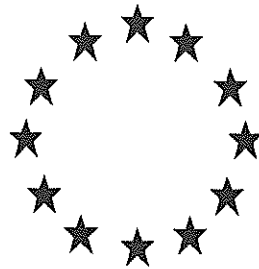


Regulation (EU) No 528/2012 concerning the  
making available on the market and use of biocidal  
products

**PRODUCT ASSESSMENT REPORT OF A  
BIOCIDAL PRODUCT FOR THE RENEWAL OF  
NATIONAL AUTHORISATION**



Protect Revolution rodenticide pellet

Product type 14

Bromadiolone

Case Number in R4BP: BC-VJ014108-37

Evaluating Competent Authority: HU

Date: 20/11/2018

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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 Revolution rodenticide pellet (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
- Commission Implementing Decision (EU) 2017/1532 of 7 September 2017 addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council
- 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 (9<sup>th</sup> 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 a major and some 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 increased from [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 will be 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.

- Change the composition of the appetizer gel: the preservative component [REDACTED] will be replaced by [REDACTED] which is listed in the Annex 1/Category 1 — Substances authorised as food additives. The gel doesn't contain active substance. The human and environmental risk assessments prepared for the 50 ppm rodenticide should be considered as valid.

### Minor change:

-Conditions of use/Changed instructions for use:

For professional and trained professional users the currently approved 90 g granule tray will contain separately 50 g appetizing gel also. The way of application, dosage will not be changed. The change does not adversely affect the exposure.

The tray with granule bait and appetizer gel has already approved for non-professional user category.

### Administrative changes:

- Changes of the name of the biocidal product:

The English name of the product was Protect Revolution rodenticide granule bait, but will be changed to Protect Revolution rodenticide pellet. The Hungarian and the Slovak name remain unchanged.

- 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 See section 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 See section 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 may allow prof. category according to their practice.
- Efficacy against target organisms** See section 2.2.5
- Composition.** (See confidential annex)

**1.2 Conclusion:**

The 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.

Post-authorisation data requirement:

The applicant will have to provide the results of a 2-year ambient long term storage stability test for both the gel and the granule bait. The reports should be submitted within 2 years from the date of the renewal decision i.e. by 20. November 2020.

Several new studies have been submitted to support the major change of the product. All available relevant guidance has been taken into account for the re-assessment. 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

Identifier <sup>1</sup>	Country (if relevant)
Protect Revolution rágcsálóirtó granulátum Protect Revolution rodenticide pellet	Hungary

##### 2.1.1.2 Authorisation holder

<b>Name and address of the authorisation holder</b>	<b>Name</b>	Babolna Bio Limited (Member of the Bromadiolone Task Force)
	<b>Address</b>	Babolna Bio Limited (Part of the Bromadiolone Task Force)
<b>Authorisation number</b>	HU-2014-SP-14-00120-0000	
<b>Date of the authorisation</b>	25.11.2014.	
<b>Expiry date of the authorisation</b>	31.12.2022.	

##### 2.1.1.3 Manufacturer(s) of the product

<b>Name of manufacturer</b>	Babolna Bio Limited
<b>Address of manufacturer</b>	H-1107 Budapest, Szállás u. 6 Hungary
<b>Location of manufacturing sites</b>	H-2943 Bábolna, Dr. Köves János u. 1-3. Hungary

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

<b>Active substance</b>	Bromadiolone
<b>Name of manufacturer</b>	Babolna Bio Limited (Member of the Bromadiolone Task Force)
<b>Address of manufacturer</b>	Dr Tezza S.r.l.  Via Tre Ponti 37050 S. Maria di Zevio Italy
<b>Location of manufacturing sites</b>	PM Tezza S.r.l.  Via Tre Ponti

<sup>1</sup> Please fill in here the identifying product name from R4BP.

37050 S. Maria di Zevio Italy
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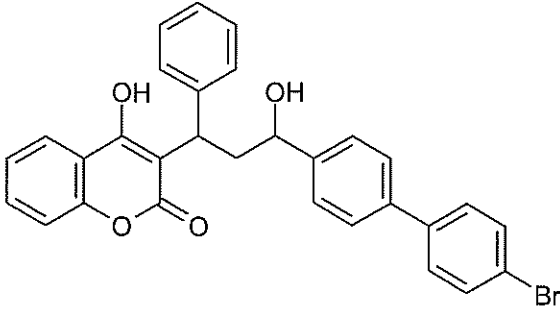
## 2.1.2 Product (family) composition and formulation

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

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

Yes   
No

### 2.1.2.1 Identity of the active substance

Main constituent(s)	
<b>ISO name</b>	Bromadiolone
<b>IUPAC or EC name</b>	3-[(1R,3R;1R,3S)-3-(4'-bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxycoumarin
<b>EC number</b>	249-205-9
<b>CAS number</b>	28772-56-7
<b>Index number in Annex VI of CLP</b>	607-716-00-8
<b>Minimum purity / content</b>	Minimum purity: 98 % w/w Content: 0.0027% w/w
<b>Structural formula</b>	

### 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 persistent, bioaccumulative and toxic. However, in spite of the 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 (%)
<b>Bromadiolone</b>	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 substances*			ad 100%

**\*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 pellet
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### 2.1.3 Hazard and precautionary statements

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

<b>Classification</b>	
Hazard category	STOT RE 2
Hazard statement	H373 May cause damage to organs (blood) through prolonged or repeated exposure
<b>Labelling</b>	
Signal words	Warning (GHS08: Health Hazard)
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 Use description

##### **Use # 1 – House mice and rats – general public – indoor**

<b>Product Type</b>	PT14 - Rodenticide
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides
<b>Target organism (including development stage)</b>	<i>Mus musculus</i> (house mouse) – adults and juveniles <i>Rattus norvegicus</i> (brown rat) adults and juveniles
<b>Field of use</b>	Indoor
<b>Application method(s)</b>	Ready-to-use bait to be used in tamper-resistant bait stations
<b>Application rate(s) and frequency</b>	Against mice: Tray: 1 tray containing 75g or 90 g bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5 meters.  Filter paper or plastic sachet: Up to 100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5 meters.

	<p>Against rats:</p> <p>Tray: 1 tray containing 150g bait or 2 trays containing 75g, 90g or 125g 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).</p> <p>Filter paper or plastic sachet: 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).</p>
<b>Category(ies) of users</b>	general public
<b>Pack sizes and packaging material</b>	<ul style="list-style-type: none"> <li>• plastic tray containing 75, 90, 125, 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.</li> <li>• filter paper sachets containing 10, 20, 25 or 50 g bait in carton box. Up to 150 g.</li> <li>• 20 or 25 g filter paper sachets, 2 sachets in plastic baiting box. 1 or 2 boxes in paper box.</li> <li>• plastic sachet or aroma permeable sachet containing 100 or 150 g bait in carton paper box. Up to 150 g.</li> <li>• plastic sachet containing 100 or 150 g bait.</li> </ul>

#### 2.1.4.1.1 Use-specific instructions for use

When used against mice:

- The bait stations should be visited at least every 2 to 3 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. Re-fill bait when necessary.

When used against rats:

- 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.

#### 2.1.4.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.1.4.2 Use description

**Use # 2 – Rats – general public – outdoor around buildings**

<b>Product Type</b>	PT14 - Rodenticide
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides
<b>Target organism (including development stage)</b>	<i>Rattus norvegicus</i> (brown rat) adults and juveniles
<b>Field of use</b>	Outdoor around buildings
<b>Application method(s)</b>	Ready-to-use bait to be used in tamper-resistant bait stations
<b>Application rate(s) and frequency</b>	<p>Tray: 1 tray containing 150g bait or 2 trays containing 75g, 90g or 125g bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be from 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation).</p> <p>Filter paper or plastic sachet: 150 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be from 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation).</p>
<b>Category(ies) of users</b>	general public
<b>Pack sizes and packaging material</b>	<ul style="list-style-type: none"> <li>• plastic tray containing 75, 90, 125, 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.</li> <li>• plastic tray containing 75 or 90 g bait covered by filter paper + 50 g appetizing gel with aluminium foil covering, in paper box. 1-2 trays in paper box. Up to 150 g.</li> <li>• filter paper sachets containing 10, 20, 25 or 50 g bait in carton box. Up to 150 g</li> <li>• 20 or 25 g filter paper sachets, 2 sachets in plastic baiting box. 1 or 2 boxes in paper box.</li> <li>• plastic sachet or aroma permeable sachet containing 100 or</li> </ul>

	<p>150 g bait in carton paper box. Up to 150 g</p> <ul style="list-style-type: none"> <li>• plastic sachet containing 100 or 150 g bait.</li> </ul>
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2.1.4.2.1 Use-specific instructions for use

<ul style="list-style-type: none"> <li>- Place the bait stations in areas not liable to flooding.</li> <li>- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.</li> <li>- 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.</li> </ul>
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2.1.4.2.2 Use-specific risk mitigation measures

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2.1.4.2.3 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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2.1.4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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

-
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2.1.4.3 Use description

**Use # 3 – House mice – professionals – indoor**

<b>Product Type</b>	PT14 - Rodenticide
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides

<b>Target organism (including development stage)</b>	<i>Mus musculus</i> (house mouse) – adults and juveniles
<b>Field of use</b>	Indoor
<b>Application method(s)</b>	Ready-to-use bait to be used in tamper-resistant bait stations
<b>Application rate(s) and frequency</b>	<p><b>Bulk:</b> Up to 100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5 meters.</p> <p><b>Tray:</b> 1 tray containing 75g or 90 g bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5 meters.</p> <p><b>Filter paper sachet:</b> Up to 100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5 meters.</p>
<b>Category(ies) of users</b>	professional
<b>Pack sizes and packaging material</b>	<ul style="list-style-type: none"> <li>• plastic tray containing 75, 90, 125, 150 or 175 g bait covered by filter paper, in paper box. Up to 20 kg.</li> <li>• filter paper sachets containing 20, 25 or 50 g bait in carton box. Up to 20 kg.</li> <li>• bulk in plastic bucket. Up to 20 kg with separate inner packages of maximum 10 kg in plastic bags.</li> <li>• bulk in paper barrel. Up to 30 kg with separate inner packages of maximum 10 kg in plastic bags.</li> <li>• bulk in plastic sachet in carton box. Up to 25 kg with separate inner packages of maximum 10 kg in plastic bags.</li> <li>• bulk in paper bag. Up to 25 kg with separate inner packages of maximum 10 kg in plastic bags.</li> </ul>

#### 2.1.4.3.1 Use-specific instructions for use

- The bait stations should be visited at least every 2 to 3 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. Re-fill bait when necessary.  
- Follow any additional instructions provided by the relevant code of best practice.

#### 2.1.4.3.2 Use-specific risk mitigation measures

-

#### 2.1.4.3.3 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.

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

-

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

-

2.1.4.4 Use description

**Use # 4 – Rats – professionals – indoor**

<b>Product Type</b>	PT14 - Rodenticide
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides
<b>Target organism (including development stage)</b>	<i>Rattus norvegicus</i> (Brown rat) – adults and juveniles
<b>Field of use</b>	Indoor
<b>Application method(s)</b>	Ready-to-use bait to be used in tamper-resistant bait stations
<b>Application rate(s) and frequency</b>	<p><b>Bulk:</b> Up to 250 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be from 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation).</p> <p><b>Tray:</b> 1 tray containing 150g or 175g bait or 2 trays containing 75g, 90g or 125g bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be from 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation).</p> <p><b>Filter paper sachet:</b> Up to 250g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be from 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation).</p>
<b>Category(ies) of users</b>	professional

<b>Pack sizes and packaging material</b>	<ul style="list-style-type: none"> <li>• plastic tray containing 75, 90, 125, 150 or 175 g bait covered by filter paper, in paper box. Up to 20 kg.</li> <li>• plastic tray containing 75 or 90 g bait with filter paper covering + 50 g appetizing gel with aluminium foil covering, in paper box. Up to 20 kg.</li> <li>• filter paper sachets containing 20, 25 or 50 g bait in carton box. Up to 20 kg.</li> <li>• bulk in plastic bucket. Up to 20 kg with separate inner packages of maximum 10 kg in plastic bags.</li> <li>• bulk in paper barrel. Up to 30 kg with separate inner packages of maximum 10 kg in plastic bags.</li> <li>• bulk in plastic sachet in carton box. Up to 25 kg with separate inner packages of maximum 10 kg in plastic bags.</li> <li>• bulk in paper bag. Up to 25 kg with separate inner packages of maximum 10 kg in plastic bags.</li> </ul>
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#### 2.1.4.4.1 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.

#### 2.1.4.4.2 Use-specific risk mitigation measures

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#### 2.1.4.4.3 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.

