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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

Product identifier in R4BP	Secuverd 26
Product type(s):	14 (Rodenticide)
Active ingredient(s):	Coumatetralyl
Case No. in R4BP	BC-WA026164-52
Asset No. in R4BP	DE-0015601-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/14.00024 710-05-14-00024-00-00-00-0000
Date	13.02.2018

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1 Conclusion

The assessment presented in this report has shown the efficacy but no unacceptable risks, if the ready-to-use product, "Secuverd 26" with the active substance coumatetralyl (0.0027 % w/w) is used as an rodenticide (product-type 14) for the control of norway rats in and around buildings and the control of voles (of the types bank vole (*Myodes glareolus*) and common vole (*Microtus arvalis*)) around buildings and for use in bait stations.

The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[1] are fulfilled.

Please find detailed information on the uses appropriate for authorisation in chapter 2.4.
General directions for use of the product are summarised in chapter 2.5.

A classification according to Regulation (EC) No 1272/2008[2] is not necessary. Detailed information on classification and labelling is provided in chapter 2.3.

The assessment of the intended use(s) as applied for by the applicant (see chapter 3.1) has taken the following into consideration:

1. The conclusions and recommendations of the Danish Assessment Report for the approval of the active substance coumatetralyl including the "elements to be taken into account by Member States when authorising products" as requested by the Danish CA.
2. The specific provisions from the renewal of the approval of the active substance (PT14) coumatetralyl (Commission implementing regulation (EU) 2017/1378).

Approval of the active substance
The active substance coumatetralyl is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

(1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance. In addition, pursuant to point 10 of Annex

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.
[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied.

(2) Products shall only be authorised for use in Member States where at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 is satisfied.

(3) The nominal concentration of coumatetralyl in the products shall not exceed 375 mg/kg in products other than contact formulations.

(4) Products shall contain an aversive agent and a dye.

(5) Products shall not be authorised in the form of tracking powder.

(6) Products shall not be authorised for use in permanent or pulse baiting treatments.

(7) Only ready-to-use products shall be authorised.

(8) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include for example the restriction to professional or trained professional use when possible and setting additional specific conditions per user category.

(9) Dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the summary of the product characteristics of the national authorisation and be reflected on the product label.

In addition to the general conditions, the authorisations of biocidal products to be used by the general public are subject to the following conditions:

(10) Products shall only be authorised for use in tamper-resistant bait stations.

(11) Products shall only be supplied with a maximum quantity of bait per pack of:

- for products against rats only, or mice and rats:
  - for paste baits: 750 g

(12) Products against Rattus norvegicus and Rattus rattus shall only be authorised for use indoors or in and around buildings.

(13) Persons making products available on the market shall ensure that the products are accompanied by information on the risks associated with anticoagulant rodenticides in general, measures to limit their use to the minimum necessary and appropriate precautionary steps to be taken.

Composition and formulation

The ready-to-use paste bait “Secuverd 26” contains the active substance coumatetralyl.

No substance of concern has been identified.

Please refer to chapter 2.2 (Composition and formulation) and 5.1 (Full composition of the product) for detailed information.

Physical, chemical and technical properties

The physical, chemical and technical properties have been determined and deemed acceptable (please find more information in chapter 3.2).

Physical hazards and respective characteristics

Physical-chemical hazard(s) were not identified (please find more information in chapter 3.3).

Methods for detection and identification

Information on the analytical methods for the active substance is provided in chapter 3.4. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms

The product has been shown to be efficacious for the uses appropriate for authorisation listed in chapter 2.4. Please find more information on efficacy of the product in chapter 3.5.

Risk assessment for human health

Since no relevant substance of concern has been identified the human health risk assessment for this product is based on the active substance.
Accordingly, the human health risk assessment for this product is based on the active substance

A human health risk assessment has been carried out for non-professional use of the product (see chapter 3.6) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to non-professional users, bystanders and residents. Regarding non-professional users health protection, there are no objections against the intended uses if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

Risk assessment for the environment

Since no relevant substance of concern has been identified the risk assessment for the environment for this product is based on the active substance.
A risk assessment for the environment has been carried out for non-professional use of the product (see chapter 3.8) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable risk for the environment if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

Comparative Assessment

Since the active substance coumatetralyl has been identified as a candidate for substitution (see also chapter 2.2.4) a comparative assessment has been necessary (see chapter 3.10). The corresponding Comparative Assessment Report was forwarded to ECHA on 17.01.2018.

The German CA concludes that without coumatetralyl based products there is not an adequate chemical diversity.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Secuverd 26

2.1.2 Manufacturer(s) of the product

Name of manufacturer	Bayer S.A.S.
Address of manufacturer	16 rue Jean-Marie Leclair 69266 Lyon (Cedex 09) France
Location of manufacturing sites	INDUSTRIALCHIMICA Srl Via Sorgaglia 40 I-35020 Arre (PD) Italy

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

Active substance	Coumatetralyl
Name of manufacturer	Bayer S.A.S.
Address of manufacturer	16 rue Jean-Marie Leclair 69266 Lyon (Cedex 09) France
Location of manufacturing sites	AlzChem Trostberg GmbH Chemiepark Trostberg, Dr. Albert Frank Str. 32 83308 Trostberg Germany
	The decision on the technical equivalence of the active substance from this source was taken by the German CA before the Regulation (EU) No 528/2012 entered into force. The corresponding Technical Equivalence Report

	(TER_DE_130624.pdf) can be found in the R4BP (DE-0002228-0000).

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Coumatetralyl	4-Hydroxy-3-(1,2,3,4-tetrahydro-1-naphthalenyl)-2H-chromen-2-one	Active substance	5836-29-3	227-424-0	0.0027

- Information on the full composition is provided in the confidential[3] annex (see chapter 5).

- 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 ☒

- According to the information provided the product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012.

2.2.2 Information on technical equivalence

- Is the source of the active substance(s) the same as the one 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 ☐

[3] Access level: "Restricted" to applicant and authority

2.2.3 Information on the substance(s) of concern

No substance of concern was identified.

2.2.4 Candidate(s) for substitution

The following candidate(s) for substitution was/were identified:

- Coumatetralyl

The following exclusion criteria are met:

- Toxic for reproduction category 1B

2.2.5 Type of formulation

Ready-to-use paste bait

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008

Besides the active substance coumatetralyl the other components do not affect the classification of the biocidal product.
A harmonised classification for the active substance coumatetralyl exists. The current harmonised classification of the active substance coumatetralyl is based on Commission Regulation (EU) No. 2016/1179 (9th ATP).

Classification of the biocidal product pursuant to the Regulation (EC) 1272/2008 is not required.
Since the biocidal product has no classification, no labelling according to Regulation (EC) No 1272/2008 is required.

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.5 and if applicable to chapter 2.4.

2.4 Use(s) appropriate for authorisation[4]

2.4.1 Use 1 appropriate for authorisation – Norway rats

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Norway rats (*Rattus norvegicus*),(adults and juveniles)
Field(s) of use	In and around buildings
Application method(s)	Ready-to-use bait In tamper-resistant bait stations
Application rate(s) and frequency	200 g/baiting station If more than one bait station is needed, the minimum distance between bait stations should be of 5-20 meters
Category(ies) of users	General public
Pack sizes and packaging material	10 g tea bag (long fiber paper) in bottle (up to 750 g, PET) or in sachet (up to 750 g, COEX PET/PE) or in sachet (90g-750 g, LDPE) Tertiary packaging: COEX PET/PE sachets in cardboard case; LDPE sachets in PP bucket

2.4.1.1 Use-specific instructions for use

None

2.4.1.2 Use-specific risk mitigation measures

None

4 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

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

None

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

None

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

None

2.4.2 Use 2 appropriate for authorisation – Voles

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Voles of the types bank vole (Myodes glareolus) and common vole (Microtus arvalis),(adults and juveniles)
Field(s) of use	Around buildings
Application method(s)	Ready-to-use bait In tamper-resistant bait stations
Application rate(s) and frequency	20g/ baiting station. One to three applications within 10 days. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters
Category(ies) of users	General public
Pack sizes and packaging material	10 g tea bag (long fiber paper) in bottle (up to 750 g, PET) or in sachet (up to 750 g, COEX PET/PE) or in sachet (90g-750 g, LDPE) Tertiary packaging: COEX PET/PE sachets in cardboard case; LDPE sachets in PP bucket

2.4.2.1 Use-specific instructions for use

None

2.4.2.2 Use-specific risk mitigation measures

None

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

None

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

None

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

None

2.5 General directions for use

2.5.1 Instructions for use

1) Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it. 2) Prior to the use of rodenticide products, non-chemical control methods should be considered. Especially for the control of voles and occasionally appearing rats, traps should be considered.

The use of biocidal products is the last method of choice and should always be reduced to a minimum.

3) The preferred places of rodent activity (travel paths, nesting sites, feedlots) in and around buildings have to be determined by e.g. displaying small amount of poison free baits such as oat flakes. Signs of gnawing and rodent faeces are also indications for rodent activity. Note that the poison free baits should be removed before the actual rodent control measure.
4) 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.
5) Bait stations should be placed where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, etc.).
6) Where possible, bait stations must be fixed to the ground or other structures.
7) Do not open the tea bags containing the bait.
8) Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.
9) Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
10) Do not place bait stations near water drainage systems where they can come into contact with water.
11) When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
12) Prior to the rodent control measure all users of the premises and buildings and their surroundings, where baits are placed, have to be informed about the risks for humans, pets and wild animals. They also have to be informed about measures in the case of poisoning, bait spillage or the discovery of dead rodents (according to the product label).
13) The campaign has to be terminated if there is no further consumption of baits.
14) Remove the remaining bait or the bait stations at the end of the treatment period.
15) Undamaged bait stations can be reused.
16) To avoid a re-infestation after a successful control operation, the following measures should be taken:
    - Food and water sources (food, rubbish, etc.) should be removed or covered.
    - Elimination of debris and waste that might be used as hideouts. The vegetation cover in the immediate vicinity of buildings should be removed where necessary.
    - Make all eventually existing entries in buildings (e.g. cleaving, loopholes, cat flaps, drainages) inaccessible to rodents as far as possible.
17) Place the bait stations in areas not liable to flooding.
18) Replace any bait in a bait station in which bait has been damaged by water or contaminated by

dirt.

19) 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.

2.5.2 Risk mitigation measures

1) Keep out of the reach of children.
2) Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).
3) 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")
4) Bait stations have to be used. Baits must be secured in the bait stations to prevent carriage of the baits by rodents, unless this is not possible due to the formulation of the baits and the design of the bait stations. Placing of baits without bait stations presents a high risk of poisoning for humans, pets and wild animals.
5) 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.
6) Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.
7) Dispose dead rodents in household waste or in a rendering plant. Avoid direct contact.
8) Do not apply this product directly in the burrows.
9) Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.

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

1) 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.
2) Antidote: Vitamin K1 administered by medical/veterinary personnel only.

3) In case of:
   Dermal exposure, wash skin with water and then with water and soap.
   Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
   Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label. Contact a veterinary surgeon in case of ingestion by a pet.
4) Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name "; "active substance(s)" and "in case of incident, call a poison centre [insert national phone number]".
5) Hazardous to wildlife.

2.5.4 Instructions for safe disposal of the product and its packaging

1) At the end of the treatment, dispose uneaten bait and the packaging in accordance with local requirements.
2) Prevent skin contact when disposing remains of baits.
3) Use of gloves is recommended.

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

1) Store in places prevented from the access of children, birds, pets and farm animals.
2) Keep away from food, drink and animal feeding stuffs.
3) Shelf life: 24 months.

2.5.6 Other information

1) Because of their delayed mode of action, anticoagulant rodenticides take from 4 to 10 days to be effective after consumption of the bait.
2) Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.
3) This product contains a bittering agent and a dye.

2.6 Packaging

Table 2

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Tea bag	10 g	long fiber paper	-	General public	Yes
Tea bags in bottle	up to 750 g	PET			
Tea bags in sachet	up to 750 g	COEX PET/PE			
	90 g – 750 g	LDPE			

The product is a bait for against voles and rats. Such products shall only be supplied to the general public with a maximum quantity of 750 g bait per pack.

3 Assessment of the product

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

3.1.1 Intended use 1 – Norway rats control

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Norway rats (*Rattus norvegicus*), adults and juveniles
Field(s) of use	In and around buildings
Application method(s)	Bait application: Open and in bait stations
Application rate(s) and frequency	High infestation: 100-200 g/ bait point Low infestation: 60–100 g/ bait point
Category(ies) of users	General public
Pack sizes and packaging material	10 g tea bag (long fiber paper) in bottle (up to 1kg, PET) or in sachet (up to 1.5kg, COEX PET/PE) or in sachet (90g-1,5kg, LDPE)

3.1.2 Intended use 2 – Voles control

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Bank voles (*Microtidae*), adults and juveniles; Water voles (*Microtidae*), adults and juveniles
Field(s) of use	Around buildings
Application method(s)	Bait application: Open in burrows.
Application rate(s) and frequency	20g/ baiting point. One to three applications within 10 days.
Category(ies) of users	General public
Pack sizes and packaging material	10 g tea bag (long fiber paper) in bottle (up to 1kg, PET) or in sachet (up to 1.5kg, COEX PET/PE) or in sachet (90g-1,5kg, LDPE)

3.2 Physical, chemical and technical properties

Table 3: Physical, chemical and technical properties of the Biocidal product

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual assessment	Coumatetralyl RB 0,0029, Batch No.: 2015-009027, 0.002709% coumatetralyl	Solid soft block	Rodriguez, N., *Determination of physico-chemical properties and storage stability test for Coumatetralyl RB 0.0029 in Cardboard boxes with PET/ PE bags,* Study No. Mo5394, **2016**.
Colour at 20 °C and 101.3 kPa	Visual assessment		Blue	
Odour at 20 °C and 101.3 kPa	Olfactory assessment		Weak cereal-like	
Acidity / alkalinity	CIPAC MT 75.3	Coumatetralyl RB 0,0029, Batch No.: 2015-009027, 0.002709% coumatetralyl	1% w/v dilution: pH 6.4 at 21.5°C	Rodriguez, N., *Determination of physico-chemical properties and storage stability test for Coumatetralyl RB 0.0029 in Cardboard boxes with PET/ PE bags,* Study No. Mo5394, **2016**.
Relative density / bulk density	EU Method A.3	Coumatetralyl RB 0,0029, Batch No.: 2015-009027, 0.002709% coumatetralyl	1.183 g/cm^3 at 20°C	Rodriguez, N., *Determination of physico-chemical properties and storage stability test for Coumatetralyl RB 0.0029 in Cardboard boxes with PET/ PE bags,* Study No. Mo5394, **2016**.
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Coumatetralyl RB 0,0029, Batch No.: 2015-009027, 0.002709% coumatetralyl	Storage: 14 days at 54°C **Active substance content:** ▫ Initial: 0.002709% ▫ After 14 days at 54°C: 0.002603%	Rodriguez, N., *Determination of physico-chemical properties and storage stability test for Coumatetralyl RB 0.0029 in Cardboard boxes with PET/ PE*

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			(-3.9%) **Bittering agent content:** ▫ Initial: 0.0019% ▫ After 14 days at 54°C: 0.0018% (-5.3%) **Weight loss:** ▫ Initial: - ▫ After 14 days at 54°C: -1.20% **pH value (1 % in deionized water, according to CIPAC MT 75.3):** ▫ Initial: 6.4 ▫ After 14 days at 54°C: 6.4 **Water content (according to CIPAC MT 30.5):** ▫ Initial: 5.18% ▫ After 14 days at 54°C: 4.52% **Density at 20±2 °C (according to EU Method A.3):** ▫ Initial: 1.183 g/cm³ ▫ After 14 days at 54°C: 1.223 g/cm³ No significant decrease in active substance content and no significant variation in the technical characteristics of the product were observed. The product is stable for 14 days at 54°C.	*bags,* Study No. Mo5394, **2016**.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Storage stability test – **long term storage at ambient temperature**	CLI Technical Monograph No. 17	Coumatetralyl RB 0,0029, Batch No.: 2015-009027, 0.002709% coumatetralyl	On-going 12 months interim report: **Active substance content:** ▫ Initial: 0.002709% ▫ After 12 months at 20°C: 0.002638 % (-2.6 %) **Bittering agent content:** ▫ Initial: 0.0019 % ▫ After 12 months at 20°C: 0.0018% (-5.3%) **Weight loss:** ▫ Initial: - ▫ After 12 months at 20°C: +0.37 % **pH value (1 % in deionized water, according to CIPAC MT 75.3):** ▫ Initial: 6.4 ▫ After 12 month at 20°C: 6.4 **Water content (according to CIPAC MT 30.5):** ▫ Initial: 5.18 % ▫ After 12 months at 20 °C: 5.00 % **Density at 20±2 °C (according to EU Method A.3):** ▫ Initial: 1.183 g/cm³ ▫ After 12 months at 20°C: 1.186 g/cm³	Manka, S., *Determination of physico-chemical properties and storage stability test for Coumatetralyl RB 0.0026 in Cardboard boxes with PET/ PE bags,* Study No. Mo5394, **2017**. **Please note,** The interims report was not yet included in the IUCLID dossier. The German authorisation is granted under the condition that the final report is submitted until 08.10.2018.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			No significant decrease in active substance content and no significant variation in the technical characteristics of the product were observed. The product is assumed to be stable for 24 months at 20°C. Study period: 06 January 2016 to 08 April 2018	
Storage stability test – **low temperature stability test for liquids**	-	-	Not applicable.	Waiving[5]
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	Not required as packaging precludes light.	Waiving[5]
Effects on content of the active substance and technical	-	-	Waiving for the effect of humidity on the stability of the test material (active substance not hygroscopic and hydrolytically stable). Effects of temperature have been	Waiving[5]

[5] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
characteristics of the biocidal product – **temperature and humidity**			addressed in the accelerated storage stability study.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			The data about the packaging material are sufficient.	
Wettability	-	-	Data requirement not relevant for the ready-to-use product (soft block).	Waiving[5]
Suspensibility, spontaneity and dispersion stability	-	-	Data requirement not relevant for the ready-to-use product (soft block).	Waiving[5]
Wet sieve analysis and dry sieve test	-	-	Data requirement not relevant for the ready-to-use product (soft block).	Waiving[5]
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Data requirement not relevant for the ready-to-use product (soft block).	Waiving[5]
Disintegration time	-	-	Data requirement not relevant for the	Waiving[5]

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			ready-to-use product (soft block).	
Particle size distribution, content of dust/fines, attrition, friability	-	-	Data requirement only valid for powders and granules, not relevant for the ready-to-use product (soft block, highly viscous paste).	Waiving[5]
Persistent foaming	-	-	Data requirement not relevant for the ready-to-use product (soft block).	Waiving[5]
Flowability/Pourability/ Dustability	-	-	Data requirement not relevant for the ready-to-use product (soft block).	Waiving[5]
Burning rate — smoke generators	-	-	Data requirement not relevant for the ready-to-use product (soft block).	Waiving[5]
Burning completeness — smoke generators	-	-	Data requirement not relevant for the ready-to-use product (soft block).	Waiving[5]
Composition of smoke — smoke generators	-	-	Data requirement not relevant for the ready-to-use product (soft block).	Waiving[5]
Spraying pattern — aerosols	-	-	Data requirement not relevant for the ready-to-use product (soft block).	Waiving[5]
Physical compatibility	-	-	Data requirement not relevant. The product is not intended to be used with other products.	Waiving[5]
Chemical compatibility	-	-	Data requirement not relevant. The product is not intended to be used with other products.	Waiving[5]
Degree of dissolution	-	-	Data requirement not relevant for the ready-to-use product (soft block).	Waiving[5]

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
and dilution stability				
Surface tension	-	-	Data requirement only relevant for liquids.	Waiving[5]
Viscosity	-	-	Data requirement only relevant for liquids.	Waiving[5]

Table 4

Conclusion on the physical, chemical and technical properties
The data provided by the applicant was acceptable.

