Product Assessment Report

Toxan® Płyn

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Authorisation no: PL/2014/0114

Granting date of authorisation: 28.02.2014

Biocidal product assessment report related to product authorisation under Biocidal Products Regulation No 528/2012

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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
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1.2 Information about the product application

Application received:	28.06.2011
Application reported complete:	04.01.2012
Type of application:	national authorisation
Further information:	No

1.3 Information about the biocidal product

1.3.1 General information

Trade name:	Toxan® Płyn
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 0.005 %
Formulation type:	Liquid
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):	▪ In and around buildings (e.g. live-stock buildings); ▪ Open areas (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:	Professional Non-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*: 100 ml of liquid bait per bait station spaced at 10 – 15 m. *Mice*: 100 ml of liquid bait per bait station spaced at 3 – 4 m.
Potential for release into the environment (yes/no):	Yes
Potential for contamination of food/ feedingstuff (yes/no)	No
Proposed Label:	
Use Restrictions:	Please refere to section 2.9

1.3.3 Information on active substance

Active substance chemical name:	Bromadiolone 3-[3-(4'-bromo[1,1'-bifenyl]-4-ylo)-3-hydroksy-1-fenylopropylo]-4-hydroksy-2H-1-benzopiran-2-on
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 Limited
Address:	Unit 13 Newman Lane Alton
City:	Hampshire
Postal Code:	GU34 2QR
Country:	UK
Telephone:	+ 44 (0)1420 80744
Fax:	+ 44 (0)1420 80733
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 Limited 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® Płyn contains the active substance bromadiolone (0.005%) (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® Płyn are outlined below for non-professional and professional users.

Packing type	Pack sizes for non-professional use	Pack sizes for professional use
LDPE bottle with a safety plug, closed with safe cap securing from unwanted opening. On front of the bottle clearly warning „*Keep out of the reach of children*"	100 ml	100 ml
HDPE bottle with a safety plug, closed with safe cap securing from unwanted opening. On front of the bottle clearly warning „*Keep out of the reach of children*"	200 ml	200 ml
HDPE bottle with a safety plug, closed with safe cap securing from undesirable opening	-	1 l

2.3 Physical-chemical properties and analytical methods

Product Toxan® Płyn is ready-to-use product in a form of liquid containing active substance – bromadiolone which is supplied to the producer, „FREGATA" S.A., by PelGar International Limited company (one of the active substance notifiers) in a form of a concentrate for which full, detailed composition is submitted to the Polish Competent Authority by data owner.

Toxan® Płyn is dark purple-coloured product with no oxidizing nor explosive properties. It is also not fulfilling a criterion for highly flammable. The self ignition occurred at 560°C. Density of the product is equal to 1.005 g/cm^3. The product pH is slight alkaline and it is equal to 8.89 before and 9.02 after storage stability test. Water suspension of the product gives light-acetic pH (1%, pH = 6.25 to 5.56 – after storage stability test).

Active substance content increased from 0.048 g/kg to 0.051 g/kg after storage stability test. The change of 6.25% is acceptable taking into consideration formulation type. Low temperature stability test was also conducted and the product is considered to be stable.

Taking into consideration results from the accelerated storage stability test, 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 from PelGar International Limited., 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 Płyn batch no (lot No.) 24022011 Specification.: SP-TOXAN PŁYN-01/11 with additional statement	liquid	EMC 372600019 study code: BF-07/11
Colour	Farmakopea Polska, wyd. VI (2002) and according to EPA Product Properties Test Guideline OPPTS 830.6303	Toxan Płyn batch no (lot No.) 24022011 Specification.: SP-TOXAN PŁYN-01/11 with additional statement	dark purple-coloured	EMC 372600019 study code: BF-07/11
Odour	Farmakopea Polska, wyd. VI (2002) and according to EPA Product Properties Test Guidelines OPPTS 830.6304	Toxan Płyn batch no (lot No.) 24022011 Specification.: SP-TOXAN PŁYN-01/11 with additional statement	characteristic	EMC 372600019 study code: BF-07/11
Explosive properties	A.14, procedures W03-WNU W04-WNT W17-OŁS	Toxan Płyn batch no (lot No.) 24022011 Specification.: SP-TOXAN PŁYN-01/11 with additional statement	Toxan® Płyn does not possess explosive properties	EMC 372600010 study code: BW-02/11
Oxidizing properties	A.21, procedure	Toxan Płyn batch no (lot No.) 24022011	Toxan® Płyn does not possess oxidizing properties	EMC 372600012

	Method	Purity/ Specification	Results	Reference
	SPR/BC-FC/05/b	Specification: SP-TOXAN PŁYN-01/11 with additional statement		study code: BC-04/11
Flash point	A.9 procedure SPR/BC/ 09/b	Toxan Płyn batch no (lot No.) 24022011 Specification.: SP-TOXAN PŁYN-01/11 with additional statement	Toxan Płyn is not highly flammable	EMC 372600012 study code: BC-04/11
Autoflammability	A.15 procedure SPR/BC/06/b	Toxan Płyn batch no (lot No.) 24022011 Specification.: SP-TOXAN PŁYN-01/11 with additional statement	the self-ignition of Toxan® Płyn occured at 590°C)	EMC 372600012 study code: BC-04/11
Other indications of flammability	n.a.	n.a.	n.a.	n.a.
Acidity / Alkalinity	CIPAC MT 31.2.3	Toxan Płyn batch no (lot No.) 24022011 Specification.: SP-TOXAN PŁYN-01/11 with additional statement	alkalinity of product Toxan Płyn is 0% before and after storage stability test.	EMC 372600019 study code: BF-07/11
pH	CIPAC MT 75.3	Toxan Płyn batch no (lot No.) 24022011 Specification.: SP-TOXAN PŁYN-01/11 with additional statement	pH of product Toxan Płyn is 8.89 before and 9.02 after accelerated storage stability test. pH of 1% water suspension is 6.25 before and 5.56 after storage stability test.	EMC 372600019 study code: BF-07/11
Density / relative density	CIPAC MT 3	Toxan Płyn batch no (lot No.) 24022011 Specification: SP-TOXAN PŁYN-01/11 with additional statement	density before and after storage stability test is 1.005 g/ml	EMC 372600019 study code: BF-07/11
Storage stability – stability and shelf life	CIPAC MT 46 (2 weeks 54 °C) CIPAC MT 39.3 (7 days 0 °C)	Toxan Płyn batch no (lot No.) 24022011 Specification.: SP-TOXAN PŁYN-01/11 with additional statement	Toxan® Płyn is stable for two weeks in 54 °C Toxan® Płyn is stable for 7 days in 0 °C	EMC 372600019 study code: BF-07/11
Effects of temperature	CIPAC MT 46 CIPAC MT 39.3 (7 days 0 °C)	Toxan Płyn batch no (lot No.) 24022011 Specification.: SP-TOXAN PŁYN-01/11 with additional statement	Toxan Ziarno is stable for two weeks in 54 °C Toxan® Płyn is stable for 7 days in 0 °C	EMC 372600019 study code: BF-07/11

	Method	Purity/ Specification	Results	Reference
Reactivity towards container material	CIPAC MT 46	Toxan Płyn batch no (lot No.) 24022011 Specification.: SP-TOXAN PŁYN-01/11 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 372600019 study code: BF-07/11
Technical characteristics in dependence of the formulation type	n.a	n.a.	n.a	n.a
Compability with other products	n.a.	n.a.	Toxan Płyn will not be used with other products (especially biocidal products)	n.a.
Surface tension	EEC A.5:1.6.4	Toxan Płyn batch no (lot No.) 24022011 Specification.: SP-TOXAN PŁYN-01/11 with additional statement	surface tension in 25°C is 56.7 mN/m	EMC 372600019 study code: BF-07/11
Viscosity	PN-EN ISO 3104, PN-EN ISO 3105.	Toxan Płyn batch no (lot No.) 24022011 Specification: SP-TOXAN PŁYN-01/11 with additional statement	kinematic viscosity in 20°C is1,3646 mm^2/s and dynamic viscosity in 20°C is 1,3714 mPa• s	EMC 372600019 study code: BF-07/11
Particle size distribution	n.a.	n.a.	n.a.	n.a.

