Product Assessment Report

BROMIRAT BLOCK

October 2012

Internal registration/file n° :	I.5.i.d.2/2011/231
Authorisation /Registration n°:	IT/2013/00106/Aut.
Granting date/entry into of Authorisation /Registration:	08/05/2013
Expiry date of Authorisation /Registration:	30/06/2016
Active ingredient:	Bromadiolone
Product type:	PT 14 : Rodenticides
Applicant :	COPYR SpA

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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Italy

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1.2. ACTIVE INGREDIENT SUPPLIER

Dr TEZZA
Via Tre Ponti, 22
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Italy

1.3. MANUFACTURER/FORMULATOR OF PRODUCT

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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	BROMIRAT BLOCK	
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[a]	Up to 100
[a] 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 BROMIRAT BLOCK 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:	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.

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.

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.)

BROMIRAT BLOCK labels for professional use and non professional use should be revised accordingly.

2.5. INTENDED USE

BROMIRAT BLOCK is a ready to use rodenticidal bait formulated as block bait, 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*).

BROMIRAT BLOCK 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 wax block bait each) per 100 m² of infested area (60-100 g bait/100 m²) are used.

For mouse control, 2 bait stations (containing 20 wax block bait each) per 100 m² of infested area (40 g bait/100 m²) 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 ACTIBLOCK-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 ACTIBLOCK-BROM for the authorisation of the biocidal product BROMIRAT. Activa states that BROMIRAT and ACTIBLOCK-BROM compositions are identical.

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

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

3. PHYSICOCHEMICAL PROPERTIES AND ANALYTICAL METHODS

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

4. RISK ASSESSMENT FOR PHYSICO-CHEMICAL PROPERTIES

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

5. EFFECTIVENESS AGAINST TARGET ORGANISMS

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

6. EXPOSURE ASSESSMENT

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

7. RISK ASSESSMENT FOR HUMAN HEALTH

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

8. RISK ASSESSMENT FOR THE ENVIRONMENT

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

9. MEASURES TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

Refer to section 2.9 of the ACTIBLOCK-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 BROMIRAT BLOCK.

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

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.