3.3 Physical hazards and respective characteristics

Table 5: Physical hazards and respective characteristics of the product

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	Regulation (EC) No 440/2008, EU Method A.14	Coumatetralyl RB 0.0375, Batch No.: 2010-006340, 0.0333 % coumatetralyl	BAM Fallhammer: not sensitive to shock Koenen Test: not explosive when heated under defined confinement BAM friction apparatus: not sensitive to friction	No explosive properties according to EU test method A.14. Not classified based on GHS/CLP criteria	Dornhagen. J., Racumin Paste in PE-Beutel und Faltschachtel, EXPLOSIVE PROPERTIES A.14., Report-No.: 20100586.02, 2010
Flammable gases	study scientifically unjustified			Waiver	IUCLID[6]
Flammable aerosols	study scientifically unjustified			Waiver	IUCLID[6]
Oxidising gases	study scientifically unjustified			Waiver	IUCLID[6]

[6] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Gases under pressure	study scientifically unjustified			Waiver	IUCLID[6]
Flammable liquids	study scientifically unjustified			Waiver	IUCLID[6]
Flammable solids	Regulation (EC) No 440/2008, EU Method A.10	Coumatetralyl RB 0.0375, Batch No.: 2010-006340, 0.0333 % coumatetralyl	Preliminary test: The test item could not be ignited with a flame.	Not classified based on GHS/CLP criteria	Dornhagen. J., Racumin Paste in PE-Beutel und Faltschachtel, FLAMMABILITY (SOLIDS) A.10. Report-No.: 20100586.01, 2010
Self-reactive substances and mixtures	study scientifically not necessary			Waiver: The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.	IUCLID[6]
Pyrophoric liquids	study scientifically unjustified			Waiver	IUCLID[6]
Pyrophoric solids	study scientifically not necessary			Waiver: The study does not need to be conducted because the substance is known to be stable in contact with air at room temperature for prolonged periods of time (days) and hence, the classification procedure does not need to be applied.	IUCLID[6]
Self-heating	UN Test N.4 (in	Coumatetr	100 mm sample cube	Not classified based on GHS/CLP criteria	Krack M.,

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
substances and mixtures	Part III of the UN-MTC)	alyl RB 0.0026, Batch No.: 2017-004299,, 0.00228 % Coumatetralyl	(140°C): 156 °C max. temperature Due to an exothermal temperature rise <60 K the result was evaluated as negative.		Coumatetralyl RB 0.0026, TEST FOR SELF-HEATING SUBSTANCES (UN N.4) Report-No.: PS20170265-2, 2017
Substances and mixtures which in contact with water emit flammable gases	study scientifically not necessary			Waiver: The study does not need to be conducted because the experience in production or handling shows that the substance does not react with water, e.g. the substance is manufactured with water or washed with water.	IUCLID[6]
Oxidising liquids	study scientifically unjustified			Waiver	IUCLID[6]
Oxidising solids	study scientifically not necessary	Coumatetralyl RB 0.0375, Batch No.: 2010-006340, 0.0333 % coumatetralyl		Waiver: All compounds of the test item, which could be chemically relevant, contain oxygen atoms which are chemically bonded only to carbon or hydrogen and hence, the classification procedure does not need to be applied.	Dornhagen. J., Racumin Paste in PE-Beutel und Faltschachtel, OXIDIZING PROPERTIES OF SOLIDS A.17. Report-No.: 20100586.04, 2010
Organic peroxides	study scientifically not			Waiver: The study does not need to be conducted because the product does not fall under the	IUCLID[6]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
	necessary			definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	
Corrosive to metals	study scientifically unjustified			Waiver	IUCLID[6]
Auto-ignition temperature (liquids and gases)	study scientifically unjustified			Waiver	IUCLID[6]
Relative self-ignition temperature for solids	Regulation (EC) No 440/2008, Method A.16	Coumatetralyl RB 0.0026, Batch No.: 2017-004299,, 0.00228 % Coumatetralyl		No self-ignition observed under the test conditions up to 400 °C	Krack M., Coumatetralyl RB 0.0026, AUTO-FLAMMABILITY (SOLIDS-DETERMINATION OF RELATIVE SELF-IGNITION TEMPERATURE) A.16. Report-No.: PS20170265-1, 2017
Dust explosion hazard	study scientifically not necessary			Waiver: It is considered to be scientifically justified to omit this study on the basis that the product does not contain, and is not able to produce, dust that can ignite or explode in air.	IUCLID[6]

Table 6

Conclusion on the physical hazards and respective characteristics
The data provided by the applicant was acceptable. Experimental data for the endpoints “self-heating substances and mixtures” and “relative self-ignition temperature for solids” were provided for the product. The read-across from supporting substance (structural analogue or surrogate) is acceptable for the endpoints “Explosives”, “Flammable solids” and “Oxidising properties”. Based on experience in production and handling it can be concluded that the product is not pyrophoric and does not evolve flammable gases in contact with water. Conclusions on classification and labelling: Classification and labelling with regard to the physical hazards are not proposed.

3.4 Methods for detection and identification

Table 7

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**LOQ or other limits**	**Reference**
					Range	Mean	RSD		
Coumatetralyl in Coumatetralyl RB 0,0029, Batch No.: 2015-009027	HPLC-UV	Analyte identity was confirmed by retention time match with analytical standards. No interferences at >3% of the total peak area were present at the retention time of interest.	Linearity ranqe: 0.0009 - 0.0024 mg/mL R^2=1.00 (triplicate determination at six concentrations)	70-130% ▫ Level 1 (70%): 0.001051 mg/mL ▫ Level 2 (100%): 0.001502 mg/mL) ▫ Level 3 (130%): 0.001953 mg/mL) triplicate determination at three concentrations	▫ Level 1: 97.1-98.8% ▫ Level 2: 96.3-97.9% ▫ Level 3: 97.3-99.8%	▫ Level 1: 97.7% ▫ Level 2: 96.9% ▫ Level 3: 98.6% Overall mean (n=9): 97.7%	▫ Level 1: 1.0% ▫ Level 2: 0.9% ▫ Level 3: 1.3% Overall mean (n=9): 1.2%	Not required.	Matyssek, F., *Validation of Method MV130: BCS: HPLC - Determination of Coumatetralyl in Coumatetralyl RB 0,0029*, Study No. Mo5393, **2015**.
Denatonium Benzoate in Coumatetralyl RB 0,0029, Batch No.:	HPLC-MS	Analyte identity was confirmed by retention time match with	Linearity ranqe: 0.3018 – 0.8048 µg/mL R^2=1.00	70-130% ▫ Level 1 (70%): 0.3521 µg/mL	▫ Level 1: 101.9-110.1% ▫ Level 2:	▫ Level 1: 105.2% ▫ Level 2: 104.3%	▫ Level 1: 1.0% ▫ Level 2: 0.9%	Not required.	Matyssek, F., *Validation of Method MV131: BCS: HPLC-MS- Determination of*

2015-011504		analytical standards. No interferences at >3% of the total peak area were present at the retention time of interest.	(triplicate determination at six concentrations)	▫ Level 2 (100%): 0.5030 µg/mL) ▫ Level 3 (130%): 0.6539 µg/mL) triplicate determination at three concentrations	102.6-105.9% ▫ Level 3: 94.0-100.1%	▫ Level 3: 96.8% Overall mean (n=9): 102.1%	▫ Level 3: 1.3% Overall mean (n=9): 4.8%		*Denatonium Benzoate in Coumatetralyl RB 0,0029*, Study No. Mo5410, **2016**.

Table 8

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	Coumatetralyl	0.05 mg/kg	Common limit
Drinking water	Coumatetralyl	0.1 µg/L	Minimal requirement of the Drinking Water Act (Trinkwasser-VO)
Surface water	Coumatetralyl	0.1 µg/L	PNEC water, based on NOEC fish, AF 50, CAR, doc IIA, 4.4.1,
Air	Coumatetralyl	0.005 µg/m³	AEL subchronic: 0.017 µg/kg bw/d, AR for PT14; list of endpoints, 02/2009
Animal and human body fluids and tissues	Coumatetralyl	0.05 mg/L 0.1 mg/kg	Classified as very toxic, AR for PT14; list of endpoints, 02/2009
Food of plant origin	Coumatetralyl	0.01 mg/kg	AR for PT14; chapter 3.5, 02/2009
Food of animal origin	Coumatetralyl	0.01 mg/kg	AR for PT14; chapter 3.5, 02/2009

Table 9

Analytical methods for drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Coumatetralyl	LC-MS/MS, HyPurity Aquastar, ESI+, m/z 293→175	Blank value < 30 % of LOQ, specific, but 2nd mass transition is missing	0.042 – 10.5 ng/mL, R^2=1.0000	0.052 µg/L / 10 10.5 µg/L / 10	*Not applicable due to direct injection*		*8.2* *8.3*	*0.05 µg/L*	CAR; Doc IIIA; A4.2.3; Brumhard (2004);

Table 10

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R²)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Coumatetralyl	LC-MS/MS, Superspher 100 RP18, ESI+, m/z 293→175	Blank value < 30 % of LOQ, specific, but 2nd mass transition is missing	0.25 – 10 ng/mL corresponding to 0.0005 – 0.02 mg/kg in samples, R²=0.9995	0.001 mg/kg / 10 (Soil Höfchen) 0.01 mg/kg / 5 (Soil Höfchen) 0.001 mg/kg / 10 (soil Laacher Hof) 0.01 mg/kg / 5 (soil Laacher Hof)	70-122 81-114 68-112 90-113	89 95 81 107	20 15 16 9.3	0.001 mg/kg	CAR; Doc IIIA, A4.2.1; Brumhard (2004);

Table 11:

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R²)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Method not required, because of the low vapour pressure of a.s. (<1E-03 Pa, 20°C, CAR, Doc I., list of endpoints, 01/2009)									

Table 12

Analytical methods for surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R²)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Coumatetralyl	LC-MS/MS, HyPurity Aquastar, ESI+, m/z 293→175	Blank value < 30 % of LOQ, specific, but 2nd mass transition is missing	0.042 – 10.5 ng/mL, R²=1.0000	0.052 µg/L / 10 10.5 µg/L / 10	*Not applicable due to direct injection*		*8.2* *8.3*	*0.05 µg/L*	CAR; Doc IIIA; A4.2.3; Brumhard (2004);

Table 13

Analytical methods for animal and human body fluids and tissues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Coumatetralyl	LC-MS/MS; Luna C18, ESI-, m/z 291→141, 291→135	Blank values > 30 % LOQ, highly specific	0.5 – 100 ng/mL corresponding to 0.005 – 1 mg/L in samples, R^2= 0.9964 and 0.9974	0.05 mg/L / 5 0.5 mg/L / 5 (m/z 291→141) 0.05 mg/L / 5 0.5 mg/L / 5 (m/z 291→135)	81-88 82-90 83-87 81-89	85 85 85 85	3 4 2 4	0.05 mg/L	CAR, Doc IIIA, 4.2.2; Bacher (2007)

Table 14

Analytical methods for monitoring of active substances and residues in food and feeding stuff of plant origin									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Analytical methods were not submitted for this application. The following statement is given in the AR for product type 14: "The following studies or information should be submitted when applying for authorisation of a biocidal product…a) due to possible accidental or deliberate contamination, analytical methods for residues in/on foodstuffs." In the draft renewal assessment report an analytical method for coumatetralyl in food of plant origin is cited (Bendig, 2015, report no. 3565G). Therefore, no additional information is necessary.									

Table 15

Analytical methods for monitoring of active substances and residues in food and feeding stuff of animal origin									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Analytical methods were not submitted for this application. The following statement is given in the AR for product type 14: "The following studies or information should be submitted when applying for authorisation of a biocidal product…a) due to possible accidental or deliberate contamination analytical methods for residues in/on foodstuffs." In the draft renewal assessment report an analytical method for coumatetralyl in food of animal origin is cited (Bendig, 2015, report no. 3566 G). Therefore, no additional information is necessary.									

Table 16

Data waiving was acceptable for the following information requirements	
Information requirement	5.2.2. Air
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 17

Conclusion on the methods for detection and identification
The method(s) provided regarding the active substance(s) in the BP were acceptable. The residue analytical methods for coumatetralyl in soil, drinking and surface water and body fluids (blood) were acceptable. Residue analytical methods for coumatetralyl in food of plant and animal origin are available from the draft renewal report. Nevertheless, the submitted analytical methods in soil and drinking water are not highly specific, therefore a validated confirmatory method or the validation of a 2nd MS/MS transition should be provided for the renewal of the active substance. Method(s) regarding residues in air and substances of concern were not necessary. Analytical methods for food / foodstuffs of plant and animal origin were not provided. According to the AR, chapter 3.5 (b) an analytical method for the residues in/on food or feedstuffs should be provided due to possible accidental or deliberate contamination. This should be considered during the renewal of the active substance.

3.5 Efficacy against target organisms

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

Secuverd 26 is intended to be used by non-professionals to control rodents. The target organisms to be controlled are norway rats (*Rattus norvegicus*) in and around buildings and voles (family Cricetidae, e.g. bank, common and water voles) around buildings.

The products, organisms or objects to be protected are indoor (public, private buildings and farms) and outdoor environments (around buildings).

Secuverd 26 is intended to be used against bank voles (*Myodes glareolus*) and common voles (Microtus arvalis) which are important reservoir hosts and transmitters of human pathogenic Hantavirus (serotype Puumala), as well as of water voles (*Arvicola terrestris; syn. Arvicola amphibius*) which may cause structural damage to buildings. The product is intended for application in bait boxes around buildings against bank and common voles as well as for application into the burrow systems of water voles.
The inclusion of the active substance coumatetralyl in Annex I was only justified with being considered as essential for reasons of public health and hygiene. An authorisation of Secuverd 26 mainly for use against water voles must therefore be regarded as unjustifiable, since these rodents have no significant importance as disease hosts or transmitters of pathogens. However, bank and common voles are of considerable importance as hosts and transmitters of Hantavirus in Germany. The efficacy of the product had to be proven for bank as well as water voles, since both species differ in size as well as in their feeding habits.

3.5.2 Effects on target organisms, including unacceptable suffering

Anticoagulant rodenticides disrupt the blood-clotting mechanisms. Signs of poisoning in rodents are those associated with an increased tendency to bleed, leading ultimately to profuse haemorrhage. After feeding on bait containing the active substance the animal becomes lethargic, weak and slow moving. Signs of bleeding such as blood in feces or urine and nasal bleeding are often noticeable. As symptoms develop, the animal will lose its appetite and will remain in its burrow or nest for increasingly long periods of time. As the active substance has a long acting action, death will usually occur within 4 to 20 days of ingesting a lethal dose and animals often die out of sight in their nest or burrow.

It is recognised that such substances do cause pain in rodents but it is considered that this is not in conflict with the requirements of Article 19 b) ii) BPR (unnecessary suffering and pain for vertebrates) as long as effective, but comparable less painful alternative biocidal substances or biocidal products or even non-biocidal alternatives are not available.

3.5.3 Mode of action, including time delay

Anticoagulant rodenticides are vitamin K antagonists. The main site of action is the liver and the main effect is inhibition of blood clotting by interference with the hepatic synthesis of the vitamin K-dependent clotting factors II, VII, IX and X which effectively inhibits de-novo synthesis of vitamin K1, thereby interrupting cellular recycling of vitamin K1. Vitamin K1 in its hydroquinone form is an essential co-factor for the synthesis of functional clotting factors. The function of vitamin K1 is the post translational transformation of the precursor protein to respective functional clotting factors by γ-carboxylation of their glutamic acid moieties, which in turn, enhances the binding of Ca++ by chelating phosphate on the phospholipids, thus accelerating, and providing a template for, the blood clotting mechanism. Concomitant with the γ-carboxylation of glutamic acid residues to form clotting factors, an epoxidation reaction occurs, converting the active form of vitamin K1, the hydroquinone, to vitamin K1 2, 3-epoxide, which in turn is returned to vitamin K1 quinone by vitamin K1 2, 3-epoxide reductase, which in turn has to be reduced to vitamin K1 hydroquinone, thus forming the vitamin K1 cycle. The regeneration of vitamin K1 quinone from vitamin K1 2, 3-epoxide is the step inhibited by coumatetralyl.