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® Płyn 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. The self

ignition occurred at 560°C. A part of physical-chemical properties characteristics of the product is done before and after accelerated storage stability test. The product Toxan® Płyn is found as slightly surface active with surface tension in 25°C equal to 56.7 mN/m.

2.5 Effectiveness against target organisms

Function

The biocidal product Toxan® Płyn 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 according to Applicant will be used by non-professional and professional users.

Organisms to be controlled

Toxan® Płyn 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
Brown rat *(Rattus norvegicus)*	Field test done according to method KES-01/2009	The size of rodents population was evaluated by measure of control bait intake at the beginning and the end of the study. 100 ml Toxan® Płyn was 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 80.6 – 82.7% 2) intake of tested bait was reduced 81.8 – 82.4% 3) percentage of active holes was reduced to 23.8 – 25%	III-B 5.10.2(1)
Brown rat *(Rattus*	Palatability test done	Control group(10 males and 10 females)	Total mortality of rats has reached	III-B 5.10.2(2)

norvegicus)	according to method EPPO 1982 "Laboratory tests for evaluation of the toxicity and acceptability of rodenticides and rodenticide preparations"	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)	100% and edibility was at the level 38.8%. Palatability ratio for males was 1.1 and for females 0.5. The average mortality for males has occurred at 7.4 day (5 – 11 days) with average consumption of bait 15.2 mg/kg b.w. For females average mortality has occurred at 10.1 day (7 – 15) with average consumption of bait 11.5 mg/kg b.w.	
House mouse *(Mus musculus)*	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 mice has reached 100% and edibility was at the level 39.6%. Palatability ratio for males was 0.7 and for females 0.7. The average mortality for males has occurred at 10.4 day (6 – 16 days) with average consumption of bait 50.9 mg/kg b.w. For females average mortality has occurred at 11.3 day (6 – 18) with average consumption of bait 49.6 mg/kg b.w.	III-B 5.10.2(3)
House mouse	Field test done according to	The size of rodents population was	The study indicates that:	III-B 5.10.2(4)

(Mus musculus) Field mouse *(Apodemus agrarius)*	method KES-01/2009	evaluated by measure of control bait intake at the beginning and the end of the study. 100 ml Toxan® Płyn was placed into each bait station located every 3 – 4 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	1) intake of control bait was reduced 80.5% 2) intake of tested bait was reduced 82.9% 3) percentage of active holes was reduced to 16.7%	

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 stations.

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® Płyn is liquid bait for the effective control of rodent species, both indoors and outdoors. Toxan® Płyn takes the form of a ready to use liquid bait containing 0.005 % w/w (50 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.

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® Płyn. New exposure studies have not been submitted and the risk assessment was performed based on the information presented in CAR[1].

2.7 Risk assessment for human health

The biocidal product Toxan® Płyn is in the form of ready to use liquid bait placed in drinking dispenser (see Annex 9) that must be put in tamper resistant bait stations. It contains 0.005% of the active substance bromadiolone. It belongs to PT 14 product group. Toxan® Płyn is designed for use by professional and non-professional users.

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

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

[1] *Competent Authority Report* available at *https://circabc.europa.eu*

2.7.1.2 Toxicology of the substance(s) of concern

The biocidal product Toxan® Płyn does not contain in its composition the toxicologically relevant substances (classified as dangerous according to Directive 77/548/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® Płyn 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[2] were granted to „FREGATA" S.A. by PelGar International Limited as bromadiolone manufacturer (based on data from letter of access dated on 28.02.2011) for the registration of a biocidal product Toxan® Płyn.

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

Dermal absorption studies for biocidal product were not performed. The absorption for biocidal product will be comparable to dermal absorption of the active substance. Two values of dermal absorption were taken into account for the calculation of dermal exposure for professional and non-professional users: 10% and 75%.

Oral LD_{50} (rat)

11.2 – 16.8 g/kg b.w. (female)

Dermal LD_{50} (rabbit)

34.2 g/kg b.w. (male and female)

Inhalation LC_{50} (rat):

8.6 mg/l (male and female)

[2] *Assessment Report* is part of *Competent Authority Report* with is available at *https://circabc.europa.eu*

Inhalation acute studies for biocidal product were not performed. Due to that bromadiolone has a low vapour pressure (2.13×10^{-6} Pa at room temperature) and the product is not dust releasing and exposure via inhalation is expected to be negligible.

Irritation to skin

Not irritation to skin

Irritation to eye

Not irritation to eye

Sensitization to skin

Not a skin sensitizer

2.7.2 Exposure

Exposure calculations performed by the applicant have been done basing 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) placed in document „*HEEG opinion on Harmonising the number of manipulations in the assessment of rodenticides (anticoagulants)*" (as one of the approach). However, it can be applicable only in the case of solid formulations. Therefore, the conclusion includes only the calculations of exposure which 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" (TNsG June 2007)* implementing the objectives of the Directive 98/8/EC concerning the placing of biocidal products on the market. For detailes, please see Document IIB.

Main paths of human exposure

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

2.7.2.1 Exposure of professional users

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

- Toxan® Płyn is supplied to the customer in tightly-closed bottle.

- The inhalation exposure was not estimated. Toxan® Płyn is not applied in a way that generate inhalable droplets 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® Płyn 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, using appropriate 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)
- Due to the lack of dermal absorption studies on the product, the calculations of dermal exposure were carried out using the default values of dermal absorption 10% (based on the phisico-chemical properties of the active substances with logPow <-1 or >4, and MW >500 g/mol) and 75% (taking into consideration that the active substance is in the concentration ≤5%). Both values are consistent with the approach of the European Community countries. However, it is assumed that the value of 10% is sufficient for a final risk assessment of the product.

2.7.2.1.1 Calculation of exposure performed according to TNsG

According to *TNsG*, for professional users the application phase and disposal phase of the product should be considered. The calculations were performed according to formulas presented in the *TNsG* June 2007. Detailed calculations are presented in Document IIB.

