Product Assessment Report

Toxan® Płatki

Authorisation no:

Granting date:

Expiry date of authorisation:

Authorisation no:

Biocidal product assessment report related to product authorisation under Directive 98/8/EC

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1 General information about the product application

1.1 Applicant

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1.1.1 Person authorised for communication on behalf of the applicant

Name:	Halina Daraż
Function:	Chairman of the management board
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1.2 Information about the product application

Application received:	28.06.2011
Application reported complete:	02.12.2011
Type of application:	Product authorisation
Further information:	No

1.3 Information about the biocidal product

1.3.1 General information

Trade name:	Toxan® Płatki
Manufacturer's development code number(s), if appropriate:	–
Product type:	14 (Rodenticides)
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	Bromadiolone 0.004%
Formulation type:	Flakes
Ready to use product (yes/no):	Yes
Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); **If yes: authorisation/registration no. and product name:** **or** **Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):**	No

1.3.2 Information on the intended use

Overall use pattern (manner and area of use):	Indoors (e.g. live-stock buildings); Outdoors (e.g. parks, tennis courts, camping sites and other places of the public utility, waste dumps)
Target organisms:	Brown rat *(Rattus norvegicus)* House mouse *(Mus musculus)* Field mouse *(Apodemus agrarius*)
Category of users:	Non-professional Professional
Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	*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)
Potential for release into the environment (yes/no):	Yes
Potential for contamination of food/ feedingstuff (yes/no)	No
Proposed Label:	Annex 9
Use Restrictions:	Please referee to section 2.9

1.3.3 Information on active substance

Active substance chemical name:	Bromadiolone 3-[3-(4'-Bromo[1,1'- biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]- 4-hydroxy-2H-1- benzopyran-2-one
CAS No:	28772-56-7
EC No:	249–205–9
Purity (minimum, g/kg or g/l):	> 969 g/kg
Inclusion directive:	2009/92/EC
Date of inclusion:	01.07.2011
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes

Manufacturer of active substance used in the biocidal product

Company Name:	PelGar International Ltd
Address:	Unit 13 Newman Lane Alton
City:	Hampshire
Postal Code:	GU34 2QR
Country:	UK
Telephone:	+ 44 (0)1420 80744
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E-mail address:	info@pelgar.co.uk

1.3.4 Information on the substance(s) of concern

Substance chemical name	–
CAS No:	–
EC No :	–
Purity (minimum, g/kg or g/l):	–
Typical concentration (minimum and maximum, g/kg, or g/l):	–
Relevant toxicological/ecotoxicological information:	–
Original ingredient (trade name):	–

1.4 Documentation

1.4.1 Data submitted in relation to product application

Please see to Annex 2.

1.4.2 Access to documentation

Fregata S.A. has letter of access to data held by PelGar International Ltd which was used to support the Annex I listing of the active substance bromadiolone according to Directive 98/8/EC.

2 Summary of the product assessment

2.1 Identity related issues

The biocidal product Toxan® Płatki contains the active substance bromadiolone (0.004%) (purity >969 g/kg).

The source of active substance used in the biocidal product is different to the active substance that is listed in Annex I of 98/8/EC but the technical equivalence of new source of bromadiolone in comparison to original one is established.

2.2 Classification, labelling and packaging

2.2.1 Harmonised classification of the biocidal product

Product classification: None

2.2.2 Labelling of the biocidal product

The current Classification of bromadiolone under EC 1272/2008 is:

Acute Toxic, Category 1	H330 Fatal if Inhaled,
	H310 Fatal in contact with the skin
	H300 Fatal if swallowed
Stot RE, Category 1	H372 Causes damage to organs through prolonged or repeated exposure .
Aquatic Acute, Category 1	H400 Very toxic to aquatic life
Aquatic Chronic, Category 1	H410 Very toxic to aquatic life with long lasting effects

Classification and labelling of the product:

H–phrases

None

P–phrases

P102 – Keep out of reach of children.

P280 – Wear protective gloves.

2.2.3 Packaging of the biocidal product

The packaging details for the biocidal product, Toxan® Płatki, are outlined below for non-professional and professional users.

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

2.3 Physical-chemical properties and analytical methods

Product Toxan® Płatki is ready-to-use product in a form of flakes containing active substance – bromadiolone which is supplied to the producer, Fregata S.A., by PelGar International Ltd company (one of the active substance notifiers) in a form of a concentrate for which full, detailed composition is submitted to the Competent Authority.

Toxan® Płatki is pink-straw-coloured grain smelling product with no oxidizing nor explosive properties. It is also not fulfilling a criterion for highly flammable and is self igniting at 329°C. Pour bulk density of the product is equal to 0.45 g/cm^3 and tap bulk density is 0.53 g/cm^3. Water suspension of the product gives light-acetic pH (1%, pH = 6.28 to 5.72 – after storage stability test).

The technical characteristics of a product are well documented. Attrition resistance, dustiness and nominal size with particle size distribution were tested before and after accelerated storage stability test, which also confirms the stability of the product for two weeks in 54°C.

Active substance content decreased from 0.044 g/kg to 0.039 g/kg after storage stability test. The loss of 11.4% is acceptable taking into consideration formulation type. According to "*Manual on development and use of FAO and WHO specifications for pesticides*" the acceptable tolerance of content for substances present in a heterogeneous formulations in concentration up to 25 g/kg is ±25%. The formulation type – flakes are considered by Evaluating Authority to be close-related to granules and is considered to be heterogeneous.

Taking into consideration results from the accelerated storage stability test and also stability of technical characteristics, the shelf life of the product is considered acceptable up to two years in ambient conditions.

The HPLC analytical method based on SANCO/3030/99 rev. 4 requirements is fully validated and it is acceptable for determination of the active substance content in the product.

2.3.1 Physical-chemical properties

Physical-chemical properties of the active substance:

The letter of access form PelGar International Ltd., granted to Fregata S.A., has been submitted for the active substance therefore no additional information for this point is needed.

Physical-chemical properties of the biocidal product:

	Method	Purity/ Specification	Results	Reference
Physical state and nature	Farmakopea Polska, wyd. VI (2002) and according to EPA Product Properties Test Guideline OPPTS 830.6302	Toxan Płatki, partia nr (lot No.) TP1009048 Specification.: SP-TOXAN PŁATKI -01/10 with additional statement	solid, flakes	EMC 373100019 study code: BF-21/11
Colour	Farmakopea Polska, wyd. VI (2002) and according to EPA Product Properties Test Guideline OPPTS 830.6303	Toxan Płatki, partia nr (lot No.) TP1009048 Specification.: SP TOXAN PŁATKI -01/10 with additional statement	pink-straw-coloured	EMC 373100019 study code: BF-21/11
Odour	Farmakopea Polska, wyd. VI (2002) and according to EPA Product Properties Test Guidelines OPPTS 830.6304	Toxan Płatki, partia nr (lot No.) TP1009048 Specification.: SP-TOXAN PŁATKI-01/10 with additional statement	of grain	EMC 373100019 study code: BF-21/11
Explosive properties	A.14, procedures W03-WNU W04-WNT W17-OŁS	Toxan Płatki, partia nr (lot No.) 811170 Specification.: SP-TOXAN PŁATKI -01/10 with additional statement	Toxan® Płatki does not possess explosive properties	31/W/51/2008
Oxidizing properties	A.17, procedure SPR/BC-FC/03/b	Toxan Płatki, partia nr (lot No.) 811170 Specification.: SP-TOXAN PŁATKI -01/10 with additional statement	Toxan® Płatki does not possess oxidizing properties	EMC 363000012 study code: BC/22/08
Flash point	A.10 procedure SPR/BC-FC/08/b	Toxan Płatki, partia nr (lot No.) 811170 Specification.:	Toxan Płatki is not highly flammable	EMC 363000012 study code:

	Method	Purity/ Specification	Results	Reference
		SP-TOXAN PŁATKI -01/10 with additional statement		BC/22/08
Autoflammability	A.16 procedure SPR/BC-FC/12/b	Toxan Płatki, partia nr (lot No.) 811170 Specification.: SP-TOXAN PŁATKI -01/10 with additional statement	The self-ignition temperature of a product is 329 °C	EMC 363000012 study code: BC/22/08
Other indications of flammability	n.a.	n.a.	n.a.	n.a.
Acidity / Alkalinity	CIPAC MT 75.3	Toxan Płatki, partia nr (lot No.) TP1009048 Specification.: SP-TOXAN PŁATKI-01/10 with additional statement	pH of 1% water suspension is 6.28 before and 5.72 after accelerated storage stability test	EMC 373100019 study code: BF-21/11
Relative density / bulk density	CIPAC MT 186	Toxan Płatki, partia nr (lot No.) TP1009048 Specification.: SP-TOXAN PŁATKI -01/10 with additional statement	bulk density is 0.45 g/ml (pour) and 0.53 g/ml (tap)	EMC 373100019 study code: BF-21/11
Storage stability – stability and shelf life	CIPAC MT 46 (2 weeks 54 °C)	Toxan Płatki, partia nr (lot No.) TP1009048 Specification.: SP- TOXAN PŁATKI -01/10 with additional statement	Toxan Płatki is stable for two weeks in 54 °C	RB/FGA/03/01
Effects of temperature	CIPAC MT 46	Toxan Płatki, partia nr (lot No.) TP1009048 Specification.: SP- TOXAN PŁATKI -01/10 with additional statement	Toxan Płatki is stable for two weeks in 54 °C	EMC 373100019 study code: BF-21/11
Reactivity towards container material	CIPAC MT 46	Toxan Płatki, partia nr (lot No.) TP1009048 Specification.: SP- TOXAN PŁATKI -01/10 with additional statement	the weight, colour and shape of container as well as physical-chemical properties of product did not change during storage stability test	EMC 373100019 study code: BF-21/11
Technical characteristics in dependence of the formulation type ***Attrition resistance***	CIPAC MT 178	Toxan Płatki, partia nr (lot No.) TP1009048	99.05% before accelerated storage stability test	EMC 373100019

	Method	Purity/ Specification	Results	Reference
		Specification.: SP- TOXAN PŁATKI -01/10 with additional statement	99.18% after accelerated storage stability test	study code: BF-21/11
Dustiness	CIPAC MT 171	Toxan Płatki, partia nr (lot No.) TP1009048 Specification.: SP- TOXAN PŁATKI -01/10 with additional statement	Essentially non dusty (13.45 mg before and 13.75 after accelerated storage stability test)	EMC 373100019 study code: BF-21/11
Nominal size range	CIPAC MT 59	Toxan Płatki, partia nr (lot No.) TP1009048 Specification.: SP- TOXAN PŁATKI -01/10 with additional statement	Nearly 98% of the flakes are of size up to 4750 µm before and after accelerated storage stability test (based on particle size distribution test)	EMC 373100019 study code: BF-21/11
Compability with other products	n.a.	n.a.	Toxan Płatki will not be used with other products (expecially biocidal products)	n.a.
Surface tension	n.a.	n.a.	n.a.	n.a.
Viscosity	n.a.	n.a.	n.a.	n.a.
Particle size distribution	CIPAC MT 59	Toxan Płatki, partia nr (lot No.) TP1009048 Specification.: SP- TOXAN PŁATKI -01/10 with additional statement	before accelerated storage stability test: 0.63% ≥ 4750µm 3150 µm ≤ 32.49% < 4750µm 1400µm ≤ 36.08% < 3150µm 1000 µm ≤ 6.47% < 1400 µm 500 µm ≤ 7.21% < 1000µm 250 µm ≤ 5.05% < 500µm 125 µm ≤ 5.25% < 250 µm 75 µm ≤ 3.84% < 125 µm 45 µm ≤ 2.53% < 75 µm 0.47% < 45 µm after accelerated storage stability test: 2.16% ≥ 4750µm 3150 µm ≤ 30.71% < 4750µm 1400µm ≤ 37.45% < 3150µm 1000 µm ≤ 6.13% < 1400 µm 500 µm ≤ 6.93% < 1000µm 250 µm ≤ 4.92% < 500µm 125 µm ≤ 5.13% < 250 µm 75 µm ≤ 3.61% < 125 µm 45 µm ≤ 2.16% < 75 µm 0,81% < 45 µm	EMC 373100019 study code: BF-21/11

2.3.2 Analytical methods

	Principle of method
Technical active substance as manufactured:	-
Impurities in technical active substance:	-
Active substance in the formulation:	Specific analytical method with validation data was established for determination of content of the active substance in the product. The HPLC method is based on SANCO/3030/99 rev. 4 requirements.

2.4 Risk assessment for physical-chemical properties

Based on the physical-chemical data submitted for Toxan® Płatki it can be concluded that there are no additional, specific physical-chemical risks for the product. The product has no explosive nor oxidizing properties. The product is not highly flammable and in case of autoflammability the self ignition temperature is 329°C which in normal or worst realistic conditions of use will never be a case. Extensive technical properties characteristics of the product are done before and after accelerated storage stability test. No additional risks are found based on technical characteristics of a product (e.g. no potential inhalation danger since particles size < 50 μm are present as trace (0.47% < 45 μm and less than 10% up to 100 μm)). There are some indications of dust ability of a product (dust content less than 14 mg of dust from 30 g of sample) but the result makes the product to be considered as essentially non dusty.

2.5 Effectiveness against target organisms

Function

The biocidal product Toxan® Płatki will be used as rodenticide (PT 14) for the control of commensal rodent species. The product is intended for use indoors (e.g. live-stock buildings) and outdoors (e.g. parks, tennis courts, camping sites and other places of the public utility, waste dumps) and will be used by professional and non-professional users.

Organisms to be controlled

Toxan® Płatki is intended to be used against *Rattus norvegicus* (brown rat), *Mus musculus* (house mouse) and *Apodemus agrarius* (field mouse).

2.5.1 Dose / mode of action

Test organism(s)	Test system	Test conditions	Test results	Reference
House mouse *(Mus musculus)* Field mouse *(Apodemus agrarius)*	Field test done according to method FRE/RT-03/2007	The size of rodents population was evaluated by measure of control bait intake at the beginning and the end of the study. 100g Toxan® Płatki has been placed into each bait station spaced every 1.5 – 2 meters in infested area. Bait stations were refilled 5 times every 3 days. After 20 days three parameters were tested : 1) percentage loss of intake control bait 2) percentage loss of intake poison bait percentage of active holes	The study indicates that: 1) intake of control bait was reduced 94.4% 2) intake of tested bait was reduced 90.8% 3) percentage of active holes was reduced to 8.35%	III-B 5.10.2(1)
Brown rat *(Rattus norvegicus)*	Field test done according to method FRE/RT-03/2007	The size of rodents population was evaluated by measure of control bait intake at the beginning and the end of the study. 200g Toxan® Płatki has been placed into each bait station located every 10 – 15 meters in infested area. Bait stations were refilled 5 times every 3 days. After 20 days three parameters were tested : 1) percentage loss of intake control bait, 2) percentage loss of intake poison bait 3) percentage of active holes	The study indicates that 1) intake of control bait was reduced 87.5% 2) intake of tested bait was reduced 87.3% 3) percentage of active holes was reduced to 8.7%	III-B 5.10.2(1)
House mouse *(Mus musculus)*	Palatability test done according to method EPPO 1982	Control group (10 males and 10 females) Tested group (10 males and 10 females) Total time of study	Total mortality of mice has reached 90% and edibility was at the level 86.6%.	III-B 5.10.2(3)

	"Laboratory Tests for Evaluation of the Toxicity and Acceptability of Rodenticides and Rodenticide Preparations"	22 days includes pre-treatment period (4 days), treatments period (4 days) and observation period (14 days)	Palatability ratio for males was 4.7 and for females 10.5. The average mortality for males has occurred at 10.8 day (6-16 days) with average consumption of bait 26.7 mg/kg b.w. For females average mortality has occurred at 11.0 day (7-18) with average consumption of bait 28.0 mg/kg b.w.	
Brown rat *Rattus norvegicus*	Palatability test done according to method EPPO 1982 "Laboratory Tests for Evaluation of the Toxicity and Acceptability of Rodenticides and Rodenticide Preparations"	Control group (10 males and 10 females) Tested group (10 males and 10 females) Total time of study 22 days includes pre-treatment period (4 days), treatments period (4 days) and observation period (14 days)	Total mortality of rats has reached 100% and edibility was at the level 83.1%. Palatability ratio for males was 3.1 and for females 29.0. The average mortality for males has occurred at 8.0 day (5-13 days) with average consumption of bait 10.0 mg/kg b.w. For females average mortality has occurred at 9.3 day (5 – 16) with average consumption of bait 14.3 mg/kg b.w.	III-B 5.10.2(2)

2.5.2 Known limitation

In order to limit risk of poisoning and contamination of environment the following conditions should be ensured:

1) the nominal concentration of the active substance in the products shall not exceed 50 mg/kg and only ready for use baits shall be authorised;
2) product shall contain an aversive agent and where appropriate a dye;
3) products shall not be used as tracking powder;
4) primary as well as secondary exposure of humans, non-target animals and the environment are minimized, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, setting an upper limit to package size and laying down obligations to use tamper resistant and secured bait boxes.

