Product Assessment Report
RATIFEN PELLET
November 2011

Internal registration/file no:	
Authorisation/Registration no:	IT/2012/00062/AUT
Granting date/entry into force of authorisation/ registration:	09/08/2012
Expiry date of authorisation/ registration:	31/03/2015
Active ingredient:	Difenacoum
Product type:	PT14: Rodenticides
Applicant:	COPYR 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

1.1. APPLICANT

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20157 – Milano
Italy

Contact person
Dr. Alessandra LONGONI (R&D Manager)
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1.2. ACTIVE INGREDIENT SUPPLIER

ACTIVA S.R.L.
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20132 Milano
Italy

1.3. MANUFACTURER/FORMULATOR OF PRODUCT

INDUSTRIALCHIMICA S.r.l.
Via Sorgaglia, 25
35020 – Arre (PD)
Italy

1.4. AUTHORISATION HOLDER

As in 1.1.

2. GENERAL PRODUCT INFORMATION

2.1. IDENTITY OF THE BIOCIDAL PRODUCT

Trade name	RATIFEN PELLET	
Ingredients of preparation	**Function**	**Content (%w/w)**
Difenacoum (CAS 56073-07-5)	Active ingredient	0.005
Denatonium Benzoate (CAS 3734-33-6)	Human taste deterrent	0.001
Other Components	Confidential information[a]	Up to 100
[a] please, refer to confidential information in Annex B (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 Difenacoum. Activa supported Difenacoum inclusion into Annex I of BPD in a Task Force with PelGar. Since the manufacturer of the active substance used in RATIFEN PELLET 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.

Symbol(s):	None
Indication(s) of danger:	None
Risk phrases:	None
Safety phrases:	S 2: Keep out of reach of children. S 13: Keep away from food, drink and animal feeding stuffs. S 20/21: When using, do not eat, drink or smoke S 24: Avoid contact with skin S 46: If swallowed, seek medical advice immediately (show the label where possible). S 61: Avoid release to the environment. Refer to special instructions/Safety data sheet.

Further, the content of the label should be updated with the additional safety phrases recommended in the Assessment Report (2009):

- Baits must be securely deposited in a way so as to minimize the risk of consumption by other 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 the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits.
- Remove all baits after treatment and dispose of them in accordance with local requirements

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

Pictogram(s):	None
Signal word(s):	None
Hazard statements:	None
Precautionary statements	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.

RATIFEN PELLET labels for professional use and non professional use should be revised accordingly.

2.5. INTENDED USE

The formulation RATIFEN PELLET consists in a pellet bait intended for both professional and non-professional use to control rodent pests in and around industrial, commercial and residential buildings. The formulation is a ready to use bait containing 0.005 % w/w of the anticoagulant active ingredient difenacoum with a minimum purity of 995 g/kg. The treatment frequency is 2-4 applications per year, 3-6 month apart. The amount of used product per application is often 40-100 g per 10 square meters. Baiting points are placed typically every 5-10 m. The product is placed with an appropriate calibrated dispenser (20 g) in plastic bait boxes such that rats and mice can eat them. In situations where bait boxes cannot be used, the bait is covered such that non-target organisms cannot reach them. Baiting points are inspected frequently (at least weekly) and replenished when bait has been eaten. Dead rodents are removed for disposal in order to prevent them being eaten by non-target animals and birds. Carcasses removal is on a daily bases for industrial applications (professional) and as soon as possible for non-professional uses. When no more bait is eaten and rodent activity stops, the remains of all bait are removed for disposal.

2.6. DOCUMENTATION

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

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

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

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

The ACTIPELLET-DIFE Product Assessment Report (PAR) is attached (Annex A).

3. PHYSICOCHEMICAL PROPERTIES

Refer to section 3 of Annex A.

4. HUMAN HEALTH RISK ASSESSMENT

Refer to section 4 of Annex A.

5. ENVIRONMENTAL RISK ASSESSMENT

Refer to section 5 of Annex A.

6. EFFICACY

Refer to section 6 of Annex A.

7. MEASURES TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

Refer to section 7 of Annex A.

8. DECISION

8.1. NECESSARY ISSUES ACCOUNTED FOR IN THE PRODUCT LABEL

The following elements have been taken into account when authorising RATIFEN PELLET:

- The use of appropriate personal protective equipment should be guided in the use instructions.
- Exposure assessment shows that professional and non professional exposure is acceptable.
- The restriction of product to specific areas and manners of use has been considered.
- The size of the package placed on the public market should be limited to 500g.
- Product design and use restrictions should be optimised in order to ensure sufficient efficient rodent control while at the same time minimizing the risk for primary poisoning. This includes the use of tamper resistant bait boxes and the need to secure the baits so that rodents cannot remove the bait from the bait box.
- When tamper-resistant bait stations are used, they should be clearly marked to show that they contain rodenticides and that they should not be disturbed.
- Difenacoum baits should not be placed where food, feedingstuffs or drinking water could be contaminated.
- In case no standard safety phrases are required on the product label, adequate safety instructions should be provided in the use instructions.
- Baits must be securely deposited in a way so as to minimise the risk of consumption by other 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 the supervision of a pest control operator or other competent person, 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.
- The population size of the target rodent should be evaluated before a control campaign. The number of baits and the timing of the control campaign should be in proportion to the size of the infestation.
- A complete elimination of rodents in the infested area should be achieved.

- Resistant management strategies should be developed, and difenacoum should not be used in an area where resistance to this substance is suspected.

- The authorisation holder shall report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management.

- When the product is being used in public areas, the areas treated must be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

RATIFEN PELLET labels for professional use and non professional use should be revised accordingly.