For the calculations the following element were used:

Application phase:

- frequency of events per day: 4 bait stations per day (*TNsG* June 2007)
- the amount of the product per event: 100 ml per event (*Document IIIB5*);

100 ml × 1.005 g/cm^3 (*Document IIIB3)* = 100.5 g

Disposal/utilization phase:

- frequency of events per day: 4 bait stations per day (*TNsG* June 2007)
- the amount of the removed product per event: 30% of the amount of the product per event i.e. 30 ml, 30.15 g (*TNsG* June 2007)

Two values of dermal absorption were taken into account for the calculation of exposure, that is 10% and 75%.

The operator body weight used in the calculation: 60 kg (*TNsG* June 2007)

Product density: 1.005 g/cm^3 (Document IIIB3)

	Dermal absorption value = 10%		**Dermal absorption value = 75%**	
	Level 1 [mg/kg b.w./day]	**Level 2 [mg/kg b.w./day]**	**Level 1 [mg/kg b.w./day]**	**Level 2 [mg/kg b.w./day]**
Application phase	0.0469	0.00469	0.35175	0.035175
Removal of the preparation phase	0.014	0,0014	0.106	0.0106
Total exposure	0.0609	0,00609	0.458	0.0458

The second level includes gloves and 10% uptake.

2.7.2.1.2 Alternative calculations of exposure performed on the basis of approach submitted by the external expert being on the list of experts cooperating with The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

The approach was modified for the adjustment to the real use of the product, based on the materials submitted by the Applicant. Two values was used as the default value of the product amount remaining in the hands: 0.02 ml (version I) and 0.05 ml (version II) per operation. Please see Doc. IIB and IIC for details.

Version I

Application phase:

Hands contaminations per operation	0.02 ml
Frequency of events per day	8 bait stations per day (*information given by the Applicant*)
Hands contaminations per day	0.02 × 8 bait stations per day = 0.16 ml
Amount of product in contact with skin	100%
Dermal exposure to product	0.16 ml
Concentration of bromadiolone in product	0.05 mg/ml
Dermal exposure to bromadiolone	0.16 ml × 0.05 mg/ml = 0.008 mg/day
Dermal absorption	10%
Absorbed dose	0.008 mg/day × 10% = 0.0008 mg/day
Body weight	60 kg
Exposure	0.0008 mg/day / 60 kg = **0.000013 mg/kg b.w./day**

Disposal:

Hands contaminations per operation	0.02 ml
Frequency of events per day	4 bait stations per day (*information given by the Applicant*)
Hands contaminations per day	0.02 ml × 4 bait stations per day = 0.08 ml
Amount of product in contact with skin	100%
Dermal exposure to product	0.08 ml
Concentration of bromadiolone in product	0.05 mg/ml
Dermal exposure to bromadiolone	0.05 mg/ml × 0.08 ml = 0.004 mg/dzień
Dermal absorption	10%
Absorbed dose	0.004 mg/day × 10% = 0.0004 mg/day
Body weight	60 kg
Exposure	0.0004 mg/day /60 kg = **0.0000067 mg/kg b.w. /day**

Level I (without PPE)

∑ exposure = 0.0000197 mg bromadiolone/kg b.w./day

Level II (taking into account 90% hands protection result from using PPE)

∑ exposure = 0.00000197 mg bromadiolone/kg b.w./day

Version II

Application phase:

Hands contaminations per operation	0.05 ml
Frequency of events per day	8 bait stations per day (*information given by the Applicant*)
Hands contaminations per day	0.05× 8 bait stations per day = 0.4 ml
Amount of product in contact with skin	100%
Dermal exposure to product	0.4 ml
Concentration of bromadiolone in product	0.05 mg/ml
Dermal exposure to bromadiolone	0.4 ml × 0.05 mg/ml = 0.02 mg/day
Dermal absorption	10%
Absorbed dose	0.02 mg/day × 10% = 0.002 mg/day
Body weight	60 kg
Exposure	0.002 mg/day / 60 kg = **0,000033 mg/kg b.w./day**

Disposal:

Hands contaminations per operation	0.05 ml
Frequency of events per day	4 bait stations per day (*information given by the Applicant*)
Hands contaminations per day	0.05 ml × 4 bait stations per day = 0.2 ml
Amount of product in contact with skin	100%
Dermal exposure to product	0.2 ml
Concentration of bromadiolone in product	0.05 mg/ml
Dermal exposure to bromadiolone	0.05 mg/ml x 0.2 ml = 0.01 mg/dzień
Dermal absorption	10%
Absorbed dose	0.01 mg/day x 10% = 0.001 mg/day
Body weight	60 kg
Exposure	0.001 mg/day / 60 kg = **0.000017 mg/kg b.w. /day**

Level I (without PPE)

∑ exposure = 0.00005 mg bromadiolone/kg b.w./day

Level II (taking into account 90% hands protection result from using PPE)

∑ exposure = 0.000005 mg bromadiolone/kg b.w./day

2.7.2.1.3 Calculations of exposure performed on the basis of proposals received from the HEEG members (Human Exposure Expert Group)

Application phase:

- Frequency of events per day: 8 bait stations per day (*information given by the Applicant*)
- The amount of the product per event:
  100 ml per event (*information given by the Applicant*);
  100 ml × 1.005 g/cm^3 (*density of the product, information given by the Applicant*) = 100.5 g

Disposal/utilization phase:

- Frequency of events per day: 4 bait stations per day (*TNsG* June 2007)
- The amount of the removed product per event: 30% of the amount of the product per event i.e. 30 ml, 30.15 g (*TNsG* June 2007)

The total amount to which the skin is exposed is estimated by two equations, taking into account two cases – the layer approach and the volume of spilled product approach:

The layer approach

$$A_{der} = Q_{prod} / V_{prod} \times Fc_{prod} \times TH_{der} \times AREA_{der} \quad [mg]$$

The volume of spilled product approach

$$A_{der} = Q_{prod} / V_{prod} \times Fc_{prod} \times V_{der} \quad [mg]$$

The exposure value of active substance calculated / kg body weight/day is estimated by equation:

$$[(A_{der} \times \text{Frequency of events per day}) / BW] / (\%\text{dermal absorption}/100)$$

A_{der} Amount of active substance on skin [mg, mg/event]

Q_{prod} Amount of undiluted product used [mg]

Fc_{prod} Weight fraction of active substance in the product

V_{prod} Volume of undiluted product [cm^3]

V_{der} Volume of spilled product – Default: 6 cm^3

TH_{der} Thickness of layer of product in contact with skin [cm]- Default: 0.01 cm

$AREA_{der}$ Surface area of exposed skin [cm^2] – 840 cm^2 with the exposure from splashes to be about of 6 ml/event to the hands

BW The operator body weight used in the calculation: 60 kg (*TNsG* June 2007)

The layer approach

- application phase

  Ader = 100500 / 100 × 0.00005 × 0.01 × 840 = 0.422 [mg]

  [(0.422 × 8) / 60] × (10/100) = **0.0056 [mg/kg b.w./day]**

- disposal

  Ader = 30150 / 30 × 0.00005 × 0.01 × 840 = 0.422 [mg]

  [(0.422 × 4) / 60] × (10/100) = **0.0028 [mg/kg b.w./day]**

Level I (whithout PPE)

∑ exposure = **0.0084 mg/kg b.w./day**

Level II (taking into account 90% hands protection result from using PPE)

∑ exposure = **0.00084 mg/kg b.w./day**

The volume of spilled product approach

- application phase

  Ader = 100500 / 100 × 0.00005 × 6 = 0.3 [mg]

  [(0.3 × 8) / 60] × (10/100) = **0.004 [mg/kg b.w./day]**

- disposal

  Ader = 30150 / 30 × 0.00005 × 6 = 0.3 [mg]

  [(0.3 × 4) / 60] × (10/100) = **0.002 [mg/kg b.w./day]**

Level I (whithout PPE)

∑ exposure = **0.006 mg/kg b.w./day**

Level II (taking into account 90% hands protection result from using PPE)

∑ exposure = **0.0006 mg/kg b.w./day**

2.7.2.2 Exposure of non-professional users and the general public

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 and disposal phase of the product should be considered.

