor with large numbers of cables carried in cable runs at ceiling level. On the ground floor where most of the mice were being seen, gaps around the service pipes to the old metal radiators were found leading into the floor voids. These locations have also been carpeted, making further inspections difficult. Just inside the entrance on the ground floor is a substantial void which is purported to be the location of the underground 'secret' tunnel. **Pre-trial survey:** It was decided to focus the study to two distinct and manageable areas, both with 'natural' boundaries such as open corridors or solid wall structures. The trial site was systematically surveyed for evidence of infestation, such as holes, droppings, footprints, and signs of damage or feeding. Rodents that were observed were visually identified as *Mus musculus*. At the time of the trial starting, whilst mice remained an issue on the ground floor of the hotel, there was an 'influx' of rat activity in the basement plant room and behind the contractors lift shaft. Mice were still active in periphery locations to the edge of the immediate vicinity where the rats were present; which is typical mouse behaviour as they are intimidated by rats and do not cohabit with them. The only movement detected for much of the basement in the early stages of the trial was rats. **Pre-treatment census:** The pre and post baiting monitoring was carried out using peanuts (determined by pre-treatment census baiting using different foodstuffs), all food and bait was presented to the mice in plastic trays. A total of 31 pre-census points were used each containing 50 g of the pre-census diet. After 24 hours and on each of the following three days the residual census diet in each tray was inspected, weighed to the nearest 1.0 g on a portable electronic balance and, where a measurable take had occurred, replenished.	Selontra® rodent bait, BAS 410 05 I, treatment resulted in a significant reduction of mouse activity by day 17 of the treatment period. All the indices of treatment success based on the census diet and tracking data indicate 98 - 100% control. There was also a 100% reduction in the small isolated rat infestation. Therefore, the results show that in an urban area, against *Mus musculus*, exhibiting neophobic behaviour, Selontra® rodent bait is an efficacious rodenticide bait. **TABLE 1**. Central London: Summary Of Results Using Selontra®, BAS 410 05 I **1A.** Pre-Treatment Census **Day** | **Total Pre-Census Diet Take, g** | **Total Pre-Census Tracking Score** 1 | 11 | 18 2 | 10 | 15 3 | 21 | 26 4 | 32 | 25 **Total** | **74** | **84** **Mean** | **19** | **21** **1B.** Treatment **Day** | **Total Treatment Bait Take, g** | **Total Treatment Tracking Score** 1 | 100* | 23# 2 | 44** | 21## 3 -8 | 24*** | 23### 9 - 15 | 1 | 2 16 - 17 | 0 | 0 **Total** | **169** | **69** * 89 g was consumed from the rat bait points # rat tracking score was 8 ** 11 g was consumed from the rat bait points ## rat tracking score was 9*** 15 g was consumed from the rat bait points ### rat tracking score was 5 **1C.** Post – Treatment Census **Day** | **Total Post-Census Diet Take, g** | **Total Post-Census Tracking Score** 1 | 0 | 0 2 | 0 | 2 3 | 0 | 0 4 | 0 | 0 Total | 0 | 2 Mean | 0 | 0.5	Hughes (2018a)

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
		For each tracking patches (ca. 100 x 100 mm) UV tracking dust was placed in locations following the pre-trial survey, 31 tracking patches were used throughout the trial site. Following activity in a location, footprints were cleaned away and where necessary, additional dust (using different colour powders if appropriate) were applied to help determine fresh movement. Marks on the tracking patches were recorded on an arbitrary scale, erased, and the patches recoated. The scale was as follows: 0 = no tracks 1 = from 1 to 5 footprints 2 = from 6 footprints to 25% of the patch tracked 3 = from 25% to 95% of the patch tracked 4 = more than 95% of the patch covered with tracks The tracking patches were left in position to be utilised again during the Selontra® rodent bait treatment and the post-treatment census. The pre-census results indicated the presence of what is considered to be considered a medium level of infestation for an urban environment. **Pre-Treatment Lag Period:** The pre-treatment census was followed by a pre-treatment lag period. The duration of this lag period was 12 days. During this period no census diet or bait was available on site and no observations were made on the infestations. **Treatment period** The treatment was carried out on Selontra® rodent bait, BAS 410 05 I, conventional bait trays each containing approximately 20g (1 block) of the bait, were laid in protected situations sited strategically throughout the infested areas. A total of 31 bait points were laid at the site. At the start of the bait treatment, it was apparent that at some isolated locations in the basement rats and not mice were now present. Rats were confirmed by fresh droppings and paw prints in the tracking medium. Mice were not detected at these isolated locations. Therefore, the quantity of bait placed	**TABLE 2.** Central London: Estimates Of Population Reduction Selontra®, BAS 410 05 I **Total bait Take, g** / **Percent Reduction In Population** **Diet census take** / **Tracking indices score** Day 4 / Day 1- 4 / Day 4 / Day 1- 4 169 / 100 / 100 / 98 / 98 Percent reduction = (pre-treatment census - mean post-treatment census) *x* 100 / pre-treatment census.	

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance	**Test organism(s)**	**Test method, Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		at 4 of the 31 bait points was increased to a rat bait point size (100 g – 5 blocks) to control the rats. Rats were not detected at any other part of the trial site. The following day the baits were checked visually for takes, weighed to the nearest 1.0 g and, replenished. Similar observations and records were made at each visit. The bait was further replenished on days 4, 8 and 15. Observations and recordings continued until significantly reduced signs of mice had been detected for at least two days, when the bait was removed from the site. At each visit during the treatment period activity on the tracking patches was recorded and each freshly coated with tracking powder, as during the pre-treatment census. Searches for any non-target animals were also made at each visit. **Post- Treatment Lag Period** The treatment period was followed by a 10 day lag period to enable any remaining mice a reasonable time in which to die, or recover, from any dose of rodenticide they may have ingested before beginning the post-treatment census. **Post-treatment census** The census diet trays were returned to their original positions. The post-treatment census was conducted in exactly the same way as the pre-treatment census.		

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol. Post 24-months storage at ambient conditions (aged bait)	House mouse, (*Mus musculus domesticus*) Wild derived (Bromadiolone resistant strain (Y139C)).	**Choice feeding cage study (aged bait):** Pre-census period: After the 1 month acclimatisation period, the pre-census diet was the same control diet presented in the same container in the same position as for the acclimatisation period. The diet plus container, weighing approximately 2kg, was weighed to the nearest 1 g. After 24 h the diet and container were re-weighed to the nearest 1 g. The amount of diet ingested was calculated by subtraction, this represents pre-test diet take. The amount of diet ingested was recorded for three consecutive 24h periods. An estimation of the population size was calculated by assuming each mouse ingested 5g of control diet per day. The choice feeding test period followed immediately after the pre-census period. Four test bait points were placed in the pen. They were placed along the walls of the pen equidistant apart. The bait points were labelled T1, T2, T3 or T4. Each bait point consisted of 2 soft blocks (approximately 40g) of Selontra bait threaded on wire and securely attached to a wooden tray. The wooden tray was placed on an aluminium tray. As the baiting regime was that of "surplus baiting", any significant bait take was replenished on a daily basis. The control diet and container remained in the middle of the pen. The control diet plus container and each of the bait points were weighed to the nearest 1g. After a period of 24h, and every 24 hours thereafter for 4 days, the diet plus the container and the bait points were re-weighed to the nearest 1g. The amounts of control diet and bait ingested were calculated by subtraction. The bait takes from all four bait trays were summed. General observations of mice behaviour were also recorded, including bait avoidance. On the first day of the baiting period control diet and total bait take recordings were used to calculate the corresponding palatability ratio at that point (day 1) Palatability Ratio (PR) = Total TB/Total CD PR = Palatability Ratio; TB = consumption of test bait (g); CD= consumption of control diet (g) Dead and moribund mice were searched for at least once a day, but not to the extent that the integrity of the trial was compromised. The bodyweight, and where	**Table 1:** Pre-Census Diet Take **Pre-Census Diet, g** **Day** / **Take** 1: 134 2: 204 3: 161 **Mean**: **166** **Table 2:** Test Period with Selontra Bait (BAS 410 05I) **Bait Take, g** / **Control** / **Palatability Ratio** **Day** / **T1** / **T2** / **T3** / **T4** / **Total** / **Take, g** 1: 26 / 30 / 33 / 27 / **116** / 1 / 116 2: 20 / 15 / 12 / 18 / **65** / 27 / 2.4 3: 0 / 3 / 0 / 0 / **3** / 13 4: 0 / 0 / 0 / 0 / **0** / 4 5: 0 / 0 / 0 / 0 / **0** / 11 6 -7: 0 / 0 / 0 / 0 / **0** / 4 **TOTAL**: **46** / **48** / **45** / **45** / **185** / **60** **Table 3:** Mortality **Day** / **No Deaths** 1: 0 2: 0 3: 23 4: 10 5: 6: 7: **Total Deaths**: **41** **Total Survivors**: **0** **Mean Days to Death**: **2.8** **Range Days to Death**: **2 -7**	[redacted] (2015a)

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
		possible sex, at death and days to death, were recorded. Any mice exhibiting severe signs of cholecalciferol toxicity were culled by a Schedule 1 Method. At the end of the test observation period any survivors were sexed, culled by a Schedule 1 method and their body weight recorded.	**Table 4:** Bodyweight of the culled/dead mice **Bodyweight, g** / **Number of Mice** (Males / Females) 5 -9: 0 / 0 10 -12: 1 / 0 13 -15: 7 / 11 16 -18: 5 / 5 19 -21: 3 / 4 22 -24: 1 / 3 25 -27: 0 / 1 28 -30: 0 / 0 31+: 0 / 0 **TOTAL: 17 / 21**	

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

Test substance	Test organism(s)	Test method, Test system / concentrations applied / exposure time	Test results: effects	Reference
Selontra® A soft block paste bait containing 750ppm cholecalciferol. Post 36-months storage at ambient conditions (aged bait)	House mouse, (*Mus musculus domesticus*) Wild derived (Bromadiolone resistant strain (Y139C)).	**Choice feeding cage study (aged bait):** The choice feeding (palatability) test consisted of an acclimatisation period of 7 days, a 3d pre-census period, a choice feeding test period and a 14d observation period. The test period continued for 21 days. At the end of the test period, if there were any surviving mice, then a 14d observation period would follow. Control diet and water were available *ad libitum* throughout the study. The food was standard laboratory diet presented in a single meshed container placed on the bridge. After the 7 days, the pre-census diet was the same control diet, but presented in a meshed container in the same position as for the acclimatisation period. The diet was weighed to the nearest 0.1g. After 24h, the diet was re-weighed to the nearest 0.1g. The amount of diet ingested was calculated by subtraction, this represents pre-test diet take. The amount of diet ingested was recorded for three consecutives 24h periods. The choice feeding test period followed immediately after the pre-census period. Two containers with test bait were placed at the outer edges of the bridge. Each contained 2 soft blocks (approximately 30 to 40 g) of Selontra Soft Block rodenticide bait threaded on wire and securely attached to the feed container. The bridge was placed in the centre of the pen. As the baiting regime was that of "surplus baiting" any significant bait take was replenished on a daily basis. A meshed feeding container filled with approximately 250 g pelleted laboratory diet was placed on the bridge in the centre of the pen and any significant take was replenished daily. The control diet and the bait were weighed to the nearest 0.1g. After a period of 24h, and every 24 hours for 21 days the control diet and the bait were re-weighed to the nearest 0.1g. The amounts of control diet and bait ingested were calculated by subtraction. On the first day of the baiting test period, control diet and bait take recordings were used to calculate the corresponding palatability ratio at that point.	**Table 1:** Pre-Census Diet Take **Day** | **Pre-Census Diet, Take (g)** 1 | 31.6 2 | 42.8 3 | 49.5 **Mean** | **41.3** **Table 2:** Test period with Selontra Soft Block rodenticide bait (BAS 410 05 I) Day | Bait Take, g T1 | T2 | **Total** | Control Take, g | Palatability Ratio 1 | 20.6 | 22.4 | **43.0** | 7.5 | **5.73** 2 | 0.9 | 6.6 | **7.5** | 9.7 | **0.77** 3 | 0.0 | 0.1 | **0.1** | 3.2 | **0.03** 4 | 0.1 | 0.1 | **0.2** | 2.3 | **0.09** 5 | 0.0 | 0.0 | **0.0** | 3.8 | **0.00** 6 | 0.0 | 0.0 | **0.0** | 0.0 | **-** **TOTAL** | **21.6** | **29.2** | **50.8** | **26.5** | **1.92** **Table 3:** Mortality **Day** | **No. Deaths** 1 | 0 2 | 0 3 | 2 4 | 3 5 | 1 6 | 6 **Total Deaths** | **12** **Total Survivors** | **0** **Mean Days to Death** | **4.9** **Range Days to Death** | **3 – 6**	[redacted] (2016a)

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance	**Test organism(s)**	**Test method, Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		Palatability Ratio =Day 1. Total Test bait take /Day 1. Control diet take. Dead and moribund mice were searched for at least once a day, but not to the extent that the integrity of the trial was compromised. The bodyweight, and where possible sex, at death and days to death were recorded. Any mice exhibiting severe signs of cholecalciferol toxicity, such that death was expected, were culled and recorded as dead on that day. At the end of the 14-day post-treatment observation period, any survivors were sexed, culled and their bodyweight recorded.	**Table 4:** Bodyweight of culled / dead mice **Bodyweight (g)** / **Number of mice** (Males / Females) 5 – 9.9: 0 / 0 10 – 12.9: 0 / 0 13 – 15.9: 0 / 5 16 – 18.9: 2 / 1 19 – 21.9: 3 / 0 22 – 24.9: 1 / 0 25 – 27.9: 0 / 0 28 – 30.9: 0 / 0 31+: 0 / 0 **TOTAL: 6 / 6**	

Conclusion on the efficacy of the product

Summary:

Ready-to-use rodenticidal baits containing 750 ppm cholecalciferol are intended for use in and around buildings for the control of rodent pests. The bait is placed in discrete locations within the infested area, it is not dispersed or broadcast within the environment.

Laboratory choice and no-choice feeding tests indicate that Selontra® is palatable and efficacious against *Rattus norvegicus*, *Rattus rattus* and *Mus musculus*. Efficacy is also proven against the major anticoagulant resistant strains of *Rattus norvegicus* and bromadiolone resistant (Y139C) *Mus musculus*. Field trials have confirmed efficacy against *Rattus norvegicus*, *Rattus rattus* and *Mus musculus*. A shelf-life of 36 months is supported by the palatability and potency of 36 month (stored) aged product. In all studies the efficacy and mortality criteria in the TNsG have been met.

The studies demonstrate efficacy of Selontra® (BAS 410 05 I) against *Rattus norvegicus*:

- In 3 laboratory no-choice feeding tests, the pass criterion of ≥90% mortality within a relevant time frame was met in all tests (100% mortality in all) with a mean time to death of < 3 days.
- In 6 laboratory choice tests, the pass criterion of ≥0.20 for the palatability ratio (T/C) was exceeded in all tests, with 100% mortality in all studies but one which exhibited 90 - 100 % mortality (male and female respectively).
- In 5 field tests, 94 -100% control was demonstrated based on pre- and post-census bait take and tracking activity measurement. Depending on the trial, the bait points were applied with either 100 g or 150 g of bait and were stationed up to 10 meters apart.
- Note, the claimed upper label rate of 140 g (7 x 20 g units of Selontra®) is supported as the average amount of take per bait point in all of the rat field studies using 150 g of Selontra® per bait point shows that reducing the bait point down to 140 g would not negatively impact efficacy. For example, in the submitted field study Hughes, (2013o), the average bait point take is 16 g, which is well below the applied dose rate of 150 g. Furthermore, the bait take for any of the bait points in this study did not exceed 114 g, yet the census diet and tracking data indicate 100% control of the rat infestation.
- The effectiveness against anticoagulant resistant populations was proven by testing the *Rattus norvegicus* strains: Welsh (Y139S, first generation anticoagulant resistant), Hampshire (L120Q, difenacoum and bromadiolone tolerant) and Berkshire (L120Q, difenacoum and bromadiolone resistant) in choice and no-choice feeding tests with a mortality of 90 - 100% (100% mortality in all studies but one which exhibited 90 - 100 % mortality (male and female respectively)).
- The shelf-life of Selontra® is supported by a choice feeding test on aged bait (36 months old) where the pass criterion of ≥0.20 for the palatability ratio (T/C) was exceeded, with a mortality of 100%. This confirms that the product is still palatable and effective against *Rattus norvegicus* after 36 months storage.

The studies demonstrate efficacy of Selontra® (BAS 410 05 I) against *Rattus rattus*:

- In 2 field tests, 100% control was demonstrated based on pre- and post-census bait take and tracking activity measurement. Depending on the trial, the bait points were applied with either 100 g or 140 g of bait and were stationed up to 10 meters apart.
- The shelf-life of Selontra® is supported by a choice feeding test on aged bait (36 months old) where the pass criterion of ≥0.20 for the palatability ratio (T/C) was exceeded, with a mortality of 90%. This confirms that the product is still palatable and effective against *Rattus rattus* after 36 months storage.

The studies demonstrate efficacy of Selontra® (BAS 410 05 I) against *Mus musculus*:

- In 6 laboratory choice tests, the pass criterion of ≥0.20 for the palatability ratio (T/C) was exceeded in all tests, with 100% mortality in all studies but one which exhibited 90 - 100 % mortality (male and female respectively).
- In 5 field tests, 92 -100% control was demonstrated based on pre- and post-census bait take and tracking activity measurement. Depending on the trial, bait points were applied with 20, 35 or 40 g of bait, and were stationed 1 - 2 meters apart.

- The effectiveness against anticoagulant resistant populations was proven by testing a *Mus musculus* Bromadiolone resistant strain (Y139C) in 3 choice feeding tests with 100 % mortality.
- The shelf-life of Selontra® is supported by a choice feeding test on aged bait (36 months old) where the pass criterion of ≥0.20 for the palatability ratio (T/C) was exceeded, with a mortality of 100%. This confirms that the product is still palatable and effective against *Mus musculus* after 36 months storage.

Overall conclusion:

Selontra® (BAS 410 05 I) is very palatable to *Rattus norvegicus*, *Rattus rattus* and *Mus musculus* and causes mortality as required for satisfactory control of rodent infestations, including those resistant to anticoagulant rodenticides.

- Selontra® is effective in controlling *Rattus norvegicus* and *Rattus rattus* "In and around buildings" when used at a dosage of 100 to 140 grams of bait per bait station or covered and protected bait points with bait points spaced up to 10 m apart.

- Selontra® is effective in controlling *Mus musculus* "In and around buildings" when used at 20 - 40 grams of bait per bait station or covered and protected bait points with bait points spaced 1 - 2 m apart.

2.2.5.6 Occurrence of resistance and resistance management

No occurrences of resistance were seen to Selontra® (containing 750 ppm cholecalciferol) in any of the studies. Although resistance to anticoagulants has become widespread in rats throughout the EU, no reported cases of resistance to cholecalciferol have been noted, either in the EU or globally. This is supported by the active substance data for cholecalciferol which demonstrated that the LD_{50} for cholecalciferol active substance does not differ greatly across the different strains of *Rattus norvegicus* (Norway rat) tested (male rats 40-56 mg/kg body weight, female rats 60-62 mg/kg body weight), regardless of anticoagulant resistance status.

The mode of action of cholecalciferol is such that the risk of the development of resistance remains low. Cholecalciferol (Vitamin D_3) is an essential component for life and growth of mammals including rodents. Therefore, being a dose dependent toxin, if resistance mechanisms were to develop in the population, they are likely to have extreme effects on physiological processes and development, such that those individuals would be at a huge competitive disadvantage.

Therefore, as the risk of development of resistance is considered to be low, no specific management strategies are considered necessary for the use of this product, beyond the good rodenticide practice outlined on the product label.

Furthermore, the UK Rodenticide Action Group (http://www.bpca.org.uk/pages/index.cfm?page_id=53) and the global Rodenticide Resistance Action Committee (http://www.rrac.info/) have advocated the use of cholecalciferol-containing baits for the control of anticoagulant-resistant rodents.

2.2.5.7 Known limitations

The bait should never be broadcast or placed indiscriminately and unprotected.

2.2.5.8 Evaluation of the label claims

The proposed label claims have been evaluated for their efficacy claims. The label wording is substantiated by robust effectiveness data demonstrating the palatability and the efficacy of the product to mice, brown rats and black rats.

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

Not applicable.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

2.2.6.1.1 Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	No classification
Justification for the value/conclusion	See below
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Study scientifically unjustified
Justification	The acute dermal irritation of the product can be derived from the active substance data and that for other classified co-formulants. In the absence of study data, mixtures may be classified for irritancy using the summation method under Regulation (EC) No. 1272/2008 (CLP). When considering all classified components of Selontra® by the conventional method (Annex II Part A, 5.3.1b; Part B, 4.1), the cumulative total effects do not indicate a classification of the product. Furthermore, none of the substances classified for skin irritation are present at concentrations greater than or equal to the applicable concentrations defined in the table of Article 3(3). When considering all classified components of Selontra® by the summation method (Annex I Point 3.2.3 and Table 3.2.3), the cumulative total effects do not indicate a classification of the product. Synergistic effects are not expected. Since no substances of concern, relevant for skin irritation, have been identified in accordance with Article 3 Point 1(f) of Regulation (EU) No. 528/2012, it is not necessary to classify this product as 'irritating'. A study is not required, nor considered an appropriate use of animals.

2.2.6.1.2 Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	No classification
Justification for the value/conclusion	See below
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Study scientifically unjustified
Justification	The acute eye irritation of the product can be derived from the active substance data and that for other classified co-formulants. In the absence I of study data, mixtures may be classified for irritancy using the summation method under Regulation (EC) No. 1272/2008 (CLP). When considering all classified components of Selontra® by the conventional method (Annex II Part A, 5.1.1b; Part B 4.1 and Annex II Part A, 5.2.1b; Part B, 4.1), the cumulative total effects do not indicate a classification of the product. Furthermore, none of the substances classified for eye irritation are present at concentrations greater than or equal to the applicable concentrations defined in the table of Article 3(3). When considering all classified components of Selontra® by the summation method (Annex I Point 3.3.3 and Table 3.3.3), the cumulative total effects do not indicate a classification of the product. Synergistic effects are not expected. Since no substances of concern, relevant for eye irritation, have been identified in accordance with Article 3 Point 1(f) of Regulation (EU) No. 528/2012, it is not necessary to classify this product as 'irritating'. A study is not required, nor considered an appropriate use of animals.

