Product Assessment Report

Atrax® Płatki

Authorisation no: PL/2012/0033/A

Granting date: 04.10.2012

Expiry date of authorisation: 31.03.2015

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

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

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Contents

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

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

Application received:	29.06.2010
Application reported complete:	25.10.2011
Type of application:	Authorisation
Further information:	No

1.3 Information about the biocidal product

1.3.1 General information

Trade name:	Atrax® Płatki
Manufacturer's development code number(s), if appropriate:	-
Product type:	14
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	Difenacoum 0.005%
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:	*Rattus norvegicus* *Rattus rattus* *Mus musculus/domesticus* *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*: 200 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:	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin
CAS No:	56073-07-5
EC No:	259-978-4
Purity (minimum, g/kg or g/l):	> 960 g/kg
Inclusion directive:	2008/81/EC
Date of inclusion:	01.04.2010
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
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 Ltd which was used to support the Annex I listing of the active substance difenacoum according to Directive 98/8/EC.

2 Summary of the product assessment

2.1 Identity related issues

The biocidal product Atrax® Płatki contains the active substance difenacoum (0.005%) (purity > 960 g/kg).
The source of active substance used in the biocidal product is identical to the active substance that is listed in Annex I of 98/8/EC.

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 difenacoum under Dir 67/548/EEC is:
T+: R28, R48/25,
N R50/53.

Classification and labelling of the product:

R-phrases
None

S-phrases
S2 - Keep out of the reach of children.
S13 - Keep away from food, drink and animal feedingstuffs.
S37 - Wear suitable gloves (professional use only).

2.2.3 Packaging of the biocidal product

The packaging details for the biocidal product, Atrax® 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 resistant to tearing with the label "close - open". On front of the bag clearly warning „Keep out of the reach of children”	200 g	200 g
Welded PET/PE bag resistant to tearing with the label "close - open". On front of the bag clearly warning „Keep out of the reach of children”	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. Scoop and protective gloves inside bucket	1400 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

Atrax® Płatki is ready-to-use product in a form of flakes containing difenacoum active substance 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.

Atrax® Płatki is green-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 288°C. Pour bulk density of the product is equal to 0.48 g/cm^3 and tap bulk density is 0.57 g/cm^3. Water suspension of the product gives light-acetic pH (1%, pH=6.05 to 5.82 – after storage stability test).

The technical characteristics of a product is 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 0.0437 g/kg to 0.0382 g/kg after storage stability test. The loss of 12.6%. 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	Atrax Płatki, partia nr (lot No.) AP001 Specification.: SP-ATRAX PŁATKI-01/10 with additional statement	solid, flakes	EMC 373100019 study code: BF-18/11
Colour	Farmakopea Polska, wyd. VI (2002) and according to EPA Product Properties Test Guideline OPPTS 830.6303	Atrax Płatki, partia nr (lot No.) AP001 Specification.: SP-ATRAX PŁATKI-01/10 with additional statement	green-straw-coloured	EMC 373100019 study code: BF-18/11
Odour	Farmakopea Polska, wyd. VI (2002) and according to EPA Product Properties Test Guideline OPPTS 830.6304	Atrax Płatki, partia nr (lot No.) AP001 Specification.: SP-ATRAX PŁATKI-01/10 with additional statement	of grain	EMC 373100019 study code: BF-18/11
Explosive properties	A.14, procedures W03-WNU W04-WNT	Atrax Płatki, partia nr (lot No.) 002 Specification.: SP-	Atrax® Płatki does not possess explosive properties	34/W/54/2008

	Method	Purity/ Specification	Results	Reference
	W17-OŁS	ATRAX PŁATKI-01/10 with additional statement		
Oxidizing properties	A.17, procedure SPR/BC-FC/03/b	Atrax Płatki, partia nr (lot No.) 002 Specification.: SP-ATRAX PŁATKI-01/10 with additional statement	Atrax® Płatki does not possess oxidizing properties	EMC 363000012 study code: BC/25/08
Flash point	A.10 procedure SPR/BC-FC/08/b	Atrax Płatki, partia nr (lot No.) 002 Specification.: SP-ATRAX PŁATKI-01/10 with additional statement	Atrax® Płatki is not highly flammable	EMC 363000012 study code: BC/25/08
Autoflammability	A.16 procedure SPR/BC-FC/12/b	Atrax Płatki, partia nr (lot No.) 002 Specification.: SP-ATRAX PŁATKI-01/10 with additional statement	The self-ignition temperature of a product is 288 °C	EMC 363000012 study code: BC/25/08
Other indications of flammability	n.a.	n.a.	n.a.	n.a.
Acidity / Alkalinity	CIPAC MT 75.3	Atrax Płatki, partia nr (lot No.) AP001 Specification.: SP-ATRAX PŁATKI-01/10 with additional statement	pH of 1% water suspension is 6.05 before and 5.82 after accelerated storage stability test	EMC 373100019 study code: BF-18/11
Relative density / bulk density	CIPAC MT 186	Atrax Płatki, partia nr (lot No.) AP001 Specification.: SP-ATRAX PŁATKI-01/10 with additional statement	bulk density is 0.48 g/ml (pour) and 0.57 g/ml (tap)	EMC 373100019 study code: BF-18/11
Storage stability – stability and shelf life	CIPAC MT 46 (2 weeks 54 °C)	Atrax Płatki, partia nr (lot No.) AP001 Specification.: SP-ATRAX PŁATKI-01/10 with additional statement	Atrax® Płatki is stable for two weeks in 54 °C	RB/FGA/02/02