Approximately 4 to 20 days after ingestion, the rodents die from hemorrhages.

3.5.4 Efficacy data

General note

In the lab trials with norway rats and bank voles as well as in the field study with norway rats, a product with an identical composition to Secuverd 26 was used. However, the product contained 29 mg/kg coumatetralyl, instead of 27 mg/kg as in Secuverd 26. In order to minimise the number of animal experiments, we regarded the difference of 2 mg/kg as negligible and decided to accept studies with the product containing 29 mg/kg for the efficacy evaluation of Secuverd 26.

Efficacy on norway rats (*Rattus norvegicus*)

The reports of a choice feeding laboratory trial and two field trials were submitted for norway rats as target organisms. Field studies were conducted according to EPPO-Standards. In both field trials, the

bait was applied in bait boxes. Both trials revealed efficacy rates of 100%, measured as 100% reduction in feed uptake as well as tracking activity. The laboratory choice trial reached an efficacy of 91.7% and a palatability of 32%. All these rates exceed the TNsG minimum requirements of 90% mortality and 20% palatability, thus demonstrating a sufficient efficacy of Secuverd 26 against norway rats.

Efficacy on voles of the type's bank vole (*Myodes glareolus*) and common vole (*Microtus arvalis*)

Two reports of laboratory choice-feeding tests with bank voles (*Myodes glareolus* wild strain) were submitted (Anonymous 2016a and 2016c). These trials were conducted according to EPPO-Standards and each with 10 females and 10 males in separated groups. The mortality of these gender groups reached 100% in both trials. The palatability showed rates of 45% and 60% for male / female (Anonymous 2016c) and 79% and 83% for male / female in Anonymous (2016a). As a positive control, a product containing coumatetralyl at 375 mg/kg bait was tested also in Anonymous (2016a). Mortality was 100%, palatability reached 85% and 79% for female / male groups.

To demonstrate the efficacy of the product against common and bank voles in the field, the applicant submitted a study with the common vole *Microtus arvalis* (Anonymous 2017). At 12 burrow openings, the voles were offered continuously baits with 27 mg/kg coumatetralyl in bait boxes. The feeding activity increased after the first application and then broke down to zero on day 9. Activity rates were compared with those of untreated settlements. The overall efficacy was estimated to be 93.9%, which fulfils the TNsG criteria of 90% mortality or higher.

In an expert statement, it was shown that bank und common voles are very similar in biology, feeding, behaviour and sensitivity against coumatetralyl. Therefore, and in order to minimize animal experiments, the lab choice trials with bank voles and the field trial with common voles using bait stations were regarded as sufficient for the efficacy evaluation of both species.

In conclusion, the efficacy of Secuverd 26 was convincingly demonstrated against voles of the type's bank vole (Myodes glareolus) and common vole (Microtus arvalis) for application in bait boxes.

Efficacy on water voles (*Arvicola terrestris*)

The applicant further submitted a field study report (Anonymous 2016) with water voles (*Arvicola terrestris*). The study was conducted according to a modified EPPO-Standard. The bait was placed directly in the vole burrows, and the study revealed a mortality (measured as reduction of vole activity) of 69%. The mortality is thus below 90% and, although the TNSG do not provide specific threshold values for tests with voles, can be regarded as too low to demonstrate that Secuverd 26 is sufficiently efficient against the target organism, since at least 30% of the original vole population survived the pest control operation.

The applicant was given the opportunity to explain the insufficiently low mortality rate. In an expert statement, the applicant argues that:

1) Due to the fact that the study area was not closed, an immigration during the test period might have reduced the study´s efficacy rates. In the study area´s close neighborhood were untreated burrows. The study took place in April, which is the peak of the spring reproduction of water voles, and dispersing young water voles likely increased activity rates in the treated burrows, thus reducing the efficacy rates of the study.
2) The burrows were treated only twice with Secuverd 26 to estimate the minimum number of bait applications to reduce the animal population. It remains unclear if the efficacy would be better with three treatment.
3) In addition, the census was conducted 10 days after the last treatment due to weather constraints, and not after 14 days, as originally planned. However, although coumatetralyl is known for its delayed action, it remains unclear if the time difference of four days affected the overall efficacy values significantly.

Following Directive (EU) 2017/1378 (*renewing the approval of coumatetralyl as an active substance for use in biocidal products of product-type 14*) from 25th of July 2017, for the use by the general public, products containing coumatetralyl shall only be authorised for application in tamper-resistant bait stations.

In accordance with the usage originally envisaged, in the field study the bait was applied in directly in the burrows. Hence, the efficacy of the Secuverd 26 against water voles when applied in bait stations has therefore not been demonstrated.

Table 18

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Rodenticide	Pest control against brown rat and voles	Coumatetralyl at 29 mg/kg in baits identical to Secuverd 26	Norway rats *(Rattus norvegicus)* wild strain	Laboratory choice-feeding experiment	Choice-feeding experiment with individually caged Norway rats in a 9 days treatment. Test baits with 29 mg/kg Coumatetralyl	91.7% mortality, 32% palatibility	Anonymous 2016b
Rodenticide	Pest control against brown rat and voles	Coumatetralyl at 29 mg/kg in baits identical to Secuverd 26	Norway rats *(Rattus norvegicus)* wild strain	Field trial EPPO PP 1 114(2)	Feed of pre- and post-baiting census: Rolled oats Baiting period 14 d: Bait containing 0.0029% coumatetralyl: Bait points: 7 Black plastic bait stations with two entrances (30cmx15cmx15cm)	100% efficacy (100% reduction in feed uptake and in tracking activity)	Anonymous 2015a
Rodenticide	Pest control against brown rat and voles	Coumatetralyl at 29 mg/kg in baits identical to Secuverd 26	Brown rat *(Rattus norvegicus)* wild strain	Field trial EPPO PP 1 114(2)	Feed of pre- and post-baiting census: Rolled oats Baiting period 18 d: Bait containing 0.0029% coumatetralyl: Bait points: 3 Black plastic bait stations with two entrances	100% efficacy (100% reduction in feed uptake and in tracking activity)	Anonymous 2015b

Rodenticide	Pest control against brown rat and voles	Coumatetralyl at 27 mg/kg in baits (Secuverd 26)	Water vole (*Arvicola terrestris*)	Field trial Modified EPPO Guideline	Bait application in 6 burrows; Pre-treatment census and post-treatment census were conducted by counting occupied galleries. One to four galleries were opened on each of eleven burrow sites by removing one spate of ground. A few galleries were opened at their end, and therefore only one single end of a gallery was obvious in these holes, but not two. After two days, the number of refilled single open ends was counted and set into relation to the number of openings as an indicator of vole activity. Fossorial water voles close open galleries within one day. The single open ends were considered individually in every opened gallery. The post-baiting census was scheduled for 14 days after the first treatment. However, due to the weather forecast it was conducted already after 7 days.	69.0% Efficacy (% refilled single open ends)	Anonymous 2016
Rodenticide	Pest control against brown rat and voles	Coumatetralyl at 29 mg/kg in baits identical to Secuverd 26	Bank vole (*Myodes glareolus*) wild strain	Laboratory choice-feeding test EPPO PP 1/113(2)	Test with bait containing 29 mg/kg coumatetralyl versus cereals with groups each of 10 male and 10 female bank voles. Exposition 7 days; each group of 10 individuals in pen 60cm x 69cm, with 2 feed-bowls and water ad lib.	Mortality: 100% male and 100% female; palatibility 45% male and 60% female	Anonymous 2016c

Rodenticide	Pest control against brown rat and voles	Coumatetralyl at 29 mg/kg in baits Secuverd 26 Positive control Coumatetralyl at 375 mg/kg	Bank vole (*Myodes glareolus*) wild strain	Laboratory choice-feeding test EPPO PP 1/113(2)	Test with bait containing 29 mg/kg coumatetralyl versus Standard pellet bait for guinea pigs based on vegetables with groups each of 10 male and 10 female bank voles. Exposition 7 days; each group of 10 individuals in pen 60cm x 69cm, with 2 feed-bowls and water ad lib.	Mortality: 100% male and female; palatibility 79% male and 83% female positive controle Mortality: 100% male and female; palatibility index 79% male and 85 %female	Anonymous 2016a
Rodenticide	Pest control against brown rat and voles	Coumatetralyl at 27 mg/kg; (COUMATETRALYL RB 0.0029)	Common Vole *(Microtus arvalis)*	Field trial TNsG Appendices to Chapter 7 Product TYPE 14 and EPPO PP1/169 (2)	The baits were placed inside commercially available lockable mouse bait stations and positioned next to each active holes in the treated zone (feeding = activity). The untreated control groups activity was the removing of an entrance blocking paper leaf for 3 days.	93,9% Efficacy (reduced activity in the treated zone in comparison with the untreated control zone)	Anonymous 2017

3.5.5 Occurrence of resistance and resistance management

Resistance to the first generation anticoagulants has been widely reported in both *Rattus norvegicus* and *Mus domesticus* since the late 1950's (PELZ & FREISE 2009[7]). The incidence of resistance to first generation anticoagulants in areas in which it is established is commonly 25-85%.
Vein et al. 2011 (Ecotoxicology (20):1432–1441) reported the possibility of resistance of water voles against bromadiolone in heavily treated areas in France. Rodents resistant to bromadiolone are likely to be also resistant against coumatetralyl. However, we do not consider this paper as practically relevant for the field of use envisaged for the product evaluated here, since the intended fields of use require only locally and temporally limited applications. The selection pressure by rodent control measures is thus low and development of resistance is expected to be unlikely in voles.

Strategies to avoid resistance in susceptible populations:
Ensure that all baiting points are inspected weekly and old bait replaced where necessary. Carry out treatment according to the label instructions until the infestation is completely cleared. Ensure that complete elimination of the infestation is achieved.
On completion of the treatment, remove all unused baits. Do not use anticoagulant rodenticides as permanent baits. Monitoring of rodent activity should be undertaken using visual survey, through the use of non-toxic placebo monitors or by other effective means. Record details of treatment. Where rodent activity persists due to problems other than resistance, use alternative baits or baiting strategies, extend the baiting program or apply alternative control techniques to eliminate the residual infestation. As appropriate during the rodenticide treatment apply effective Integrated Pest Management measures (remove alternative food sources, remove water sources, remove harbourage and proof susceptible areas against rodent access).
Where rodent infestations containing resistant individuals are identified, immediately use an alternative anticoagulant of higher potency. If in doubt, seek expert advice on the local circumstances. Alternatively, use an acute or sub-acute but non anticoagulant rodenticide. In both cases it is essential that a complete elimination of the rodent population is achieved. Where residual activity is identified, apply intensive trapping to eliminate remaining rodents. Gassing or fumigation may be useful in specific situations. Apply thorough Integrated Pest Management procedures (environmental hygiene, proofing and exclusion). Do not use anticoagulant rodenticides as permanent baits routinely. Record details of treatment. Where there are indications that resistance may be more extensive than a single infestation, apply area or block control rodent programs. The area under such management should extend at least to the boundaries of the area of known resistance and ideally beyond. These programs must be

[7] *PELZ, H.-J. & J. FREISE: Antikoagulantien-Resistenz bei kommensalen Nagern. Mitt. Julius Kühn-Inst. 421, 2009, p. 68-75.*

effectively coordinated and should encompass the procedures identified above. In the last decades many tests have been developed to identify anticoagulant-resistant rats. In a Technical Monograph of the Rodenticide Resistance Action Committee of Crop Life International (RRAC) several standard methodologies are provided (RRAC 2003b: A Reappraisal of Blood Clotting Response Tests for Anticoagulant Resistance and a Proposal for a Standardised BCR Test Methodology. Technical Monograph, Brussels, Belgium.). Blood clotting response (BCR) resistance tests are available for a number of anticoagulant rodenticides. The published protocol (RRAC 2003b) can be used to provide information on the incidence and degree of resistance in a particular rodent population and to provide a simple comparison of resistance factors between active ingredients, thus giving clear information about cross resistance for any given strain. The introduced methodology has a sound statistical basis in being based on the EC50 response, and requires much fewer animals than the resistance tests in current use. The tests presented in RRAC (2003b) can be used to give a clear indication of the likely practical impact of the resistance on field efficacy.

3.5.6 Known limitations

The bait is provided in 10 g ready-to-use “tea bags” (long fiber paper). Following Directive (EU) 2017/1378 (renewing the approval of coumatetralyl as an active substance for use in biocidal products of product-type 14) from 25th of July 2017, products containing coumatetralyl can only be authorised for use in tamper-resistant bait stations. The bait must not be applied in periods with strong rainfall. It is recommended to bait voles prior to or after the summer season in order to limit food alternatives. Bait stations are to be inspected in at least weekly intervals, and refilled according to consumption.
It can be expected that multiple doses of the product must be applied to achieve sufficiently high mortality rates. Against bank and common voles, the product is only allowed to be used in bait stations around buildings.

3.5.7 Evaluation of the label claims

The submitted study reports proved that Secuverd 26 has shown a sufficient efficacy for control of norway rats and voles (of the types bank vole (Myodes glareolus) and common vole (Microtus arvalis)). For the general public, the area of use of Secuverd 26 is restricted to in and around buildings in bait stations for norway rats and around buildings in bait stations for voles.

Directive (EU) 2017/1378 restricts the application of Secuverd 26 to bait stations when used by the general public. As the efficacy of Secuverd 26 against water voles under these conditions was not sufficiently demonstrated, the use against water voles must not be subject of the label.

Secuverd 26 is supplied in “tea bags” (long fiber paper). The amount of bait per bait station must not exceed the authorised application rates.

3.5.8 Data waiving and conclusion

Table 19

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 20

Conclusion on the efficacy
On the basis of the efficacy data submitted, the level of efficacy of the product Secuverd 26 for the following uses are acceptable: Against norway rats in and around buildings using bait boxes and against voles of the types bank vole (*Myodes glareolus*) and common vole (*Microtus arvalis*) around buildings using bait boxes

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Table 21

Coumatetralyl	Value	Study	Safety factor
AEL medium-term	0.000017 mg/kg bw/d = 0.017 x 10^{-3} mg/kg bw/d[1,2,3]	Subchronic rat (dietary); correction for 75 % oral absorption; Andrews & Romeike (1997)	300
AEL acute	0.000031 mg/kg bw/d = 0.031 x 10^{-3} mg/kg bw/d [1,2,3]	Developmental toxicity rabbit (oral); correction for 75 % oral absorption; Becker & Biedermann (1996b)	300

[1] Based on CAR (Denmark (2009))
[2] Based on Assessment-Report (Denmark (2009))
[3] An additional AF of 3 was applied within AR and CAR in calculation of the total AF, which is in accordance with the decision at TM III/06 to take account of the potential severity of the effect on development for all anticoagulant anti-vitamin K (AVK) rodenticides.

Table 22

Coumatetralyl	Value	Reference
Inhalative absorption	Default value: 100 %	Not established in CAR or Assessment Report[1,2]
Oral absorption	75 %[1,2] used for risk assessment	ADME rat (oral): 75 % and 86 % absorption of single oral dose in males and females, respectively Anonymous (1999)
Dermal absorption	100 % 1.14 %[1,2] (at 24 hours following initiation of exposure for 8 hours, *in vivo* and *in vitro* studies performed with Racumin ® paste: 0.375 mg coumatetralyl / g formulation)	Default value *In vivo* study rat Odin-Feurtet (2003a) & *In vitro* study human, *in vitro* study rat Anonymous (2003b)

	1 %[4] (Racumin ® foam concentrate, unfoamed no propellant: 7.1-8.7 mg/cm^2 concentrate, corr. to 0.033-0.040 mg/cm^2 a.s.)	In vitro human skin, Anonymous (2013)[4]

[1] Based on CAR (Denmark (2009))
[2] Based on Assessment-Report (Denmark (2009))
[3] An additional AF of 3 was applied within AR and CAR in calculation of the total AF, which is in accordance with the decision at TM III/06 to take account of the potential severity of the effect on development for all anticoagulant anti-vitamin K (AVK) rodenticides.
[4] New study provided at product authorisation stage

3.6.2 Assessment of effects of the product on human health

The applicant submitted toxicological studies carried out with the formulation Coumatetralyl RB 0.0375 (specification no. 10200007452). These studies can be considered as a worst case for the biocidal product Secuverd 26. The acute toxicity profile of this product can be extrapolated from studies with the formulation Coumatetralyl RB 0.0375.

The comparison of both formulations indicates that the only potentially toxicological relevant change between the two products consists in a 14-fold decrease in the concentration of the active substance coumatetralyl in Secuverd 26 compared to Coumatetralyl RB 0.0375 (i.e. 0.0026 %, w/w versus 0.0375 %, w/w). The biocidal product and the test formulations mainly consist in food stuff without toxicological relevance. The concentrations and chemical composition of these ingredients is very similar in both formulations. Other components as solvents or bittering agents are identical. The different concentrations in both formulations do not affect toxicological properties. The exchange of the dye has also no outcome on the toxicological profile.

3.6.2.1 Skin corrosion and irritation

Table 23

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle(s), Dose levels, Duration(s) of exposure**	**Results**[8]	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 404 Yes 1	Rabbit Himalayan Male 3	Racumin paste (0.0375 %) Used as delivered 500 mg/patch Exposure: 4 h	Erythema: 24 h: 0/0/0 48 h: 0/0/0 72 h: 0/0/0 Average: 0/0/0 Oedema: 24 h: 0/0/0 48 h: 0/0/0 72 h: 0/0/0 Average: 0/0/0	-	Anonymous (1997)

Table 24

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to the skin.
Justification for the value/conclusion	Based on an animal study according to OECD 404.
Classification of the product according to CLP	Classification for skin irritation/corrosion is not required.