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

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

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## 2.1.4.5 Use description

**Use # 5 – House mouse and rat – professional – around buildings**

<b>Product Type</b>	PT14 - Rodenticide
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides
<b>Target organism (including development stage)</b>	<i>Rattus norvegicus</i> (Brown rat) – adults and juveniles <i>Mus musculus</i> (house mouse) – adults and juveniles
<b>Field of use</b>	Outdoor - around buildings
<b>Application method(s)</b>	Ready-to-use bait to be used in tamper-resistant bait stations
<b>Application rate(s) and frequency</b>	<p>For mice</p> <p>Bulk: Up to 100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5 meters.</p> <p>Tray: 1 tray containing 75g or 90 g bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5 meters.</p> <p>Filter paper sachet: Up to 100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5 meters.</p> <p>For rats:</p> <p>Bulk: Up to 250g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be from 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation).</p> <p>Tray: 1 tray containing 150g or 175g bait or 2 trays containing 75g, 90g or 125g bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be from 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation).</p> <p>Filter paper sachet: Up to 250g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be from 7 meters (for high levels of infestation) to 10 meters (for low levels of infestation).</p>
<b>Category(ies) of users</b>	professional

<b>Pack sizes and packaging material</b>	<ul style="list-style-type: none"> <li>• plastic tray containing 75, 90, 125, 150 or 175 g bait covered by filter paper, in paper box. Up to 20 kg.</li> <li>• plastic tray containing 75 or 90 g bait with filter paper covering + 50 g appetizing gel with aluminium foil covering, in paper box. Up to 20 kg.</li> <li>• filter paper sachets containing 20, 25 or 50 g bait in carton box. Up to 20 kg.</li> <li>• bulk in plastic bucket. Up to 20 kg with separate inner packages of maximum 10 kg in plastic bags.</li> <li>• bulk in paper barrel. Up to 30 kg with separate inner packages of maximum 10 kg in plastic bags.</li> <li>• bulk in plastic sachet in carton box. Up to 25 kg with separate inner packages of maximum 10 kg in plastic bags.</li> <li>• bulk in paper bag. Up to 25 kg with separate inner packages of maximum 10 kg in plastic bags.</li> </ul>
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#### 2.1.4.5.1 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 at least every 2 to 3 days (for mice) and only 5 to 7 days after the beginning of the treatment (for rats) 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.

#### 2.1.4.5.2 Use-specific risk mitigation measures

Do not apply this product directly in the burrows.

#### 2.1.4.5.3 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.

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

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

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## 2.1.4.6 Use description

**Use # 6 – House mice and rats - trained professionals - indoor**

<b>Product Type</b>	PT14 - Rodenticide
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides
<b>Target organism (including development stage)</b>	<i>Rattus norvegicus</i> (Brown rat) – adults and juveniles <i>Mus musculus</i> (house mouse) – adults and juveniles
<b>Field of use</b>	Indoor
<b>Application method(s)</b>	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.
<b>Application rate(s) and frequency</b>	For mice Bulk: Up to 100g of bait per baiting point. Tray: 1 tray containing 75g or 90 g bait per baiting point. Filter paper sachet: Up to 100g of bait per baiting point.  For rats: Bulk: Up to 250g of bait per baiting point. Tray: 1 tray containing 150g or 175g bait or 2 trays containing 75g, 90g or 125g bait per baiting point. Filter paper sachet: Up to 250g of bait per baiting point.  Permanent baiting: Up to 250g of bait per baiting point.
<b>Category(ies) of users</b>	Trained professional
<b>Pack sizes and packaging material</b>	<ul style="list-style-type: none"> <li>• plastic tray containing 75, 90, 125, 150 or 175 g bait covered by filter paper, in paper box. Up to 20 kg.</li> <li>• plastic tray containing 75 or 90 g bait with filter paper covering + 50 g appetizing gel with aluminium foil covering, in paper box. Up to 20 kg.</li> <li>• filter paper sachets containing 20, 25 or 50 g bait in carton box. Up to 20 kg.</li> <li>• bulk in plastic bucket. Up to 20 kg with separate inner packages of maximum 10 kg in plastic bags.</li> <li>• bulk in paper barrel. Up to 30 kg with separate inner packages of maximum 10 kg in plastic bags.</li> <li>• bulk in plastic sachet in carton box. Up to 25 kg with separate inner packages of maximum 10 kg in plastic bags.</li> <li>• bulk in paper bag. Up to 25 kg with separate inner packages of maximum 10 kg in plastic bags.</li> </ul>

#### 2.1.4.6.1 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.

#### 2.1.4.6.2 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 apply this product directly in the burrows.

- 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.

#### 2.1.4.6.3 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.

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

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#### 2.1.4.6.5 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

**Use # 7 – House mice and rats - trained professionals – outdoor around buildings**

<b>Product Type</b>	PT14 - Rodenticide
<b>Where relevant, an exact description of the authorised use</b>	Not relevant for rodenticides
<b>Target organism (including development stage)</b>	<i>Rattus norvegicus</i> (Brown rat) – adults and juveniles <i>Mus musculus</i> (house mouse) – adults and juveniles
<b>Field of use</b>	Outdoor: around buildings
<b>Application method(s)</b>	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.
<b>Application rate(s) and frequency</b>	For mice Bulk: Up to 100g of bait per baiting point. Tray: 1 tray containing 75g or 90 g bait per baiting point. Filter paper sachet: Up to 100g of bait per baiting point.  For rats: Bulk: Up to 250g of bait per baiting point. Tray: 1 tray containing 150g or 175g bait or 2 trays containing 75g, 90g or 125g bait per baiting point. Filter paper sachet: Up to 250g of bait per baiting point.  Permanent baiting: Up to 250g of bait per baiting point.
<b>Category(ies) of users</b>	Trained professional
<b>Pack sizes and packaging material</b>	<ul style="list-style-type: none"> <li>• plastic tray containing 75, 90, 125, 150 or 175 g bait covered by filter paper, in paper box. Up to 20 kg.</li> <li>• filter paper sachets containing 20, 25 or 50 g bait in carton box. Up to 20 kg.</li> <li>• bulk in plastic bucket. Up to 20 kg with separate inner packages of maximum 10 kg in plastic bags.</li> <li>• bulk in paper barrel. Up to 30 kg with separate inner packages of maximum 10 kg in plastic bags.</li> <li>• bulk in plastic sachet in carton box. Up to 25 kg with separate inner packages of maximum 10 kg in plastic bags.</li> <li>• bulk in paper bag. Up to 25 kg with separate inner packages of maximum 10 kg in plastic bags.</li> </ul>

## 2.1.4.7.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions. Place the baiting points in areas not liable

to flooding.

- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- 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.

#### 2.1.4.7.2 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 apply this product directly in the burrows.
- 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.

#### 2.1.4.7.3 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.

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

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

-

### 2.1.5 General directions for use

#### 2.1.5.1 Instructions for use

##### **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.

##### **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 (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.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 5.3 for the information to be shown on the label).
- [If national policy or legislation require it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice

explaining the risk of primary or secondary poisoning by the 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 (glove material to be specified by the authorisation holder within the product information)
  - When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
  - If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait stations 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 rodents 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.

#### **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.
- 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).
- [If national policy or legislation require it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the 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 (glove material to be specified by the authorisation holder within the product information)

- 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 stations 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 rodents 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.
- Instructions for use that are "bait-specific":**
- Bait in filter paper sachets: Do not open the sachets containing the bait.
  - Bait in trays: Do not open the cover of the trays containing the bait.
  - Trays with appetizing gel: Remove the grey aluminium foil before application while leaving the white foil on the tray without opening it. The white foil being aroma permeable, allows the rodents to find the rodenticide. It also increases the safety of the application since no exposure occurs to the rodenticide. Should the appetizing gel dry up, pour on approx. 50 ml of water. When the water is absorbed, the gel recovers its initial consistence. Take care to keep the granules away from water. Rehydrate gel only when the protect film covering pellets is intact. The appetizing gel is a non-hazardous mixture according to manufacturer and in compliance with Reg. 1272/2008/EC.

#### 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**

- 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.
- To reduce risk of secondary poisoning, search for and remove dead rodents at

frequent intervals during treatment (e.g. at least twice a week).

- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.

- Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

- The product information (i.e. label and/or leaflet) shall clearly show that: the product shall not be supplied to the general public (e.g. "for professionals only"). the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").

users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations").

- Using this product should eliminate rodents within 35 days.

The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

- Do not wash the bait stations with water between applications.

- Dispose dead rodents in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

#### **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 [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

#### **- 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 for several minutes with eyes-rinse liquid or water

- 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

Post-authorisation data requirement: The applicant will have to provide the results of a 2-year ambient long term storage stability test for both the gel and the granule bait. The reports should be submitted within 2 years from the date of the renewal decision, i.e. by 20/11/2020.

#### 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, 90, 125, 150 or 175 g bait covered by filter paper, in paper box	Up to 20 kg	PVC + paper		Professional	Yes

plastic tray containing 75 or 90 g bait with filter paper covering + 50 g appetizing gel with aluminium foil covering, in paper box	Up to 20 kg	PVC + paper		Professional	Yes
filter paper sachets containing 20, 25 or 50 g bait in carton box	Up to 20 kg	carton paper		Professional	Yes
bulk in plastic bucket	Up to 20 kg. The packaging is divided into separate inner packages of maximum 10 kgs. The separate packages are packed in (PE) bags.	polypropylene (PP)		Professional	Yes
bulk in paper barrel	Up to 30 kg. The packaging is divided into separate inner packages of maximum 10 kgs. The separate packages are packed in (PE) bags.	carton paper		Professional	Yes
bulk in plastic sachet in carton box	Up to 25 kg. The packaging is divided into separate inner packages of maximum 10 kgs. The	biaxially oriented polypropylene film (BOPP)/polyethylene (PE) + carton paper		Professional	Yes

	separate packages are packed in (PE) bags.				
bulk in paper bag	Up to 25 kg. The packaging is divided into separate inner packages of maximum 10 kgs. The separate packages are packed in (PE) bags.	paper		Professional	Yes
plastic tray containing 75, 90, 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)		Non-professional	Yes
plastic tray containing 75 or 90 g bait with filter paper covering + 50 g appetizing gel with aluminium foil covering, in paper box (against rats)	1 or 2 trays in box. Up to 150 g.	PVC + paper		Non-professional	Yes
filter paper sachets containing 10, 20, 25 or 50 g bait in carton box	Up to 150 g	carton paper		Non-professional	Yes
20 or 25 g filter paper sachets, 2 sachets in plastic baiting box	1 or 2 boxes in paper box.	PVC + paper	Tamper-resistant, ready-to-use bait box	Non-professional	Yes
plastic sachet or aroma permeable sachet	Up to 150 g.	biaxially oriented polypropylene film (BOPP)/polyethylene (PE) or filter paper		Non-professional	Yes

containing 100, or 150 g bait in carton paper box		+ carton paper			
plastic sachet containing 100 or 150 g bait	Up to 150 g.	biaxially oriented polypropylene film (BOPP)/polyethylene (PE)		Non-professional	Yes

## 2.1.8 Documentation

### 2.1.8.1 Data submitted in relation to product application

No new studies have been performed for the renewal of Protect Revolution rodenticide pellet. The conclusions of the initial assessment of the biocidal product are still considered valid. Human and environmental 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.

### 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 1. 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)	<i>Mus musculus</i> (House mouse) – adults and juveniles <i>Rattus norvegicus</i> (Brown rat) – adults and juveniles
Field of use	Indoor Outdoor - around buildings
Application method(s)	Bulk: Use a suitable (disposable) respirator when pouring the product.  Filter paper sachets or trays: Place the filter paper sachets or trays containing the



	<p>rodenticide bait – without opening the sachet or filter paper covering – to the locations visited by rats or mice, near the rodent runs and their supposed hiding places.</p> <p>Trays with appetizing gel: Remove the grey aluminium foil before application while leaving the white foil on the tray without opening it. The white foil being aroma permeable, allows the rodents to find the rodenticide. It also increases the safety of the application since no exposure occurs to the rodenticide. Should the appetizing gel dry up, pour on approx. 50 ml of water. When the water is absorbed, the gel recovers its initial consistence. Take care to keep the granules away from water. The appetizing gel does not contain any harmful ingredients and is not dangerous to humans or animals.</p>
Application rate(s) and frequency	<p>Bulk: 200-250 grams every 7-10 metres to control rats. 50-100 grams per 5 m<sup>2</sup> to control mice.</p> <p>Tray: 1 tray containing 150g or 175g bait or 2 trays containing 75g or 90g bait every 7-10 metres to control rats. 1 or 2 trays containing 75g or 90g bait every 5 m<sup>2</sup> to control mice.</p> <p>Filter paper sachet: 200-240 grams every 7-10 metres to control rats. 20-100 grams per 5 m<sup>2</sup> to control mice.</p>
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\***

\* Babolna Bio is aware that due to Regulation 2016/1179 (9<sup>th</sup> ATP to the CLP regulation, providing a harmonised classification for bromadiolone), non-professional use of 50 ppm products will not be allowed from 01.03.2018.