	Method	Purity/ Specification	Results	Reference
Effects of temperature	CIPAC MT 46	Atrax Płatki, partia nr (lot No.) AP001 Specification.: SP-ATRAX PŁATKI-01/10 with additional statement	Atrax® Płatki is stable for two weeks in 54 °C	EMC 373100019 study code: BF-18/11
Reactivity towards container material	CIPAC MT 46	Atrax Płatki, partia nr (lot No.) AP001 Specification.: SP-ATRAX 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-18/11
Technical characteristics in dependence of the formulation type Attrition resistance	CIPAC MT 178	Atrax Płatki, partia nr (lot No.) AP001 Specification.: SP-ATRAX PŁATKI-01/10 with additional statement	99.89 % before accelerated storage stability test 99.96 % after accelerated storage stability test	EMC 373100019 study code: BF-18/11
Dustiness	CIPAC MT 171	Atrax Płatki, partia nr (lot No.) AP001 Specification.: SP-ATRAX PŁATKI-01/10 with additional statement	essentially non dusty (20.55 mg before and 20.80 mg after accelerated storage stability test)	EMC 373100019 study code: BF-18/11
Nominal size range	CIPAC MT 59	Atrax Płatki, partia nr (lot No.) AP001 Specification.: SP-ATRAX 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-18/11
Compability with other products	n.a.	n.a.	Atrax® 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	Atrax Płatki, partia nr (lot No.) AP001 Specification.: SP-	before accelerated storage stability test: 1,19 % ≥ 4750 µm 3150 µm ≤ 23,48 % < 4750 µm	EMC 373100019 study code:

	Method	Purity/ Specification	Results	Reference
		ATRAX PŁATKI-01/10 with additional statement	1400 µm ≤ 39,77 % < 3150 µm 1000 µm ≤ 7,25 % < 1400 µm 500 µm ≤ 8,71 % < 1000 µm 250 µm ≤ 4,94 % < 500 µm 125 µm ≤ 4,72 % < 250 µm 75 µm ≤ 3,44 % < 125 µm 45 µm ≤ 4,26 % < 75 µm 2,26 % < 45 µm after accelerated storage stability test: 0,74 % ≥ 4750 µm 3150 µm ≤ 24,73 % < 4750 µm 1400 µm ≤ 41,90 % < 3150 µm 1000 µm ≤ 6,90 % < 1400 µm 500 µm ≤ 7,77 % < 1000 µm 250 µm ≤ 4,46 % < 500 µm 125 µm ≤ 4,08 % < 250 µm 75 µm ≤ 3,21 % < 125 µm 45 µm ≤ 3,93 % < 75 µm 2,30 % < 45 µm	BF-18/11

Some studies were performed on Atrax Plus which is another (previous) name for Atrax® Płatki.

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 Atrax® 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 288°C which in normal or worst realistic conditions of use will never be a case. Extensive technical properties characteristics of the product is 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 (2.30 % <45 µm and less than 10 % up to 100 µm. There are some indications of dust ability of

a product (dust content less than 21 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 Atrax® Płatki will be used as rodenticide (PT14) for the control of commensal rodent species. The product is intended for use in 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

Atrax® Płatki is intended to be used against *Rattus norvegicus* (brown rat), *Rattus rattus* (black rat), *Mus musculus/domesticus* (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. 200g Atrax® 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 and 3) percentage of active holes	The study indicates that 1) intake of control bait was reduced 90.9% 2) intake of tested bait was reduced 93.9% 3) percentage of active holes was reduced to 5%	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 Atrax® 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 and 3) percentage of active holes	The study indicates that 1) intake of control bait was reduced 86.7% 2) intake of tested bait was reduced 87.0% 3) percentage of active holes was reduced to 4.2%	III-B 5.10.2(1)
House mouse *Mus*	Palatability test done according to method EPPO	Control group (10 males and 10 females) Tested group (10 males and 10	Total mortality of mice has reached 95% and edibility was at the	III-B 5.10.2(2)

musculus	1982 "Laboratory Tests for Evaluation of the Toxicity and Acceptability of Rodenticides and Rodenticide Preparations"	females) Total time of study 22days includes pre-treatment period (4days), treatments period (4 days) and observation period (14days)	level 86.9%. Palatability ratio for males was 6.4 and for females 6.4. The average mortality for males has occurred at 9.1 day (4-17 days) with average consumption of bait 30.9 mg/kg b. w. For females average mortality has occurred at 9.8 day (6-16) with average consumption of bait 35.6 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 22days includes pre-treatment period (4days), treatments period (4 days) and observation period (14days)	Total mortality of rats has reached 90% and edibility was at the level 84.6%. Palatability ratio for males was 3.8 and for females 18.4. The average mortality for males has occurred at 7.1 day (6-8 days) with average consumption of bait 13.0 mg/kg b. w. For females average mortality has occurred at 9.2 day (7-13) with average consumption of bait 18.2 mg/kg b.w.	III-B 5.10.2(3)

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 75 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

Some degree of resistance of difenacoum has been reported in the UK, Denmark, France and Germany but this is usually found in certain populations of rodents highly resistant to first generation of anticoagulants. The resistance mechanism of difenacoum is not clear. Cross-resistance has also been observed between difenacoum, bromadiolone and brodifacoum.

