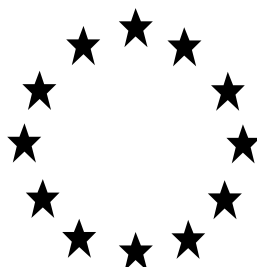


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL  
PRODUCT FOR NATIONAL AUTHORISATION  
APPLICATIONS**



Product identifier in R4BP	<i>Secuverd 27</i> <i>(formerly Ratten Portionsköder (before Secuverd 26))</i>
Product type(s):	14 (Rodenticide)
Active ingredient(s):	Coumatetralyl
Case No. in R4BP	BC-XP048498-98
Asset No. in R4BP	DE-0015601-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/14.00024 710-05-14-00024-00-04-00-0000
Date	29.11.2019

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## Overview of applications

**Table 1 - Overview regarding all relevant applications**

<b>Application type</b>	<b>refMS</b>	<b>Case number in the refMS</b>	<b>Decision date</b>	<b>Assessment carried out (i.e. first authorisation / amendment)</b>	<b>Page</b>
NA-ADC	DE	BC-DN037964-26	23.03.2018	Administrative change (product name(s), authorisation holder, manufacturers of BP)	14
NA-ADC	DE	BC-ED048494-49	21.01.2019	Administrative change (product name(s), authorisation holders address, manufacturers of BP)	16
NA-ADC	DE	BC-GX051231-28	09.05.2019	Administrative change (additional trade name(s) in Germany)	-
NA-MAC	DE	BC-XP048498-98	29.11.2019	Major change (replacement of one non-active substance, addition of two target organisms, addition of secondary packaging)	17

# **Current consolidated Summary of the product assessment**

## **Summary of product characteristics**

**Secuverd 27**

**Product type(s) 14**

**Authorisation number DE-0015601-14**

**R4BP asset number DE-0015601-0000**

# 1 Administrative information

## 1.1 Trade name(s) of the product

Trade name(s)
Secuverd 27

## 1.2 Authorisation holder

Name and address of the authorisation holder	Name	SBM DEVELOPPEMENT
	Address	60 chemin des Mouilles 69130 Ecully France
Authorisation number	DE-0015601-14	
R4BP asset number	DE-0015601-0000	
Date of the authorisation	13.02.2018	
Expiry date of the authorisation	13.02.2023	

## 1.3 Manufacturer(s) of the product

Name of manufacturer	INDUSTRIALCHIMICA Srl
Address of manufacturer	Via Sorgaglia 40 35020 Arre (PD) Italy
Location of manufacturing sites	Via Sorgaglia 40 35020 Arre (PD) Italy

<b>Name of manufacturer</b>	Kollant S.r.l.
<b>Address of manufacturer</b>	via C. Colombo 7/7 A 30030 Vigonovo (VE) Italy
<b>Location of manufacturing sites</b>	via C. Colombo 7/7 A 30030 Vigonovo (VE) Italy

<b>Name of manufacturer</b>	IRIS
<b>Address of manufacturer</b>	1126 A, avenue du Moulins, route de St Privas 30340 Salindres France
<b>Location of manufacturing sites</b>	1126 A, avenue du Moulins, route de St Privas 30340 Salindres France

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

<b>Active substance</b>	Coumatetralyl
<b>Name of manufacturer</b>	Bayer S.A.S.
<b>Address of manufacturer</b>	16 rue Jean-Marie Leclair 69266 Lyon (Cedex 09) France
<b>Location of manufacturing sites</b>	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 Product composition and formulation

### 2.1 Qualitative and quantitative information on the composition of the product

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

### 2.2 Type of formulation

Ready-to-use paste bait
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## 3 Hazard and precautionary statements

Hazard statements	None
Precautionary statements	None

## 4 Authorised use(s)

### 4.1 Authorised use 1 – Rats

Product Type	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Norway rats ( <i>Rattus norvegicus</i> ), ( adults and juveniles) House rats ( <i>Rattus rattus</i> ), ( adults and juveniles)
Field(s) of use	In and around buildings
Application method(s)	Ready-to-use bait in tamper-resistant bait stations