2.5.3 Resistance

1) The population size of the target rodent should be evaluated before a control campaign.
2) The number of baits and the timing of the control campaign should be in proportion to the size of the infestation.
3) A complete elimination of rodents in the infested area should be achieved.
4) The use instructions of products should contain guidance on resistance management for rodenticides.
5) Bromadiolone should not be used in an area where resistance to this substance is suspected.
6) The authorisation holder shall report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management.

2.6 Exposure assessment

2.6.1 Description of the intended use

Toxan® Płatki is a rodenticide product in a form of flakes for the effective control of rodent species, both indoors and outdoors, in and around a variety of places including but not limited to buildings, open areas and waste dumps. Toxan® Płatki takes the form of a ready to

use flakes bait containing 0.004% w/w (40 ppm) bromadiolone second generation and single dose anticoagulant, which causes death due to massive internal haemorrhages after several days of ingestion as a consequence of an accumulated lethal dose. The target species are brown rat (*Rattus norvegicus*), house mouse (*Mus musculus*) and field mouse *(Apodemus agrarius)*. Other than the active ingredient, the product is composed of food-grade materials forming a bait base.

2.6.2 Assessment of exposure to humans and the environment

The active substance bromadiolone is the only substance of concern in biocidal product Toxan® Płatki. New exposure studies have not been submitted and the risk assessment was performed based on the information presented in CAR.

2.7 Risk assessment for human health

The biocidal product Toxan® Płatki is in the form of ready to use flakes that should be put in tamper resistant bait stations (200 g of product/station for rats and 100 g of product/station for mice). It contains 0.004% of the active substance bromadiolone. It belongs to PT 14 product group. Toxan® Płatki is designed for use by professionals and non-professional users. Potential exposure to product is possible for people both during the product formulation and its use.

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

The letter of access form PelGar International Ltd., granted to Fregata S.A., has been submitted for the active substance bromadiolone therefore no additional information for this point is needed.

2.7.1.2 Toxicology of the substance(s) of concern

The biocidal product Toxan® Płatki does not contain in its composition the toxicologically relevant substances (classified as dangerous according to Directive 67/548/EEC and present at concentrations likely to cause harmful effects to humans, animals or the environment), other than the active substance. The only substance important from a toxicological point of view is active substance bromadiolone.

2.7.1.3 Toxicology of the biocidal product

The toxicological studies for a biocidal product Toxan® Płatki were not performed. The toxicological evaluation of this product was based on toxicological data for the active substance bromadiolone.

Information on the assessment of the active substance bromadiolone were granted to Fregata S.A. by PelGar International Ltd. as bromadiolone manufacturer (based on data from letter of access dated on 28.02.2011) for the registration of a biocidal product Toxan® Płatki.

Summary of toxicity data for the biocidal product Toxan® Płatki:

Dermal absorption studies for biocidal product were not performed. The absorption for biocidal product will be comparable to dermal absorption of the active substance and was set at 1.6% (according to *Assessment Report for bromadiolone*). For the calculation of exposure to operator the dermal absorption was set at 100% as the worst case scenario (according to *TNsG*).

Oral LD_{50} (rat):

14.0 – 21.0 g/kg bw (female)

Dermal LD_{50} (rabbit):

42.75 g/kg bw (male and female)

Inhalation LC_{50} (rat):

10.75 mg/l (male and female)

Inhalation acute studies for biocidal product were not performed. Due to that bromadiolone has a low vapour pressure (2.0×10^{-6} Pa at room temperature), the product is essentially non dusty and consists of solid particles exposure via inhalation is expected to be negligible.

Irritation to skin

Not irritation to skin

Irritation to eye

Not irritation to eye

Sensitizing to skin

Not sensitizing to skin

2.7.2 Exposure

The calculations of exposure have been performed in accordance with the assumptions of document published by the European Commission, "*The Technical Notes for Guidance: Human Exposure to Biocidal Products*" Guidance on Exposure Estimation (B4 3040/2000/291079/MAR/E2), and the Human Exposure to biocidal products (*TNsG* June 2007) implementing the objectives of the Directive 98/8/EC concerning the placing of biocidal products on the market.

Additionally, exposure calculations have been done based on the data from a study by J.G Chambers and P.J. Snowdon, "*Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits*" (2004) to which Fregata S.A. submitted the letter of access.

Main paths of human exposure

Route of exposure	Industrial use	Professional user	Non-professional user	Bystanders
inhalation	Yes	No	No	No
dermal	Yes	Yes	Yes	Yes
oral	No	No	No	Yes

Potential exposure is identified during the formulation of a biocidal product. According to the declaration of the applicant the packaging and the final preparing of the product is fully automatic process and no direct contact with the product is expected. For this reason the calculation of exposure at this stage was omitted. Exposure during use of the product was calculated according to the recommended scenarios and taking into account the specifications of the product.

2.7.2.1 Exposure of professional users

2.7.2.1.1 Exposure during the formulation of biocidal product

The results of inhalation exposure measurements and information on dermal exposure during production of the biocidal product are not available. However, data on the manufacturing process, contained in Doc. IIIB 6.6 indicates that the dermal and inhalation exposure for people working in the hall of the product formulation is likely. Data contained in Doc. 6.6 IIIB were used to calculate the exposure according to the EASE model (EUSES 2.1).

EASE – Estimations of exposure to the active substance during the formulation of the biocidal product:

Exposure path	Inhalation exposure	Dermal exposure
Estimations	powder – the product is not volatile - exposure to particulate matter – closed system: 0.0000044 mg/kg bw/day	powder – incidental contact with skin – all hands – direct contact with the skin during handling of the product: 0 mg/kg bw/day

The packaging of the product is done in a separate hall than the formulation, using the confection machine and without the involvement of operators. From the confection machine, product packed in a tightly-closed foil bags goes to the line of confection and where these plastic bags are packed in cartons by people working at the confection line. The inhalation and dermal exposure to the product during its packaging is not expected and therefore the calculation of that has been omitted.

2.7.2.1.2 Exposure during the use of biocidal product

In the estimation of exposure the following elements were taken into consideration:

- Toxan® Płatki is supplied to the customer in tightly-closed foil units PET/PE.
- The inhalation exposure was not estimated. Toxan® Płatki is essentially non dusty and the active substance bromadiolone is not volatile – the risk of inhalation exposure is considered negligible.
- The dermal exposure was estimated. During the use, the Toxan® Płatki should be put in tamper resistant bait stations. In that case dermal exposure may be limited only to the surface of the hands.
- The oral exposure was not estimated. It is unlikely that the product will be swallowed by professional users. It is possible, however, that contamination of the skin may indirectly lead to oral exposure.

  However, for professional users is assumed to deliberate and professional use of personal protective equipment, including protective gloves. For this reason, the risk of oral exposure in this way during the use of the product is considered to be insignificant.
- The dermal exposure was estimated at two levels:
  - Level 1 – the application without the use of personal protective equipment PPE (without gloves)
  - Level 2 – application with the use of personal protective equipment PPE (with gloves).

Estimations according to *TNsG*:

According to *TNsG*, for professional users the application phase (use) and disposal phase of the product should be considered. The calculations were performed according to formulas presented *TNsG* June 2007. Detailed calculations are presented in Doc. II B.

For the calculations the following element were used:

Application phase:

- frequency of events per day: 16 bait stations per day (*TNsG* June 2007)
- the amount of the product per event: 200 g (Doc. IIIB 5)

Disposal/utilization phase:

- the amount of the removed product per event: 30 g (*TNsG* June 2007)
- frequency of events per day: 16 bait stations per day

It is assumed that dermal absorption value is 1.6% (*Assessment Report for bromadiolone*)
The operator body weight used in the calculation: 60 kg (*TNsG* June 2007)
Product density: 0.45 g/m3 (Doc. IIIB 3)

	Level 1 [mg/kg bw/day]	**Level 2 [mg/kg bw/day]**
Application phase	0.0015	0.00015
Removal of the preparation phase	0.0015	0.00015
Total exposure	0.003	0.0003

The second level includes gloves and 10% uptake.

Estimations based on the data from a study by J.G. Chambers and P.J. Snowdon

The exposure calculations have been done also based on the data from a study by J.G. Chambers and P.J. Snowdon, "*Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits*" (2004) to which Fregata S.A. submitted the letter of access. Detailed calculations are presented in Doc. II B.