Resistance management strategies

In order to prevent the development of resistance to difenacoum among controlled rodents many factors should be considered during biocidal product application:

1) The population size of the target rodent should be evaluated before a control campaign. The number of baits and the timing of the control campaign should be in proportion to the size of the infestation.
2) A complete elimination of rodents in the infested area should be achieved.
3) The use instructions of products should contain guidance on resistance management for rodenticides.
4) Resistance management strategies should be developed, and difenacoum should not be used in an area where resistance to this substance is suspected.
5) The authorisation holder shall report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management.
6) About 5-9-fold doses are needed to kill difenacoum resistant rat.

2.6 Exposure assessment

2.6.1 Description of the intended use

Atrax® Płatki is a rodenticide flakes bait 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. Atrax® Płatki takes the form of a ready to use flakes bait containing 0.005% w/w (50 ppm) difenacoum, a second generation 4-hydroxy coumarin or superwafarin 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*), black rat (*Rattus rattus*), house mouse (*Mus musculus*/*domesticus*) 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 difenacoum is the only substance of concern in biocidal product Atrax® 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 Atrax® 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 both rats and mice). It contains 0.005% of the

active substance difenacoum. It belongs to PT 14 product group. Atrax® 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 difenacoum therefore no additional information for this point is needed.

2.7.1.2 Toxicology of the substance(s) of concern

The biocidal product Atrax® 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 difenacoum.

2.7.1.3 Toxicology of the biocidal product

The toxicological studies for a biocidal product Atrax® Płatki were not performed. The toxicological evaluation of this product was based on toxicological data for the active substance difenacoum.
Information on the assessment of the active substance difenacoum were granted to Fregata S.A. by PelGar International Ltd. as difenacoum manufacturer (based on data from letter of access dated on 17.05.2010) for the registration of a biocidal product Atrax® Płatki.

Summary of toxicity data for the biocidal product Atrax® Płatki:
Dermal absorption studies for biocidal product were not performed. For this reason it was set at 100% but only for the calculation of exposure to operator during the formulation of the biocidal product. In fact, the absorbance of the product does not reach this value because of its composition and formulation. It has been decided that the absorption for biocidal product will be comparable to dermal absorption of the active substance and was set at 3%.

Oral LD_{50} (rat):
- 36 g/kg bw (male)
- 52 g/kg bw (female)

Dermal LD_{50} (rat):
- 1260 g/kg bw (male)
- 1030.8 g/kg bw (female)

(95% confidence limits for 680-1700 g/kg bw) (male)

Inhalation LC_{50} (rat):

0.3254 -0.4148 g/l/4 h (only nose)

0.073 – 0.117 g/l/4 h (only head) – based on the data placed in Assessment Report for difenacoum for which Fregata S.A. does not submitted the letter of access. However, these results present the worst case and for this reason they should be used by the RMS for the risk assessment.

Not irritation to skin

Not irritation to eye

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 production of a biocidal product where during the formulation of the product the contact with the active substance and intermediates is possible. According to the declaration of the aplicant 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: 0.00000595 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:

- Atrax® Płatki is supplied to the customer in tightly-closed foil units PET/PE.
- The inhalation exposure was not estimated. The results of physico-chemical studies makes the Atrax® Płatki to be considered as essentially non dusty and the the active substance difenacoum is not volatile - the risk of inhalation exposure is considered negligible.
- The dermal exposure was estimated. During the use, the Atrax® 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) and Level 2 - application with the use of personal protective equipment PPE (with gloves).

Estimations according to TNsG:

Accordint to TNsG, for professionl 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: 20 g (TNsG June 2007)

– frequency of events per day: 16 bait stations per day

It is assumed that dermal absorption value is 3% (Assessment Report for difenacoum)

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

Product density: 0.48 g/m3 (Doc. IIIB 3)

	Level 1 [mg/kg bw/day]	**Level 2 [mg/kg bw/day]**
Application phase	0.00384	0.000384
Removal of the preparation phase	0.000384	0.0000384
Total exposure	0.004224	0.0004224

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
- the amount of the product per event: 200 g (Doc. IIIB 5)

- recommended value to potential exposure: 3.79 mg (per one action)

Total exposure for the professional user during the use/day = 10.22×10^{-6} mg/kg bw/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:

Accordint to TNsG, for professionl 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: 20 g (TNsG June 2007)

– frequency of events per day: 2 bait stations per day

	Exposure value [mg/kg bw/day]
Application phase	0.00048
Removal of the preparation phase	0.000048
Total exposure	0.000528

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 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 g (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 = 10.11×10^{-7} mg/kg bw/day

While use of the biocidal product, bystanders 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 granules 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 oral 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	0.025

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 Inclussion Revision of Charter 4.1: Quantitative Human Heath Risk Characterisation), based on the determined values of MOE and AEL.