2.2.6.1.3 Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	See below
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Study scientifically unjustified
Justification	The respiratory irritation of the product can be derived from the active substance data and that for other classified co-formulants. In the absence of study data, mixtures may be classified for irritation using the summation method under Regulation (EC) No. 1272/2008 (CLP). Synergistic effects are not expected. Selontra® contains no compounds classified as respiratory irritants. Since no substances of concern, relevant for sensitisation, have been identified in accordance with Article 3 Point 1(f) of Regulation (EU) No. 528/2012, it is not necessary to classify this product as 'sensitising'. A study is not required, nor considered an appropriate use of animals.

2.2.6.1.4 Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	No classification
Justification for the value/conclusion	See below
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Study scientifically unjustified
Justification	The acute skin sensitisation of the product can be derived from the active substance data and that for other classified co-formulants. In the absence of study data, mixtures may be classified for sensitisation using the summation method under Regulation (EC) No. 1272/2008 (CLP). Synergistic effects are not expected. Selontra® contains no compounds classified as skin sensitisers as verified by the data contained in supplier Safety Data Sheets. Since no substances of concern, relevant for sensitisation, have been identified in accordance with Article 3 Point 1(f) of Regulation (EU) No. 528/2012, it is not necessary to classify this product as 'sensitising'. A study is not required, nor considered an appropriate use of animals.

2.2.6.1.5 Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	No classification
Justification for the value/conclusion	See below
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Study scientifically unjustified
Justification	The respiratory sensitisation of the product can be derived from the active substance data and that for other classified co-formulants. In the absence of study data, mixtures may be classified for sensitisation using the summation method under Regulation (EC) No. 1272/2008 (CLP). Synergistic effects are not expected.Selontra® contains no compounds classified as respiratory sensitisers. Since no substances of concern, relevant for sensitisation, have been identified in accordance with Article 3 Point 1(f) of Regulation (EU) No. 528/2012, it is not necessary to classify this product as 'sensitising'. A study is not required, nor considered an appropriate use of animals.

2.2.6.1.6 Acute toxicity

2.2.6.1.6.1 Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	No classification
Justification for the selected value	See below
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Study scientifically unjustified
Justification	The acute toxicity of the product can be derived from the active substance data and that for other classified co-formulants. In the absence of study data, mixtures may be classified for acute toxicity using the summation method under Regulation (EC) No. 1272/2008 (CLP). When considering all classified components of Selontra® by the conventional method (Annex II Part A, 2.1.1b; Part B, 1.1 and Annex II Part A, 3.1.1b; Part B, 1.1), the cumulative total effects do not indicate a classification of the product. Furthermore, none of the substances classified for acute oral toxicity are present at concentrations greater than or equal to the applicable concentrations defined in the table of Article 3(3). When considering all classified components of Selontra® by the summation method (Annex I Point 3.1.3 and Table 3.1.2), the cumulative total effects do not indicate a classification of the product. Synergistic effects are not expected. Since no substances of concern, relevant for acute oral toxicity, have been identified in accordance with Article 3 Point 1(f) of Regulation (EU) No. 528/2012, it is not necessary to classify this product for oral toxicity. A study is not required, nor considered an appropriate use of animals.

2.2.6.1.6.2 Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	No classification
Justification for the selected value	See below
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Study scientifically unjustified
Justification	The acute toxicity of the product can be derived from the active substance data and that for other classified co-formulants. In the absence of study data, mixtures may be classified for acute toxicity using the summation method under Regulation (EC) No. 1272/2008 (CLP). When considering all classified components of Selontra® by the conventional method (Annex II Part A, 1.1.1b; Part B, 1.1 and Annex II Part A, 3.1.1b; Part B, 1.1) the cumulative total effects do not indicate a classification of the product. Furthermore, none of the substances classified for acute inhalation toxicity are present at concentrations greater than or equal to the applicable concentrations defined in the table of Article 3(3). When considering all classified components of Selontra® by the summation method (Annex I Point 3.1.3 and Table 3.1.2), the cumulative total effects do not indicate a classification of the product. Synergistic effects are not expected. Since no substances of concern, relevant for acute inhalation toxicity, have been identified in accordance with Article 3 Point 1(f) of Regulation (EU) No. 528/2012, it is not necessary to classify this product for inhalation toxicity. A study is not required, nor considered an appropriate use of animals.

2.2.6.1.6.3 Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	No classification
Justification for the selected value	See below
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Study scientifically unjustified
Justification	The acute toxicity of the product can be derived from the active substance data and that for other classified co-formulants. In the absence of study data, mixtures may be classified for acute toxicity using the summation method under Regulation (EC) No. 1272/2008 (CLP). When considering all classified components of Selontra® by the conventional method (Annex II Part A, 2.1.1b; Part B, 1.1) the cumulative total effects do not indicate a classification of the product. Furthermore, none of the substances classified for acute dermal toxicity are present at concentrations greater than or equal to the applicable concentrations defined in the table of Article 3(3). When considering all classified components of Selontra® by the summation method (Annex I Point 3.1.3 and Table 3.1.2), the cumulative total effects do not indicate a classification of the product. Synergistic effects are not expected. Since no substances of concern, relevant for acute dermal toxicity, have been identified in accordance with Article 3 Point 1(f) of Regulation (EU) No. 528/2012, it is not necessary to classify this product for dermal toxicity. A study is not required, nor considered an appropriate use of animals.

2.2.6.1.7 Information on dermal absorption

Summary table of in vitro studies on dermal absorption					
Method, Guideline, GLP status, Reliability	**Species, Number of skin samples tested per dose, Other relevant information about the study**	**Test substance, Doses**	**Absorption data for each compartment and final absorption value**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 428	*In vitro*, human skin (female), radiolabelled active substance. Receptor fluid 1,2, 3, 4, 6,8, 10, 12,16, 20 and 24h post application, remaining epidermis, excluding all five tape strips	750 ppm w/w cholecalciferol (Selontra®, BAS 410 05 I), 10 mg product/cm^2	Receptor fluid: 0.015% ± 0.0008% Receptor wash: discarded Donor chamber wash: 0.039% ± 0.088% Stripped skin: 0.097% ± 0.104% Total absorbable dose: 0.113% ± 0.110% Standard deviation added to mean due to high variability. **Final absorption value: 0.2%**	Recovery: 97.2%. All tape strips have been excluded as over 75% of the total occurred within half of the duration of the total sampling period.	Johnson, I. R. (2013)

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Cholecalciferol
Value(s)*	0.2%
Justification	750 ppm w/w cholecalciferol (Selontra®), 10 mg product/cm^2, Johnson, I. R. (2013)

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

Selontra® consists of a soft edible foodstuff bait base containing 0.075% w/w (0.75 g/kg) of pharmaceutical grade active substance, cholecalciferol. The components of the foodstuff base are inert ingredients of no toxicological significance.

Selontra® also contains small quantities of additional classified co-formulants, and the human taste deterrent, denatonium benzoate. In the absence of study data, mixtures may be classified for toxicological effects using the summation method under Regulation (EC) No. 1272/2008 (CLP). There is no indication of synergistic effects between any of the components.

When considering all classified components of Selontra® the cumulative total effects do not indicate a classification of the product. Since no substances of concern, of toxicological relevance, have been identified in accordance with Article 3 Point 1(f) of Regulation (EU) No. 528/2012, it is not considered necessary to classify this product for toxicological effects. More information on identification of substances of concern is presented in the confidential Annex.

In conclusion, no classification is appropriate on the basis of the non-active substances, and no additional studies are required.

No community workplace exposure limits are given for any of the co-formulants.

2.2.6.1.9 Endocrine Disruption (ED) assessment

Active substance

As stated in the BPC opinion for cholecalciferol (adopted on December 13 2017; ECHA/BPC/180/2017), cholecalciferol is a pro-hormone metabolised into biologically active metabolites that together with parathyroid hormone are important for maintaining calcium and phosphorous homeostasis. Based on the results from toxicological studies, high dose (0.3 mg/kg bw/d in rats) administration of cholecalciferol causes hypercalcemia and tissue mineralisation in rats and in other vertebrate non-target organisms. Consequently, cholecalciferol fulfils the criteria in section A and B of the Annex to Regulation (EU) No 2017/2100.

Co-formulants

The endocrine disruption assessment of the co-formulants is presented in the Confidential Annex.

Selontra® contains <0.1% (in total) of classified co-formulants: the human taste deterrent denatonium benzoate, a PT 06 preservative and [redacted]. None are substances of concern. [redacted], hence do not need to be considered further at product authorisation. In the case of the PT 06 preservative, it is an approved active substance under the BPR and therefore community level procedures are in place to assess any ED potential.

Conclusion

Selontra® is considered to have ED properties according to point 2.1 (9)(a) of CA-March18-Doc.7.3.b-final (The implementation of scientific criteria for the determination of endocrine-disrupting properties in the context of biocidal product authorisation), as the active substance, cholecalciferol, fulfils the criteria in section A and B of the Annex to Regulation (EU) No 2017/2100.

However, as outlined in the following exposure assessments, use of Selontra® is not expected to result in unacceptable endocrine disruption effects in the end users. Selontra® was a representative product that was evaluated by the Rapporteur Member State (Sweden) for the approval of the active substance, and in the Assessment Report they concluded "In spite of the endocrine properties, there is no risk to human health identified. The exposure from limited rodenticide use is estimated to be in the range of vitamin D supplementation. The combined exposure from rodenticide use, supplements and food is expected to be well within the tolerable daily upper intake level." This conclusion is also supported by the exposure assessment presented here.

Regarding non-target organisms, the applied risk mitigation measures will limit exposure to bait (or poisoned mice). Should a non-target animal accidentally animal ingest cholecalciferol, either through primary or secondary poisoning, the chronic effects associated with endocrine disruptors are not expected with the use of cholecalciferol in Selontra® at the applied use levels. Sublethal effects due to mild hypercalcemia do normally not result in significant alteration of structure or function of the organism, and studies investigating secondary poisoning have shown that animals experiencing moderate toxic effects such as anorexia and reduced body weight gradually return to pre-treatment levels during the recovery phase (see 'Summary table of studies on acceptance by ingestion by non-target organisms'). Therefore, under field conditions, using Selontra® to control rodent infestations is not expected to result in unacceptable ED effects in non-target organisms.

2.2.6.1.10 Available toxicological data relating to a mixture

Selontra® is a ready-to-use bait and is not intended to be mixed with other biocidal products.

2.2.6.1.11 Other

Product Use and Potential for Contamination of Food/Feedingstuff
The manner of use of bait containing cholecalciferol is not intended to cause contact with food and the label expressly states this, as follows: 'Place the product away from food, drink and animal feeding

stuffs, as well as from utensils or surfaces that have contact with these' and 'Search for and remove dead rodents during treatment at frequent intervals'.

The manner of use of the product is described as follows
Rodenticidal baits (containing 0.75 g/kg cholecalciferol, as the active substance) may be used in and around buildings.

The product is used in the same manner in all these situations; the bait is placed in discrete locations within the infested area, it is not dispersed or broadcast within the environment.

Baits points are placed in dry locations, protected from the weather and in appropriate positions to help prevent access by non-target animals.

The common strategy for best rat control, given that rats generally live outdoors, is to place in tamper-resistant bait stations (professionals) or in covered bait points or in bait boxes (trained professionals) where rats live and feed so that they encounter the bait before encountering alternative foods. Tamper-resistant bait stations are thus best placed around harbourages and living areas, along runs where rats habitually travel, at entry points into buildings and around areas where rats are known to feed. As mice are sporadic feeders, and generally live indoors within inaccessible spaces and voids, the strategy for best mouse control is to place many bait points throughout the area where mice are known to feed.

One use of the product is in the farm storage situation to protect public health, i.e. to guard against the potential transmission of disease to humans by rodents, protecting food supplies from contamination. Indeed, this is reflected in the Commission borderline guidance document which states that the main purpose for the use of rodenticides on plant products is considered to be for human hygiene, i.e. to protect public health.

Estimate of Contamination of Food/Feedingstuff
For the reasons given above, the estimation of potential residues in grain has been chosen to illustrate that negligible contamination of food/feedingstuffs would occur during use of the product. The 'in and around buildings' scenario in the Emission Scenario Document (ESD) for biocides used as rodenticides has been used as the basis for estimating contamination of the environment around the bait and both worst case and normal use of the product have been considered, in line with the ESD.

Scenarios and assumptions
A scenario for the realistic use of oral bait rodenticides on a rodent infested farm is described on page 19 of the 'ESD for biocides used as rodenticides'. 21 days is considered to represent a realistic worst case for the duration of a rodenticide campaign, and it is assumed that during that period, all of the bait will be eaten. Exposure to the terrestrial environment is via direct release during application and assumes 1%. Indirect release via ingestion of bait and return as urine and faeces is also a potential source of contamination, although in the case of cholecalciferol there will be no contribution from either urine or faeces. Therefore, it is estimated that the sum of direct and indirect release to the environment will be 1%.

Grain stores typically hold 50 to 500 tonnes of grain. As a worst case, a relatively small grain silo holding 50 tonnes (50,000 kg) grain has been used in this estimate. Although the rodents would only effectively have access to the edges and surface of the grain, the grain is homogenised during drying and processing, therefore it is appropriate to consider the potential for residues to be distributed within the bulked sample. The bait trays are typically placed at intervals of 10 metres apart. It is estimated that a grain store will require 4 bait points, placed at floor level around the outer walls inside the building. [The rodenticide ESD states 'On the basis on this data, a realistic average for a rodent infested farm would be 10 bait boxes placed around the farm buildings, with a large variation. Weight depends on product type and replenishment is on demand/use (pg. 19). Therefore, if there are only 10 bait points on a farm, it is not unreasonable that 4 of these are around one grain store.] The amount of cholecalciferol product used in a control operation for each bait box is up to 200 g and the amount of active substance in the product is 0.00075 mg (0.075%), equivalent to 0.15 g cholecalciferol.

Worst case scenario
It is stated that during a campaign each bait point would be filled, inspected and replenished 5 times (days 1, 3, 7, 14 and 21). The realistic worst-case exposure of grain from application and use over the 21 day baiting period will therefore be as follows:

4 bait points x 200 g of product x 5 refillings x 0.01 (1 percent) release into environment = 40 g of product = (40 g x 0.075% AS concentration) 30 mg of cholecalciferol

On the assumption that a grain silo holds 50 tonnes of grain, the calculation '30 mg cholecalciferol / 50,000 kg grain' provides the value of 0.0006 mg cholecalciferol per kg of grain.

Therefore, worst case exposure of grain from application and use of Selontra® in a rodent infested farm is 0.0006 mg cholecalciferol per kg of grain.

Normal use scenario
The ESD outlines a typical campaign (normal use) with bait applied on day 1, replenished 100% on day 3. On day 7 there would be 25-50% replenishment, on day 14, 10% replenishment, and on day 21, 0% (CEFIC 2002). This roughly equates to 1.5 x 100% replenishments corresponding to a total release over the 21 day baiting period of:

4 bait points × 200 g of product × 1.5 refillings × 0.01 (1 percent) = 12 g product = (12 g x 0.075% AS concentration) 9 mg of cholecalciferol.

Again, on the assumption that a grain silo holds 50 tonnes of grain, the calculation '9 mg cholecalciferol / 50,000 kg grain' provides the value of 0.00018 mg cholecalciferol per kg of grain

Therefore, normal use exposure of grain from application and use of Selontra® in a rodent infested farm is 0.00018 mg cholecalciferol per kg of grain.

Calculation of Acceptable Daily Intake (ADI)
A Scientific Opinion on the Tolerable Upper Intake Level of Vitamin D was published by EFSA in 2012 (EFSA Journal 2012;10(7):2813)[4].

The critical effect of excess intake of vitamin D_3 leading to hypervitaminosis D_3 or vitamin D_3 toxicity is hypercalcaemia. Based on a NOAEL of 250 µg/day (range 234-275 µg/day) and the use of an uncertainty factor of 2.5, the UL for adults (including pregnant and lactating women) is estimated at 100 µg/day.

The UL for infants from 0-12 months of age is 25 µg vitamin D_3/day.

Children in the phase of rapid bone formation and growth were not considered to have a lower tolerance for vitamin D3 compared with adults. Thus, the UL for adolescents aged 11-17 years is 100 µg/day, and the UL for children aged 1-10 years is 50 µg/day to account for their smaller body size.

Group	**Tolerable Upper Intake Level (UL) for vitamin D_3 (µg/day)**
Children 0-1	25
Children 1-10	50
Adolescents 11-17	100
Adults 18+	100

Long-term (chronic) and short-term (acute) consumer exposures to potential cholecalciferol residues are estimated using the EFSA PRIMo model (below). The model uses toxicological reference doses expressed per kilogram body weight, so it is necessary to convert the Tolerable Upper Intake Levels

4 EFSA Journal 2012;10(7):2813
https://www.efsa.europa.eu/en/efsajournal/pub/2813

from µg/person/day to mg/kg bw/day. The age range and body weight for each consumer group in the PRIMo model are known and the appropriate Tolerable Upper Intake Level for each group can thus be divided by the body weight for that group to arrive at a reference dose in mg/kg bw/day, for use in both the chronic and acute risk assessment. Where the given age ranges encompassed more than one of the Tolerable Upper Intake Levels, the body weight was used to estimate the most appropriate value in each case. In each such case, the body weight given fell in the adult range and so a Tolerable Upper Intake Level of 100 µg/person/day was used in the calculation. The results are tabulated below, ranked in increasing order of calculated reference dose.

Country	**Group**	**Age (years)**	**Body Weight (kg)**	**Tolerable intake (µg/person/ day)**	**Ref Dose (mg/kg bw/day)**
IT	Children	1-17	41.6	50	0.0012
FI	Adults	25-64	77.1	100	0.0013
UK	Adults	19-64	76	100	0.0013
IE	Adults	18-64	75.2	100	0.0013
DK	Adults	18-75	74	100	0.0014
LT	Adults	19-64	70	100	0.0014
ES	Children	7-12	34.5	50	0.0014
ES	Adults	17-60	68.5	100	0.0015
UK	Vegetarian	19-64	66.7	100	0.0015
IT	Adults	18-64	66.5	100	0.0015
NL	General	1-97	63	100	0.0016
PL	General	1-96	62.8	100	0.0016
FR	All	All	60	100	0.0017
PT	General	All	60	100	0.0017
SE	General	1-74	60	100	0.0017
WHO B	General	n/a	60	100	0.0017
WHO F	General	n/a	60	100	0.0017
WHO E	General	n/a	60	100	0.0017
WHO D (European)	General	n/a	60	100	0.0017
DK	Children	4-6	22	50	0.0023
UK	Children	4-6	20.5	50	0.0024
BE	Toddlers	2.5-6.5	17.8	50	0.0028
FR	Infants	7-12 mnth	8.8	25	0.0028
UK	Infants	6-12 mnth	8.7	25	0.0029
NL	Children	1-6	17.1	50	0.0029
DE	Children	2-5	16.15	50	0.0031
UK	Toddlers	1.5-4	14.5	50	0.0034
FR	Toddlers	13-18 mnth	10.6	50	0.0047

Calculation of the Acute Reference Dose (ARfD)

The Tolerable Upper Intake Levels established above are applicable also to short-term (acute) exposure assessment.

Estimation of Potential and Actual Exposure Through Diet

Long-term (chronic) and short-term (acute) consumer exposures to potential cholecalciferol residues are estimated using the EFSA PRIMo model for consumer risk assessment. The Theoretical Maximum Daily Intake (TMDI) and International Estimate of Short-Term Intake (IESTI) values are calculated based on the proposed uses of cholecalciferol as a rodent bait around grain stores. The residue level present in each grain commodity in the PRIMo model has been assumed to be at the worst-case theoretical residue of 0.0006 mg cholecalciferol per kg of grain, derived above. This residue has been applied to the cereal group (500000), consisting of barley, buckwheat, maize, millet, oats, rice, rye, sorghum, wheat and other cereals.

Chronic Exposure
Running the PRIMo model with the worst-case theoretical residue of 0.0006 mg/kg in cereal grain and employing the appropriate reference dose for each consumer group produces a range of TMDI values. The highest TMDI for cholecalciferol consumption through possible residues in cereal grains represents only 0.42% of the ADI, for Italian children (1-17 years) and WHO cluster diet B.

Acute (short-term) Exposure
Running the PRIMo model with the worst-case theoretical residue of 0.0006 mg/kg in cereal grain and employing the appropriate reference dose for each consumer group produces a range of IESTI values. The highest IESTI for cholecalciferol through possible residues in cereal grains represents less than 0.72% of the ARfD.

Characterisation of the Risk
Data from European populations indicate that vitamin D3 intakes from all sources in high consumers are below the UL for all population subgroups (EFSA Journal 2012;10(7):2813)[5], about 25%, 75%, 30% and 8% of the UL for adults, infants, children and adolescents, respectively. Thus, the additional potential exposure to cholecalciferol residues which might arise from the use of rodenticide baits around grain stores, even using worst-case assumptions, is several orders of magnitude lower than levels to which consumers may be exposed from other sources.

Conclusion
The results of the consumer risk assessment calculations indicate that there is no unacceptable chronic or acute risk to human health from the consumption of cereal grain which may have been stored in grain stores around which cholecalciferol may have been used for rodent control.

5 EFSA Journal 2012;10(7):2813
https://www.efsa.europa.eu/en/efsajournal/pub/2813

2.2.6.2 Exposure assessment

2.2.6.2.1 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[1]	**Professional use[2]**	**Non-professional use**	**Industrial use**	**Professional use**	**General public[3]**	**Via food**
Inhalation[4]	n.a.	Negligible	n.a.	n.a.	No	Negligible	No
Dermal[5]	n.a.	Yes	n.a.	n.a.	No	No	No
Oral[6]	n.a.	No	n.a.	n.a.	No	Yes (toddlers)	No

1) Industrial use (manufacture of active substance and formulation of products) is not covered by BPR.
2) Includes non-trained professionals.
3) Transient mouthing by toddlers is included in the scenarios for general public.
4) The CEFIC data (pilot study) showed levels of inhalation exposure for pest control operators using wax block baits were negligible. The vapour pressure for cholecalciferol is also very low, i.e. 6 x 10^{-5} at 25 °C.
5) The product is placed on the market in packs of a maximum size of 10 kg and therefore decanting into smaller packs for use is not expected to occur.
6) As a major path of exposure, the oral route is realistic only for toddlers accidentally ingesting the product. The User Guidance states that oral exposure during handling of baits is also possible for operators, if insufficient hygiene measures are followed.