In this study, three phases of use of the product were indicated:

Initial phase – preparation of the product, mixing and pouring into smaller, more practical containers

- use of approximately 12.6 kg of product per day, decanting of the product to the containers in batches of 3 kg
- recommended value to potential exposure: 52.3 mg (per one action)

Application phase – loading and placing of the biocidal product in places of rodents' presence

- frequency of events per day: 63
- the amount of the product per event: 200 g (Doc. IIIB 5)
- the recommended value of potential exposure: 2.04 mg (per one action)

Final phase – including the removal of unused biocidal product

- frequency of events per day: 16
- recommended value to potential exposure: 3.79 mg b.p. (per one action)

	Level 1 [mg/kg bw/day]	**Level 2 [mg/kg bw/day]**
Total exposure	4.36×10^{-6}	4.36×10^{-7}

The second level includes gloves and 10% uptake.

2.7.2.2 Exposure of non-professional users

To estimate the exposure for non-professional users the same elements were taken into account as for the professional users (see above).

Estimations to non-professionals according to *TNsG*:

According to *TNsG*, for non-professional users the application phase (use) and disposal phase of the product should be considered.

Application phase:

- frequency of events per day: 2 bait stations per day (*TNsG* June 2007)
- the amount of the product per event: 200 g (Doc. IIIB 5)

Disposal/utilization phase:

- the amount of the removed product per event: 30 g (*TNsG* June 2007)
- frequency of events per day: 2 bait stations per day

	Exposure value [mg/kg bw/day]
Application phase	0.000192
Removal of the preparation phase	0.000192
Total exposure	0.000384

Estimations to non-professionals based on the data from a study by J.G. Chambers and P.J. Snowdon

The exposure calculations have been done also based on the data from a study by J.G. Chambers and P.J. Snowdon, "*Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits*" (2004) to which Fregata S.A. submitted the letter of access. Detailed calculations are presented in Doc. II B.

In order to harmonize the method of estimation of the exposure with the other EU countries the guideline of *TNsG* was rejected (two applications per day), as unrealistic and it was assumed that non-professional user use this type of product 5 times per day as a realistic worst case. In addition, due to the fact that the recommended pack size can not exceed 1.5 kg, the initial phase of decanting of the product from large to smaller pack was ommited.

In this study, there are two phases of use of the product:

Application phase – loading and placing of the biocidal product in places of rodents' presence

- frequency of events per day: 5
- the amount of the product per event: 200 g (Doc. IIIB 5)
- the recommended value of potential exposure: 3.57 mg (per one action)

Final phase – including the removal of unused biocidal product

- frequency of events per day: 5
- the amount of the product per event: 200 mg (Doc. IIIB 5)
- the recommended value of potential exposure: 4.52 mg (per one action)

Total exposure for the non-professional user during the use/day = 4.31×10^{-7} mg/kg bw/day

While use of the biocidal product, by standers including for example children and infants may come into contact with a biocidal product. For example, putting poison in cardboard bait station can not prevent the child from contact with this poison. There is also likely to eat the poison by the child directly from the container in which the biocidal product is placed. Technical guidelines assume that the child can eat at one time about 5 g. The scenario assumes that a handful of flakes weighs about the same.

The method of assessing the potential exposure for bystanders were based on default values, contained in the guidelines for Human Exposure to Biocidal Products, Section 5, Anex 4 (*TNsG* June 2007). The assumptions were adopted for the worst-case envisaged scenario – worst case scenario.

There is also potential exposure for the skin after taking the poison by hand. However, it is assumed that the exposure at this type of situation is far less compared to oral exposure and therefore dermal exposure was not calculated.

For the calculations the following element were used:

- the amount of eaten product: 5 g (*TNsG* June 2007)
- it is assumed that dermal absorption value is 100% (*TNsG* June 2007)
- body weight of child: 10 kg (*TNsG* June 2007)

	Exposure value [mg/kg bw/day]
Exposure for child	0.02

2.7.2.3 Exposure to residues in food

Not applicable.

2.7.3 Risk Characterisation

The risk characterisation was performed in accordance with the recommendations of the technical guidelines *TNsG* (*Annex I Inclussion Revision of Charter 4.1: Quantitative Human Health Risk Characterisation*), based on the determined values of MOE and AEL.

According to information submitted by applicant, the biocidal product Toxan® Płatki does not contain in its composition any toxicologically relevant substances other than the active substance bromadiolone. For this reason, the assessment of toxicological properties of the biocidal product was based only on the data for the active substance bromadiolone, for which Fregata S.A. submitted the letter of access.

According to the information placed in the *Assessment Report* for the active substance bromadiolone this substance does not have local toxic effects. For this reason the AEC value was not set and the risk characterisation has not been made with regard to local effects.

According to the information placed in the *Assessment Report* bromadiolone has systemic toxicity. This substance is a so-called second generation anticoagulant, which causes death of target organism due to massive internal haemorrhages after several days of ingestion of a lethal dose. Determined on the basis of developmental studies LOAEL value equal to 0.002 mg/kg bw/day was used to estimation of acceptable level of exposure (AEL).

LOAEL mg/kg bw	**Assessment factor (AF)**			**Reference doses**	
	Intraspecies AF	**Interspecies AF**	**Total AF**	**Absorption [%]**	**AEL [mg/kg bw/day]**

Teratogenicity (rabbit) 0.002	10	10	600*	70	1.2×10^{-6}

* This value results from the use of additional factors related to the extrapolation of doses (2) and the general factor for anticoagulants (3).

2.7.3.1 Risk for Professional Users

Formulation of biocidal product

Kind of exposure	Exposure value [mg/kg bw/day]	AEL [mg/kg bw/day]	%AEL (exposure/ AEL × 100%)	MOE* (NOEL/ exposure)
Inhalation exposure	0.0000044	1.2×10^{-6}	366.6	113.6

*Safe value ≥300

The applicant provided rather general information about the use of the active substance and contact with it at this level. Therefore EASE model was used as most appropriate in such situations. Please note that this model gives results with a rather large margin of safety. However, the obtained results indicate that the potential exposure may be higher than the acceptable level. The applicants should be required, in accordance with theirs' declarations to supply the workers, which are in contact with the active substance with the personal protective equipment. In addition, it should be noted that safety at job is subject to different legislation, defining the rules of work and provide for the inspection of work safety.

Professional user

Scenario	Exposure [mg/kg bw/day]	AEL [mg/kg bw/day]	%AEL (exposure/ AEL × 100%)	MOE* (NOEL/ exposure)
Estimations according to TNsG				
Level I	3×10^{-3}	1.2×10^{-6}	25×10^{4}	0.17
Level II	3×10^{-4}	1.2×10^{-6}	2.5×10^{4}	1.67
Estimations according to J.G. Chambers and P.J. Snowdon				
Level I	4.36×10^{-6}	1.2×10^{-6}	363.33	114.68
Level II	4.36×10^{-7}	1.2×10^{-6}	36.33	1146.79

*Safe value ≥300

The use of the data contained in the publication J.G. Chambers and P.J. Snowdon, which publication is recommended to determine the exposure to rodenticides indicates less exposure than the acceptable exposure level, in the presence of protective gloves.

In the absence of protective gloves the exposure value is higher than the acceptable exposure level.

It can be concluded that there is no real risk associated with use of the product Toxan® Płatki for professional users but only when the protective gloves are used.

In connection with above, protective gloves should be used.

2.7.3.2 Risk for non-professional users and the general public

2.7.3.2.1 Non-professional user

Scenario	Exposure [mg/kg bw/day]	AEL [mg/kg bw/day]	%AEL (exposure/ AEL x 100%)	MOE* (NOEL/ exposure)
Estimations according to TNsG				
Level I	3.84×10^{-4}	1.2×10^{-6}	3.2×10^{4}	1.30
Estimations according to J.G. Chambers and P.J. Snowdon				
Level I	4.31×10^{-7}	1.2×10^{-6}	35.92	1 160.09

*Safe value ≥300

The use of the data contained in the publication J.G. Chambers and P.J. Snowdon, which publication is recommended to determine the exposure to rodenticides do not indicate the risk due to use of the product Toxan® Płatki for non-professional users. It should be emphasized that due to the fact that the applicant does not declare the production of a biocidal product in containers larger than 1.5 kg, decanting and mixing levels were not taken into consideration in the risk assessment.

