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*ANNEX*

**SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT**

BROMAX G

**Product type(s)**

PT14: Rodenticides

**Authorisation number:** IT/2018/00505/AUT

**R4BP asset number:** IT-0018278-0000

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## 1. ADMINISTRATIVE INFORMATION

### 1.1. Trade name(s) of the product

Trade name(s)	BROMAX G 50
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### 1.2. Authorisation holder

Name and address of the authorisation holder	Name	REA srl
	Address	S.S. 87 -Km 20.700 81025 Marcianise Italy
Authorisation number	IT/2018/00505/AUT	
<i>R4BP asset number</i>	IT-0018278-0000	
Date of the authorisation	30/10/2013	
Expiry date of the authorisation	31/12/2026	

### 1.3. Manufacturer(s) of the product

Name of manufacturer	REA SRL
Address of manufacturer	S.S. 87 - Km 20.700 81025 MARCIANISE (CE) Italy
Location of manufacturing sites	S.S. 87 - Km 20.700 81025 MARCIANISE (CE) Italy

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

Active substance	Bromadiolone
Name of manufacturer	Laboratorios Agrochem S.L.
Address of manufacturer	C/Tres Rieres, 10 - Pol.Ind. Sud 08292 ESPARREGUERA Spain
Location of manufacturing sites	C/Tres Rieres, 10 - Pol.Ind. Sud 08292 ESPARREGUERA Spain

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## 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 (%)
Bromadiolone	3-[3-(4'-Bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2-one	active substance	28772-56-7	249-205-9	0,005
Triethanolamine	2-[bis(2-hydroxyethyl)amino]ethanol	Non-active substance	102-71-6	203-049-8	0,05
Propylene glycol		Non-active substance	57-55-6	200-338-0	1,873

### 2.2. Type(s) of formulation

CB Bait concentrate

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### 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H360D: May damage the unborn child.  H372: Causes damage to organs blood through prolonged or repeated exposure { 1:state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard: }.
Precautionary statements	P102: Keep out of reach of children.  P202: Do not handle until all safety precautions have been read and understood.  P280: Wear protective gloves.  P270: Do not eat, drink or smoke when using this product.  P308+P313: IF exposed or concerned: Get medical advice.  P501: Dispose of contents to national or international regulations.

## 4. AUTHORISED USE(S)

### 4.1. Use description

**Table 1. Professional**

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	indoor use outdoor use
Target organism(s) (including development stage)	Scientific name: Muridae: Muridae: Common name: murids Development stage: adults  Scientific name: Rattus norvegicus Common name: rodents Development stage: adults  Scientific name: Mus musculus Common name: rodents Development stage: adults
Field(s) of use	indoor use outdoor use
Application method(s)	Method: bait application  Detailed description: ingestion toxin ingestion by eating long-term action anticoagulant
Application rate(s) and frequency	Application rate: 10, 20, 25, 30 or 50g  Dilution (%): 100  Number and timing of application: The bait is manually place in the rodent infested area. The bait has to be placed in tamper resistant bait station, correctly labelled. For the control of rats, baits up to 100g should be placed each 10m <sup>2</sup> For the control of mice, baits up to 50g should be placed each 10m <sup>2</sup> Baits points have to be checked every 2-3 days during the first 14 days of the treatment. Bait points should be removed, in a typical campaign, 6 weeks after initial placement.
Category(ies) of users	industrial ; trained professional ; professional
Pack sizes and packaging material	PET or HDPE or CARTON containing 500g to 25 kg.  For professional users: Remove all packaging, uneaten baits and bait boxes after treatment and dispose of them in accordance with current regulations through registered establishment or undertaking carrying out waste management operations.

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#### **4.1.1. Use-specific instructions**

The bait is manually place in the rodent infested area. The bait has to be placed in tamper resistant bait station, correctly labelled. For the control of rats, baits up to 100g should be placed each 10m<sup>2</sup> For the control of mice, baits up to 50g should be placed each 10m<sup>2</sup> Baits points have to be checked every 2-3 days during the first 14 days of the treatment. Bait points should be removed, in a typical campaign, 6 weeks after initial placement.

#### **4.1.2. Use-specific risk mitigation measures**

#### **4.1.3. Use-specific risk mitigation measures**

The use of protective gloves is recommended during the handling of the product and dead rodents in all cases for hygiene reasons. Wash hands and exposed skin after use and before meals. Place the bait station in areas inaccessible to infants, children, companion animals and non-target animals. Baits should not be placed where food, feedingstuffs or drinking water could be contaminated. Do not use anticoagulant rodenticides as permanent baits. Alternate the use of bromadiolone baits with other active substance baits, in order to avoid resistance.

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

The product is an anticoagulant rodenticide / Vitamin K antagonists intended to control *Mus Musculus* and *Rattus Norvergicus*, by professional (trained and non-trained) users in and around buildings

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

Do not throw the product on the ground, into a water course, into the sink or down the drain. Remove all packaging, uneaten baits and bait boxes after treatment and dispose of them in accordance with current regulations through registered establishment or undertaking carrying out waste management operations.

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

Store in the original container in dry and well ventilated place. Keep away from sun radiation and other heat sources. Protect against frost. The product is stable for more than 2 years.

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## **5. GENERAL DIRECTIONS FOR USE<sup>1</sup>**

### **5.1. Instructions for use**

The use of protective gloves is recommended during the handling of the product and dead rodents in all cases for hygiene reasons. Wash hands and exposed skin after use and before meals. Place the bait station in areas inaccessible to infants, children, companion animals and non-target animals. Baits should not be placed where food, feedingstuffs or drinking water could be contaminated. Do not use anticoagulant rodenticides as permanent baits. Alternate the use of bromadiolone baits with other active substance baits, in order to avoid resistance.

### **5.2. Risk mitigation measures**

Risk Phrases: Any risk phrase is considered necessary

### **5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Poisoning may cause: Bleeding diathesis, derivated from the antiprothrombin effect - prolonged prothrombin time- that may became evident at minimum 24 - maximum 72 hours (a normal prothrombin time when the patient is admitted in the hospital, does not exclude the diagnosis).

### **5.4. Instructions for safe disposal of the product and its packaging**

Do not throw the product on the ground, into a water course, into the sink or down the drain. Remove all packaging, uneaten baits and bait boxes after treatment and dispose of them in accordance with current regulations through registered establishment or undertaking carrying out waste management operations.

### **5.5. Conditions of storage and shelf-life of the product under normal conditions of storage**

Store in the original container in dry and well ventilated place. Keep away from sun radiation and other heat sources. Protect against frost. The product is stable for more than 2 years.

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<sup>1</sup>Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

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## **6. OTHER INFORMATION**