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

According to the information placed in the Assessment Report for the active substance difenacoum 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 difenacoum 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 0.001 mg/kg bw/day (at which the prolongation of bleeding and coagulation of blood in females were observed) was used to estimation of acceptable level of exposure (AEL).

NOAEL [mg/kg bw]	LOAEL [mg/kg bw]	Assessment factor (AF)			Reference doses	
		Intraspecies AF	Interspecies AF	Total AF	Absorption [%]	AEL [mg/kg bw/day]
lack	Teratogenicity (rabbit) 0.001	10	10	600*	68	$1{,}1 \times 10^{-6}$

* 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 x 100%)	MOE* (NOEL/exposure)
Dermal exposure	5.95×10^{-6}	1.1×10^{-6}	541	84

*Safe value ≥300

The applicant provided rather general information about the use of the active substance and contact with her 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 applicants should be required, in accordance with theirs' declarations to supplied the workers which are in contact with the active substance the basic personal protective equipment (at least gloves). 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. To conclude on the basis of the data, it is recommended to use the protective gloves, at least at the stage of formulation of the biocidal product.

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	4.22×10^{-3}	1.1×10^{-6}	3.8×10^{5}	1.2×10^{-1}
Level II	4.22×10^{-4}	1.1×10^{-6}	3.8×10^{4}	1.18
Estimations according to J.G. Chambers and P.J. Snowdon				
Level I	10.22×10^{-6}	1.1×10^{-6}	929	48.92
Level II	10.22×10^{-7}	1.1×10^{-6}	92.9	489

*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 Atrax® 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	5.28×10^{-4}	1.1×10^{-6}	4.8×10^{4}	0.95
Estimations according to J.G. Chambers and P.J. Snowdon				
Level I	10.11×10^{-7}	1.1×10^{-6}	91.9	494.6

*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 not indicated the risk due to use of the product Atrax® Płatki for non-professional users. It must be emphasized that due to the fact that the applicant did not declare the production of a biocidal product in pack larger than 1.5 kg in the risk assessment did not include decanting and mixing stage of the biocidal product.

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	0.025	1.1×10^{-6}	2.27×10^{6}	0.02

*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 (eg Bitrex)
- The use by the non-professional only closed bait stations made of durable material
- Take special care when lining poison by professionals without the use of bait stations.

2.7.3.3 Risk for consumers via residues

Not applicable.

2.8 Risk assessment for the environment

Biocidal product Atrax® Płatki is intended to be used to control rodent pests (rats and mice).

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

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 Atrax® 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 only substance of concern in biocidal product Atrax® Płatki. Therefore PNEC values for difenacoum were used in risk assessment.

2.8.1 Aquatic environment

In and around buildings, open areas, waste sites

In case of the use Atrax® Płatki in and around buildings, in open areas and waste sites exposure of surface water to active substance – difenacoum 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 sites

Difenacoum has a low vapour pressure ($6.7 \times 10^{-9} – 5.4 \times 10^{-14}$ Pa). Henry's Law constant calculated based on vapour pressure is $1,75 \times 10^{-6}$ Pa m^3 mol^{-1}. Therefore release to air during use of Atrax® Płatki within bait boxes is considered to be negligible. Based on the lack of exposure and rapid photo-oxidative degradation of difenacoum, 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 difenacoum 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 $PNEC_{soil}$ – 0.877 $mg_{difenacoum}$/kg (according to report for active substance).

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

Emission scenario	PEC_{soil} [$mg_{difenakum}$/kg]	$PNEC_{soil}$ [$mg_{difenakum}$/kg]	PEC/PNEC
Worst case use	0.0348	0.877	0.04
Normal use	0.01	0.877	0.011

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

2.8.3.2 Open areas

Exposure of soil organisms to difenacoum - active substance in Atrax® 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 $PNEC_{soil}$ – 0.877 $mg_{difenacoum}$/kg (according to report for active substance).

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

Emission scenario	PEC_{soil} [$mg_{difenakum}$/kg]	$PNEC_{soil}$ [$mg_{difenakum}$/kg]	PEC/PNEC

Worst case realistic scenario	0.346	0.877	0.39
Worst case realistic scenario (+ bait stations)	0.138	0.877	0.16

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

2.8.3.3 Waste sites

Exposure of soil organisms to difenacoum - active substance in Atrax® Płatki due to direct contamination of soil may occur following use on waste sites. 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 $PNEC_{soil}$ – 0.877 $mg_{difenacoum}$/kg (according to report for active substance).

