



**Centro Nazionale Sostanze Chimiche**

Viale Regina Elena, 299 - 00161 Roma  
Tel. 0649906141 - Fax 0649903176

Roma,

Prot. N. 0040585 del 28/09/2011  
0043857 del 18/10/2011

A: **MINISTERO DELLA SALUTE**  
Dipartimento dell'Innovazione  
Direzione Generale dei Farmaci e  
dei Dispositivi Medici  
Ufficio VII  
Via Giorgio Ribotta, 5  
00144 R O M A

Istituto Superiore di Sanità  
Prot 13/11/2012-0041139



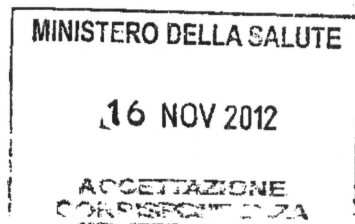
Class: CSC.05

1

Oggetto: parere autorizzazione prodotto biocida RODEXION PELLETS

In riferimento all'oggetto, si trasmettono in allegato il parere redatto da questo Istituto e le relative proposte di etichetta.

Il Direttore  
Centro Nazionale Sostanze Chimiche  
Dott.ssa Rosa DRAISCI



Ministero della Salute  
DGFSC  
0080203-A-20/11/2012



113607189

# Product Assessment Report

## RODEXION PELLETS

October 2012

Internal registration/file no:

Authorisation/Registration no:

Granting date/entry into force of  
authorisation/ registration:

Expiry date of authorisation/  
registration:

Active ingredient:

Bromadiolone

Product type:

PT14: Rodenticides

Applicant:

I.N.D.I.A. INDUSTRIE CHIMICHE S.p.A.

---

Biocidal Product Assessment Report (PAR) related to Product  
Authorisation under Directive 98/8/EC.

**Contents**

1. APPLICANT, ACTIVE INGREDIENT MANUFACTURER, PRODUCT FORMULATOR AND AUTHORISATION HOLDER.....	3
1.1. Applicant .....	3
1.2. Active Ingredient supplier .....	3
1.3. Manufacturer/formulator of product.....	3
1.4. Authorisation holder .....	3
2. GENERAL PRODUCT INFORMATION .....	4
2.1. Identity of the Biocidal Product .....	4
2.2. Statement of technical equivalence .....	4
2.3. Product Type .....	4
2.4. Classification and Labelling .....	4
2.5. Intended Use .....	5
2.6. Documentation .....	6
3. PHYSICOCHEMICAL PROPERTIES AND ANALYTICAL METHODS .....	6
4. RISK ASSESSMENT FOR PHYSICO-CHEMICAL PROPERTIES .....	6
5. EFFECTIVENESS AGAINST TARGET ORGANISMS.....	6
6. EXPOSURE ASSESSMENT .....	6
7. RISK ASSESSMENT FOR HUMAN HEALTH.....	6
8. RISK ASSESSMENT FOR THE ENVIRONMENT.....	6
9. MEASURES TO PROTECT MAN, ANIMALS AND THE NVIRONMENT ...	6
10. DECISION.....	7

ANNEX A, Summary of Product Characteristics (SPC)

ANNEX B. ACTIPELLET BROM Product Assessment Report

**1. APPLICANT, ACTIVE INGREDIENT MANUFACTURER, PRODUCT  
FORMULATOR AND AUTHORISATION HOLDER**

**1.1. APPLICANT**

I.N.D.I.A. INDUSTRIE CHIMICHE S.p.A.  
Nona Strada, 55/57  
35129 – Padova  
Italy

**Contact person**

Mrs. Silvano ZABEO  
E-mail: s.zabeo@indiacare.it

**1.2. ACTIVE INGREDIENT SUPPLIER**

Dr TEZZA  
Via Tre Ponti, 22  
37050 - S.Maria di Zevio (VR)  
Italy

**1.3. MANUFACTURER/FORMULATOR OF PRODUCT**

I.N.D.I.A. INDUSTRIE CHIMICHE S.p.A.  
Nona Strada, 55/57  
35129 – Padova  
Italy

**1.4. AUTHORISATION HOLDER**

As in 1.1.

## 2. GENERAL PRODUCT INFORMATION

### 2.1. IDENTITY OF THE BIOCIDAL PRODUCT

Trade name	RODEXION PELLETS	
Ingredients of preparation	Function	Content (%w/w)
Bromadiolone (CAS 28772-56-7)	Active ingredient	0.005
Denatonium Benzoate (CAS 3734-33-6)	Human taste deterrent	0.001
Other Components	Confidential information <sup>a</sup>	Up to 100

<sup>a</sup> please, refer to confidential information in Annex A (Summary of Product Characteristics)

### 2.2. STATEMENT OF TECHNICAL EQUIVALENCE

The applicant provided a Letter of Access (LoA) from Activa S.r.l..

The LoA refers to Annex I dossier of the active substance Bromadiolone. Activa supported Bromadiolone inclusion into Annex I of BPD as a member of "The Bromadiolone Task Force". Since the manufacturer of the active substance used in RODEXION PELLETS is the same, technical equivalence should not to be addressed.

### 2.3. PRODUCT TYPE

Rodenticide (PT14)

### 2.4. CLASSIFICATION AND LABELLING

The current classification and labelling according to Directive 99/45/EC and Regulation (EC) 1272/2008, are provided in the tables below.