<b>Application rate(s) and frequency</b>	200 g/baiting station If more than one bait station is needed, the minimum distance between bait stations should be of 5-20 meters
<b>Category(ies) of users</b>	General public
<b>Pack sizes and packaging material</b>	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) or in a sealed can (10-750 g, tinfoil) Tertiary packaging: COEX PET/PE sachets in cardboard case; LDPE sachets in PP bucket

#### 4.1.1 Use-specific instructions for use

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

#### 4.1.2 Use-specific risk mitigation measures

None

#### 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

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

None

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

None



## 4.2 Authorised use 2 – Voles

<b>Product Type</b>	14
<b>Where relevant, an exact description of the use</b>	Rodenticide
<b>Target organism(s) (including development stage)</b>	Voles of the types bank vole ( <i>Myodes glareolus</i> ) and common vole ( <i>Microtus arvalis</i> ), (adults and juveniles)
<b>Field(s) of use</b>	Around buildings
<b>Application method(s)</b>	Ready-to-use bait in tamper-resistant bait stations
<b>Application rate(s) and frequency</b>	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
<b>Category(ies) of users</b>	General public
<b>Pack sizes and packaging material</b>	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) or in a sealed can (10-750 g, tinplate) Tertiary packaging: COEX PET/PE sachets in cardboard case; LDPE sachets in PP bucket

### 4.2.1 Use-specific instructions for use

The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

### 4.2.2 Use-specific risk mitigation measures

None

### 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

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

None

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

None

## 5 General directions for use

### 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.

## 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.

### **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]".
- 4) Hazardous to wildlife.

### **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.

### **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.

## **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.

## Changes after first authorisation

### 7 Change 1 - NA-ADC - BC-DN037964-26

Case No.	BC-DN037964-26
Internal registration/file no:	5.0-710 05/14.00024 710-05-14-00024-00-01
Case type(s)	Administrative change (NA-ADC)
CMS	---
Entry into force of change / amendment	23.03.2018

#### 7.1 Changes sought / amendment necessary

- Change of product name from “Secuverd 26” to “Ratten Portionsköder”.
- Change of the authorisation holder:

Authorisation holder	Current	Future
<b>Name</b>	Bayer S.A.S.	SBM DEVELOPPEMENT
<b>Address</b>	16 rue Jean-Marie Leclair CS90106 69266 LYON CEDEX 09 France	111 chemin du Petit Bois  69130 Ecully France

- Addition of three manufacturers of the product:

<b>Name of manufacturer</b>	INDUSTRIALCHIMICA Srl
<b>Address of manufacturer</b>	Via Sorgaglia 40 35020 Arre (PD) Italy
<b>Location of manufacturing sites</b>	Via Sorgaglia 40 35020 Arre (PD) Italy

<b>Name of manufacturer</b>	Kollant S.r.l.
<b>Address of manufacturer</b>	via C. Colombo 7/7 A 30030 Vigonovo (VE) Italy
<b>Location of manufacturing sites</b>	via C. Colombo 7/7 A 30030 Vigonovo (VE) Italy

<b>Name of manufacturer</b>	IRIS
<b>Address of manufacturer</b>	1126 A, avenue du Moulinas, route de St Privas 30340 Salindres France
<b>Location of manufacturing sites</b>	1126 A, avenue du Moulinas, route de St Privas 30340 Salindres France

## 8 Change 2 - NA-ADC - BC-ED048494-49

Case No.	BC-ED048494-49
Internal registration/file no:	5.0-710 05/14.00024 710-05-14-00024-00-03
Case type(s)	Administrative change (NA-ADC)
CMS	---
Entry into force of change / amendment	21.01.2019

### 8.1 Changes sought / amendment necessary

- Change of product name from “Ratten Portionsköder” to “Secuverd 27”.
- Change of the authorisation holders address:

	<b>Current</b>	<b>Future</b>
<b>Address</b>	111 chemin du Petit Bois  69130 Ecully France	60 chemin des Mouilles  69130 Ecully France

- Deletion of one manufacturer of the product:

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



## 9 Change 3 - NA-MAC - BC-XP048498-98

Case No.	BC-XP048498-98
Internal registration/file no:	5.0-710 05/14.00024 710-05-14-00024-00-04
Case type(s)	Major change (NA-MAC)
CMS	Austria (AT), Belgium (BE), France (FR), Poland (PL), Slovakia (SK), Spain (ES), United Kingdom (UK)
Entry into force of change / amendment	29.11.2019

### 9.1 Changes sought

#### 9.1.1 Replacement of a non-active substance:

For details please consider the confidential annex (page 22).

#### 9.1.2 Addition of uses:

- House rat (*Rattus rattus*) – Non Professionals - In and around building

#### 9.1.3 Addition of a secondary packaging

- Sealed can (tinplate)

### 9.2 Assessment of new data

#### 9.2.1 Replacement of a non-active substance:

For details please consider the confidential annex (page 22).

This change does not require an amendment of the in classification and labelling and the human exposure and risk assessment. The replaced co-formulant does not affect the assessment for human health.

## 9.2.2 Addition of uses:

### Black Rat (*Rattus rattus*) – Non Professionals - In and around building

A laboratory choice trial conducted with Black rats (*Rattus rattus*) was submitted (Anonymous, 2017), mortality was 100%. Additionally, a field study conducted in the attic of a residential home was submitted (Anonymous, 2017). The reduction of the population achieved was 100%. Efficacy against Black Rats is therefore considered as proven.

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 black rats	Coumatetralyl at 29 mg/kg in baits identical to Secuverd 26	Black rats ( <i>Rattus rattus</i> )	Laboratory choice trial	Choice-feeding experiment with individually caged Black rats in a 4 days treatment.	100% mortality on day 7, 25% palatability	Anonymous, 2017
Rodenticide	Pest control against black rats	Coumatetralyl at 27 mg/kg in baits identical to Secuverd 26	Black rats ( <i>Rattus rattus</i> )	Field trial in the attic of a residential home	Baiting period 14 d: Bait containing 0.0027% coumatetralyl: Bait points: lockable plastic bait stations	100% efficacy  (100% reduction in feed uptake and in tracking activity)	Anonymous, 2017a

**9.2.3 Addition of a secondary packaging**

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 90 g – 750 g	COEX PET/PE			
Tea bags in sealed can	10 g – 750 g	Tin plate	-	General public	Yes

The addition of the new packaging requires no amendment of the risk or efficacy assessment because from the different secondary packaging no effects are to be expected.

**9.3 List of new data**

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	6.7	PALATABILITY AND EFFICACY STUDY OF A PASTE BAIT CONTAINING 0.0029% COUMATETRALYL IN BLACK RAT ( <i>Rattus rattus</i> )	Anonymous <sup>1</sup>	2017	SBM DEVELOPPEMENT
2	6.7	EVALUATION OF THE EFFICACY OF A PASTE RODENTICIDE CONTAINING 27mg/kg COUMATETRALYL FOR THE CONTROL OF BLACK RAT INFESTATION IN AN ATTIC. ONE FIELD TRIAL: ISERE; FRANCE, 2017	Anonymous <sup>1</sup>	2017	SBM DEVELOPPEMENT

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<sup>1</sup> Study with vertebrates. Please, refer to IUCLID file for the name of the author(s).

## **9.4 Conclusion**

The efficacy against the additional target organism House rats (*Rattus rattus*) was proven.

Furthermore, the replacement of the non-active substance requires no amendment of the risk or efficacy assessment because from the change in composition is so small that no effects are to be expected.

Finally, the additional secondary packaging applied for was considered acceptable.