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 RENEWAL NATIONAL AUTHORISATION APPLICATIONS

Protect rodenticide grain bait

Product type 14

Bromadiolone

Authorisation Number:
HU-2013-PA-14-00035-0000

Evaluating Competent Authority: HU

Date:17/12/2019

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1 CONCLUSION

1.1 Competent Authority Report on the renewal of the biocidal product

In line with Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012, the authorisation holder, Bábolna Bio Ltd. applied for the renewal of the authorisation of the product named **Protect rodenticide grain bait (PT14).**

During the renewal, the HU CA takes into consideration the:
-Applicants Assessment on the new information relevant to the renewal.
-Commission Implementing Regulation (EU) 2017/1380 of 25 July 2017 renewing the approval of bromadiolone as an active substance for use in biocidal products of product-type 14
-Biocidal Products Committee Draft Opinion on a request according to Article 75(1)(g): Comparative assessment of anticoagulant rodenticides,
-Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (9th ATP)
-Points of the standardised Risk Mitigation Measures ("SPC translations for AVKs")
-New studies that are submitted in order to support efficacy of the product.

In parallel with the renewal of the authorisation, the applicant also applied for numerous major, minor and administrative changes that are assessed in this version of the PAR.
Major change:
- Decreasing of the bromadiolone active substance content from 50 ppm to 27 ppm. Simultaneously [redacted] content has been [redacted] Other quality and quantity parameters of the composition remain unchanged. The physical-chemical properties of the product have not changed. The analytical method to determinate the active substance in the product was revalidated to ensure the method validity at 27 ppm ± 20 % concentration level. The human and environmental risk assessments prepared for the 50 ppm rodenticide should be considered to cover the 27 ppm product as well. The product efficacy is supported by laboratory,semi-field and field studies.
Minor changes:
- Increase or reduction, addition, deletion or replacement of a non-active substance intentionally incorporated in the product:
Change of the colorant from *Sepisperse 4G rouge* to *Allura red*, the quantity of the dye remained same. The physical-chemical properties, risk and efficacy profile of the product has not changed due to the colorant replacement.
- Change in the pack size
Administrative changes:
-change the trade name only in Hungary: new trade name will be Protect BB rágcsálóirtó csalétek
-change the trade name only in Hungary**:** new trade name will be **"Protect rágcsálóirtó csalétek" instead of** "Protect BB rágcsálóirtó csalétek"
- Additional of name: only in Slovenia:
addition of "TERMINATOR X žitna vaba" as second brand name to the existing "BROMRAT žitna vaba"
- Removal of a particular claim, such as a specific target organism or a specific use:
target organism will be only the rat instead of the currently approved rat and mouse species.

- Change to the classification and labelling, where the change is limited to what is necessary to comply with newly applicable requirements of Regulation (EC) No 1272/2008 of the European Parliament and of the Council: update of the classification of the product in accordance with Ninth ATP to CLP Regulation.

The points affected during the renewal are:
-the classification of the active substance, therefore **classification of the product**, according to the 9th ATP (2.1.3).
-**RMMs and restrictions for the certain user categories** according to standardised RMMs and Commission Implementing Regulation (EU) 2017/1380 renewing the approval of bromadiolone (2.1.5.2).
-Professional user category is assessed, but it will be excluded from the Hungarian national SPC as in Hungary, only general public and trained prof. users are acknowledged. However member states are may allow prof. category according to their practice.
-**Efficacy against target organisms** (2.2.5.).

1.2 Conclusion:

HU CA is on the opinion that the product is eligible for renewal. The changes in the authorisation are evaluated and acceptable. The conditions of use and limitations are laid down in the related SPC.
Concerned member states may adapt some sentences of the SPC (e.g. references to user categories, some instructions for use, poison control centres, disposal of dead rodents or packaging waste, etc…) in order to refer to nationally available best practice codes or to meet the requirements in some relevant national provisions.

Several new studies have been submitted to support the major change of the product. All available relevant guidance have been taken into account for the re-assesment. According to the bromadiolone assessment report, the active substance is considered a PBT substance. The product poses unacceptable risks of primary and secondary poisoning to birds and mammals. These identified risks must be mitigated by applying all appropriate and available risk mitigation measures.
The calculated predicted environmental concentration in groundwater is near the limit value of 0.1 µg/L (point 68 of Annex VI of Regulation (EU) No 528/2012). However, bromadiolone is strongly adsorbed to soil and it is unlikely move through the soil and reach groundwater in significant amount due to its immobility in soil. Furthermore, risk mitigation measures are likely to substantially reduce bromadiolone contamination to soil, relative to the worst case exposure scenario.

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[1]	**Country (if relevant)**
Protect rodenticide grain bait Protect rágcsálóirtó csalétek	Hungary

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Babolna Bio Limited (Member of the Bromadiolone Task Force)
	Address	H-1107 Budapest, Szállás u. 6 Hungary
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Babolna Bio Limited
Address of manufacturer	H-1107 Budapest, Szállás u. 6 Hungary
Location of manufacturing sites	H-2943 Bábolna, Dr. Köves János u. 3 Hungary

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

Active substance	Bromadiolone
Name of manufacturer	Dr Tezza srl
Address of manufacturer	Via Tre Ponti 37050 S. Maria di Zevio Italy
Location of manufacturing sites	Via Tre Ponti 37050 S. Maria di Zevio Italy

1 Please fill in here the identifying product name from R4BP.

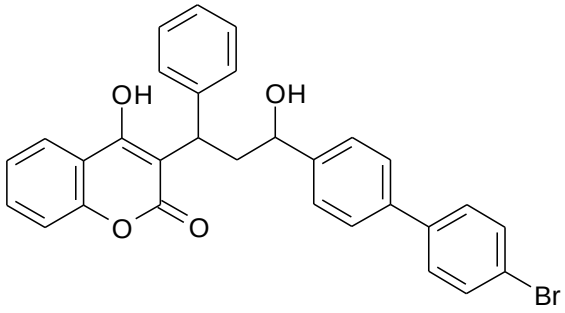
2.1.2 Product (family) composition and formulation

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

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

Yes ☐
No X

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Bromadiolone
IUPAC or EC name	3-[3-(4'-Bromo[1,1'- biphenyl]-4-yl)-3- hydroxy-1-phenylpropyl]- 4-hydroxy-2H-1- benzopyran-2-one
EC number	249-205-9
CAS number	28772-56-7
Index number in Annex VI of CLP	607-716-00-8
Minimum purity / content	Minimum purity: 98 % w/w Content: 0.0027% w/w
Structural formula	

2.1.2.2 Candidate(s) for substitution

The Biocidal Products Committee (BPC) document "Opinion on the application for renewal of the approval of the active substance" for bromadiolone PT14 (Ref ECHA/BPC/111/2016) states the following:

"Bromadiolone does meet the exclusion criteria laid down in Article 5(1)(c) and (e) of Regulation (EU) No 528/2012.

Bromadiolone does meet the conditions laid down in Article 10(1)(a) and (e) of Regulation (EU) No 528/2012, and is therefore considered as a candidate for substitution.

The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR" and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR" agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies

that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1) (a, b, d, e and f).

POP Criteria

Bromadiolone is considered to be potentially persistent, potentially bioaccumulative and toxic. However, in spite of the potential persistency of the active substance, no potential for long-range environmental transport is expected, either. Subsequently, it is concluded that bromadiolone is not expected to meet the POP criteria.

Results from public consultation

As bromadiolone is considered as a candidate for substitution ECHA launched the public consultation in accordance with Article 10(3) of Regulation (EU) No 528/2012 together with all others anticoagulant rodenticides for which applications for renewals have been submitted. The public consultation took place from 17 December 2015 to 15 February 2016.

In total 80 contributions were submitted by stakeholder's organisations, companies, nongovernmental organisations, independent experts and national bodies. Below a summary of the information submitted is presented where it should be noted that no peer review has taken place.

Most contributions are based on position papers prepared by the European Chemical Industry Council (CEFIC) and the Confederation of European Pest Management Associations (CEPA) and stating that currently no significant and effective alternative to anti-coagulant rodenticides is readily available. In addition, it is sometimes suggested that a major improvement for the environment would be to limit the use of rodenticides, based on integrated pest management and/or professional pest management companies only. In the CEPA position paper it is stated that until recently no common harmonized requirement existed across Europe for the licensing and monitoring of either the pest management companies themselves, or the technicians who undertake the application. In 2015, "EN 16636 Pest management services - Requirements and competences" was published. This standard and an accompanying certification scheme have since been launched by CEPA".

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 (%)
Bromadiolone	3-[(1RS,3RS;1RS,3SR)-3-(4′-bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxycoumarin	Active substance	28772-56-7	249-205-9	0.0027
		Non-active substance*			

The product contains bittering agent and dye.
***Full composition of the product can be found in the Confidential annex.**

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

The product is a single product and not a family.

2.1.2.5 Information on technical equivalence

The notified source of bromadiolone (Dr Tezza SRL) is the same as that considered for the active substance inclusion/approval. No further consideration regarding technical equivalence is required.

2.1.2.6 Information on the substance(s) of concern

No substances of concern are present in the product besides the active substance. Please see the confidential annex for further details.

2.1.2.7 Type of formulation

RB - Bait (ready for use): rodenticide grain bait

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	STOT RE 2
Hazard statement	H373 May cause damage to organs (blood) through prolonged or repeated exposure
Labelling	
Pictogram	 GHS08: Health Hazard
Signal words	Warning
Hazard statements	H373 May cause damage to organs (blood) through prolonged or repeated exposure
Precautionary statements	P102 Keep out of reach of children P202 Do not handle until all safety precautions have been read and understood. P280 Wear protective gloves/protective clothing. P308+313 IF exposed or concerned: Get medical advice/attention. P405 Store locked up. P501 Dispose of contents and container in accordance with the local requirements / the instruction of the label
Note	**-**

2.1.4 Authorised use(s)

2.1.4.1 Table 1. Use description

Table 2. **Use # 1 – Rats – general public – indoor**

Product Type	PT14 - Rodenticide
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat) 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	Tray:

	1 tray containing 100g, 125g or 150g bait or 2 trays containing 75g bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation). Filter paper or plastic sachet: 100-150 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation).
Category(ies) of users	general public
Pack sizes and packaging material	• plastic tray containing 75, 100, 125, 150 bait covered by filter paper, in paper box or plastic sachet 1-2 trays in paper box or plastic sachet • filter paper sachets containing 10, 20, 25 or 50 g bait in carton box Up to 150 g • plastic sachet containing 50, 100, 150 g bait in carton paper or in plastic box or in metal box Up to 150 g • plastic sachet containing 50. 100 or 150 g bait "single dose"

2.1.4.2 Use-specific instructions for use

- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

2.1.4.3 Use-specific risk mitigation measures

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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

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

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

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2.1.4.7 Use description

Table 3. **Use # 2 – Rats – general public – outdoor around buildings**

Product Type	PT14 - Rodenticide
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat) 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	Tray: 1 tray containing 100g, 125g or 150g bait or 2 trays containing 75g bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation). Filter paper or plastic sachet: 100-150 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation).
Category(ies) of users	general public
Pack sizes and packaging material	• plastic tray containing 75, 100, 125, 150 bait covered by filter paper, in paper box or plastic sachet 1-2 trays in paper box or plastic sachet • filter paper sachets containing 10, 20, 25 or 50 g bait in carton box Up to 150 g • plastic sachet containing 50, 100, 150 g bait in carton paper or in plastic box or in metal box Up to 150 g • plastic sachet containing 50, 100 or 150 g bait "single dose"

2.1.4.8 Use-specific instructions for use

- 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. - The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

2.1.4.9 Use-specific risk mitigation measures

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

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

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

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2.1.4.13 Use description

Table 4. **Use # 3 – Rats – professionals – indoor**

Product Type	PT14 - Rodenticide
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (Brown rat) – 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	Bulk: 200-250 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation). Tray: 1 tray containing 125g, 150g or 175g bait or 2 trays containing 75g or 100g bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation). Filter paper sachet:

	200-250 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation).
Category(ies) of users	professional
Pack sizes and packaging material	• plastic tray containing 75, 100, 125, 150 or 175 g bait covered by filter paper, in paper box Up to 20 kg filter paper sachets containing 20, 25 or 50 g bait • in carton box Up to 20 kg • bulk in plastic bucket Up to 20 kg • bulk in paper barrel Up to 30 kg • bulk in plastic sachet in carton box Up to 25 kg • bulk in paper bag Up to 25 kg

2.1.4.14 Use-specific instructions for use

-The bait stations should be visited at least every 5 to 7 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies.

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

- Re-fill bait when necessary.

2.1.4.15 Use-specific risk mitigation measures

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2.1.4.16 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.

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

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

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2.1.4.19 Use description

Table 5. **Use # 4 –rat – professional – around buildings**

Product Type	PT14 - Rodenticide
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (Brown rat) – 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	Bulk: 200-250 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation). Tray: 1 tray containing 125g, 150g or 175g bait or 2 trays containing 75g or 100g bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation). Filter paper sachet: 200-250 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation).
Category(ies) of users	professional
Pack sizes and packaging material	• plastic tray containing 75, 100, 125, 150 or 175 g bait covered by filter paper, in paper box Up to 20 kg filter paper sachets containing 20, 25 or 50 g bait • in carton box Up to 20 kg • bulk in plastic bucket Up to 20 kg • bulk in paper barrel Up to 30 kg • bulk in plastic sachet in carton box Up to 25 kg • bulk in paper bag Up to 25 kg

2.1.4.20 Use-specific instructions for use

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding. - The bait stations should be visited only 5 to 7 days after the beginning of the treatment

and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. - 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.

2.1.4.21 Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

2.1.4.22 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 surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

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

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

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2.1.4.25 Use description

Table 6. **Use # 5 –rats - trained professionals - indoor**

Product Type	PT14 - Rodenticide
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (Brown rat) – adults and juveniles
Field of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations or covered and protected baiting points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations.
Application rate(s) and frequency	For rats: Bulk:

	200-250 g of bait per baiting point. Tray: 1 tray containing 125g, 150g or 175g bait or 2 trays containing 75g or 100g bait per baiting point. Filter paper sachet: 200-250 g of bait per baiting point. Permanent baiting: 200-250 g of bait per baiting point.
Category(ies) of users	Trained professional
Pack sizes and packaging material	• plastic tray containing 75, 100, 125, 150 or 175 g bait covered by filter paper, in paper box Up to 20 kg filter paper sachets containing 20, 25 or 50 g bait • in carton box Up to 20 kg • bulk in plastic bucket Up to 20 kg • bulk in paper barrel Up to 30 kg • bulk in plastic sachet in carton box Up to 25 kg • bulk in paper bag Up to 25 kg

2.1.4.26 Use-specific instructions for use

- Remove the remaining product at the end of treatment period.
For 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.

2.1.4.27 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
- 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.

- Products may only be used in permanent treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient.
- Do not use the product in pulsed baiting treatments.

In case of permanent baiting:
- 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.

2.1.4.28 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 system, ensure that bait contact with water is avoided.

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

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

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2.1.4.31 Use description

Table 7. **Use # 6 –rats - trained professionals – outdoor around buildings**

Product Type	PT14 - Rodenticide
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (Brown rat) – adults and juveniles
Field of use	Outdoor: around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations or covered and protected baiting points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations.
Application rate(s) and frequency	Bulk: 200-250 g of bait per baiting point. Tray: 1 tray containing 125g, 150g or 175g bait or 2 trays containing 75g or 100g bait per baiting point. Filter paper sachet: 200-250 g of bait per baiting point. Permanent baiting: 200-250 g of bait per baiting point.
Category(ies) of users	Trained professional

Pack sizes and packaging material	• plastic tray containing 75, 100, 125, 150 or 175 g bait covered by filter paper, in paper box Up to 20 kg filter paper sachets containing 20, 25 or 50 g bait • in carton box Up to 20 kg • bulk in plastic bucket Up to 20 kg • bulk in paper barrel Up to 30 kg • bulk in plastic sachet in carton box Up to 25 kg • bulk in paper bag Up to 25 kg

2.1.4.32 Use-specific instructions for use

Remove the remaining product at the end of treatment period.
For 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. For application in covered and protected bait points:- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
- Follow any additional instructions provided by the relevant code of best practice.

2.1.4.33 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
- 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.
- Products may only be used in permanent treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient.
- Do not use the product in pulsed baiting treatments.

In case of permanent baiting:
- 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.