8 Average score (from findings at 24, 48 & 72h) for erythema and oedema for each animal/observations and time point of onset, reversibility (14 d); other adverse local / systemic effects, histopathological findings

3.6.2.2 Eye irritation

Table 25

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance,Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 405 Yes 1	Rabbit Himalayan Male 3	Racumin paste (0.0375 %) Used as delivered 100 mg Exposure: 72 h	Cornea: 24 h: 0/0/0 48 h: 0/0/0 72 h: 0/0/0 Average: 0/0/0 Iris: 24 h: 0/0/0 48 h: 0/0/0 72 h: 0/0/0 Average: 0/0/0 Conjunctiva redness: 24 h: 0/0/0 48 h: 0/0/0 72 h: 0/0/0 Average: 0/0/0 Conjunctiva chemosis: 24 h: 0/0/0 48 h: 0/0/0 72 h: 0/0/0 Average: 0/0/0	-	Anonymous (1997)

Table 26

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating to the eye.
Justification for the value/conclusion	Based on an animal study according to OECD 405.
Classification of the product according to CLP	Classification for eye irritation/damage is not required.

3.6.2.3 Respiratory tract irritation

Data waiving	
Information requirement	Annex III of BPR, point 8.7.1, “other endpoints”
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the biocidal product has to be made according to the rules of the Regulation (EC) No 1272/2008. The biocidal product does not contain components classified for respiratory irritation.

Table 27

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the value/conclusion	Based on intrinsic properties of individual components the biocidal product is considered as not irritating to the respiratory tract.
Classification of the product according to CLP	Classification for respiratory tract irritation is not required.

3.6.2.4 Skin sensitisation

Table 28

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**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 406 (GPMT) Yes 2	Guinea pigs Hsd Poc : DH Female Test group: 20 animals Control group: 10 animals	Coumatetralyl 0.0375 % paste bait Methyl ethyl ketone Induction: 50 % Challenge: 50 %	Test group Observation after 48 h: 7/17 Observation after 48 h: 4/17 Control group: Observation after 48 h: 0/8 Observation after 48 h: 0/8	1. A standard modification was made for the first induction due to the nature of the formulation (paste), which produced a suspension in vehicle that was not injectable: four intradermal injections(FCA + vehicle) and topical patches placed between and on the injection sites. 2. Five animals (3 in the test-article group and 2 controls) did not survive until the scheduled challenge date.	Anonymous, (2004)
OECD 429 (LLNA) Yes 1	Mice CBA/J Female Test groups: 6 animals at 4 doses Negative control group: 6 animals Positive control group: 6 animals	Coumatetralyl 0.0375 % paste bait (Racumin paste) Vehicle: 1 % aqueous pluronic acid	Stimulation index: Negative control: 1 1 % racumin: 1.0 2.5 % racumin: 1.3 5 % racumin: 1.1 10 % racumin: 1.7 Positive control: 3.3	Concentrations were selected after pretest: irritation was observed at racumin paste concentrations of 25 and 50 %.	Anonymous (2006)

According to the study of Anonymous (2003) the test substance is skin-sensitising. The applicant considers this study as false positive with the following argumentation:

"*In a Magnusson and Kligman test, the racumin paste showed some skin-sensitization potential (Anonymous, 2003). However due to the nature and physical properties of the racuminpaste formulation, i.e. solid formulation, it was not easily dissolved. The vehicle which was found to be the most appropriate was methyl ethyl ketone. Nevertheless, the resulting suspension was not injectable as methyl ketone is known to be toxic to the guinea pig. Therefore a standard modification of the first induction was made. Animals received four injections of complete Freund's adjuvant and vehicle then the racumin paste in vehicle was applied in patches placed between and on the injection sites. These patches were covered by occlusive bandage and held securely for 24 hours.*

Importantly, three animals of the treated group (n° 12, 16 and 23) exhibited clinical signs, including laboured breathing, piloerection and palor from day 10 to death at day 12, 10 to 16 and 17 to death at day 19, respectively.

Animal n° 18 of the test item group died at day 10 of the study. Forty eight hours following the intradermal induction (first induction), the animals showed red wheals at the injection sites. After 7 days, red wheals and encrustation were observed at the injection site of these animals. Although it was not injected directly, the test suspension could well have penetrated through these wheals thus resulting in the exposure of the animals to the toxic vehicle methyl ketone as indicated by the clear toxicity reported in this study. This may have influence on the induction of skin sensitization, i.e. enhancing a weak sensitizing effect of the racumin paste and/or one of its components. These modifications of the standard protocol required due to the physical nature of the paste are likely to have enhanced the skin sensitisation potential of the formulation and caused the positive results. For all these reasons, BES considers that this study should be considered as a false positive."

Considering this argumentation and the fact that the test formulation does not contain any known sensitiser the applicant performed a more suitable (reliable) LLNA, resulting in a negative result.

The argumentation and the conclusions of the applicant are comprehensible and are supported. The biocidal product is considered as not skin-sensitising.

Table 29

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin-sensitising
Justification for the value/conclusion	Based on an animal study according to OECD 429.
Classification of the product according to CLP	Classification for skin sensitisation is not required.

3.6.2.5 Respiratory sensitisation (ADS)

Table 30

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. Data on respiratory sensitisation for the biocidal product or their components are not available.

Table 31

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Based on the available data respiratory sensitisation is not expected.
Justification for the value/conclusion	Data on respiratory sensitisation for the biocidal product or their components are not available.
Classification of the product according to CLP	Classification for respiratory sensitisation is not required.

3.6.2.6 Acute toxicity

3.6.2.6.1 Acute toxicity by oral route

Table 32

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levelsType of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 423 Yes 1	Rat Wistar Female 3/group	Coumatetralyl 0.0375 % paste bait Used as delivered 300 mg/kg bw 2000 mg/kg bw gavage	300 mg/bw: no mortality, no clinical signs of toxicity 2000 mg: Mortality: 2/3 animals within 24h, all treated animals: decreased motility, laboured breathing, vocalisation and tachypnea	LD_{50} cut-off: 1000 mg/kg bw	-	Anonymous (2003)

Table 33

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50}: > 2000 mg/kg bw
Justification for the selected value	The applicant submitted an acute oral toxicity study with a formulation containing 14-fold more active substance than the biocidal product. Except for the active substance both formulations are comparable (for details refer to 3.6.2). For acute toxicity, the toxicological profile of the biocidal product is based on the toxicological properties of the active substance. Other components do not play a significant role. Hence, the result of toxicity with the test formulation clearly overestimates the toxicity of the biocidal product. Since the oral LD_{50} of the test formulation was about 1000 mg/kg bw, it must be assumed that the oral LD_{50} of the biocidal product with a 14-fold lower active substance concentration is > 2000 mg/kg bw. The LD_{50} calculated from values for the single components is also >> 2000 mg/kg bw.
Classification of the product according to CLP	Classification for acute oral toxicity is not required.

3.6.2.6.2 Acute toxicity by inhalation

Table 34

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation
Justification	A study on acute inhalation toxicity of the biocidal product is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 “Acute toxicity” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), “testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” For the biocidal product the composition is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no indication of synergistic effects between any of the components. Consequently, classification of the biocidal product can be made according to the calculation rules laid down in Regulation (EC) No 1272/2008 and testing of the biocidal product is not required.

Table 35

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route.
Justification for the selected value	Based on the inhalation LC_{50} available for the single components the inhalation LC_{50} of the biocidal product is estimated as > 5 mg/L.
Classification of the product according to CLP	Classification for acute inhalation toxicity is not required.

3.6.2.6.3 Acute toxicity by dermal route

Table 36

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 402 Yes 1	Rat Wistar Male / Female 5 / sex / group	Coumatetralyl 0.0375 % paste bait Used as delivered 4000 mg/kg bw (limit dose) semi-occlusive	4000 mg/bw: no mortality, no clinical signs of toxicity	> 4000 mg/kg bw	-	Anonymous (2003)

Table 37

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD_{50}: > 4000 mg/kg bw
Justification for the selected value	Based on an animal study according to OECD 402.
Classification of the product according to CLP	Classification for acute dermal toxicity is not required.

3.6.2.7 Information on dermal absorption

Table 38

Summary table of in vitro studies on dermal absorption					
Method, Guideline, GLP status, Reliability	**Species, Age/Sex, Localisation, No. Number of skin samples and donors tested per dose, exposure and post-exposure time, oOther relevant information about the study**	**Test substance, Formulation details incl. identify and concentration Doses (total volume/mass applied per area, amount of a.s. applied per area)**	**Absorption data for each compartment (mean and SD as percentage of dose), absorption[9] (percentage of dose) calculated in accordance with EFSA Guidance on Dermal Absorption (2012) and final absorption value**	**Remarks (e.g. major deviations statements on variability and time-course, justification of non-inclusion of certain compartments, other relevant information, e.g. receptor fluid)**	**Reference**
OECD 428 GLP: Yes Reliabilty: 2	Species: human Age/sex: 32, 44, 73 y; female Localisation: abdomen	Racumin Paste Concentration a.s.: 0.375 g/100 g (target concentration)	Dislodgeable dose Skin wash after 8 and 24 hours: 80.43 ± 5.71 Donor chamber wash: 0.13 ± 0.12 Skin associated dose Tape strips 1 - 2: 0.12 ± 0.08 Tape strips 3 - x: 0.08 ± 0.04	Cell type: Flow-through diffusion cells Flow rate: 1.5 mL/h Exposed skin area: 1 cm^2	Anonymous, 2013a

9 Usually also includes absorbable dose as defined in OECD TG 428, and takes into account variability, recovery and time-course.

	No. of skin samples: 6 (3 donors) Skin thickness: 499-563 µm Skin type: dermatomed Source: tissue bank Exposure time: 8 h Post exposure time: 16 h Integrity test: TWEL	Area dose: 2.6 µg = 2.6 µL/cell	Skin preparation 0.28 0.11 Absorbed dose Receptor fluid 0.068 0.024 Receptor chamber wash 0 0 Total recovery 81.11 5.85 Absorption complete? No Absorbed at t_0.5 [1] 52.85 3.72 Absorption estimate, if t_0.5<=75 % [1] 0.42 0.15 Absorption estimate, if t_0.5>75 % [1] N/A N/A Absorption estimate normalized [2] 0.52 0.15 Relevant absorption estimate [3] 0.67 Final estimate 0.7 [1] Absorption (measured as amount in the receptor fluid) is considered complete if more than 75 % of the doses is absorbed in the first 12 h. In case of complete absorption tape strips 3 - x need not to be added. In this study tape strips 3 - x are added. [2] If the total recovery for a single sample is below 95 %, normalisation to 100 % is required. In this study the recovery was below 95 % in all samples. Hence, normalisation was performed. [3] If the variation of the absorption estimate is above 25 %, one SD is added. One SD is added in this study. Some values for the receptor fluid (sampled in 1-h-time intervals) were given as “zero”. As no LOQ or LOD of the analytical method is specified in the study report, all zero values were corrected with the lowest measured value (0.002 %).	Receptor medium: Eagle's medium supplemented by 5 % bovine serum albumin and gentamycin (50mg/L), pH 7.4 Solubility of the a.s.: yes (2.2 mg/mL) Washing solution post exposure: 1 % v/v Tween 80 in PBS The study contains also data for rat skin, which are summarised above	
OECD 428 GLP: Yes Reliabilty: 2	Species: rat (Wistar rats Rj:WI) Age/sex: 6 – 8 w; male	Racumin Paste Concentration a.s.: 0.375 g/100 g	Dislodgeable dose Skin wash after 8 and 24 hours 84.44 5.27 Donor chamber wash 0.45 0.43 Skin associated dose	Cell type: Flow-through diffusion cells Flow rate: 1.5 mL/h	Anonymous, 2013a

	Localisation: abdomen No. of skin samples: 6 (3 donors) Skin thickness: 380-420 µm Skin type: dermatomed Exposure time: 8 h Post exposure time: 16 h Integrity test: TWEL	(target concentration) Area dose: 2.6 µg = 2.6 µL/cell	Tape strips 1 - 2: 0.55 / 0.44 Tape strips 3 - x: 0.56 / 0.28 Skin preparation: 0.91 / 0.18 Absorbed dose Receptor fluid: 0.52 / 0.17 Receptor chamber wash: 0.065 / 0.158 Total recovery: 87.42 / 5.47 Absorption complete?: No Absorbed at t_0.5 [1]: 59.77 / 6.64 Absorption estimate, if t_0.5<=75 % [1]: 1.98 / 0.36 Absorption estimate, if t_0.5>75 % [1]: N/A / N/A Absorption estimate normalized [2]: 2.27 / 0.39 Relevant absorption estimate [3]: 2.27 Final estimate: 2 [1] Absorption (measured as amount in the receptor fluid) is considered complete if more than 75 % of the dose is absorbed in the first 12 h. In case of complete absorption tape strips 3 - x need not to be added. In this study tape strips 3 - x are added. [2] If the total recovery for a single sample is below 95 %, normalisation to 100 % is required. In this study the recovery was below 95 % in all samples. Hence, normalisation was performed. [3] If the variation of the absorption estimate is above 25 %, one SD is added. Not required for this study. Some values for the receptor fluid (sampled in 1-h-time intervals) were given as “zero”. As no LOQ or LOD of the analytical method is specified in the study report, all zero values were corrected with the lowest measured value (0.002 %).	Exposed skin area: 1 cm^2 Receptor medium: Eagle's medium supplemented by 5 % bovine serum albumin and gentamycin (50mg/L), pH 7.4 Solubility of the a.s.: yes (2.2 mg/mL) Washing solution post exposure: 1 % v/v Tween 80 in PBS The study contains also data for human skin, which are summerised below	

Table 39

Summary table of animal studies on dermal absorption					
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, localisation No/group, exposure and post-exposure time, other information**	**Concentration of test substance / Label, Formulation details incl. identify and concentration, Doses (total volume/mass applied per area, amount of a.s. applied per area) Duration of exposure**	**Absorption data for each compartment (mean and SD as percentage of dose), absorption[10] (percentage of dose) calculated in accordance with EFSA Guidance on Dermal Absorption (2012) and final absorption value**	**Remarks (e.g. major deviations statements on variability and time-course, justification of non-inclusion of certain compartments, other relevant information) Signs of toxicity**	**Reference**
OECD 428 GLP: Yes Reliabilty: 2	Species: rat (Wistar rats Rj:WI) Age/sex: 6 – 8 w; male 4 groups of 4 animals exposure time: 8, 24,	Racumin Paste Concentration a.s.: 0.375 g/100 g (target concentration) Application volume: 2 x 30 mg (5	**8 h after dosing:** Recovery [%] / Mean / SD Dislodgeable dose Skin wash and application equipment: 88.65 / 2.91 Skin associated dose Tape strips 1 - 2: 0.14 / 0.09 Tape strips 3 - x: 0.68 / 0.36 Skin preparation: 2.08 / 0.94	Skin wash: up to 20 times after exposure with 1 % v/v Tween 80 in PBS	Anonymous, 2013b

10 Usually also includes absorbable dose as defined in OECD TG 427 unless there were serial non-detects in excreta, and takes into account variability, recovery and time-course.

	48, 168 h Exposure area: dorsal, 2 x 6 cm^2 Exposure system: plastic protective saddles, semi-occlusive	mg/cm^2)			

Absorbed dose		
Excreta	0.13	0.21
Exhaled CO_2	N/A	N/A
Carcass	1.18	0.12
Total recovery	92.86	1.55
Absorption complete?	No	
Absorbed at t_0.5 [1]	No data	
Absorption estimate, if t_0.5 ≤ 75 %	4.07	1.31
Absorption estimate, if t_0.5>75 %	N/A	N/A
Absorption estimate normalised [2]	4.40	1.49
Relevant absorption estimate [3]	5.89	
Final estimate	6	

[1] Absorption is considered complete if more than 75 % of the doses is absorbed in the first half of exposure time This cannot be determined here. Hence, in this study tape strips 3 - x are added.
[2] If the total recovery for a single sample is below 95 %, normalisation to 100 % is required. In this study the recovery was below 95 % in all samples. Hence, normalisation was performed.
[3] If the variation of the absorption estimate is above 25 %, one SD is added. One SD is added in this study.

24 h after dosing:

Recovery [%]	Mean	SD
Dislodgeable dose		
Skin wash and application equipment	86.13	3.96
Skin associated dose		
Tape strips 1 - 2	0.07	0.06
Tape strips 3 - x	0.32	0.21

Skin preparation		1.64		0.85	
Absorbed dose					
Excreta		2.07		2.08	
Exhaled CO_2	N/A		N/A		
Carcass		1.38		0.53	
Total recovery		91.61		2.90	
Absorption complete?		No			
Absorbed at t_0.5 [1)]		2.12		2.41	
Absorption estimate, if t_0.5<=75 %		5.42		1.56	
Absorption estimate, if t_0.5>75 %	N/A		N/A		
Absorption estimate normalised [2)]		5.94		1.80	
Relevant absorption estimate [3)]		7.74			
Final estimate		8			

[1)] Absorption is considered complete if more than 75 % of the doses is absorbed in the first half of exposure time If absorption is not complete tape strips 3 - x are added. Hence, in this study tape strips 3 - x are added.
[2)] If the total recovery for a single sample is below 95 %, normalisation to 100 % is required. In this study the recovery was below 95 % in all samples. Hence, normalisation was performed.
[3)] If the variation of the absorption estimate is above 25 %, one SD is added. One SD is added in this study.