2.2.6.2.2 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 - Loading bait boxes for rat control	Professionals
2.	Application	Primary exposure - Cleaning up previously loaded bait for rat control	Professionals
3.	Application	Primary exposure - Loading bait boxes for mouse control	Professionals
4.	Application	Primary exposure - Cleaning up loaded bait for mouse control	Professionals
5.	Indirect exposure	Secondary exposure – Adults handling dead rodents	Bystanders (general public)
6.	Indirect exposure	Secondary exposure – Transient mouthing of bait by toddler	Bystanders (general public)

The formulated product has a nominal active substance content of 0.075 % w/w. The intended use is in and around buildings e.g. domestic, public, commercial and agricultural buildings, for control of rats and mice. The bait size is 20 g with a maximum rate per box of 40 g or 140 g (mouse and rat respectively). For rat control bait points containing up to 7 units of bait are used at intervals of up to 10 m apart. For mouse control, 2 units of bait are used per bait point, which are spaced 1 to 2 m

apart. For non-trained professionals, the product may be used in tamper-resistant bait stations to minimise exposure of non-target animals.

Bait points are inspected frequently, and the bait point is replenished when bait take is observed. When no further take is observed it is considered that control has been achieved and bait points are removed from the site.

2.2.6.2.3 Industrial exposure

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

2.2.6.2.4 Professional exposure

2.2.6.2.4.1 Scenario 1 - Loading bait boxes for rat control by professional users

Description of Scenario 1		
Dermal exposure occurs through handling the paste bait when loading the bait boxes. Indicative 75th percentile values for various work tasks are derived from Chambers, J.G and Snowdon, P.J. 2004, Sponsors CEFIC/EBPF Rodenticide Data Development Group (RDDG), Unpublished. These values were agreed by HEEG (Opinion 12, Harmonised approach for the assessment of rodenticides (anticoagulants)) to provide a harmonised approach for the exposure assessment of rodenticide products. Data determined by Chambers *et al.* (2004) for wax blocks are used to predict exposure for enrobed bait unit type products, as the handling and characteristics of these products are comparable. This principle was agreed at TM III 2006. Frequency of tasks during use of bait is taken from Vetter, T. and Sendor, T. Estimation of the frequency of dermal exposure during the occupational use of rodenticides. CEFFIC Rodenticides Working Group, report and addendum 2006. Agreed in HEEG opinion 10 (Harmonising the number of manipulations in the assessment of rodenticides) and reproduced in Biocides Human Health Exposure Methodology[6] p 73. The resulting exposure values are reported below. Full details of the exposure assessment calculations can be found in Appendix 3.2. NB: The number of contacts (7) differs to the number used in risk assessment in the cholecalciferol Assessment Report (8 contacts). This is because the bait unit was initially 17 g when first developed but subsequently increased to 20 g once manufacturing was scaled up. At the time of submitting the cholecalciferol dossier, the bait unit was 17 g and in the years following, the use pattern was refined based on the increase in bait unit size and the additional efficacy data generated.		
Tier 1	Parameters	Value
	Concentration of active substance in biocidal Product	0.075% w/w
	Bait unit	20 g enrobed paste bait Rat 7 contacts per loading (manipulation), 140 g per bait box
	Task Duration	60 loadings of bait stations/day
	Potential hand exposure (75th percentile) per manipulation	38.906 mg biocidal product/manipulation* (loading), for 7 contacts (27.79 mg bp/ 5 contacts x 7 contacts)
	Dermal absorption	0.2%
	Body weight	60 kg

**Manipulation=loading or cleaning of one bait box.*

[6] ECHA Biocides Human Health Exposure Methodology, 1st Edition. October 2015.

Calculations for Scenario 1

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenario 1	1 / No PPE	negligible	5.8×10^{-5}	negligible	5.8×10^{-5}

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

2.2.6.2.4.2 Scenario 2 - Cleaning bait boxes for rat control by professional users

Description of Scenario 2		
Dermal exposure occurs through inspection of the bait boxes. Uneaten bait and residues are swept up and disposed of. Indicative 75th percentile values for various work tasks are derived from Chambers, J.G and Snowdon, P.J. 2004, Sponsors CEFIC/EBPF Rodenticide Data Development Group. Unpublished. These values were agreed by HEEG (Opinion 12, Harmonised approach for the assessment of rodenticides (anticoagulants)) to provide a harmonised approach for the exposure assessment of rodenticide products. Data determined by Chambers *et al.* (2004) for wax blocks are used to predict exposure for enrobed bait unit type products, as the handling and characteristics of these products are comparable. This principle was agreed at TM III 2006. Frequency of tasks during use of bait is taken from Vetter, T. and Sendor, T. Estimation of the frequency of dermal exposure during the occupational use of rodenticides. CEFFIC Rodenticides Working Group, report and addendum 2006. Agreed in HEEG opinion 10 (Harmonising the number of manipulations in the assessment of rodenticides) and reproduced in Biocides Human Health Exposure Methodology[7] p 73.		
Tier 1	Parameters	Value
	Concentration of active substance in biocidal Product	0.075% w/w
	Task Duration	15 bait stations cleaned/day
	Potential hand exposure (75th percentile) per manipulation	5.7 mg biocidal product /manipulation (clean-up)
	Dermal absorption	0.2%
	Body weight	60 kg

[7] ECHA Biocides Human Health Exposure Methodology, 1st Edition. October 2015.

Calculations for Scenario 2

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenario 2	1 / No PPE	negligible	2.1×10^{-6}	negligible	2.1×10^{-6}

Further information and considerations on scenario 2
No further information or considerations are required for this scenario as estimated levels of exposure using precautionary assumptions demonstrate an acceptable margin of safety.

2.2.6.2.4.3 Scenario 3 - Loading bait boxes for mouse control by professional users

Description of Scenario 3

Dermal exposure occurs through inspection of the bait boxes. Uneaten bait and residues are swept up and disposed of. Indicative 75th percentile values for various work tasks are derived from Chambers, J.G and Snowdon, P.J. 2004, Sponsors CEFIC/EBPF Rodenticide Data Development Group. Unpublished. These values were agreed by HEEG (Opinion 12, Harmonised approach for the assessment of rodenticides (anticoagulants)) to provide a harmonised approach for the exposure assessment of rodenticide products.

Data determined by Chambers et al. (2004) for wax blocks are used to predict exposure for enrobed bait unit type products, as the handling and characteristics of these products are comparable. This principle was agreed at TM III 2006.

Frequency of tasks during use of bait is taken from Vetter, T. and Sendor, T. Estimation of the frequency of dermal exposure during the occupational use of rodenticides. CEFFIC Rodenticides Working Group, report and addendum 2006. Agreed in HEEG opinion 10 (Harmonising the number of manipulations in the assessment of rodenticides) and reproduced in Biocides Human Health Exposure Methodology[8] p 73.

The resulting exposure values are reported below. Full details of the exposure assessment calculations can be found in Appendix 3.2.

Tier 1	Parameters	Value
	Concentration of active substance in biocidal Product	0.075% w/w
	Bait unit	20 g enrobed paste bait Mouse control = 2 contacts per loading (manipulation), 40 g per bait box
	Task Duration	60 loadings of bait stations/day
	Potential hand exposure (75th percentile) per manipulation	11.116 mg biocidal product/manipulation* (loading), for 2 contacts
	Dermal absorption	0.2%
	Body weight	60 kg

**Manipulation=loading or cleaning of one bait box.*

[8] ECHA Biocides Human Health Exposure Methodology, 1st Edition. October 2015.

Calculations for Scenario 3

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenario 3	1 / No PPE	negligible	1.7×10^{-5}	negligible	1.7×10^{-5}

Further information and considerations on scenario 3
No further information or considerations are required for this scenario as estimated levels of exposure using precautionary assumptions demonstrate an acceptable margin of safety.

2.2.6.2.4.4 Scenario 4 - Cleaning bait boxes for mouse control by professional users

Description of Scenario 4		
Dermal exposure occurs through inspection of the bait boxes. Uneaten bait and residues are swept up and disposed of. Indicative 75th percentile values for various work tasks are derived from Chambers, J.G and Snowdon, P.J. 2004, Sponsors CEFIC/EBPF Rodenticide data Development group. Unpublished. These values were agreed by HEEG (Opinion 12, Harmonised approach for the assessment of rodenticides (anticoagulants)) to provide a harmonised approach for the exposure assessment of rodenticide products. Data determined by Chambers *et al.* (2004) for wax blocks are used to predict exposure for enrobed bait unit type products, as the handling and characteristics of these products are comparable. This principle was agreed at TM III 2006. Frequency of tasks during use of bait is taken from Vetter, T. and Sendor, T. Estimation of the frequency of dermal exposure during the occupational use of rodenticides. CEFFIC Rodenticides Working Group, report and addendum 2006. Agreed in HEEG opinion 10 (Harmonising the number of manipulations in the assessment of rodenticides) and reproduced in Biocides Human Health Exposure Methodology[9] p 73.		
Tier 1	Parameters	Value
	Concentration of active substance in biocidal Product	0.075% w/w
	Task Duration	15 bait stations cleaned/day
	Potential hand exposure (75th percentile) per manipulation	5.7 mg biocidal product /manipulation (clean-up)
	Dermal absorption	0.2%
	Body weight	60 kg

[9] ECHA Biocides Human Health Exposure Methodology, 1st Edition. October 2015.

Calculations for Scenario 4

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenario 4	1 / No PPE	negligible	2.1×10^{-6}	negligible	2.1×10^{-6}

Further information and considerations on scenario 4
No further information or considerations are required for this scenario as estimated levels of exposure using precautionary assumptions demonstrate an acceptable margin of safety.

2.2.6.2.4.5 Combined scenarios

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 1 and 2	negligible	6.0×10^{-5}	negligible	6.0×10^{-5}
Scenario 3 and 4	negligible	1.9×10^{-5}	negligible	1.9×10^{-5}

2.2.6.2.5 Exposure of the general public

2.2.6.2.5.1 Scenario 5 – Secondary exposure: Adults handling dead rodents

Description of Scenario 5
Professional users and adult bystanders are not anticipated to handle dead rodents directly. Even in the event that rodents are found, this is not likely to be a source of exposure in the case of Selontra® because (1) the bait works by ingestion, so only small amounts of active substance on the outer surface of the rodent is anticipated and (2) professional pest control operators and non-professionals are averse to handling dead animals and so will do so carefully and only while wearing gloves to help protect against rodent-borne diseases. Therefore, potential exposure to cholecalciferol associated with handling dead rodents is expected to be negligible. The Technical Meeting on Biocides (conclusion of the anti-coagulant expert meeting of May 18th 2006, TM II 2006,) agreed that "children handling dead rodents" is not a relevant exposure scenario. No assessment has therefore been made.

Further information and considerations on scenario 5
No further information or considerations are required for this scenario as estimated levels of exposure to cholecalciferol associated with handling dead rodents is expected to be negligible.

2.2.6.2.5.2 Scenario 6 – Secondary exposure: Toddler Ingesting Bait

Description of Scenario 6		
The ingestion of poison bait by toddler (body weight 10 kg) was discussed at the Technical Meeting on Biocides (TM III) in 2008 (Ispra 04/07/2008). The scenario was re-defined as "Mouthing of poison bait - an exceptional scenario" and concerns the situation where an toddler manages to access a bait block, despite the preventive measures taken, and then licks the block, or ingests a piece of the block. Exposure is thus acute and is expected to occur only exceptionally. An assessment is given for this scenario. Where a bittering agent is used, as in the case of Selontra®, the amount ingested is assumed to be 10 mg (TNsG, Part 3, June 2002 / Final, Page 58).		
Tier 1	Parameters	Value
	Concentration of active substance in biocidal Product	0.075% w/w
	Amount of bait ingested (product formulated with bittering agent)	10 mg
	Oral absorption	100%
	Body weight	10 kg

Calculations for Scenario 6

Summary table: estimated exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Scenario 6	1 / No PPE	negligible	negligible	7.5×10^{-4}	7.5×10^{-4}

Further information and considerations on scenario 6
It should be noted that if the product is placed in bait stations that are to be placed where access is not likely and taste deterrent is included in the product this will further reduce the likelihood that children ingest it.

2.2.6.2.6 Monitoring data

None available

2.2.6.2.7 Dietary exposure

Dietary intake plus supplements of cholecalciferol, estimated upper intake within EU (EFSA, 2012)[10]

Dietary intake plus supplements	
Age (years)	**Upper 95th percentile Intake (food plus supplement) µg/day**
Adults ≥ 18 years	24.2
Adolescents 14-17	8
Children 1-14	15.4
Infants (≤ 1)	19.3[1]

[1]90th percentile

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

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

Disposal of unused bait from previous baiting operations, i.e. cleaning operations is considered in the exposure and risk assessments given for professional users.

2.2.6.3 Risk characterisation for human health

Reference values used in Risk Characterisation

Reference	**Study**	**NOAEL (LOAEL)**	**AF[1]**	**Correction for oral absorption**	**Value (mg/kg bw/day)**
AELshort-term (adult)	EFSA 2012	250 µg/day	2.5	50%	0.00083
AELshort-term (toddler)	EFSA 2012	250 µg/day	5	NA – route of exposure is oral only.	UL 0.005 (1-14 years)*
AELmedium-term	EFSA 2012	250 µg/day	2.5	50%	0.00083
AELlong-term	EFSA 2012	250 µg/day	2.5	50%	0.00083
ARfD	NA	NA	NA	NA	NA
ADI	NA	NA	NA	NA	NA

[1]Assessment Factor
* Oral absorption (OA) under the parameters of Scenario 6 (pg.116) is not taken into account when calculating the exposure for Scenario 6. The reference value (50 µg/day) used in the risk characterisation (RC) section (pg. 117) is taken from EFSA (2012). This reference value is drawn from a consideration of numerous clinical studies in human patients via oral dosing. As the route of exposure for this scenario is oral only and the reference dose is also based on the oral route, an adjustment for OA is not necessary. Therefore, the calculated exposure from

10 EFSA Journal 2012;10(7):2813
https://www.efsa.europa.eu/en/efsajournal/pub/2813

Scenario 6 is comparable to the reference value used in the RC section with no further adjustments to either value required.

2.2.6.3.1 Risk for industrial users

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

2.2.6.3.2 Risk for professional users

Systemic effects

Task/ Scenario	Tier	NOAEL	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1-Primary exposure - Loading bait boxes for rat control	1	250 µg/day (0.0021 mg/kg, 60 kg bw, 50% oral abs.)	0.00083	5.8×10^{-5}	7.0	Yes
2-Primary exposure - Cleaning up previously loaded bait for rat control	1	250 µg/day (0.0021 mg/kg, 60 kg bw, 50% oral abs.)	0.00083	2.1×10^{-6}	0.3	Yes
3-Primary exposure - Loading bait boxes for mouse control	1	250 µg/day (0.0021 mg/kg, 60 kg bw, 50% oral abs.)	0.00083	1.7×10^{-5}	2.0	Yes
4-Primary exposure - Cleaning up loaded bait for mouse control	1	250 µg/day (0.0021 mg/kg, 60 kg bw, 50% oral abs.)	0.00083	2.1×10^{-6}	0.3	Yes

Combined scenarios

Scenarios combined	Tier	NOAEL	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1 and 2	1	250µg/day (0.0021 mg/kg, 60 kg bw, 50% oral abs.)	0.00083	6.0×10^{-5}	7.3	Yes
3 and 4	1			1.9×10^{-5}	2.3	Yes

2.2.6.3.2.1 Conclusion

The risk associated with direct use of the product is considered acceptable. The predicted levels of exposure are within the AEL without the use of PPE.

2.2.6.3.3 Risk for the general public

Systemic effects

Task/ Scenario	Tier	NOAEL	UL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ UL (%)	Acceptable (yes/no)
5 / Secondary exposure – Adults handling dead rodents	Not quantified. Levels of exposure are expected to be negligible					Yes
6 / Secondary exposure – Transient mouthing of bait by toddler	2	250 µg/day	UL 0.005 (1-14 years)*	7.5×10^{-4}	15	Yes

*UL (50 µg/d) / body weight (10 kg)

2.2.6.3.3.1 Conclusion

Indirect exposure (via inhalation, handling of dead rodents or via the environment) to Selontra® is expected to be negligible due to the formulation type and the preventive measures to be taken. The assessment of indirect exposure considers the scenario "mouthing of poison bait by toddler" since this has been requested for previous evaluations of rodenticides under the biocides directive 98/8/EC.

Since the assessment of secondary exposure of an toddler only considers oral exposure it is appropriate to compare intake values with the UL rather than using systemic values. The exposure level in this scenario is compared to the UL for a 1-14 year old child.

The Tier 2 assessment for mouthing of poison bait by toddlers, which considers the use of a bittering agent (as formulated in Selontra®) confirms levels of exposure will be within the UL for children of 1 to 14 years. It should be noted that as the product is placed in bait stations that are to be placed where access is not likely and as a taste deterrent is included in the product, this will further reduce the likelihood that children may ingest it.

2.2.6.3.4 Combined exposure (rodenticide use plus supplement and food exposure in food)

To assess the combined intake of cholecalciferol from food and food supplements and from rodenticide use, the upper 95th percentile of the daily intake reported in µg/day in the EFSA 2012 survey was converted to mg/kg bw/ day assuming a body weight of 60 kg for adults and 10 kg for toddlers.

Exposure scenario	**Professional exposure[1]**	**Non-professional exposure**	**Secondary Exposure[2]**
Exposure estimates use as rodenticide (mg/kg bw/day, internal dose)	6.0 x 10^{-5} (worst case, rat)	n.a.	7.5 x 10^{-4} (product with deterrent)
Dietary Intake, (mg/kg bw/day, internal dose, 50% oral absorption)	0.00020	n.a.	0.00077
Total exposure (internal dose)	2.60 x 10^{-4}	n.a.	0.00152
% of AEL[3] rodenticide use only	7.3%	n.a.	15%
% of AEL dietary intake only	24%	n.a.	15%
% of AEL[3] from total use	31%	n.a.	30%

[1] 60 kg body weight (adult). [2] 10 kg body weight (toddler), [3] AEL_{adult} 0.00083 mg/kg/day, $AEL_{toddler}$ 0.005 mg/kg bw/day

2.2.6.3.4.1 Conclusion

Combined exposure is not anticipated from different biocidal uses of cholecalciferol. However, when assessing the risk, the exposure level from biocidal use is added to the intake values from food and supplements.

The estimated exposure levels in professional users and toddlers accidently ingesting bait are below the AELs derived provided Selontra®.

The additional exposure from sun is difficult to estimate since it varies depending on several factors such as skin type, latitude, base-line vitamin D level, type of clothing used etc. However, since the total exposure from the biocidal use and the dietary and supplement intake is well within the AEL based on the tolerable upper limit, there is an acceptable margin of safety for additional exposure from the sun.

2.2.7 Risk assessment for animal health

The product is formulated as an enrobed pre-prepared paste bait (soft block bait/pasta, paste bait). Trained professionals may place Selontra® in covered bait points or in bait boxes throughout the infested area, professionals are restricted to tamper-resistant bait boxes. All bait points are placed in dry locations and are protected to help prevent access by non-target animals. Bait points are inspected frequently. When no further take is observed, bait points are removed from the site.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

Trained professionals may place Selontra® in covered bait points or in bait boxes. For professional users, the product may be used in tamper-resistant bait stations to minimise exposure of non-target animals. The product is not intended to be placed indiscriminately or broadcast in the environment. Therefore, exposure will be localised to the areas around the individual bait points (with limited quantities of active substance and limited frequency of use).

According to the EUBEES ESD PT 14 for this exposure scenario the main exposure of the environment is expected to be soil, and other environmental compartments are considered not to be relevant. Nevertheless, the environmental risk assessment concluded that the product will not result in unacceptable risk to the terrestrial compartment.

The risk assessment for the terrestrial compartment is also done for the co-formulant 2-phenylphenol functioning as a preservative in the product. 2-phenylphenol was identified as a substance of concern for the environment. According to the 'Guidance on the Biocidal Products Regulation, Vol. IV Environment – Assessment and Evaluation (Parts B+C), V.2.0, October 2017' (BPR vol. IV, Parts B+C), this co-formulant is identified as substance of concern (SoC) for the environment – for the following reasons: Although 2-phenylphenol is not present in the biocidal product at a concentration leading the product to be regarded as hazardous or dangerous, is not a POP, PBT or vPvB substance, and although its concentration in the product (of 0.0496%) is <0.1% (the SoC trigger value), it is considered as a substance of concern because it is an active substance (acting as a co-formulant) that has a $PNEC_{soil}$ of 0.048 mg/kg ww – which is lower than the cholecalciferol $PNEC_{soil}$ of 5.78 mg/kg ww.

Assessment of primary and secondary poisoning is not considered necessary for the substance of concern 2-phenylphenol, since the active substance fails the primary and secondary poisoning risk assessments. 2-phenylphenol does not act as rodenticide and is not expected to significantly increase the risk of primary and secondary poisoning. Also, 2-phenylphenol has a low potential to bioaccumulate (BCF 21.7 whole fish, 114-115 lipid content) and toxicity to birds and mammals is considerably lower compared to the active substance.

2.2.8.1.1 Summary of PNEC values for the active substance and substance of concern

Summary table for PNECs used in Risk Assessment		
Parameters	**Concentration**	**Notes**
Cholecalciferol		
$PNEC_{soil}$	5.78 mg/kg wwt	As specified in Doc IIA, Section 4.2.3.2
$PNEC_{oral,\ bird}$	0.2 mg a.s./kg food	Tier 1 (tree sparrow) - chronic
$PNEC_{oral,\ bird}$	0.025 mg a.s./(kg bw·d)	Tier 2 (tree sparrow) – chronic
$PNEC_{oral,\ mammals}$	0.003 mg a.s./kg food	Tier 1 (dog) – chronic
$PNEC_{oral,\ mammals}$	0.0001 mg a.s./(kg bw·d)	Tier 2 (dog) – chronic
2-phenylphenol (biphenyl-2-ol)		
$PNEC_{soil}$	0.048 mg/kg wwt	AR of 2-phenylphenol (biphenyl-2-ol)[1]

[1]In the assessment report the conversion of the PNECsoil 0.054 mg/kg dw in mg/kg ww was mistakenly derived by multiplication with 1.13 (resulting in a PNECsoil 0.061 µg/kg ww) and not by division (resulting in a PNECsoil 0.048 µg/kg ww).

2.2.8.1.2 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

Not applicable.

2.2.8.1.3 Further Ecotoxicological studies

No data are available.

Data waiving	
Information requirement	-
Justification	The data provided for the active substance (summarised in Doc IIA) are sufficient to assess the toxicity / classification of the product by extrapolation. No further consideration to the product is therefore required.