2.7.3.2.2 Incidental ingestion by child

Scenario	Exposure [mg/kg bw/day]	AEL [mg/kg bw/day]	%AEL (Exposure /AEL x 100%)	MOE* (NOEL/ exposure)
Estimations according to TNsG				
Incidental ingestion of product	0.02	2.3×10^{-6}	8.7×10^{5}	0.025

*Safe value ≥300

The risk of accidental ingestion by the infant was identified. Unfortunately there is no possibility of total elimination of risk for this scenario, for this reason it is recommended to enter as many as possible restrictions to minimize these risks.

For this purpose, it is recommended to:

- limit the size of the product for the non-professional user to reduce the likelihood of product storage;

- the use of this type of packaging that will prevent or significantly impede the opening by the children;
- reduce the attractiveness of the packaging and the product for a child;
- use of special substances, limiting intake;
- use only closed bait stations made of durable material;

2.7.3.3 Risk for consumers via residues

Not applicable.

2.8 Risk assessment for the environment

Biocidal product Toxan® Płatki is intended to be used as rodenticide for the control of commensal rodent species – rats and mice.

Product should be used in tamper resistant bait stations 200 g of product/station for rats and 100g of product/station for mice. Product has been evaluated in the following use situations: in and around buildings, in open areas and around waste dumps.

The risk assessment was carried out for the case where the target organism is a rat (assuming that this is the worst case and bait station contains 200 g of bait). The risk assessment for mouse was not performed. In calculation was assumed that during control of mice the environmental risk will not be greater than during the control of rats. Predicted environmental concentrations (PECs) has been calculated according to the guidelines in the *ESD* (Emission Scenario Document CA-Jun03-Doc.8.2-PT14), taking into consideration possible scenarios for the use of the product Toxan® Płatki.

Regional and continental PEC concentrations are not calculated, as in the case of rodenticides consumption of rodenticides is small with the result that the regional concentrations are negligible (in accordance with point 2.2 *ESD*).

The active substance is the only substance of concern in biocidal product Toxan® Płatki. Therefore PNEC values for bromadiolone were used in risk assessment.

2.8.1 Aquatic environment

In and around buildings, open areas, waste dumps

In case of the use of Toxan® Płatki in and around buildings, in open areas and waste dumps exposure of surface water to active substance – bromadiolone is negligible (detailed explanation in Doc IIB). Therefore no calculations of PECs in surface water were made. Full risk assessment for aquatic compartment is not necessary.

2.8.2 Atmosphere

In and around buildings, open areas, around waste dumps

Bromadiolone has a low vapour pressure (2.13×10^{-8} Pa). Henry's Law constant calculated based on vapour pressure is 8.99×10^{-7} Pa m^3 mol^{-1}. Therefore release to air during use of Toxan® Płatki within bait boxes is considered to be negligible. Based on the lack of exposure and rapid photo–oxidative degradation of bromadiolone, the compound is not expected to contribute to global warming, ozone depletion in the stratosphere, or acidification.

2.8.3 Soil

2.8.3.1 In and around buildings

Exposure of soil organisms to bromadiolone due to direct contamination of soil may occur following use in and around buildings. Predicted environmental concentration for soil (PEC_{soil}) is presented in table below. Detailed calculations are in Doc. II B. The results of calculations were compared to $PNEC_{soil}$ – 0.099 $mg_{bromadiolone}$/kg (*Assessment Report for bromadiolone*).

Terrestrial PEC/PNEC ratio as a result of Toxan® Płatki use in and around buildings

Emission scenario	PEC_{soil} [$mg_{bromadiolone}$/kg]	$PNEC_{soil}$ [$mg_{bromadiolone}$/kg]	PEC/PNEC
Worst case use	0.0292	0.099	0.2944
Normal use	0.0087	0.099	0.0883

The calculated PEC/PNEC values indicate that there is no concern for the terrestrial compartment as a result of use of Toxan® Płatki in this specific emission scenario.

2.8.3.2 Open areas

Exposure of soil organisms to bromadiolone – active substance of Toxan® Płatki due to direct contamination of soil may occur following use in open areas.

Predicted environmental concentration for soil (PEC_{soil}) is presented in table below. Detailed calculations are in Doc. II B. The results of calculations were compared to $PNEC_{soil}$ – 0.099 $mg_{bromadiolone}$/kg (*Assessment Report for bromadiolone*).

Terrestrial PEC/PNEC ratio as a result of Toxan® Płatki use in open areas

Emission scenario	PEC_{soil} [$mg_{bromadiolone}$/kg]	$PNEC_{soil}$ [$mg_{bromadiolone}$/kg]	PEC/PNEC
Worst case realistic scenario	0.277	0.099	2.796
Worst case realistic scenario (+ bait stations)	0.111	0.099	1.118

The calculated PEC/PNEC values indicate a small unacceptable risk for the terrestrial compartment during use of Toxan® Płatki in this specific emission scenario.

2.8.3.3 Waste dumps

Exposure of soil organisms to bromadiolone – active substance in Toxan® Płatki due to direct contamination of soil may occur following use on waste dumps. Predicted environmental concentration for soil (PEC_{soil}) is presented in table below. Detailed calculations are in Doc. II B. The results of calculations were compared to $PNEC_{soil}$ – 0.099 $mg_{bromadiolone}$/kg (*Assessment Report for bromadiolone*).

Terrestrial PEC/PNEC ratio as a result of Toxan® Płatki use on waste dumps

Emission scenario	PEC_{soil} [$mg_{bromadiolone}$/kg]	$PNEC_{soil}$ [$mg_{bromadiolone}$/kg]	PEC/PNEC
Worst case scenario	0.004	0.099	0.043

The calculated PEC/PNEC values indicate that there is no concern for the terrestrial compartment from use of Toxan® Płatki in this specific emission scenario.

2.8.4 Risk characterisation for groundwater used as drinking water

Exposure of groundwater to pollution by the active substance derived from the product Toxan® Płatki was calculated using equations No. 67 and 68 included in the *TGD* (EC, 2003). Thus calculated concentrations for normal use in and around buildings, in open areas and waste dumps are respectively 0.03 µg /L, 0.42 µg/L and 0.02 µg/L. In accordance

with Directive 98/83/EC maximum permissible concentration of pesticides (which, according to the legislation, also include rodenticides) can not exceed 0.1 µg/L. In the case of use of the product Toxan® Płatki in open areas estimated bromadiolone concentration in groundwater exceeds the permissible level. However, it should be noted that, in accordance with the guidelines of the *TGD*, it is assumed that the concentration in the water in the pores of the soil is an indicator of the concentration of active substance in groundwater. This is the unrealistic worst possible assumption, which ignores the possibility of degradation of the substance and dilution in the deeper layers of the soil.

2.8.5 Non compartment specific effects relevant to the food chain (primary and secondary poisoning)

Non-target vertebrates may be directly exposed to bromadiolone in the product Toxan® Płatki through consumption of the product (primary poisoning) or indirectly through the consumption of rodents containing residues of bromadiolone (secondary poisoning).

2.8.5.1 Primary poisoning

Tier 1

The Tier 1 assessment of primary poisoning is based on the comparison of the concentration of rodenticide in the bait and the $PNEC_{oral}$ related to the concentration in food.

Concentration of the bait is compared to the PNECoral expressed as the concentration in food

	PEC_{oral} [mg/kg food]	**PNEC [mg/kg food]**	**PEC/PNEC**
Birds	40	0.0033	12 121
Mammals	40	0.00019	210 526

Results indicate very high risk for both birds and mammals.

Tier 2

According to the *ESD* the comparison of concentration in the non-target animals and the $PNEC_{oral}$ describes the long-term risk for primary poisoning. The expected concentrations in the non-target animals are calculated after five days intake and elimination. The calculations show that mammals and birds would suffer long-term effects of bromadiolone if they would ingest Toxan® Płatki.

Tier 2 risk characterisation of primary poisoning. The expected concentrations (EC) in the non-target animals after five days exposure have been calculated with the Step 2 assumptions, i.e, PT=0.8 and AV=0.9. The PNECoral is expressed as the daily dose

Species	PEC EC_5 [mg/kg bw]	$PNEC_{oral}$ [mg/kg bw/d]	PEC/PNEC
Dog	0.9733	0.0000056	173 812
Pig	0.1217	0.0000056	21 726
Pig young	0.3893	0.0000056	69 524
Tree sparrow	5.6041	0.00038	14 748
Chaffinch	4.8667	0.00038	12 807
Wood pigeon	1.7580	0.00038	4 626
Pheasant	1.7482	0.00038	4 601

Conclusion on primary poisoning

The risk characterisation indicates a very high risk to non-target mammals and birds from direct eating of bait. Primary poisoning incidents can be minimised by preventing the access of non-target animals to the baits. It is assumed in the *ESD* that if the rodenticide baits are used according to the label instructions, the risk for primary poisoning is negligible. However, it may not be possible to exclude exposure of all non-target animals, as the baits have to be accessible to target rodents, they may as well be accessible to non-target mammals and birds of equal or smaller size than the target rodents.