2.1.4.34 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 surface waters (e.g. rivers, ponds, water channels,

dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

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

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

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2.1.5 General directions for use

2.1.5.1 Instructions for use

General public - Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it. - Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered. - 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. - Bait stations should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.). - Where possible, bait stations must be fixed to the ground or other structures. - Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals. - Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these. - Do not place bait stations near water drainage systems where they can come into contact with water. - When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product. - Remove the remaining bait or the bait stations at the end of the treatment period. - Instructions for use that are "bait-specific":- Bait in filter paper sachets: Do not open the sachets containing the bait. **Professional and trained professional:** 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. - 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.

- 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.
- 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.).
- 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.).
- 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).
- 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 anticoagulant 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.
- Wear protective chemical resistant gloves during product handling phase
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.
- 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, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Remove the remaining bait or the bait stations at the end of the treatment period.

- Instructions for use that are "bait-specific":- Bait in filter paper sachets: Do not open the sachets containing the bait.

2.1.5.2 Risk mitigation measures

General public:
- Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).
- The product information (i.e. label and/or leaflet) shall clearly show that:
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.
- Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.
- Dispose dead rodents in accordance with local requirements.

Professional and trained professional:
- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign
- 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".
- Do not use in areas where resistance to the active substance can be suspected.
- 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 rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- Dispose dead rodents in accordance with local requirements.

- For bulk packages, for professionals and trained professionals:
Use a suitable (disposable) respirator when decanting the product.

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

- This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
- Antidote: Vitamin K1 administered by medical/veterinary personnel only.
- In case of:
- Dermal exposure, wash skin with water and then with water and soap.
- Eye exposure, always check for and remove contact lenses, rinse eyes with eyes-rinse liquid or water, keep eye lids open for at least 10 minutes
- Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label. 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
- 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. Use of gloves is recommended.

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 in places prevented from the access of children, birds, pets and farm animals. - Shelf life: 24 months

2.1.6 Other information

- Because of their delayed mode of action, anticoagulant rodenticides take from 4 to 10 days to be effective after consumption of the 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

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)**
plastic tray containing 75, 100, 125, 150 or 175 g bait covered by filter paper, in paper box	Up to 20 kg	PVC + paper		Trained professional and Professional	Yes
filter paper sachets containing 20, 25	Up to 20 kg	carton paper		Trained professional and Professional	Yes

or 50 g bait in carton box					
bulk in plastic bucket	Up to 20 kg	polypropylene (PP)		Trained professional and Professional	Yes
bulk in paper barrel	Up to 30 kg	carton paper		Trained professional and Professional	Yes
bulk in plastic sachet in carton box	Up to 25 kg	biaxially oriented polypropylene film (BOPP)/polyethylene (PE) + carton paper		Trained professional and Professional	Yes
bulk in paper bag	Up to 25 kg	paper		Trained professional and Professional	Yes
plastic tray containing 75, 100, 125 or 150 g bait covered by filter paper, in paper box or plastic sachet	1-2 trays in paper box or plastic sachet Up to 150 g	paper or biaxially oriented polypropylene film (BOPP)/polyethylene (PE)		General public	Yes
filter paper sachets containing 10, 20, 25 or 50 g bait in carton box	Up to 150 g	carton paper		General public	Yes
plastic sachet containing 50, 100, 150 g bait in carton paper box	Up to 150 g	biaxially oriented polypropylene film (BOPP)/polyethylene (PE) + carton paper or plastic sachet or metal box		General public	Yes

or in plastic box or in metal box					
plastic sachet containing 50, 100, 150 g bait	single dose	biaxially oriented polypropylene film (BOPP)/polyethylene (PE)		General public	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

-Three new efficacy studies were submitted to support the major change in parallel with the renewal of the product. See the summaries of these studies under point 2.2.5.5. of the PAR. For the former studies, please refer to the previous PAR.
-A study report was submitted to supplement validation of HPLC method for determination of bromadiolone at concentration level 27 mg/kg. New range of validation is 20 – 33 mg/kg.

2.1.8.2 Access to documentation

Babolna Bio Ltd. is the owner of the bromadiolone active substance dossier, is a Substance Supplier and an RP Participant, therefore no Letter of Access is necessary, nor being attached.

2.2 Assessment of the biocidal product

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

Table 8. **Intended use # 1 – Professional use**

Product Type(s)	PT14 - Rodenticide
Where relevant, an exact description of the authorised use	For professional and non-professional use against rats and mice in and around buildings
Target organism (including development stage)	*Mus musculus* (House mouse) – adults and juveniles *Rattus norvegicus* (Brown rat) – adults and juveniles
Field of use	Indoor Outdoor - around buildings
Application method(s)	Bulk: In the case of bulk packs use a suitable (disposable) respirator when pouring the product. Tray: Place the trays containing the rodenticide bait – without opening filter-paper covering – to the locations

	visited by rats, near the rodent runs and their supposed hiding places. Filter paper sachets: Place the filter paper sachets to the locations visited by mice and rats, near the rodent runs and their assumed hiding places.
Application rate(s) and frequency	Bulk: 50-100 g per 5 m^2 to control mice. 200-250 g every 7-10 metres to control rats. Tray: 1 or 2 trays containing 75g or 100g bait every 5 m^2 to control mice. 1 tray containing 150g or 175g bait or 2 trays containing 75g or 100g bait every 7-10 metres to control rats. Filter paper sachet: 20-100 g per 5 m^2 to control mice. 200-250 g every 7-10 metres to control rats.
Category(ies) of user(s)	Professional and trained professional
Pack sizes and packaging material	Please see the relevant section.

Table 2. **Intended use # 2 – Non-professional use**

Product Type(s)	PT14 - Rodenticide
Where relevant, an exact description of the authorised use	For professional and non-professional use against rats and mice in and around buildings
Target organism (including development stage)	*Mus musculus* (House mouse) – adults and juveniles *Rattus norvegicus* (Brown rat) – adults and juveniles
Field of use	Indoor Outdoor - around buildings
Application method(s)	Place the rodenticide bait – without opening the filter-paper covering or the sachet – to the locations visited by mice and rats, near the rodent runs and their assumed hiding places.
Application rate(s) and frequency	Tray: 1 or 2 trays containing 75g or 100g bait every 5 m^2 to control mice 1 tray containing 150g or 125g bait or 2 trays containing 75g or 100g rodenticide bait every 7-10 metres to control rats. Filter paper sachet: 10-100 g per 5 m^2 to control mice. 200 g every 7-10 metres to control rats.
Category(ies) of user(s)	Non-professional
Pack sizes and packaging material	Please see the relevant section.

* HU CA: Maximum packaging sizes (application rate as well) for general public users were limited to 150 g to meet the requirements of Commission Implementing Regulation (EU) 2017/1380 renewing the approval of bromadiolone
** HUCA: target organism *Mus musculus* (House mouse) was removed from other parts of the PAR, because the applicant requested it as an administrative change.

2.2.2 Physical, chemical and technical properties

The physical, chemical and technical properties have been presented and evaluated during the first authorisation of Protect rodenticide grain bait. The results are still relevant, no further studies have been performed, no new data have become available. For the parameters please refer to the previous PAR of the product.

HU CA: The physical, chemical and technical properties of Protect rodenticide grain bait containing 27 ppm active substance have been waived by the applicant.
Following changes were performed:

Component	**Old product**	**New product**
active substance: bromadiolon	0.005%	0.0027%
solvent: [redacted]	[redacted]	[redacted]
Replacement of colourant: [redacted] instead of Sepisperse 4G rouge	0.24%	0.24%

Changes in the composition are minimal and are not expected to influence the physico-chemical ant technical parameters of the product. The data available for product conatinig 50 ppm bromadiolone are considered relevant for the product containing 27 ppm bromadiolone.
For the parameters please refer to the previous PAR of the product.

2.2.3 Physical hazards and respective characteristics

The physical hazards and respective characteristics have been presented and evaluated during the first authorisation of Protect rodenticide grain bait containing 50 ppm bromadiolone. The results are relevant for the product with decreased bromadiolone concentration. No further studies have been performed, no new data have become available. For the parameters please refer to the previous PAR of the product.

2.2.4 Methods for detection and identification

Analytical methods for determination and identification have been presented and evaluated during the first authorisation of Protect rodenticide grain bait. The analytical method to determine bromadiolone content in the product was revalidated. The results show that the original method is also valid at 27 ppm ± 20% concentration level. For the analytical methods, results and other information, please refer to the previous PAR of the product and new studies for determination active substance in the product and revalidation of determination of bromadiolon in the product at 27 ppm level
Studies:

1. Partial Validation of the Analytical Method for the Determination of Bromadiolone in Protect Rodenticide Grain Bait, GLP, Study No: 484-100-2751, Dat: August, 2017
2. Determination of Bromadiolone Active Ingredient Content in Protect Rodenticide grain Bait, GLP, Study No.: 484-195-2752, Date: August, 2017

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Protect rodenticide grain bait is a rodenticide (product type 14) for trained professional, professional and general public use.

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

Protect rodenticide grain bait is to be used against rats.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The active substance of the product, bromadiolone, is a second-generation single-dose anticoagulant rodenticide. It disrupts the normal blood clotting mechanisms resulting in increased bleeding tendency and, eventually, profuse haemorrhage and death.

The use of anticoagulant rodenticides is necessary as there are at present no other equally effective measures available to control the rodent population. Rodent control is needed to prevent disease transmission, contamination of food and feeding stuffs and structural damage. Currently comparable less painful alternative biocidal substances or biocidal products or even non-biocidal alternatives are not available.

2.2.5.4 Mode of action, including time delay

Anticoagulant rodenticides are vitamin K antagonists. The main site of their action is the liver, where several of the blood coagulation precursors undergo vitamin K dependent post translation processing before they are converted into the respective procoagulant zymogens. The specific point of action is thought to be the inhibition of K1 epoxide reductase. The anticoagulants accumulate and are stored in the liver until broken down. The plasma prothrombin (procoagulant factor II) concentration provides a suitable guide to the severity of acute intoxication and to the effectiveness and required duration of the antidotal therapy (vitamin K1).
Signs of poisoning in rodents and other mammals are those associated with an increased tendency to bleed leading ultimately to profuse haemorrhage. After feeding on bait containing the active ingredient for 2-3 days the animal becomes lethargic and slow moving. Signs of bleeding are often noticeable and blood may be seen around the nose and anus. As symptoms develop the animal loses its appetite and will remain in its burrow or nest for increasingly long periods of time.
Death will usually occur within 4-5 days of ingesting a lethal dose and animals often die out of sight in their nest or burrow.

2.2.5.5 Efficacy data

In palatability–mortality tests the bait is considered effective when acceptance by the target species is not significantly less than 20% compared to the standard EPA meal and mortality in the test is not less than 90%.
The Bromadiolone Product Dossier Task Force has carried out extensive laboratory and semi-field trials on its Bromadiolone Grain Bait (containing 0.005% w/w bromadiolone). Efficacy reports are presented for both of the laboratory and semi-field evaluation of this formulation against Rattus norvegicus and Mus musculus.

Supporting the major change (reduced active ingredient content) the applicant submitted further trials performed with Protect rodenticide grain bait
It can be concluded from the test results that the Protect rodenticide grain bait is sufficiently attractive to be effective in the control of rats.
[redacted]HU CA: 3 new studies were submitted, 1 laboratory, 1 semi-field and 1 field study. Each was performed with on norway rats.
The studies conducted with Protect rodenticide pellet prove that with the reduced active substance content, 0.0027% bromadiolone, the bait is still efficacious norway rats (Rattus norvegicus).
It may be pointed out that there were no new studies submitted with the aged bait. However from previous studies preformed with the aged Bromadiolone granule bait (0.005% a.s.) it can be concluded that after 2 years of storage, the bait did not lose its palatability. Acceptance of the bait remained above the required 20% for mice and rats as well.
Afterall, it is strongly suspected that the bait will retain its efficacy through 2 years of storage. Therefore HU CA will accept the claimed 2 years of storage in abstence of new efficacy tests regarding the palatability of the aged bait.
[redacted]
The following efficacy studies were carried out with Protect rodenticide grain bait:

* Test product was named **Bromadiolone grain bait** in the former assessment of the product. Now the product is referred as **Protect rodenticide grain bait**. The difference between the products is decrease of the bromadiolone active substance content from 50 ppm to 27 ppm. Simultaneously [redacted] content has been [redacted]. At the same time the the colorant is also changed from Sepisperse 4G rouge to Allura red, the quantity of the dye remained same (0.24%). Other quality and quantity parameters of the composition remain unchanged.

Test product	Test organisms	Test system/Concentration applied/exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference
Bromadiolone Grain Bait in filter paper sachet	House mouse (*Mus musculus*) 10 laboratory bred wild animals (5 males, 5 females)	Laboratory test. Palatability – mortality trial study. Choice feeding test: fresh baits. 3-day pre-test normal diet (CRLT/N) intake assessment. 5 day bait feeding period and 6 day normal diet period. Unrestricted access to the test bait and to palatable and	The animals were individually caged. Normal laboratory requirements: • temperature: 22 ± 2ºC • relative humidity: min. 40% ± 10% • continuous change of air (ventilation) • 12-hour light-dark cycle	[redacted] The efficacy was total: 100% [redacted].	Biological Laboratory of Babolna Bio Ltd., Hungary 111.013

		familiar alternative food (challange diet – EPA STANDARD) during the 5-day test period. The quantitiy of food placed in each pot was *sufficient to meet each animal's daily needs.*			
Bromadiolone Grain Bait	Norway rat (*Rattus norvegicus*) 10 laboratory bred wild animals (5 males, 5 females)	Laboratory test. Palatability – mortality trial study. Choice feeding test: fresh baits. 3-day pre-test normal diet (CRLT/N) intake assessment. 5 day bait feeding period and 6 day normal diet period. Unrestricted access to the test bait and to palatable and familiar alternative food (challange diet – EPA STANDARD) during the 5-day test period. The quantitiy of food placed in each pot was *sufficient to meet each animal's daily needs.*	The animals were individually caged. Normal laboratory requirements: • temperature: 22 ± 2ºC • relative humidity: min. 40% ± 10% • continuous change of air (ventilation) • 12-hour light-dark cycle	[redacted] The efficacy was total: 100% [redacted].	Biological Laboratory of Babolna Bio Ltd., Hungary 111.025
Bromadiolone Grain Bait in plastic tray covered by filter paper	House mouse (*Mus musculus*) 10 laboratory bred wild animals (5 males, 5 females)	Semi-field test carried out in a semi-field trial room (4 sqm). Palatability – mortality trial study. Choice feeding test: fresh baits. 3-day pre-test normal diet (CRLT/N) intake assessment. 5 day bait feeding period. Unrestricted access to the test bait and to palatable and familiar alternative food (challange diet – EPA STANDARD) during the 5-day test period. The quantitiy of food	Semi-natural conditions. Semi-field trial room: 3.1 x 1.18 m, airspace: 8. 34 m^3 Normal laboratory requirements: • temperature: 22 ± 2ºC • relative humidity: min. 40% ± 10% • continuous change of air (ventilation) • 12-hour light-dark cycle	[redacted] The efficacy was total: 100% [redacted].	Biological Laboratory of Babolna Bio Ltd., Hungary 111.046

		was *2 trays of Bromadiolone Grain bait and 2 trays filled with EPA STANDARD.*			
Bromadiolone Grain Bait in filter paper sachet	House mouse (*Mus musculus*) 10 laboratory bred wild animals (5 males, 5 females)	Semi-field test carried out in a semi-field trial room (4 sqm). Palatability – mortality trial study. Choice feeding test: fresh baits. 3-day pre-test normal diet (CRLT/N) intake assessment. 5 day bait feeding period. Unrestricted access to the test bait and to palatable and familiar alternative food (challange diet – EPA STANDARD) during the 5-day test period. The quantitiy of food placed in each pot was *sufficient to meet each animal's daily needs*.	Semi-natural conditions. Semi-field trial room: 3.1 x 1.18 m, airspace: 8. 34 m^3 Normal laboratory requirements: • temperature: 22 ± 2ºC • relative humidity: min. 40% ± 10% • continuous change of air (ventilation) • 12-hour light-dark cycle	[redacted] The efficacy was total: 100% [redacted].	Biological Laboratory of Babolna Bio Ltd., Hungary 111.037
Bromadiolone Grain Bait in filter paper sachet	Norway rat (*Rattus norvegicus*) 10 laboratory bred wild animals (5 males, 5 females)	Semi-field test carried out in semi-field trial rooms I and II. (total: 7.7 sqm). Palatability – mortality trial study. Choice feeding test: fresh baits. 3-day pre-test normal diet (CRLT/N) intake assessment. 5 day bait feeding period. Unrestricted access to the test bait and to palatable and familiar alternative food (challange diet – EPA STANDARD) during the 5-day test period. The quantitiy of food placed in each pot was *sufficient to meet each animal's daily needs*.	Semi-natural conditions. Semi-field trial rooms: I.: 3.1 x 1.18 m, airspace: 8.34 m^3 II.: 3.1 x 1.30 m, airspace: 9.19 m^3 Normal laboratory requirements: • temperature: 22 ± 2ºC • relative humidity: min. 40% ± 10% • continuous change of air (ventilation) • 12-hour light-dark cycle	[redacted] The efficacy was total: 100% [redacted].	Biological Laboratory of Babolna Bio Ltd., Hungary 111.063

