

## Annex I: Summary of product characteristics

(a) **Product trade name:** WARIN'S B5 GRANO

**(b) (i) Qualitative and quantitative information on the composition of the biocidal product**

NB: This information is confidential and should not be disclosed to third parties

Active substance(s)				Contents				
Common name	IUPAC name	CAS number	EC number	Concentration	Unit <sup>1</sup>	w/w (%)	Minimum purity (% w/w)	Same source as for Annex I inclusion
Bromadiolone	3-[3-(4'-Bromo[1,1'- biphenyl]-4-yl)-3- hydroxy-1-phenylpropyl]- 4-hydroxy-2H-1- benzopyran-2-one	28772-56-7	249-205-9	0.005	%	w/w		<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

Co-formulants					Contents				
Common name	IUPAC name	Function	CAS number	EC number	Concentration	Unit	w/w (%)	Classification	Substance of concern

<b>Sum</b>	<b>100.0</b>	<b>%</b>	<b>w/w</b>
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<sup>1</sup> g/l, g/kg, other. For biological products, the concentration should state the number of activity units/units of potency (as appropriate) per defined unit of formulation (e.g. per gramme or per litre).

**(b) (ii) Is the product identical to the representative product, assessed for the purpose of the Annex I inclusion?**

**yes**       **no**       **unknown**

**If not, briefly describe the difference.**

**The product presented is grain bait. The contain of the active substance is the same but the co-formulants are not the same**

**(b) (iii) Does the biocidal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?**

**yes**       **no**

If yes, does the product comply with Directive 2001/18/EC?

**yes**       **no**

A copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes where provided for by Part B of the above-mentioned Directive was provided.

(c) Manufacturer(s) of the active substance(s) (name(s) and address(es) including location of plant(s))<sup>2</sup>

Name of the active substance: bromadiolone			
Manufacturer			
Company Name: LABORATORIOS AGROCHEM S.L.			
Address:	Tres Rieras, 10 POL. IND. SUR		
City:	Esparreguera	Postal Code: 08292	Country: España
Telephone:	+34937774853	Fax: +34937775059	E-Mail: laboratorio@agrochem.es
Intra-Community VAT number or, for non EU companies, company registration number: [REDACTED]			
Formulation site(s) (if different)			
Company Name:	[REDACTED]		
Address:	[REDACTED]		
City:	[REDACTED]	Postal Code: [REDACTED]	Country: [REDACTED] ▼
Telephone:	[REDACTED]	Fax: [REDACTED]	E-Mail: [REDACTED]
Intra-Community VAT number or, for non EU companies, company registration number: [REDACTED]			

(d) Formulator(s) of the biocidal product (name(s) and address(es) including location of plant(s))<sup>2</sup>

Formulator			
Company Name: SANYS S.A.			
Address:	Cuestas de Móstoles, 8-10 Pol .Ind. La Laguna		
City:	FUENLABRADA	Postal Code: 28942	Country: SPAIN
Telephone:	+34916070075	Fax: +34916070060	E-Mail: tecnico@sanys.net
Intra-Community VAT number or, for non EU companies, company registration number: ESA28581809			
Formulation site(s) (if different)			
Company Name	[REDACTED]		
Address:	[REDACTED]		
City:	[REDACTED]	Postal Code: [REDACTED]	Country: SPAIN
Telephone:	Fax: [REDACTED]	E-Mail: [REDACTED]	
Intra-Community VAT number or, for non EU companies, company registration number:			

<sup>2</sup> All sites involved in the manufacturing process of each active substance and of the product must be listed.

***Physical state and nature of the biocidal product:***

- (e) Type of formulation: grain bait
- (f) Ready-to-use product:  no  yes

***Classification and labelling statements of the biocidal product:***

- (g) Product classification: No classification
- (h) Risk and Safety Phrases:
  - a. Risk phrases: Any risk phrase is considered necessary
  - b. Safety phrases:
    - S2: Keep out of the reach of children
    - S13: Keep away from food, drink and animal feedingstuffs
    - S37: Wear gloves
    - S46: If swallowed, seek medical advice immediately and show this container or label
- (i) Product classification according to GHS: The biocidal product does not require any classification and precautionary statements are:
  - P102: Keep out of reach of children.
  - P103: Read label before use.
  - P280: Wear protective gloves
  - P301+P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
- (j) Hazard statement according to GHS: Any hazard statement is considered necessary