72 h after dosing:

Recovery [%]	Mean	SD
Dislodgeable dose		
Skin wash and application equipment	90.62	1.59
Skin associated dose		
Tape strips 1 - 2	0.06	0.02

			Tape strips 3 - x		0.15	0.04		
			Skin preparation		1.84	1.11		
			Absorbed dose					
			Excreta		0.12	0.01		
			Exhaled CO_2	N/A	N/A			
			Carcass		1.43	0.14		
			Total recovery		94.22	0.77		
			Absorption complete?		No			
			Absorbed at t_0.5 [1)]		1.67	0.94		
			Absorption estimate, if t_0.5 ≤ 75 %		3.54	1.10		
			Absorption estimate, if t_0.5 > 75 %	N/A	N/A			
			Absorption estimate normalised [2)]		3.72	1.20		
			Relevant absorption estimate [3)]		4.92			
			Final estimate		5			

[1)] Absorption is considered complete if more than 75 % of the doses is absorbed in the first half of exposure time If absorption is not complete tape strips 3 - x are added. Hence, in this study tape strips 3 - x are added.
[2)] If the total recovery for a single sample is below 95 %, normalisation to 100 % is required. In this study the recovery was below 95 % in three samples. Hence, normalisation was performed for these samples.
[3)] If the variation of the absorption estimate is above 25 %, one SD is added. One SD is added in this study.

168 h after dosing:

Recovery [%]	Mean	SD
Dislodgeable dose		
Skin wash and application equipment	85.23	5.13
Skin associated dose		
Tape strips 1 - 2	0.06	0.04

			Tape strips 3 - x		0.12	0.10	
			Skin preparation		2.35	1.72	
			Absorbed dose				
			Excreta		0.50	0.30	
			Exhaled CO_2	N/A	N/A		
			Carcass		1.56	0.29	
			Total recovery		89.83	3.38	
			Absorption complete?		No		
			Absorbed at t_0.5 [1]		5.79	4.75	
			Absorption estimate, if t_0.5 ≤ 75 %		4.54	2.10	
			Absorption estimate, if t_0.5>75 %	N/A	N/A		
			Absorption estimate normalised [2]		5.10	2.56	
			Relevant absorption estimate [3]		7.67		
			Final estimate		8		
			[1] Absorption is considered complete if more than 75 % of the doses is absorbed in the first half of exposure time If absorption is not complete tape strips 3 - x are added. Hence, in this study tape strips 3 - x are added. [2] If the total recovery for a single sample is below 95 %, normalisation to 100 % is required. In this study the recovery was below 95 % in three samples. Hence, normalisation was performed for these samples. [3] If the variation of the absorption estimate is above 25 %, one SD is added. One SD is added in this study.				

The applicant has access to dermal absorption studies submitted for active substance evaluation. These studies were re-evaluated according to the EFSA Guidance on Dermal Absorption (2012). These values are higher than those calculated during active substance evaluation. These differences result mainly from the inclusion of tape strips to the absorbed doses, a surcharge for strong variation and a normalisation for low recoveries.

The studies (in-vivo rat; in vitro rat; in vitro human) were performed with the same test substance. Hence, a triple pack approach was performed. This approach would result in dermal absorption value, which is higher than the value obtained in the human in-vitro study. According to the EFSA

Guidance on Dermal Absorption (2012), rat data generally over predict dermal absorption. Therefore, it is justified to take the lower value from human in vitro data in cases this occurs. Hence, the dermal absorption for the test substance is identical to the value derived from the human in vitro study (0.7 %).

The biocidal product is not identical to the test formulation. With respect to foodstuff/bait components, the solvent and the bittering agent the biocidal product and the test substance are considered sufficiently similar. The exchange of the dye is also not expected to have any impact on dermal absorption. The main difference is the active substance concentration, which is 14.3-fold lower. It is generally accepted that the percentage of dermal absorption is inversely correlated to the active substance concentration. As a worst case a linear correlation can be assumed. This pro rata approach leads to an estimated dermal absorption of 10 %. This value has been used for exposure and risk assessment.

Table 40

Value(s) used in the Risk Assessment – Dermal absorption	
Substance exposure scenario(s)	Primary exposure to the biocidal product during application and disposal.
Value(s)	10 %
Justification for the selected value(s)	Based on an in-vitro dermal absorption study, adapted for lower active substance concentration (pro-rata-approach).

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

The applicant provided safety data sheets for the single components. Based on this information and other public available information (e.g. ECHA registry) it is concluded that the other non-active substances have no significant outcome on the toxicological profile of the biocidal product.

3.6.2.9 Available toxicological data relating to a mixture

Not relevant.

3.6.2.10 Other

Not available.

3.6.2.11 Summary of effects assessment

Table 41

Endpoint	Brief description
Skin corrosion and irritation	Based on the results of an animal study classification for skin irritation or corrosion is not required.
Eye irritation	Based on the results of an animal study classification for eye irritation or damage is not required.
Respiratory tract irritation	Not classified for respiratory tract irritation.
Skin sensitisation	Based on the results of animal studies classification for skin sensitisation is required.
Respiratory sensitization (ADS)	Not classified for respiratory sensitisation. Data on respiratory sensitisation for the single components or the biocidal product are not available.
Acute toxicity by oral route	Not classified for acute oral toxicity. Estimated oral LD_{50}: > 2000 mg/kg bw.
Acute toxicity by inhalation	Not classified for acute inhalation toxicity. Inhalation LC_{50} calculated from information on the ingredients: > 5.0 mg/L.
Acute toxicity by dermal	Not classified for acute dermal toxicity.

route	Dermal LD_{50} from an animal study: > 2000 mg/kg bw.
Information on dermal absorption	10 % dermal absorption for exposure assessment based on an in-vitro dermal absorption study and pro rata approach for lower active substance concentration.
Available toxicological data relating to non-active substance(s)	Other components than the-active substances have no significant outcome on the toxicological profile of the biocidal product.
Available toxicological data relating to a mixture	Not relevant.
Other relevant information	Not available.

3.6.3 Exposure assessment

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

Table 42

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.	n.a.	Not relevant	n.a.	n.a.	Not relevant	n.a.
Dermal	n.a.	n.a.	yes	n.a.	n.a.	Not relevant	n.a.
Oral	n.a.	n.a.	no	n.a.	n.a.	yes	no

List of scenarios

Table 43

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Application and disposal	Primary exposure - biocidal product in sachets is placed in bait stations by an adult; max. 20 sachets per bait point, 5 bait points	Non-professional user
2.	Application and disposal	Primary exposure - biocidal product in sachets is speared on a wire by an adult; max. 20 sachets per bait point, 5 bait points	Non-professional user
3.	Mouthing	Swallowing/ingestion of baits by toddlers a) Swallowing of one bite b) Transient mouthing of a bait (e.g. with repellent)	General public

3.6.3.1.1 Non-professional exposure

The primary exposure scenario is based on an exposure study already submitted for active substance evaluation of coumatetralyl (Maasfeld, W.; Müller, G.; 2004). This study was re-evaluated taken into consideration the Biocides Human Health Exposure Methodology (2015) and the TNsG on Human Exposure (2007).

During active substance approval the geometric mean and the maximum values were chosen for exposure and risk assessment. It was assumed that these values represent average and worst case conditions. An evaluation of the exposure study considering the uncertainty of the indicative exposure values as proposed to the TNsG on Human Exposure (2007) was not performed. The approach is also included in the Biocides Human Health Exposure Methodology (2015).

According to the TNsG on Human Exposure the selection of the indicative exposure values should base on the uncertainty of the corresponding data. This uncertainty is defined from the number of measured values and their variability or - more precisely - from the 90 % confidence interval of the 75th percentile.

In the following exposure assessment the indicative values were selected in accordance to the TNsG on Human Exposure, section 2.12. Although the number of data points were very small (5 values for scenario 1 and 6 values for scenario 2) the 75th percentile could be selected for exposure and risk assessment.

The study of Maasfeld and Müller (2004) monitored the following exposure scenarios

a) Application by professional: spearing of 20 sachets to wires
b) Disposal by professional: removal of 10 sachets from wires (5 prepared as if partly eaten)
c) Application by amateur: placing of 5 sachets into bait boxes
d) Disposal by amateur: removal of 3 sachets from bait boxes (two prepared as partly eaten)

Based on scenario a) and b) of this study indicative exposure values for scenario 2 in this PAR were derived. Based on scenario c) and d) of this study indicative exposure values for scenario 1 in this PAR were derived.

Scenario a) and b) were performed by six professional users. They wear protective gloves (nitrile gloves) during application. Exposure was determined on gloves (potential exposure) and in gloves (actual exposure). For non-professional exposure assessment exposure in and on gloves was summed up. Based on the simple conduction of this scenario and the minimal knowledge, which is needed to perform this task the exposure values from this part of study (derived from professional users) can also be used for non-professional users.

Scenario c and d were performed by no-professional users not wearing protective gloves.

The samples were prepared for analysis by LC-MS/MS. The LoQ of the analytical method was 0.1 µg a.s per sample. For samples below the LoQ an amount of 0.05 µg a.s. per sample was assumed.

The study was performed with Racumin paste containing an nominal concentration 0.0375 % coumatetralyl.

The results are summarised in the following tables.

Table 44 Scenarios a) and b) of the study, professional exposure, spearing sachets on wires (mg b.p./person/sachet), potential (on gloves) and actual exposure (in gloves) are summed up, relevant for scenario 2 of the PAR

Person A	Person B	Person C	Person D	Person E	Person F	Geometric mean	SD	75th percentile
Application								
1.9267	2.3867	2.3933	1.7867	2.5667	2.7667	2.2777	0.2985	2.5233
Disposal								
1.2640	1.1627	0.8800	1.2848	1.2907	2.9200	1.3576	0.4843	1.2892

Table 45 Scenarios c) and d) of the study, non-professional exposure, placing sachets into bait station (mg b.p./person/sachet), relevant for scenario 1 of the PAR

Person A	Person B	Person C	Person D	Person E	Geometric mean	SD	75th percentile
Application							
0.2235	0.1664	0.0267	0.6827	0.4917	0.2016	0.2152	0.4917
Disposal							
0.0444	0.1556	0.1138	0.0444	0.0444	0.0689	0.0433	0.1138

- **Scenario [1]**

Table 46

Description of Scenario [1]		
The biocidal product is directly applied by the non-professional user, who places the bait sachets at the baiting points. For disposal the non-professional user collects the sachets, which might be partly eaten and damaged. Indicative exposure values were derived from the exposure study "Determination of Operator Exposure to Coumatetralyl during Application and Disposal of Racumin® Paste by Professionals and Amateurs (Maasfeld, W. and Müller, G.; 2004)". The biocidal product and the test formulation belong to the same formulation type (paste bait in sachets). One exposure scenario simulated in the study (direct application of the paste bait packaged into sachets to baiting points by non-professional users) is comparable to this primary exposure scenario evaluated for the biocidal products. Hence, the exposure study is appropriate for the biocidal product and the application proposed by the applicant. In the exposure study the non-professional users placed 5 baits and disposed 3 baits. Data were adapted to exposure per bait (sachet). According to the HEEG opinion No. 10 the non-professional user normally place 5 baits at 5 bait points (in total 25 baits) unless the description of the application as provided by the applicant implies a higher number of baits. For Secuverd 26 the applicant noted that the maximum number of baits per baiting point is 20. Hence, the maximum number of baits for this biocidal product is 100. Based on the physico-chemico properties of the active substance and the specific use inhalation and oral exposure is considered not relevant.		
	Parameters	Value
Tier 1	Indicative exposure value, application (75th percentile, Maasfeld and Müller, 2004)	0.4917 mg BP / bait (sachet)
	Indicative exposure value, disposal (75th percentile, Maasfeld and Müller, 2004)	0.1138 mg BP / bait (sachet)
	No. of baits	100
	Concentration a.s. in BP	0.0027 g / 100 g
	Dermal absorption (Odin-Feurtet, 2013a+b)	10 %
	Body weight adult (HEEG opinion No. 17)	60 kg

Calculations for Scenario [1]

Systemic exposure

$Exposure_{dermal}$ = (indicative exposure application + indicative exposure disposal) x no. of baits x concentration a.s. in BP x dermal absorption / body weight adult

= (0.4917 mg + 0.1138 mg) x 100 x 0.0027 % x 10 % / 60 kg

= 2.72 x 10^{-6} mg/kg bw

Total systemic exposure =2.72 x 10^{-6} mg/kg bw

Table 47

Description of Scenario [2]		
The biocidal product is applied by the non-professional user, who secures the bait sachets after spearing them on a wire. For disposal the non-professional user collects the speared sachets, which might be partly eaten and damaged. This scenario represents a worst case for all applications where the biocidal product has to be fixed (e.g. to avoid that they are dragged away). Indicative exposure values were derived from the exposure study "Determination of Operator Exposure to Coumatetralyl during Application and Disposal of Racumin® Paste by Professionals and Amateurs (Maasfeld, W. and Müller, G.; 2004)". The biocidal product and the test formulation belong to the same formulation type (paste bait in sachets). One exposure scenario simulated in the study (spearing the paste bait packaged into sachets onto wires by professional users) is comparable to this primary exposure scenario evaluated for the biocidal products. Based on the simple conduction of this scenario and the minimal knowledge, which is needed to perform this task the exposure values from this part of study (derived from professional users) can also be used for non-professional users. Hence, the exposure study is appropriate for the biocidal product and the application proposed by the applicant. In the exposure study professional users placed 20 baits and disposed 10 baits. Data were adapted to exposure per bait (sachet). According to the HEEG opinion No. 10 the non-professional user normally place 5 baits at 5 bait points (in total 25 baits) unless the description of the application as provided by the applicant implies a higher number of baits. For Secuverd 26 the applicant noted that the maximum number of baits per baiting point is 20. Hence, the maximum number of baits placed and collected for disposal is 100 in this case. Based on the physico-chemico properties of the active substance and the specific use inhalation and oral exposure is considered not relevant.		
	Parameters	Value
Tier 1	Indicative exposure value application (75th percentile, Maasfeld and Müller, 2004)	2.5233 mg BP / bait (sachet)
	Indicative exposure value disposal (75th percentile, Maasfeld and Müller, 2004)	1.2892 mg BP / bait (sachet)
	No. of baits (applicant)	100
	Concentration a.s. in BP	0.0027 g / 100 g
	Dermal absorption (Odin-Feurtet, 2013 a + b)	10 %
	Body weight, adult (HEEG opinion No. 17)	60 kg

Calculations for Scenario [2]

Systemic exposure

$Exposure_{dermal}$ = (indicative exposure application + indicative exposure disposal) x no. of baits x concentration a.s. in BP x dermal absorption / body weight adult

= (2.5233 mg + 1.2892 mg) x 100 x 0.0027 % x 10 % / 60 kg

= 1.72×10^{-5} mg/kg bw

Total systemic exposure =1.72×10^{-5} mg/kg bw

Table 48

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	1	-	2.72×10^{-6} mg/kg bw	-	2.72×10^{-6} mg/kg bw
Scenario [2]	1	-	1.72×10^{-5} mg/kg bw	-	1.72×10^{-5} mg/kg bw

- **Combined scenarios**

Not relevant.

3.6.3.1.2 Secondary exposure of the general public

- **Scenario [3]**

Table 49

Description of Scenario [3]
Ingestion and mouthing of rodenticide bait. The ingestion of rodenticide bait is considered as an exceptional scenario, which may occur accidentally. Based on the TNsG on human exposure (2007) it is assumed that a child (toddler) may consume up to 5 g, particularly if no bait boxes are used and no bittering agent is added. For other cases when the risk of oral exposure is minimised by addition of an aversive agent and by an appropriate covering of baits (e.g. by use of a bait station) an ingested amount of 10 mg is expected since the bait is only mouthed but not swallowed as such. Inhalation exposure is considered not relevant due to the physico-chemico properties and the specific use conditions. Potential dermal exposure is covered by the oral exposure assessment.

	Parameters	Value
Tier 1	a) Ingested amount by swallowing, no aversive agent, no covered application (TNsG on Human Exposure, 2007)	5000 mg
	b) Ingested amount by mouthing, aversive agent, covered application (TNsG on Human Exposure, 2002)	10 mg
	Concentration a.s. in BP	0.0027 g / 100 g
	Oral absorption (AR, 2009, 2016)	75 %
	Body weight, toddler (HEEG opinion No. 17)	10 kg

Calculations for Scenario [3]

$Exposure_{oral}$ = Ingested amount x concentration a.s. in BP x oral absorption / body weight adult

a)

$Exposure_{oral}$ = 5000 mg x 0.0027 % x 75 % / 10 kg

= 0.010125 mg/kg bw

b)

$Exposure_{oral}$ = 10 mg x 0.0027 % x 75 % / 10 kg

= 2.025×10^{-5} mg/kg bw

Table 50

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3a]	1	-	-	0.010125 mg/kg bw	0.010125 mg/kg bw
Scenario [3b]	1	-	-	2.025×10^{-5} mg/kg bw	2.025×10^{-5} mg/kg bw

- **Combined scenarios**

Not relevant.

3.6.3.2 Dietary exposure

The intended use descriptions of the coumatetralyl containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The products are to be used for control Norways rats, bank voles and water voles by non-professional bait application that does not come in direct contact with food, feedstuff or livestock animals.

3.6.4 Risk characterisation for human health

3.6.4.1 Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report(s) as in Table 21 and 22 in chapter 3.6.1.

3.6.4.2 Maximum residue limits or equivalent

No MRLs are required.

3.6.4.3 Risk for non-professional users

Table 51: Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw	AEL mg/kg bw	Estimated uptake mg/kg bw	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1	1	0.0125	0.000031	2.72×10^{-6}	8.8	yes
2	1	0.0125	0.000031	1.72×10^{-5}	55	yes

- **Local effects**

Not relevant.

Conclusion

Non-professional use is considered safe if the biocidal product is used as intended and all advices are followed.