2.8.5.2 Secondary poisoning

Secondary poisoning via aquatic and terrestrial food chains

In case of the use Toxan® Płatki in and around buildings, in open areas and around waste dumps exposure of surface water to active substance – bromadiolone is negligible (detailed explanation in Doc IIB). Therefore risk of poisoning via the aquatic food chain is also considered negligible.

In case of the use Toxan® Płatki in and around buildings, in open areas and around waste dumps soil is main exposed environmental compartment. Therefore secondary poisoning in terrestrial food chain

soil → earthworms → earthworms eating birds or mammals

is possible.

Secondary poisoning via earthworms

	$PEC_{oral,\ predators}$ [mg/kg earthworm]	**$PNEC_{oral}$ [mg/kg food]**	**PEC/PNEC**
Birds	0.0287	0.00038	76
Mammals	0.0287	0.0000056	5 125

Despite of the calculated risk, the Competent Authority considers the secondary poisoning via earthworms less important than secondary poisoning via the food chain

bait → rodent → rodent-eating birds or mammals.

Tier 1

The Tier 1 assessment of secondary poisoning is based on the concentration in the predator's or scavenger's food, i.e. poisoned rodents. The rodents are assumed to consume entirely the bait (PD = 1), while half of the predator's or scavenger's daily food intake is poisoned rodents (F_{rodent} = 0.5). The rodents are assumed to eat the baits in five or fourteen successive days, whereas the predator or the scavenger is assumed to eat the poisoned rodents during one day. The predator is assumed to caught the rodent after last meal on day 5 or day 14. The $PNEC_{oral}$ is based on the highest concentration causing no effects in the test with long-term exposure.

Calculations indicate that there is a risk for both birds and mammals. The risk exists for predators or scavengers eating the rats susceptible to bromadiolone (eating bait for 5 days) and resistant (eating the bait for 14 days).

Tier 1 risk characterisation of secondary poisoning

	PEC EC in rodent [mg/kg]	**$PNEC_{oral}$ [mg/kg food]**	**PEC/PNEC**
Rodent caught on day 5 after meal			
Bird	2.81	0.00038	7 398
Mammal	2.81	0.0000056	501 986
Rodent caught on day 14 after meal			
Bird	2.82	0.00038	7 413
Mammal	2.82	0.0000056	503 018

Tier 2

In the Tier 2 assessment of long-term secondary poisoning the expected concentration in predators is compared to $PNEC_{oral}$ expressed as a daily dose. The predators accumulate bromadiolone by feeding on poisoned target rodents during one day. The rodents are

assumed to eat entirely the bait (PD = 1), whereas half of the predator's or scavenger's daily food intake is poisoned rodents (F_{rodent} = 0.5). The rodents are assumed to eat the baits in five or fourteen successive days.

Tier 2 risk characterisation of secondary poisoning

Species		PEC EC in predator [mg/kg bw]		$PNEC_{oral}$ [mg/kg bw/d]	PEC/PNEC	
		Rodent caught on day 5	Rodent caught on day 14		Rodent caught on day 5	Rodent caught on day 14
Barn owl	*Tyto alba*	0.70	0.70	0.00038	1 834	1 838
Kestrel	*Falco tinnunculus*	0.80	0.80	0.00038	2 093	2 097
Little owl	*Athene noctua*	0.64	0.64	0.00038	1 686	1 690
Tawny owl	*Strix aluco*	1.06	1.06	0.00038	2 786	2 791
Fox	*Vulpes vulpes*	0.26	0.26	0.0000056	45 813	45 907
Polecat	*Mustela putorius*	0.53	0.54	0.0000056	95 370	95 566
Stoat	*Mustela erminea*	0.76	0.77	0.0000056	136 393	136 674
Weasel	*Mustela nivalis*	1.10	1.10	0.0000056	196 811	197 215

Also the Tier 2 risk characterisation shows a high risk for secondary poisoning. The $PNEC_{oral}$ expressed as a dose is approximately equal for birds and mammals, and the sensitivity of the species used in calculations is determined predominantly by the ratio of daily food consumption to body weight. Only one day exposure of predators is assumed in the *ESD*, but it is mentioned that predators could be exposed over several days. This would mean higher accumulation in predators, because daily elimination of bromadiolone from the predators is assumed to be less than the ingested amount.

2.8.5.3 Monitoring data

Monitoring data for barn owls (Newton et al, 1997) provides a basis for calculations to determine what relevance the worst case calculations, which indicate large implications on non target bird and mammal populations, may have in the environment. The data based on 1 100 birds shows that 30% of the birds collected the recent decades have residues of second generation rodenticides. It also shows that ca 1% of the collected birds had died of rodenticide poisoning. It is not known if all birds killed by rodenticides were retrieved or how the more detailed picture for each year looks.

Rodenticide residues in livers of barn owls killed by rodenticides

Owl no.	Rodenticide	Rodenticide concentration [mg/kg liver]
1	bromadiolone	0.13
2	bromadiolone	0.05
	brodifacoum	0.002
	flocoumafen	0.003
3	difenacoum	0.17
4	bromadiolone	1.07
5	brodifacoum	0.87
6	bromadiolone	1.72
	brodifacoum	0.07
7	bromadiolone	0.33
8	brodifacoum	0.42

The lowest lethal dose of bromadiolone is 0.13 mg/kg liver for barn owls, and if liver concentrations were kept below this level all of the barn owls in the study would probably have been protected with the exception for owl number two, but the liver of this owl also contained two other, more potent anticoagulants – brodifacoum and flocoumafen.

In study performed also estimation of the maximum concentration of rodenticides in a rat, which does not cause an accumulation of rodenticides in the predatory bird's liver at concentrations of greater than 0.13 mg/kg. The liver constitutes about 4% of the total body weight which then for a barn owl is 0.012 kg liver. According to the *ESD*, a campaign lasts for 21 days and the daily feed intake of the owl is 0.075 kg.

The lowest total amount of bromadiolone that will cause lethality in a barn owl, if reaching the liver, is 0.00156 mg. To determine the maximum daily bromadiolone consumption during a campaign that may be lethal for a barn owl, the lowest lethal bromadiolone amount is divided by the number of days for a normal treatment period, i.e. 0.00156 mg/21 days = 0.000074 mg/d. Thus, less than 0.074 µg bromadiolone may be consumed daily during the campaign.

The limit of concentration in rats is then calculated as the maximum daily consumption divided by the body weight of rat consumed each day, i.e. 0.074 µg/0.075 kg = 0.99 µg kg bw. Thus, 0.99 µg/kg bw is the maximum bromadiolone concentration in rats that would not cause lethality according to monitoring data. It is assumed that 0.99 µg/kg bw is PNEC and was compared with the PEC_{oral} in rodent (2.81 mg/kg).

The PEC_{oral}/PNEC ratio is very high (2 839) and confirms that there is a very high risk of secondary poisoning for predatory birds and mammals.

Conclusion on secondary poisoning

Both theoretical calculations and monitoring data clearly show that bromadiolone poses a risk for secondary poisoning. While all available information indicates risk, it does not tell the frequency of secondary poisoning incidents among wildlife.

2.8.6 PBT assessment

Bromadiolone is not readily biodegradable, has a relatively high bioconcentration factor and is very toxic to both aquatic organisms and mammals. Thus, a PBT assessment was performed.

Persistence

The *P* screening criterion is fulfilled for bromadiolone since it is *not readily biodegradable* in water, which is further supported by that it is found *not inherently biodegradable*. Bromadiolone is also stable to hydrolysis. Moreover, despite the fact that bromadiolone shows primary degradation in soil with DT_{50} < 120 days, some metabolites of bromadiolone, which probably have a similar level of toxicity as bromadiolone itself, have the half-lives exceeding 120 days. In conclusion, the *P* screening criterion for water is fulfilled.