***Intended uses and efficacy:***

- (k) PT: 14
- (l) Target harmful organisms:
  - I.1 *Rodentia*
  - I.1.1 *Muridae Murids*
  - I.1.1.1 *Rattus norvegicus*
  - I.1.1.3 *Mus musculus*
- (m) Development stage of target organisms:
  - II.1 Juveniles
  - II.2 Adults
- (n) Function/mode of action:
  - III.2 long-term action
  - III.2.1 anticoagulant
  - III.2.1.1 ingestion toxin
  - III.2.1.1.1 ingestion by eating
- (o) Field of use:
  - IV.1 indoor use
- (p) Application aim:
  - VII.1 Stored product protection
  - VII.2 Health protection
  - VII.3 Material protection
- (q) User category:
  - V.1 non-professional / general public
  - V.2 professional
  - V.3 specialised professional

- (r) Application method<sup>3</sup>:  
VI.2.1 in bait stations

**Directions for use<sup>4</sup>:**

- (s) Manner and area of use<sup>5</sup>:

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

- (t) Conditions of use<sup>6</sup>:

The bait is manually placed in the rodent infested area.

The bait has to be placed in tamper resistant bait stations, correctly labelled.

For the control of rats, baits up to 100g should be placed each 10 m<sup>2</sup>.  
For the control of mice, baits up to 50g should be placed each 10 m<sup>2</sup>.

Bait points have to be checked every 2-3 days during the first 14 days of treatment. Bait points should be removed, in a typical campaign, 6 weeks after initial placement

- (u) Instructions for safe use of the product:<sup>7</sup>

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.

Use tamper-resistant bait stations and place them in inaccessible areas to prevent the access non-target species, children and companion animals.

Collect dead rodent during all control operations to minimise the risk of consumption and poisoning to children, companion animals and other non-target animals.

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3 Indicate how the product will be applied (e.g. brush, spray, dipping, bait, etc). Where the product is to be used by more than one user category, indicate the application method(s) intended for each user category.

4 Provide in the following sections the information as it is proposed to appear on the product label or appropriate product literature.

5 Indicate information on the target organisms, the mode of action, the field of use, the application aim, the user category and the application method. All efficacy claims should be reflected.

6 Include the details of the directions for use. This should be expressed in terms of amount of product per unit area or a length of application (e.g. dip for 3 minutes). For aerosols and sprays a discharge rate should be included. If the product is a concentrate, indicate the dilution rate(s) here (e.g. *dilute 1 part of product with x parts of water*).

7 Where appropriate, indicate here the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by man or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during use, storage and transport (e.g. personal protective clothing and equipment, measures for protection against fire, covering of furniture, removal of food and feedingstuff and directions to prevent animals from being exposed).

For professional users: Remove all dead rodents after treatment and dispose of them in accordance with current regulations through registered establishment or undertaking carrying out waste management operations.

For non-professional users: Dead rodents must be deposited at collection points or points established by the local authority in accordance with their respective ordinances.

- (v) Particulars of likely direct or indirect adverse effects and first aid instructions

Poisoning may cause:

- Bleeding diathesis, derived from antiprothrombin effect – prolonged prothrombin time – that may become evident at minimum 24 – maximum 72 hours (A normal prothrombin time when the patient is admitted in the hospital, does not exclude the diagnosis)

First aid:

- Move the person away from the contaminated zone
- Remove contaminated or spattered clothing
- Rinse the eyes with plenty of water for 15 minutes. Do not forget remove the contact lenses
- Wash off the skin with soap and plenty of water, without rubbing
- If swallowed, do not make him/her vomit
- Keep the patient warm and at rest
- Check the breath. If necessary, give artificial respiration
- If the person is unconscious, make him/her lie on his/her side, with the head at lower level than the rest of the body, bending the legs.
- Take person to a hospital and show the label or packaging where possible

DO NOT LEAVE POISONED PERSON ALONE UNDER ANY CIRCUMSTANCE

**Medical advice for doctors and sanitary staff**

- If less than 2 hours has passed from the intake, gastric emptying must be performed, and activated carbon dispensed (25 g)
- Antidote: Vitamin K.
- Check the prothrombin time
- Treat symptomatically

IN CASE OF ACCIDENT CONTACT THE POISON CENTER

- (w) 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.

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.

For non-professional users: Packaging, uneaten baits and bait boxes must be deposited at collection points or points established by the local authority in accordance with their respective ordinances.

- (x) 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 2 years

(y) Additional information:

**Packaging:**

The product is placed on the market inside individual sachets of 10, 20, 25 o 50g. They are delivered inside paper, plastic or carton bags of 100, 200, 250,, 500 g and 1kg for non-trained professional and non-professional users; or of 500 g and 1, 2, 2.5, 5, 10, 15, 20 or 25kg for trained professional users.