3.6.4.4 Risk for the general public

Table 52: Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw	AEL mg/kg bw	Estimated uptake mg/kg bw	Estimated uptake/ AEL (%)	Acceptable (yes/no)
3a	1	0.0125	0.000031	1.01×10^{-2}	32661	No
3b	1	0.0125	0.000031	2.03×10^{-5}	65	Yes, with appropriate RMM

- **Local effects**

Not relevant.

Conclusion

For secondary exposure, a risk is been identified for children ingesting larger amount of the baits accidentally. Hence, specific risk mitigation measures are required to prevent such an exposure. For selection of appropriate risk mitigation measures the Note for Guidance “Harmonised sentences to be used in the different sections of the SPC for anticoagulant rodenticides” and the Summary of product characteristics for a biocidal product containing anticoagulant active substances (on the basis of the harmonised SPC including derogations according to article 37 in Germany) are taken into account.

3.6.4.5 Risk for consumers via residues in food

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

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

Risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product is not required as the product contains only the active substance coumatetralyl and no SoC.

3.7 Risk assessment for animal health

Based on the human exposure and risk assessment, a risk for pets and other domestic animals must also be expected by ingestion of this rodenticide. Hence, specific risk mitigation measures are required to prevent such an exposure.

3.8 Risk assessment for the environment

3.8.1 General information

The biocidal product contains no substance of concern. Consequently, the environmental risk assessment for the product Secuverd 26 is based on the active substance coumatetralyl (see Assessment Report (AR) Coumatetralyl PT 14, July 2016 and Competent Authority Report (CAR) Coumatetralyl (Bayer Environmental Science; RMS Denmark; January 2009)). No new information compared to the CAR has been provided within product authorisation for Secuverd 26, so that the environmental risk assessment is based upon data given in the CAR and the AR for coumatetralyl. However, it should be noted that the content of the a.s. in the product Secuverd 26, i.e. 26 ppm, is much lower than that of the most rodenticides containing coumatetralyl (i.e. 375 ppm).

3.8.2 Effects assessment

The environmental effects assessment is based on the data provided within the approval of the a.s. coumatetralyl. No ecotoxicity data has been provided for the biocidal product.

3.8.2.1 Aquatic compartment (including sediment and STP)

No release to the sewage treatment plant (STP) and surface water occurs from the use of the product in and around buildings. Therefore, the appropriate PNECs are not relevant for this PAR.

3.8.2.2 Terrestrial compartment

From the acute 14-d study with earthworms (*Eisenia fetida*) the following $PNEC_{soil}$ was derived.

PNECsoil = 0.2 mg a.s./kg ww

3.8.2.3 Primary and secondary poisoning

3.8.2.3.1 Further ecotoxicological studies

For the acute exposure situation, no $PNEC_{oral}$ is determined and no quantitative risk characterisation is performed. Instead a qualitative assessment is done by comparing LD_{50} values to the expected contents of the active substances in birds and mammals.
For the qualitative assessment of acute primary and secondary poisoning the LD_{50} from acute oral studies are used. The lowest LD_{50} value for birds was > 2000 mg/kg bw, determined for Japanese quail (*Coturnix coturnix japonica)*. For mammals the LD_{50} value of 35 mg/kg bw from the acute oral toxicity study with dogs is used.

The $PNEC_{oral}$ for birds is derived from a chronic reproduction study with Japanese quail (*Coturnix coturnix japonica*). A NOEC of 20 mg a.s./kg food (equivalent to 2 mg a.s./kg bw/d) was derived in this study. An assessment factor of 30 is applied according to the BPR Guidance Vol. IV Part B (2015).

$PNEC_{oral,bird}$ = 0.667 mg a.s./kg food or **0.0667 mg a.s./kg bw/d**

The $PNEC_{oral}$ for mammals is based on a subchronic oral toxicity study with rats resulting in a NOEC of 13 mg a.s./kg food and a NOAEL of 0.0068 mg a.s./kg bw/d from the 90-day rat repeated dose toxicity test. An assessment factor of 90 is applied.

$PNEC_{oral,mammal}$ = 0.14 mg a.i./kg food or **0.0001 mg a.i./kg bw/d**

3.8.3 Fate and behaviour

The summary of information about the active substance coumatetralyl is carried out with the data from the Assessment Report (AR) of coumatetralyl for the first approval and for the renewal. Some new studies regarding fate and distribution in the environment have been submitted for renewal, these are hydrolysis, phototransformation in water and adsorption/desorption. Since these new information should be considered for assessment of a.s. and b.p. the results of the recently provided studies and the harmonised endpoints have been applied for the assessment of Secuverd 26. However, the new studies did not alter the conclusions from the first approval.
For biodegradation in soil new FOCUS kinetic calculations were submitted which are based on the same laboratory studies as evaluated in the first a.s. approval. At BPC WG ENV I/2016 it was agreed a further discussion at EU level is needed before the new FOCUS kinetic calculation can be used. Until

then it was decided to use the degradation half-life from the first approval; the half-life in soil was less than 30 days (primary degradation) under aerobic conditions.

3.8.3.1 Terrestrial compartment (including groundwater)

The assessment report of coumatetralyl for first approval indicates an octanol/water partition coefficient log Kow = 1.5 at 293 K under neutral conditions and an organic carbon-water partitioning coefficient Koc = 301.8 $cm^3 \cdot g^{-1}$ (average value from the adsorption/desorption screening test with 5 soils, supplied values from 71 - 735 $cm^3 \cdot g^{-1}$). A new adsorption/desorption study according to the OECD 106 guideline for coumatetralyl has been provided for the renewal of coumatetralyl. The Koc-values range from 61.6 to 771 $cm^3 \cdot g^{-1}$ (five soils) and did not change the conclusions from the first approval. For the risk assessment the arithmetic mean of Koc-values of all soils (study for first approval and study for renewal) has been used. The organic carbon-water partitioning coefficient Koc results in 295.99 $cm^3 \cdot g^{-1}$. Thus, a soil water partitioning coefficient Ksoil-water of 9.054 $m^3 \cdot m^{-3}$ is calculated.

3.8.3.2 Aquatic compartment

Coumatetralyl is slightly soluble in water ($4.6 \cdot 10^{-1}$ $g \cdot L^{-1}$ at neutral conditions and 293 K corresponding to $4.099 \cdot 10^{-1}$ $g \cdot L^{-1}$ at 285 K). According to the available tests coumatetralyl is considered stable to hydrolysis at environmentally relevant temperatures for all pH. Hydrolytic degradation is not expected to be a significant process in the environment. Coumatetralyl undergoes rapid phototransformation in aqueous solution.

3.8.3.3 Air compartment

Coumatetralyl is not expected to volatilise to air in significant quantities due to the low vapour pressure (vapour pressure $<1 \cdot 10^{-3}$ Pa at 293 K). A half-life of about 7 hours is estimated for coumatetralyl due to phototransformation in air (OH radical concentration of $5 \cdot 10^5$ $radicals \cdot cm^{-3}$ over 24 hours). The calculation is made using AOPWIN, version 1.91. Thus, no accumulation potential of the a.s. is assumed in the atmosphere.

3.8.3.4 Bioconcentration

The Log Kow of coumatetralyl ranges from -0.1 at pH 9 to 3.4 at pH 5. The Log Kow is below the screening criterion of ≥4.5 for being considered as bioaccumulative. A fish bioconcentration study is

available and this gives bioconcentration factors for edible parts, viscera and whole fish of 3.32, 20.8 and 11.4 respectively.

3.8.4 Exposure assessment

3.8.4.1 General information

The environmental exposure to coumatetralyl was assessed for the use of the active substance formulated as Secuverd 26 as a rodenticide paste bait (product type 14) for use indoors and around buildings (scenario 1), target organisms are the Brown rat (*Rattus norvegicus*) and for use by direct application into the burrows of bank and water voles (scenario 2). This application corresponds to the scenario open area in the ESD and is assessed accordingly.

Table 53

Assessed PT	*PT 14 Rodenticides*
Assessed scenarios	*Scenario 1: in and around buildings, high infestation* *Scenario 2: open areas, bait application in burrows*
ESD(s) used	*Emission Scenario Document for biocides used as rodenticides (ESD PT 14, EUBEES 2),, May 2003*
Approach	*in and around buildings: direct and indirect emission to soil open areas: direct emission to soil*
Distribution in the environment	*Calculation based on Guidance on the Biocidal Product Regulation Vol. IV Environment – Part B Risk Assessment (active substances) version 1.0, April 2015 (Guidance BPR IV ENV B (2015))*
Groundwater simulation	Refinement for groundwater assessment was made by using FOCUS PEARL 4.4.4 for both scenarios
Confidential Annexes	
Life cycle steps assessed	*Scenario 1 + 2:* *Production: No* *Formulation No* *Use: Yes* *Service life: No*
Remarks	

3.8.4.2 Fate and distribution in exposed environmental compartments

Table 54

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Soil	Ground-water	Air	Other
Scenario 1	No	No	No	No	No	Yes	Yes	No	Neither
Scenario 2	No	No	No	No	No	Yes	Yes	No	Neither

Table 55

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	292.3	g/Mol	
Melting point	441.95	K	
Boiling point		°C	no boiling point (LoEP)
Vapour pressure (at 12°C)	$5.614 \cdot 10^{-4}$	Pa	
Water solubility (at 12°C)	409.9	mg/L	
Log Octanol/water partition coefficient	1.5	Log 10	
Organic carbon/water partition coefficient (Koc)	295.99	L/kg	arithm. mean from 10 soils
Henry's Law Constant (at 12°C)	$4.008 \cdot 10^{-4}$	$Pa/m^3/mol$	calculated
Biodegradability	no		
Rate constant for STP	0	h^{-1}	
DT_{50} for biodegradation in surface water		d or hr (at 12ºC)	no data available
DT_{50} for hydrolysis in surface water		d or hr (at 12ºC /pH)	hydrolytically stable
DT_{50} for photolysis in surface water	< 1	d	
DT_{50} for degradation in soil	< 30	d (at 12ºC)	
DT_{50} for degradation in air	7	hr	

3.8.4.3 Aquatic compartment (including sediment and STP)

Scenario 1 and 2:

According to the ESD PT14 (EUBEES 2003) direct exposure of the sewerage system is assessed to be very limited and only to expect if rodent burrows are close to eroded sewerage systems. Therefore direct emissions are regarded to be negligible. Also direct emissions to surface water are assumed as negligible because the baits are applied in bait stations (Scenario 1) or introduced directly deep into the rat holes (Scenario 2).

3.8.4.4 Terrestrial compartment (including groundwater)

- **Emission estimation**

According to the ESD PT14 (EUBEES 2003), emission of the active substance (a.s.) to soil is the most relevant contribution to local environmental exposure resulting from rodenticide application in the environment.
The estimation of the local PEC for the terrestrial compartment includes also the groundwater. The PECgroundwater is calculated as a first worst-case estimation according to equation 68, chapter 2.3.8.6, Guidance BPR IV ENV B (2015).

- **Scenario [1]: In and around buildings**

Direct and indirect releases of coumatetralyl to soil following application of Secuverd 26 are estimated according to chapter 2.4 in ESD PT14. The direct releases from the sachets date from spills at refilling or cleaning operations of bait boxes, whereas the indirect releases are expected from rodents' urine, faeces and carcasses. According to the decision on TM 1/2006 the rate of a.s. released directly to soil could be reduced from 1% to 0.1% for paste baits in sachets.
The resulting concentrations due to the direct and indirect releases from Secuverd 26 applied in protected bait points in and around buildings and the predicted environmental concentration in soil (PECsoil) are estimated using equations (2) to (5) from ESD PT14. The input parameters are summarised in Table 149.

Table 56

Input parameters for calculating the local emission			
Input according to chapter 2.4.3.2, ESD PT14 (2003)	**Value**	**Unit**	**Remarks**
Scenario*: in and around building*			
Amount of product used at each refilling in the control operation for each bait - Q_{prod} box	200	*g*	S
Fraction of active substance in the product - Fc_{prod}	0.000026	-	S
Number of application sites - N_{sites}	10	-	D
Number of refilling times - N_{refil}	5	-	D
Fraction of a.s. released directly to soil - $F_{release\text{-}D,soil}$	0.001	-	According to decision at TM 1/2006 for paste

			baits in sachets
Fraction of a.s. that is metabolised - F_{metab}	0.93	-	S
Fraction of a.s. released indirectly to soil - $F_{release-ID,soil}$	0.07	-	S
Area directly exposed to rodenticide (around the box) - $AREA_{exposed-D}$	0.09	m^2	D
Area indirectly exposed to rodenticide - $AREA_{exposed-ID}$	550	m^2	D
Depth of exposed soil - $DEPTH_{soil}$	0.1	m	D
Density of exposed soil – RHO_{soil}	1700	$kg \cdot m^{-3}$	D
Output			
Local direct emission rate of active substance to soil from a campaign - $E_{local,soil-D-campaign}$	0.26	mg	
Local indirect emission rate of active substance to soil from a campaign - $E_{local,soil-ID-campaign}$	18.18	mg	
Concentration in soil due to direct release after a campaign - $C_{local\ soil-D}$	$1.7 \cdot 10^{-3}$	$mg \cdot kg^{-1}$	
Concentration in soil due to indirect (disperse) release after a campaign - $C_{local\ soil-ID}$	$1.94 \cdot 10^{-4}$	$mg \cdot kg^{-1}$	
Predicted environmental concentration in soil taking into account both direct and indirect releases - $\boldsymbol{PEC_{soil}}$	$1.89 \cdot 10^{-3}$	$mg \cdot kg^{-1}$	

The PECsoil of coumatetralyl resulting from application of Secuverd 26 in bait boxes in and around buildings is equal to **$1.89 \cdot 10^{-3}$ mg.kg^{-1}**.

The PEC in groundwater according to the first tier assessment results in **0.356 µg·L^{-1}**. This value exceeds the trigger value of 0.1 µg·L^{-1} of the Drinking Water Directive 98/83/EC and of the Ground Water Directive 2006/118/EC. Therefore a refinement of the groundwater assessment is necessary. Indirect emissions to soil via urine and faeces are 7% of the active substance and 72.5% metabolites (see CAR coumatetralyl January 2009, Doc II, Appendix II, chapter 2.1.1.1). The refinement for groundwater was performed for the a. s. and for the major metabolite 13-hydroxycoumatetralyl by using FOCUS groundwater scenarios (PEARL 4.4.4 model) according to the recommendations of Petersohn (2014). For use in and around buildings 10 bait points are assumed per building with 11 buildings per hectare. It is assumed that baits are dispersed 5 times during a campaign: on 15th September, 17th September, 21st September, 28th September and 5th October. The crops grass/alfalfa and apples are be used as typical crops (according to the availability in FOCUS crop scenarios) in the close neighbourhood of buildings. The application rate for coumatetralyl is calculated to 0.041 g·ha^{-1} and for the metabolite to 0.415 g·ha^{-1}. The input-parameters for the FOCUS PEARL model are summarized in Table 57.

Table 57 Summary of chemical parameters of coumatetralyl and metabolite 13-hydroxycoumatetralyl used for FOCUS PEARL 4.4.4 simulations

	Coumatetralyl		**13-hydroxy-coumatetralyl**	
Parameter	**Value**	**Remarks**	**Value**	**Remarks**
Physico-Chemical parameters				
Molecular weight [g/mol]	292.3	CAR 2009	308.34	EPI-Win 4.0 calculation (US-EPA software tool)
Water solubility [mg/L] (20°C)	460 (pH 7)	CAR 2009	80.9	EPI-Win 4.0 calculation (US-EPA software tool)
Vapour pressure [Pa] (20°C)	1.0×10^{-3}	CAR 2009	0.335×10^{-7}	EPI-Win 4.0 calculation (US-EPA software tool)
Degradation in soil				
DT_{50} soil [d]	30 at 22°C	DocIIIA7.2.1-01/02	30 at 22°C	EPI-Win 4.0 calculation (US-EPA software tool)
Sorption to soil				
K_{oc} [mL/g]	295.99	See above ch. 2.8.3.1	55.7	KOCWIN-calculation from the applicant
K_{om} [mL/g]	171.7	Derivation from K_{oc}	32.3	Derivation from K_{oc}
Freundlich exponent 1/n [-]	0.9	FOCUS recommendation	0.9	FOCUS recommendation
Crop/ Management related parameters				
a) Gras / alfalfa				
b) Apple trees				
Plant uptake factor [-]	0	FOCUS recommendation for non-systemic a.s.	0	FOCUS recommendation for non-systemic a.s.
Application Schemes				
Application type	to the soil surface	Indirect release via urine, faeces and carcasses	to the soil surface	Indirect release via urine, faeces and carcasses
Gras / alfalfa: Dosage [kg/ha]	$5 \times 4.1 \cdot 10^{-5}$	5 times (ref. to text here above)	$5 \times 4.15 \cdot 10^{-4}$	

From the FOCUS PEARL calculation it can be seen that the average concentrations of coumatetralyl closest to the 80th percentile are <0.000001 $\mu g \cdot L^{-1}$ and for the major metabolite 13-hydroxy-coumatetralyl are <0.006 $\mu g \cdot L^{-1}$. This applies to all 9 EU-Scenarios at 1 m soil depth and both the grass/alfalfa and apple scenario.

- **Scenario [2]**

For the estimation of direct emissions to soil and calculation of the local predicted environmental concentration in soil (PECsoil) the emission scenario from ESD PT14 “open areas” was applied. RMS decided to use this scenario for estimation because the type of application (direct introduction of baits into the holes) corresponds exactly to the scenario open areas as described in the ESD; although the real application takes place in the close neighbourhood of buildings according to the information of the applicant. Additionally it is considered that this scenario supplies the strongest assessment and thus, the realistic worst case is described for this type of use. The release of coumatetralyl to soil and the predicted environmental concentration in soil (PECsoil) are estimated according to chapter 2.5, equations (9) and (10) from ESD PT14, the input parameters are summarised in Table 58.