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	No new information or studies were submitted for Selontra® ready-to-use bait. All information for this authorisation is based on the active substance, cholecalciferol.
Justification for the value/conclusion	The risk assessment is based on the data obtained from the active substance cholecalciferol (final Competent Authority Report according to Regulation 528/2012, Product Type 14 (Rodenticides), Rapporteur Member State: Sweden, November 2017). The performance of further ecotoxicological studies with the biocidal product is not considered to be required since read-across from the environmental toxicity data of the active substance is justified.

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

Data waiving	
Information requirement	-
Justification	This is not a core data requirement. Information concerning the potential for the product to cause adverse effects on non-target organisms (flora and fauna) can be extrapolated from information on the active substance.

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

No data are available on acceptance by ingestion of the biocidal product by any non-target organisms.

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

The table below summarises the main findings from the references on secondary poisoning (refer to Doc IIIA section 7.5.6 for additional details) from repeated exposure under exaggerated, "no-choice" feed studies.

Summary table of studies on secondary poisoning of non-target organisms						
Species	**Endpoint / Type of test**	**Exposure[1,2]**		**Results**	**Remarks**	**Reference**
		Design	**Duration**			
Feral cats	Mortality, appetite, body weight, and serum calcium levels.	Dietary, fed whole carcasses of cholecalciferol poisoned possums as their only food (~1 kg of possum tissue)	5 consecutive days plus observation (63 days)	No mortalities No change on body weight No lack of appétit Mean serum calcium concentrations remained within, or very close to, the normal range for cats (2.0–2.7 mmol/litre)	The risk of secondary poisoning to cats with cholecalciferol is very low	[redacted] et al (2000)
Domestic dogs	Blood samples: serum calcium levels and urea nitrogen	Dietary, fed tissue from cholecalciferol poisoned possums	5 consecutive days plus observation (up to 28 days)	No mortalities Dogs experienced reduced appetite and body weight which gradually returned to pre-treatment levels during recovery phase Mean total serum concentrations of calcium and urea nitrogen were above normal values Histopathological examination revealed dystrophic mineralisation of the kidneys	Mild toxicosis can occur in dogs eating a diet of 100 % cholecalciferol contaminated possum meat.	[redacted] et al (2000)

Summary table of studies on secondary poisoning of non-target organisms						
Species	**Endpoint / Type of test**	**Exposure[1,2]**		**Results**	**Remarks**	**Reference**
		Design	**Duration**			
Beagle dogs	Clinical observation and mortality	Dogs fed baited rat carcasses (no-choice feeding study)	14 consecutive days	All 6 dogs survived showing no signs of cholecalciferol intoxication or hypervitaminosis D. No pathological abnormalities were noted.	The risk from secondary poisoning to dogs was demonstrated to be low.	[redacted] (1984)
Foxes and minks	Clinical obs, mortality, histopathological exam (gastric mucosa, bones and organs)	Contaminated fish feed was provided via diet or stomach tube	14 to 150 days	Foxes: 5 IU vitamin D_3/bw daily (equivalent to 0.000125 mg/kg / bw/d) did not produce any clinical symptoms. However, 10 IU/g, showed loss of appetite, had difficulty in moving, were apathetic and developed dark coloured faeces. Markedly raised calcium values in blood. 2x weekly by stomach tube acted more toxic than via feed. Minks: 0.7 to 15 IU vitamin D_3/bw daily (equivalent to 0.0000175 to 0.000375 mg/kg / bw/d) did not produce any clinical symptoms	Fur-bearing animals are adapted to tolerate higher levels of required vitamin D_3 doses.	[redacted] & [redacted] (1978)

Summary table of studies on secondary poisoning of non-target organisms						
Species	**Endpoint / Type of test**	**Exposure[1,2]**		**Results**	**Remarks**	**Reference**
		Design	**Duration**			
Wild cats	Mortality, appetite, body weight, and serum calcium levels.	Cats were fed 930 g poisoned possum carcasses	5 consecutive days plus observation (7 weeks)	No significant effect on appetite No change in body weight Slight transient increase in calcium levels No signs of toxicity (NOEC = 186 g poisoned carcass/d) Slight increase in serum calcium	None of the symptoms of primary poisoning seen in possums were observed in cats after secondary poisoning. The risk from secondary poisoning to cats was demonstrated to be low.	[redacted] et al (1996)
Red-tailed hawk (*Buteo iamaicensis*) Turkey vultures (*Cathartes aura*)	Mortality	Dietary, fed poisoned rat carcasses (0.075% rodent bait)	10 days, plus observation	No mortalities, no clinical symptoms observed	This study suggests that even under a worse-case scenario there appears little or no potential secondary hazard to hawks or turkey vultures should they feed on rats poisoned with cholecalciferol	[redacted] (1990)

[1] Cholecalciferol levels in carcasses prior to feeding test animals were not determined in any of the studies.
[2] The majority of the studies exposed non-target birds and mammals to possum carcasses because the concentration of cholecalciferol in possum baits is typically 10 times greater than that used for rodents. Hence possum poisoning with cholecalciferol possum baits are likely to provide the "worst-case" exposure scenario in terms of potential secondary poisoning.

The results from the secondary poisoning studies demonstrate minimal adverse effects to non-target animals. Most of the studies exposed non-target birds and mammals to possum carcasses since cholecalciferol possum baits are likely to provide the "worst-case" exposure scenario in terms of potential secondary poisoning due to the required increase in cholecalciferol concentration to reach a lethal dose for possums. Other studies are available where animals were fed rat or fish carcasses. In all the studies, the conclusion was that the probability of secondary poisoning from the use of cholecalciferol is low, even when the animals were repeatedly exposed to 100% contaminated diet, "no choice diet", for extended periods of time; 5 to 14 consecutive days and observed afterwards for

several weeks. As cholecalciferol is readily metabolised within organisms, exposure to the metabolites can also be assumed to have been considered in the studies.

Conclusion used in Risk Assessment – secondary poisoning of non-target organisms	
Value/conclusion	The results from the secondary poisoning studies repeatedly demonstrate minimal adverse effects to non-target animals. These trials indicate that cholecalciferol has a low risk of causing secondary poisoning, especially to pets. This is considered the most distinguishing feature of cholecalciferol when compared to other commonly used rodenticides.
Justification for the value/conclusion	There are no indications from the available information that non-target animals are at risk from the cholecalciferol potentially obtained from secondary exposure since the physical and biological availability of cholecalciferol is minimal mainly due to the anti-feedant effect* limiting body residues.

* As demonstrated by efficacy data, cessation of feeding occurs in both rats and mice within 1-2 days after bait ingestion. This is the anti-feedant effect, and as rats and mice do not continue to consume the bait up until death (unlike anticoagulant rodenticides), body residues are limited. Furthermore, it should be noted that cholecalciferol is rapidly metabolised (half-live of cholecalciferol, 25-hydroxycholecalciferol, and 1,25-dihydroxy vitamin D_3 in plasma are 4–5 days, 15–30 days, and 10–20 hrs, respectively) thus reducing its potential to bioaccumulate in non-target animals. The issue whereby certain anticoagulant residues accumulate in non-target animals is not expected to similarly occur with cholecalciferol.

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

Data waiving	
Information requirement	-
Justification	Not relevant. According to the intended use a large proportion of a specific habitat type will not be treated. Therefore, no additional studies are required.

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

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

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

A leaching test is not required for this type of product.

2.2.8.1.10 Leaching behaviour (ADS)

A leaching test is not required for this type of product

2.2.8.1.11 Testing for distribution and dissipation in soil (ADS)

No further data are required.

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

No further data are required.

2.2.8.1.13 Testing for distribution and dissipation in air (ADS)

No further data are required.

2.2.8.1.14 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)

The biocidal product will not be sprayed. Not relevant.

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

The biocidal product will not be sprayed. Not relevant.

2.2.8.2 Exposure assessment

Selontra®, containing 0.075% w/w (0.75 g/kg) cholecalciferol, is ready-to-use rodenticide soft block bait, for the control of mice and rats for use by trained professionals and professionals in and around domestic, commercial and agricultural buildings. Trained professionals may place Selontra® in covered bait points or in bait boxes throughout the infested area. For professionals, the product may be used in tamper-resistant bait stations to minimise exposure of non-target animals.

Selontra® is intended to be used in and around buildings, only. All bait points are placed in dry locations and are protected to help prevent access by non-target animals. Bait points are inspected frequently, and the bait point is replenished when bait take is observed. When no further take is observed it is considered that control has been achieved and bait points are removed from the site. The bait is placed in discrete locations within the infested area; it is not dispersed or broadcast within the environment, nor used in burrows.

General information

Assessed PT	PT 14
Assessed scenarios	In and around buildings, low rat infestation In and around buildings, high rat infestation In and around buildings, low mice infestation In and around buildings, high mice infestation In and around buildings, standard rat infestation (Nrefill 5) In and around buildings, standard rat infestation (Nrefill 1)
ESD(s) used	EUBEES Emission Scenario Document for Product Biocides Used as Rodenticides, May 2003.
Approach	Scenario 1: Low rat infestation Scenario 2: High rat infestation Scenario 3: Low mice infestation Scenario 4: High mice infestation Scenario 5a: Standard rat infestation (Nrefill 5) Scenario 5b: Standard rat infestation (Nrefill 1)
Distribution in the environment	Calculated based on EUBEES ESD (2003) and on the 'Guidance on the Biocidal Products Regulation, Vol. IV Environment – Assessment and Evaluation (Parts B+C), V.2.0, October 2017' (BPR vol. IV, Parts B+C).
Groundwater simulation	Calculated using equation 70 from the BPR Vol. IV (Parts B+C) guidance to calculate the PECporewater for the proposed scenarios. The values are presented in the 'Output' section of 'Scenario 1 to 4' tables and in the 'Summary table on calculated PEC values'. FOCUS PEARL 4.4.4 modelling is performed for 2-phenylphenol (substance of concern).
Confidential Annexes	No
Life cycle steps assessed	All environmental exposure scenarios assessed the use of the rodenticide. Production: No Formulation: No Use: Yes Service life: No
Remarks	None

2.2.8.2.1 Emission estimation

2.2.8.2.1.1 Emission to soil

As stated in the ESD for PT 14, exposure to the terrestrial environment is via direct release during application (1%) and indirect release via ingestion of bait and return to the soil as urine and faeces (90%). The area affected by indirect release during application is assumed to be 55 m long by 10 m wide according to the ESD for PT 14.

According to the intended use for rats up to 140 g (7 units) per bait point 10 m apart are used (scenario 1) or 1 m apart (scenario 2). For mice, up to 40 g (2 units) per bait point 2 m apart in light infestations are used (scenario 3) and 1 m apart in heavy infestations (scenario 4).

In addition, exposure to soil is estimated for the substance of concern, 2-phenylphenol using a concentration of 0.0496% w/w. Soil and soil porewater exposure calculations were performed for the exposure scenarios assessed for the active substance, cholecalciferol: Scenarios 1-4 for low rat infestation, high rat infestation, low mouse infestation and a high mouse infestation, respectively. All input parameters used were the same as for the active substance with the exception of the 'Fraction of active substance in product' (FCproduct).

Since Scenario 2 (worst-case for rats) yielded a PEC/PNECsoil ratio >1 for 2-phenylphenol, two additional scenarios were assessed: Scenarios 5a and 5b. Both scenarios consider an increased spacing of 5 m in between the baits (as a more realistic approach since, according to the ESD PT14, 'for rats, bait boxes are usually placed 5 to 10 m apart'); therefore, the number of sites (Nsites) assessed is 10 (based on 55m/5m -1 = 10) . However, as a Tier 1, Scenario 5a, the scenario taken directly from the ESD for PT14, considers the default Nrefill = 5 and as a Tier 2 Scenario 5b considers Nrefill = 1. This refinement is an exceptional case only for Selontra and 2-phenylphenol and cannot be extrapolate to products containing cholecalciferol or other rodenticides.

Scenarios 1 to 5a were performed considering various levels of rat and mice infestations and considering the default number of bait station refills (Nrefill) of 5 from the ESD for PT14. However, cholecalciferol has an anti-feeding effect, and available efficacy data for Selontra®, from field trials conducted on Norway rats, Black rats and House mice, demonstrate that under practical conditions the typical use of Selontra® will only require a single refill to achieve an acceptable level of control, i.e. Nrefill = 1. In addition, the substance of concern, 2-phenylphenol, is readily biodegradable and is shown to have a very rapid DT50 value in soil (2.7 hours at 20°C or 5.1 hours at 12°C). Therefore, in order to refine the risk assessment for 2-phenylphenol, the additional scenario 5b was considered. This Scenario was assumed the same as Scenario 5a except that Nrefill was reduced to 1 in Scenario 5b. The refined Nrefill of 1 is appropriate for the refined assessment of 2-phenylphenol in Selontra® due to the demonstrated anti-feeding effect of Selontra®, and the rapid degradation of 2-phenylphenol. It should not be considered to create a precedent for the authorisation of other cholecalciferol-containing products. Further detail is given at 2.2.8.2.1.1 (Emission to soil).

According to the ESD PT14, for realistic worst-case assumptions, bait boxes are inspected and replenished 5 times (i.e. on day 1, 3, 7, 14 and 21). However, available efficacy data for Selontra®, from field trials conducted on Norway rats, Black rats and House mice, demonstrate that under practical conditions the typical use of Selontra® will only require a single refill to achieve an acceptable level of control. The active substance in Selontra® is cholecalciferol, which is regarded as a sub-acute rodenticide that induces an anti-feeding effect. As demonstrated by the efficacy data, cessation of feeding occurs in both rats and mice within 1-2 days after bait ingestion. Therefore, rats and mice do not continue to consume the bait up until death (unlike the anticoagulant rodenticides). Also demonstrated by the efficacy data, the majority of bait points (over 90%) only require 1 refill during a treatment campaign. Indeed, the mean number of bait point of refills from the efficacy trials is 1.1 for mice and 1.15 for rats (brown and black). Therefore, it is justified to refine the Nrefill number to 1 to reflect realistic conditions (Scenario 5b).

In addition, it is appropriate to consider the known properties of the compound being assessed; in particular, where the degradation rate in soil of a substance is rapid, there would be expected to be no accumulation in soil between refills, and in such instances it would also be appropriate to consider exposure from a single refill. In the Assessment Report for 2-phenylphenol (biphenyl-2-ol PT 6, July 2015) a DT_{50} value of 30 days, derived from the results of the ready biodegradation study and standard assumptions from the BPR vol. IV, Parts B+C, was used at the first tier, with the results of the aerobic soil degradation study being used for higher tier refinements. On page 24 of the assessment Report (Section 2.2.2.1)), it states that an SFO DT_{50} value of 1 day could be used for refinement calculations as a worst case, based upon the calculated DT_{50} value of 2.7 hours (20 °C) from an aerobic soil degradation study. When normalised to 12 °C, the aerobic soil DT_{50} value is calculated as 5.1 hours.

The worst-case aerobic soil DT_{50} value of 1 day, suggests that 25% of 2-phenylphenol present in soil as a result of the first treatment would remain in soil at the time of the first refill 2 days later

(assuming SFO kinetics as reported in the AR). However, as stated in the AR, this value is a worst-case value, and when the actual reported value from the study is considered it is realistic to assume that none of the substance deposited onto soil would remain in the soil at the time of the next refill. Assuming single first order kinetics, based on the DT_{50} of 2.7 hours (0.1125 days) – derived at 20 °C, there will be 7.5E-04% of 2-phenylphenol remaining in soil prior to the next refill (assuming the shortest, and therefore most conservative, interval between refills of 2 days). Even when considering the normalised DT_{50} in soil (at 12 °C) of 5.1 hours (0.213 days), assuming single first order kinetics, there will be 0.206% of 2-phenylphenol remaining in soil prior to the next refill (assuming the shortest, and therefore most conservative, interval between refills of 2 days). This soil concentration is negligible and no accumulation in soil from application to application therefore needs to be considered.

According to the ESD PT14 (EUBESS, 2003) bait boxes are placed along the wall length of a structure. The default length is considered to be 55 m (which represents the perimeter of a farm). Based on this, the number of sites was calculated by dividing 55 m by the distance between the baits, then the output value is rounded down to the nearest integer (if the output is a fraction) or is subtracted by 1 (if the output is a whole number); the latter is done in order to take into account the space taken up by the bait itself. Therefore:

for scenario 1, N_{site} is calculated as 55 m / 10 m = 5.5 → 5 (fraction is rounded down to the nearest integer);

for scenarios 2 and 4, N_{site} is calculated as 55 m / 1 m = 55 → 55 - 1 = 54 (whole number is subtracted by 1);

for scenario 3, N_{site} is calculated as 55 m / 2 m = 27.5 → 27 (fraction is rounded down to the nearest integer).

for scenarios 5a and 5b, the default N_{sites} of 10 is used (55m/5m -1 = 10)

In accordance to this, the following equations (from PT 14 ESD, eq. 2-5) were used:

Calculations for emission to soil (scenario 1, 2 and 3):

$$\mathbf{Elocal_{soil\text{-}D\text{-}campaign}} = Q_{prod} \times Fc_{prod} \times N_{sites} \times N_{refil} \times F_{release,soil}$$

$$\mathbf{Clocal_{soil\text{-}D}} = Elocal_{soil\text{-}D\text{-}campaign} \times 10^3 / (AREA_{exposed\text{-}D} \times DEPTH_{soil} \times RHO_{soil} \times N_{sites})$$

$$\mathbf{Clocal_{soil\text{-}ID}} = Q_{prod} \times Fc_{prod} \times N_{sites} \times N_{refil} \times 10^3 \times F_{released\text{-}ID,soil} \times (1- F_{released\text{-}D,soil}) / (AREA_{exposed\text{-}ID} \times DEPTH_{soil} \times RHO_{soil})$$

$$\mathbf{Clocal_{soil} = Clocal_{soil\text{-}D} + Clocal_{soil\text{-}ID}}$$

For the Tier I groundwater assessment, equation 70 from the BPR vol. IV (Parts B+C) guidance was used:

$$\mathbf{PEClocal_{soil,pore\ water}} = (PEC_{soil} * RHO_{soil})/(K_{soil\text{-}water} * 1000)$$

Ksoil-water in turn is evaluated using equations 27, 26 and 24 as well as using the defaults listed in Table 3 of the BPR vol. IV (Parts B+C) guidance.

2.2.8.2.1.1.1 Scenario 1

Input parameters for calculating the local emission					
Variable/Parameter	**Symbol**	**Unit**	**Value**		**S/D/ O/P[1]**
Scenario: In and around buildings, low rat infestation					
Input					
Amount of product used at each refilling in the control operation for each bait box	Q_{prod}	g	140		S
Fraction of active substance and SoC in product	$FC_{product}$	[-]	0.00075 a.s. 0.000496 SoC		S
Number of application sites – (10 m apart)	N_{sites}	[-]	5		S
Number of refilling times	N_{refil}	[-]	5		D
Fraction of product released directly to soil	$F_{released\text{-}D,\ soil}$	[-]	0.01		D
Area directly exposed to rodenticide (around the box)	$AREA_{exposed\text{-}D}$	m^2	0.09		D
Depth of exposed soil	$DEPTH_{soil}$	m	0.1		D
Density of exposed soil	RHO_{soil}	$kg.m^{-3}$	1700		D
Fraction released indirectly to soil as parent	$F_{released\text{-}ID,soil}$	[-]	0.9		D
Area indirectly exposed to rodenticide	$AREA_{exposed\text{-}ID}$	m^2	550		D
Output					
			Active substance	SoC	
Local direct emission rate of active substance to soil from a campaign	$Elocal_{soil\text{-}D\text{-}campaign}$	g	2.63E-02	1.74E-02	O
Local concentration in soil due to direct release after a campaign	$Clocal_{soil\text{-}D}$	$mg.kg^{-1}$ wwt	3.43E-01	2.27E-01	O
Concentration in soil due to indirect (disperse) release after a campaign	$Clocal_{soil\text{-}ID}$	$mg.kg^{-1}$ wwt	2.50E-02	1.65E-02	O
Total concentration in the soil ($Clocal_{soil}$) around the bait box taking into account both direct and disperse releases	$Clocal_{soil}$	$mg.kg^{-1}$ wwt	3.68E-01	2.43E-01	O
Predicted environmental concentration in porewater/groundwater	$PEClocal_{soil,porew}$	$\mu g.l^{-1}$	0.0489	38.9	O

[1] S = Set parameter provided by applicant; D = default value; O = Output value; P = Picklist value

2.2.8.2.1.1.2 Scenario 2

Input parameters for calculating the local emission					
Variable/Parameter	**Symbol**	**Unit**	**Value**		**S/D/ O/P[1]**
Scenario: In and around buildings, high rat infestation					
Input					
Amount of product used at each refilling in the control operation for each bait box	Q_{prod}	g	140		S
Fraction of active substance and SoC in product	$FC_{product}$	[-]	0.00075 a.s. 0.000496 SoC		S
Number of application sites – (1 m apart)	N_{sites}	[-]	54		S
Number of refilling times	N_{refil}	[-]	5		D
Fraction of product released directly to soil	$F_{released\text{-}D,\ soil}$	[-]	0.01		D
Area directly exposed to rodenticide (around the box)	$AREA_{exposed\text{-}D}$	m^2	0.09		D
Depth of exposed soil	$DEPTH_{soil}$	m	0.1		D
Density of exposed soil	RHO_{soil}	$kg.m^{-3}$	1700		D
Fraction released indirectly to soil as parent	$F_{released\text{-}ID,soil}$	[-]	0.9		D
Area indirectly exposed to rodenticide	$AREA_{exposed\text{-}ID}$	m^2	550		D
Output					
			Active substance	SoC	
Local direct emission rate of active substance to soil from a campaign	$Elocal_{soil\text{-}D\text{-}campaign}$	g	2. 84E-01	1.87E-01	O
Local concentration in soil due to direct release after a campaign	$Clocal_{soil\text{-}D}$	$mg.kg^{-1}$ wwt	3.43E-01	2.27E-01	O
Concentration in soil due to indirect (disperse) release after a campaign	$Clocal_{soil\text{-}ID}$	$mg.kg^{-1}$ wwt	2.70E-01	1.79E-01	O
Total concentration in the soil ($Clocal_{soil}$) around the bait box taking into account both direct and disperse releases	$Clocal_{soil}$	$mg.kg^{-1}$ wwt	6.13E-01	4.06E-01	O
Predicted environmental concentration in porewater/groundwater	$PEClocal_{soil,porew}$	$\mu g.l^{-1}$	0.0815	65.1	O

[1] S = Set parameter provided by applicant; D = default value; O = Output value; P = Picklist value