Terrestrial PEC/PNEC ratio as a result of Atrax® Płatki use on waste sites

Emission scenario	PEC_{soil} [$mg_{difenakum}$/kg]	$PNEC_{soil}$ [$mg_{difenakum}$/kg]	PEC/PNEC
Worst case scenario	0.005	0.877	0.0057

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

2.8.4 Risk characterisation for groundwater used as drinking water

Possible movement from soil to groundwater is calculated according to the TGD (2003), where concentration in porewater of agricultural soil is taken as an indication for potential groundwater levels. According to the TGD this is a worst-case assumption, neglecting transformation and dilution in deeper soil layers. Aerial deposition is negligible. Accordingly calculated groundwater concentrations (details presented in Doc II-B) from the uses in and around buildings, open areas and waste sites are below maximum permissible concentration determined by directive 80/778/EEC (amended by 98/83/EC) of 0.1 µg/l

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

Non-target vertebrates may be directly exposed to difenacoum in the product Atrax® Płatki through consumption of the product (primary poisoning) or indirectly through the consumption of rodents containing residues of difenacoum (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 PNECoral related to the concentration in food

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

	PEC [mg/kg food]	PNEC [mg/kg food]	PEC/PNEC
Birds	50	0.0001	500 000
Mammals	50	0.0003	166 667

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 PNECoral 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 calculations show that mammals and birds would suffer long-term effects of difenacoum if they would ingest Atrax® 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 $PNEC_{oral}$ is expressed as the daily dose

Species	PEC EC_5 [µg/kg bw]	$PNEC_{oral.}$ [µg/kg bw/d]	PEC/PNEC
Dog	3920	0.3	13066
Pig	520	0.3	1733
Pig young	1570	0.3	5233
Tree sparrow	2 560	0.1	225600
Chaffinch	19580	0.1	195800
Wood pigeon	7050	0.1	70500
Pheasant	7040	0.1	70400

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 Atrax® Płatki in and around buildings, in open areas and around waste sites exposure of surface water to active substance - difenacoum 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 Atrax® Płatki in and around buildings, in open areas and around waste sites 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

	$PEC_{oral,\ predators}$ [µg/kg earthworm]	**$PNEC_{oral}$ [µg/kg food]**	**PEC/PNEC**
Birds	240	0.5	480
Mammals	240	7	34.3

Despite of the calculated risk, the RMS 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 (Frodent = 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 difenacoum (eating bait for 5 days) and resistant (eating the bait for 14 days).

Tier 1 risk characterisation of secondary poisoning

	PEC EC in rodent [µg/kg]	**$PNEC_{oral}$ [µg/kg food]**	**PEC/PNEC**
Rodent caught on day 5 after meal			
Bird	5760	0.5	11520
Mammal	5760	7	823
Rodent caught on day 14 after meal			
Bird	6250	0.5	12500
Mammal	6250	7	893

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 difenacoum 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 (Frodent = 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 [µg/kg bw] Rodent caught on day 5**	**PEC EC in predator [µg/kg bw] Rodent caught on day 14**	**$PNEC_{oral}$ [µg/kg bw/d]**	**PEC/PNEC Rodent caught on day 5**	**PEC/PNEC Rodent caught on day 14**
Barn owl	*Tyto alba*	1430	1550	0.1	14300	15500
Kestrel	*Athene noctua*	2170	2350	0.1	21700	23500
Little owl	*Strix aluco*	1630	1770	0.1	16300	17700
Tawny owl	*Falco tinnunculus*	1310	1420	0.1	13100	14200
Fox	*Vulpes vulpes*	530	570	0.3	1767	1900
Polecat	*Mustela putorius*	1100	1190	0.3	3667	3967
Stoat	*Mustela erminea*	1570	1700	0.3	5233	5667
Weasel	*Mustela nivalis*	2260	2450	0.3	7533	8167

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 difenacoum from the predators is assumed to be less than the ingested amount.

Experimental data

Applicant has access to the documentation of the active substance, which included studies of secondary poisoning of barn owls. Birds were fed with rodents that had been fed on rodenticidal baits containing difenacoum. The results show that the PEC/PNEC ratio based on measured concentrations of difenacoum in rodents were lower than those calculated according to the ESD, however, much higher than 1, which means a high risk of secondary poisoning of barn owls.

Monitoring data

In UK, the possibility of pesticide poisoning is monitored by the Wildlife Incident Investigation Scheme (WIIS). During the monitoring cases of rodenticide poisoning, including difenacoum were confirmed.

Incidents of dienacoum poisoning in the UK reported by the Wildlife Incident Investi-gation Scheme (WIIS).

Year	No of incidents	Species
1998	9	Buzzard, pheasant, red kite, dog, cat
1999	19	Buzzard, house sparrow, red kite, tawny owl, fox, cat, dog
2000	15	Buzzard, red kite, badger, fox, cat, dog,
2001	8	Buzzard, red kite, badger, pine marten
2002	24	Buzzard, feral pigeon, red kite, fox, cat, dog
2003	11	Crow, dove, red kite, badger, rabbit, cat, dog
2004	20	Buzzard, blackbird, crow, house sparrow, red kite, sparrow hawk, badger, fox, pony, cat, dog
2005	15	Buzzard, kestrel, red kite, badger, fox, grey squirrel, rat, bantam chicken, cat, dog, goose
2006	20	Buzzard, barn owl, red kite, rabbit, rat, stoat, weasel, cat, dog, peacock