Not classified in accordance with the Directive 1999/45/EC

<b>Symbol(s):</b>	None
<b>Indication(s) of danger:</b>	None
<b>Risk phrases:</b>	None
<b>Safety phrases:</b>	S1/2 Keep locked up and out of the reach of children. S13 Keep away from food, drink and animal feeding stuffs. S20/21 When using, do not eat, drink or smoke S24 Avoid contact with skin S37 Wear suitable gloves (professionals only) S46 If swallowed, seek medical advice immediately (show the label where possible) S61 Avoid release to the environment. Refer to special instructions/Safety data sheet

Not classified in accordance with the Regulation EC 1272/2008.

<b>Pictogram(s):</b>	None
<b>Signal word(s):</b>	None
<b>Hazard statements:</b>	None
<b>Precautionary statements</b>	P102: Keep out of reach of children. P103: Read label before use. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P301+310: IF SWALLOWED: Immediately call a poison centre or doctor/physician. P501: Dispose of contents/container to hazardous waste facilities in accordance with national regulations.

Further, the content of the label should be updated with the additional safety phrases recommended in the Combined Assessment Report (2010):

- Baits must be securely deposited in a way so as to minimise the risk of consumption by non-target animals or children. Where possible, secure baits so that they cannot be dragged away.
- Search for and remove dead rodents at frequent intervals during treatment (unless used in sewers), at least as often as when baits are checked and/or replenished. Dispose of dead rodents in accordance with local requirements.
- Unless under supervision of a pest control operator or other competent persons, do not use anticoagulant rodenticides as permanent baits.
- Remove all baits after treatment and dispose of them in accordance with local requirements.
- Keep out of the reach of children. (This last safety precaution should always be carried on the label of the products, if not already legally required by 1999/45/EC. The others could be stated elsewhere on the packaging or on the accompanying leaflet together with the other directions for use and disposal of the product required by article 20(3) of Directive 98/8/EC.)

RODEXION PELLETS labels for professional use and non professional use should be revised accordingly.

## 2.5. INTENDED USE

RODEXION PELLETS is a ready to use rodenticidal bait formulated as pellet, based on the active substance Bromadiolone. It is intended to be used for control of rodent pests in and around buildings, in cellars, garages, closets and gardens. For professional use also in and around industrial buildings (warehouses and holds included), farms and civilian buildings. The target species are brown rat (*Rattus norvegicus*), black rat (*Rattus rattus*) and house mouse (*Mus musculus*).

RODEXION PELLETS is applied via tamper resistant bait stations. Bait is deposited and fixed in the bait stations. The number of bait points employed is dependent on: the treatment site; the size and severity of the infestation; the user; and the user requirements and needs.

For rat control, 3-5 bait stations (containing 20 g of pellet bait each) per 100 m<sup>2</sup> of infested area (60-100 g pellet bait/100 m<sup>2</sup>) are used.

For mouse control, 2 bait stations (containing 20 g of pellet bait each) per 100 m<sup>2</sup> of infested area (40 g pellet bait/100 m<sup>2</sup>) are used.

## **2.6. DOCUMENTATION**

The applicant provided two LoAs from Activa: one LoA referred to the Annex I dossier of active substance Bromadiolone and the other one to the dossier data of the formulated product ACTIPELLET-BROM.

Activa is owner of all the data on the active substance difenacoum as it was part of the "Bromadiolone Task Force", which submitted the Annex II complete dossier to RMS Sweden.

Activa authorises IT Competent Authority to use data on biocidal product ACTIPELLET-BROM for the authorisation of the biocidal product RODEXION PELLETS. Activa states that RODEXION PELLETS and ACTIPELLET-BROM compositions are identical.

Activa is owner of all the data on the biocidal product ACTIPELLET-BROM and submitted the complete dossier to RMS Italy.

The ACTIPELLET-BROM Product Assessment Report (PAR) is attached (Annex B).

## **3. PHYSICO-CHEMICAL PROPERTIES AND ANALYTICAL METHODS**

Refer to section 2.3 of the ACTIPELLET-BROM PAR (Annex B).

## **4. RISK ASSESSMENT FOR PHYSICO-CHEMICAL PROPERTIES**

Refer to section 2.4 of the ACTIPELLET-BROM PAR (Annex B).

## **5. EFFECTIVENESS AGAINST TARGET ORGANISMS**

Refer to section 2.5 of the ACTIPELLET-BROM PAR (Annex B).

## **6. EXPOSURE ASSESSMENT**

Refer to section 2.6 of the ACTIPELLET-BROM PAR (Annex B).

## **7. RISK ASSESSMENT FOR HUMAN HEALTH**

Refer to section 2.7 of the ACTIPELLET-BROM PAR (Annex B).

## **8. RISK ASSESSMENT FOR THE ENVIRONMENT**

Refer to section 2.8 of the ACTIPELLET-BROM PAR (Annex B).

## **9. MEASURES TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT**

Refer to section 2.9 of the ACTIPELLET-BROM PAR (Annex B).

## 10. DECISION

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for granting an authorisation of the biocidal product RODEXION PELLETS.

All the elements listed in Doc I, section 3.3, of the CAR on Bromadiolone (Sweden, 2010) have been taken into account when authorising RODEXION PELLETS.

Due to the unacceptable risk calculated for infants ingesting the product, it is considered appropriate to limit aspects of the packaging for non professional use as a further risk mitigation measure.

Non-professional baits are to be used in refillable tamper-resistant bait stations and supplied as inner packs or units containing at most enough bait for one bait-point (either rat or mouse) with a maximum pack-size of 500g.