20 g Bromadiolone Grain Bait in aroma permeable filter paper sachet, after 1 year of storage	House mouse (*Mus musculus*) 10 laboratory bred wild animals (5 males, 5 females)	Laboratory test. Palatability – mortalitiy trial study. Choice feeding test: aged baits. 3-day pre-test normal diet (CRLT/N) intake assessment. 5 day bait feeding period and 6 day normal diet period. Unrestricted access to the test bait and to palatable and familiar alternative food (challange diet – EPA STANDARD) during the 5-day test period. The quantitiy of food placed in each pot was *sufficient to meet each animal's daily needs.*	The animals were individually caged. Normal laboratory requirements: • temperature: 22 ± 2ºC • relative humidity: min. 40% ± 10% • continuous change of air (ventilation) • 12-hour light-dark cycle	[redacted] The efficacy was total: 100% [redacted].	Biological Laboratory of Babolna Bio Ltd., Hungary 121.015
Bromadiolone Grain Bait, after 1 year of storage	Norway rat (*Rattus norvegicus*) 10 laboratory bred wild animals (5 males, 5 females)	Laboratory test. Palatability – mortalitiy trial study. Choice feeding test: aged baits. 3-day pre-test normal diet (CRLT/N) intake assessment. 5 day bait feeding period and 6 day normal diet period. Unrestricted access to the test bait and to palatable and familiar alternative food (challange diet – EPA STANDARD) during the 5-day test period. The quantitiy of food placed in each pot was *sufficient to meet each animal's daily needs.*	The animals were individually caged. Normal laboratory requirements: • temperature: 22 ± 2ºC • relative humidity: min. 40% ± 10% • continuous change of air (ventilation) • 12-hour light-dark cycle	[redacted] The efficacy was total: 100% [redacted].	Biological Laboratory of Babolna Bio Ltd., Hungary 121.006
20 g Bromadiolone Grain Bait, in aroma permeable filter paper	House mouse (*Mus musculus*) 10 laboratory bred wild animals	Laboratory test. Palatability – mortalitiy trial study. Choice feeding test: aged baits. 3-day pre-test normal diet	The animals were individually caged. Normal laboratory requirements: • temperature: 22 ± 2ºC • relative humidity: min. 40% ± 10%	[redacted]	Biological Laboratory of Babolna Bio Ltd., Hungary 121.059

sachet, after 1,5 years of storage	(5 males, 5 females)	(CRLT/N) intake assessment. 5 day bait feeding period and 6 day normal diet period. Unrestricted access to the test bait and to palatable and familiar alternative food (challange diet – EPA STANDARD) during the 5-day test period. The quantitiy of food placed in each pot was *sufficient to meet each animal's daily needs.*	• continuous change of air (ventilation) • 12-hour light-dark cycle	The efficacy was total: 100% [redacted].	
Bromadiolone Grain Bait, after 1,5 years of storage	Norway rat (*Rattus norvegicus*) 10 laboratory bred wild animals (5 males, 5 females)	Laboratory test. Palatability – mortalitiy trial study. Choice feeding test: aged baits. 3-day pre-test normal diet (CRLT/N) intake assessment. 5 day bait feeding period and 6 day normal diet period. Unrestricted access to the test bait and to palatable and familiar alternative food (challange diet – EPA STANDARD) during the 5-day test period. The quantitiy of food placed in each pot was *sufficient to meet each animal's daily needs.*	The animals were individually caged. Normal laboratory requirements: • temperature: 22 ± 2ºC • relative humidity: min. 40% ± 10% • continuous change of air (ventilation) • 12-hour light-dark cycle	[redacted] The efficacy was total: 100% [redacted].	Biological Laboratory of Babolna Bio Ltd., Hungary 121.061
Bromadiolone Grain Bait, in filter paper sachet, after 2 years of storage	House mouse (*Mus musculus*) 10 laboratory bred wild animals (5 males, 5 females)	Laboratory test. Palatability – mortalitiy trial study. Choice feeding test: aged baits. 3-day pre-test normal diet (CRLT/N) intake assessment. 5 day bait feeding period and 6 day normal diet period. Unrestricted access to the test	The animals were individually caged. Normal laboratory requirements: • temperature: 22 ± 2ºC • relative humidity: min. 40% ± 10% • continuous change of air (ventilation) • 12-hour light-dark cycle	[redacted] The efficacy was total: 100% [redacted]	Biological Laboratory of Babolna Bio Ltd., Hungary 131.011

		bait and to palatable and familiar alternative food (challange diet – EPA STANDARD) during the 5-day test period. The quantitiy of food placed in each pot was *sufficient to meet each animal's daily needs.*			
Bromadiolone Grain Bait, after 2 years of storage	Norway rat (*Rattus norvegicus*) 10 laboratory bred wild animals (5 males, 5 females)	Laboratory test. Palatability – mortalitiy trial study. Choice feeding test: aged baits. 3-day pre-test normal diet (CRLT/N) intake assessment. 5 day bait feeding period and 6 day normal diet period. Unrestricted access to the test bait and to palatable and familiar alternative food (challange diet – EPA STANDARD) during the 5-day test period. The quantitiy of food placed in each pot was *sufficient to meet each animal's daily needs.*	The animals were individually caged. Normal laboratory requirements: • temperature: 22 ± 2ºC • relative humidity: min. 40% ± 10% • continuous change of air (ventilation) • 12-hour light-dark cycle	[redacted] The efficacy was total: 100% [redacted].	Biological Laboratory of Babolna Bio Ltd., Hungary 131.012
STUDIES SUBMITTED TO SUPPORT THE MAJOR CHANGE IN PARALLEL WITH THE RENEWAL OF THE PRODUCT ARE LISTED BELOW					
Protect rodenticide grain bait *(0,0027 % bromadiolone)	Norway rat (*Rattus norvegicus*) 10 laboratory bred wild animals (5 males, 5 females)	Laboratory test. Palatability – mortalitiy trial study. Choice feeding test: 3-day pre-test normal diet (CRLT/N) intake assessment. 5 day bait feeding period and 6 day normal diet period. Unrestricted access to the test bait and to palatable and familiar alternative food (challange diet – EPA STANDARD) during the 5-day	The animals were individually caged. Normal laboratory requirements: • temperature: 22 ± 2ºC • relative humidity: min. 40% ± 10% • continuous change of air (ventilation) • 12-hour light-dark cycle	[redacted] The efficacy (mortality) was 90%.	Biological Laboratory of Babolna Bio Ltd., Hungary 161.019

		test period. The quantitiy of food placed in each pot was sufficient to meet each animal's daily needs.			
Protect rodenticide grain bait *(0,0027 % bromadiolone)	Norway rat (*Rattus norvegicus*) 10 laboratory bred wild animals (5 males, 5 females)	Semi-field test carried out in semi-field trial rooms I and II. (total: 7.7 sqm). Palatability – mortality trial study. Choice feeding test: fresh baits. 3-day pre-test normal diet (CRLT/N) intake assessment. 5 day bait feeding period. Unrestricted access to the test bait and to palatable and familiar alternative food (challange diet – EPA STANDARD) during the 5-day test period. The quantitiy of food placed in each pot was *sufficient to meet each animal's daily needs*.	[redacted] Normal laboratory requirements: • temperature: 22 ± 2ºC • relative humidity: min. 40% ± 10% • continuous change of air (ventilation) • 12-hour light-dark cycle	[redacted] The efficacy (mortality) was 100%.	Biological Laboratory of Babolna Bio Ltd., Hungary 171.003
Protect rodenticide grain bait *(0,0027 % bromadiolone)	Norway rat (*Rattus norvegicus*) wild population Genetically confirmed to be susceptible (not resistant) to AVK active substances as bromadiolone.	Field test on a hen yard The rat population consisted of 6 individuals approximately. In the pre treatment and post treatment periods reference food (grain) was put in plastic bait stations. During treatment 2x150g grams of bait was placed the bait stations. Food and bait consumption was measured daily and replenished. Bait stations were 7-10 meters apart. Tracking patches were also used to monitor rodent activity.	pre-feeding period: 8 days pre-lag period 5 days baiting period: 10 days post-baiting lag period: 4 days post treatment period: 8 days	After the 10-day baiting period and the during the post-treatment period no rodent activity was observed from consumption values and tracking patches.	IZIPEST® ref. no.: 17RnBA004

2.2.5.6 Occurrence of resistance and resistance management

Regarding the considerations of resistance issues please refer to the PAR of the first authorisation of Protect rodenticide grain bait.
HU CA accepts the reasoning of the applicant on the issue of resistance. The submitted trial (study no. 16BA001) supports the view that if administered in the sufficient dose, a bait with 0,0027% bromadiolone content is capable of controlling AVK resistant brown rats. Therefore it is suspected that a bait with 0,005% bromadiolone content, applied by professional users will have adequate efficacy. Taking into account the other points of the applicant on resistance monitoring and the risk mitigation measures on product labels addressing resistance, HU CA considers that the criteria of avoiding, delaying and managing resistance is fulfilled.

2.2.5.7 Known limitations

Not relevant.

2.2.5.8 Evaluation of the label claims

The results of the efficacy studies have supported the label claims of the product.

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

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

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

No new studies have been performed for the renewal of Protect rodenticide grain bait; the studies submitted for the first authorisation and presented again below are still considered valid. Human exposure and risk assessment calculations have been amended to incorporate new relevant guidance recommendations, however the resulting conclusions remain the same as in the original authorisation.

Skin corrosion and irritation

In vitro skin corrosion/irritation studies were not performed with the product.

A skin irritation study is available on rabbits with Protect rodenticide grain bait

Based on the results of this study, it can be concluded that the product is non-irritating to skin and does not meet the classification criteria for this endpoint based on CLP regulation (EC) 1272/2008.

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 404, GLP, Reliability: 1	Albino rabbit, New Zealand white, 3 males	**Grain bait** (0.005% bromadiolone), no vehicle (test item moistened with water), [redacted]	**No irritation symptoms.** [redacted]	-	[redacted]

No human data are available on skin corrosion/irritation.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Protect rodenticide grain bait is not irritating to skin
Justification for the value/conclusion	[redacted]
Classification of the product according to CLP and DSD	No classification is required for Protect rodenticide grain bait for this endpoint.

Eye irritation

In vitro eye irritation studies were not performed with the product.

In the eye irritation study on rabbits performed with Protect rodenticide grain bait no irreversible eye irritant effects were observed.

[redacted]

[redacted] According to CLP regulation 1272/2008 criteria the product does not need to be classified for this endpoint.

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance,Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 405, GLP, Reliability: 1	Albino rabbit, New Zealand white 3 males	**Grain bait** (0.005% bromadiolone [redacted]	[redacted]	-	[redacted]

No human eye irritation data are available.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Protect rodenticide grain bait is not an eye irritant.
Justification for the value/conclusion	[redacted]. The product was not found to be irritating to rabbit eyes
Classification of the product according to CLP and DSD	No classification is required for Protect rodenticide grain bait for this endpoint.

Respiratory tract irritation

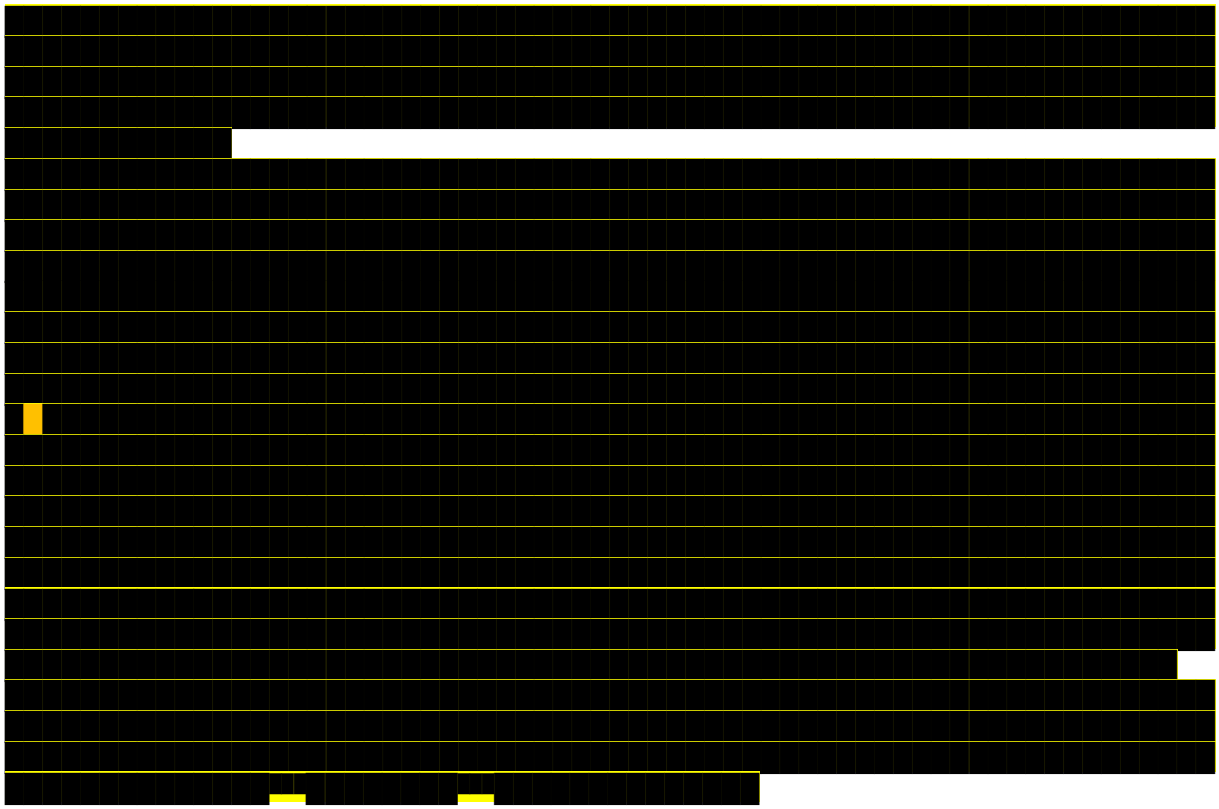
No animal studies or human data are available on respiratory tract irritation.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	The product Protect rodenticide grain bait is not expected to be irritating to the respiratory tract. The skin irritation study with the product showed that Protect rodenticide grain bait is not a skin irritant furthermore none of the components in the product are classified as respiratory irritants.
Classification of the product according to CLP and DSD	No classification is required for Protect rodenticide grain bait for this endpoint.

Data waiving	
Information requirement	Respiratory tract irritation study performed with the product
Justification	The study with the product is scientifically not justified. The skin irritation study performed with the product was negative and there are no indications that Protect rodenticide grain bait could be a respiratory irritant. Data on the active substance and other co-formulants also show that the product is not expected to possess such property (none of the components are respiratory irritants). It can be concluded that no classification is necessary for respiratory tract irritation.

Skin sensitization

A skin sensitization study is available with Protect rodenticide grain bait performed according to the Buehler method.



Based on the results it could be concluded that the product is a non-sensitizer and no classification is required.

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 406, GLP, Reliability: 1	Guinea pigs, Dunkin Hartley, Range finding: 2 males/ concentration, Test group: 20 males Control group: 10 males	**Grain bait** (0.005% bromadiolone), [redacted]	[redacted]	-	[redacted]

No human skin sensitization data are available.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Protect rodenticide grain bait is not a skin sensitizer.
Justification for the value/conclusion	The results of the study described above show that the product has no skin sensitizing potential. [redacted]
Classification of the product according to CLP and DSD	No classification is required for Protect rodenticide grain bait for this endpoint.

Respiratory sensitization (ADS)

The product Protect rodenticide grain bait is not a skin sensitizer based on the available study (see above). Furthermore, none of the components in the product are classified as respiratory or skin sensitizers. Currently no standard tests or guidelines exist for this

endpoint however the product is not expected to possess such property. No further studies are considered relevant.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	The product is not considered a respiratory sensitizer.
Justification for the value/conclusion	The product is not a skin sensitizer and none of the constituents are classified for respiratory or skin sensitisation.
Classification of the product according to CLP and DSD	No classification is required for this endpoint.

Data waiving	
Information requirement	Respiratory sensitization study performed with the product
Justification	No standard tests or guidelines exist for this endpoint. A skin sensitisation study on the product has shown that Protect rodenticide grain bait is not a skin sensitizer. None of the components in Protect rodenticide grain bait are classified as respiratory sensitizers or skin sensitizers, the product is not expected to possess such property either. No further studies are considered relevant.