Conclusion on secondary poisoning

Both theoretical calculations, experimental results and monitoring data clearly show that difenacoum 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

Difenacoum is active substance in biocidal product Atrax® Płatki. Difenacoum is not readily or inherently biodegradable and half-life in marine or freshwater sediment is expected to be more than 180 days or 120 days, respectively. Difenacoum is also hydrolytically stable, but photolytic degradation in water is rapid. However the photolytic degradation is not regarded as a major transformation pathway in nature. Difenacoum has a high potential for bioaccumulation based on the calculated log Kow and BCF. Based on both the ecotoxicological and toxicological data, difenacoum fulfils the T criterion. Therefore, according to the TNsG, difenacoum potentially fulfils the PBT (persistent, bioaccumulative, toxic) or vPvB (very persistent, very bioaccumulative) criteria.

2.9 Measures to protect man, animals and the environment

1. The baits must be always placed in tamper resistant bait stations made of durable material.
2. Bait must be secured in tamper resistant bait boxes in areas away from drains, water courses and non-target organisms

3. Tamper resistant bait stations must be clearly marked to show that they contain rodenticides that should not be distributed.
4. In public areas (such as business premises, schools, hospitals etc) it must be clearly signed that rodenticide control is in operation. Signage 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 carried on the label, packaging or accompanying leaflet:

   "When the product is being used in public areas, the areas treated must be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits".Always read the label before use and follow the instructions provided
6. Dead rodent bodies must be collected during all control operations to minimise the risk of consumption and poisoning to children, companion animals and other non-target animals
7. Remove all baits and bait stations after treatment and dispose of them in accordance with local requirements
8. Do not use anticoagulant rodenticides as permanent baits
9. Prevent accidental exposure of the product to the environment
10. Prevent access to bait by children, birds, and non-target animals (particularly dogs, cats, pigs and poultry)
11. Product should be stored in original container in a dry place, at room temperature
12. Keep unused bait locked-up and in secure storage containers
13. Keep/store out of reach of children and companion animals
14. Keep away from food, drink and animal feeding stuffs
15. Wear suitable gloves
16. Do not smoke, eat or drink while handling this product
17. Wash hands and face after application of the product
18. Limit the size of the product for the non-professional user to reduce the likelihood of product storage
19. The use of this type of packaging that will prevent or significantly impede the opening by the children
20. Reduce the attractiveness of the packaging and the product for a children
21. Use of special substances, limiting intake (e.g. Bitrex)

3 Proposal for decision

1. Product Formulation - active substance content	% w/w	Manufacturer of active substance
concentrate of difenacoum (pure difenacoum content)	0.200 (0.005)	PelGar

2. Formulation type	Flakes
3. Product type	PT14
4. User	Non-professional (general public) 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: 200 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) *Rattus rattus* (black rat), *Mus musculus*/*domesticus* (house mouse) *Apodemus agrarius* (field mouse)
10. Shelf life	Up to 2 years
11. Expiry data of the authorisation	31 march 2015
12. Any other specific conditions:	Please referee to PAR section 2.9 Additionaly: - Methylparaben as non-notified in PT6 active substance should be exchanged on preservative included into Annex I according to Directive 98/8/EC after 31 march 2015 - In the case 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: Atrax Płatki

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

Active substance(s)				Contents				
Common name	**IUPAC name**	**CAS number**	**EC number**	**Concentration**	**Unit**	**w/w (%)**	**Minimum purity (% w/w)**	**Same source as for Annex I inclusion**
Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-napthyl)-4- hydroxycoumarin	56073-07-5	259-978-4	0,05	g/kg	0.005	96	☒ **yes** ☐ **no**

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

no

If not, briefly describe the difference.

Differences in non-active ingredients of formulation.

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

no

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

n/a

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

Name of the active substance: DIFENACOUM

Manufacturer

Company Name:	PelGar International Ltd,				
Address:	Unit 13, Newman Lane, Alton				
City:	Hampshire	Postal Code:	GU34 2QR	Country:	UK
Telephone:	+ 44 1420 80744	Fax:	+ 44 1420 80733	E-Mail:	info@pelgar.co.uk

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

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

Formulator

Company Name:	FREGATA S.A.				
Address:	Grunwaldzka 497				
City:	Gdańsk	Postal Code:	80-309	Country:	PL
Telephone:	(0-58) 552 00 27 do 29	Fax:	(0-58) 552 48 31	E-Mail:	fregata@fregata.gda.pl

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

Physical state and nature of the biocidal product:

(e) Type of formulation: flakes

(f) Ready-to-use product: yes

Classification and labelling statements of the biocidal product:

(g) Product classification: none

(h) Risk and Safety Phrases:

Risk Phrases: not applicable

Safety Phrases:
S2 Keep out of the reach of children
S13 Keep away from food, drink and animal feedingstuffs.
S37 Wear suitable gloves

(i) Product classification according to GHS: none

(j) Hazard statement according to GHS: none

Intended uses and efficacy:

(k) PT: 14 (Rodenticides)

(l) Target harmful organisms:

Brown rat (*Rattus norvegicus*)
Roof rat, house rat (*Rattus rattus*)
House mouse (*Mus musculus/domesticus*)
Field mouse *(Apodemus agrarius)*