Application phase:

- frequency of events per day: 2 bait stations per day (*information given by the Applicant*)
- the amount of the product per event:

  100 ml per event (*Document IIIB5*);

  100 ml × 1.005 g/cm^3 (*Document IIIB3*) = 100.5 g

Disposal/utilization phase:

- frequency of events per day: 1 bait station per day (*TNsG* June 2007)
- the amount of the removed product per event: 30% of the amount of the product per event i.e. 30 ml, 30.15g (*TNsG* June 2007)

	Dermal absorption value = 10%	**Dermal absorption value = 75%**
	Exposure value [mg/kg b.w./day]	**Exposure value [mg/kg b.w./day]**
Application phase	0.0235	0.176
Removal of the preparation phase	0.0035	0.0264
Total exposure	0.027	0.2024

While use of the biocidal product, bystanders including for example children and infants may come into contact with a biocidal product. There is likely to drink the poison by the child e.g. directly from the container in which the biocidal product is placed. Technical guidelines assume that the child can consume at one time about 5 g. 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 byhand. 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 b.w./day]
Exposure for child	0.025

2.7.2.3 Exposure to residues in food

Not applicable.

2.7.3 Risk Characterisation

The risk characterization was performed in accordance with the recommendations of the technical guidelines *TNsG* (Annex I Inclusion 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® Płyn 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 characterization 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.

$AEL_{medium,\ chronic}$ eqal to 1.2×10^{-6} mg/kg b.w. was set based on the subchronic study in rabbit in which NOAEL is 0.5 µg/kg b.w. The safety factor of 300 (10 for interspecies and 10 for intraspecies variability, an extra factor of 3 for severity of effects) and correction of 70% oral absorption were also included.

AEL_{acute} equal to 2.3×10^{-6} mg/kg b.w. was set based on the the teratogenicity study in rabbits in which LOAEL of 2µg/kg b.w. The safety factor of 600 (10 for interspecies and 10 for intraspecies variability, an extra factor of 3 for severity of effects, 2 for using LOAEL instead of NOAEL) and with correction of 70% oral absorption were also included.

2.7.3.1 Risk for Professional Users

2.7.3.1.1 Risk characterisation on the basis of estimations according to TNsG

As the safety at job is subject to different legislation, which defining the rules of work and provide for the inspection of work safety, the risk assessment during the manufacture of the active substance and formulation of product was not performed. However, the applicant should in accordance with declarations placed in submitted documentation (Document IIIB6.6.1, 6.6.2) supply the workers which are in contact with the active substance the personal protective equipment

Professional user (dermal absorption value = 10%)

Scenario	Exposure [mg/kg b.w./day]	AEL [mg/kg b.w./day]	%AEL (exposure/ AEL × 100%)	MOE* (NOAEL/ exposure)
Estimations according to TNsG				
Level I	0.0609	1.2×10^{-6}	5.08×10^{6}	0.006
Level II	0.00609	1.2×10^{-6}	0.508×10^{6}	0.06

*Safe value ≥300, corrected for oral absorption of approximately 70%

Professional user (dermal absorption value = 75%)

Scenario	Exposure [mg/kg b.w./day]	AEL [mg/kg b.w./day]	%AEL (exposure/ AEL × 100%)	MOE* (NOAEL/ exposure)
Estimations according to TNsG				
Level I	0.458	1.2×10^{-6}	38.17×10^{6}	0.0008
Level II	0.0458	1.2×10^{-6}	3.817×10^{6}	0.008

*Safe value ≥300, corrected for oral absorption of approximately 70%

It can be concluded there is non acceptable risk associated with use of the product Toxan® Płyn for professional users even using the protective gloves and taking into consideration that dermal absorption is 10%.

2.7.3.1.2 Risk characterisation on the basis of results of alternative calculations of exposure performed on the basis of approach submitted by the external expert being on the list of experts cooperating with The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Version I

Level I (without PPE)

∑ exposure = 0.0000197 mg bromadiolone/kg b.w./day

%AEL = 0.0000197 mg/kg b.w./day / 0.0000012 mg/kg b.w./day x 100% = **1642%** (after taking account the above exposure and AEL = 0.0000012 mg/kg b.w./day)

MOE = 17.8 (after taking account NOAEL = 0.0005 mg/kg b.w./day and a correction for bromadiolone absorption from digestive system)

Level II (taking into account 90% hands protection result from using PPE)

∑ exposure = 0.00000197 mg bromadiolone/kg b.w./day

%AEL = 0.00000197 mg/kg b.w./day / 0.0000012 mg/kg b.w./day x 100% **= 164.2 %** (after taking account the above exposure and AEL = 0.0000012 mg/kg b.w./day)

MOE = 178 (safety factor ≥300)

It can be concluded there is non acceptable risk associated with use of the product Toxan®Płyn for professional users even using the protective gloves and taking into consideration that dermal absorption is 10%.

Version II

Level I (without PPE)

∑ exposure = 0.00005 mg bromadiolone/kg b.w./day

%AEL = 0.00005 mg/kg b.w./day / 0.0000012 mg/kg b.w./day x 100% = **4167%** (after taking account the above exposure and AEL = 0.0000012 mg/kg b.w./day)

MOE = 7 (after taking account NOAEL = 0.0005 mg/kg b.w./day and a correction for bromadiolone absorption from digestive system)

Level II (taking into account 90% hands protection result from using PPE)

∑ exposure = 0.000005 mg bromadiolone/kg b.w./day

%AEL = 0.000005 mg/kg b.w./day / 0.0000012 mg/kg b.w./day x 100% **= 416.7 %** (after taking account the above exposure and AEL = 0.0000012 mg/kg b.w./day)

MOE = 70 (safety factor ≥300)

It can be concluded there is non acceptable risk associated with use of the product Toxan®Płyn for professional users even using the protective gloves and taking into consideration that dermal absorption is 10%.

2.7.3.1.3 Risk characterisation on the basis of results of exposure calculations according to proposals received from the HEEG members (Human Exposure Expert Group)

Scenario	Exposure [mg/kg b.w./day]	AEL [mg/kg b.w./day]	%AEL (exposure/ AEL × 100%)	MOE* (NOAEL=0.0005 mg/kg b.w./ exposure)
The layer approach				
Level I	0.0084	1.2×10^{-6}	700000	0.04
Level II	0.00084	1.2×10^{-6}	70000	0.4
The volume of spilled product approach				
Level I	0.006	1.2×10^{-6}	500000	0.06
Level II	0.0006	1.2×10^{-6}	50000	0.6

*Safe value ≥300; after taking account a correction for bromadiolone absorption from digestive system >70% (71 – 77%)

It can be concluded there is non acceptable risk associated with use of the product Toxan® Płyn for professional users even using the protective gloves and taking into consideration that dermal absorption is 10%.