Bioaccumulation

Due to low reliability of laboratory studies on bioconcentration in fish, the calculation method was used to assess the *B* criterion. The BCF values based on log K_{ow} measured at pH 6 and pH 7, are both below the trigger value for fulfillment of the screening *B* criterion. Despite this, some uncertainty regarding the fulfillment of the *B* criterion remains since there are monitoring studies available that show residues of bromadiolone in wildlife in which most of the incidents of contamination are believed to be due to feeding of contaminated prey. However, it is not possible to draw any conclusions in relation to the *B/vB* criteria as the exposure situation is not known. The metabolite bromadiolone ketone has a predicted log K_{ow} of 6.8 and thus fulfils the screening *B* criterion. In conclusion, there is a possibility that the screening criterion for *B* is fulfilled for bromadiolone.

Toxicity

Bromadiolone is very toxic and is classified as T+, R26/27/28, R48/23/24/25 and N R50/53. The substance should therefore be considered as fulfilling the *T* criterion. Based on structural similarities, there is reason to assume that some of the metabolites (particularly bromadiolone ketone) are as toxic as the parent substance. Regarding the *T* criterion for environment bromadiolone is potentially toxic based on results from short-term toxicity data on aquatic organisms. In conclusion, the *T* criterion is fulfilled for bromadiolone.

Conclusion: The *P* criterion and the *T* criterion are fulfilled for bromadiolone. As the uncertainties with regard to the *B* criterion can not be clarified at the moment bromadiolone should be considered as potential PBT.

2.9 Measures to protect man, animals and the environment

1. **The biocidal product must be used only in tamper resistant bait stations made of durable material.**
2. Tamper resistant bait stations should be fixed to the ground and must be clearly marked to show that they contain rodenticides and that they should not be distributed. The bait station must be placed in areas away from drains, water courses, inaccessible to children and other non target animals (birds, dogs, cats, pigs and poultry).
3. The product must never be placed indiscriminately.
4. When the product is being used in and around buildings, the tamper resistant bait station should be placed along walls and in places where there are signs of rodent activity. In public areas (such as business premises, schools, hospitals etc) the treated place must be clearly signed that rodenticide control is in operation. Marking must provide information on the risks of interfering with the product and dead rodents.
5. For product to be used in public areas the following safety precautions shall be put 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".

6. Wear suitable protective gloves (for professional user).
7. It is recommended to wear protective gloves (for non-professional user).
8. Prevent accidental exposure of the product to the environment.
9. 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).
10. 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).Do not use anticoagulant rodenticides as permanent baits.
11. Do not use anticoagulant rodenticides as permanent baits.
12. Always read the label before use and follow the instructions provided.
13. Wash hands and face after application and use of the product, and before eating, drinking or smoking
14. While handling this product and during using this product do not eat, drink or smoke
15. Keep away from food, drink and animal feeding stuffs.
16. Product should be stored in original container at room temperature in dry place inaccessible to children and pets.
17. Reduce the attractiveness of the packaging and the product for children.
18. Use of type of packaging that will prevent or significantly impede the opening by the children.
19. Limit to 1.5 kg the size of the packaging of the product for the non-professional user in order to reduce the likelihood of storage the open product.
20. Do not reuse packaging of product.
21. The label should include information that the product contains a substance limiting the risk of consumption of the product.

3 Proposal for decision

1. Product Formulation - active substance content	**% w/w**	**Manufacturer of active substance**
concentrate of bromadiolone (pure bromadiolone content)	0.160% (0.004%)	PelGar International Ltd Unit 13 Newman Lane Alton Hampshire GU34 2QR, United Kingdom

2. Formulation type	flakes
3. Product type	PT14
4. User	Non-professional and professional
5. Packaging	Please referee to PAR section 2.2.3
6. Application	Indoors (e.g. live-stock buildings) Outdoors (e.g. parks, tennis courts, camping sites and other places of the public utility, waste dumps)
7. Application Method	Bait has been placed into tamper resistance bait station
8. Application Rate	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)
9. Organism controlled	*Rattus norvegicus* (brown rat) *Mus musculus* (house mouse) *Apodemus agrarius* (field mouse)
10. Shelf life	Up to 2 years
11. Expiry data of the authorisation	30 June 2016
12. Any other specific conditions:	Please referee to PAR section 2.9 additionaly: – Methylparaben as non-notified in PT 6 active substance should be exchanged on preservative included into Annex I according to Directive 98/8/EC after 30 June 2016 – In the case 100g, 200 g and 400 g package types the big visible warning "Keep Out of Reach of Children" should be placed in the front of label.

Annex 1: Summary of product characteristics

(a) Product trade name:

(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[1]**	**w/w (%)**	**Minimum purity (% w/w)**	**Same source as for Annex I inclusion**
								☐ yes ☐ no
Add rows as necessary								

Co-formulants					Contents				
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Concentration**	**Unit**	**w/w (%)**	**Classification**	**Substance of concern**
									☐ yes ☐ no
Add rows as necessary									

Sum	**0.0**		**0.0**

1 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.

(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))[2]

Name of the active substance:

Manufacturer

Company Name:

Address:

City: Postal Code: Country:

Telephone: Fax: E-Mail:

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

Manufacturing site(s) (if different)

Company Name:

Address:

City: Postal Code: Country:

Telephone: Fax: E-Mail:

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

(d) Formulator(s) of the biocidal product (name(s) and address(es) including location of plant(s))**Błąd! Nie zdefiniowano zakładki.**

Formulator

Company Name:

Address:

City: Postal Code: Country:

Telephone: Fax: E-Mail:

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

Formulation site(s) (if different)

Company Name:

Address:

City: Postal Code: Country:

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

Telephone: Fax: E-Mail:

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

Physical state and nature of the biocidal product:

(e) Type of formulation: (Select from pre-defined list)

(f) Ready-to-use product: ☐ no ☐ yes

Classification and labelling statements of the biocidal product:

(g) Product classification: (Select from pre-defined list)

(h) Risk and Safety Phrases: (Select from pre-defined list)

(i) Product classification according to GHS: (Select from pre-defined list)

(j) Hazard statement according to GHS: (Select from pre-defined list)

Intended uses and efficacy:

(k) PT: (Select from pre-defined list)

(l) Target harmful organisms: (Select from pre-defined list)

(m) Development stage of target organisms: (Select from pre-defined list)

(n) Function/mode of action: (Select from pre-defined list)

(o) Field of use: (Select from pre-defined list)

(p) Application aim: (Select from pre-defined list)

(q) User category (Select from pre-defined list)

(r) Application method[3]: (Select from pre-defined list)

(Repeat box as necessary)

Directions for use[4]:

(s) Manner and area of use[5]:

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.

(t) Conditions of use[6]:

(u) Instructions for safe use of the product:[7]

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

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

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

(y) Additional information:

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).

Annex 2: List of studies reviewed

List of <u>new data</u> submitted in support of the evaluation of the biocidal product

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
III-B	3.1.1 3.1.2 3.1.3 3.5 3.6 3.8	Al Amin Idris	2011	Toxan Płatki Badania właściwości fizykochemicznych przed i po przyśpieszonym starzeniu Instytut Przemysłu Organicznego (Warszawa) Kod badania: BF-21/11	FREGATA SA	☐	☒	☒	☐
III-B	3.7	Wróblewski Dominik	2010	Badanie stabilności preparatu Toxan Płatki – przyspieszone starzenie TCI Laboratories (Gdynia) Nr dok. RB/FGA/03/01	FREGATA SA	☐	☒	☒	☐
III-B	3.2	Buczkowski Daniel, Sałaciński Tomasz, Witkowski Waldemar	2008	Toxan Płatki Oznaczanie właściwości wybuchowych Instytut Przemysłu Organicznego (Warszawa) Nr sprawozdania: 31/W/51/2008	FREGATA SA	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
III-B	3.3 3.4	Chmielewska Agata, Frączak Michał	2008	Toxan Płatki Oznaczanie właściwości utleniających, względnej temperatury samozapalenia oraz palności Instytut Przemysłu Organicznego (Warszawa) Kod badania: BC/22/08	FREGATA SA	☐	☒	☒	☐
III-B	4.1	Gwóźdź Ewa Jolanta	2009	Opracowanie i walidacja metody oznaczania substancji aktywnej w preparacie Toxan Płatki Instytut Przemysłu Organicznego (Warszawa) Kod badania: BA – 11/08	FREGATA SA	☐	☒	☒	☐
III-B	5.10.2 (1)	Ignatowicz Stanisław	2010	Badanie skuteczności preparatu Toxan Płatki przeznaczonego do zwalczania gryzoni zgodnie z „Metodyką badań skuteczności preparatu przeznaczonego do zwalczania gryzoni", FRE/RT-03/2007 Szkoła Główna Gospodarstwa Wiejskiego (Warszawa) Kod badania: brak	FREGATA SA	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
III-B	5.10.2 (2)	Gruszka Katarzyna	2011	Toxan Płatki Badanie skuteczności i akceptacji rodentycydów na szczurach laboratoryjnych Instytut Przemyslu Organicznego Oddział w Pszczynie Kod badania: SK-9/11	FREGATA SA	☐	☒	☒	☐
III-B	5.10.2 (3)	Gruszka Katarzyna	2011	Toxan Płatki Badanie skuteczności i akceptacji rodentycydów na myszach laboratoryjnych Instytut Przemyslu Organicznego Oddział w Pszczynie Kod badania: SK-10/11	FREGATA SA	☐	☒	☒	☐
IIIB	6.6/1 6.6/2	FREGATA SA	2012	Toxan Płatki Oszacowanie ekspozycji oraz ryzyka	FREGATA SA	☐	☒	☒	☐

Annex 3: Analytical methods residues – active substance

< Bromadiolone >

Date: May 2013

No new data for the active substance residues was submitted. For datailed information please see the CAR for active substance bromadiolone.