2.2.8.2.1.1.3 Scenario 3

Input parameters for calculating the local emission					
Variable/Parameter	**Symbol**	**Unit**	**Value**		**S/D/ O/P[1]**
Scenario: In and around buildings, low mice infestation					
Input					
Amount of product used at each refilling in the control operation for each bait box	Q_{prod}	g	40		S
Fraction of active substance and SoC in product	$FC_{product}$	[-]	0.00075 a.s. 0.000496 SoC		S
Number of application sites – (2 m apart)	N_{sites}	[-]	27		S
Number of refilling times	N_{refil}	[-]	5		D
Fraction of product released directly to soil	$F_{released\text{-}D,\ soil}$	[-]	0.01		D
Area directly exposed to rodenticide (around the box)	$AREA_{exposed\text{-}D}$	m^2	0.09		D
Depth of exposed soil	$DEPTH_{soil}$	m	0.1		D
Density of exposed soil	RHO_{soil}	$kg.m^{-3}$	1700		D
Fraction released indirectly to soil as parent	$F_{released\text{-}ID,soil}$	[-]	0.9		D
Area indirectly exposed to rodenticide	$AREA_{exposed\text{-}ID}$	m^2	550		D
Output					
			Active substance	SoC	
Local direct emission rate of active substance to soil from a campaign	$Elocal_{soil\text{-}D\text{-}campaign}$	g	4.05E-02	2.68E-02	O
Local concentration in soil due to direct release after a campaign	$Clocal_{soil\text{-}D}$	$mg.kg^{-1}$ wwt	9.80E-02	6.48E-02	O
Concentration in soil due to indirect (disperse) release after a campaign	$Clocal_{soil\text{-}ID}$	$mg.kg^{-1}$ wwt	3. 86E-02	2.55E-02	O
Total concentration in the soil ($Clocal_{soil}$) around the bait box taking into account both direct and disperse releases	$Clocal_{soil}$	$mg.kg^{-1}$ wwt	1.37E-01	9.04E-02	O
Predicted environmental concentration in porewater/groundwater	$PEClocal_{soil,porew}$	$\mu g.l^{-1}$	0.0182	14.5	O

[1] S = Set parameter provided by applicant; D = default value; O = Output value; P = Picklist value

2.2.8.2.1.1.4 Scenario 4

Input parameters for calculating the local emission					
Variable/Parameter	**Symbol**	**Unit**	**Value**		**S/D/ O/P[1]**
Scenario: In and around buildings, high mice infestation					
Input					
Amount of product used at each refilling in the control operation for each bait box	Q_{prod}	g	40		S
Fraction of active substance and SoC in product	$FC_{product}$	[-]	0.00075 a.s. 0.000496 SoC		S
Number of application sites – (1 m apart)	N_{sites}	[-]	54		S
Number of refilling times	N_{refil}	[-]	5		D
Fraction of product released directly to soil	$F_{released\text{-}D,\ soil}$	[-]	0.01		D
Area directly exposed to rodenticide (around the box)	$AREA_{exposed\text{-}D}$	m^2	0.09		D
Depth of exposed soil	$DEPTH_{soil}$	m	0.1		D
Density of exposed soil	RHO_{soil}	$kg.m^{-3}$	1700		D
Fraction released indirectly to soil as parent	$F_{released\text{-}ID,soil}$	[-]	0.9		D
Area indirectly exposed to rodenticide	$AREA_{exposed\text{-}ID}$	m^2	550		D
Output					
			Active substance	SoC	
Local direct emission rate of active substance to soil from a campaign	$Elocal_{soil\text{-}D\text{-}campaign}$	g	8.10E-02	5.36E-02	O
Local concentration in soil due to direct release after a campaign	$Clocal_{soil\text{-}D}$	$mg.kg^{-1}$ wwt	9.80E-02	6.48E-02	O
Concentration in soil due to indirect (disperse) release after a campaign	$Clocal_{soil\text{-}ID}$	$mg.kg^{-1}$ wwt	7.72E-02	5.10E-02	O
Total concentration in the soil ($Clocal_{soil}$) around the bait box taking into account both direct and disperse releases	$Clocal_{soil}$	$mg.kg^{-1}$ wwt	1.75E-01	1.16E-01	O
Predicted environmental concentration in porewater/groundwater	$PEClocal_{soil,porew}$	$\mu g.l^{-1}$	0.0233	18.6	O

[1] S = Set parameter provided by applicant; D = default value; O = Output value; P = Picklist value

2.2.8.2.1.1.5 Scenario 5a

Input parameters for calculating the local emission					
Variable/Parameter	**Symbol**	**Unit**	**Value**		**S/D/ O/P[1]**
Scenario: In and around buildings, standard rat infestation (Nrefill 5)					
Input					
Amount of product used at each refilling in the control operation for each bait box	Q_{prod}	g	140		S
Fraction of active substance and SoC in product	$FC_{product}$	[-]	0.00075 a.s. 0.000496 SoC		S
Number of application sites – (10 m apart)	N_{sites}	[-]	10		S
Number of refilling times	N_{refil}	[-]	5		D
Fraction of product released directly to soil	$F_{released\text{-}D,\ soil}$	[-]	0.01		D
Area directly exposed to rodenticide (around the box)	$AREA_{exposed\text{-}D}$	m^2	0.09		D
Depth of exposed soil	$DEPTH_{soil}$	m	0.1		D
Density of exposed soil	RHO_{soil}	$kg.m^{-3}$	1700		D
Fraction released indirectly to soil as parent	$F_{released\text{-}ID,soil}$	[-]	0.9		D
Area indirectly exposed to rodenticide	$AREA_{exposed\text{-}ID}$	m^2	550		D
Output					
			Active substance	SoC	
Local direct emission rate of active substance to soil from a campaign	$Elocal_{soil\text{-}D\text{-}campaign}$	g	5.25E-02	3.47E-02	O
Local concentration in soil due to direct release after a campaign	$Clocal_{soil\text{-}D}$	$mg.kg^{-1}$ wwt	3.43E-01	2.27E-01	O
Concentration in soil due to indirect (disperse) release after a campaign	$Clocal_{soil\text{-}ID}$	$mg.kg^{-1}$ wwt	5.00E-02	3.31E-02	O
Total concentration in the soil ($Clocal_{soil}$) around the bait box taking into account both direct and disperse releases	$Clocal_{soil}$	$mg.kg^{-1}$ wwt	3.93E-01	2.60E-01	O
Predicted environmental concentration in porewater/groundwater	$PEClocal_{soil,porew}$	$\mu g.l^{-1}$	0.0522	41.7	O

[1] S = Set parameter provided by applicant; D = default value; O = Output value; P = Picklist value

2.2.8.2.1.1.6 Scenario 5b

Input parameters for calculating the local emission					
Variable/Parameter	**Symbol**	**Unit**	**Value**		**S/D/ O/P[1]**
Scenario: In and around buildings, standard rat infestation (Nrefill 1)					
Input					
Amount of product used at each refilling in the control operation for each bait box	Q_{prod}	g	140		S
Fraction of active substance and SoC in product	$FC_{product}$	[-]	0.00075 a.s. 0.000496 SoC		S
Number of application sites – (10 m apart)	N_{sites}	[-]	10		S
Number of refilling times	N_{refil}	[-]	1		D
Fraction of product released directly to soil	$F_{released\text{-}D,\ soil}$	[-]	0.01		D
Area directly exposed to rodenticide (around the box)	$AREA_{exposed\text{-}D}$	m^2	0.09		D
Depth of exposed soil	$DEPTH_{soil}$	m	0.1		D
Density of exposed soil	RHO_{soil}	$kg.m^{-3}$	1700		D
Fraction released indirectly to soil as parent	$F_{released\text{-}ID,soil}$	[-]	0.9		D
Area indirectly exposed to rodenticide	$AREA_{exposed\text{-}ID}$	m^2	550		D
Output					
			Active substance	SoC	
Local direct emission rate of active substance to soil from a campaign	$Elocal_{soil\text{-}D\text{-}campaign}$	g	1.05E-02	6.94E-03	O
Local concentration in soil due to direct release after a campaign	$Clocal_{soil\text{-}D}$	$mg.kg^{-1}$ wwt	6.86E-02	4.54E-02	O
Concentration in soil due to indirect (disperse) release after a campaign	$Clocal_{soil\text{-}ID}$	$mg.kg^{-1}$ wwt	1.00E-02	6.62E-03	O
Total concentration in the soil ($Clocal_{soil}$) around the bait box taking into account both direct and disperse releases	$Clocal_{soil}$	$mg.kg^{-1}$ wwt	7.86E-02	5.20E-02	O
Predicted environmental concentration in porewater/groundwater	$PEClocal_{soil,porew}$	$\mu g.l^{-1}$	0.0104	8.33	O

[1] S = Set parameter provided by applicant; D = default value; O = Output value; P = Picklist value

2.2.8.3 Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	No	No	No	No	No	No	Yes	Yes	Yes: primary and secondary poisoning
Scenario 2	No	No	No	No	No	No	Yes	Yes	Yes: primary and secondary poisoning
Scenario 3	No	No	No	No	No	No	Yes	Yes	Yes: primary and secondary poisoning
Scenario 4	No	No	No	No	No	No	Yes	Yes	Yes: primary and secondary poisoning
Scenario 5a,b	No	No	No	No	No	No	Yes	Yes	Yes: primary and secondary poisoning

Input parameters (only set values) for calculating the fate and distribution in the environment				
	Active substance	SoC		
Input	Value	Value	Unit	Remarks
Molecular weight	384.7	170.2	g/mol	
Vapour pressure (at 25°C)	6.0×10^{-5}	0.906	Pa	
Water solubility (at 20°C)	0.5	560 000	µg/l	
Log Octanol/water partition coefficient (at 20°C)	>5.0	3.18	Log 10	
Organic carbon/water partition coefficient (Koc)	426580	347	mL/g	(log K_{OC} > 5.63 at 1 µg/L)
Biodegradability	Not readily biodegradable	Readily bio-degradable		
DT_{50} for degradation in soil (at 12 °C)	62.4	0.213	d	0.11 d at 20 °C

2.2.8.3.1 Calculated PEC values – Tier 1

Summary table on calculated PEC values		
	PEClocal$_{soil}$	
	[mg/kg wwt]	
	Active substance	**SoC**
Scenario 1: In and around buildings, low rat infestation	0.368	0.243
Scenario 2: In and around buildings, high rat infestation	0.613	0.406
Scenario 3: In and around buildings, low mice infestation	0.137	0.090
Scenario 4: In and around buildings, high mice infestation	0.175	0.116
Scenario 5a: In and around buildings, standard rat infestation (Nrefill 5)	0.393	0.260
Scenario 5b: In and around buildings, standard rat infestation (Nrefill 1)	0.079	0.052
	PECporewater	
	[µg/L]	
Scenario 1: In and around buildings, high rat infestation	0.0489	38.9
Scenario 2: In and around buildings, high rat infestation	0.0815	65.1
Scenario 3: In and around buildings, low mice infestation	0.0182	14.5
Scenario 4: In and around buildings, high mice infestation	0.0233	18.6
Scenario 5a: In and around buildings, standard rat infestation (Nrefill 5)	0.052	41.7
Scenario 5b: In and around buildings, standard rat infestation (Nrefill 1)	0.010	8.33

First Tier – Groundwater: $PEC_{localsoil,porewater}$ calculations

The predicted Tier 1 concentrations of the active substance in pore water are <1 µg/L for the active substance in all scenarios and thus no refinement is needed.

The predicted Tier 1 concentrations of the substance of concern in pore water are >0.1 µg/L in all scenarios. The calculated $PEC_{localsoil,porewater}$ are considered to be very conservative as they do not take into account the degradation, transformation and dilution of 2-phenylphenol in soil layers. Given that the 2-phenylphenol is readily biodegradable and has a short DT_{50} in soil (0.213 day, at 12 °C), it is anticipated that it would degrade rapidly in soil and therefore would be unlikely to reach groundwater. To evidence the above, the predicted concentrations in pore water were refined with FOCUS PEARL 4.4.4.

Higher Tier – Groundwater: Modelling using FOCUS PEARL 4.4.4 for 2-phenylphenol

The standard higher tier assessment for groundwater described in the Revised ESD for PT 14, considers 10 bait stations per house (5 m apart). The application rates are calculated for the individual applications, with the FOCUS PEARL modelling performed considering a total of five refills. Therefore, the higher tier modelling performed represents the individual application rates considered in Scenario 5a and 5b.

Summary of the input parameters used are indicated below and summary of the output $PEC_{groundwater}$ values are provided thereafter.

Input parameters used for groundwater modelling			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	170.2	g/mol	AR*
Vapour pressure (at 25°C)	0.906	Pa	AR*
Water solubility (at 20°C)	560	mg/l	At pH 7; AR*
K_{oc}	347	L/kg	Arithmetic mean value of 4 soils; AR* and also EFSA Scientific Report (2008) 217, 52-67
K_{om}	201.3	L/kg	Koc/1.724
Freundlich exponent (1/n)**	0.82	-	Arithmetic mean value of 4 soils; EFSA Scientific Report (2008) 217, 52-67
DT_{50} for degradation in soil***	30	days (at 20ºC)	Default DT_{50} in soil. However, the standardised value is set at 12ºC, meaning that the default DT_{50} in soil is actually 15.8 days, at 20ºC. Therefore, represents a very worst case.
	0.11	days (at 20ºC)	According to the AR* (Section 2.2.2.1.) Also in the EFSA Scientific Report (2008) 217, 52-67
Plant uptake factor	0	-	Revised ESD for PT 14 (Table 28)

* AR = Assessment Report for Biphenyl-2-ol (2-phenylphenol) in PT 6 (July 2015, Spain)
** The Freundlich exponent was not reported in the Assessment Report, however, it is the same data as reported in the EFSA conclusion.
*** The degradation rate value is required at 20 ºC for modelling purposes (the model applies temperature correction as part of its internal routines)

Based on the Revised ESD for PT 14[11], Table 27, for application around buildings in bait boxes/stations, there is direct exposure to soil via direct and indirect emissions. The agronomic input parameters used for groundwater modelling according to Table 28 of the Revised ESD for PT 14 are summarized below.

Application type	To the soil surface
Application time	September: 15th, 17th, 21th, 28th October: 5th
Crop type	Grass/alfalfa
Application rate	6.95 g a.s./ha (See table below)

In the following table, based on standard higher tier assessment for groundwater using FOCUS PEARL detailed in the Revised ESD for PT14, the rodenticide application amount arising from direct and indirect emissions per application for an area of 1 ha is calculated. It is assumed that 11 buildings with a wall length of 55 m are located per ha. The number of houses per ha was deduced from standard house scenarios used in other ESDs, e.g. from the ESD for PT 8 (OECD, 2013). The standard house is 17.5 m long and 7.5 m wide and covers an area of 131.25 m². Taking into account the 10-meter zone around the house as the zone most frequented by rodents, the resulting $AREA_{exposed\text{-}ID}$ is 900 m² (= $AREA_{total}$ – $AREA_{house}$). So, 11 houses are located on 1 ha (11 x 900 m^2 = 9900 m^2). Hence, the number of bait stations/boxes per ha accounts for 110 for rat control and 220 for mice control.

11 Revised Emission Scenario Document for Product Type 14 (Rodenticides), August 2018.

Because the amount of product use for rat control per bait box per refill is 3.5 time higher than for mice control, the assessment on rat control represents a worst case, and covers Scenario 3 (low mice infestation) and Scenario 4 (high mice infestation).

The table below shows how the application rate, used in the FOCUS PEARL model, was calculated for applications around buildings on unpaved ground.

Parameter	**Nomenclature**	**Unit**	**Value**	**Origin**
Amount of product used at each refilling in the control operation for each bait box	Q_{prod}	g	140 (rat control)	S
Fraction of active substance in product	$FC_{product}$	[-]	4.96E-04	S
Number of application sites – Rat control	N_{sites}	[ha^{-1}]	110	S
Fraction of active substance released directly to soil	$F_{released\text{-}D,\ soil}$	[-]	0.01 (bagged bait)	D
Fraction of active substance released indirectly to soil	$F_{released\text{-}ID,soil}$	[-]	0.9	D
Fraction of active substance metabolised	F_{metab}	[-]	0	
Output				
Local direct emission rate to soil from one application per ha	$Elocal_{soil\text{-}D,\ one\ appl}$	[g/ha]	7.64E-02	O
Local indirect emission rate to soil from one application per ha	$Elocal_{soil\text{-}ID,\ one\ appl}$	[g/ha]	6.87E+00	O
Application rate to soil from one application per ha	App_rate	[kg/ha]	**6.95E-03**	O
Calculation				
$Elocal_{soil\text{-}D,\ one\ appl} = Q_{prod} * Fc_{product} * N_{sites} * F_{released\text{-}D,\ soil}$				
$Elocal_{soil\text{-}ID,\ one\ appl} = Q_{prod} * Fc_{product} * N_{sites} * F_{released\text{-}ID,\ soil}$				
App_rate = $(Elocal_{soil\text{-}D,\ one\ appl} + Elocal_{soil\text{-}ID,\ one\ appl})/1000$				

The results for the different FOCUS groundwater scenarios are presented below. The results demonstrate an acceptable risk to groundwater from 2-phenylphenol considering both the DT_{50} value of 30 days and the DT_{50} value of 0.11 days.

Grass/alfalfa*		
LOCATION	**$PEC_{groundwater}$ (µg/L)**	
	$DT_{50\ soil}$ = 30 days	**$DT_{50\ soil}$ = 0.11 days)**
CHATEAUDUN	< 0.000001	< 0.000001
HAMBURG	< 0.000001	< 0.000001
JOKIOINEN	< 0.000001	< 0.000001
KREMSMUENSTER	< 0.000001	< 0.000001
OKEHAMPTON	< 0.000001	< 0.000001
PIACENZA	< 0.000001	< 0.000001
PORTO	< 0.000001	< 0.000001
SEVILLA	< 0.000001	< 0.000001
THIVA	< 0.000001	< 0.000001
*According to PT14 ESD, Table 28: Application scheme and crop parameter for FOCUS PEARL calculations.		

The predicted groundwater concentrations were <<0.1 µg/L in all FOCUS scenarios.

2.2.8.3.2 Primary and secondary poisoning

The formulation of cholecalciferol, Selontra®, contains 0.075% (w/w) per bait. Trained professionals may place Selontra® in covered bait points or in bait boxes throughout the infested area. For professionals, the product may be used in tamper-resistant bait stations to minimise exposure of non-target animals. The combined factors of bait delivery methods, product make-up and adherence to the product label reduces the risk of primary and secondary poisoning exposure to non-target animals. Cholecalciferol is not known to be frequently associated with poisoning incidents to non-target animals due to primary or secondary exposure. Although the risk for birds and mammals may be considered minimal, as with all rodenticides primary and secondary poisoning is still a possibility and needs to be addressed. To evaluate the potential toxicity to non-target animals, the following primary and secondary poisoning assessments are presented below.

Assessment of primary and secondary poisoning for the substance of concern (co-formulant 2-phenylphenol functioning as preservative) is not considered necessary, since the active substance fails the primary and secondary poisoning risk assessments. 2-phenylphenol does not act as rodenticide and is not expected to significantly increase the risk of primary and secondary poisoning. Also, 2-phenylphenol has a low potential to bioaccumulate (BCF 21.7 whole fish, 114-115 lipid content) and toxicity to birds and mammals is considerably lower compared to the active substance.

2.2.8.3.2.1 Primary poisoning

In a **primary poisoning scenario**, non-target animals come into direct contact with the product if bait stations are not adequately protected or have been damaged. Also, well protected bait may be encountered by animals that are small enough to reach or touch the bait, e.g. weasels, stoats and juvenile cats/dogs. Page 47 of the Emission Scenario Document for PT 14 mentions in addition to wild-living animals, domestic animals such as hens and pigs may also be among animals that are at risk of being poisoned accidentally because they prefer many types of vegetable food (like PT 14 baits).

Normal use

When the ready-to-use bait product is applied according to the label directions, (i.e. in covered bait points or in bait boxes for trained professionals, and in tamper-resistant bait stations to minimise exposure of non-target animals for professional use) primary exposure to non-target organisms to the bait is considered unlikely. The estimated daily uptake rates are therefore considered to be negligible for all example species, as also acknowledged in the ESD for PT 14.

In use scenarios where the units are placed in protected bait points, there is the risk of primary poisoning mainly for birds and mammals of equal size or smaller than the target rodents, which may be able to enter the bait points. However, the primary poisoning hazard to mammals and birds (both wild and domestic) from use in and around building is expected to be small due to the use of specific risk mitigation measures (the use of protected bait points, stringent use of careful baiting practises, for example the cleaning up of spillage afterwards).

Realistic worst case Tier 1 and Tier 2)

Worst case exposure estimations, for primary poisoning, were based on the formulae and default values proposed for mammals and birds by the ESD for PT 14. Specifically, the Step 1 assumes that there is no bait avoidance by the non-target animals and that they obtain 100 % of their diet in the treated area. Whereas the Step 2 exposure estimates are based on adapted default values of AV = 0.9 for mammals and AV = 0.5 for birds (instead of 1; CA-Nov 06.Doc. 4.3), PT = 0.8 (instead of 1), and an elimination factor of 0.3 (instead of 0.1) as recommended in the ESD for PT 14 for anticoagulant rodenticides.

In accordance to this, the following equations (from PT 14 ESD, eq.19-20) were used:

$$\mathbf{ETE} = (FIR / BW) \times C \times AV \times PT \times PD$$

$$\mathbf{EC} = ETE \times (1 - EI)$$

$$\mathbf{ECn} = \sum_{i=1}^{n-1} ETE \times (1 - EI)^{i}$$

Where:

Input parameters for calculating the local emission				
Variable/Parameter	**Symbol**	**Unit**	**Value**	**S/D/O/P[12]**
Realistic-worst-case assessment				
Input				
Body weight	BW	g	*(See picklist: ESD PT 14, Table 3.1 p.51)*	P
Food intake rate of indicator species (fresh weight)	FIR	g.d-1	*(See picklist: ESD PT 14, Table 3.1 p.51)*	P
Concentration of active compound in fresh diet (bait)	C	mg.kg-1	750	S
Avoidance factor (1 = no avoidance; 0 = complete avoidance)	AV	[-]	Step 1: 1 Step 2: 0.9	D
Fraction of diet obtained in treated area (value between 0 and 1)	PT	[-]	Step 1: 1 Step 2: 0.8	D
Fraction of food type in diet (value between 0 and 1; one type or more types)	PD	[-]	1	S
Fraction of daily uptake eliminated (value between 0 and 1)	El	[-]	Step 1: 0.1 Step 2: 0.3	S
Number of days the animal is feeding on the treated food	N	d	Step 1: 5 Step 2: 5	S
Output				
Estimated daily uptake of a compound	ETE	mg.kg-1 bw.d-1	*	O
Expected concentration of active substance in the animal	EC	mg.kg-1	*	O
Expected concentration of active substance in the animal before new meal on day "n"	ECn	mg.kg-1	*	O
*See tables below for summary of output values				

The fraction of food type in diet (PD = 1) is based on the assumption that 100% of the rodents' food consists of poisoned bait.