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)	<i>Mus musculus</i> (House mouse) – adults and juveniles <i>Rattus norvegicus</i> (Brown rat) – adults and juveniles
Field of use	Indoor Outdoor - around buildings
Application method(s)	Trays, filter paper sachets, plastic sachets: Place the bait – without opening the covering – to the locations visited by rats or mice, near the rodent runs and

	<p>their supposed hiding places.</p> <p>Trays with appetizing gel: Remove the grey aluminium foil before application while leaving the white foil on the tray without opening it. The white foil being aroma permeable, allows the rodents to find the rodenticide. It also increases the safety of the application since no exposure occurs to the rodenticide. Should the appetizing gel dry up, pour on approx. 50 ml of water. When the water is absorbed, the gel recovers its initial consistence. Take care to keep the granules away from water. The appetizing gel does not contain any harmful ingredients and is not dangerous to humans or animals.</p>
Application rate(s) and frequency	<p>Tray: 1 tray containing 150g or 175g bait or 2 trays containing 75g or 90g bait every 7-10 metres to control rats. 1 or 2 trays containing 75g or 90g bait every 5 m<sup>2</sup> to control mouse.</p> <p>Filter paper sachet or plastic sachet: 200 g every 7-10 metres to control rats. 20-100 g per 5 m<sup>2</sup> to control mice.</p>
Category(ies) of user(s)	Non-professional
Pack sizes and packaging material	Please see the relevant section.

### 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 Revolution rodenticide pellet. 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.

The physical, chemical and technical properties of Protect Revolution rodenticide pellet containing 27 ppm active substance have been waived by the applicant.

Following changes were performed:

Component	old product	new product
active substance: bromadiolone	0.005%	0.0027%
solvent: ██████████	██████████	██████████

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

6, 12, 18 and 24 months long storage stability studies at ambient temperature were performed with product containing 50 ppm bromadiolone in original packaging with two batches. During these studies maximum decrease of bromadiolone content was 6%. Individual palatability mortality trials were performed after 12, 18 and 24 months storage with *Mus musculus* and *Rattus norvegicus* as well.

Based on the original storage stability data, the new formulation (with 27 ppm bromadiolone) is expected to similarly remain stable, therefore, no new data were required for authorisation.

During the MRS phase of the renewal the Competent Authority of Spain did not accept the above reasoning. They considered that the data available for the 50 ppm product is not relevant. Therefore the applicant submitted two additional studies:

- *Determination of the appearance (physical state, colour, odour) of Protect Revolution Rodenticide Pellet* which was manufactured on 20th October 2016 and stored in GMP certified warehouse of Bábolna Bio Ltd at 22-28°C – TOXI-COOP ZRT - Study Report 484-630-4134
- *Determination of Bromadiolon active ingredient content in Protect Revolution Rodenticide Pellet* which was manufactured on 20th October 2016 and stored in GMP certified warehouse of Bábolna Bio Ltd at 22-28°C. – TOXI-COOP ZRT - Study Report 484-195-4133

Bromadiolon concentration was measured using a validated analytical method in GLP Lab on 13rd October 2018.

Bromadiolon content: 25.5± 0.47 mg/kg

– 13rd October 2018 – GLP lab TOXI-COOP ZRT

Bromadiolon content: 27 mg/kg, in house method Bromadiolon decrease in %: far below 10%

– 26 October 2016 –

Regarding the product stability after two years of storage the result is very reassuring, but this measurement cannot replace a real stability study.

Thus, HU-CA accepts the Spanish opinion, that Babolna Bio Ltd. should submit the interim and final results of long term stability studies of Protect Revolution Rodenticide Pellet for both the appetizing gel and the pellet as post-authorization requirements. It is not enough to submit the results at the next renewal of the authorisation of the product.

There is a change of preservative in the composition of appetizing gel, metil-paraben was replaced by sodium-benzoate as it is on Annex I of Reg. 528/2012/EU. According the real time storage stability report only one year old appetizer gel samples are available which show no change in colour, odour and state. Only 0.2% weight loss of gel was detected in original packaging. The stability study of appetizing gel is still ongoing..

The applicant will have to provide the results of a 2-year ambient long term storage stability test for both the gel and the garnule bait. The reports should be subbmitted within 2 years from the date of the renewal decision.

### 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 Revolution rodenticide pellet. The results are still relevant for the product with decreased bromadiolone content, 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 Revolution rodenticide pellet. The analytical method to determine bromadiolone content in the product was revalidated. The results show that method is also valid at 27 ppm  $\pm$  20% concentration level. For the analytical methods, results and other information, please refer to the previous PAR of the product and new determination and revalidation study of bromadiolone content at 27 ppm level.

Studies:

1. Partial Validation of the Analytical Method for the Determination of Bromadiolone in Protect Rodenticide Pellet, GLP, Study No: 484-100-2757, Dat: August, 2017
2. Determination of Bromadiolone Active Ingredient Content in Protect Rodenticide pellet, GLP, Study No.: 484-195-2758, Date: August, 2017

### 2.2.5 Efficacy against target organisms

#### 2.2.5.1 Function and field of use

Protect Revolution rodenticide pellet is a rodenticide (product type 14) for professional and non-professional use.

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

Protect Revolution rodenticide pellet is to be used against rats and mice.

#### 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

HU CA: 9 new studies were submitted, 3 laboratory, 3 semi-field and 3 field studies. Each type was performed with rats and mice as well.

The studies conducted with Protect rodenticide pellet and Protect Revolution rodenticide pellet prove that with the reduced active substance content, 0.0027% bromadiolone, the bait is still efficacious against house mice (*Mus musculus*) and norway rats (*Rattus norvegicus*).

In the field study performed on a norway rat population, the efficacy was calculated 94.2%. Rodent activity ceased after 8 days of baiting, but during the post-baiting period footprints on tracking patches and some consumption of wheat was observed as signs of slight rodent activity. The level of efficacy is still acceptable in this study. HU CA however has contacted the applicant to ask their point of view on this phenomenon. The applicant submitted a supportive declaration on the matter, that is accepted by the CA.

It is suspected that after the baiting period a rodent could have reinfestated the the site from untreated neighbouring areas.

The applicant also submitted another field study on wild brown rats, in a similar setup, where the treatment with the product resulted in 100% control of the rat infestation.

Efficacy test with the appetizing gel-associated packages were only performed against rats, so these packages are to be used against rats only. Efficacy of the rodenticide pellets is supported against mice as well.

It may be pointed out that there were no new studies submitted with the aged bait. However from previous studies performed 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.

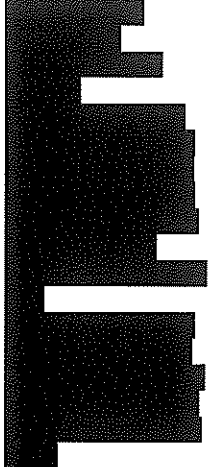

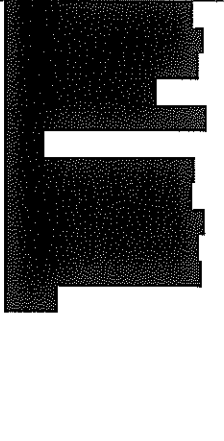

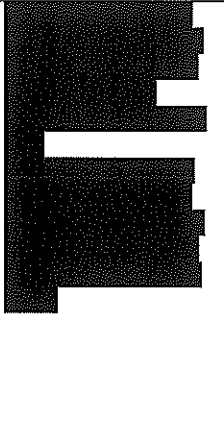

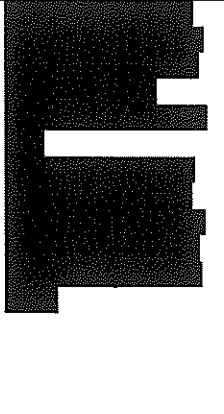

Afterall, it is strongly suspected that the bait will retain its efficacy through 2 years of storage. Therefore HU CA will accept the claimed 2 years of storage in abstinence of new efficacy tests regarding the palatability of the aged bait.

The following efficacy studies were carried out with Protect rodenticide pellet:

\* Test product was named **Bromadiolone granule bait** in the former assessment of the product. Now the product is referred as **Protect Revolution rodenticide pellet**. The difference between the products is the decrease of the bromadiolone active substance content from 50 ppm to 27 ppm. Simultaneously [REDACTED] content has been increased from [REDACTED] to [REDACTED]. Other quality and quantity parameters of the composition remain unchanged.

In some of the studies, the test product is also referred as **Protect Revolution rodenticide pellet**, its composition is identical to Protect rodenticide pellet. The sole difference is that when the study names Prtotect Revolution rodenticide pellet then the rodenticide pellet was packed with the appetizer gel.

Test product	Test organisms	Test system/Concentration applied/exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference
Bromadiolone Granule Bait (50 ppm)	House mouse ( <i>Mus musculus</i> ) 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 9 day normal diet period. Unrestricted access to the test bait and to palatable and familiar alternative food (challenge diet – EPA STANDARD) during the 5-day test period. The quantity of food placed in each pot was <i>ad libitum</i> .	[REDACTED]	[REDACTED]  The efficacy was total: 100% [REDACTED]	[REDACTED]
Bromadiolone Granule Bait (50 ppm)	Norway rat ( <i>Rattus norvegicus</i> ) 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 9 day normal diet period. Unrestricted access to the test bait and to palatable and familiar alternative food (challenge diet – EPA STANDARD) during the 5-day test period. The quantity of food placed in each pot was <i>ad libitum</i> .	[REDACTED]	[REDACTED]  The efficacy was total: 100% [REDACTED]	[REDACTED]
Bromadiolone Granule Bait (50 ppm)	House mouse ( <i>Mus musculus</i> ) 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 (challenge diet – EPA STANDARD) during the 5-day test period. The quantity of food placed in each pot was <i>ad libitum</i> .	[REDACTED]	[REDACTED]  The efficacy was total: 100% [REDACTED]	[REDACTED]

<p>Bromadiolone Granule Bait (50 ppm)</p>	<p>Norway rat (<i>Rattus norvegicus</i>) 10 laboratory bred wild animals (5 males, 5 females)</p>	<p>Semi-field test carried out in a semi-field trial rooms (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 (challenge diet – EPA STANDARD) during the 5-day test period. The quantity of food placed in each pot was <i>ad libitum</i>.</p>		<p>The efficacy was total: 100%</p>	
<p>Bromadiolone Granule Bait, after 1 year of storage (50 ppm)</p>	<p>House mouse (<i>Mus musculus</i>) 10 laboratory bred wild animals (5 males, 5 females)</p>	<p>Laboratory test. Palatability – mortality 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 (challenge diet – EPA STANDARD) during the 5-day test period. The quantity of food placed in each pot was <i>ad libitum</i>.</p>		<p>The efficacy was total: 100%</p>	
<p>Bromadiolone Granule Bait, after 1 year of storage (50 ppm)</p>	<p>Norway rat (<i>Rattus norvegicus</i>) 10 laboratory bred wild animals (5 males, 5 females)</p>	<p>Laboratory test. Palatability – mortality 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 (challenge diet – EPA STANDARD) during the 5-day test period. The quantity of food placed in each pot was <i>ad libitum</i>.</p>		<p>The efficacy was total: 100%</p>	
<p>Bromadiolone Granule Bait, after 1,5 years of storage (50 ppm)</p>	<p>House mouse (<i>Mus musculus</i>) 10 laboratory bred wild animals (5 males, 5 females)</p>	<p>Laboratory test. Palatability – mortality 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 (challenge diet – EPA STANDARD) during the 5-day test period. The quantity of food placed in</p>		<p>The efficacy was total: 100%</p>	

		each pot was <i>ad libitum</i> .			
Bromadiolone Granule Bait, after 1,5 years of storage	Norway rat ( <i>Rattus norvegicus</i> ) 10 laboratory bred wild animals (5 males, 5 females)	Laboratory test. Palatability – mortality 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 (challenge diet – EPA STANDARD) during the 5-day test period. The quantity of food placed in each pot was <i>ad libitum</i> .		 The efficacy was total: 100%	
Bromadiolone Granule Bait, after 2 years of storage (50 ppm)	House mouse ( <i>Mus musculus</i> ) 10 laboratory bred wild animals (5 males, 5 females)	Laboratory test. Palatability – mortality trial study. Choice feeding test: aged baits. 3-day pre-test normal diet (CRLT/N) intake assessment. 5 day bait feeding period and 9 day normal diet period. Unrestricted access to the test bait and to palatable and familiar alternative food (challenge diet – EPA STANDARD) during the 5-day test period. The quantity of food placed in each pot was <i>ad libitum</i> .		 The efficacy was total: 100%	
Bromadiolone Granule Bait, after 2 years of storage (50 ppm)	Norway rat ( <i>Rattus norvegicus</i> ) 10 laboratory bred wild animals (5 males, 5 females)	Laboratory test. Palatability – mortality trial study. Choice feeding test: aged baits. 3-day pre-test normal diet (CRLT/N) intake assessment. 5 day bait feeding period and 9 day normal diet period. Unrestricted access to the test bait and to palatable and familiar alternative food (challenge diet – EPA STANDARD) during the 5-day test period. The quantity of food placed in each pot was <i>ad libitum</i> .		 The efficacy was total: 100%	
Bromadiolone Granule Bait with appetizer gel (50 ppm)	Norway rat ( <i>Rattus norvegicus</i> ) 10 laboratory bred wild animals (5 males, 5 females)	Semi-field test Palatability - mortality trial study Choice feeding test: Bromadiolone Granule bait without gel vs. Bromadiolone Granule bait packed with appetizer gel 3-day acclimatisation period 3-day pre feeding period normal diet (CRLT/N) intake measured 5-day feeding period CRLT/N feed withdrawn, 4 feeding points in parallel		 Efficacy was total 100%	