2.7.3.2 Risk for non-professional users and the general public

Non-professional user (dermal absorption value = 10%)

Scenario	Exposure [mg/kg b.w./day]	AEL [mg/kg b.w./day]	%AEL (exposure/ AEL × 100%)	MOE* (NOAEL/ exposure)
Estimations according to TNsG				
Level I	0.027	2.3×10^{-6}	1.2×10^{6}	0.03

*Safe value ≥600, corrected for oral absorption of approximately 70%

Non-professional user (dermal absorption value = 75%)

Scenario	Exposure [mg/kg b.w./day]	AEL [mg/kg b.w./day]	%AEL (exposure/ AEL × 100%)	MOE* (NOAEL/ exposure)
Estimations according to TNsG				
Level I	0.2024	2.3×10^{-6}	8.8×10^{6}	0.003

*Safe value ≥600, corrected for oral absorption of approximately 70%

It can be concluded there is non acceptable risk associated with use of the product Toxan® Płyn for non-professional users even taking into consideration that dermal absorption is 10%.

2.7.3.2.1 Incidental ingestion by child

Scenario	Exposure [mg/kg b.w./day]	AEL [mg/kg b.w./day]	%AEL (Exposure /AEL × 100%)	MOE* (NOAEL/ exposure)
Estimations according to TNsG				
Incidental ingestion of product	0.025	2.3×10^{-6}	1.087×10^{6}	0.03

*Safe value ≥600, corrected for oral absorption of approximately 70%

The non acceptable risk related to 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 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® Płyn is liquid bait containing 0,05g/kg bromadiolone and is intended to be used by non-professional and professional users as rodenticide for the control of commensal rodent species – rats and mice in the following use situations: in and around buildings, in open areas and waste dumps.

The amount of used product per application is 100 ml per bait station for rats and for mice.

The biocidal product must be placed only in special (intended to liquid formulation) tamper resistant bait stations (see Annex 9). The bait station should be fixed to the ground.

Baiting points must be inspected frequently and replenished when bait has been eaten. Dead rodents, bait uneaten and contaminated should be removed for disposal in order to prevent them being eaten by non-target animals. When no more bait is eaten and rodent activity stops, the remains of all bait must be removed for disposal.

Bromadiolone contamination in environment will occur both from direct contamination when bait are deployed outside the bait station and from indirect contamination via dead bodies, urine and faeces of the target organisms.

Environmental assessment was performed based on scenarios outlined in *ESD*[3] and *TGD*[4] taking into consideration possible scenarios for the use of the product Toxan® Płyn.

The risk assessment was performed by comparing the Predicted Environmental Concentration (PEC) with the Predicted No Effect Concentration (PNEC). The PNEC values have been derived from *Assessment Report* for which company „FREGATA" S.A. submitted a letter of access. The PEC values have been derived through calculation presented in detail in Document IIB.

Regional and continental PEC concentrations were not calculated due to the low consumption and the anticipated very local emission patterns of the use of rodenticides with soil as the main receiving compartment (in accordance with point 2.2 *ESD*).

Considering the composition of the product Toxan® Płyn only the active substance bromadiolone should be considered as of concern for environment and the risk characterisation was therefore only performed for bromadiolone.

2.8.1 Aquatic environment

2.8.1.1 In and around buildings

Exposure of surface water arising from the use Toxan® Płyn in and around buildings is not expected to be significant (detailed explanation in Document IIB). Therefore PECs in surface water have not been calculated and aquatic PEC/PNEC quotients are not presented. Risk assessment was performed only for groundwater since this is the only water compartment that can be contaminated.

[3] Larsen J. (2003) *Emission Scenario Document for Biocides used as Rodenticides.* Supplement to the methodology for risk evaluation of biocides CA -Jun03-Doc.8.2-PT14. (EUBBES 2).

[4] *Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances. Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market*. Part II. Published.

2.8.1.2 Open areas

Exposure of surface water arising from the use Toxan® Płyn in open areas is not expected to be significant (detailed explanation in Document IIB). Therefore calculations of PECs in surface water have not been performed and aquatic PEC/PNEC quotients are not presented. Risk assessment was performed only for groundwater since this is the only water compartment that can be contaminated.

2.8.1.3 Waste dumps

Exposure of surface water arising from the use Toxan® Płyn in waste dumps is not expected to be significant (detailed explanation in Document IIB). Therefore calculations of PECs in surface water have not been performed and aquatic PEC/PNEC quotients are not presented. Risk assessment was performed only for groundwater since this is the only water compartment that can be contaminated.

2.8.2 Atmosphere

Bromadiolone has a low vapour pressure (2.13×10^{-8} Pa) and Henry's Law constant (8.99×10^{-7} Pa m^3 mol^{-1}). Therefore bromadiolone is not volatile and release to air during use of Toxan® Płyn within bait station is considered to be negligible.

Taking into account above, it is concluded that during use of biocidal product in and around buildings, open areas and in waste dumps, released into the atmosphere significant amounts of bromadiolone is highly unlikely. Therefore, PEC for that substance in the air was not determined. Ii is not expects that bromadiolone 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 to Toxan® Płyn may occur when bait is placed in and around buildings. It is assumed that exposure of soil organisms arise through a direct and indirect (via dead bodies, urine and faeces of the target organisms) contamination of soil.

Predicted Environmental Concentration for soil (PEC_{soil}) for biocidal product Toxan® Płyn was calculated in Document IIB and compared to $PNEC_{soil}$ – 0.099 $mg_{bromadiolone}/kg_{wwt}$ value. The calculated PEC/PNEC ratios for soil summarised in Table below.

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

Emission scenario	PEC_{soil} [mg/kg_{wwt}]	$PNEC_{soil}$ [mg/kg_{wwt}]	PEC/PNEC
Worst case use	0.036	0.099	0.368
Normal use	0.011	0.099	0.110

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

2.8.3.2 Open areas

Exposure of soil organisms to biocidal product Toxan® Płyn may occur when bait is placed in open areas. It is assumed that exposure of soil organisms arise through a direct and indirect (via dead bodies, urine and faeces of the target organisms) contamination of soil.
Predicted Environmental Concentration for soil (PEC_{soil}) was calculated in Document IIB and compared to $PNEC_{soil}$ – 0.099 $mg_{bromadiolone}/kg_{wwt}$ value. The calculated PEC/PNEC ratios for soil summarised in Table below.

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

Emission scenario	PEC_{soil} [mg/kg_{wwt}]	$PNEC_{soil}$ [mg/kg_{wwt}]	PEC/PNEC
Worst case use	0.346	0.099	3.495
Normal use	0.138	0.099	1.398

Estimated PEC/PNEC ratios are slightly above one, which means that there is a low risk for soil organisms during use of biocidal product Toxan® Płyn in open areas.