Table 58

Input parameters for calculating the local emission[11]			
Input	**Value**	**Unit**	**Remarks**
Scenario: *open area (application direct in vole corridors)*			
Amount of product used at each refilling in the control campaign per hole - *Qprod*	20	*g*	S
Fraction of a.s. in product - *Fcprod*	0.000026	-	S
Number of application sites - *Nsites*	1	-	D
Number of refilling times - *Nrefil*	2	-	D
Fraction of a.s. released to soil during application - *Frelease, soil, appl*	0.05	-	D
Fraction of a.s. released to soil during use - *Frelease, soil, use*	0.2	-	D
Density of exposed soil - *RHOsoil*	1700	$kg \cdot m^{-3}$	D
Soil volume exposed to a.s. - *Vsoilexposed*	$8.48 \cdot 10^{-3}$	m^3	D/O
Output			
Local emission rate of active substance to soil during control campaign – *Elocal,soil-campaign*	$2.6 \cdot 10^{-1}$	mg	O
Predicted environmental concentration in soil at each hole per control campaign - ***PECsoil***	$1.8 \cdot 10^{-2}$	$mg \cdot kg^{-1}$	O

The PECsoil of coumatetralyl resulting from application of Secuverd 26 in vole corridors in the vicinity of individual bait points is equal to **$1.8 \cdot 10^{-2}$ mg·kg^{-1}**.
The PEC in groundwater according to the first tier assessment results in **33.8 µg·L^{-1}**. This value clearly exceeds the trigger value of 0.1 µg·L^{-1} of the Drinking Water Directive 98/83/EC and of the Ground Water Directive 2006/118/EC. Therefore a refinement of the groundwater assessment also for this scenario is necessary.
The refinement of the PECs in groundwater were calculated using the FOCUS groundwater scenarios (PEARL 4.4.4 model) according to Petersohn (2014). For use in open areas 100 bait points are assumed per hectare. It is assumed that baits are dispersed 3 times per season on 15th March, 17th March, 22nd March in spring and 15th September, 17th September, 22nd September in autumn. The crops grass/alfalfa are be used as typical crops. The application rate for coumatetralyl is calculated to 0.013 g·ha^{-1} and for the metabolite to 0.00754 g·ha^{-1}. The input-parameters for the a.s. as well as for the metabolite in FOCUS PEARL model are the same as for scenario 1.
From the FOCUS PEARL calculation it can be seen that the average concentrations of coumatetralyl closest to the 80th percentile are <0.000001 µg·L^{-1} and for the major metabolite 13-hydroxy-coumatetralyl are <0.000008 µg·L^{-1}. This applies to all 9 EU-Scenarios at 1 m soil depth for the grass/alfalfa scenario.

3.8.4.5 Atmosphere

Scenario 1 and 2:
In view of the limited volatility of coumatetralyl and the anticipated use pattern, emissions to the air are regarded to be not significant in relation to the intended use pattern and are assumed to be negligible.

3.8.4.6 Non-compartment specific effects

- **Primary poisoning**

Rodenticide bait formulations entail the possibility of bait consumption by non-target animals. Particularly birds and mammals of the same size as the target rodents are vulnerable to primary poisoning as these are able to enter bait stations. Moreover, target animals can carry baits away from bait stations/points and thus, non-target animals may be exposed. According to ESD PT14 and to the 23rd CA meeting a qualitative and quantitative risk assessment is conducted for the acute and long-term poisoning situation, respectively.
The qualitative first tier assessment (short term situation) assumes that non-target animals are directly exposed to the bait, without considering bait avoidance and assuming that the non-target animal obtains

the diet exclusively in the treated area. The estimation of daily uptake (ETE) of coumatetralyl by non-target animals is calculated according to equation 19 of ESD PT14. In the second tier assessment, the avoidance factor and the fraction of diet obtained in the treated area are set to 0.9 and 0.8, respectively. An elimination factor of 0.3 (default-value) is used to calculate the expected concentration (EC1) in the non-target animal after one day of exposure (ref. to eq. 20 in ESD PT14).

The highest values for ETE and EC1 are received by the tree sparrow as representative for birds and the dog as representative for mammals and were shown in table 151 (AV=0.9, PT=0.8).

Table 59

Summary table on estimated theoretical exposition (ETE)		
	ETE	**EC1**
	[mg/kg_{bw}]	[mg/kg_{bw}]
tree sparrow	6.47	4.53
dog	1.12	0.79

To carry out an estimation for a long-term exposure, the expected concentration in non-target animals after 5 days of exposure taking elimination into account should be calculated according to ESD PT14 (ref. to eq. 21). For a worst case situation the values for AV, PD, and PT are set to 1.
These EC5 values are used for quantitative risk assessment of primary poisoning in long-term situation (as agreed upon at 23rd CA-Meeting). The maximum values of expected coumatetralyl concentration for long-term (poisoning) situation due to primary poisoning are calculated again for tree sparrow with EC5 = 12.55 mg/kg and for dogs with EC5 = 2.18 mg/kg (AV=0.9, PT=0.8).

Secuverd 26 is a ready-to-use bait in form of 10 g sachets. According to the use instructions it is recommended for

- in and around building to apply in bait boxes or to placed, secured with wire or nail and covered, in a manner to be inaccessible to children and non-target organisms;
- application direct in the burrows to place by hand two 10 g sachets deeply into each corridor and afterwards every corridor should be closed carefully. The bait sachets must be placed hidden and safe inside the burrow gallery, in a manner to be inaccessible to children and non-target organisms.

Spillage of bait is extremely unlikely due to the nature of the delivery (highly viscous, dough-like log in a paper sachet). Therefore birds and carnivorous mammals are normally without possibility to reach the baits and if accidentally happen the baits are unattractive based on the paste formulation and its color (blue). Baits in a burrow would also be inaccessible to domestic pets such as dogs. Concerning the product it is assumed that non-target animals are not directly exposed to coumatetralyl from direct consumption of the rodenticide bait, thus only a very limited risk is to be expected.

- **Secondary poisoning**

Predatory birds and mammals are especially susceptible for indirect poisoning effects caused by the intake of already accumulated substances with their prey. Two different accumulation pathways have to be distinguished: first the bioaccumulation of rodenticide via the aquatic food chain in fish and consequently in fish-eating birds or mammals and second the bioaccumulation of rodenticide via the terrestrial food chain in earthworms and consequently in worm eating birds or mammals. Only the second pathway is relevant for Secuverd 26, as the b.p. is only applied in and around buildings or in burrows around buildings and normally no releases to the aquatic environment are assumed.

The bioaccumulation of coumatetralyl via the terrestrial food chain in earthworms and consequently in worm eating birds or mammals is calculated according to chapter 3.8.3.7 of the Guidance BPR IV ENV B (2015). The $PEC_{oral,predator}$ is a function of PEC_{soil}, $PEC_{porewater}$ as well as bioconcentration for earthworms. The predicted environmental concentration of a.s. and its residues in food via this pathway are estimated for the scenarios in and around buildings and open areas, the values are shown in Table 60.

Table 60 Summary of $PEC_{oral, predator}$ via terrestrial food chain

Scenario/Application	$PEC_{oral, predator}$ [mg.kg-1]
Scenario 1: In and around buildings (bait boxes)	$2.91 \cdot 10^{-4}$
Scenario 2: Open areas (rat holes)	$2.77 \cdot 10^{-2}$

The secondary poisoning assessment of non-target animals via food chain according to the Guidance BPR IV ENV B (2015) considers the oral intake of coumatetralyl via fish and worms. However, rodenticide active substances may enter the food chain of terrestrial predators also via rodenticide bait → rodent → rodent-eating mammal or rodent-eating bird. For estimation of secondary poisoning risk through poisoned rats or voles, the amount of coumatetralyl in the target animals is estimated in the same way as the non-target body concentrations for primary poisoning (eq. 19 and 21 in ESD PT14).

In the calculation for **short-term** (poisoning) situation of non-target animals (qualitative estimation), PEC_{oral} is defined as the concentration in the rodent immediately after a last meal on day 5. The fraction of the food type in the diet (PD) is set to 1 and F_{rodent} = 1 (non-target animals consume 100 % of their daily intake on poisoned rats).

PEC_{oral} (EC5) is equal to 7.21 $mg \cdot kg^{-1}$.

For the **long-term** (poisoning) situation a tired quantitative assessment is carried out for secondary poisoning. Following the first tier, the PEC_{oral} is the concentration in rodent after a last meal on day 5; PD = 1 and F_{rodent} = 0.5. PEC_{oral} is equal to 3.605 $mg \cdot kg^{-1}$.

The **PEC_{oral}** in tier 2 evaluation is the concentration in non-target animals after a single day of exposure (ref. to ESD PT14 and 23rd CA-Meeting). The values for PEC_{oral} resulting from tier 2 evaluation are summarised in Table 61.

Table 61: Expected concentration PEC_{oral} of coumatetralyl in non-target animals due to secondary poisoning after a single day of exposure, rodents caught by predators on day 5

Species	**$PEC_{oral, predator}$** [$mg \cdot kg^{-1}$]
Barn owl	0.89
Kestrel	**1.36**
Little owl	1.02
Tawny owl	0.82
Fox	0.33
Polecat	0.69
Stoat	0.98
Weasel	**1.41**

The maximum values of expected coumatetralyl concentration for long-term (poisoning) situation due to secondary poisoning are calculated for weasel (mammals) and kestrel (birds), cf. bold values in Table 61. Bold values are used as PEC_{oral} for the second tier quantitative risk characterisation of secondary poisoning for birds and mammals, respectively.

3.8.4.7 Calculated PEC values

Table 62

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/m^3]	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg/kg]	[µg/L]	[mg/m^3]
Scenario 1	-	-	-	-	-	$1.89 \cdot 10^{-3}$	0.356	-
Scenario 2	-	-	-	-	-	0.018	33.8	-

The refinement of the PECs in groundwater by using the FOCUS PEARL 4.4.4 model results in average concentrations closest to the 80th percentile <0.000001 $\mu g \cdot L^{-1}$ and <0.006 $\mu g \cdot L^{-1}$ for coumatetralyl and major metabolite 13-hydroxy-coumatetralyl, respectively. This applies to all 9 EU-Scenarios at 1 m soil depth for both scenario 1 and 2 and for all crops. The results are represented below.

Scenario 1 (in and around buildings):

Scenario 1	Coumatetralyl		Metabolite	
	Grass	Apples	Grass	Apples
CHATEAUDUN	0.000000	0.000000	0.000676	0.001442
HAMBURG	0.000000	0.000000	0.002694	0.005458
JOKIOINEN	0.000000	0.000000	0.000575	0.000620
KREMSMUENSTER	0.000000	0.000000	0.001019	0.001802
OKEHAMPTON	0.000000	0.000000	0.002933	0.003700
PIACENZA	0.000000	0.000000	0.003891	0.005182
PORTO	0.000000	0.000000	0.002852	0.003364
SEVILLA	0.000000	0.000000	0.000368	0.001875
THIVA	0.000000	0.000000	0.000615	0.001979

Scenario 2 (open area):

Scenario 2	grass	
	Coumatetralyl	Metabolite
CHATEAUDUN	0.000000	0.000001
HAMBURG	0.000000	0.000004
JOKIOINEN	0.000000	0.000000
KREMSMUENSTER	0.000000	0.000001
OKEHAMPTON	0.000000	0.000004
PIACENZA	0.000000	0.000007
PORTO	0.000000	0.000003
SEVILLA	0.000000	0.000000
THIVA	0.000000	0.000000

3.8.5 Risk characterisation

The risk characterisation is performed for the biocidal product Secuverd 26 for the use in and around buildings by the general public. The use of the product in burrows has been disregarded within the risk characterisation as the general public is only allowed to use the product in bait stations (see Commission implementing regulation (EU) 2017/1378). The product is a ready-to-use bait in form of 10 g sachets (up to 200 g per baiting point), which are placed into temper-resistant bait stations.
The active substance coumatetralyl is present in the product at a concentration of 0.0026 % w/w.
The biocidal product contains no substance of concern. Therefore, the risk characterisation is based on the risk characterisation of the active substance with respect to the environmental exposure assessment.

3.8.5.1 Aquatic compartment (sediment and STP)

The ESD PT14 specifies release to the sewage and further to the STP and surface water as “not relevant” for the application scenario in and around buildings. Thus, exposure of microorganisms in the STP, of surface water and sediment can be regarded as negligible for these use patterns of Secuverd 26.

3.8.5.2 Terrestrial compartment (Soil/Groundwater)

According to the ESD PT14 direct emissions to soil may occur from the use of the product around buildings. It should be noted that no risk characterization has been performed for the application of Secuverd 26 directly into rodent burrows as the non-professional use of rodenticides containing coumatetralyl has been restricted to bait stations within the renewal of the a.s. (see Commission implementing regulation (EU) 2017/1378).

Table 63 PEC/PNEC ratios for soil resulting from application of Secuverd 26

Exposure scenario / Application	**PEC** [mg/kg ww]	**PNEC** [mg/kg ww]	**PEC / PNEC**
In and around buildings	0.002	0.2	0.01

Conclusion to the risk assessment

The PEC/PNEC ratio for the exposure scenario in and around building is below 1. Therefore, no risk for the terrestrial compartment is indicated for this exposure scenario.

- **Groundwater**

Leaching of the active substance from the soil to the groundwater was calculated according to the BPR Annex VI point 68. The PECgroundwater is calculated as a first worst-case estimation according to equation 68, chapter 2.3.8.6, Guidance on the Biocidal Product Regulation Vol. IV Environment – Part B Risk Assessment (active substances) version 1.0, April 2015 (Guidance BPR IV ENV B (2015)).

Table 64 PEC/PNEC ratios for groundwater resulting from application of Secuverd 26.

Exposure scenario / Application	**PEC** [µg/L]	**Trigger** [µg/L]*	**PEC / Trigger value**
In and around buildings	0.356	0.1*	3.56

* The maximum permissible concentration of the active substance or of any other substance of concern in groundwater must not exceed the limit value of 0.1 µg l^{-1} as laid down by Directive 98/93/EC.

The PEC in groundwater following application of Secuverd 26 in and around buildings results in 0.356 $\mu g \cdot L^{-1}$. This value exceeds the trigger value of 0.1 $\mu g \cdot L^{-1}$ of the Drinking Water Directive 98/83/EC. Therefore a refinement of the groundwater assessment was necessary. The FOCUS model PEARL 4.4.4 was used for the refinement.
From the FOCUS PEARL calculation it can be seen that the average concentrations of coumatetralyl closest to the 80th percentile are <0.000001 $\mu g \cdot L^{-1}$ and for the major metabolite 13-hydroxy-coumatetralyl are <0.006 $\mu g \cdot L^{-1}$. This applies to all 9 EU-Scenarios at 1 m soil depth and both the grass/alfalfa and apple scenario.

Conclusion to the risk assessment
The calculated PEC of the active substance does not exceed the limit value of 0.1 µg/L as laid down in Directive 98/93/EC. Therefore, no risk for groundwater is indicated using Secuverd 26 in and around buildings.

3.8.5.3 Atmosphere

Coumatetralyl is not expected to partition to the atmosphere to any significant extent due to low vapour pressure and Henry's Law constant. Coumatetralyl was degraded rapidly by light under artificial not environmentally relevant conditions to a number of degradation products. It can be concluded, that coumatetralyl has a potential for rapid photolytic degradation in the air. Coumatetralyl is not expected to have a potential for long-range atmospheric transport or contribute to global warming, ozone depletion or acidification on the basis of its physical and chemical properties.

Due to low vapour pressure of the active substance coumatetralyl, no adverse effects of the product Secuverd 26 are expected via atmospheric exposure. In conclusion there is no risk in relation to the intended use pattern.

3.8.5.4 Primary and secondary poisoning

The exposure of primary and secondary poisoning has been assessed according to the scenarios developed for rodenticides (hereafter called ESD). Pursuant to ESD PT14 and to Appendix 6 of the BPR Guidance Vol. IV Part B (2015), a qualitative and quantitative risk assessment is conducted for the acute and long-term poisoning situation, respectively.

Table 65: PNECs to be used in the risk characterisation of primary and secondary poisoning

Species	**PNECoral** [mg/kg food]	**PNECoral** [mg/kg bw/d]
Birds	0.667	0.0667
Mammals	0.14	0.0001

- **Primary poisoning**

Secuverd 26 is a ready-to-use bait in form of 10 g sachets to be used together with bait stations for the control of rats in and around buildings and voles around buildings.

Qualitative risk assessment for the short-term situation
The maximum values of expected coumatetralyl concentration (PECs) for short-term (poisoning) situation due to primary poisoning are calculated for dogs (mammals) and tree sparrow (birds) (cf. Table 59). For the acute exposure situation, no $PNEC_{oral}$ is determined and no quantitative risk characterisation is performed. Instead a qualitative assessment is done by comparing LD_{50} values to the expected contents of the active substances in birds and mammals after 1 day exposure (EC1) and under consideration of excretion.

Table 66: Qualitative comparison of EC1 and LD_{50} values for birds and mammals

Species	**PEC EC1** [mg/kg bw]	**LD_{50}** [mg/kg bw]
Birds	4.53	2000
Mammals	0.79	35

Regarding the values given in Table 66, it can be followed that one day consumption of baits containing coumatetralyl is assumed not to be lethal to birds and mammals. The expected concentration of the active substance in the non-target animals after a single meal (EC1) is several times lower than the dose required to kill half of a test population (LD_{50}) of either mammals or birds. It is therefore assumed that Secuverd 26 exhibit a low acute toxicity to birds, whereas mammals appear to be more susceptible.