Acute toxicity

Acute toxicity by oral route

[redacted]

[redacted]

Protect rodenticide grain bait was therefore not found to have acute oral toxic property. LD50 was greater than 2000 mg/kg. Classification based on CLP regulation (EC) 1272/2008 is not necessary.

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels Type of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 423, GLP, Reliability: 1	Rat, Crl(WI)BR 6 females (3/step)	**Grain bait** (0.005% bromadiolone) [redacted]	[redacted]	> 2000 mg/kg	-	[redacted]

No human acute oral toxicity data are available.

Value used in the Risk Assessment – Acute oral toxicity	
Value	Oral LD50 > 2000 mg/kg
Justification for the selected value	No mortality was observed in the above-mentioned study following administration of a single dose of 2000 mg/kg product.
Classification of the product according to CLP and DSD	No classification is required for this endpoint.

Acute toxicity by inhalation

No acute inhalation toxicity studies were performed with Protect rodenticide grain bait. The active substance is not volatile, other co-formulants in the product – mostly food grade materials – are not relevant for inhalation toxicity based on their classification and/or content. Inhalation exposure to the solid grain formulation is not possible, no dust will be produced.

No human acute inhalation toxicity data are available.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	The product does not have any toxic effects via the inhalation route
Justification for the selected value	Inhalation exposure can be excluded. The active substance is not volatile, the product does not produce any dust. Protect rodenticide grain bait is not expected to elicit any acute inhalation toxic effects.
Classification of the product according to CLP and DSD	No classification is required for this endpoint.

Data waiving	
Information requirement	Acute inhalation toxicity study performed with the product
Justification	[redacted] An inhalation toxicity study is not considered relevant.

Acute toxicity by dermal route

The following acute dermal toxicity study is available with Protect rodenticide grain bait[redacted]

[redacted]

The results show that the product does not have any acute dermal toxicity. The acute dermal LD50 was greater than 2000 mg/kg. Classification is therefore not required based on CLP Regulation (EC) 1272/2008.

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 402, GLP Reliability: 1	Rat, Crl(WI)BR Preliminary study: 2/dose Main study: 10/dose (5 male, 5 female)	**Grain bait** (0.005% bromadiolone) [redacted]	No mortality observed in preliminary or main study (limit test). [redacted]	> 2000 mg/kg	-	[redacted]

No human acute dermal toxicity data are available.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Dermal LD50 > 2000 mg/kb
Justification for the selected value	No mortality was observed in a limit test performed with Protect rodenticide grain bait.
Classification of the product	No classification is required for this endpoint.

according to CLP and DSD	

Information on dermal absorption

An *in vitro* dermal absorption study (Toner F, 2008) is available from the active substance dossier. Detailed results can be found in the final CAR.

The study was conducted according to OECD Guideline 428. Bromadiolone was tested incorporated into a granule bait:saline (1:1 w/w) formulation (test preparation 1) and a wax block formulation (test preparation 2). The dermal absorption for test preparation 1 (0.0025 %, w/w) was approximately 0.36% based on the sum of the absorbed dose and the exposed skin (incl. tape strip 1-20). The dermal absorption for test preparation 2 (0.005 %, w/w) was approximately 0.04% based on the sum of the absorbed dose and the exposed skin (incl. tape strip 1-20).

[redacted] The dermal absorption of **0.36%** from the solubilised granule formulation thus represents a worst case value, which is considered relevant for Protect rodenticide grain bait. This value was used in the risk assessment of the product. The co-formulants are not expected to influence dermal absorption to an extent that would result in a higher absorption than this value.

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 Guideline 428, GLP, Reliability: 1	5 human skin samples (female)	Test preparation 1: bait:saline, 0.0025% Test preparation 2: wax block, 0.005%	Bait:saline: 0.36% Wax block: 0.04%	-	Toner F (2008)

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	Bromadiolone (in product)		
Value(s)*	0.36%		

Justification for the selected value(s)	This value, obtained from a solubilised granule formulation, represents a worst case dermal absorption value, which is also valid for Protect rodenticide grain bait.		

Data waiving	
Information requirement	Dermal absorption study performed with the product
Justification	A dermal absorption study with Protect rodenticide grain bait is not considered scientifically justified as relevant dermal absorption data exist from the bromadiolone dossier, performed with bait:saline and wax block test preparations. The worst case value from this available *in vitro* study was taken further to risk assessment calculations. The dermal absorption of Protect rodenticide grain bait is not expected to be higher than this chosen value.

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

There are no substances of concern present in the product. The co-formulants of Protect rodenticide grain bait are mostly food-grade materials which are not classified, or present in such low concentrations that they do not have any influence on the non-toxic property of the product[redacted]. The available studies on the product also show that no toxic effect is to be expected.

Available toxicological data relating to a mixture

Available toxicological data relating to a mixture that a substance(s) of concern is a component of

No substances of concern are present in the product Protect rodenticide grain bait. The co-formulants of Protect rodenticide grain bait are mostly food-grade materials which are not classified, or present in such low concentrations that they do not have any influence on the non-toxic property of the product.

Other

Not applicable

2.2.6.2 Exposure assessment

Protect rodenticide grain bait contains 0.0027% bromadiolone. The intended uses are professional and non-professional use in and around buildings, against rats and mice. The bait is formulated in sachets, ready-to-use trays, ready-to-use bait boxes, or ready-to-use bags (not to be opened) for non-professionals, and sachets, ready-to-use trays or in bulk form for professional users (see further details below in the relevant sections).

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

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

The following exposure scenarios have been identified for Protect rodenticide grain bait:

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.	Mixing & loading	Primary exposure Decanting of grain bait	Professionals
2.	Application	Primary exposure Loading and placing bait boxes	Professionals
3.	Post-application	Primary exposure Cleaning of bait boxes	Professionals
4.	Application	Primary exposure Loading and placing bait boxes	Non-professionals
5.	Post-application	Primary exposure Cleaning of bait boxes	Non-professionals
6.	Toddler oral exposure	Secondary exposure Toddler ingesting part of the bait	General public-toddlers
7.	Child oral exposure	Secondary exposure Child ingesting part of the bait	General public - children

Industrial exposure

Industrial use of Protect rodenticide grain bait is not intended.

Professional exposure

Protect rodenticide grain bait is used by professionals in and around buildings, for the control of rats and mice. These users (e.g. from private companies and local authorities) are trained operators who handle rodenticides on a daily basis. They can be expected to wear protective clothing (gloves) when handling the product. After use, unused product is likely to be collected and disposed of in a controlled way.

The product is formulated in one of the following packaging:
- 75, 100, 125, 150 or 175 g grain bait in plastic tray covered by filter paper, in paper box up to 20 kg
- 20, 25 or 50 g bait in filter paper sachets, in cardboard box up to 20 kg
- bulk in plastic bucket, up to 20 kg
- bulk in paper barrel, up to 30 kg
- bulk in plastic sachet and in carton box, up to 25 kg
- bulk in paper bag, up to 25 kg

Min. net weight: 3 kg.

The maximum dose per bait point is 250 g for rats and 100 g for mice.

The worst case scenario for professional users is when the operator uses the product in bulk form. Three use phases can be identified for this use of Protect rodenticide grain bait. In the first step, the grain bait from larger packages has to be decanted, this is the "mixing & loading" phase. This is followed by application when bait is loaded into bait boxes. The last phase is post-application, when bait boxes are cleaned.

The active substance bromadiolone is not volatile. The solid grain bait is not friable or dusty thus airborne particles will not be produced. The product is therefore not respirable and does not produce respirable particles or respirable vapours. Consequently, **inhalation exposure** of professional users is expected to be negligible. Nevertheless, inhalation exposure calculations are included below for the mixing & loading phase, based on the approach taken in HEEG Opinion 12 on a "Harmonised approach for the assessment of rodenticides (anticoagulants)". Inhalation is considered negligible during application and cleaning, according to HEEG Opinion 12 and also on the basis of the product characteristics.

The bait is not likely to reach the mouth of professional users. Therefore, the risk of **oral exposure** during use is considered to be negligible. The bait also contains a bittering agent (denatonium benzoate) in order to prevent accidental ingestion.

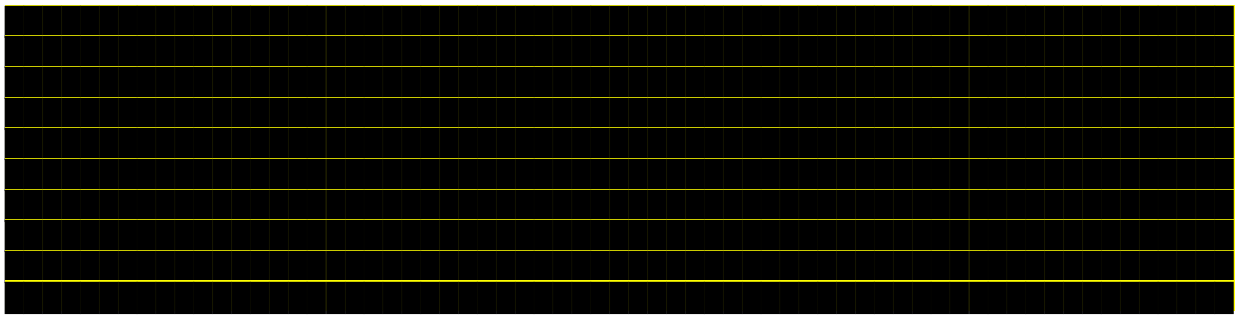
The main route of **exposure is dermal**, dermal exposure of professional users is likely to be limited to the hands only. Exposure of other parts of the body can be regarded as negligible.

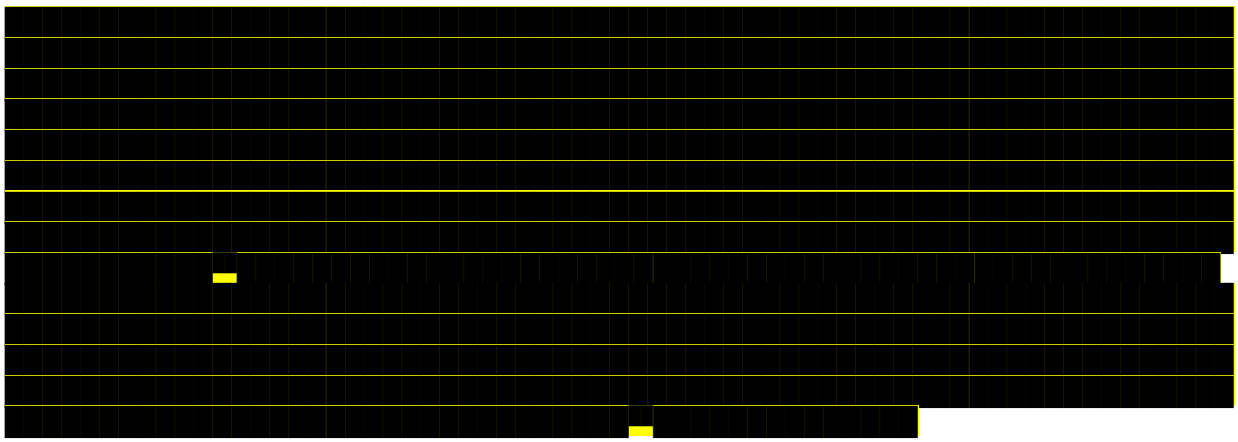
Exposure assessment calculations are based on HEEG Opinion 10 on "Harmonising the number of manipulations in the assessment if rodenticides (anticoagulants)" agreed at TM III 2010 and HEEG Opinion 12 on a "Harmonised approach for the assessment of rodenticides (anticoagulants)".

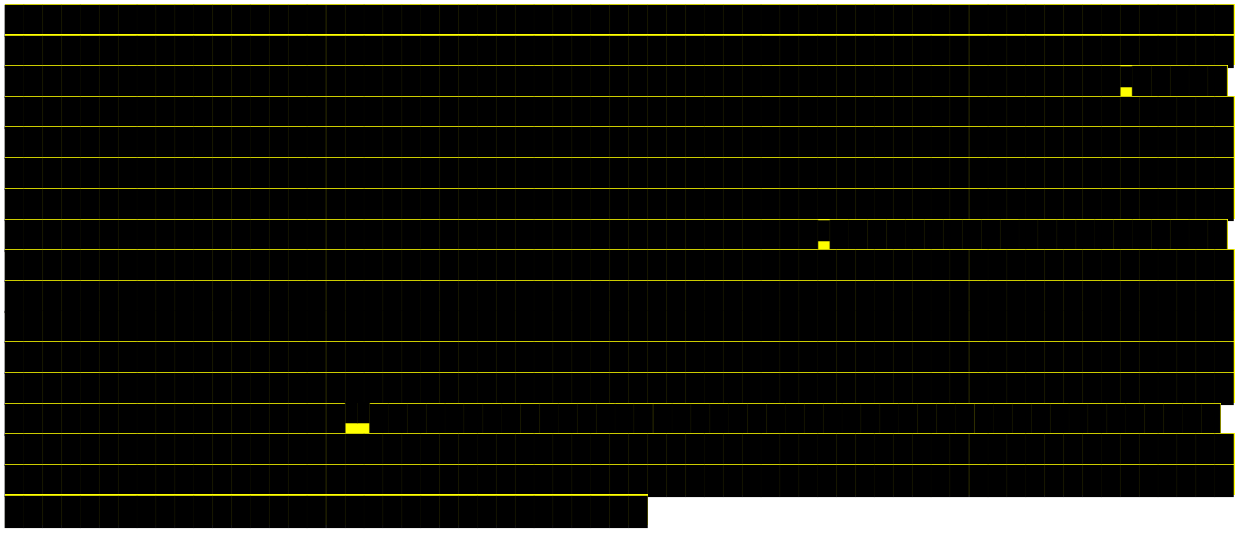
Based on the HEEG documents, the number of loadings of grain bait for professional users is 63, the number of cleaning manipulations is 16. According to HEEG Opinion 12, the "Assessment of grain baits" model is valid for the product.

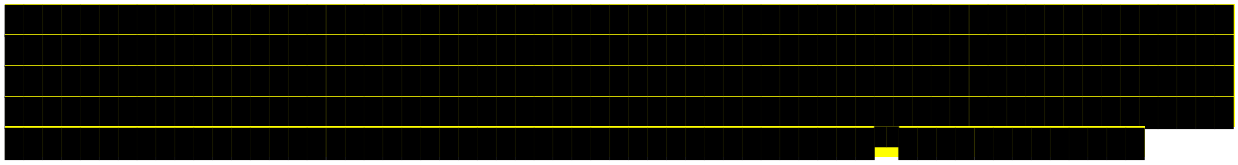
The dermal absorption value of 0.36% was used in the calculations. Default user body weight is considered to be 60 kg. PPE (use of protective gloves) is assumed to reduce the exposure to 10% of the original value.

Scenario [1]









Description of Scenario [1]		
Mixing & loading – decanting of grain bait Primary exposure of professional users Worst case: decanting of grain bait from large bulk package into a bucket without and with PPE without and with RPE		
	Parameters[1]	Value
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[1] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.
[2] Only include the parameters changed with respect to the previous Tier.

Calculations for Scenario [1]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	Tier 1, no PPE, no RPE	[redacted]	[redacted]	[redacted]	[redacted]
Scenario [1]	Tier 2, with PPE, no RPE	[redacted]	[redacted]	[redacted]	[redacted]
Scenario [1]	Tier 2, with PPE, with RPE	[redacted]	[redacted]	[redacted]	[redacted]

Further information and considerations on scenario [1]

No further information applicable.

Scenario [2]

[redacted]

[redacted]Inhalation exposure in this use phase is considered negligible.

Description of Scenario [2]		
Application – loading and placing bait boxes Primary exposure of professional users Worst case: loading grain bait from a bucket into bait stations using a plastic scoop without and with PPE		
	Parameters[1]	Value
[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[1] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.
[2] Only include the parameters changed with respect to the previous Tier.