(m) Development stage of target organisms:

Juveniles
Adults

(n) Function/mode of action:

long-term action
anticoagulant
ingestion toxin
ingestion by eating

(o) Field of use:

indoor use,
outdoor use (e.g. parks, tennis courts, camping sites and other places of the public utility, waste dumps)

(p) Application aim:

stored product protection / food protection
health protection
material protection (e.g. historical buildings, technical objects)

(q) User category

non-professional (general public)
professional

(r) Application method:

Covered application (only tamper resistance bait stations)

Directions for use:

(s) Manner and area of use:

See"intended uses and efficacy" above

(t) Conditions of use:

The baits must be always placed in tamper resistance bait stations made of durable material.

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

Mice: 200 g of flakes per bait station spaced at 1.5-2m. Typical treatment time 20 days (according to field trial)

(u) Instructions for safe use of the product:

Bait must be secured in tamper resistant bait boxes in areas away from drains, water courses and non-target organisms.

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

In public areas (such as business premises, schools, hospitals etc) it must be clearly signed that rodenticide control is in operation. Signage must provide information on the risks of interfering with the product and dead rodents.

For product to be used in public areas the following safety precautions shall be carried on the label, packaging or accompanying leaflet:
"When the product is being used in public areas, the areas treated must be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits". Always read the label before use and follow the instructions provided.

Do not use anticoagulant rodenticides as permanent baits.

Prevent accidental exposure of the product to the environment.

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

Wear suitable gloves.

Do not smoke, eat or drink while handling this product.

Wash hands and face after application of the product.

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

Difenacoum is an anticoagulant which may produce bleeding.
Antidote: Treatment with Vitamin K1 administered under medical supervision.

ORAL:	If swallowed, seek medical advice immediately (show label if possible).
DERMAL:	In the case of the contact with the skin wash the contaminated place with water and soap.
EYES:	In the case of eyes contamination rinse them with a plenty of water.
INHALATION:	In the case of inhalation exposure, in the event of disturbing symptoms appearing, seek medical advice.

In case of emergency contact the Poison Centres in Poland:

Gdańsk – (58) 682 04 04
Poznań – (61) 847 69 46
Kraków – (12) 411 99 99
Warszawa – (22) 619 66 54

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

Dead rodent bodies must be collected during all control operations to minimize the risk of consumption and poisoning to children, companion animals and other non-target animals.

Remove all baits and bait stations after treatment and dispose of them in accordance with local requirements.

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

Keep/store out of reach of children and companion animals.

Keep away from food, drink and animal feeding stuffs.

Product should be stored in original container in a dry place, at room temperature.

Keep unused bait locked-up and in secure storage containers.

Shelf life of up to 2 years supported.

(y) Additional information:

Authorization number: PL/2012/0033/A
Granting date: 04.10.2012
Expiring date: 31.03.2015

Packaging type	Pack sizes for non professional use	Pack sizes for professional use
Welded PET/PE bag resistant to tearing with the label "close-open". On front of the bag clearly warning "Keep out of the reach of children"	200 g	200 g
Welded PET/PE bag resistant to tearing with the label "close-open". On front of the bag clearly warning "Keep out of the reach of children"	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. Scoop and protective gloves inside bucket.	1400 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

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	2008	Atrax Płatki Badania właściwości fizykochemicznych Instytut Przemysłu Organicznego (Warszawa) Kod badania: BF-28/08	„FREGATA" SA	☐	☒	☒	☐
III-B	3.1.1 3.1.2 3.1.3 3.5 3.6 3.7 3.8 3.11	Al Amin Idris	2011	Atrax Płatki Badania właściwości fizykochemicznych przed i po przyśpieszonym starzeniu Instytut Przemysłu Organicznego (Warszawa) Kod badania: BF-18/11 Zgodnie z zasadami dobrej praktyki laboratoryjnej Niepublikowany	„FREGATA" SA	☐	☒	☒	☐
III-B	3.7	Wróblewski Dominik	2010	Badanie stabilności preparatu Atrax Płatki – przyspieszone starzenie TCI Laboratories (Gdynia) Nr dok. RB/FGA/02/02	„FREGATA" SA	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
III-B	3.2	Buczkowski Daniel, Sałaciński Tomasz, Witkowski Waldemar	2008	Atrax Plus Oznaczanie właściwości wybuchowych Instytut Przemysłu Organicznego (Warszawa) Nr sprawozdania: 34/W/54/2008 Niepublikowany	„FREGATA" SA	☐	☒	☒	☐
III-B	3.3 3.4	Chmielewska Agata, Frączak Michał	2008	Atrax Plus Oznaczanie właściwości utleniających, względnej temperatury samozapalenia oraz palności Instytut Przemysłu Organicznego (Warszawa) Kod badania: BC/25/08 Zgodnie z zasadami dobrej praktyki laboratoryjnej Niepublikowany	„FREGATA" SA	☐	☒	☒	☐
III-B	4.1	Gwóźdź Ewa Jolanta	2009	Opracowanie i walidacja metody oznaczania substancji aktywnej w preparacie Atrax Plus Instytut Przemysłu Organicznego (Warszawa) Kod badania: BA – 01/09 Zgodnie z zasadami dobrej praktyki laboratoryjnej Niepublikowany	„FREGATA" SA	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
III-B	5.10.2(1)	Ignatowicz Stanisław	2010	Badanie skuteczności preparatu Atrax Plus 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	☐	☒	☒	☐
III-B	5.10.2(3)	Gruszka Katarzyna	2011	Atrax Płatki Badanie skuteczności i akceptacji rodentycydów na szczurach laboratoryjnych Instytut Przemyslu Organicznego Oddział w Pszczynie Kod badania: SK-3/11 Zgodnie z zasadami dobrej praktyki laboratoryjnej Niepublikowany	„FREGATA" SA	☐	☒	☒	☐
III-B	5.10.2(2)	Gruszka Katarzyna	2011	Atrax Płatki Badanie skuteczności i akceptacji rodentycydów na myszach laboratoryjnych Instytut Przemyslu Organicznego Oddział w Pszczynie Kod badania: SK-4/11 Zgodnie z zasadami dobrej praktyki laboratoryjnej Niepublikowany	„FREGATA" SA	☐	☒	☒	☐
IIIB	6.6	„FREGATA" SA	2011	Atrax Płatki. Oszacowanie ekspozycji oraz ryzyka	„FREGATA" SA	☐	☒	☒	☐