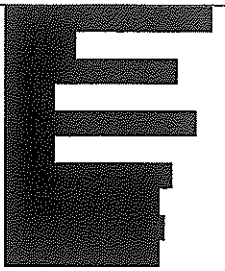
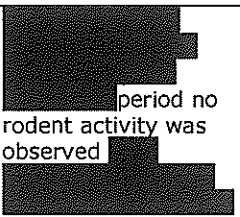
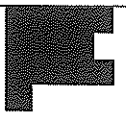
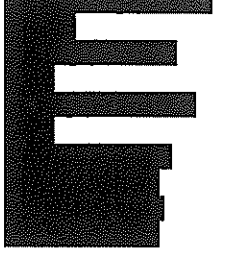
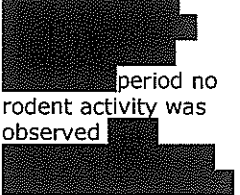

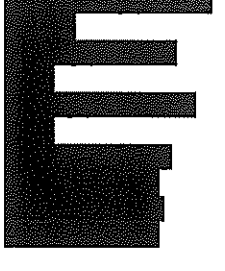
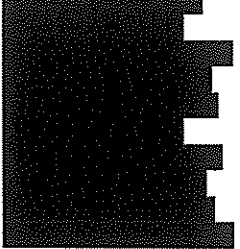






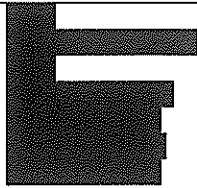

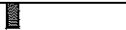
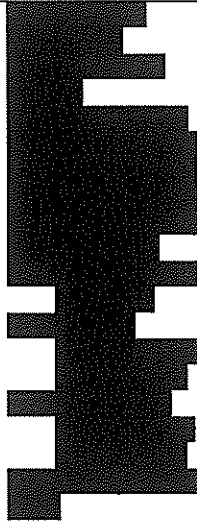
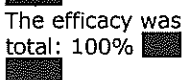
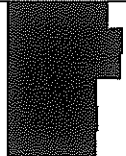

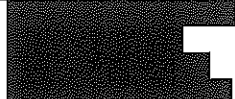
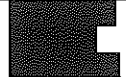
		(2 feeding points with granule bait and 2 feeding points with granule bait and appetizer gel) drinking water is available ad libitum. Consumption measured daily. At the end of the feeding period, test bait is replaced with CRLT/N diet.			
Bromadiolone Granule Bait with appetizer gel (50 ppm)	Norway rat ( <i>Rattus norvegicus</i> ) 10 laboratory bred wild animals (5 males, 5 females) per test set up	Semi-field test Palatability - mortality trial study No-choice feeding test: Bromadiolone Granule bait packed with water vs. Bromadiolone Granule bait packed with appetizer gel. 3-day acclimatisation period 3-day pre feeding period normal diet (CRLT/N) intake measured 5-day feeding period CRLT/N feed withdrawn, <u>setup 1</u> : 2 feeding points in parallel, both containing granule and appetizer gel. Drinking water is also available separately ad libitum. <u>setup2</u> : 2 feeding points in parallel, both containing granule and water next to it. Other source of drinking water is also available separately ad libitum. Water, gel and bait consumption measured daily. At the end of the feeding period, test bait is replaced with CRLT/N diet.			

**NEW STUDIES SUBMITTED TO SUPPORT THE RENEWAL AND THE MAJOR CHANGE OF THE PRODUCT AUTHORISATION ARE LISTED BELOW**

Test product	Test organisms	Test system/Concentration applied/exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference
Protect rodenticide pellet* (27 ppm)	House mouse ( <i>Mus musculus</i> ) 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 9 day normal diet period. Unrestricted access to the test bait and to palatable and familiar alternative		The efficacy was total: 100%	

		food (challenge diet – EPA STANDARD) during the 5-day test period. The quantity of food placed in each pot was <i>ad libitum</i> .			
Protect rodenticide pellet* (27 ppm)	Norway rat ( <i>Rattus norvegicus</i> ) 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 9 day normal diet period. Unrestricted access to the test bait and to palatable and familiar alternative food (challenge diet – EPA STANDARD) during the 5-day test period. The quantity of food placed in each pot was <i>ad libitum</i> .		The efficacy was total: 100%	
Protect rodenticide pellet* (27 ppm)	House mouse ( <i>Mus musculus</i> ) 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 (challenge diet – EPA STANDARD) during the 5-day test period. The quantity of food placed in each pot was <i>ad libitum</i> . The test bait was placed inside plastic bait boxes in filter paper sachets containing 50 g bait. The dose was 2x50 g bait / 4 m <sup>2</sup>		The efficacy was total: 100%	
Protect rodenticide pellet* (27 ppm)	Norway rat ( <i>Rattus norvegicus</i> ) 10 laboratory bred wild animals (5 males, 5 females)	Semi-field test carried out in semi-field trial rooms (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 (challenge diet – EPA STANDARD) during the 5-day test period. The quantity of food placed in each pot was <i>ad libitum</i> . The test bait was placed inside plastic bait boxes in plastic trays containing 150 g bait. The dose was		The efficacy was total: 100%	

<p>Protect rodenticide pellet* (27 ppm)</p>	<p>House mouse (<i>Mus musculus</i>) wild population</p>	<p>2x150g bait / 7.7 m<sup>2</sup> Field test in an attic of a residential house. The mouse population consisted of 15 individuals approximately. In the pre treatment and post treatment periods reference food (semolina) was put in plastic bait stations. During treatment 2x50g grams of bait was placed in bait stations. Food and bait consumption was measured daily and replenished. Bait stations were 5 meters apart. Tracking patches were also used to monitor rodent activity.</p>		<p>period no rodent activity was observed</p> 	
<p>Protect rodenticide pellet* (27 ppm)</p>	<p>Norway rat (<i>Rattus norvegicus</i>) wild population  Genetically confirmed to be susceptible (not resistant) to AVK active substances as bromadiolone.</p>	<p>Field test in an amateur hen yard. The rat population consisted of 12 individuals approximately. In the pre treatment and post treatment periods reference food (wheat) was put in plastic bait stations. During treatment 3x150 g grams of bait altogether was placed in 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.</p>		<p>period no rodent activity was observed</p> 	
<p>Protect Revolution rodenticide pellet (27 ppm, with appetizer gel)*</p>	<p>Norway rat (<i>Rattus norvegicus</i>) wild population  Genetically confirmed to be susceptible (not resistant) to AVK active substances as bromadiolone.</p>	<p>Field test in an amateur hen yard. The rat population consisted of 14 individuals approximately. In the pre treatment and post treatment periods reference food (wheat) was put in plastic bait stations. During treatment 4x90 grams of bait + 4x50 g of appetizer gel altogether was placed in 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.</p>		<p>Comparing average consumption values of the pre-baiting plateau and post baiting period, the efficacy is 94.2%</p> 	
<p>Protect Revolution</p>	<p>Norway rat (<i>Rattus norvegicus</i>)</p>	<p>Field test in an amateur hen yard. The rat population</p>			

<p>rodenticide pellet (27 ppm, with appetizer gel)*</p>	<p>) wild population  Genetically confirmed to be susceptible (not resistant) to AVK active substances as bromadiolone.</p>	<p>consisted of 12 individuals approximately. In the pre treatment and post treatment periods reference food (wheat) was put in plastic bait stations. During treatment 3x90 grams of bait + 3x50 g of appetizer gel altogether was placed in 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.</p>		<p>period no rodent activity was observed</p> 	
<p>Protect Revolution rodenticide pellet (27 ppm, with appetizer gel)*</p>	<p>Norway rat (<i>Rattus norvegicus</i>) 10 laboratory bred wild animals (5 males, 5 females)</p>	<p>Semi-field test carried out in semi-field trial rooms (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 (challenge diet – EPA STANDARD) during the 5-day test period. The quantity of food placed in each pot was <i>ad libitum</i>. The test bait was placed inside plastic bait boxes in plastic trays containing 90 g bait and 50 g appetizer gel. The dose was 2x90g bait / 7.7 m<sup>2</sup></p>		<p>The efficacy was total: 100%</p> 	
<p>Protect Revolution rodenticide pellet (27 ppm, with appetizer gel)*</p>	<p>Norway rat (<i>Rattus norvegicus</i>) trapped wild animals (5 males, 5 females)  Confirmed resistant to anticoagulants. Homozygous mutants (Y139F)</p>	<p>Laboratory test. mortality trial study. No-choice feeding test: 1-week pre-test, normal diet intake assessment.  5 day bait feeding period with clinical observation and consumption measurements. During baiting the rodenticide pellet, appetizer gel and water is available <i>ad libitum</i>. After the bait feeding animals are observed and mortality is recorded.</p>		<p>The efficacy was 100% by day 8.</p> 	

#### 2.2.5.6 Occurrence of resistance and resistance management

HU CA: Resistance to anticoagulant (anti-vitamin-K) rodenticides is known to occur in many parts of Europe in certain populations of Norway rats and house mice as well. Depending on the genetic variation, the degree of resistance may be different. Nevertheless, the spread and development of resistant rodents is to be avoided. Therefore steps should be taken to recognise and counter resistant rodents.

The applicant has concluded their opinion on resistance in the "applicant's assessment". The results of a supporting test were also submitted in the assessment.

**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. 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

#### 2.2.7 Risk assessment for human health

##### 2.2.7.1 Assessment of effects on Human Health

No new studies have been performed for the renewal of Protect Revolution rodenticide pellet; 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.

Protect Revolution rodenticide pellet is a pellet bait (formerly referred to as granule bait) that is packed in ready-to-use bait boxes, plastic trays, bait sachets, plastic bags (not to be opened), as bulk, or for certain packaging types (90 g granule tray) with 50 g of appetizing gel. This appetizer gel provides source of water for the target species in a different compartment on the same tray with the granules. The package containing the appetizer gel is intended for rat control for amateur users. The gel comprises mostly of

water, none of the components of the gel have a human toxicological relevance (the components are not classified for human endpoints or are present in such low concentrations that they are irrelevant). The composition of the appetizer gel and the pellet bait can be found in the confidential composition statement. The following studies were performed with the pellet (granule) bait, which is the only part of the product with a toxicological significance. The gel is not expected to affect human risk in any way.

### ***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 the pellet bait (previously named as granule bait) of Protect Revolution rodenticide pellet. [REDACTED]

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.

<b>Summary table of animal studies on skin corrosion /irritation</b>
--

Method, Guideline, GLP status, Reliability	Species, Strain, Sex, No/group	Test substance, Vehicle, Dose levels, Duration of exposure	Results <i>Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings</i>	Remarks <i>(e.g. major deviations)</i>	Reference
OECD Guideline 404, GLP, Reliability: 1	Albino rabbit, New Zealand white, 3 males	Granule bait (0.005% bromadiolone), no vehicle (test item moistened with water), [REDACTED]	<b>Test item non-irritating.</b> [REDACTED]	-	[REDACTED]

No human data are available on skin corrosion/irritation.