In the ESD for PT 14 (2003) it is stated that as anticoagulant rodenticides are eliminated from the body mainly through faeces, a reasonable default value for elimination is 30% per day (default value

[12] S = Set parameter provided by applicant; D = default value; O = Output value; P = Picklist value

of 0.3%). No studies on the elimination of cholecalciferol from rodents are provided, but in humans 50% is considered a reasonable conservative estimate regarding uptake, hence 50% excretion is assumed (cholecalciferol Doc IIA, Section 4.1; Doc III A6.2.1). Therefore, it can be assumed that 30% excretion from rodents is feasible, particularly as the major excretion route for cholecalciferol and its metabolites is through faeces. Thus, the default elimination rates are used (El = 0.3 in Tier 2, Step 2).

The number of days the animal is feeding on the treated food (n = 5) is based on the default in the ESD for PT 14 (2003).

Expected concentrations of the active substance in selected non-target animals in primary poisoning scenarios after one meal followed by a 24 hour elimination period (concentration of cholecalciferol in rodenticide bait 0.0750%)

	Symbol	Variable/parameter	Normal Use*	Realistic worst case Step 1**	Realistic worst case Step 2 ***
				mg/kg BW****	mg/kg BW****
OUTPUT	ETE dog	estimated daily uptake of a compound	≅ 0	45	32.4
	EC	estimated conc. of a.i. in indicator species	≅ 0	40.5	22.7
	ETE pig	estimated daily uptake of a compound	≅ 0	5.6	4.1
	EC	estimated conc. of a.i. in indicator species	≅ 0	5.1	2.8
	ETE young pig	estimated daily uptake of a compound	≅ 0	18	13.0
	EC	estimated conc. of a.i. in indicator species	≅ 0	16.2	9.1
	ETE tree sparrow	estimated daily uptake of a compound	≅ 0	259.1	103.6
	EC	estimated conc. of a.i. in indicator species	≅ 0	233.2	72.5
	ETE chaffinch	estimated daily uptake of a compound	≅ 0	225	90.0
	EC	estimated conc. of a.i. in indicator species	≅ 0	202.5	63.0
	ETE wood pigeon	estimated daily uptake of a compound	≅ 0	81.3	32.5
	EC	estimated conc. of a.i. in indicator species	≅ 0	73.1	22.8
	ETE pheasant	estimated daily uptake of a compound	≅ 0	80.8	32.3
	EC	estimated conc. of a.i. in indicator species	≅ 0	72.7	22.6

Small birds could potentially enter a bait station but would only ingest a limited amount of Selontra® as the product is in the form of a soft block bait and thus the bird must repeatedly peck at it to break off bite-sized pieces. Larger birds that cannot get into a bait station will not ever encounter a full block. Therefore, for such birds it is impractical to do a calculation based upon the assumption a bird eats its full daily ration. The dog is considered as an example of a larger mammal which is potentially at risk from direct consumption of baits placed in and around a house. If label instructions are followed, as should be the case for normal use, the primary poisoning risk for dogs could be negligible.

** Step 1: AV = 1, PT = 1, PD = 1, EL = 0.1
*** Step 2: AV = 0.9 for mammals and AV = 0.5 for birds, PT = 0.8, PD = 1, El = 0.3.
****ETE is expressed in mg/(kg bw•day), EC is expressed in mg/kg BW

Expected concentrations (EC_n) of a.i. [mg/kg bw] in selected non-target animals after 5 days exposure, relevant for the assessment of long-term primary poisoning Tier 2.

Species	Estimated daily uptake ETE [mg/(kg bw·day)]*	Expected concentration after 5 days EC_n [mg/kg bw]**	PEC_{oral} (maximum EC_n)
Dog	32.4	57.4	Mammals: 57.4 mg/kg bw
Pig	4.1	7.3	
Young pig	13.0	23.1	
Tree sparrow	103.6	183.7	Birds: 183.7 mg/kg bw
Chaffinch	90.0	159.6	
Wood pigeon	32.5	57.6	
Pheasant	32.3	57.3	
* AV = 0.9 for mammals and AV = 0.5 for birds, PT = 0.8, PD = 1, EI = 0.3 ** *n* = 5 days			

2.2.8.3.2.2 Secondary poisoning

The proposed use pattern of the supported product (trained professionals may place Selontra® in covered bait points or in bait boxes. For professionals, the product may be used in tamper-resistant bait stations to minimise exposure of non-target animals.) and the design of the product act to mitigate the potential for secondary poisoning, which is considered an unlikely event.

Estimates of secondary poisoning (worst case, intermediate case and normal case acute exposure and chronic exposure, for rodents feeding 5 days) *via* the food chain were calculated in EUBEES using the following equations (from PT 14 ESD, eq.21):

$$EC_n = \sum_{n-1}^{n-1} ETE \times (1 - EI)^n$$

Where:

Symbol		Variable/parameter	Unit	Type of data	Realistic worst case	Inter-mediate	Normal case
INPUTI	FIR/BW	Rodent: Food intake rate per bodyweight	[-]	D	0.1	0.1	0.1
	C	Concentration of active compound in fresh diet (bait)	mg/kg	S	750	750	750
	AV	Rodent: Avoidance factor (1 = no avoid, 0 = complete avoid)	[-]	D/S	1	1	1
	PT	Rodent: Fraction of diet obtained in treated area	[-]	D/S	1	1	1
	PD	Rodent: Fraction of food type (treated bait) in diet	[-]	D/S	1	0.5	0.2
	EI	Fraction of daily uptake eliminated	(per day)	S	0.3	0.3	0.3
	F_{rodent}	Fraction of poisoned rodents in predator's diet (acute = 1)	[-]	D	1	1	1
		Fraction of poisoned rodents in predator's diet (chronic = 0.5)	[-]	S	0.5	0.5	0.5
	n	Days the rodent is feeding on rodenticide until caught by predator**	[-]	S	5	5	5
OUTPUT	ETE	Estimated daily uptake of the rodent	mg/(kg bw·day)	O	*75	*37.5	*15.0
	EC_n	Expected concentration in rodent on day 5 before feeding	mg/kg bw	O	* 132.98	* 66.49	* 26.60
	$PEC_{oral, predator}$	**PEC in food of predator on day 5 after last meal ('acute')**	**mg/kg rodent**	**O**	* 207.98	* 103.99	* 41.60
		PEC in food of predator on day 5 after last meal ('chronic')	**mg/kg rodent**	**O**	* 103.99	* 52.00	* 20.80

* See text regarding how ETE, EC_n, and $PEC_{oral, predator}$ were derived
** set to N = 5 as agreed at BPC WG I, 2017.

2.2.8.4 Risk characterisation

2.2.8.4.1 Atmosphere

Conclusion: The exposure of air is considered negligible in the scenario 'in and around buildings' according to the ESD for PT 14 and in addition cholecalciferol has a low vapour pressure of 6.0×10^{-5} Pa at 25°C. Consequently, exposure of air will be negligible. Air was neither considered a compartment of concern for 2-phenylphenol (Assessment Report for biphenyl-2-ol PT 6 July 2015, Spain).

2.2.8.4.2 Sewage treatment plant (STP)

Conclusion: No direct emissions to STP should occur from the use of cholecalciferol as a rodenticide and 2-phenylphenol as preservative in and around buildings. Consequently, exposure of STP will be negligible.

2.2.8.4.3 Aquatic compartment

The cholecalciferol products are intended to be used in and around buildings, only. Trained professionals may place Selontra® in covered bait points or in bait boxes. For professionals, the product may be used in tamper-resistant bait stations to minimise exposure of non-target animals. According to the EUBEES ESD PT 14 for this exposure scenario the main exposure of the environment is expected to be soil, and other environmental compartments, such as the aquatic compartment, are considered not to be relevant. The use pattern of Selontra® precludes contamination of aquatic ecosystems, both freshwater and marine, and therefore PNECwater and PNECsed have not been calculated.

Conclusion: No direct emissions to surface water (freshwater and marine) should occur from the use of cholecalciferol as a rodenticide and 2-phenylphenol as preservative in and around buildings. Therefore, aquatic PEC/PNEC ratios for the proposed use of cholecalciferol and 2-phenylphenol have not been determined.

2.2.8.4.4 Terrestrial compartment

Calculated PEC/PNEC values				
	Active substance	**SoC**	**Active substance PNECsoil= 5.78 mg/kg wwt**	**SoC PNECsoil= 0.048 mg/kg wwt**
	PEClocalsoil [mg/kg wwt]	**PEClocalsoil [mg/kg wwt]**	**PEC/PNEC$_{soil}$**	**PEC/PNEC$_{soil}$**
Scenario 1 (low rat infestation)	0.368	0.243	0.064	5.063
Scenario 2 (high rat infestation)	0.613	0.406	0.106	8.458
Scenario 3 (low mice infestation)	0.137	0.090	0.024	1.875
Scenario 4 (high mice infestation)	0.175	0.116	0.030	2.417
Scenario 5a standard rat infestation (Nrefill 5)	0.393	0.260	0.068	5.417
Scenario 5b standard rat infestation (Nrefill 1)	0.079	0.052	0.014	1.083

Conclusion: Based on realistic worst case assumptions for control of rats and mice, PEC/PNEC ratios are < 1 for the active substance.

An unacceptable risk was identified for 2-phenylphenol in the original scenarios calculated for the active substance. The unacceptable risk was due to the $PNEC_{soil}$ of the 2-phenylphenol which was two orders of magnitude lower than $PNEC_{soil}$ of the active substance.

To refine the risk assessment two additional scenarios, 5a and 5b were considered. The standard input parameters were used for the scenario 5a and 5b, except Nrefill was reduced to 1 in Scenario 5b. Nrefill of 1 was justified due to anti-feeding effect of Selontra. In addition, rapid degradation rate in soil further justified the Nrefil of 1 for 2-phenylphenol. The refinement of the risk assessment is further explained in Section 2.2.8.2.1.1.

Scenarios 1 to 5a were performed considering various levels of rat and mice infestations and considering the default number of bait station refills (Nrefill) of 5 from the ESD for PT14. However, cholecalciferol can have an anti-feeding effect, and available efficacy data for Selontra®, from field trials conducted on Norway rats, Black rats and House mice, demonstrate that under practical conditions the typical use of Selontra® will only require a single refill to achieve an acceptable level of control, i.e. Nrefill = 1. In addition, the substance of concern, 2-phenylphenol, is readily biodegradable and is shown to have a very rapid DT50 value in soil (2.7 hours at 20°C or 5.1 hours at 12°C). Therefore, in order to refine the risk assessment for 2-phenylphenol, the additional scenario 5b was considered. This Scenario was assumed the same as Scenario 5a except that Nrefill was reduced to 1 in Scenario 5b. The refined Nrefill of 1 is appropriate for the refined assessment of 2-phenylphenol in Selontra® due to the demonstrated anti-feeding effect of Selontra®, and the very rapid degradation of 2-phenylphenol. It should not be considered to create a precedent for the authorisation of other cholecalciferol-containing products. Further detail is given at 2.2.8.2.1.1 (Emission to soil).

Even after the refinement, the PEC/PNEC ratio of 1 was slightly exceeded. The risk is considered acceptable taking into consideration that considerably higher PEC/PNEC ratios have been identified for primary and secondary poisoning and Selontra has to be approved on the basis of Article 19(5) of the BPR (528/2012/EU).

2.2.8.4.5 Groundwater

It has been agreed (TAB 1.3) that a groundwater assessment should always be performed, even for rodenticides when only hot spot applications are considered. Equation 70 from BPR vol. IV Parts B+C of ECHA guidance on the BPR was used to calculate the $PEC_{porewater}$ based on the worst case PEC_{soil} calculations as 0.0815 μg/L for the active substance. This is below the threshold value of 0.1 μg/L.

The soil porewater concentrations of 2-phenylphenol exceeded the threshold value of 0.1 µg/L in the Tier 1 calculations and a higher tier assessment was performed with FOCUS PEARL 4.4.4. The groundwater concentrations (80^{th} percentiles of the annual average concentrations) were < 0.000001 µg/L in all FOCUS scenarios.

Conclusion: Exposure to porewater via soil contamination is considered to be negligible as it can be considered as a localised spot contamination immediately around the bait stations or bait points. Due to its high log Kow of >5.9 and poor water solubility (<0.005 mg/L at 20 °C) Cholecalciferol will partition to soil. This is also confirmed by the measured log Koc value of > 5.63 (Koc value > 426580). In addition, the ESD for PT 14 states that a detailed groundwater scenario is not considered necessary due to the limited quantities of active substance, the limited frequency of use and the limited treated area. Therefore, groundwater contamination is unlikely. 2-phenylphenol is not expected to contaminate groundwaters as the predicted concentrations were <0.000001 µg/L in all FOCUS scenarios.

2.2.8.4.6 Primary and secondary poisoning

2.2.8.4.6.1 Primary poisoning

To assess the risks of **acute primary poisoning**, an assessment was performed in accordance with guidance (Addendum relevant to Biocides to the TGD on Risk Assessment, endorsed at the 23rd CA meeting Nov. 2006). The estimated daily uptake quantified as ETE (estimated theoretical exposure) of cholecalciferol was compared to acute effect data for birds and mammals, showing that the estimated exposure is a factor of 8–20 below the LD_{50} for birds, whereas for mammals the exposure is in the same range as the LD_{50}. Thus, birds are less likely to be affected from acute primary poisoning; the situation for mammals is more uncertain. It is important to stress that this assessment only gives a first indication of the acute toxicity of the substance.

Regarding dogs, only LD_{50} values of low reliability are available (internal review reports and a conference abstract). These data indicate that exposure of eating mainly bait during one day exceeds the LD_{50}, which is of course not acceptable (>50% probability of death), and it illustrates the need for risk-mitigation measures such as use of bait boxes[13]. Reporting of cases where dogs have accidentally eaten cholecalciferol bait, and died or been severely sick, further underlines the need for such risk mitigations.

2.2.8.4.6.1.1 Acute Qualitative assessment

Estimated daily uptake (ETE) of the a.s. in indicator species (see Doc IIB 3.3) – tree sparrow and dog						
Symbol	**Variable/parameter**	**Normal Use***	**Realistic worst case Step 1****	**Realistic worst case Step 2 *****	**LD_{50} [mg/kg bw]**	**ETE exceeds LD_{50}**
ETE tree sparrow	estimated daily uptake of a compound [mg/(kg bw•day)]	≅ 0	259.1	103.6	> 2000	No
EC	estimated conc. of a.s. in indicator species [mg/kg bw]	≅ 0	233.2	72.5		
ETE dog	estimated daily uptake of a compound [mg/(kg bw•day)]	≅ 0	45	32.4	10–80	yes
EC	estimated conc. of a.s. in indicator species [mg/kg bw]	≅ 0	40.5	22.7		

* Small birds could potentially enter a bait station but would only ingest a limited amount of Selontra® as the product is in the form of a soft block bait and thus the bird must repeatedly peck at it to break off bite-sized pieces. Larger birds that cannot get into a bait station will not ever encounter a full block. Therefore, for such birds it is impractical to do a calculation based upon the assumption a bird eats its full daily ration. The dog is considered as an example of a larger mammal which is potentially at risk from direct consumption of baits placed in and around a house. If label instructions are followed, as should be the case for normal use, the primary poisoning risk for dogs could be negligible.

** Step 1: AV = 1, PT = 1, PD = 1, EL = 0.1
*** Step 2: AV = 0.9 for mammals and AV = 0.5 for birds, PT = 0.8, PD = 1, EL = 0.3.

13 It might be more appropriate to use available oral acute toxicity data for other, smaller mammalian species, since these data are more reliable (rat, mice LD_{50} values have RI = 1–2), and thereby add more weight of evidence to the calculation. However, the risk for acute primary poisoning is so obvious that further refinement of this calculation is not motivated.

The results from the long-term primary poisoning risk assessment are presented below. Irrespective of method used (ETE or EC), the calculated PEC/PNEC ratios for long-term primary poisoning far exceed the trigger limit of 1, and risk quotients are even higher in the second tier than in the first tier calculations. Even if a refinement would be undertaken where the exposure is only 1 % of the calculated PEC_{oral}, the long-term risk to mammals would still be very high, with a risk quotient above 2000. It should be noted the calculations are conservative due to the assumption that the non-target animals feed on a diet exclusively or largely consisting of rodenticide bait. Nevertheless, it should also be noted that the $PNEC_{oral\_mammal}$ has been derived from a 90-days study on rats, although it is not considered likely that non-target mammals in an area would be continuously exposed to rodenticide bait during such a long time as 90 days (depending on the intensity of pest control in their habitat and / or territory).

As indicated by the PEC/PNEC ratios a long-term primary poisoning risk for non-target animals cannot be excluded if the theoretical assumption is made that their diet exclusively or largely consists of rodenticide bait. However, this theoretical assumption is considered to be an unlikely scenario and if repeated exposure were to occur, both birds and mammals were shown to tolerate exaggerated contaminated-feeding. However, if the product, Selontra®, is used as instructed and according to the proposed-use pattern, and specific risk mitigation measures are undertaken (the use of protected bait points, careful baiting practises such as the cleaning up of spillage afterwards) the risk of primary poisoning is considered to be lower. However, risk of primary poisoning of non-target animals cannot be excluded.

2.2.8.4.6.1.2 Long term Tier 2:

Summary table on primary poisoning[1]						
	$PEC_{oral\ bird}$	**PEC_{oral} mammal**	**$PNEC_{oral}$ bird**	**$PNEC_{oral}$ mammal**	**PEC/PNEC birds**	**PEC/PNEC mammals**
Tier 1	750 mg /kg food	750 mg /kg food	0.2 mg a.s./kg food	0.003 mg a.s./kg food	3750	250000
Tier 2*	183.7 mg/kg bw	57.4 mg/kg bw	0.025 mg a.s./(kg bw·d)	0.0001 mg a.s./(kg bw·d)	7348	574000
Tier 2**	103.6 mg/(kg bw·d)	32.4 mg/(kg bw·d)	0.025 mg a.s./(kg bw·d)	0.0001 mg a.s./(kg bw·d)	4144	324000

[1] PEC_{oral} / $PNEC_{oral}$ ratios using the different PNEC values and PEC values from tier 1 and tier 2 assessments (tree sparrow and dog) - chronic
*In accordance with guidance (ESD, PT 14 (2003) and "Addendum relevant to Biocides to the TGD on Risk Assessment" (endorsed at the 23rd CA meeting Nov. 2006)), using EC_n as $PEC_{oral,bird}$
**In accordance with guidance (ESD, PT 14 (2003) and "Addendum relevant to Biocides to the TGD on Risk Assessment" (endorsed at the 23rd CA meeting Nov. 2006)), using ETE from step 2 as $PEC_{oral,\ bird}$

2.2.8.4.6.1.3 Conclusion

The PEC/PNEC ratio for primary poisoning is greater than the trigger limit of 1. Therefore, there is a theoretical long-term primary poisoning risk for non-target birds and mammals, assuming that their diet consists largely of rodenticide bait (worse-case conditions).

However, it should be noted the consumption of a diet largely consisting of rodenticide bait is considered very unlikely. Similarly, if repeated exposure were to occur, both birds and mammals were shown to tolerate exaggerated contaminated-feeding conditions in several reported secondary

poisoning studies (please refer to Doc IIIA section 7.5.6 for details). The formulation of cholecalciferol, Selontra®, is applied as soft block bait and is placed in discrete locations restricted to within the infested area. Trained professionals may place Selontra® in covered bait points or in bait boxes. For professionals, the product may be used in tamper-resistant bait stations to minimise exposure of non-target animals. It is not dispersed or broadcast within the environment. If accidental exposure was to occur; it is highly unrealistic this would be a repeated occurrence. Risk mitigation measures can significantly control the potential exposure to non-target animals; hence reducing any risk of acute or repeated primary poisoning.

It can be concluded that Selontra® poses a potential primary poisoning risk to non-target animals following acute and long-term exposure in the worst-case scenario. However, if the product, Selontra®, is used as instructed and according to the proposed-use pattern, and specific risk mitigation measures are undertaken (the use of protected bait points, careful baiting practises such as the cleaning up of spillage afterwards) the risk of primary poisoning is considered low. However, accidental risk of primary poisoning of non-target animals cannot be excluded.

2.2.8.4.6.2 Secondary poisoning

Since birds and mammals consume worms with their gut contents and the gut of earthworms can contain substantial amounts of soil, the exposure of the predators may be affected by the amount of substance that is in this soil. The log Kow of >5.0 indicate potential for bioaccumulation and the results of a BCF study gave a $BCF_{earthworm}$ of 0.15 $kg_{soil,dw}/kg_{earthworm,dw}$) (cholecalciferol Doc III A7.5.2.1).

In order to confirm a low risk to earthworm-eating birds, a risk assessment should be performed. According to the 'Guidance on the Biocidal Products Regulation, Vol. IV Environment – Assessment and Evaluation (Parts B+C), V.2.0, October 2017' (BPR vol. IV, Parts B+C) the $PEC_{oral,predator}$ is calculated according to:

$$PEC_{oral,predator} = C_{earthworm}$$

Where $C_{earthworm}$ is the total concentration of the substance in the worm as a result of bioaccumulation in worm tissues and the adsorption of the substance to the soil present in the gut. When no information is provided on the bioaccumulation in earthworms, a theoretical BCF according to the guidance provided in the BPR vol. IV, Parts B+C (Eq 104d). For cholecalciferol, a BAF at steady state (0.15 $kg_{soil,dw}/kg_{earthworm,dw}$) was provided by the applicant which we therefore use for the secondary poisoning assessment for earthworm-eating birds.

Since the BAF_{SS} was determined on a dry weight basis, a conversion factor ($CONV_{Soil}$) has to be applied to the PEC_{Soil}, which is expressed as wet weight. A worst case PEC_{soil} of 0.613 mg/kg ww (realistic worst case for rats) is used in the assessment. The PEC_{soil} is multiplied with 0,5 as 50 % of the diet comes from a local area and 50 % of the diet comes from the regional area. The tissue concentration derived from the BAF_{SS} and the PEC_{Soil} is on a dry weight basis. Therefore, a conversion factor ($F_{dw,earthworm}$) for earthworm concentration dry-wet weight tissue is applied. The calculated $C_{earthworm}$ is then based on wet weight. This concentration is directly applied as the PEC_{oral}.