Annex 3: Analytical methods residues – active substance

Difenacoum

Date: 29.06.2012

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

Annex 4: Toxicology and metabolism –active substance

Difenacoum

Date: 29.06.2012

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

Annex 5: Toxicology – biocidal product

Atrax® Płatki

Date: 29.06.2012

General information

Formulation Type:	flakes
Active substance(s) (incl. content)	0.005% difenacoum
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)	36 g/kg bw to the male rat, 52 g/kg bw to the female rat
Rat LD_{50} dermal (OECD 402)	1260 g/kg bw (95% confidence limits 680-1700 g/kg bw) to the male rat 1030.8 g/kg bw to the female
Rat LC_{50} inhalation (OECD 403)	0.073–0.117 g/l/4 h, head only
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 difenacoum.
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 difenacoum
Further toxicological information	Not required

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Directive 1999/45/EC	Product classification: NONE

Annex 6: Safety for professional operators

Atrax® Płatki

Date: 29.06.2012

See point 2.7.3.1 above

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

Atrax® Płatki

Date: 29.06.2012

See tables 2.7.3.2.1 and 2.7.3.2.2 above

Annex 8: Residue behaviour

Difenacoum

Date: 29.06.2012

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

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

Atrax® 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 oraz na terenach otwartych (parki, korty tenisowe, kempingi, itp.)

Pozwolenie Prezesa Urzędu nr:

Substancja czynna:

- difenakum 0,005 % (0,05 g/kg) - substancja czynna z grupy antykoagulantów jednodawkowych II generacji,

Zawiera:

- benzoesan denatonium - gorzka substancja zniechęcająca do spożycia przez ludzi

Sposób użycia:

Atrax® 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 200 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 rodentycyd, który nie może być roznoszony. W przypadku stosowania produktu w miejscach publicznych (takich jak przedsiębiorstwa, szkoły, szpitale, itp.), dany teren musi zostać oznakowany na czas deratyzacji i zawierać informacje dotyczące ryzyka zatrucia po spożyciu przynęty, umieszczoną na obszarze objętym deratyzacją.

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

Gryzonie zaczynają padać po 5 – 7 dniach. Typowy okres stosowania przynęty wynosi 20 dni.

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

Zabieg powtórzyć w razie ponownego pojawienia się 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 nie podlegającymi zwalczaniu (psy, koty, świnie, drób, itp.). Przed i po wyłożeniu

preparatu umyć ręce wodą z mydłem. Unikać kontaktu z ustami. Nie jeść, nie pić i nie palić podczas pracy z preparatem.

S 2 Chronić przed dziećmi.
S 13 Nie przechowywać razem z żywnością, napojami i paszami dla zwierząt.
S 37 Nosić odpowiednie rękawice ochronne.

Uwaga:
Postępowanie z odpadami produktu, odpadami opakowaniowymi i padłymi gryzoniami:
Padłe gryzonie należy systematycznie usuwać. Pozostałości produktu i jego opakowanie po zakończonym zabiegu usuwać w sposób bezpieczny (np. jako odpady komunalne lub utylizować przez spalanie w autoryzowanych firmach, itp.), ale zawsze zgodny z aktualnymi przepisami. Produkt przechowywać w oryginalnym opakowaniu, w suchym miejscu w temperaturze pokojowej. Preparatu nie przechowywać razem z substancjami chemicznymi, które mogłyby zmienić atrakcyjny dla gryzoni zapach środka. Zapobiegać przedostawaniu się do środowiska.

Tam gdzie wykazano lub tam gdzie podejrzewa się oporność na difenakum należy zastosować strategię przeciwdziałania zjawisku oporności i należy zastosować produkty zawierające alternatywną substancję czynną.

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