<b>Conclusion used in Risk Assessment – Skin corrosion and irritation</b>	
Value/conclusion	Protect Revolution rodenticide pellet is not irritating to skin
Justification for the value/conclusion	[REDACTED] The test item is non-irritating.
Classification of the product according to CLP and DSD	No classification is required for Protect Revolution rodenticide pellet 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 the pellet bait (previously named as granule bait) of Protect Revolution rodenticide pellet, the product was not found to be an eye irritant.

[REDACTED]

[REDACTED]

[REDACTED]

[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 <i>Average score (24, 48, 72h)/ observations and time point of onset, reversibility</i>	Remarks <i>(e.g. major deviations)</i>	Reference
OECD Guideline 405, GLP, Reliability: 1	Albino rabbit, New Zealand white 3 males	Granule bait (0.005% bromadiolone) [REDACTED]	[REDACTED]	-	[REDACTED]

No human eye irritation data are available.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Protect Revolution rodenticide pellet is not an eye irritant.
Justification for the	[REDACTED]



value/conclusion	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 Revolution rodenticide pellet for this endpoint.

### ***Respiratory tract irritation***

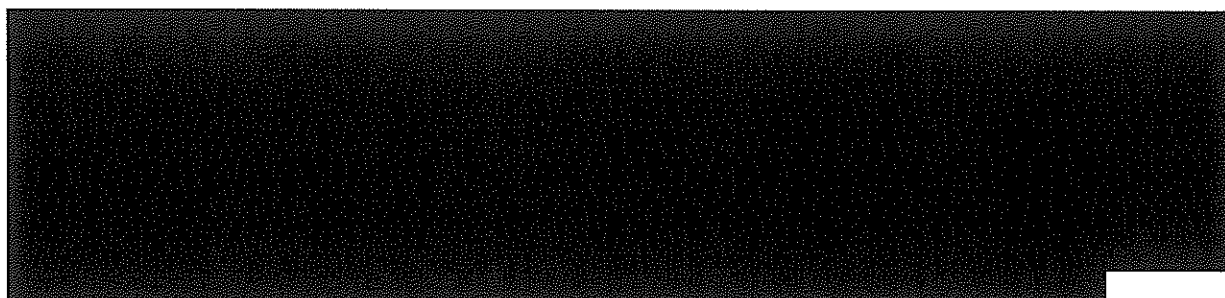
No animal studies or human data are available on respiratory tract irritation.

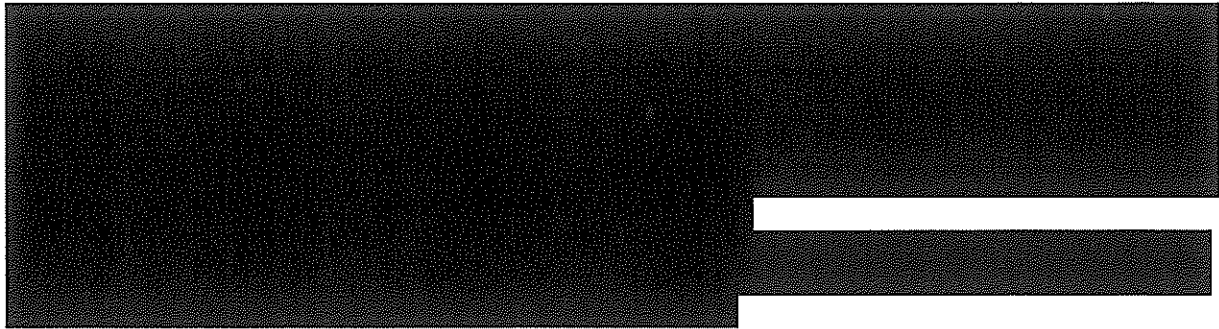
<b>Conclusion used in the Risk Assessment – Respiratory tract irritation</b>	
Justification for the conclusion	The product Protect Revolution rodenticide pellet is not expected to be irritating to the respiratory tract. The skin irritation study with the pellet product showed that Protect Revolution rodenticide pellet 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 Revolution rodenticide pellet for this endpoint.

<b>Data waiving</b>	
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 pellet (granule) product was negative and there are no indications that Protect Revolution rodenticide pellet 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 the pellet bait (previously named as granule bait) of Protect Revolution rodenticide pellet 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	Granule bait (0.005% bromadiolone), [REDACTED]	[REDACTED]	-	[REDACTED]

No human skin sensitization data are available.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Protect Revolution rodenticide pellet 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]

	████████████████████ Furthermore, there are no sensitizing components in the product.
Classification of the product according to CLP and DSD	No classification is required for Protect Revolution rodenticide pellet for this endpoint.

### ***Respiratory sensitization (ADS)***

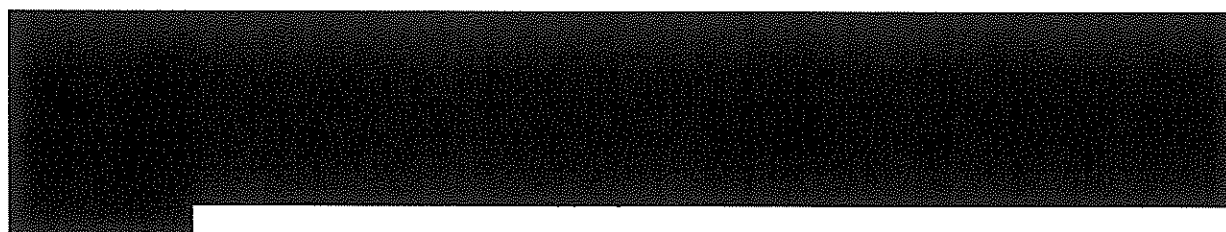
The product Protect Revolution rodenticide pellet is not a skin sensitizer based on the available study (see above). Furthermore, none of the components in the product are classified as respiratory or skin sensitizers. Currently no standard tests or guidelines exist for this endpoint however the product is not expected to possess such property. No further studies are considered relevant.

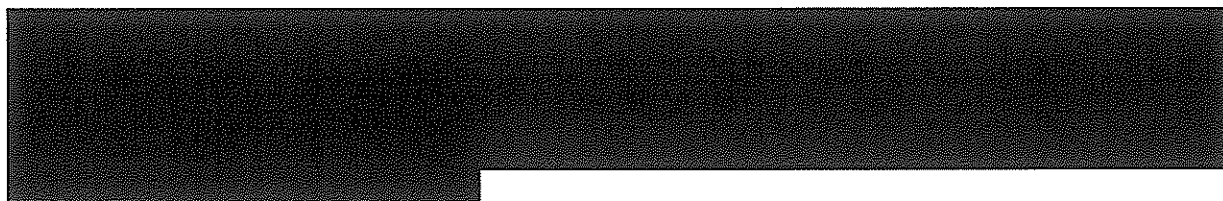
<b>Conclusion used in Risk Assessment – Respiratory sensitisation</b>	
Value/conclusion	The product is not considered a respiratory sensitizer.
Justification for the value/conclusion	The product is not a skin sensitizer and none of the constituents are classified for respiratory or skin sensitisation.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

<b>Data waiving</b>	
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 Revolution rodenticide pellet is not a skin sensitizer. None of the components in Protect Revolution rodenticide pellet 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*





Protect Revolution rodenticide pellet 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 administrati on (gavage, in diet, other)	Signs of toxicity (nature, onset, duration, severity, reversibility)	Value LD50	Remar ks (e.g. major deviati ons)	Referen ce
OECD Guideline 423, GLP, Reliability: 1	Rat, CrI(WI)BR 6 females (3/step)	<b>Granule bait</b> (0.005% bromadiolone)	[REDACTED]	> 2000 mg/kg	-	[REDACTED]

No human acute oral toxicity data are available.

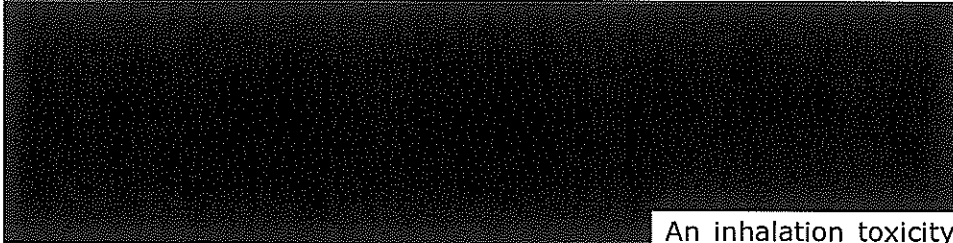
Value used in the Risk Assessment – Acute oral toxicity	
Value	Oral LD50 > 2000 mg/kg
Justification for the selected value	No mortality was observed in the above-mentioned study following administration of a single dose of 2000 mg/kg product.
Classification of the product according to CLP and DSD	No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

#### Acute toxicity by inhalation

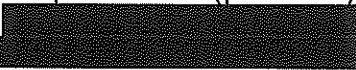
No acute inhalation toxicity studies were performed with Protect Revolution rodenticide pellet. The active substance is not volatile, other co-formulants in the product – mostly food grade materials – are not relevant for inhalation toxicity based on their classification and/or content. Inhalation exposure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


No human acute inhalation toxicity data are available.

<b>Value used in the Risk Assessment – Acute inhalation toxicity</b>	
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 Revolution rodenticide pellet 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.

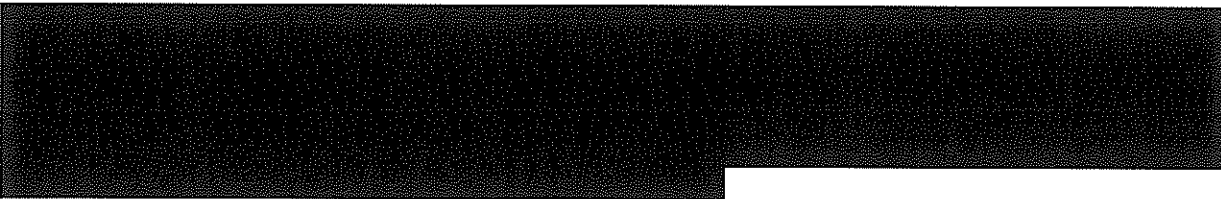
<b>Data waiving</b>	
Information requirement	Acute inhalation toxicity study performed with the product
Justification	 <p>An inhalation toxicity study is not considered relevant.</p>

Acute toxicity by dermal route

The following acute dermal toxicity study is available with the pellet bait (previously named as granule bait) of Protect Revolution rodenticide pellet. 







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.

<b>Summary table of animal studies on acute dermal toxicity</b>						
<b>Method, Guideline, GLP status, Reliability</b>	<b>Species, strain, Sex, No/group</b>	<b>Test substance, Vehicle, Dose levels, Surface area</b>	<b>Signs of toxicity (nature, onset, duration, severity, reversibility)</b>	<b>LD50</b>	<b>Remarks (e.g. major deviations)</b>	<b>Reference</b>
OECD Guideline 402, GLP Reliability: 1	Rat, CrI(WI)BR Preliminary study: 2/dose (female) Main study: 10/dose (5 male, 5 female)	<b>Granule bait</b> (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.

<b>Value used in the Risk Assessment – Acute dermal toxicity</b>	
Value	Dermal LD50 > 2000 mg/kg
Justification for the selected value	No mortality was observed in a limit test performed with the pellet bait (previously named as granule bait) of Protect Revolution rodenticide pellet.
Classification of the product according to CLP and DSD	No classification is required for this endpoint.

### **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).


The dermal absorption of **0.36%** from the solubilised granule formulation thus represents a worst case value, which is considered relevant for Protect Revolution rodenticide pellet. 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.

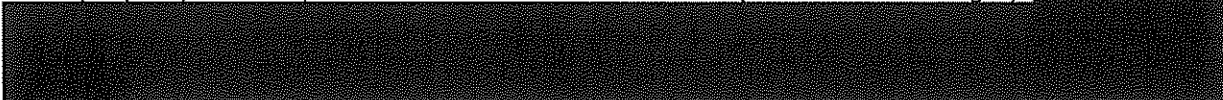
<b>Summary table of in vitro studies on dermal absorption</b>					
<b>Method, Guideline, GLP status, Reliability</b>	<b>Species, Number of skin samples tested per dose, Other relevant information about the study</b>	<b>Test substance, Doses</b>	<b>Absorption data for each compartment and final absorption value</b>	<b>Remarks (e.g. major deviations)</b>	<b>Reference</b>
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)

<b>Value(s) used in the Risk Assessment – Dermal absorption</b>			
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 Revolution rodenticide pellet.		