2.8.3.3 Waste dumps

Exposure of soil organisms to biocidal product Toxan® Płyn may occur when bait is placed on waste dumps. It is assumed that exposure of soil organisms arise through a direct and indirect (via dead bodies, urine and faeces of the target organisms) contamination of soil.
Predicted Environmental Concentration for soil (PEC_{soil}) was calculated in Document IIB and compared to $PNEC_{soil}$ – 0.099 $mg_{bromadiolone}/kg_{wwt}$ value. The calculated PEC/PNEC ratios for soil summarised in Table below.

Terrestrial PEC/PNEC ratio as a result of Toxan® Płyn use on waste sites

Emission scenario	PEC_{soil} [mg/kg_{wwt}]	$PNEC_{soil}$ [mg/kg_{wwt}]	PEC/PNEC
Worst case scenario	0.007	0.099	0.075

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

2.8.4 Risk characterisation for groundwater used as drinking water

Exposure of groundwater to the active substance derived from the product Toxan® Płyn was calculated using equations No. 67 and 68 from in the *TGD*, where concentration in pore water of agricultural soil is taken as an indicator for potential groundwater level. It should be noted that this is a worst-case assumption, neglecting transformation and dilution in deeper soil layers. 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 (detailed information in Document IIB). 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.

The comparison above indicates a slight risk of groundwater contamination during use of the product Toxan® Płyn in open areas. 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. It should be underlined that only small amount of soil close to bait station is exposed. Moreover use of risk mitigation measures, including prudent use of the product Toxan® Płyn, can significantly reduce concentration of active substance bromadiolone in soil, and thus reduce the risk to groundwater.

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

Non-target vertebrates may be exposed to the biocidal product Toxan® Płyn either directly by ingestion of exposed bait (primary poisoning) or indirectly by consumption of poisoned rodents and other aquatic and terrestrial organisms that contain residues of the bromadiolone (secondary poisoning).

Considering the different ingredient in the biocidal product Toxan® Płyn only the active substance bromadiolone as potentially can cause risk for the environment. Therefore the risk characterisation was performed only for bromadiolone. The $PNEC_{oral}$ values for birds and mammals were taken from the *Assessment report*. The $PNEC_{oral}$ values are presented in Table below.

$PNEC_{oral}$ value expressed as the concentration in food and as the daily dose for birds and mammals

	PNEC [mg/kg$_{food}$]	**PNEC [mg/kg b.w./d]**
Birds	3.3×10^{-3}	3.8×10^{-4}
Mammals	1.9×10^{-4}	5.6×10^{-6}

2.8.5.1 Primary poisoning

The biocidal product Toxan® Płyn will be placed only in special (intended to liquid bait) tamper resistant bait station. Non–target birds and mammals may be exposed to product if they are small enough to get to inside bait station, when bait station is not property secured or where the station is damaged. Moreover taking in to account type of formulation (liquid) it is not possible that bait will be dragged outside bait station by target rodent.

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.

In the Tier 1 assessment of primary poisoning it is assumed that the whole day's food requirement is satisfied by consumption of bait and therefore the concentration in food will be the same as the concentration of active substance in the bait, 50 mg/kg. This is then compared to the PNECs for birds and mammals.

Concentration of the bait is compared to the $PNEC_{oral}$ expressed as the concentration in food

	PEC_{oral} [mg/kg$_{food}$]	**PNEC [mg/kg$_{food}$]**	**PEC/PNEC**
Birds	50	3.3×10^{-3}	15 152
Mammals	50	1.9×10^{-4}	263 158

The resulting PEC/PNEC ratios in the Table above reveal a high risk for both birds and mammals of long-term primary poisoning.

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 concentration in the non–target animals are calculated after five days intake and elimination. The elimination is assumed to be 71%. The calculations show that mammals and birds would suffer long-term effects of bromadiolone if they would ingest Toxan® Płyn.

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 $PNEC_{oral}$ is expressed as the daily dose

Species		PEC EC_5 [mg/kg b.w.]	$PNEC_{oral}$ [mg/kg b.w./d]	PEC/PNEC
Dog	*Canis familiaris*	1.2167	5.6×10^{-6}	217 265
Pig	*Sus scrofa*	0.1521	5.6×10^{-6}	27 158
Pig young	*Sus scrofa*	0.4867	5.6×10^{-6}	86 906
Tree sparrow	*Passer montanus*	7.0052	3.8×10^{-4}	18 435
Chaffinch	*Fringilla coelebs*	6.0834	3.8×10^{-4}	16 009
Wood pigeon	*Columba palumbus*	2.1975	3.8×10^{-4}	5 783
Pheasant	*Phasianus colchicus*	2.1853	3.8×10^{-4}	5 751

Qualitative assessment of acute primary poisoning

One day consumption of Toxan® Płyn is not assumed to kill birds. The situation for mammals is more uncertain – dogs are at risk. The assumption based on the comparison of expected concentration in animals after one day. The assumption based on the comparison of expected concentration in animals after one day exposure with and without elimination. In assessment assumed that PT and AV values are 0.8 and 0.9, respectively. The species specific sensitivity differences are not taken into account in this assumption and hence this description must not be considered as a risk characterisation.

Qualitative assessment of acute primary poisoning

Species		ETE after one day exposure without elimination [mg/kg b.w./d]	EC after one day exposure and eliminstion [mg/kg·b.w.]	LD_{50} [mg/kg b.w.]
Dog	*Canis familiaris*	2.16	0.63	0,56
Pig	*Sus scrofa*	0.27	0.08	0,56
Pig young	*Sus scrofa*	0.86	0.25	0,56
Tree sparrow	*Passer montanus*	12.44	3.61	134
Chaffinch	*Fringilla coelebs*	10.80	3.13	134
Wood pigeon	*Columba palumbus*	3.90	1.13	134
Pheasant	*Phasianus colchicus*	3.88	1.13	134

Conclusion on primary poisoning

The risk characterisation indicates a very high risk to non-target vertebrates, mammals and birds feeding on bait. Primary poisoning incidents can be minimised by preventing the access of non-target animals to the baits.

According to *ESD* if the baits are used in accordance with the label instructions, the risk for primary poisoning is negligible. The risk of primary poisoning is likely to be overestimated because the direct exposure to bromadiolone is mitigated by the use of bait station. Nevertheless, the risk cannot be excluded. 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® Płyn in and around buildings, in open areas and waste dumps exposure of surface water to active substance bromadiolone is negligible (detailed explanation in Document IIB). Therefore risk of poisoning via the aquatic food chain is also considered negligible.

Animals living in soil contaminated bromadiolone accumulate this substance. Therefore birds and mammals feeding on these animals are at risk of secondary poisoning. Secondary poisoning is possible in chain:

soil → earthworms → earthworms eating birds or mammals.

However the Polish Competent Authority considers that the secondary poisoning via earthworms less important than secondary poisoning via the food chain

bait → rodent → rodent-eating birds or mammals.

Results of risk assessment of secondary poisoning via terrestrial food chain presented in Table below.