Adapted from Equation 103c in the BPR Vol. IV (Parts B+C):

$$C_{earthworm,ww} = \frac{(BAF_{SS} \cdot (PEC_{Soil} \cdot 0.5 \cdot CONV_{Soil})) \cdot F_{dw,earthworm} + PEC_{Soil} \cdot 0.5 \cdot F_{Gut} \cdot CONV_{Soil}}{1 + F_{Gut} \cdot CONV_{Soil}}$$

Where:

$C_{earthworm}$	= Concentration of a.s. in earthworm on wet weight basis [mg/kg]
BAF_{SS}	= Bioaccumulation factor at steady state [$kg_{Soil,dw}/kg_{Biota,\ dw}$]
PEC_{Soil}	= Predicted environmental concentration in soil [mg/kg_{Soil} ww]
$CONV_{Soil}$	= Conversion factor for soil concentration wet-dry weight soil [kg_{ww}/kg_{dw}]
$F_{dw,earthworm}$	= Fraction solids in earthworm [kg_{dw}/kg_{ww}] – Water content in earthworm from terrestrial bioaccumulation study is 84% which gives a $F_{dw,earthworm}$ of 0.16.
F_{Gut}	= Fraction of gut loading in worm [kg_{dw}/kg_{ww}] – default 0.1.

Where:

$$CONV_{Soil} = \frac{RHO_{Soil}}{F_{Solid} \cdot RHO_{Solid}} = \frac{1700}{0.6 \cdot 2500} = 1.13$$

$$C_{earthworm,ww} = \frac{0.15 \cdot 0.613 \cdot 0.5 \ \cdot \ 1.13 \cdot 0.16 + 0.613 \cdot 0.5 \ \cdot \ 0.1 \cdot 1.13}{1 + 0.1 \cdot 1.13} = 0.0385\ mg/kg\ ww$$

Based on a worst case scenario it is assumed that birds feed on contaminated earthworms solely (remember: $PEC_{oral} = C_{earthworm,\ ww}$).

Birds
5 days dietary avian **LC_{50}** = 600 mg/kg feed.
AF = 3000 (Table 25, , BPR Vol. IV (Parts B+C))
$PNEC_{oral}$ = 0.2 mg/kg feed
Risk ratio = **$PEC_{oral}/PNEC_{oral}$** = 0.0385 / 0.2 = 0.193.

Mammals

$$NOEC_{mammals} = NOAEL_{mammals} \cdot CONV_{mammals}$$

90 days NOAEL (*Rattus norvegicus*) = 0.012 mg/kg bw/day
$CONV_{mammals}$ for *Rattus norvegicus* (>6 weeks) = 20
$NOEC_{mammals}$ = 0.24 mg/kg feed
AF = 90 (Table 25, BPR Vol. IV (Parts B+C))
$PNEC_{oral}$ = 0.0027 mg/kg feed

Risk ratio = **PEC_{oral} / $PNEC_{oral}$** = 0.0385 / 0.0027 = 14.259.

The risk characterisation for secondary poisoning of earthworm-eating birds and mammals is also presented below. The PEC/PNEC ratios indicate a risk to earthworm-eating mammals.

Risk characterisation for secondary poisoning of earthworm-eating birds and mammals			
Selontra	**PECoral [mg/kg feed]**	**PNECoral [mg/kg feed]**	**PEC/PNEC**
Birds	0.0385	0.2	0.193
Mammals	0.00385	0.0027	14.259

In order to confirm a low risk to earthworm-eating birds, a risk assessment should be performed. To assess the risks of acute secondary poisoning, a qualitative risk assessment was performed in accordance with guidance (Addendum relevant to Biocides to the TGD on Risk Assessment, endorsed at the 23rd CA meeting Nov. 2006). The calculated concentration of Selontra® in the predator after one meal was compared to acute effect data for birds and mammals, showing that the estimated exposure is significantly below the LD_{50} value for birds, whereas for mammals the exposure is potentially in the same range as the LD_{50}.

Thus, birds are not likely to die from acute secondary poisoning, whereas the situation for mammals is more uncertain. It is important to stress that this qualitative assessment only intends to give a first indication of the acute secondary toxicity of the substance. There are lab studies where dogs, cats and snakes have been fed poisoned carcasses (possums, rats), with mild secondary poisoning (toxicosis) observed (in dogs).

2.2.8.4.6.2.1 Acute secondary poisoning (Qualitative assessment):

Summary table on acute secondary poisoning[1]						
Scenario	**$PEC_{oral,}$ acute bird** mg/kg feed	**$PEC_{oral,}$ acute mammal** mg/kg feed	**$C_{internal, pred.}$ bird** mg/(kg BW)	**$C_{internal, pred.}$ mammal** mg/(kg BW)	**$C_{internal,}$ pred. / $PNEC_{bird}$** (0.025 mg/kg BW·d)	**$C_{internal,}$ pred./ $PNEC_{mammal}$** (0.0001 mg/ kg BW·d)
Realistic worst case*	208.0	208.0	52.0	81.1	2080	811122
Intermediate**	104.0	104.0	26.0	40.6	1040	405561
Normal case***	41.6	41.6	10.4	16.2	416	162240

[1] Acute secondary poisoning ratios ($C_{internal, pred}$ / $PNEC_{oral}$) using the different PNEC values and PEC values (barn owl and weasel) – acute
*PD =1 (assuming that 100% of the rodents' food consists of poisoned bait)
**PD = 0.5 (assuming that 50% of the rodents' food consists of poisoned bait)
***PD = 0.2 (assuming that 20% of the rodents' food consists of poisoned bait)

The results from the long-term secondary poisoning risk assessment are presented below.

The PEC/PNEC ratio is greater than the trigger limit of 1 and, therefore, a theoretical long-term secondary poisoning risk for birds and mammals cannot be excluded, if assuming that their diet largely consists of poisoned rodents. Based on data provided during active substance approval there have been no reported secondary poisoning incidents to animals arising from the ingestion of dead rodents in areas treated with cholecalciferol. It is recommended this product is only used according to instructions in accordance with the EU-harmonised risk mitigation measures for PT 14.

2.2.8.4.6.2.2 Chronic secondary poisoning

Summary table on long term secondary poisoning[1]						
Scenario	**$PEC_{oral,\ chronic\ bird}$** mg/kg feed	**$PEC_{oral,\ chronic\ mammal}$** mg/kg feed	**$C_{internal,\ pred.\ bird}$** mg/(kg BW)	**$C_{internal,\ pred.\ mammal}$** mg/(kg BW)	**$C_{internal,\ pred.}$ / $PNEC_{bird}$** (0.025 mg/kg BW·d)	**$C_{internal,\ pred.}$/ $PNEC_{mammal}$** (0.0001 mg/ kg BW·d)
Realistic worst case*	104.0	104.0	26.0	40.6	1040	405561
Intermediate**	52.0	82.0	13.0	20.3	520	202800
Normal case***	16.4	20.8	5.2	8.1	208	81120

[1]Long-term secondary poisoning ratios ($C_{internal,\ pred.}$ /PNECoral) using the different PNEC values and PEC values (barn owl and weasel)
*PD =1 (assuming that 100% of the rodents' food consists of poisoned bait)
**PD = 0.5 (assuming that 50% of the rodents' food consists of poisoned bait)
***PD = 0.2 (assuming that 20% of the rodents' food consists of poisoned bait)

2.2.8.4.6.2.3 Conclusion:

As indicated by the PEC/PNEC ratios presented above there is a secondary poisoning risk for non-target animals if the theoretical assumption is made that their diet largely consists of contaminated rodents.

Cholecalciferol is applied as a bait and is placed in discrete locations restricted to within the infested area in and around buildings. Trained professionals may place Selontra® in covered bait points or in bait boxes. For professionals, the product may be used in tamper-resistant bait stations to minimise exposure of non-target animals. Risk mitigation measures significantly control the potential exposure to non-target animals and to dead rodents; hence reducing any risk of acute or repeated secondary poisoning.

It can be concluded that Selontra® poses a potential risk of secondary poisoning to non-target animals following acute and long-term exposure in the worst-case scenario. However, if the product, Selontra®, is used as instructed and according to the proposed-use pattern, and specific risk mitigation measures are undertaken (the use of protected bait points, careful baiting practises such as the cleaning up of spillage afterwards) the risk of secondary poisoning is considered low. However, the risk of secondary poisoning of non-target animals cannot be excluded.

2.2.8.4.7 Mixture toxicity

Screening steps

Screening Step 1: Identification of the concerned environmental compartments

Based on the use of the product, emissions may occur to soil, groundwater and to fauna (*via* primary and secondary poisoning) of which only soil is considered relevant for the mixture toxicity assessment. Assessment of primary and secondary poisoning is not considered necessary, since the active substance fails the primary and secondary poisoning risk assessments. 2-phenylphenol does not act as rodenticide and is not expected to significantly increase the risk of primary and secondary poisoning caused by Selontra. Also, 2-phenylphenol has a low potential to bioaccumulate (BCF 21.7 whole fish, 114-115 lipid content and toxicity to birds and mammals is considerably lower compared to the active substance.

Screening Step 2: Identification of relevant substances

The product contains 2-phenylphenol (biphenyl-2-ol). According to the 'Guidance on the Biocidal Products Regulation, Vol. IV Environment – Assessment and Evaluation (Parts B+C), V.2.0, October 2017' (BPR vol. IV, Parts B+C), this co-formulant is identified as substance of concern (SoC) for the environment – for the following reasons: Although 2-phenylphenol is not present in the biocidal product at a concentration leading the product to be regarded as hazardous or dangerous, is not a POP, PBT or vPvB substance, and although its concentration in the product (of 0.0496%) is <0.1% (the SoC trigger value), it is considered as a substance of concern because it is an active substance (acting as a co-formulant) that has a $PNEC_{soil}$ of 0.048 mg/kg dw – which is lower than the cholecalciferol $PNEC_{soil}$ of 5.78 mg/kg dw.

Screening Step 3: Screen on synergistic interactions

Synergistic interactions are not anticipated.

Screening step	
Significant exposure of environmental compartments? (Y/N)	Y
Number of relevant substances >1? (Y/N)	Y
Indication for synergistic effects for the product or its constituents in the literature? (Y/N)	N
Conclusion: An assessment of mixture toxicity is required. Synergistic interactions are not anticipated, therefore additive toxicity is considered in the mixture toxicity assessment as a worst-case approach	

To assess mixture toxicity for the soil organisms, PEC/PNEC values for cholecalciferol and 2-phenylphenol were summed up for each scenario.

	Active substance	**SoC**	**ΣPEC/PNEC**
Scenario 1 (low rat infestation)	0.064	5.063	5.126
Scenario 2 (high rat infestation)	0.106	8.458	8.564
Scenario 3 (low mice infestation)	0.024	1.875	1.899
Scenario 4 (high mice infestation)	0.030	2.417	2.447
Scenario 5a (standard rat infestation (Nrefill 5)	0.068	5.417	5.485
Scenario 5b (standard rat infestation (Nrefill 1)	0.014	1.083	1.097

An unacceptable risk was identified for 2-phenylphenol in soil and subsequently the PEC/PNEC ratios for the sum of the active substance and 2-phenylphenol exceed 1. The scenario 5b is a higher tier assessment where only one refill is considered. Nrefill 1 is considered justified due to stop feeding effect of Selontra and due to rapid degradation rate of 2-phneylphenol in soil (see further explanations in Section 2.2.8.2.1.1). Mixture toxicity was mostly explained by the toxicity of 2-phenylphenol to soil organisms. The risk for mixture toxicity is considered acceptable taking into consideration that considerably higher PEC/PNEC ratios were identified for primary and secondary poisoning and therefore Selontra will be approved on the basis of Article 19(5) of BPR (528/2012/EU).

The actual risk caused by Selontra is assumed to be lower. Bait boxes prevent the bait from contact with soil. Selontra is placed outdoors around buildings at discrete locations (restricted to within the infested area). In many places the soil cannot be considered to have environmental relevance as it is close to buildings and will most likely have concrete within because the bait are often placed in an area where the foundations of a building have been built.

Conclusion: Based on the above, the risk to the environment due to mixture toxicity is acceptable.

2.2.8.4.8 Aggregated exposure (combined for relevant emission sources)

Aggregated exposure is not relevant because Selontra® is designed to be used in highly localised areas i.e. only in and around buildings only where rodent infestations are present. It is used within covered and protected bait points or in bait boxes with limited quantities of active substance and limited frequency of use. The product is not intended to be placed indiscriminately or broadcast in the environment and as such aggregated exposure will not occur.

Overall conclusion on the risk assessment for the environment of the product

Ecotoxicological data was not provided for the evaluation of Selontra®. The environmental risk assessment is based on the data obtained from the existing active substance cholecalciferol (final Competent Authority Report according to Regulation No. 528/2012, Active substance in Biocidal Products, Cholecalciferol, Product Type 14 (Rodenticides), Rapporteur Member State: Sweden, November 2017. In addition, risk assessment was performed for 2-phenylphenol which was identified as a substance of concern for the environment.

An environmental risk assessment was performed for the intended use(s) of Selontra® (in & around buildings). An acceptable risk was identified for the atmosphere, STP, aquatic, and groundwater environmental compartments. The risk identified for the terrestrial compartment and mixture toxicity was considered acceptable despite of slight exceedance of PEC/PNEC of 1. An unacceptable risk was identified for primary and secondary poisoning of non-target organisms.

The rodenticide product is non-selective and can consequently pose a risk of primary and secondary poisoning to non-target animals. There are many uncertainties associated with quantification of the risk associated with the use of the product. Cholecalciferol is metabolised and not bioaccumulated, which may lead to a reduction of the risks in the emission scenario. The implementation of appropriate risk mitigation measures are considered essential given the overall potential toxic nature of rodenticides and the overriding public health requirement for such products. Primary as well as secondary exposure of humans, non-target animals and the environment shall be minimised, by considering and applying all appropriate and available risk mitigation measures.

2.2.9 Measures to protect man, animals and the environment

Recommended methods and precautions concerning storage of active substance/biocidal product; shelf-life of biocidal product
Keep away from food, drink and animal feeding stuffs.
Odour-sensitive: segregate from products releasing odours. Keep away from heat. Protect against moisture. Protect from direct sunlight.

Recommended methods and precautions concerning handling and transport
Handling and use:
No specific measures are necessary if stored and handled correctly.

Recommended methods and precautions concerning fire; in case of fire nature of reaction products, combustion gases etc.
In the event of a fire, wear self-contained breathing apparatus and chemical-protective clothing. Suitable extinguishing media: water spray, dry chemical, foam or carbon dioxide. Do not allow the spread of fire-fighting media and prevent its run-off from entering drains or watercourses. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations. In case of fire and/or explosion do not breathe fumes. Keep containers cool by spraying with water if exposed to fire. In the event of a fire, carbon dioxide, carbon monoxide and nitrogen oxides can be released.

Particulars of likely direct or indirect adverse effects
Ingestion of toxic doses causes hypercalcaemia. Antidotal therapies are available.

First aid instructions
- If medical advice is needed, have product container or label at hand.
- IF INHALED: Get medical advice/attention if you feel unwell.
- IF ON SKIN: Get medical advice/attention if you feel unwell.
- IF IN EYES: If symptoms occur; rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
-

IF SWALLOWED: Rinse mouth. Get immediate medical advice/attention. Contact a veterinary surgeon in case of ingestion by a pet.

Emergency measures to protect environment in case of accident
Spill control: Any spillages should be cleared up immediately and disposed of safely. Clean contaminated floors and objects thoroughly with water and detergents, observing environmental regulations.
Personal precautions: Use personal protective clothing. Avoid contact with the skin, eyes and clothing.
Environmental protection: Do not discharge into the subsoil/soil. Do not discharge into drains/surface waters/groundwater.

Control measures of repellents or poison included in the biocidal product, to prevent action against non-target organisms (relevant for biocidal products only)
The product contains the human taste deterrent, denatonium benzoate to help prevent accidental human consumption.

Possibility of destruction or decontamination following release in or on the following:
Air
Concentrations in air will be negligible and decontamination measures are not considered relevant.
Water, including drinking water:
Concentrations in surface water, sewage treatment plant, ground water and sediment are not considered to be relevant. As such, decontamination measures are not considered relevant.
Soil:
Predicted concentrations in soil are reported elsewhere. Decontamination of contaminated soil is not practicably feasible. Containment, collection and destruction are the only practicable route.

Procedures for waste management of active substance/biocidal product, and if appropriate, its packaging:
Possibility of reuse or recycling

The product should only be used for the intended purpose.
Possibility of neutralisation of effects
There is no known possibility of neutralisation.

Conditions for controlled discharge including leachate qualities on disposal
Not applicable. Discharge is not permitted.

Conditions for controlled incineration
Any disposal must comply with Local and National Requirements which are derived from the EU Directives 94/67/EC of 16 December 1994 and 2000/76/EC of 4 December 2000 on the incineration of hazardous waste. These Directives establish operating conditions under which hazardous/controlled waste must be incinerated and include details such as a minimum temperature of 850 °C, as measured near the inner wall or at another representative point of the combustion chamber as authorised by the competent authority, for two seconds; prescribe limits for air emissions; control discharges of waste water; control the disposal of incineration residues; and provide prescriptive methods and calculations for the determination of air emissions etc.

Instructions for safe disposal of the biocidal product and its packaging for different groups of users (relevant for biocidal products only)
Any contaminated materials must be disposed of as controlled waste. Any disposal must comply with Local and National Requirements. Refer also to relevant EU provisions.

Procedures, if any, for cleaning application equipment (relevant for biocidal products only)
Clean thoroughly with water and detergents, observing the relevant environmental regulations.

2.2.10 Assessment of a combination of biocidal products

Selontra® will not be authorised for use with another biocidal product.

2.2.11 Comparative assessment

The active substance cholecalciferol fulfils the exclusion criteria in Article 5(1)(d) of Regulation (EU) No 528/2012 on the basis of having endocrine disrupting properties as defined in Regulation (EU) No 2017/2100. Furthermore, as there is a concern with respect to the occurrence of primary and secondary poisoning, even when applying restrictive risk management measures, cholecalciferol fulfils criterion (e) of Article 10 of Regulation (EU) No 528/2012.

Therefore, in line with Article 23 (1) of Regulation (EU) No 528/2012, a comparative assessment for the product Selontra® has been conducted.

At the 60th meeting of representatives of Members States Competent Authorities for the implementation of Regulation (EU) No 528/2012 (held on 20 and 21 May 2015) all Member States submitted to the Commission a number of questions to be addressed at Union level in the context of the comparative assessment to be carried out at the renewal of anticoagulant rodenticide biocidal products ('anticoagulant rodenticides'). The questions submitted were the following:

(a) Is the chemical diversity of the active substances in authorised rodenticides in the Union adequate to minimise the occurrence of resistance in the target harmful organisms?;

(b) For the different uses specified in the applications for renewal, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?;

(c) Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?;

(d) Are these alternatives sufficiently effective?;

(e) Do these alternatives present no other significant economic or practical disadvantages?

The information addressing these questions is provided in the Annex of the Commission Implementing Decision (EU) 2017/1532.

The answers to these questions are relevant not only to anticoagulant rodenticides, but also to cholecalciferol-containing rodenticides (i.e. Selontra®) in determining whether the criteria in Article 23(3)(a) and (b) of Regulation (EU) No 528/2012 are met.

Pursuant to Article 75(1)(g) of Regulation (EU) No 528/2012, the Commission requested from the European Chemicals Agency ('Agency') to formulate an opinion addressing the questions for the different uses that may be authorised in anticoagulant rodenticides according to the conditions and risk mitigation measures referred to in the opinions adopted by the Biocidal Products Committee of the Agency at its 16th meeting for the renewal of the active substance approvals.

On 2 March 2017, the Biocidal Products Committee of the Agency adopted its opinion (Opinion ECHA/BPC/145/2017)[14] which concluded that in the absence of anticoagulant rodenticides, the use of rodenticide biocidal products containing other active substances would lead to an inadequate chemical diversity to minimise the occurrence of resistance in the target harmful organisms. These products also showed some significant practical or economical disadvantages for the relevant uses.

The opinion (Opinion ECHA/BPC/145/2017) also considered a number of non-chemical control or prevention methods ("non-chemical alternatives"), which may provide sufficient efficacy in certain circumstances on their own or in a combination of them. However, there is insufficient scientific evidence to prove that those non-chemical alternatives are sufficiently effective according to the criteria established in agreed Technical Guidance Note on the comparative assessment of biocidal products (TGN)[15], with a view to prohibit or restrict the authorised uses of anticoagulant rodenticides.

The rationale supporting these conclusions are also applicable to Selontra® for the following reasons.

Chemical diversity of PT 14 authorised products – is it currently adequate without Selontra®?

Regarding the question "*Is the chemical diversity of the active substances in authorised rodenticides in the EU adequate to minimise the occurrence of resistance in the target harmful organisms?*" the BPC referred to section 6.1.1 of the TGN, which addresses the assessment of chemical diversity. The BPC considered the following points as outlined in the TGN:

- Chemical diversity should be adequate for all different user categories. An inadequate chemical diversity for one user category could lead to resistance occurrence, which might spread afterwards across the target organism population.

- As a general rule, at least three different and independent "active substances/mode of action" combinations should be available for a given use (e.g. mice-general public-indoor).

For the chemical alternatives to anticoagulant rodenticides, the PT 14 products considered eligible for the comparative assessment contained one of the following active substances: alpha chloralose, aluminium phosphide (releasing phosphine) and carbon dioxide. The authorised uses (as defined in Table 1 of the BPC opinion ECHA/BPC/145/2017) which are covered by these products are summarised in the table below. Relevant for Selontra®, also included in this table are the uses covered by the

[14] Biocidal Products Committee (BPC) Opinion on a request according to Article 75(1)(g) of Regulation (EU) No 528/2012 on Questions regarding the comparative assessment of anticoagulant rodenticides. Adopted 2 March 2017. ECHA/BPC/145/2017.
https://echa.europa.eu/documents/10162/21680461/bpc_opinion_comparative-assessment_ar_en.pdf/bf81f0a5-3e95-6b7d-d601-37db9bb16fa5

[15] CA-May15-Doc.4.3.a-Final.
https://circabc.europa.eu/w/browse/f39ab8d9-33ff-4051-b163-c938ed9b64c3

anticoagulant rodenticides. Since the comparative assessment was performed, products containing hydrogen cyanide have also been authorised under Regulation (EU) No 528/2012 and this active and its corresponding uses are included the table (uses shown are based on information available from product SPCs).