<b>Data waiving</b>	
Information requirement	Dermal absorption study performed with the product
Justification	A dermal absorption study with Protect Revolution rodenticide pellet 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 <i>in vitro</i> study was taken further to risk assessment calculations. The dermal absorption of Protect Revolution rodenticide pellet 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 Revolution rodenticide pellet are mostly food-grade materials which are not classified, or are present in such low concentrations that they do not have any influence on the non-toxic property of the product. Denatonium benzoate (in the bait and gel) 

  
The available studies on the pellet 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 Revolution rodenticide pellet. The co-formulants of Protect Revolution rodenticide pellet 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



### 2.2.7.2 Exposure assessment

Protect Revolution rodenticide pellet 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. For certain packaging types (90 g granule tray) the product is also packaged with 50 g of appetizing gel. This appetizer gel provides source of water for the target species in a different compartment on the same tray with the granules. The package containing the appetizer gel is intended for rat control for amateur users. The gel comprises mostly of water, none of the components of the gel have a human toxicological relevance (the constituents are not classified for human endpoints or are present in such low concentrations that they are irrelevant). The composition of the appetizer gel and the pellet bait can be found in the confidential composition statement.

#### 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	negligible	no
Oral	n.a.	no	no	n.a.	no	yes	no

The following exposure scenarios have been identified for Protect Revolution rodenticide pellet:

### ***List of scenarios***

<b>Summary table: scenarios</b>			
<b>Scenario number</b>	<b>Scenario (e.g. mixing/loading)</b>	<b>Primary or secondary exposure Description of scenario</b>	<b>Exposed group (e.g. professionals, non-professionals, bystanders)</b>
1.	Application	Primary exposure Loading and placing bait boxes	Professionals
2.	Post-application	Primary exposure Cleaning of bait boxes	Professionals
3.	Application	Primary exposure Loading and placing bait boxes	Non-professionals
4.	Post-application	Primary exposure Cleaning of bait boxes	Non-professionals
5.	Toddler oral exposure	Secondary exposure Toddler ingesting part of the bait	General public-toddlers
6.	Child oral exposure	Secondary exposure Child ingesting part of the bait	General public - children

### ***Industrial exposure***

Industrial use of Protect Revolution rodenticide pellet is not intended.

### ***Professional exposure***

Protect Revolution rodenticide pellet 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, 90, 125, 150 or 175 g bait in plastic tray covered by filter paper, in paper box up to 20 kg
- 75 or 90 g rodenticide bait with filter paper covering + 50 g appetizing gel with aluminium foil covering in 1 tray – up to 20 kg
- 20, 25 or 50 g bait in filter paper sachets, in carton paper box, up to 20 kg
- bulk in plastic bucket, up to 10 kg

- bulk in paper barrel, up to 10 kg
  - bulk in plastic sachet and in carton box, up to 10 kg
  - bulk in paper bag, up to 10 kg
- Min. net weight: 3 kg.

The maximum dose per bait point is 250 g for rats and 2 x 90 g for mice.

The worst case scenario for professional users is when the operator uses the product in bulk form. The maximum size of the packages is 10 kg, therefore (according to HEEG Opinion 12) mixing & loading phase (decanting of the bulk product) is not needed. Apart the mixing & loading two use phases can be identified for this use of Protect Revolution rodenticide pellet: application when bait is loaded into bait boxes; and post-application, when bait boxes are cleaned.

The active substance bromadiolone is not volatile. The solid pellet 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.

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 of 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 pellet 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.

[REDACTED]

[REDACTED]

[REDACTED]



Inhalation exposure in this use phase is considered negligible.

<b>Description of Scenario [1]</b>		
<b>Application – loading and placing bait boxes</b>		
Primary exposure of professional users		
Worst case: loading pellet bait from a bucket into bait stations using a plastic scoop without and with PPE		
	Parameters <sup>1</sup>	Value
[Redacted]	[Redacted]	[Redacted]
	[Redacted]	[Redacted]
	[Redacted]	[Redacted]
	[Redacted]	[Redacted]
	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]

<sup>1</sup> Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.

<sup>2</sup> Only include the parameters changed with respect to the previous Tier.

**Calculations for Scenario [1]**

<b>Summary table: estimated exposure from professional uses</b>					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1]	Tier 1, no PPE	[Redacted]	[Redacted]	[Redacted]	[Redacted]

Scenario [1]	Tier 2, with PPE	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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**Further information and considerations on scenario [1]**

No further information applicable.

Scenario [2]

[REDACTED]

[REDACTED]

[REDACTED]

Inhalation exposure in this use phase is considered negligible.

<b>Description of Scenario [2]</b>		
<b>Post-application – Cleaning of bait boxes</b>		
Primary exposure of professional users		
Worst case: emptying a loaded bait station containing pellet bait into a bucket without and with PPE		
	Parameters <sup>1</sup>	Value
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

<sup>1</sup> Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.

<sup>2</sup> Only include the parameters changed with respect to the previous Tier.

### Calculations for Scenario [2]

<b>Summary table: estimated exposure from professional uses</b>					
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake</b>	<b>Estimated dermal uptake</b>	<b>Estimated oral uptake</b>	<b>Estimated total uptake</b>
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.

#### 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.

<b>Summary table: combined systemic exposure from professional uses</b>				
<b>Scenarios combined</b>	<b>Estimated inhalation uptake</b>	<b>Estimated dermal uptake</b>	<b>Estimated oral uptake</b>	<b>Estimated total uptake</b>
Scenarios [1, 2]* Tier 1	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Scenarios [1, 2] Tier 2 with PPE	[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. 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 pellet 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, 90, 125, 150 or 175 g bait in plastic tray covered by filter paper, 1 or 2 trays in paper box or in plastic sachet
- 75 or 90 g rodenticide bait with filter paper covering + 50 g appetizing gel with aluminium foil covering in 1 tray – 1 or 2 trays in box
- 10, 20, 25 or 50 g bait in filter paper sachets, in carton paper box – up to 400 g
- 20 or 25 g bait in filter paper sachet, 2 sachet in plastic baiting box, 1 or 2 boxes in paper box
- 100, 150, 200, 250 or 300g bait in plastic sachet or aroma permeable sachet in carton paper box – up to 400 g
- 100, 150, 200, 250 or 300g bait in plastic sachet – up to 400 g

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.

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 [3]***

[REDACTED]

[REDACTED]

[REDACTED]

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

<b>Description of Scenario [3]</b>		
<b>Application – loading and placing bait boxes</b>		
Primary exposure of non-professional users		
Based on the exposure estimates of HEEG opinion 12 for loading pellet 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 <sup>1</sup>	Value
[REDACTED]	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

<sup>1</sup> Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.

<sup>2</sup> Only include the parameters changed with respect to the previous Tier.

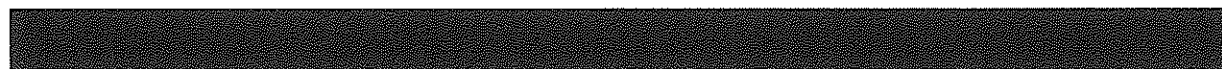
**Calculations for Scenario [3]**

<b>Summary table: systemic exposure from non-professional uses</b>					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [3]	Tier 1, no PPE	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

**Further information and considerations on scenario [3]**

No further information applicable.

Scenario [4]





[REDACTED]

[REDACTED]

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

<b>Description of Scenario [4]</b>		
<b>Post-application – Cleaning of bait boxes</b>		
Primary exposure of non-professional users without PPE		
	Parameters <sup>1</sup>	Value
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

<sup>1</sup> Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.

<sup>2</sup> Only include the parameters changed with respect to the previous Tier.

**Calculations for Scenario [4]**

<b>Summary table: systemic exposure from non-professional uses</b>					
<b>Exposure scenario</b>	<b>Tier/PPE</b>	<b>Estimated inhalation uptake</b>	<b>Estimated dermal uptake</b>	<b>Estimated oral uptake</b>	<b>Estimated total uptake</b>
Scenario [4]	Tier 1, no PPE	[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.

<b>Summary table: combined systemic exposure from non-professional uses</b>				
<b>Scenarios combined</b>	<b>Estimated inhalation uptake</b>	<b>Estimated dermal uptake</b>	<b>Estimated oral uptake</b>	<b>Estimated total uptake</b>
Scenarios [4,5] <sup>1</sup> Tier 1				

<sup>1</sup> Please include the Tier where relevant

### **Exposure of the general public**

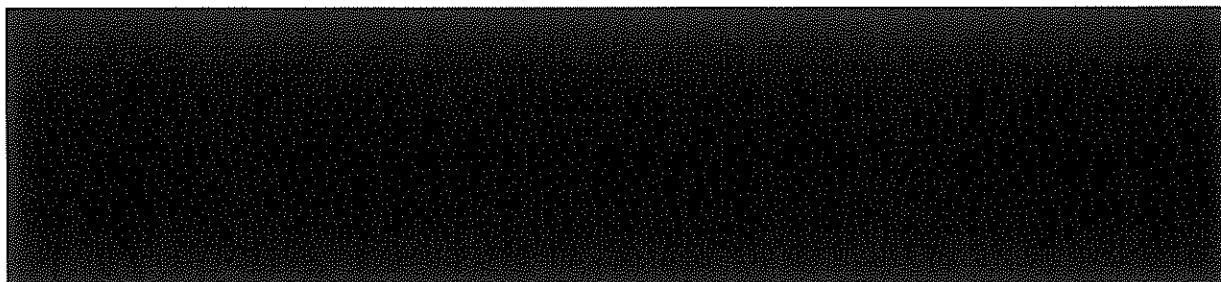
**Inhalation exposure** of non-users to residues during or after application via the environment is considered to be negligible. The active substance bromadiolone is not volatile, the product does not produce any dust and it is applied in bait stations or in ready-to-use trays, boxes or sachets which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

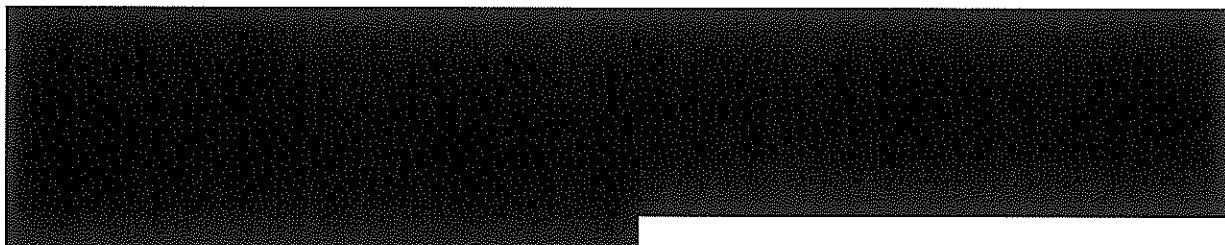
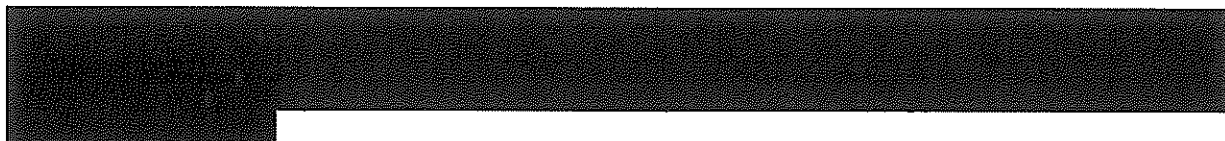
For adult non-users, the risk of **dermal exposure** to residues is considered negligible. Similarly, **oral exposure** is not considered to be relevant.

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 [5]





<b>Description of Scenario [5]</b>		
Toddler (1-2 years old, 10 kg) chewing and ingesting bait Secondary exposure PPE not relevant		
	Parameters <sup>1</sup>	Value

<sup>1</sup> Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.

<sup>2</sup> Only include the parameters changed with respect to the previous Tier.

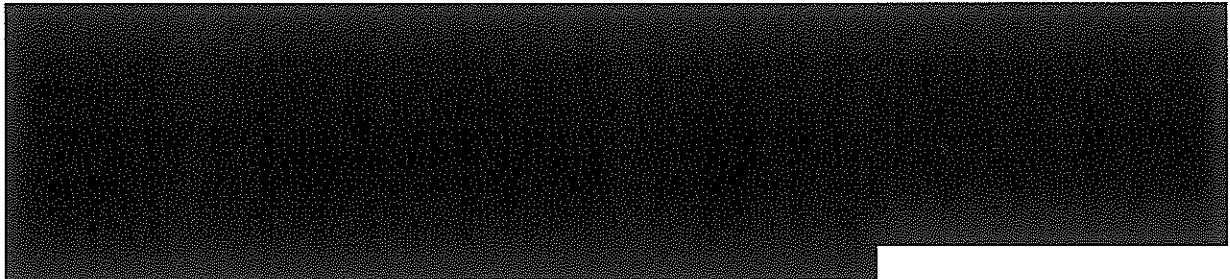
**Calculations for Scenario [5]**

<b>Summary table: systemic exposure from non-professional uses</b>					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [5]	Tier 1, no PPE				

**Further information and considerations on scenario [5]**

No further information applicable

*Scenario [6]*



<b>Description of Scenario [6]</b>		
Child (15.6 kg) chewing and ingesting bait Secondary exposure PPE not relevant		
	Parameters <sup>1</sup>	Value
[Redacted]	[Redacted]	[Redacted]
	[Redacted]	[Redacted]
	[Redacted]	[Redacted]
	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]

<sup>1</sup> Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.