Secondary poisoning via terrestrial food chain

	$PEC_{oral,\ predators}$ [$mg/kg_{wet\ earthworm}$]	$PNEC_{oral}$ [mg/kg food]	PEC/PNEC
Birds	0.0253	3.8×10^{-4}	67
Mammals	0.0253	5.6×10^{-6}	4 519

The calculated PEC/PNEC ratios are more than one, therefore it should be noted that there is a risk of secondary poisoning in the terrestrial food chain during use of biocidal product Toxan® Płyn.

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. Only resistant rodents are assumed to eat bait for 14 days. 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	3.51	3.80×10^{-4}	9 247
Mammal	3.51	5.60×10^{-6}	627 483
Rodent caught on day 14 after meal			
Bird	3.52	3.80×10^{-4}	9 266
Mammal	3.52	5.60×10^{-6}	628 773

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 b.w.]		$PNEC_{oral}$ [mg/kg b.w./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*	0.87	0.87	3.80×10^{-4}	2 293	2 298
Kestrel	*Falco tinnunculus*	0.99	1.00	3.80×10^{-4}	2 616	2 622
Little owl	*Athene noctua*	0.80	0.80	3.80×10^{-4}	2 108	2 112
Tawny owl	*Strix aluco*	1.32	1.33	3.80×10^{-4}	3 482	3 489
Fox	*Vulpes vulpes*	0.32	0.32	5.60×10^{-6}	57 266	57 384
Polecat	*Mustela putorius*	0.67	0.67	5.60×10^{-6}	119 213	119 458
Stoat	*Mustela erminea*	0.95	0.96	5.60×10^{-6}	170 492	170 842
Weasel	*Mustela nivalis*	1.38	1.38	5.60×10^{-6}	246 013	246 519

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.

Qualitative assessment of acute secondary poisoning

A qualitative assessment of the acute secondary poisoning is made by comparing the concentration in the rodents to LD_{50} values from acute oral studies. Rodents are assumed to eat entirely on bait containing bromadiolone and the non-target animals are assumed to consume entirely poisoned rodents. The calculations of PECs are explained in Document IIB. The qualitative assessment indicates that birds survive and mammals die if they eat poisoned rats. The species specific sensitivity differences or other factors normally covered by the assessment factors are not taken into account in the qualitative assessment.

Qualitative assessment of acute secondary poisoning

Fraction of food type in diet (PD)	EC in rat on day 5 after last meal [mg/kg b.w.]	Birds LD_{50} [mg/kg b.w.]	Mammals LD_{50} [mg/kg b.w.]
1	7.03	134	0.56
0.5	3.51	134	0.56
0.2	1.41	134	0.56

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 b.w. Thus, 0.99 µg/kg b.w. is the maximum bromadiolone concentration in rats that would not cause lethality according to monitoring data. It is assumed that 0.99 µg/kg b.w. 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

PBT assessment has to be done according to the *TGD* especially for substances which can be shown both to persist for long periods and bioaccumulate in biota, and can give rise to toxic effects after a greater time and greater distances than chemicals without these properties. As bromadiolone is not readily biodegradable, have a relatively high

bioconcentration factor and is very toxic to both aquatic organisms and mammals thus a PBT assessment is important.

Persistence

The *P* screening criterion is fulfilled for bromadiolone since it is *not readily biodegradable,* 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 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

Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying the following appropriate and available risk mitigation measures:

1. The biocidal product should be placed only in special (intended to liquid formulation) commercially available tamper resistant bait stations. The bait station should be fixed to the ground (photo of exemplary bait station intended for liquid formulation – see Annex 9).

2. The bait in bait station should be protected from weather, accidental ingestion by children or non-target animals and environmental dispersion.

3. The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. The biocidal product Toxan® Płyn should not be used in an area where resistance to bromadiolone is suspected.

4. Always read the label before use and follow the instructions provided.

5. The size of the target rodent population should be evaluated before a control campaign.

6. The number of baits and the timing of the control campaign should be in proportion to the size of the infestation.

7. Do not use anticoagulant rodenticides as permanent baits. In most cases, anticoagulant bait should have achieved control within 35 days. If after this period rodent activity persists determine the cause of the lack of effectiveness.

8. When the product is being used in and around buildings, tamper resistant bait stations should be placed along walls and in places where there are signs of rodent activity.

9. The biocidal product must never be placed indiscriminately.

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

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

12. Biocidal product should not be used where food, feeding stuffs or drinking water could be contaminated

13. Places when the biocidal product is being used should be clearly marked to show that they contain rodenticides and that they should not be disturbed.

14. For use only in areas that are inaccessible to children and non-target animals (particularly dogs, cats, pigs, poultry and wild birds).

15. Keep out of the reach of children.

16. 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.

17. Avoid release to the environment.

18. Avoid contamination of soil, surface water or sanitary sewer system from product or packaging the product.

19. In case of accidental release into the environment, the product should be collected avoiding direct contact with the skin and must be delivered to authorised company which are empowered for utilization of hazardous wastes and their disposal (e.g. incineration). Do not mix with municipal solid waste.

20. In case of contamination of the surface with the product, collect product thoroughly into suitable containers and delivered to authorised company which are empowered for utilization of hazardous wastes and their disposal (e.g. incineration). Do not mix with municipal solid waste. In case of an extensive environmental contamination, inform the authorities.

21. If all bait is consumed quickly in a particular area, increase the number of baiting points in that area.

22. Search for and remove dead rodents and the bait which is contaminated at frequent intervals during treatment, at least as often as when baits are checked and/or replenished. Daily inspection may be required in some circumstances. All residues and dead rodent must be delivered to authorised company which are empowered for utilization of hazardous wastes and their disposal (e.g. incineration). Do not mix with municipal solid waste. Wear protective gloves.

23. After the campaign remove dead rodents, the bait contaminated by dirt, bait stations and package. Wear protective gloves. These residues must be delivered to authorised company which are empowered for utilization of hazardous wastes and their disposal (e.g. incineration). Do not mix with municipal solid waste.

24. Packaging of the product, any contaminated materials, the remains of the product after use (closed in a labeled container) and dead rodents must be delivered to authorised company which are empowered for utilization of hazardous wastes and their disposal (e.g. incineration). Do not mix with municipal solid waste.

25. The product must not be used to protect plants and plant products.

26. Avoid contact with eye and skin.

27. Avoid contact with clothing.

28. Wash hands and exposed skin before eating, drinking smoking and after use.

29. The biocidal product Toxan® Płyn is not intended for mixing with other products.

30. If swallowed, seek medical advice immediately – show packaging and the label.

31. Wear protective gloves.

32. When using do not eat, drink or smoke.

33. Keep away from food, drink and animal foodstuffs.

34. Product should be stored in original, labelled and closed containers in temperature not lower than 5ºC, in dry and well-ventilated area.

35. Keep away from children and non-target organisms (particularly dogs, cats, pigs, poultry and wild birds). Protect from direct light.

36. Product should not be stored with chemicals which could have a direct effect on smell of bait.

37. Reduce the attractiveness of the packaging and the product for children.

38. The product must be packed in such a way as to prevent or significantly impede opening by children.

39. Product placed in bait station and uneaten by rodent cannot be reused. Packaging should not be used for any other purpose.