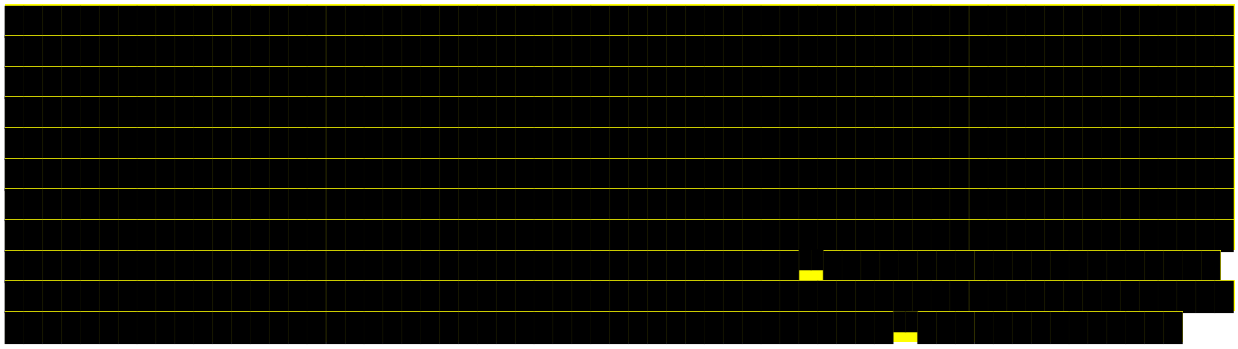
Calculations for Scenario [2]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	Tier 1, no PPE	[redacted]	[redacted]	[redacted]	[redacted]
Scenario [2]	Tier 2, with PPE	[redacted]	[redacted]	[redacted]	[redacted]

Further information and considerations on scenario [2]

No further information applicable.

Scenario [3]



Inhalation exposure in this use phase is considered negligible.

Description of Scenario [3]		
Post-application – Cleaning of bait boxes Primary exposure of professional users Worst case: emptying a loaded bait station containing grain bait into a bucket without and with PPE		
	Parameters[1]	Value

[1] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.
[2] Only include the parameters changed with respect to the previous Tier.

Calculations for Scenario [3]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Scenario [3]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Further information and considerations on scenario [3]

No further information applicable.

Combined scenarios

The combination of the mixing & loading, application and post-application scenarios is considered relevant, as the same user will perform all phases in most cases. The combined values of all the scenarios can be found in the table below.

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [1, 2, 3]* Tier 1	[redacted]	[redacted]	[redacted]	[redacted]
Scenarios [1, 2, 3] Tier 2 with PPE, no RPE	[redacted]	[redacted]	[redacted]	[redacted]
Scenarios [1, 2, 3] Tier 2 with PPE, with RPE	[redacted]	[redacted]	[redacted]	[redacted]

* Please include the Tier where relevant

The above-mentioned operator exposure values represent a worst case assumption. Calculations are based on the HEEG model, where inhalation during decanting is taken into account. However, the product is non-dusty and the active substance is not volatile, thus the actual inhalation exposure is expected to be negligible.

The product is also supplied in the form of ready-to-use trays and sachets, exposure to these kinds of formulations is much lower than during the application of the bulk grain bait.

Therefore, the calculations presented above cover the exposure to all other formulation types as well.

Non-professional exposure

Non-professional users may use the product in and around buildings for the control of rats and mice. For non-professional use, the product is formulated in one of the following packaging:

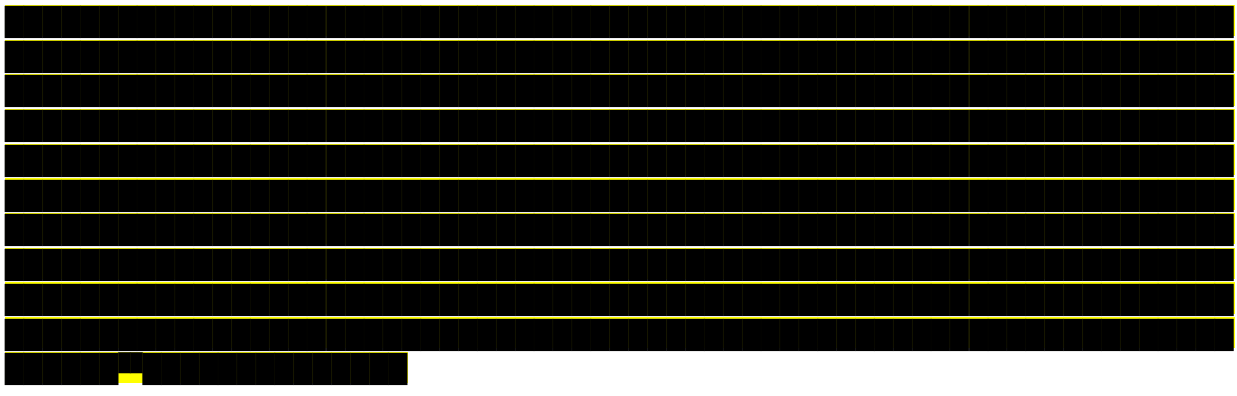
- 75, 100, 125, 150 g grain bait in plastic tray covered by filter paper or 1 or 2 trays in paper box
- 10, 20, 25 or 50 g bait in filter paper sachets, in carton paper box – up to 150 g
- 50, 100, 150g , bait in plastic sachet in carton paper box or in plastic box or in metal box–150 g
- 50, 100, 150g bait in plastic sachet single dose

According to the HEEG Opinion 10 on harmonising the number of manipulations in the assessment of rodenticides (anticoagulants), a default number of 5 manipulations should be used for application, and 5 for clean-up for non-professional users. The maximum dose to be used is 200 g for the control of rats and 100 g for the control of mice.

Bulk bait is not available for non-professional use. Only ready-to-use boxes, trays, bags or sachets are available, which reduce any exposure to a negligible level. Nevertheless, calculations are presented based on worst case assumptions. No guidance exists on the default exposure values for non-professional users, therefore as a worst case, the values indicated in the HEEG Opinion 12 were used. Mixing & loading is not relevant for non-professional users as no decanting is required for the existing types of packaging. Only application and clean-up phases will occur.

Non-professional users are assumed not to wear any personal protective equipment.

Scenario [4]



Inhalation exposure is negligible according to the HEEG guidance and also on the basis of the product properties. Protect rodenticide grain bait is non-dusty and the active substance is not volatile.

Description of Scenario [4]		
Application – loading and placing bait boxes Primary exposure of non-professional users Based on the exposure estimates of HEEG opinion 12 for loading grain bait from a bucket with a scoop (worst case calculation, actual exposure is much lower as only ready-to-use packaging types are manufactured for non-professionals) without PPE		
	Parameters[1]	Value
Tier 1	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
Tier 2[2]	[redacted]	[redacted]
Tier 3	[redacted]	[redacted]

[1] Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.
[2] Only include the parameters changed with respect to the previous Tier.

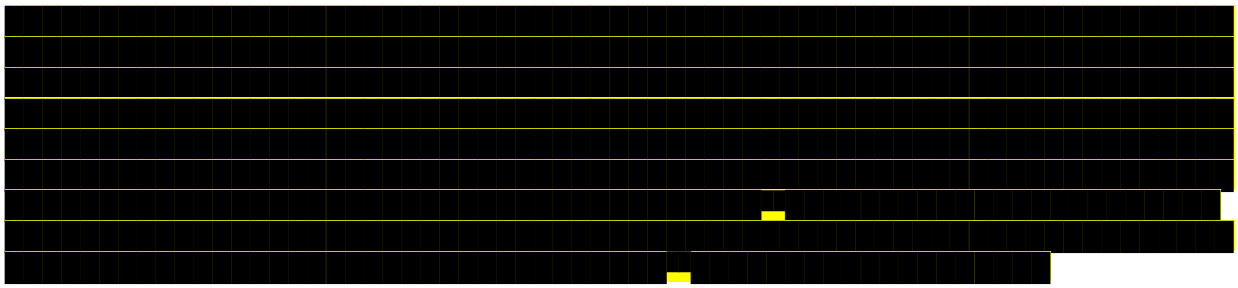
Calculations for Scenario [4]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [4]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Further information and considerations on scenario [4]

No further information applicable.

Scenario [5]



Inhalation exposure is negligible according to the HEEG guidance and also on the basis of the product properties. Protect rodenticide grain bait is non-dusty and the active substance is not volatile.

Description of Scenario [5]		
Post-application – Cleaning of bait boxes Primary exposure of non-professional users without PPE		
	Parameters[1]	Value

[1] Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.
[2] Only include the parameters changed with respect to the previous Tier.

Calculations for Scenario [5]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [5]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Further information and considerations on scenario [5]

No further information applicable.

Combined scenarios

Combined scenarios are considered relevant as in most cases it is likely that the same person will perform application and clean-up.

Summary table: combined systemic exposure from non-professional uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [4,5][1] Tier 1	[redacted]	[redacted]	[redacted]	[redacted]

[1] Please include the Tier where relevant

Exposure of the general public

Inhalation exposure of non-users to residues during or after application via the environment is considered to be negligible. The active substance bromadiolone is not volatile, the product does not produce any dust and it is applied in bait stations or in ready-to-use trays, boxes or sachets which prevents exposure. Inhalation exposure of the general public is thus not considered relevant.

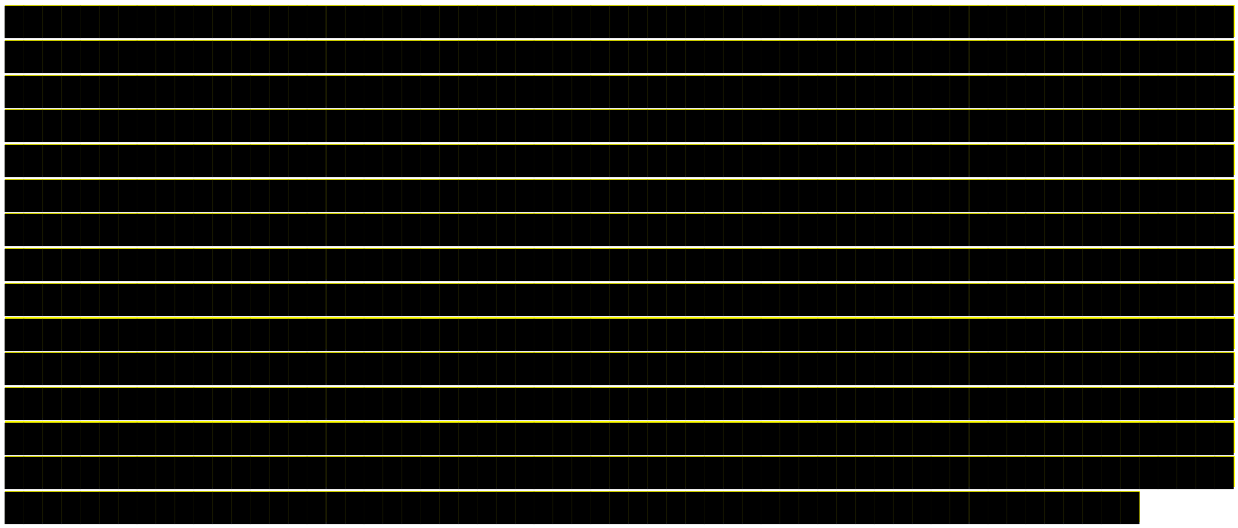
For adult non-users, the risk of **dermal exposure** to residues is considered negligible. Similarly, **oral exposure** is not considered to be relevant.

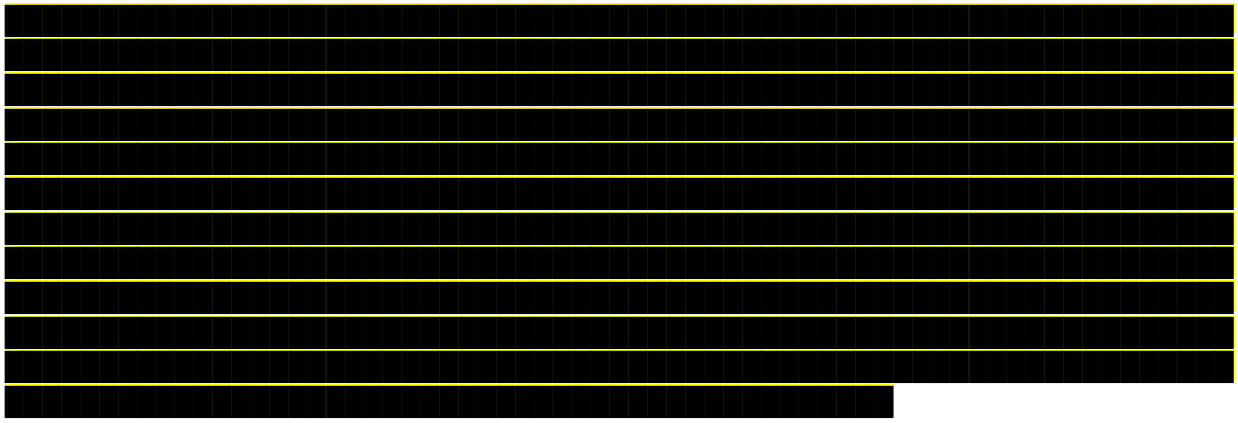
Exposure of adults or children to the active substance by handling dead rodents is assumed to be negligible. Dead rodents as such already pose a risk to human health and should be disposed of with care.

Children or infants could potentially be the group most at risk as they may play inside or around buildings where baits have been placed. For products applied in tamper resistant bait boxes the exposure will be very limited. Furthermore, product labels and good practice advise users to prevent access to bait by children, and so in practice the risk of exposure to bromadiolone is considered to be negligible. The bait also contains a bittering agent

(denatonium benzoate) in order to prevent children and infants chewing and ingesting the bait.

Scenario [6]





Description of Scenario [6]		
Toddler (1-2 years old, 10 kg) chewing and ingesting bait Secondary exposure PPE not relevant		
	Parameters[1]	Value
[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[1] Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.
[2] Only include the parameters changed with respect to the previous Tier.

Calculations for Scenario [6]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [6]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Further information and considerations on scenario [6]

No further information applicable

Scenario [7]

[redacted]

[redacted]

Description of Scenario [7]		
Child (15.6 kg) chewing and ingesting bait Secondary exposure PPE not relevant		
	Parameters[1]	Value
[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[1] Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.
[2] Only include the parameters changed with respect to the previous Tier.

Calculations for Scenario [7]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [7]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Further information and considerations on scenario [7]

No further information applicable

Combined scenarios

The secondary exposure scenarios discussed above cannot be combined thus combined secondary exposure calculations are not relevant.

Monitoring data

No monitoring data are available with Protect rodenticide grain bait.

Dietary exposure

Dietary exposure to Protect rodenticide grain bait is not considered to be relevant thus no calculations have been performed.

List of scenarios

Not considered relevant for Protect rodenticide grain bait.

Information of non-biocidal use of the active substance

Not considered relevant for Protect rodenticide grain bait. No non-biocidal use is intended.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not considered relevant for Protect rodenticide grain bait.

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

Not considered relevant for Protect rodenticide grain bait.

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

Not considered relevant for Protect rodenticide grain bait.

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

The active substance (Tezza) is manufactured in a closed system which is described in the confidential annex of the dossier supporting the approval of the active substance. Full PPE is required (gloves, coverall, face-shield and respirator) during filling and maintenance. No cleaning of the apparatus occurs since only bromadiolone is produced in the system. The only operator contact with the active ingredient is during sampling for quality. No accidents have occurred during the past years of production and operators are subject to medical surveillance.

Exposure during formulation of the product Protect rodenticide grain bait is expected to be minimal due to operating in a closed system. Measurement and mixing of components is automated and controlled by computer. During the production, every worker must wear protective glasses, plastic gloves, mask and overall. Therefore, no hazard identified during manufacturing, and no risk assessment is needed.

Aggregated exposure

Aggregated exposure is not considered relevant for Protect rodenticide grain bait.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1.	Professionals	Tier 1, no PPE	[redacted]
1.	Professionals	Tier 2, with PPE, no RPE	[redacted]
1.	Professionals	Tier 2, with PPE and RPE	[redacted]
2.	Professionals	Tier 1, no PPE	[redacted]
2.	Professionals	Tier 2, with PPE, no RPE	[redacted]
3.	Professionals	Tier 1, no PPE	[redacted]
3.	Professionals	Tier 2, with PPE	[redacted]
4.	Non-professionals	Tier 1, no PPE	[redacted]
5.	Non-professionals	Tier 1, no PPE	[redacted]
6.	Toddlers	Tier 1, no PPE	[redacted]
7.	Children	Tier 1, no PPE	[redacted]

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	Developmental toxicity study, rabbit	LOAEL: 2 µg/kg bw/day	600	oral absorption: 70%	0.0023 µg/kg bw/day
AELmedium-term	90-day rabbit	NOAEL: 0.5 µg/kg bw/day	300	oral absorption: 70%	0.0012 µg/kg bw/day
AELlong-term	90-day rabbit	NOAEL: 0.5 µg/kg bw/day	300	oral absorption: 70%	0.0012 µg/kg bw/day
ARfD	n.a.	n.a.	n.a.	n.a.	n.a.
ADI	n.a.	n.a.	n.a.	n.a.	n.a.