Annex 4: Toxicology and metabolism –active substance

< Bromadiolone >

Date: May 2013

No new data for the active substance was submitted. For datailed information please see the CAR for active substance bromadiolone.

Annex 5: Toxicology – biocidal product

< Toxan® Płatki >

Date: May 2013

General information

Formulation Type:	flakes
Active substance(s) (incl. content)	0.004% bromadiolone
Category	PT 14- rodenticides

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)	
Rat LD_{50} oral (OECD 420)	14.0 – 21.0 g/kg bw (female rat)
Rat LD_{50} dermal (OECD 402)	42.75 g/kg bw (male and female rats)
Rat LC_{50} inhalation (OECD 403)	10.75 mg/l (male and female)
Skin irritation (OECD 404)	Not irritating
Eye irritation (OECD 405)	Not irritating
Skin sensitisation (OECD 429; LLNA)	Not a skin sensitizer

Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)	
Short-term toxicity studies	Not required
Toxicological data on active substance(s) (not tested with the preparation)	For datailed information please see the CAR for active substance bromadiolone.
Toxicological data on non-active substance(s) (not tested with the preparation)	The biocidal produkt does not contain any toxicologically relevant substances other then the active substance bromadiolone
Further toxicological information	Not required

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
EC 1272/2008	Product classification: NONE

Annex 6: Safety for professional operators

<Toxan® Płatki>

Date: May 2013

See point 2.7.3.1 above

Annex 7: Safety for non-professional operators and the general public

< Toxan® Płatki >

Date: May 2013

See tables 2.7.3.2.1 and 2.7.3.2.2 above

Annex 8: Residue behaviour

<Bromadiolone>

Date: May 2013

No new data for the active substance was submitted. For datailed information please see the CAR for active substance bromadiolone.

Annex 9: Proposed Label

Podmiot odpowiedzialny: „FREGATA" S.A.
80-309 Gdańsk - Oliwa
ul. Grunwaldzka 497
tel.: (58) 552 00 27 do 29, faks: (58) 552 48 31
www.fregata.gda.pl

Toxan® Płatki

Gotowa do wyłożenia przynęta
w postaci płatków, do użytku powszechnego i profesjonalnego,
przeznaczona do zwalczania myszy i szczurów. Do stosowania wewnątrz i wokół budynków (w obiektach inwentarskich, w parkach, kortach tenisowych, kempingach i innych miejscach użyteczności publicznej) oraz na wysypiskach śmieci.

Pozwolenie Prezesa Urzędu nr:

Substancja czynna:

- bromadiolon 0,004% (0,04 g/kg) - substancja czynna z grupy antykoagulantów jednodawkowych II generacji.

Zawiera:

- benzoesan denatonium - gorzka substancja zniechęcająca do spożycia przez ludzi.

Sposób użycia:

Toxan® Płatki należy wykładać w miejscach występowania gryzoni, do zaplombowanych, bezpiecznych i odpornych na manipulację karmników deratyzacyjnych, w porcjach po 200 g – przy zwalczaniu szczurów (w odstępach co 10-15 m) i po 100 g – przy zwalczaniu myszy (w odstępach co 1,5-2 m). Karmniki deratyzacyjne powinny być przytwierdzone do podłoża, odpowiednio oznaczone i zawierać informację, że zawierają środek gryzoniobójczy, który nie może być roznoszony. W przypadku stosowania produktu w miejscach ogólnie dostępnych, miejsca te powinny być w trakcie zabiegu odpowiednio oznaczone. W pobliżu wyłożonej przynęty, w miejscu dostępnym, powinna znaleźć się informacja o ryzyku pierwotnego i wtórnego zatrucia oraz działaniach, które należy podjąć w przypadku zatrucia.

Spożyty preparat systematycznie uzupełniać do momentu całkowitego wytępienia gryzoni (okres 6-10 dni).

Gryzonie zaczynają padać po 5-6 dniach.

Pomieszczenie zaraz po zabiegu może być użytkowane z zachowaniem wymienionych środków ostrożności.

Zabieg powtórzyć w razie ponownego pojawienia się gryzoni.

Nigdy nie rozmieszczać produktu w sposób przypadkowy.

W przypadku wykładania produktu wewnątrz i wokół budynków, karmniki deratyzacyjne powinny być rozmieszczone wzdłuż ścian budynków oraz w miejscach istnienia oznak aktywności gryzoni.

Środki ostrożności:

Preparat może być szkodliwy dla ludzi i organizmów niebędących przedmiotem zwalczania w przypadku spożycia dużych ilości. Preparat zabezpieczyć przed kontaktem z dziećmi, ptakami i organizmami niepodlegającymi zwalczaniu (psy, koty, świnie, drób, itp.). Przed i po wyłożeniu preparatu umyć ręce wodą z mydłem. Unikać kontaktu z ustami (bardzo gorzki smak). Nie jeść, nie pić i nie palić podczas używania produktu.

P102 Chronić przed dziećmi.

P280 Stosować rękawice ochronne.

Uwaga:

Postępowanie z odpadami produktu, odpadami opakowaniowymi i padłymi gryzoniami:

Padłe gryzonie, zawilgoconą i zanieczyszczoną przynętę oraz przynętę znalezioną poza karmnikiem deratyzacyjnym należy systematycznie usuwać w sposób bezpieczny i zgodny z aktualnymi przepisami (np. utylizować w autoryzowanych firmach). Pozostałości produktu i jego opakowanie po zakończonym zabiegu usuwać w sposób bezpieczny (np. jako odpady komunalne lub unieszkodliwiać przez spalanie w autoryzowanych firmach, itd.), ale zawsze zgodny z aktualnymi przepisami. Nie wykorzystywać powtórnie zużytych opakowań. Produkt przechowywać w oryginalnym opakowaniu, w temperaturze pokojowej, w miejscu suchym, poza zasięgiem dzieci i zwierząt. Preparat chronić przed bezpośrednim nasłonecznieniem i wilgocią. Nie przechowywać razem z żywnością, napojami i paszami dla zwierząt. Preparatu nie przechowywać razem z substancjami chemicznymi, które mogłyby zmienić atrakcyjny dla

gryzoni zapach środka. Nie dopuścić do przypadkowego przedostania się produktu do środowiska.

Tam gdzie wykazano lub tam gdzie podejrzewa się oporność na bromadiolon należy zastosować strategię przeciwdziałania zjawisku oporności i należy zastosować produkty zawierające alternatywną substancję czynną. Nie należy stosować rodentycydów zawierających antykoagulanty w zapobiegawczej ochronie przed gryzoniami.

Pierwsza pomoc:
W razie połknięcia lub wystąpienia niepokojących objawów (np. osłabienie lub krwawienia) zasięgnąć porady lekarza. **Antidotum: Witamina K_1** podawana pod nadzorem lekarza.
W razie zanieczyszczenia skóry, miejsce zabrudzenia dokładnie umyć wodą z mydłem.
W razie zanieczyszczenia oczu przemyć je dużą ilością wody.
W razie narażenia inhalacyjnego, w przypadku wystąpienia niepokojących objawów – zasięgnąć porady lekarza.

- W nagłych wypadkach kontaktować się z ośrodkami toksykologicznymi w Polsce:
  Gdańsk – (58) 682 04 04, Kraków – (12) 411 99 99,
  Poznań – (61) 847 69 46, Warszawa – (22) 619 66 54.

Zawartość netto: …
Data ważności i nr serii na opakowaniu.