<sup>2</sup> Only include the parameters changed with respect to the previous Tier.

**Calculations for Scenario [6]**

<b>Summary table: systemic exposure from non-professional uses</b>					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [6]	Tier 1, no PPE	[Redacted]	[Redacted]	[Redacted]	[Redacted]

**Further information and considerations on scenario [6]**

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 Revolution rodenticide pellet.

### **Dietary exposure**

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

### List of scenarios

Not considered relevant for Protect Revolution rodenticide pellet.

### Information of non-biocidal use of the active substance

Not considered relevant for Protect Revolution rodenticide pellet. No non-biocidal use is intended.

### Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not considered relevant for Protect Revolution rodenticide pellet.

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

Not considered relevant for Protect Revolution rodenticide pellet.

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

Not considered relevant for Protect Revolution rodenticide pellet.

### **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 Revolution rodenticide pellet 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 Revolution rodenticide pellet.

### ***Summary of exposure assessment***

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

### 2.2.7.3 Risk characterisation for human health

#### Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF <sup>1</sup>	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.

<sup>1</sup> 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 Revolution rodenticide pellet

#### Specific reference value for groundwater

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

#### Risk for industrial users

Industrial use of Protect Revolution rodenticide pellet is not intended.

#### Risk for professional users

For medium and long-term repeated exposure and risk calculations, an AEL<sub>medium-term</sub> and AEL<sub>chronic</sub> 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 application	Tier 1, no PPE	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	yes
Scenario 1. Professional application	Tier 2, with PPE	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	yes
Scenario 2., Professional cleaning	Tier 1, no PPE	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	yes
Scenario 2., Professional cleaning	Tier 2, with PPE	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	yes

Combination of scenarios 1 and 2 is considered relevant as 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, application + cleaning	Tier 1, no PPE	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	yes
Scenario 1+2, application + cleaning	Tier 2, with PPE	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	yes

**Local effects**

The product Protect Revolution rodenticide pellet 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 Revolution rodenticide pellet on a daily basis, wearing protective equipment, is acceptable.

Protective gloves are required for all use phases of the product ( application and cleanup). As the decanting phase can be omitted, respiratory equipment is not needed. Otherwise, inhalation exposure is negligible during other use phases. The presented calculations represent a worst case scenario of use.

In the worst case scenarios when no gloves are used, the AEL% values are [REDACTED] for application and clean-up, respectively, with a combined value of [REDACTED]. The risk is acceptable even without PPE, but as professional workers usually wear gloves, the risk is calculated for this case too.

In Tier 2, assessments with PPE [REDACTED], respectively, with a combined value of [REDACTED]

The calculations presented above show that the risk for professional users when using Protect Revolution rodenticide pellet is acceptable.

## ***Risk for non-professional users***

For the calculation of risks to non-professional users, the AEL<sub>acute</sub> of bromadiolone was used. The AEL<sub>acute</sub> 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<sub>acute</sub> 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**

<b>Task/ Scenario</b>	<b>Tier</b>	<b>Systemic LOAEL µg/kg bw/d</b>	<b>AEL µg/kg bw/d</b>	<b>Estimated uptake µg/kg bw/d</b>	<b>Estimated uptake/ AEL (%)</b>	<b>Acceptable (yes/no)</b>
Scenario 3. Non- professional application	Tier 1, no PPE	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	yes
Scenario 4. Non- professional cleaning	Tier 1, no PPE	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	yes

**Combined scenarios**

Scenarios combined	Tier	Systemic LOAEL $\mu\text{g}/\text{kg bw}/\text{d}$	AEL $\mu\text{g}/\text{kg bw}/\text{d}$	Estimated uptake $\mu\text{g}/\text{kg bw}/\text{d}$	Estimated uptake/AEL (%)	Acceptable (yes/no)
Scenario 3+4, application + cleaning	Tier 1, no PPE	██████████	██████████	██████████	██████████	yes

**Local effects**

The product Protect Revolution rodenticide pellet 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 the scenario recommended by HEEG opinion 10, the estimated AEL% is ██████████ for the application and ██████████ for the clean-up of Protect Revolution rodenticide pellet. 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 ██████████. This represents the risks for 5 manipulations. As with the use of 10g sachets 5 manipulations result in only 50g of placed bait and for non-professional users the highest dose recommended for rats is 150g, this means that the worst-case risk is ██████████ of the AEL (representing 15 manipulations). When larger sachets than 10g are used the number of manipulations and thus the risk will also be less, thus this value of ██████████ represents the worst-case situation.

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 $\text{mg}/\text{kg bw}/\text{d}$	AEL $\text{mg}/\text{kg bw}/\text{d}$	Estimated uptake $\text{mg}/\text{kg bw}/\text{d}$	Estimated uptake/AEL (%)	Acceptable (yes/no)
Scenario 5, toddler ingesting bait	Tier 1, no PPE	██████████	██████████	██████████	██████████	no

Scenario 6, child ingesting bait	Tier 1, no PPE					no
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### Combined scenarios

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

### Local effects

The product Protect Revolution rodenticide pellet 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 Revolution rodenticide pellet, it can be concluded that the available scenarios do not represent realistic events. The pellet 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 Revolution rodenticide pellet 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 Revolution rodenticide pellet 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 Revolution rodenticide pellet 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.

### **2.2.8 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 Revolution

rodenticide pellet 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.

## 2.2.9 Risk assessment for the environment

### 2.2.9.1 Effects assessment on the environment

No new studies have been performed for the renewal of Protect revolution rodenticide pellet. The conclusions of the initial assessment of the biocidal product are still considered valid. Environmental 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.

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 Revolution rodenticide pellet can be assessed based on the data on the active substance.

The formulation of bromadiolone in Protect Revolution rodenticide pellet 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<sub>50</sub> was between 5.8 and 23.6 days, DT<sub>90</sub> 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 (t<sub>1/2</sub> 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<sub>50</sub> was 2.86 for *Oncorhynchus mykiss*.

*D. magna* was the least sensitive, with a 48-hour EC<sub>50</sub> 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  $\mu$ g/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
<b>Fish</b>			
<i>Oncorhynchus mykiss</i>	96 hours	mortality	$LC_{50}$ = 2.86 mg/L (nominal)
<b>Invertebrates</b>			
<i>Daphnia magna</i>	48 hours	lethality immobilisation	$EC_{50}$ = 5.79 mg/L (nominal)
<b>Algae</b>			
<i>Pseudokirchneriella subcapitata</i>	72 hours	growth inhibition (gr)	$E_rC_{50}$ = 1.14 mg/L (geometric mean of the initial measured conc. and half the LOQ)
<b>Microorganisms</b>			
Activated sludge	3 hours	respiration inhibition	$EC_{50}$ = 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	$E_r C_{50} = 1.14$ mg/L	1000x3	$3.8 \cdot 10^{-4}$ 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 ( <i>Coturnix coturnix japonica</i> ) 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: $5 \cdot 10^{-4}$ 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 Revolution rodenticide pellet 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.

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 Revolution rodenticide pellet.

<b>Data waiving</b>	
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 Revolution rodenticide pellet 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 Revolution rodenticide pellet.

<b>Data waiving</b>	
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 Revolution rodenticide pellet are necessary.

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

No further trials have been conducted with Protect Revolution rodenticide pellet. 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.

<b>Data waiving</b>	
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 Revolution rodenticide pellet are necessary.
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***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 Revolution rodenticide pellet. 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.

<b>Data waiving</b>	
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 Revolution rodenticide pellet 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 Revolution rodenticide pellet 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 Revolution rodenticide pellet 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, the vapour pressure is very low ( $2.13 \times 10^{-8}$  Pa, 20°C), the Henry's law constant is very low ( $4.25 \times 10^{-4}$  Pa.m<sup>3</sup>.mol<sup>-1</sup>) and bromadiolone is rapidly degraded in air (DT<sub>50</sub> ~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 Revolution rodenticide pellet. 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.

<b>Data waiving</b>	
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 Revolution rodenticide pellet 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 Revolution rodenticide pellet. 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.

<b>Data waiving</b>	
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 Revolution rodenticide pellet 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 Revolution rodenticide pellet. 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.

<b>Data waiving</b>	
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 Revolution rodenticide pellet 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 Revolution rodenticide pellet. See justification below.

<b>Data waiving</b>	
Information requirement	Testing for distribution and dissipation in air (ADS)
Justification	The concentration of bromadiolone present in the product is very

	low, the vapour pressure is very low ( $2.13 \times 10^{-8}$ Pa, 20°C), the Henry's law constant is very low ( $4.25 \times 10^{-4}$ Pa.m <sup>3</sup> .mol <sup>-1</sup> ) and bromadiolone is rapidly degraded in air (DT <sub>50</sub> ~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.
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***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 pellet 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 pellet 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 Revolution rodenticide pellet. The product is an anticoagulant rodenticide which will not present any risks to bees and other arthropods.

### 2.2.9.2 Exposure assessment

#### General information

Assessed PT	PT 14
Assessed scenarios	Scenario 1: Use of Protect Revolution rodenticide pellet 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 Revolution rodenticide pellet in and around buildings**

Protect Revolution rodenticide pellet contains 0.0027 % w/w bromadiolone, for the use by professional and non-professional users against brown rat (*Rattus norvegicus*) and house mouse (*Mus musculus*).

The maximum amount of product used per application is 250 g bait against rats and 100 g against mice (professional users). For non-professional users, the maximum applied dose is 2 x 90 g for rats and 100 g for mice.

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.

<b>Input parameters for calculating the local emission</b>			
<b>Input</b>	<b>Value</b>	<b>Unit</b>	<b>Remarks</b>
<b>Scenario: Use of Protect Revolution rodenticide pellet in and around buildings</b>			
Application rate of biocidal product	maximum 250	g	per baiting point professional use against rats
	maximum 100	g	per baiting point professional use against mice
	maximum 2 x 90	g	per baiting point non-professional use against rats
	maximum 100	g	per baiting point non-professional use against mice
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***

<b>Identification of relevant receiving compartments based on the exposure pathway</b>									
	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.

<b>Input parameters (only set values) for calculating the fate and distribution in the environment</b>			
<b>Input</b>	<b>Value</b>	<b>Unit</b>	<b>Remarks</b>
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)	$2.13 \times 10^{-8}$	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)	$4.25 \times 10^{-4}$	Pa m <sup>3</sup> /mol	
Biodegradability	not readily biodegradable		
Rate constant for STP [if measured data available]	not available		
DT <sub>50</sub> for biodegradation in surface water	not readily biodegradable		
DT <sub>50</sub> for hydrolysis in surface water	no hydrolysis		
DT <sub>50</sub> for photolysis in surface water	between 2.98 and 30.4	minutes	
DT <sub>50</sub> for degradation in soil	between 5.8 and 23.6	d (at 20°C)	
DT <sub>50</sub> for degradation in air	not relevant		

<b>Calculated fate and distribution in the STP [if STP is a relevant compartment]</b>		
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 <sub>STP</sub>	PEC <sub>water</sub>	PEC <sub>sed</sub>	PEC <sub>seawater</sub>	PEC <sub>seased</sub>	PEC <sub>soil</sub>	PEC <sub>GW</sub> <sup>1</sup>	PEC <sub>air</sub>
	[ng/l]	[ng/l]	[mg/kg <sub>wwt</sub> ]	[mg/l]	[mg/kg <sub>wwt</sub> ]	[mg/kg]	[mg/l]	[mg/m <sup>3</sup> ]
Scenario 1	n.a.	n.a.	n.a.	n.a.	n.a.	████	████	n.a.

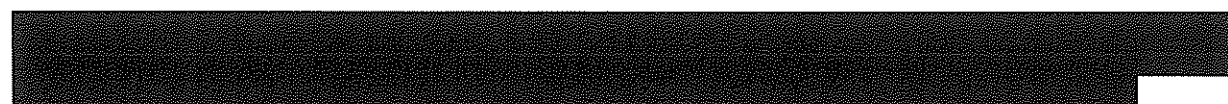
<sup>1</sup> If the PEC<sub>GW</sub> was calculated by using a simulation tool (e.g. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table.