[1] AF 300: 10 for interspecies, 10 for intraspecies variability and an extra factor of 3 for severity of effects
AF 600: 10 for interspecies, 10 for intraspecies variability, 2 for using LOAEL instead of NOAEL and an extra factor of 3 for severity of effects

Maximum residue limits or equivalent

Not considered relevant for Protect rodenticide grain bait

Specific reference value for groundwater

The permissible concentration laid down by Directive 98/83/EC is $1*10^{-4}$ mg/l, which was used in the environmental risk assessment for groundwater.

Risk for industrial users

Industrial use of Protect rodenticide grain bait is not intended.

Risk for professional users

For medium and long-term repeated exposure and risk calculations, an $AEL_{medium\text{-}term}$ and $AEL_{chronic}$ of 0.0012 µg/kg bw/day has been derived for the active substance bromadiolone. This value originates from the subchronic study on rabbits. The NOAEL in this study was 0.5 µg/kg bw/day based on the prolonged prothrombin time seen at 1 µg/kg bw/day. A safety factor of 300 has been set and a correction of 70% for oral absorption used. This value is deemed suitable for the assessment of repeated exposure and risks of professional pest control operators.

Risks for professional users from the different scenarios can be found in the following table.

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL µg/kg bw/d	AEL µg/kg bw/d	Estimated uptake µg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1. Professional Mixing & loading	Tier 1, no PPE	[redacted]	[redacted]	[redacted]	[redacted]	no
Scenario 1. Professional Mixing & loading	Tier 2, with PPE, no RPE	[redacted]	[redacted]	[redacted]	[redacted]	no
Scenario 1. Professional Mixing & loading	Tier 2, with PPE and RPE	[redacted]	[redacted]	[redacted]	[redacted]	yes
Scenario 2. Professional application	Tier 1, no PPE	[redacted]	[redacted]	[redacted]	[redacted]	yes
Scenario 2. Professional application	Tier 2, with PPE	[redacted]	[redacted]	[redacted]	[redacted]	yes
Scenario 3., Professional cleaning	Tier 1, no PPE	[redacted]	[redacted]	[redacted]	[redacted]	yes
Scenario 3., Professional cleaning	Tier 2, with PPE	[redacted]	[redacted]	[redacted]	[redacted]	yes

Combination of scenarios 1, 2 and 3 is considered relevant as mixing & loading (decanting), application and clean-up are usually performed by the same person. Combined risk is as follows.

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL µg/kg bw/d	AEL µg/kg bw/d	Estimated uptake µg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1+2+3, mixing&loading + application + cleaning	Tier 1, no PPE	[redacted]	[redacted]	[redacted]	[redacted]	no
Scenario 1+2+3, mixing&loading + application + cleaning	Tier 2, with PPE, no RPE	[redacted]	[redacted]	[redacted]	[redacted]	no
Scenario 1+2+3, mixing&loading + application + cleaning	Tier 2, with PPE and RPE	[redacted]	[redacted]	[redacted]	[redacted]	yes

Local effects

The product Protect rodenticide grain bait does not have any local effects. A risk assessment for local effects is not considered relevant.

Conclusion

Exposure and risk for professional operators applying Protect rodenticide grain bait on a daily basis, wearing protective equipment, is acceptable.

Protective gloves are required for all use phases of the product (mixing&loading, application and cleanup). Based on the calculations, respiratory protective equipment also has to be used, but only during the decanting of the loose bulk grain product. Inhalation exposure is negligible during other use phases. Even during decanting, the exposure and risk from inhalation is expected to be much lower than the calculated amount based on the HEEG model as the product does not produce any dust and the active substance or other co-formulants are not volatile. The presented calculations represent a worst case scenario of use.

RPE is not necessary during the use of ready-to-use products, where no mixing&loading (decanting) phase occurs. In these cases, inhalation exposure is negligible.

In the worst case scenarios when no gloves are used, the AEL% values are [redacted] or mixing&loading, application and clean-up, respectively, with a combined value of [redacted]. The risk form this estimation is too high, therefore Tier 2 assessment with PPE was also performed. Professional users are trained operators who are expected to wear protective gloves when handling he product.

In Tier 2, assessments with PPE but without RPE, and assessments with PPE and RPE for decanting have been performed. With PPE but without RPE, the AEL% for mixing&loading, application and cleaning is [redacted] respectively, with a combined value of [redacted]

If RPE is used during decanting (inhalation is negligible during other use phases), the AEL% for mixing&loading is reduced to [redacted] With the use of PPE, the AEL% during application and cleaning remains [redacted] respectively. A combined risk when PPE is used for all phases and RPE is also used for decanting, is [redacted]. These results are within the acceptable levels.

The calculations presented above show that the risk for professional users when using Protect rodenticide grain bait is acceptable, if appropriate protective equipment is worn.

Risk for non-professional users

For the calculation of risks to non-professional users, the AEL_{acute} of bromadiolone was used. The AEL_{acute} is derived from a developmental toxicity study on rabbit. No NOAEL could be determined in this study, the LOAEL was found to be 2 µg/kg bw/day. A safety factor of 600 has been set (10 for interspecies, 10 for intraspecies variability, 2 for using LOAEL instead of NOAEL and an extra factor of 3 for severity of effects) and a correction of 70% for oral absorption implemented. The resulting AEL_{acute} value is 0.0023 µg/kg bw/day.

Risks for non-professional users from the different scenarios can be found in the following table.

Systemic effects

Task/ Scenario	Tier	Systemic LOAEL µg/kg bw/d	AEL µg/kg bw/d	Estimated uptake µg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 4. Non-professional application	Tier 1, no PPE	[redacted]	[redacted]	[redacted]	[redacted]	yes
Scenario 5. Non-professional cleaning	Tier 1, no PPE	[redacted]	[redacted]	[redacted]	[redacted]	yes

Combined scenarios

Scenarios combined	Tier	Systemic LOAEL µg/kg bw/d	AEL µg/kg bw/d	Estimated uptake µg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 4+5, application + cleaning	Tier 1, no PPE	[redacted]	[redacted]	[redacted]	[redacted]	yes

Local effects

The product Protect rodenticide grain bait does not have any local effects. A risk assessment for local effects is not considered relevant.

Conclusion

The considered worst case scenario for non-professional users largely overestimates the expected exposure as the model with handling of loose bulk bait was used due to the absence of any available non-professional application models. However, this approach provides a risk envelope, and as it was shown that the risk is acceptable even for this worst case use, it can be concluded that the risk arising from actual use is also acceptable.

In this considered worst case scenario, the estimated AEL% is [redacted] for the application and [redacted] for the clean-up of Protect rodenticide grain bait. A combined scenario is considered relevant, as most likely it will be the same person performing both tasks. The combined scenario resulted in an AEL% of [redacted]%.

Consequently, it can be concluded based on the presented calculations, that the risk for non-professional users is acceptable in all assessed scenarios.

Risk for the general public

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 6, toddler ingesting bait	Tier 1, no PPE	[redacted]	[redacted]	[redacted]	[redacted]	no
Scenario 7, child ingesting bait	Tier 1, no PPE	[redacted]	[redacted]	[redacted]	[redacted]	no

Combined scenarios

Combined exposure and risk is not considered relevant for the presented secondary exposure scenarios of Protect rodenticide grain bait.

Local effects

The product Protect rodenticide grain bait does not have any local effects. A risk assessment for local effects is not considered relevant.

Conclusion

Risk calculations for secondary exposure of children, based on default TNsG data, do not result in acceptable values. However, considering the formulation type and use of Protect rodenticide grain bait, it can be concluded that the available scenarios do not represent realistic events. The grain bait is contained within bait stations where the product will not be accessible to children. The product also contains a bittering agent, denatonium benzoate, which prevents ingestion of the bait. Product labels and good practice also advise users to prevent access to bait by children. It is also important to dispose of unused product and dead rodents.

As a conclusion, with the implementation of the above-mentioned risk mitigation measures, the use of Protect rodenticide grain bait is not expected to pose unacceptable risks to the general public, including toddlers and children.

Risk for consumers via residues in food

Exposure to Protect rodenticide grain bait via residues in food is not considered to be relevant.

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

Protect rodenticide grain bait only contains one active substance, bromadiolone. No other substances of concern are present in the product. Consequently, combined exposure of several active substances or substances of concern is not considered relevant.

2.2.7 Risk assessment for animal health

The product is to be placed into bait boxes where exposure of non-target animals can be prevented. Product labels also indicate that the product may be applied only at places where children and domestic animals have no access to the placed bait. Protect rodenticide grain bait also contains denatonium benzoate - an extremely bitter substance - which helps preventing incidental consumption by humans and domestic animals. These measures ensure that risk for non-target animals will be appropriately controlled.

For further considerations on non-target animals see the following section on the risk assessment for the environment.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The only ecotoxicologically relevant component in the product is the active substance, bromadiolone. Other constituents – mostly food-grade materials – are either not classified or present in such low quantities that they are not considered to influence the ecotoxicological properties of the product. The effects of Protect rodenticide grain bait can be assessed based on the data on the active substance.

The formulation of bromadiolone in Protect rodenticide grain bait has no impact on the route or rate of degradation of the active substance bromadiolone in the environment. No additional studies involving the formulated product are considered necessary.

The environmental fate and behaviour of the active substance bromadiolone has been fully evaluated during the assessment for inclusion/approval.

Bromadiolone is not readily biodegradable. No hydrolysis was found at the investigated pH 7 and 9, so hydrolysis of bromadiolone is not expected to be a significant process in the environment.

In the soil degradation study (OECD 307) bromadiolone was tested in 4 different soil types. Degradation was detected during the test; DT_{50} was between 5.8 and 23.6 days, DT_{90} was between 76 and 183 days at 20°C. The main degradation product is the bromadiolone ketone.

Bromadiolone is strongly adsorbed to soil and Koc values range between 3530 and 41600 ml/g (mean value: 14770 ml/g), which corresponds to 'slightly mobile' to 'non-mobile'. Bromadiolone is unlikely to reach groundwater in significant amount due to its immobility in soil.

The rapid photolysis rate in air (t½ ca.2 hours), the low vapour pressure of bromadiolone and the low Henry's law constant together show that bromadiolone is not expected to volatilise to or persist in air in significant quantities.

The BCF of bromadiolone was derived by calculation from log Kow, resulting in BCF values of 339. It can be concluded that bromadiolone has a potential to bioaccumulate.

Based on the results of toxicity studies, bromadiolone is toxic to fish. In the test performed under static conditions, the 96-hour LC_{50} was 2.86 for *Oncorhynchus mykiss*.

D. magna was the least sensitive, with a 48-hour EC_{50} of 5.79 mg/l.

Algae represented the most sensitive of the three aquatic trophic levels tested, the 72-hour E_rC_{50} of *Pseudokirchneriella subcapitata* was 1.14 mg/l.

Effects of bromadiolone were not found on earthworms at 1331 mg/kg dw, which is equal to a NOEC of 918 mg/kg ww calculated for wet soil.

In the acute toxicity study to birds, Japanese quail were exposed to bromadiolone once and then observed for 14 days. This study was conducted to determine the lethal dose, but it

also made it possible to determine effect concentrations at which birds did cower, which was found to be a dose dependent effect. The LD50 was, on average for both sexes, 134 mg/kg bw. The acute dietary toxicity test with partridge resulted in a LC_{50} of 28.9 mg/kg food.

In the reproduction test bromadiolone was supplied via drinking water. It was difficult to determine any clear effects on reproduction in this study, but it showed effects on liver weight, spleen weight and testes weight. Effects on 14-day survival of the hatchlings were also found and there were indications of decreased body weight gain of the adult birds. The NOEC was determined to be 39 µg/kg bw/day or 0.26 mg/l drinking water (measured concentration).

Three studies are available on secondary poisoning of birds by anticoagulant rodenticides. From the studies it can be concluded that the investigated rodenticides posed a high risk of secondary poisoning to owls and that consumption of 3 mice that were poisoned with the related substance brodifacoum caused lethality to barn owls. Lethal liver concentrations were found between 0.63 and 1.7 mg brodifacoum/kg fw. This correlates well with a field report where liver concentrations of dead hawks after a field trial were investigated and found to be on average 0.23 mg brodifacoum/kg fw.

According to the bromadiolone assessment report, the active substance is considered a PBT substance.

Bromadiolone toxicity data for aquatic species (most sensitive species of each group) are the following:

Species	Time-scale	Endpoint	Toxicity
Fish			
Oncorhynchus mykiss	96 hours	mortality	LC50 = 2.86 mg/L (nominal)
Invertebrates			
Daphnia magna	48 hours	lethality immobilisation	EC50 = 5.79 mg/L (nominal)
Algae			
Pseudokirchneriella subcapitata	72 hours	growth inhibition (gr)	ErC50 = 1.14 mg/L (geometric mean of the initial measured conc. and half the LOQ)
Microorganisms			
Activated sludge	3 hours	respiration inhibition	EC50 = 132.8 mg/L (extrapolated)

The following PNEC values have been identified for bromadiolone in the Assessment Report:

Compartment	Organism/test	Results	Assessment factor	PNEC
Freshwater	Alga/ growth inhibition	E_rC_{50} = 1.14 mg/L	1000x3	3.8 10^{-4} mg/L
STP microorganisms	Sewage sludge/ respiration inhibition	EC_{50} = 132.8 mg/L	100	1.33 mg/L
Sediment	Calculated/ EPM	-	-	0.83 mg/kg ww
Soil	Calculated/ EPM	-	-	0.099 mg/kg

The following long-term PNECs were identified for birds and mammals:

	Species/test	Results	AF	PNEC (concentration in food)	PNEC (dose)
Birds	Japanese quail (*Coturnix coturnix japonica*) reproduction test	NOEC: 0.039 mg/kg bw/day 0.26 mg/l drinking water	30	0.0087 mg/l	0.0013 mg/kg bw/day
Mammals	Rabbit 90-day	NOAEL: 5*10^{-4} mg/kg bw/day	90	0.00019 mg/kg	0.0000056 mg/kg bw/day

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

The product Protect rodenticide grain bait contains substances that are mostly food-grade materials. The active substance bromadiolone, present in 0.0027% w/w, is the most toxic constituent of the product. There are no substances of concern present in the product. [redacted] Consequently, there are no ecotoxicologically relevant components in the product apart from the active substance. The product is not classified for environmental endpoints.

Further Ecotoxicological studies

No further data are available other than the studies presented in the dossier of bromadiolone. The ecotoxicity of the product can be assessed on the basis of the active substance as no other ecotoxicologically relevant components are present in Protect rodenticide grain bait.

Data waiving	
Information requirement	Further ecotoxicological studies performed with the product
Justification	There are no co-formulants in the product that are ecotoxicologically relevant. Co-formulants are mostly food-grade materials that are not classified or are present in such low concentration [redacted] that they do not influence the ecotoxicity of the product and are not relevant for this endpoint. The ecotoxic properties of the product can be fully extrapolated based on active substance data. No further ecotoxicological studies with Protect rodenticide grain bait are necessary.

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

No further data are available other than the studies presented in the dossier of bromadiolone. The ecotoxicity of the product can be assessed on the basis of the active substance as no other ecotoxicologically relevant components are present in Protect rodenticide grain bait.

Data waiving	
Information requirement	Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk
Justification	There are no co-formulants in the product that are ecotoxicologically relevant. Co-formulants are mostly food-grade materials that are not classified or are present in such low concentration [redacted] that they do not influence the ecotoxicity of the product and are not relevant for this endpoint. The ecotoxic properties of the product can be fully extrapolated based on active substance data. No further ecotoxicological studies with Protect rodenticide grain bait are necessary.

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

No further trials have been conducted with Protect rodenticide grain bait. The ecotoxicity of the product can be assessed on the basis of the studies available for the active substance as no other ecotoxicologically relevant components are present in the product.

Data waiving	
Information requirement	Supervised trials to assess risks to non-target organisms under field conditions
Justification	There are no co-formulants in the product that are ecotoxicologically relevant. Co-formulants are mostly food-grade

	materials that are not classified or are present in such low concentration [redacted] that they do not influence the ecotoxicity of the product and are not relevant for this endpoint. The ecotoxic properties of the product can be fully extrapolated based on active substance data. No further ecotoxicological studies with Protect rodenticide grain bait are necessary.

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

No further studies on acceptance by ingestion of the biocidal product by any non-target organisms have been conducted with Protect rodenticide grain bait. The ecotoxicity of the product can be assessed on the basis of the studies available for the active substance as no other ecotoxicologically relevant components are present in the product.

Data waiving	
Information requirement	Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk
Justification	There are no co-formulants in the product that are ecotoxicologically relevant. Co-formulants are mostly food-grade materials that are not classified or are present in such low concentration ([redacted]) that they do not influence the ecotoxicity of the product and are not relevant for this endpoint. The ecotoxic properties of the product can be fully extrapolated based on active substance data. No further ecotoxicological studies with Protect rodenticide grain bait are necessary.