40. The biocidal product must contain an aversive agent –substance limiting the risk of consumption of the product.

41. The label should include information that the product contains an aversive agent – substance limiting the risk of consumption of the product.

42. The authorisation holder shall report any observed resistance incidents to appropriate sanitary authority.

3 Proposal for decision

1. Product Formulation

Active substance content	% w/w	Manufacturer of active substance
concentrate of bromadiolone (pure bromadiolone content)	0.2% (0.005%)	PelGar International Limited Unit 13 Newman Lane Alton Hampshire GU34 2QR, United Kingdom

2. Formulation type	Liquid
3. Product type	PT14
4. User	▪ professional
5. Packaging	please refer to PAR section 2.2.3
6. Application	▪ in and around buildings (e.g. live stock buildings) ▪ open areas (e.g. parks, tennis courts, camping sites and other places of the public utility). ▪ waste dumps
7. Application Method	liquid bait placed in drinking dispenser that must be placed in special (intended to liquid formulation) tamper resistance bait station (see Annex 9)
8. Application Rate	Mice: 100 ml of liquid bait per bait station spaced at 3 – 4 m. Rats: 100 ml of liquid bait per bait station spaced at 10 – 15 m.
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	5 years as of the date of granting the authorisation
12. Any other specific conditions:	please refer to PAR section 2.9

Information presented in table above is Applicant proposal.

Taking into account risk characterisation (please see section 2.7.3) it can be concluded there is non acceptable risk associated with use of the product Toxan® Płyn for non-professional and professional users (even using the protective gloves by professional users). Therefore, the Polish Competent Authority for reasons reported above **cannot concluded** that the requirements laid down in Article 19 paragraph 1. point (b) subpoint (iii)

of Biocidal Product Regulation (EU) No 512/2012 are fulfilled to granting an authorisation for Toxan® Płyn.

However the Applicant has submitted many opinions indicating how important is availability on the Polish market rodenticides in liquid formulation such as Toxan® Płyn. These arguments have been submitted by many Polish experts and professional users who have many years of experience in the field of rodent control.

According to these experts the use of liquid rodenticides is often the only way to carry out an effective rodenticide campaign. The use of liquid rodenticides is necessary e.g. in magazines with dry products, some livestock, bakeries and in other places with lack or limited access to water. In places where rodents have unlimited access to attractive food, the use of cereal-based products is ineffective – they are not attractive. Additionally according to experts when rodenticides in solid form (e.g. wax blocks, grain, pellets, flakes) are placed in this type of places, it should be taken into consideration that bait could be dragged away outside the bait station and then contamination of stored products could occur.

In the opinion of experts, the combined use of rodenticides in liquid and solid formulations have a significant impact on the speed and the effectiveness of rodent control and thus prevent the development of resistance.

According to these experts, non granting authorisation for biocidal product Toxan® Płyn will cause serious consequences and negative effects on the professional rodent control – significant limitations of the range of tools used in the integrated method of rodent control, moreover in some cases may affect unsuccessful rodent campaign.

Therefore taking into account reasons reported above and proposed risk mitigation measure which minimise exposure for humans and environment (available in section 2.9), Polish Competent Authority has decided to grant an authorisation for biocidal product Toxan® Płyn according to Article 19 paragraph 5 of Biocidal Product Regulation (EU) No 528/2012. Moreover Polish CA has decided to grant authorisation only for professional users.

Annex 1: 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 3.7 3.10	Al Amin Idris	2011	Toxan Płyn Oznaczanie właściwości fizykochemicznych przed i po przyspieszonym starzeniu Instytut Przemysłu Organicznego (Warszawa) Kod badania: BF-07/11	„FREGATA” S.A.	☐	☒	☒	☐
III B	3.2	Sałaciński Tomasz	2011	Toxan Płyn. Oznaczanie właściwości wybuchowych Instytut Przemysłu Organicznego (Warszawa) Nr sprawozdania: BW-02/11	„FREGATA” S.A.	☐	☒	☒	☐
III B	3.3 3.4	Drzemnicka Agata, Borzym Rafał, Frączak Michał	2011	Toxan Płyn Oznaczanie temperatury zapłonu, samozapłonu oraz właściwości utleniających Instytut Przemysłu Organicznego (Warszawa) Kod badania: BC-04/11	„FREGATA” S.A.	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
III B	4.1	Neubart Kinga	2011	Opracowania i walidacja metody oznaczania bromadiolonu w preparacie Toxan Płyn Instytut Przemysłu Organicznego (Warszawa) Kod badania: BA-07/11	„FREGATA" S.A.	☐	☒	☒	☐
III B	5.10.2(1)	Ignatowicz Stanisław	2010	Badanie skuteczności preparatu Toxan® Płyn przeznaczonego do zwalczania gryzoni zgodnie z „Metodą badania skuteczności produktów biobójczych zawierających antykoagulanty przeznaczonych do zwalczania gryzoni", KES-01/2009 Szkoła Główna Gospodarstwa Wiejskiego (Warszawa)	„FREGATA" S.A.	☐	☒	☒	☐
III B	5.10.2(2)	Gruszka Katarzyna	2011	Toxan® Płyn Badanie skuteczności i akceptacji rodentycydów na szczurach laboratoryjnych Instytut Przemysłu Organicznego Oddział w Pszczynie Kod badania: SK – 13/11	„FREGATA" S.A.	☐	☒	☒	☐
III B	5.10.2(3)	Gruszka Katarzyna	2011	Toxan® Płyn Badanie skuteczności i akceptacji rodentycydów na myszach laboratoryjnych Instytut Przemysłu Organicznego Oddział w Pszczynie Kod badania: SK – 14/11	„FREGATA" S.A.	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
III B	5.10.2(4)	Ignatowicz Stanisław	2012	Uzupełniające badanie skuteczności produktu biobójczego Toxan Płyn przeznaczonego do zwalczania gryzoni zgodnie z „Metodą badania skuteczności produktów biobójczych zawierających antykoagulanty przeznaczonych do zwalczania gryzoni KES-01/2009 Szkoła Główna Gospodarstwa Wiejskiego (Warszawa)	„FREGATA” S.A.	☐	☒	☒	☐
III B	6.6/1 6.6/2	FREGATA SA	2012	Toxan Płyn. Oszacowanie ekspozycji oraz ryzyka	„FREGATA” S.A.	☐	☒	☒	☐

Annex 2: Analytical methods residues – active substance

< Bromadiolone >

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

Annex 3: Toxicology and metabolism –active substance

< Bromadiolone >

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

Annex 4: Toxicology – biocidal product

< Toxan® Płyn>

General information

Formulation Type:	liquid
Active substance(s) (incl. content)	0.005% 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)	11.2 – 16.8 g/kg b.w. (female)
Rat LD_{50} dermal (OECD 402)	34.2 g/kg b.w. (male and female)
Rat LC_{50} inhalation (OECD 403)	8.6 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 5: Safety for professional operators

<Toxan® Płyn>

See point 2.7.3.1 above

Annex 6: Safety for non-professional operators and the general public

< Toxan® Płyn>

See Tables 2.7.3.2.1 and 2.7.3.2.2 above

Annex 7: Residue behaviour

<Bromadiolone>

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

Annex 8: Photo of exemplary bait station intended for liquid formulation