### 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

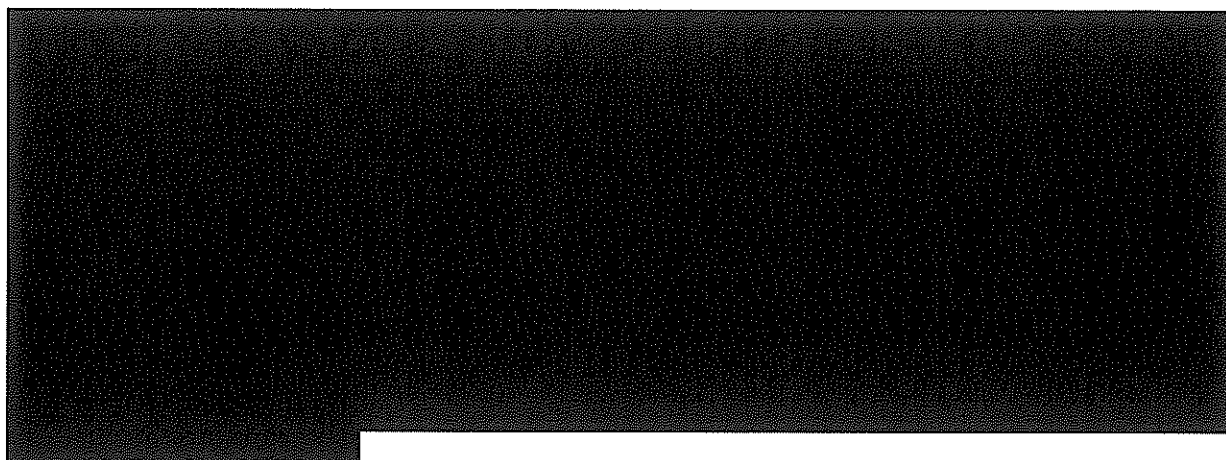
Non-target animals, such as wild and domestic animals may come in contact with baits if the bait is incompletely protected or if bait stations have been damaged. Also, well protected bait may be encountered by animals which are small enough to be able to reach the bait, and therefore may be subject to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



#### 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	████
Mammals	Rabbit 90-day	████





$$ETE = (FIR/BW) * C * AV * PT * PD \text{ (mg/kg bw/day)} \quad \text{(ESD - Eq. 19)}$$

**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	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Pig	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Pig, young	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Tree sparrow	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Chaffinch	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Wood pigeon	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Pheasant	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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 (EI) have to be considered. According to the ESD, a default value of 0.3 for EI can be used if no studies are submitted that show different.

Calculations are performed according to equation 20 in the ESD.

$$EC = ETE * (1 - EI) \quad \text{(Eq. 20)}$$

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

Pig, young	
Tree sparrow	
Chaffinch	
Wood pigeon	
Pheasant	

### 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).



$$ETE = (FIR/BW) * C * AV * PT * PD \text{ (mg/kg bw/day)} \quad (\text{ESD - Eq. 19})$$

This equation gives the concentration of bromadiolone in the rat ( $PEC_{\text{oral}}$ ) 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:

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

(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	■	■	■
Day 2 before new meal	■	■	■
Day 5 after the last meal	■	■	■
Day 7 mean time to death	■	■	■

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<sub>oral</sub>.

For the Tier 2 assessment the average food intake for each species and the average weight of the species have been considered, and the values are taken from table 3.5 in the ESD. The amount of a.i. consumed by the non-target animal is 7.49 mg/kg bw for rodents caught on day 5 and 8.94 mg/kg bw for resistant rodents caught on day 14, also assuming that the non-target animals feed to 50 % on the rodents, all in accordance with the ESD. By knowing the amount of a.i. consumed by the non-target animal and the weight of the animal the PEC (concentration in non-target animal) after one day consumption of rodents can be calculated. The results are presented in the table below.

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 ( <i>Tyto alba</i> )	■	■	■	■	■	■
Kestrel ( <i>Falco tinnunculus</i> )	■	■	■	■	■	■
Little owl ( <i>Athene noctua</i> )	■	■	■	■	■	■
Tawny owl ( <i>Strix aluco</i> )	■	■	■	■	■	■
Fox ( <i>Vulpes vulpes</i> )	■	■	■	■	■	■
Polecat ( <i>Mustela putorius</i> )	■	■	■	■	■	■
Stoat ( <i>Mustela erminea</i> )	■	■	■	■	■	■
Weasel ( <i>Mustela nivalis</i> )	■	■	■	■	■	■

### 2.2.9.3 Risk characterisation

#### ***Atmosphere***

Conclusion: Since bromadiolone will be used only locally and since it has a low vapour pressure,  $1 \cdot 10^{-7}$  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 <sub>STP</sub>
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 <sub>water</sub>	PEC/PNEC <sub>sed</sub>	PEC/PNEC <sub>seawater</sub>	PEC/PNEC <sub>seased</sub>
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<sub>soil</sub>, which is the sum of the direct and indirect contamination, was determined to be [REDACTED].

PEC/PNEC<sub>soil</sub> = [REDACTED]

Calculated PEC/PNEC values	
	PEC/PNEC <sub>soil</sub>
Scenario 1	█

Conclusion:

The risk for soil organisms when bromadiolone is used around buildings is acceptable

### **Groundwater**

Scenario 1 (use in and around buildings):

PEC<sub>groundwater</sub> was assumed to be equal to PEC<sub>local porewater</sub>, i.e. dilution is not taken into account, and was calculated to be █.

The maximum permissible concentration according to directive 98/83/EC is  $1 \cdot 10^{-4}$  mg/l.

Conclusion:

The calculated predicted concentration is below the trigger value of 0.1 µg/L. Therefore, the risk for groundwater is acceptable.

### **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	A F	PEC (concentration in food, mg/kg)	PNEC (concentration in food)	PEC/PNEC
Birds	Japanese quail (Coturnix coturnix japonica) reproduction test	█	█	█	█	█
Mammals	Rabbit 90-day	█	█	█	█	█

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 quantitatively to the LD50 values in the table.

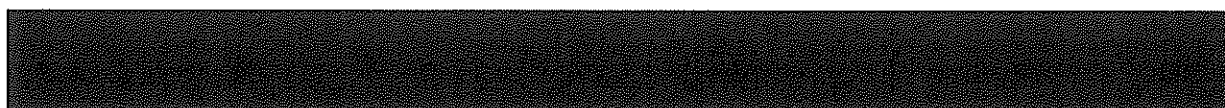
Non-target animal	PECoral = ETE, concentration of bromadiolone after one meal (mg/kg)		LD50 (mg/kg bw/d)	PECoral higher than LD50 (y/n)	
	Step 1	Step 2		Step 1	Step 2
Dog				n	n
Pig				n	n
Pig, young				n	n
Tree sparrow				n	n
Chaffinch				n	n
Wood pigeon				n	n
Pheasant				n	n

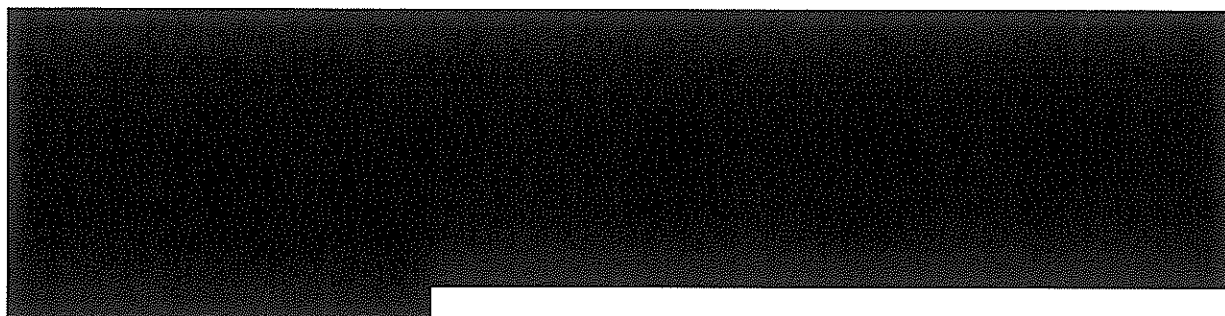
The long-term PNEC values used for mammals and birds are those from rabbit and Japanese quail and they are presented in the table below.

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

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





**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)
	PD = 0.2	PD = 0.5	PD = 1	
Mammals	█	█	█	█
Birds	█	█	█	█

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<sub>oral</sub> 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.

	PNEC <sub>oral</sub> (conc. in food)	PEC <sub>oral</sub> Bromadiolone conc. in target rodent (mg/kg bw), ESD default values	PEC/PNEC
Birds	█	█	█
Mammals	█	█	█

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 ( <i>Tyto alba</i> )	████	████	██	████	████	██
Kestrel ( <i>Falco tinnunculus</i> )	████	████	██	████	████	██
Little owl ( <i>Athene noctua</i> )	████	████	██	████	████	██
Tawny owl ( <i>Strix aluco</i> )	████	████	██	██	████	██
Fox ( <i>Vulpes vulpes</i> )	████	████	██	████	████	██
Polecat ( <i>Mustela putorius</i> )	████	████	██	████	████	██
Stoat ( <i>Mustela erminea</i> )	████	████	██	████	████	██
Weasel ( <i>Mustela nivalis</i> )	████	████	██	████	████	██

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 Revolution rodenticide pellet. 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; ██████████  
 ██████████  
 ██████████  
 (for the exact concentration see confidential composition statement) 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 Revolution rodenticide pellet.

<b>Screening step</b>	
	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 Revolution rodenticide pellet.

***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 Revolution rodenticide pellet.

Decision steps:

Other regulatory areas: No

Different user categories: Yes

Overlap in time and space: No

Conclusion: No aggregated exposure estimation required



### **2.2.12 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<sup>2</sup>

### 3.1 List of studies for the biocidal product

Physical-chemical studies:

1. Partial Validation of the Analytical Method for the Determination of Bromadiolone in Protect Rodenticide Pellet, GLP, Study No: 484-100-2757, Dat: August, 2017
2. Determination of Bromadiolone Active Ingredient Content in Protect Rodenticide pellet, GLP, Study No.: 484-195-2758, Date: August, 2017
3. Determination of the appearance (physical state, colour, odour) of Protect Revolution Rodenticide Pellet which was manufactured on 20th October 2016 and stored in GMP certified warehouse of Bábolna Bio Ltd at 22-28°C – TOXI-COOP ZRT - Study Report 484-630-4134
4. Determination of Bromadiolon active ingredient content in Protect Revolution Rodenticide Pellet which was manufactured on 20th October 2016 and stored in GMP certified warehouse of Bábolna Bio Ltd at 22-28°C. – TOXI-COOP ZRT - Study Report 484-195-4133

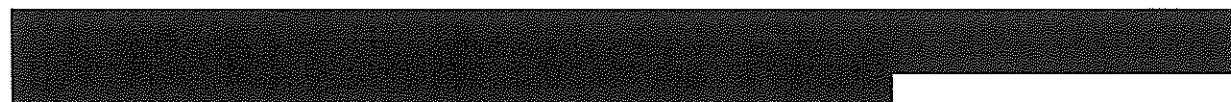
Efficacy:

8 new efficacy studies were submitted to support the major change in parallel with the renewal of the product.:

1. Laboratory test. Palatability – mortality trial study. Biological Laboratory of Bábolna Bio Ltd., Hungary study no.:161.039
2. Laboratory test. Palatability – mortality trial study. Biological Laboratory of Bábolna Bio Ltd., Hungary study no.:161.041
3. Semi-field test carried out in a semi-field trial room Biological Laboratory of Bábolna Bio Ltd., Hungary study no.:161.095
4. Semi-field test carried out in semi-field trial rooms Biological Laboratory of Bábolna Bio Ltd., Hungary study no.:161.100
5. Field test in an attic of a residential house. IZIPEST® ref. no.: 17MmBA003
6. Field test in an amateur hen yard. IZIPEST® ref. no.: 17RnBA005
7. Field test in an amateur hen yard. IZIPEST® ref. no.: 17RnBA007
8. Semi-field test carried out in semi-field trial rooms Biological Laboratory of Bábolna Bio Ltd., Hungary study no.:161.032
9. Laboratory no-choice test with resistant Norway rats. IZIPEST® ref. no.: 16BAB001

### 3.2 Output tables from exposure assessment tools

#### Environmental exposure calculations and considerations for scenario 1 – use in and around buildings



<sup>2</sup> When an annex is not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

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

(ESD - Eq. 3)

[Redacted]

[Redacted]

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

[Redacted]

[Redacted]

[Redacted]

[Redacted]



### **Calculation of PEC in groundwater**

[REDACTED]

[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)**

Nine 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**

See confidential annex below.

### **3.7 Other**

Not applicable.