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

Treatment of a large proportion of a specific habitat type is not foreseen. Further studies on secondary ecological effects is not relevant for the product.

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

Protect rodenticide grain bait is to be placed into bait stations inaccessible to children and non-target organisms. The product contains 27 mg/kg bromadiolone. The product is intended to be used in and around buildings by trained professional, professional and non-professional users.

For the intended area of use of this product, the *Emission scenario document for biocides used as rodenticides* (Larsen, 2003, EUBEES2, "ESD") states that only local exposure is

expected. The area of use and the manufacturing process of the active substance and formulation processes of the biocidal product will not cause any regional pollution due to the physical characteristics of the product. Regional background concentrations can be regarded as negligible according to the ESD due to the very local emissions of the substance, the physical characteristics of the substance and the low overall usage of the product.

Environmental exposure during manufacturing of the active substance and formulation of the product Protect rodenticide grain bait can be excluded due to operating in a closed system. There will be no releases into the environment.

During use in and around buildings, the main exposure of the environment is expected to be soil, contaminated by spills during application, refilling and disposal operations. However, the contributions from disperse release of rodenticide via urine and faeces is also relevant. Emission to groundwater is also calculated. Primary and secondary exposure of non-target animals cannot be completely excluded for this scenario.

The concentration of bromadiolone present in the product is very low (0.0027% w/w), the vapour pressure is very low (2.13 x 10^{-8} Pa, 20°C), the Henry's law constant is very low (4.25 x 10^{-4} $Pa.m^3.mol^{-1}$) and bromadiolone is rapidly degraded in air (DT_{50} ~2 hours). Emission into air is therefore considered to be negligible.

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

No further studies on the fate and behaviour in the environment have been conducted with Protect rodenticide grain bait. The ecotoxicity of the product can be assessed on the basis of the studies available for the active substance as no other ecotoxicologically relevant components are present in the product.

Data waiving	
Information requirement	Further studies on fate and behaviour in the environment (ADS)
Justification	There are no co-formulants in the product that are ecotoxicologically relevant. Co-formulants are mostly food-grade materials that are not classified or are present in such low concentration [redacted] that they do not influence the ecotoxicity of the product and are not relevant for this endpoint. The ecotoxic properties of the product can be fully extrapolated based on active substance data. No further ecotoxicological studies with Protect rodenticide grain bait are necessary.

Leaching behaviour (ADS)

Bromadiolone is strongly adsorbed to soil and Koc values range between 3530 and 41600 ml/g (mean value: 14770 ml/g), which corresponds to 'slightly mobile' to 'non-mobile'. Bromadiolone is unlikely move through the soil and reach groundwater in significant amount due to its immobility in soil. Further leaching tests are not considered relevant for the product.

Testing for distribution and dissipation in soil (ADS)

No further tests for distribution and dissipation in soil have been conducted with Protect rodenticide grain bait. The ecotoxicity of the product can be assessed on the basis of the studies available for the active substance as no other ecotoxicologically relevant components are present in the product.

Data waiving	
Information requirement	Testing for distribution and dissipation in soil (ADS)
Justification	There are no co-formulants in the product that are ecotoxicologically relevant. Co-formulants are mostly food-grade materials that are not classified or are present in such low concentration [redacted] that they do not influence the ecotoxicity of the product and are not relevant for this endpoint. The ecotoxic properties of the product can be fully extrapolated based on active substance data. No further ecotoxicological studies with Protect rodenticide grain bait are necessary.

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

No further tests for distribution and dissipation in water and sediment have been conducted with Protect rodenticide grain bait. The ecotoxicity of the product can be assessed on the basis of the studies available for the active substance as no other ecotoxicologically relevant components are present in the product.

Data waiving	
Information requirement	Testing for distribution and dissipation in water and sediment (ADS)
Justification	There are no co-formulants in the product that are ecotoxicologically relevant. Co-formulants are mostly food-grade materials that are not classified or are present in such low concentration [redacted] that they do not influence the ecotoxicity of the product and are not relevant for this endpoint. The ecotoxic properties of the product can be fully extrapolated based on active substance data. No further ecotoxicological studies with Protect rodenticide grain bait are necessary.

Testing for distribution and dissipation in air (ADS)

No tests for distribution and dissipation in water and sediment have been conducted with Protect rodenticide grain bait. See justification below.

Data waiving	
Information requirement	Testing for distribution and dissipation in air (ADS)
Justification	The concentration of bromadiolone present in the product is very low (0.0027% w/w), the vapour pressure is very low (2.13 x 10^{-8} Pa, 20°C), the Henry's law constant is very low (4.25 x 10^{-4} Pa.m^3.mol^{-1}) and bromadiolone is rapidly degraded in air (DT_{50} ~2 hours). Emission into air is therefore considered to be negligible. No other ecotoxicologically relevant components are present in the product. Testing for distribution and dissipation in air is therefore not considered relevant.

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)

Data waiving	
Information requirement	Overspray study to assess risks to aquatic organisms or plants under field conditions
Justification	The product is a solid grain bait and is not intended to be sprayed. The study is not relevant.

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

The product is a solid grain bait formulation and is not intended to be sprayed outside. No dust formation will occur during use or disposal of the product. Data on overspray behaviour is not considered relevant for Protect rodenticide grain bait. The product is an anticoagulant rodenticide which will not present any risks to bees and other arthropods.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 14
Assessed scenarios	Scenario 1: Use of Protect rodenticide grain bait in and around buildings
ESD(s) used	Emission scenario document for biocides used as rodenticides (EUBEES 2, Larsen 2003), Technical Guidance Document on Risk Assessment, Part II, ECHA Guidance on the Biocidal Products Regulation Volume IV Environment – Part B Risk Assessment
Approach	Scenario 1: Realistic worst case consumption
Distribution in the environment	Calculated based on above-mentioned ESD-s
Groundwater simulation	Not performed. Concentration in groundwater was calculated according to the ECHA Guidance on the Biocidal Products Regulation Volume IV Environment – Part B Risk Assessment.
Confidential Annexes	No
Life cycle steps assessed	Production: No (a.s. is manufactured in a closed system which is described in the confidential annex of the a.s. dossier). Formulation: No (product is manufactured in a closed system, which is automated and controlled by computer). Use: Yes Service life: Yes
Remarks	none

Emission estimation

Scenario [1] - Use of Protect rodenticide grain bait in and around buildings

Protect rodenticide grain bait contains 0.0027% w/w bromadiolone, for the use by professional and non-professional users against brown rat (*Rattus norvegicus*).

The maximum amount of product used per application is 250 g bait against rats (professional users). For non-professional users, the maximum applied dose is 150 g for rats.

The only ecotoxicologically relevant component in the product is bromadiolone (see above). The environmental exposure calculations are therefore based on the active substance. The approach is same as the one used in the bromadiolone dossier.

For the calculations, the following guidance was used: Emission scenario document for biocides used as rodenticides (EUBEES 2, Larsen 2003), Technical Guidance Document on Risk Assessment, Part II and ECHA Guidance on the Biocidal Products Regulation Volume IV Environment – Part B Risk Assessment. The calculations are based, similarly to the bromadiolone dossier, on a worst case approach. This approach is expected to overestimate the exposure, however it provides an "envelope" showing that even worst case exposures would remain within acceptable limits.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: **Use of Protect rodenticide grain bait in and around buildings**			
Application rate of biocidal product	maximum 250	g	per baiting point professional use against rats
	maximum 150	g	per baiting point non-professional use against rats
Concentration of active substance in the product	27	mg/kg	

For the calculations, the worst case parameters were chosen on the basis of the ESD and the TGD/ECHA guidance. **See details in Annex 3.2.**

Calculations for Scenario [1]

Calculations are included in **Annex 3.2**. See the Annex for the relevant details.

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	n.a.	n.a.	no	no	yes	yes	n.a.

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	527.4	g/mol	
Melting point	172.4-201.7	°C	(98.8%)
	198.3-199.8	°C	(~100%)
Boiling point	Decomposition before boiling		

Vapour pressure (at 25°C)	$2.13x10^{-8}$	Pa	
Water solubility (at 25°C)	12.5	mg/l	
Log Octanol/water partition coefficient	4.3	Log 10	
Organic carbon/water partition coefficient (Koc)	14770	ml/g	
Henry's Law Constant (at 20°C)	$4.25x10^{-4}$	Pa m^3/mol	
Biodegradability	not readily biodegradable		
Rate constant for STP *[if measured data available]*	not available		
DT_{50} for biodegradation in surface water	not readily biodegradable		
DT_{50} for hydrolysis in surface water	no hydrolysis		
DT_{50} for photolysis in surface water	between 2.98 and 30.4	minutes	
DT_{50} for degradation in soil	between 5.8 and 23.6	d (at 20ºC)	
DT_{50} for degradation in air	not relevant		

Calculated fate and distribution in the STP *[if STP is a relevant compartment]*		
Compartment	Percentage [%]	Remarks
	Scenario 1	
Air	n.a.	
Water	n.a.	
Sludge	n.a.	
Degraded in STP	n.a.	

Emission into the STP is considered negligible in the 'in and around buildings' scenario.

Calculated PEC values

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}[1]**	**PEC_{air}**

	[ng/l]	[ng/l]	[mg/kg$_{wwt}$]	[mg/l]	[mg/kg$_{wwt}$]	[mg/kg]	[mg/l]	[mg/m^3]
Scenario 1	n.a.	n.a.	n.a.	n.a.	n.a.	[redacted]	[redacted]	n.a.

[1] If the PEC$_{GW}$ was calculated by using a simulation tool (e.g. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table.

Primary and secondary poisoning

The risk of bromadiolone to non-target birds and mammals has been assessed according to the ESD and the TGD II /ECHA guide. Assessment of secondary poisoning through the aquatic food chain is not performed, the risk assessment indicates that there will be very low concentrations of bromadiolone in the aquatic compartment, and there was no risk identified of bromadiolone for surface water or sediment dwelling organisms. The justification for not performing an assessment of secondary poisoning via the terrestrial food chain is that secondary poisoning will be limited due to the small area that potentially is contaminated by bromadiolone around buildings and the limited number of earthworms inhabiting this area.

Primary poisoning

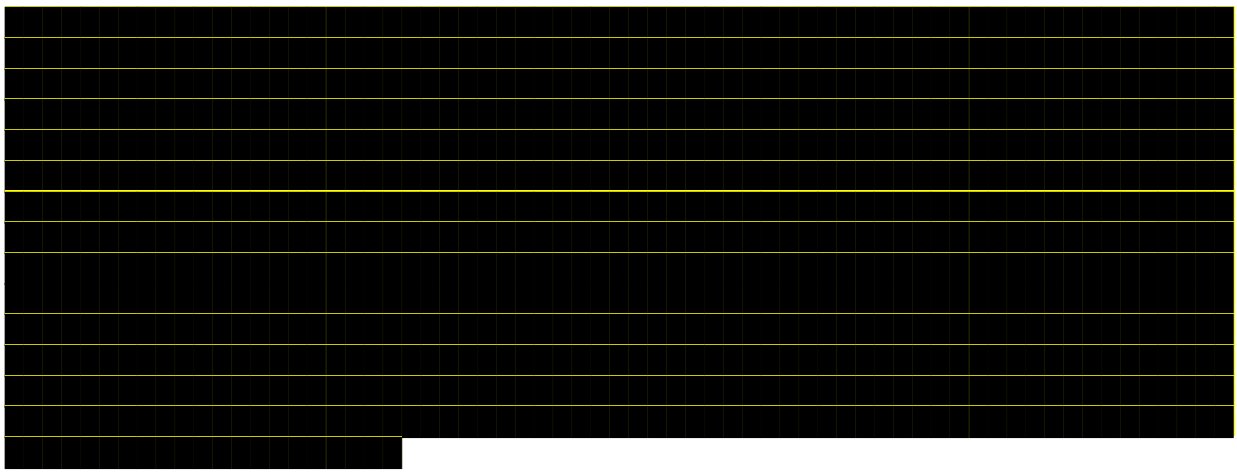
Non-target animals, such as wild and domestic animals may come in contact with baits if the bait is incompletely protected or if bait stations have been damaged. Also, well protected bait may be encountered by animals which are small enough to be able to reach the bait, and therefore may be subject to primary poisoning.

[redacted]

PEC values for Tier 1 assessment, long-term exposure

	Species/test	*PEC (concentration in food, mg/kg)*
Birds	Japanese quail (Coturnix coturnix japonica) reproduction test	[redacted]
Mammals	Rabbit 90-day	[redacted]

[redacted]



ETE = (FIR/BW) * C * AV * PT * PD (mg/kg bw/day) (ESD - Eq. 19)

Primary poisoning, Tier2

Non-target animal	Typical bodyweight (g)	Daily mean food intake (g bw/day)	Concentration of bromadiolone in bait (mg/kg)	ETE (mg/kg bw)	
				Step 1	Step 2
Dog					
Pig					
Pig, young					
Tree sparrow					
Chaffinch					
Wood pigeon					
Pheasant					

a According to table 3.1 in the ESD
b Calculated from log FIR=0.822 log BW-0.629 according to equation on page 50 ESD

The long-term risks of bromadiolone are determined by the expected concentrations (EC) in the animal after metabolism and elimination, which is regarded as PEC. The EC is calculated by using the actual dose of the substance consumed by a non-target animal each day (ETE) using the realistic worst case scenario (step 2). When calculating the long-term risks, elimination and metabolism of the substance (El) have to be considered. According to the ESD, a default value of 0.3 for El can be used if no studies are submitted that show different.

Calculations are performed according to equation 20 in the ESD.

EC = ETE * (1-El) (Eq. 20)

Non-target animal	PEC = EC, concentration of bromadiolone after one day of elimination (mg/kg)

Dog	[redacted]
Pig	[redacted]
Pig, young	[redacted]
Tree sparrow	[redacted]
Chaffinch	[redacted]
Wood pigeon	[redacted]
Pheasant	[redacted]

Secondary poisoning

Secondary poisoning of bromadiolone occurs when poisoned rodents are caught by predators and eaten by scavengers that hunt and forage around bromadiolone treated areas. It has been reported by Shore et al. (1999) that there is an increased hazard of exposure for predators during the winter months which might be caused by that there is less prey available in the winter season. It should also be considered that behaviour of poisoned rodents might change as presented in two reports referred to in the ESD. According to these reports more than half of the rats that died by rodenticide poisoning died away from cover. Moreover, it seemed as the rats changed their behaviour when still alive and were more active during the days than rats normally are and also spent more time unprotected above ground. Such behaviour can make them easy prey to predators and they are also more easily found by scavengers. It was found, when water voles were studied during a campaign that 38 % of them died above ground (Saucy et al, 2001, in ESD).

[redacted]

ETE = (FIR/BW) * C * AV * PT * PD (mg/kg bw/day) (ESD - Eq. 19)

This equation gives the concentration of bromadiolone in the rat (PEC_{oral}) after a meal the first day. Considering the elimination rate and that the mean time to death is seven days the concentration in the rodents each day can be calculated by:

$$ECn = \sum_{n=1}^{n-1} \mathrm{ETE} * (1 - \mathrm{EL})^{n}$$

(ESD - Eq 21)

Residues in target animals at specific point in times and varying bait consumptions

Residues in target animal (mg/kg bw), with bait consumption in % of daily consumption (PD)			
	20 %	**50%**	**100 %**
Day 1 after the first meal	[redacted]	[redacted]	[redacted]
Day 2 before new meal	[redacted]	[redacted]	[redacted]
Day 5 after the last meal	[redacted]	[redacted]	[redacted]
Day 7 mean time to death	[redacted]	[redacted]	[redacted]

The concentrations of bromadiolone in rats are at peak after consuming bait for 5 days; thereafter the concentrations in rodents are decreasing until day 7 due to excretion and metabolism of the rodenticide. The values from day 5 are used as PEC_{oral}.

[redacted]

Species	**Body weight (g)**	**Daily mean food intake (g/day)**	**Amount a.i. consumed by non-target animal (mg)**	**Conc. in non-target animal (=PEC) (mg/kg)**	**Amount a.i. consumed by non-target animal (mg)**	**Conc. in non-target animal (mg/kg)**
Barn owl *(Tyto alba)*	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Kestrel *(Falco tinnunculus)*	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Little owl *(Athene noctua)*	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Tawny owl *(Strix aluco)*	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Fox *(Vulpes vulpes)*	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Polecat *(Mustela putorius)*	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Stoat *(Mustela erminea)*	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Weasel *(Mustela nivalis)*	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: Since bromadiolone will be used only locally and since it has a low vapour pressure, 1 10^{-7} Pa, and low Henry's law constant, the concentration of bromadiolone in the atmosphere will be negligible. Therefore, no risk assessment is performed for the atmosphere.

Sewage treatment plant (STP)

Scenario 1 (use in and around buildings): exposure and therefore risk is negligible.

Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{STP}$
Scenario 1	negligible

Conclusion: It can be concluded that the risk for STP microorganisms caused by bromadiolone used for control of rodents in and around buildings is negligible.

Aquatic compartment

Scenario 1 (use in and around buildings):
Contamination of surface waters or sediments with bromadiolone used in and around buildings is considered negligible. Consequently, no risk will arise from this use.

Summary table on calculated PEC/PNEC values				
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
Scenario 1	negligible	negligible	n.a.	n.a.

Conclusion:

No exposure or risk will arise from the use in and around buildings for this compartment.

Terrestrial compartment

Scenario 1 (use in and around buildings):

Bromadiolone contamination of soil around buildings will occur both from direct contamination when bait is deployed outdoors and from indirect contamination via dead

bodies, urine and faeces from the target organisms. PEC_{soil}, which is the sum of the direct and indirect contamination, was determined to be [redacted]

$PEC/PNEC_{soil}$ = [redacted]

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Scenario 1	[redacted]

Conclusion:
*T*he risk for soil organisms when bromadiolone is used around buildings is acceptable

Groundwater

Scenario 1 (use in and around buildings):

$PEC_{groundwater}$ was assumed to be equal to $PEC_{local\ porewater}$, i.e. dilution is not taken into account, and was calculated to be [redacted]

The maximum permissible concentration according to directive 98/83/EC is $1*10^{-4}$ mg/l, which is exceeded by the predicted concentration.

The comparison above indicates a slight risk of groundwater contamination in this scenario. However, the 'in and around buildings' scenario is a true worst case scenario, which describes the situation in very localised spots of soil, and no consideration is given to dilution when bromadiolone migrates through soil layers. Furthermore, risk mitigation measures are likely to substantially reduce bromadiolone contamination to soil relative to the worst case exposure scenario.

Primary and secondary poisoning

Primary poisoning

In the Tier 1 assessment of primary poisoning the calculated PEC values are compared to the long-term PNEC values for birds and mammals. The resulting PEC/PNEC ratios reveal a high risk for both birds and mammals of long-term primary poisoning.

PEC/PNEC ratios for Tier 1 assessment, long-term exposure

	Species/test	Results	AF	PEC (concentration in food, mg/kg)	PNEC (concentration in food)	PEC/PNEC
Birds	Japanese quail (Coturnix coturnix japonica) reproduction test	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Mammals	Rabbit 90-day	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

In the Tier 2 assessment the ETE values calculated for acute exposure for the worst case (step 1) and realistic worst case (step 2) are compared qualitatively to the LD50 values in the table.

Non-target animal	PECoral = ETE, concentration of bromadiolone after one meal (mg/kg)		LD50 (mg/kg bw/d)	PECoral higher than LD50 (y/n)	
	Step 1	Step 2		Step 1	Step 2
Dog	[redacted]	[redacted]	[redacted]	n	n
Pig	[redacted]	[redacted]	[redacted]	n	n
Pig, young	[redacted]	[redacted]	[redacted]	n	n
Tree sparrow	[redacted]	[redacted]	[redacted]	n	n
Chaffinch	[redacted]	[redacted]	[redacted]	n	n
Wood pigeon	[redacted]	[redacted]	[redacted]	n	n
Pheasant	[redacted]	[redacted]	[redacted]	n	n

The long-term PNEC values used for mammals and birds are those from rabbit and Japanese quail and they are presented in the table below.

Non-target animal	PEC = EC, concentration of bromadiolone after one day of elimination (mg/kg)	PNEC dose (mg/kg bw/day)	PEC/PNEC
Dog	[redacted]	[redacted]	[redacted]
Pig	[redacted]	[redacted]	[redacted]
Pig, young	[redacted]	[redacted]	[redacted]
Tree sparrow	[redacted]	[redacted]	[redacted]
Chaffinch	[redacted]	[redacted]	[redacted]
Wood pigeon	[redacted]	[redacted]	[redacted]
Pheasant	[redacted]	[redacted]	[redacted]

The result of the PEC/PNEC calculations shows that there are very high risks for long-term primary poisoning of both mammals and birds. The calculations are based on that bait is consumed only during one day and then eliminated from the animal, but it should also be considered that an animal might consume bait again before the first dose is eliminated. On the other hand, it should be taken into consideration that the actual doses are strictly worst case and that consumption of these quantities of bromadiolone bait by the non-target animals exemplified above are generally not realistic.

Secondary poisoning

[redacted]

[redacted]

Calculated PECs and recalculated LC50 values for mammals and birds

	PEC Expected concentration in rodent (mg/kg) caught on day 5 after meal			LC50 (mg/kg food)
	[redacted]	[redacted]	[redacted]	
Mammals				
Birds				

This qualitative assessment indicates no risk for secondary poisoning of birds or mammals.

To assess the risk of long-term secondary poisoning to birds and mammals, the PEC in rodents after 5 days is used and compared to the long-term $PNEC_{oral}$ for birds and mammals. For birds, the PNEC value from the reproduction test is used, and for mammals the PNEC value calculated from the 90-day test with rabbits.

	PNECoral (conc. in food)	PECoral Bromadiolone conc. in target rodent (mg/kg bw), ESD default values	PEC/PNEC
Birds	[redacted]	[redacted]	[redacted]
Mammals	[redacted]	[redacted]	[redacted]

The PEC/PNEC ratios indicate very high risks for long-term secondary poisoning of birds and mammals by consumption of rodenticide poisoned rodents.

For the Tier 2 assessment, the results of the PEC/PNEC calculations are presented in the table below. For birds the PNEC (dose) from the reproduction test is used, and for mammals the PNEC (dose) calculated from the 90-day rabbit test.

Expected concentrations (PEC) in non-target animals after a single day of exposure and resulting PEC/PNEC ratios. PNEC values expressed as dose (mg/kg bw/day) are used in the calculations

Species	PEC day 5 (conc. in food, mg/kg bw)	PNEC (dose, mg/kg bw/day)	PEC/ PNEC (day 5)	PEC day 14 (conc. in food, mg/kg bw)	PNEC (dose, mg/kg bw/day)	PEC/ PNEC (day 14)
Barn owl *(Tyto alba)*	[redacted]					
Kestrel *(Falco tinnunculus)*						
Little owl *(Athene noctua)*						
Tawny owl						

(Strix aluco)						
Fox *(Vulpes vulpes)*	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Polecat *(Mustela putorius)*	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Stoat *(Mustela erminea)*	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Weasel *(Mustela nivalis)*	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

The worst case calculations according to the ESD show high risks for secondary poisoning of bromadiolone to both birds and mammals.

Conclusion:

According to the calculations in accordance with the ESD and TGD II/ECHA guidance, the evaluated product with bromadiolone will cause unacceptable risks both for acute and long-term exposure and both for primary and secondary poisoning. The very high risk quotients indicate that birds and mammals that have rodents as prey or feed on carcasses of rodents are significantly threatened by the use of bromadiolone. These identified risks must be mitigated by applying all appropriate and available risk mitigation measures.

Mixture toxicity

Mixture toxicity is not relevant in case of Protect rodenticide grain bait. There are no substances of concern present in the product, the majority of the components are food-grade materials. None of the co-formulants are ecotoxicologically relevant; [redacted] at which level they do not pose any concern to the environment.

Screening step

Screening Step 1: Identification of the concerned environmental compartments

The environmental compartments that are likely to be exposed are the terrestrial compartment and groundwater.

Screening Step 2: Identification of relevant substances
No ecotoxicologically relevant co-formulants are present in the product, only the active substance.

Screening Step 3: Screen on synergistic interactions

Synergistic interactions are not expected to occur in Protect rodenticide grain bait.

Screening step	
	Significant exposure of environmental compartments? No
	Number of relevant substances >1? No

	Indication for synergistic effects for the product or its constituents in the literature? No

Conclusion: mixture toxicity is not relevant for Protect rodenticide grain bait.

Aggregated exposure (combined for relevant emission sources)

Based on the available information and the following decision scheme it can be stated that aggregated exposure is not relevant for bromadiolone and consequently for Protect rodenticide grain bait.

Decision steps:
Other regulatory areas: No
Different user categories: Yes
Overlap in time and space: No
Conclusion: No aggregated exposure estimation required

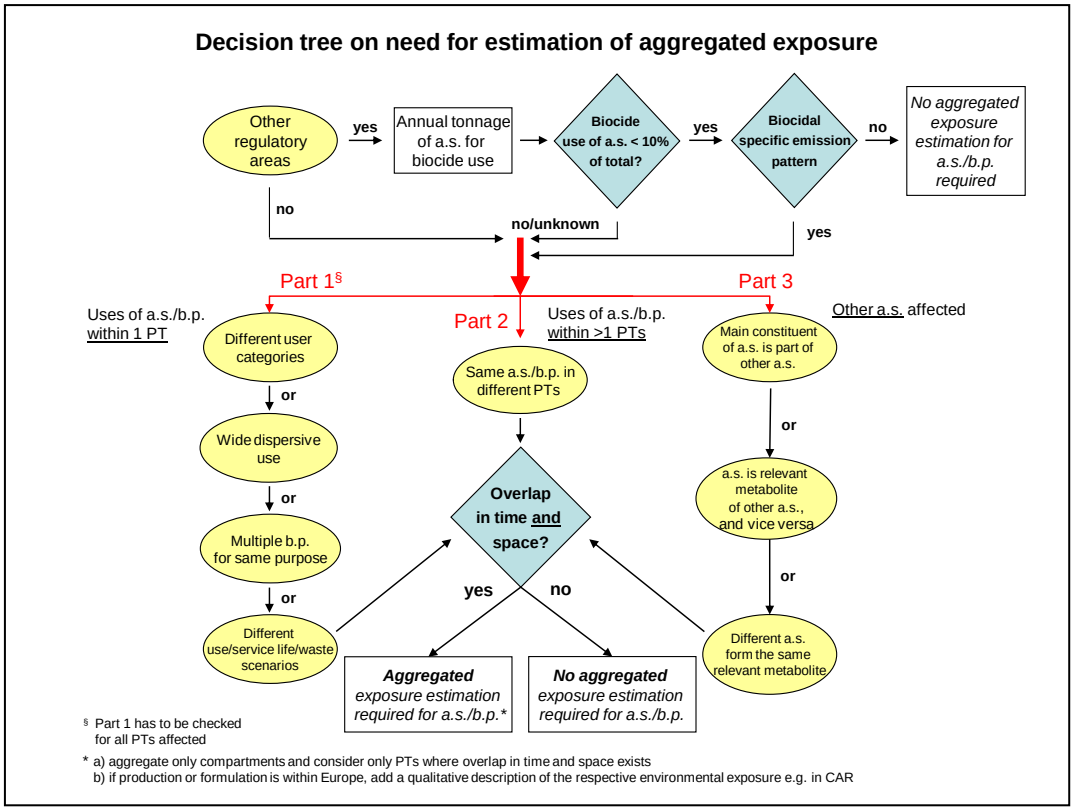


Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product
The risk assessment showed that the product Protect rodenticide grain bait is not expected to pose risks in any of the environmental compartments. Unacceptable risks were however identified from primary and secondary toxicity, this risk has to be mitigated by applying all appropriate and available risk mitigation measures.

2.2.9 Measures to protect man, animals and the environment

The measures to protect man, animals and the environment are same as specified before for the first authorisation of the product. No new data have become available since then, consequently the conclusions remain the same. For the relevant information please refer to the previous PAR.

2.2.10 Assessment of a combination of biocidal products

Protect rodenticide grain bait is not intended to be authorised for use with other biocidal products.

2.2.11 Comparative assessment

The ECHA Biocidal Products Committee (BPC) has provided a comparative assessment of anticoagulant rodenticides. For the conclusions of the report please refer to the ECHA document "Questions regarding the comparative assessment of anticoagulant rodenticides", ECHA/BPC/145/2017.

3 ANNEXES[2]

3.1 List of studies for the biocidal product

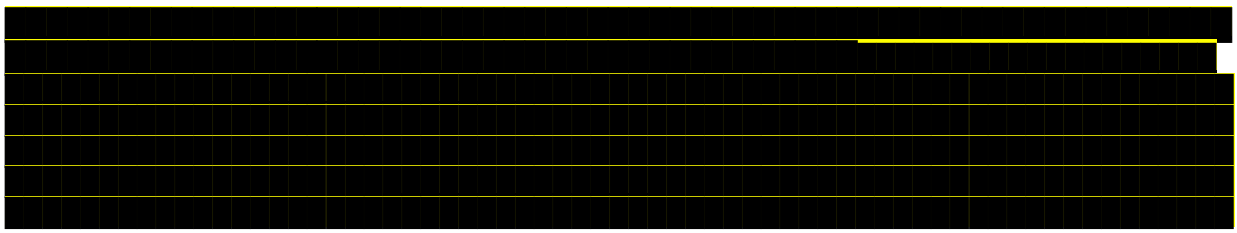
Two new phys- chem. studies were submitted:
1. Partial Validation of the Analytical Method for the Determination of Bromadiolone in Protect Rodenticide Grain Bait, GLP, Study No: 484-100-2751, Dat: August, 2017
2. Determination of Bromadiolone Active Ingredient Content in Protect Rodenticide grain Bait, GLP, Study No.: 484-195-2752, Date: August, 2017

Three new efficacy studies were submitted to support the major change in parallel with the renewal of the product.:
1. Laboratory test. Palatability – mortalitiy trial study. Biological Laboratory of Babolna Bio Ltd.,Hungary study no.:161.019
2. Semi-field test Biological Laboratory of Babolna Bio Ltd., Hungary study no.:171.003
3. Field test IZIPEST® ref. no.: 17RnBA004

See the summaries of these studies under point 2.2.5.5. of the PAR.

For the former studies, please refer to the previous PAR.

3.2 Output tables from exposure assessment tools



2 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

[redacted]

$$Clocal_{soil-D} = \frac{Elocal_{soil-D-campaign} \times 10^3}{AREA_{exposed-D} \times DEPTH_{soil} \times RHO_{soil} \times N_{sites}}$$

[redacted]

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

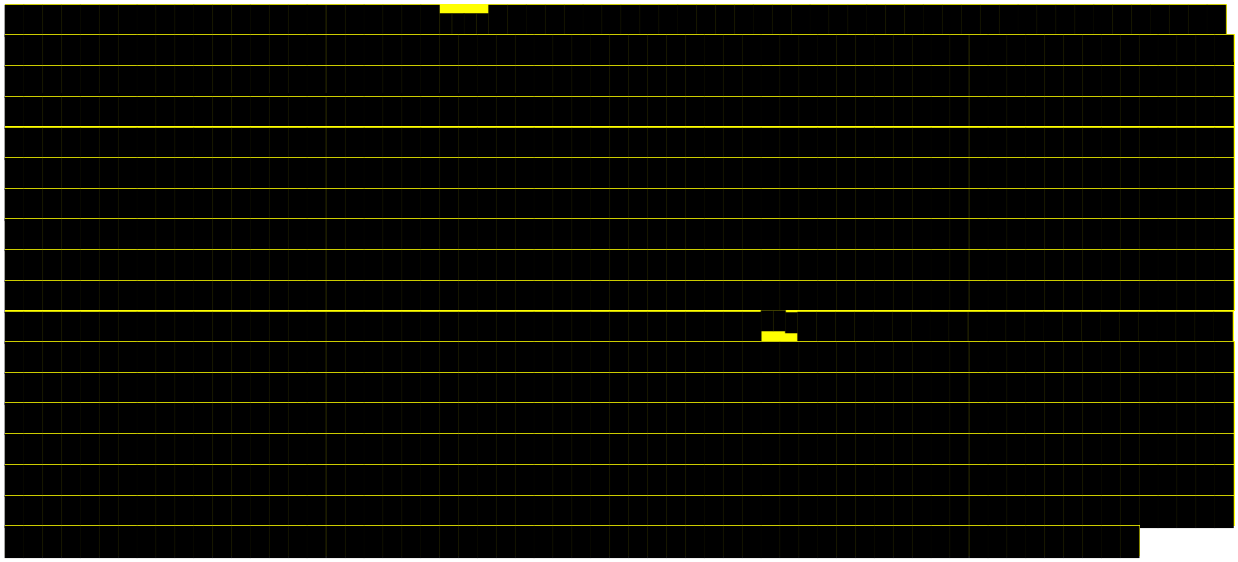
[redacted]

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

[redacted]

[redacted]

[redacted]



3.3 New information on the active substance

No new information is available on the active substance.

3.4 Residue behaviour

Not applicable.

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

Three new efficacy studies were submitted to support the major change in parallel with the renewal of the product. See the summaries of these studies under point 2.2.5.5. of the PAR.

3.6 Confidential annex

3.7 Other

Not applicable