



**Office for Registration  
of Medicinal Products, Medical Devices and Biocidal Products**  
41 Żąbkowska Str., 03-736 Warsaw, Poland; phone +48 22 492-11-00, fax + 48 22-492-11-09  
NIP 521-32-14-182 REGON 015249601

## **Summary of Product Characteristics**

### **Toxan Płatki**

#### **Authorisation**

**Active substance: 3-[3-(4'-Bromo[1,1'- biphenyl]-4-yl)-3- hydroxy-1-phenylpropyl]- 4-hydroxy-2H-1- benzopyran-2-one /Bromadiolone, (CAS: 28772-56-7), PT 14**

**Authorization holder: „FREGATA” S.A.**

*This document has no legal value and it's for information purposes only. It is neither an authorisation of a biocidal product nor a translation of an authorisation. It has only informative value as a document for exchange of information between Member states and the European Commission and represents an “identity card” of the product. Only the original and signed authorisation certificate issued by The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products has legal value.*

### Summary of the product characteristics

(a) **Product trade name:** Toxan Płatki

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

Active substance(s)				Contents				
Common name	IUPAC name	CAS number	EC number	Concentration	Unit	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	0.004	g/100g	0.004	98	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

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

no

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

Differences in non-active ingredients of formulation.
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**(b) (iii) Does the biocidal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?**

no

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

n/a

(c) Manufacturer(s) of the active substance(s) (name(s) and address(es))

Name of the active substance: BROMADIOLONE

Manufacturer

Company Name: PelGar International Ltd,

Address: Unit 13, Newman Lane, Alton

City: Hampshire Postal Code: GU34 2QR Country: UK

Telephone: + 44 1420 80744 Fax: + 44 1420 80733 E-Mail: [info@pelgar.co.uk](mailto:info@pelgar.co.uk)

Intra-Community VAT number or, for non EU companies, company registration number: GB651223078

(d) Formulator(s) of the biocidal product (name(s) and address(es))

Formulator

Company Name: "FREGATA" S.A.

Address: Grunwaldzka 497

City: Gdańsk Postal Code: 80-309 Country: PL

Telephone: (58) 552 00 27 do 29 Fax: (58) 552 48 31 E-Mail: [fregata@fregata.gda.pl](mailto:fregata@fregata.gda.pl)

Intra-Community VAT number or, for non EU companies, company registration number: 584-030-44-37

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

- (e) Type of formulation: flakes
- (f) Ready-to-use product: yes

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

- (g) Product classification: none
- (h) Risk and Safety Phrases:
- (i) Product classification according to GHS: none
- (j) Hazard statement according to GHS: none

P102 – Keep out of reach of children.

P280 – Wear protective gloves.

**Intended uses and efficacy:**

- (k) PT: 14 (Rodenticides)
- (l) Target harmful organisms:
  - Brown rat (*Rattus norvegicus*)
  - House mouse (*Mus musculus*)
  - Field mouse (*Apodemus agrarius*)
- (m) Development stage of target organisms:
  - Juveniles
  - Adults
- (n) Function/mode of action:
  - long-term action
  - anticoagulant
  - ingestion toxin
  - ingestion by eating
- (o) Field of use:
  - indoor use,
  - outdoor use (e.g. parks, tennis courts, camping sites and other places of the public utility, waste dumps)
- (p) Application aim:

	health protection material protection (e.g. historical buildings, technical objects)
(q)	User category  non-professional (general public) professional
(r)	Application method:  Covered application:  in bait stations

***Directions for use:***

(s) Manner and area of use:

See "intended uses and efficacy" above

(t) Conditions of use:

Commercially available tamper resistant bait stations only are authorized.

Rats: 200 g of flakes per bait station spaced at 10-15 m. Typical treatment time 20 days (according to field trial)

Mice: 100 g of flakes per bait station spaced at 1.5-2m. Typical treatment time 20 days (according to field trial)

(u) Instructions for safe use of the product:

The biocidal product must be used only in tamper resistant bait stations made of durable material.

Tamper resistant bait stations must be clearly marked to show that they contain rodenticides that should not be distributed.

Read the label before use.

Do not use anticoagulant rodenticides as permanent baits.

Prevent accidental exposure of the product to the environment.

Prevent access to bait by children, birds, and non-target animals (particularly dogs, cats, pigs and poultry).

Do not eat, drink or smoke when using this product.

Wash exposed skin before meal and after application of the product.

Wear suitable gloves (for professional user).

It is recommended to wear protective gloves (for non-professional user).

For product to be used in public areas the following safety precautions shall be carried on the label, packaging or accompanying leaflet:

“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”.

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

Bromadiolone is an anticoagulant which may produce bleeding.

Antidote: Treatment with Vitamin K1 administered under medical supervision.

ORAL: If swallowed or in the event of disturbing symptoms appearing seek medical advice.

DERMAL: In the case of the contact with the skin wash the contaminated place with water and soap.

EYES: In the case of eyes contamination rinse them with a plenty of water.

INHALATION: In case of inhalation exposure, in the event of disturbing symptoms appearing, seek medical advice.

In case of emergency contact the Poison Centres in Poland:

Gdańsk – (58) 682 04 04

Poznań – (61) 847 69 46

Kraków – (12) 411 99 99

Warszawa – (22) 619 66 54

(w) Instructions for safe disposal of the product and its packaging:

Search for and remove dead rodent, the bait damaged by water or contaminated by dirt and bait found outside the bait station, at least as often as when baits are checked and/or replenished. All residues should be disposed of in accordance with local regulations (e.g. in the authorized companies).

After the campaign remove dead rodents, the bait damaged by water or contaminated by dirt, bait found outside the bait station, bait stations and package. These residues should be disposed of in accordance with local regulations (e.g. in the authorized companies).

(x) Conditions of storage and shelf-life of the product under normal conditions of storage:

Keep away from food, drink and animal feeding stuffs.

Product should be stored in original container at room temperature in dry place inaccessible to children and pets.

Keep/store out of reach of children.

Shelf life of up to 2 years supported.

(y) Additional information:

**Authorization number: PL/2013/0080/A**

**granting date: 27.05.2013**

**expiring date: 2016.06.30**

Packing type	Pack sizes for non professional use	Pack sizes for professional use
Welded PET/PE bag made of foil resistant to tearing. On front of the bag clearly warning “Keep out of the reach of children”	100 g	100 g
Welded PET/PE bag made of foil resistant to tearing with the label “close-open”. On front of the bag clearly warning “Keep out of the reach of children”. 100 and 200 g measure graphics on the bag	200 g	200 g
Welded PET/PE bag made of foil resistant to tearing with the label “close-open” placed inside carton box. On front of the box clearly visible warning “Keep out of the reach of children”. Measure cup and protective gloves inside the box	400 g	400 g
Polyethylene bag closed with clamped seal placed additionally in a HDPE or polypropylene bucket, closed with clamped lid on the container, protected with an additional seal. Measure cup and protective gloves inside bucket	1 500 g	–
Polyethylene bag closed with clamped seal placed additionally in a HDPE or polypropylene bucket, closed with clamped lid on the container, protected with an additional seal.	–	3 kg
Welded PE bag resistant to tearing placed additionally in a paper bag	–	15 kg