Rodenticides uses covered by AVKs and other alternative chemical products:

	Use number as defined in Table 1 of BPC opinion (ECHA/BPC/145/2017)									
	#1	**#2**	**#3**	**#4**	**#5**	**#6**	**#7**	**#8**	**#9**	**#10**
Alpha chloralose	Yes			Yes			Only mice			
Aluminium phosphide releasing phosphine								Only for *R. norvegicus*	Only for *R. norvegicus*	
Carbon dioxide							Only mice			
Hydrogen cyanide							Only rats			
Anticoagulant rodenticides	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

When the anticoagulant rodenticides were compared against alpha chloralose, aluminium phosphide (releasing phosphine) and carbon dioxide, the BPC concluded:

"*The data shows that the minimum requirement of three different alternatives is not reached for any given use. This evaluation shows therefore an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms*."

As shown in the previous table, taking all this information together – including the anticoagulant rodenticides and hydrogen cyanide – this .conclusion is still applicable. Thus, on the basis of chemical diversity and to minimise the development of resistance in harmful target organisms, Selontra® should be authorised and made available for all applied user categories (#4, #5, #6, #7 and #8).

Do the current alternatives to Selontra® present significant economic or practical disadvantages?

Regarding the question "*Do these alternatives present no other significant economic or practical disadvantages?*" the BPC considered the chemical alternatives which were identified as eligible, summarised in Table 6 of the BPC opinion (Opinion ECHA/BPC/145/2017). None of the non-chemical alternatives were included in this assessment as they were all considered as not eligible. As there have been no developments on information regarding non-chemical alternatives, they remain out of scope in this assessment.

The BPC thus concluded in its opinion (Opinion ECHA/BPC/145/2017):

"The assessment of other significant economic or practical disadvantages shows that for aluminium phosphide releasing phosphine and carbon dioxide it can be concluded that these products lead to significant practical or economical disadvantages compared to ARs. The control of the target organisms would be at very high efforts and/or disproportionate cost.

For alpha chloralose, for the uses specified, providing that the products are used in low temperature environments, there are no significant practical or economical disadvantages. However, considering the chemical diversity replacing or restricting the use of ARs with only this substance would not be advised in order to minimize the occurrence of resistance."

As previously mentioned, since the comparative assessment was performed, products containing hydrogen cyanide have also been authorised under Regulation (EU) No 528/2012. Regarding any practical and economical disadvantages with these products, the same points raised for aluminium phosphide releasing phosphine can also apply to hydrogen cyanide: the use of this substance is by gas release, products may be used only by specially trained professionals in confined environments and

the gas released is extremely toxic. Therefore, strict RMMs are needed to avoid occurrence of fatal accidents.

Selontra® is a bait product (soft bait/paste/pasta) which is used in a very similar manner as the anticoagulant rodenticides. Therefore, aluminium phosphide releasing phosphine, carbon dioxide and hydrogen cyanide carry significant practical disadvantages compared to Selontra®, as they do the anticoagulant rodenticides. Regarding alpha chloralose, providing that the products are used in low temperature environments, there are no significant practical disadvantages compared to Selontra®. However, considering the current chemical diversity, not authorising Selontra® due to the availability of alpha chloralose and the anticoagulants rodenticides would not be advised in order to minimise the occurrence of resistance.

Conclusion

Therefore, with the absence of Selontra®, the use of rodenticide biocidal products containing other active substances (aluminium phosphide releasing phosphine, carbon dioxide and hydrogen cyanide, alpha chloralose and anticoagulant rodenticides) would lead to an inadequate chemical diversity to minimise the occurrence of resistance in the target harmful organisms. The alternatives aluminium phosphide releasing phosphine, carbon dioxide and hydrogen cyanide also showed some significant practical disadvantages for the relevant uses.

This is in line with the conclusion reached at the 62th meeting of the Standing Committee on Biocidal Products where it was agreed that the non-approval of cholecalciferol as an active substance would have a disproportionate negative impact on society in comparison to the risks arising from the use of the substance. The condition set out in Article 5(2)(c) is thus satisfied.

In summary it can be concluded that the criteria according Article 23(3) (a) and Article 23(3) (b) of Regulation (EU) No 528/2012 are not fulfilled. Therefore, the authorisation of the product Selontra® will be granted.

3 ANNEXES

3.1 List of studies

Author	Year	Title	Publication	Testing laboratory	Report no.	Legal entity owner	Report date	IUCLID Endpoint names	GLP/ GEP	Data Protection Claimed
BASF plc	2017	SDS: Selontra® (BAS 410 05 I) Version: 3.0	Published			BASF		Measures to protect humans, animals and the environment	No	No
BASF plc	2019	Draft label : Selontra® 22 March 2019				BASF		Classification and labelling	No	No
Guicherd A	2018	Evaluation of the efficacy of Selontra rodenticide bait (BAS 410 05 I), containing 0.75g/Kg cholecalciferol for the control of black rat infestations in a henhouse.		[redacted]	18BASRrF001	BASF	2018-05-31	Efficacy data to support these claims (Black rat) Guicherd (2018a)_BPR TNsG TP14	GEP	Yes
Guicherd A	2018	Evaluation of the efficacy of Selontra rodenticide bait (BAS 410 05 I), containing 0.75g/Kg cholecalciferol for the control of black rat infestations in a Typical farm. Bait point size 5 Selontra blocks.		[redacted]	18BASRrF003	BASF	2018-08-18	Efficacy data to support these claims (Black rat) Guicherd (2018b)_BPR TNsG TP14	GEP	Yes
[redacted]	2013	Three day No-Choice feeding tests on 750ppm Cholecalciferol soft block bait (BAS 410 05 I) against male and female *Rattus norvegicus* Hampshire (L120Q, Difenacoum and Bromadiolone tolerant) strain		[redacted]	LR001/13	BASF	2013-01-28	Efficacy data to support these claims (Brown Rat) [redacted] (2013a)_BPR TNsG TP14	GEP	Yes
[redacted]	2013	Three day No-Choice Feeding Tests on 750ppm cholecalciferol soft block bait (BAS 410 05 I) against male and female *Rattus norvegicus* Berkshire (L120Q, Difenacoum and Bromadiolone resistant) strain		[redacted]	LR012/13	BASF	2013-02-14	Efficacy data to support these claims (Brown Rat) [redacted] (2013b)_BPR TNsG TP14	GEP	Yes

Author	Year	Title	Publication	Testing laboratory	Report no.	Legal entity owner	Report date	IUCLID Endpoint names	GLP/ GEP	Data Protection Claimed
[redacted]	2013	Three day No-Choice feeding tests on 750ppm cholecalciferol soft block bait (BAS 410 05 I) against male and female *Rattus norvegicus* Welsh (Y139S, first generation anticoagulant resistant) Strain.		[redacted]	LR009/13	BASF	2013-02-11	Efficacy data to support these claims (Brown Rat) [redacted] (2013c)_BPR TNsG TP14	GEP	Yes
[redacted]	2013	Choice feeding pen trial study on 750ppm cholecalciferol soft block rodenticide bait (BAS 410 05 I), using the surplus bait method, against a colony of wild derived *Mus domesticus*, Bromadiolone resistant strain (Y139C).		[redacted]	LR006/13	BASF	2013-02-14	Efficacy data to support these claims (House mouse) [redacted] (2013d)_BPR TNsG TP14	GEP	Yes
[redacted]	2013	Choice feeding pen study with soft block bait (BAS 410 05 I) containing 750ppm cholecalciferol, against wild derived house mouse (*Mus domesticus*).		[redacted]	LR004/13	BASF	2013-01-31	Efficacy data to support these claims (House mouse) [redacted] (2013e)_BPR TNsG TP14	GEP	Yes
[redacted]	2013	Choice feeding pen trial study on 750ppm cholecalciferol soft block rodenticide bait (BAS 410 05 I), using the surplus bait method, against a colony of wild derived *Mus domesticus* (Experiment 8009)		[redacted]	LR005/13	BASF	2013-02-01	Efficacy data to support these claims (House mouse) [redacted] (2013f)_BPR TNsG TP14	GEP	Yes
[redacted]	2013	Choice feeding (palatability) cage tests with soft block bait (BAS 410 05 I) containing 750ppm cholecalciferol, against CD1 (anticoagulant susceptible) strain house mouse (*Mus domesticus*).		[redacted]	LR008/13	BASF	2013-02-11	Efficacy data to support these claims (House mouse) [redacted] (2013g)_BPR TNsG TP14	GEP	Yes
[redacted]	2013	Choice feeding tests on the experimental rodenticide 750ppm cholecalciferol soft block rodenticide bait (BAS 410 05 I) against male and female *Rattus norvegicus* Wistar strain.		[redacted]	LR007/13	BASF	2013-02-01	Efficacy data to support these claims (Brown Rat) [redacted] (2013h)_BPR TNsG TP14	GEP	Yes

Author	Year	Title	Publication	Testing laboratory	Report no.	Legal entity owner	Report date	IUCLID Endpoint names	GLP/ GEP	Data Protection Claimed
Hughes CS	2013	Field trial study on 750ppm cholecalciferol soft block rodenticide bait (BAS 410 05 I) for the control of Norway rat, *Rattus norvegicus*, at Frankton Grange Stud Farm, Ellesmere, Shropshire.		[redacted]	LR003/13	BASF	2013-01-29	Efficacy data to support these claims (Brown Rat) Hughes (2013i)_BPR TNsG TP14	GEP	Yes
Hughes CS	2013	Field trial study on 750ppm cholecalciferol soft block rodenticide bait (BAS 410 05 I) for the control of Norway rat, *Rattus norvegicus*, at New Crickett Farm, Ellesmere, Shropshire		[redacted]	LR013/13	BASF	2013-02-25	Efficacy data to support these claims (Brown Rat) Hughes (2013j)_BPR TNsG TP14	GEP	Yes
[redacted]	2013	Choice Feeding (Palatability) tests on 750ppm cholecalciferol soft block Rodenticide bait (BAS 410 05 I) against male and female *Rattus norvegicus*, Hampshire (L120Q, Difenacoum and bromadiolone tolerant) strain		[redacted]	LR019/13	BASF	2013-04-29	Efficacy data to support these claims (Brown Rat) [redacted] (2013l)_BPR TNsG TP14	GEP	Yes
[redacted]	2013	Choice Feeding (Palatability) tests on 750ppm cholecalciferol soft block Rodenticide bait (BAS 410 05 I) against male and female *Rattus norvegicus*, Welsh (Y139S, First Generation Anticoagulant Resistant) strain		[redacted]	LR020/13	BASF	2013-05-03	Efficacy data to support these claims (Brown Rat) [redacted] (2013m)_BPR TNsG TP14	GEP	Yes
[redacted]	2013	Choice Feeding (Palatability) tests on 750ppm cholecalciferol soft block Rodenticide bait (BAS 410 05 I) against male and female *Rattus norvegicus*, Berkshire (L120Q, Difenacoum and bromadiolone Resistant) Strain.		[redacted]	LR021/13	BASF	2013-05-17	Efficacy data to support these claims (Brown Rat) [redacted] (2013n)_BPR TNsG TP14	GEP	Yes
Hughes CS	2013	Field trial study on 750ppm cholecalciferol soft block rodenticide bait (BAS 410 05 I) for the control of Norway rat, *Rattus*		[redacted]	LR028/13	BASF	2013-08-05	Efficacy data to support these claims (Brown Rat) Hughes (2013o)_BPR TNsG TP14	GEP	Yes

Author	Year	Title	Publication	Testing laboratory	Report no.	Legal entity owner	Report date	IUCLID Endpoint names	GLP/ GEP	Data Protection Claimed
		norvegicus, at Ken Probert Timber, Oswestry, Shropshire.								
Hughes CS	2014	Field trial study on 750ppm cholecalciferol soft block rodenticide bait (BAS 410 05 I) for the control of the House mouse, *Mus domesticus*, at Old Crickett Storage Units, Oswestry, Shropshire.		[redacted]	LR005/14	BASF	2014-03-06	Efficacy data to support these claims (House mouse) Hughes (2014b)_BPR TNsG TP14	GEP	Yes
Hughes CS	2014	Field trial study on 750ppm cholecalciferol soft block rodenticide bait (BAS 410 05 I - Selontra) for the control of the House mouse, *Mus domesticus*, at Pentredaffydd Farm, Oswestry, Shropshire.		[redacted]	LR006/14	BASF	2014-03-10	Efficacy data to support these claims (House mouse) Hughes (2014c)_BPR TNsG TP14	GEP	Yes
Hughes CS	2014	Field Trial Study on Selontra Bait (BAS 410 05 I), Using the Reduced Replenishment Baiting Regime, For the Control Of The House Mouse *Mus Domesticus*, At Pentredaffydd Farm, Oswestry, Shropshire. (Expt 9101)		[redacted]	LR014/14	BASF	2014-06-03	Efficacy data to support these claims (House Mouse) Hughes (2014d)_BPR TNsG TP14	GEP	Yes
[redacted]	2015	Choice feeding pen trial study on Selontra rodenticide bait (BAS 410 05 I) post 24 month stored at ambient conditions, against a colony of wild derived *Mus domesticus*, Bromadiolone resistant strain (Y139C)		[redacted]	LR019/15	BASF	2015-03-24	Efficacy data to support these claims (House Mouse) [redacted] (2015a)_BPR TNsG TP14	GEP	Yes
[redacted]	2015	Choice feeding (palatability) tests on Selontra bait (BAS 410 05 I), fresh and post 24 month stored at ambient conditions (GLP Study ID 412005-1) against male and female Wistar rats		[redacted]	LR021/15	BASF	2015-03-30	Efficacy data to support these claims (Norway rat) [redacted] (2015b)_BPR TNsG TP14	GEP	Yes

Author	Year	Title	Publication	Testing laboratory	Report no.	Legal entity owner	Report date	IUCLID Endpoint names	GLP/ GEP	Data Protection Claimed
Hughes CS	2018	Field trial study on Selontra® Rodent Bait, BAS 410 05 I, for the Control of house mouse, *Mus musculus*, in London.		[redacted]	LR002/18	BASF	2018-02-12	Efficacy data to support these claims (House mouse) Hughes (2018a)_BPR TNsG TP14	GEP	Yes
Hughes CS	2018	Field trial study on Selontra rodent bait (BAS 41005I) for the control of the Norway rat, Rattus norvegicus, at Ken Probert Timber, Oswestry, Shropshire, bait point size 5 blocks		[redacted]	LR004/18	BASF	2018-05-24	Efficacy data to support these claims (Brown rat) Hughes (2018b)_BPR TNsG TP14	GEP	Yes
Johnson IR	2013	750 ppm Cholecalciferol Soft Block (BAS 410 05 I) - In Vitro Absorption of Cholecalciferol through Human Epidermis using [3H]-Radiolabelled Cholecalciferol.		[redacted]	JV2205-REG	BASF	2013-04-16	Dermal absorption. (In Vitro: Human) Johnson (2013)_OECD 428	GLP	Yes
Klemann N	2013	Field trial to determine the efficacy of the rodenticide soft block formulation (BAS 410 05 I), containing 750ppm cholecalciferol, in controlling House mice (*Mus musculus domesticus*), in and around buildings		[redacted]	KLN/BASF/2013-1	BASF	2013-03-13	Efficacy data to support these claims (House mouse) Klemann (2013a)_BPR TNsG TP14	GEP	Yes
Klemann N	2013	Field trial to determine the efficacy of the rodenticide soft block formulation (BAS 410 05 I), containing 750ppm cholecalciferol, in controlling Norway rats (*Rattus norvegicus*), in and around buildings.		[redacted]	KLN/BASF/2013-2	BASF	2013-03-13	Efficacy data to support these claims (Brown Rat) Klemann (2013b)_BPR TNsG TP14	GEP	Yes
Klink D	2014	Validation of the Analytical Method AFL0907/02 for the Determination of the Total Amount of Cholecalciferol in BAS 410 05 I by UHPLC-(QqQ)MS		[redacted]	GLP-021/14	BASF SE, Agrarzentrum Limburgerhof, 67117 Limburgerhof, Germany	2014-09-26	Methods of detection for the determination of active substance in the biocidal product. Klink (2014) Updated	GLP	Yes

Author	Year	Title	Publication	Testing laboratory	Report no.	Legal entity owner	Report date	IUCLID Endpoint names	GLP/ GEP	Data Protection Claimed
Klink D	2015	Validation of the Analytical Method AFL09221/01 for the Determination of the Amount of Denatonium Benzoate (Determined as Denatonium) in BAS 410 05 I by UHPLC-(QqQ)MS			GLP-013-15	BASF SE, Agrarzentrum Limburgerhof, 67117 Limburgerhof, Germany	2015-04-28	Validation of the analytical method for denatonium benzoate in the biocidal product	GLP	Yes
Kroehl T	2018	Physical and Chemical Properties of BAS 410 05 I: Storage Stability up to 260 weeks at 25°C in one batch in original containers - 156 week report			412005_2	BASF SE, Crop Protection	2016-04-25	Long term storage stability test (156 weeks at 25 °C). Kroehl (2018)	GLP	Yes
Kroehl T	2013	Physical and Chemical Properties of BAS 410 05 I: Accelerated Storage Stability up to 2 weeks at 54 °C in glass bottles			412002_1	BASF SE, Crop Protection	2013-02-28	Appearance (at 20°C and 101.3 kPa). Kroehl (2013)_OPPTS 830.6303; OPPTS 830.6302; OPPTS 830.6304 Acidity, alkalinity. Kroehl (2013)_OPPTS 830.7000 & CIPAC MT 75.3 Accelerated storage stability test (2 weeks at 54 °C). Kroehl (2013)_CIPAC MT 46.3 Temperature (2 weeks at 54 °C). Kroehl (2013)_CIPAC MT 46.3	GLP	Yes

Author	Year	Title	Publication	Testing laboratory	Report no.	Legal entity owner	Report date	IUCLID Endpoint names	GLP/ GEP	Data Protection Claimed
[redacted]	2016	Choice Feeding Pen Trial Study On Selontra Soft Block Rodenticide Bait (BAS 410 05 I) Post 36 Months Stored At Ambient Conditions, Against A Population Of Wild Derived *Mus musculus domesticus*, Bromadiolone resistant strain (Y139C)		[redacted]	ASF-16-009-R	BASF	2016-04-04	Efficacy data to support these claims (House Mouse)_After 36 months storage_[redacted] (2016a)_BPR TNsG TP14	GEP	Yes
[redacted]	2016	Choice Feeding (Palatability) Test On Selontra Soft Block Rodenticide Bait (BAS 410 05 I) Against Male And Female *Rattus norvegicus* – Efficacy Post 36-Months Stored At Ambient Conditions		[redacted]	ASF-16-010-R	BASF	2016-04-04	Efficacy data to support these claims (Brown rat)_After 36 months storage_ [redacted] (2016b)_BPR TNsG TP14	GEP	Yes
[redacted]	2018	Choice feeding pen trial study on Selontra® rodent bait (BAS 410 05 I) post 36 months stored at ambient conditions, against a population of *Rattus rattus*		[redacted]	ASF-18-004-R	BASF	2018-08-18	Efficacy data to support these claims (Black rat) [redacted] (2018)_BPR TNsG TP14	GEP	Yes
Weller D	2013	Validation of the Analytical Method AM/01278/02: Determination of the total Amount of Cholecalciferol in BAS 410 05 I by HPLC		[redacted]	12L00388	BASF SE, Crop Protection, Product Characterization & Performance Management, 67117 Limburgerhof, Germany	2013-03-14	Methods of detection and identification for the determination of active substance in the biocidal product. Weller (2013)_OPPTS 830.1000 & OPPTS 830.1800	GLP	Yes

3.1.1 List of confidential studies

Refer to the Confidential Annex document.

3.2 Output tables from exposure assessment tools

Exposure of professional users

Application phase - Loading bait boxes

Rat control

Up to 7 units of paste bait are used per bait point. So, for each manipulation (bait point) the indicative dermal exposure value is 27.79 / 5 contacts x 7 contacts = 38.906 mg b.p./ manipulation.
Amount of exposure to product (75th percentile overall) during loading 7 bait units per manipulation: 27.79 mg b.p. / 5 contacts x 7 contacts = 38.906 mg b.p.
Potential dermal exposure for 60 manipulations: 38.906 mg b.p. x 60 = 2334.36 mg b.p.
Amount of a.s. (0.075% w/w) 2334.36 mg x 0.00075 = 1.751 mg a.s.
Systemic dose (dermal absorption 0.2%, bw 60 kg) : 5.8×10^{-5} mg/kg bw/day

Mouse control

2 units of paste bait are used per bait point. So, for each manipulation the indicative dermal exposure value is 27.79 / 5 contacts x 2 contacts = 11.116 mg b.p./ manipulation.
Amount of exposure to product (75th percentile overall) during loading 2 bait units per manipulation: 27.79 mg b.p. / 5 contacts x 2 contacts = 11.116 mg b.p.
Potential dermal exposure for 60 manipulations: 11.116 mg b.p. x 60 = 666.96 mg b.p.
Amount of a.s. (0.075% w/w): 666.96 mg x 0.00075 = 0.5002 mg a.s.
Systemic dose (dermal absorption 0.2%, bw 60 kg): 1.7×10^{-5} mg/kg bw/day

Post application - Cleaning up loaded bait

The indicative dermal exposure value (5.7 mg b.p.) is potential hand exposure for cleaning one bait point. This value is valid also for different sized blocks.
Potential dermal exposure for 15 manipulations: 5.70 mg b.p. x 15 = 85.5 mg b.p.
Amount of a.s. (0.075% w/w): 85.5 mg x 0.00075 = 0.0641 mg a.s.
Systemic dose (dermal absorption 0.2%, bw 60 kg): 2.1×10^{-6} mg/kg bw/day

Toddler Ingesting Bait (Acute)

The ingestion of poison bait by toddler is defined as "Mouthing of poison bait - an exceptional scenario" and concerns the situation where a toddler manages to access a bait block, despite the preventive measures taken, and then licks the block, or ingests a piece of the block. Exposure is thus acute and is expected to occur only exceptionally.

Where a bittering agent is used, as in the case of Selontra®, the amount ingested is assumed to be 10 mg (TNsG, Part 3, June 2002 / Final, PAGE 58).

An toddler is assumed to ingest 10 mg of bait (0.075% w/w), by accident. Complete absorption of ingested bait is assumed (i.e. 100%). For a toddler body weight of 10 kg, this corresponds to an estimated acute dose of cholecalciferol of ***0.00075 mg/kg bw*** ((0.00075 x 10 mg product)/10 kg bw).

3.3 New information on the active substance

Not applicable

3.4 Residue behaviour

Not applicable.

3.5 Summaries of efficacy studies

Please refer to IUCLID, section 6.

3.6 Confidential Annex

See separate document.