3.8.5.4.1.1 Quantitative risk assessment for the long-term situation

3.8.5.4.1.2 Tier 1 Assessment

The Tier 1 assessment of primary poisoning is based on the comparison of the concentration of the a.s. in the food (bait) and the $PNEC_{oral}$ related to the concentration in food.

Table 67: PEC/PNEC ratios for primary poisoning of non-target animals. PECoral is the concentration of the a.s. in the bait

Species	**PECoral** [mg/kg] Concentration of a.s. in bait	**PNEC** [mg/kg] Concentration of a.s. in food	**PEC/PNEC**
Birds	26	0.667	**39**
Mammals	26	0.14	**186**

The uptake of Secuverd 26 by non-target animals poses a risk of primary poisoning to both birds and mammals in the Tier 1 scenario. This is quite obvious as the purpose of rodenticide baits is to kill target rodents and the mode of action of anticoagulant rodenticides is similar in all warm-blooded organisms.

3.8.5.4.1.3 Tier 2 Assessment

According to the ESD PT 14 the comparison of the concentration in a non-target animal with the $PNEC_{oral}$ describes the long-term risk for primary poisoning. The expected concentration in the non-target animals are calculated after five days exposure (EC5) under consideration of excretion.

Table 68: Tier 2 risk characterisation for long-term situation. PECoral is the expected concentration of the a.s. in a non-target animal after five days exposure

Species		**PECoral (EC5)** [mg/kg bw]	**PNEC** [mg/kg bw/d]	**PEC/PNEC**
Tree sparrow	*Passer montanus*	12.55	0.0667	**188**
Dog	*Canis familiaris*	2.18	0.0001	**21800**

The results of the risk characterisation show that in a long-term situation Secuverd 26, if ingested by mammals or birds on five consecutive days, poses a high risk for primary poisoning even if taking

excretion into account. Again mammals appear to be at a higher risk in comparison to birds, although the ratio of food intake to body weight is higher for birds.

3.8.5.4.1.4 Conclusion from primary poisoning

Non-target mammals and birds are at risk for primary poisoning if they get access to Secuverd 26. Lethal and sub-lethal effects are likely in both animal groups especially in a long-term situation. Primary poisoning incidents can be minimized by preventing the access of non-target animals to the baits. It is assumed in the ESD that if the rodenticide baits are used according to the label instructions i.e. in bait stations, the risk for primary poisoning can be mitigated significantly. However, it may not be possible to exclude exposure of all non-target animals. As the baits have to be accessible to target rodents, they will be accessible to non-target mammals and birds of equal or smaller size than the target rodents as well.

- **Secondary poisoning**

Terrestrial food chains

Avian and mammalian predators of the terrestrial food chains may be at risk for secondary poisoning if they feed on contaminated soil organisms such as earthworms. The risk characterisation is done for both worm-eating birds and mammals to be consequent with the calculations done according to the ESD.

Table 69: Secondary poisoning via terrestrial food chain

Species	**$PEC_{oral,\ Predator}$** [mg/kg]	**$PNEC_{oral}$** [mg/kg food]	**PEC/PNEC**
Birds	$2.91 \cdot 10^{-4}$	0.667	**$4.36 \cdot 10^{-4}$**
Mammals	$2.91 \cdot 10^{-4}$	0.14	**$2.08 \cdot 10^{-3}$**

It can be followed from the results that both animal groups are not at risk when get exposed to Secuverd 26 via the terrestrial food chain.

It has to be noted the exposition to the aquatic compartment due to the use of Secuverd 26 in and around buildings has been considered negligible and thus the risk for secondary poisoning via the aquatic food chain has not been assessed.

Qualitative assessment for the short-term situation

A qualitative assessment of the acute secondary poisoning is made by comparing the expected concentration of the a.s. in rodents to LD_{50} values from acute oral toxicity studies with birds and mammals. Rodents are assumed to eat entirely on bait containing coumatetralyl and the non-target animals are assumed to consume 100 % of their daily intake on poisoned rodents.

Table 70: Qualitative assessment of acute secondary poisoning. Expected concentration (EC) in rodent after five days exposure

Species	**PEC_{oral} (EC5)** [mg · kg_{bw}^{-1}]	**LD_{50}** [mg · kg_{bw}^{-1}]
Birds	7.21	2000
Mammals	7.21	35

The expected concentration of the active substance in the rodent immediately after a last meal on day five (EC5) is several orders of magnitude lower than the dose required to kill half of a test population (LD_{50}) of birds. This comparison indicate that birds are not likely to die if they eat rodents poisoned with Secuverd 26. The EC5 for mammals is also lower than the respective LD50 value, however only by a factor of approximately 5. Considering the species specific sensitivity differences and other aspects normally covered by the assessment factors which have not been taken into account in the qualitative assessment, death of mammals which consume poisoned rodents cannot be excluded.

Quantitative risk assessment for the long-term situation

3.8.5.4.1.5 Tier 1 assessment

The Tier 1 assessment of secondary poisoning is based on the concentration in the predators' or scavengers' food i.e. poisoned rodents. In the first tier of the long-term assessment of secondary poisoning, it is assumed that rodents are consuming only the bait (PD = 1) on five consecutive days (EC5), while the daily dietary of predators or scavengers consists to 50 % of poisoned rodents (F_{rodent} = 0.5). The predators or the scavengers are assumed to eat the poisoned rodents during one day.

Table 71: PEC/PNEC ratios for long-term situation of secondary poisoning in the first tier. PECoral is the expected concentration (EC) in the rodent after a five days exposure

Species	**PEC_{oral} (EC5)** [mg/kg] Concentration in rodent	**PNEC** [mg/kg] Concentration in food	**PEC/PNEC**
Birds	3.605	0.667	**5**
Mammals	3.605	0.14	**26**

The Tier 1 risk characterisation shows that birds and mammals are at risk when feeding on rodents which have taken up Secuverd 26 over five days.

Tier 2 assessment

In the Tier 2 assessment of long-term secondary poisoning the expected concentration in predators after a single day of exposure (PECoral) is compared to $PNEC_{oral}$ related to the daily dose. The predator is assumed to catch the rodent after its last meal on day 5. Furthermore, it is assumed that the non-target animal consume 50 % of its daily intake on poisoned rats.

Table 72: PEC/PNEC ratios for long-term situation of secondary poisoning in the second tier. PEC oral is the expected concentration (EC) of a non-target animals after one day exposure.

Species	**PEC_{oral}** EC1 [mg/kg bw]	**PNEC** [mg/kg bw/d]	**PEC/PNEC**
Birds (Kestrel)	1.36	0.0667	**20**
Mammals (Weasel)	1.41	0,0001	**14130**

The second tier risk characterisation shows that non-target organisms are at risk of secondary poisoning, too. No data are available on the sensitivity of the example species to coumatetralyl. Only one day exposure of predators is assumed in the ESD, but it is mentioned that predators could be exposed over several days. This would mean higher accumulation in predators because daily elimination of coumatetralyl in predators is assumed to be less than the daily intake.

3.8.5.4.1.6 Conclusion from secondary poisoning

The theoretical calculations demonstrate that the use of Secuverd 26 poses risks of primary and secondary poisoning to non-target birds and mammals. These risk appears to be higher for mammals, which turned out to be more sensitive towards the active substance. In contrast, no risk has been identified for the terrestrial food chain.

3.8.5.5 PBT assessment

According to the Assessment Report by the eCA Denmark for the renewal of the approval of coumatetralyl (July 2016) the active substance fulfils the criteria to be considered toxic (T) but does not satisfy the criteria to be considered either persistent/very persistent (P/vP) or bioaccumulative/very bioaccumulative (B/vB). The PBT-assessment is presented in detail in the following:

P-criterion: Coumatetralyl is stable to hydrolysis at environmentally relevant pHs and temperatures; however it is susceptible to aqueous photolysis with a DT_{50} of 8.64 hours under experimental conditions, equivalent to half-lives of between 0.821 d (summer) and 3.60 d (winter) for the near surface of clear natural water bodies (all at latitude 40° north). Salicylic acid and an unidentified degradation product were the major metabolites detected. Coumatetralyl is not readily or inherently biodegradable; however, it is rapidly degraded in soil with DT50s at 22 °C of 5.9 to 8.7 days corresponding to 13.1 and 19.4 days at 12o C (FOMC and DFOP kinetics).

Although stable to hydrolysis, coumatetralyl is highly susceptible to photolysis. Also, although classified as not readily or inherently biodegradable, coumatetralyl is not persistent in soil with DT50s below the thresholds given for soil.

On this basis coumatetralyl is not considered to fulfil the criteria to be considered P or vP.

B-criterion: The Log Kow values of coumatetralyl ranges from -0.1 at pH 9 to 3.4 at pH 5. The Log Kow is below the screening criterion of ≥ 4.5 for being considered as bioaccumulative. A fish bioconcentration study is available and this gives bioconcentration factors for edible parts, viscera and whole fish of 3.32, 20.8 and 11.4 respectively.

On this basis coumatetralyl is not considered to fulfil the criteria to be considered B or vB.

T-criterion: Coumatetralyl is very toxic to fish, algae and Daphnia with the lowest NOEC-value of 5 µg/L derived from a chronic 21-d fish study with *Onchorhynchus mykiss*.

On this basis coumatetralyl is considered to fulfil the criteria to be considered T.

Overall, coumatetralyl is not considered to be a PBT substance. Moreover, coumatetralyl is not considered a persistent organic pollutant (POP) as it does not have a potential for long-range atmospheric transport.

3.8.5.6 Endocrine disrupting properties

According to the Assessment Report by the eCA Denmark for the renewal of the approval of coumatetralyl (July 2016) and taking into account the interim criteria, described in Article 5.3 of Regulation (EU) No 528/2012, the active substance shall not be considered as having endocrine-disrupting properties.

3.8.5.7 Summary of risk characterisation

The biocidal product Secuverd 26 contains no substance of concern. Therefore, the environmental risk assessment for the product is based on the active substance coumatetralyl (see CAR Coumatetralyl (Bayer Environmental Science; RMS Denmark; January 2009) and the Assessment Report Coumatetralyl (PT 14, July 2016).

No release to STP and surface water occurs from the use of the product in and around buildings. Therefore, no risk assessment for the aquatic compartment and STP was conducted.

The risk assessment based on the biocidal product Secuverd 26 demonstrates that the intended use of the product do not cause an unacceptable risk in the terrestrial environment (including ground water) and in the atmosphere.

The identified risks for primary and secondary poisoning of non-target animals can be mitigated when the rodenticide baits are used according to the label instructions and in compliance with the applied risk mitigating measures. Risks however remain even when applying all available risk mitigation measures, because small non-target animals may enter bait stations and predatory birds or mammals cannot be prevented from feeding on contaminated rodents. Therefore, releases to the environment have to be minimised effectively. This can only be achieved by appropriate risk mitigation measures which have to be applied in the form of specific provisions.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

Background

The German CA for biocides has processed an application for authorisation for the biocidal product Secuverd 26 which contains the active substance coumatetralyl. The active substance coumatetralyl meets the criteria for exclusion according to Article 5(1) BPR as well as for substitution according to Article 10 BPR (for details see chapter 2.2.4).
Therefore, in line with Article 23 (1) BPR a comparative assessment for the product Secuverd 26 has to be conducted.

At the 60th meeting of representatives of Members States Competent Authorities for the implementation of BPR held on 20 and 21 May 2015, all Member States submitted to the Commission a number of questions to be addressed at Union level in the context of the comparative assessment to be carried out at the renewal of anticoagulant rodenticide biocidal products ('anticoagulant rodenticides'). The questions submitted were the following:
(a) Is the chemical diversity of the active substances in authorised rodenticides in the Union adequate to minimise the occurrence of resistance in the target harmful organisms?;
(b) For the different uses specified in the applications for renewal, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?;
(c) Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?;
d) Are these alternatives sufficiently effective?;
(e) Do these alternatives present no other significant economic or practical disadvantages?

The information addressing these questions is provided in the Annex of the Commission Implementing Decision (EU) 2017/1532.[12] According to Article 1 of Commission Implementing Decision (EU) 2017/1532 the German CA considered the information in the Annex during the comparative assessment of anticoagulant rodenticide biocidal products.

[12] COMMISSION IMPLEMENTING DECISION (EU) 2017/1532 of 7th 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

Conclusion

Based on the information provided in the Annex of the Commission Implementing Decision (EU) 2017/1532 the German CA came to the conclusion that in the absence of anticoagulant rodenticides, the use of rodenticides containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms. These products also showed some significant practical or economical disadvantages for the relevant uses.

The German CA also considered a number of non-chemical control or prevention methods ("non-chemical alternatives"), which in our view provide sufficient efficacy in certain circumstances on their own or in a combination of them. However, the available Technical Guidance Note (TGN) on comparative assessment[13] does not contain criteria for the evaluation of non-chemical control methods. We therefore were not able to evaluate the available information in order to prove that those non-chemical alternatives are sufficiently effective according to the TGN with a view to prohibit or restrict the authorised uses of anticoagulant rodenticides.

In summary it can be concluded that the criteria according Article 23(3) a), b) BPR are not fulfilled. Therefore, the authorisation of the product Secuverd 26 will be granted for 5 years.

Another conclusion is that criteria and clearly defined requirements for the assessment of non-chemical control methods in the framework of comparative assessment according to Article 23 of the BPR are not available and thus should be elaborated prior to the next renewal of anticoagulant rodenticides. Otherwise, the result of comparative assessment of anticoagulant rodenticides with non-chemical methods in the future will always be that no adequate non-chemical alternatives are available and anticoagulant rodenticides will remain approved although they practically fail to fulfil the conditions for approval according to Article 4 of the BPR.

[13] Technical guidance note on Comparative assessment of biocidal products, available at https://circabc.europa.eu/w/browse/d309607f-f75b-46e7-acc4-1653cadcaf7e

4 Annexes

4.1 List of studies for the biocidal product

Table 73

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	3.1 3.1.1 3.1.2 3.1.3 3.2 3.3 3.4.1.1 3.4.1.2	Determination of physicochemical properties and storage stability test for Coumatetralyl RB 0.0029 in Cardboard boxes with PET/ PE bags	Rodriguez, N.	2016	Bayer S.A.S.
2	4.1	EXPLOSIVE PROPERTIES A.14. (OPPTS 830.6316)	Dornhagen J.	2010a	Bayer S.A.S.
3	4.7	FLAMMABILITY (SOLIDS) A.10.	Dornhagen J.	2010b	Bayer S.A.S.
4	4.11	TEST FOR SELF-HEATING SUBSTANCES (UN N.4)	Krack M.	2017	Bayer S.A.S.
5	4.14	OXIDIZING PROPERTIES OF SOLIDS A.17.	Dornhagen J.	2010c	Bayer S.A.S.
6	4.17.2	Determination of Safety-Relevant Data of Racumin Paste	Heinz, U	2002	Bayer S.A.S.

7	4.17.2	AUTO-FLAMMABILITY (SOLIDS-DETERMINATION OF RELATIVE SELF-IGNITION TEMPERATURE) A.16	Krack M.	2017	Bayer S.A.S.
8	5.1	Validation of Method MV130: BCS: HPLC - Determination of Coumatetralyl in Coumatetralyl RB 0,0029	Matyssek, F.	2015	Bayer S.A.S.
9	5.1	Validation of Method MV131: BCS: HPLC-MS-Determination of Denatonium Benzoate in Coumatetralyl RB 0,0029	Matyssek, F.	2016	Bayer S.A.S.
10	6.7	Field trial to determine the efficacy of paste bait containing coumatetralyl (29 mg/kg) in controlling Norway rats (Rattus norvegicus).	Anonymous[14]	2015a	Bayer S.A.S.
11	6.7	Palatability and Efficacy of Bait Containing Coumatetralyl at 29 mg/kg in Norway rats (Rattus norvegicus)	Anonymous[14]	2016b	Bayer S.A.S.
12	6.7	Efficacy of Bait Containing Coumatetralyl at 29 mg/kg in bank voles (Myodes glareolus)	Anonymous[14]	2016a	Bayer S.A.S.
13	6.7	Field Trial with Bait Containing Coumatetralyl (29 mg/kg): Control of Norway Rats (Rattus norvegicus) at a Residential Home	Anonymous[14]	2015b	Bayer S.A.S.
14	6.7	Efficacy of Bait Containing Coumatetralyl at 29 mg/kg in a choice test with bank voles (Myodes glareolus)	Anonymous[14]	2016c	Bayer S.A.S.
15	6.7	Field trial to determine the efficacy of the coumatetralyl paste bait (27ppm) in controlling the water vole (Arvicola amphibius).	Anonymous[14]	2016	Bayer S.A.S.

[14] Study with vertebrates. Please, refer to IUCLID file for the name of the author(s).

	6.7	EVALUATION OF THE EFFICACY OF A PASTE RODENTICIDE CONTAINING 27mg/kg COUMATETRALYL FOR THE CONTROL OF VOLE INFESTATION AROUND BUILDINGS. ONE FIELD TRIAL: AVEYRON; FRANCE, 2017.	Anonymous[14]	2017	SBM Life Science
	7.10.1	HUMAN SAFETY – OCCUPATIONAL AND RESIDENTIAL EXPOSURE Secuverd 26	Georg Hamacher, David Richard	2017	Bayer S.A.S.
	8.6	HUMAN SAFETY – OCCUPATIONAL AND RESIDENTIAL EXPOSURE Secuverd 26	Georg Hamacher, David Richard	2017	Bayer S.A.S.

4.2 List of studies for the active substance(s)

4.2.1 Coumatetralyl

- The applicant has access to the data from the active substance approval (see chapter 4.2.1.1 for details).

4.2.1.1 Access to data from active substance approval

The applicant provided a letter of access to the dossier assessed for the approval (respectively the inclusion into Annex I of Directive 98/8/EC[15]) of the active substance Coumatetralyl for use in Rodenticide (product-type 14). Please, refer to the corresponding Assessment Report for a reference list.

15 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.